

IOWA ADMINISTRATIVE BULLETIN

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PREFACE

The Iowa Administrative Bulletin is published in pamphlet form biweekly pursuant to Iowa Code Chapter 17A and contains Notices of Intended Action on rules, Filed and Filed Emergency rules by state agencies [continue to refer to General Information for drafting style and form].

It also contains Proclamations and Executive Orders of the Governor which are general and permanent in nature; Economic Impact Statements to proposed rules and filed emergency rules; Objections filed by Administrative Rules Review Committee, Governor or the Attorney General; and Delay by the Committee of the effective date of filed rules; Regulatory Flexibility Analyses and Agenda for monthly Administrative Rules Review Committee meetings. Other "materials deemed fitting and proper by the Administrative Rules Review Committee" include summaries of Attorney General Opinions and Supreme Court Decisions.

The Bulletin may also contain Public Funds Interest Rates [453.6]; Workers' Compensation Rate Filings [515A.6(7)]; Usury [535.2(3)"a"]; Agricultural Credit Corporation Maximum Loan Rates [535.12]; and Regional Banking--Notice of Application and Hearing [524.1905(2)].

PLEASE NOTE: Italics indicate new material added to existing rules; strike-through letters indicate deleted material.

GUIDE FOR RULE MAKING, see FIRST VOLUME IOWA ADMINISTRATIVE CODE (Gray, Yellow, Red, Blue and Green Tabs)

The ARC number which appears before each agency heading is assigned by the Administrative Rules Coordinator for identification purposes and should always be used when referring to this item in correspondence and other communications.

The Iowa Administrative Code Supplement is also published every other week in loose-leaf form, pursuant to Iowa Code section 17A.6. It contains replacement pages for the Iowa Administrative Code. These replacement pages incorporate amendments to existing rules, new rules or emergency or temporary rules which have been filled with the administrative rules coordinator and published in the Bulletin.

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Schedule for Rule Making

1992

		HEARING	FIRST POSSIBLE		FIRST	POSSIBLE
	NOTICE	OR	ADOPTION	ADOPTED	POSSIBLE	EXPIRATION
FILING	PUB.	COMMENTS	DATE	PUB.	EFFECTIVE	OF NOTICE
DEADLINE	DATE	20 DAYS	35 DAYS	DATE	DATE	180 DAYS
Dec. 6 '91	Dec. 25 '91	Jan. 14	Jan. 29	Feb. 19	Mar. 25	June 22
Dec. 20 '91	Jan. 8	Jan. 28	Feb. 12	Mar. 4	Apr. 8	July 6
<u>Jan. 3</u>	Jan. 22	Feb. 11	Feb. 26	Mar. 18	Apr. 22	July 20
Jan. 17	Feb. 5	Feb. 25	Mar. 11	Apr. 1	May 6	Aug. 3
Jan. 31	Feb. 19	Mar. 10	Mar. 25	Apr. 15	May 20	Aug. 17
Feb. 14	Mar4	Mar. 24	Apr. 8	Apr. 29	June 3	Aug. 31
Feb. 28	Mar. 18	Apr. 7	Apr. 22	May 13	June 17	Sep. 14
Mar. 13	Apr. 1	Apr. 21	May 6	May 27	July 1	Sep. 28
Mar. 27	Apr. 15	May 5	May 20	June 10	July 15	Oct. 12
Apr. 10	Apr. 29	May 19	June 3	June 24	July 29	Oct. 26
Apr. 24	May 13	June 2	June 17	July 8	Aug. 12	Nov. 9
May 8	May 27	June 16	July 1	July 22	Aug. 26	Nov. 23
May 22	June 10	June 30	July 15	Aug. 5	Sept. 9	Dec. 7
June 5	June 24	July 14	July 29	Aug. 19	Sep. 23	Dec. 21
June 19	July 8	July 28	· Aug. 12	Sep. 2	Oct. 7	Jan. 4 '93
July 3	July 22	Aug. 11	Aug. 26	Sep. 16	Oct. 21	Jan. 18 '93
July 17	Aug. 5	Aug. 25	Sep. 9	Sept. 30	Nov. 4	Feb. 1 '93
July 31	Aug. 19	Sep. 8	Sep. 23	Oct. 14	Nov. 18	Feb. 15 '93
Aug. 14	Sep. 2	Sep. 22	Oct. 7	Oct. 28	Dec. 2	Mar. 1 '93
Aug. 28	Sep. 16	Oct. 6	Oct. 21	Nov. 11	Dec. 16	Mar. 15 '93
Sep. 11	Sept. 30	Oct. 20	Nov. 4	Nov. 25	Dec. 30	Mar. 29 '93
Sep. 25	Oct. 14	Nov. 3	Nov. 18	Dec. 9	Jan. 13 '93	Apr. 12 '93
Oct. 9	Oct. 28	Nov. 17	Dec. 2	Dec. 23	Jan. 27 '93	Apr. 26 '93
Oct. 23	Nov. 11	Dec. 1	Dec. 16	Jan. 6 '93	Feb. 10 '93	May 10 '93
Nov. 6	Nov. 25	Dec. 15	Dec. 30	Jan. 20 '93	Feb. 24 '93	May 24 '93
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Dec. 4	Dec. 23	Jan. 12 '93	Jan. 27 '93	Feb. 17 '93	Mar. 24 '93	June 21 '93
Dec. 18	Jan. 6 '93	Jan. 26 '93	Feb. 10 '93	Mar. 3 '93	Apr. 7 '93	July 5 '93

20 days from the publication date is the minimum date for a public hearing or cutting off public comment.

180 days See 17A.4(1)"b." If the agency does not adopt rules within this time frame, the Notice should be terminated.

ISSUE NUMBER	PRINTING SCHEDULE FOR IAB SUBMISSION DEADLINE.	ISSUE DATE
26	Friday, June 5, 1992	June 24, 1992
1	Friday, June 19, 1992	July 8, 1992
2	Friday, July 3, 1992	July 22, 1992

PLEASE NOTE:

Rules will not be accepted after 12 o'clock noon on the Friday filing deadline days unless prior approval has been received from the Administrative Rules Coordinator's office.

If the filing deadline falls on a legal holiday, submissions made on the following Monday will be accepted.

³⁵ days from the publication date is the earliest possible date for the agency to consider a noticed rule for adoption. It is the regular effective date for an adopted rule.

The Administrative Rules Review Committee will hold its regular, statutory meeting Tuesday, June 9, 1992, 10 a.m. and Wednesday, June 10, 1992, 8:30 a.m. in Senate Committee Room 22, State Capitol. The following rules will be reviewed:

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Consent for the sale of goods and services, ch. 7, Filed ARC 2993A. 5717/92 Indigent defense— claims for compensation, ch. 9, Filed ARC 2993A. 5713/92 Food and food service establishment inspections — temperature of seafood, requirements for toilets, lavatories, mobile food units and pushcarts, 31.4, 31.9, 32.3(6), 32.3(6), 32.4, Filed ARC 2992A. 5713/92 INSURANCE DIVISION[191] COMMERCE DEPARTMENT[181]*umbrella* Motor vehicle service contracts — late filing fees, 23.10(2)*b,* 23.12, Notice ARC 3021A. 5727/92 Health maintenance organizations, 40.1, 40.20, 40.21, Filed ARC 2982A. 5713/92 LABOR SERVICES DIVISION[347] EMPLOYMENT SERVICES DEPARTMENT[341]*umbrella* General industry safety and health rules, 26.1, Filed Emergency After Notice ARC 3017A. 5727/92 Bungce jumping, 62.2(13), Notice ARC 2990A, also Filed Emergency After Notice ARC 3017A. 5727/92 Bungce jumping, 62.2(13), Notice ARC 2990A, also Filed Emergency After Notice ARC 3017A. 5713/92 MEDICAL EXAMINERS BOARD[653] PUBIC REALTH DEPARTMENT[641]*umbrella* Licensure requirements, 11.1, Filed ARC 3002A. 5713/92 NURSING BOARD[655] RUBLIC REALTH DEPARTMENT[641]*umbrella* Continuing education, 5.1, 5.2(2)*f* and "g," 5.3(2)*d*(8) and (9), Notice ARC 2856A Terminated ARC 2994A. 5713/92 NATURAL RESOURCE COMMISSION[571] NOTICE ARC 3047A. 5727/92 Boating safety equipment — lights on vessels while at anchor, flame arrester, 37.2, 37.6, Notice ARC 3045A. 5727/92 Lands and waters conservation fund program, 27.2(1), 27.5(6), 27.6(3), 27.7, 27.10, Notice ARC 3047A. 5727/92 Boating safety equipment — lights on vessels while at anchor, flame arrester, 37.2, 37.6, Notice ARC 3045A. 5727/92 Boating safety equipment — lights on vessels while at anchor, flame arrester, 37.2, 37.6, Notice ARC 3045A. 5727/92 Boating safety equipment — lights on vessels while at anchor, flame arr	202.13(3), 202.16(1)"f," Notice ARC 3040A	5/27/92
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Licensure requirements, 11.1, Filed ARC 3002A NURSING BOARD[655] PUBLIC HEALTH DEPARTMENT[641]"umbrella" Continuing education, 5.1, 5.2(2)"f" and "g," 5.3(2)"d"(8) and (9), Notice ARC 2856A Terminated ARC 2994A 5/13/92 NATURAL RESOURCE COMMISSION[571] NATURAL RESOURCES DEPARTMENT[561]"umbrella" Issuance of free combination hunting and fishing license to low-income persons 65 years of age and older or low-income persons who are permanently disabled, 15.7(3)"c," Notice ARC 2761A Terminated ARC 3041A 5/27/92 Volunteer hunter education instructors, 15.8, Filed ARC 3057A Lands and waters conservation fund program, 27.2(1), 27.5(6), 27.6(3), 27.7, 27.10, Notice ARC 3047A Soluting safety equipment — lights on vessels while at anchor, flame arrester, 37.2, 37.6, Notice ARC 3045A 5/27/92 Wildlife refuges, 52.1(1), 52.1(2)"b," Notice ARC 3048A 5/27/92 State parks and recreation areas — Backbone and Wilson Island cabin rental, 61.2, 61.3(5)"a," 61.4(1)"a," 61.4(2)"a," "f," "h" to "j," "n" to "p," "61.4(3), 61.5(8)"a" and "d," Filed ARC 3054A 5/27/92 Nonresident deer hunting, 94.1, 94.2, 94.8, Filed ARC 3055A Common snipe, Virginia rail and sora, woodcock and ruffed grouse hunting seasons, 97.1 to 97.4, Filed ARC 3056A Sizzing Wild turkey fall hunting, 99.1, 99.1(1), 99.1(2), 99.3(1), 99.4, 99.5, Filed ARC 3036A 5/27/92 Deer hunting regulations, 106.1, 106.2, 106.5(1), 106.5(2)"i," 106.5(3), 106.6(1) to 106.6(3), 106.7(1), 106.8(2), 106.8(3), 106.10, Filed ARC 3037A Sizing ARC 3046A Sizzing Mink, muskrat, raccoon, badger, opossum, weasel, striped skunk, fox (red and gray), beaver, coyote, otter	Bungee jumping, 62.2(13), Notice ARC 2990A, also Filed Emergency ARC 2989A	5/13/92
NURSING BOARD[655] PUBLIC HEALTH DEPARTMENT[641]"umbrella" Continuing education, 5.1, 5.2(2)"f" and "g," 5.3(2)"d"(8) and (9), Notice ARC 2856A Terminated ARC 2994A 5/13/92 NATURAL RESOURCE COMMISSION[571] NATURAL RESOURCES DEPARTMENT[561]"umbrella" Issuance of free combination hunting and fishing license to low-income persons 65 years of age and older or low-income persons who are permanently disabled, 15.7(3)"c," Notice ARC 2761A Terminated ARC 3041A 5/27/92 Volunteer hunter education instructors, 15.8, Filed ARC 3057A 5/27/92 Lands and waters conservation fund program, 27.2(1), 27.5(6), 27.6(3), 27.7, 27.10, Notice ARC 3047A 5/27/92 Boating safety equipment — lights on vessels while at anchor, flame arrester, 37.2, 37.6, Notice ARC 3045A 5/27/92 Wildlife refuges, 52.1(1), 52.1(2)"b," Notice ARC 3048A 5/27/92 State parks and recreation areas — Backbone and Wilson Island cabin rental, 61.2, 61.3(5)"a," 61.4(1)"a," 61.4(2)"a," "f," "h" to "j," "n" to "p," 61.4(3), 61.5(8)"a" and "d," Filed ARC 3054A 5/27/92 Nonresident deer hunting, 94.1, 94.2, 94.8, Filed ARC 3055A 5/27/92 Common snipe, Virginia rail and sora, woodcock and ruffed grouse hunting seasons, 97.1 to 97.4, Filed ARC 3056A 5/27/92 Wild turkey fall hunting, 99.1, 99.1(1), 99.1(2), 99.3(1), 99.4, 99.5, Filed ARC 3036A 5/27/92 Wild turkey fall hunting, 99.1, 99.1(1), 99.1(2), 99.3(1), 99.4, 99.5, Filed ARC 3036A 5/27/92 Deer hunting regulations, 106.1, 106.2, 106.5(1), 106.5(2)"i," 106.5(3), 106.6(1) to 106.6(3), 106.7(1), 106.8(2), 106.8(3), 106.10, Filed ARC 3037A 5/27/92 Mink, muskrat, raccoon, badger, opossum, weasel, striped skunk, fox (red and gray), beaver, coyote, otter	DIRLIC HEALTH DEDARTMENT (641 ""umbusila"	
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ADMINISTRATIVE RULES REVIEW COMMITTEE MEMBERS

Regular statutory meetings are held the second Tuesday of each month at the seat of government as provided in Iowa Code section 17A.8. A special meeting may be called by the chairperson at any place in the state and at any time.

Representative Emil S. Pavich, Vice Chair

EDITOR'S NOTE: Terms ending April 30, 1995.

1706 - 15th Avenue

Senator Berl E. Priebe, Chair RFD 2, Box 145A Algona, Iowa 50511 Senator Donald V. Doyle P. O. Box 941 Sioux City, Iowa 51102 Senator H. Kay Hedge R.R. 1, Box 39 Fremont, Iowa 52561 Senator John P. Kibbie R.R. 1, Box 139A Emmetsburg, Iowa 50536 Senator Dale L. Tieden

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R.R. 2, Box 159
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IAB 5/27/92 ARC 3045A

PUBLIC HEARINGS

To All Agencies: The Administrative Rules Review Committee voted to request that Agencies comply with Iowa Code section 17A.4(1)"b" by allowing the opportunity for oral presentation (hearing) to be held at least twenty days after publication of Notice in the Iowa Administrative Bulletin. DATE AND TIME OF HEARING HEARING LOCATION AGENCY **BANKING DIVISION[187]** State banks — securities activities, 2.15 Conference Room June 17, 1992 IAB 5/27/92 ARC 3020A 200 E. Grand Ave. 9:30 a.m. Des Moines, Iowa **CORRECTIONS DEPARTMENT[201]** Institutional community placement, 20.17 Conference Room June 16, 1992 1 to 3 p.m. 523 E. 12th St. IAB 5/27/92 ARC 3028A Des Moines, Iowa **DEAF SERVICES DIVISION[429]** Conference Room June 18, 1992 Organization; services and procedures; forms, 1.1 to 1.3, 2.1 to 2.4, 4.1 Third Floor, Side 1 1 p.m. IAB 5/27/92 ARC 3060A Lucas State Office Bldg. Des Moines, Iowa **ENVIRONMENTAL PROTECTION COMMISSION[567]** Meeting Room June 4, 1992 Water quality standards, 61.2(5), 61.3(5)"e," IAB 5/13/92 ARC 3004A Chamber of Commerce 1 p.m. 128 N. 12th St. Centerville, Iowa Meeting Room June 4, 1992 Public Library 7 p.m. 400 N. 2nd St. Red Oak, Iowa Meeting Room June 5, 1992 Public Library 1 p.m. 112 Albany St. Orange City, Iowa Conference Room June 8, 1992 Fifth Floor West 10 a.m. Wallace State Office Bldg. Des Moines, Iowa Meeting Room B June 8, 1992 Public Library 1 p.m. 123 S. Linn St. · Iowa City, Iowa LABOR SERVICES DIVISION[347] Labor Services Division June 9, 1992 Safety procedures for bungee jumping, 62.2(13) 1000 E. Grand Ave. 9 a.m. IAB 5/13/92 ARC 2990A Des Moines, Iowa (If requested) (See also ARC 2989A) **NATURAL RESOURCE COMMISSION[571]** June 23, 1992 Lands and waters conservation fund program-Conference Room federal cost-sharing, 27.2, 27.5 to 27.7, 27.10 IAB 5/27/92 ARC 3047A Fourth Floor, West Half 10 a.m. Wallace State Office Bldg. Des Moines, Iowa June 17, 1992 Conference Room Boating safety equipment, 9:30 a.m. Fourth Floor West 37.2, 37.6

Wallace State Office Bldg.

Des Moines, Iowa

May 28, 1992

10 a.m.

(If requested)

NATURAL RESOURCE COMMISSION[571](cont'd)

Farm trailer registration and inspection

exemption, 400.1(3)

IAB 4/29/92 ARC 2960A

Wildlife refuges, June 17, 1992 Conference Room 52.1 Fourth Floor West 10 a.m. IAB 5/27/92 ARC 3048A Wallace State Office Bldg. Des Moines, Iowa Educational project and wildlife rehabili-Conference Room June 17, 1992 tation permits, 111.1, 111.4, 111.7 Fourth Floor West 10 a.m. IAB 5/27/92 ARC 3042A Wallace State Office Bldg. Des Moines, Iowa PETROLEUM UNDERGROUND STORAGE TANK FUND BOARD, IOWA COMPREHENSIVE[591] Installations and inspections of underground Administrator's Office June 2, 1992 liquid storage systems, ch 15 Conference Room 10 a.m. 1000 Illinois St. IAB 5/13/92 ARC 2991A Des Moines, Iowa PUBLIC HEALTH DEPARTMENT[641] Radiation — general provisions, Conference Room — 3rd Floor June 17, 1992 ch 38 Lucas State Office Bldg. 9 a.m. IAB 5/27/92 ARC 3051A Des Moines, Iowa Registration of radiation machine facilities, Conference Room — 3rd Floor June 17, 1992 licensure of radioactive materials and Lucas State Office Bldg. 9 a.m. transportation of radioactive materials, Des Moines, Iowa ch 39 IAB 5/27/92 ARC 3052A Standards for protection against Conference Room — 3rd Floor June 17, 1992 radiation, ch 40 Lucas State Office Bldg. 9 a.m. IAB 5/27/92 ARC 3053A Des Moines, Iowa Safety requirements for the use of Conference Room — 3rd Floor June 17, 1992 radiation machines and certain uses of Lucas State Office Bldg. 9 a.m. radioactive materials, ch 41 Des Moines, Iowa IAB 5/27/92 ARC 3049A Radiation safety requirements for Conference Room — 3rd Floor June 17, 1992 industrial radiographic operations, Lucas State Office Bldg. 9 a.m. ch 45 Des Moines, Iowa IAB 5/27/92 ARC 3050A PUBLIC SAFETY DEPARTMENT[661] Fire marshal, 5.1(5), 5.100, 5.650 IAB 5/13/92 ARC 3007A Conference Room June 24, 1992 Third Floor, East Half 10:30 a.m. Wallace State Office Bldg. Des Moines, Iowa Building code. Conference Room — 2nd Floor June 25, 1992 amendments to ch 16 Wallace State Office Bldg. 10 a.m. and 1 p.m. IAB 5/27/92 ARC 3013A Des Moines, Iowa **SECRETARY OF STATE**[721] Constitutional amendment on ballot, Secretary of State Office June 18, 1992 21.1(4) Second Floor 1:30 p.m. IAB 5/27/92 ARC 3014A Hoover State Office Bldg. Des Moines, Iowa TRANSPORTATION DEPARTMENT[761]

Conference Room

100 Euclid Avenue

Des Moines, Iowa

Park Fair Mall

AGENCY IDENTIFICATION NUMBERS

Due to reorganization of state government by 1986 Iowa Acts, chapter 1245, it was necessary to revise the agency identification numbering system, i.e., the bracketed number following the agency name.

"Umbrella" agencies and elected officials are set out below at the left-hand margin in CAPITAL letters.

Divisions (boards, commissions, etc.) are indented and set out in lowercase type under their statutory "umbrellas".

Other autonomous agencies which were not included in the original reorganization legislation as "umbrella" agencies are included alphabetically in small capitals at the left-hand margin, e.g., BEEF INDUSTRY COUNCIL, IOWA [101].

Implementation of reorganization is continuing and the following list will be updated as changes occur:

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AGRICULTURE AND LAND STEWARDSHIP DEPARTMENT[21]
   Agricultural Development Authority[25]
   Soil Conservation Division[27]
ATTORNEY GENERAL[61]
AUDITOR OF STATE[81]
BEEF INDUSTRY COUNCIL, IOWA[101]
BLIND, DEPARTMENT FOR THE[111]
CAMPAIGN FINANCE DISCLOSURE COMMISSION[121]
CITIZENS' AIDE[141]
CIVIL RIGHTS COMMISSION[161]
COMMERCE DEPARTMENT[181]
   Alcoholic Beverages Division[185]
   Banking Division[187]
   Credit Union Division[189]
   Insurance Division[191]
   Professional Licensing and Regulation Division[193]
      Accountancy Examining Board[193A]
      Architectural Examining Board[193B]
Engineering and Land Surveying Examining Board[193C]
      Landscape Architectural Examining Board [193D]
      Real Estate Commission[193E]
      Real Estate Appraiser Examining Board[193F]
   Savings and Loan Division[197]
   Utilities Division[199]
CORRECTIONS DEPARTMENT[201]
   Parole Board[205]
CULTURAL AFFAIRS DEPARTMENT[221]
   Arts Division[222]
   Historical Division[223]
   Library Division[224]
   Public Broadcasting Division[225]
ECONOMIC DEVELOPMENT, IOWA DEPARTMENT OF [261]
   City Development Board[263]
   Iowa Finance Authority[265]
   High Technology Council[267]
EDUCATION DEPARTMENT[281]
   Educational Examiners Board[282]
   College Student Aid Commission[283]
   Higher Education Loan Authority[284]
   Iowa Advance Funding Authority[285]
School Budget Review Committee[289]
EGG COUNCIL[301]
ELDER AFFAIRS DEPARTMENT[321]
EMPLOYMENT SERVICES DEPARTMENT[341]
   Industrial Services Division[343]
   Job Service Division[345]
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Labor Services Division[347]

EXECUTIVE COUNCIL[361]

FAIR BOARD[371]

GENERAL SERVICES DEPARTMENT[401]

HEALTH DATA COMMISSION[411]

HUMAN RIGHTS DEPARTMENT[421]

Children, Youth, and Families Division[425]
Community Action Agencies Division[427]
Criminal and Juvenile Justice Planning Division[428]

Deaf Services, Division of [429] Persons With Disabilities Division[43]

Spanish-Speaking People Division[433] Status of Blacks Division[434]

Status of Women Division[435]

HUMAN SERVICES DEPARTMENT[441]

INSPECTIONS AND APPEALS DEPARTMENT[481]

Employment Appeal Board[486] Foster Care Review Board[489] Racing and Gaming Commission[491]

INTERNATIONAL NETWORK ON TRADE(INTERNET)[497]

LAW ENFORCEMENT ACADEMY[501]

LIVESTOCK HEALTH ADVISORY COUNCILIS211

MANAGEMENT DEPARTMENT[541]

Appeal Board, State[543] City Finance Committee[545] County Finance Committee [547]

NARCOTICS ENFORCEMENT ADVISORY COUNCIL[551]

NATURAL RESOURCES DEPARTMENT[561]

Energy and Geological Resources[565]

Environmental Protection Commission[567]

T-27

Natural Resource Commission[571]

Preserves, State Advisory Board[575]

PERSONNEL DEPARTMENT[581]

PETROLEUM UNDERGROUND STORAGE TANK FUND BOARD, IOWA COMPREHENSIVE[591]

PREVENTION OF DISABILITIES POLICY COUNCIL[597]

PUBLIC DEFENSE DEPARTMENT[601]

Disaster Services Division[607]

Military Division[611]

Veterans Affairs Division[613]

PUBLIC EMPLOYMENT RELATIONS BOARD[621]

PUBLIC HEALTH DEPARTMENT[641]

Substance Abuse Commission[643]

Professional Licensure Division[645]

Dental Examiners 650 Medical Examiners[653]

Nursing Board[655]

Pharmacy Examiners[657]

PUBLIC SAFETY DEPARTMENT[661]

RECORDS COMMISSION[671]

REGENTS BOARD[681]

Archaeologist[685]

REVENUE AND FINANCE DEPARTMENT[701]

Lottery Division[705]

SECRETARY OF STATE[721]

SHEEP AND WOOL PROMOTION BOARD, IOWA[741]

TRANSPORTATION DEPARTMENT[761]

Railway Finance Authority, Iowa[765]

TREASURER OF STATE[781]

UNIFORM STATE LAWS COMMISSION[791]

VETERINARY MEDICINE BOARD[811]

VOTER REGISTRATION COMMISSION[821]

WALLACE TECHNOLOGY TRANSFER FOUNDATION[851]

REORGANIZATION--NOT IMPLEMENTED

Agencies listed below are identified in the Iowa Administrative Code with white tabs. These agencies have not yet implemented government reorganization.

Citizens' Aide[210]

Product Development Corporation[636]

Iowa Advance Funding Authority[515]

Records Commission[710]

CITATION of Administrative Rules

The Iowa Administrative Code shall be cited as (agency identification number) IAC (chapter, rule, subrule, lettered paragraph, or numbered subparagraph).

441 IAC 79	(Chapter)
441 IAC 79.1(249A)	(Rule)
441 IAC 79.1(1)	(Subrule)
441 IAC 79.1(1)"a"	(Paragraph)
441 IAC 79.1(1)"a"(1)	(Subparagraph)

The Iowa Administrative Bulletin shall be cited as IAB (volume), (number), (publication date), (page number), (ARC number).

ARC 3061A

ARC 3020A

AGRICULTURE AND LAND STEWARDSHIP DEPARTMENT[21]

Notice of Termination

Pursuant to the authority of Iowa Code sections 159.5(11) and 17A.4(1)"b," the Department of Agriculture and Land Stewardship terminates the rule making initiated by its Notice of Intended Action published in the Iowa Administrative Bulletin on October 2, 1991, as ARC 2382A, amending Chapter 1, "Administration," Iowa Administrative Code.

The Notice [1.1(4), 1.6] proposed changing the name of the Regulatory Division of the Department to the Consumer and Producer Protection Division.

The Department has decided not to pursue this change at this time.

NOTICE—AGRICULTURAL CREDIT CORPORATION MAXIMUM LOAN RATE

In accordance with the provisions of Iowa Code section 535.12, the Superintendent of Banking has determined that the maximum rate of interest that may be charged on loans by Agricultural Credit Corporations as defined in Iowa Code section 535.12, subsection 4, shall be:

'	
August 1, 1989 – August 31, 1989	10.25%
September 1, 1989 – September 30, 1989	9.75%
October 1, 1989 – October 31, 1989	10.00%
November 1, 1989 – November 30, 1989	10.00%
December 1, 1989 – December 31, 1989	9.75%
January 1, 1990 – January 31, 1990	9.65%
February 1, 1990 – February 28, 1990	9.75%
March 1, 1990 – March 31, 1990	9.85%
April 1, 1990 – April 30, 1990	9.85%
May 1, 1990 – May 31, 1990	9.85%
June 1, 1990 – June 30, 1990	10.00%
May 1, 1990 – May 31, 1990 June 1, 1990 – June 30, 1990 July 1, 1990 – July 31, 1990	9.75%
August 1, 1990 – August 31, 1990	9.80%
September 1, 1990 – September 30, 1990	9.55%
October 1, 1990 – October 31, 1990	9.55%
November 1, 1990 – November 30, 1990	9.50%
December 1, 1990 – December 31, 1990	9.05%
January 1, 1991 – January 31, 1991	9.15%
February 1, 1991 – February 28, 1991	8.70%
March 1, 1991 – March 31, 1991	8.20%
April 1, 1991 – April 30, 1991	8.25%
May 1, 1991 – May 31, 1991	8.00%
June 1, 1991 – June 30, 1991	7.75%
July 1, 1991 – July 31, 1991	7.75%
August 1, 1991 – August 31, 1991	7.60%
September 1, 1991 – September 30, 1991	7.70%
October 1, 1991 – October 31, 1991	7.55%
November 1, 1991 – November 30, 1991	7.25%
December 1, 1991 – December 31, 1991	6.95%
January 1, 1992 – January 31, 1992	6.65%
February 1, 1992 - February 29, 1992	6.05%
March 1, 1992 – March 31, 1992	6.00%
April 1, 1992 – April 30, 1992	6.10%
May 1, 1992 – May 31, 1992	6.20%

BANKING DIVISION[187]

Notice of Intended Action

Twenty-five interested persons, a governmental subdivision, an agency or an association of 25 or more persons may demand an oral presentation hereon as provided in Iowa Code §17A.4(1)"b."

Notice is also given to the public that the Administrative Rules Review Committee may, on its own motion or on written request by any individual or group, review this proposed action under \$17A.8(6) at a regular or special meeting where the public or interested persons may be heard.

Pursuant to the authority of Iowa Code sections 17A.3 and 524.213, the Banking Division of the Department of Commerce hereby gives Notice of Intended Action to amend Chapter 2, "Application Procedures," Iowa Administrative Code.

Specifically, this amendment will revise the present rules relating to the ability of state-chartered banks to engage in securities activities with any company that directly engages in the sale, distribution, or underwriting of stocks, bonds, debentures, notes or other securities. The Division of Banking's original rules establishing procedures for engaging in securities activities, effective on March 6, 1988, precluded a state bank from entering into an agreement with an affiliated securities company, unless the securities company was a bona fide subsidiary of the state bank. The purpose of the revision is to allow statechartered banks to engage in securities activities with an affiliated company other than a subsidiary of the state bank to the same extent that a national chartered bank may engage in similar activities. Numerous bank holding companies, those located in Iowa and those located outside the boundaries, now own and operate separate securities companies and would like to establish business relationships with their affiliated state banks. The amendment would allow the Division of Banking's rules to mirthe Federal Deposit Insurance Corporation's regulations pertaining to association with affiliated securities companies. This amendment will also preclude an employee of a securities company whose responsibilities involve customer contact from performing any deposit functions at the state bank.

Any interested person may make written suggestions or comments on these proposed amendments prior to June 16, 1992. Such written materials should be directed to the Superintendent of Banking, Banking Division, Department of Commerce, 200 East Grand Avenue, Suite 300, Des Moines, Iowa 50309. Persons who want to convey their views orally should contact the Superintendent of Banking, Banking Division, Department of Commerce, at (515) 281-4014 or at 200 East Grand Avenue, Suite 300.

Also, there will be a public hearing on Wednesday, June 17, 1992, at 9:30 a.m. in the Banking Division Conference Room at 200 East Grand Avenue. Persons may present their views at this public hearing either orally or in writing. Persons who wish to make oral presentations at the public hearing should contact the Superintendent of Banking at least one day prior to the date of the public hearing.

This amendment is intended to implement Iowa Code section 524.825.

The following amendment is proposed.

ITEM 1. Amend 187—2.15(524), introductory paragraph, to read as follows:

NOTICES IAB 5/27/92

BANKING DIVISION[187](cont'd)

187—2.15(524) Securities activities. Procedures to establish securities activities of state bank subsidiaries—state bank transactions with unaffiliated securities companies pursuant to 1987 Iowa Acts, chapter-171, section 14 Iowa Code section 524.825.

ITEM 2. Amend subrule 2.15(1), paragraph "a," as follows:

- a. A representation as to whether the securities activities to be engaged in will be conducted through a state bank subsidiary or transacted through an *affiliated or* unaffiliated securities company. (State banks may engage in securities activities directly where such activities are limited to discount brokerage or referral services.)
- ITEM 3. Amend subrule 2.15(1), paragraphs "g" and "h," as follows:
- g. If the securities activities will be transacted through an *affiliated or* unaffiliated securities company, all of the following conditions must be met:
- (1) The securities business of the unaffiliated securities company must be physically separate and distinct from the core functions of the state bank, but may share a common entrance with the state bank. The securities company's office location must be clearly identified as belonging to the securities company.

(2) The state bank and unaffiliated securities company

shall share no common officers or directors.

- (3) Any securities activities conducted by the unaffiliated securities company on the premises of the state bank that involve customer contact and provide any type of investment advice to the customer shall be performed by an employee of the securities company. The unaffiliated securities company shall be totally responsible for activities of that employee. This requirement shall not be construed to prohibit the state bank from providing remuneration to the employee of the unaffiliated securities company. Any employee of the unaffiliated securities company whose responsibilities involve customer contact shall be prohibited from performing any lending or deposit functions at the state bank.
- (4) The unaffiliated securities company shall conduct business pursuant to independent policies and procedures designed to adequately inform customers and prospective customers of the securities company that the securities company is a separate organization from the state bank and that the investments recommended, offered, or sold by the securities company are not state bank deposits, are not insured by the Federal Deposit Insurance Corporation, and are not obligations of or guaranteed by the state bank.

(5) A copy of the agreement between the state bank and unaffiliated securities company shall accompany the

applications.

- h. A state bank which has established and operates a securities subsidiary or transacts business with an affiliated or unaffiliated securities company must comply with all of the requirements set forth in Federal Deposit Insurance Corporation Rules and Regulations 12 CFR section 337.4(e) and section 337.4(h) (December 14, 1987).
- ITEM 4. Amend subrule 2.15(4), paragraph "b," as follows:
- b. The state bank, or its subsidiary or the securities company has sufficient managerial resources to engage in the proposed securities activities.
- ITEM 5. Amend subrule 2.15(6), introductory paragraph and paragraph "a," as follows:

2.15(6) Revocation. The superintendent may suspend or revoke the approval of the state bank or its subsidiary to engage in securities activities and the approval of the state bank to enter into an agreement with a securities company to provide securities activities, pursuant to the contested case provisions of Iowa Code chapter 17A, if any of the following occur:

a. The capital, assets, management, earnings, or liquidity of the state bank, its subsidiary or the securities

company becomes unsatisfactory.

ARC 3028A

CORRECTIONS DEPARTMENT[201]

Notice of Intended Action

Twenty-five interested persons, a governmental subdivision, an agency or an association of 25 or more persons may demand an oral presentation hereon as provided in Iowa Code §17A.4(1)"b."

Notice is also given to the public that the Administrative Rules Review Committee may, on its own motion or on written request by any individual or group, review this proposed action under §17A.8(6) at a regular or special meeting where the public or interested persons may be heard.

Pursuant to the authority of Iowa Code Supplement section 246.910, the Department of Corrections hereby gives Notice of Intended Action to amend Chapter 20, "Institutions Administration," Iowa Administrative Code.

Proposed new rule 20.17(246), "Institutional community placement," authorizes the Department to place selected inmates into community programs for the purpose of employment, education, or home care, such as child or adult dependency/care. Placement can include daily release from an institution, placement into a community corrections facility, or placement into an approved community-living environment.

A public hearing has been scheduled for 1 p.m. to 3 p.m. on June 16, 1992, in the Corrections Conference Room, 523 East 12th Street, Des Moines, Iowa 50319.

Written comment may be submitted to the Director no later than June 16, 1992, at the address above.

This new rule was approved by the Department on May 8, 1992.

This rule is intended to implement Iowa Code Supplement section 246.910.

The following new rule is proposed.

201-20.17(246) Institutional community placement.

20.17(1) Home care program. This program allows for selected inmates to be released from institutional confinement for a set period of time for the purpose of caring for the inmate's immediate family. Release may be to a community correction residential facility/halfway house or to the inmate's home, home of an immediate family member, or other approved arrangements, provided the living environment is suitable to institutional requirements. Release may be for a set number of hours or days as appropriate.

a. Eligibility criteria.

(1) The inmate must be the natural parent or legal guardian of the child/children.

(2) The inmate must show cause that this program can provide more suitable care than the present living situation of the child/children.

CORRECTIONS DEPARTMENT[201](cont'd)

(3) The child/children must be minor(s).

(4) The inmate must have been the primary caretaker of the child/children prior to incarceration.

(5) Investigating staff must be able to confirm that the inmate had satisfactorily served this care prior to incarceration.

(6) The proposed living arrangements shall provide a suitable environment for the inmate and dependents.

(7) The physical structure of the residence shall provide for adequate space, meet sanitary, health and safety requirements, and be in good repair. A functional telephone must be maintained in the residence at all times.

- (8) It will be verified that the inmate, including spouse or immediate family member living at the same residence, can and will provide adequate support towards the child, children, or other dependent. Eligibility requirements for assistance through the department of human services programs (ADC, food stamps, etc.) will be verified prior to final approval.
- (9) It will be verified that the inmate or immediate family living at the residence can provide adequate transportation or that public transportation is available.
- (10) Adequate support services (medical, psychological, education, as well as other treatment programs) must be arranged and available to both the inmate and dependents.
- (11) Dependent care for an adult member of the inmate's immediate family must include a medically documented need with periodic supervision or other approved arrangements by a health-trained professional.

b. Requirements.

(1) Education/employment/child care/adult dependent care. Where all dependents are involved in full-time school, participation in an educational or employment program may be required of the inmate. Where such dependents are not yet in school, child care may be considered as full-time employment.

(2) Child care/adult dependent care. As authorized under Iowa Code chapter 247A, child care shall be provided in the home. Therefore, the residence will be considered as the designated place of assignment. Deviations

from same shall be reported to staff in advance.

20.17(2) Work program—eligibility criteria. This program allows for selected inmates to be released from institutional confinement for a period of time for gainful employment in the community. The program may also include placement in a community corrections residential facility/halfway house or to the inmate's home, home of an immediate member, or other approved arrangements, provided the living environment is suitable to institutional requirements. Release may be for a set number of hours or days as appropriate.

a. The inmate must show a substantial need and inter-

est for participation in the program.

b. The inmate must seek and apply for employment through established procedures of the furlough program or through institutional correspondence, telephone, or visiting procedures.

c. Suitable employment and verification must be ob-

tained by staff prior to consideration.

20.17(3) Educational program—eligibility criteria. This program allows for selected inmates to be released from institutional confinement for a period of time for educational opportunities in the community. This program may also include placement in a community corrections residential facility/halfway house or to the inmate's home, home of an immediate family member, or other ap-

proved arrangements, provided the environment is suitable to institutional requirements. Release may be for a set number of hours or days as appropriate.

a. The inmate must show a substantial need and inter-

est for participation in the program.

b. The inmate must seek educational opportunities and financial support through established procedures of the furlough program or through institutional correspondence, telephone, or visiting procedures (financial arrangements can only include family support or grants). Educational loans or loans of any type will not be allowed while on institutional count. Additional community corrections restriction may apply while under community supervision.

20.17(4) General requirements for all three programs.

a. Participation in any of these programs at any level is a privilege, not a right, of which participating inmates are subject to and held accountable for all provisions of this policy as well as the specific program plan.

b. Institutional progress and recommended program participation must reflect an average or above rating.

- c. Inmates must be furlough-eligible in accordance with furlough eligibility standards in DOC policy IN-V-44 and rule 20.12(246).
- d. If applicable, community corrections residential/halfway house rules and regulations will apply as well as institutional rules including all program plan rules.

e. Local authorities will be contacted to determine possible concerns (correctional services, county attorney,

law enforcement).

f. The inmate may be required to submit to periodic or regular U.A. Testing (this procedure may be completed at any correctional institution, community corrections facility/office, or at the residence).

g. All activity will be monitored by community

corrections staff and institutional staff as agreed.

h. All employment and educational earnings, less payroll deductions including education grants and expenses, shall be surrendered to the residential facility/halfway house staff according to established procedures or to the institution business manager, whichever applies, according to the program plan. Employment earning deductions will be prioritized in accordance with Iowa Code section 246.905 for all levels of placement.

i. Contact frequency. A minimum of one home visit and one other face-to-face contact per month are required of staff. Furthermore, a sufficient number of collateral contacts will be made each month to ensure that the inmate is meeting requirements of the program plan.

j. Special needs. In situations where inmates or the family have special needs, a case planning system shall be incorporated to address needs, capabilities, and specific goals. Special attention shall be given to past or immediate problems.

k. Travel. Supervisory staff may grant permission for travel within the state. Standard policy will apply to out-

of-state travel.

1. Temporary absence. Inmates may temporarily leave the residence for necessary purposes such as shopping, religious services, family recreation, medical appointments, employment, etc., as indicated on the plan.

20.17(5) Application procedures.

a. Applications must be made to the present institutional classification committee (utilizing Form 1).

b. The application must contain all pertinent information and resources for the requested program.

c. The classification committee shall review each case considering all standards and criteria.

CORRECTIONS DEPARTMENT[201](cont'd)

d. The classification committee's recommendation must be approved by the warden/superintendent.

e. If approved by the warden/superintendent, the recommendation and all pertinent information shall be for-

warded to the deputy director for final approval.

f. If the recommendation is approved by the deputy director, the inmate must agree to abide by all rules established in the program plan including institutional rules and community corrections rules as well as all local, state, and federal laws.

g. Each level of review has the authority to deny the application or to make changes in the program plan including level of placement, i.e., institutional, residential/halfway house, home, as well as electronic monitoring de-

vices.

h. This status may be revoked for any reason which may not necessarily include a discipline report deemed appropriate by the warden/superintendent or designee.

i. Inmates placed in any of these programs will not be relieved of paying restitution or any other financial obligation as required by the court or institution.

20.17(6) Violations.

a. Violation of any rule set forth in the program planincluding any additional rules set forth by any authority listed in this policy may constitute the revocation of participation in either program at any level.

b. Revocation may also occur for improper care of children or dependents, inadequate earnings, failure to maintain employment or unacceptable employment conduct, rule violations, or failure to meet program expecta-

tions.

This rule is intended to implement Iowa Code section 246.910.

ARC 3060A

DEAF SERVICES DIVISION[429]

Notice of Intended Action

Twenty-five interested persons, a governmental subdivision, an agency or an association of 25 or more persons may demand an oral presentation hereon as provided in Iowa Code §17A.4(1)"b."

Notice is also given to the public that the Administrative Rules Review Committee may, on its own motion or on written request by any individual or group, review this proposed action under §17A.8(6) at a regular or special meeting where the public or interested persons may be heard.

Pursuant to the authority of Iowa Code section 601K.115, the Division of Deaf Services hereby gives Notice of Intended Action to amend Chapter 1, "Organization," Chapter 2, "Services and Procedures," and Chapter 4, "Forms," Iowa Administrative Code.

The purpose of the amendments is to update the rules and incorporate changes in location, programs, and refer-

ence terms

Item 1 incorporates the hard-of-hearing community in the mission of the agency as an additional constituency group.

Item 2 amends the subrule to reflect current locations of regional offices across the state as a result of a reduction in force.

Item 3 addresses changes in division office locations regarding method of contact.

Item 4 clarifies the services provided by interpreters and includes a functional definition of the provision of oral interpreting services.

Item 5 revises reference of the title, "Consultant for the

handicapped" to "Consultant."

Item 6 adds a subrule to define the use of resolution forms for commissioners to vote on issues needing immediate attention between commission meetings.

Item 7 provides for current and appropriate definitions for "deaf"; adds language to definition of "obligated agency" to include provisions of the Americans with Disabilities Act of 1990; and includes a new definition for "hard-of-hearing" to be used in lieu of "hearing impaired."

Item 8 adds the hard-of-hearing individual/community under the eligibility and residency requirements of consumers who may receive advocacy, assistance and ser-

vices from the agency.

Items 9 and 10 correct reference made to interpreters in private practice by removing the term "free-lance."

Item 11 revises reference of the title, "Consultant for

the handicapped" to "Consultant."

Item 12 includes a new section regarding the procedures for overdue library books loaned from the Library on Deafness and the assessment of fines.

Item 13 strikes language on the News Break program and the Sign Language Instructional program which have been discontinued.

Item 14 adds provisions of the Americans with Disabilities Act of 1990 under the rules on Fees for Interpreting Services.

Item 15 removes reference to the term "hearing impaired" and replaces with the term "hard-of-hearing."

Item 16 amends the fee scale for interpreting services provided by division staff to reflect current market rates as suggested by a recent survey.

Item 17 allows for a one-hour minimum to be charged for interpreting assignments that are billed to an obligated agency which last less than one hour, and allows the division to assess fees for time spent coordinating interpreting services which exceed three hours in length.

Item 18 removes the client intake form previously used

by the agency.

Item 19 corrects reference made to interpreters in private practice by removing the term "free-lance."

Item 20 strikes the subrule on the Des Moines Metropolitan Transit Authority (MTA) form previously used by the agency.

Item 21 provides for additional information necessary in completing invoices for interpreting services provided

under the fee-for-service program.

Item 22 provides for the use of two new forms (meeting/presentation documentation forms and a court proceedings waiver).

Item 23 amends implementation clauses at the end of 429—Chapters 1, 2, and 4.

Any interested person may make written or oral suggestions or comments on these proposed amendments on or before June 16, 1992. Comments should be directed to Diana Leonard, Administrator, Deaf Services Commission of Iowa, Department of Human Rights, Lucas State Office Building, Des Moines, Iowa 50319-0090, telephone (515)281-3164, voice and TTY.

There will be a public hearing on June 18, 1992, at 1 p.m. in the Third Floor Side 1, Conference Room, Lucas State Office Building, Des Moines, Iowa, at which time persons may present their views either orally or in writing. At the hearing, persons will be asked to give their

DEAF SERVICES DIVISION[429](cont'd)

names and addresses for the record, and to confine their remarks to the subject of the amendments. Sign language and oral interpreting services will be available.

The following amendments are proposed.

ITEM 1. Amend rule 429—1.1(601K) as follows:

429—1.1(601K) Function. The division of deaf services, within the department of human rights, was created pursuant to Iowa Code section 601K.1 and is required to coordinate, implement, and provide services to deaf and hard-of-hearing citizens. The commission on the deaf is responsible for establishing policies for the division of deaf services program programs to be carried out by the administrator of the division as set out in Iowa Code section 601K.114.

ITEM 2. Amend subrule 1.2(1) as follows:

1.2(1) Location. The division of deaf services consists of a central office, five and three regional offices, and one branch office. Hours of operation for regional offices are 8 a.m. to 4:30 p.m., Monday through Friday. See paragraph_g" for the branch office hours.

a. The central office is located in the Department of Human Rights, First Floor, Lucas State Office Building, Des Moines, Iowa 50319-0090. The telephone number is

(515)281-3164, voice and TDD TTY.

b. The Cedar Rapids regional office is located in the Iowa Building, 221 4th Avc. S.E., Cedar Rapids, Iowa 52401. The telephone number is (319)398-4005, voice and TDD:

- c. The Council Bluffs regional office is located in the City of Council Bluffs Health Department, City Hall, Lower Level, 209 Pearl Street, Council Bluffs, Iowa 51503. The telephone number is (712)328-3195, voice and TDD TTY.
- d. The Sioux City regional office is located in the Jewish Community Center, 525 14th Street, Sioux City, Iowa 51105. The telephone number is (712)258-8407, voice and TDD.
- e. The Davenport regional office is located in the Community Resource Center, Inc., 605 North Main Street, Suite #221, Davenport, Iowa 52803. The telephone number is (319)322-0255, voice and TDD TTY.
- f. The Fort Dodge regional office is located at the Warden Plaza, 920 1st Avenue South, Suite A, Fort Dodge, Iowa 50501. The telephone number is (515)955-2539, voice and TDD TTY.
- g. The Waterloo branch office is located in the Civil Defense Office, City Hall Basement, 715 Mulberry Street, Waterloo, Iowa 50703. The telephone number is (319)291-4262, voice and TDD. The hours of operation are 9 a.m. to 3:30 p.m. on Wednesdays. Telephone interpreting services are provided from 9 to 10 a.m. on Wednesdays.

ITEM 3. Amend subrule 1.2(2) as follows:

- 1.2(2) Method of contacting the division of deaf services. Citizens may contact the division of deaf services central, or regional, or branch offices by phone, mail or personal visits for any of the services provided unless otherwise stated under the specific service.
- a. Citizens may call the central office in Des Moines from within the state, station-to-station collect.
- b. Citizens who call branch or regional offices may ask the division of deaf services' staff to return the call on the division of deaf services' telephone line.
- c. Citizens who request services from a branch office may leave a message there. Since branch office hours are

limited, citizens may prefer to call the regional or central offices to request services.

ITEM 4. Amend subrule 1.2(3), paragraph "b," as follows:

b. Interpreters. The interpreters provide sign language and oral interpreting services by changing English into sign language for hearing impaired persons and by changing sign language into English for persons who are hearing. Pursuant to Iowa Code chapter 622B; Supreme Court Rules on Qualifications and Compensation of Interpreters. dated May 1981; and Iowa Code section 804.31, the division of deaf services interpreters shall hold a Comprehensive Skills Certificate (CSC) or a Certificate of Interpretation (CI) and Certificate of Transliteration (CT) from the Registry of Interpreters for the Deaf, Inc. Applicants that are hired as staff interpreters who do not possess a CSC or CI and CT shall attain this level of certification within six months of hire as a condition of employment. The interpreters plan, coordinate, and schedule requests to provide direct and contractual/referral interpreting services and coordinate contractual/referral interpreting requests when appropriate. The interpreters document services provided for statistical purposes, maintain cooperative working relationships with clients served, and perform related work as required. Advocacy issues or issues requiring assistance will be referred to the consultant for the handicapped or administrator.

ITEM 5. Amend subrule 1.2(3), paragraph "c," by striking the words, "for the handicapped" where they appear three times.

ITEM 6. Amend subrule 1.3(2) by adding the following paragraph:

h. The commission may vote on issues in the form of resolutions which will be read and recorded at the following regular meeting.

ITEM 7. Amend 429—2.1(601K) as follows:

- 1. Add the words "The following definitions reflect a service-oriented approach to communication and do not reflect or imply a degree of hearing loss:" following the catchword "Definitions."
- 2. Rescind the definitions of "Deaf persons" and "Hearing impaired persons" and insert the following in alphabetical sequence:

"Deaf persons" means those individuals who use sign language as their primary mode of communication. They may use interpreters to facilitate communication.

"Hard-of-hearing persons" means those individuals who are unable to hear easily within conversational range. They may use speechreading, assistive listening devices or oral interpreters to facilitate communication.

"Oral interpreter" means an interpreter who is fluent in

transliterating, paraphrasing and voicing.
"Sign language interpreter" means an

"Sign language interpreter" means an interpreter who is able to interpret from sign language to English and English to sign language.

3. Amend the first sentence of the definition of "Obli-

gated agency" to read as follows:

"Obligated agency" means any program or activity that receives federal financial assistance or that is conducted by any executive agency of the federal government or by the U.S. Postal Service or any covered, public or private entity defined under the Americans with Disabilities Act of 1990.

ITEM 8. Amend rule 429—2.2(601K) as follows:

429-2.2(601K) Eligibility and residency requirements. The division of deaf services makes services available to Iowa residents and deaf or hard-of-hearing nonresidents who may be visiting or conducting business within the state of Iowa. Services provided by the division of deaf services are also provided up to 20 miles beyond the borders of this state for deaf or hard-of-hearing Iowans or for deaf or hard-of-hearing nonresidents of this state who are employed in Iowa. Granting of benefits is contingent on eligibility and availability of resource resources.

ITEM 9. Amend subrule 2.3(2), introductory paragraph and paragraphs "d" and "e," as follows:

2.3(2) Contractual interpreting services. The division of deaf services provides contractual interpreting services by using free-lance interpreters in private practice who have entered into a contractual agreement with the agency. Contractual interpreting funding will not be used when any party is willing or obligated by state or federal law to pay for interpreting services.

d. General terms and conditions are listed on the individual contracts. Detailed procedures for contractual services are specified in the contractual interpreting manual printed for free-lance interpreters in private practice who

contract their services through the division.

e. Free-lance interpreters Interpreters in private practice may enter into a contract with the division of deaf services by contacting the agency and filling out an interpreter update form and signing a contract upon which they are in agreement.

ITEM 10. Amend subrule 2.3(3), paragraphs "a" to "c," as follows:

2.3(3) Referral interpreting services. The division of deaf services provides an interpreter referral service to persons needing an interpreter when the staff interpreter is not available or when the request goes beyond regular hours of operation.

a. The division of deaf services will attempt to secure free-lance interpreting services where state or federal laws mandate compensation for services or when any party is

willing to provide for compensation of services.

b. Free-lance interpreters Interpreters in private practice may contact the agency to request an interpreter update form. Upon completion and return of this form, the free-lance interpreter interpreter's name will be added to the listing.

c. Staff interpreters are permitted to function on a freelance private basis, beyond regular hours of operation, provided there is no conflict with employment services.

ITEM 11. Amend subrule 2.3(5) by striking the words "for the handicapped" where they appear twice following the word "consultant".

ITEM 12. Amend subrule 2.3(7) by adding a new para-

graph as follows:

i. Persons not returning materials to the library on or before the date due will be assessed a fine of \$.05 per day, per item, not to exceed a total of \$4.00 per item. The exception will be videocassette tapes which will be assessed at \$.25 per day, per item, not to exceed a total of \$4.00 per tape. A day of grace will be given if a return date falls on a holiday. No other materials may be borrowed until all outstanding fines are paid.

ITEM 13. Rescind subrules 2.3(9) and 2.3(11).

ITEM 14. Amend rule 429—2.4(601K) as follows:

429—2.4(601K) Fee for interpreting service. Pursuant to the Americans with Disabilities Act of 1990 and Section 504 of the Vocational Rehabilitation Act of 1973, as amended in 1978 and in accordance with the Civil Rights Restoration Act of 1987, which applies to health care and social service programs, schools, colleges, vocational centers, housing, transportation, and other public services:

... no otherwise covered, public or private entity shall discriminate against a qualified handicapped individual with a disability, in the United States, as defined in Section 7(6), No such person shall, solely by reason of his the person's handicap, be excluded from the participation in, be denied the benefits of, or be subjected to discrimination under any program or activity provided by any covered, public or private entity in accordance with the authority referenced above. receiving Federal financial assistance or by any activity conducted by any Executive Agency or by the United States Postal Service. ...

Under this authority the authority referenced in the preceding paragraph and in accordance with the 1988 Iowa Acts, Senate File 2310, section 13 Iowa Code section 601K.117, the division of deaf services shall invoice obligated agencies for interpreting services provided by staff interpreters.

ITEM 15. Amend subrules 2.4(1) and 2.4(2) by striking the words "hearing impaired" where they appear three times and inserting the words "hard-of-hearing".

ITEM 16. Amend subrule 2.4(3), paragraph "b," as follows:

b. The fee schedule for division staff is:

\$23.00 30.00/hour Legal Setting \$20.00/hour Mental Health Setting **Health Setting** \$17:00 15.00/hour Community Service Setting \$13.00 15.00/hour \$13.00 15.00/hour Consumer Service Setting Personal Matter Setting \$13.00 15.00/hour \$13.00 15.00/hour **Employment Setting** \$13.00 15.00/hour **Educational Setting**

ITEM 17. Amend subrule 2.4(3) by adding new paragraphs "c" and "e" and relettering existing paragraph "c" as paragraph "d" as follows:

c. Fees shall be calculated on a portal-to-portal basis with a one-hour minimum for assignments that run less

than one hour in length.

e. The division will provide coordination of interpreting services and fees shall be calculated for actual number of hours which exceed three hours in length according to the category and fee scale listed under 2.4(3).

ITEM 18. Rescind subrule 4.1(1).

ITEM 19. Amend subrule 4.1(11) as follows:

4.1(11) Interpreter update form. This form is required to be filled out by free-lance interpreters in private practice in serving on referral or contractual listings for the division. Information requested relates to an individual's background, experience, certification, and education in the interpreting field along with times of availability, counties served, and personal data. These forms are confidential although listings derived from these forms are made public to those consumers requesting the listings.

ITEM 20. Rescind subrule 4.1(14).

DEAF SERVICES DIVISION[429](cont'd)

ITEM 21. Amend subrule 4.1(15) by adding a new paragraph "g" as follows:

g. Account numbers, case numbers or other necessary information to verify services were provided.

ITEM 22. Insert new subrules 4.1(17) and 4.1(18):

4.1(17) Meeting/presentation request form. This form is used by staff to record requests for presentations and meetings handled by the division. Request form data is used for statistical purposes and destroyed after it is officially recorded in the annual report.

4.1(18) Court proceedings waiver form. This form is used by staff who are not certified to provide services in court proceedings only when all reasonable efforts have been made to secure a certified interpreter and the case is either urgent or routine in nature. This form is to be used only when parties have waived the right to a certified interpreter and the administrator has been consulted.

ITEM 23. Rescind the implementation clauses at the end of 429—Chapters 1, 2, and 4 and insert the following:

These rules are intended to implement Iowa Code sections 601K.111 to 601K.116 and Iowa Code Supplement section 601K.117.

ARC 3012A

HUMAN SERVICES DEPARTMENT[441]

Notice of Intended Action

Twenty-five interested persons, a governmental subdivision, an agency or an association of 25 or more persons may demand an oral presentation hereon as provided in Iowa Code §17A.4(1)"b."

Notice is also given to the public that the Administrative Rules Review Committee may, on its own motion or on written request by any individual or group, review this proposed action under \$17A.8(6) at a regular or special meeting where the public or interested persons may be heard.

Pursuant to the authority of Iowa Code section 249A.4, the Department of Human Services proposes to amend Chapter 78, "Amount, Duration and Scope of Medical and Remedial Services," appearing in the Iowa Administrative Code.

This amendment revises the periodicity schedule for Early and Periodic Screening, Diagnosis and Treatment (EPSDT) health screens and establishes the periodicity schedules for hearing, vision, and dental screens.

The Omnibus Budget Reconciliation Act of 1989 requires that each state shall develop periodicity schedules for health screening services, vision services, hearing services, and dental services in the EPSDT program after consultation with recognized medical organizations involved in child health care. The Department consulted with an advisory committee comprised of representatives from various medical organizations, the Department of Public Health, and the Department of Public Instruction; and a decision was made to adopt the American Academy of Pediatrics standards in medical, vision, and hearing. The dental schedule is similar to that of the American Dental Association.

Under current policy, payment will be approved for four health screenings in the first year of life, two screenings between the ages of 1 and 2, one screening between the ages of 2 and 3, one screening between the ages of 3

and 4, one screening between the ages of 4 and 6, one screening between the ages of 6 and 9, one screening between the ages of 9 and 13, one screening between the ages of 13 and 17, and one screening between the ages of 17 and 21, a total of 13 screenings. Under these amendments, payment will be approved for six screenings in the first year of life, four screenings between the ages of 1 and 2, one screening a year at ages 3, 4, 5, and 6, and one screening at ages 8, 10, 12, 14, 16, 18, and 20, a total of 21 screenings. Dental screenings are payable at the same intervals as the health screenings until a separate dental screening referral is made at 12 months. One screening is payable at age 24 months and at six-month intervals thereafter up to age 21.

If Iowa met the federal goal of 52 percent of eligibles receiving EPSDT screens, the maximum cost for the additional eight EPSDT screens from ages 0 to 21 would be a total of approximately \$1,106,000, \$700,000 in federal funds and \$406,000 in state funds. Currently, only 13 percent of eligibles are receiving EPSDT screens.

Consideration will be given to all written data, views, and arguments thereto received by the Bureau of Policy Analysis, Department of Human Services, Hoover State Office Building, Des Moines, Iowa 50319-0114, on or before June 17, 1992.

This amendment is intended to implement Iowa Code section 249A.4.

The following amendment is proposed.

Rescind subrule 78.18(3) and insert the following in lieu thereof:

78.18(3) Periodicity schedules for health, hearing, vision, and dental screenings.

- a. Payment will be approved for health, vision, and hearing screenings as follows:
 - (1) Six screenings in the first year of life.
 - (2) Four screenings between the ages of 1 and 2.
 - (3) One screening a year at ages 3, 4, 5, and 6.
- (4) One screening a year at ages 8, 10, 12, 14, 16, 18, and 20.
- b. Payment for dental screenings will be approved in conjunction with the health screenings up to age 12 months. Screenings will be approved at ages 12 months and 24 months and thereafter at six-month intervals up to age 21.
- c. Interperiodic screenings will be approved as medically necessary.

ARC 3010A

HUMAN SERVICES DEPARTMENT[441]

· Notice of Intended Action

Twenty-five interested persons, a governmental subdivision, an agency or an association of 25 or more persons may demand an oral presentation hereon as provided in Iowa Code §17A.4(1)"b."

Notice is also given to the public that the Administrative Rules Review Committee may, on its own motion or on written request by any individual or group, review this proposed action under §17A.8(6) at a regular or special meeting where the public or interested persons may be heard.

Pursuant to the authority of Iowa Code section 249A.4, the Department of Human Services proposes to amend

Chapter 78, "Amount, Duration and Scope of Medical and Remedial Services," appearing in the Iowa Administrative Code.

These amendments incorporate rule changes agreed to in the settlement of the Ronald Sonnenberg et al. vs. Charles M. Palmer et al. court case (United States District Court for the southern district of Iowa, Civil No. 88-122-B). The revisions provide clarification that rehabilitation agency services are available for illness, injury, or any disabling condition; clarification of the circumstances in which maintenance therapy is a payable service; clarification that diagnostic or trial therapy is payable for up to two months when specific criteria are met; and clarification that a reevaluation can be covered after 12 months of maintenance therapy.

The specific criteria which must be met for payment of

diagnostic or trial therapy are as follows:

- 1. Therapy is payable only once per year for the same issue. Requests for subsequent diagnostic or trial therapy for the same issue would require documentation reflecting a significant change. Further diagnostic or trial therapy for the same issue would not be considered appropriate when progress was not achieved, unless the reasons which blocked change previously are listed and the reasons the new diagnostic or trial therapy would not have these blocks are provided.
 - 2. Therapy shall not exceed 12 hours per month.
- 3. There must be face-to-face interaction with a licensed therapist.
 - 4. Services must be provided on an individual basis.
- 5. Documentation of the diagnostic therapy or trial therapy must reflect the provider's plan for therapy and the recipient's response.
- 6. When a recipient has a previous history of rehabilitative service, a significant change must have occurred since the last therapy and the recipient shall have incorporated the regimen recommended during prior treatment into the recipient's daily life.
- 7. Referrals from residential, vocational or other rehabilitation personnel that do not meet present evaluation, restorative or maintenance criteria shall be considered for trial therapy.

These amendments do not represent changes, but clarifications of policy as currently applied by the Department's fiscal agent, Unisys.

An advisory group assisted the Department in establishing the criteria for diagnostic or trial therapy services to ensure that these services are appropriately utilized.

Consideration will be given to all written data, views, and arguments thereto received by the Bureau of Policy Analysis, Department of Human Services, Hoover State Office Building, Des Moines, Iowa 50319-0114, on or before June 17, 1992.

This rule is intended to implement Iowa Code section 249A.4.

The following amendments are proposed.

ITEM 1. Amend subrule 78.19(1), paragraph "a," as follows:

Amend subparagraphs (2), (3), (4), and (5) as follows:

- (2) All services must be determined to be medically necessary, reasonable, and meet a significant need of the recipient that cannot be met by a significant other, friend, or medical staff personnel; must meet accepted standards of medical practice; and must be a specific and effective treatment for a patient's medical or disabling condition.
- (3) In order for a service to be payable, a licensed skilled therapist must complete a plan of treatment every

30 days and indicate the type of service required. The plan of treatment must also contain the following information: noted in subrule 78.19(2). patient's medical condition and functional abilities, a brief summary of the initial evaluation, patient's rehabilitation potential, discipline of the person providing the service, frequency and duration of the service, measurable short-term and long-term goals, the physician's signature and date (within the certification period), certification period, patient's progress in measurable statistics, and the estimated date of discharge, if applicable.

(4) There is no specific limitation on the number of visits for which payment through the program will be made so long as that amount of service is medically necessary in the individual case, is related to a diagnosed medical impairment or disabling condition, and meets the current standards of practice in each related field. Documentation must be submitted with each claim to support the need for the number of services being provided.

(5) Payments will be made both for restorative service and also for maintenance types of service. Essentially, maintenance services means services to a patient whose condition is stabilized and who requires observation by a therapist of conditions defined by the physician as indicating a possible deterioration of health status. This would include persons with long-term illnesses or a disabling condition whose condition status is stable rather than posthospital. Refer to 78.19(1)"b"(7) and (8) for guidelines under restorative and maintenance therapy.

Amend subparagraph (6), first line, and numbered

paragraph "4" as follows:

(6) Therapy Restorative or maintenance therapy must meet the following criteria:

4. Progress must be documented in measurable statistics in the progress notes in order for services to be reimbursed. Refer to 78.19(1)"b"(7) and (8) for guidelines under restorative and maintenance therapy.

Add a new subparagraph (7) as follows:

- (7) Payment will be made for an appropriate period of diagnostic therapy or trial therapy (up to two months) to determine a patient's rehabilitation potential and establish appropriate short-term and long-term goals. Documentation must be submitted with each plan to support the need for diagnostic or trial therapy. Refer to 78.19(1)"b"(16) for guidelines under diagnostic or trial therapy.
- ITEM 2. Amend subrule **78.19(1)**, paragraph "b," as follows:

Amend subparagraphs (1), (5), (7), (8), (10), (12), and (15) and add a new subparagraph (16) as follows:

- (1) To be covered under rehabilitation agency services, physical therapy services must relate directly and specifically to an active written treatment plan, follow a treatment plan established by the licensed skilled therapist after consultation with the physician, be reasonable and necessary to the treatment of the person's illness, or injury, or disabling condition, be specific and effective treatment for the patient's medical or disabling condition, and be of such a level of complexity and sophistication, or the condition of the patient must be such that the services required can be safely and effectively performed only by a qualified physical therapist or under the supervision of the therapist.
- (5) It must be demonstrated that there is a need to establish a safe and effective maintenance program related to a specific disease state, illness, injury, or disabling condition.

(7) Restorative therapy must be reasonable and necessary to the treatment of the person's illness and patient's injury or disabling condition. The expected restorative potential must be practical and in relation to the extent and duration of the treatment. There must be an expectation that the patient's medical or disabling condition will show functional improvement in a reasonable period of time. Functional improvement means that demonstrable measurable increases have occurred in the patient's level of independence outside the therapeutic environment.

(8) Maintenance therapy is, generally, repetitive exercises to maintain function which do not require the services of a qualified physical therapist and are not Generally, maintenance therapy means reimbursable. services to a patient whose condition is stabilized and who requires observation by a therapist of conditions defined by the physician as indicating a possible deterioration of health status. This includes persons long-term illnesses or disabling conditions whose status is stable rather than posthospital. Maintenance therapy is also appropriate for individuals whose condition is such that a professionally established program of activities, exercises, or stimulation is medically necessary to prevent deterioration or maintain present functioning

Certain conditions or situations may require a maintenance program established by a qualified therapist; for example, a patient with Parkinson's disease who has not been under a restorative physical therapy program. In these eases; Where a maintenance program is appropriate, the initial evaluation and the instruction of the patient, family members, home health aides, or facility personnel, or other caregivers to carry out the program are considered a covered physical therapy service. In these eases payment Payment shall be made for a maximum of three visits to establish the evaluation and instruction of a maintenance program and instruct the caregivers. Payment for supervisory visits to monitor the program would be is limited to two per month for a maximum period of 12 months. The plan of treatment must specify the anticipated monitoring activity for the supervisor.

Beyond evaluation, instruction, and monitoring, maintenance therapy is not reimbursable.

After 12 months of maintenance therapy, a reevaluation is a covered service, if medically necessary. A reevaluation will be considered medically necessary only if there is a significant change in residential or employment situation or the patient exhibits an increase or decrease in functional ability or motivation, clearing of confusion, or the remission of some other medical condition which previously counterindicated restorative therapy. A statement by the interdisciplinary team of a person with developmental disabilities recommending a reevaluation and stating the basis for medical necessity will be considered as supporting the necessity of a reevaluation and may expedite approval.

(Restorative and maintenance therapy definitions also

apply to speech and occupational therapy.)

When a patient is under a restorative physical therapy program, the patient's condition is regularly evaluated and the program adjusted by the physical therapist. It is expected then, that prior to discharge, a maintenance program has been designed by the physical therapist. Consequently, where a maintenance program is not established until after the restorative program has been completed, it would not be considered reasonable and

necessary to the treatment of the patient's condition and would be excluded from coverage.

(10) Gait training and gait evaluation and training constitute a covered service if the patient's ability to walk has been impaired by a neurological, muscular or skeletal condition or illness. The gait training must be expected to significantly improve the patient's ability to walk or level of independence.

Repetitious exercise to increase endurance of feeble weak or unstable patients can be safely provided by supportive personnel, e.g., aides, nursing personnel. Therefore it is not a covered physical thereps across

fore, it is not a covered physical therapy service.

(12) Range of motion tests must be performed by a qualified physical therapist. Range of motion exercises require the skills of a qualified therapist only when they are part of the active treatment of a specific disease or disabling condition which has resulted in a loss or restriction of mobility.

Documentation must reflect the degree of motion lost, the eorreet degree normal range of motion, and the degree to be restored.

Range of motion to unaffected joints only does not constitute a covered physical therapy service.

(15) Use of isokinetic or isotonic type equipment in physical therapy is covered when normal ambulation or range of motion of a joint is affected due to bone, joint, ligament or tendon injury or postsurgical trauma. Billing can only be made for the time actually spent by the therapist in instructing the patient and assessing the patient's progress.

(16) When recipients do not meet restorative or maintenance therapy criteria, diagnostic or trial therapy may be utilized. When the initial evaluation is not sufficient to determine whether there are rehabilitative goals that should be addressed, diagnostic or trial therapy to establish goals shall be considered appropriate. Diagnostic or trial therapy may be appropriate for recipients who need evaluation in multiple environments in order to adequately determine their rehabilitative potential. Diagnostic or trial therapy consideration may be appropriate when there is a need to assess the patient's response to treatment in the recipient's environment.

When during diagnostic or trial therapy a recipient has been sufficiently evaluated to determine potential for restorative or maintenance therapy, or lack of therapy potential, diagnostic or trial therapy ends. When, as a result of diagnostic or trial therapy, restorative or maintenance therapy is found appropriate, claims shall be submitted noting restorative or maintenance therapy (instead of diagnostic or trial therapy).

At the end of diagnostic or trial therapy, the rehabilitation provider shall recommend continuance of services under restorative therapy, recommend continuance of services under maintenance therapy, or recommend discontinuance of services. Continuance of services under restorative or maintenance therapy will be reviewed based on the criteria in place for restorative or mainte-

nance therapy.

Trial therapy shall not be granted more often than once per year for the same issue. If the recipient has a previous history of rehabilitative services, trial therapy for the same type of services generally would be payable only when a significant change has occurred since the last therapy. Requests for subsequent diagnostic or trial therapy for the same issue would require documentation reflecting a significant change. See number "4" below for guidelines under a significant change. Further diagnostic

or trial therapy for the same issue would not be considered appropriate when progress was not achieved, unless the reasons which blocked change previously are listed and the reasons the new diagnostic or trial therapy would not have these blocks are provided.

The number of diagnostic or trial therapy hours authorized in the initial treatment period shall not exceed 12 hours per month. Documentation of the medical necessity and the plan for services under diagnostic trial therapy are required as they will be reviewed in the determination of the medical necessity of the number of hours of service provided.

Diagnostic or trial therapy standards also apply to speech and occupational therapy.

The following criteria additionally must be met:

1. There must be face-to-face interaction with a licensed therapist. (An aide's services will not be payable.)

2. Services must be provided on an individual basis. (Group diagnostic or trial therapy will not be payable.)

3. Documentation of the diagnostic therapy or trial therapy must reflect the provider's plan for therapy and

the recipient's response.

- 4. If the recipient has a previous history of rehabilitative services, trial therapy for the same type of services generally would be payable only when a significant change has occurred since the last therapy. A significant change would be considered as having occurred when any of the following exist: new onset, new problem, new need, new growth issue, a change in vocational or residential setting that requires a reevaluation of potential, or surgical intervention that may have caused new rehabilitative potentials.
- 5. For persons who received previous rehabilitative treatment, consideration of trial therapy generally should occur only if the person has incorporated any regimen recommended during prior treatment into the person's daily life to the extent of the person's abilities.

6. Documentation should include any previous attempts to resolve problems using nontherapy personnel (i.e., residential group home staff, family members, etc.) and whether follow-up programs from previous therapy have been carried out.

7. Referrals from residential, vocational or other rehabilitation personnel that do not meet present evaluation, restorative or maintenance criteria shall be considered for trial therapy. Documentation of the proposed service, the medical necessity and the current medical or disabling condition, including any secondary rehabilitative diagnosis, will need to be submitted with the claim.

8. Claims for diagnostic or trial therapy shall reflect the progress being made toward the initial diagnostic or

trial therapy plan.

ITEM 3. Amend subrule 78.19(1), paragraph "c," sub-

paragraphs (1) and (2), as follows:

(1) To be covered under rehabilitation agency services, occupational therapy services must be included in a plan of treatment, improve or restore practical functions which have been impaired by illness, or injury or disabiling condition, or enhance the person's ability to perform those tasks required for independent functioning, be prescribed by a physician under a plan of treatment, be performed by a qualified licensed occupational therapist or a qualified licensed occupational therapist assistant under the general supervision of a qualified licensed occupational therapist as set forth in the department of health, professional licensure division, rule 645--201.9(148B), and

be reasonable and necessary for the treatment for the person's illness, or injury, or disabling condition.

(2) Restorative therapy is covered when an expectation exists that the therapy will result in a significant prac-

tical improvement in the person's condition.

However, in these cases where there is a valid expectation of improvement met at the time the occupational therapy program is instituted, but the expectation goal is not realized, services would only be covered up to the time one would reasonably conclude the patient would not improve.

The guidelines under restorative therapy, and maintenance therapy, and diagnostic or trial therapy for physical therapy in 78.19(1)"b"(7), and (8), and (16) apply to oc-

cupational therapy.

ITEM 4. Amend subrule 78.19(1), paragraph "d," sub-

paragraphs (2) and (5), as follows:

(2) Speech therapy activities which are considered covered services include: restorative therapy services to restore functions affected by illness, or injury, or disabling condition resulting in a communication impairment or to develop functions where deficiencies currently exist. Communication impairments fall into the general categories of disorders of voice, fluency, articulation, language, and swallowing disorders resulting from any condition other than mental impairment. Treatment of these conditions is payable if restorative criteria are met.

- (5) Maintenance therapy (the carrying out of any activity or exercise program required to maintain speech communication at the level to which it has been restored, is not a covered service. Where a maintenance program is appropriate, the initial evaluation, the instruction of the patient and caregivers to carry out the program, and supervisory visits to monitor progress are covered services. Beyond evaluation, instruction, and monitoring, maintenance therapy is not reimbursable. However, designing a maintenance program established by a qualified speech pathologist for a patient who has not been under a restorative speech therapy program could be considered a covered service in accordance with the requirements of maintenance therapy and monitoring the progress are covered.
- (6) The guidelines under and limits on restorative therapy, and maintenance therapy, and diagnostic or trial therapy for physical therapy in 78.19(1)"b"(7), and (8), and (16) apply to speech therapy. If the only goal of prior rehabilitative speech therapy was to learn the prerequisite speech components, then number "5" under 78.19(1)"b"(16) will not apply to trial therapy.
- ITEM 5. Amend subrule 78.19(2), paragraph "a," as follows:
- a. The minimum information to be included on medical information forms and treatment plans includes:

(1) The patient's current medical condition and functional abilities, including any disabling condition.

(2) The physician's signature and date (within the certification period.

(3) Certification period.

(4) Patient's progress in measurable statistics. (Refer to 78.19(1)"b"(16).

(1) (5) The place services are rendered.

(2) (6) Dates of prior hospitalization (if applicable or known).

(3) (7) Dates of prior surgery (if applicable or known). (4) (8) The date the patient was last seen by the physician (if available).

(5) (9) A diagnosis relevant to the medical necessity for treatment.

(6) (10) Dates of onset of any diagnoses for which treatment is being rendered (if applicable).

(7) (11) A brief summary of the initial evaluation or baseline.

(8) (12) The patient's prognosis. (9) (13) The services to be rendered.

(10) (14) The frequency of the services and discipline of the person providing the service.

(11) (15) The anticipated duration of the services and the estimated date of discharge (if applicable).

(12) (16) Assistance Assistive devices to be used.

(13) (17) Functional limitations.

(14) (18) The patient's rehabilitative potential and the extent to which the patient has been able to apply the skills learned in the rehabilitation setting to everyday living outside the therapy sessions.

(15) (19) The date of the last episode of instability or the date of the last episode of acute recurrence of illness

or symptoms (if applicable).

(16) (20) Quantitative, measurable short-term and long-term functional goals.

(17) (21) The period of time of a session.

(18) (22) Prior treatment (history related to current diagnosis) if available or known.

ARC 3040A

HUMAN SERVICES DEPARTMENT[441]

Notice of Intended Action

Twenty-five interested persons, a governmental subdivision, an agency or an association of 25 or more persons may demand an oral presentation hereon as provided in Iowa Code §17A.4(1)"b."

Notice is also given to the public that the Administrative Rules Review Committee may, on its own motion or on written request by any individual or group, review this proposed action under §17A.8(6) at a regular or special meeting where the public or interested persons may be heard.

Pursuant to the authority of Iowa Code sections 217.6 and 234.6, the Department of Human Services proposes to amend Chapter 202, "Foster Care Services," appearing in the Iowa Administrative Code.

These amendments remove the requirement that departmental service workers make a two-week follow-up visit after a child is initially placed in a foster care group facility or foster family home and correct organizational references.

These amendments reduce visitation requirements for departmental workers in order to allow them to provide services more effectively by enabling the workers to better allocate their time and by reducing travel time and expense. Workers will be able to allocate their time to address the permanency goals of individual children and prioritize direct service delivery. Workers will be encouraged to make phone contact with the child prior to the first scheduled visit and to make visits earlier if the situation warrants.

Consideration will be given to all written data, views, and arguments thereto received by the Bureau of Policy Analysis, Department of Human Services, Hoover State

Office Building, Des Moines, Iowa 50319-0114, on or before June 17, 1992.

These amendments are intended to implement Iowa Code section 234.6.

The following amendments are proposed.

ITEM 1. Amend rule 441—202.1(234), definitions of "Department," "District administrator," and "Eligible child" as follows:

"Department" shall mean the Iowa department of human services and includes the local; county; and district

regional offices of the department.

"District Regional administrator" shall mean the department employee responsible for managing department offices and personnel within the district region and for implementing policies and procedures of the department.

"Eligible child" shall mean a child for whom the court has given guardianship to the department or has transferred legal custody to the department or for whom the department has agreed to provide foster care services on the basis of a signed placement agreement or who has been placed in emergency care for a period of not more than 30 days upon the approval of the commissioner director or the commissioner's director's designee.

ITEM 2. Amend subrule 202.2(5), first paragraph and

paragraph "a," as follows:

202.2(5) The need for foster care and the efforts to prevent placement shall be evaluated by a review committee prior to placement, or, for emergency placements only, within 30 days after the date of placement. For children who are mentally retarded or developmentally disabled and receive case management services, this requirement may be met by the interdisciplinary staffing described in 441—Chapter 24, as long as the district regional administrator approves, the department worker attends the staffing, and the staffing meets the requirements of paragraphs "b" to "g" below.

a. Department staff on the review committee shall be

a. Department staff on the review committee shall be the child's service worker, a supervisor knowledgeable in child welfare, and one or more additional persons appointed by the district regional administrator. At least one of these persons shall not be responsible for the case management or the delivery of services to either the child or the parents or guardian who are the subject of the re-

view.

ITEM 3. Amend rule 441—202.3(234) as follows: Amend subrule 202.3(2) as follows:

202.3(2) When the voluntary placement is of a child who is under age 18 a Voluntary Foster Care Placement Agreement, Form SS-2604, shall be completed and signed by the parent(s) or guardian and the local county office where the parent or guardian resides. Voluntary Foster Care Placement Agreements shall not be used to place children outside Iowa and shall not be signed with parents or guardians who reside outside Iowa. Voluntary Foster Care Placement Agreements shall terminate if the child's parent or guardian moves outside Iowa after the placement.

Amend subrule 202.3(3), paragraphs "a" and "b," as follows:

a. When the voluntary placement is of a child who is age 18 or older and who has a court-ordered guardian, the Voluntary Foster Care Placement Agreement, Form SS-2604, shall be completed and signed by the guardian and the local county office where the guardian resides. Voluntary Foster Care Placement Agreements shall not be

used to place children outside Iowa and shall not be signed with guardians who reside outside Iowa. Voluntary Foster Care Placement Agreements shall terminate if the child's guardian moves outside Iowa after the placement.

b. When the voluntary placement is of a child who is age 18 or older and who does not have a court-appointed guardian, the Voluntary Foster Care Placement Agreement, Form SS-2604, shall be completed and signed by the child and the local county office where the child resides.

Amend subrule 202.3(4) as follows:

202.3(4) All voluntary placements shall be approved by the district regional administrator or designee.

ITEM 4. Amend rule 441—202.6(234) as follows: Rescind and reserve subrule 202.6(3).

Amend subrule 202.6(5), first paragraph, as follows:

202.6(5) In conjunction with the case plan review, the case shall be presented every six months to a review committee which conforms to the requirements in subrule 202.2(5) except those cases being reviewed by a local foster care review board in the sixth judicial district as authorized in Iowa Code section 237.19 shall not be subject to a review by the department's review committee. When the court, interdisciplinary team established according to 441—Chapter 24, or a local foster care review board reviews the placement, the district regional administrator may approve that review as meeting this requirement as long as the review meets the requirements of subrule 202.2(5), paragraphs "b" to "g" and of subrule 202.6(5), paragraphs "a" to "e." The review committee shall:

ITEM 5. Amend rule 441—202.7(234) as follows:

441-202.7(234) Out-of-district region placements.

202.7(1) When the department makes a placement of a child in the foster care system out of the district region in which the child resides, such this placement shall occur only when there is no appropriate placement within the district region, when the placement is necessary to facilitate reunification of the child with the parents, or when an out-of-district region agency is closer to the community where the child resides than an in-district region agency offering the same services.

202.7(2) The authority for approving out-of-district region placements rests with both the placing and receiv-

ing district regional administrators.

202.7(3) Transfer of responsibility for supervision, planning, and visitation shall be approved by the placing and receiving district regional administrators and, when appropriate, by the court.

This rule is intended to implement Iowa Code section

234.6(6)"b."

ITEM 6. Amend subrule 202.8(1), first paragraph, as follows:

202.8(1) The department shall make an out-of-state foster family care placement only with the approval of the district regional administrator. Approval shall be granted only when the placement will not interfere with the goals of the child's case plan and when one of the following conditions exists:

• ITEM 7. Amend rule 441—202.9(234) as follows:

Amend subrule 202.9(1), paragraph "a," subparagraph

(9), and paragraph "b," as follows:

(9) Have the approval of the district regional administrator of the district region where the child resides.

b. Exceptions to the work (or work training) requirement may be allowed with the prior approval of the director, division of community services chief, office of field services, if the child can demonstrate involvement in some alternative daily activity and the exception is in the child's best interest.

Amend subrule 202.9(2), paragraph "b," as follows:

b. Optional services. The following may be provided to a child under the age of 18 depending on the needs, objectives and services described in the child's individual case plan. An exception to allow the provision of optional services to a child aged 18 or older may be allowed with the prior approval of the director, division of community services chief, office of field services, if the exception is necessary for the child to complete high school or a GED.

Amend subrule 202.9(3) as follows:

202.9(3) Time limit. A child shall be eligible for independent living services for a maximum time period of 18 months. In unusual circumstances, services may be extended beyond this time limit with the approval of the district regional administrator and the director, division of community services chief, office of field services, when both determine that an extension is necessary for the child to obtain a high school diploma or GED. Each extension shall be for a specified period of time not to exceed six months.

ITEM 8. Amend subrule 202.13(3) as follows:

202.13(3) If a foster family objects in writing within seven days from the date that the information of plans to remove the child is mailed, the district regional administrator shall grant a conference to the foster family to determine that the removal is in the child's best interest.

This conference shall not be construed to be a contested case under the Iowa administrative procedure Act,

Iowa Code chapter 17A.

The conference shall be provided before the child is removed except in instances listed in 202.13(1)"a" to "c." The district regional administrator shall review the propriety of the removal and explain the decision to the foster family.

The district regional administrator, on finding that the removal is not in the child's best interests, may overrule the removal decision unless a court order or parental decision prevents the department from doing so.

ITEM 9. Amend subrule 202.16(1), paragraph "f," as follows:

f. References from the district regional administrator for the department district region in which the proposed psychiatric medical institution for children would be located, the chief juvenile court officer of the judicial district in which the proposed psychiatric medical institution for children would be located and the applicant's licensor from the department of inspections and appeals or department of public health.

ARC 3021A

INSURANCE DIVISION[191]

Notice of Intended Action

Twenty-five interested persons, a governmental subdivision, an agency or an association of 25 or more persons may demand an oral presentation hereon as provided in Iowa Code §17A.4(1)"b."

Notice is also given to the public that the Administrative Rules Review Committee may, on its own motion or on written request by any individual or group, review this proposed action under \$17.8.86 at a regular or special meeting where the public or interested persons may be heard.

Pursuant to the authority of Iowa Code section 321I.7, the Iowa Division of Insurance hereby gives Notice of Intended Action to amend Chapter 23, "Motor Vehicle Service Contracts," Iowa Administrative Code.

The proposed amendments will increase late filing fees, thereby encouraging motor vehicle service contract providers to timely file copies of the service contract and the provider's reimbursement insurance policy, as required by Iowa Code section 321I.3.

The proposed amendments also establish a two-tiered system for the assessment of late filing fees. First, all filings postmarked after August 1 will be assessed a \$25 late filing fee. Second, all filings postmarked after September 1 will be assessed a \$50 late filing fee.

Any person may make written comments not later than June 16, 1992, to Dennis Britson, Insurance Division, Lucas State Office Building, Des Moines, Iowa 50319.

These amendments are intended to implement Iowa Code sections 321I.3 and 321I.7.

The following amendments are proposed.

ITEM 1. Amend 23.10(2)"b" to read as follows:

b. The annual filing shall be accompanied by a filing fee of \$100. If the annual filing is not filed or postmarked by the first day of August, the filing shall be accompanied by a late filing fee of \$15 \$25. If the annual filing is not filed or postmarked by the first day of September, the filing shall be accompanied by a late filing fee of \$50.

ITEM 2. Amend rule 191—23.12(321) to read as follows:

191—23.12(321I) Fees. The following fees are hereby established by the commissioner:

monstron by the commissioner.	
Annual filing fee	\$100.00
Certification	. \$ 5.00
Name change	. \$ 10.00
Photocopies of records (per page)	. \$ 0.50
Printout of providers	
Printout of insurance companies	\$ 10.00
Late fee (if filed or postmarked	
after August 1st)	\$ 25.00
Late fee (if filed or postmarked	
after September 1st)	\$ 50.00

ARC 3041A

NATURAL RESOURCE COMMISSION[571]

Notice of Termination

Pursuant to the authority of Iowa Code sections 110.24 and 17A.4(1)"b," the Department of Natural Resources

terminates the rule making initiated by its Notice of Intended Action published in the Iowa Administrative Bulletin on February 5, 1992, as ARC 2761A, amending Chapter 15, "General License Regulations," Iowa Administrative Code.

This amendment to 15.7(3)"c" was also Adopted and Filed Emergency as ARC 2721A. The Notice was published to solicit comments. Since no comments were received and no changes are required to the emergency adopted amendment, there is no further need to proceed with rule making for ARC 2761A.

ARC 3047A

NATURAL RESOURCE COMMISSION[571]

Notice of Intended Action

Twenty-five interested persons, a governmental subdivision, an agency or an association of 25 or more persons may demand an oral presentation hereon as provided in Iowa Code §17A.4(1)"b."

Notice is also given to the public that the Administrative Rules Review Committee may, on its own motion or on written request by any individual or group, review this proposed action under §17A.8(6) at a regular or special meeting where the public or interested persons may be heard.

Pursuant to the authority of Iowa Code subsection 455A.5(6), the Natural Resource Commission hereby gives Notice of Intended Action to amend Chapter 27, "Lands and Waters Conservation Fund Program," Iowa Administrative Code.

These amendments are necessary to update the rules and bring them into conformance with project selection processes approved by the National Park Service which administers the federal cost-sharing program.

Any interested person may file written comments or suggestions on these amendments through June 23, 1992. Such written comments should be directed to the Recreation Programs Bureau, Department of Natural Resources, Wallace State Office Building, 900 East Grand Avenue, Des Moines, Iowa 50319-0034; FAX (515)281-6794. Comments may be made by telephone at (515)281-5815.

Persons are also invited to present oral or written comments at a public hearing which will be held on June 23, 1992, at 10 a.m. in the West Half Fourth Floor Conference Room at the Department of Natural Resources, Wallace State Office Building, 900 East Grand Avenue, Des Moines, Iowa. At the hearing, persons will be asked to give their names and addresses for the record and to confine their remarks to the subject of the rule.

These amendments are intended to implement the provisions of Iowa Code section 107.30.

The following amendments are proposed.

ITEM 1. Amend subrule 27.2(1) as follows:

27.2(1) Iowa apportionment. The state expects to receive an annual apportionment from the L&WCF for the twenty-five year life of the program. This annual apportionment, after deducting any amount necessary to cover the department's costs of administering the program and state outdoor recreation planning costs, shall be divided into two shares for state and local entity grants with the local entity share being not less than 50 percent.

NATURAL RESOURCE COMMISSION[571](cont'd)

ITEM 2. Amend subrule 27.5(6) as follows:

27.5(6) Application acceptance. Applications for state projects will be accepted from the Iowa department of natural resources and any other state agency who submits an eligible project application. Notification of the application process and applications will be sent to all state agencies who may possibly participate in the L&WCF program. Agencies will be encouraged to submit projects that will benefit minority and handicapped populations.

ITEM 3. Amend subrule 27.6(3) as follows:

27.6(3) Application rating system for local projects. The committee will apply a numerical rating system to each grant application which is considered for fund assistance. The following criteria, with a weight factor for each, will be considered:

Criteria	Weight factor
Relationship to SCORP priorities	4 5
Direct recreation benefits	1
Local need	1
Quality of site	1

Each criterion will be given a score of from one to 10 which is then multiplied by the weight factor. The following additional criteria will be considered in the rating system:

a. Prior assistance. Any applicant that has never received a grant will be given a bonus of five points. Any applicant that has received prior assistance which is more than its fair share will be assessed penalty points. Fair share will be computed by dividing 50 percent of Iowa's total apportionment from the L&WCF by the total state population and multiplying this amount by the population of the applicant agency. Penalty points will be assessed in accordance with the following schedule:

Prior Assistance in Excess of Fair Share Penalty Points

0
1
2
3
4
5

b. Additional points will be added to the total score for the following:

Projects which have special features for the elderly and handicapped above the normal access requirements for this population will receive three points.

Projects which serve an area of greater minority population than the state average of 2.6 percent as follows:

Minority population greater than 3.5 percent 1 point 4.0 percent 2 points 4.5 percent 3 points

Projects which show evidence that the specific project has been through the normal channels of review and approval by proper local decision makers, thereby ensuring that public support and a commitment to develop and operate the facility are present and that the project under consideration is a part of (or does not conflict with) broader plans which exist may receive up to three bonus points.

All points will be totaled for each application and those applications receiving the highest scores will be selected for fund assistance to the extent of the allotment for each review period. However, no application shall be selected

which has received a score of less than 110 60. Such applications shall be returned to the applicant.

ITEM 4. Amend rule 571—27.7(107) as follows:

571—27.7(107) Public participation. The Iowa office for management and all All regional planning agencies will be advised of the time and place of review sessions. Written comments will be accepted prior to each review session. A time period for public comment will be allowed immediately prior to each review session.

Potential applicants will be advised of any changes in the project evaluation and selection processes and criteria; but in any event, state agencies, regional planning agencies, county conservation boards and the Iowa League of Municipalities will be advised of the availability of program funding at least once every two years.

Notices will also be published in at least two newspapers of statewide or regional significance regarding the review sessions. All projects being considered will be described in the notice. Written comments will be invited. The notice will also advise the public of the opportunity for verbal comment immediately prior to the review session:

ITEM 5. Amend rule 571—27.10(107) as follows:

571—27.10(107) Grant amendments. Projects for which grants have been approved may be amended to increase or decrease project scope or to increase or decrease project costs and fund assistance. Amendments to increase project costs and fund assistance due to cost overruns will not be approved for any project for which a grant is approved after October 1, 1978. A percentage of each year's appropriation may be reserved for amendments.

ARC 3045A

NATURAL RESOURCE COMMISSION[571]

Notice of Intended Action

Twenty-five interested persons, a governmental subdivision, an agency or an association of 25 or more persons may demand an oral presentation hereon as provided in Iowa Code §17A.4(1)"b."

Notice is also given to the public that the Administrative Rules Review Committee may, on its own motion or on written request by any individual or group, review this proposed action under §17A.8(6) at a regular or special meeting where the public or interested persons may be heard.

Pursuant to the authority of Iowa Code subsection 455A.5(6), the Natural Resource Commission hereby gives Notice of Intended Action to amend Chapter 37, "Boating Safety Equipment," Iowa Administrative Code.

These amendments delete the existing wording in rule 37.6(106), and replace it with new wording which is consistent with Federal Navigation Rules as required by the U. S. Coast Guard. They also create new rule 37.2(106), relating to flame arrester equipment required.

Any interested person may make written suggestions or comments on the proposed amendments prior to June 16, 1992. Such written materials should be directed to the Law Enforcement Bureau, Department of Natural Resources, Wallace State Office Building, Des Moines, Iowa 50319-0034; FAX (515)281-8895. Persons who wish to

NATURAL RESOURCE COMMISSION[571](cont'd)

convey their views orally should contact the Law Enforcement Bureau at (515)281-4515 or at the enforcement offices on the fourth floor of the Wallace State Office Building.

There will be a public hearing on June 17, 1992, at 9:30 a.m. in the Fourth Floor West Conference Room of the Wallace State Office Building, at which time persons may present their views either orally or in writing. At the hearing, persons will be asked to give their names and addresses for the record, and to confine their remarks to the subject of the amendments.

These amendments are intended to implement the pro-

visions of Iowa Code section 106.3.

The following amendments are proposed.

ITEM 1. Adopt the following new rule:

571—37.2(106) Flame arrester required. All motorboat engines, except outboard engines, shall be equipped with an efficient flame arrester, backfire trap or other similar device.

An acceptable flame arrester shall have one of the following markings:

1. U. S. Coast Guard approval number.

2. "Complies with UL 1111 per tests by (name of test-

ing facility)".

- 3. "Evidence of compliance with the standard shall be indicated by the marking SAE J-1928 with the word MARINE arranged in a suitable manner."
- ITEM 2. Rescind rule 571—37.6(106) and adopt the following new rule:
- 571—37.6(106) Lights on vessels while at anchor. A vessel at anchor shall exhibit where it can best be seen:
- In the fore part, an all-round white light or one ball;
- 2. At or near the stern, and at a lower level than the light prescribed in paragraph "1" above, an all-round white light.

A vessel of less than 50 meters in length may exhibit an all-round white light where it can best be seen instead of the lights prescribed in paragraph "1" above.

Chapter 52 implements the establishment of wildlife refuges or sanctuaries on state-owned lands and waters under the jurisdiction of the Department of Natural Resources for the purpose of preserving the biological balance and for the protection of public parks, public health, safety and welfare, and to effect sound wildlife management. The purpose of the amendments is to bring 571—Chapter 52 into compliance with the rules of management for Fallen Rock State Preserve; to correct the listing of Turkey River Mounds State Preserve; and to delete the Pool Slough Wildlife Area as a refuge because the area is no longer used as a nesting site for the bald eagle.

Any interested person may make written comments on these proposed amendments prior to June 17, 1992. Such written materials should be directed to the Bureau Chief, Preserves and Ecological Services Bureau, Department of Natural Resources, Wallace State Office Building, Des Moines, Iowa 50319-0034.

Persons who wish to convey their views orally should contact the Bureau of Preserves and Ecological Services at (515)281-8524 or at the bureau offices on the fourth floor of the Wallace State Office Building prior to the above date.

Also, there will be a public hearing on June 17, 1992, at 10 a.m. in the Fourth Floor West Conference Room of the Wallace State Office Building, at which time persons may express their views either orally or in writing. At the hearing, persons will be asked to give their names and addresses for the record and to confine their remarks to the subject of the rule.

These amendments are intended to implement Iowa Code section 109.39.

ITEM 1. Amend subrule 52.1(1) by deleting the entry for Fallen Rock in Hardin County and by amending the entry for Turkey River as follows:

Turkey River Mounds Guthrie Clayton

ITEM 2. Amend subrule **52.1(2)** by rescinding paragraph "b."

ARC 3042A

ARC 3048A

NATURAL RESOURCE COMMISSION[571]

Notice of Intended Action

Twenty-five interested persons, a governmental subdivision, an agency or an association of 25 or more persons may demand an oral presentation hereon as provided in Iowa Code §17A.4(1)"b."

Notice is also given to the public that the Administrative Rules Review Committee may, on its own motion or on written request by any individual or group, review this proposed action under §17A.8(6) at a regular or special meeting where the public or interested persons may be heard.

Pursuant to the authority of Iowa Code section 109.39 and Iowa Code Supplement section 455A.5(6), the Natural Resource Commission hereby gives Notice of Intended Action to amend Chapter 52, "Wildlife Refuges," Iowa Administrative Code.

NATURAL RESOURCE COMMISSION[571]

Notice of Intended Action

Twenty-five interested persons, a governmental subdivision, an agency or an association of 25 or more persons may demand an oral presentation hereon as provided in Iowa Code §17A.4(1)"b."

Notice is also given to the public that the Administrative Rules Review Committee may, on its own motion or on written request by any individual or group, review this proposed action under \$17A.8(6) at a regular or special meeting where the public or interested persons may be heard.

Pursuant to the authority of Iowa Code Supplement subsection 455A.5(6) and Iowa Code section 109.65, the Natural Resource Commission of the Department of Natural Resources hereby gives Notice of Intended Action to amend Chapter 111, "Scientific Collecting and Wildlife Rehabilitation," Iowa Administrative Code.

These amendments clarify the definition of educational project permit, requirements for the educational project permit and allow for the establishment of a committee to

evaluate facilities and standards for educational project permits and wildlife rehabilitation permits.

Any interested person may make written suggestions or comments on these proposed amendments prior to June 17, 1992. Such written material should be directed to the Chief of the Bureau of Preserves and Ecological Services, Department of Natural Resources, Wallace State Office Building, Des Moines, Iowa 50319-0034. Persons who wish to convey their views orally should contact the Bureau of Preserves and Ecological Services at (515)281-8524 or at the bureau offices on the fourth floor of the Wallace State Office Building prior to the above date.

Also, there will be a public hearing on June 17, 1992, at 10 a.m. in the Fourth Floor West Conference Room of the Wallace State Office Building, at which time persons may present their views either orally or in writing. At the hearing, persons will be asked to give their names and addresses for the record and to confine their remarks to the subject of the rule.

These amendments are intended to implement Iowa Code section 109.65.

ITEM 1. Amend rule 571—111.1(109), definition of "Educational project permit," as follows:

"Educational project permit" means a permit which authorizes may authorize the holder to take and possess live

state-protected birds, mammals, amphibians, reptiles, fish or invertebrates for educational or zoological displays.

ITEM 2. Amend rule 571—111.4(109) by adding the following new paragraph at the end of the rule.

Any animals which are obtained from legal sources outside of Iowa are exempt from these permit requirements. Proof of origin of each animal is the responsibility of the owner.

ITEM 3. Add the following new rule 571—111.7(109) and renumber rules 111.7(109) and 111.8(109) as 111.8(109) and 111.9(109):

571—111.7(109) Evaluation committee. For the purpose of evaluating facilities and standards of care employed by holders of education project permits and wildlife rehabilitation permits, the director may establish an ad hoc committee of persons with expertise in wildlife care, rehabilitation, veterinary science and wildlife education. Upon request by the director, the committee shall inspect facilities, care procedures and educational programs and provide the department with appropriate recommendations. The recommendations may be used as a basis for placing certain conditions on a permit or modifying or terminating a permit.

ARC 3051A

PUBLIC HEALTH DEPARTMENT[641]

Notice of Intended Action

Twenty-five interested persons, a governmental subdivision, an agency or an association of 25 or more persons may demand an oral presentation hereon as provided in Iowa Code §17A.4(1)"b."

Notice is also given to the public that the Administrative Rules Review Committee may, on its own motion or on written request by any individual or group, review this proposed action under §17A.8(6) at a regular or special meeting where the public or interested persons may be heard.

Pursuant to the authority of Iowa Code section 136C.3, the Iowa Department of Public Health hereby gives Notice of Intended Action to rescind Chapter 38, "General Provisions," and adopt a new Chapter 38, "General Provisions," Iowa Administrative Code.

The action taken is appropriate because of the number and magnitude of the additions which need to be made to the rules in order to keep current with the standards set forth by the Conference of Radiation Control Program Directors' "Suggested State Regulations for the Control of Radiation" (SSRCRs) and to remain compatible with the U.S. Nuclear Regulatory Commission (NRC) pursuant to the Agreement State Program between the Governor and the NRC. No information has been deleted from the rules; however, the additions to Chapter 38 necessitated renumbering of the entire chapter. These additions are specified below.

1. The Department is implementing a comprehensive program which is in accordance with the law prescribed in Iowa Code sections 136C.4 and 136C.5. The contents of new rule 641—38.9(136C), "Procedure for imposing requirements by order, or for modification, suspension, or revocation of a license, registration, or certificate or for imposing civil penalties," which has been added to Chapter 38, establishes general policy and procedures to be followed by Radiological Health Section (RHS) in initiating and enforcement, and by presiding officers of the state Attorney General's office in reviewing these actions, pursuant to the authority provided for in 641—38.9(136C).

2. New Chapter 38 has appendixes, which is again consistent with the SSRCRs. This format is much easier to work with. The material was previously contained in the body of the rules of each chapter. In addition, the appendix material is now in the same chapter as the rule which refers to it, thus making the rules easier to work with.

Any interested person may make written suggestions or comments on the proposed chapter on or before close of business June 17, 1992. Such written material should be directed to Donald A. Flater, Chief, Bureau of Environmental Health, Iowa Department of Public Health, Lucas State Office Building, Des Moines, Iowa 50319, FAX (515)242-5284.

A public hearing will be held on June 17, 1992, at 9 a.m. in the Third Floor Conference Room, Lucas State Office Building, at which time persons may present their views orally or in writing. At the hearing, persons will be asked to give their name, address, and whom they represent. Presenters will also be asked to confine their remarks to the subject of the rules.

These rules are intended to implement Iowa Code chapter 136C.

Rescind 641—Chapter 38 and adopt the following in lieu thereof:

CHAPTER 38 GENERAL PROVISIONS

641—38.1(136C) Purpose and scope. Except as otherwise specifically provided, these rules apply to all persons who receive, possess, use, transfer, own, or acquire any source of radiation; provided, however, that nothing in these rules shall apply to any person to the extent such person is subject to regulation by the U.S. Nuclear Regulatory Commission. Attention is directed to the fact that regulation by the state of source material, by-product material, and special nuclear material in quantities not sufficient to form a critical mass is subject to the provisions of the agreement between the state and the U.S. Nuclear Regulatory Commission and to 10 CFR Part 150 of the Commission's regulations. All references to Code of Federal Regulations (CFRs) in this chapter are those in effect as of September 1, 1992.

641—38.2(136C) Definitions. As used in these rules, these terms have the definitions set forth below. Additional definitions used only in a certain chapter will be found in that chapter.

"A₁" means the maximum activity of special form ra-

dioactive material permitted in a Type A package.

"A₂" means the maximum activity of radioactive material, other than special form radioactive material, permitted in a Type A package. These values are either listed in Appendix E of 641—Chapter 39, Table I, or may

be derived in accordance with the procedure prescribed in Appendix E of 641—Chapter 39.

"Accelerator-produced material" means any material

made radioactive by a particle accelerator.

"Act" means 1984 Iowa Acts, chapter 1286, relating to regulation of radiation machines and radioactive materi-

als. (Iowa Code chapter 136C).

"Agency" means the Iowa department of public health.

"Agreement state" means any state with which the
U.S. Nuclear Regulatory Commission or the U.S. Atomic

Energy Commission has entered into an effective agreement under subsection 274b. of the Atomic Energy Act of 1954 as amended (73 Stat. 689).

"Airborne radioactive material" means any radioactive material dispersed in the air in the form of dusts, fumes, mists, vapors, or gases.

"Airborne radioactivity area" means (1) any room, enclosure, or operating area in which airborne radioactive material exists in concentrations in excess of the amounts specified in Appendix B of 641—Chapter 40; or (2) any room, enclosure, or operating area in which airborne radioactive material exists in concentrations which, averaged over the number of hours in any week during which individuals are in the area, exceed 25 percent of the amounts specified in Appendix B of 641—Chapter 40.

"By-product material" means (1) any radioactive material, except special nuclear material, yielded in or made radioactive by exposure to the radiation incident to the process of producing or utilizing special nuclear material, and (2) the tailings or wastes produced by the extraction or concentration of uranium or thorium from any ore processed primarily for its source material content.

"Calendar quarter" means not less than 12 consecutive weeks nor more than 14 consecutive weeks. The first calendar quarter of each year shall begin in January and subsequent calendar quarters shall be so arranged such that no day is included in more than one calendar quarter and no day in any one year is omitted from inclusion within a calendar quarter. The method used by the licensee or registrant in determining quarters for purposes of these rules shall not be changed except at the beginning of a calendar year.

"Calibration" means the determination of (1) the response or reading of an instrument relative to a series of known radiation values over the range of the instrument, or (2) the strength of a source of radiation relative to a

standard.

"CFR" means Code of Federal Regulations.

"Chelating agent" means amine polycarboxylic acids, hydroxy-carboxylic acids, gluconic acid, and polycarbox-

ylic acids.

"Curie" means a unit of quantity of radioactivity. One curie (Ci) is that quantity of radioactive material which decays at the rate of 3.7×10^{10} transformations per second (tps). Commonly used submultiples of the curie are the millicurie and the microcurie. One millicurie (mCi) = 0.001 curie = 3.7×10^7 tps. One microcurie (μ Ci) = 0.000001 curie = 3.7×10^4 tps (see 38.1(136C) for SI equivalent becquerel).

"Depleted uranium" means the source material uranium in which the isotope uranium-235 is less than 0.711 weight percent of the total uranium present. Depleted uranium

nium does not include special nuclear material.

"Dose" means absorbed dose or dose equivalent as ap-

propriate:

a. "Absorbed dose" is the energy imparted to matter by ionizing radiation per unit mass of irradiated material at the place of interest. The special unit of absorbed dose is the rad (see "Rad") (see 38.1(136C) for SI equivalent

gray).

b. "Dose equivalent" is a quantity that expresses on a common scale for all radiation a measure of the postulated effect on a given organ. It is defined as the absorbed dose in rads times certain modifying factors. The unit of dose equivalent is the rem (see "Rem") (see 38.1(136C) for SI equivalent sievert).

"Explosive material" means any chemical compound, mixture, or device which produces a substantial instantaneous release of gas and heat spontaneously or by contact

with sparks or flame.

"Exposure" means the quotient of dQ by dm where "dQ" is the absolute value of the total charge of the ions of one sign produced in air when all the electrons (negatrons and positrons) liberated by photons in a volume element of air having mass "dm" are completely stopped in air. (The special unit of exposure is the roentgen (R) (see 38.2(136C) for SI equivalent coulomb per kilogram). When not underlined as above or when indicated as 'exposure' or (X), the term "exposure" has a more general meaning in these rules.

"Exposure rate" means the exposure per unit of time, such as roentgen per minute and milliroentgen per hour.

"Former U.S. Atomic Energy Commission (AEC) or U.S. Nuclear Regulatory Commission (NRC) licensed facilities" means nuclear reactors, nuclear fuel reprocessing plants, uranium enrichment plants, or critical mass experimental facilities where AEC or NRC licenses have been terminated.

"Hazardous waste" means those wastes designated as hazardous by U.S. Environmental Protection Agency regulations in 40 CFR Part 261.

"Healing arts" means the occupational fields of diagnosing or treating disease, providing health care and improving health by the practice of medicine, osteopathy, chiropractic, podiatry, dentistry, nursing, veterinary medicine, and supporting professions, such as physician assistants, nurse practitioners, radiologic technologists, and dental hygienists.

"High radiation area" means any area, accessible to individuals, in which there exists radiation at such levels that a major portion of the body could receive in any one hour a dose in excess of 100 millirems (1 millisievert).

"Human use" means the internal or external administration of radiation or radioactive material to human beings.

"Individual" means any human being.

"Inspection" means an official examination or observation including, but not limited to, tests, surveys, and monitoring to determine compliance with rules, regulations, orders, requirements, and conditions of the agency.

"Interlock" means a device arranged or connected such that the occurrence of an event or condition is required before a second event or condition can occur or continue

to occur.

"License" means:

a. Specific license: a written document issued by the agency which authorizes a person to receive, possess, store, use, own, or transfer sources of radioactive materials, or

b. General license: authorization to receive, possess, store, use, own, or transfer sources of radioactive materials as specified in 641—subrules 39.4(21) and 39.4(22).

"Licensing state" means any state with regulations equivalent to the suggested state regulations for control of radiation relating to, and an effective program for, the regulatory control of NARM and which has been granted final designation by the Conference of Radiation Control Program Directors, Inc.

"Major processor" means a user processing, handling, or manufacturing radioactive material exceeding Type A quantities as unsealed sources or material, or exceeding four times Type B quantities as sealed sources, but does not include nuclear medicine programs, universities, industrial radiographers, or small industrial programs. Type A and B quantities are defined in 641—subrule 39.5(2).

"NARM" means any naturally occurring or accelerator-produced radioactive material. It does not include by-product, source, or special nuclear material.

"Natural radioactivity" means radioactivity of naturally occurring nuclides. For the purpose of meeting the definition of a licensing state by the Conference of Radiation Control Program Directors, Inc., (CRCPD), NARM refers only to discrete sources of NARM. Diffuse sources of NARM are excluded from consideration by the CRCPD for licensing state designation purposes.

"Package" means the packaging together with its ra-

dioactive contents as presented for transport.

"Particle accelerator" means any machine capable of accelerating electrons, protons, deuterons, or other charged particles in a vacuum and of discharging the resultant particulate or other radiation into a medium at energies usually in excess of 1 MeV.

"Personnel monitoring equipment" means devices such as film badges, pocket dosimeters, and thermoluminescent dosimeters designed to be worn or carried by an individu-

al for the purpose of estimating the dose received by the individual.

"Pharmacist" means an individual licensed by this state to compound and dispense drugs, prescriptions, and poisons.

"Physician" means a person who is currently licensed in Iowa to practice medicine and surgery, osteopathic

medicine and surgery, or osteopathy.

"Pyrophoric liquid" means any liquid that ignites spontaneously in dry or moist air at or below 130°F (54.4°C). A pyrophoric solid is any solid material, other than one classed as an explosive, which under normal conditions is liable to cause fires through friction, retained heat from manufacturing or processing, or which can be ignited readily and, when ignited, burns so vigorously and persistently as to create a serious transportation, handling, or disposal hazard. Included are spontaneously combustible and water-reactive materials.

"Rad" means the special unit of absorbed dose. One rad equals one hundredth of a joule per kilogram of material; for example, if tissue is the material of interest, then 1 rad equals 100 ergs per gram of tissue (10 milligrays).

"Radiation" means ionizing radiation which includes any or all of the following: gamma and X-rays, alpha and beta particles, high-speed electrons, neutrons, high-speed

protons, and other atomic particles.

"Radiation area" means any area, accessible to individuals, in which there exists radiation at such levels that a major portion of the body could receive in any one hour a dose in excess of 5 millirems (0.05 millisievert), or in any five consecutive days a dose in excess of 100 millirems (1 millisievert).

"Radiation machine" means any device capable of producing radiation except those which produce radiation

only from radioactive material.

"Radiation safety officer" means one who has the knowledge and responsibility to apply appropriate radiation protection regulations.

"Radioactive material" means any solid, liquid, or gas

which emits radiation spontaneously.

"Radioactivity" means the transformation of unstable

atomic nuclei by the emission of radiation.

"Registrant" means any person who is registered with the agency and is legally obligated to register with the agency pursuant to these rules and the Act.

"Registration" means registration with the agency in

accordance with the rules adopted by the agency.

"Regulations of the U.S. Department of Transportation" means the regulations in 49 CFR Parts 100-189.

"Regulations of the U.S. Nuclear Regulatory Commission" means the regulations in 10 CFR Parts 0-199.

"Rem" means a special unit of dose equivalent. One millirem (mrem) = 0.001 rem. For the purpose of these rules, any of the following is considered to be equal to 1 rem:

a. An exposure of 1 roentgen of x or gamma radiation.

- b. An absorbed dose of 1 rad due to x, gamma, or beta radiation.
- c. An absorbed dose of 0.05 rad due to particles heavier than protons and with sufficient energy to reach the lens of the eye.
- d. An absorbed dose of 0.1 rad due to neutrons or high energy protons. If it is more convenient to measure the neutron flux, or equivalent, than to determine the neutron absorbed dose in rads, 1 rem of neutron radiation may, for purposes of these rules, be assumed to be equiva-

lent to 14 million neutrons per square centimeter incident upon the body; or, if there exists sufficient information to estimate with reasonable accuracy the approximate distribution in energy of the neutrons, the incident number of neutrons per square centimeter equivalent to 1 rem may be estimated from Table 1.

"Research and development" means (1) theoretical analysis, exploration, or experimentation; or (2) the extension of investigative findings and theories of a scientific or technical nature into practical application for experimental and demonstration purposes, including the experimental production and testing of models, devices, equipment, materials, and processes. Research and development does not include the internal or external administration of radiation or radioactive material to human beings.

"Restricted area" means any area access to which is controlled by the licensee or registrant for purposes of protection of individuals from exposure to radiation and radioactive material. A restricted area shall not include any areas used for residential quarters, although a separate room or rooms in a residential building may be set apart as a restricted area.

"Roentgen" means the special unit of <u>exposure</u>. One roentgen (R) equals 2.58 x 10⁴ coulombs/kilogram of air (see "<u>Exposure</u>").

TABLE 1
Neutron Flux Dose Equivalents

Neutron millienergy (MeV)	Number of neutrons per square centimeter for a dose equivalent of 1 rem(10 milli- sieverts) (neutrons/cm ²)	Average flux density to deliver 100 rems (1 millisievert) in 40 hours (neutrons/ cm ² per second)
Thermal	970 x 10 ⁶	670
		500
		570
0.02	400 x 10 ⁶	280
0.1	120 x 10 ⁶	80
		30
		18
2.5	29 x 10 ⁶	20
5.0	26 x 10 ⁶	18
		17
		17
		4.0
10 to 30	14 x 10°	10

"Sealed source" means radioactive material that is permanently bonded or fixed in a capsule or matrix designed to prevent release and dispersal of the radioactive material under the most severe conditions which are likely to be encountered in normal use and handling.

"Source material" means (1) uranium or thorium, or any combination thereof, in any physical or chemical form; or (2) ores which contain by weight one-twentieth of 1 percent (0.05 percent) or more of (a) uranium, (b) thorium, or (c) any combination thereof. Source material does not include special nuclear material.

"Source material milling" means any activity that results in the production of by-product material as defined

by definition (2) of by-product material.

"Source of radiation" means any radioactive material or any device or equipment emitting, or capable of producing, radiation.

"Special form radioactive material" means radioactive material which satisfies the following conditions:

a. It is either a single solid piece or is contained in a sealed capsule that can be opened only by destroying the

b. The piece or capsule has at least one dimension not

less than 5 millimeters (0.197 inch); and

c. It satisfies the test requirements specified by the U.S. Nuclear Regulatory Commission. A special form encapsulation designed in accordance with the U.S. Nuclear Regulatory Commission requirements in effect on June 30, 1983, and constructed prior to July 1, 1985, may continue to be used. A special form encapsulation either designed or constructed after June 30, 1985, must meet requirements of this definition applicable at the time of its design or construction.

Special nuclear material in quantities not sufficient to form a critical mass" means uranium enriched in the isotope U-235 in quantities not exceeding 350 grams of contained U-235; uranium-233 in quantities not exceeding 200 grams; plutonium in quantities not exceeding 200 grams; or any combination of them in accordance with the following formula: For each kind of special nuclear material, determine the ratio between the quantity of that special nuclear material and the quantity specified above for the same kind of special nuclear material. The sum of such ratios for all of the kinds of special nuclear material in combination shall not exceed 1. For example, the following quantities in combination would not exceed the limitation and are within the formula:

"Survey" means an evaluation of the production, use, release, disposal, or presence of sources of radiation under a specific set of conditions to determine actual or potential radiation hazards. When appropriate, such evaluation includes, but is not limited to, tests, physical examina-tions, and measurements of levels of radiation or concentrations of radioactive material present.

"Test" means the process of verifying compliance with

an applicable regulation.
"These rules" means 641—Chapters 38 to 46.

"U.S. Department of Energy" means the Department of Energy established by Public Law 95-91, August 4, 1977, 91 Stat. 565, 42 U.S.C. 7101 et seq., to the extent that the department exercises functions formerly vested in the U.S. Atomic Energy Commission, its chairman, members, officers and components and transferred to the U.S. Energy Research and Development Administration and to the administrator thereof pursuant to sections 104(b), (c) and (d) of the Energy Reorganization Act of 1974 (Public Law 93-438, October 11, 1974, 88 Stat. 1233 at 1237, effective January 19, 1975) and retransferred to the Secretary of Energy pursuant to section 301(a) of the Department of Energy Organization Act (Public Law 95-91, August 4, 1977, 91 Stat. 565 at 577-578, 42 U.S.C. 7151, effective October 1, 1977).

"Unrefined and unprocessed ore" means ore in its natural form prior to any processing, such as grinding,

roasting, beneficiating, or refining.
"Unrestricted area" means any area to which access is not controlled by the licensee or registrant for purposes of protection of individuals from exposure to radiation and radioactive material, and any area used for residential

"Waste" means those low-level radioactive wastes that are acceptable for disposal in a land disposal facility. For the purposes of this definition, low-level waste has the same meaning as in the Low-Level Radioactive Waste Policy Act, P.L. 96-573, as amended by P.L. 99-240, effective January 15, 1986; that is, radioactive waste (1) not classified as high-level radioactive waste, spent nuclear fuel, or by-product material as defined in Section 11e.(2) of the Atomic Energy Act (uranium or thorium tailings and waste) and (2) classified as low-level radioactive waste consistent with existing law and in accordance with (1) by the U.S. Nuclear Regulatory Commission.

Waste handling licensees" means persons licensed to receive and store radioactive wastes prior to disposal or

persons licensed to dispose of radioactive waste.

"Worker" means an individual engaged in work under a license or registration issued by the agency and controlled by a licensee or registrant, but does not include the licensee or registrant.

641—38.3(136C) Exemptions from the regulatory requirements.

38.3(1) General provision. The agency may, upon application therefor or upon its own initiative, grant such exemptions or exceptions from the requirements of these rules as it determines are authorized by law and will not result in undue hazard to public health and safety or prop-

38.3(2) U.S. Department of Energy Contractors and U.S. Nuclear Regulatory Commission Contractors. Any U.S. Department of Energy contractor or subcontractor and any U.S. Nuclear Regulatory Commission contractor or subcontractor of the following categories operating within this state is exempt from these rules to the extent that such contractor or subcontractor under his contract receives, possesses, uses, transfers or acquires sources of radiation:

a. Prime contractors performing work for the U.S. Department of Energy at U.S. government-owned or controlled sites, including the transportation of sources of radiation to or from such sites and the performance of contract services during temporary interruptions of such transportation;

b. Prime contractors of the U.S. Department of Energy performing research in, or development, manufacture, storage, testing, or transportation of, atomic weapons or

components thereof;

c. Prime contractors of the U.S. Department of Energy using or operating nuclear reactors or other nuclear devices in a United States government-owned vehicle or vessel; and

d. Any other prime contractor or subcontractor of the U.S. Department of Energy or of the U.S. Nuclear Regulatory Commission when the state and the U.S. Nuclear Regulatory Commission jointly determine:

(1) That the exemption of the prime contractor or sub-

contractor is authorized by law; and

(2) That under the terms of the contract or subcontract, there is adequate assurance that the work thereunder can be accomplished without undue risk to the public health and safety.

641—38.4(136C) General regulatory requirements.

38.4(1) Records. Each licensee and registrant shall maintain records showing the receipt, transfer, and dispos-

al of all sources of radiation. Additional record requirements are specified elsewhere in these rules.

38.4(2) Inspections.

a. Each licensee and registrant shall afford the agency at all reasonable times opportunity to inspect sources of radiation and the premises and facilities wherein such sources of radiation are used or stored.

b. Each licensee and registrant shall make available to the agency for inspection, upon reasonable notice, records

maintained pursuant to these rules.

- 38.4(3) Tests. Each licensee and registrant shall perform upon instructions from the agency, or shall permit the agency to perform, such reasonable tests as the agency deems appropriate or necessary including, but not limited to, tests of:
 - a. Sources of radiation;
- b. Facilities wherein sources of radiation are used or stored:
- c. Radiation detection and monitoring instruments; and
- d. Other equipment and devices used in connection with utilization or storage of licensed or registered sources of radiation.
- 38.4(4) Additional requirements. The agency may, by rule, regulation, or order, impose upon any licensee or registrant such requirements in addition to those established in these rules as it deems appropriate or necessary to minimize danger to public health and safety or property.
- 641—38.5(136C) Enforcement requirements. Upon determination by the agency that Iowa Code chapter 136C or any rule adopted pursuant to that chapter has been or is being violated, the agency may implement the policies and procedures specified in Appendix A.
- 641—38.6(136C) Prohibited uses. The use of hand-held fluoroscopic screens or shoe-fitting fluoroscopic devices is prohibited.
- 641—38.7(136C) Communications. All communications and reports concerning these rules, and applications filed thereunder, should be addressed to the agency at its office located at the Iowa Department of Public Health, Bureau of Environmental Health, Lucas State Office Building, Des Moines, Iowa 50319.

641—38.8(136C) Fees.

38.8(1) Radiation machines. Each registrant shall, at the time of registration and each year thereafter, remit to the agency a fee in an amount sufficient to defray the cost of registering and inspecting the registrant's radiation machine. All fees shall be made payable to the Iowa Department of Public Health and shall be in the amount computed by the following schedule:

ANNUAL FEE SCHEDULE

Type of X-ray machine	Fee per tube	Maximum fee
1. Medical	\$51.00	\$1500
2. Osteopathy	\$51.00	\$1500
3. Chiropractic	\$51.00	\$1500
4. Dentistry	\$39.00	\$1000
5. Podiatry	\$39.00	\$1000
6. Veterinary		
Medicine	\$25.00	
7. Radiography		
(Industrial Use)	\$50.00	

8. Analytical	\$50.00	
9. Sterilization	\$80.00	
10. Production		
Accelerator	\$500.00	
11. Other Accelerators	\$100.00	
12. Electron Microscope	\$20.00	

Fees for radiation machines not listed in the above schedule shall not be less than \$50 per unit/tube.

38.8(2) Radioactive materials licensing and inspection.

a. Licensing.

- (1) Fees associated with licensing of the possession and use of radioactive materials in Iowa are identical to those specified in 10 CFR 170.31 entitled "Schedule of Fees for Materials Licenses and Other Regulatory Services."
- (2) All required fees for new radioactive materials licenses, amendments to licenses, or renewal of licenses, shall accompany the application for the requested action and be made payable to the Treasurer, State of Iowa.

b. Inspections.

- (1) After completion of an inspection, an inspection fee shall be assessed to a facility based on the fees for inspection found in 10 CFR 170.32 entitled "Schedule of Fees for Health and Safety, and Safeguards Inspections for Materials Licenses."
- (2) All required fees for inspections conducted by the agency shall be paid within 30 days after receipt of the agency notification following the inspection and shall be made payable to the Treasurer, State of Iowa.

38.8(3) Industrial radiography testing and certification.

a. A nonrefundable fee of \$100 shall be submitted with each application for taking an industrial radiography examination to become certified by the agency. The fee shall be made payable to the Treasurer, State of Iowa.

b. A fee of \$25 shall be made payable to the Treasurer, State of Iowa to cover the cost of replacing lost identification cards issued to industrial radiographers by the

agency pursuant to 641—subrule 45.11(3).

38.8(4) Owner-assessed expenses. In cases in which the agency determines that the cost of regulating or inspecting registered radiation machine facilities or radioactive materials licensees significantly exceeds the fees charged to the facility, it may assess an additional fee to the owner or user of the source(s) of radiation to cover the

actual expenses incurred by the agency.

38.8(5) Environmental surveillance fee. A fee may be levied against any licensee for environmental surveillance activities which are necessary to access the radiological impact of activities conducted by the registrant or licensee. This fee shall be sufficient to defray actual costs incurred by the agency, including, but not limited to, salaries of agency employees, per diem, travel, and costs of laboratory analysis of samples, when required. This fee shall also be sufficient to cover the costs of leak test analysis of wipes taken by agency employees during surveillance activities.

38.8(6) Certification fees. Diagnostic radiographers, radiation therapists, and nuclear medicine technologists, other than license practitioners of the healing arts, are required to pay fees sufficient to defray the cost of administering 641—Chapter 42. Fees are as follows:

a. Annual fee. Each individual must submit a \$45 initial fee for the first year and \$35 annually in the form of a

money order or check made payable to the Iowa Department of Public Health.

b. Examination fee.

(1) Each individual making application to take an examination given by the agency as a general radiographer under 641-42.1(4)"b"(3) must pay a nonrefundable fee of \$25 each time the individual takes the examination required by 641—Chapter 42.

(2) Each individual making application to take an examination given by the agency as a limited radiographer under 641—42.1(4)"b"(1) or (2) must pay a nonrefundable fee of \$35 each time the individual takes the ex-

amination required by 641—Chapter 42.

38.8(7) Returned check and late fees. Persons who fail to pay required fees to the agency are subject to the

following penalties:

- a. \$15 for each payment received by the agency in accordance with these rules, for which insufficient funds are available to fulfill the obligation of such payment to the
- b. \$25 for each month for failure to pay annual radiation machine registration or diagnostic radiation operator fee starting the first day of the month after the expiration of the facility's registration or operator's permit to practice. This fee is added to the unpaid annual fee.
- c. Late fees for 641—Chapter 42 continuing education requirements.
- (1) For any individual who completes the required continuing education before the continuing education due date but fails to submit the required proof within 30 days after the continuing education due date, the certification shall be terminated and the renewal fee will not be refunded.
- (2) For any individual who fails to complete the required continuing education before the continuing education due date but submits a written plan of correction to obtain the required hours, that person shall be allowed no more than 60 days after the original continuing education due date to complete the plan of correction and submit the documentation of completion of continuing education requirements. After 60 days, the certification shall be terminated and the individual shall not function as a diagnostic radiographer, radiation therapist, or nuclear medicine technologist in Iowa.

(3) Once certification has been terminated, any individual who requests permission to reestablish certification within six months of the initial continuing education due date must submit proof of continuing education hours and shall submit a late fee of \$30 in addition to the annual fee

in order to obtain reinstatement of certification.

38.8(8) Reciprocity. Fees paid for reciprocal recognition of out-of-state persons wishing to utilize radiation machines or radioactive materials in Iowa shall allow the out-of-state person to operate for a total of 180 days during the one-year period starting the date the fee is received by the agency.

a. Radiation machines. Any out-of-state person who wishes to bring an industrial X-ray machine or linear accelerators into the state to perform work or services shall pay a reciprocity fee of \$100 for each source of radiation

pursuant to 38.8(7).

b. Radioactive materials. Out-of-state persons wishing to bring sources of radioactive material into Iowa for business purposes may be subject to a reciprocity fee depending on the type of activity to be performed and the type of radioactive materials license possessed (refer to 641—subrule 39.4(90). If a reciprocity fee is applicable, it shall be assessed at the rate of \$600 for each 365-day reciprocity period. In addition, if the agency performs an inspection of the out-of-state person's activities while in Iowa, the appropriate inspection fee as specified in 10 CFR 170.31 will be assessed.

This rule is intended to implement Iowa Code section 136C.3.

Procedure for imposing require-641—38.9(136C) ments by order, or for modification, suspension, or revocation of a license, registration, or certificate or for imposing civil penalties.

38.9(1) Scope.

- a. This rule prescribes the procedure in cases initiated by the staff, or upon a request by any person, to impose requirements by order, or to modify, suspend, or revoke a license, registration, or certificate or to take other action as may be proper against any person subject to the jurisdiction of the agency. The term "regulated entity" as used in this rule refers to any facility, person, partnership, corporation or other organization which is regulated by the agency by virtue of these rules, the Iowa Code, licensing documents, registrations, certificates, or other official regulatory promulgation.
- b. This rule also prescribes the procedures in cases initiated by the staff to impose civil penalties pursuant to Iowa Code section 136C.4.

38.9(2) Notice of violation.

- a. Before instituting any proceeding to modify, suspend, or revoke a license, registration, or certificate or to take other action for alleged violation of any provision of the Code or these rules or the conditions of a license, the supervisor, radiological health section (RHS) will serve on the licensee, registrant, certified person or other person subject to the jurisdiction of the agency a written notice of violation, except as provided in 38.9(2)"c." The notice of violation will concisely state the alleged violation(s) and will require that the regulated entity submit, within 30 days of the date of the notice or other specified time, a written explanation or statement in reply including:
- (1) Corrective steps which have been taken by the regulated entity and the results achieved;

(2) Corrective steps which will be taken; and

- (3) The date when full compliance will be achieved.
- b. The notice may require the regulated entity subject to the jurisdiction of the agency to admit or deny the violation and to state the reasons for the violation, if admitted. It may provide that, if an adequate reply is not received within the time specified in the notice, the RHS supervisor or the supervisor's designee may issue an order to show cause why the license, registration, certificate or other document subject to regulation by the agency should not be modified, suspended, or revoked or why such other action as may be proper should not be taken.
- c. When the RHS supervisor or the supervisor's designee finds that the public health, safety, or interest so requires, or that the violation is willful, the notice of violation may be omitted and an order to show cause issued.

38.9(3) Order to show cause.

- a. The RHS supervisor, as appropriate, may institute a proceeding to modify, suspend, or revoke a license, registration, or certificate or for such other action as may be proper by serving on the regulated entity an order to show cause which will:
- (1) Allege the violations with which the regulated entity is charged, or the potentially hazardous conditions or

other facts deemed to be sufficient grounds for the proposed action;

- (2) Provide that the regulated entity may file a written answer to the order under oath or affirmation within 20 days of its date, or such other time as may be specified in the order:
- (3) Inform the regulated entity of its right, within 20 days of that date of the order, or such other time as may be specified in the order, to demand a hearing;

(4) Specify the issues; and

(5) State the effective date of the order.

- b. A regulated entity who receives an order may respond to an order to show cause by filing a written answer under oath or affirmation. The answer shall specifically admit or deny each allegation or charge made in the order to show cause and may set forth the matters of fact and law on which the regulated entity relies. The answer may demand a hearing.
- c. If the answer demands a hearing, the agency will issue an order designating the time and place of hearing.
- d. An answer or stipulation may consent to the entry of an order in substantially the form proposed in the order to show cause.
- e. The consent of the regulated entity to the entry of an order shall constitute a waiver by the regulated entity of a hearing, findings of fact and conclusions of law, and of all right to seek agency and judicial review or to contest the validity of the order in any forum. The order shall have the same force and effect as an order made after hearing by a presiding officer or the agency.

hearing by a presiding officer or the agency.

f. When the RHS supervisor or the supervisor's designee, as appropriate, finds that the public health, safety, or interest so requires or that the violation is willful, the order to show cause may provide, for stated reasons, that the proposed action be temporarily effective pending further

order.

38.9(4) Settlement and compromise. At any time after the issuance of an order designating the time and place of hearing in a proceeding to modify, suspend, or revoke a license, registration, or certificate, or for other action, the staff and a regulated entity may enter into a stipulation for the settlement of the proceeding or the compromise of a civil penalty. The stipulation or compromise shall be subject to approval by the designated presiding officer or, if none has been designated, by the chief administrative law judge, according due weight to the position of the staff. The presiding officer, or if none has been designated, the chief administrative law judge, may order such adjudication of the issues as deemed to be required in the public interest to dispose of the proceeding. If approved, the terms of the settlement or compromise shall be embodied in a decision or order settling and discontinuing the proceeding

38.9(5) Order for modification of license. The agency may modify a license, registration or certificate by issuing an amendment on notice to the regulated entity that the regulated entity may demand a hearing with respect to all or any part of the amendment within 20 days from the date of the notice or such longer period as the notice may provide. The amendment will become effective on the expiration of the 20-day period during which the regulated entity may demand a hearing. If the regulated entity requests a hearing during this 20-day period, the amendment will become effective on the date specified in an order made following the hearing. When the agency finds that the public health, safety, or interest so requires, the order may be made immediately effective.

38.9(6) Civil penalties.

a. Before instituting any proceeding to impose a civil penalty under Iowa Code section 136C.4, the RHS supervisor or the supervisor's designee, as appropriate, shall serve a written notice of violation upon the person charged. This notice may be included in a notice issued pursuant to 38.9(2). The notice of violation shall specify the date or dates, facts, and the nature of the alleged act or omission with which the person is charged and shall identify specifically the particular provision or provisions of the law, rule, regulation, license, permit, or cease and desist order involved in the alleged violation and must state the amount of each proposed penalty. The notice of violation shall also advise the person charged that the civil penalty may be paid in the amount specified therein, or the proposed imposition of the civil penalty may be protested in its entirety or in part, by a written answer, either denying the violation or showing extenuating circum-The notice of violation shall advise the person charged that upon failure to pay a civil penalty subsequently determined by the agency, if any, unless compromised, remitted, or mitigated, the fee shall be collected by civil action, pursuant to Iowa Code section 136C.4.

b. Within 20 days of the date of a notice of violation or other time specified in the notice, the person charged may either pay the penalty in the amount proposed or answer the notice of violation. The answer to the notice of violation shall state any facts, explanations, and arguments denying the charges of violation, or demonstrating any extenuating circumstances, error in the notice of violation, or other reason why the penalty should not be imposed and may request remission or mitigation of the

penalty.

c. If the person charged with violation fails to answer within the time specified in 38.9(6)"b," an order may be issued imposing the civil penalty in the amount set forth in the notice of violation described in 38.9(6)"p."

in the notice of violation described in 38.9(6)"a."
d. If the person charged with violation files an answer

to the notice of violation, the RHS supervisor or the supervisor's designee, upon consideration of the answer, will issue an order dismissing the proceeding or imposing, mitigating, or remitting the civil penalty. The person charged may, within 20 days of the date of the order or other time specified in the order, request a hearing.

e. If the person charged with violation requests a hearing, the agency will issue an order designating the

time and place of hearing.

f. If a hearing is held, an order will be issued after the hearing by the presiding officer or the agency dismissing the proceeding or imposing, mitigating, or remitting the civil penalty.

g. The RHS supervisor or the supervisor's designee, as appropriate, may compromise any civil penalty, subject

to the provisions of 38.9(4).

h. If the civil penalty is not compromised, or is not remitted by the RHS supervisor or the supervisor's designee, as appropriate, the presiding officer, or the agency, and if payment is not made within ten days following either the service of the order described in 38.9(6)"c" or "f," or the expiration of the time for requesting a hearing described in 38.9(6)"d," the RHS supervisor or the supervisor's designee, as appropriate, may refer the matter to the attorney general for collection.

i. Except when payment is made after compromise or mitigation by the Department of Justice or as ordered by a court of the state, following reference of the matter to the attorney general for collection, payment of civil penalties

imposed under Iowa Code section 136C.4 shall be made by check, draft, or money order payable to the Treasurer, State of Iowa, and mailed to the Director, Iowa Department of Public Health.

38.9(7) Requests for action under this rule.

- a. Any person may file a request to institute a proceeding pursuant to 38.9(3) to modify, suspend, or revoke a license, registration, or certificate, or for such other action as may be proper. Such a request shall be addressed to the Supervisor, Radiological Health Section, Bureau of Environmental Health, Iowa Department of Public Health, Lucas State Office Building, Des Moines, Iowa 50319. The requests shall specify the action requested and set forth the facts that constitute the basis for the request. The RHS supervisor will discuss the matter with staff to determine appropriate action in accordance with 38.9(7)"b."
- b. Within a reasonable time after a request pursuant to 38.9(7)"a" has been received, the RHS supervisor shall either institute the requested proceeding in accordance with this rule or shall advise the person who made the request in writing that no proceeding will be instituted, in whole or in part, with respect to the request, and the reasons for the decision.
- c.(1) The RHS supervisor's decisions under this rule will be filed and within 25 days after the date of the RHS supervisor's decision under this rule that no proceeding will be instituted or other action taken in whole or in part, the agency may on its own motion review that decision, in whole or in part, to determine if the RHS supervisor has abused his discretion. This review power does not limit in any way either the agency's supervisory power over delegated staff actions or the agency's power to consult with the staff on a formal or informal basis regarding institution of proceedings under this rule.
- (2) No petition or other request for agency review of an RHS supervisor's decision under this rule will be entertained by the agency.

CHAPTER 38—APPENDIX A

GENERAL STATEMENT OF POLICY AND PROCEDURE FOR RHS ENFORCEMENT ACTIONS

The following statement of general policy and procedure explains the enforcement policy of the Iowa department of public health, (agency), bureau of environmental health, radiological health section, and its staff in initiating enforcement actions, and of presiding officers of the state attorney general's office in reviewing these actions. This statement is applicable to enforcement in matters involving the public health and safety and the environment. This is a policy statement and not a rule, and, therefore, the agency may deviate from this statement of policy and procedure as is appropriate under the circumstances of a particular case. *(Any reference made to "licensee" or license" in this statement also refers to any registration [registrant], certification [certificate holder], or any other document and holder of such document authorizing specific activities related to the use of radioactive materials or radiation-producing machines, which has been issued by and is subject to the regulatory authority of the agency).

I. Introduction and purpose.

A. The purpose of the RHS enforcement program is to promote and protect the radiological health and safety of the public, including employee's health and safety and the environment by:

*Brackets supplied by agency; underscoring for emphasis

- (1) Ensuring compliance with RHS rules and license conditions:
- (2) Obtaining prompt correction of violations and adverse quality conditions which may affect safety;
- (3) Deterring future violations and occurrences of conditions adverse to quality; and
- (4) Encouraging improvement of licensee performance and, by example, that of industry, including the prompt identification and reporting of potential safety problems.
- B. Consistent with the purpose of this program, prompt and vigorous enforcement action will be taken when dealing with licensees who do not achieve the necessary meticulous attention to detail and the high standard of compliance which RHS expects. Each enforcement action is dependent on the circumstances of the case and requires the exercise of discretion after consideration of these policies and procedures. In no case, however, will licensees who cannot achieve and maintain adequate levels of protection be permitted to conduct licensed activities.
 - II. Statutory authority and procedural framework.

A. Statutory authority.

The RHS's enforcement jurisdiction is drawn from Iowa Code chapter 17A, Iowa administrative procedure Act.

B. Procedural framework.

Rule 641—38.9(136C) sets forth the procedures the RHS uses in exercising its enforcement authority. Subrule 38.9(2) sets forth the procedures for issuing notices of violation.

The procedure to be used in assessing civil penalties is set forth in 38.9(6). This subrule provides that the appropriate IDPH employee initiates the civil penalty process by issuing a notice of violation and proposed imposition of a civil penalty. The licensee is provided an opportunity to contest in writing the proposed imposition of a civil penalty. After evaluation of the licensee's response, the RHS supervisor may mitigate, remit, or impose the civil penalty. An opportunity is provided for a hearing if a civil penalty is imposed.

The procedure for issuing an order to show cause why a license should not be modified, suspended, or revoked or why such other action should not be taken is set forth in 38.9(3). The mechanism for modifying a license by order is set forth in 38.9(5). These subrules provide an opportunity for a hearing to the affected licensee. However, the RHS is authorized to make orders immediately effective if the public health, safety or interest so requires or, in the case of an order to show cause, if the alleged violation is willful.

III. Severity of violations.

Regulatory requirements have varying degrees of safety, safeguards, or environmental significance. Therefore, the relative importance of each violation must be identified as the first step in the enforcement process.

Consequently, violations are categorized in terms of five categories of severity to show their relative importance within each of the following five activity areas:

- 1. Radioactive materials.
- 2. Electronic products.
- 3. Radon.
- 4. Tanning facilities/operators and other sources of nonionizing radiation.
- 5. 641—Chapter 42 credentialing (see appropriate sections of Supplements III, IV, and VII).

These categories of severity for violations are listed separately for each of the section's regulatory programs in

the supplements near the end of this appendix.

Within each activity area, Severity Level I has been assigned to violations that are the most significant and Severity Level V violations are the least significant. Severity Levels I and II violations are of very significant regulatory concern. In general, violations that are included in these severity categories involve actual or high potential impact on the public. Severity Level III violations are cause for significant concern. Severity Level IV violations are less serious but are of more than minor concern; i.e., if left uncorrected, they could lead to a more serious concern. Severity Level V violations are of minor safety or environmental concern.

Comparisons of significance between activity areas are inappropriate. For example, the immediacy of any hazard to the public associated with Severity Level I violations in the radioactive materials program is not necessarily directly comparable to that associated with Severity Level I violations in electronic products program or radon program. While examples are provided in Supplements I through V for determining the appropriate severity level for violations in each of the five activity areas, the examples are neither exhaustive nor controlling.

These examples do not create new requirements. Each is designed to illustrate the significance which the RHS places on a particular type of violation of RHS requirements. Each of the examples in the supplements is predi-

cated on a violation of a regulatory requirement.

In each case, the severity level of a violation will be characterized at the level best suited to the significance of the particular violation. In some cases, violations may be evaluated in the aggregate and a single severity level as-

signed for a group of violations.

The severity level of a violation may be increased if the circumstances surrounding the matter involve careless disregard of requirements, deception, or other indication of willfulness. The term "willfulness" as used here embraces a spectrum of violations ranging from deliberate intent to violate or falsify to and including careless disregard for requirements. Willfulness does not include acts which do not rise to the level of careless disregard, e.g., inadvertant clerical errors in a document submitted to the RHS. In determining the specific severity level of a violation involving willfulness, consideration will be given to such factors as the position of the person involved in the violation (e.g., first-line supervisor or senior manager), the significance of any underlying violation, the intent of the violator (e.g., negligence not amounting to careless disregard or deliberateness), and the economic advantage, if any, gained as a result of the violation. The relative weight given to each of these factors in arriving at the appropriate severity level will be dependent on the circumstances of the violation.

The RHS expects licensees to provide full, complete, timely, and accurate information and reports. Accordingly, unless otherwise categorized in the supplements, the severity level of a violation involving the failure to make a required report to the RHS will be based upon the significance of and the circumstances surrounding the matter that should have been reported. A licensee will not normally be cited for a failure to report a condition or event unless the licensee was actually aware of the condition or event which it failed to report. However, the severity level of an untimely report, in contrast to no report, may be reduced depending on the circumstances surrounding the matter.

IV. Enforcement conferences.

Whenever the RHS has learned of the existence of a potential violation for which a civil penalty or other escalated enforcement action may be warranted, or recurring noncompliance on the part of a licensee, the RHS will normally hold an enforcement conference with the licensee prior to taking enforcement action. The RHS may also elect to hold an enforcement conference for other violations, e.g., Severity Level IV violation which, if repeated, could lead to escalated enforcement action. The purpose of the enforcement conference is to (1) discuss the violations, their significance and causes, and the licensee's corrective actions, (2) determine whether there are any aggravating or mitigating circumstances, and (3) obtain other information which will help determine the appropriate enforcement action.

In addition, during the enforcement conference, the licensee will be given an opportunity to explain to the RHS what corrective actions, if any, were taken or will be taken following discovery of the potential violation. Licensees will be told when a meeting is an enforcement conference. Enforcement conferences will not normally be open to the public.

When needed to protect the public health and safety, escalated enforcement action, such as the issuance of an immediately effective order modifying, suspending, or revoking a license, will be taken prior to the enforcement conference. In such cases, an enforcement conference may be held after the escalated enforcement action is taken

V. Enforcement actions.

This section describes the enforcement sanctions available to RHS and specifies the conditions under which each may be used. The basic sanctions are notices of violations, civil penalties, and orders of various types. Additionally, related administrative mechanisms such as bulletins, confirmatory action letters, and notices of deviation are used to supplement the enforcement program. In selecting the enforcement sanctions to be applied, RHS will consider enforcement actions taken by other federal and state regulatory bodies having concurrent jurisdiction, such as in transportation matters. Usually whenever a violation of RHS requirements is identified, enforcement action is taken. The nature and extent of the enforcement action is intended to reflect the seriousness of the violation involved. For the vast majority of violations, action by RHS is appropriate in the form of a notice of violation requiring a formal response from the recipient describing its corrective actions. The relatively small number of cases involving elevated enforcement action receives substantial attention by the public, and may have significant impact on the licensee's operation. These elevated enforcement actions include civil penalties; orders modifying, suspending or revoking licenses; or orders to cease and desist from designated activities.

Notice of violation.

A notice of violation is a written notice setting forth one or more violations of a legally binding requirement. The notice normally requires the recipient to provide a written statement describing (1) corrective steps which have been taken and the results achieved; (2) corrective steps which will be taken to prevent recurrence; and (3) the date when full compliance will be achieved. RHS may require responses to notices of violation to be under oath. Normally, responses under oath will be required only in connection with civil penalties and orders.

RHS uses the notice of violation as the standard method for formalizing the existence of a violation. A notice

of violation is normally the only enforcement action taken, except in cases where the criteria for civil penalties and orders, as set forth in Sections V.B. and V.C., respectively, are met. In such cases, the notice of violation will be issued in conjunction with the elevated actions.

However, violation findings warranting the exercise of discretion under Section V.G.1. will generally not result in a notice of violation. In addition, for isolated Severity Level V violations, a notice of violation normally will not be issued regardless of who identifies the violation provided that the licensee has initiated appropriate corrective action before the inspection ends. In these situations, a formal response from the licensee is not required and the inspection report or official field notes serve to document the violations and the corrective actions. However, a notice of violation will normally be issued for willful violations, if past corrective actions for similar violations have not been sufficient to prevent recurrence, or if the circumstances warrant increasing the severity of Level V violations to a higher severity level.

Licensees are not ordinarily cited for violations resulting from matters not within their control, such as equipment failures that were not avoidable by reasonable licensee quality assurance measures or management controls. Generally, however, licensees are held responsible for the acts of their employees. Accordingly, this policy should not be construed to excuse personnel errors.

B. Civil penalty.

A civil penalty is a monetary penalty that may be imposed for violation of (1) certain specified licensing provisions of the Code of Iowa or supplementary RHS rules or orders, (2) any requirement for which a license may be revoked, or (3) reporting requirements under 641—Chapter 40. Civil penalties are designed to emphasize the need for lasting remedial action and to deter future violations.

Civil penalties are proposed absent mitigating circumstances for Severity Level I and II violations, are considered for Severity Level III violations, and may be imposed for Severity Level IV violations that are similar to previous violations for which the licensee did not take effective corrective action.

In applying this guidance for Severity Level III violations, RHS may, notwithstanding the mitigating and escalating factors in this section, refrain from proposing a civil penalty for violations that warrant the exercise of discretion under Section V.G. As to Severity Level IV violations, RHS normally considers civil penalties only for similar Severity Level IV violations that occur after the date of the last inspection or within two years, whichever period is greater.

Civil penalties will normally be assessed for knowing and conscious violations of the reporting requirements of 641—Chapter 40, and for any willful violation of any agency requirement including those at any severity level.

RHS imposes different levels of penalties for different severity level violations and different classes of licensees. Tables 1A and 1B show the basic civil penalties for various regulated programs. The structure of these tables generally takes into account the gravity of the violation as a primary consideration and the ability to pay as a secondary consideration. Generally, operations involving greater nuclear material inventories and greater potential consequences to the public and health of employees receive higher civil penalties. Regarding the secondary factor of ability of various classes of licensees to pay the civil penalties, it is not the RHS's intention that the economic im-

pact of a civil penalty be such that it puts a licensee out of business (orders rather than civil penalties are used when the intent is to terminate licensed activities) or adversely affects a licensee's ability to safely conduct licensed activities. The deterrent effect of civil penalties is best served when the amount of such penalties takes into account a licensee's "ability to pay." In determining the amounts of civil penalties for licensees for whom the tables do not reflect the ability to pay, RHS will consider as necessary and increase or decrease on a case-by-case basis.

RHS attaches great importance to comprehensive licensee programs for detection, correction, and reporting of problems that may constitute, or lead to, violation of regulatory requirements. This is emphasized by giving credit for effective licensee audit programs when licensees find, correct, and report problems expeditiously and effectively. To encourage licensee self-identification and correction of violations and to avoid potential concealment of problems of safety significance, application of the adjustment factors set forth below may result in no civil penalty being assessed for violations which are identified, reported (if required), and effectively corrected by the licensee.

On the other hand, ineffective licensee programs for problem identification or correction are unacceptable. In cases involving willfulness, flagrant RHS-identified violations, repeated poor performance in an area of concern, or serious breakdown in management controls, RHS intends to apply its full enforcement authority where such action is warranted, including issuing appropriate orders and assessing civil penalties for continuing violations on a per day basis, up to the statutory limit of \$1000 per violation per day. In this regard, while management involvement, direct or indirect, in a violation may lead to an increase in the civil penalty, the lack of such involvement may not be used to mitigate a civil penalty.

Allowance of mitigation could encourage lack of management involvement in licensed activities and a decrease

in protection of the public health and safety.

RHS reviews each proposed civil penalty case on its own merits and adjusts the base civil penalty values upward or downward appropriately. Tables 1A and 1B identify the base civil penalty values for different severity levels, activity areas, and classes of licensees. In accordance with Iowa Code section 136C.4, the values expressed in Table 1A may be invoked upon any violator of these rules repeatedly for each day of continuing violation. After considering all relevant circumstances, adjustments to these values may be made for the factors described below:

(1) Identification and reporting.

Reduction of up to 50 percent of the base civil penalty shown in Table 1A may be given when a licensee identifies the violation and promptly reports the violation to the RHS. In weighing this factor, consideration will be given to, among other things, the opportunity available to discover the violation, the ease of discovery and the promptness and completeness of any required report. No consideration will be given to a reduction in penalty if the licensee does not take immediate action to correct the problem upon discovery. On the other hand, the base penalty may be increased by as much as 50 percent if the RHS identifies the violation provided the licensee should have reasonably discovered the violation before the RHS identified it.

(2) Corrective action to prevent recurrence.

Recognizing that corrective action is always required to meet regulatory requirements, the promptness and extent to which the licensee takes corrective action, including actions to prevent recurrence, may result in up to a 50 percent increase or decrease in the base civil penalty shown in Table 1A. For example, very extensive corrective action may result in reducing the proposed civil penalty as much as 50 percent of the base value shown in Table 1A. On the other hand, the civil penalty may be increased as much as 50 percent of the base value if initiation of corrective action is not prompt or if the corrective action is only minimally acceptable. In weighing this factor, consideration will be given to, among other things, the timeliness of the corrective action, degree of licensee initiative, and comprehensiveness of the corrective action, such as whether the action is focused narrowly to the specific violation or broadly to the general area of concern.

(3) Past performance.

Reduction by as much as 100 percent of the base civil penalty shown in Table 1A may be given for prior good performance. On the other hand, the base civil penalty may be increased as much as 100 percent for prior poor performance.

In weighing this factor, consideration will be given to, among other things, the effectiveness of previous corrective action for similar problems, overall performance, and prior performance including Severity Level IV and V violations in the area of concern. For example, failure to implement previous corrective action for prior similar problems may result in an increase in the civil penalty. For purpose of assessing past performance, violations within the past two years of inspection at issue or the period within the last two inspections, whichever is longer, will be considered.

(4) Prior notice of similar events.

The base civil penalty may be increased as much as 100 percent for cases where the licensee had prior knowledge of a potential problem as a result of a licensee review, a specific RHS or industry notifications or other reasonable indication of a potential problem, and had failed to take effective preventive steps. Prior notice may include findings of RHS, the licensee, or industry made at other facilities of the licensee where it is reasonable to expect the licensee to take action to prevent similar problems at the facility subject to the enforcement action at

5) Multiple occurrences.

The base civil penalty may be increased as much as 100 percent where multiple examples of a particular violation are identified during the inspection period.

(6) Duration.

The duration of the violation may also be considered in assessing a civil penalty. A greater civil penalty may be imposed if a violation continues for more than a day. For example:

1. If a licensee is aware of the existence of a condition which results in an ongoing violation and fails to initiate corrective action, each day the condition existed may be considered as a separate violation and, as such, subject to a separate additional civil penalty.

2. If a licensee (a) is unaware of a condition resulting in a continuing violation but clearly should have been aware of the condition or (b) had an opportunity to correct the condition but failed to do so, a separate violation and attendant civil penalty may be considered for each day

that the licensee clearly should have been aware of the condition or had an opportunity to correct the condition, but failed to do so.

3. Alternatively, whether or not a licensee is aware or clearly should have been aware of a violation that continues for more than one day, the base civil penalty may be increased as much as 100 percent to reflect the added significance resulting from the duration of the violation.

The above factors are additive. Notwithstanding the statements in subparagraph (6), paragraphs "1" to "3" above, civil penalties for any one violation shall not exceed \$1000 per day, with a maximum amount of \$5000.

regardless of its duration.

The tables and the mitigating factors determine the civil penalties which may be addressed for each violation. However, to focus on the fundamental underlying causes of a problem for which enforcement action appears to be warranted, the cumulative total for all violations which contributed to or were unavoidable consequences of that problem may be based on the amount shown in the table for a problem of that severity level, as adjusted. If an evaluation of such multiple violations shows that more than one fundamental problem is involved, each of which, if viewed independently, could lead to civil penalty action by itself, then separate civil penalties may be assessed for each such fundamental problem. In addition, the failure to make a required report of an event requiring such reporting is considered a separate problem and will normally be assessed a separate civil penalty, if the licensee is aware of the matter that should have been reported.

C. Orders.

An order is a written RHS directive to modify, suspend, or revoke a license; to cease and desist from a given practice or activity; or to be proper (see 38.9(3) and 38.9(5).

Orders may also be issued in lieu of, or in addition to, civil penalties, as appropriate.

Orders may also be issued as follows:

(1) License modification orders are issued when some change in licensee, equipment, procedures, or management controls is necessary.

- (2) Suspension orders may be used:1. To remove a threat to the public health and safety or the environment;
- To stop facility construction when further work could preclude or significantly hinder the identification or correction of an improperly constructed safety-related system or component, or the licensee's quality assurance program implementation is not adequate to provide confidence that construction activities are being properly
- 3. When the licensee has not responded adequately to other enforcement action:
- 4. When the licensee interferes with the conduct of an inspection or investigation; or

5. For any reason not mentioned above for which li-

cense revocation is legally authorized.

Suspensions may apply to all or part of the licensed activity. Ordinarily, a licensed activity is not suspended (nor is a suspension prolonged) for failure to comply with requirements where such failure is not willful and adequate corrective action has been taken.

(3) Revocation orders may be used:

- 1. When a licensee is unable or unwilling to comply with RHS requirements,
 - 2. When a licensee refuses to correct a violation,

3. When a licensee does not respond to a notice of violation where a response was required,

4. When a licensee refuses to pay a fee required by

Iowa Code section 136C.10, or

5. For any other reason for which revocation is authorized under the rules.

(4) Cease and desist orders are typically used to stop an unauthorized activity that has continued after notifica-

tion by RHS that such activity is unauthorized.

Orders are made effective immediately, without prior opportunity for hearing, whenever it is determined that the public health, interest, or safety so requires, or when the order is responding to a violation involving willfulness. Otherwise, a prior opportunity for a hearing on the order is afforded. For cases in which the RHS believes a basis could reasonably exist for not taking the action as proposed, the licensee will ordinarily be afforded an opportunity to show cause why the order should not be issued in the proposed manner.

D. Escalation of enforcement sanctions.

RHS considers violations of Severity Level I, II, or III to be serious. If serious violations occur, RHS will, where necessary, issue orders in conjunction with civil penalties to achieve immediate corrective actions and to deter further recurrence of serious violations. RHS carefully considers the circumstances of each case in selecting and applying the sanction(s) appropriate to the case in accordance with the criteria described in Sections V.B. and V.C.

Examples of enforcement actions that could be taken for similar Severity Level I, II, or III violations are set forth in Table 2. The actual progression to be used in a particular case will depend on the circumstances. However, enforcement sanctions will normally escalate for recurring similar violations.

E. Enforcement actions involving individuals.

Enforcement actions involving individuals are significant personnel actions, which will be closely controlled and judiciously applied. An enforcement action will normally be taken only when there is little doubt that the individual fully understood, or should have understood, the responsibility; knew, or should have known, the required actions; and knowingly, or with careless disregard (i.e., with more than mere negligence) failed to take required actions which have actual or potential safety significance. Most transgressions of individuals at the level of Severity Level III, IV, or V violations will be handled by citing only the facility licensee.

More serious violations, including those involving the integrity of an individual (e.g., lying to the RHS) concerning matters within the scope of the individual's responsibilities, will be considered for enforcement action against the individual. Action against the individual, however, will not be taken if the improper action by the individual was caused by management failures. The following ex-

amples of situations illustrate this concept:

 Inadvertent individual mistakes resulting from inadequate training or guidance provided by the facility licensee

- Inadvertently missing an insignificant procedural requirement when the action is routine, fairly uncomplicated, and there is no unusual circumstance indicating that the procedures should be referred to and followed step-by-step.
- Compliance with an express direction of management resulted in a violation unless the individual did not express concern or objection to the direction.

 Individual error directly resulting from following the technical advice of an expert unless the advice was clearly unreasonable and the licensed individual should have recognized it as such.

 Violations resulting from inadequate procedures unless the individual used a faulty procedure knowing it was faulty and had not attempted to get the procedure cor-

rected.

Examples of situations which could result in enforcement actions against individuals include, but are not limited to, violations which involve:

 Recognizing a violation of procedural requirements and willfully not taking corrective action.

Willfully defeating alarms which have safety significance.

- Inattention to duty such as sleeping, being intoxicated while on duty, or otherwise not meeting requirements for fitness for duty.
- Falsifying records required for RHS rules or by the facility license.
 - Willfully failing to take "immediate actions" of

emergency procedures.
Willfully withholding significant safety information rather than making such information known to appropriate

supervisory or technical personnel.

Any proposed enforcement action against individuals must be done with the concurrence of the RHS Supervisor, Bureau of Health Protection (BEH) Chief, and Division of Health Protection Director. The opportunity for an enforcement conference with the individual will usually be provided.

In addition, RHS may take enforcement action where the conduct of the individual places in question the RHS's reasonable assurance that licensed activities will be properly conducted. The RHS may take enforcement action for reasons that would warrant refusal to issue a license on an original application. Accordingly, enforcement action may be taken regarding matters that raise issues of integrity, competence, fitness for duty, or other matters that may not necessarily be a violation of specific agency requirements.

In the case of an unlicensed individual, an order modifying the facility license to require the removal of the individual from all nuclear-related activities for a specified period of time or indefinitely may be appropriate.

F. Reopening closed enforcement actions.

If significant new information is received or obtained by RHS which indicates that an enforcement sanction was incorrectly applied, consideration may be given, dependent on the circumstances, to reopening a closed enforcement action to increase or decrease the severity of a sanction or to correct the record. Reopening decisions will be made on a case-by-case basis, are expected to occur rarely, and require the specific approval of the division director.

G. Exercise of discretion.

Because the RHS wants to encourage and support licensee initiative for self-identification and correction of problems, RHS may exercise discretion as follows:

1. RHS may refrain from issuing a notice of violation for a violation described in an inspection report or official field notes that meets all of the following criteria:

a. It was identified by the licensee;

b. It is normally classified at a Severity Level IV or V;

c. It was reported, if required;

- d. It was or will be corrected, including measures to prevent recurrence, within a reasonable time; and
- e. It was not a willful violation or a violation that could reasonably be expected to have been prevented by the licensee's corrective action for a previous violation.
- 2. The RHS may refrain from issuing a notice of violation or a proposed civil penalty for violations described in an inspection report or official field notes that meet all of the following criteria:
- a. The RHS has taken significant enforcement action based upon a major safety event contributing to an extended shutdown of a material license or other regulated facility, or the licensee is forced into an extended work stoppage related to generally poor performance over a long period; the licensee has developed and is aggressively implementing during the shutdown a comprehensive program for problem identification and correction; and RHS concurrence is needed by the licensee prior to resuming activities;
- b. Nonwillful violations are identified by the licensee as the result of its comprehensive program or as a result of an employee allegation to the licensee. If RHS identifies the violation, the RHS should determine whether enforcement action is necessary to achieve remedial action;
- The violations are based upon activities of the licensee prior to the events leading to the work stoppage;
 and
- d. The violations would normally not be categorized as higher than Severity Level III violations under the RHS's enforcement policy.
- 3. The RHS may refrain from proposing a civil penalty for a Severity Level III violation not involving an overexposure or release of radioactive material that meets all of the following criteria:
 - a. It was identified by the licensee and reported;
- b. Comprehensive corrective action has been taken or is well under way within a reasonable time following identification;
- c. It was not a violation that either was reasonably preventable by the licensee's action in response to a previous regulatory concern identified within the past two years of the inspection or since the last two inspections whichever is longer or reasonably should have been corrected prior to the violation because the licensee had prior notice of the problem involved; and
- d. It was not a willful violation or indicative of a breakdown in management controls.
- 4. The RHS may refrain from proposing a civil penalty for a Severity Level III violation involving a past problem that meets the following criteria:
- a. It was identified by a licensee as a result of a licensee's voluntary formal effort such as defined in the radiation safety program, internal audit procedures or other program that has a defined scope and timetable which is being aggressively implemented and reported;
- b. Comprehensive corrective action has been taken or is well under way within a reasonable time following identification; and
- c. It is not likely to be identified by routine licensee efforts such as normal surveillance or QA activities.
- 5. If the RHS issues an enforcement action for a violation at a Severity Level III violation and as part of the corrective action for that violation, the licensee identifies other examples of the violation with the same root cause, the RHS may refrain from issuing an additional enforcement action. In determining whether to exercise this discretion, the RHS will consider whether the licensee

acted reasonably and in a timely manner appropriate to the safety significance of the initial violation, the comprehensiveness of the corrective action, whether the matter was reported, and whether the additional violation(s) substantially changes the safety significance or character of the regulatory concern arising out of the initial violation.

Notwithstanding paragraphs 2, 3, 4, and 5 above, a civil penalty may be proposed when judgment warrants it on the basis of the circumstances of the individual case. For example, civil penalties may be warranted where multiple Severity Level III violations are discovered or where the violation is willful. In addition, as provided in Section VIII, Responsibilities, the RHS supervisor may refrain from issuing a civil penalty or a notice of violation based on the merits of the case after considering the guidance in this statement of policy and such factors as the age of the violation, the safety significance of the violation, the overall performance of the licensee, and circumstances, if any, that have changed since the violation provided prior notice has been given the agency. This discretion is expected to be exercised only where application of the normal guidance in the policy is unwarranted.

H. Related administrative actions.

In addition to the formal enforcement mechanisms of notice of violation, civil penalties, and orders, RHS also uses administrative mechanisms, such as bulletins, information notices, generic letters, notices of deviation, and confirmatory action letters to supplement its enforcement program. RHS expects licensees to adhere to any obligations and commitments resulting from these processes and will not hesitate to issue appropriate orders to licensees to make sure that such commitments are met.

(1) Bulletins, information notices, and generic letters are written notifications to groups of licensees identifying specific problems and recommending specific actions.

(2) Notices of deviation are written notices describing a licensee's failure to satisfy a commitment where the commitment involved has not been made a legally binding requirement. A notice of deviation requests a licensee to provide a written explanation or statement describing corrective steps taken (or planned), the results achieved, and the date when corrective action will be completed.

(3) Confirmatory action letters are letters confirming a licensee's agreement to take certain actions to remove significant concerns about health and safety, safeguards, or the environment.

I. Referrals to attorney general's office.

Alleged or suspected criminal violations of Iowa's radiation machines and radioactive materials rules are referred to the state assistant attorney general's office for investigation. Referral to the attorney general's office does not preclude the RHS from taking other enforcement action under this general statement of policy. However, such actions will be coordinated with the attorney general's office to the extent practicable.

VI. Inaccurate and incomplete information.

A violation of the rules on submitting complete and accurate information, whether or not considered a material false statement, can result in the full range of enforcement sanctions. The labeling of a communication failure as a material false statement will be made on a case-by-case basis and will be reserved for egregious violations. Violations involving inaccurate or incomplete information or the failure to provide significant information identified by a licensee normally will be categorized based on the guidance herein, Section III "Severity of Violations," and in Supplement VII.

The agency recognizes that oral information may in some situations be inherently less reliable than written submittals because of the absence of an opportunity for reflection and management review. However, the agency must be able to rely on oral communications from licensee officials concerning significant information. A licensee official for purposes of application of the enforcement policy means a first-line supervisor, or above, as well as a licensed individual, radiation safety officer, or a person listed on a license as an authorized user of licensed material. Therefore, in determining whether to take enforcement action for an oral statement, consideration may be given to such factors as (1) the degree of knowledge that the communicator should have had regarding the matter, in view of the communicator's position, training, and experience, (2) the opportunity and time available prior to the communication to ensure the accuracy or completeness of the information, (3) the degree of intent or negligence, if any, involved, (4) the formality of the communication, (5) the reasonableness of RHS reliance on the information, (6) the importance of the information which was wrong or not provided, and (7) the reasonableness of the explanation for not providing complete and accurate information.

Absent at least careless disregard, an incomplete or inaccurate unsworn oral statement normally will not be subject to enforcement action unless it involves significant information provided by a licensee official. However, enforcement action may be taken for an unintentionally incomplete or inaccurate oral statement provided to the RHS by a licensee official or others on behalf of a licensee, if a record was made of the oral information and provided to the licensee thereby permitting an opportunity to correct the oral information, such as if a transcript of the communication or meeting summary containing the error was made available to the licensee and was not subsequently corrected in a timely manner.

When a licensee has corrected inaccurate or incomplete information, the decision to issue a citation for the initial inaccurate or incomplete information normally will be dependent on the circumstances, including the ease of detection of the error, the timeliness of the correction, whether the RHS of the licensee identified the problem with the communication, and whether the RHS relied on the information prior to the correction. Generally, if the matter was promptly identified and corrected by the licensee prior to reliance by the RHS, or before the RHS raised a question about the information, no enforcement action will be taken for the initial inaccurate or incomplete information. On the other hand, if the misinformation is identified after the RHS relies on it, or after some question is raised regarding the accuracy of the information, then some enforcement action normally will be taken even if it is in fact corrected. However, if the initial submittal was accurate when made but later turns out to be erroneous because of newly discovered information or advance in technology, a citation normally would not be appropriate if, when the new information became available, the initial submittal was corrected.

The failure to correct inaccurate or incomplete information, which the licensee does not identify as significant, normally will not constitute a separate violation. However, the circumstances surrounding the failure to correct may be considered relevant to the determination of enforcement action for the initial inaccurate or incom-

plete statement. For example, an unintentionally inaccurate or incomplete submission may be treated as a more severe matter if the licensee later determines that the initial submittal was in error and does not correct it or if there were clear opportunities to identify the error. If information not corrected was recognized by a licensee as significant, a separate citation may be made for the failure to provide significant information. In any event, in serious cases where the licensee's actions in not correcting or providing information raise questions about the licensee's commitment to safety or fundamental trustworthiness, the agency may exercise its authority to issue orders modifying, suspending, or revoking the license. The agency recognizes that enforcement determination must be made on a case-by-case basis, taking into consideration the issues described above.

VII. Public disclosure of enforcement actions.

In accordance with Iowa Code chapter 22, all enforcement actions and licensees' responses are publicly available for inspection. In addition, press releases are generally issued for civil penalties and orders. In the case of orders and civil penalties related to violations at Severity Level I, II, or III, press releases are issued at the time of the order or the proposed imposition of the civil penalty. Press releases are not normally issued for notices of violation.

VIII. Responsibilities.

The RHS supervisor, as the principal enforcement officer of the RHS, has been delegated the authority to issue notices of violation, civil penalties, and orders. The RHS supervisor will sign all notices of violation in concurrence with the signatures of inspectors, and inspectors will sign transmittal letters. In recognition that the regulation of nuclear activities in many cases does not lend itself to a mechanistic treatment, the RHS supervisor must exercise judgment and discretion in determining the severity levels of the violations and the appropriate enforcement sanctions, including the decision to issue a notice of violation, or to propose or impose a civil penalty and the amount of such penalty, after considering the general principles of this statement of policy and the technical significance of the violations and the surrounding circumstances.

The chief, BEH and, as appropriate, the director of the division of health protection will be provided written notification of all enforcement actions involving civil penalties or orders. The chief, BEH, will be consulted prior to taking action in the following situations (unless the urgency of the situation dictates immediate action):

(1) An action affecting a licensee's operation that requires balancing the public health and safety implications of not operating with the potential radiological or other hazards associated with continued operation;

(2) Proposals to impose civil penalties in amounts greater than 100 percent of the Severity Level I values shown in Table 1A;

- (3) Any proposed enforcement action that involves a Severity Level I violation;
- (4) Any enforcement action that involves a finding of a material false statement;
- (5) Refraining from taking enforcement action for matters meeting the criteria of Section V.G.2.
- (6) Any action the RHS supervisor believes warrants agency involvement; or
- (7) Any proposed enforcement action on which the agency asks to be consulted.

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PUBLIC HEALTH DEPARTMENT[641](cont'd)

CHAPTER 38— APPENDIX A SUPPLEMENTS I-VII

Supplement I—Severity categories for topics addressing certain health physics matters in 641—Chapter 40 $(1\bar{3}6C).$

A. Severity I—Violations involving, for example:

- 1. Single exposure of a worker in excess of 25 rems of radiation to the whole body, 150 rems to the skin of the whole body, or 375 rems to the feet, ankles, hands, or
- 2. Annual whole body exposure of a member of the public in excess of 2.5 rems of radiation;
- 3. Release of radioactive material to an unrestricted area in excess of ten times the limits of 641—subrule 40.2(6);
- 4. Disposal of licensed material in quantities or concentrations in excess of ten times the limits of 641—subrule 40.4(3); or
- 5. Exposure of a worker in restricted areas of ten times the limits of 641—subrule 40.2(3).

B. Severity II—Violations involving, for example:

- 1. Single exposure of a worker in excess of 5 rems of radiations to the whole body, 30 rems to the skin of the whole body, or 75 rems to the feet, ankles, hands or forearms:
- 2. Annual whole body exposure of a member of the public in excess of 0.5 rems of radiation;
- 3. Release of radioactive material to an unrestricted area in excess of five times the limits of 641—subrule 40.2(6);
- 4. Failure to make an immediate notification as required by 641—paragraphs 40.5(3)"a" and "b";
- 5. Disposal of licensed material in quantities or concentrations in excess of five times the limits of 641—subrule 40.4(3); or
- 6. Exposure of a worker in restricted areas in excess of five times the limits of 641—subrule 40.2(3).
 - C. Severity III—Violations involving, for example:
- 1. Single exposure of a worker in excess of 3 rems of radiation to the whole body, 7.5 rems to the skin of the whole body, or 18.75 rems to the feet, ankles, hands or forearms:
- 2. A radiation level in an unrestricted area such that an individual could receive greater than 100 millirem in a one-hour period or 500 millirem in any seven consecutive days;

Failure to make a 24-hour notification as required by 641—paragraph 40.5(3)"b" or an immediate notifica-

tion required by 641—paragraph 40.5(3)"a";

- 4. Substantial potential for an exposure or release in excess of 641—Chapter 40 whether or not such exposure or release occurs (e.g., entry into high radiation areas, such as in the vicinity of exposed radiographic sources, without having performed an adequate survey, or operation of a radiation facility with a nonfunctional interlock system);
- 5. Release of radioactive material to an unrestricted area in excess of the limits of 641—subrule 40.2(6);
- 6. Improper disposal for licensed material not covered in Severity Levels I and II;
- 7. Exposure of a worker in restricted areas in excess of the limits of 641—subrule 40.2(3):
- 8. Release for unrestricted use of contaminated or radioactive material or equipment which poses a realistic potential for significant exposure to members of the public, or which reflects a programmatic (rather than isolated) weakness in the radiation control program;

Cumulative worker exposure above regulatory limits when such cumulative exposure reflects a programmatic rather than an isolated weakness in radiation protection;

10. Conduct of licensee activities by a technically un-

qualified person;

11. Significant failure to control licensed material: or

12. Breakdown in the radiation safety program involving a number of violations that are related or, if isolated, that are recurring that collectively represent a potentially significant lack of attention or carelessness toward licensed responsibilities.

D. Severity IV—Violations involving, for example:

- 1. Exposures in excess of the limits of 641—subrule 40.2(1) not constituting Severity Level I, II, or III violations;
- A radiation level in an unrestricted area such that an individual could receive greater than 2 millirem in a one-hour period or 100 millirem in any seven consecutive days;

3. Failure to make a 30-day notification required by 641—subrule 40.5(5);

- 4. Failure to make a follow-up written report as required by 641—subrule 40.5(2) and 641—subrule 40.6(4);
- 5. Any other matter that has more than minor safety or environmental significance.
- E. Severity V—Violations that have minor safety or environmental significance.

Supplement II—Severity categories referring to certain transportation issues.

- A. Severity I—Violations of RHS transportation requirements involving, for example:
- 1. Annual whole body radiation exposure of a member of the public in excess of 2.5 rems of radiation;
- 2. Surface contamination in excess of 50 times the RHS limit: or
- 3. External radiation levels in excess of 10 times the RHS limit.
- B. Severity II—Violations of RHS transportation requirements involving, for example:
- 1. Annual whole body exposure of a member of the public in excess of 0.5 rems of radiation;
- Surface contamination in excess of 10 but not more than 50 times the RHS limit;
- 3. External radiation levels in excess of 5, but not more than 10 times the RHS limit; or
- 4. Failure to make required initial notifications associated with Severity Level I or II violations.
- C. Severity III—Violations of RHS transportation requirements involving, for example:
- 1. Surface contamination in excess of 5 but not more than 10 times the RHS limit;
- 2. External radiation in excess of 1 but not more than 5 times the RHS limit;
- 3. Any noncompliance with labeling, placarding, shipping paper, packaging, loading, or other requirements that could reasonably result in the following:

a. Significant failure to identify the type, quantity, or form of material;

b. Failure of the carrier or recipient to exercise adequate controls; or

c. Substantial potential for personnel exposure or contamination, or improper transfer of material;

4. Failure to make required initial notification associated with Severity Level III violations; or

5. Breakdown in the licensee's program for the transportation of licensed material involving a number of

violations that are related or, if isolated, that are recurring violations that collectively reflect a potentially significant lack of attention or carelessness toward licensed responsibilities.

D. Severity Level IV—Violations of RHS transportation requirements involving, for example:

1. Breach of package integrity without external radiation levels exceeding the RHS limit or without contamination levels exceeding 5 times the RHS limits;

2. Surface contamination in excess of but not more

than 5 times the RHS limit;

Failure to register as an authorized user of RHS-Certified Transport packages;

4. Noncompliance with shipping papers, marking, labeling, placarding, packaging or loading not amounting to a Severity Level I, II, or III violation;

5. Failure to demonstrate that packages for special form radioactive material meet applicable regulatory re-

quirements;
6. Failure to demonstrate that packages meet DOT specifications for 7A Type A packages; or

7. Other violations that have more than minor safety or environmental significance.

E. Severity V—Violations that have minor safety or environmental significance.

Supplement III—Severity categories relative to radioactive materials.

A. Severity I-Violations involving, for example:

1. Radiation levels, contamination levels, or releases that exceed 10 times the limits specified in the license; or

- 2. A system designed to prevent or mitigate a serious safety event not being operable when actually required to perform its design function;
 - B. Severity II—Violations involving, for example:
- 1. Radiation levels, contamination levels, or releases that exceed 5 times the limits specified in the license; or
- 2. A system designed to prevent or mitigate a serious safety event being inoperable.
 - C. Severity III—Violations involving, for example:
- 1. Failure to control access to licensed materials for radiation purposes as specified by RHS requirements;
- 2. Possession or use of unauthorized equipment or materials in the conduct of licensee activities which degrades safety;

3. Use of radioactive material on humans where such

use is not authorized;

- Conduct of licensed activities by a technically unqualified person;
- 5. Radiation levels, contamination levels, or releases that exceed the limits specified in the license;
- 6. Medical therapeutic misadministration or the failure to report such misadministration;
- 7. Multiple errors of the same or similar root cause that result in diagnostic misadministrations over the inspection period or a recurrent violation from the previous inspection period that results in a diagnostic misadministration;
- 8. Breakdown in the control of licensed activities involving a number of violations that are related or, if isolated, that are recurring violations that collectively represent a potentially significant lack of attention or carelessness toward licensed responsibilities; or
- 9. Failure, during radiographic operations, to have present or use radiographic equipment, radiation survey instruments, or personnel monitoring devices as required by 641—Chapter 40.

D. Severity IV—Violations involving, for example:

1. Failure to maintain patients hospitalized who have cobalt-60, cesium-137, radium-226, or iridium-192 implants or to conduct required leakage or contamination tests, or to use properly calibrated equipment;

2. Other violations that have more than minor safety

or environmental significance; or

3. Medical diagnostic misadministration or a failure to report such a misadministration.

E. Severity V—Violations that have minor safety or environmental significance.

Supplement IV—Severity categories relative to electronic products.

A. Severity I—Violations involving, for example:

1. Maximum fluoroscopic X-ray output exceeds limitations by 200 percent; or

2. No means to shield tube housing (e.g., fish bowl tube).

B. Severity II—Violations involving, for example:

1. Maximum fluoroscopic X-ray output exceeds limitations by 100 percent; or

2. Failure to provide protected area for operator of ma-

chine(s).

C. Severity III—Violations involving, for example:

1. Conduct of regulated activities by a technically unqualified person;

- 2. Positive beam limitation device not operating in accordance with manufacturer's specifications or the rules:
- 3. Failure of primary beam intercept for fluoroscopic X-ray units;
 - 4. Violation of beam quality (HVL) requirements;

5. No technique indication, as appropriate;

- 6. Source-to-skin distance not in accordance with requirements of these rules;
- 7. Light field not of sufficient intensity to meet standards or does not exist at all;
 - 8. Centering device inoperative or not available;
- 9. Timers not operating in accordance with standards and rules;
 - 10. Failure to control access to radiation areas;
- 11. Multiple errors of the same or similar root cause that result in overexposure(s) or a recurrent violation from the previous inspection period that results in overexposure(s);
- 12. Breakdown in the control of regulated activities involving a number of violations that collectively represent a potentially significant lack of attention or carelessness toward regulated responsibilities; or
- 13. Any violation based on manufacturer specifications which is not of such significance as to merit a Severity II violation.
 - D. Severity IV—Violations involving, for example:
 - 1. Absence of or incomplete technique chart;
- 2. No plan review of facility prior to beginning regulated activities at the facility;
 - 3. Possession of unauthorized equipment; or
 - 4. Failure to indicate source-to-image distance (SID).
 - E. Severity V—Violations including, for example:
- 1. Failure to provide safety regulations to operators of machines; or
- Failure to provide records of maintenance or associated information on machines.

Supplement V—Severity categories relative to radon testing and mitigation.

A. Severity I—Violations involving, for example:

1. Fan installation under a living area; or

2. Inadequate sealing that leads to backdrafting; or

3. Failure to conduct diagnostic testing; or

4. Conducting testing or mitigation without certification.

B. Severity II—Violations involving, for example:

1. Failure to follow National Electrical Code for installation of radon mitigation systems such as using outdoor wiring outside, using conduit when penetrating floors, having a dedicated line at breaker, and shutoff mechanism near fan; or

2. Using a testing device for which an individual is not

listed on the RMP; or

3. Failure to report to IDPH radon levels found to be 100 pCi/L or more.

Severity III—Violations involving, for example:

- 1. Failure to provide copies of appropriate waivers; or 2. Failure to provide audible or visual alarms that indicate that the system is operating properly; or
- 3. Failure to ensure that postmitigation testing was performed; or
- 4. Improper use of testing device in conjunction with release of data.
 - D. Severity IV—Violations involving, for example:
- 1. Inadequate or absence of support for mitigation system components; or

2. No radiation labels on mitigation systems; or

- 3. Failure to provide ultraviolet coating to appropriate mitigation system components; or
- 4. Failure to brief homeowner on mitigation system operation.
- E. Severity V-Violations that have minor safety or environmental significance such as:
- 1. Failure to brief homeowner on mitigation system operation; or
- 2. Failure to maintain records showing name, address, and telephone numbers of homes tested or mitigated; or
- 3. Failure to submit required information to IDPH in a timely manner; or
- 4. Failure to supply or provide a mitigation system dia-
 - 5. Failure to report changes in program to IDPH.

Supplement VI—Severity categories relative to tanning facilities/operators and other forms of nonionizing radiation.

- A. Severity I—Violations involving, for example:
- 1. Allowing the consumer to use the tanning device without requiring the use of protective eye wear;
- 2. Allowing the consumer to use the tanning device when no operator is present; or

 - 3. No emergency shutoff switch on device.B. Severity II—Violations involving, for example:
- 1. Failure to follow tanning device exposure schedules;
- 2. Using unauthorized lamps or timers or unauthorized devices;
- 3. Failure to provide appropriate warning statements and other representative lists of photosensitizing drugs and agents information to tanning consumers; or
 - 4. Use of inappropriate ultraviolet filters.
 - C. Severity III—Violations involving, for example:
- 1. Conduct of tanning activities by an untrained person:

- 2. Multiple errors of the same or similar root cause that result in overexposure to ultraviolet radiation or a recurrent violation from the previous inspection period that results in an overexposure to ultraviolet radiation;
- 3. Breakdown in the control of activities involving a number of violations that are related or, if isolated, that are recurring violations that collectively represent a potentially significant lack of attention or carelessness toward responsibilities;

4. Failure to replace lamps and filters at the required

frequency;

- 5. Failure to provide physical barriers to protect the general public from coming in contact with lamps or bulbs: or
 - 6. Use of a device when not authorized by the agency.
 - D. Severity IV—Violations involving, for example:
 - 1. Failure to post appropriate warning signs; or

- 2. Failure to have proper device labeling.E. Severity V—Violations that have minor safety or environmental significance, such as:
 - 1. Failure to use appropriate consent forms;
 - 2. Use of inappropriate promotional material;
 - 3. Tanning permit not posted; or
 - No procedures for cleaning devices.

Supplement VII—Severity categories relative to miscellaneous matters.

- A. Severity I—Violations involving, for example:
- 1. Inaccurate or incomplete information that is provided to the RHS (a) deliberately with the knowledge of a licensee official that the information is incomplete or inaccurate, or (b) if the information, had it been complete. and accurate at the time provided, likely would have resulted in regulatory action such as an immediate order required by the public health and safety considerations;
- 2. Incomplete or inaccurate information that the RHS requires be kept by a licensee which is (a) incomplete or inaccurate because of falsification by or with the knowledge of a licensee official, or (b) if the information, had it been complete and accurate when reviewed by the RHS, likely would have resulted in regulatory action such as an immediate order required by public health and safety con-
- 3. Information that the licensee has identified as having significant implications for public health and safety or the common defense and security ("significant information identified by a licensee") and is deliberately withheld from the agency:

4. Action by senior corporate management in violation of regulations against an employee;

- 5. A knowing and intentional failure to provide the notice required by these rules; or
- Failure to substantially implement the required fitness-for-duty program.
 - B. Severity II—Violations involving, for example:
- 1. Inaccurate or incomplete information which is provided to the RHS (a) by a licensee official because of careless disregard for the completeness or accuracy of the information, or (b) if the information, had it been complete and accurate at the time provided, likely would have resulted in regulatory action such as a show cause order or a different regulatory position;
- 2. Incomplete or inaccurate information which the RHS requires be kept by a licensee which is (a) incomplete or inaccurate because of careless disregard for the accuracy

of the information on the part of a licensee official, or (b) if the information, had it been complete and accurate when reviewed by the RHS, likely would have resulted in regulatory action such as a show cause order or a different regulatory position;

3. "Significant information identified by a licensee" and not provided to the agency because of careless disre-

gard on the part of a licensee official;

4. Action by management above first-line supervision

in violation or regulations against an employee;

- 5. Failure to remove an individual from unescorted access who has been involved in the sale, use, or possession of illegal drugs within the protected area or to take action for on-duty misuse of alcohol, prescription drugs, or over-the-counter drugs;
- 6. Failure to test for cause when observed behavior within the protected area or credible information concerning activities within the protected area indicate possible unfitness for duty based on drug or alcohol use; or
- 7. Deliberate failure of the licensee's employee assistance program to notify licensee's management when the EAP's staff is aware that an individual's condition may adversely affect safety-related activities.

C. Severity III—Violations involving, for example:

- 1. Incomplete or inaccurate information which is provided to the RHS (a) because of inadequate actions on the part of licensee officials but not amounting to a Severity Level I or II violation, or (b) if the information, had it been complete and accurate at the time provided, likely would have resulted in a reconsideration of a regulatory position or substantial further inquiry such as an additional inspection or a formal request for information;
- 2. Incomplete or inaccurate information which the RHS requires be kept by a licensee which is (a) incomplete or inaccurate because of inadequate actions on the part of licensee officials but not amounting to a Severity Level I or II violation, or (b) if the information, had it been complete and accurate when reviewed by the RHS, likely would have resulted in a reconsideration of a regulatory position or substantial further inquiry such as an additional inspection or a formal request for information;
- 3. Failure to provide "significant information identified by a licensee" to the agency and not amounting to a Severity Level I or II violation;
- 4. Action by first-line supervision in violation of regulations against an employee;
- 5. Inadequate review or failure to review such that, if an appropriate review had been made as required, a report pursuant to 641—subrule 40.5(6) would have been made; or
- 6. Failure to take the required action for a person confirmed to have been tested positive for illegal drug use or take action for on-site alcohol use, not amounting to a Severity Level II violation.
 - D. Severity IV—Violations involving, for example:
- 1. Incomplete or inaccurate information of more than minor significance which is provided to the RHS but not amounting to a Severity Level I, II, or III violation;
- 2. Information which the RHS requires be kept by a licensee and which is incomplete or inaccurate and of more than minor significance but not amounting to a Severity Level I, II, or III violation; or
- 3. Inadequate review or failure to review under reporting requirements of these rules or other procedural violations associated with reporting requirements with more than minor safety significance.

E. Severity V—Violations of minor procedural requirements related to reporting requirements.

1. Incomplete or inaccurate information which is provided to the agency and the incompleteness or inaccuracy is of minor significance;

2. Information which the RHS requires be kept by a licensee which is incomplete or inaccurate and the incompleteness or inaccuracy is of minor significance; or

3. Minor procedural requirements related to reporting.

TABLE 1A—Base Civil Penalties

			Transportation	
		Health Physics and EP	Greater than Type A Quantity	Type A Quantity or less
a.	Industrial users of material ³	1000	500	200
b.	Waste disposal of radioactive material	1000	500	200
c.	Academic and medical institu- tions	1000	500	200
d.	Other material licensees	1000	500	200
e.	Radiation ma- chine users	1000		
f.	Radon testers and mitigators	250		 –
g.	641—Chapter 42	100	—	
h.	Tanning facili- ties/operators and other sources of nonionizing radi- ation		~	
		500	····· —	

¹ Includes irradiated fuel, high level waste, unirradiated fissile material and any other quantities requiring Type B packaging.

Includes low specific activity waste (LSA), low-level waste, Type A packages, and excepted quantities and articles.

Includes industrial radiographers, nuclear pharmacies, and other industrial users.

TABLE 1B —Base Civil Penalties

Severity Level	Base Civil Penalty Amount	
	(Percent of amount listed in Table 1A)	
I	100	
II	80	
ш	50	
IV	15	
V	5	

TABLE 2—Examples of Progression of Escalated Enforcement Actions for Similar Violations in the Same Activity Area Under the Same License, Registration, or Certificate.

Number of similar violations from the date of the last inspection or within the previous two years (whichever period is greater)

1st 2nd 3rd
1. 2nd 3rd
2. 3rd
3. 3rd
3. 3rd

a

a+b

a+b

a+b+c

a. Civil penalty

II.

III.

b. Suspension of affected operations until the office director is satisfied that there is reasonable assurance that the regulated entity can operate in compliance with the applicable requirements; or modification of the license or other document, as appropriate.

c. Show cause for modification or revocation of the

license or other document, as appropriate.

d. Further action, as appropriate.

These rules are intended to implement Iowa Code chapter 136C.

ARC 3052A

PUBLIC HEALTH DEPARTMENT[641]

Notice of Intended Action

Twenty-five interested persons, a governmental subdivision, an agency or an association of 25 or more persons may demand an oral presentation hereon as provided in Iowa Code §17A.4(1)"b."

Notice is also given to the public that the Administrative Rules Review Committee may, on its own motion or on written request by any individual or group, review this proposed action under §17A.8(6) at a regular or special meeting where the public or interested persons may be heard.

Pursuant to the authority of Iowa Code section 136C.3, the Iowa Department of Public Health hereby gives Notice of Intended Action to rescind Chapter 39, "Registration of Radiation Machines and Licensure of Radioactive Material," and adopt a new Chapter 39, "Registration of Radiation Machine Facilities, Licensure of Radioactive Materials and Transportation of Radioactive Materials," Iowa Administrative Code.

The action taken is appropriate because of the number and magnitude of the additions which need to be made to the rules in order to keep current with the standards set forth by the Conference of Radiation Control Program Directors' "Suggested State Regulations for the Control of Radiation" (SSRCRs) and to remain compatible with the U.S. Nuclear Regulatory Commission (NRC) pursuant to the Agreement State Program between the Governor and the NRC. Nothing has been deleted from the rules; however, the additions to Chapter 39 necessitated renumbering of the entire chapter. These additions are specified below.

1. Subrule 39.4(26), "Financial assurance and record keeping for decommission," is an "Item of Compatibility" pursuant to the Agreement State Program with NRC. In essence, the subrule requires certain radioactive materials licensees to develop and submit to the Department a decommissioning plan and proof of financial assurance adequate to carry out the decommissioning plan.

2. All rules related to the use of radionuclides in the healing arts which were previously located in Chapter 39 have been moved to 641—41.2(136C). This is consistent with Part G of the SSRCRs and will greatly facilitate use

of the rules.

3. The language for Reciprocal Recognition of Out-of-State Radioactive Materials Licensees, subrule 39.4(90), has been modified as follows:

a. Rather than allowing the licensees to operate in the state for 180 days during a calendar year, the new rule stipulates that the licensee may operate in the state for a period of 180 days during the one-year period following receipt of reciprocity fee. The Department deemed this appropriate to preclude a licensee who pays a reciprocity fee in December of one year from having to pay an additional fee in January of the new year, especially if the licensee only intends to operate in the state for a relatively short period of time.

b. The reciprocity fee has been changed to be 100 percent of the fee charged for a new license, rather than 85 percent. Since our rules tie us directly to 10 CFR 170.31 and 170.32 for fees for users of radioactive materials, it

was necessary to make this adjustment.

4. New Chapter 39 has appendixes, which is again consistent with the SSRCRs. This format is much easier to work with. The material was previously contained in the body of the rules of each chapter. In addition, the appendix material is now in the same chapter as the rule which refers to it, thus making the rules easier to use.

Any interested person may make written suggestions or comments on the proposed chapter on or before close of business June 17, 1992. Such written material should be directed to Donald A. Flater, Chief, Bureau of Environmental Health, Iowa Department of Public Health, Lucas State Office Building, Des Moines, Iowa 50319, FAX (515)242-5284.

A public hearing will be held on June 17, 1992, at 9 a.m., in the Third Floor Conference Room, Lucas State Office Building, at which time persons may present their views orally or in writing. At the hearing, persons will be asked to give their name, address, and whom they represent. Presenters will also be asked to confine their remarks to the subject of the rules.

These rules are intended to implement Iowa Code chapter 136C.

The following chapter is proposed.

Rescind 641—Chapter 39 and insert the following in lieu thereof:

CHAPTER 39

REGISTRATION OF RADIATION MACHINE FACILITIES, LICENSURE OF RADIOACTIVE MATERIALS AND TRANSPORTATION OF RADIOACTIVE MATERIALS

641-39.1(136C) Purpose and scope.

39.1(1) All persons possessing radiation machines within the state shall be registered in accordance with this chapter, except as specifically exempted.

39.1(2) No person shall receive, possess, use, transfer, own, or acquire radioactive material except as authorized in a specific or general license issued pursuant to this chapter or as otherwise provided in these rules.

39.1(3) All references to any Code of Federal Regulations (CFR) in this chapter are those in effect as of Sep-

tember 1, 1992.

- 641—39.2(136C) Definitions. As used in this chapter, "facility" means the location at which one or more devices or sources are installed and located within one building, vehicle, or under one roof and are under the same administrative control.
- 641—39.3(136C) Requirements for registration of Xray and other electronic machines that produce radiation.

39.3(1) Exemptions.

- a. Electronic equipment that produces radiation incidental to its operation for other purposes is exempt from the registration and notification requirements of this chapter, provided that the dose equivalent rate averaged over an area of 10 square centimeters does not exceed 0.5 millirem (5 µSv) per hour at 5 centimeters from any accessible surface of such equipment. The production, testing, or factory servicing of such equipment shall not be exempt.
- b. Radiation machines while in transit or storage incident thereto are exempt from the requirements of this chapter.

c. Domestic television receivers are exempt from the requirements of this chapter.

39.3(2) Application for registration of radiation machine facilities. Each person having a radiation machine facility shall:

- Apply for registration of such facility with the agency within 30 days following the effective date of these rules or thereafter prior to the operation of a radiation machine facility. Application for registration shall be completed on forms furnished by the agency and shall include the following:
 - (1) Name, address, and telephone number of:
 - The facility;
 - 2. The owner of the facility;
- 3. The individual responsible for the use of the facility; and
 - The individual designated under 39.3(2)"b."
- (2) The manufacturer, model number, and type of each radiation machine located within the facility.
- (3) If the facility is mobile, the geographic areas within the state to be covered by the operations of the facility.
- The signature of the individual designated under (4) 39.3(2)"b."
- (5) Name of the radiation machine supplier, installer and service agent.
- (6) The date of application and signature of the individual responsible for the use of the facility.
- b. Designate on the application form an individual to be responsible for radiation protection.
- c. Each registrant shall prohibit any person from furnishing radiation machine servicing or services as described in 39.3(3)"d" to the registrant's radiation machine facility until such person provides evidence that the person has been registered with the agency as a provider of services in accordance with 39.3(3).
- 39.3(3) Application for registration of servicing and
- a. Each person who is engaged in the business of installing or offering to install radiation machines or is en-

gaged in the business of furnishing or offering to furnish radiation machine servicing or services in this state shall apply for registration of such services with the agency within 30 days following the effective date of these rules or thereafter prior to furnishing or offering to furnish any such services.

b. Application for registration shall be completed on forms furnished by the agency and shall contain all information required by the agency as indicated on the forms and accompanying instructions.

c. Each person applying for registration under this

chapter shall specify:

(1) That the person has read and understands the requirements of these rules;

(2) The services for which the person is applying for registration;

- (3) The training and experience that qualify the person to discharge the services for which the person is applying for registration;
- (4) The type of measurement instrument to be used, frequency of calibration, and source of calibration; and
- (5) The type of personnel dosimeters supplied, frequency of reading, and replacement or exchange schedule.
- d. For the purpose of 39.3(3), services may include but shall not be limited to:
- (1) Installation and servicing of radiation machines and associated radiation machine components,
- (2) Calibration of radiation machines or radiation measurement instruments or devices,
- (3) Radiation protection or health physics consultations or surveys, and
 - (4) Personnel dosimetry services.
- e. No individual shall perform services which are not specifically stated for that individual on the notice of registration issued by the agency.
 - 39.3(4) Issuance of notice of registration.
- a. Upon a determination that an applicant meets the requirements of this chapter, the agency shall issue a notice of registration.
- b. The agency may incorporate in the notice of registration at the time of issuance or thereafter by appropriate rule, regulation, or order, such additional requirements and conditions with respect to the registrant's receipt, possession, use, and transfer of radiation machines as it deems appropriate or necessary.
- 39.3(5) Expiration of notice of registration. Except as provided by 39.3(6)"b," each notice of registration shall expire within 12 months of issuance or at the end of the specified day in the month and year stated therein.

39.3(6) Renewal of notice of registration.

- a. Application for renewal of registration shall be filed in accordance with 39.3(2) or 39.3(3).
- b. In any case in which a registrant has properly filed an application for renewal of current registration within 90 days prior to the expiration of the existing registration, such existing registration shall not expire until the application status has been finally determined by the agency.
- 39.3(7) Report of changes. The registrant shall notify the agency in writing before making any change which would render the information contained in the application for registration or the notice of registration no longer accurate
- 39.3(8) Approval not implied. No person, in any advertisement, shall refer to the fact that the person or the person's facility is registered with the agency pursuant to the provisions of 39.3(2) or 39.3(3), and no person shall

state or imply that any activity under such registration has been approved by the agency.

39.3(9) Assembler and transfer obligation.

a. Any person who sells, leases, transfers, lends, disposes of, assembles, or installs radiation machines in this state shall notify the agency within 15 days of:

(1) The name and address of persons who have received these machines:

(2) The manufacturer, model, and serial number of each radiation machine transferred; and

(3) The date of transfer of each radiation machine.

- b. No person shall make, sell, lease, transfer, lend, assemble, or install radiation machines or the supplies used in connection with such machines unless such supplies and equipment, when properly placed in operation and used, shall meet the requirements of 641—Chapters 38, 39, 40 and 41.
- c. In the case of diagnostic X-ray systems which contain certified components, a copy of the assembler's report prepared in accordance with the requirements of the federal diagnostic X-ray standard (21 CFR 1020.30(d)) shall be submitted to the agency within 15 days following completion of the assembly. Such report shall suffice in lieu of any other report by the assembler.

39.3(10) Reciprocity—out-of-state radiation machines.

- Whenever any radiation machine is to be brought into the state, for any temporary use, the person proposing to bring such machine into the state shall give written notice to the agency at least two working days before such machine is to be used in the state. The notice shall include:
 - (1) The type of radiation machine;

(2) The nature, duration, and scope of use;

(3) The exact location(s) where the radiation machine is to be used; and

(4) States in which this machine is registered.

- b. If, for a specific case, the two-working-day period would impose an undue hardship on the person, upon application to the agency, permission to proceed sooner may be granted.
 - c. The person referred to in 39.3(10)"a" shall:
 - (1) Comply with all applicable rules of the agency;

(2) Supply the agency with such other information as the agency may reasonably request; and

- (3) Not operate within the state on a temporary basis in excess of 180 calendar days in a one-year period. The one-year period starts on the day the agency receives the appropriate fee, as specified in 641—subrule 38.8(8), and ends exactly 365 days later. It is the registrant's responsibility to ensure the 180-day limit is not exceeded during the one-year reciprocity period and to ensure that the reciprocal recognition is renewed 30 days prior to the expiration of the one-year period.
- 39.3(11) An exemption is granted to persons who receive, possess, use, process, transfer, distribute, and dispose of materials containing or contaminated at concentrations less than 20 picocuries per gram of radium.

641-39.4(136C) Requirements for licensing of radioactive materials.

39.4(1) In addition to the requirements of this chapter, all licensees are subject to the requirements of 641—Chapters 38, 40 and 41. Furthermore, licensees engaged in industrial radiographic operations are subject to the requirements of 641—Chapter 45; licensees using radionuclides in the healing arts are subject to the requirements of 641-41.2(136C); licensees engaged in land disposal of radioactive material are subject to the requirements of 641—Chapter 40; and licensees engaged in wireline and subsurface tracer studies are subject to the requirements of 641—41.5(136C).

39.4(2) Source material.

NOTICES

a. Any person is exempt from this chapter to the extent that such person receives, possesses, uses, owns, or transfers source material in any chemical mixture, compound, solution, or alloy in which the source material is by weight less than 1/20 of 1 percent (0.05 percent) of the mixture, compound, solution, or alloy.

b. Any person is exempt from this chapter to the extent that such person receives, possesses, uses, or transfers unrefined and unprocessed ore containing source material; provided that, except as authorized in a specific license,

such person shall not refine or process such ore.

c. Any person is exempt from this chapter to the extent that such person receives, possesses, uses, or transfers:

(1) Any quantities of thorium contained in:

1. Incandescent gas mantles,

2. Vacuum tubes,

Welding rods.

- 4. Electric lamps for illuminating purposes, provided that each lamp does not contain more than 50 milligrams of thorium,
- 5. Germicidal lamps, sunlamps, and lamps for outdoor or industrial lighting, provided that each lamp does not contain more than 2 grams of thorium,

6. Rare earth metals and compounds, mixtures, and products containing not more than 0.25 percent by weight thorium, uranium, or any combination of these, or

- 7. Personnel neutron dosimeters, provided that each dosimeter does not contain more than 50 milligrams of thorium.
- (2) Source material contained in the following prod-
- 1. Glazed ceramic tableware, provided that the glaze contains not more than 20 percent by weight source material,
- 2. Glassware containing not more than 10 percent by weight source material, but not including commercially manufactured glass brick, pane glass, ceramic tile, or other glass or ceramic used in construction.
- 3. Glass enamel or glass enamel frit containing not more than 10 percent by weight source material imported or ordered for importation into the United States, or initially distributed by manufacturers in the United States, before July 25, 1983, or
- 4. Piezoelectric ceramic containing not more than 2 percent by weight source material.
- (3) Photographic film, negatives, and prints containing uranium or thorium.
- (4) Any finished product or part fabricated of, or containing, tungsten-thorium or magnesium-thorium alloys, provided that the thorium content of the alloy does not exceed 4 percent by weight and that this exemption shall not be deemed to authorize the chemical, physical, or metallurgical treatment or processing of any such product or part.
- (5) Uranium contained in counterweights installed in aircraft, rockets, projectiles, and missiles, or stored or handled in connection with installation or removal of such counterweights, provided that:
- 1. The counterweights are manufactured in accordance with a specific license issued by the U.S. Nuclear Regu-

latory Commission, authorizing distribution by the licensee pursuant to 10 CFR Part 40.

2. Each counterweight has been impressed with the following legend clearly legible through any plating or other covering: "DEPLETED URANIUM,"

Each counterweight is durably and legibly labeled or marked with the identification of the manufacturer and the statement: "UNAUTHORIZED ALTERATIONS

PROHIBITED," and

4. This exemption shall not be deemed to authorize the chemical, physical, or metallurgical treatment or processing of any such counterweights other than repair or restoration of any plating or other covering.

(7) Natural or depleted uranium metal used as shielding constituting part of any shipping container, provided

that:

- 1. The shipping container is conspicuously and legibly impressed with the legend "CAUTION—RADIOACTIVE SHIELDING—URANIUM," and
- 2. The uranium metal is encased in mild steel or equally fire-resistant metal of minimum wall thickness of 1/8 inch (3.2 mm).
- (8) Thorium contained in finished optical lenses, provided that each lens does not contain more than 30 percent by weight of thorium, and that this exemption shall not be deemed to authorize either:
- 1. The shaping, grinding, or polishing of such lens or manufacturing processes other than the assembly of such lens into optical systems and devices without any alteration of the lens, or
- 2. The receipt, possession, use, or transfer of thorium contained in contact lenses, or in spectacles, or in eyepieces in binoculars or other optical instruments.
- (9) Uranium contained in detector heads for use in fire detection units, provided that each detector head contains not more than 0.005 microcurie of uranium.
- (10) Thorium contained in any finished aircraft engine part containing nickel-thoria alloy, provided that:
- 1. The thorium is dispersed in the nickel-thoria alloy in the form of finely divided thoria (thorium dioxide), and
- 2. The thorium content in the nickel-thoria alloy does not exceed 4 percent by weight.
- d. The exemptions in 39.4(2) do not authorize the manufacture of any of the products described.
- e. The requirements specified in 39.4(2)"c"(5)"2" and "3" need not be met by counterweights manufactured prior to December 31, 1969, provided that such counterweights are impressed with the legend, "CAUTION—RADIOACTIVE MATERIAL—URANIUM," as previously required by the rules.

39.4(3) Radioactive material other than source material.

a. Exempt concentrations.

(1) Except as provided in 39.4(3)"a"(2), any person is exempt from this chapter to the extent that such person receives, possesses, uses, transfers, owns or acquires products containing radioactive material introduced in concentrations not in excess of those listed in Appendix A of this chapter.

(2) No person may introduce radioactive material into a product or material knowing or having reason to believe that it will be transferred to persons exempt under 39.4(3)"a"(1) or equivalent regulations of the U.S. Nuclear Regulatory Commission, any agreement state or licensing state, except in accordance with a specific license issued pursuant to 39.4(29) or the general license provided in 39.4(90).

b. Exempt quantities.

(1) Except as provided in 39.4(3)"b"(3) and (4), any person is exempt from these rules to the extent that such person receives, possesses, uses, transfers, owns, or acquires radioactive material in individual quantities, each of which does not exceed the applicable quantity set forth in Appendix B of this chapter.

(2) Any person who possesses radioactive material received or acquired under the general license issued for manufacture of devices and equipment under special license from NRC is exempt from the requirements for a license set forth in this chapter to the extent that such person possesses, uses, transfers or owns such radioactive material. Such exemption does not apply for radium-226.

(3) This paragraph (39.4(3)"b") does not authorize the production, packaging or repackaging of radioactive material for purposes of commercial distribution, or the incorporation of radioactive material into products intended

for commercial distribution.

(4) No person may, for purposes of commercial distribution, transfer radioactive material in the individual quantities set forth in Appendix B of this chapter, knowing or having reason to believe that such quantities of radioactive material will be transferred to persons exempt under 39.4(3) or equivalent regulations of the U.S. Nuclear Regulatory Commission, any agreement state or licensing state, except in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission pursuant to Section 32.18 of 10 CFR 32 or by the agency pursuant to 39.4(29)"b," which license states that the radioactive material may be transferred by the licensee to persons exempt under 39.4(3)"b" or the equivalent regulations of the U.S. Nuclear Regulatory Commission, an agreement state, or licensing state. Authority to transfer possession or control by the manufacturer, processor, or producer of any equipment, device, commodity, or other product containing by-product material whose subsequent possession, use, transfer, and disposal by all other persons are exempted from regulatory requirements may be obtained only from the U.S. Nuclear Regulatory Commission, Washington, D.C. 20555.

c. Exempt items.

(1) Certain items containing radioactive material. Except for persons who apply radioactive material to, or persons who incorporate radioactive material into, the following products, any person is exempt from these rules to the extent that the person receives, possesses, uses, transfers, owns, or acquires the following products:

1. Timepieces or hands or dials containing not more than the following specified quantities of radioactive material and not exceeding the following specified radiation

dose rate:

25 millicuries (925 MBq) of tritium per timepiece;

5 millicuries (185 MBq) of tritium per hand;

- 15 millicuries (555 MBq) of tritium per dial (bezels when used shall be considered as part of the dial);
- 100 microcuries (3.7 MBq) of promethium-147 per watch or 200 microcuries (7.4 MBq) of promethium-147 per any other timepiece;

• 20 microcuries (0.74 MBq) of promethium-147 per watch hand or 40 microcuries (1.48 MBq) of

promethium-147 per other timepiece hand;

• 60 microcuries (2.22 MBq) of promethium-147 per watch dial or 120 microcuries (4.44 MBq) of promethium-147 per other time piece dial (bezels when used shall be considered as part of the dial).

- 2. The radiation dose rate from hands and dials containing promethium-147 will not exceed, when measured through 50 milligrams per square centimeter of absorber:
- For wrist watches, 0.1 millirad (1 μGy) per hour at 10 centimeters from any surface.
- For pocket watches, 0.1 millirad (1 μ Gy) per hour at 1 centimeter from any surface.
- For any other timepiece, 0.2 millirad (2 μGy) per hour at 10 centimeters from any surface.
- One microcurie (37 kBq) of radium-226 per timepiece in timepieces acquired prior to the effective date of this rule.
- 3. Lock illuminators containing not more than 15 millicuries (555 MBq) of tritium or not more than 2 millicuries (74 MBq) of promethium-147 installed in automobile locks. The radiation dose rate from each lock illuminator containing promethium-147 will not exceed 1 millirad (10 μ Gy) per hour at 1 centimeter from any surface when measured through 50 milligrams per square centimeter of absorber.
- 4. Precision balances containing not more than 1 millicurie (37 MBq) of tritium per balance or not more than 0.5 millicurie (18.5 MBq) of tritium per balance part.
- 5. Automobile shift quadrants containing not more than 25 millicuries (925 MBq) of tritium.
- 6. Marine compasses containing not more than 750 millicuries (27.8 GBq) of tritium gas and other marine navigational instruments containing not more than 250 millicuries (9.25 GBq) of tritium gas.
- 7. Thermostat dials and pointers containing not more than 25 millicuries (925 MBq) of tritium per thermostat.
- 8. Electron tubes, provided that each tube does not contain more than one of the following specified quantities of radioactive material:
- 150 millicuries (5.55 GBq) of tritium per microwave receiver protector tube or 10 millicuries (370 MBq) of tritium per any other electron tube;
 - 1 microcurie (37 kBq) of cobalt-60;
 - 5 microcuries (185 kBq) of nickel-63;
 - 30 microcuries (1.11 MBq) of krypton-85;
 - 5 microcuries (185 kBq) of cesium-137; and
 - 30 microcuries (1.11 MBq) of promethium-147.
- And provided further, that the radiation dose rate from each electron tube containing radioactive material will not exceed 1 millirad (10 µGy) per hour at 1 centimeter from any surface when measured through 7 milligrams per square centimeter of absorber. For purposes of 39.4(3)"c"(1)"8," "electron tubes" include spark gap tubes, power tubes, gas tubes including glow lamps, receiving tubes, microwave tubes, indicator tubes, pick-up tubes, radiation detection tubes, and any other completely sealed tube that is designed to conduct or control electrical currents
- 9. Ionizing radiation measuring instruments containing, for purposes of internal calibration or standardization, one or more sources of radioactive material, provided that:
- Each source contains no more than one exempt quantity set forth in Appendix B of this chapter;
- Each instrument contains no more than ten exempt quantities. For purposes of this requirement, an instrument's source(s) may contain either one or different types of radionuclides and an individual exempt quantity may be composed of fractional parts of one or more of the exempt quantities in Appendix B of this chapter, provided that the sum of such fractions shall not exceed unity; or

- For americium-241, 0.05 microcurie (1.85 kBq) is considered an exempt quantity under 39.4(3)"c"(1)"9."
- 10. Spark gap irradiators containing not more than 1 microcurie (37 kBq) of cobalt-60 per spark gap irradiator for use in electrically ignited fuel oil burners having a firing rate of at least 3 gallons (11.4 l) per hour.
- (2) Self-luminous products containing radioactive material,
- 1. Tritium, krypton-85, or promethium-147. Except for persons who manufacture, process, or produce selfluminous products containing tritium, krypton-85, or promethium-147, any person is exempt from these rules to the extent that such person receives, possesses, uses, transfers, owns, or acquires tritium, krypton-85 or promethium-147 in self-luminous products manufactured, processed, produced, imported, or transferred in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission pursuant to Section 32.22 of 10 CFR Part 32, which license authorizes the transfer of the product to persons who are exempt from regulatory requirements. The exemption in 39.4(3)"c"(2) does not apply to tritium, krypton-85, or promethium-147 used in products primarily for frivolous purposes or in toys or adornments.
- 2. Radium-226. Any person is exempt from these rules to the extent that such person receives, possesses, uses, transfers, or owns articles containing less than 0.1 microcurie (3.7 kBq) of radium-226 which were acquired prior to the effective date of these rules.
- (3) Gas and aerosol detectors containing radioactive material.
- 1. Except for persons who manufacture, process, or produce gas and aerosol detectors containing radioactive material, any person is exempt from 641—Chapters 38, 39, 40, and 41 to the extent that such person receives, possesses, uses, transfers, owns, or acquires radioactive material in gas and aerosol detectors designed to protect life or property from fires and airborne hazards, provided that detectors containing radioactive material shall have been manufactured, imported, or transferred in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission pursuant to Section 32.27 of 10 CFR Part 32; or a licensing state pursuant to 39.4(29)"c," which authorizes the transfer of the detectors to persons who are exempt from regulatory requirements.
- 2. Gas and aerosol detectors previously manufactured and distributed to general licensees in accordance with a specific license issued by an agreement state shall be considered exempt under 39.4(3)"c"(3)"1," provided that the device is labeled in accordance with the specific license authorizing distribution of the generally licensed device, and provided further that they meet the requirements of 39.4(29)"c."
- 3. Gas and aerosol detectors containing NARM previously manufactured and distributed in accordance with a specific license issued by a licensing state shall be considered exempt under 39.4(3)"c"(3)"1," provided that the device is labeled in accordance with the specific license authorizing distribution, and provided further that they meet the requirements of 39.4(29)"c."
- (4) Resins containing scandium-46 and designed for sand consolidation in oil wells. Any person is exempt from these rules to the extent that such person receives, possesses, uses, transfers, owns or acquires synthetic plastic resins containing scandium-46 which are designed for sand consolidation in oil wells. Such resins shall have

been manufactured or imported in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission, or shall have been manufactured in accordance with the specifications contained in a specific license issued by the agency or any agreement state to the manufacturer of such resins pursuant to licensing requirements equivalent to those in Sections 32.16 and 32.17 of 10 CFR Part 32 of the regulations of the U.S. Nuclear Regulatory Commission. This exemption does not authorize the manufacture of any resins containing scandium-46.

39.4(4) to 39.4(19) Reserved.

39.4(20) Types of licenses. There are two types of licenses for radioactive materials: general and specific.

a. General licenses provided in this chapter are effective without the filing of applications with the agency or the issuance of licensing documents to the particular persons, although the filing of a certificate with the agency may be required by the particular general license. The general licensee is subject to all other applicable portions of these rules and any limitations of the general license.

b. Specific licenses require the submission of an application to the agency and the issuance of a licensing document by the agency. The licensee is subject to all applicable portions of these rules as well as any limitations specified in the licensing document.

39.4(21) General licenses—source material.

a. A general license is hereby issued authorizing commercial and industrial firms, research, educational and medical institutions, and state and local government agencies to use and transfer not more than 15 pounds (6.82 kg) of source material at any one time for research, development, educational, commercial, or operational purposes. A person authorized to use or transfer source material, pursuant to this general license, may not receive more than a total of 150 pounds (68.2 kg) of source material in any one calendar year.

b. Persons who receive, possess, use, or transfer source material pursuant to the general license issued in 39.4(21)"a" are exempt from the provisions of 641—Chapter 40 to the extent that such receipt, possession, use, or transfer is within the terms of such general license; provided, however, that this exemption shall not be deemed to apply to any such person who is also in possession of source material under a specific license issued

c. Persons who receive, possess, use, or transfer source material pursuant to the general license in 39.4(21)"a" are prohibited from administering source material, or the radiation therefrom, either externally or internally, to human beings except as may be authorized by the agency in a

specific license.

pursuant to this chapter.

d. A general license is hereby issued authorizing the receipt of title to source material without regard to quantity. This general license does not authorize any person to receive, possess, use, or transfer source material.

e. Depleted uranium in industrial products and devices.

- (1) A general license is hereby issued to receive, acquire, possess, use, or transfer, in accordance with the provisions of 39.4(21)"e"(2), (3), (4), and (5), depleted uranium contained in industrial products or devices for the purpose of providing a concentrated mass in a small volume of the product or device.
- (2) The general license in 39.4(21)"e"(1) applies only to industrial products or devices which have been manufactured either in accordance with a specific license issued to the manufacturer of the products or devices

pursuant to 39.4(29)"m" or in accordance with a specific license issued to the manufacturer by the U.S. Nuclear Regulatory Commission or an agreement state which authorizes manufacture of the products or devices for distribution to persons generally licensed by the U.S. Nuclear Regulatory Commission or an agreement state.

- (3) 1. Persons who receive, acquire, possess, or use depleted uranium pursuant to the general license established by 39.4(21)"e"(1) shall file Agency Form "Certificate—Use of Depleted Uranium Under General License" with the agency. The form shall be submitted within 30 days after the first receipt or acquisition of such depleted uranium. The general licensee shall furnish on the Agency Form "Registration Certificate—Use of Depleted Uranium Under a General License" the following information and such other information as may be required by that form:
 - Name and address of the general licensee;
- A statement that the general licensee has developed and will maintain procedures designed to establish physical control over the depleted uranium described in 39.4(21)"e"(1) and designed to prevent transfer of such depleted uranium in any form, including metal scrap, to persons not authorized to receive the depleted uranium; and
- Name and title, address, and telephone number of the individual duly authorized to act for and on behalf of the general licensee in supervising the procedures identified in 39.4(21)"e"(3)"1."
- 2. The general licensee possessing or using depleted uranium under the general license established by 39.4(21)"e"(1) shall report in writing to the agency any changes in information furnished by the general licensee in Agency Form "Registration Certificate—Use of Depleted Uranium Under General License." The report shall be submitted within 30 days after the effective date of such change.
- (4) A person who receives, acquires, possesses, or uses depleted uranium pursuant to the general license established by 39.4(21)"e"(1):
- 1. Shall not introduce such depleted uranium, in any form, into a chemical, physical, or metallurgical treatment or process, except a treatment or process for repair or restoration of any plating or other covering of the depleted uranium;
 - 2. Shall not abandon such depleted uranium;
- Shall transfer or dispose of such depleted uranium only by transfer in accordance with the provisions of 39.4(41). In the case where the transferee receives the depleted uranium pursuant to the general license established by 39.4(21)"e"(1), the transferor shall furnish the transferee a copy of 641—Chapter 39 and a copy of Agency Form "Registration Certificate—Use of Depleted Uraniun Under General License." In the case where the transferee receives the depleted uranium pursuant to a general license contained in the U.S. Nuclear Regulatory Commission's or agreement state's regulation equivalent to 39.4(21)"e"(1), the transferor shall furnish the transferee a copy of 641—Chapter 39 and a copy of the Agency Form "Registration Certificate—Use of Depleted Uranium Under General License" accompanied by a note explaining that use of the product or device is regulated by the U.S. Nuclear Regulatory Commission or agreement state under requirements substantially the same as those in 641—Chapters 38, 39, 40, 41 and 45;
- 4. Within 30 days of any transfer, shall report in writing to the agency the name and address of the person re-

ceiving the depleted uranium pursuant to such transfer; and

5. Shall not export such depleted uranium except in accordance with a license issued by the U.S. Nuclear Regulatory Commission pursuant to 10 CFR Part 110.

(5) Any person receiving, acquiring, possessing, using, or transferring depleted uranium pursuant to the general license established by 39.4(21)"e"(1) is exempt from the requirements of 641—Chapter 40 with respect to the depleted uranium covered by that general license.

39.4(22) General licenses—radioactive material other than source material. (Note: Different general licenses are issued in this subrule, each of which has its own spe-

cific conditions and requirements.)

- a. Certain devices and equipment. A general license is hereby issued to transfer, receive, acquire, own, possess, and use radioactive material incorporated in the following devices or equipment which have been manufactured, tested and labeled by the manufacturer in accordance with a specific license issued to the manufacturer by the U.S. Nuclear Regulatory Commission for use pursuant to Section 31.3 of 10 CFR Part 31. This general license is subject to the provisions of 641—38.4(136C) to 641—38.5(136C), 39.4(3)"a"(2), 39.4(32), 39.4(41), 39.4(51), 641—39.5(136C), and 641—Chapter 40. Attention is directed particularly to the provisions of 641—Chapter 40, which relate to the labeling of containers.
- (1) Static elimination device. Devices designed for use as static eliminators which contain, as a sealed source or sources, radioactive material consisting of a total of not more than 500 microcuries (18.5 MBq) of polonium-210 per device.
- (2) Ion generating tube. Devices designed for ionization of air which contain, as a sealed source or sources, radioactive material consisting of a total of not more than 500 microcuries (18.5 MBq) of polonium-210 per device or a total of not more than 50 millicuries (1.85 GBq) of hydrogen-3 (tritium) per device.
 - b. Reserved.
 - c. Reserved.
 - d. Certain measuring, gauging or controlling devices.
- (1) A general license is hereby issued to commercial and industrial firms and to research, educational and medical institutions, individuals in the conduct of their business, and state or local government agencies to own, receive, acquire, possess, use or transfer, in accordance with the provisions of 39.4(22)"d"(2), (3), and (4), radioactive material, excluding special nuclear material, contained in devices designed and manufactured for the purpose of detecting, measuring, gauging or controlling thickness, density, level, interface location, radiation, leakage, or qualitative or quantitative chemical composition, or for producing light or an ionized atmosphere.
- (2) The general license in 39.4(22)"d"(1) applies only to radioactive material contained in devices—which have been manufactured and labeled in accordance with the specifications contained in a specific license issued by the agency pursuant to 39.4(29)"d" or in accordance with the specifications contained in a specific license issued by the U.S. Nuclear Regulatory Commission, an agreement state or a licensing state, which authorizes distribution of devices to persons generally licensed by the U.S. Nuclear Regulatory Commission, an agreement state or a licensing state. Regulations under the Federal Food, Drug, and Cosmetic Act authorizing the use of radioactive control devices in food production require certain additional labeling thereon which is found in 21 CFR 179.21.

(3) Any person who owns, receives, acquires, possesses, uses, or transfers radioactive material in a device pursuant to the general license in 39.4(22)"d"(1):

1. Shall ensure that all labels affixed to the device at the time of receipt, and bearing a statement that removal of the label is prohibited, are maintained thereon and shall comply with all instructions and precautions provided by

such labels;

- 2. Shall ensure that the device is tested for leakage of radioactive material and proper operation of the "on-off" mechanism and indicator, if any, at no longer than sixmonth intervals or at such other intervals as are specified in the label; however, devices containing only krypton need not be tested for leakage of radioactive material, and devices containing only tritium or not more than 100 microcuries (3.7 MBq) of other beta/gamma-emitting material or 10 microcuries (0.37 MBq) of alpha-emitting material, and devices held in storage in the original shipping container prior to initial installation need not be tested for any purpose;
- 3. Shall ensure that other testing, installation, servicing, and removal from installation involving the radioactive material, its shielding or containment, are performed in accordance with the instructions provided by the labels, or by a person holding an applicable specific license from the agency, the U.S. Nuclear Regulatory Commission, an agreement state or a licensing state to perform such activities;
- 4. Shall maintain records showing compliance with the requirements of 39.4(22)"d"(3)"2" and "3." The records shall show the results of tests. The records also shall show the dates of performance of, and the names of persons performing, testing, installation, servicing, and removal from installation concerning the radioactive material, its shielding or containment. Records of tests for leakage of radioactive material required by 39.4(22)"d"(3)"2" shall be maintained for one year after the next required leak test is performed or until the sealed source is transferred or disposed of. Records of tests of the "on-off" mechanism and indicator required by 39.4(22)"d"(3)"2" shall be maintained for one year after the next required test of the "on-off" mechanism and indicator is performed or until the sealed source is transferred or disposed of. Records which are required by 39.4(22)"d"(3)"3" shall be maintained for a period of two years from the date of the recorded event or until the device is transferred or disposed of;
- 5. Upon the occurrence of a failure of or damage to, or any indication of a possible failure of or damage to, the shielding of the radioactive material or the "on-off" mechanism or indicator, or upon the detection of 0.005 microcurie (185 Bq) or more removable radioactive material, shall immediately suspend operation of the device until it has been repaired by the manufacturer or other person holding an applicable specific license from the agency, the U.S. Nuclear Regulatory Commission, an agreement state or a licensing state to repair such devices, or disposed of by transfer to a person authorized by an applicable specific license to receive the radioactive material contained in the device and, within 30 days, furnish to the agency a report containing a brief description of the event and the remedial action taken;
- 6. Shall not abandon the device containing radioactive material;
- 7. Except as provided in 39.4(22)"d"(3)"8," shall transfer or dispose of the device containing radioactive material only by transfer to a specific licensee of the

agency, the U.S. Nuclear Regulatory Commission, an agreement state or a licensing state whose specific license authorizes the person to receive the device and, within 30 days after transfer of a device to a specific licensee, shall furnish to the agency a report containing identification of the device by manufacturer's name and model number and the name and address of the person receiving the device. No report is required if the device is transferred to the specific licensee in order to obtain a replacement device;

8. Shall transfer the device to another general licensee

only:

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- Where the device remains in use at a particular location. In such case the transferor shall give the transferee a copy of this regulation and any safety documents identified in the label on the device and, within 30 days of the transfer, report to the agency the manufacturer's name and model number of the device transferred, the name and address of the transferee, and the name and position of an individual who may constitute a point of contact between the agency and the transferee; or
- Where the device is held in storage in the original shipping container at its intended location of use prior to initial use by a general licensee; and
- 9. Shall comply with the provisions of 641—subrules 40.5(2) and 40.5(3) for reporting radiation incidents, theft, or loss of licensed material, but shall be exempt from the other requirements of 641—Chapter 40.
- (4) The general license in 39.4(22)"d"(1) does not authorize the manufacture of devices containing radioactive material.
- (5) The general license provided in 39.4(22)"d"(1) is subject to the provisions of 641—38.4(136C) to 641—38.5(136C), 39.4(32), 39.4(41), 39.4(51), and 641-39.5(136C).
 - e. Luminous safety devices for aircraft.
- (1) A general license is hereby issued to own, receive, acquire, possess, and use tritium or promethium-147 contained in luminous safety devices for use in aircraft, pro-
- Each device contains not more than 10 curies (370 GBq) of tritium or 300 millicuries (11.1 GBq) of promethium-147; and
- 2. Each device has been manufactured, assembled or imported in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission, or each device has been manufactured or assembled in accordance with the specifications contained in a specific license issued by the agency or any agreement state to the manufacturer or assembler of such device pursuant to licensing requirements equivalent to those in Section 32.53 of 10 CFR Part
- (2) Persons who own, receive, acquire, possess, or use luminous safety devices pursuant to the general license in 39.4(22)"e"(1) are exempt from the requirements of 641—Chapter 40 except that they shall comply with the provisions of 641—subrules 40.5(2) and 40.5(3).
- (3) This general license does not authorize the manufacture, assembly, or repair of luminous safety devices containing tritium or promethium-147.
- (4) This general license does not authorize the ownerreceipt, acquisition, possession or use of promethium-147 contained in instrument dials.
- (5) This general license is subject to the provisions of 641—38.4(136C) to 641—38.5(136C), 39.4(32), 39.4(41), 39.4(51), and 641—39.5(136C).
- Ownership of radioactive material. A general license is hereby issued to own radioactive material without

regard to quantity. Notwithstanding any other provisions of this chapter, this general license does not authorize the manufacture, production, transfer, receipt, possession or use of radioactive material.

g. Calibration and reference sources.

- (1) A general license is hereby issued to those persons listed below to own, receive, acquire, possess, use, and transfer, in accordance with the provisions 39.4(22)"g"(4) and (5), americium-241 in the form of calibration or reference sources:
- 1. Any person who holds a specific license issued by the agency which authorizes the person to receive, possess, use, and transfer radioactive material; and
- 2. Any person who holds a specific license issued by the U.S. Nuclear Regulatory Commission which authorizes the person to receive, possess, use, and transfer special nuclear material.
- (2) A general license is hereby issued to own, receive, possess, use, and transfer plutonium in the form of calibration or reference sources in accordance with the provisions of 39.4(22)"g"(4) and (5) to any person who holds a specific license issued by the agency which authorizes the person to receive, possess, use, and transfer radioactive material.
- (3) A general license is hereby issued to own, receive, possess, use, and transfer radium-226 in the form of calibration or reference sources in accordance with the provisions of 39.4(22)"g"(4) and (5) to any person who holds a specific license issued by the agency which authorizes the person to receive, possess, use, and transfer radioactive material.
- (4) The general licenses in 39.4(22)"g"(1), (2), and (3) apply only to calibration or reference sources which have been manufactured in accordance with the specifications contained in a specific license issued to the manufacturer or importer of the sources by the U.S. Nuclear Regulatory Commission pursuant to Section 32.57 of 10 CFR Part 32 or Section 70.39 of 10 CFR Part 70 or which have been manufactured in accordance with the specifications contained in a specific license issued to the manufacturer by the agency, any agreement state or licensing state pursuant to licensing requirements equivalent to those contained in Section 32.57 of 10 CFR Part 32 or Section 70.39 of 10 CFR Part 70.
- (5) The general licenses provided in 39.4(22)"g"(1), (3) are subject to the provisions of 641—38.4(136C) to 641—38.5(136C), 39.4(32), 39.4(41), 39.4(51), 641—39.5(136C), and 641—Chapter 40. In addition, persons who own, receive, acquire, possess, use, or transfer one or more calibration or reference sources pursuant to these general licenses:
- 1. Shall not possess at any one time, at any one location of storage or use, more than 5 microcuries (185 kBq) of americium-241, 5 microcuries (185 kBq) of plutonium, or 5 microcuries (185 kBq) of radium-226 in such sources;
- Shall not receive, possess, use, or transfer such source unless the source, or the storage container, bears a label which includes one of the following statements, as appropriate, or a substantially similar statement which contains the information called for in one of the following statements, as appropriate:
- The receipt, possession, use and transfer of this source, Model , Serial No. , are subject to a general license and the regulations of the U.S. Nuclear Regulatory Commission or of a state with which the

Commission has entered into an agreement for the exercise of regulatory authority. Do not remove this label.

CAUTION—RADIOACTIVE MATERIAL—THIS SOURCE CONTAINS (AMERICIUM-241). (PLUTONIUM) (showing only the name of the appropriate material) DO NOT TOUCH RADIOACTIVE PORTION OF THIS SOURCE.

Name of manufacturer or importer

OR

• The receipt, possession, use and transfer of this source, Model _____, Serial No. _____, are subject to a general license and the regulations of a licensing state. Do not remove this label.

CAUTION—RADIOACTIVE MATERIAL—THIS SOURCE CONTAINS RADIUM-226. DO NOT TOUCH RADIOACTIVE PORTION OF THIS SOURCE.

Name of manufacturer or importer

- 3. Shall not transfer, abandon, or dispose of such source except by transfer to a person authorized by a license from the agency, the U.S. Nuclear Regulatory Commission, an agreement state or a licensing state to receive the source;
- 4. Shall store such source, except when the source is being used, in a closed container adequately designed and constructed to contain americium-241, plutonium, or radium-226 which might otherwise escape during storage; and
- 5. Shall not use such source for any purpose other than the calibration of radiation detectors or the standardization of other sources.
- (6) These general licenses do not authorize the manufacture of calibration or reference sources containing americium-241, plutonium, or radium-226.
 - h. Reserved.

i. General license for use of radioactive material for certain in vitro clinical or laboratory testing. The New Drug Provisions of the Federal Food, Drug, and Cosmetic Act also govern the availability and use of any specific diagnostic drugs in interstate commerce.

- (1) A general license is hereby issued to any physician, veterinarian, clinical laboratory or hospital to receive, acquire, possess, transfer or use, for any of the following stated tests, in accordance with the provisions of 39.4(22)"i"(2), (3), (4), (5), and (6), the following radioactive materials in prepackaged units for use in in vitro clinical or laboratory tests not involving internal or external administration of radioactive material, or the radiation therefrom, to human beings or animals:
- 1. Carbon-14, in units not exceeding 10 microcuries (370 kBq) each.
- 2. Cobalt-57, in units not exceeding 10 microcuries (370 kBq) each.
- 3. Hydrogen-3 (tritium), in units not exceeding 50 microcuries (1.85 MBq) each.
- 4. Iodine-125, in units not exceeding 10 microcuries (370 kBq) each.
- 5. Mock iodine-125 reference or calibration sources, in units not exceeding 0.05 microcurie (1.85 kBq) of iodine-129 and 0.005 microcurie (1.85 Bq) of americium-241 each.

- 6. Iodine-131, in units not exceeding 10 microcuries (370 kBg) each.
- 7. Iron-59, in units not exceeding 20 microcuries (740 kBq) each.
- 8. Selenium-75, in units not exceeding 10 microcuries (370 kBq) each.
- (2) No person shall receive, acquire, possess, use or transfer radioactive material pursuant to the general license established by 39.4(22)"i"(1) until the person has filed an Agency Form "Certificate—In Vitro Testing with Radioactive Material Under General License" with the agency and received from the agency a validated copy of the form with certification number assigned. The physician, veterinarian, clinical laboratory or hospital shall furnish the following information on the form and such other information as may be required by the form:
- 1. Name and address of the physician, veterinarian, clinical laboratory or hospital;
 - 2. The location of use: and
- 3. A statement that the physician, veterinarian, clinical laboratory or hospital has appropriate radiation measuring instruments to carry out in vitro clinical or laboratory tests with radioactive material as authorized under the general license in 39.4(22)"i"(1) and that such tests will be performed only by personnel competent in the use of such instruments and in the handling of the radioactive material.
- (3) A person who receives, acquires, possesses or uses radioactive material pursuant to the general license established by 39.4(22)"i"(1) shall comply with the following:
- 1. The general licensee shall not possess at any one time, pursuant to the general license in 39.4(22)"i"(1), at any one location of storage or use, a total amount of iodine-125, iodine-131, selenium-75, iron-59, or cobalt-57 in excess of 200 microcuries (7.4 MBq).
- 2. The general licensee shall store the radioactive material, until used, in the original shipping container or in a container providing equivalent radiation protection.
- 3. The general licensee shall use the radioactive material only for the uses authorized by 39.4(22)"i"(1).
- 4. The general licensee shall not transfer the radioactive material to a person who is not authorized to receive it pursuant to a license issued by the agency, the U.S. Nuclear Regulatory Commission, any agreement state or licensing state, nor transfer the radioactive material in any manner other than in the unopened, labeled shipping container as received from the supplier.
- 5. The general licensee shall dispose of the mock iodine-125 reference or calibration sources described in 39.4(22)"i"(1)"8" as required by 641—subrule 40.4(1).
- (4) The general licensee shall not receive, acquire, possess, or use radioactive material pursuant to 39.4(22)"i"(1):
- 1. Except as prepackaged units which are labeled in accordance with the provisions of an applicable specific license issued pursuant to 39.4(29)"h" or in accordance with the provisions of a specific license issued by the U.S. Nuclear Regulatory Commission, any agreement state or licensing state which authorizes the manufacture and distribution of iodine-125, iodine-131, carbon-14, hydrogen-3 (tritium), iron-59, selenium-75, cobalt-57, or mock iodine-125 to persons generally licensed under 39.4(22)"i" or its equivalent, and
- 2. Unless one of the following statements, as appropriate, or a substantially similar statement which contains the information called for in one of the following statements, appears on a label affixed to each prepackaged unit or ap-

pears in a leaflet or brochure which accompanies the package:

• This radioactive material shall be received, acquired, possessed, and used only by physicians, veterinarians, clinical laboratories or hospitals and only for in vitro clinical or laboratory tests not involving internal or external administration of the material, or the radiation therefrom, to human beings or animals. Its receipt, acquisition, possession, use, and transfer are subject to the regulations and a general license of the U.S. Nuclear Regulatory Commission or of a state with which the Commission has entered into an agreement for the exercise of regulatory authority.

Name of manufacturer

• This radioactive material shall be received, acquired, possessed, and used only by physicians, veterinarians, clinical laboratories or hospitals and only for in vitro clinical or laboratory tests not involving internal or external administration of the material, or the radiation therefrom, to human beings or animals. Its receipt, acquisition, possession, use and transfer are subject to the regulations and a general license of a licensing state.

Name of manufacturer

- (5) The physician, veterinarian, clinical laboratory or hospital possessing or using radioactive material under the general license of 39.4(22)"i"(1) shall report in writing to the agency any changes in the information furnished in the "Certificate—In Vitro Testing with Radioactive Material Under General License," Agency Form V. The report shall be furnished within 30 days after the effective date of such change.
- (6) Any person using radioactive material pursuant to the general license of 39.4(22)"i"(1) is exempt from the requirements of 641—Chapter 40 with respect to radioactive material covered by that general license, except that such persons using the mock iodine-125 described in 39.4(22)"i"(1)"8" shall comply with the provisions of 641—subrules 40.4(1), 40.5(2) and 40.5(3).

i. Ice detection devices.

- (1) A general license is hereby issued to own, receive, acquire, possess, use, and transfer strontium-90 contained in ice detection devices, provided each device contains not more than 50 microcuries (1.85 MBq) of strontium-90 and each device has been manufactured or imported in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission or each device has been manufactured in accordance with the specifications contained in a specific license issued by the agency or an agreement state to the manufacturer of such device pursuant to licensing requirements equivalent to those in Section 32.61 of 10 CFR Part 32.
- (2) Persons who own, receive, acquire, possess, use, or transfer strontium-90 contained in ice detection devices pursuant to the general license in 39.4(22)"j"(1):
- 1. Shall, upon occurrence of visually observable damage such as a bend or crack or discoloration from overheating to the device, discontinue use of the device until it has been inspected, tested for leakage and repaired by a person holding a specific license from the U.S. Nuclear Regulatory Commission or an agreement state to man-

ufacture or service such devices; or shall dispose of the device pursuant to the provisions of 641—subrule 40.4(1):

- 2. Shall ensure that all labels affixed to the device at the time of receipt, and which bear a statement which prohibits removal of the labels, are maintained thereon; and
- 3. Are exempt from the requirements of 641—Chapter 40 except that such persons shall comply with the provisions of 641—subrules 40.4(1), 40.5(2) and 40.5(3).
- (3) This general license does not authorize the manufacture, assembly, disassembly or repair of strontium-90 in ice detection devices.
- (4) This general license is subject to the provisions of 641—38.4(136C) to 641—38.5(136C), 39.4(32), 39.4(41), 39.4(51), and 641—39.5(136C).

39.4(23) Reserved.

39.4(24) Filing application for specific licenses.

a. Applications for specific licenses shall be filed in

duplicate on a form prescribed by the agency.

- b. The agency may at any time after the filing of the original application, and before the expiration of the license, require further statements in order to enable the agency to determine whether the application should be granted or denied or whether a license should be modified or revoked.
- c. Each application shall be signed by the applicant or licensee or a person duly authorized to act for and on the applicant's or licensee's behalf.

d. An application for a license may include a request for a license authorizing one or more activities.

- e. In the application, the applicant may incorporate by reference information contained in previous applications, statements, or reports filed with the agency, provided such references are clear and specific.
- f. Applications and documents submitted to the agency may be made available for public inspection except that the agency may withhold any document or part thereof from public inspection if disclosure of its content is not required in the public interest and would adversely affect the interest of a person concerned.

39.4(25) General requirements for the issuance of specific licenses. A license application will be approved if the agency determines that:

- a. The applicant is qualified by reason of training and experience to use the material in question for the purpose requested in accordance with 641—Chapters 38, 39, 40, 41 and 45 in such a manner as to minimize danger to public health and safety or property;
- b. The applicant's proposed equipment, facilities, and procedures are adequate to minimize danger to public health and safety or property;
- c. The issuance of the license will not be inimical to the health and safety of the public; and
- d. The applicant satisfies any applicable special requirements in 39.4(26), 39.4(27), 39.4(28), 641—41.2(136C), 641—41.5(136C) or 641—Chapter 45.
- e. In the case of an application for a license to receive and possess radioactive material for commercial waste disposal by land burial, or for the conduct of any other activity which the agency determines will significantly affect the quality of the environment, the agency, before commencement of construction of the plant or facility in which the activity will be conducted, has concluded, after weighing the environmental, economic, technical and other benefits against environmental costs and considering available alternatives, that the action called for is the is-

suance of the proposed license, with any appropriate conditions to protect environmental values. Commencement of construction prior to such conclusion shall be grounds for denial of a license to receive and possess radioactive material in such plant or facility. As used in this paragraph, the term "commencement of construction" means any clearing of land, excavation, or other substantial action that would adversely affect the environment of a site. The term does not mean site exploration, necessary roads for site exploration, borings to determine foundation conditions, or other preconstruction monitoring or testing to establish background information related to the suitability of the site or the protection of environmental val-

f. Reserved.

39.4(26) Financial assurance and record keeping for decommissioning.

- a. Each applicant for a specific license authorizing the possession and use of unsealed radioactive material of half-life greater than 120 days and in quantities set forth in Appendix B of 641—Chapter 40 shall submit a decommissioning funding plan as described in 39.4(26)"e." The decommissioning funding plan must also be submitted when a combination of isotopes is involved if R divided by 10⁵ is greater than 1 (unity rule), where R is defined here as the sum of the ratios of the quantity of each isotope to the applicable value in Appendix B.
- b. Each applicant for a specific license authorizing possession and use of radioactive material of half-life greater than 120 days and in quantities specified in 39.4(26)"d" shall either:

Submit a decommissioning funding plan as de-

scribed in 39.4(26)"e"; or

- (2) Submit a certification that financial assurance for decommissioning has been provided in the amount prescribed by 39.4(26)"d" using one of the methods described in 39.4(26)"f." For an applicant, this certification may state that the appropriate assurance will be obtained after the application has been approved and the license issued but prior to the receipt of licensed material. As part of the certification, a copy of the financial instrument obtained to satisfy the requirements of 39.4(26)"f" is submitted to the agency.
- c. (1) Each holder of a specific license issued on or after July 27, 1990, which is of a type described in 39.4(26)"a" or "b," shall provide financial assurance for decommissioning in accordance with the criteria set forth in this subrule.
- Each holder of a specific license issued before September 30, 1992, and of a type described in 39.4(26)"a," shall submit, on or before July 1, 1993, a decommissioning funding plan or a certification of financial assurance for decommissioning in an amount at least equal to \$750,000 in accordance with the criteria set forth in this subrule. If the licensee submits the certification of financial assurance rather than a decommissioning funding plan at this time, the licensee shall include a decommissioning funding plan in any application for license renewal.
- (3) Each holder of a specific license issued before September 30, 1992, and of a type described in 39.4(36)"b," shall submit, on or before July 1, 1993, a certificate of financial assurance for decommissioning or a decommissioning funding plan in accordance with the criteria set forth in this subrule.
- d. Table of required amounts of financial assurance for decommissioning by quantity of material.

Greater than 10° but less than or equal to 10⁵ times the applicable quantities of Appendix B of 641— Chapter 40 in unsealed form. (For a combination of isotopes, if R, as defined in 39.4(26)"a," divided by 10⁴ is greater than 1, but R divided by 10⁵ is less than or equal to 1.) 750,000

Greater than 103 but less than or equal to 104 times the applicable quantities of Appendix B of 641—Chapter 40 in unsealed form. (For a combination of isotopes, if R, as defined in 39.4(26)"a," divided by 10³ is greater than 1, but R divided by

Greater than 10¹⁰ times the applicable quantities of Appendix B or 641—Chapter 40 in sealed sources or plated foils. (For a combination of isotopes, if R, as defined in 39.4(26)"a," divided by 10¹⁰ is greater

- e. Each decommissioning funding plan must contain a cost estimate for decommissioning and a description of the method of assuring funds for decommissioning from 39.4(26)"f," including means of adjusting cost estimates and associated funding levels periodically over the life of the facility.
- f. Financial assurance for decommissioning must be provided by one or more of the following methods:
- (1) Prepayment. Prepayment is the deposit prior to the start of operation into an account segregated from licensee assets and outside the licensee's administrative control of cash or liquid assets such that the amount of funds would be sufficient to pay decommissioning costs. Prepayment may be in the form of a trust, escrow account, government fund, certificate of deposit, or deposit of government securities.
- (2) A surety method, insurance, or other guarantee method. These methods guarantee that decommissioning costs will be paid should the licensee default. A surety method may be in the form of a surety bond, letter of credit, or line of credit. A parent company guarantee of funds for decommissioning costs based on a financial test may be used if the guarantee and test are as contained in Appendix F of this chapter. A parent company guarantee may not be used in combination with other financial methods to satisfy the requirements of this subrule. Any surety method or insurance used to provide financial assurance for decommissioning must contain the following conditions:
- The surety method or insurance must be open-ended or, if written for a specified term, such as five years, must be renewed automatically unless 90 days or more prior to the renewal date, the issuer notifies the agency, the beneficiary, and the licensee of its intention not to renew. The surety method or insurance must also provide that the full face amount be paid to the beneficiary automatically prior to the expiration without proof of forfeiture if the licensee fails to provide a replacement acceptable to the agency within 30 days after receipt of notification of cancellation.
- 2. The surety method or insurance must be payable to a trust established for decommissioning costs. The trustee and trust must be acceptable to the agency. An acceptable trustee includes an appropriate state or federal gov-

ernment agency or an entity which has authority to act as a trustee and whose trust operations are regulated and examined by a federal or state agency.

3. The surety method or insurance must remain in ef-

fect until the agency has terminated the license.

- (3) An external sinking fund in which deposits are made at least annually, coupled with a surety method or insurance, the value of which may decrease by the amount being accumulated in the sinking fund. An external sinking fund is a fund established and maintained by setting aside funds periodically in an account segregated from licensee assets and outside the licensee's administrative control in which the total amount of funds would be sufficient to pay decommissioning costs at the time termination of operation is expected. An external sinking fund may be in the form of a trust, escrow account, government fund, certificate of deposit, or deposit of government securities. The surety or insurance provisions must be as stated in 39.4(26)"f"(2).
- (4) In the case of federal, state, or local government licensees, a statement of intent containing a cost estimate for decommissioning or an amount based on the Table in 39.4(26)"d," and indicating that funds for decommissioning will be obtained when necessary.
- g. Each person licensed under this chapter shall keep records of information important to the safe and effective decommissioning of the facility in an identified location until the license is terminated by the agency. If records of relevant information are kept for other purposes, reference to these records and their locations may be used. Information the agency considers important to decommissioning consists of:
- (1) Records of spills or other unusual occurrences involving the spread of contamination in and around the facility, equipment, or site. These records may be limited to instances when contamination remains after any clean-up procedures or when there is reasonable likelihood that contaminants may have spread to inaccessible areas as in the case of possible seepage into pourous materials such as concrete. These records must include any known information on identification of involved nuclides, quantities, forms, and concentrations.
- (2) As-built drawings and modifications of structures and equipment in restricted areas where radioactive materials are used, stored, or both, and of locations of possible inaccessible contamination such as buried pipes which may be subject to contamination. If required drawings are referenced, each relevant document need not be indexed individually. If drawings are not available, the licensee shall substitute appropriate records of available information concerning these areas and locations.
- (3) Records of the cost estimate performed for the decommissioning funding plan or of the amount certified for decommissioning, and records of the funding method used for assuring funds if either a funding plan or certification is used.
- 39.4(27) Special requirements for issuance of certain specific licenses for radioactive material.
 - a. to d. Reserved.
- e. Use of sealed sources in industrial radiography. In addition to the requirements set forth in 39.4(25), a specific license for use of sealed sources in industrial radiography will be issued if:
- (1) The applicant will have an adequate program for training radiographic personnel and submits to the agency a schedule or description of such program which specifies the:

- 1. Initial training,
- 2. Periodic training,
- 3. On-the-job training, and
- 4. Means to be used by the licensee to determine the radiographic personnel's knowledge and understanding of and ability to comply with agency regulations and licensing requirements, and the operating and emergency procedures of the applicant.
- (2) The applicant has established and submits to the agency satisfactory written operating and emergency procedures described in 641—Chapter 45.
- (3) The applicant will have an internal inspection system adequate to ensure that 641—Chapters 38, 39, 40, 41 and 45, license provisions, and the applicant's operating and emergency procedures are followed by radiographic personnel. The inspection system shall include the performance of internal inspections at intervals not to exceed three months and the retention of records of such inspections for two years.
- (4) The applicant submits to the agency a description of the overall organizational structure pertaining to the industrial radiography program, including specified delegations of authority and responsibility for operation of the program.
- (5) The applicant who desires to conduct leak tests has established adequate procedures to be followed in testing sealed sources for possible leakage and contamination and submits to the agency a description of such procedures including:
 - 1. Instrumentation to be used,
 - 2. Method of performing tests, and
- 3. Pertinent experience of the individual who will perform the test.
- (6) The licensee shall conduct a program for inspection and maintenance of radiographic exposure devices and storage containers to ensure proper functioning of components important to safety.
- 39.4(28) Special requirements for specific licenses of broad scope. This subrule prescribes requirements for the issuance of specific licenses of broad scope for radioactive material and certain rules governing holders of such licenses. Authority to transfer possession or control by the manufacturer, processor, or producer of any equipment, device, commodity, or other product containing byproduct material whose subsequent possession, use, transfer, and disposal by all other persons are exempted from regulatory requirements may be obtained only from the U.S. Nuclear Regulatory Commission, Washington, D.C. 20555.
- a. The different types of broad scope licenses are set forth below:
- (1) A "Type A specific license of broad scope" is a specific license authorizing receipt, acquisition, ownership, possession, use and transfer of any chemical or physical form of the radioactive material specified in the license, but not exceeding quantities specified in the license, for any authorized purpose. The quantities specified are usually in the multicurie range.
- (2) A "Type B specific license of broad scope" is a specific license authorizing receipt, acquisition, ownership, possession, use and transfer of any chemical or physical form of radioactive material specified in Appendix D of this chapter, for any authorized purpose. The possession limit for a Type B license of broad scope, if only one radionuclide is possessed thereunder, is the quantity specified for that radionuclide in Appendix D, Column I. If two or more radionuclides are possessed

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thereunder, the possession limit for each is determined as follows: For each radionuclide, determine the ratio of the quantity possessed to the applicable quantity specified in Appendix D, Column I, for that radionuclide. The sum of the ratios for all radionuclides possessed under the license shall not exceed unity.

- (3) A "Type C specific license of broad scope" is a specific license authorizing receipt, acquisition, ownership, possession, use, and transfer of any chemical or physical form of radioactive material specified in Appendix D of this chapter, for any authorized purpose. The possession limit for a Type C license of broad scope, if only one radionuclide is possessed thereunder, is the quantity specified for that radionuclide in Appendix D, Column II. If two or more radionuclides are possessed thereunder, the possession limit is determined for each as follows: For each radionuclide, determine the ratio of the quantity possessed to the applicable quantity specified in Appendix D, Column II, for that radionuclide. The sum of the ratios for all radionuclides possessed under the license shall not exceed unity.
- b. An application for a Type A specific license of broad scope will be approved if:
- (1) The applicant satisfies the general requirements specified in 39.4(25);
- (2) The applicant has engaged in a reasonable number of activities involving the use of radioactive material; and
- (3) The applicant has established administrative controls and provisions relating to organization and management, procedures, record keeping, material control and accounting, and management review that are necessary to ensure safe operations, including:
- 1. The establishment of a radiation safety committee composed of such persons as a radiation safety officer, a representative of management, and persons trained and experienced in the safe use of radioactive material;
- 2. The appointment of a radiation safety officer who is qualified by training and experience in radiation protection, and who is available for advice and assistance on radiation safety matters; and
- 3. The establishment of appropriate administrative procedures to ensure:
- Control of procurement and use of radioactive material;
- Completion of safety evaluations of proposed uses of radioactive material which take into consideration such matters as the adequacy of facilities and equipment, training and experience of the user, and the operating or handling procedures; and
- Review, approval, and recording by the radiation safety committee of safety evaluations of proposed uses prepared in accordance with 39.4(28)"b"(3)"3" prior to use of the radioactive material.
- c. An application for a Type B specific license of broad scope will be approved if:
- (1) The applicant satisfies the general requirements specified in 39.4(25); and
- (2) The applicant has established administrative controls and provisions relating to organization and management, procedures, record keeping, material control and accounting, and management review that are necessary to ensure safe operations, including:
- 1. The appointment of a radiation safety officer who is qualified by training and experience in radiation protection, and who is available for advice and assistance on radiation safety matters, and

- 2. The establishment of appropriate administrative procedures to ensure:
- Control of procurement and use of radioactive material;
- Completion of safety evaluations of proposed uses of radioactive material which take into consideration such matters as the adequacy of facilities and equipment, training and experience of the user, and the operating or handling procedures; and
- Review, approval, and recording by the radiation safety officer of safety evaluations of proposed uses prepared in accordance with 39.4(28)"c"(2)"2" prior to use of the radioactive material.
- d. An application for a Type C specific license of broad scope will be approved if:
- (1) The applicant satisfies the general requirements specified in 39.4(25).
- (2) The applicant submits a statement that radioactive material will be used only by, or under the direct supervision of, individuals who have received:
- 1. A college degree at the bachelor level, or equivalent training and experience, in the physical or biological sciences or in engineering; and
- 2. At least 40 hours of training and experience in the safe handling of radioactive material, and in the characteristics of ionizing radiation, units of radiation dose and quantities, radiation detection instrumentation, and biological hazards of exposure to radiation appropriate to the type and forms of radioactive material to be used.
- (3) The applicant has established administrative controls and provisions relating to procurement of radioactive material, procedures, record keeping, material control and accounting, and management review necessary to ensure safe operations.
- e. Specific licenses of broad scope are subject to the following conditions:
- (1) Unless specifically authorized, persons licensed pursuant to 39.4(28) shall not:
- 1. Conduct tracer studies in the environment involving direct release of radioactive material;
- 2. Receive, acquire, own, possess, use, or transfer devices containing 100,000 curies (3.7 PBq) or more of radioactive material in sealed sources used for irradiation of materials:
- 3. Conduct activities for which a specific license issued by the agency under 39.4(27), 39.4(29) or 641—41.2(136C) is required; or
- 4. Add or cause the addition of radioactive material to any food, beverage, cosmetic, drug, or other product designed for ingestion or inhalation by, or application to, a human being.
- (2) Each Type A specific license of broad scope issued under this chapter shall be subject to the condition that radioactive material possessed under the license may only be used by, or under the direct supervision of, individuals approved by the licensee's radiation safety committee.
- (3) Each Type B specific license of broad scope issued under this chapter shall be subject to the condition that radioactive material possessed under the license may only be used by, or under the direct supervision of, individuals approved by the licensee's radiation safety officer.
- (4) Each Type C specific license of broad scope issued under this chapter shall be subject to the condition that radioactive material possessed under the license may only be used by, or under the direct supervision of, individuals who satisfy the requirements of 39.4(28)"d."

39.4(29) Special requirements for a specific license to manufacture, assemble, repair, or distribute commodities, products, or devices which contain radioactive material.

a. Licensing the introduction of radioactive material

into products in exempt concentrations.

- In addition to the requirements set forth in 39.4(25), a specific license authorizing the introduction of radioactive material into a product or material owned by or in the possession of the licensee or another to be transferred to persons exempt under 39.4(3)"a"(1) will be issued if:
- 1. The applicant submits a description of the product or material into which the radioactive material will be introduced, intended use of the radioactive material and the product or material into which it is introduced, method of introduction, initial concentration of the radioactive material in the product or material, control methods to ensure that no more than the specified concentration is introduced into the product or material, estimated time interval between introduction and transfer of the product or material, and estimated concentration of the radioactive material in the product or material at the time of transfer; and
- The applicant provides reasonable assurance that the concentrations of radioactive material at the time of transfer will not exceed the concentrations in Appendix A of this chapter, that reconcentration of the radioactive material in concentrations exceeding those in Appendix A is not likely, that use of lower concentrations is not feasible, and that the product or material is not likely to be incorporated in any food, beverage, cosmetic, drug or other commodity or product designed for ingestion or inhalation

- by, or application to, a human being.

 (2) Each person licensed under 39.4(29)"a" shall file an annual report with the agency which shall identify the type and quantity of each product or material into which radioactive material has been introduced during the reporting period; name and address of the person who owned or possessed the product or material, into which radioactive material has been introduced, at the time of introduction; the type and quantity of radionuclide introduced into each such product or material; and the initial concentrations of the radionuclide in the product or material at time of transfer of the radioactive material by the licensee. If no transfers of radioactive material have been made pursuant to 39.4(29)"a" during the reporting period, the report shall so indicate. The report shall cover the year ending June 30, and shall be filed within 30 days thereafter.
- b. Licensing the distribution of radioactive material in exempt quantities. Authority to transfer possession or control by the manufacturer, processor, or producer of any equipment, device, commodity, or other product containing by-product material whose subsequent possession, use, transfer, and disposal by all other persons are exempted from regulatory requirements may be obtained only from the U.S. Nuclear Regulatory Commission, Washington, D.C. 20555.

(1) An application for a specific license to distribute NARM to persons exempted from these rules pursuant to

39.4(3)"b" will be approved if:

The radioactive material is not contained in any food, beverage, cosmetic, drug, or other commodity designed for ingestion or inhalation by, or application to, a human being;

2. The radioactive material is in the form of processed chemical elements, compounds, mixtures, tissue samples, bioassay samples, counting standards, plated or encapsu-

lated sources, or similar substances identified as radioactive and to be used for its radioactive properties, but is not incorporated into any manufactured or assembled commodity, product, or device intended for commercial distribution: and

3. The applicant submits copies of prototype labels and brochures and the agency approves such labels and

(2) The license issued under 39.4(29)"b"(1) is subject

to the following conditions:

1. No more than ten exempt quantities shall be sold or transferred in any single transaction. However, an exempt quantity may be composed of fractional parts of one or more of the exempt quantity provided the sum of the fractions shall not exceed unity.

- 2. Each exempt quantity shall be separately and individually packaged. No more than ten such packaged exempt quantities shall be contained in any outer package for transfer to persons exempt pursuant to 39.4(3)"b." The outer package shall be such that the dose rate at the external surface of the package does not exceed 0.5 millirem (5 µSv) per hour.
- 3. The immediate container of each quantity or separately packaged fractional quantity of radioactive material shall bear a durable, legible label which:
- Identifies the radionuclide and the quantity of radioactivity, and

Bears the words "Radioactive Material."

- 4. In addition to the labeling information required by 39.4(29)"b"(2)"3," the label affixed to the immediate container, or an accompanying brochure, shall:
- State that the contents are exempt from licensing

state requirements,

· Bear the words "Radioactive Material-Not for Human Use-Introduction into Foods, Beverages, Cosmetics, Drugs, or Medicinals, or into Products Manufactured for Commercial Distribution is Prohibited-Exempt Quantities Should Not Be Combined," and

 Set forth appropriate additional radiation safety precautions and instructions relating to the handling, use,

storage, and disposal of the radioactive material.

- (3) Each person licensed under 39.4(29)"b" shall maintain records identifying, by name and address, each person to whom radioactive material is transferred for use under 39.4(3)"b" or the equivalent regulations of a licensing state, and stating the kinds and quantities of radioactive material transferred. An annual summary report stating the total quantity of each radionuclide transferred under the specific license shall be filed with the agency. Each report shall cover the year ending June 30, and shall be filed within 30 days thereafter. If no transfers of radioactive material have been made pursuant to 39.4(29)"b" during the reporting period, the report shall so indicate.
- c. Licensing the incorporation of naturally occurring and accelerator-produced radioactive material into gas and aerosol detectors. An application for a specific license authorizing the incorporation of NARM into gas and aerosol detectors to be distributed to persons exempt under 39.4(3)"c"(3) will be approved if the application satisfies requirements equivalent to those contained in Section 32.26 of 10 CFR Part 32. The maximum quantity of radium-226 in each device shall not exceed 0.1 microcurie (3.7 kBq).

d. Licensing the manufacture and distribution of devices to persons generally licensed under 39.4(22)"d.

(1) An application for a specific license to manufacture or distribute devices containing radioactive material,

excluding special nuclear material, to persons generally licensed under 39.4(22)"d" or equivalent regulations of the U.S. Nuclear Regulatory Commission, an agreement state, or a licensing state will be approved if:

1. The applicant satisfies the general requirements of

39.4(25);

- 2. The applicant submits sufficient information relating to the design, manufacture, prototype testing, quality control, labels, proposed uses, installation, servicing, leak testing, operating and safety instructions, and potential hazards of the device to provide reasonable assurance
- The device can be safely operated by persons not having training in radiological protection,
- Under ordinary conditions of handling, storage, and use of the device, the radioactive material contained in the device will not be released or inadvertently removed from the device, and it is unlikely that any person will receive in any period of 1 calender quarter a dose in excess of 10 percent of the limits specified in 641—subrule 40.2(1), and
- Under accident conditions such as fire and explosion associated with handling, storage, and use of the device, it is unlikely that any person would receive an external radiation dose or dose commitment in excess of the following organ doses:

Whole body; head and trunk; active blood-forming organs; gonads; or lens of eye 15 rems (150 mSv)

Hands and forearms; feet and ankles; localized areas of skin averaged over areas no larger than 1 square centimeter 200 rems (2 Sv)

Other organs 50 rems (500 mSv)

3. Each device bears a durable, legible, clearly visible label or labels approved by the agency, which contain in a clearly identified and separate statement:

 Instructions and precautions necessary to ensure safe installation, operation, and servicing of the device. Documents such as operating and service manuals may be identified in the label and used to provide this information;

· The requirement, or lack of requirement, for leak testing, or for testing any "on-off" mechanism and indicator, including the maximum time interval for such testing, and the identification of radioactive material by isotope, quantity of radioactivity, and date of determination of the

 The information called for in one of the following statements, as appropriate, in the same or substantially

similar form:

The receipt, possession, use, and transfer of this device, Model _, Serial No. (the model, serial number, and name of the manufacturer or distributor may be omitted from this label provided the in information is elsewhere specified in labeling affixed to the device) are subject to a general license or the equivalent and the chapter of the U.S. Nuclear Regulatory Commission or a state with which the U.S. Nuclear Regulatory Commission has entered into an agreement for the exercise of regulatory authority. This label shall be

maintained on the device in a legible condition. Removal of this label is prohibited.

CAUTION—RADIOACTIVE MATERIAL

Name of manufacturer or distributor

The receipt, possession, use, and transfer of this device, Model_ _, Serial No. are subject to a general license or the equivalent, and the regulations of a licensing state. This label shall be maintained on the device in a legible condition. Removal of this label is prohibited.

CAUTION—RADIOACTIVE MATERIAL

Name of manufacturer or distributor

- (2) In the event the applicant desires that the device be required to be tested at intervals longer than six months, either for proper operation of the "on-off" mechanism and indicator, if any, or for leakage of radioactive material or for both, the applicant shall include in the application sufficient information to demonstrate that such longer interval is justified by performance characteristics of the device or similar devices and by design features which have a significant bearing on the probability or consequences of leakage of radioactive material from the device or failure of the "on-off" mechanism and indicator. In determining the acceptable interval for the test for leakage of radioactive material, the agency will consider information which includes, but is not limited to:
 - 1. Primary containment or source capsule;
 - 2. Protection of primary containment;
 - 3. Method of sealing containment;
 - 4. Containment construction materials;
 - 5. Form of contained radioactive material;
- 6. Maximum temperature withstood during prototype tests;
- 7. Maximum pressure withstood during prototype tests;
- 8. Maximum quantity of contained radioactive material;
- 9. Radiotoxicity of contained radioactive material; and
- Operating experience with identical devices or

similarly designed and constructed devices.

(3) In the event the applicant desires that the general licensee under 39.4(22)"d," or under equivalent regulations of the U.S. Nuclear Regulatory Commission, an agreement state, or a licensing state be authorized to install the device, collect the sample to be analyzed by a specific licensee for leakage of radioactive material, service the device, test the "on-off" mechanism and indicator, or remove the device from installation, the applicant shall include in the application written instructions to be followed by the general licensee, estimated calendar quarter doses associated with such activity or activities, and bases for such estimates. The submitted information shall demonstrate that performance of such activity or activities by an individual untrained in radiological protection, in addition to other handling, storage, and use of devices under the general license, is unlikely to cause that individual to receive a calendar quarter dose in excess of 10 percent of the limits specified in 641—subrule 40.2(1).

(4) Each person licensed under 39.4(29)"d" to distribute devices to generally licensed persons shall:

- 1. Furnish a copy of the general license contained in 39.4(22)"d" to each person to whom that person directly or through an intermediate person transfers radioactive material in a device for use pursuant to the general license contained in 39.4(22)"d";
- 2. Furnish a copy of the general license contained in the U.S. Nuclear Regulatory Commission's, agreement state's, or licensing state's regulation equivalent to 39.4(22)"d," or alternatively, furnish a copy of the general license contained in 39.4(22)"d" to each person to whom that person directly or through an intermediate person transfers radioactive material in a device for use pursuant to the general license of the U.S. Nuclear Regulatory Commission, the agreement state, or the licensing state. If a copy of the general license in 39.4(22)"d" is furnished to such a person, it shall be accompanied by a note explaining that the use of the device is regulated by the U.S. Nuclear Regulatory Commission, agreement state, or licensing state under requirements substantially the same as those in 39.4(22)"d";
- 3. Report to the agency all transfers of such devices to persons for use under the general license in 39.4(22)"d." Such report shall identify each general licensee by name and address, an individual by name and position who may constitute a point of contact between the agency and the general licensee, the type and model number of device transferred, and the quantity and type of radioactive material contained in the device. If one or more intermediate persons will temporarily possess the device at the intended place of use prior to its possession by the user, the report shall include identification of each intermediate person by name, address, contact, and relationship to the intended user. If no transfers have been made to persons generally licensed under 39.4(22)"d" during the reporting period, the report shall so indicate. The report shall cover each calender quarter and shall be filed within 30 days thereafter;
 - 4. Furnish reports to other agencies.
- Report to the U.S. Nuclear Regulatory Commission all transfers of such devices to persons for use under the U.S. Nuclear Regulatory Commission general license in Section 31.5 of 10 CFR Part 31.
- Report to the responsible state agency all transfers of devices manufactured and distributed pursuant to 39.4(29)"d" for use under a general license in that state's regulations equivalent to 39.4(22)"d."
- Such reports shall identify each general licensee by name and address, an individual by name and position who may constitute a point of contact between the agency and the general licensee, the type and model of the device transferred, and the quantity and type of radioactive material contained in the device. If one or more intermediate persons will temporarily possess the device at the intended place of use prior to its possession by the user, the report shall include identification of each intermediate person by name, address, contact, and relationship to the intended user. The report shall be submitted within 30 days after the end of each calendar quarter in which such a device is transferred to the generally licensed person.
- If no transfers have been made to U.S. Nuclear Regulatory Commission licensees during the reporting period, this information shall be reported to the U.S. Nuclear Regulatory Commission.
- If no transfers have been made to general licensees within a particular state during the reporting period, this

information shall be reported to the responsible state agency upon request of that agency; and

- 5. Keep records showing the name, address, and the point of contact for each general licensee to whom the person directly or through an intermediate person transfers radioactive material in devices for use pursuant to the general license provided in 39.4(22)"d," or equivalent regulations of the U.S. Nuclear Regulatory Commission, an agreement state, or a licensing state. The records shall show the date of each transfer, the radionuclide and the quantity of radioactivity in each device transferred, the identity of any intermediate person, and compliance with the report requirements of 39.4(29)"d"(4).
- e. Special requirements for the manufacture, assembly, or repair of luminous safety devices for use in aircraft. An application for a specific license to manufacture, assemble, or repair luminous safety devices containing tritium or promethium-147 for use in aircraft, for distribution to persons generally licensed under 39.4(22)"e," will be approved if:

39.4(22)"e," will be approved if:

(1) The applicant satisfies the general requirements specified in 39.4(25); and

(2) The applicant satisfies the requirements of Sections 32.53, 32.54, 32.55, 32.56, and 32.101 of 10 CFR Part 32, or their equivalent.

- f. Special requirements for license to manufacture calibration sources containing americium-241, plutonium or radium-226 for distribution to persons generally licensed under 39.4(22)"g." An application for a specific license to manufacture calibration and reference sources containing americium-241, plutonium or radium-226 to persons generally licensed under 39.4(22)"g" will be approved if:
- (1) The applicant satisfies the general requirements of 39.4(25); and
- (2) The applicant satisfies the requirements of Sections 32.57, 32.58, 32.59, and 32.102 of 10 CFR Part 32 and Section 70.39 of 10 CFR Part 70, or their equivalent.

g. Reserved.

- h. Manufacture and distribution of radioactive material for certain in vitro clinical or laboratory testing under general license. An application for a specific license to manufacture or distribute radioactive material for use under the general license of 39.4(22)"i" will be approved if:
- (1) The applicant satisfies the general requirements specified in 39.4(25).
- (2) The radioactive material is to be prepared for distribution in prepackaged units of:
- 1. Carbon-14 in units not exceeding 10 microcuries (370 kBq) each.
- 2. Cobalt-57 in units not exceeding 10 microcuries (370 kBq) each.
- 3. Hydrogen-3 (tritium) in units not exceeding 50 microcuries (1.85 MBq) each.
- 4. Iodine-125 in units not exceeding 10 microcuries (370 kBq) each.
- 5. Mock iodine-125 in units not exceeding 0.05 microcurie (1.85 kBq) of iodine-129 and 0.005 microcurie (185 Bq) of americium-241 each.
- 6. Iodine-131 in units not exceeding 10 microcuries (370 kBq) each.
- 7. Iron-59 in units not exceeding 20 microcuries (740 kBq) each.
- 8. Selenium-75 in units not exceeding 10 microcuries (370 kBq) each.
- (3) Each prepackaged unit bears a durable, clearly visible label:

1. Identifying the radioactive contents as to chemical form and radionuclide, and indicating that the amount of radioactivity does not exceed 10 microcuries (370 kBq) of iodine-125, iodine-131, carbon-14, cobalt-57, or selenium-75; 50 microcuries (1.85 MBq) of hydrogen-3 (tritium); 20 microcuries (740 kBq) of iron-59; or mock iodine-125 in units not exceeding 0.05 microcurie (1.85 kBq) of iodine-129 and 0.005 microcurie (185 Bq) of americium-241 each; and

2. Displaying the radiation caution symbol described in 641—subparagraph 40.3(3)"a"(1) and the words, "CAUTION—RADIOACTIVE MATERIAL," and "Not for Internal or External Use in Humans or Animals."

(4) One of the following statements, as appropriate, or a substantially similar statement which contains the information called for in one of the following statements, appears on a label affixed to each prepackaged unit or appears in a leaflet or brochure which accompanies the package:

1. This radioactive material may be received, acquired, possessed, and used only by physicians, veterinarians, clinical laboratories or hospitals and only for in vitro clinical or laboratory tests not involving internal or external administration of the material, or the radiation therefrom, to human beings or animals. Its receipt, acquisition, possession, use, and transfer are subject to the regulations and a general license of the U.S. Nuclear Regulatory Commission or of a state with which the Commission has entered into an agreement for the exercise of regulatory authority.

Name of manufacturer

2. This radioactive material may be received, acquired, possessed, and used only by physicians, veterinarians, clinical laboratories or hospitals and only for in vitro clinical or laboratory tests not involving internal or external administration of the material, or the radiation therefrom, to human beings or animals. Its receipt, acquisition, possession, use, and transfer are subject to the regulations and a general license of a licensing state.

. Name of manufacturer

- (5) The label affixed to the unit, or the leaflet or brochure which accompanies the package, contains adequate information as to the precautions to be observed in handling and storing such radioactive material. In the case of the mock iodine-125 reference or calibration source, the information accompanying the source must also contain directions to the licensee regarding the waste disposal requirements set out in 641—subrule 40.4(1).
- i. Licensing the manufacture and distribution of ice detection devices. An application for a specific license to manufacture and distribute ice detection devices to persons generally licensed under 39.4(22)"j" will be approved if:
- (1) The applicant satisfies the general requirements of 39.4(25); and
- (2) The criteria of Sections 32.61, 32.62, and 32.103 of 10 CFR Part 32 are met.
- j. Manufacture and distribution of radiopharmaceuticals containing radioactive material for medical use under group licenses. An application for a specific license to manufacture and distribute radiopharmaceuticals containing radioactive material for use by persons licensed pur-

- suant to this chapter for the uses listed in 641—subrules 41.2(31), 41.2(33), and 41.2(37) will be approved if:
- (1) The applicant satisfies the general requirements specified in 39.4(25);
 - (2) The applicant submits evidence that:
- 1. The radiopharmaceutical containing radioactive material will be manufactured, labeled, and packaged in accordance with the Federal Food, Drug and Cosmetic Act or the Public Health Service Act, such as a new drug application (NDA) approved by the Food and Drug Administration (FDA), or a "Notice of Claimed Investigational Exemption for a New Drug" (IND) that has been accepted by the FDA, or
- 2. The manufacture and distribution of the radiopharmaceutical containing radioactive material is not subject to the Federal Food, Drug and Cosmetic Act and the Public Health Service Act;
- (3) The applicant submits information on the radionuclide, chemical and physical form, packaging including maximum activity per package, and shielding provided by the packaging of the radioactive material which is appropriate for safe handling and storage of radiopharmaceuticals by group licensees; and
- (4) 1. The label affixed to each package of the radiopharmaceutical contains information on the radionuclide, quantity, and date of assay and the label affixed to each package, or the leaflet or brochure which accompanies each package, contains a statement that the radiopharmaceutical is licensed by the agency for distribution to persons licensed pursuant to this chapter for the uses listed in 641—subrules 41.2(31), 41.2(33), and 41.2(37) or under equivalent licenses of the U.S. Nuclear Regulatory Commission, an agreement state, or a licensing state.

2. The labels, leaflets, or brochures required by 39.4(29)"j"(4)"1" are in addition to the labeling required by the Food and Drug Administration (FDA) and they may be separate from or, with the approval of the FDA, may be combined with the labeling required by the FDA.

- k. Manufacture and distribution of generators or reagent kits for preparation of radiopharmaceuticals containing radioactive material. Although the agency does not regulate the manufacture and distribution of reagent kits that do not contain radioactive material, it does regulate the use of such reagent kits for the preparation of radiopharmaceuticals containing radioactive material as part of its licensing and regulation of the users of radioactive material. Any manufacturer of reagent kits that do not contain radioactive material who desires to have their reagent kits approved by the agency for use by persons licensed pursuant to 641—subrule 41.2(33) may submit the pertinent information specified in 39.4(29)"k." An application for a specific license to manufacture and distribute generators or reagent kits containing radioactive material for preparation of radiopharmaceuticals by persons licensed pursuant to this chapter for the uses listed in 641—subrule 41.2(33) will be approved if:
- (1) The applicant satisfies the general requirements specified in 39.4(25);
 - (2) The applicant submits evidence that:
- 1. The generator or reagent kit is to be manufactured, labeled and packaged in accordance with the Federal Food, Drug and Cosmetic Act or the Public Health Service Act, such as a new drug application (NDA) approved by the Food and Drug Administration (FDA), or a "Notice of Claimed Investigational Exemption for a New Drug" (IND) that has been accepted by the FDA, or

2. The manufacture and distribution of the generator or reagent kit are not subject to the Federal Food, Drug and Cosmetic Act and the Public Health Service Act;

(3) The applicant submits information on the radionuclide, chemical and physical form, packaging including maximum activity per package, and shielding provided by the packaging of the radioactive material contained in the generator or reagent kit;

(4) The label affixed to the generator or reagent kit contains information on the radionuclide, quantity, and

date of assay; and

(5) The label affixed to the generator or reagent kit, or the leaflet or brochure which accompanies the generator

or reagent kit, contains:

- 1, Adequate information, from a radiation safety standpoint, on the procedures to be followed and the equipment and shielding to be used in eluting the generator or processing radioactive material with the reagent kit, and
- 2. A statement that this generator or reagent kit, as appropriate, is approved for use by persons licensed by the agency pursuant to 641—subrule 41.2(33) or under equivalent licenses of the U.S. Nuclear Regulatory Commission, an agreement state, or a licensing state. The labels, leaflets, or brochures required by 39.4(29)"k" are in addition to the labeling required by the Food and Drug Administration (FDA) and they may be separate from or, with the approval of the FDA, may be combined with the labeling required by the FDA.

1. Manufacture and distribution of sources or devices containing radioactive material for medical use. An application for a specific license to manufacture and distribute sources and devices containing radioactive material to persons licensed pursuant to 641—41.2(136C) for use as a calibration or reference source or for the uses listed in 641—subrules 41.2(41) and 41.2(43) will be approved if:

(1) The applicant satisfies the general requirements in

39.4(25);

(2) The applicant submits sufficient information regarding each type of source or device pertinent to an evaluation of its radiation safety, including:

1. The radioactive material contained, its chemical

and physical form, and amount,

- 2. Details of design and construction of the source or levice,
- 3. Procedures for, and results of, prototype tests to demonstrate that the source or device will maintain its integrity under stresses likely to be encountered in normal use and accidents.
- 4. For devices containing radioactive material, the radiation profile of a prototype device,
- 5. Details of quality control procedures to ensure that production sources and devices meet the standards of the design and prototype tests,
- 6. Procedures and standards for calibrating sources and devices,
- 7. Legend and methods for labeling sources and devices as to their radioactive content, and
- 8. Instructions for handling and storing the source or device from the radiation safety standpoint. These instructions are to be included on a durable label attached to the source or device or attached to a permanent storage container for the source or device, provided that instructions which are too lengthy for such label may be summarized on the label and printed in detail on a brochure which is referenced on the label;

- (3) The label affixed to the source or device, or to the permanent storage container for the source or device, contains information on the radionuclide, quantity, and date of assay, and a statement that the source or device is licensed by the agency for distribution to persons licensed pursuant to 641—41.2(136C) and 641—subrules 41.2(41) and 41.2(43) or under equivalent licenses of the U.S. Nuclear Regulatory Commission, an agreement state, or a licensing state, provided that such labeling for sources which do not require long term storage may be on a leaf-let or brochure which accompanies the source;
- (4) In the event the applicant desires that the source or device be required to be tested for leakage of radioactive material at intervals longer than six months, the applicant shall include in the application sufficient information to demonstrate that such longer interval is justified by performance characteristics of the source or device or similar sources or devices and by design features that have a significant bearing on the probability or consequences of leakage of radioactive material from the source; and
- (5) In determining the acceptable interval for test of leakage of radioactive material, the agency will consider information that includes, but is not limited to:
 - 1. Primary containment or source capsule,
 - 2. Protection of primary containment,
 - 3. Method of sealing containment,
 - 4. Containment construction materials,
 - 5. Form of contained radioactive material,
- Maximum temperature withstood during prototype tests,
- 7. Maximum pressure withstood during prototype tests,
- Maximum quantity of contained radioactive material,
- Radiotoxicity of contained radioactive material, and
 10. Operating experience with identical sources or devices or similarly designed and constructed sources or devices.
- m. Requirements for license to manufacture and distribute industrial products containing depleted uranium for mass-volume applications.
- (1) An application for a specific license to manufacture industrial products and devices containing depleted uranium for use pursuant to 39.4(21)"d" or equivalent regulations of the U.S. Nuclear Regulatory Commission or an agreement state will be approved if:

1. The applicant satisfies the general requirements specified in 39.4(25);

- 2. The applicant submits sufficient information relating to the design, manufacture, prototype testing, quality control procedures, labeling or marking, proposed uses, and potential hazards of the industrial product or device to provide reasonable assurance that possession, use, or transfer of the depleted uranium in the product or device is not likely to cause any individual to receive in any period of one calender quarter a radiation dose in excess of 10 percent of the limits specified in 641—paragraph 40.2(1)"a" of these rules; and
- 3. The applicant submits sufficient information regarding the industrial product or device and the presence of depleted uranium for a mass-volume application in the product or device to provide reasonable assurance that unique benefits will accrue to the public because of the usefulness of the product or device.
- (2) In the case of an industrial product or device whose unique benefits are questionable, the agency will

approve an application for a specific license under 39.4(29)"m" only if the product or device is found to combine a high degree of utility and low probability of uncontrolled disposal and dispersal of significant quantities of depleted uranium into the environment.

(3) The agency may deny any application for a specific license under 39.4(29)"m" if the end use(s) of the industrial product or device cannot be reasonably foreseen.

(4) Each person licensed pursuant to 39.4(29)"m"(1)

shall:

- 1. Maintain the level of quality control required by the license in the manufacture of the industrial product or device, and in the installation of the depleted uranium into the product or device;
 - 2. Label or mark each unit to:
- Identify the manufacturer of the product or device and the number of the license under which the product or device was manufactured, the fact that the product or device contains depleted uranium, and the quantity of depleted uranium in each product or device; and

• State that the receipt, possession, use, and transfer of the product or device are subject to a general license or the equivalent and the regulations of the U.S. Nuclear

Regulatory Commission or an agreement state;

3. Ensure that the depleted uranium before being installed in each product or device has been impressed with the following legend clearly legible through any plating or

other covering: "Depleted Uranium";

- 4. Furnish a copy of the general license contained in 39.4(21)"d" and a copy of the agency form used to register the device to each person to whom the person transfers depleted uranium in a product or device for use pursuant to the general license contained in 39.4(21)"d," or furnish a copy of the general license contained in the U.S. Nuclear Regulatory Commission's or agreement state's regulation equivalent to 39.4(21)"d" and a copy of the U.S. Nuclear Regulatory Commission's or agreement state's certificate, or alternatively, furnish a copy of the general license contained in 39.4(21)"d" and a copy of the agency form used to register to each person to whom the person transfers depleted uranium in a product or device for use pursuant to the general license of the U.S. Nuclear Regulatory Commission or an agreement state, with a note explaining that use of the product or device is regulated by the U.S. Nuclear Regulatory Commission or an agreement state under requirements substantially the same as those in 39.4(21)"d";
- 5. Report to the agency all transfers of industrial products or devices to persons for use under the general license in 39.4(21)"d." Such report shall identify each general licensee by name and address, an individual by name and position who may constitute a point of contact between the agency and the general licensee, the type and model number of device transferred, and the quantity of depleted uranium contained in the product or device. The report shall be submitted within 30 days after the end of each calendar quarter in which such a product or device is transferred to the generally licensed person. If no transfers have been made to persons generally licensed under 39.4(21)"d" during the reporting period, the report shall so indicate:
- 6. Report to the U.S. Nuclear Regulatory Commission all transfers of industrial products or devices to persons for use under the U.S. Nuclear Regulatory Commission general license in Section 40.25 of 10 CFR Part 40; and shall report to the responsible state agency all transfers of

devices manufactured and distributed pursuant to 39.4(29)"m" for use under a general license in that state's regulations equivalent to 39.4(21)"d." Such report shall identify each general licensee by name and address, an individual by name and position who may constitute a point of contact between the agency and the general licensee, the type and model number of the device transferred, and the quantity of depleted uranium contained in the product or device. The report shall be submitted within 30 days after the end of each calendar quarter in which such product or device is transferred to the generally licensed person. If no transfers have been made to U.S. Nuclear Regulatory Commission licensees during the reporting period, this information shall be reported to the U.S. Nuclear Regulatory Commission. If no transfers have been made to general licensees within a particular agreement state during the reporting period, this information shall be reported to the responsible agreement state agency upon the request of that agency; and

7. Keep records showing the name, address, and point of contact for each general licensee to whom the person transfers depleted uranium in industrial products or devices for use pursuant to the general license provided in 39.4(21)"d" or equivalent regulations of the U.S. Nuclear Regulatory Commission or an agreement state. The records shall be maintained for a period of two years and shall show the date of each transfer, the quantity of depleted uranium in each product or device transferred, and compliance with the report requirements of

641—Chapters 39 and 40.

39.4(30) Reserved.

39.4(31) Issuance of specific licenses.

a. Upon a determination that an application meets the requirements of the Iowa Code and the rules of the agency, the agency will issue a specific license authorizing the proposed activity in such form and containing such conditions and limitations as it deems appropriate or necessary.

b. The agency may incorporate in any license at the time of issuance, or thereafter by appropriate rule, regulation, or order, such additional requirements and conditions with respect to the licensee's receipt, possession, use, and transfer of radioactive material subject to this chapter as it deems appropriate or necessary in order to:

(1) Minimize danger to public health and safety or

property;

(2) Require such reports and the keeping of such records, and to provide for such inspections of activities under the license as may be appropriate or necessary; and

(3) Prevent loss or theft of material subject to this

chapter.

39.4(32) Specific terms and conditions of licenses.

a. Each license issued pursuant to this chapter shall be subject to all the provisions of the Iowa Code, now or hereafter in effect, and to all rules, regulations, and orders

of the agency.

b. No license issued or granted under this chapter and no right to possess or utilize radioactive material granted by any license issued pursuant to this chapter shall be transferred, assigned, or in any manner disposed of, either voluntarily or involuntarily, directly or indirectly, through transfer of control of any license to any person unless the agency shall, after securing full information, find that the transfer is in accordance with the provisions of the Iowa Code, now or hereafter in effect, and to all valid rules,

regulations, and orders of the agency, and shall give its consent in writing.

- c. Each person licensed by the agency pursuant to this chapter shall confine use and possession of the material licensed to the locations and purposes authorized in the license.
- d. Each licensee shall notify the agency in writing when the licensee decides to permanently discontinue all activities involving materials authorized under the license.
- e. Each licensee shall notify the agency in writing immediately following the filing of a voluntary or involuntary petition for bankruptcy under any Chapter of Title 11 (Bankruptcy) of the United States Code by or against:

(1) The licensee;

(2) An entity (as that term is defined in 11 U.S.C. 101(14)) controlling the licensee or listing the license or licensee as property of the estate; or

(3) An affiliate (as that term is defined in 11 U.S.C.

101(2)) of the licensee.

f. The notification specified in 39.4(32)"e" shall indicate the bankruptcy court in which the petition for bankruptcy was filed and the date of the filing of the petition.

39.4(33) Expiration and termination of licenses.

- a. Except as provided in 39.4(34)"b," each specific license shall expire at the end of the specified day in the month and year stated therein.
- b. Each licensee shall notify the agency immediately, in writing, and request termination of the license when the licensee decides to terminate all activities involving radioactive material authorized under the license. This notification and request for termination of the license must include the reports and information specified in 39.4(33)"d"(1)"4" and "5."
- c. No less than 30 days before the expiration date specified in the license, the licensee shall either:
- (1) Submit an application for license renewal under 39.4(34); or
- (2) Notify the agency, in writing, if the licensee decides not to renew the license.
- d. (1) If a licensee does not submit an application for license renewal under 39.4(34), the licensee shall, on or before the expiration date specified in the license:
 - 1. Terminate use of radioactive material;
- 2. Remove radioactive contamination to the extent practicable;
 - 3. Properly dispose of radioactive material;

4. Submit a completed Agency Form "Certificate of Disposition of Materials"; and

- 5. Submit a radiation survey report to confirm the absence of radioactive material or to establish the levels of residual radioactive contamination, unless the licensee demonstrates the absence of residual radioactive contamination in some other manner. The licensee shall, as appropriate:
- Report levels of radiation in units of microrads per hour of beta and gamma radiation at 1 centimeter and gamma radiation at 1 meter from surfaces and report levels of radioactivity, including alpha, in units of transformations per minute (or microcuries) per 100 square centimeters removable and fixed on surfaces, microcuries per milliliter in water, and picocuries per gram in contaminated solids such as soils or concrete; and
- Specify the instrumentation used and certify that each instrument was properly calibrated and tested.
- (2) If no residual radioactive contamination attributable to activities conducted under the license is detected,

the licensee shall submit a certification that no detectable radioactive contamination was found. The agency will notify the licensee, in writing, of the termination of the license.

- (3) 1. If detectable levels of residual radioactive contamination attributable to activities conducted under the license are found, the license continues in effect beyond the expiration date, if necessary, with respect to possession of residual radioactive material present as contamination until the agency notifies the licensee in writing that the license is terminated. During this time the licensee is subject to the provisions of 39.4(33)"e."
- 2. In addition to the information submitted under 39.4(33)"d"(1)"4" and "5," the licensee shall submit a plan for decontamination, if required, as regards residual radioactive contamination remaining at the time the license expires.
- e. Each licensee who possesses residual radioactive material under 39.4(33)"d"(3) following the expiration date specified in the license shall:
- (1) Limit actions involving radioactive material to those related to decontamination and other activities related to preparation for release for unrestricted use; and
- (2) Continue to control entry to restricted areas until they are suitable for release for unrestricted use and the agency notifies the licensee in writing that the license is terminated.
 - 39.4(34) Renewal of licenses.
- a. Applications for renewal of specific licenses shall be filed in accordance with 39.4(24).
- b. In any case in which a licensee, not less than 30 days prior to expiration of an existing license, has filed an application in proper form for renewal or for a new license authorizing the same activities, such existing license shall not expire until final action by the agency.
- 39.4(35) Amendment of licenses at request of licensee. Applications for amendment of a license shall be filed in accordance with 39.4(24) and shall specify the respects in which the licensee desires the license to be amended and the grounds for such amendment.
- 39.4(36) Agency action on applications to renew or amend. In considering an application by a licensee to renew or amend the license, the agency will apply the criteria set forth in 39.4(25), 39.4(27), 39.4(28), and 39.4(29) and in 641—Chapters 38, 40, 41, 42, 43, 44 and 45, as applicable.
- 39.4(37) Persons possessing a license for source, byproduct, or special nuclear material in quantities not sufficient to form a critical mass on effective date of these
 rules. Any person who, on the effective date of these
 rules, possesses a general or specific license issued by the
 U.S. Nuclear Regulatory Commission for source, byproduct, or special nuclear material in quantities not sufficient to form a critical mass, shall be deemed to possess a
 like license issued under this chapter and the Iowa Code,
 such license to expire either 90 days after receipt from the
 agency of a notice of expiration of such license, or on the
 date or expiration specified in the U.S. Nuclear Regulatory Commission license, whichever is earlier.
- 39.4(38) Persons possessing naturally occurring and accelerator-produced radioactive material on effective date of these rules. Any person who, on the effective date of these rules, possesses NARM for which a specific license is required by the Iowa Code or this chapter shall be deemed to possess such a license issued under the Iowa Code and this chapter. Such license shall expire 90 days

after the effective date of these rules; provided, however, that if within the 90 days the person possessing such material files an application in proper form for a license, such existing license shall not expire until the application has been finally determined by the agency.

39.4(39) and 39.4(40) Reserved.

39.4(41) Transfer of material.

a. No licensee shall transfer radioactive material ex-

cept as authorized pursuant to 39.4(41).

- b. Except as otherwise provided in the license and subject to the provisions of 39.4(41)"c" and "d," any licensee may transfer radioactive material:
- (1) To the agency (a licensee may transfer material to the agency only after receiving prior approval from the agency);

(2) To the U.S. Department of Energy;

(3) To any person exempt from these rules to the ex-

tent permitted under such exemption;

- (4) To any person authorized to receive such material under terms of a general license or its equivalent, or a specific license or equivalent licensing document, issued by the agency, the U.S. Nuclear Regulatory Commission, any agreement state or any licensing state, or to any person otherwise authorized to receive such material by the federal government or any agency thereof, the agency, an agreement state, or a licensing state; or
 - (5) As otherwise authorized by the agency in writing.
- c. Before transferring radioactive material to a specific licensee of the agency, the U.S. Nuclear Regulatory Commission, an agreement state or a licensing state, or to a general licensee who is required to register with the agency, the U.S. Nuclear Regulatory Commission, an agreement state or a licensing state prior to receipt of the radioactive material, the licensee transferring the material shall verify that the transferee's license authorizes the receipt of the type, form, and quantity of radioactive material to be transferred.
- d. Any of the following methods for the verification required by 39.4(41)"c" is acceptable:
- (1) The transferor may possess and read a current copy of the transferee's specific license or registration certificate.
- (2) The transferor may possess a written certification by the transferee that the transferee is authorized by license or registration certificate to receive the type, form, and quantity of radioactive material to be transferred, specifying the license or registration certificate number, issuing agency, and expiration date.
- (3) For emergency shipments, the transferor may accept oral certification by the transferee that the transferee is authorized by license or registration certificate to receive the type, form, and quantity of radioactive material to be transferred, specifying the license or registration certificate number, issuing agency, and expiration date, provided that the oral certification is confirmed in writing within ten days.
- (4) The transferor may obtain other information compiled by a reporting service from official records of the agency, the U.S. Nuclear Regulatory Commission, an agreement state, or a licensing state regarding the identity of licensees and the scope and expiration dates of licenses and registration.
- (5) When none of the methods of verification described in 39.4(41)"d"(1) through (4) are readily available or when a transferor desires to verify that information received by one of such methods is correct or up to date, the

transferor may obtain and record confirmation from the agency, the U.S. Nuclear Regulatory Commission, an agreement state, or a licensing state that the transferee is licensed to receive the radioactive material.

e. Shipment and transport of radioactive material shall be in accordance with the provisions of 641—39.5(136C).

39.4(42) to 39.4(50) Reserved.

39.4(51) Modification and revocation of licenses.

a. The terms and conditions of all licenses shall be subject to amendment, revision, or modification or the license may be suspended or revoked by reason of amendments to the Iowa Code, or by reason of rules, regulations, and orders issued by the agency.

b. Any license may be revoked, suspended, or modified, in whole or in part, for any material false statement in the application or any statement of fact required under provisions of the Iowa Code, or because of conditions revealed by such application or statement of fact or any report, record, or inspection or other means which would warrant the agency to refuse to grant a license on an original application, or for violation of, or failure to observe

any of the terms and conditions of the Iowa Code, or of

the license, or of any rule, regulation, or order of the agency.

- c. Except in cases of willfulness or those in which the public health, interest or safety requires otherwise, no license shall be modified, suspended, or revoked unless, prior to the institution of proceedings therefor, facts or conduct which may warrant such action shall have been called to the attention of the licensee in writing and the licensee shall have been accorded an opportunity to demonstrate or achieve compliance with all lawful requirements.
 - 39.4(52) to 39.4(89) Reserved.

39.4(90) Reciprocal recognition of licenses.

- a. Licenses of by-product, source, and special nuclear material in quantities not sufficient to form a critical mass.
- (1) Subject to 641—Chapter 39, any person who holds a specific license from the U.S. Nuclear Regulatory Commission or an agreement state, and issued by the agency having jurisdiction where the licensee maintains an office for directing the licensed activity and at which radiation safety records are normally maintained, is hereby granted a general license to conduct the activities authorized in such licensing document within this state for a period not in excess of 180 days in a one-year period. The one-year period starts on the day the licensee's reciprocity fee, as specified in 641—subrule 38.8(8), is received by the agency and ends exactly 365 days later. Licensees are responsible for ensuring they do not exceed the 180-day limit within the one-year period and must apply for renewal 30 days prior to the expiration date of the one-year reciprocal recognition period. Out-of-state persons wishing to operate in the state in excess of 180 calendar days must obtain an Iowa radioactive materials license, which requires that the person have a permanant office in Iowa where records are maintained pertaining to licensed activities and where material can be stored, and must have at least one full-time employee and a telephone.
- (2) The licensing document referenced in 39.4(90)"a"(1) shall not limit the activity authorized by such document to specified installations or locations.
- (3) The out-of-state licensee shall notify the agency in writing at least three days prior to engaging in activities in the state. Such notification shall indicate the location, pe-

riod, and type of proposed possession and use within the state, and shall be accompanied by a copy of the pertinent licensing document initially. If, for a specific case, the three-day period would impose an undue hardship on the out-of-state licensee, the licensee may, upon application to the agency, obtain permission to proceed sooner. The agency may waive the requirement for filing additional written notifications during the remainder of the one-year reciprocity period following the receipt of the initial notification from a person engaging in activities under the general license provided by 39.4(90)"a."

(4) The out-of-state licensee shall comply with all applicable rules of the agency and with all the terms and conditions of the licensing document, except any such terms and conditions which may be inconsistent with ap-

plicable rules of the agency.

(5) The out-of-state licensee shall supply other in-

formation as the agency may request.

(6) The out-of-state licensee shall not transfer or dispose of radioactive material possessed or used under the general license provided by 39.4(90)"a" except by transfer to a person:

1. Specifically licensed by the agency, another agreement state or the U.S. Nuclear Regulatory Commission to

receive such material, or

2. Exempt from the requirements for a license for such

material under 39.4(3)"a."

- (7) Notwithstanding the provisions of 39.4(90)"a"(1), any person who holds a specific license issued by the U.S. Nuclear Regulatory Commission or an agreement state authorizing the holder to manufacture, transfer, install, or service a device described in 39.4(22)"d"(1) within areas subject to the jurisdiction of the licensing body is hereby granted a general license to install, transfer, demonstrate, or service such a device in this state provided that:
- 1. Such person shall file a report with the agency within 30 days after the end of each calendar quarter in which any device is transferred to or installed in this state. Each such report shall identify each general licensee to whom such device is transferred by name and address, the type of device transferred, and the quantity and type of radioactive material contained in the device;
- 2. The device has been manufactured, labeled, installed, and serviced in accordance with applicable provisions of the specific license issued to such person by the U.S. Nuclear Regulatory Commission or an agreement state;
- 3. Such person shall ensure that any labels required to be affixed to the device under regulations of the authority which licensed manufacture of the device bear a statement that "Removal of this label is prohibited"; and
- 4. The holder of the specific license shall furnish to each general licensee to whom the holder transfers such device or on whose premises the holder installs such device a copy of the general license contained in 39.4(22)"d" or in equivalent regulations of the agency having jurisdiction over the manufacture and distribution of the device.
- (8) The agency may withdraw, limit, or qualify its acceptance of any specific license or equivalent licensing document issued by the U.S. Nuclear Regulatory Commission or an agreement state, or any product distributed pursuant to such licensing document, upon determining that such action is necessary in order to prevent undue hazard to public health and safety or property.

- (9) The agency may revoke or suspend an out-of-state radiographer's ID card issued by the U.S. Nuclear Regulatory Commission, a licensing state, or another agreement state in accordance with the provisions of 641—45.1(10)"h."
- b. Licenses of naturally occurring or acceleratorproduced radioactive material.
- (1) Subject to 641—Chapter 39, any person who holds a specific license from the U.S. Nuclear Regulatory Commission or an agreement state, and issued by the agency having jurisdiction where the licensee maintains an office for directing the licensed activity and at which radiation safety records are normally maintained, is hereby granted a general license to conduct the activities authorized in such licensing document within this state for a period not in excess of 180 days in a one-year period. The one-year period starts on the day the licensee's reciprocity fee, as specified in 641—subrule 38.8(8), is received by the agency and ends exactly 365 days later. Licensees are responsible for ensuring they do not exceed the 180-day limit within the one-year period and must apply for renewal 30 days prior to the expiration date of the one-year reciprocal recognition period. Out-of-state persons wishing to operate in the state in excess of 180 calendar days must obtain an Iowa radioactive materials license, which requires that the person have a permanant office in Iowa where records are maintained pertaining to licensed activities and where material can be stored, and must have at least one full-time employee and a telephone.

(2) The licensing document referenced in 39.4(90)"a"(1) shall not limit the activity authorized by such document to specified installations or locations.

- (3) The out-of-state licensee shall notify the agency in writing at least three days prior to engaging in activities in the state. Such notification shall indicate the location, period, and type of proposed possession and use within the state, and shall be accompanied by a copy of the pertinent licensing document initially. If, for a specific case, the three-day period would impose an undue hardship on the out-of-state licensee, the licensee may, upon application to the agency, obtain permission to proceed sooner. The agency may waive the requirement for filing additional written notifications during the remainder of the one-year reciprocity period following the receipt of the initial notification from a person engaging in activities under the general license provided by 39.4(90)"b."
- (4) The out-of-state licensee shall comply with all applicable rules of the agency and with all the terms and conditions of the licensing document, except any such terms and conditions which may be inconsistent with applicable rules of the agency.

(5) The out-of-state licensee shall supply other in-

formation as the agency may request.

(6) The out-of-state licensee shall not transfer or dispose of radioactive material possessed or used under the general license provided by 39.4(90)"b" except by transfer to a person:

1. Specifically licensed by the agency, another agreement state or the U.S. Nuclear Regulatory Commission to

receive such material, or

2. Exempt from the requirements for a license for such material under 39.4(3)"a."

(7) Notwithstanding the provisions of 39.4(90)"b"(1), any person who holds a specific license issued by the U.S. Nuclear Regulatory Commission or an agreement state

authorizing the holder to manufacture, transfer, install, or service a device described in 39.4(22)"d"(1) within areas subject to the jurisdiction of the licensing body is hereby granted a general license to install, transfer, demonstrate, or service such a device in this state provided that:

- Such person shall file a report with the agency within 30 days after the end of each calendar quarter in which any device is transferred to or installed in this state. Each such report shall identify each general licensee to whom such device is transferred by name and address, the type of device transferred, and the quantity and type of radioactive material contained in the device;
- The device has been manufactured, labeled, installed, and serviced in accordance with applicable provisions of the specific license issued to such person by the U.S. Nuclear Regulatory Commission or an agreement
- 3. Such person shall ensure that any labels required to be affixed to the device under regulations of the authority which licensed manufacture of the device bear a statement that "Removal of this label is prohibited"; and
- 4. The holder of the specific license shall furnish to each general licensee to whom the holder transfers such device or on whose premises the holder installs such device a copy of the general license contained in 39.4(22)"d" or in equivalent regulations of the agency having jurisdiction over the manufacture and distribution of the device.
- (8) The agency may withdraw, limit, or qualify its acceptance of any specific license or equivalent licensing document issued by the U.S. Nuclear Regulatory Commission or an agreement state, or any product distributed pursuant to such licensing document, upon determining that such action is necessary in order to prevent undue hazard to public health and safety or property.

(9) The agency may revoke or suspend an out-of-state radiographer's ID card issued by the U.S. Nuclear Regulatory Commission, a licensing state, or another agreement state in accordance with the provisions of 641—45.1(10)"h."

39.4(91) to 39.4(104) Reserved.

641—39.5(136C) Transportation of radioactive mate-

39.5(1) Purpose and scope. This rule establishes requirements for packaging, preparation for shipment, and transportation of radioactive material and applies to any person who transports radioactive material or delivers radioactive material to a carrier for transport. All references to Code of Federal Regulations(CFRs) in this rule are those in effect as of September 1, 1992.

39.5(2) Definitions. As used in this rule, the following

definitions apply:

"Carrier" means a person engaged in the transportation of passengers or property by land or water as a common.

contract, or private carrier, or by civil aircraft.

"Closed transport vehicle" means a transport vehicle equipped with a securely attached exterior enclosure that during normal transportation restricts the access of unauthorized persons to the cargo space containing the radioactive material. The enclosure may be either temporary or permanent but shall limit access from top, sides, and ends. In the case of packaged materials, it may be of the "see-through" type.

"Exclusive use" means the sole use of a conveyance by a single consignor and for which all initial, intermediate, and final loading and unloading are carried out in accordance with the direction of the consignor or consignee.

The term "exclusive use" is used interchangeably with the terms "sole use" or "full load" in other regulations, such as Title 49 of the Code of Federal Regulations.

"Fissile material" means any special nuclear material consisting of or containing one or more fissile radionu-Fissile radionuclides are plutonium-238, plutonium-239. plutonium-241, uranium-233, uranium-235. Neither natural nor depleted uranium is fissile material. Agency jurisdiction extends only to special nuclear material if quantities are not sufficient to form a critical mass as defined in 641—Chapter 38.

- a. Fissile Class I: A package which may be transported in unlimited numbers and in any arrangement, and which requires no nuclear criticality safety controls during transportation. A transport index is not assigned for purposes of nuclear criticality safety but may be required because of external radiation levels.
- b. Fissile Class II: A package which may be transported together with other packages in any arrangement but, for criticality control, in numbers which do not exceed an aggregate transport index of 50. These shipments require no other nuclear criticality safety control during transportation. Individual packages may have a transport index not less than 0.1 and not more than 10.

"Low specific activity material" means any of the fol-

lowing:

- a. Uranium or thorium ores and physical or chemical concentrates of those ores;
- b. Unirradiated natural or depleted uranium or unirradiated natural thorium:
- c. Tritium oxide in aqueous solutions provided the concentration does not exceed 5.0 millicuries (185 MBq)
- d. Material in which the radioactivity is essentially uniformly distributed and in which the estimated average concentration per gram of contents does not exceed:

(1) 0.0001 millicurie (3.7 kBq) of radionuclides for which the A₂ quantity in Appendix E of this chapter is not more than 0.05 curie (1.85 GBq);

(2) 0.005 millicurie (185 kBq) of radionuclides for which the A₂ quantity in Appendix E of this chapter is more than 0.05 curie (1.85 GBq) but not more than 1 curie (37 GBq); or

(3) 0.3 millicurie (11.1 MBq) of radionuclides for which the A₂ quantity in Appendix E of this chapter is

more than 1 curie (37 GBq);

e. Objects of nonradioactive material externally contaminated with radioactive material, provided that the radioactive material is not readily dispersible, and the surface contamination, when averaged over an area of 1 square meter, does not exceed 0.0001 millicurie per square centimeter (3.7 kBq/cm²) of radionuclides for which the A2 quantity in Appendix E of this chapter is not more than 0.05 curie (1.85 GBq) or 0.001 millicurie per square centimeter (37 kBq/cm²) for other radionuclides.

"Normal form radioactive material" means radioactive material which has not been demonstrated to qualify as

special form radioactive material.

"Packaging" means the assembly of components necessary to ensure compliance with the packaging requirements of this chapter. It may consist of one or more receptacles, absorbent materials, spacing structures, thermal insulation, radiation shielding, and devices for cooling or absorbing mechanical shocks. The vehicle, tie-down system, and auxiliary equipment may be designated as part of the packaging.

"Regulations of the U.S. Department of Transportation" means the regulations in 49 CFR Parts 100-189.

"Specific activity" of a radionuclide means the radioactivity of a radionuclide per unit mass of that nuclide. The specific activity of a material in which the radionuclide is essentially uniformly distributed is the radioactivity per unit mass of the material.

"Transport index" (TI) means the dimensionless number, rounded up to the first decimal place, placed on the label of a package to designate the degree of control to be exercised by the carrier during transportation. The transport index is the number expressing the maximum radiation level in millirem per hour at one meter from the external surface of the package.

"Type A quantity" means a quantity of radioactive material, the aggregate radioactivity of which does not exceed A₁ for special form radioactive material or A₂ for normal form radioactive material, where A₁ and A₂ are given in Appendix E of this chapter or may be determined by procedures described in Appendix E of this chapter.

"Type B package" means a Type B packaging together with its radioactive contents. A Type B package design is designated as B(U) or B(M). B(U) refers to the need for unilateral approval of international shipments; B(M) refers to the need for multilateral approval. There is no distinction made in how packages with these designations may be used in domestic transportation. To determine their distinction for international transportation, refer to 49 CFR Part 173. A Type B package approved prior to September 6, 1983, was designated only as Type B. Limitations on its use are specified in 39.5(8).

"Type B packaging" means a packaging designed to retain the integrity of containment and shielding when subjected to the normal conditions of transport and hypothetical accident test conditions set forth in 10 CFR Part

/1.

"Type B quantity" means a quantity of radioactive ma-

terial greater than a Type A quantity.

39.5(3) Requirement for license. No person shall transport radioactive material or deliver radioactive material to a carrier for transport except as authorized in a general or specific license issued by the agency or as exempted in 39.5(4).

39.5(4) Exemptions.

- a. Common and contract carriers, freight forwarders, and warehousemen which are subject to the requirements of the U.S. Department of Transportation in 49 CFR 170 through 189 or the U.S. Postal Service in the Postal Service Manual (Domestic Mail Manual), Section 124.3 incorporated by reference, 39 CFR 111.11 (1974), and the U.S. Postal Service are exempt from the requirements of this chapter to the extent that they transport or store radioactive material in the regular course of their carriage for others or storage incident thereto. Common and contract carriers who are not subject to the requirements of the U.S. Department of Transportation or U.S. Postal Service are subject to 39.5(3) and other applicable requirements of 641—Chapters 38 to 46.
- b. Any licensee is exempt from the requirements of this chapter to the extent that the licensee delivers to a carrier for transport a package containing radioactive material having a specific activity not greater than 0.002 microcurie per gram (74 Bq/gm).

c. With the exception of 39.5(5) and 39.5(16), a licensee is exempt from all requirements of this chapter, with respect to shipment or carriage of the following:

(1) A package containing no more than a Type A quantity of radioactive material if the package contains no

fissile material; or

(2) Packages transported between locations within the United States which contain only americium or plutonium in special form with an aggregate radioactivity not to exceed 20 curies (740 GBq).

39.5(5) Transportation of licensed material.

a. Each licensee who transports licensed material outside of the confines of the licensee's plant or other place of use, or who delivers licensed material to a carrier for transport, shall:

(1) Comply with the applicable requirements, appropriate to the mode of transport, of the regulations of

the U.S. Department of Transportation; and

(2) Ensure that any special instructions needed to safely open the package are sent to or have been made avail-

able to the consignee.

b. If, for any reason, the regulations of the U.S. Department of Transportation are not applicable to a shipment of licensed material, the licensee shall conform to the standards and requirements of those regulations to the same extent as if the shipment was subject to the regulations.

39.5(6) General licenses for carriers.

- a. A general license is hereby issued to any common or contract carrier not exempt under 39.5(4) to receive, possess, transport, and store radioactive material in the regular course of their carriage for others or storage incident thereto, provided the transportation and storage is in accordance with the applicable requirements, appropriate to the mode of transport, of the U.S. Department of Transportation insofar as such requirements relate to the loading and storage of packages, placarding of the transporting vehicle, and incident reporting. Any notification of incidents referred to in those U.S. Department of Transportation requirements shall be filed with, or made to, the agency.
- b. A general license is hereby issued to any private carrier to transport radioactive material, provided the transportation is in accordance with the applicable requirements, appropriate to the mode of transport, of the U.S. Department of Transportation insofar as such requirements relate to the loading and storage of packages, placarding of the transporting vehicle, and incident reporting. Any notification of incidents referred to in those U.S. Department of Transportation requirements shall be filed with, or made to, the agency.
- c. Persons who transport radioactive material pursuant to the general licenses in 39.5(6)"a" or "b" are exempt from the requirements of 641—Chapter 40 to the extent that they transport radioactive material.

39.5(7) General license—approved packages.

- a. A general license is hereby issued to any licensee of the agency to transport, or to deliver to a carrier for transport, licensed material in a package for which a license, certificate of compliance, or other approval has been issued by the U.S. Nuclear Regulatory Commission.
 - b. This general license applies only to a licensee who:

(1) Has a copy of the specific license, certificate of compliance, or other approval of the package and has the drawings and other documents referenced in the approval relating to the use and maintenance of the packaging and to the actions to be taken prior to shipment;

(2) Complies with the terms and conditions of the license, certificate, or other approval, as applicable, and the

applicable requirements of this chapter;

(3) Prior to the licensee's first use of the package, has registered with the U.S. Nuclear Regulatory Commission; and

(4) Has a quality assurance program required by

39.5(20) and approved by the agency.

- c. The general license in 39.5(7)"a" applies only when the package approval authorizes use of the package under this general license.
- d. For previously approved Type B packages which are not designated as either B(U) or B(M) in the certificate of compliance, this general license is subject to additional restrictions of 39.5(8).
- 39.5(8) General license—previously approved Type B packages. A Type B package previously approved by the U.S. Nuclear Regulatory Commission, but not designated as B(U) or B(M) in the certificate of compliance, may be used under the general license of 39.5(7) with the following additional limitations:
- a. Fabrication of the packaging was satisfactorily completed before August 31, 1986, as demonstrated by application of its model number in accordance with U.S. Nuclear Regulatory Commission regulations; and
- b. The package may not be used for a shipment to a location outside the United States after August 31, 1986, except approved under special arrangement in accordance with 49 CFR 173.471.

39.5(9) General license—specification container.

- a. A general license is issued to any licensee of the agency to transport, or to deliver to a carrier for transport, licensed material in a specification container for a Type B quantity of radioactive material as specified in 49 CFR Parts 173 and 178.
- b. This general license applies only to a licensee who has a quality assurance program required by 39.5(20) and approved by the agency.
 - c. This general license applies only to a licensee who:

(1) Has a copy of the specification; and

- (2) Complies with the terms and conditions of the specification and the applicable requirements of this chapter.
- d. The general license in 39.5(9)"a" is subject to the limitation that the specification container may not be used for a shipment to a location outside the United States after August 31, 1986, except approved under special arrangements in accordance with 49 CFR 173.472.

39.5(10) General license—use of foreign approved package.

- a. A general license is issued to any licensee of the agency to transport, or to deliver to a carrier for transport, licensed material in a package, the design of which has been approved in a foreign national competent authority certificate which has been revalidated by the U.S. Department of Transportation as meeting the applicable requirements of 49 CFR 171.12.
- b. This general license applies only to international shipments.
 - c. This general license applies only to a licensee who:
- (1) Has a copy of the applicable certificate, the revalidation, and the drawings and other documents referenced

in the certificate relating to the use and maintenance of the packaging and to the actions to be taken prior to shipment; and

(2) Complies with the terms and conditions of the certificate and revalidation and with the applicable require-

ments of 641—Chapter 39.

39.5(11) General license—Type A, fissile Class II

package.

a. A general license is hereby issued to any licensee to transport fissile material, or to deliver fissile material to a carrier for transport, if the material is shipped as a fissile Class II package.

b. This general license applies only when a package contains no more than a Type A quantity of radioactive

material, including only one of the following:

(1) Up to 40 grams of uranium-235; or (2) Up to 30 grams of uranium-233; or

(3) Up to 25 grams of the fissile radionuclides of plutonium, except that for encapsulated plutonium-beryllium neutron sources in special form, an A₁ quantity of plutonium may be present; or

(4) A combination of fissile radionuclides in which the sum of the ratios of the amount of each radionuclide to the corresponding maximum amounts in 39.5(11)"b"(1),

(2), and (3) does not exceed unity.

c. (1) Except as specified in 39.5(11)"c"(2), this general license applies only when a package containing more than 15 grams of fissile radionuclides is labeled with a transport index not less than the number given by the following equation:

Minimum Transport Index = (0.4x + 0.67y + z) (1-15)x+y+z

where the package contains x grams of uranium-235, y grams of uranium-233, and z grams of the fissile radionuclides of plutonium.

- (2) For a package in which the only fissile material is in the form of encapsulated plutonium-beryllium neutron sources in special form, the transport index based on criticality considerations may be taken as 0.026 times the number of grams of the fissile radionuclides of plutonium in excess of 15 grams.
- (3) In all cases, the transport index must be rounded up to one decimal place and may not exceed 10.0.

39.5(12) General license—restricted, fissile Class II

package.

- a. A general license is hereby issued to any licensee to transport fissile material, or to deliver fissile material to a carrier for transport, if the material is shipped as a fissile Class II package.
- b. This general license applies only when all of the following requirements are met:
- (1) The package contains no more than a Type A quantity of radioactive material.
- (2) Neither beryllium nor hydrogenous material enriched in deuterium is present.
- (3) The total mass of graphite present does not exceed 150 times the total mass of uranium-235 plus plutonium.
- (4) Substances having a higher hydrogen density than water are not present, except that polyethylene may be used for packing or wrapping.

(5) Uranium-233 is not present, and the amount of plutonium does not exceed 1 percent of the amount of

uranium-235.

(6) The amount of uranium-235 is limited as follows:

1. If the fissile radionuclides are not uniformly distributed, the maximum amount of uranium-235 per package may not exceed the value given in the following table:

Table 1

Uranium enrichment in weight percent of uranium-235 not exceeding	Permissible maximum grams of uranium-235 per package
24	40
20	42
15	45
11	48
10	51
9.5	. 52
9	54
8.5	55 ~
8	57
7.5	59
7	60
. 6.5	62
6	65
5.5	68
5 4.5	72
4.5	76
4	80
3.5	88
3 2.5	100
2.5	120
2	164
1.5	272
1.35	320
1	680*
0.92	1200*

- *Pursuant to the agency's agreement with the U.S. Nuclear Regulatory Commission, jurisdiction extends only to 350 grams of uranium-235.
- 2. If the fissile radionuclides are distributed uniformly, the maximum amount of uranium-235 per package may not exceed the value given in the following table:

Table 2

Uranium enrichment in weight percent of uranium-235 not exceeding	Permissible maximum grams of uranium-235 per package	
4	84	
3.5	92	
3	112	
2.5	148	
2	240	
1.5	560*	
1.35	800 *	

- *Pursuant to the agency's agreement with the U.S. Nuclear Regulatory Commission, jurisdiction extends only to 350 grams of uranium-235.
- (7) The transport index of each package based on criticality considerations is taken as ten times the number of grams of uranium-235 in the package divided by the maximum allowable number of grams per package in accordance with Table 1 or 2 above as applicable.
- 39.5(13) Fissile material—assumptions as to unknown properties. When the isotopic abundance, mass, concentration, degree of irradiation, degree of moderation, or

other pertinent property of fissile material in any package is not known, the licensee shall package the fissile material as if the unknown properties had credible values that would cause the maximum nuclear reactivity.

39.5(14) Preliminary determinations. Prior to the first use of any packaging for the shipment of radioactive ma-

terial:

a. The licensee shall ascertain that there are no defects which could significantly reduce the effectiveness of the packaging;

- b. Where the maximum normal operating pressure will exceed 34.3 kilopascal (5 psi) gauge, the licensee shall test the containment system at an internal pressure at least 50 percent higher than the maximum normal operating pressure to verify the capability of that system to maintain its structural integrity at that pressure;
- c. The licensee shall determine that the packaging has been fabricated in accordance with the design approved by the U.S. Nuclear Regulatory Commission; and
- d. The licensee shall conspicuously and durably mark the packaging with its model number, gross weight, and a package identification number assigned by the U.S. Nuclear Regulatory Commission.

39.5(15) Routine determinations. Prior to each shipment of licensed material, the licensee shall determine

that:

- a. The package is proper for the contents to be shipped;
- b. The package is in unimpaired physical condition except for superficial defects such as marks or dents;
- c. Each closure device of the packaging, including any required gasket, is properly installed and secured and free of defects;
- d. Any system for containing liquid is adequately sealed and has adequate space or other specified provision for expansion of the liquid;
- e. Any pressure relief device is operable and set in accordance with written procedures;
- f. The package has been loaded and closed in accordance with written procedures;
- g. Any structural part of the package which could be used to lift or tie down the package during transport is rendered inoperable for that purpose unless it satisfies design requirements specified by the U.S. Nuclear Regulatory Commission;
- h. (1) The level of removable radioactive contamination on the external surfaces of each package offered for shipment is as low as reasonably achievable. The level of removable radioactive contamination may be determined by wiping an area of 300 square centimeters of the surface concerned with an absorbent material, using moderate pressure, and measuring the activity on the wiping material. Sufficient measurements must be taken in the most appropriate locations to yield a representative assessment of the removable contamination levels. Except as provided in 39.5(15)"h"(2), the amount of radioactivity measured on any single wiping material, when averaged over the surface wiped, must not exceed the limits given in Table 3 below at any time during transport. Other methods of assessment of equal or greater efficiency may be used. When other methods are used, the detection efficiency of the method used must be taken into account and in no case may the removable contamination on the external surfaces of the package exceed ten times the limits listed in Table 3.

Table 3 Removable External Radioactive Contamination Wipe Limits

Maximum Permissible Limits μCi/cm^{2*} Contaminant dpm/cm² Beta/gamma-emitting radionuclides; all radionuclides with half-lives less than ten days; natural uranium; natural thorium; uranium-235; uranium-238; thorium-232; thorium-228 and thorium-230 when contained in ores or physical concentrates 10-5 22 All other alpha-emitting radionuclides 10⁻⁶ 2.2

*To convert microcuries (µCi) to SI units of megabecquerels, multiply the values by 37.

(2) In the case of packages transported as exclusive use shipments by rail or highway only, the removable radioactive contamination at any time during transport must not exceed ten times the levels prescribed in 39.5(15) "h"(1). The levels at the beginning of transport must not exceed the levels in 39.5(15)"h"(1);

i. External radiation levels around the package and around the vehicle, if applicable, will not exceed 200 millirems per hour (2 mSv/h) at any point on the external surface of the package at any time during transportation.

The transport index shall not exceed ten;

For a package transported in exclusive use by rail, highway or water, radiation levels external to the package may exceed the limits specified in 39.5(15)"i" but shall not exceed any of the following:

- (1) 200 millirems per hour (2 mSv/h) on the accessible external surface of the package unless the following conditions are met, in which case the limit is 1000 millirems per hour (10 mSv/h):
 - 1. The shipment is made in a closed transport vehicle,
- 2. Provisions are made to secure the package so that its position within the vehicle remains fixed during transportation, and
- 3. There are no loading or unloading operations between the beginning and end of the transportation;
- (2) 200 millirems per hour (2 mSv/h) at any point on the outer surface of the vehicle, including the upper and lower surfaces, or, in the case of a flat-bed style vehicle, with a personnel barrier, ** at any point on the vertical planes projected from the outer edges of the vehicle, on the upper surface of the load (or enclosure, if used) and on the lower external surface of the vehicle;
- (3) 10 millirems per hour (0.1 mSv/h) at any point two meters from the vertical planes represented by the outer lateral surfaces of the vehicle, or, in the case of a flat-bed style vehicle, at any point two meters from the vertical planes projected from the outer edges of the vehicle; and
- (4) 2 millirems per hour (0.02 mSv/h) in any normally occupied positions of the vehicle, except that this provi-

sion does not apply to private motor carriers when persons occupying these positions are provided with special health supervision, personnel radiation exposure monitoring devices, and training in accordance with 641-subrule 40.6(3); and

k. A package must be prepared for transport so that in still air at 100 degrees Fahrenheit (38 degrees Celsius) and in the shade, no accessible surface of a package would have a temperature exceeding 122 degrees Fahrenheit (50 degrees Celsius) in a nonexclusive use shipment or 180 degrees Fahrenheit (82 degrees Celsius) in an exclusive use shipment. Accessible package surface temperatures shall not exceed these limits at any time during transportation.

39.5(16) Air transport of plutonium. Notwithstanding the provisions of any general licenses and notwithstanding any exemptions stated directly in this subrule or included indirectly by citation of the U.S. Department of Transportation regulations, as may be applicable, the licensee shall ensure that plutonium in any form is not transported by air, or delivered to a carrier for air transport, unless:

a. The plutonium is contained in a medical device de-

signed for individual human application; or

b. The plutonium is contained in a material in which the specific activity is not greater than 0.002 microcuries per gram (74 Bq/gm) of material and in which the radioactivity is essentially uniformly distributed; or

c. The plutonium is shipped in a single package containing no more than an A_2 quantity of plutonium in any isotope or form and is shipped in accordance with 39.5(5);

d. The plutonium is shipped in a package specifically authorized for the shipment of plutonium by air in the certificate of compliance for that package issued by the U.S. Nuclear Regulatory Commission.

39.5(17) Shipment records. Each licensee shall maintain for a period of two years after shipment a record of each shipment of licensed material not exempt under 39.5(4), showing, where applicable:

a. Identification of the packaging by model number;

- b. Verification that there were no significant defects in the packaging, as shipped;
 - c. Volume and identification of coolant;
- Type and quantity of licensed material in each package, and the total quantity of each shipment;
 - e. Date of the shipment;
 - f. Name and address of the transferee;
 - Address to which the shipment was made; and
 - h. Results of the determinations required by 39.5(15).
- The licensee shall report to the 39.5(18) Reports. agency within 30 days:
- a. Any instance in which there is significant reduction in the effectiveness of any authorized packaging during use; and
- b. Details of any defects with safety significance in the packaging after first use, with the means employed to repair the defects and prevent their recurrence.

39.5(19) Advance notification of transport of nuclear waste.

a. Prior to the transport of any nuclear waste outside of the confines of the licensee's facility or other place of use or storage, or prior to the delivery of any nuclear waste to a carrier for transport, each licensee shall provide advance notification of such transport to the governor, or governor's designee, of each state through which the waste will be transported. A list of the mailing addresses of the governors' and governors' designees is available upon request

^{**}A flat-bed style vehicle with a personnel barrier shall have radiation levels determined at vertical planes. If no personnel barrier, the package cannot exceed 200 millirems per hour (2 mSv/h) at the surface.

from the Director, State Programs, Office of Governmental and Public Affairs, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555.

b. Advance notification is required only when:

(1) The nuclear waste is required to be in Type B packaging for transportation;

(2) The nuclear waste is being transported to, through, or across state boundaries to a disposal site or to a collection point for transport to a disposal site; and

(3) The quantity of licensed material in a single pack-

age exceeds:

- 1. 5,000 curies (185 TBq) of special form radionuclides;
- 2. 5,000 curies (185 TBq) of uncompressed gases of argon-41, krypton-85m, krypton-87, xenon-131m, or xenon-135;
- 3. 50,000 curies (1.85 PBq) of argon-37, or of uncompressed gases of krypton-85 or xenon-133, or of hydrogen-3 as a gas, as luminous paint, or absorbed on solid material;

4. 20 curies (740 GBq) of other nonspecial form radionuclides for which A, is less than or equal to 4 curies (148

- 5. 200 curies (7.4 TBq) of other nonspecial form radionuclides for which A₂ is greater than 4 curies (148
- c. Each advance notification required by 39.5(19)"a" shall contain the following information:
- (1) The name, address, and telephone number of the shipper, carrier, and receiver of the shipment;
- (2) A description of the nuclear waste contained in the shipment as required by 49 CFR 172.202 and 172.203(d);
- (3) The point of origin of the shipment and the sevenday period during which departure of the shipment is estimated to occur:

(4) The seven-day period during which arrival of the shipment at state boundaries is estimated to occur;

- (5) The destination of the shipment, and the seven-day period during which arrival of the shipment is estimated to occur; and
- (6) A point of contact with a telephone number for

current shipment information.

- d. The notification required by 39.5(19)"a" shall be made in writing to the office of each appropriate governor, or governor's designee, and to the agency. A notification delivered by mail must be postmarked at least seven days before the beginning of the seven-day period during which departure of the shipment is estimated to occur. A notification delivered by messenger must reach the office of the governor, or governor's designee, at least four days before the beginning of the seven-day period during which departure of the shipment is estimated to occur. A copy of the notification shall be retained by the licensee for one year.
- e. The licensee shall notify each appropriate governor, or governor's designee, and the agency of any changes to schedule information provided pursuant to 39.5(19)"a." Such notification shall be by telephone to a responsible individual in the office of the governor, or governor's designee, of the appropriate state or states. The licensee shall maintain for one year a record of the name of the individual contacted.
- f. Each licensee who cancels a nuclear waste shipment, for which advance notification has been sent, shall send a cancellation notice to the governor, or governor's designee, of each appropriate state and to the agency. A

copy of the notice shall be retained by the licensee for one

39.5(20) Quality assurance requirements.

a. Each licensee shall establish, maintain, and execute a quality assurance program to verify by procedures such as checking, auditing, and inspection that deficiencies, deviations, and defective material and equipment relating to the shipment of packages containing radioactive material are promptly identified and corrected.

b. The licensee shall identify the material and components to be covered by the quality assurance program.

- c. Each licensee shall document the quality assurance program by written procedures or instructions and shall carry out the program in accordance with those procedures throughout the period during which packaging is used.
- d. Prior to the use of any package for the shipment of radioactive material, each licensee shall obtain approval by the agency of its quality assurance program.
- e. The licensee shall maintain sufficient written records to demonstrate compliance with the quality assurance program. Records of quality assurance pertaining to the use of a package for shipment of radioactive material shall be maintained for a period of two years after shipment.

CHAPTER 39—APPENDIX A **EXEMPT CONCENTRATIONS**

		•	Column
		Column	п
		I	Liquid and
Element		Gas con- centration	solid con- centration
(atomic number)	Radionuclide		μCi/ml 2/
Antimony (51)	Sb-122	•	3 x 10 ⁴
	Sb-124	,	2×10^{4}
	Sb-125		1 x 10 ³
Argon (18)	Ar-37	1 x 10 ⁻³	•
	Ar-41	4×10^{-7}	
Arsenic (33)	As-73		5×10^{-3}
	As-74	•	5×10^{4}
	As-76		2 x 10 ⁴
	As-77		8×10^4
Barium (56)	Ba-131		2×10^{-3}
	Ba-140		3×10^4
Beryllium (4)	Be-7		2×10^{-2}
Bismuth (83)	Bi-206	-	4×10^4
Bromine (35)	Br-82	4 x 10 ⁻⁷	3×10^{-3}
Cadmium (48)	Cd-109		2×10^{-3}
	Cd-115m		3×10^{4}
	Cd-115	•	3×10^4
Calcium (20)	Ca-45	•	9 x 10 ⁻⁵
•	Ca-47		5 x 10 ⁻⁴
Carbon (6)	C-14	1 x 10 ⁻⁶	8 x 10 ⁻³

APPENDIX A(con	t'd)	Column I Gas con-	Column II Liquid and solid con-			Column I Gas con-	Column II Liquid and solid con-
Element (atomic number)	Radionuclide	centration µCi/ml 1/	centration μCi/ml <u>2</u> /	Element (atomic number)	Radionuclide	centration µCi/ml 1/	centration µCi/ml <u>2</u> /
Cerium (58)	Ce-141		9 x 10 ⁻⁴	Lanthanum (57)	La-140		2 x 10 ⁴
	Ce-143		4 x 10 ⁻⁴	Lead (82)	Pb-203		4×10^{-3}
	Ce-144		1 x 10 ⁻⁴	Lutetium (71)	Lu-177		1×10^{-3}
Cesium (55)	Cs-131	•	2×10^{-2}	Manganese (25)	Mn-52		3×10^4
•	Cs-134m		6 x 10 ⁻²		Mn-54		1×10^{-3}
	Cs-134		9 x 10 ⁻⁵		Mn-56		1×10^{-3}
Chlorine (17)	C1-38	9 x 10-7	4×10^{-3}	Mercury (80)	Hg-197m		2×10^{-3}
Chromium (24)	Cr-51		2 x 10 ⁻²		Hg-197		3×10^{-3}
Cobalt (27)	Co-57		5 x 10 ⁻³		Hg-203		2 x 10 ⁴
	Co-58		1×10^{-3}	Molybdenum (42)	Mo-99	•	2×10^{-3}
	Co-60		5 x 10 ⁻⁴	Neodymium (60)	Nd-147		6 x 10 ⁴
Copper (29)	Cu-64		3×10^{-3}		Nd-149		3×10^{-3}
Dysprosium (66)	Dy-165		4×10^{-3}	Nickel (28)	Ni-65		1×10^{-3}
	Dy-166		4 x 10 ⁻⁴	Niobium	·		
Erbium (68)	Er-169		9 x 10 ⁻⁴	(Columbium) (41)	Nb-95		1 x 10 ⁻³
	Er-171 .		1×10^{-3}		Nb-97		9×10^{-3}
Europium (63)	Eu-152(9.2h)	•	6 x 10 ⁻⁴	Osmium (76)	Os-185		7 x 10 ⁻⁴
	Eu-155		2 x 10 ⁻³	,	Os-191m		3×10^{-2}
Fluorine (9)	F-18	2 x 10-6	8 x 10 ⁻³		Os-191		2 x 10 ⁻³
Gadolinium (64)	Gd-153		2 x 10 ⁻³		Os-193	-	6 x 10 ⁻⁴
	Gd-159		8 x 10 ⁻⁴	Palladium (46)	Pd-103		3×10^{-3}
Gallium (31)	Ga-72		4 x 10 ⁻⁴		Pd-109		9 x 10 ⁻⁴
Germanium (32)	Ge-71		2×10^{-2}	Phosphorus (15)	P-32		2 x 10 ⁴
Gold (79)	Au-196		2 x 10 ⁻³	Platinum (78)	Pt-191		1 x 10 ⁻³
	Au-198		5 x 10 ⁻⁴	•	Pt-193m		1 x 10 ⁻²
	Au-199		2×10^{-3}		Pt-197m		1 x 10 ⁻²
Hafnium (72)	Hf-181		7 x 10 ⁻⁴		Pt-197	•	1 x 10 ⁻³
Hydrogen (1)	H-3	5 x 10-6	3 x 10 ⁻²	Potassium (19)	K-42	,	3×10^{-3}
Indium (49)	In-113m		1 x 10 ⁻²	Praseodymium (59)	Pr-142		3 x 10 ⁴
	In-114m		2 x 10 ⁻⁴		Pr-143		5 x 10 ⁴
Iodine (53)	I-126	3 x 10-9	2 x 10 ⁻⁵	Promethium (61)	Pm-147		2 x 10 ⁻³
	I-131	3 x 10-9	2 x 10 ⁻⁵		Pm-149		4 x 10 ⁴
	I-132	8 x 10-8	6 x 10 ⁻⁴	Rhenium (75)	Re-183		6×10^{-3}
	I-133	1 x 10-8	7 x 10 ⁻⁵		Re-186		9 x 10 ⁴
	I-134	2 x 10-7	1 x 10 ⁻³	•	Re-188	•	6×10^{4}
Iridium (77)	Ir-190	•	2 x 10 ⁻³	Rhodium (45)	Rh-103m		1 x 10 ⁻¹
	Ir-192		4 x 10 ⁻⁴		Rh-105		1 x 10 ⁻³
	Ir-194		3 x 10 ⁻⁴	Rubidium (37)	Rb-86		7 x 10 ⁻⁴
Iron (26)	Fe-55	,	8 x 10 ⁻³	Ruthenium (44)	Ru-97		4×10^{-3}
	Fe-59		6 x 10 ⁴		Ru-103		8 x 10 ⁻⁴
Krypton (36)	Kr-85m		1 x 10 ⁻⁶		Ru-105		1 x 10 ⁻³
	Kr-85		3 x 10 ⁻⁶		Ru-106		1 x 10 ⁻⁴

APPENDIX A(con	t'd)	Column I Gas con-	Column II Liquid and solid con-
Element (atomic number)	Radionuclide	centration	centration µCi/ml 2/
Samarium (62)	Sm-153		8 x 10 ⁻⁴
Scandium (21)	Sc-46		4 x 10 ⁻⁴
	Sc-47		9 x 10 ⁻⁴
	Sc-48		3 x 10 ⁻⁴
Selenium (34)	Se-75		3 x 10 ⁻³
Silicon (14)	Si-31		9 x 10 ⁻³
Silver (47)	Ag-105		1 x 10 ⁻³
, ,	Ag-110m		3 x 10 ⁻⁴
	Ag-111	•	4 x 10 ⁻⁴
Sodium (11)	Na-24		2 x 10 ⁻³
Strontium (38)	Sr-85		1 x 10 ⁻³
	Sr-89		1 x 10-4
	Sr-91		7 x 10 ⁻⁴
	Sr-92		7 x 10 ⁻⁴
Sulfur (16)	S-35	9 x 10 ⁻⁸	6 x 10 ⁻⁴
Tantalum (73)	Ta-182		4 x 10 ⁻⁴
Technetium (43)	Tc-96m		1 x 10 ⁻¹
	Tc-96		1 x 10 ⁻³
Tellurium (52)	Te-125m	•	2 x 10 ⁻³
	Te-127m		6 x 10 ⁻⁴
	Te-127	-	3 x 10 ⁻³
	Te-129m		3 x 10 ⁻⁴
	Te-131m		6 x 10 ⁴
	Te-132		3 x 10 ⁻⁴
Terbium (65)	Tb-160		4 x 10 ⁻⁴
Thallium (81)	T1-200		4 x 10 ⁻³
	T1-201		3 x 10 ⁻³
	T1-202		1 x 10 ⁻³
	T1-204		1 x 10 ⁻³
Thulium (69)	Tm-170		5 x 10 ⁻⁴
	Tm-171		5 x 10 ⁻³
Tin (50)	Sn-113		9 x 10 ⁻⁴
	Sn-125		2 x 10 ⁻⁴
Tungsten			, .
(Wolfram) (74)	W-181		4×10^{-3}
T7 11 (00)	W-187		7 x 10 ⁻⁴
Vanadium (23)	V-48		3 x 10 ⁻⁴
Xenon (54)	x e-131m	4 x 10 ⁻⁶	
	x e-133	3 x 10 ⁻⁶	
Variable (50)	x e-135	1 x 10 ⁻⁶	
Ytterbium (70)	Yb-175		1 x 10 ⁻³

Element (atomic number)	Radionuclide	Column I Gas concentration µCi/ml 1/	Column II Liquid and solid concentration µCi/ml 2/
Yttrium (39)	Y-90		2 x 10 ⁻⁴
	Y-91m		3×10^{-2}
	Y-91		3×10^4
•	Y-92		6 x 10 ⁴
	Y-93		3×10^4
Zinc (30)	Zn-65		1×10^{-3}
	Zn-69m		7×10^4
_	Zn-69		2×10^{-2}
Zirconium (40)	Zr-95 ·		6 x 10 ⁴
•	Zr-97		2 x 10 ⁴
Beta/gamma- emitting radioactive material not listed above with half-life of less than 3 years		1 x 10 ⁻¹⁰	1 x 10 ⁶

1/ Values are given in Column I only for those materials normally used as gases.

2/ μCi/g for solids.

NOTE 1: Many radionuclides transform into other radionuclides. In expressing the concentrations in Appendix A, the activity stated is that of the parent radionuclide and takes into account the radioactive decay products.

NOTE 2: For purposes of 39.4(3) where there is involved a combination of radionuclides, the limit for the combination should be derived as follows: Determine for each radionuclide in the product the ratio between the radioactivity concentration present in the product and the exempt radioactivity concentration established in Appendix A for the specific radionuclide when not in combination. The sum of such ratios may not exceed "1."

EXAMPLE: Concentration of Radionuclide A in Product +
Exempt concentration of Radionuclide A

Concentration of Radionuclide B in Product ≤1 Exempt concentration of Radionuclide B

NOTE 3: To convert µCi/ml to SI units of megabecquerels per liter multiply the above values by 37.

EXAMPLE: Zirconium (40) Zr-97 (2x10 4 µCi/ml multiplied by 37 is equivalent to $74x10^4$ MBq/l)

CHAPTER 39—APPENDIX B

EXEMPT QUANTITIES

Radioactive Material	Microcuries
Antimony-122 (Sb 122)	100

Antimony-124 (Sb 124) Antimony-125 (Sb 125) Arsenic-73 (As 73) Arsenic-74 (As 74) Arsenic-76 (As 76) Arsenic-77 (As 77) Barium-131 (Ba 131) Barium-140 (Ba 140) Bismuth-210 (Bi 210)	10 · 10 · 10 · 10 · 10 · 10 · 10 · 10 ·	Gadolinium-159 (Gd 159) Gallium-67 (Ga 67) Gallium-72 (Ga 72) Germanium-68 (Ge 68) Germanium-71 (Ge 71) Gold-195 (Au 195) Gold-198 (Au 198) Gold-199 (Au 199) Hafnium-181 (Hf 181)	100 100 10 10 100 100 100
Arsenic-73 (As 73) Arsenic-74 (As 74) Arsenic-76 (As 76) Arsenic-77 (As 77) Barium-131 (Ba 131) Barium-133 (Ba 133) Barium-140 (Ba 140)	100 10 10 100 10 10	Gallium-72 (Ga 72) Germanium-68 (Ge 68) Germanium-71 (Ge 71) Gold-195 (Au 195) Gold-198 (Au 198) Gold-199 (Au 199)	10 10 100 10 100
Arsenic-74 (As 74) Arsenic-76 (As 76) Arsenic-77 (As 77) Barium-131 (Ba 131) Barium-140 (Ba 140)	10 10 100 10 10	Germanium-68 (Ge 68) Germanium-71 (Ge 71) Gold-195 (Au 195) Gold-198 (Au 198) Gold-199 (Au 199)	. 10 100 10 100
Arsenic-76 (As 76) Arsenic-77 (As 77) Barium-131 (Ba 131) Barium-133 (Ba 133) Barium-140 (Ba 140)	10 100 10 10 10	Germanium-71 (Ge 71) Gold-195 (Au 195) Gold-198 (Au 198) Gold-199 (Au 199)	100 10 100
Arsenic-77 (As 77) Barium-131 (Ba 131) Barium-133 (Ba 133) Barium-140 (Ba 140)	100 10 10 10	Gold-195 (Au 195) Gold-198 (Au 198) Gold-199 (Au 199)	10 100
Barium-131 (Ba 131) Barium-133 (Ba 133) Barium-140 (Ba 140)	10 10 10	Gold-198 (Au 198) Gold-199 (Au 199)	100
Barium-133 (Ba 133) Barium-140 (Ba 140)	10 10	Gold-199 (Au 199)	
Barium-140 (Ba 140)	10	· · ·	100
· · ·		Hafnium-181 (Hf 181)	100
Bismuth-210 (Bi 210)	1		10
**		Holmium-166 (Ho 166)	100
Bromine-82 (Br 82)	10	Hydrogen-3 (H 3)	1,000
Cadmium-109 (Cd 109)	10	Indium-111 (In 111)	100
Cadmium-115m (Cd 115m)	10	Indium-113m (In 113m)	100
Cadmium-115 (Cd 115)	100	Indium-114m (In 114m)	10
Calcium-45 (Ca 45)	10	Indium-115m (In 115m)	100
Calcium-47 (Ca 47)	10	Indium-115 (In 115)	10
Carbon-14 (C 14)	100	Iodine-123 (I 123)	100
Cerium-141 (Ce 141)	100	Iodine-125 (I 125)	1
Cerium-143 (Ce 143)	100	Iodine-126 (I 126)	. 1
Cerium-144 (Ce 144)	1	Iodine-129 (I 129)	0.1
Cesium-129 (Cs 129)	100	Iodine-131 (I 131)	1
Cesium-131 (Cs 131)	1,000	Iodine-132 (I 132)	10
Cesium-134m (Cs 134m)	100	Iodine-133 (I 133)	1
Cesium-134 (Cs 134)	1	Iodine-134 (I 134)	10
Cesium-135 (Cs 135)	10	Iodine-135 (I 135)	10
Cesium-136 (Cs 136)	10	Iridium-192 (Ir 192)	10
Cesium-137 (Cs 137)	10 -	Iridium-194 (Ir 194)	100
Chlorine-36 (Cl 36)	10	Iron-52 (Fe 52)	10
Chlorine-38 (Cl 38)	10	Iron-55 (Fe 55)	100
Chromium-51 (Cr 51)	1,000	Iron-59 (Fe 59)	10
Cobalt-57 (Co 57)	100	Krypton-85 (Kr 85)	100
Cobalt-58m (Co 58m)	10	Krypton-87 (Kr 87)	10
Cobalt-58 (Co 58)	10	Lanthanum-140 (La 140)	. 10
Cobalt-60 (Co 60)	1	Lutetium-177 (Lu 177)	100
Copper-64 (Cu 64)	100	Manganese-52 (Mn 52)	10
Dysprosium-165 (Dy 165)	10	Manganese-54 (Mn 54)	10
Dysprosium-166 (Dy 166)	100	Manganese-56 (Mn 56)	10
Erbium-169 (Er 169)	100	Mercury-197m (Hg 197m)	100
Erbium-171 (Er 171)	100	Mercury-197 (Hg 197)	100
Europium-152 (Eu 152)9.2h	100	Mercury-203 (Hg 203)	10
Europium-152 (Eu 152)13 yr	.1	Molybdenum-99 (Mo 99)	100
Europium-154 (Eu 154)	1	Neodymium-147 (Nd 147)	100
Europium-155 (Eu 155)	10	Neodymium-149 (Nd 149)	. 100
Fluorine-18 (F 18)	1,000	Nickel-59 (Ni 59)	100
Gadolinium-153 (Gd 153)	1,000	Nickel-63 (Ni 63)	10

APPENDIX B (cont'd) Radioactive Material	Microcuries	Radioactive Material	Microcuries
Nickel-65 (Ni 65)	100	Sodium-24 (Na 24)	10
Niobium-93m (Nb 93m)	10	Strontium-85 (Sr 85)	10
Niobium-95 (Nb 95)	10	Strontium-89 (Sr 89)	1
Niobium-97 (Nb 97)	10	Strontium-90 (Sr 90)	0.1
Osmium-185 (Os 185)	10	Strontium-91 (Sr 91)	_ 10
Osmium-191m (Os 191m)	100	Strontium-92 (Sr 92)	10
Osmium-191 (Os 191)	100	Sulphur-35 (S 35)	100
Osmium-193 (Os 193)	100	Tantalum-182 (Ta 182)	10
Palladium-103 (Pd 103)	100	Technetium-96 (Tc 96)	10
Palladium-109 (Pd 109)	100	Technetium-97m (Tc 97m)	100
Phosphorus-32 (P 32)	10	Technetium-97 (Tc 97)	100
Platinum-191 (Pt 191)	100	Technetium-99m (Tc 99m)	100
Platinum-193m (Pt 193m)	100	Technetium-99 (Tc 99)	10
Platinum-193 (Pt 193)	100	Tellurium-125m (Te 125m)	10
Platinum-197m (Pt 197m)	100	Tellurium-127m (Te 127m)	10
Platinum-197 (Pt 197)	100	Tellurium-127 (Te 127)	100
Polonium-210 (Po 210)	0.1	Tellurium-129m (Te 129m)	10
Potassium-42 (K 42)	10	Tellurium-129 (Te 129)	100
Potassium-43 (K 43)	10	Tellurium-131m (Te 131m)	. 10
Praseodymium-142 (Pr 142)	100	Tellurium-132 (Te 132)	10
Praseodymium-143 (Pr 143)	100	Terbium-160 (Tb 160)	10
Promethium-147 (Pm 147)	10	Thallium-200 (Tl 200)	100
Promethium-149 (Pm 149)	10	Thallium-201 (Tl 201)	100
Rhenium-186 (Re 186)	100	Thallium-202 (Tl 202)	100
Rhenium-188 (Re 188)	100	Thallium-204 (Tl 204)	10
Rhodium-103m (Rh 103m)	100	Thulium-170 (Tm 170)	10
Rhodium-105 (Rh 105)	100	Thulium-171 (Tm 171)	10
Rubidium-81 (Rb 81)	10	Tin-113 (Sn 113)	10
Rubidium-86 (Rb 86)	10	Tin-125 (Sn 125)	10
Rubidium-87 (Rb 87)	10	Tungsten-181 (W 181)	10
Ruthenium-97 (Ru 97)	100	Tungsten-185 (W 185)	10
Ruthenium-103 (Ru 103)	10	Tungsten-187 (W 187)	100
Ruthenium-105 (Ru 105)	10	Vanadium-48 (V 48)	10
Ruthenium-106 (Ru 106)	1	Xenon-131m (x e 131m)	1,000
Samarium-151 (Sm 151)	10	Xenon-133 (x e 133)	. 100
Samarium-153 (Sm 153)	100	Xenon-135 (x e 135)	100
Scandium-46 (Sc 46)	10	Ytterbium-175 (Yb 175)	100
Scandium-47 (Sc 47)	100	Yttrium-87 (Y 87)	. 10
Scandium-48 (Sc 48)	10	Yttrium-88 (Y 88)	10
Selenium-75 (Se 75)	10	Yttrium-90 (Y 90)	10
Silicon-31 (Si 31)	100	Yttrium-91 (Y 91)	10
Silver-105 (Ag 105)	10	Yttrium-92 (Y 92)	100
Silver-110m (Ag 110m)	1	Yttrium-93 (Y 93)	100
Silver-111 (Ag 111)	100	Zinc-65 (Zn 65)	10
Sodium-22 (Na 22)	10	Zinc-69m (Zn 69m)	100

Radioactive Material

Calcium-47

Carbon-14

Cerium-141

Cerium-143

Cerium-144

Cesium-131 Cesium-134m

Cesium-134

Cesium-135

Cesium-136

Cesium-137

Chlorine-36

Chlorine-38

Cobalt-57

Cobalt-58

Cobalt-60

Copper-64

Erbium-169

Erbium-171

Europium-154

Europium-155

Dysprosium-165

Dysprosium-166

Europium-152 (9.2 h)

Europium-152 (13 y)

Cobalt-58m

Chromium-51

Column I

curies

10

100

10

10

100

100

0.1

0.1

1

10

0.1

1

100

100

10

100

1

0.1

10

100

10

10

10

10

0.1

0.1

1

Column II

curies

0.1

1.

0.1

0.1

1.

1.

0.001

0.001

0.01

0.1

0.001

0.01

1.

1.

0.1

1. 0.01

0.001

0.1

1.

0.1

0.1

0.1

0.1

0.001

0.001

0.01

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APPENDIX B (cont'd) Radioactive Material	Microcuries
Zinc-69 (Zn 69)	1,000
Zirconium-93 (Zr 93)	10
Zirconium-95 (Zr 95)	. 10
Zirconium-97 (Zr 97)	10
Any radioactive material not listed above other than alphaemitting radioactive material	0.1

NOTE 1: For purposes of 39.4(25)"f"(5)"2" where there is involved a combination of radionuclides, the limit for the combination should be derived as follows:

Determine the amount of each radionuclide possessed and 1,000 times the amount in Appendix B for each of those radionuclides when not in combination. The sum of the ratios of those quantities may not exceed 1.

EXAMPLE:

Amt. of Radionuclide A		Amt. of Radionuclide B		
possessed	+	possessed	μ1	
1000 x Appendi x B quantity		1000 x Appendi x B quantity		
for Radionuclide A		for Radionuclide B		

NOTE 2: To convert microcuries (µCi) to SI units of kilobecquerels (kBq), multiply the above values by 37.

EXAMPLE: Zirconium-97 (10 μ Ci multiplied by 37 is equivalent to 370 kBq).

CHAPTER 39—APPENDIX C

Reserved

CHAPTER 39—APPENDIX D

LIMITS FOR BRO	DAD LICENSES	(39.4(27))	Fluorine-18	100	1.
	Column I	Column II	Gadolinium-153	- 1	0.01
Radioactive Material	curies	curies	Gadolinium-159	10	0.1
Antimony-122	1 _	0.01	Gallium-72	10	0.1
Antimony-124	1	0.01	Germanium-71	100	1.
Antimony-125	1	0.01	Gold-198	10	0.1
Arsenic-73	10	0.1	Gold-199	10	0.1
Arsenic-74	1	0.01	Hafnium-181	1	0.01
Arsenic-76	1	0.01	Holmium-166	10	0.1
Arsenic-77	10	0.1	Hydrogen-3	100	1.
Barium-131	10	0.1	Indium-113m	100	1.
Barium-140	1	0.01	Indium-114m	1	0.01
Beryllium-7	10	0.1	Indium-115m	100	1.
Bismuth-210	0.1	0.001	Indium-115	1	0.01
Bromine-82	10	0.1	Iodine-125	0.1	0.001
Cadmium-109	1	0.01	Iodine-126	0.1	0.001
Cadmium-115m	1	0.01	Iodine-129	0.1	0.001
Cadmium-115	10	0.1	Iodine-131	0.1	0.001
Calcium-45	1	0.01	Iodine-132	10	0.1

APPENDIX D(cont'd) Radioactive Material	Column I curies	Column II curies	Radioactive Material	Column I curies	Column II curies
Iodine-133	1	0.01	Rhenium-186	10	0.1
Iodine-134	10	0.1	Rhenium-188	10	0.1
Iodine-135	1	0.01	Rhodium-103m	1,000	10.
Iridium-192	1	0.01	Rhodium-105	10	0.1
Iridium-194	10	0.1	Rubidium-86	. 1	0.01
Iron-55	10	0.1	Rubidium-87	1	0.01
Iron-59	1	0.01	Ruthenium-97	100	1.
Krypton-85	100	1.	Ruthenium-103	1	0.01
Krypton-87	10	0.1	Ruthenium-105	10	0.1
Lanthanum-140	1	0.01	Ruthenium-106	0.1	0.001
Lutetium-177	10	0.1	Samarium-151	1	0.01
Manganese-52	1	0.01	Samarium-153	10	0.1
Manganese-54	1	0.01	Scandium-46	1	. 0.01
Manganese-56	10	0.1	Scandium-47	10	0.1
Mercury-197m	10 -	0.1	Scandium-48	1	0.01
Mercury-197	10	0.1	Selenium-75	1	0.01
Mercury-203	· 1	0.01	Silicon-31	10	0.1
Molybdenum-99	10	0.1	Silver-105	1	0.01
Neodymium-147	10	0.1	Silver-110m	0.1	0.001
Neodymium-149	10	0.1	Silver-111	10	0.1
Nickel-59	10	0.1	Sodium-22	0.1	0.001
Nickel-63	1	0.01	Sodium-24	1 -	0.01
Nickel-65	10	0.1	Strontium-85m	1,000	10.
Niobium-93m	1	0.01	Strontium-85	1	0.01
Niobium-95	1	0.01	Strontium-89	1	0.01
Niobium-97	100	1.	Strontium-90	0.01	0.0001
Osmium-185	1	0.01	Strontium-91	10	0.1
Osmium-191m	100	1.	Strontium-92	10	0.1
Osmium-191	10	0.1	Sulphur-35	10	0.1
Osmium-193	10	0.1	Tantalum-182	1	0.01
Palladium-103	10	0.1	Technetium-96	10	0.1
Palladium-109	10	0.1	Technetium-97m	10	0.1
Phosphorus-32	1	0.01	Technetium-97	10	0.1
Platinum-191	10	0.1	Technetium-99m	100	1.
Platinum-193m	100	1.	Technetium-99	1	0.01
Platinum-193	10	0.1	Tellurium-125m	1	0.01
Platinum-197m	100	1.	Tellurium-127m	1 -	0.01
Platinum-197	10	0.1	Tellurium-127	10 .	0.1
Polonium-210	0.01	0.0001	Tellurium-129m	1	0.01
Potassium-42	1	0.01	Tellurium-129	100	1.
Praseodymium-142	10	0.1	Tellurium-131m	10	0.1
Praseodymium-143	10	0.1	Tellurium-132	1	0.01
Promethium-147	1	0.01	Terbium-160	1	. 0.01
Promethium-149	10	0.1	Thallium-200	10	0.1
Radium-226	0.01	0.0001	Thallium-201	10	0.1

APPENDIX D(cont'd) Radioactive Material	Column I curies	Column II curies
Thallium-202	10	0.1
Thallium-204	1	0.01
Thulium-170	1	0.01
Thulium-171	1	. 0.01
Tin-113	1	0.01
Tin-125	1	0.01
Tungsten-181	1	0.01
Tungsten-185	1 .	0.01
Tungsten-187	10	0.1
Vanadium-48	1	0.01
Xenon-131m	1,000	10.
Xenon-133	100	1.
Xenon-135	100	1.
Ytterbium-175	10 ·	0.1
Yttrium-90	1	0.01
Yttrium-91	1	0.01
Yttrium-92	10	0.1
Yttrium-93	1	0.01
Zinc-65	ì	0.01
Zinc-69m	10	0.1
Zinc-69	100	1.
Zirconium-93	1	0.01
Zirconium-95	. 1	0.01
Zirconium-97	1	0.01
Any radioactive material other than source material, special nuclear material, or alpha-emitting radioactive material not listed above.	0.1	0.001

NOTE 1: To convert curies (Ci) to SI units of gigabecquerels (GBq), multiply the above values by 37.

EXAMPLE: Zirconium-97 (Col. II) (0.01 Ci multiplied by 37 is equivalent to 0.37 GBq).

CHAPTER 39—APPENDIX E DETERMINATION OF A₁ AND A₂

I. Single Radionuclides.

1. For a single radionuclide of known identity, the values of A_1 and A_2 are taken from Table I if listed there. The values A_1 and A_2 in Table I are also applicable for the radionuclide contained in (a,n) or (c,n) neutron sources.

2. For any single radionuclide whose identity is known but which is not listed in Table I, the value of A_1 and A_2 is determined according to the following procedure:

(a) If the radionuclide emits only one type of radiation, A, is determined according to the following method. For radionuclides emitting different kinds of radiation, A, is the most restrictive value of those determined for each kind of radiation. However, in either case, A₁ is restricted to a maximum of 1000 curies (37 TBq). If a parent nuclide decays into a shorter lived daughter with a half-life

not greater than ten days, A, is calculated for both the parent and the daughter, and the more limiting of the two values is assigned to the parent nuclide.

(1) For gamma emitters, A₁ is determined by the ex-

$$A_1 = 9$$
 curies

where C is the gamma-ray constant, corresponding to the dose in roentgens per curie-hour at 1 meter, and the number 9 results from the choice of 1 rem per hour at a distance of 3 meters as the reference dose-equivalent rate;

(2) For X-ray emitters, A, is determined by the atomic number of the nuclide:

for
$$Z \mu 55$$
, $A_1 = 1000 \text{ Ci } (37 \text{ TBq})$; and

for
$$Z > 55$$
, $A_1 = 200 \text{ Ci } (7.4 \text{ TBq})$

where Z is the atomic number of the nuclide;

(3) For beta emitters, A, is determined by the maxi-

mum beta energy (E_{max}) according to Table II; and
(4) For alpha emitters, A₁ is determined by the expres-

$$A_1 = 1000 A_3$$

where A₃ is the value listed in Table III;

(b) A, is the more restrictive of the following two values:

(1) The corresponding A₁; and

(2) The value A₃ obtained from Table III.
3. For any single radionuclide whose identity is unknown, the value of A₁ is taken to be 2 Ci (74 GBq) and the value of A₂ is taken to be 0.002 Ci (74 MBq). However, if the atomic number of the radionuclide is known to be less than 82, the value of A_1 is taken to be 10 Ci (370 GBq) and the value of A_2 is taken to be 0.4 Ci (14.8 GBq).

II. Mixtures of Radionuclides, Including Radioactive Decay Chains.

1. For mixed fission products, the activity limit may be assumed if a detailed analysis of the mixture is not carried out.

$$A_1 = 10 \text{ Ci } (370 \text{ GBq})$$

$$A_2 = 0.4 \text{ Ci } (14.8 \text{ GBq})$$

- 2. A single radioactive decay chain is considered to be a single radionuclide when the radionuclides are present in their naturally occurring proportions and no daughter nuclide has a half-life either longer than ten days or longer than that of the parent nuclide. The activity to be taken into account and the A₁ or A₂ value from Table I to be applied are those corresponding to the parent nuclide of that chain. When calculating A₁ or A₂ values, radiation emitted by daughters must be considered. However, in the case of radioactive decay chains in which any daughter nuclide has a half-life either longer than ten days or greater than that of the parent nuclide, the parent and daughter nuclides are considered to be mixtures of different nuclides.
- 3. In the case of a mixture of different radionuclides. where the identity and activity of each radionuclide are known, the permissible activity of each radionuclide R_1 , $R_2 ldots R_n$ is such that $F_1 + F_2 + \ldots F_n$ is not greater than unity, where:

 $F_1 = Total activity of R_1$

 $F_2 = Total activity of R_2$

 $F_n = \frac{\text{Total activity of } R_n}{\text{and}}$ $A_i(R_i)$

A₁ (R₁, R₂...R_n) is the value of A₁ or A₂ as appropriate for the nuclide R₁, R₂...R_n.

4. When the identity of each radionuclide is known

but the individual activities of some of the radionuclides are not known, the formula given in paragraph 3 above is applied to establish the values of A_1 or A_2 as appropriate. All the radionuclides whose individual activities are not known (their total activity will, however, be known) are classed in a single group and the most restrictive value of A₁ and A₂ applicable to any one of them is used as the value of A₁ or A₂ in the denominator of the fraction.

5. Where the identity of each radionuclide is known

but the individual activity of none of the radionuclides is known, the most restrictive value of A₁ or A₂ applicable to any one of the radionuclides present is adopted as the ap-

6. When the identity of none of the nuclides is known, the value of A, is taken to be 2 Ci (74 GBq) and the value of A, is taken to be 0.002 Ci (74 MBq). However, if alpha emitters are known to be absent, the value of A₂ is taken to be 0.4 Ci (14.8 GBq).

Table I A₁ and A₂ Values for Radionuclides (See Footnotes at end of Table)

Symbol of radionuclide	Element and atomic number	A ₁ (Ci)	A ₂ (Ci)	Specific activity (Ci/g)
Ac-227	Actinium (89)	1000	0.003	7.2 x 10 ¹
Ac-228		10	4 .	2.2 x 10 ⁶
Ag-105	Silver (47)	40	40	3.1×10^4
Ag-110m	,	7 -	.7	4.7×10^3
Ag-111		100	20	1.6 x 10 ⁵
Am-241	Americium (95)	8	0.008	3.2
Am-243		8	0.008	1.9×10^{-1}
Ar-37 (compressed or uncompressed)*	Argon (18)	1000	1000	1.0 x 10 ⁵
Ar-41 (uncompressed)*		20	20	4.3×10^7
Ar-41 (compressed)*		1 .	1	4.3×10^{7}
As-73	Arsenic (33)	1000	400	2.4 x 10 ⁴
As-74		20	20	1.0×10^{5}
As-76		10	10	1.6 x 10 ⁶
As-77		300	20	1.1×10^6
At-211	Astatine (85)	200	7	2.1 x 10 ⁶
Au-193	Gold (79)	200	200	9.3 x 10 ⁵
Au-196		- 30	30	1.2 x 10 ⁵
Au-198		40	20	2.5 x 10 ⁵
Au-199		200	25	2.1 x 10 ⁵
Ba-131	Barium (56)	40	40	8.7 x 10 ⁴
Ba-133		40	40	4.0×10^2
Ba-140		20	20	7.3 x 10 ⁴
Be-7	Beryllium (4)	300	300	3.5 x 10 ⁵
Bi-206	Bismuth (83)	5	5	9.9 x 10 ⁴
Bi-207	•	10	10	2.2×10^{2}
Bi-210 (RaE)		100	4	1.2 x 10 ⁵
Bi-212 .		6	6	1.5×10^7
Bk-249	Berkelium (97)	1000	1	1.8×10^3
Br-77	Bromine (35)	70	25	7.1×10^{5}
Br-82		6	6	1.1 x 10 ⁶

Symbol of radionuclide	Element and atomic number	A ₁ (Ci)	A ₂ (Ci)	Specific activity (Ci/g)
C-11	Carbon (6)	20	20	8.4 x 10 ⁸
C-14		1000	60	4.6
Ca-45	Calcium (20)	1000	25	1.9 x 10 ⁴
Ca-47		. 20	20	5.9 x 10 ⁵
Cd-109	Cadmium (48)	1000	70	2.6×10^3
Cd-115m		30	30	2.6×10^4
Cd-115		80	20	5.1 x 10 ⁵
Ce-139	Cerium (58)	100	100	6.5×10^3
Ce-141		300	25	2.8 x 10 ⁴
Ce-143	٠	60	20	6.6 x 10 ⁵
Ce-144		10	7	3.2×10^3
Cf-249	Californium (98)	2	0.002	3.1
Cf-250		7	0.007	1.3×10^{2}
Cf-252		2	0.009	6.5×10^2
Cl-36	Chlorine (17)	300	10	3.2×10^{-2}
C1-38		10	10	1.3×10^8
Cm-242	Curium (96)	200	0.2	3.3×10^3
Cm-243		. 9	0.009	4.2×10^{1}
Cm-244		10	0.01	8.2×10^{1}
Cm-245		6	0.006	1.0×10^{-1}
Cm-246		6 ·	0.006	3.6 x 10 ⁻¹
Co-56	Cobalt (27)	5	5	3.0×10^4
Co-57		90	90	8.5×10^3
Co-58m		1000	1000	5.9 x 10 ⁶
Co-58		20	20	3.1×10^4
Co-60		. 7	7	1.1×10^3
Cr-51	Chromium (24)	600	600	9.2 x 10 ⁴
Cs-129	Cesium (55)	40	40	7.6 x 10 ⁵
Cs-131		1000	1000	1.0 x 10 ⁵
Cs-134m	,	1000	10	7.4×10^6
Cs-134	•	10	10	1.2×10^3
Cs-135		1000	25	8.8 x 10 ⁻⁴
Cs-136		7	7	7.4×10^4
Cs-137		30	10	9.8 x 10 ¹
Cu-64	Copper (29)	80	25 ·	3.8×10^6
Cu-67		200	25	7.9 x 10 ⁵
Dy-165	Dysprosium (66)	100	20	8.2 x 10 ⁶
Dy-166		1000	200	2.3 x 10 ⁵
Er-169	Erbium (68)	1000	. 25	8.2 x 10 ⁴
Er-171		50	20	2.4×10^6
Eu-152m	Europium (63)	30	30	2.2 x 10 ⁶
Eu-152		20	10	1.9×10^{2}
Eu-154	•	10	5	1.5×10^2
Eu-155		400	60	1.4×10^3
F-18	Fluorine (9)	20	20	9.3 x 10 ⁷

Symbol of radionuclide	Element and atomic number	A ₁ (Ci)	A ₂ (Ci)	Specific activity (Ci/g)
Fe-52	Iron (26)	5	5	7.3 x 10 ⁶
Fe-55		1000	1000	2.2×10^3
Fe-59	· •	10	10	4.9 x 10 ⁴
Ga-67	Gallium (31)	100	100	6.0 x 10 ⁵
Ga-68		20	20	4.0×10^7
Ga-72		7	7	3.1 x 10 ⁶
Gd-153	Gadolinium (64)	200	100	3.6×10^3
Gd-159		300	20	1.1×10^6
Ge-68	Germanium (32)	. 20	10	7.0×10^3
Ge-71		1000	1000	1.6 x 10 ⁵
H-3	Hydrogen (1)	(see T-Tritium)		•
Hf-181	Hafnium (72)	30	25	1.6 x 10 ⁴
Hg-197m	Mercury (80)	200	200	6.6 x 10 ⁵
Hg-197		200	200	2.5 x 10 ⁵
Hg-203	•	80	25	1.4 x 10 ⁴
Ho-166	Holmium (67)	30	30	6.9 x 10 ⁵
I-123	Iodine (53)	50	50	1.9 x 10 ⁶
I-125		1000	, 70	1.7 x 10 ⁴
I-126		40	10	7.8 x 10 ⁴
I-131		40	10	1.2 x 10 ⁵
I-132	•	- 7	7	1.1 x 10 ⁷
I-133		30	10	1.1 x 10 ⁶
I-134	•	- 8	8	2.7 x 10 ⁷
I-135		10	10	3.5 x 10 ⁶
In-111	Indium (49)	30	25	4.2 x 10 ⁵
In-113m		60	60	1.6 x 10 ⁷
In-114m		30	20	2.3 x 10 ⁴
In-115m		100	20	6.1 x 10 ⁶
Ir-190	Iridium (77)	10	10	6.2 x 10 ⁴
Ir-192		20	10	9.1 x 10 ³
Ir-194		10	10	8.5 x 10 ⁵
K-42	Potassium (19)	10	10	6.0 x 10 ⁶
K-43		20	10	3.3 x 10 ⁶
Kr-85m (uncompressed)*	Krypton (36)	100	100	8.4 x 10 ⁶
Kr-85m (compressed)*		3	3	8.4 x 10 ⁶
Kr-85 (uncompressed)*		1000	1000	4.0×10^{2}
Kr-85 (compressed)*		5	5	4.0×10^{2}
Kr-87 (uncompressed)*		20	20	2.8 x 10 ⁷
Kr-87 (compressed)*		0.6	0.6	2.8×10^7
La-140	Lanthanum (57)	30	30	5.6 x 10 ⁵
Lu-177	Lutetium (71)	300	. 25	1.1 x 10 ⁵
MFP	Mixed Fission products	10	0.4	
Mg-28 .	Magnesium (12)	6	. 6	5.2 x 10 ⁶
Mn-52	Manganese (25)	5	5	
		<i>3</i>	J	4.4 x 10 ⁵

Symbol of radionuclide	Element and atomic number	A _i (Ci)	A ₂ (Ci)	Specific activity (Ci/g)
 Mn-56		5	5	2.2 x 10 ⁷
Mo-99	Molybdenum (42)	100	20	4.7 x 10 ⁵
N-13	Nitrogen (7)	20	10	1.5 x 10 ⁹
Na-22	Sodium (11)	8	8	6.3×10^3
Na-24		5	5	8.7 x 10 ⁶
Nb-93m	Niobium (41)	1000	200	1.1×10^3
Nb-95		20	20	3.9×10^4
Nb-97	-	20	20	2.6×10^7
Nd-147	Neodymium (60)	100	20	8.0 x 10 ⁴
Nd-149	, , ,	30 ´	20	1.1 x 10 ⁷
Ni-59	Nickel (28)	1000	900	8.1 x 10 ⁻²
Ni-63		1000	100	4.6 x 10 ¹
Ni-65		10	10	1.9×10^7
Np-237	Neptunium (93)	5	0.005	6.9 x 10 ⁻⁴
Np-239		200	25	2.3 x 10 ⁵
Os-185	Osmium (76)	20	20	7.3×10^3
Os-191		600	200	4.6 x 10 ⁴
Os-191m		200	200	1.2 x 10 ⁶
Os-193		100	20	5.3 x 10 ⁵
P-32	Phosphorus (15)	30	30	2.9 x 10 ⁵
Pa-230	Protactinium (91)	20	0.8	3.2 x 10 ⁴
Pa-231	Tiotaethitun (51)	2	0.002	4.5 x 10 ⁻²
Pa-233	-	100	100	2.1 x 10 ⁴
Pb-201	Lead (82)	20	20	1.7 x 10 ⁶
Pb-210	. Lead (62)	100	0.2	8.8 x 10 ¹
Pb-212		6	5	1.4 x 10 ⁶
Pd-103	Palladium (46)	1000	700	7.5 x 10 ⁴
Pd-109	r arradium (40)	100	20	2.1 x 10 ⁶
Pm-147	Promethium (61)	1000	25	9.4×10^2
	Fromedium (61)	100	20	4.2 x 10 ⁵
Pm-149	Polonium (84)	200	0.2	4.5×10^3
Po-210 Pr-142	Praseodymium (59)	10	10	1.2 x 10 ⁴
	Praseodylinium (39)	300	20	6.6 x 10 ⁴
Pr-143	Platinum (78)	100	100	2.3 x 10 ⁵
Pt-191	Platifium (78)			2.0 x 10 ⁵
Pt-193m		200	200	1.2×10^7
Pt-197m		300	20	
Pt-197	DI :	300	20	8.8 x 10 ⁵
Pu-238	Plutonium (94)	3	0.003	1.7×10^{1}
Pu-239		2	0.002	6.2 x 10 ⁻²
Pu-240		2	0.002	2.3 x 10 ⁻¹
Pu-241	•	1000	0.1	1.1×10^2
Pu-242		3 .	0.003	3.9 x 10 ⁻³
Ra-223	Radium (88)	50	0.2	5.0 x 10 ⁴
Ra-224		6	0.5	1.6×10^{5}
Ra-226		10	0.05	1.0

Symbol of radionuclide	Element and atomic number	A ₁ (Ci)	A ₂ (Ci)	Specific activity (Ci/g)
Ra-228	-	10 -	0.05	2.3 x 10 ²
Rb-81	Rubidium (37)	30	24	. 8.2 x 10 ⁶
Rb-86		30	30	8.1 x 10 ⁴
Rb-87		Unlimited	Unlimited	6.6 x 10 ⁻⁸
Rb (natural)	,	Unlimited	Unlimited	1.8 x 10 ⁻⁸
Re-186	Rhenium (75)	100	20	1.9 x 10 ⁵
Re-187		Unlimited	Unlimited	3.8 x 10 ⁻⁸
Re-188		10	10	1.0×10^6
Re (natural)		Unlimited	Unlimited	2.4 x 10 ⁻⁸
Rh-103m	Rhodium (45)	1000	1000	3.2×10^7
Rh-105		200	25	8.2 x 10 ⁵
Rn-222	Radon (86)	10	2	1.5 x 10 ⁵
Ru-97	Ruthenium (44)	80	80	5.5 x 10 ⁵
Ru-103		30	25	3.2 x 10 ⁴
Ru-105		20	20	6.6×10^6
Ru-106		10	· 7	3.4×10^3
S-35	Sulphur (16)	1000	60	4.3 x 10 ⁴
Sb-122	Antimony (51)	30	30	3.9 x 10 ⁵
Sb-124		5	5	1.8×10^4
Sb-125		40	25	1.4×10^3
Sc-46	Scandium (21)	8	8	3.4 x 10 ⁴
Sc-47		200	20	8.2 x 10 ⁵
Sc-48		5	5	1.5 x 10 ⁶
Se-75	Selenium (34)	40	40	1.4×10^4
Si-31	Silicon (14)	100	20	3.9×10^7
Sm-147	Samarium (62)	Unlimited	Unlimited	2.0 x 10 ⁻⁸
Sm-151		1000	90	2.6 x 10 ¹
Sm-153		300	20	4.4 x 10 ⁵
Sn-113 .	Tin (50)	60	60	1.0 x 10 ⁴
Sn-119m		100	100	4.4×10^3
Sn-125		10	10	1.1 x 10 ⁵
Sr-85m	Strontium (38)	80	. 80	3.2×10^7
Sr-85		30	30	2.4 x 10 ⁴
Sr-85m		50	50	1.2 x 10 ⁷
Sr-89		100	·10	2.9 x 10 ⁴
Sr-90		10	0.4	1.5×10^2
Sr-91		10	10	3.6×10^6
Sr-92		10	10	1.3×10^7
T (uncompressed)*	Tritium (1)	1000	1000	9.7×10^3
T (compressed)*		1000	1000	9.7×10^3
T (activated luminous paint)		1000	1000	9.7×10^3
T (adsorbed on solid carrier)		1000	1000	9.7×10^3
T (tritiated water)		1000	1000	9.7×10^3
T (other forms)		20	20	9.7×10^3
Ta-182	Tantalum (73)	20	20	6.2×10^3

Symbol of radionuclide	Element and atomic number	A ₁ (Ci)	A ₂ (Ci)	Specific activity (Ci/g)
Tb-160	Terbium (65)	20	10	1.1 x 10 ⁴
Tc-96m	Technetium (43)	1000	1000	3.8 x 10 ⁷
Tc-96		6	6	3.2 x 10 ⁵
Tc-97m		1000	200	1.5 x 10 ⁴
Tc-97		1000	400	1.4 x 10 ⁻³
Tc-99m	•	100	100	5.2 x 10 ⁶
Tc-99	•	1000	25	1.7 x 10 ⁻²
Te-125m	Tellurium (52)	1000 -	100	1.8 x 10 ⁴
Te-127m		300	20	4.0×10^4
Te-127		300	20	2.6 x 10 ⁶
Te-129m		30	10	2.5 x 10 ⁴
Te-129	•	100	20	2.0×10^7
Te-131m		10	. 10	8.0 x 10 ⁵
Te-132		· 7	7	3.1 x 10 ⁵
Th-227	Thorium (90)	200	0.2	3.2 x 10 ⁴
Th-228		6	0.008	8.3×10^{2}
Th-230		3	0.003	1.9 x 10 ⁻²
Th-231		1000	25	5.3 x 10 ⁵
Th-232		Unlimited	Unlimited	1.1 x 10 ⁻⁷
Th-234		10	10	2.3 x 10 ⁴
Th (natural)		Unlimited	Unlimited	2.2 x 10 ⁻⁷
Th (irradiated)**	•			
T1-200	Thallium (81)	20	20	5.8 x 10 ⁵
T1-201		200	200	2.2 x 10 ⁵
T1-202		40	40	5.4 x 10 ⁴
T1-204	•	300	10	4.3×10^2
Tm-170	Thulium (69)	300	10	6.0×10^3
Tm-171		1000	100	1.1×10^3
U-230	Uranium (92)	100	0.1	2.7 x 10 ⁴
U-232	•	30	0.03	2.1×10^{1}
U-233		100	0.1	9.5 x 10 ⁻³
U-234	•	100	0.1	6.2×10^{-3}
U-235		100	0.2	2.1 x 10 ⁻⁶
U-236		200	0.2	6.3 x 10 ⁻⁵
U-238	•	Unlimited	Unlimited	3.3 x 10 ⁻⁷
U (natural)		Unlimited	Unlimited	(see Table IV)
U (enriched) <20%		Unlimited	Unlimited	(see Table IV)
U (enriched) 20% or greater		100	0.1	(see Table IV)
U (depleted)		Unlimited	Unlimited	(see Table IV)
U (irradiated)***		, ,		
V-48	Vanadium (23)	6	6	1.7 x 10 ⁵
W-181	Tungsten (74)	200	100	5.0×10^3
W-185		1000	25	9.7 x 10 ⁻³
W-187		40	20	7.0 x 10 ^s
		- -		

Symbol of radionuclide	Element and atomic number	A ₁ (Ci)	A ₂ (Ci)	Specific activity (Ci/g)
Xe-127 (compressed)*		5	5	2.8 x 10 ⁴
Xe-131m (compressed)*	•	10	10	1.0 x 10 ⁵
Xe-131m (uncompressed)*		· 100	100	1.0 x 10 ⁵
Xe-133 (uncompressed)*		1000	1000	1.9 x 10 ⁵
Xe-133 (compressed)*		5	5	1.9 x 10 ⁵
Xe-135 (uncompressed)*		70	70	2.5 x 10 ⁵
Xe-135 (compressed)*	•	2	2	2.5 x 10 ⁵
Y-87	Yttrium (39)	20	20	4.5 x 10 ¹
Y-90	-	10	10	2.5 x 10 ⁵
Y-91m		30	30	4.1×10^7
Y-91		30	. 30	2.5 x 10 ⁴
Y-92		10	10	9.5 x 10 ⁶
Y-93	•	10	10	3.2 x 10 ⁶
Yb-169	Ytterbium (70)	80	80	2.3 x 10 ⁵
Yb-175		400	25	1.8 x 10 ⁵
Zn-65	Zinc (30)	30	30	8.0 x 10 ³
Zn-69m	,	40	20	3.3 x 10 ⁶
Zn-69		300	20	5.3 x 10 ⁷
Zr-93.	Zirconium (40)	1000	200	3.5×10^{-3}
Zr-95	,	20	20	2.1 x 10 ⁴
Zr-97	,	20	20	2.0 x 10 ⁶

^{*} For the purpose of Table I, compressed gas means a gas at a pressure which exceeds the ambient atmospheric pressure at the location where the containment system was closed.

Table II Relationship Between A_1 and E_{max} for Beta Emitters

A ₁ (Ci)	
1000	
300	
100	
30	
10	

Table III Relationship Between A₃ and the Atomic Number of the Radionuclide

	Α,			
Atomic Number	Half-life less than 1000 days	Half-life 1000 days to 10 ⁶ years	Half-life greater than 10 ⁶ years	
1 to 81	3 Ci	0.05 Ci -	3 Ci	
82 and above	0.002 Ci	0.002 Ci	3 Ci	

^{**}The values of A₁ and A₂ must be calculated in accordance with the procedure specified in Appendix A, paragraph II, 3, taking into account the activity of the fission products and of the uranium-233 in addition to that of the thorium.

*** The values of A₁ and A₂ must be calculated in accordance with the procedure specified in Appendix A, paragraph II, 3, taking into account the activity of the fission products and plutonium isotopes in addition to that of the uranium.

Table IV

Activity-Mass Relationships for Uranium/Thorium

Thorium and Ura- nium Enrichment* wt % U-235 present	Specific Activity			
	Ci/g	g/Ci		
0.45	5.0 x 10 ⁻⁷	2.0 x 10 ⁶		
0.72 (natural)	7.06 x 10 ⁻⁷	1.42 x 10 ⁶		
1.0	7.6 x 10 ⁻⁷	1.3 x 10 ⁶		
1.5	1.0 x 10 ⁻⁶	1.0×10^6		
5.0	2.7 x 10 ⁻⁶	3.7×10^{5}		
10.0	4.8 x 10 ⁻⁶	2.1 x 10 ⁵		
20.0	1.0 x 10 ⁻⁵	1.0 x 10 ⁵		
35.0	2.0×10^{-5}	5.0 x 10 ⁴		
50.0	2.5 x 10 ⁻⁵	4.0 x 10 ⁴		
90.0	5.8 x 10 ⁻⁵	1.7 x 10 ⁴		
93.0	7.0 x 10 ⁻⁵	1.4×10^4		
95.0	9.1-x 10 ⁻⁵	1.1 x 10 ⁴		
Natural Thorium	2.2 x 10 ⁻⁷	4.6 x 10 ⁶		

^{*}The figures for uranium include representative values for the activity of the uranium-234 which is concentrated during the enrichment process. The activity for thorium includes the equilibrium concentration of thorium-228.

CHAPTER 39—APPENDIX F

Criteria Relating to Use of Financial Tests and Parent Company Guarantees for Providing Reasonable Assurance of Funds for Decommissioning

I. Introduction.

An application or license may provide reasonable assurance of the availability of funds for decommissioning based on obtaining a parent company guarantee that funds will be available for decommissioning costs and on a demonstration that the parent company passes a financial test. This appendix establishes criteria for passing the financial test and for obtaining the parent company guarantee

- II. Financial Test.
- A. To pass the financial test, the parent company must meet the criteria of either paragraph A,1 or A,2 of this section:
 - 1. The parent company must have:
- (1) Two of the following three ratios: A ratio of total liabilities to net worth less than 2.0; a ratio of the sum of net income plus depreciation, depletion, and amortization to total liabilities greater than 0.1; a ratio of current assets to current liabilities greater than 1.5; and
- (2) Net working capital and tangible net worth each at least six times the current decommissioning cost estimates (or prescribed amount if a certification is used); and
 - (3) Tangible net worth of at least \$10 million; and
- (4) Assets located in the United States amounting to at least 90 percent of total assets or at least six times the cur-

rent decommissioning cost estimates (or prescribed amount if a certification is used).

2. The parent company must have:

(1) A current rating for its most recent bond issuance of AAA, AA, A, or BBB as issued by Standard and Poor's or Aaa, Aa, or Baa as issued by Moody's; and

(2) Tangible net worth at least six times the current decommissioning cost estimate (or prescribed amount if a

certification is used); and

(3) Tangible net worth of at least \$10 million; and

(4) Assets located in the United States amounting to at least 90 percent of total assets or at least six times the current decommissioning cost estimates (or prescribed

amount if a certification is used).

- B. The parent company's independent certified public accountant must have compared the data used by the parent company in the financial test, which is derived from the independently audited, year-end financial statements for the latest fiscal year, with the amounts in such financial statement. In connection with that procedure the licensee shall inform BRH within 90 days or any matters coming to the auditor's attention which cause the auditor to believe that the data specified in the financial test should be adjusted and that the company no longer passes
- C.1. After the initial financial test, the parent company must repeat the passage of the test within 90 days after the close of each succeeding fiscal year.
- 2. If the parent company no longer meets the requirements of paragraph A of this section, the licensee must send notice to the BRH of intent to establish alternate financial assurance as specified in BRH rules. The notice must be sent by certified mail within 90 days after the end of the fiscal year for which the year-end financial data show that the parent company no longer meets the financial test requirements. The licensee must provide alternate financial assurance within 120 days after the end of such fiscal year.

III. Parent Company Guarantee.

The terms of a parent company guarantee which an applicant or licensee obtains must provide that:

- A. The parent company guarantee will remain in force unless the guarantor sends notice of cancellation by certified mail to the licensee and the BRH. Cancellation may not occur, however, during the 120 days beginning on the date of receipt of the notice of cancellation by both the licensee and BRH, as evidenced by the return receipts.
- B. If the licensee fails to provide alternate financial assurance as specified in BRH rules within 90 days after receipt by the licensee and BRH notice of cancellation of the parent company guarantee from the guarantor, the guarantor will provide such alternative financial assurance in the name of the licensee.
- C. The parent company guarantee and financial test provisions must remain in effect until the BRH has terminated the license.
- D. If a trust is established for decommissioning costs, the trustee and trust must be acceptable to BRH. An acceptable trustee includes an appropriate state or federal government agency or an entity which has the authority to act as a trustee and whose trust operations are regulated and examined by a federal or state agency.

These rules are intended to implement Iowa Code chapter 136C.

ARC 3053A

PUBLIC HEALTH **DEPARTMENT[641]**

Notice of Intended Action

Twenty-five interested persons, a governmental subdivision, an agency or an association of 25 or more persons may demand an oral presentation hereon as provided in Iowa Code §17A.4(1)"b."

Notice is also given to the public that the Administrative Rules Review Committee may, on its own motion or on written request by any individual or group, review this proposed action under §17A.8(6) at a regular or special meeting where the public or interested persons may be heard.

Pursuant to the authority of Iowa Code section 136C.3. the Iowa Department of Public Health hereby gives Notice of Intended Action to rescind Chapter 40, "Standards for Protection Against Radiation," Iowa Administrative Code, and to adopt a new chapter with the same title.

The action taken is appropriate because of the number and magnitude of the additions which need to be made to the rules in order to keep current with the standards set forth by the Conference of Radiation Control Program Directors' "Suggested State Regulations for the Control of Radiation" (SSRCRs) and to remain compatible with the U.S. Nuclear Regulatory Commission (NRC) pursuant to the Agreement State Program between the Governor and the NRC. Nothing has been deleted from the rules; however, the additions to Chapter 40 necessitated renumbering of the entire chapter. These additions are specified below.

1. The proposed Chapter 40 will remain the same except for renumbering of the rules and the addition of 40.5(6), "Reporting of Defects and Noncompliance," which is modified from 10 CFR 21 to exclude portions related to power reactors. The Department deemed this addition appropriate since it requires reporting to the Department of defects in facilities or components thereof which may adversely affect the public health and safety with regard to radiation used in these facilities, such as linear accelerator facilities and positron emitting tomography facilities in which defects in the facility of basic components could be very detrimental to safety.

2. The proposed Chapter 40 has appendixes, which is again consistent with the SSRCRs. This format is much easier to work with. The material was previously contained in the body of the rules of each chapter. In addition, the appendix material is now in the same chapter as the rule which refers to it, thus making the rules easier to

use

Any interested person may make written suggestions or comments on the proposed new Chapter 40 on or before close of business June 17, 1992. Such written material should be directed to Donald A. Flater, Chief, Bureau of Environmental Health, Iowa Department of Public Health, Lucas State Office Building, Des Moines, Iowa 50319, FAX (515)242-5284.

A public hearing will be held on June 17, 1992, at 9 a.m. in the Third Floor Conference Room, Lucas State Office Building, at which time persons may present their views orally or in writing. At the hearing, persons will be asked to give their name, address, and whom they represent. Presenters will also be asked to confine their remarks to the subject of the rules.

These rules are intended to implement Iowa Code chapter 136C.

The following new chapter is proposed. Rescind 641—Chapter 40 and insert the following in lieu thereof:

CHAPTER 40

STANDARDS FOR PROTECTION AGAINST RADIATION

641—40.1(136C) Purpose and scope.

40.1(1) This chapter establishes standards for protection against radiation hazards. Except as otherwise specifically provided, this chapter applies to all licensees and registrants. It is the purpose of the rules in this chapter to control the possession, use, and transfer of sources of radiation by any licensee or registrant in such a manner that the total dose to an individual does not exceed the standards of radiation protection prescribed in this chapter. Nothing in this chapter shall be interpreted as limiting the intentional exposure of patients to radiation for the purpose of medical diagnosis or therapy.

40.1(2) In addition to complying with the requirements set forth in this chapter, every reasonable effort should be made to maintain radiation exposures and releases of radioactive material in effluents to unrestricted areas as low as is reasonably achievable (ALARA). The term "as low as is reasonably achievable" means as low as is reasonably achievable taking into account the state of technology and the economics of improvements in relation to benefits to the public health and safety, other societal and socioeconomic considerations, and in relation to the utilization of ionizing radiation in the public inter-

40.1(3) All references to any Code of Federal Regulations (CFR) in this chapter are those in effect as of September 1, 1992.

641-40.2(136C) Permissible doses, levels, and concentrations.

- 40.2(1) Radiation dose standards for individuals in restricted areas. A dose from X- or gamma rays up to 10 MeV may be assumed to be equivalent to the exposure measured by a properly calibrated appropriate instrument in air at or near the body surface in the region of the highest dose rate.
- a. In accordance with the provisions of 40.2(2)"a," and except as provided in 40.2(1)"b," no licensee or registrant shall possess, use, receive, or transfer sources of radiation in such a manner as to cause any individual in a restricted area to receive in any period of one calendar quarter from all sources of radiation a total occupational dose in excess of the standards specified in the following table:

Rems (Sv) per Calendar Ouarter

Whole body; head and trunk; active blood-forming organs; Hands and forearms; feet and Skin of whole body 7 1/2 (75 mSv)

- b. A licensee or registrant may permit an individual in a restricted area to receive a total occupational dose to the whole body greater than that permitted under 40.2(1)"a,"
- (1) During any calendar quarter, the total occupational dose to the whole body shall not exceed 3 rems (30 mSv);

(2) The dose to the whole body, when added to the accumulated occupational dose to the whole body, shall not exceed 5(N-18) rems (50(N-18) mSv) where "N" equals the individual's age in years at the last birthday; and

(3) The licensee or registrant has determined the individual's accumulated occupational dose to the whole body on agency Form Y or on a clear and legible record containing all the information required in that form and has otherwise complied with the requirements of 40.2(2). As used in 40.2(1)"b," "dose to the whole body" shall be deemed to include any dose to the whole body, gonads, active blood-forming organs, head and trunk, or lens of

40.2(2) Determination of accumulated dose.

a. (1) Each licensee or registrant shall require any individual, prior to first entry of the individual into the licensee's or registrant's restricted area during each employment or work assignment under such circumstances that the individual will receive or is likely to receive in any period of one calendar quarter an occupational dose in excess of 25 percent of the applicable standards specified in 40.2(1) a and 40.2(4) a to disclose in a written, signed statement either

1. That the individual had no prior occupational dose

during the current calendar quarter, or

The nature and amount of any occupational dose which the individual may have received during the specifically identified current calendar quarter from sources of radiation possessed or controlled by other persons.

(2) Each licensee or registrant shall maintain records of such statements until the agency authorizes disposition.

- b. Pursuant to 40.2(1)"b," before permitting any individual in a restricted area to receive an occupational radiation dose in excess of the standards specified in 40.2(1)"a," each licensee or registrant shall:
- (1) Obtain a certificate on agency form: Current Occupational External Radiation Exposure," or on a clear and legible record containing all the information required in that form, signed by the individual, showing each period of time after the individual attained the age of 18 in which the individual received an occupational dose of radiation; and
- (2) Calculate on agency form "Current Occupational External Radiation Exposure" in accordance with the instructions appearing therein, or on a clear and legible record containing all the information required in that form, the previously accumulated occupational dose received by the individual and the additional dose allowed for that individual under 40.2(1)"b."
- c. (1) In the preparation of agency form "Current Occupational External Radiation Exposure," or a clear and legible record containing all the information required in that form, the licensee or registrant shall make a reasonable effort to obtain reports of the individual's previously accumulated occupational dose. For each period for which the licensee or registrant obtains such reports, the licensee or registrant shall use the dose shown in the report in preparing the form. In any case where a licensee or registrant is unable to obtain reports of the individual's occupational dose for a previous complete calendar quarter, it shall be assumed that the individual has received the occupational dose specified in whichever of the following columns apply:

Column 1 Assumed Dose in Rems (mSv) for Calendar **Quarters Prior** to January 1. 1961

Column 2 Assumed Dose in Rems (mSv) for Calendar Ouarters Beginning on or After January 1, 1961

Part of Body

Whole body, gonads, active blood-forming organs, head and trunk,

3 3/4 (37.5 mSv) 1 1/4(12.5 mSv)

- (2) The licensee or registrant shall retain and preserve records used in preparing agency form "Current Occupational External Radiation Exposure" until the agency authorizes their disposition. If calculation of the individual's accumulated occupational dose for all periods prior to January 1, 1961, yields a result higher than the applicable accumulated dose value for the individual as of that date, as specified in 40.2(1)"b"(2), the excess may be disregarded.
- **40.2(3)** Exposure of individuals to concentrations of radioactive material in air in restricted areas.
- a. (1) No licensee shall possess, use, or transfer radioactive material in such a manner as to permit any individual in a restricted area to inhale a quantity of radioactive material in any period of one calendar quarter greater than the quantity which would result from inhalation for 40 hours per week for 13 weeks at uniform concentrations of radioactive material in air specified in Appendix A, Table I, Column 1 of this chapter.

1. Since the concentration specified for tritium oxide vapor assumes equal intakes by skin absorption and inhalation, the total intake permitted is twice that which would result from inhalation alone at the concentration specified for H-3(S) in Appendix A, Table I, Column 1 of

this chapter for 40 hours per week for 13 weeks.

2. For radon-222, the limiting quantity is that inhaled in a period of one calendar year. For radioactive material designated "Sub" in the "Radionuclide" column of the table, the concentration value specified is based upon exposure to the material as an external radiation source. Individual exposures to these materials may be accounted for as part of the limitation on individual dose in 40.2(1). These nuclides shall be subject to the precautionary procedures required by 40.2(3)"b"(1).

3. Multiply the concentration values specified in Appendix A, Table I, Column 1 of this chapter by 6.3 x 108 milliliters to obtain the quarterly quantity limit. Multiply the concentration value specified in Appendix A, Table I, Column 1 of this chapter by 2.5 x 10° milliliters to obtain

the annual quantity limit for Rn-222.

(2) If the radioactive material is of such form that intake by absorption through the skin is likely, individual exposures to radioactive material shall be controlled so that the uptake of radioactive material by any organ from either inhalation or absorption or both routes of intake in any calendar quarter does not exceed that which would result from inhaling such radioactive material for 40 hours per week for 13 weeks at uniform concentrations specified in Appendix A, Table I, Column 1 of this chapter.

1. Significant intake by ingestion or injection is presumed to occur only as a result of circumstances such as accident, inadvertence, poor procedure, or similar special conditions. Such intakes must be evaluated and accounted for by techniques and procedures as may be appropriate to the circumstances of the occurrence. Exposures so evaluated shall be included in determining whether the limitation on individual exposures in 40.2(3)"a"(1) has been exceeded.

2. Regulatory guidance on assessment of individual intakes of radioactive material is given in U.S. Nuclear Regulatory Commission Regulatory Guide 8.9, "Acceptable Concepts, Models, Equations and Assumptions for a Bioassay Program." Single copies of Regulatory Guide 8.9 are available from the Office of Standards Development, U.S. Nuclear Regulatory Commission, Washington,

D.C. 20555, upon written request.

(3) No licensee shall possess, use, or transfer mixtures of U-234, U-235, and U-238 in soluble form in such a manner as to permit any individual in a restricted area to inhale a quantity of such material in excess of the intake limits specified in Appendix A, Table I, Column 1 of this chapter

1. If such soluble uranium is of a form such that absorption through the skin is likely, individual exposures to such material shall be controlled so that the uptake of such material by any organ from either inhalation or absorption or both routes of intake does not exceed that which would result from inhaling such material at the limits specified in Appendix A, Table I, Column 1 of this chapter.

2. Significant intake by ingestion or injection is presumed to occur only as a result of circumstances such as accident, inadvertence, poor procedure, or similar special conditions. Such intakes must be evaluated and accounted for by techniques and procedures as may be appropriate to the circumstances of the occurrence. Exposures so evaluated shall be included in determining whether the limitation on individual exposures in

40.2(3)"a"(1) has been exceeded.

- (4) For purposes of determining compliance with the requirements of 40.2(3), the licensee shall use suitable measurements of concentrations of radioactive material in air for detecting and evaluating airborne radioactivity in restricted areas and in addition, as appropriate, shall use measurements of radioactivity in the body, measurements of radioactivity excreted from the body, or any combination of such measurements as may be necessary for timely detection and assessment of individual intakes of radioactivity by exposed individuals. It is assumed that an individual inhales radioactive material at the airborne concentration unless the individual uses respiratory protective equipment pursuant to 40.2(3)"c." When assessment of a particular individual's intake of radioactive material is necessary, intakes less than those which would result from inhalation for 2 hours in any one day or for 10 hours in any one week at uniform concentrations specified in Appendix A, Table I, Column 1 of this chapter need not be included in such assessment, provided that for any assessment in excess of these amounts the entire amount is included.
- b. (1) The licensee shall, as a precautionary procedure, use process or other engineering controls, to the extent practicable, to limit concentrations of radioactive material in air to levels below those which delimit an airborne radioactivity area as defined in 641—38.2(136C).

- (2) When it is impracticable to apply process or other engineering controls to limit concentrations of radioactive material in air below those defined in 641—38.2(136C), other precautionary procedures, such as increased surveillance, limitation of working times, or provision of respiratory protective equipment, shall be used to maintain intake of radioactive material by any individual within any period of seven consecutive days as far below that intake of radioactive material which would result from inhalation of such material for 40 hours at the uniform concentrations specified in Appendix A, Table I, Column 1 of this chapter as is reasonably achievable. Whenever the intake of radioactive material by any individual exceeds this 40-hour control measure, the licensee shall make such evaluations and take such actions as are necessary to ensure against recurrence. The licensee shall maintain records of such occurrences, evaluations, and actions taken in a clear and readily identifiable form suitable for summary review and evaluation.
- c. When respiratory protective equipment is used to limit the inhalation of airborne radioactive material pursuant to 40.2(3)"b"(2), the licensee may make allowance for such use in estimating exposures of individuals to such material provided that such equipment is used as stipulated in U.S. Nuclear Regulatory Commission Regulatory Guide 8.15, "Acceptable Programs for Respiratory Protection." Single copies of U.S. Nuclear Regulatory Commission Regulatory Guide 8.15 are available from the Office of Standards Development, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, upon written request.

d. Notwithstanding the provisions of 40.2(3)"b" and "c," the agency may impose further restrictions:

- (1) On the extent to which a licensee may make allowance for use of respirators in lieu of provision of process, containment, ventilation, or other engineering controls, if application of such controls is found to be practicable; and
- (2) As might be necessary to ensure that the respiratory protective program of the licensee is adequate in limiting exposures of personnel to airborne radioactive material.
- e. The licensee shall notify, in writing, the agency at least 30 days before the date that respiratory protective equipment is first used under the provisions of 40.2(3).
- f. A licensee who was authorized to make allowance for use of respiratory protective equipment prior to the effective date of these rules shall bring the licensee's respiratory protective program into conformance with the requirements of 40.2(3)"c" within one year of that date and is exempt from the requirements of 40.2(3)"e."

40.2(4) Exposure of minors. For determining the doses specified in 40.2(4), a dose from X- or gamma rays up to 10 MeV may be assumed to be equivalent to the exposure measured by a properly calibrated appropriate instrument in air at or near the body surface in the region of the highest dose rate.

- a. No licensee or registrant shall possess, use, or transfer sources of radiation in such a manner as to cause any individual within a restricted area, who is under 18 years of age, to receive in any period of one calendar quarter from all sources of radiation-in such licensee's or registrant's possession a dose in excess of 10 percent of the standards specified in the table in 40.2(1)"a."
- b. No licensee shall possess, use, or transfer radioactive material in such a manner as to cause any individual

within a restricted area, who is under 18 years of age, to be exposed to airborne radioactive material in an average concentration in excess of the limits specified in Appendix A, Table II, of this chapter. For purposes of this paragraph, concentrations may be averaged over periods not greater than a week.

c. The provisions of 40.2(3)"b"(2) and 40.2(3)"c" shall apply to exposures subject to 40.2(4)"b" except that the references in 40.2(3)"b"(2) and 40.2(3)"c" to Appendix A, Table I, Column 1 of this chapter shall be deemed to be references to Appendix A, Table II, Column 1 of this

chapter.

- **40.2(5)** Permissible levels of radiation from external sources in unrestricted areas. It is the intent of this subrule to limit radiation levels so that it is unlikely that individuals in unrestricted areas would receive a dose to the whole body in excess of 0.5 rem (5.0 mSv) in any one year. If in specific instances it is determined by the agency that this intent is not met, the agency may, pursuant to 641—subrule 38.4(4), impose such additional requirements on the licensee or registrant as may be necessary to meet the intent.
- Except as authorized by the agency pursuant to 40.2(5)"b," no licensee or registrant shall possess, use, or transfer sources of radiation in such a manner as to create in any unrestricted area from such sources of radiation in the possession of the licensee or registrant:

(1) Radiation levels which, if an individual were continuously present in the area, could result in the individual's receiving a dose in excess of 2 millirems (0.02 mSv)

in any one hour; or

(2) Radiation levels which, if an individual were continuously present in the area, could result in the individual's receiving a dose in excess of 100 millirems (1.0 mSv)

in any seven consecutive days.

- b. Any person may apply to the agency for proposed limits upon levels of radiation in unrestricted areas in excess of those specified in 40.2(5)"a" resulting from the applicant's possession or use of sources of radiation. Such applications should include information as to anticipated average radiation levels and anticipated occupancy times for each unrestricted area involved. The agency will approve the proposed limits if the applicant demonstrates to the satisfaction of the agency that the proposed limits are not likely to cause any individual to receive a dose to the whole body in any period of one calendar year in excess of 0.5 rem (5.0 mSv).
- 40.2(6) Concentration of radioactivity in effluents to unrestricted areas.
- A licensee shall not possess, use, or transfer licensed material so as to release to an unrestricted area radioactive material in concentrations which exceed the limits specified in Appendix A, Table II of this chapter, except as authorized pursuant to 40.4(2) or this subrule. For purposes of this subrule, concentrations may be averaged over a period not greater than one year.

b. An application for a license or amendment may include proposed limits higher than those specified in 40.2(6)"a." The agency will approve the proposed limits

if the applicant demonstrates:

- (1) That the applicant has made a reasonable effort to minimize the radioactivity contained in effluents to unrestricted areas; and
- (2) That it is not likely that radioactive material discharged in the effluent would result in the exposure of an

individual to concentrations of radioactive material in air or water exceeding the limits specified in Appendix A, Table II of this chapter.

An application for higher limits pursuant to 40.2(6)"b" shall include information demonstrating that the applicant has made a reasonable effort to minimize the radioactivity discharged in effluents to unrestricted

areas and shall include, as pertinent:

- (1) Information as to flow rates, total volume of effluent, peak concentration of each radionuclide in the effluent, and concentration of each radionuclide in the effluent averaged over a period of one year at the point where the effluent leaves a stack, tube, pipe, or similar conduit;
- (2) A description of the properties of the effluents, including:

1. Chemical composition,

- 2. Physical characteristics, including suspended solids content in liquid effluents, and nature of gas or aerosol for air effluents,
- 3. The hydrogen ion concentrations (pH) of liquid effluents, and
- 4. The size range of particulates in effluents released
- (3) A description of the anticipated human occupancy in the unrestricted area where the highest concentration of radioactive material from the effluent is expected and, in the case of a river or stream, a description of water uses downstream from the point of release of the effluent;
- (4) Information as to the highest concentration of each radionuclide in an unrestricted area, including anticipated concentrations averaged over a period of one year:

In air at any point of human occupancy, or

- In water at points of use downstream from the point of release of the effluent;
- (5) The background concentration of radionuclides in the receiving river or stream prior to the release of liquid
- A description of the environmental monitoring equipment, including sensitivity of the system, and procedures and calculations to determine concentrations of radionuclides in the unrestricted area and possible reconcentrations of radionuclides; and
- (7) A description of the waste treatment facilities and procedures used to reduce the concentration of radionuclides in effluents prior to their release.
- d. For the purposes of this subrule the concentration limits in Appendix A, Table II of this chapter shall apply at the boundary of the restricted area. The concentration of radioactive material discharged through a stack, pipe, or similar conduit may be determined with respect to the point where the material leaves the conduit. If the conduit discharges within the restricted area, the concentration at the boundary may be determined by applying appropriate factors for dilution, dispersion, or decay between the point of discharge and the boundary.
- e. In addition to limiting concentrations in effluent streams, the agency may limit quantities of radioactive material released in air or water during a specified period of time if it appears that the daily intake of radioactive material from air, water, or food by a suitable sample of an exposed population group, averaged over a period not exceeding one year, would otherwise exceed the daily intake resulting from continuous exposure to air or water containing one-third the concentration of radioactive material specified in Appendix A, Table II of this chapter.

f. The provisions of this subrule do not apply to disposal of radioactive material into sanitary sewage systems, which is governed by 40.4(3).

g. In addition to other requirements of this chapter, licensees engaged in uranium fuel cycle operations shall comply with the provisions of 40 CFR Part 190, "Environmental Radiation Protection Standards for Nuclear

Power Operations."

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40.2(7) Orders requiring furnishing of bioassay services. Where necessary or desirable in order to aid in determining the extent of an individual's exposure to concentrations of radioactive material, the agency may incorporate license provisions or issue an order requiring a licensee or registrant to make available to the individual appropriate bioassay services and to furnish a copy of the reports of such services to the agency.

641-40.3(136C) Precautionary procedures.

40.3(1) Surveys. Each licensee or registrant shall make or cause to be made such surveys as may be necessary to establish compliance with these rules and are reasonable under the circumstances to evaluate the extent of radiation hazards that may be present.

40.3(2) Personnel monitoring.

a. Each licensee or registrant shall supply appropriate personnel monitoring equipment to and require its use by:

(1) Each individual who enters a restricted area under such circumstances that the individual receives, or is likely to receive, a dose in any calendar quarter in excess of 25 percent of the applicable value specified in 40.2(1)"a:"

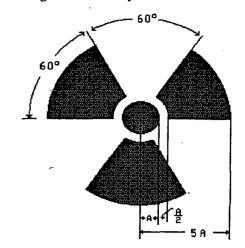
- (2) Each individual under 18 years of age who enters a restricted area under such circumstances that the individual receives, or is likely to receive, a dose in any calendar quarter in excess of 5 percent of the applicable value specified in 40.2(1)"a."
 - (3) Each individual who enters a high radiation area.
- b. Except as noted in 40.2(3)"c," all personnel dosimeters that require processing to determine the radiation dose and are utilized by licensees or registrants to comply with 40.2(3)"a," with other applicable chapters of these rules, or with conditions specified in a license or a certificate of registration shall be processed and evaluated by a dosimetry processor currently accredited by the National Voluntary Laboratory Accreditation Program of the National Institute of Standards and Technology and approved in this accreditation process for the type of radiation or radiations that most closely approximate the type of radiation or radiations for which the individual wearing the dosimeter is monitored.
- c. The requirements of 40.2(3)"b" do not apply to personnel dosimeters used to measure the dose to hand and forearms and feet and ankles.
 - 40.3(3) Caution signs, labels, and signals.

a. General.

(1) Except as otherwise authorized by the agency, symbols prescribed by this subrule shall use the conventional radiation caution colors (magenta or purple on yellow background). The symbol prescribed by this paragraph is the conventional three-blade design:

RADIATION SYMBOL

- 1. Gray area in diagram below is to be magenta or purple.
 - 2. Background is to be yellow.



- (2) In addition to the contents of signs and labels prescribed in this paragraph, a licensee or registrant may provide on or near such signs and labels any additional information which may be appropriate in aiding individuals to minimize exposure to radiation.
- b. Radiation areas. Each radiation area shall be conspicuously posted with a sign or signs bearing the radiation caution symbol and the words:

CAUTION (or "DANGER") RADIATION AREA

c. High radiation areas.

(1) Each high radiation area shall be conspicuously posted with a sign or signs bearing the radiation caution symbol and the words:

CAUTION (or "DANGER") HIGH RADIATION AREA

- (2) Each entrance or access point to a high radiation area shall be:
- 1. Equipped with a control device which shall cause the level of radiation to be reduced below that at which an individual might receive a dose of 100 millirems (1.0 mSv) in one hour upon entry into the area; or
- 2. Equipped with a control device which shall energize a conspicuous visible or audible alarm signal in such a manner that the individual entering the high radiation area and the licensee or a supervisor of the activity are made aware of the entry; or

3. Maintained locked except during periods when access to the area is required, with positive control over each individual entry.

(3) The controls required by 40.3(3)"c"(2) shall be established in such a way that no individual will be prevented from leaving a high radiation area.

(4) In the case of a high radiation area established for a period of 30 days or less, direct surveillance to prevent unauthorized entry may be substituted for the controls required by 40.3(3)"c"(2).

(5) Any licensee or registrant may apply to the agency for approval of methods not included in 40.3(3)"c"(2) and (4) for controlling access to high radiation areas. The agency will approve the proposed alternatives if the licensee or registrant demonstrates that the alternative methods of control will prevent unauthorized entry into a high radiation area and that the requirement of 40.3(3)"c"(3) is met.

(6) Each area in which there may exist radiation levels in excess of 500 rems (5.0 Sv) in one hour at one meter from a sealed radioactive source that is used to irradiate materials shall have entry control devices and alarms meeting the criteria specified in 20.203(c)(6) of 10 CFR

Part 20.

- (7) The requirements of 40.3(3)"c"(6) shall not apply to radioactive sources that are used in teletherapy, industrial radiography, or in completely self-contained irradiators. In the case of open field irradiators in which certain of the criteria specified in 40.3(3)"c"(6) are impracticable, equivalent protection shall be provided by license conditions. At least one of the alternative measures must include an entry-preventing interlock control based on a physical measurement of radiation that ensures the absence of high radiation levels before an individual can gain access to an area where such sources are used.
- d. Airborne radioactivity areas. Each airborne radioactivity area shall be conspicuously posted with a sign or signs bearing the radiation caution symbol and the words:

CAUTION (or "DANGER") AIRBORNE RADIOACTIVITY AREA

e. Additional requirements.

(1) Each area or room in which any radioactive material other than natural uranium or thorium is used or stored in an amount exceeding 10 times the quantity of radioactive material specified in Appendix B of this chapter shall be conspicuously posted with a sign or signs bearing the radiation caution symbol and the words:

CAUTION (or "DANGER") RADIOACTIVE MATERIAL

(2) Each area or room in which natural uranium or thorium is used or stored in an amount exceeding 100 times the quantity specified in Appendix B of this chapter shall be conspicuously posted with a sign or signs bearing the radiation caution symbol and the words:

CAUTION (or "DANGER") RADIOACTIVE MATERIAL

f. Containers.

(1) Except as provided in 40.3(3)"f"(3), each container of radioactive material shall bear a durable, clearly visible label identifying the radioactive contents.

(2) A label required pursuant to 40.3(3)"f"(1) shall

bear the radiation caution symbol and the words:

CAUTION (or "DANGER") RADIOACTIVE MATERIAL

It shall also provide sufficient information to permit individuals handling or using the containers, or working in the vicinity thereof, to take precautions to avoid or minimize exposures. As appropriate, the information will include

radiation levels, kinds of material, estimate of activity, date for which activity is estimated, etc.

(3) Notwithstanding the provisions of 40.3(3)"f"(1),

labeling is not required:

1. For containers that do not contain radioactive material in quantities greater than the applicable quantities listed in Appendix B of this chapter;

2. For containers containing only natural uranium or thorium in quantities no greater than 10 times the applicable quantities listed in Appendix B of this chapter;

- 3. For containers that do not contain radioactive material in concentrations greater than the applicable concentrations listed in Appendix A, Table I, Column 2 of this chapter;
- 4. For containers when they are attended by an individual who takes the precautions necessary to prevent the exposure of any individual to radiation or radioactive material in excess of the limits established by the rules in this chapter;
- 5. For containers when they are in transport and packaged and labeled in accordance with regulations published
- by the U.S. Department of Transportation;
- 6. For containers which are accessible only to individuals authorized to handle or use them (for example, containers in locations such as water-filled canals, storage vaults, or hot cells) or to work in the vicinity thereof, provided that the contents are identified to such individuals by a readily available written record; and

7. For manufacturing and process equipment such as

piping and tanks.

- (4) Each licensee shall, prior to disposal of an empty uncontaminated container to unrestricted areas, remove or deface the radioactive material label or otherwise clearly indicate that the container no longer contains radioactive material.
- g. All radiation machines shall be labeled in a manner which cautions individuals that radiation is produced when the machine is being operated.

40.3(4) Exceptions from posting and labeling requirements. Notwithstanding the provisions of 40.3(3):

- a. A room or area is not required to be posted with a caution sign because of the presence of a sealed source, provided the radiation level 12 inches (30.5 cm) from the surface of the source container or housing does not exceed 5 millirems per hour (0.05 mSv/h).
- b. Rooms or other areas in hospitals are not required to be posted with caution signs, and control of entrance or access thereto pursuant to 40.3(3)"c" is not required, because of the presence of patients containing radioactive material provided that there are personnel in attendance who will take the precautions necessary to prevent the exposure of any individual to radiation or radioactive material in excess of the limits established in the rules in this chapter.
- c. Caution signs are not required to be posted in areas or rooms containing radioactive material for periods of less than eight hours provided that:
- (1) The material is constantly attended during such periods by an individual who shall take the precautions necessary to prevent the exposure of any individual to radiation or radioactive material in excess of the limits established in this chapter, and

(2) Such area or room is subject to the licensee's or

registrant's control.

d. A room or other area is not required to be posted with a caution sign, and control is not required for each entrance or access point to a room or other area which is a

high radiation area solely because of the presence of radioactive material prepared for transport and packaged and labeled in accordance with regulations of the U.S. Department of Transportation.

40.3(5) Instruction of personnel. Instructions required for individuals working in or frequenting any portion of a

restricted area are specified in 40.6(3).

40.3(6) Storage and control of sources of radiation.

a. Sources of radiation shall be secured against unauthorized removal from the place of storage.

b. Sources of radiation in an unrestricted area and not in storage shall be tended under the constant surveillance and immediate control of the licensee or registrant.

40.3(7) Procedures for picking up, receiving, and

opening packages.

- a. (1) Each licensee or registrant who expects to receive a package containing quantities of radioactive material in excess of the A₁ or A₂ quantities specified in Appendix E of 641—Chapter 39 shall:
- 1. If the package is to be delivered to the licensee's or registrant's facility by the carrier, make arrangements to receive the package when it is offered for delivery by the carrier; or
- 2. If the package is to be picked up by the licensee or registrant at the carrier's terminal, make prior arrangements to receive notification from the carrier of the arrival of the package, at the time of arrival.

(2) Each licensee or registrant who picks up a package of radioactive material from a carrier's terminal shall pick up the package expeditiously upon receipt of notification

from the carrier of its arrival.

- b. (1) Each licensee or registrant, upon receipt of a package of radioactive material, shall monitor the external surfaces of the package for radioactive contamination caused by leakage of the radioactive contents. The monitoring shall be performed as soon as practicable after receipt, but no later than 3 hours after the package is received at the licensee's facility if received during the licensee's normal working hours or 18 hours if received after normal working hours. Such monitoring need not be performed on:
- 1. Packages containing no more than 10 microcuries (370 kBq) of alpha-emitting radioactive material or no more than 1 millicurie (37 MBq) of other radioactive material;
- 2. Packages containing no more than 10 millicuries (370 MBq) of radioactive material consisting solely of tritium, carbon-14, sulfur-35, or iodine-125;

3. Packages containing only special form radioactive material or gases;

4. Packages containing only radioactive material in other than liquid form, including Mo-99/Tc-99m generators, and no more than the A₂ quantity specified in Appendix E of 641—Chapter 39; and

5. Packages containing only radionuclides with halflives of less than 30 days and a total quantity of no more

than 100 millicuries (3.7 GBq).

- (2) If removable radioactive contamination in excess of 0.01 microcurie (370 Bq) per 100 square centimeters of package surface is found on the external surfaces of the package, the licensee or registrant shall immediately notify, by telephone and telegraph, the final delivering carrier and the agency.
- c. (1) Each licensee or registrant, upon receipt of a package containing quantities of radioactive material in excess of the A, or A₂ quantities specified in Appendix E

of 641—Chapter 39, other than those transported by exclusive use vehicle, shall monitor the radiation levels external to the package. The package shall be monitored as soon as practicable after receipt, but no later than 3 hours after the package is received at the licensee's facility if received during the licensee's normal working hours, or 18 hours if received after normal working hours.

(2) If radiation levels are found on the external surface of the package in excess of 200 millirems per hour (2.0 mSv/h), or in excess of 10 millirems per hour (0.1 mSv/h) at 3 feet (0.9 m) from the external surface of the package, the licensee or registrant shall immediately notify, by telephone and telegraph, the final delivering carrier and

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d. Each licensee or registrant shall establish and maintain procedures for safely opening packages in which radioactive material is received and shall ensure that such procedures are followed and that due consideration is given to special instructions for the type of package being opened.

641-40.4(136C) Waste disposal.

40.4(1) General requirement. No licensee shall dispose of any radioactive material except:

a. By transfer to an authorized recipient as provided in

641—39.4(40), or

b. As authorized pursuant to 40.2(6), 40.4(2), 40.4(3), or 40.4(4).

40.4(2) Method of obtaining approval of proposed disposal procedures.

- a. Any person may apply to the agency for approval of proposed procedures to dispose of radioactive material in a manner not otherwise authorized in this chapter. Each application shall include a description of the radioactive material, including the quantities and kinds of radioactive material and levels of radioactivity involved, and the proposed manner and conditions of disposal. The application, where appropriate, should also include an analysis and evaluation of pertinent information as to the nature of the environment, including topographical, geological, meteorological, and hydrological characteristics; usage of ground and surface waters in the general area; the nature and location of other potentially affected facilities; and procedures to be observed to minimize the risk of unexpected or hazardous exposures.
- b. The agency will not approve any application for a license to receive radioactive material from other persons for disposal on land not owned by a state or the federal government.

40.4(3) Disposal by release into sanitary sewage systems

 a. No licensee shall discharge radioactive material into a sanitary sewage system unless:

(1) It is readily soluble or dispersible in water;

(2) The quantity of any radioactive material released into the system by the licensee in any one day does not exceed the larger of:

1. The quantity which, if diluted by the average daily quantity of sewage released into the sewer by the licensee, will result in an average concentration equal to the limits specified in Appendix A, Table I, Column 2 of this chapter, or

2. Ten times the quantity of such material specified in

Appendix B of this chapter;

(3) The quantity of any radioactive material released in any one month, if diluted by the average monthly quan-

tity of water released by the licensee, will not result in an average concentration exceeding the limits specified in Appendix A, Table I, Column 2 of this chapter; and

(4) The gross quantity of radioactive material, excluding hydrogen-3 and carbon-14, released into the sewage system by the licensee does not exceed 1 curie (37 GBq) per year. The quantities of hydrogen-3 and carbon-14 released into the sanitary sewage system may not exceed 5 curies (185 GBq) per year for hydrogen-3 and 1 curie (37 GBq) per year for carbon-14.

b. No licensee shall discharge radioactive material into an individual sewage disposal system used for the treatment of wastewater serving only a single dwelling, office building, industrial plant, or institution except as specifically approved by the agency pursuant to 40.2(6) and

40.4(2).

c. Excreta from individuals undergoing medical diagnosis or therapy with radioactive material shall be exempt from any limitations contained in this subrule.

40.4(4) Disposal by burial in soil. No licensee shall dispose of radioactive material by burial in soil except as specifically approved by the agency pursuant to 40.4(2).

- 40.4(5) Disposal by incineration. No licensee shall incinerate radioactive material for the purpose of disposal or preparation for disposal except as specifically approved by the agency pursuant to 40.2(6) and 40.4(2).
 - 40.4(6) Disposal of specific wastes.

a. Any licensee may dispose of the following radioactive material without regard to its radioactivity:

- (1) 0.05 microcurie (1.850 kBq) or less of hydrogen-3 or carbon-14 per gram of medium used for liquid scintillation counting, and
- (2) 0.05 microcurie (1.850 kBq) or less of hydrogen-3 or carbon-14 per gram of animal tissue averaged over the weight of the entire animal; provided, however, tissue may not be disposed of under this subrule in a manner that would permit its use either as food for humans or as animal feed.
- b. Nothing in 40.4(6)"a," however, relieves the licensee of maintaining records showing the receipt, transfer and disposal of such radioactive material as specified in 641—subrule 38.4(1).
- c. Nothing in 40.4(6)"a" relieves the licensee from complying with other applicable federal, state, and local regulations governing any other toxic or hazardous property of these materials.

40.4(7) Classification of radioactive waste for near-surface disposal.

- a. Considerations. Determination of the classification of waste involves two considerations. First, consideration must be given to the concentration of long-lived radionuclides (and their shorter-lived precursors) whose potential hazard will persist long after such precautions as institutional controls, improved waste form, and deeper disposal have ceased to be effective. These precautions delay the time when long-lived radionuclides could cause exposures. In addition, the magnitude of the potential dose is limited by the concentration and availability of the radionuclide at the time of exposure. Second, consideration must be given to the concentration of shorter-lived radionuclides for which requirements on institutional controls, waste form, and disposal methods are effective.
 - b. Classes of waste.
- (1) Class A waste is waste that is usually segregated from other waste classes at the disposal site. The physical form and characteristics of Class A waste must meet the minimum requirements set forth in 40.4(8)"a." If Class A

waste also meets the stability requirements set forth in 40.4(8)"b," it is not necessary to segregate the waste for disposal.

- (2) Class B waste is waste that must meet more rigorous requirements on waste form to ensure stability after disposal. The physical form and characteristics of Class B waste must meet both the minimum and stability requirements set forth in 40.4(8).
- (3) Class C waste is waste that not only must meet more rigorous requirements on waste form to ensure stability but also requires additional measures at the disposal facility to protect against inadvertent intrusion. The physical form and characteristics of Class C waste must meet both the minimum and stability requirements set forth in 40.4(8).
- c. Classification determined by long-lived radionuclides. If the waste contains only radionuclides listed in Table 1, classification shall be determined as follows:
- (1) If the concentration does not exceed 0.1 times the value in Table 1, the waste is Class A.
- (2) If the concentration exceeds 0.1 times the value in Table 1 but does not exceed the value in Table 1, the waste is Class C.
- (3) If the concentration exceeds the value in Table 1, the waste is not generally acceptable for near-surface disposal.
- (4) For wastes containing mixtures of radionuclides listed in Table 1, the total concentration shall be determined by the sum of fractions rule described in 40.4(7)"g."

Table 1

Radionuclide	Concentration (curies/cubic meter	
C-14	 8	
C-14 in activated metal	80	
Ni-59 in activated metal	220	
Nb-94 in activated metal	0.2	
Tc-99	3	
I-129	0.08	
Radionuclide	Concentration (curies/cubic meter)*	

Alpha-emitting transuranic radionuclides with half-life greater than five years 100 (*)
Pu-241 3,500 (*)
Cm-242 20,000 (*)
Ra-226 100 (*)

(*) Units are nanocuries per gram. To convert nanocuries to becquerels (Bq), multiply by 37. To convert curies to gigabecquerels (GBq), multiply by 37.

- d. Classification determined by short-lived radionuclides. If the waste does not contain any of the radionuclides listed in Table 1, classification shall be determined based on the concentrations shown in Table 2. If the waste does not contain any nuclides listed in either Table 1 or 2, it is Class A.
- (1) If the concentration does not exceed the value in Column 1, the waste is Class A.

- (2) If the concentration exceeds the value in Column 1, but does not exceed the value in Column 2, the waste is Class B.
- (3) If the concentration exceeds the value in Column 2, but does not exceed the value in Column 3, the waste is Class C.
- (4) If the concentration exceeds the value in Column 3, the waste is not generally acceptable for near-surface disposal.
- (5) For wastes containing mixtures of the radionuclides listed in Table 2, the total concentration shall be determined by the sum of fractions rule described in 40.4(7)"g."

Table 2

Radionuclide	Concentration (curies/cubic meter)* Column 1 Column 2 Column 3				
Total of all radio nuclides with less than 5-year half-life	700		(*)		
	700	\mathcal{T}	(T) .		
H-3	40	· (*)	(7)		
Co-60	700	(*)	(*)		
Ni-63	3.5	70	700		
Ni-63 in activated					
metal	35	700	7000		
Sr-90	0.04	150	7000		
Cs-137	1	44	4600		

- (*) There are no limits established for these radionuclides in Class B or C wastes. Practical considerations such as the effects of external radiation and internal heat generation on transportation, handling, and disposal will limit the concentrations for these wastes. These wastes shall be Class B unless the concentrations of other radionuclides in Table 2 determine the waste to be Class C independent of these radionuclides. To convert nanocuries to becquerels (Bq), multiply by 37. To convert curies to gigabecquerels (GBq), multiply by 37.
- e. Classification determined by both long- and shortlived radionuclides. If the waste contains a mixture of radionuclides, some of which are listed in Table 1, and some of which are listed in Table 2, classification shall be determined as follows:
- (1) If the concentration of a radionuclide listed in Table 1 does not exceed 0.1 times the value listed in Table 1, the class shall be that determined by the concentration of radionuclides listed in Table 2.
- (2) If the concentration of a radionuclide listed in Table 1 exceeds 0.1 times the value listed in Table 1, but does not exceed the value in Table 1, the waste shall be Class C, provided the concentration of radionuclides listed in Table 2 does not exceed the value shown in Column 3 of Table 2.
- f. Classification of wastes with radionuclides other than those listed in Tables 1 and 2. If the waste does not contain any radionuclides listed in either Table 1 or 2, it is Class A.
- g. The sum of the fractions rule for mixtures of radionuclides. For determining classification for waste that contains a mixture of radionuclides, it is necessary to determine the sum of fractions by dividing each radionuclide's concentration by the appropriate limit and adding

the resulting values. The appropriate limits must all be taken from the same column of the same table. The sum of the fractions for the column must be less than, or equal to, 1.0 if the waste class is to be determined by that column. Example: A waste contains Sr-90 in a concentration of 50 Ci/m³ (1.85 TBq/m³) and Cs-137 in a concentration of 22 Ci/m³ (814 GBq/m³). Since the concentrations both exceed the values in Table 2, Column 1, they must be compared to Column 2 values. For Sr-90 fraction, 50/150 = 0.33; for Cs-137 fraction, 22/44 = 0.5; the sum of the fractions = 0.83. Since the sum is less than 1.0, the waste is Class B.

h. Determination of concentrations in wastes. The concentration of a radionuclide may be determined by indirect methods such as use of scaling factors which relate the inferred concentration of one radionuclide to another that is measured, or radionuclide material accountability, if there is reasonable assurance that the indirect methods can be correlated with actual measurements. The concentration of a radionuclide may be averaged over the volume of the waste, or weight of the waste if the units are expressed as nanocuries per gram.

40.4(8) Radioactive waste characteristics.

a. The following are minimum requirements for all classes of waste and are intended to facilitate handling and provide protection of health and safety of personnel at the disposal site.

(1) Wastes shall be packaged in conformance with the conditions of the license issued to the site operator to which the waste will be shipped. Where the conditions of the site license are more restrictive than the provisions of these rules, the site license conditions shall govern.

(2) Wastes shall not be packaged for disposal in cardboard or fiberboard boxes.

(3) Liquid waste shall be solidified or packaged in sufficient absorbent material to absorb twice the volume of the liquid.

- (4) Solid wastes containing liquid shall contain as little freestanding and noncorrosive liquid as is reasonably achievable, but in no case shall the liquid exceed 1 percent of the volume.
- (5) Waste shall not be readily capable of detonation or of explosive decomposition or reaction at normal pressures and temperatures, or of explosive reaction with water
- (6) Waste shall not contain, or be capable of generating, quantities of toxic gases, vapors, or fumes harmful to persons transporting, handling, or disposing of the waste. This does not apply to radioactive gaseous waste packaged in accordance with 40.4(8)"a"(8).

(7) Waste shall not be pyrophoric. Pyrophoric materials contained in wastes shall be treated, prepared, and packaged to be nonflammable.

(8) Wastes in gaseous form shall be packaged at a gauge pressure that does not exceed 1.5 atmospheres at 20 degrees Celsius. Total activity shall not exceed 100 curies (3.7 TBq) per container.

(9) Wastes containing hazardous, biological, pathogenic, or infectious material shall be treated to reduce to the maximum extent practicable the potential hazard from the nonradiological materials.

b. The following are minimum requirements intended to provide stability of the waste. Stability is intended to ensure that the waste does not degrade and affect overall stability of the site through slumping, collapse, or other failure of the disposal unit and thereby lead to water in-

filtration. Stability is also a factor in limiting exposure to an inadvertent intruder, since it provides a recognizable and nondispersible waste.

- (1) Waste shall have structural stability. A structurally stable waste form will generally maintain its physical dimensions and its form, under the expected disposal conditions such as weight of overburden and compaction equipment, the presence of moisture, and microbial activity, and internal factors such as radiation effects and chemical changes. Structural stability can be provided by the waste form itself, processing the waste to a stable form, or placing the waste in a disposal container or structure that provides stability after disposal.
- (2) Notwithstanding the provisions in 40.4(8)"a"(3) and (4), liquid wastes, or wastes containing liquid, shall be converted into a form that contains as little freestanding and noncorrosive liquid as is reasonably achievable, but in no case shall the liquid exceed 1 percent of the volume of the waste when the waste is in a disposal container designed to ensure stability, or 0.5 percent of the volume of the waste for waste processed to a stable form.
- (3) Void spaces within the waste and between the waste and its package shall be reduced to the extent practicable.
- **40.4(9)** Labeling. Each package of waste shall be clearly labeled to identify whether it is Class A, Class B, or Class C waste, in accordance with 40.4(7).

40.4(10) Reserved.

40.4(11) Transfer for disposal and manifests.

- a. Each shipment of waste to a licensed land disposal facility shall be accompanied by a shipment manifest that contains the name, address, and telephone number of the person generating the waste. The manifest shall also include the name, address, and telephone number of the person transporting the waste to the land disposal facility. The manifest shall also indicate as completely as practicable: a physical description of the waste; the waste volume; radionuclide identity and quantity; the total radioactivity; and the principal chemical form. The solidification agent shall be specified. Wastes containing more than 0.1 percent chelating agents by weight shall be identified and the weight percentage of the chelating agent estimated. Wastes classified as Class A, Class B, or Class C in 40.4(7) shall be clearly identified as such in the manifest unless transferred to a waste processor who treats or repackages wastes. The total quantity of the radionuclides H-3, C-14, Tc-99, and I-129 shall be shown.
- b. The manifest required in 40.4(11)"a" may be shipping papers used to meet U.S. Department of Transportation or U.S. Environmental Protection Agency regulations or requirements of the receiver, provided all the required information is included.
- c. Each manifest shall include a certification by the waste generator that the transported materials are properly classified, described, packaged, marked, and labeled and are in proper condition for transportation according to the applicable regulations of the U.S. Department of Transportation and the agency. An authorized representative of the waste generator shall sign and date the manifest.
- d. Any generating licensee who transfers waste to a land disposal facility or a licensed waste collector shall comply with the following requirements. Any generating licensee who transfers waste to a licensed waste processor who treats or repackages waste shall comply with the requirements of 40.4(11)"d"(4) through (8). A licensee shall:

- (1) Prepare all wastes so that the waste is classified according to 40.4(7) and meets the waste characteristics requirements in 40.4(8);
- (2) Label each package of waste to identify whether it is Class A, Class B, or Class C waste, in accordance with 40.4(7):
- (3) Conduct a quality control program to ensure compliance with 40.4(7) and 40.4(8); the program must include management evaluation of audits;
- (4) Prepare shipping manifests to meet the requirements of 40.4(11)"a" and "c";
- (5) Forward a copy of the manifest to the intended recipient at the time of shipment, or deliver to a collector at the time the waste is collected, obtaining acknowledgment of receipt in the form of a signed copy of the manifest from the collector;
- (6) Include one copy of the manifest with the shipment;
- (7) Retain a copy of the manifest with documentation of acknowledgment of receipt as the record of transfer of licensed material as required by these rules; and
- (8) For any shipments or any part of a shipment for which acknowledgment of receipt has not been received within the times set forth in 40.4(11), conduct an investigation in accordance with 40.4(11)"h."
- e. Any waste collector licensee who handles only prepackaged waste shall:
- (1) Acknowledge receipt of the waste from the generator within one week of receipt by returning a signed copy of the manifest:
- (2) Prepare a new manifest to reflect consolidated shipments; the new manifest shall serve as a listing or index for the detailed generator manifests. Copies of the generator manifests shall be a part of the new manifest. The waste collector may prepare a new manifest without attaching the generator manifests, provided the new manifest contains for each package the information specified in 40.4(11)"a." The collector licensee shall certify that nothing has been done to the waste which would invalidate the generator's certification;
- (3) Forward a copy of the new manifest to the land disposal facility operator at the time of shipment;
- (4) Include the new manifest with the shipment to the disposal site;
- (5) Retain a copy of the manifest with documentation of acknowledgment of receipt as the record of transfer of licensed material as required by these rules and retain information from generator manifests until disposition is authorized by the agency; and
- (6) For any shipments or any part of a shipment for which acknowledgment of receipt is not received within the times set forth in 40.4(11), conduct an investigation in accordance with 40.4(11)"h."
- f. Any licensed waste processor who treats or repackages wastes shall:
- (1) Acknowledge receipt of the waste from the generator within one week of receipt by returning a signed copy of the manifest;
- (2) Prepare a new manifest that meets the requirements of 40.4(11)"a" and "c." Preparation of the new manifest reflects that the processor is responsible for the waste;
- (3) Prepare all wastes so that the waste is classified according to 40.4(7) and meets the waste characteristics requirement in 40.4(8);

(4) Label each package of waste to identify whether it is Class A, Class B, or Class C waste, in accordance with 40.4(7) and 40.4(9);

(5) A quality control program shall be conducted to ensure compliance with 40.4(7) and 40.4(8). The program shall include management evaluation of audits;

(6) Forward a copy of the new manifest to the disposal site operator or waste collector at the time of shipment, or deliver to a collector at the time the waste is collected, obtaining acknowledgment of receipt in the form of a signed copy of the manifest by the collector;

(7) Include the new manifest with the shipment;

- (8) Retain copies of original manifests and new manifests with documentation of acknowledgment of receipt as the record of transfer of licensed material required by these rules; and
- (9) For any shipment or part of a shipment for which acknowledgment is not received within the times set forth in 40.4(11), conduct an investigation in accordance with 40.4(11)"h."

g. The land disposal facility operator shall:

- (1) Acknowledge receipt of the waste within one week of receipt by returning a signed copy of the manifest to the shipper. The shipper to be notified is the licensee who last possessed the waste and transferred the waste to the operator. The returned copy of the manifest shall indicate any discrepancies between materials listed on the manifest and materials received;
- (2) Maintain copies of all completed manifests until

the agency authorizes their disposition; and (3) Notify the shipper and the agency was a simple of the

- (3) Notify the shipper and the agency when any shipment or part of a shipment has not arrived within 60 days after the advance manifest was received.
- h. Any shipment or part of a shipment for which acknowledgment is not received within the times set forth in 40.4(11) shall:
- (1) Be investigated by the shipper if the shipper has not received notification of receipt within 20 days after transfer; and
- (2) Be traced and reported. The investigation shall include tracing the shipment and filing a report with the agency. Each licensee who conducts a trace investigation shall file a written report with the agency within two weeks of completion of the investigation.

641-40.5(136C) Records, reports, and notifications.

40.5(1) Records of surveys, radiation monitoring, and disposal.

- a. Each licensee or registrant shall maintain records showing the radiation exposures of all individuals for whom personnel monitoring is required under 40.3(2). Such records shall be kept on agency Form, "Current Occupational External Radiation Exposure History," in accordance with the instructions contained in that form, or on clear and legible records containing all the information required by agency Form, "Current Occupational External Radiation Exposure History." The doses entered on the forms or records shall be for periods of time not exceeding one calendar quarter.
- b. Each licensee or registrant shall maintain records in the same units used in this chapter, showing the results of surveys required by 40.3(1), monitoring required by 40.3(7)"b" and 40.3(7)"c," and disposal made under 40.4(2), 40.4(3), 40.4(4), 40.4(5), and 40.4(6).
- c. (1) Records of individual exposure to radiation and to radioactive material which must be maintained pursuant to the provisions of 40.5(1)"a" and records of bioas-

says, including results of whole body counting examinations, made pursuant to 40.2(7) shall be preserved until the agency authorizes disposition.

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(2) Records of the results of surveys and monitoring which must be maintained pursuant to 40.5(1)"b" shall be preserved for two years after completion of the survey except that the following records shall be maintained until the agency authorizes their disposition:

1. Records of the results of surveys to determine com-

pliance with 40.2(3)"a";

- 2. In the absence of personnel monitoring data, records of the results of surveys to determine external radiation dose; and
- 3. Records of the results of surveys used to evaluate the release of radioactive effluents to the environment.
- (3) Records of disposal of licensed material made pursuant to 40.4(2), 40.4(3), 40.4(4), 40.4(5), and 40.4(6) are to be maintained until the agency authorizes their disposition.
- (4) Records which must be maintained pursuant to this chapter may be the original or a reproduced copy or microfilm if such reproduced copy or microfilm is duly authenticated by authorized personnel and the microfilm is capable of producing a clear and legible copy after storage for the period specified by agency rules.
- (5) If there is a conflict between the agency's rules in this chapter, license condition, or other written agency approval or authorization pertaining to the retention period for the same type of record, the retention period specified in the rules in this chapter for such records shall apply unless the agency, pursuant to 641—subrule 38.3(1) has granted a specific exemption from the record retention requirements specified in this chapter.
- d. The discontinuance of, or curtailment of, activities does not relieve the licensee or registrant of responsibility for retaining all records required by 40.5(1). A licensee or registrant may, however, request the agency to accept such records. The acceptance of the records by the agency relieves the licensee or registrant of subsequent responsibility only in respect to their preservation as required by 40.5(1).
- 40.5(2) Reports of theft or loss of sources of radiation. Each licensee or registrant shall report by telephone and telegraph to the agency the theft or loss of any source of radiation immediately after such occurrence becomes known.

40.5(3) Notification of incidents.

- a. Immediate notification. Each licensee or registrant shall immediately report any events involving any source of radiation possessed by the licensee or registrant that may have caused or threatens to cause:
- (1) A dose to the whole body of any individual of 25 rems (250 mSv) or more of radiation; a dose to the skin of the whole body of any individual of 150 rems (1.50 Sv) or more of radiation; or a dose to the feet, ankles, hands, or forearms of any individual of 375 rems (3.75 Sv) or more of radiation; or
- (2) The release of radioactive material in concentrations which, if averaged over a period of 24 hours, would exceed 5,000 times the limits specified for such materials in Appendix A, Table II of this chapter; or

(3) A loss of one working week or more of the opera-

tion of any facilities affected; or

(4) Damage to property in excess of \$200,000.

b. Twenty-four hour notification. Each licensee or registrant shall within 24 hours notify the agency by telephone and telegraph of any incident involving any source

of radiation possessed by the licensee or registrant which may have caused or threatens to cause:

- (1) A dose to the whole body of any individual of 5 rems (50 mSv) or more of radiation; a dose to the skin of the whole body of any individual of 30 rems (300 mSv) or more of radiation; or a dose to the feet, ankles, hands, or forearms of 75 rems (750 mSv) or more of radiation; or
- (2) The release of radioactive material in concentrations which, if averaged over a period of 24 hours, would exceed 500 times the limits specified for such materials in Appendix A, Table II of this chapter; or

(3) A loss of one day or more of the operation of any

facilities affected; or

(4) Damage to property in excess of \$2,000.

c. Any report filed with the agency pursuant to this subrule shall be prepared in such a manner that names of individuals who have received excessive doses will be stated in a separate part of the report.

40.5(4) Reserved.

- 40.5(5) Reports of overexposures and excessive levels and concentrations.
- a. In addition to any notification required by 40.5(3), each licensee or registrant shall make a report in writing within 30 days to the agency of:
- (1) Each exposure of an individual to radiation in excess of the applicable standards in 40.2(1), 40.2(4)"a," or the license;
- (2) Each exposure of an individual to radioactive material in excess of the applicable limits in 40.2(3)"a"(1), 40.2(3)"a"(2), 40.2(4)"b," or the license;
- (3) Levels of radiation or concentrations of radioactive material in a restricted area in excess of any other applicable limit in the license;
- (4) Any incident for which notification is required by 40.5(3); and
- (5) Levels of radiation or concentrations of radioactive material, whether or not involving excessive exposure of any individual, in an unrestricted area in excess of ten times any applicable limit set forth in this chapter or in the license.
- b. Each report required under 40.5(5)"a" shall describe the extent of exposure of individuals to radiation or to radioactive material, including estimates of each individual's exposure as required by 40.5(5)"c"; levels of radiation and concentrations of radioactive material involved; the cause of the exposure, levels, or concentrations; and corrective steps taken or planned to ensure against a recurrence.
- c. Any report filed with the agency pursuant to this subrule shall include for each individual exposed the name, social security number, and date of birth, and an estimate of the individual's dose. The report shall be prepared so that this information is stated in a separate part of the report.

40.5(6) Reporting of defects and noncompliance.

- a. This subrule applies to any individual, director, or responsible officer of a firm constructing, owning, operating or supplying the components of any facility or activity which is licensed, registered, or otherwise regulated by the agency, who obtains information reasonably indicating:
- (1) That the facility, activity or basic component supplied to such facility or activity fails to comply with the Iowa Code or any applicable rule, regulation, order, license, registration document or certificate of the agency relating to substantial safety hazards; or

- (2) That the facility, activity, or basic component supplied to such facility or activity contains defects which could create a substantial safety hazard to immediately notify the agency of such failure to comply or such defect, unless the individual has actual knowledge that the agency has been adequately informed of such defect or failure to comply.
- b. These rules apply, except as specifically provided otherwise in 641—Chapters 38, 39, 41, 43, 44, 45, or 46, to each individual, partnership, corporation, or other entity licensed, registered, or certified pursuant to these rules to possess, use, measure, or mitigate, or transfer within Iowa sources of radiation and to each director and responsible officer of such a licensee, registrant or certified per-These rules also apply to each out-of-state individual, corporation, partnership or other entity doing business in Iowa. Nothing in these rules should be deemed to preclude either an individual or a manufacturer/supplier of a commercial grade item not subject to these rules from reporting to the agency a known or suspected defect or failure to comply and, as authorized by law, the identity of anyone so reporting will be withheld from disclosure.

c. Definitions. As used in this subrule:

"Activity" means any activity by a licensed, registered, certified, or any other person subject to regulation by these rules that includes any involvement with any form of radiation regulated by the agency.

"Agency" means the Iowa department of public health.

"Basic component" means a component, structure, system, or part thereof that is directly procured by the licensee, certificate holder, or registrant of a facility or activity subject to these rules and in which a defect or failure to comply with any applicable rule, order, license, certificate, or registration issued by the agency could create a substantial safety hazard. In all cases the basic component includes design, inspection, testing or consulting services important to safety that are associated with the component hardware, whether these services are performed by the component supplier or others. A commercial grade item is not a part of a basic component until after dedication.

"Commercial grade item" means an item that is (1) not subject to design or specification requirements that are unique to facilities or activities licensed, certified, or registered pursuant to these rules, (2) used in applications other than facilities or activities licensed, certified, or registered pursuant to these rules, and (3) to be ordered from the manufacturer/supplier on the basis of specifications set forth in the manufacturer's published product description (for example, a catalog).

"Constructing" or "construction" means the design, manufacture, fabrication, placement, erection, installation, modification, inspection, or testing of a facility or activity which is subject to these rules and consulting services related to the facility or activity that are important

to safety.

"Dedication" of a commercial grade item occurs after receipt when that item is designated for use as a basic component.

"Defect" means:

(1) A deviation in a basic component delivered to a purchaser for use in a facility or an activity subject to these rules if, on the basis of an evaluation, the deviation could create a substantial safety hazard; or

(2) The installation, use, or operation of a basic component containing a defect as defined in paragraph (1) above.

"Deviation" means a departure from the technical requirements included in a procurement document.

"Director" means an individual, appointed or elected according to law, who is authorized to manage and direct the affairs of a corporation, partnership, or other entity. In the case of an individual partnership, "director" means the individual.

'Evaluation" means the process accomplished by or for a licensee, registrant, or certified person to determine whether a particular deviation could create a substantial safety hazard.

"Facility" means any building, laboratory, room, plant, area or other such place as may be utilized to conduct activities involving the receipt, use, transfer, storage, possession, ownership, or acquisition of radioactive materials or a radiation-producing machine as regulated by the agency. With regard to radon measurement or mitigation. the "facility" is the house, school, business or any other

building in which measurements are taken or in which a radon mitigation system is installed.

"Operating" or "operation" means the operation of a facility or the conduct of a licensed, certified, or registered activity_which is subject to these rules and consulting services related to operations that are important to safety.

"Procurement document" means a contract that defines the requirements which facilities or basic components must meet in order to be considered acceptable by the

purchaser.

"Responsible officer" means the president, vice president or other individual in the organization of a corporation, partnership, or other entity who is vested with executive authority over activities subject to these rules.

Substantial safety hazard" means a loss of safety function to the extent that there is a major reduction in the degree of protection provided to public health and safety for any facility or activity licensed, registered or certified by

Supplying" or "supplies" means contractually responsible for a basic component used or to be used in a facility

or activity which is subject to these rules.

d. Except as specifically authorized by the agency in writing, no interpretation of the meaning of these rules by any officer or employee of the agency, other than a written interpretation by the assistant attorney general, will be recognized to be binding upon the agency.

e. Communications. Except where otherwise specified in these rules, all communications and reports concerning these rules should be addressed to the Director, Iowa Department of Public Health, Lucas State Office Building, Des Moines, Iowa 50319. Communications and reports may also be delivered in person at the agency offices at Lucas State Office Building, Twelfth and Walnut, Des

Moines, Iowa.

- f. Exemptions. The agency may, upon application of any interested person or upon its own initiative, grant such exemptions from the requirements of these rules as it determines are authorized by law and will not endanger life or property and are otherwise in the public interest. Suppliers of commercial grade items are exempt from the provisions of these rules to the extent that they supply commercial grade items.
- g. Notification of failure to comply or existence of a defect.

- (1) Each individual, corporation, partnership or other entity subject to these rules shall adopt appropriate proce-
- 1. Provide for evaluating deviations; or informing the licensee, registrant or purchaser of the deviation in order that the licensee, registrant or other purchaser may cause the deviation to be evaluated unless the deviation has been corrected; and
- 2. Ensure that a director or responsible officer is informed if the construction or operation of a facility, or activity, or a basic component supplied for such facility or activity fails to comply with any applicable rule, order, license, registration or certificate issued by the agency relating to a substantial safety hazard or contains a defect.
- (2) 1. A director or responsible officer subject to these rules or a designated person shall notify the agency when the person obtains information reasonably indicating a failure to comply or a defect affecting the construction or operation of a facility or an activity within Iowa that is subject to the licensing or registration requirements of these rules and that is within the organization's responsibility or a basic component that is within the organization's responsibility and is supplied for a facility or an activity within Iowa that is subject to the licensing or registration requirements of these rules. The above notification is not required if such individual has actual knowledge that the agency has been adequately informed of such defect or such failure to comply.
- 2. Initial notification required by this paragraph shall be made within two days following receipt of the information. Notification shall be made to the Director, Iowa Department of Public Health, Lucas State Office Building, Des Moines, Iowa 50319. If initial notification is by means other than written communication, a written report shall be submitted within five days after the information is obtained.

3. The written report required by this paragraph shall include, but need not be limited to, the following information, to the extent known:

· Name and address of the individuals informing the

agency

- Identification of the facility, the activity, or the basic component supplied for such facility or such activity within Iowa which fails to comply or contains a defect;
- Identification of the firm constructing the facility or supplying the basic component which fails to comply or contains a defect:
- Nature of the defect or failure to comply and the safety hazard which is created or could be created by such defect or failure to comply:

The date on which the information of such defect or

failure to comply was obtained;

- In the case of a basic component which contains a defect or fails to comply, the number and location of all such components in use at, supplied for, or being supplied for one or more facilities or activities subject to these
- The corrective action which has been, is being, or will be taken. The name of the individual or organization responsible for the action. The length of time that has been or will be taken to complete the action;
- Any device related to the defect or failure to comply about the facility, activity, or basic component that has been, is being, or will be given to purchasers, licensees, or
- 4. The director or responsible officer may authorize an individual to provide the notification required by this

paragraph, provided that this shall not relieve the director or responsible officer of the responsibility under this paragraph.

(3) Individuals subject to 40.5(6)"g"(2) may be required by the agency to supply additional information re-

lated to the defect or failure to comply.

- h. Procurement documents. Each individual, corporation, partnership, or other entity subject to these rules shall ensure that each procurement document for a facility, or a basic component issued by the individual, corporation, partnership or other entity on or after September 1. 1992, specifies, when applicable, that the provisions of this subrule apply.
 - i. Maintenance of records.

(1) Each licensee or registrant of a facility or activity subject to these rules shall maintain such records in connection with the licensed or registered facility or activity as may be required to ensure compliance with these rules.

- (2) Each individual, corporation, partnership, or other entity subject to these rules shall prepare records in connection with the designs, manufacture, fabrication, placement, erection, installation, modification, inspection, or testing of any facility, basic component supplied for any licensed or registered facility or to be used in any licensed activity sufficient to ensure compliance with these rules. After delivery of the facility or component and prior to the destruction of the records relating to evaluations or notifications to the agency such records shall be offered to the purchaser of the facility or component. If such purchaser determines any such records:
- 1. Are not related to the creation of a substantial safety hazard, the purchaser may authorize such records to be
- Are related to the creation of a substantial safety hazard, the purchaser shall cause such records to be offered to the organization to which basic components are supplied or for which a facility or activity is constructed. If such purchaser is unable to make the determination as required above, then the responsibility for making the determination shall be transferred to the individual, corporation, partnership, or other entity subject to these rules that issued the procurement to the purchaser. In the event that the determination cannot be made at that level, then the responsibility shall be transferred in a similar manner to another individual, corporation, partnership, or other entity subject to these rules, until, if necessary, the licensee or registrant shall make the determination.

3. Records that are prepared only for the purpose of ensuring compliance with these rules and are not related to evaluations or notifications to the agency may be destroyed after delivery of the facility or component.

 Failure to notify. Any director or responsible officer subject to these rules who knowingly and consciously fails to provide the notice required by 40.5(6)"g" shall be subject to a civil penalty equal to the amount provided for

in 641—Chapter 38, Appendix A.

40.5(7) Vacating premises. Each specific licensee shall, no less than 30 days before vacating or relinquishing possession or control of premises which may have been contaminated with radioactive material as a result of the licensee's activities, notify the agency in writing of intent to vacate. When deemed necessary by the agency, the licensee shall decontaminate the premises in such a manner as the agency may specify.

40.5(8) Notifications and reports to individuals.

- a. Requirements for notification and reports to individuals of exposure to radiation or radioactive material are specified in 40.6(4).
- b. When a licensee or registrant is required, pursuant to 40.5(5), to report to the agency any exposure of an individual to radiation or radioactive material, the licensee or registrant shall also notify the individual. Such notice shall be transmitted at a time not later than the transmittal to the agency and shall comply with the provisions of 40.6(4)"a."

641—40.6(136C) Notices, instructions, and reports to workers-inspections.

- 40.6(1) Purpose and scope. This rule establishes requirements for notices, instructions and reports by licensees or registrants to individuals engaged in activities under a license or registration and options available to such individuals in connection with agency inspections of licensees or registrants to ascertain compliance with the provisions of the Code of Iowa and rules, orders, and licenses issued thereunder regarding radiological working conditions. This rule applies to all persons who receive, possess, use, own, or transfer sources of radiation registered with or licensed by the agency pursuant to 641—39.3(136C) and 641—39.4(136C).
 - 40.6(2) Posting of notices to workers.
- a. Each licensee or registrant shall post current copies of the following documents:

- (1) This subrule and 641—Chapter 40;(2) The license, certificate of registration, conditions or documents incorporated into the license by reference and amendments thereto;
- 3) The operating procedures applicable to activities under the license or registration; and
- Any notice of violation involving radiological working conditions, proposed imposition of civil penalty, or order issued pursuant to 641—Chapter 38, and any response from the licensee or registrant.
- b. If posting of a document specified in 40.6(2)"a"(1), (2), or (3) is not practicable, the licensee or registrant may post a notice which describes the document and states where it may be examined.
- c. Agency form "Notice to Employees" shall be posted by each licensee or registrant as required by these rules.
- d. Agency documents posted pursuant to 40.6(2)"a"(4) shall be posted within five working days after receipt of the documents from the agency; the licensee's or registrant's response, if any, shall be posted within five working days after dispatch from the licensee or registrant. Such documents shall remain posted for a minimum of five working days or until action correcting the violation has been completed, whichever is later.
- e. Documents, notices, or forms posted pursuant to 40.6(2) shall appear in a sufficient number of places to permit individuals engaged in work under the license or registration to observe them on the way to or from any particular work location to which the document applies, shall be conspicuous, and shall be replaced if defaced or altered.

40.6(3). Instructions to workers.

- a. All individuals working in or frequenting any portion of a restricted area:
- (1) Shall be kept informed of the storage, transfer, or use of sources of radiation in such portions of the restricted area;

(2) Shall be instructed in the health protection problems associated with exposure to radiation or radioactive material, in precautions or procedures to minimize exposure, and in the purposes and functions of protective devices employed:

3) Shall be instructed in and instructed to observe, to the extent within the worker's control, the applicable provisions of these rules and licenses for the protection of personnel from exposures to radiation or radioactive ma-

terial occurring in such areas:

(4) Shall be instructed of their responsibility to report promptly to the licensee or registrant any condition which may constitute, lead to, or cause a violation of the Code of Iowa, these rules, and licenses or unnecessary exposure to radiation or radioactive material;

(5) Shall be instructed in the appropriate response to warnings made in the event of any unusual occurrence or malfunction that may involve exposure to radiation or ra-

dioactive material; and

- (6) Shall be advised as to the radiation exposure reports which workers shall be furnished pursuant to 40.6(4).
- b. The extent of these instructions shall be commensurate with potential radiological health protection problems in the restricted area.

40.6(4) Notifications and reports to individuals.

a. Radiation exposure data for an individual and the results of any measurements, analyses, and calculations of radioactive material deposited or retained in the body of an individual shall be reported to the individual as specified in this subrule. The information reported shall include data and results obtained pursuant to these rules, orders, or license conditions, as shown in records maintained by the licensee or registrant pursuant to 40.5(1). Each notification and report shall:

Be in writing;

(2) Include appropriate identifying data such as the name of the licensee or registrant, the name of the individual, and the individual's social security number;

(3) Include the individual's exposure information; and

(4) Contain the following statement: "This report is furnished to you under the provisions of 641—subrule 40.6(4) of Iowa's Radiation Machine and Radioactive Materials Rules. You should preserve this report for further reference.'

b. Each licensee or registrant shall advise each worker annually of the worker's exposure to radiation or radioactive material as shown in records maintained by the licensee or registrant pursuant to 40.5(1)"a" and "c.

- Each licensee or registrant shall furnish to each worker a report of the worker's exposure to radiation or radioactive material upon termination of employment. Such report shall be furnished within 30 days from the time of termination of employment or within 30 days after the exposure of the individual has been determined by the licensee or registrant, whichever is later. The report shall cover each calendar quarter in which the worker's activities involved exposure to sources of radiation and shall include the dates and locations of work under the license or registration in which the worker participated.
- d. When a licensee or registrant is required pursuant to 40.5(5) to report to the agency any exposure of an individual to radiation or radioactive material, the licensee or the registrant shall also provide the individual a report on the exposure data included therein. Such reports shall be

transmitted at a time not later than the transmittal to the agency.

e. At the request of a worker who is terminating employment in a given calendar quarter with the licensee or registrant in work involving radiation dose, or of a worker who, while employed by another person, is terminating assignment to work involving radiation dose in the licensee's or registrant's facility in that calendar quarter, each licensee or registrant shall provide to each such worker, or to the worker's designee, at termination, a written report regarding the radiation dose received by that worker from operations of the licensee or registrant during that specifically identified calendar quarter or fraction thereof, or provide a written estimate of that dose if the finally determined personnel monitoring results are not available at that time. Estimated doses shall be clearly indicated as

such.
40.6(5) Presence of representatives of licensees or reg-

istrants and workers during inspection.

- a. Each licensee or registrant shall afford to the agency at all reasonable times opportunity to inspect materials, machines, activities, facilities, premises, and records pursuant to these rules.
- b. During an inspection, agency inspectors may consult privately with workers as specified in 40.6(6). The licensee or registrant may accompany agency inspectors during other phases of an inspection.
- c. If, at the time of inspection, an individual has been authorized by the workers to represent them during agency inspections, the licensee or registrant shall notify the inspectors of such authorization and shall give the workers' representative an opportunity to accompany the inspectors during the inspection of physical working conditions.
- d. Each workers' representative shall be routinely engaged in work under control of the licensee or registrant and shall have received instructions as specified in 40.6(3)
- e. Different representatives of licensees or registrants and workers may accompany the inspectors during different phases of an inspection if there is no resulting interference with the conduct of the inspection. However, only one workers' representative at a time may accompany the inspectors.
- f. With the approval of the licensee or registrant and the workers' representative, an individual who is not routinely engaged in work under control of the licensee or registrant, for example, a consultant to the licensee or registrant or to the workers' representative, shall be afforded the opportunity to accompany agency inspectors during the inspection of physical working conditions.
- g. Notwithstanding the other provisions of 40.6(5), agency inspectors are authorized to refuse to permit accompaniment by any individual who deliberately interferes with a fair and orderly inspection. With regard to areas containing information classified by an agency of the U.S. government in the interest of national security, an individual who accompanies an inspector may have access to such information only if authorized to do so. With regard to any area containing proprietary information, the workers' representative for that area shall be an individual previously authorized by the licensee or registrant to enter that area

40.6(6) Consultation with workers during inspections. a. Agency inspectors may consult privately with workers concerning matters of occupational radiation protec-

tion and other matters related to applicable provisions of these rules and licenses to the extent the inspectors deem necessary for the conduct of an effective and thorough inspection.

b. During the course of an inspection, any worker may bring privately to the attention of the inspectors, either orally or in writing, any past or present condition which the worker has reason to believe may have contributed to or caused any violation of the Code of Iowa, these rules, or license condition, or any unnecessary exposure of an individual to sources of radiation under the licensee's or registrant's control. Any such notice in writing shall comply with the requirements of 40.6(7)"a."

c. The provisions of 40.6(6)"b" shall not be interpreted as authorization to disregard instructions pursuant to

40.6(3).

40.6(7) Requests by workers for inspections.

a. Any worker or representative of workers believing that a violation of the Code of Iowa, these rules, or license conditions exists or has occurred in work under a license or registration with regard to radiological working conditions in which the worker is engaged may request an inspection by giving notice of the alleged violation to the Iowa Department of Public Health, Bureau of Environmental Health, Radiological Health Section, Lucas State Office Building, Des Moines, Iowa 50319. Any such notice shall be in writing, shall set forth the specific grounds for the notice, and shall be signed by the worker or representative of the workers. A copy shall be provided to the licensee or registrant by the agency no later than at the time of inspection except that, upon the request of the worker giving such notice, such worker's name and the name of individuals referred to therein shall not appear in such copy or on any record published, released, or made available by the agency, except for good cause shown.

b. If, upon receipt of such notice, the agency determines that the complaint meets the requirements set forth in 40.1500(7)"a," and that there are reasonable grounds to believe that the alleged violation exists or has occurred, an inspection shall be made as soon as practicable to determine if such alleged violation exists or has occurred. Inspections pursuant to this subrule need not be limited to

matters referred to in the complaint.

c. No licensee, registrant, or contractor or subcontractor of a licensee or registrant shall discharge or in any manner discriminate against any worker because such worker has filed any complaint or instituted or caused to be instituted any proceeding under these rules or has testified or is about to testify in any such proceeding or because of the exercise by such worker on behalf of such worker or others of any option afforded by this subrule.

40.6(8) Inspections not warranted; informal review.

a. (1) If the agency determines, with respect to a complaint under 40.6(7), that an inspection is not warranted because there are no reasonable grounds to believe that a violation exists or has occurred, the agency shall notify the complainant in writing of such determination. The complainant may obtain review of such determination by submitting a written statement of position with the assistant attorney general's office. Such agency will provide the licensee or registrant with a copy of such statement by certified mail excluding, at the request of the complainant, the name of the complainant. The licensee or registrant may submit an opposing written statement of

position with the assistant attorney general's office. Such

agency will provide the complainant with a copy of such

statement by certified mail.

(2) Upon the request of the complainant, the assistant attorney general's office may hold an informal conference in which the complainant and the licensee or registrant may orally present their views. An informal conference may also be held at the request of the licensee or registrant, but disclosure of the identity of the complainant will be made only following receipt of written authorization from the complainant. After considering all written and oral views presented, the assistant attorney general's office shall affirm, modify, or reverse the determination of the agency and furnish the complainant and the licensee or registrant a written notification of the decision and the reason therefor.

b. If the agency determines that an inspection is not warranted because the requirements of 40.6(7)"a" have not been met, the complainant shall be notified in writing of such determination. Such determination shall be without prejudice to the filing of a new complaint meeting the

requirements of 40.6(7)"a.

CHAPTER 40 APPENDIX A CONCENTRATIONS IN AIR AND WATER ABOVE NATURAL BACKGROUND (See notes at end of Appendix)

	Radio- nuclide <u>1</u> /		Table I		Table II	
Element (atomic number)			Column 1 Air (µCi/ml)	Column 2 Water (µCi/ml)	Column 1 Air (µCi/ml)	Column 2 Water (µCi/ml)
Actinium (89)	Ac-227	S	2X10 ⁻¹²	6X10 ⁻⁵	8X10 ⁻¹⁴	2X10 ⁻⁶
		I	3X10 ¹¹	9X10 ⁻³	9X10 ⁻¹³ .	3X10⁴
• •	Ac-228	S	8X10 ⁸	3X10 ⁻³	3X10 ⁻⁹	9X10 ⁻⁵
		I	2X10 ⁸	3X10 ⁻³	6X10 ⁻¹⁰	9X10 ⁻⁵
Americium (95)	Am-241	S .	6X10 ⁻¹²	1X10 ⁻⁴	2X10 ⁻¹³	4X10⁴
		I	1X10 ¹⁰	8X10-4	4X10 ⁻¹²	3X10 ⁻⁵

			Table I		Table II	
Element (atomic number)	Radio- nuclide <u>1</u> /		Column 1 Air (µCi/ml)	Column 2 Water (µCi/ml)	Column 1 Air (µCi/ml)	Column 2 Water (µCi/ml)
	Am-242m	S -	6X10 ⁻¹²	- 1X10 ⁻⁴	2X10 ⁻¹³	4X10-6
		I	3X10 ⁻¹⁰	3X10 ⁻³	9X10 ⁻¹²	9X10 ⁻⁵
	Am-242	S	4X10 ⁸	4X10 ⁻³	1X10 ⁻⁹	1X10 ⁻⁴
		I	5X10 ⁸	4X10 ⁻³	2X10 ⁻⁹	1X10 ⁻⁴
	Am-243	S	6X10 ⁻¹²	1X10⁴	2X10 ⁻¹³	4X10 ⁻⁶
		I	1X10 ⁻¹⁰	8X10⁴	4X10 ⁻¹²	3X10 ⁻⁵
•	Am-244	S	4X10 ⁻⁶	1X10 ⁻¹	1X10 ⁻⁷	5X10 ⁻³
•		Ι .	2X10 ⁻⁵	1X10 ⁻¹	8X10 ⁻⁷	5X10 ⁻³
Antimony (51)	Sb-122	S	2X10 ⁷	8X10-4	6X10 ⁻⁹	3X10 ⁻⁵
		I	1X10 ⁷	8X10 ⁻⁴	5X10 ⁻⁹	3X10 ⁻⁵
	Sb-124	S	2X10 ⁻⁷	7X10 ⁻⁴	5X10 ⁻⁹	2X10 ⁻⁵
		I	2X10 ⁻⁸	7X10⁴	7X10 ⁻¹⁰	2X10 ⁻⁵
	Sb-125	S	5X10 ⁷	3X10 ⁻³	2X10 ⁻⁸	1X10 ⁻⁴
		I .	3X10 ⁻⁸	3X10 ⁻³	9X10 ⁻¹⁰	1X10 ⁴
Argon (18)	Ar-37	Sub <u>2</u> /	6X10 ⁻³	· ′	1X10⁴	
	Ar-41	Sub	2X10 ⁶		4X10 ⁻⁸	
Arsenic (33)	As-73	S	2X10 ⁻⁶	1X10 ⁻²	7X10 ⁻⁸	5X10⁴
, ,		I	4X10 ⁷	1X10 ⁻²	1X10 ⁻⁸	5X10 ⁴
	As-74	S	3X10 ⁻⁷	2X10 ⁻³	1X10 ⁻⁸	5X10 ⁻⁵
		I	1X10 ⁻⁷	2X10 ⁻³	4X10 ⁻⁹	5X10 ⁻⁵
	As-76	S	1X10 ⁻⁷	6X10⁴	4X10 ⁻⁹	2X10 ⁻⁵
		I	1X10 ⁻⁷	6X10⁴	3X10 ⁻⁹	2X10 ⁻⁵
	As-77	S	5X10 ⁷	2X10 ⁻³	2X10 ⁻⁸	8X10 ⁻⁵
		Í	4X10 ⁻⁷	2X10 ⁻³	1X10 ⁻⁸	8X10 ⁻⁵
Astatine (85)	At-211	S	7X10 ⁻⁹	5X10 ⁻⁵	2X10 ⁻¹⁰	2X10-6
		I	3X10 ⁻⁸	2X10 ⁻³	1X10 ⁻⁹	7X10 ⁻⁵
Barium (56)	Ba-131	S	1X10 ⁶	5X10 ⁻³	4X10 ⁻⁸	2X10 ⁻⁴
		Ι	4X10 ⁷	5X10 ⁻³	1X10 ⁻⁸	2X10 ⁴
	Ba-140	S	1X10 ⁷	8X10 ⁻⁴	4X10 ⁻⁹	3X10 ⁻⁵
	•	I	4X10*	7X10⁴	1X10 ⁻⁹	2X10 ⁻⁵
Berkelium (97)	Bk-249	S	9X10 ⁻¹⁰	2X10 ⁻²	3X10 ⁻¹¹	6X10⁴
		I	1X10 ⁷	2X10 ⁻²	4X10 ⁻⁹	6X10⁴
	Bk-250	S	1X10 ⁷	6X10 ⁻³	5X10 ⁻⁹	2X10 ⁻⁴
		I	1X10 ⁶	6X10 ⁻³	4X10 ⁻⁸	2X10 ⁻⁴
Beryllium (4)	Be-7	S	6X10 ⁶	5X10 ⁻²	2X10 ⁻⁷	2X10 ⁻³
		I	1X10 ⁻⁶	5X10 ⁻²	4X10 ⁻⁸	2X10 ⁻³

•			Table I			Table II	
Element	Radio-		Column 1	Column 2	Column 1	Column 2	
(atomic number)	nuclide <u>1</u> /		Air (μCi/ml)	Water (µCi/ml)	Air (μCi/ml)	Water (μCi/ml)	
Bismuth (83)	Bi-206	S	2X10 ⁻⁷	1X10 ⁻³	6X10 ⁻⁹	4X10 ⁻⁵	
		Ι΄.	1X10 ⁷	1X10 ⁻³	5X10 ⁻⁹	4X10 ⁻⁵	
	Bi-207	S	2X10 ⁷	2X10 ⁻³	6X10 ⁻⁹	6X10 ⁻⁵	
		I	1X10 ⁸	2X10 ⁻³	5X10 ⁻¹⁰	6X10 ⁻⁵	
	Bi-210	S	6X10°	1X10 ⁻³	2X10 ⁻¹⁰	4X10 ⁻⁵	
		I	6X10°	1X10 ⁻³	2X10 ⁻¹⁰	4X10 ⁻⁵	
	Bi-212	S	1X10 ⁷	1X10 ⁻²	3X10 ⁻⁹	4X10⁴	
		I	2X10 ⁷	1X10 ⁻²	7X10 ⁻⁹	4X10 ⁻⁴	
Bromine (35)	Br-82	S	1X10 ⁶ .	8X10 ⁻³	4X10 ⁻⁸	3X10 ⁻⁴	
		I	2X10 ⁷	1X10 ⁻³	6X10 ⁻⁹	4X10 ⁻⁵	
		-	-				
Cadmium (48)	Cd-109	S	5X10 ⁸	5X10 ⁻³	2X10 ⁻⁹	2X10⁴	
		I	7X10 ⁸	5X10 ⁻³	3X10 ⁻⁹	2X10 ⁻⁴	
	Cd-115m	S	4X10 ⁸	7X10 ⁻⁴	1X10 ⁻⁹	3X10 ⁻⁵	
		I	4X10 ⁸	7X10 ⁻⁴	1X10 ⁻⁹	3X10 ⁻⁵	
	Cd-115	S	2X10 ⁷	1X10 ⁻³	8X10 ⁻⁹	3X10 ⁻⁵	
		·I	2X10 ⁷	1X10 ⁻³	6X10 ⁻⁹	4X10 ⁻⁵	
Calcium (20)	Ca-45	S	3X10 ⁸	3X10 ⁴	1X10 ⁻⁹	9X10 ⁻⁶	
Calcium (20)	Ca-45	I	1X10 ⁷	5X10 ⁻³	4X10 ⁻⁹	2X10 ⁻⁴	
	Ca-47	S	2X10 ⁷	1X10 ⁻³	6X10 ⁻⁹	5X10 ⁻⁵	
	Ca-47	I	2X10 ⁷	1X10 ⁻³	6X10 ⁻⁹	3X10 ⁻⁵	
		-				-	
Californium (98)	Cf-249	s '	2X10 ¹²	1X10 ⁻⁴	5X10 ⁻¹⁴	4X10⁴	
		I	1X10 ¹⁰	7X10⁴	3X10 ⁻¹²	2X10 ⁻⁵	
	Cf-250	S	5X10 ¹²	4X10 ⁻⁴	2X10 ⁻¹³	1X10 ⁻⁵	
		I	1X10 ¹⁰	7X10⁴	3X10 ⁻¹²	3X10 ⁻⁵	
	Cf-251	S	2X10 ¹²	1X10 ⁻⁴	6X10 ⁻¹⁴	4X10-6	
		I	1X10 ⁻¹⁰	8X10 ⁴	3X10 ⁻¹²	3X10 ⁻⁵	
	Cf-252	S	6X10 ⁻¹²	2X10 ⁴	2X10 ⁻¹³	7X10 ⁻⁶	
		I	3X10 ⁻¹¹	2X10 ⁴	1X10 ⁻¹²	7X10 ⁻⁶	
	Cf-253	S	8X10 ¹⁰	4X10 ⁻³	3X10 ⁻¹¹	1X10 ⁻⁴	
		I	8X10 ⁻¹⁰	4X10 ⁻³	3X10 ⁻¹¹	1X10 ⁴	
	Cf-254	S	5X10 ⁻¹²	4X10 ⁻⁶	2X10 ⁻¹³	1X10 ⁻⁷	
		I	5X10 ¹²	4X10 ⁻⁶	2X10 ⁻¹³	1X10 ⁻⁷	
Carbon (6)	C-11*	Sub <u>2</u> /	4X10⁴	•			
	C-14	S	4X10-6	2X10 ⁻²	1X10 ⁻⁷	8X10 ⁻⁴	
	(CO ₂)	Sub_2/	5X10 ⁻⁵	******	1X10 ⁻⁶		
Cerium (58)	Ce-141	s	4X10 ⁻⁷	3X10 ⁻³	2X10 ⁻⁸	9X10 ⁻⁵	
Cerruii (36)		_		~			

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			Table I		Table II	
Element (atomic number)	Radio- nuclide <u>1</u> /	· .	Column 1 Air (µCi/ml)	Column 2 Water (µCi/ml)	Column 1 Air (µCi/ml)	Column 2 Water (µCi/ml)
	Ce-143	S	3X10 ⁻⁷	1X10 ⁻³	9X10 ⁻⁹	4X10 ⁻⁵
		I	2X10 ⁻⁷	1X10 ⁻³	7X10 ⁻⁹	4X10 ⁻⁵
	Ce-144	S	1X10 ⁻⁸	3X10⁴	3X10 ⁻¹⁰	1X10 ⁻⁵
-	·	I	6X10 ⁻⁹	3X10⁴	2X10 ⁻¹⁰	1X10 ⁻⁵
Cesium (55)	Cs-131	S	1X10 ⁻⁵	7X10 ⁻²	4X10 ⁻⁷	2X10 ⁻³
		I	3X10⁻⁴	3X10 ⁻²	1X10 ⁻⁷	9X10⁴
	Cs-134m	S	4X10 ⁻⁵	2X10 ⁻¹	1X10 ⁻⁶	6X10 ⁻³
		I	6X10 ⁻⁶	3X10 ⁻²	2X10 ⁻⁷	1X10 ⁻³
	Cs-134	S	4X10 ⁸	3X10 ⁻⁴	1X10 ⁻⁹	9X10 ⁻⁶
		I	1X10 ⁸	1X10 ⁻³	4X10 ⁻¹⁰	4X10 ⁻⁵
	Cs-135	S	5X10 ⁷	3X10 ⁻³	2X10 ⁻⁸	1X10 ⁻⁴
		I	9X10 ⁸	7X10 ⁻³	3X10 ⁻⁹	2X10 ⁻⁴
	Cs-136	S	4X10 ⁻⁷	2X10 ⁻³	1X10 ⁻⁸	9X10 ⁻⁵
•		1	$2X10^{-7}$	2X10 ⁻³	6X10 ⁻⁹	6X10 ⁻⁵
	Cs-137	S	6X10 ⁸	4X10 ⁻⁴	2X10 ⁻⁹	2X10 ⁻⁵
		I	1X10 ⁸	1X10 ⁻³	5X10 ⁻¹⁰	4X10 ⁻⁵
Chlorine (17)	C1-36	S	4X10 ⁻⁷	2X10 ⁻³	1X10 ⁻⁸	8X10 ^{-s}
		I	2X10 ⁸	2X10 ⁻³	8X10 ⁻¹⁰	6X10 ⁻⁵
	C1-38	S	3X10 ⁶	1X10 ⁻²	9X10 ⁻⁸	4X10⁴
		I	2X10 ⁻⁶	1X10 ⁻²	7X10 ⁻⁸	4X10 ⁻⁴
Chromium (24)	Cr-51	S	1X10 ⁵	5X10 ⁻²	4X10 ⁻⁷	2X10 ⁻³
		I	2X10 ⁻⁶	5X10 ⁻²	8X10 ⁻⁸	2X10 ⁻³
Cobalt (27)	Co-57	S	3X10 ⁻⁶	2X10 ⁻²	1X10 ⁻⁷	5X10 ⁴
•		I	2X10 ⁻⁷	1X10 ⁻²	6X10 ⁻⁹	4X10 ⁻⁴
	Co-58m	S	2X10 ⁻⁵	8X10 ⁻²	6X10 ⁻⁷	3X10 ⁻³
		1	9X10 ⁶	6X10 ⁻²	3X10 ⁻⁷	2X10 ⁻³
	Co-58	S	8X10 ⁻⁷	4X10 ⁻³	3X10 ⁻⁸	1X10⁴
		I	5X10 ⁸	3X10 ⁻³	2X10 ⁻⁹	9X10 ⁻⁵
	. Co-60	S	3X10 ⁻⁷	1X10 ⁻³	1X10 ⁻⁸	5X10 ⁻⁵
		I	9X10 ⁻⁹	1X10 ⁻³	. 3X10 ⁻¹⁰	3X10 ⁻⁵
Copper (29)	Cu-64	S	2X10 ⁻⁶	1X10 ⁻²	7X10 ⁻⁸	3X10 ⁻⁴
		I	1X10 ⁻⁶	6X10 ⁻³	4X10 ⁻⁸	2X10 ⁻⁴
Curium (96)	Cm-242	S	1X10 ⁻¹⁰	7X10⁴	4X10 ⁻¹²	2X10 ⁻⁵
·	•	I	2X10 ⁻¹⁰	7X10 ⁻⁴	6X10 ⁻¹²	2X10 ⁻⁵
	Cm-243	S	6X10 ⁻¹²	1X10 ⁻⁴	2X10 ⁻¹³	5X10 ⁻⁶
		I	1X1Q ⁻¹⁰	7X10⁴	3X10 ⁻¹²	2X10 ⁻⁵
	Cm-244	S	9X10 ¹²	2X10 ⁻⁴	3X10 ⁻¹³	7X10⁻⁵
		I	1X10 ⁻¹⁰	8X10 ⁻⁴	3X10 ⁻¹²	3X10 ⁻⁵

			Т	able I	Ta	ıble II
Element (atomic number)	Radio- nuclide <u>1</u> /		Column 1 Air (µCi/ml)	Column 2 Water (µCi/ml)	Column 1 Air (µCi/ml)	Column 2 Water (µCi/ml)
	Cm-245	S	5X10 ⁻¹²	1X10 ⁻⁴	2X10 ⁻¹³	4X10-6
		I	1X10 ¹⁰	8X10 ⁻⁴	4X10 ⁻¹²	3X10 ⁻⁵
•	Cm-246	S	5X10 ⁻¹²	1X10 ⁴	2X10 ⁻¹³	4X10 ⁻⁶
		I	1X10 ¹⁰	8X10 ⁴	4X10 ⁻¹²	3X10 ⁻⁵
-	Cm-247	S	5X10 ¹²	1X10 ⁴	2X10 ⁻¹³	4X10 ⁻⁶
		I	1X10 ¹⁰	6X10⁴	4X10 ⁻¹²	2X10 ⁻⁵
	Cm-248	S	6X10 ¹³	1X10 ⁻⁵	2X10 ⁻¹⁴	4X10 ⁻⁷
		I	1X10 ¹¹	4X10 ⁻⁵	4X10 ⁻¹³	1X10 ⁻⁶
	Cm-249	S	1X10 ⁻⁵	6X10 ⁻²	4X10 ⁻⁷	2X10 ⁻³
		I	1X10 ⁻⁵	6X10 ⁻²	4X10 ⁻⁷	2X10 ⁻³
Dysprosium (66)	Dy-165	s	3X10 ⁶	1X10 ⁻²	9X10 ⁻⁸	4X10 ⁻⁴
		I	2X10 ⁻⁶	1X10 ⁻²	7X10 ⁻⁸	4X10⁴
	Dy-166	S	2X10 ⁷	1X10 ⁻³	8X10-9	4X10 ⁻⁵
	•	I	2X10 ⁷	1X10 ⁻³	7X10 ⁻⁹	4X10 ⁻⁵
Einsteinium (99)	Es-253	S .	8X10 ⁻¹⁰	7X10 ⁻⁴	3X10 ⁻¹¹	2X10 ⁻⁵
	•	I	6X10 ⁻¹⁰	7X10 ⁻⁴	2X10 ⁻¹¹	-2X10 ⁻⁵
	Es-254m	S	5X10°	5X10⁴	2X10 ⁻¹⁰	2X10 ⁻⁵
	•	I	6X10°	5X10 ⁻⁴	2X10 ⁻¹⁰	2X10 ⁻⁵
	Es-254	S	2X10 ⁻¹¹	4X10 ⁻⁴	6X10 ⁻¹³	1X10 ⁻⁵
		I	1X10 ¹⁰	4X10 ⁻⁴	4X10 ⁻¹²	1X10 ⁻⁵
	Es-255 .	S	5X10 ⁻¹⁰	8X10 ⁻⁴	2X10 ⁻¹¹	3X10 ⁻⁵
		Ι	4X10 ¹⁰	8X10 ⁻⁴	1X10 ⁻¹¹	3X10 ⁻⁵
Erbium (68)	Er-169	S	6X10 ⁷	3X10 ⁻³	2X10 ⁻⁸	9X10 ⁻⁵
		I	4X10 ⁷	3X10 ⁻³	1X10 ⁻⁸	9X10 ⁻⁵
	Er-171	S	7X10 ⁷	3X10 ⁻³	2X10 ⁻⁸	1X10.4
		Ι	6X10 ⁷	3X10 ⁻³	2X10 ⁻⁸	1X10⁴
Europium (63)	Eu-152	S ·	4X10 ⁷	2X10 ⁻³	1X10 ⁻⁸	6X10 ⁻⁵
	(T _r =9.2 hrs)	I	3X10 ⁷	2X10 ⁻³	1X10 ⁻⁸	6X10 ⁻⁵
	Eu-152	S	1X10 ⁻⁸	2X10 ⁻³	4X10 ⁻¹⁰	8X10 ⁻⁵
,	$(T_r=13 \text{ yrs})$	I	2X10 ⁸	2X10 ⁻³	6X10 ⁻¹⁰	-8X10-5
	Eu-154	S	4X10 ⁹	6X10⁴	1X10 ⁻¹⁰	2X10 ⁻⁵
		I	7X10°	6X10 ⁻⁴	2X10 ⁻¹⁰	2X10 ⁻⁵
	Eu-155	S	9X10 ⁸	6X10 ⁻³	3X10 ⁻⁹	2X10 ⁻⁴
		I	7X10 ⁸	6X10 ⁻³	3X10 ⁻⁹	2X10 ⁻⁴
Fermium (100)	Fm-254	S	6X10 ⁻⁸	4X10 ⁻³	2X10 ⁻⁹	1X10 ⁻⁴
		I	7X10 ⁻⁸	4X10 ⁻³	2X10 ⁻⁹	1X10 ⁻⁴
	Fm-255	S	2X10 ⁻⁸	1X10 ⁻³	6X10 ⁻¹⁰	3X10 ⁻⁵
•		I	1X10 ⁻⁸	1X10 ⁻³	4X10 ⁻¹⁰	3X10 ⁻⁵

				Table I	Table II		
Element (atomic number)	Radio- nuclide <u>1</u> /		Column 1 Air (µCi/ml)	Column 2 Water (µCi/ml)	Column 1 Air (µCi/ml)	Column 2 Water (µCi/ml)	
	Fm-256	S	3X10 ⁻⁹	3X10 ⁻⁵	1X10 ⁻¹⁰	9X10 ⁻⁷	
		I	2X10°	3X10 ⁻⁵	6X10 ⁻¹¹	9X10 ⁻⁷	
Fluorine (9)	F-18	S	5X10 ⁻⁶	2X10 ⁻²	2X10 ⁻⁷	8X10⁴	
		I	3X10 ⁶	1X10 ⁻²	9X10 ⁻⁸	5X10⁴	
Gadolinium (64)	Gd-153	S	2X10 ⁷	6X10 ⁻³	8X10 ⁻⁹	2X10 ⁻⁴	
•		I	9X10 ⁻⁸	6X10 ⁻³	3X10 ⁻⁹	2X10 ⁻⁴	
	Gd-159	S	5X10 ⁻⁷	2X10 ⁻³	2X10 ⁻⁸	8X10 ⁻⁵	
		I	4X10 ⁷	2X10 ⁻³	1X10 ⁻⁸	8X10 ⁻⁵	
Gallium (31)	Ga-67*	S	9X10 ⁻⁶	3X10 ⁻²	3X10 ⁻⁷	1X10 ⁻³	
		I	6X10 ⁻⁶	6X10 ⁻²	2X10 ⁻⁷	2X10 ⁻³	
	Ga-72	S	2X10 ⁷	1X10 ⁻³	8X10 ⁻⁹	4X10 ⁻⁵	
		I	2X10 ⁷	1X10 ⁻³	6X10 ⁻⁹	4X10 ⁻⁵	
Germanium (32)	Ge-68*	S	4X10 ⁻⁶	2X10 ⁻²	1X10 ⁻⁷	8X10⁴	
		I	1X10 ⁻⁸		5X10 ⁻¹⁰		
	Ge-71	S	1X10 ⁻⁵	5X10 ⁻²	4X10 ⁻⁷	2X10 ⁻³	
		I	6X10 ⁶	5X10 ⁻²	2X10 ⁻⁷	2X10 ⁻³	
Gold (79)	Au-195*	S	8X10 ⁻⁶	4X10 ⁻²	3X10 ⁻⁷	1X10 ⁻³	
		I	6X10*	6X10 ⁻³	2X10°	2X10 ⁴	
	Au-196	· S	1X10 ⁶	5X10 ⁻³	4X10 ⁻⁸	2X10 ⁻⁴	
		I	6X10 ⁷	4X10 ⁻³	2X10 ⁻⁸	1X10 ⁴	
,	Au-198	S	3X10 ⁻⁷	2X10 ⁻³	1X10 ⁻⁸	5X10 ⁻⁵	
		I	2X10 ⁷	1X10 ⁻³	8X10 ⁻⁹	5X10 ⁻⁵	
	Au-199	S	1X10 ⁻⁶	5X10 ⁻³	4X10 ⁻⁸	2X10 ⁻⁴	
-		I	8X10 ⁷	4X10 ³	3X10 ⁻⁸	2X10 ⁻⁴	
Hafnium (72)	Hf-181	S	4X10 ⁸	2X10 ⁻³	1X10 ⁻⁹	7X10 ⁻⁵	
		Ι	7X10 ⁸	2X10 ⁻³	3X10 ⁻⁹	7X10 ⁻⁵	
Holmium (67)	Ho-166	S	2X10 ⁻⁷	9X10⁴	7X10 ⁻⁹	3X10 ⁻⁵	
		I	2X10 ⁷	9X10 ⁻⁴	6X10 ⁻⁹	- 3X10 ⁻⁵	
Hydrogen (1)	H-3	S	5X10 ⁶	1X10 ⁻¹	2X10 ⁻⁷	3X10 ⁻³	
	•	I	5X10 ⁻⁶	1X10 ⁻¹	2X10 ⁻⁷	3X10 ⁻³	
		Sub <u>2</u> /	2X10 ⁻³	•	4X10 ⁻⁵		
Indium (49)	In-111*	S	5X10 ⁻⁶	5X10 ⁻²	1X10 ⁻⁷	1X10 ⁻³	
		I	8X10 ⁻⁶	3X10 ⁻²	3X10 ⁻⁷	1X10 ⁻³	

				Table I		Table II
Element (atomic number)	Radio- nuclide <u>1</u> /		Column 1 Air (µCi/ml)	Column 2 Water (µCi/ml)	Column 1 Air (µCi/ml)	Column 2 Water (μCi/ml)
	In-113m	S	8X10 ⁻⁶	4X10 ⁻²	3X10 ⁻⁷	1X10 ⁻³
		I	7X10 ⁶	4X10 ⁻²	2X10 ⁻⁷	1X10 ⁻³
	In-114m	S	1X10 ⁷	5X10⁴	4X10 ⁻⁹	2X10 ⁻⁵
		I	2X10 ⁸	5X10⁴	7X10 ⁻¹⁰	2X10 ⁻⁵
	In-115m	S	2X10 ⁻⁶	1X10 ⁻²	8X10 ⁻⁸	4X10⁴
•		I	2X10 ⁶	1X10 ⁻²	6X10 ⁻⁸	4X10⁴
	In-115	S	2X10 ⁷	3X10 ⁻³	9X10 ⁻⁹	9X10 ⁻⁵
•	,	I	3X10 ⁻⁸	3X10 ⁻³	1X10 ⁻⁹	9X10 ⁻⁵
Iodine (53)	I-123*	S I	2X10 ⁵	3X10 ⁻³	8X10 ⁻⁷	1X10⁴
	I-125	S	5X10°	4X10 ⁻⁵	8X10 ⁻¹¹	2X10 ⁻⁷
		I	2X10 ⁷	6X10 ⁻³	6X10 ⁻⁹	2X10.4
	I-126	S	8X10°	5X10 ⁻⁵	9X10 ⁻¹¹	3X10 ⁻⁷
		I	3X10 ⁷	3X10 ⁻³	1X10 ⁻⁸	9X10 ⁻⁵
•	I-129	S	2X10°	1X10 ⁻⁵	2X10 ⁻¹¹	6X10 ⁻⁸
		I	7X10 ⁻⁸	6X10 ⁻³	2X10 ⁻⁹	2X10 ⁻⁴
	I-131	S	9X10°	6X10 ⁻⁵	1X10 ⁻¹⁰	3X10 ⁻⁷
		I	3X10 ⁷	2X10 ⁻³	1X10 ⁻⁸	6X10 ⁻⁵
•	I-132	S	2X10 ⁷	2X10 ⁻³	3X10 ⁻⁹	8X10 ⁻⁶
		I	9X10 ⁷	5X10 ⁻³	3X10 ⁻⁸	2X10 ⁻⁴
	I-133	S	3X10 ⁸	2X10 ⁻⁴	4X10 ⁻¹⁰	1X10 ⁻⁶
		I	2X10 ⁷	1X10 ⁻³	7X10 ⁻⁹	4X10 ⁻⁵
	I-134 ´	S	5X10 ⁻⁷	4X10 ⁻³	6X10 ⁻⁹	2X10 ⁻⁵
		Ι.	3X10 ⁻⁶	2X10 ⁻²	1X10 ⁻⁷	6X10 ⁻⁴
	I-135	S .	1X10 ⁷	7X10 ⁴	1X10 ⁻⁹	4X10 ⁻⁶
		. I	4X10 ⁷	2X10 ⁻³	1X10 ⁸	7X10 ⁻⁵
Iridium (77)	Ir-190	S	1X10 ⁶	6X10 ⁻³	4X10*	2X10 ⁴
		I	4X10 ⁷	5X10 ⁻³	1X10 ⁻⁸	2X10 ⁴
	Ir-192	S	1X10 ⁷	1X10 ⁻³	4X10 ⁻⁹	4X10 ⁻⁵
		I	3X10 ⁻⁸	1X10 ⁻³	9X10 ⁻¹⁰	4X10 ⁻⁵
	Ir-194	S	2X10 ⁷	1X10 ⁻³	8X10 ⁻⁹	3X10 ⁻⁵
		I	2X10 ⁷	9X10 ⁴	5X10 ⁻⁹	3X10 ⁻⁵
Iron (26)	Fe-52*	s .	4X10 ⁶	8X10 ⁻³	1X10 ⁻⁷	2X10 ⁻⁴
		I	2X10 ⁶	1X10 ⁻²	9X10 ⁻⁸	4X10 ⁻⁴
	Fe-55	S	9X10 ⁷	2X10 ⁻²	3X10 ⁻⁸	8X10 ⁻⁴
•		I	1X10 ⁶	7X10 ⁻²	3X10 ⁻⁸	2X10 ⁻³
	Fe-59	S	1X10 ⁷	2X10 ⁻³	5X10 ⁻⁹	6X10 ⁻³
		I	5X10 ⁸	2X10 ⁻³	2X10 ⁻⁹	5X10 ⁻⁵
Krypton (36)	Kr-85m	Sub2/	6X10 ⁶		1X10°	
	Kr-85	Sub	1X10 ⁻⁵		3X10 ⁻⁷	*****

			Table I		Table II	
Element (atomic number)	Radio- nuclide <u>1</u> /		Column 1 Air (µCi/ml)	Column 2 Water (µCi/ml)	Column 1 Air (µCi/ml)	Column 2 Water (µCi/ml)
,	Kr-87	Sub	1X10 ⁻⁶		2X10 ⁻⁸	
	Kr-88	Sub	1X10 ⁻⁶		2X10 ⁻⁸	
Lanthanum (57)	La-140	S	2X10 ⁻⁷	7X10⁴	5X10 ⁻⁹	2X10 ⁻⁵
		I	1X10 ⁷	7X10⁴	4X10 ⁻⁹	2X10 ⁻⁵
Lead (82)	Pb-203	S	3X10 ⁻⁶	1X10 ⁻²	9X10 ⁻⁸	4X10 ⁻⁴
		I	2X10 ⁶	1X10 ⁻²	6X10 ⁻⁸	4X10⁴
	Pb-210	S	1X10 ⁻¹⁰	4X10 ⁻⁶	4X10 ⁻¹²	1X10 ⁻⁷
		I	2X10 ¹⁰	5X10 ⁻³	8X10 ⁻¹²	2X10⁴
	Pb-212	S	2X10 ⁸	6X10⁴	6X10 ⁻¹⁰	2X10 ⁻⁵
	10212	I	2X10 ⁻⁸	5X10 ⁻⁴	7X10 ⁻¹⁰	2X10 ⁻⁵
Lutetium (71)	Lu-177	S	6X10 ⁷	3X10 ⁻³	2X10 ⁻⁸	1X10⁴
(, 1)		I	5X10 ⁻⁷	3X10 ⁻³	2X10 ⁻⁸	1X10 ⁻⁴
Manganese (25)	Mn-52	S	2X10 ⁻⁷	1X10 ⁻³	7X10 ⁻⁹	3X10 ⁻⁵
	•	I	1X10 ⁻⁷	9X10⁴	5X10 ⁻⁹	3X10 ⁻⁵
•	Mn-54	S	4X10 ⁷	4X10 ⁻³	1X10 ⁻⁸	1X10⁴
		I	4X10 ⁸	3X10 ⁻³	1X10 ⁻⁹	1X10⁴
	Mn-56	S	8X10 ⁷	4X10 ⁻³	3X10 ⁻⁸	1X10⁴
		I	5X10 ⁷	3X10 ⁻³	2X10 ⁻⁸	1X10⁴
Mercury (80)	Hg-197m	s	7X10 ⁷	6X10 ⁻³	3X10 ⁻⁸	2X10⁴
		I	8X10 ⁷	5X10 ⁻³	3X10 ⁻⁸	2X10⁴
	Hg-197	S	1X10 ⁻⁶	9X10 ⁻³	4X10 ⁻⁸	3X10⁴
		I	3X10 ⁶	1X10 ⁻²	9X10 ⁻⁸	5X10⁴
	Hg-203	S	7X10 ⁸	5X10⁴	2X10 ⁻⁹	2X10 ⁻⁵
		Ι .	1X10 ⁷	3X10 ⁻³	4X10 ⁻⁹	1X10 ⁻⁴
Molybdenum (42)	Mo-99	S	7X10 ⁷	5X10 ⁻³	3X10 ⁻⁸	2X10⁴
		I	2X10 ⁻⁷	1X10 ⁻³	7X10 ⁻⁹	4X10 ⁻⁵
Neodymium (60)	Nd-144	S	8X10 ⁻¹¹	2X10 ⁻³	3X10 ⁻¹²	7X10 ⁻⁵
•		I	3X10 ¹⁰	2X10 ⁻³	1X10-11	8X10-5
	Nd-147	S	4X10 ⁻⁷	2X10 ⁻³	1X10 ⁻⁸	. 6X10 ⁻⁵
		I	2X10 ⁻⁷	2X10 ⁻³	8X10 ⁻⁹	6X10 ⁻⁵
•	Nd-149	S	2X10 ⁻⁶	8X10 ⁻³	6X10 ⁻⁸	3X10 ⁴
		I	1X10 ⁻⁶	8X10 ⁻³	5X10 ⁻⁸	3X10 ⁴
Neptunium (93)	Np-237	S	4X10 ⁻¹²	9X10 ⁻⁵	1X10 ⁻¹³	3X10 ⁻⁶
		I	1X10 ⁻¹⁰	9X10 ⁻⁴	4X10 ⁻¹²	3X10 ⁻⁵
	Np-239	S	8X10 ⁷	4X10 ⁻³	3X10 ⁻⁸	1X10 ⁴
		I	7X10 ⁻⁷	4X10 ⁻³	2X10 ⁻⁸	1X10 ⁻⁴

				Table I	· ,	Гable II
Element	Radio-		Column 1	Column 2	Column 1	Column 2
(atomic number)	nuclide <u>1</u> /		Air (μCi/ml)	Water (μCi/ml)	Air (μCi/ml)	Water (µCi/ml)
Niekal (28)	 Ni-59	S	5X10 ⁷	6X10 ⁻³	2X10 ⁻⁸	2X10 ⁻⁴
Nickel (28)	141-39	I	8X10 ⁷	6X10 ⁻²	3X10 ⁸	2X10 ⁻³
	Ni-63	S	6X10 ⁸	8X10 ⁻⁴	2X10 ⁻⁹	3X10 ⁻⁵
	141 05	I	3X10 ⁷	2X10 ⁻²	1X10 ⁻⁸	7X10 ⁻⁴
	Ni-65	S	9X10 ⁷	4X10 ⁻³	3X10 ⁻⁸	1X10 ⁻⁴
·	111 00	I	5X10 ⁻⁷	3X10 ⁻³	2X10 ⁻⁸	1X10 ⁻⁴
Niobium (41)	Nb-93m	S	1X10 ⁻⁷	1X10 ⁻²	4X10 ⁻⁹	4X10 ⁻⁴
1.10012 (*=)		1	2X10 ⁷	1X10 ⁻²	5X10 ⁻⁹	4X10 ⁻⁴
	Nb-95	S	5X107	3X10 ⁻³	2X10 ⁻⁸	1X10 ⁻⁴ .
•		I	1X10 ⁷	3X10 ⁻³	3X10 ⁻⁹	1X10 ⁻⁴
	Nb-97	S	6X10 ⁶	3X10 ⁻²	2X10 ⁻⁷	9X10⁴
		I	5X10 ⁶	3X10 ⁻²	2X10 ⁻⁷	9X10⁴
Nitrogen (7)	N-13*	Sub_2/	4X10 ⁶			•••••
		÷		•		
Osmium (76)	Os-185	S	5X10 ⁷	2X10 ⁻³	2X10 ⁻⁸	7X10 ⁻⁵
	•	I	5X10 ⁸	2X10 ⁻³	2X10 ⁻⁹	7X10 ⁻⁵
	Os-191m	S	2X10 ⁵	7X10 ⁻²	6X10 ⁻⁷	3X10 ⁻³
		1	9X10⁴	7X10 ⁻²	$3X10^{-7}$	2X10 ⁻³
	Os-191	S	1X10 ⁶	5X10 ⁻³	4X10 ⁸	2X10⁴
		I	4X10 ⁷	5X10 ⁻³	1X10 ⁻⁸	2X10⁴
	Os-193	S	4X10 ⁷	2X10 ⁻³	1X10 ⁻⁸	6X10 ⁻⁵
		I	3X10 ⁷	2X10 ⁻³	9X10 ⁻⁹	5X10 ⁻⁵ _
		,				
Oxygen (8)	O-15*	Sub <u>2</u> /	4X10 ⁶			
- 4 4 44	21.00		13710-6	15/10-2	5X10 ⁸	3X10⁴
Palladium (46)	Pd-103	S	1X10 ⁶	1X10 ⁻² 8X10 ⁻³	3X10 ⁸	3X10 ⁴
	D4 100	I	7X10 ⁷ 6X10 ⁷	3X10 ⁻³	2X10 ⁻⁸	9X10 ⁻³
	Pd-109	S I	4X10 ⁷	2X10 ⁻³	1X10 ⁻⁸	7X10 ⁻⁵
		1	4X10	2.X10	IXIO	7210
Dhambarus (15)	P-32	S	7X10 ⁸	5X10⁴	2X10 ⁻⁹	2X10 ⁻⁵
Phosphorus (15)	F-32	I	8X10 ⁸	7X10⁴	3X10 ⁻⁹	2X10 ⁻⁵
•		1	OXIO	77110	34110	
Platinum (78)	Pt-191	·S	8X10 ⁻⁷	4X10 ⁻³	3X10 ⁻⁸	1X10 ⁻⁴
Plauliulii (70)	11-191	I	6X10 ⁷	3X10 ⁻³	2X10 ⁻⁸	1X10 ⁻⁴
	Pt-193m	S	7X10 ⁻⁶	3X10 ⁻²	2X10 ⁻⁷	1X10 ⁻³
		· I	5X10 ⁻⁶	3X10 ⁻²	2X10 ⁻⁷	1X10 ⁻³
	Pt-193	S	1X10 ⁻⁶	3X10 ⁻²	4X10 ⁻⁸	9X10 ⁻⁴
		Ī	3X10 ⁻⁷	5X10 ⁻²	1X10 ⁻⁸	2X10 ⁻³
	Pt-197m	S	6X10 ⁶	3X10 ⁻²	2X10 ⁻⁷	1X10 ⁻³
-		I	5X10 ⁻⁶	3X10 ⁻²	2X10 ⁻⁷	9X10⁴

				Table I		Table II
Element (atomic number)	Radio- nuclide <u>1</u> /		Column 1 Air (µCi/ml)	Column 2 Water (µCi/ml)	Column 1 Air (µCi/ml)	Column 2 Water (µCi/ml)
	Pt-197	S	8X10 ⁻⁷	4X10 ⁻³	3X10 ⁻⁸	1X10 ⁻⁴
		I	6X10 ⁷	3X10 ⁻³	2X10 ⁻⁸	1X10⁴
Plutonium (94)	Pu-238	S	2X10 ¹²	1X10 ⁻⁴	7X10 ⁻¹⁴	5X10 ⁻⁶
		I	3X10 ⁻¹¹	8X10⁴	1X10 ⁻¹²	3X10 ⁻⁵
	Pu-239	S	2X10 ⁻¹²	1X10 ⁻⁴	6X10 ⁻¹⁴	5X10 ⁻⁶
	•	I	4X10 ¹¹	8X10 ⁻⁴	1X10 ⁻¹²	3X10 ⁻⁵
	Pu-240	S	2X10 ⁻¹²	1X10⁴	6X10 ⁻¹⁴	5X10 ⁻⁶
		I	4X10 ¹¹	8X10 ⁴	1X10 ⁻¹²	3X10 ⁻⁵
	Pu-241	S	9X10 ¹¹	7X10 ⁻³	3X10 ⁻¹²	2X10⁴
		I	4X10 ⁻⁸	4X10 ⁻²	1X10 ⁻⁹	1X10 ⁻³
	Pu-242	S	2X10 ⁻¹²	1X10⁴	6X10 ⁻¹⁴	5X10 ⁻⁶
	•	I	4X10 ¹¹	9X10⁴	1X10 ⁻¹²	3X10 ⁻⁵
	Pu-243	S	2X10 ⁻⁶	1X10 ⁻²	6X10 ⁻⁸	3X10⁴
		ľ	2X10 ⁻⁶	1X10 ⁻²	8X10 ⁻⁸	3X10⁴
	Pu-244	S	2X10 ¹²	1X10 ⁻⁴	6X10 ⁻¹⁴	4X10 ⁻⁶
	•	- I	3X10 ¹¹	3X10 ⁻⁴	1X10 ⁻¹²	1X10 ⁻⁵
Polonium (84)	Po-210	Š	5X10 ⁻¹⁰	2X10 ⁻⁵	2X10 ⁻¹¹	7X10 ⁻⁷
	•	I	2X10 ⁻¹⁰	8X10⁴	7X10 ⁻¹²	3X10 ⁻⁵
Potassium (19)	K-42	S	2X10 ⁶	9X10 ⁻³	7X10 ⁻⁸	3X10 ⁻⁴
	•	I	1X10 ⁷	6X10 ⁻⁴	4X10 ⁻⁹	2X10 ⁻⁵
	K-43*	S .	5X10 ⁻⁶	3X10 ⁻²	2X10 ⁻⁷	1X10 ⁻³
		I	9X10 ⁶	1 X 10 ⁻³	3X10 ⁻⁷	6X10 ⁻⁵
Praseodymium (59)	Pr-142	S	2X10 ⁻⁷	9X10-4	7X10 ⁻⁹	3X10 ⁻⁵
		I	2X10 ⁻⁷	9X10-4	5X10 ⁻⁹	3X10 ⁻⁵
	Pr-143	S -	3X10 ⁻⁷	1X10 ⁻³	1X10 ⁻⁸	5X10 ⁻⁵
		I	2X10 ⁷	1X10 ⁻³	6X10 ⁻⁹	5X10 ⁻⁵
Promethium (61)	Pm-147	S	6X10 ⁸	6X10 ⁻³	2X10 ⁻⁹	2X10 ⁻⁴
		I	1X10 ⁻⁷	6X10 ⁻³	3X10 ⁻⁹	2X10 ⁴
	Pm-149	S	3X10 ⁻⁷	1X10 ⁻³	1X10 ⁻⁸	4X10 ⁻⁵
		I	2X10 ⁷	1X10 ⁻³	8X10 ⁻⁹	· 4X10 ⁻⁵
Protactinium (91)	Pa-230	S	2X10°	7X10 ⁻³	6X10 ⁻¹¹	2X10 ⁴
		Ι	8X10 ⁻¹⁰	7X10 ⁻³	3X10 ⁻¹¹	2X10 ⁻⁴
	Pa-231	S	1X10 ⁻¹²	3X10 ⁻⁵	. 4X10 ⁻¹⁴	9X10 ⁻⁷
,		I	1X10 ¹⁰	8X10 ⁻⁴	4X10 ⁻¹²	2X10 ⁻⁵
	Pa-233	S	6X10 ⁻⁷	4X10 ⁻³	2X10 ⁻⁸	1X10⁴
		I	2X10 ⁷	3X10 ⁻³	6X10 ⁻⁹	1X10 ⁻⁴

			_	Table I		Table II
Element (atomic number)	Radio- nuclide <u>1</u> /		Column 1 Air (µCi/ml)	Column 2 Water (µCi/ml)	Column 1 Air (µCi/ml)	Column 2 Water (µCi/ml)
Radium (88)	Ra-223	s	2X10 ⁻⁹	2X10 ⁻⁵	6X10 ⁻¹¹	7X10 ⁻⁷
(,		I	2X10 ¹⁰	1X10 ⁴	8X10 ⁻¹²	4X10⁴
	Ra-224	S	5X10°	7X10 ⁻⁵	2X10 ⁻¹⁰	2X10⁴
		I	7X10 ¹⁰	2X10 ⁴	2X10 ⁻¹¹	5X10⁴
	Ra-226	S	3X10 ¹¹	4X10 ⁻⁷	3X10 ⁻¹²	3X10 ⁻⁸
~		I	5X10 ¹¹	9X10 ⁴	2X10 ⁻¹²	3X10 ⁻⁵
	Ra-228	S	7X10 ¹¹	8X10 ⁻⁷	2X10 ⁻¹²	3X10 ⁻⁸
•		I	4X10 ⁻¹¹	7X10 ⁻⁴	1X10 ⁻¹²	3X10 ⁻⁵
Radon (86)	Rn-220	S	3X10 ⁻⁷		1X10 ⁻⁸	
	Rn-222 <u>3</u> /	S	3X10 ⁸		3X10 ⁻⁹	
Rhenium (75)	Re-183	S	3X10 ⁻⁶	2X10 ⁻²	9X10 ⁻⁸	6X10⁴
		I	2X10 ⁷	8X10 ⁻³	5X10 ⁻⁹	3X10⁴
	Re-186	S	6X10 ⁻⁷	3X10 ⁻³	2X10 ⁻⁸	9X10 ⁻⁵
		I	2X10 ⁷	1X10 ⁻³	8X10 ⁻⁹	5X10 ⁻⁵
	Re-187	S	9X10⁴	7X10 ⁻²	3X10 ⁻⁷	3X10 ⁻³
		I	5X10 ⁻⁷	4X10 ⁻²	2X10 ⁻⁸	2X10 ⁻³
	Re-188	· S	4X10 ⁻⁷	2X10 ⁻³	1X10 ⁻⁸	6X10 ⁻⁵
•		I	2X10 ⁻⁷	9X10⁴	6X10 ⁻⁹	3X10 ⁻⁵
Rhodium (45)	Rh-103m	S	8X10 ⁻⁵	4X10 ⁻¹	3X10⁴	1X10 ⁻²
	•	I	6X10 ⁻⁵	3X10 ⁻¹	2X10 ⁻⁶	1X10 ⁻²
	Rh-105	S	8X10 ⁻⁷	4X10 ⁻³	3X10 ⁻⁸	1X10 ⁻⁴
		I	5X10 ⁷	3X10 ⁻³	2X10 ⁻⁸	1X10⁴
Rubidium (37)	Rb-86	S	3X10 ⁷	2X10 ⁻³	1X10 ⁻⁸	7X10 ^{-s}
		I	7X10 ⁸	7X10 ⁻⁴	2X10 ⁻⁹	2X10 ⁻⁵
	Rb-87	S	5X10 ⁻⁷	3X10 ⁻³	2X10 ⁻⁸	1X10 ⁻⁴
•		I	7X10*	5X10 ⁻³	2X10 ⁻⁹	2X10 ⁴
Ruthenium (44)	Ru-97	s	2X10⁴	1X10 ⁻²	8X10 ⁻⁸	4X10 ⁻⁴
		I	2X10 ⁶	1X10 ⁻²	6X10 ⁻⁸	3X10 ⁻⁴
	Ru-103	S	5X10 ⁻⁷	2X10 ⁻³	2X10 ⁻⁸	8X10 ⁻⁵
		I	8X10 ⁸	2X10 ⁻³	3X10 ⁻⁹	8X10 ⁻⁵
-	Ru-105	S	7X10 ⁻⁷	3X10 ⁻³	2X10 ⁻⁸	1X10 ⁻⁴
		I	5X10 ⁷	3X10 ⁻³	2X10 ⁻⁸	1X10 ⁻⁴
	Ru-106	S	8X10 ⁸	4X10 ⁻⁴	3X10 ⁻⁹	1X10 ⁻⁵
		I	6X10°	3X10 ⁻⁴	2X10 ⁻¹⁰	1X10 ⁻⁵
Samarium (62)	Sm-147	s	7X10 ¹¹	2X10 ⁻³	2X10 ⁻¹²	6X10 ⁻⁵
		I	3X10 ⁻¹⁰	2X10 ⁻³	9X10 ⁻¹²	7X10 ⁻⁵

			т	able I	Ta	ible II
Element (atomic number)	Radio- nuclide <u>1</u> /		Column 1 Air (µCi/ml)	Column 2 Water (µCi/ml)	Column 1 Air (µCi/ml)	Column 2 Water (µCi/ml)
	Sm-151	S	6X10 ⁸	1X10 ⁻²	2X10 ⁻⁹	4X10 ⁻⁴
		I	1X10 ⁻⁷	1X10 ⁻²	5X10 ⁻⁹	4X10 ⁻⁴
	Sm-153	S	5X10 ⁷	2X10 ⁻³	2X10 ⁻⁸	8X10 ⁻⁵
·		I	4X10 ⁷	2X10 ⁻³	1X10 ⁻⁸	8X10 ⁻⁵
	•					. ,
Scandium (21)	Sc-46	S .	2X10 ⁷	1X10 ⁻³	8X10 ⁻⁹	4X10 ⁻⁵
		, I	2X10 ⁸	1X10 ⁻³	8X10 ⁻¹⁰	4X10 ⁻⁵
	Sc-47	S	6X10 ⁷	$3X10^{-3}$	2X10 ⁻⁸	9X10 ⁻⁵
		I	5X10 ⁷	$3X10^{-3}$	2X10 ⁻⁸	9X10 ⁻⁵
	Sc-48	S	2X10 ⁻⁷	8X10⁴		3X10 ⁻⁵
		I	1X10 ⁻⁷	8X10 ⁴	5X10 ⁻⁹	3X10 ⁻⁵
Selenium (34)	Se-75	S	1X10 ⁻⁶	9X10 ⁻³	4X10 ⁻⁸	3X10 ⁻⁴
50(5.)	50 75	I	1X10 ⁷	8X10 ⁻³	4X10 ⁻⁹	3X10 ⁻⁴
		_		,		
Silicon (14)	Si-31	S	6X10 ⁻⁶	3X10 ⁻²	2X10 ⁻⁷	9X10 ⁻⁴
,		I	1X10 ⁶	6X10 ⁻³	3X10 ⁻⁸	2X10 ⁻⁴
`						
Silver (47)	Ag-105	S	6X10 ⁷	3X10 ⁻³	2X10 ⁻⁸	1X10 ⁻⁴
	•	I	8X10 ⁸	3X10 ⁻³	3X10 ⁻⁹	1X10 ⁻⁴
•	Ag-110m	S	2X10 ⁻⁷	9X10⁴	7X10 ⁻⁹	3X10 ⁻⁵
	•	I	1X10 ⁸	9X10⁴	3X10 ⁻¹⁰	3X10 ⁻⁵
	Ag-111	S	3X10 ⁻⁷	1X10 ⁻³	1X10 ⁻⁸	4X10 ⁻⁵
•		I	2X10 ⁻⁷	1X10 ⁻³	8X10 ⁻⁹	4X10 ⁻⁵
Sodium (11)	Na-22	S	2X10 ⁷	1X10 ⁻³	6X10 ⁻⁹	4X10 ⁻⁵
		I	9X10°	9X10 ⁻⁴	3X10 ⁻¹⁰	3X10 ⁻⁵
	Na-24	S	1X10 ⁶	6X10 ⁻³	4X10 ⁻⁸	2X10 ⁻⁴
		I	1X10 ⁷	8X10⁴	5X10 ⁻⁹	3X10 ⁻⁵
Strontium (28)	Sr-85m	S	4X10 ⁻⁵	2710-1	1710-6	7V10-3
Strontium (38)	21-03111	S I	3X10 ⁻⁵	2X10 ⁻¹	1X10-6	7X10 ⁻³
•	Sr-85	S	2X10 ⁷	2X10 ⁻¹ 3X10 ⁻³	1X10-6	7X10 ⁻³
· ·	. 31-03	S I	1X10 ⁷		8X10 ⁻⁹	1X10 ⁻⁴
•	Sr-89	S	3X10 ⁸	5X10 ⁻³ 3X10 ⁻⁴	4X10 ⁻⁹	2X10 ⁻⁴
	31-09	I	4X10 ⁸	8X10 ⁻⁴	3X10 ⁻¹⁰	3X10-6
	Sr-90	S	4X10 1X10°	8X10 1X10 ⁻⁵	1X10 ⁻⁹ 3X10 ⁻¹¹	3X10 ⁻⁵ 3X10 ⁻⁷
	51-70 ·	I	5X10°	1X10 1X10 ⁻³	2X10 ⁻¹⁰	4X10 ⁻⁵
	Sr-91	S	4X10 ⁷	2X10 ⁻³	2X10 ⁻⁸	
	31-31	I	3X10 ⁷	1X10 ⁻³	9X10°	7X10 ⁻⁵
•	Sr-92	S .	4X10 ⁻⁷	2X10 ⁻³	9X10° 2X10°	5X10 ⁻⁵
	31-72	s . I	3X10 ⁷	2X10 ⁻³	2X10° 1X10°	7X10 ⁻⁵
	•	ī	3710	4 X 10	1X10 -	6X10 ⁻⁵

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			_	Table I		Table II	
Element (atomic number)	Radio- nuclide <u>1</u> /		Column 1 Air (µCi/ml)	Column 2 Water (µCi/ml)	Column 1 Air (µCi/ml)	Column 2 Water (µCi/ml)	
Sulfur (16)	S-35	S	3X10 ⁻⁷	2X10 ⁻³	9X10 ⁻⁹	6X10 ⁻⁵	
		I	3X10 ⁷	8X10 ⁻³	9X10 ⁻⁹	3X10 ⁻⁴	
Tantalum (73)	Ta-182	S	4X10 ⁸	1X10 ⁻³	1X10 ⁻⁹	4X10 ⁻⁵	
		I	2X10 ⁸	1X10 ⁻³	7X10 ⁻¹⁰	4X10 ⁻⁵	
Technetium (43)	Tc-96m	s	8X10 ⁻⁵	4X10 ⁻¹	3X10 ⁻⁶	1X10 ⁻²	
		I	3X10 ⁻⁵	3X10 ⁻¹	1X10 ⁻⁶	1X10 ⁻²	
	Tc-96	S	6X10 ⁷	3X10 ⁻³	2X10 ⁻⁸	1X10⁴	
		I	2X10 ⁻⁷	1X10 ⁻³	8X10 ⁻⁹	5X10 ⁻⁵	
•	Tc-97m	S	2X10 ⁻⁶	1X10 ⁻²	8X10 ⁻⁸	4X10⁴	
		I	2X10 ⁷	5X10 ⁻³	5X10 ⁻⁹	2X10 ⁻⁴	
	Tc-97	S	1X10 ⁻⁵	5X10 ⁻²	4X10 ⁻⁷	2X10 ⁻³	
		I	3X10 ⁻⁷	2X10 ⁻²	1X10 ⁻⁸	8X10⁴	
	Tc-99m	S	4X10 ⁻⁵	2X10 ⁻¹	1X10 ⁻⁶	6X10 ⁻³	
		I	1X10 ⁻⁵	8X10 ⁻²	5X10 ⁻⁷	3X10 ⁻³	
	Tc-99	S	2X10 ⁶	1X10 ⁻²	7X10 ⁻⁸	3X10 ⁻⁴	
		I.	6X10 ⁸	5X10 ⁻³	2X10 ⁻⁹	2X10 ⁻⁴	
Tellurium (52)	Te-125m	S	4X10 ⁻⁷	5X10 ⁻³	1X10 ⁻⁸	2X10 ⁻⁴	
		I	1X10 ⁻⁷	3X10 ⁻³	4X10 ⁻⁹	1X10⁴	
•	Te-127m	S	1X10 ⁻⁷	2X10 ⁻³	5X10 ⁻⁹	6X10 ⁻⁵	
		I	4X10 ⁻⁸	2X10 ⁻³	1X10 ⁻⁹	5X10 ⁻⁵	
	Te-127	S	2X10 ⁻⁶	8X10 ⁻³	6X10 ⁻⁸	3X10⁴	
•		I	9X10 ⁷	5X10 ⁻³	3X10 ⁻⁸	2X10⁴	
	Te-129m	S	8X10 ⁻⁸	1X10 ⁻³	3X10 ⁻⁹	3X10 ⁻⁵	
		I	3X10 ⁻⁸	6X10⁴	1X10 ⁻⁹	2X10 ⁻⁵	
	Te-129	S	5X10 ⁻⁶	2X10 ⁻²	2X10 ⁻⁷	8X10⁴	
	,	I-	4X10 ⁻⁶	2X10 ⁻²	1X10 ⁻⁷	8X10⁴	
	Te-131m	S	4X10 ⁻⁷	2X10 ⁻³	1X10 ⁻⁸	6X10 ⁻⁵	
•		I	2X10 ⁻⁷	1X10 ⁻³	6X10 ⁻⁹	4X10 ⁻⁵	
	Te-132	S	2X10 ⁻⁷	9X10⁴	7X10 ⁻⁹	3X10 ⁻⁵	
		I	1X10 ⁷	6X10⁴	4X10 ⁻⁹	2X10 ⁻⁵	
Terbium (65)	Tb-160	S	1X10 ⁻⁷	1X10 ⁻³	3X10 ⁻⁹	4X10 ⁻⁵	
•		ľ	·3X10 ⁻⁸	1X10 ⁻³	1X10 ⁻⁹	4X10 ⁻⁵	
Thallium (81)	T1-200	S	3X10 ⁻⁶	1X10 ⁻²	9X10 ⁻⁸	4X10 ⁻⁴	
		I	1X10 ⁻⁶	7X10 ⁻³	4X10 ⁻⁸	2X10 ⁻⁴	
	TI-201	S	2X10 ⁻⁶	9X10 ⁻³	7X10 ⁻⁸	3X10⁴	
		I	9X10 ⁷	5X10 ⁻³	3X10 ⁻⁸	2X10⁴	
	T1-202	S	8X10 ⁷	4X10 ⁻³	3X10 ⁻⁸	1X10⁴	
		I	2X10 ⁷	2X10 ⁻³	8X10 ⁻⁹	7X10 ⁻⁵	
	T1-204	S	6X10 ⁷	3X10 ⁻³	2X10 ⁻⁸	1X10⁴	
		I	3X10 ⁻⁸	2X10 ⁻³	9X10 ⁻¹⁰	6X10 ⁻⁵	

	-			Table I		Table II
Element	Radio-		Column 1	Column 2	Column 1	Column 2
(atomic number)	nuclide <u>1</u> /		Air (μCi/ml)	Water (µCi/ml)	Air (μCi/ml)	Water (μCi/ml)
Thorium (90)	Th-227	S	3X10 ¹⁰	5X10⁴	1X10 ⁻¹¹	2X10 ⁻⁵
		I	2X10 ⁻¹⁰	5X10-4	6X10 ⁻¹²	2X10 ⁻⁵
	Th-228	S	9X10 ⁻¹²	2X10 ⁻⁴	3X10 ⁻¹³	7X10 ⁻⁶
		I	6X10 ¹²	4X10-4	2X10 ⁻¹³	1X10 ⁻⁵
-	Th-230	S	2X10 ⁻¹²	5X10 ⁻⁵	8X10 ⁻¹⁴	2X10 ⁻⁶
		I	1X10 ⁻¹¹	9X10 ⁻⁴	3X10 ⁻¹³	3X10 ⁻⁵
	Th-231	S	1X10 ⁻⁶	7X10 ⁻³	5X10 ⁻⁸	2X10 ⁻⁴
		I	1X10⁻⁵	7X10 ⁻³	4X10 ⁻⁸	2X10⁴
	Th-232	S	3X10 ⁻¹¹	5X10 ⁻⁵	1X10 ⁻¹²	2X10 ⁻⁶
		I	3X10 ⁻¹¹	1X10 ⁻³	1X10 ⁻¹²	4X10 ⁻⁵
	Th-natural	S	6X10 ⁻¹¹	6X10 ⁻⁵	2X10 ⁻¹²	2X10 ⁻⁶
	•	I	6X10 ⁻¹¹	6X10⁴	2X10 ⁻¹²	2X10 ⁻⁵
	Th-234	S	6X10 ⁻⁸	5X10⁴	2X10 ⁻⁹	2X10 ⁻⁵
		I	3X10 ⁸	5X10⁴	1X10 ⁻⁹	2X10 ⁻⁵
Thulium (69)	Tm-170	·S	4X10 ⁻⁸	1X10 ⁻³	1X10 ⁻⁹	5X10 ⁻⁵
. ,		I	3X10 ⁻⁸	1X10 ⁻³	1X10 ⁻⁹	5X10 ⁻³
	Tm-171	S	1X10 ⁷	1X10 ⁻²	4X10 ⁻⁹	5X10 ⁴
		I	2X10 ⁻⁷	1X10 ⁻²	8X10 ⁻⁹	5X10 ⁻⁴
Tin (50)	Sn-113	s	4X10 ⁻⁷	03/10-3	13/10-8	07/10-5
Tin (50)	311-113			2X10 ⁻³	1X10 ⁻⁸	9X10 ⁻⁵
	Sn-125	I S	5X10 ⁻⁸	2X10 ⁻³	2X10 ⁻⁹	8X10-5
	SII-123	S I	1X10 ⁻⁷ 8X10 ⁻⁸	5X10 ⁴ 5X10 ⁴	4X10 ⁻⁹ 3X10 ⁻⁹	2X10 ⁻⁵ 2X10 ⁻⁵
	•					
Tungsten (74)	W-181	S	2X10 ⁻⁶	1X10 ⁻²	8X10 ⁻⁸	4X10 ⁻⁴
	•	I	1X10 ⁷	1X10 ⁻²	4X10 ⁻⁹	3X10 ⁻⁴
	W-185	S	8X10 ⁷	4X10 ⁻³	3X10 ⁻⁸	1X10⁴
		· I	1X10 ⁻⁷	3X10 ⁻³	4X10 ⁻⁹	1X10⁴
	W-187	S	4X10 ⁷	$2X10^{-3}$	2X10 ⁻⁸	7X10 ⁻⁵
_		I	3X10 ⁻⁷	2X10 ⁻³	1X10 ⁻⁸	6X10 ⁻⁵
Uranium (92)	U-230	S	3X10 ⁻¹⁰	1X10 ⁻⁴	1X10 ⁻¹¹	5X10-6
		I	1X10 ⁻¹⁰	1X10⁴	4X10 ⁻¹²	5X10 ⁻⁶
•	U-232	S	1X10 ⁻¹⁰	8X10⁴	3X10 ⁻¹²	3X10 ⁻⁵
		I	3X10 ⁻¹¹	8X10⁴	9X10 ⁻¹³	3X10 ⁻⁵
	U-233	S	5X10 ⁻¹⁰	9X10⁴	2X10 ⁻¹¹	3X10 ⁻⁵
		I	1X10 ⁻¹⁰	9X10 ⁻⁴	4X10 ⁻¹²	3X10 ⁻⁵
	U-234	S <u>4</u> /	6X10 ¹⁰	9X10 ⁻⁴	2X10 ⁻¹¹	3X10 ⁻⁵
		I	1X10 ⁻¹⁰	9X10 ⁻⁴	4X10 ⁻¹²	3X10 ⁻⁵
	U-235	S <u>4</u> /	5X10 ¹⁰	8X10 ⁻⁴	2X10 ⁻¹¹	3X10 ⁻⁵
		I	1X10 ¹⁰	8X10-4	4X10 ⁻¹²	3X10 ⁻⁵
	U-236	S	6X10 ¹⁰	1X10 ⁻³	2X10 ⁻¹¹	3X10 ⁻⁵
		I .	1X10 ⁻¹⁰	1X10 ⁻³	4X10 ⁻¹²	3X10 ⁻⁵

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				Table I		Table II
Element (atomic number)	Radio- 'nuclide 1/		Column 1 Air (µCi/ml)	Column 2 Water (µCi/ml)	Column 1 Air (µCi/ml)	Column 2 Water (µCi/ml)
	U-238	S 4/	7X10 ⁻¹¹	1X10 ⁻³	3X10 ⁻¹²	4X10 ⁻⁵
	_	I	1X10 ¹⁰	1X10 ⁻³	5X10 ⁻¹²	4X10 ⁻⁵
	U-240	S	2X10 ⁷	1X10 ⁻³	8X10 ⁻⁹	3X10 ⁻⁵
		I	2X10 ⁷	1X10 ⁻³	6X10 ⁻⁹	3X10 ^{-s}
	U-natural	S 4/	1X10 ¹⁰	1X10 ⁻³	5X10 ⁻¹² .	3X10 ⁻⁵
		. I	1X10 ⁻¹⁰	1X10 ⁻³	5X10 ⁻¹²	3X10 ⁻⁵
Vanadium (23)	V-48	S	2X10 ⁻⁷	9X10 ⁴	6X10 ⁻⁹	3X10 ⁻⁵
		Ι.	6X10*	8X10⁴	2X10 ⁻⁹	3X10 ⁻⁵
Xenon (54)	Xe-131m	Sub <u>2</u> /	2X10 ⁻⁵		4X10 ⁻⁷	
	Xe-133m	Sub	1X10 ⁵		3X10 ⁻⁷	
	Xe-133	Sub	1X10 ⁵		3X10 ⁻⁷	
	Xe-135	Sub	4X10 ⁶		1X10 ⁻⁷	
Ytterbium (70)	Yb-175	S	7X10 ⁷	3X10 ⁻³	2X10 ⁻⁸	1X10 ⁴
		I	6X10 ⁻⁷	3X10 ⁻³	2X10 ⁻⁸	1X10 ⁴
Yttrium (39)	Y-87*	S	4X10 ⁻⁶	7X10 ⁻³	1X10 ⁻⁷	2X10 ⁻⁴
		I	1X10 ⁻⁶	3X10 ⁻²	4X10 ⁻⁸	7X10⁴
	Y-88*	S	3X10 ⁷	2X10 ⁻³	6X10 ⁻⁹	7X10 ⁻⁵
		Ι.	5X10 ⁻⁸	3X10 ⁻³	2X10 ⁻⁹	9X10 ⁻⁵
•	Y-90	S	1X10 ⁷	6X10 ⁻⁴	4X10 ⁻⁹	2X10 ⁻⁵
		I	1X10 ⁷	6X10⁴	3X10 ⁻⁹	2X10 ⁻⁵
	Y-91m	. S	2X10 ⁵	1X10 ⁻¹	8X10 ⁻⁷	3X10 ⁻³
	-	ľ	2X10 ⁻⁵	1X10 ⁻¹	6X10 ⁻⁷	3X10 ⁻³
	Y-91	S	4X10 ⁻⁸	8X10 ⁻⁴	1X10 ⁻⁹	3X10 ⁻⁵
~		I	3X10 ⁻⁸	8X10 ⁻⁴	1X10 ⁻⁹	3X10 ⁻⁵
	Y-92	S .	4X10 ⁻⁷	2X10 ⁻³	1X10 ⁸	6X10 ⁻⁵
		1	3X10 ⁷	2X10 ⁻³	1X10 ⁸	6X10 ⁻⁵
	Y-93	· S.	2X10 ⁷	8X10 ⁴	6X10 ⁻⁹	3X10 ⁻⁵
		I	1X10 ⁷	8X10⁴	5X10 ⁻⁹	3X10 ⁻⁵
Zinc (30)	Zn-65	S	1X10 ⁻⁷	3X10 ⁻³	4X10 ⁻⁹	1X10 ⁻⁴
		I	6X10 ⁸	5X10 ⁻³	2X10°	2X10 ⁻⁴
	Zn-69m	S	4X10 ⁷	2X10 ⁻³	1X10 ⁻⁸	7X10 ⁻⁵
		I	3X10 ⁷	2X10 ⁻³	1X10 ⁻⁸	6X10 ⁻⁵
	Z n-69	S	7X10⁴	5X10 ⁻²	2X10 ⁻⁷	2X10 ⁻³
		I	9X10 ⁻⁶	5X10 ⁻²	3X10 ⁻⁷	2X10 ⁻³
Zirconium (40)	Zr-93	S	1X10 ⁻⁷	2X10 ⁻²	4X10°	8X10 ⁻⁴
		I	3X10 ⁷	2X10 ⁻²	1X10 ⁸	8X10⁴
	Zr-95	S	1X10 ⁻⁷	2X10 ⁻³	4X10 ⁻⁹	6X10 ⁻⁵
		I	3X10 ⁸	2X10 ⁻³	1X10 ⁻⁹	6X10 ⁻⁵

				Table I		Table II
Element (atomic number)	Radio- nuclide <u>1</u> /		Column 1 Air (µCi/ml)	Column 2 Water (µCi/ml)	Column 1 Air (µCi/ml)	Column 2 Water (µCi/ml)
	Zr-97	S	1X10 ⁷	5X10 ⁴	4X10 ⁻⁹	2X10 ⁻⁵
		I	9X10 ⁸	5X10 ⁻⁴	3X10 ⁻⁹	2X10 ⁻⁵
Any single radio-	Sub 2/		1X10 ⁻⁶		3X10 ⁻⁸	
nuclide not listed		•				
above with decay			•			
mode other than					•	
alpha emission or						
spontaneous fission						
nuclide not listed						
above with decay	`.					
mode other than			•		·	
alpha emission or		•				
spontaneous fission	•		· .			
and with radioactive			•			
half-life greater						
than 2 hours.						
Any single radio-			6X10 ⁻¹³	4X10 ⁻⁷	2X10 ⁻¹⁴	3X10-8
nuclide not listed			· .			
above, which decays				=		
by alpha emission or						
spontaneous fission.			*			

*The values for C-11, Ga-67, Ge-68, Au-195, In-111, I-123, Fe-52, N-13, O-15, K-43, Y-87, and Y-88 have been calculated using the committed dose equivalent values of ICRP Publication 30 for the controlling organ.

/ Soluble (S); Insoluble (I).

2/ "Sub" means that values given are for submersion in a semispherical infinite cloud of airborne material.

3/ These radon concentrations are appropriate for protection from radon-222 combined with its short-lived radioactive decay products. Alternatively, the value in Table I may be replaced by one-third (1/3) "working level." (A "working level" is defined as any combination of short-lived radon-222 radioactive decay products, polonium-218, lead-214, bismuth-214, and polonium-214, in 1 liter of air, without regard to the degree of equilibrium, that will result in the ultimate emission of 1.3 X 10⁵ MeV of alpha particle energy.) The Table II value may be replaced by one-thirtieth (1/30) of a "working level." The limit on radon-222 concentrations in restricted areas may be based on an annual average.

4/ For soluble mixtures of U-238, U-234 and U-235 in air, chemical toxicity may be the limiting factor. If the percent by weight (enrichment) of U-235 is less than 5, the concentration value for a 40-hour workweek, Table I, is 0.2 milligrams uranium per cubic meter of air average. For any enrichment, the product of the average concentration and time of exposure during a 40-hour work week shall not exceed 8 X 10⁻³ SA µCi-hr/ml, where SA is the specific activity of the uranium inhaled. The concentration value for Table II is 0.007 milligrams uranium per cubic meter of air. The specific activity for natural uranium is 6.77 X 10⁻⁷ curies per gram uranium. The specific activity for other mixtures of U-238, U-235 and U-234, if not known, shall be:

$$SA= 3.6 \times 10^7 \text{ curies/gram U}$$
 U-depleted $SA= (0.4 + 0.38 \text{ E} + 0.0034 \text{ E}^2) 10^6 \text{ E} > 0.72$

where E is the percentage by weight of U-235, expressed as percent.

NOTE: In any case where there is a mixture in air or water of more than one radionuclide, the limiting values for purposes of this Appendix should be determined as

1. If the identity and concentration of each radionuclide in the mixture are known, the limiting values should be derived as follows: Determine, for each radionuclide in the mixture, the ratio between the quantity present in the mixture and the limit otherwise established in Appendix A for the specific radionuclide when not in a mixture. The sum of such ratios for all the radionuclides in the mixture may not exceed 1 (i.e., unity).

EXAMPLE: If radionuclides a, b, and c are present in concentrations C, C, and C, and if the applicable maximum permissible concentrations (MPCs) are MPC, MPC, and MPC, respectively, then the concentrations shall be limited so that the following relationship exists:

$$\begin{array}{cccc}
C_a & + C_b & + C_c & \leq 1 \\
\hline
MPC_a & MPC_b & MPC_c
\end{array}$$

2. If either the identity or the concentration of any radionuclide in the mixture is not known, the limiting values for purposes of Appendix "A" shall be:

a. For purposes of Table I, Col. 1 6×10^{-13} b. For purposes of Table I, Col. 2 4×10^{-7} c. For purposes of Table II, Col. 1 . . . 2×10^{-14} d. For purposes of Table II, Col. 2 3×10^{-8}

3. If any of the conditions specified below are met, the corresponding values specified below may be used in lieu of those specified in paragraph 2 above.

a. If the identity of each radionuclide in the mixture is known, but the concentration of one or more of the radionuclides in the mixture is not known, the concentration limit for the mixture is the limit specified in Appendix A for the radionuclide in the mixture having the lowest concentration limit; or

b. If the identity of each radionuclide in the mixture is not known, but it is known that certain radionuclides specified in Appendix A are not present in the mixture, the concentration limit for the mixture is the lowest concentration limit specified in Appendix A for any radionuclide which is not known to be absent from the mixture; or

		Table I	T	able II
c. Radionuclide	Column 1 Air (µCi/ml)	Column 2 Water (µCi/ml)	Column 1 Air (µCi/ml)	Column 2 Water (μCi/ml)
If it is known that Sr-90, I-125, I-126, I-129, I-131, (I-133 Table II only), Pb-210, Po-210, At-211, Ra-223, Ra-224, Ra-226, Ac-227, Ra-228, Th-230, Pa-231, Th-232, Th-nat, Cm-248, Cf-254, and Fm-256 are not present		9X10 ⁻⁵		3X10⁴
If it is known that Sr-90, I-125, I-126, I-129, (I-131, I-133, Table II only), Pb-210, Po-210, Ra-223, Ra-226, Ra-228, Pa-231,				·
Th-nat, Cm-248, Cf-254, and Fm-256 are not present	.	6X10 ⁻⁵	. ·	2X10 ⁻⁶
If it is known that Sr-90, I-129, (I-125, I-126, I-131, Table II only), Pb-210, Ra-226, Ra-228, Cm-248, and Cf-254 are not			-	-, -
present		2X10 ⁻⁵		6X10 ⁻⁷
only), Ra-226, and Ra-228 are not present		3X10 ⁻⁶		1X10 ⁻⁷
If it is known that alpha-emitters and Sr-90, I-129, Pb-210, Ac-227, Ra-228, Pa-230, Pu-241, and Bk-249 are not present	3X10 ⁻⁹		1X10 ¹⁰	
If it is known that alpha-emitters and Pb-210, Ac-227, Ra-228, and Pu-241 are not present	3X10 ⁻¹⁰		1X10 ¹¹	·
If it is known that alpha-emitters and Ac-227 are not present	3X10 ⁻¹¹	· ————	1X10 ¹²	
If it is known that Ac-227, Th-230, Pa-231, Pu-238, Pu-239, Pu-240, Pu-242, Pu-244, Cm-248, Cf-249 and Cf-251 are not present	3X10 ⁻¹²	, 	1X10 ¹³	

Material

Cobalt-58

Cobalt-60

Copper-64

Erbium-169

Erbium-171

Europium-154

Europium-155

Gadolinium-153

Gadolinium-159

Germanium-71

Hafnium-181

Holmium-166

Indium-113m

Indium-114m

Indium-115m

Indium-115

Iodine-125

Iodine-126

Iodine-129

Iodine-131

Hydrogen-3

Fluorine-18

Gallium-72

Gold-198

Gold-199

Dysprosium-165

Dysprosium-166

Europium-152 (9.2 h)

Europium-152 (13 yr)

Microcuries

10

100

100 100

100

100

1

1

10

10

10

100

100

100

100

100

100

10

100

10

1

1

1

0.1

1,000

10

1.000

10

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4. If a mixture of radionuclides consists of uranium and its daughters in ore dust prior to chemical separation of the uranium from the ore, the values specified below may be used for uranium and its daughters through radium-226, instead of those from paragraph 1, 2, or 3 above.

a. For purposes of Table I, Column 1, 1 x 10⁻¹⁰ μCi/ml gross alpha activity; or 5 x 10⁻¹¹ μCi/ml natural uranium; or 75 micrograms per cubic meter of air natural uranium.

b. For purposes of Table II, Column 1, 3 x 10^{12} μ Ci/ml gross alpha activity; 2 x 10^{12} μ Ci/ml natural uranium: or 3 micrograms per cubic meter of air natural ura-

For purposes of this note, a radionuclide may be 5. considered as not present in a mixture if (a) the ratio of the concentration of that radionuclide in the mixture (C.) to the concentration limit for that radionuclide specified in Table II of Appendix A (MPC₂) does not exceed 1/10, (i.e., C₂/MPC₃ ≤ 1/10) and (b) the sum of such ratios for all radionuclides considered as not present in the mixture does not exceed 1/4, (i.e., C/MPC, + C,/MPC, +... \leq 1/4).

NOTE: To convert µCi/ml to SI units of megabecquerels per liter multiply the above values by 37.

Example: Zirconium (40) Zr-97 S (Table I, Column 1-Air) (1x10⁻⁷ µCi/ml multiplied by 37 is equivalent to 37 $\times 10^{-7} MBq/l.$

CHAPTER 40

APPENDIX B

QUANTITIES FOR USE WITH 40.3(3) AND 40.4(3)		Iodine-131	10
QUARTITIES FOR USE WITH 40.3(3) AND 40.4(3)		Iodine-132 Iodine-133	10
Material	Microcuries 4 1	Iodine-133	10
<u>iviatoriai</u>	<u>where three</u>	Iodine-135	10
Americium-241	0.01	Iridium-192	10
Antimony-122	100	Iridium-192 Iridium-194	100
Antimony-124	100		100
Antimony-125	10	Iron-55	
Arsenic-73	100	Iron-59	10 100
	100	Krypton-85	
Arsenic-74 Arsenic-76	10	Krypton-87	10
	100	Lanthanum-140	10
Arsenic-77 Barium-131	100	Lutetium-177	100
	10	Manganese-52	10
Barium-133 Barium-140	10	Manganese-54	10
		Manganese-56	10
Bismuth-210	1	Mercury-197m	100
Bromine-82	10	Mercury-197	100
Cadmium-109	10	Mercury-203	10
Cadmium-115m	10	Molybdenum-99	100
Cadmium-115	100	Neodymium-147	100
Calcium-45	. 10	Neodymium-149	100
Calcium-47	10	Nickel-59	100
Carbon-14	100	Nickel-63	10
Cerium-141	100	Nickel-65	100
Cerium-143	100	Niobium-93m	10
Cerium-144	1	Niobium-95	10
Cesium-131	1,000	Niobium-97	10
Cesium-134m	100	Osmium-185	· 10
Cesium-134	1	Osmium-191m	100
Cesium-135	10	Osmium-191	100
Cesium-136	10	Osmium-193	100
Cesium-137	10	Palladium-103	100
Chlorine-36	10	Palladium-109	100
Chlorine-38	10	Phosphorus-32	10
Chromium-51	1,000	Platinum-191	100
Cobalt-58m	10	Platinum-193m	100

Thallium-200
Thallium-201
Thallium-202
Thallium-204
Thorium (natural) 1/

Thulium-170

			•
Material	Microcuries	<u>Material</u>	Microcuries
Platinum-193	100	Thulium-171	10
Platinum-197m	100	Tin-113	10
Platinum-197	100	Tin-125	10
Plutonium-239	0.01	Tungsten-181	10
Polonium-210	0.1	Tungsten-185	10
Potassium-42	10	Tungsten-187	100
Praseodymium-142	100	Uranium (natural) 2/	100
Praseodymium-143	100	Uranium-233	0.01
Promethium-147	10	Uranium-234/235	0.01
Promethium-149	10	Vanadium-48	10
Radium-226	0.01	Xenon-131m	1,000
Rhenium-186	100	Xenon-133	100
Rhenium-188	100	Xenon-135	100
Rhodium-103m	100	Ytterbium-175	100
Rhodium-105	. 100	Yttrium-90	10
Rubidium-86	10	Yttrium-91	10
Rubidium-87	10	Yttrium-92	100
Ruthenium-97	100	Yttrium-93	100 .
Ruthenium-103	10	Zinc-65	10
Ruthenium-105	10	Zinc-69m	100
Ruthenium-106	_ 1	Zinc-69	1,000
Samarium-151	10	Zirconium-93	10
Samarium-153	100	Zirconium-95	10
Scandium-46	10	Zirconium-97	10
Scandium-47	100	1/ Rased on alpha	disintegration rate of Th-232,
Scandium-48	10	Th-230 and their radioact	ive decay products
Selenium-75	10		ntegration rate of U-238, U-234,
Silicon-31	100	and U-235.	inegration rate of 0-236, 0-234,
Silver-105	10	•	
Silver-110m	1	Any alpha emitting	
Silver-111	100	radionuclide not listed	
Sodium-22	1	above or mixtures of	
Sodium-24	10	alpha emitters of	
Strontium-85	10	unknown composition	0.01
Strontium-89	1	Any radionuclide other	
Strontium-90	0.1	than alpha emitting	
Strontium-91	10 10	radionuclides, not	
Strontium-92	100	listed above or	
Sulphur-35	100	mixtures of beta	
Tantalum-182	10	emitters of unknown	
Technetium-96 Technetium-97m	100	composition	0.1
Technetium-97	100	•	
Technetium-99m	100		of D.203 and D.303, where there
Technetium-99	10		on of radionuclides in known
Tellurium-125m	10		combination should be derived
Tellurium-127m	10		, for each radionuclide in the
Tellurium-127	100		tween the quantity present in the
Tellurium-129m	100		it otherwise established for the
Tellurium-129	100		on not in combination. The sum
Tellurium-131m	100	of such ratios for all the i	radionuclides in the combination
Tellurium-132	10	may not exceed "1" (i.e., '	unity").
Terbium-160	10	NOTE: To convert mic	rocuries (μCi) to SI units of ki-
Thellium 200	100		aly the shove values by 37

100 100

100 10 100

10

NOTE: To convert microcuries (μ Ci) to SI units of kilobecquerels (kBq), multiply the above values by 37.

EXAMPLE: Zirconium-97 (10 μ Ci) (37) = 370 kBq. (10 μ Ci multiplied by 37 is equivalent to 370 kBq) These rules are intended to implement Iowa Code Chapter 136C.

NOTICES IAB 5/27/92

ARC 3049A

PUBLIC HEALTH **DEPARTMENT[641]**

Notice of Intended Action

Twenty-five interested persons, a governmental subdivision, an agency or an association of 25 or more persons may demand an oral presentation hereon as provided in Iowa Code §17A.4(1)"b."

Notice is also given to the public that the Administrative Rules Review Committee may, on its own motion or on written request by any individual or group, review this proposed action under §17A.8(6) at a regular or special meeting where the public or interested persons may be heard.

Pursuant to the authority of Iowa Code section 136C.3. the Iowa Department of Public Health hereby gives Notice of Intended Action to rescind Chapter 41, "Safety Requirements for Radiation Machines and Radioactive Material," and adopt a new Chapter 41, "Safety Requirements for the Health Public 19 Pu ments for the Use of Radiation Machines and Certain Uses of Radioactive Materials," Iowa Administrative

The action taken is appropriate because of the number and magnitude of the additions which need to be made to the rules in order to keep current with the standards set forth by the Conference of Radiation Control Program Directors' "Suggested State Regulations for the Control of Radiation" (SSRCRs) and to remain compatible with the U.S. Nuclear Regulatory Commission (NRC) pursuant to the Agreement State Program between the Governor and the NRC. Nothing has been deleted from the rules; however, the additions to Chapter 41 necessitated renumbering of the entire chapter. These additions are specified below.

1. All rules related to the use of radionuclides in the healing arts, which were previously located both in 641—Chapter 39 and Chapter 41, have now been moved to 641—41.2(136C). This is consistent with the SSRCRs, Part G, and will greatly facilitate use of the rules. In addition, the rules in 641-41.2(136C), "Use of Radionuclides in the Healing Arts" are now compatible with the NRC's revised version of 10 CFR 35, "Medical Use of Byproduct Material," as published in the Federal Register on March 24, 1987, 52 FR 9292. Although adoption of the new 10 CFR Part 35 in its entirety is not an item of compatibility, the Department supports the concepts of this new regulation and deems its incorporation into the rules to be advantageous to all concerned, since it will promote consistency in regulation of these licensees by NRC and the Department, and the rules are much more definitive and understandable than the old rules on this important area.

2. The rule for Reciprocal Recognition of out-of-state radioactive materials licensees, 641—subrule 39.4(90), has been modified as follows:

a. Rather than allowing the licensees to operate in the state for 180 days during a calendar year, the new rule stipulated that the licensee may operate in the state for a period of 180 days during the one year from having to pay an additional fee in January of the new year, especially if the licensee intends to operate in the state only for a short period of time.

b. The reciprocity fee has been changed to be 100 percent of the fee charged for a new license, rather than 85 percent. Since our rules tie directly to 10 CFR 170.31 and

170.32 for fee for users of radioactive materials, it was necessary to make this adjustment.

3. Chapter 41 of the rules now has appendixes, which is again consistent with the SSRCRs. This format is much easier to work with. The material was previously contained in the body of the rules of each chapter. In addition, the appendixes material is now in the same chapter as the rule which refers to it, thus making the rules easier

Any interested person may make written suggestions or comments on the proposed chapter on or before close of business June 17, 1992. Such written material should be directed to Donald A. Flater, Chief, Bureau of Environmental Health, Iowa Department of Public Health, Lucas State Office Building, Des Moines, Iowa 50319, FAX (515)242-5284.

A public hearing will be held on June 17, 1992, at 9 a.m., in the Third Floor Conference Room, Lucas State Office Building, at which time persons may present their views orally or in writing. At the hearing, persons will be asked to give their name, address, and whom they represent. Presenters will also be asked to confine their remarks to the subject of the rules.

These rules are intended to implement Iowa Code chapter 136C.

The following new chapter is proposed.

Rescind 641—Chapter 41 and insert the following in lieu thereof:

CHAPTER 41

SAFETY REQUIREMENTS FOR THE USE OF RADIATION MACHINES AND CERTAIN USES OF RADIOACTIVE MATERIALS

641—41.1(136C) X-rays in the healing arts.

41.1(1) Scope. This rule establishes requirements, for which a registrant is responsible, for use of X-ray equipment by or under the supervision of an individual authorized by and licensed in accordance with state statutes to engage in the healing arts or veterinary medicine. The provisions of this rule are in addition to, and not in substitution for, other applicable provisions of these rules. All references to any Code of Federal Regulations (CFR) in this chapter are those in effect as of September 1, 1992.

41.1(2) Definitions. As used in this chapter, the fol-

lowing definitions apply:

"Accessible surface" means the external surface of the enclosure or housing provided by the manufacturer.

"Added filtration" means any filtration which is in

addition to the inherent filtration.

"Aluminum equivalent" means the thickness of type 1100 aluminum alloy affording the same attenuation, under specified conditions, as the material in question. The nominal chemical composition of type 1100 aluminum alloy is 99.00 percent minimum aluminum, 0.12 percent copper.

'Assembler" means any person engaged in the business of assembling, replacing, or installing one or more components into an X-ray system or subsystem. The term includes the owner of an X-ray system or the employee or agent who assembles components into an X-ray system that is subsequently used to provide professional or commercial services.

"Attenuation block" means a block or stack, having dimensions 20 centimeters by 20 centimeters by 3.8 centimeters, of type 1100 aluminum alloy or other materials

having equivalent attenuation. The nominal chemical composition of type 1100 aluminum alloy is 99.00 percent minimum aluminum, 0.12 percent copper.

"Automatic <u>exposure</u> control" means a device which automatically controls one or more technique factors in order to obtain at a preselected location(s) a required quantity of radiation (see also "Phototimer").

"Barrier" (see "Protective barrier").

"Beam axis" means a line from the source through the centers of the X-ray fields.

"Beam-limiting device" means a device which provides a means to restrict the dimensions of the X-ray field.

"Beam monitoring system" means a system designed to detect and measure the radiation present in the useful beam.

"Cephalometric device" means a device intended for the radiographic visualization and measurement of the dimensions of the human head.

"Certified components" means components of X-ray systems which are subject to regulations promulgated under Public Law 90-602, the Radiation Control for Health and Safety Act of 1968.

"Certified system" means any X-ray system which has

one or more certified component(s).

"Changeable filters" means any filter, exclusive of inherent filtration, which can be removed from the useful beam through any electronic, mechanical, or physical process.

"Coefficient of variation" or "C" means the ratio of the standard deviation to the mean value of a population of observations. It is estimated using the following equation:

$$C = \frac{s}{\overline{X}} = \frac{1}{\overline{X}} \left[\sum_{i=1}^{n} \frac{(X_i - \overline{X})^2}{n-1} \right]^{1/2}$$

where:

s = Estimated standard deviation of the population.

X = Mean value of observations in sample.

 $X_i = i^{th}$ observation in sample.

n = Number of observations in sample.

"Computed tomography" means the production of a tomogram by the acquisition and computer processing of X-ray transmission data.

"Contact therapy system" means an X-ray system used for therapy with the X-ray tube port placed in contact with or within 5 centimeters of the surface being treated.

"Control panel" means that part of the X-ray control upon which are mounted the switches, knobs, pushbuttons, and other hardware necessary for manually setting the technique factors.

"Cooling curve" means the graphical relationship between heat units stored and cooling time.

"CT" (see "Computed tomography").

"Dead-man switch" means a switch so constructed that a circuit closing contact can be maintained only by continuous pressure on the switch by the operator.

"Detector" (see "Radiation detector").

"Diagnostic source assembly" means the tube housing assembly with a beam-limiting device attached.

"Diagnostic X-ray system" means an X-ray system designed for irradiation of any part of the human body for the purpose of diagnosis or visualization.

"Direct scattered radiation" means that scattered radiation which has been deviated in direction only by materials irradiated by the useful beam (see "Scattered radiation").

"Entrance <u>exposure</u> rate" means the <u>exposure</u> per unit time at the point where the center of the useful beam enters the patient.

"Equipment" (see "X-ray equipment").

"Field emission equipment" means equipment which uses an X-ray tube in which electron emission from the cathode is due solely to the action of an electric field.

"Filter" means material placed in the useful beam to

absorb preferentially selected radiations.

"Fluoroscopic imaging assembly" means a subsystem in which X-ray photons produce a fluoroscopic image. It includes the image receptor(s) such as the image intensifier and spot-film device, electrical interlocks, if any, and structural material providing linkage between the image receptor and diagnostic source assembly.

"Focal spot" means the area projected on the anode of the X-ray tube by the electrons accelerated from the cath-

ode and from which the useful beam originates.

"General purpose radiographic X-ray system" means any radiographic X-ray system which, by design, is not limited to radiographic examination of specific anatomical regions.

"Gonad shield" means a protective barrier for the

testes or ovaries.

"Half-value layer" means the thickness of specified material which attenuates the beam of radiation to an extent such that the <u>exposure</u> rate is reduced to one-half of its original value. In this definition, the contribution of all scattered radiation, other than any which might be present initially in the beam concerned, is deemed to be excluded.

"Healing arts screening" means the testing of human beings using X-ray machines for the detection or evaluation of health indications when such tests are not specifically and individually ordered by a licensed practitioner of the healing arts legally authorized to prescribe such X-ray tests for the purpose of diagnosis or treatment.

"Heat unit" means a unit of energy equal to the product of the peak kilovoltage, milliamperes, and seconds,

i.e., kVp x mA x second.

"HVL" (see "Half-value layer").

"Image intensifier" means a device, installed in its housing, which instantaneously converts an X-ray pattern into a corresponding light image of higher energy density.

"Image receptor" means any device, such as a fluorescent screen or radiographic film, which transforms incident X-ray photons either into a visible image or into another form which can be made into a visible image by further transformations.

"Image receptor support" means, for mammographic systems, that part of the system designed to support the image receptor in a horizontal plane during a mammographic examination.

"Inherent filtration" means the filtration of the useful beam provided by the permanently installed components of the tube housing assembly.

"Irradiation" means the exposure of matter to ionizing radiation.

"Kilovolts peak" (see "Peak tube potential").

"kV" means kilovolts.

"kVp" (see "Peak tube potential").

"kWs" means kilowatt second. It is equivalent to 10³ (kV)(mA)(s), i.e.,

(A) kWs = (X) kV x (Y) mA x (Z) s x kWs = XYZ kWs

$$10^3$$
 kV x mA x s 10^3

"Lead equivalent" means the thickness of lead affording the same attenuation, under specified conditions, as the material in question.

"Leakage radiation" means radiation emanating from the diagnostic or therapeutic source assembly except for:

a. The useful beam, and

b. Radiation produced when the exposure switch or

timer is not activated.

"Leakage technique factors" means the technique factors associated with the diagnostic or therapeutic source assembly which are used in measuring leakage radiation. They are defined as follows:

a. For diagnostic source assemblies intended for capacitor energy storage equipment, the maximum-rated peak tube potential and the maximum-rated number of exposures in an hour for operation at the maximum-rated peak tube potential with the quantity of charge per exposure being 10 millicoulombs, i.e., 10 milliampere seconds, or the minimum obtainable from the unit, whichever is larger.

b. For diagnostic source assemblies intended for field emission equipment rated for pulsed operation, the maximum-rated peak tube potential and the maximumrated number of X-ray pulses in an hour for operation at

the maximum-rated peak tube potential.

c. For all other diagnostic or therapeutic source assemblies, the maximum-rated peak tube potential and the maximum-rated continuous tube current for the

maximum-rated peak tube potential.

"Light field" means that area of the intersection of the light beam from the beam-limiting device and one of the set of planes parallel to and including the plane of the image receptor, whose perimeter is the locus of points at which the illumination is one-fourth of the maximum in the intersection.

"Linear attenuation coefficient" or " μ " means the quotient of dN/N divided by dl when dN/N is the fraction of uncharged ionizing radiation that experience interactions in traversing a distance dl in a specified material.

"Line-voltage regulation" means the difference between the no-load and the load line potentials expressed as a percent of the load line potential. It is calculated using the following equation:

Percent line-voltage regulation = $100 (V_n - V_1)/V_1$

where

V_n = No-load line potential and

 $V_1 =$ Load line potential.

"mA" means milliampere.

"mAs" means milliampere second.

"Maximum line current" means the root-mean-square current in the supply line of an X-ray machine operating at its maximum rating.

"Mobile X-ray equipment" (see "X-ray equipment").

"Patient" means an individual subjected to healing arts examination, diagnosis, or treatment.

"Peak tube potential" means the maximum value of the potential difference across the X-ray tube during an exposure.

"Phantom" means a volume of material behaving in a manner similar to tissue with respect to the attenuation and scattering of radiation. "Phototimer" means a method for controlling radiation exposures to image receptors by the amount of radiation which reaches a radiation monitoring device(s). The radiation monitoring device(s) is part of an electronic circuit which controls the duration of time the tube is activated (see "Automatic exposure control").

"PID" (see "Position indicating device").

"Portable X-ray equipment" (see "X-ray equipment").

"Position indicating device" means a device on dental X-ray equipment used to indicate the beam position and to establish a definite source-surface (skin) distance. It may or may not incorporate or serve as a beam-limiting device.

"Primary dose monitoring system" means a system which will monitor the useful beam during irradiation and which will terminate irradiation when a preselected number of dose monitor units have been acquired.

"Primary protective barrier" (see "Protective barrier").

"Protective apron" means an apron made of radiation absorbing materials used to reduce radiation exposure.

"Protective barrier" means a barrier of radiation absorbing material(s) used to reduce radiation exposure. The types of protective barriers are as follows:

a. "Primary protective barrier" means the material, excluding filters, placed in the useful beam, for protection

purposes, to reduce the radiation exposure.

b. "Secondary protective barrier" means a barrier sufficient to attenuate the stray radiation to the required degree.

"Protective glove" means a glove made of radiation absorbing materials used to reduce radiation exposure.

"Qualified expert" means an individual who has demonstrated to the satisfaction of the agency that such individual possesses the knowledge and training to measure ionizing radiation, to evaluate safety techniques, and to advise regarding radiation protection needs.

"Radiation detector" means a device which in the presence of radiation provides a signal or other indication suitable for use in measuring one or more quantities of in-

cident radiation.

"Radiation therapy simulation system" means a radiographic or fluoroscopic X-ray system intended for localizing the volume to be exposed during radiation therapy and confirming the position and size of the therapeutic irradiation field.

"Radiograph" means an image receptor on which the image is created directly or indirectly by an X-ray pattern and results in a permanent record.

"Radiographic imaging system" means any system whereby a permanent or semipermanent image is recorded on an image receptor by the action of ionizing radiation.

"Radiological physicist" means an individual who:

a. Is certified by the American Board of Radiology in therapeutic radiological physics, radiological physics, or

X-ray and gamma-ray physics; or

b. Has a bachelor's degree in one of the physical sciences or engineering and three years' full-time experience working in therapeutic radiological physics under the direction of a physicist certified by the American Board of Radiology. The work duties shall include duties involving the calibration and spot checks of a medical accelerator or a sealed source teletherapy unit; or

c. Has a Master's or a Doctor's degree in physics, biophysics, radiological physics, health physics, or engineering; has had one year's full-time training in therapeutic radiological physics; and has had one year's full-time work experience in a radiotherapy facility where the individual's duties involve calibration and spot checks of a medical accelerator or a sealed source teletherapy unit.

"Rating" means the operating limits as specified by the component manufacturer.

"Recording" means producing a permanent form of an

image resulting from X-ray photons.

"Registrant," as used in 641—Chapter 41, means any person who owns or possesses and administratively controls an X-ray system which is used to deliberately expose humans or animals to the useful beam of the system and is required by 641—Chapter 39 to register the X-ray system with the agency.

"Response time" means the time required for an instrument system to reach 90 percent of its final reading when the radiation-sensitive volume of the instrument system is exposed to a step change in radiation flux from zero sufficient to provide a steady state midscale reading.

"Scattered radiation" means radiation that, during passage through matter, has been deviated in direction (see "Direct scattered radiation").

"Secondary dose monitoring system" means a system which will terminate irradiation in the event of failure of the primary system.

"Secondary protective barrier" (see "Protective bar-

"Shutter" means a device attached to the tube housing assembly which can totally intercept the useful beam and which has a lead equivalency not less than that of the tube housing assembly.

"SID" (see "Source-image receptor distance").
"Source" means the focal spot of the X-ray tube.

"Source-image receptor distance" means the distance from the source to the center of the input surface of the image receptor.

"Spot check" means a procedure which is performed to ensure that a previous calibration continues to be valid.

"Spot film" means a radiograph which is made during a fluoroscopic examination to permanently record conditions which exist during that fluoroscopic procedure.

"Spot-film device" means a device intended to transport or position a radiographic image receptor between the X-ray source and fluoroscopic image receptor. It includes a device intended to hold a cassette over the input end of an image intensifier for the purpose of making a radiograph.

"SSD" means the distance between the source and the skin of the patient.

"Stationary X-ray equipment" (see "X-ray equip-

"Stray radiation" means the sum of leakage and scat-

tered radiation.
"Technique factors" means the following conditions of

a. For capacitor energy storage equipment, peak tube potential in kV and quantity of charge in mAs;

b. For field emission equipment rated for pulsed operation, peak tube potential in kV, and number of X-ray

pulses;

c. For CT X-ray systems designed for pulsed operation, peak tube potential in kV, scan time in seconds, and either tube current in mA, X-ray pulse width in seconds, and the number of X-ray pulses per scan, or the product of

tube current, X-ray pulse width, and the number of X-ray

pulses in mAs;

d. For CT X-ray systems not designed for pulsed operation, peak tube potential in kV, and either tube current in mA and scan time in seconds, or the product of tube current and exposure time in mAs and the scan time when the scan time and exposure time are equivalent; and

e. For all other equipment, peak tube potential in kV, and either tube current in mA and exposure time in seconds, or the product of tube current and exposure time in mAs

"Termination of irradiation" means the stopping of irradiation in a fashion which will not permit continuance of irradiation without the resetting of operating conditions at the control panel.

"Tomogram" means the depiction of the X-ray attenu-

ation properties of a section through the body.

"Traceable to a national standard" means that a quantity or a measurement has been compared to a national standard directly or indirectly through one or more intermediate steps and that all comparisons have been documented.

"Tube" means an X-ray tube, unless otherwise specified.

"Tube housing assembly" means the tube housing with tube installed. It includes high-voltage, filament transformers, and other appropriate elements when such are contained within the tube housing.

"Tube rating chart" means the set of curves which specify the rated limits of operation of the tube in terms of

the technique factors.

"Useful beam" means the radiation emanating from the tube housing port or the radiation head and passing through the aperture of the beam-limiting device when the exposure controls are in a mode to cause the system to produce radiation.

"Variable-aperture beam-limiting device" means a beam-limiting device which has capacity for stepless adjustment of the X-ray field size at a given SID.

"Visible area" means that portion of the input surface of the image receptor over which incident X-ray photons are producing a visible image.

"Wedge filter" means an added filter effecting continuous progressive attenuation on all or part of the useful beam.

"X-ray control" means a device which controls input power to the X-ray high-voltage generator and the X-ray tube. It includes equipment such as timers, phototimers, automatic brightness stabilizers, and similar devices, which control the technique factors of an X-ray exposure.

"X-ray equipment" means an X-ray system, subsystem, or component thereof. Types of X-ray equipment are

as follows:

a. "Mobile X-ray equipment" means X-ray equipment mounted on a permanent base with wheels or casters for moving while completely assembled.

b. "Portable X-ray equipment" means X-ray equipment designed to be hand-carried.

c. "Stationary X-ray equipment" means X-ray equipment which is installed in a fixed location.

"X-ray field" means that area of the intersection of the useful beam and any one of the set of planes parallel to and including the plane of the image receptor, whose perimeter is the locus of points at which the exposure rate is one-fourth of the maximum in the intersection.

"X-ray high-voltage generator" means a device which transforms electrical energy from the potential supplied by the X-ray control to the tube operating potential. The device may also include means for transforming alternating current to direct current, filament transformers for the X-ray tube(s), high-voltage switches, electrical protective devices, and other appropriate elements.

"X-ray subsystem" means any combination of two or

more components of an X-ray system.

"X-ray system" means an assemblage of components for the controlled production of X-rays. It includes minimally an X-ray high-voltage generator, an X-ray control, a tube housing assembly, a beam-limiting device, and the necessary supporting structures. Additional components which function with the system are considered integral parts of the system.

"X-ray tube" means any electron tube which is designed to be used primarily for the production of X-rays.

41.1(3) Administrative controls.

- a. Registrant. The registrant shall be responsible for directing the operation of the X-ray system(s) under the registrant's administrative control. The registrant or the registrant's agent shall ensure that the requirements of 41.1(3)"a"(1) are met in the operation of the X-ray system(s).
- (1) An X-ray system which does not meet the provisions of these rules shall not be operated for diagnostic or therapeutic purposes when so directed by the agency.
- (2) Individuals who will be operating the X-ray systems shall be adequately instructed in the safe operating procedures and be competent in the safe use of the equipment in accordance with 641—Chapter 42 as applicable.
- (3) A chart shall be provided in the vicinity of the diagnostic X-ray system's control panel which specifies, for all examinations performed with that system, the following information:
- 1. Patient's anatomical size versus technique factors to be utilized;
- 2. Type and size of the film or film-screen combination to be used;
- 3. Type and focal distance of the grid to be used, if any;
 - 4. Source to image receptor distance to be used; and
- 5. Type and location of placement of gonad shielding to be used.
- (4) Written safety procedures shall be provided to each individual operating X-ray equipment, including any restrictions of the operating technique required for the safe operation of the particular X-ray system. The operator shall be able to demonstrate familiarity with these procedures.
- (5) Except for patients who cannot be moved out of the room, only the staff and ancillary personnel required for the medical procedure or training shall be in the room during the radiographic exposure. Other than the patient being examined:
- 1. All individuals shall be positioned such that no part of the body will be struck by the useful beam unless protected by 0.5 millimeter lead equivalent.
- 2. Staff and ancillary personnel shall be protected from the direct scatter radiation by protective aprons or whole body protective barriers of not less than 0.25 millimeter lead equivalent.
- 3. Patients who cannot be removed from the room shall be protected from the direct scatter radiation by whole body protective barriers of 0.25 millimeter lead equivalent or shall be so positioned that the nearest portion of the body is at least 2 meters from both the tube head and the nearest edge of the image receptor.
- (6) Gonad shielding of not less than 0.25 millimeter lead equivalent shall be used for patients, who have not

passed the reproductive age, during radiographic procedures in which the gonads are in the useful beam, except for cases in which this would interfere with the diagnostic procedure.

(7) Individuals shall not be exposed to the useful beam except for healing arts purposes and unless such exposure has been authorized by a licensed practitioner of the healing arts. This provision specifically prohibits deliberate exposure for the following purposes:

1. Exposure of an individual for training, demonstra-

tion, or other nonhealing arts purposes; and

2. Exposure of an individual for the purpose of healing arts screening except as authorized by 41.1(3)"a"(1)"11."

(8) When a patient or film must be provided with aux-

iliary support during a radiation exposure:

1. Mechanical holding devices shall be used when the technique permits. The written safety procedures, required by 41.1(3)"a"(4), shall list individual projections where holding devices cannot be utilized;

2. Written safety procedures, as required by 41.1(3)"a"(4), shall indicate the requirements for selecting a holder and the procedure the holder shall follow;

3. The human holder shall be protected as required by

41.1(3)"a"(5)"2";

4. No individual shall be used routinely to hold film

or patients; and

- 5. In those cases where the patient must hold the film, except during intraoral examinations, any portion of the body other than the area of clinical interest struck by the useful beam shall be protected by not less than 0.5 millimeter lead equivalent material.
- (9) Procedures and auxiliary equipment designed to minimize patient and personnel exposure commensurate with the needed diagnostic information shall be utilized.
- 1. The speed of film or screen and film combinations shall be the fastest speed consistent with the diagnostic objective of the examinations.
- 2. The radiation exposure to the patient shall be the minimum exposure required to produce images of good diagnostic quality.
- 3. Portable or mobile X-ray equipment shall be used only for examinations where it is impractical to transfer the patient(s) to a stationary X-ray installation.
- 4. X-ray systems subject to 41.1(6) shall not be utilized in procedures where the source to patient distance is less than 30 centimeters.
- (10) All individuals who are associated with the operation of an X-ray system are subject to the requirements of 641—subrules 40.2(1), 40.2(20), and 40.3(2). In addition:
- 1. When protective clothing or devices are worn on portions of the body and a personnel monitoring device(s) is present, it (they) shall be worn in accordance with the recommendations found in Chapter 4 of the National Council of Radiation Protection and Measurements Report No. 57.
- 2. Exposure of a personnel monitoring device to deceptively indicate a dose delivered to an individual is prohibited.
- (11) Healing arts screening. Any person proposing to conduct a healing arts screening program shall not initiate such a program without prior approval of the agency. When requesting such approval, that person shall submit

the information outlined in Appendix C of this chapter. If any information submitted to the agency becomes invalid or outdated, the agency shall be immediately notified.

b. Information and maintenance record and associated information. The registrant shall maintain the following information for each X-ray system for inspection by the agency:

(1) Maximum rating of technique factors;

- (2) Model and serial numbers of all certifiable components:
- (3) Aluminum equivalent filtration of the useful beam, including any routine variation;

(4) Tube rating charts and cooling curves;

- (5) Records of surveys, calibrations, maintenance, and modifications performed on the X-ray system(s) after the effective date of 41.1(3) with the names of persons who performed such services;
- (6) A scale drawing of the room in which a stationary X-ray system is located with such drawing indicating the use of areas adjacent to the room and an estimation of the extent of occupancy by an individual in such areas. In addition, the drawing shall include:
- 1. The results of a survey for radiation levels present at the operator's position and at pertinent points outside the room at specified test conditions, or
- 2. The type and thickness of materials, or lead equivalency, of each protective barrier; and
- (7) A copy of all correspondence with this agency regarding that X-ray system.
- c. X-ray log. Each facility shall maintain an X-ray log containing the patient's name, the type of examinations, and the dates the examinations were performed. When the patient or film must be provided with human auxiliary support, the name of the human holder shall be recorded.
 - d. Plan review.
- (1) Prior to construction, the floor plans and equipment arrangement of all new installations, or modifications of existing installations, utilizing X-rays for diagnostic or therapeutic purposes shall be submitted to the agency for review and approval. The required information is denoted in Appendices A and B of this chapter.

(2) The agency may require the applicant to utilize the services of a qualified expert to determine the shielding requirements prior to the plan review and approval.

- (3) The approval of such plans shall not preclude the requirement of additional modifications should a subsequent analysis of operating conditions indicate the possibility of an individual receiving a dose in excess of the limits prescribed in 641—Chapter 40.
- e. Federal performance standards. All X-ray equipment other than radiation machines for which applicable performance standards have been prescribed under 21 CFR 1020.10-1020.50 pursuant to 42 USC 263F and which have been manufactured subsequent to the effective date of such requirements, shall comply with these federal performance standards. Persons registered to possess the affected radiation-emitting equipment in Iowa shall be responsible for maintaining the equipment in compliance with federal performance standards.
- 41.1(4) General requirements for all diagnostic X-ray systems. In addition to other requirements of this chapter, all diagnostic X-ray systems shall meet the following requirements:
- a. Warning label. The control panel containing the main power switch shall bear the warning statement, leg-

ible and accessible to view: "WARNING: This X-ray unit may be dangerous to patient and operator unless safe exposure factors and operating instructions are observed."

b. Battery charge indicator. On battery-powered X-ray generators, visual means shall be provided on the control panel to indicate whether the battery is in a state of

charge adequate for proper operation.

- c. Leakage radiation from the diagnostic source assembly. The leakage radiation from the diagnostic source assembly measured at a distance of 1 meter in any direction from the source shall not exceed 100 milliroentgens (25.8 µC/kg) in one hour when the X-ray tube is operated at its leakage technique factors. Compliance shall be determined by measurements averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters.
- d. Radiation from components other than the diagnostic source assembly. The radiation emitted by a component other than the diagnostic source assembly shall not exceed 2 milliroentgens (0.516 μ C/kg) in one hour at 5 centimeters from any accessible surface of the component when it is operated in an assembled X-ray system under any conditions for which it was designed. Compliance shall be determined by measurements averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters.
 - e. Beam quality.
 - (1) Half-value layer.
- 1. The half-value layer of the useful beam for a given X-ray tube potential shall not be less than the values shown in Table I. If it is necessary to determine such half-value layer at an X-ray tube potential which is not listed in Table I, linear interpolation or extrapolation may be made.

Table I

Design operating range (kVp)	Measured potential (kVp)	Half-value layer (mm of aluminum)
Below 50		0.3
	40 49	0.4 0.5
50 to 70	50	1.2
	60 70	1.3 1.5
Above 70	71	2.1
•	80 90	2.3 2.5
	100	2.7
	110 120	3.0 3.2
	130 140	3.5 3.8
	150	4.1

2. The requirements of 41.1(4)"e"(1)"1" will be considered to have been met if it can be demonstrated that the aluminum equivalent of the total filtration in the primary beam is not less than that shown in Table II.

Table II

Filtration Required vs. Operating Voltage

Total Filtration (inherent plus added)

Operating Voltage (kVp)

(mm aluminum equivalent)

Below 50	0.5
50 - 70	1.5
Above 70	2.5

3. Beryllium window tubes shall have a minimum of 0.5 millimeter aluminum equivalent filtration permanently installed in the useful beam.

4. For capacitor energy storage equipment, compliance with the requirements of 41.1(4)"e" shall be determined with the maximum quantity of charge per exposure.

5. The required minimal aluminum equivalent filtration shall include the filtration contributed by all materials which are always present between the source and the patient.

(2) Filtration controls. For X-ray systems which have variable kVp and variable filtration for the useful beam, a device shall link the kVp selector with the filter(s) and shall prevent an exposure unless the minimum amount of filtration required by 41.1(4)"e"(1)"1" is in the useful beam for the given kVp which has been selected.

f. Multiple tubes. Where two or more radiographic tubes are controlled by one exposure switch, the tube or tubes which have been selected shall be clearly indicated prior to initiation of the exposure. This indication shall be both on the X-ray control panel and at or near the tube housing assembly which has been selected.

g. Mechanical support of tube head. The tube housing assembly supports shall be adjusted such that the tube housing assembly will remain stable during an exposure unless tube housing movement is a designed function of the X-ray system.

h. Technique indicators.

(1) The technique factors to be used during an exposure shall be indicated before the exposure begins. If automatic exposure controls are used, the technique factors which are set prior to the exposure shall be indicated.

(2) The requirement of 41.1(4)"h"(1) may be met by permanent markings on equipment having fixed technique factors. Indication of technique factors shall be visible from the operator's position except in the case of spot films made by the fluoroscopist.

41.1(5) Fluoroscopic X-ray systems except for computed tomography X-ray systems. All fluoroscopic X-ray

systems shall meet the following requirements:

a. Limitation of useful beam.

(1) Primary barrier.

- The fluoroscopic imaging assembly shall be provided with a primary protective barrier which intercepts the entire cross section of the useful beam at any SID.
- 2. The X-ray tube used for fluoroscopy shall not produce X-rays unless the barrier is in position to intercept the entire useful beam.

(2) X-ray field.

1. The X-ray field produced by nonimage-intensified fluoroscopic equipment shall not extend beyond the entire visible area of the image receptor. This requirement applies to field size for both fluoroscopic procedures and spot filming procedures. In addition, means shall be provided for stepless adjustment of the field size; the minimum field size at the greatest SID shall be equal to or less than 5 centimeters by 5 centimeters; and compliance with 41.1(5)"a"(2)"1" shall be determined with the beam axis indicated to be perpendicular to the plane of the image

2. For image-intensified fluoroscopic equipment, neither the length nor the width of the X-ray field in the plane of the image receptor shall exceed that of the visible area of the image receptor by more than 3 percent of the SID. The sum of the excess length and the excess width shall be no greater than 4 percent of the SID. In addition, means shall be provided to permit further limitation of the field at the greatest SID to a field size of 5 centimeters by 5 centimeters or less. Compliance shall be determined with the beam axis indicated to be perpendicular to the plane of the image receptor. For rectangular X-ray fields used with circular image reception, the error in alignment shall be determined along the length and width dimensions of the X-ray field which pass through the center of

b. Activation of the fluoroscopic tube. X-ray production in the fluoroscopic mode shall be controlled by a device which requires continuous pressure by the fluoroscopist for the entire time of any exposure. When recording serial fluoroscopic images, the fluoroscopist shall be able to terminate the X-ray exposure(s) at any time, but means may be provided to permit completion of

any single exposure of the series in process.

the visible area of the image receptor.

c. Exposure rate limits.

(1) Entrance exposure rate allowable limits.

1. The exposure rate measured at the point where the center of the useful beam enters the patient shall not ex-

ceed 10 roentgens (2.58 mC/kg) per minute.

- Compliance with the requirements of 41.1(5)"c" shall be determined as follows: movable grids and compression devices shall be removed from the useful beam during the measurement; if the source is below the table, exposure rate shall be measured 1 centimeter above the tabletop or cradle; if the source is above the table, the exposure rate shall be measured at 30 centimeters above the tabletop with the end of the beam-limiting device or spacer positioned as closely as possible to the point of measurement; all C-arm fluoroscopes, both stationary and mobile, shall meet the entrance exposure rate limits in 41.1(5)"c"(1)"1," "2," and "3," 30 centimeters from the input surface of the fluoroscopic imaging assembly with the source positioned at any available SID provided that the end of the spacer assembly or beam-limiting device is not closer than 30 centimeters from the input surface of the fluoroscopic imaging assembly.
- 3. Periodic measurement of entrance exposure rate shall be performed as follows: such measurements shall be made annually or after any maintenance of the system which might affect the exposure rate; results of these measurements shall be posted where any fluoroscopist may have ready access to such results while using the fluoroscope and in the record required in 41.1(3)"b"(5). The measurement results shall be stated in roentgens per

minute and include the technique factors used in determining such results. The name of the individual performing the measurements and the date the measurements were performed shall be included in the results; personnel monitoring devices may be used to perform the measurements required by this paragraph, provided the measurements are made as described below. Conditions of periodic measurement of entrance exposure rate are as follows:

 The measurement shall be made under the conditions that satisfy the requirements of 41.1(5)"c"(1)"2";

The kVp shall be the kVp typical of clinical use of

the X-ray system;

- The X-ray system(s) that incorporates automatic exposure rate control shall have sufficient material placed in the useful beam to produce a milliamperage typical of the use of the X-ray system; and
- The X-ray system(s) that incorporates automatic exposure rate control shall utilize a milliamperage typical of the clinical use of the X-ray system. Materials should be placed in the useful beam when conducting these periodic measurements to protect the imaging system.

(2) Reserved.

- d. Barrier transmitted radiation rate limits.
- (1) The exposure rate due to transmission through the primary protective barrier with the attenuation block in the useful beam, combined with radiation from the image intensifier, if provided, shall not exceed 2 milliroentgens (0.516 µC/kg) per hour at 10 centimeters from any accessible surface of the fluoroscopic imaging assembly beyond the plane of the image receptor for each roentgen per minute of entrance exposure rate.

(2) Measuring compliance of barrier transmission.

- 1. The exposure rate due to transmission through the primary protective barrier combined with radiation from the image intensifier shall be determined by measurements averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters.
- 2. If the source is below the tabletop, the measurement shall be made with the input surface of the fluoroscopic imaging assembly positioned 30 centimeters above the tabletop.
- 3. If the source is above the tabletop and the SID is variable, the measurement shall be made with the end of the beam-limiting device or spacer as close to the tabletop as it can be placed, provided that it shall not be closer than 30 centimeters.

4. Movable grids and compression devices shall be removed from the useful beam during the measurement.

- 5. The attenuation block shall be positioned in the useful beam 10 centimeters from the point of measurement of entrance exposure rate and between this point and the input surface of the fluoroscopic imaging assembly.
- e. Indication of potential and current. During fluoroscopy and cinefluorography the kV and the mA shall be continuously indicated.
- f. Source-to-skin distance. The SSD shall not be less
- (1) 38 centimeters on stationary fluoroscopes installed after the effective date of these rules,
- (2) 35.5 centimeters on stationary fluoroscopes which were in operation prior to the effective date of these rules,
- (3) 30 centimeters on all mobile fluoroscopes, and (4) 20 centimeters for image-intensified fluoroscopes used for specific surgical application. The written safety procedures must provide precautionary measures to be adhered to during the use of this device.

g. Fluoroscopic timer.

(1) Means shall be provided to preset the cumulative on-time of the fluoroscopic X-ray tube. The maximum cumulative time of the timing device shall not exceed five minutes without resetting.

(2) A signal audible to the fluoroscopist shall indicate the completion of any preset cumulative on-time. Such signal shall continue to sound while X-rays are produced

until the timing device is reset.

h. Mobile fluoroscopes. In addition to the other requirements of 41.1(5), mobile fluoroscopes shall provide intensified imaging.

Control of scattered radiation.

- (1) Fluoroscopic table designs when combined with procedures utilized shall be such that no unprotected part of any staff or ancillary individual's body shall be exposed to unattenuated scattered radiation which originates from under the table. The attenuation required shall be not less than 0.25 millimeter lead equivalent.
- (2) Equipment configuration when combined with procedures shall be such that no portion of any staff or ancillary individual's body, except the extremities, shall be exposed to the unattenuated scattered radiation emanating from above the tabletop unless that individual:

1. Is at least 120 centimeters from the center of the useful beam, or

2. The radiation has passed through not less than 0.25 millimeter lead equivalent material including, but not limited to, drapes, Bucky-slot cover panel, or self-supporting curtains, in addition to any lead equivalency provided by the protective apron referred to in 41.1(3)"a"(5).

3) The agency may grant exemptions to 41.1(5)"i"(2) where a sterile field will not permit the use of the normal protective barriers. Where the use of prefitted sterilized covers for the barriers is practical, the agency shall not

permit such exemption.

- j. Radiation therapy simulation systems. Radiation therapy simulation systems shall be exempt from all the requirements of 41.1(5)"a," "c," "d," and "g" provided that:
- (1) Such systems are designed and used in such a manner that no individual other than the patient is in the X-ray room during periods of time when the system is producing X-rays; and
- (2) Systems which do not meet the requirements of 41.1(5)"g" are provided with a means of indicating the cumulative time that an individual patient has been exposed to X-rays. Procedures shall require in such cases that the timer be reset between examinations.
- 41.1(6) Radiographic systems other than fluoroscopic, dental intraoral, veterinarian, or computed tomography X-ray systems.

a. Beam limitation. The useful beam shall be limited to the area of clinical interest.

(1) General purpose stationary and mobile X-ray systems.

1. There shall be provided a means for stepless adjustment of the size of the X-ray field.

2. A method shall be provided for visually defining the perimeter of the X-ray field. The total misalignment of the edges of the visually defined field with the respective edges of the X-ray field along either the length or width of the visually defined field shall not exceed 2 percent of the distance from the source to the center of the visually defined field when the surface upon which it appears is perpendicular to the axis of the X-ray beam.

- 3. The agency may grant an exemption on noncertified X-ray systems to 41.1(6)"a"(1)"1" and "2" provided the registrant makes a written application for such exemption and in that application demonstrates it is impractical to comply with 41.1(6)"a"(1)"1" and "2"; and the purpose of 41.1(6)"a"(1)"1" and "2" will be met by other methods.
- (2) Additional requirements for stationary general purpose X-ray systems. In addition to the requirements of 41.1(6)"a"(1), stationary general purpose X-ray systems, both certified and noncertified, shall meet the following requirements:
- 1. A method shall be provided to indicate when the axis of the X-ray beam is perpendicular to the plane of the image receptor, to align the center of the X-ray field with respect to the center of the image receptor to within 2 percent of the SID, and to indicate the SID to within 2 percent;

2. The beam-limiting device shall indicate numerically the field size in the plane of the image receptor to

which it is adjusted; and

3. Indication of field size dimensions and SIDs shall be specified in inches or centimeters, and shall be such that aperture adjustments result in X-ray field dimensions in the plane of the image receptor which correspond to those indicated by the beam-limiting device to within 2 percent of the SID when the beam axis is indicated to be perpendicular to the plane of the image receptor.

- 3) X-ray systems designed for one image receptor Radiographic equipment designed for only one image receptor size at a fixed SID shall be provided with means to limit the field at the plane of the image receptor to dimensions no greater than those of the image receptor, and to align the center of the X-ray field with the center of the image receptor to within 2 percent of the SID, or shall be provided with means to both size and align the X-ray field such that the X-ray field at the plane of the image receptor does not extend beyond any edge of the image receptor.
- (4) Systems designed for or provided with special attachments for mammography. Radiographic systems designed only for mammography and general purpose radiographic systems, when special attachments for mammography are in service, shall be provided with means to limit the useful beam such that the X-ray field at the plane of the image receptor does not extend beyond any edge of the image receptor at any designated SID except the edge of the image receptor designed to be adjacent to the chest wall where the X-ray field may not extend beyond this edge by more than 2 percent of the SID. This requirement can be met with a system which performs as prescribed in 41.1(6)"a"(5)"3." When the beam-limiting device and image receptor support device are designed to be used to immobilize the breast during a mammographic procedure and the SID may vary, the SID indication specified in 41.1(6)"a"(5)"3" shall be the maximum SID for which the beam-limiting device or aperture is designed. In addition, each image receptor support intended for installation on a system designed only for mammography shall have clear and permanent markings to indicate the maximum image receptor size for which it is designed.
- (5) X-ray systems other than those described in 41.1(6)"a"(1), (2), (3), and (4) (Special purpose X-ray systems).
- 1. Means shall be provided to limit the X-ray field in the plane of the image receptor so that such field does not exceed each dimension of the image receptor by more

than 2 percent of the SID when the axis of the X-ray beam is perpendicular to the plane of the image receptor.

2. Means shall be provided to align the center of the X-ray field with the center of the image receptor to within 2 percent of the SID, or means shall be provided to both size and align the X-ray field such that the X-ray field at the plane of the image receptor does not extend beyond any edge of the image receptor.

3. 41.1(6)"a"(5)"1" and "2" may be met with a system that meets the requirements for a general purpose X-ray system as specified in 41.1(6)"a"(1) or, when alignment means are also provided, may be met with either:

 An assortment of removable, fixed-aperture, beamlimiting devices sufficient to meet the requirement for each combination of image receptor size and SID for which the unit is designed with each such device having clear and permanent markings to indicate the image receptor size and SID for which it is designed; or

 A beam-limiting device having multiple fixed apertures sufficient to meet the requirement for each combination of image receptor size and SID for which the unit is designed. Permanent, clearly legible markings shall indicate the image receptor size and SID for which each aperture is designed and shall indicate which aperture is in position for use.

b. Radiation exposure control devices.

- (1) Timers. Means shall be provided to terminate the exposure at a preset time interval, preset product of current and time, a preset number of pulses, or a preset radiation exposure to the image receptor. In addition, it shall not be possible to make an exposure when the timer is set to a "zero" or "off" position if either position is provided.

 (2) X-ray control.

1. An X-ray control shall be incorporated into each X-ray system such that an exposure can be terminated by the operator at any time except for exposure of one-half second or less, or during serial radiography when means shall be provided to permit completion of any single exposure of the series in process.

2. Each X-ray control shall be located in such a way as to meet the following requirements: stationary X-ray systems shall be required to have the X-ray control (or exposure switch in the case of podiatry units) permanently mounted in a protected area so that the operator is required to remain in that protected area during the entire exposure; and mobile and portable X-ray systems which

 Used for greater than one week in the same location, i.e., a room or suite, shall meet the requirements of 41.1(6)"b"(2)"2";

· Used for greater than one hour and less than one week at the same location, i.e., a room or suite, shall meet the requirement of the above paragraph or be provided with a 6.5 feet (1.98 m) high protective barrier which is placed at least 6 feet (1.83 m) from the tube housing assembly and at least 6 feet (1.83 m) from the patient; or

 Used to make an exposure(s) of a patient at the use location shall meet the requirement of the two above paragraphs or be provided with a method of X-ray control which will permit the operator to be at least 12 feet (3.66 m) from the tube housing assembly during an exposure.

3. The X-ray control shall provide visual indication observable at or from the operator's protected position whenever X-rays are produced. In addition, a signal audible to the operator shall indicate that the exposure has terminated.

(3) Automatic <u>exposure</u> controls. When an automatic <u>exposure</u> control is provided:

1. Indication shall be made on the control panel when

this mode of operation is selected;

- 2. If the X-ray tube potential is equal to or greater than 50 kVp, the minimum exposure time for field emission equipment rated for pulsed operation shall be equal to or less than a time interval equivalent to 2 pulses;
- 3. The minimum exposure time for all equipment other than that specified in 41.1(6)"b"(3)"2" shall be equal to or less than one-sixtieth second or a time interval required to deliver 5 mAs, whichever is greater;
- 4. Either the product of peak X-ray tube potential, current, and exposure time shall be limited to not more than 60 kWs per exposure, or the product of X-ray tube current and exposure time shall be limited to not more than 600 mAs per exposure except that, when the X-ray tube potential is less than 50 kVp, the product of X-ray tube current and exposure time shall be limited to not more than 2000 mAs per exposure; and
- 5. A visible signal shall indicate when an exposure has been terminated at the limits required by 41.1(6)"b"(3)"4," and manual resetting shall be required before further automatically timed exposures can be made
- (4) Reproducibility. With a timer setting of 0.5 seconds or less, the average exposure period (T) shall be greater than or equal to five times the maximum exposure period (T_{max}) minus the minimum exposure period (T_{min}) when four timer tests are performed:

$$\overline{T} \geq 5(T_{max} - T_{min})$$

- c. Source-to-skin distance. All mobile or portable radiographic systems shall be provided with means to limit the source-to-skin distance to equal to or greater than 30 centimeters.
- d. Exposure reproducibility. The coefficient of variation of exposure shall not exceed 0.10 when all technique factors are held constant. This requirement shall be deemed to have been met if, when four exposures are made at identical technique factors, the value of the average exposure (E) is greater than or equal to five times the maximum exposure (E_{max}) minus the minimum exposure (E_{max}):

$$\overline{E} \geq 5(E_{max} - E_{min})$$

- e. Radiation from capacitor energy storage equipment in standby status. Radiation emitted from the X-ray tube when the exposure switch or timer is not activated shall not exceed a rate of 2 milliroentgens (0.516 μ C/kg) per hour at 5 centimeters from any accessible surface of the diagnostic source assembly, with the beam-limiting device fully open.
- 41.1(7) Intraoral dental radiographic systems. In addition to the provisions of 41.1(3) and 41.1(4), the requirements of 41.1(7) apply to X-ray equipment and associated facilities used for dental radiography. Requirements for extraoral dental radiographic systems are covered in 41.1(6).
- a. Source-to-skin distance. X-ray systems designed for use with an intraoral image receptor shall be provided with means to limit source-to-skin distance to not less than:

- (1) 18 centimeters if operable above 50 kVp, or
- (2) 10 centimeters if not operable above 50 kVp.
- b. Field limitation. Radiographic systems designed for use with an intraoral image receptor shall be provided with means to limit the X-ray beam such that:
- (1) If the minimum source-to-skin distance (SSD) is 18 centimeters or more, the X-ray field, at the minimum SSD, shall be containable in a circle having a diameter of no more than 7 centimeters; and
- (2) If the minimum SSD is less than 18 centimeters, the X-ray field, at the minimum SSD, shall be containable in a circle having a diameter of no more than 6 centimeters.
- (3) The position indicating device shall be shielded and open-ended. The shielding shall be equivalent to the requirements of 41.1(4)"c."
- c. Timers. Means shall be provided to terminate the exposure at a preset time interval, preset product of current and time, a preset number of pulses, or a preset radiation exposure to the image receptor. In addition:

(1) It shall not be possible to make an exposure when the timer is set to a "zero" or "off" position if either posi-

tion is provided.

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(2) Reproducibility. With a timer setting of 0.5 seconds or less, the average exposure period (T) shall be greater than or equal to five times the maximum exposure period (T_{max}) minus the minimum exposure period (T_{min}) when four timer tests are performed:

$$\overline{T} \geq 5 (T_{max} - T_{min})$$

d. X-ray control.

- (1) An X-ray control shall be incorporated into each X-ray system such that an exposure can be terminated by the operator at any time, except for exposures of one-half (1/2) second or less.
- (2) Each X-ray control shall be located in such a way as to meet the following requirements:
- 1. Stationary X-ray systems shall be required to have the X-ray control permanently mounted in a protected area, so that the operator is required to remain in that protected area during the entire exposure; and

2. Mobile and portable X-ray systems which are:

- Used for greater than one week in the same location, i.e., a room or suite, shall meet the requirements of 41.1(7)"d"(2)"1";
- Used for greater than one hour and less than one week at the same location, i.e., a room or suite, shall meet the requirements of the above paragraph or be provided with a 6.5 feet (1.98 m) high protective barrier which is placed at least 6 feet (1.83 m) from the tube housing assembly and at least 6 feet (1.83 m) from the patient; or

• Used to make an exposure(s) of a patient at the use location shall meet the requirements of the above two paragraphs or be provided with a method of X-ray control which will permit the operator to be at least 12 feet (3.66 m) from the tube housing assembly during an exposure.

- (3) The X-ray control shall provide visual indication observable at or from the operator's protected position whenever X-rays are produced. In addition, a signal audible to the operator shall indicate that the exposure has terminated.
- e. Exposure reproducibility. The coefficient of variation shall not exceed 0.10 when all technique factors are held constant. This requirement shall be deemed to have been met if, when four exposures are made at identical technique factors, the value of the average exposure (E) is

greater than or equal to five times the maximum exposure (E_{min}) minus the minimum exposure (E_{min}) :

$$\overline{E} \geq 5(E_{max} - E_{min})$$

f. Administrative controls.

(1) Patient and film holding devices shall be used when the techniques permit.

(2) The tube housing and the PID shall not be hand-

held during an exposure.

(3) The X-ray system shall be operated in such a manner that the useful beam at the patient's skin does not exceed the requirements of 41.1(7)"b"(1).

(4) Dental fluoroscopy without image intensification

shall not be used.

g. Additional requirements applicable to certified systems only. Only diagnostic X-ray systems incorporating one or more certified component(s) shall be required to comply with the following additional requirement(s) which relate to that certified component(s).

(1) Reproducibility. When the equipment is operated on an adequate power supply as specified by the manufacturer, the estimated coefficient of variation of radiation exposures shall be no greater than 0.05, for any specific

combination of selected technique factors.

(2) Linearity. When the equipment allows a choice of X-ray tube current settings and is operated on a power supply as specified by the manufacturer in accordance with the requirements of applicable federal standards, for any fixed X-ray tube potential within the range of 40 to 100 percent of the maximum rating, the average ratios of exposure to the indicated milliampere-seconds product obtained at any two consecutive tube current settings shall not differ by more than 0.10 times their sum:

$$\left|\overline{X}_{1} - \overline{X}_{2}^{1}\right| \leq 0.10 \left(\overline{X}_{1} + \overline{X}_{2}\right)$$

where X_1 and X_2 are the average mR/mAs values obtained at each of two consecutive tube current settings.

(3) Accuracy. Deviation of technique factors from indicated values shall not exceed the limits specified for that system by its manufacturer.

(4) Timers. Termination of exposure shall cause automatic resetting of the timer to its initial setting or to "zero."

(5) Beam quality. All certified dental X-ray systems manufactured on and after December 1, 1980, shall have a minimum half-value layer not less than 1.5 millimeters aluminum equivalent. Systems operating above 70 kVp are subject to the filtration requirements of 41.1(4)"e"(1).

41.1(8) Therapeutic X-ray systems of less than 1 MeV.

a. Equipment requirements.

(1) Leakage radiation. When the tube is operated at its leakage technique factors, the leakage radiation shall not exceed the value specified at the distance specified for the classification of that X-ray system.

1. Contact therapy systems. Leakage radiation shall not exceed 100 milliroentgens (25.8 μ C/kg) per hour at 5 centimeters from the surface of the tube housing assembly.

2. 0-150 kVp systems. Systems which were manufactured or installed prior to the effective date of 41.1(8) shall have a leakage radiation which does not exceed 1

roentgen (0.258 mC/kg) in one hour at 1 meter from the source.

3. 0-150 kVp systems. Systems which are manufactured on or after the effective date of 41.1(8) shall have a leakage radiation which does not exceed 100 milliroentgens (25.8 μ C/kg) in one hour at 1 meter from the source.

4. 151 to 999 kVp systems. The leakage radiation shall not exceed 1 roentgen (0.258 mC/kg) in one hour at 1 meter from the source except systems that operate in excess of 500 kVp may have a leakage radiation at 1 meter from the source not to exceed 0.1 percent of the useful beam 1 meter from the source.

(2) Permanent beam-limiting devices. Permanent fixed diaphragms or cones used for limiting the useful beam shall provide the same or a higher degree of protec-

tion as required for the tube housing assembly.

(3) Removable and adjustable beam-limiting devices.

1. Removable beam-limiting devices shall, for the portion of the useful beam to be blocked by these devices, transmit not more than 1 percent of the useful beam at the maximum kilovoltage and maximum treatment filter. This requirement does not apply to auxiliary blocks or materials placed in the useful beam to shape the useful beam to the individual patient.

 Adjustable beam-limiting devices installed after the effective date of 41.1(8) shall meet the requirements of

41.1(8)"a"(3)"1."

- 3. Adjustable beam-limiting devices installed before the effective date of 41.1(8) shall, for the portion of the X-ray beam to be blocked by these devices, transmit not more than 5 percent of the useful beam at the maximum kilovoltage and maximum treatment filter.
- (4) Filter system. The filter system shall be so designed that:
- 1. The filters cannot be accidentally displaced at any possible tube orientation;
- 2. The radiation at 5 centimeters from the filter insertion slot opening does not exceed 30 roentgens (7.74 mC/kg) per hour under any operating conditions; and
- 3. Each filter is marked as to its material of construction and its thickness. For wedge filters, the wedge angle shall appear on the wedge or wedge tray.
- (5) Tube immobilization. The tube housing assembly shall be capable of being immobilized for stationary treatments.
- (6) Focal spot marking. The tube housing assembly shall be so marked that it is possible to determine the location of the focal spot to within 5 millimeters, and such marking shall be readily accessible for use during calibration procedures.
- (7) Beam block. Contact therapy tube housing assemblies shall have a removable shield of at least 0.5 millimeter lead equivalency at 100 kVp that can be positioned over the entire useful beam exit port during periods when the beam is not in use.
- (8) Beam monitor system. Systems of greater than 150 kVp manufactured after the effective date of 41.1(8) shall be provided with a beam monitor system which:
- Shall have the detector of the monitor system interlocked to prevent incorrect positioning;
- 2. Shall not allow irradiation until a preselected value of <u>exposure</u> has been made at the treatment control panel;

3. Shall independently terminate irradiation when the

preselected exposure has been reached;

4. Shall be so designed that, in the event of a system malfunction or electrical power failure, the dose adminis-

tered to a patient prior to the system malfunction or power failure can be accurately determined;

- 5. Shall have a display at the control panel from which the dose at a reference point in soft tissue can be calculated:
- Shall have a control panel display which maintains the administered dose reading until intentionally reset to zero; and
- 7. Shall have a control panel display which does not have scale multiplying factors and utilizes a design such that increasing dose is displayed by increasing numbers.
 - (9) Timer.
- 1. A timer which has a display shall be provided at the treatment control panel. The timer shall have a preset time selector and an elapsed time indicator.
- 2. The timer shall be a cumulative timer which activates with the production of radiation and retains its reading after irradiation is interrupted or terminated. After irradiation is terminated and before irradiation can be reinitiated, it shall be necessary to reset the elapsed time indicator to zero.
- 3. The timer shall terminate irradiation when a preselected time has elapsed if any dose monitoring system present has not previously terminated irradiation.
- 4. The timer shall permit accurate presetting and determination of exposure times as short as one second.
- 5. The timer shall not permit an exposure if set at
- 6. The timer shall not activate until the shutter is opened when irradiation is controlled by a shutter mechanism.
- (10) Control panel functions. The control panel, in addition to the displays required in other provisions of 41.1(8), shall have:
- 1. An indication of whether electrical power is available at the control panel and if activation of the X-ray tube is possible;
- An indication of whether X-rays are being produced;
- 3. Means for indicating X-ray tube potential and current;
 - 4. Means for terminating an exposure at any time;
- 5. A locking device which will prevent unauthorized use of the X-ray system; and
- 6. For X-ray systems manufactured after the effective date of 41.1(8), a positive display of specific filter(s) in the beam
- (11) Multiple tubes. When a control panel may energize more than one X-ray tube:
- 1. It shall be possible to activate only one X-ray tube
- 2. There shall be an indication at the control panel identifying which X-ray tube is energized.
- 3. There shall be an indication at the tube housing assembly when that tube is energized.
- (12) Source-to-skin distance. There shall be means of determining the SSD to within 1 centimeter.
- (13) Shutters. Unless it is possible to bring the X-ray output to the prescribed exposure parameters within 5 seconds, the beam shall be automatically attenuated by a shutter having a lead equivalency not less than that of the tube housing assembly. In addition:
- 1. After the unit is at operating parameters, the shutter shall be controlled electrically by the operator from the control panel; and
- 2. An indication of shutter position shall appear at the control panel.

- (14) Low-filtration X-ray tubes. Each X-ray system equipped with a beryllium or other low-filtration window shall be clearly labeled as such upon the tube housing assembly and at the control panel.
 - b. Facility design requirements for X-ray systems ca-

pable of operating above 50 kVp.

- (1) Aural communication. Provision shall be made for two-way aural communication between the patient and the operator at the control panel. However, where excessive noise levels or treatment requirements make aural communication impractical, other methods of communication shall be used.
 - (2) Viewing systems.
- 1. Windows, mirrors, closed-circuit television, or an equivalent system shall be provided to permit continuous observation of the patient during irradiation and shall be so located that the operator can observe the patient from the control panel.
- 2. When the primary viewing system is by electronic means, an alternate viewing system, which may be electronic, shall be available for use in the event of failure of the primary viewing system.
 - (3) Additional requirements for X-ray systems capa-

ble of operation above 150 kVp.

- 1. All protective barriers shall be fixed except for entrance doors or beam interceptors.
- 2. The control panel shall be located outside the treatment room.
- 3. Entrance interlocks. Interlocks shall be provided such that all entrance doors must be closed before treatment can be initiated or continued. If the radiation beam is interrupted by any door opening, it shall not be possible to restore the machine to operation without closing the door and reinitiating irradiation by manual action at the control panel.
- 4. When any door referred to in 41.1(8)"b"(3)"3" is opened while the X-ray tube is activated, the <u>exposure</u> at a distance of 1 meter from the source shall be reduced to less than 100 milliroentgens (25.8 μ C/kg) per hour.
- c. Surveys, calibrations, spot checks, and operating procedures.
 - Surveys.
- 1. All new facilities, and existing facilities not previously surveyed, shall have a survey made by, or under the direction of, a qualified expert. In addition, such surveys shall be done after any change in the facility or equipment which might cause a significant increase in radiation hazard.
- 2. The registrant shall obtain a written report of the survey from the qualified expert, and a copy of the report shall be transmitted by the registrant to the agency within 30 days of receipt of the report.
- 3. The survey and report shall indicate all instances where the installation, in the opinion of the qualified expert, is in violation of applicable regulations.
 - (2) Calibrations.
- 1. The calibration of an X-ray system shall be performed at intervals not to exceed one year and after any change or replacement of components which could cause a change in the radiation output.
- 2. The calibration of the radiation output of the X-ray system shall be performed by or under the direction of a qualified expert who is physically present at the facility during such calibration.
- 3. Calibration of the radiation output of an X-ray system shall be performed with a calibrated dosimetry system. The calibration of such system shall be traceable to

a national standard. The system shall have been calibrated within the preceding two years.

4. The calibrations shall be such that the dose at a reference point in soft tissue can be calculated to within an uncertainty of 5 percent.

5. The calibration of the X-ray system shall include, but not be limited to, the following determinations:

• Verification that the X-ray system is operating in compliance with the design specifications;

• The exposure rates as a function of field size, technique factors, filter, and treatment distance used;

- The degree of congruence between the radiation field and the field indicated by the localizing device if such device is present; and
- An evaluation of the uniformity of the largest radiation field used.
- 6. Records of calibration shall be maintained by the registrant for five years after completion of the calibration.
- 7. A copy of the most recent X-ray system calibration shall be available at or in the area of the control panel.
- (3) Spot checks. Spot checks shall be performed on X-ray systems capable of operation at greater than 150 kVp. Such spot checks shall meet the following requirements:
- 1. The spot-check procedures shall be in writing and shall have been developed by a qualified expert. A copy of the procedures shall be submitted to the agency prior to its implementation.
- 2. If a qualified expert does not perform the spotcheck measurement, the results of the spotcheck measurements shall be reviewed by a qualified expert within 15 days.
- 3. The spot-check procedures shall specify the frequency at which tests or measurements are to be performed. The spot-check procedures shall specify that the spot check shall be performed during the calibration specified in 41.1(8)"c"(2). The acceptable tolerance for each parameter measured in the spot check when compared to the value for that parameter determined in the calibration specified in 41.1(8)"c"(2) shall be stated.
- 4. The cause for a parameter exceeding a tolerance set by the qualified expert shall be investigated and corrected before the system is used for patient irradiation.
- 5. Whenever a spot check indicates a significant change in the operating characteristics of a system, as specified in the qualified expert's spot-check procedures, the system shall be recalibrated as required in 41.1(8)"c"(2).
- 6. Records of spot-check measurements shall be maintained by the registrant for two years after completion of the spot-check measurements and any necessary corrective actions.
- 7. Where a spot check involves a radiation measurement, such measurement shall be obtained using a system satisfying the requirements of 41.1(8)"c"(2) or which has been intercompared with a system meeting those requirements within the previous year.
 - (4) Operating procedures.

1. X-ray systems shall not be left unattended unless the system is secured against unauthorized use.

2. When a patient must be held in position for radiation therapy, mechanical supporting or restraining devices shall be used.

3. The tube housing assembly shall not be held by hand during operation unless the system is designed to require such holding and the peak tube potential of the system does not exceed 50 kVp. In such cases, the holder

shall wear protective gloves and apron of not less than 0.5 mm lead equivalency at 100 kVp.

4. No individual other than the patient shall be in the treatment room unless such individual is protected by a barrier sufficient to meet the requirements of 641—subrule 40.2(1). No individual other than the patient shall be in the treatment room during exposures from X-ray systems operating above 150 kVp.

5. The X-ray system shall not be used in the administration of radiation therapy unless the requirements of 41.1(8)"c"(2) and 41.1(8)"c"(3)"5" have been met.

41.1(9) X-ray and electron therapy systems with energies of 1 MeV and above. Rule 641—41.3(136C) except 41.3(11)"c" and "d" shall apply to medical facilities using therapy systems with energies 1 MeV and above.

a. Definitions. In addition to the definitions provided in 41.1(2), the following definitions shall be applicable to 41.1(9):

"Applicator" means a structure which determines the extent of the treatment field at a given distance from the virtual source.

"Beam-scattering filter" means a filter used in order to scatter a beam of electrons.

"Central axis of the beam" means a line passing through the virtual source and the center of the plane figure formed by the edge of the first beam-limiting device.

"Dose monitoring system" means a system of devices for the detection, measurement, and display of quantities of radiation.

"Dose monitor unit" means a unit response from the dose monitoring system from which the absorbed dose can be calculated.

"Existing equipment" means therapy systems subject to 41.1(9) which were manufactured on or before January 1, 1985.

"Field-flattening filter" means a filter used to provide dose uniformity over the area of a useful beam of X-rays at a specified depth.

"Field size" means the dimensions along the major axes of an area in a plane perpendicular to the specified direction of the beam of incident radiation at the normal treatment distance and defined by the intersection of the major axes and the 50 percent isodose line. Material shall be placed in the beam such that dose maximum is produced at the normal treatment distance when field size is being determined.

"Gantry" means that part of the system supporting and allowing possible movements of the radiation head.

"Interruption of irradiation" means the stopping of irradiation with the possibility of continuing irradiation without resetting of operating conditions at the control panel.

"Isocenter" means a fixed point in space located at the center of the smallest sphere through which the central axis of the beams passes in all conditions.

"Moving beam therapy" means radiation therapy with relative displacement of the useful beam and the patient during irradiation. It includes are therapy, skip therapy, and rotational therapy.

"New equipment" means systems subject to 41.1(9) which were manufactured after January 1, 1985.

"Normal treatment distance" means:

(1) For electron irradiation, the virtual source-tosurface distance along the central axis of the useful beam as specified by the manufacturer for the applicator.

(2) For X-ray irradiation, the virtual source-toisocenter distance along the central axis of the useful

beam. For nonisocentric equipment, this distance shall be that specified by the manufacturer.

'Radiation head" means the structure from which the useful beam emerges.

'Shadow tray" means a device attached to the radi-

ation head to support auxiliary beam-limiting material.

"Stationary beam therapy" means radiation therapy without relative displacement of the useful beam and the patient during irradiation.

"Target" means that part of a radiation head which by design intercepts a beam of accelerated particles with subsequent emission of other radiation.

"Virtual source" means a point from which radiation appears to originate.

b. Requirements for equipment.

(1) Leakage radiation to the patient area.

- 1. New equipment shall meet the following requirements: For operating conditions producing maximum leakage radiation, the absorbed dose in rads (grays) due to leakage radiation, including X-rays, electrons, and neutrons, at any point in a circular plane of 2 meters radius centered on and perpendicular to the central axis of the beam at the isocenter or normal treatment distance and outside the maximum useful beam size, shall not exceed 0.1 percent of the maximum absorbed dose in rads (grays) of the unattenuated useful beam measured at the point of intersection of the central axis of the beam and the plane surface. Measurements excluding those for neutrons shall be averaged over an area up to but not exceeding 100 square centimeters at the positions specified. Measurements of the portion of the leakage radiation dose contributed by neutrons shall be averaged over an area up to but not exceeding 200 square centimeters; for each system, the registrant shall determine or obtain from the manufacturer the leakage radiation existing at the positions specified above for the specified operating conditions. Records on leakage radiation measurements shall be maintained for inspection by the agency.
- 2. Existing equipment shall meet the following requirements: For operating conditions producing maximum leakage radiation, the absorbed dose in rads (grays) due to leakage radiation, excluding neutrons at any point in a circular plane of 2 meters radius centered on and perpendicular to the central axis of the beam 1 meter from the virtual source, and outside the maximum size useful beam, shall not exceed 0.1 percent of the maximum absorbed dose in rads (grays) of the unattenuated useful beam measured at the point of intersection of the central axis of the beam and the surface of the circular plane. Measurements shall be averaged over an area up to but not exceeding 100 square centimeters at the positions specified; for each system, the registrant shall determine or obtain from the manufacturer the leakage radiation existing at the positions specified above for the specified operating conditions. Records on radiation leakage shall be maintained for inspection by the agency.
- (2) Leakage radiation outside the patient area for new equipment.
- 1. The absorbed dose in rads (grays) due to leakage radiation except in the area specified in 41.1(9)"b"(1)"1" when measured at any point 1 meter from the path of the charged particle, before the charged particle strikes the target or window, shall not exceed 0.1 percent for X-ray leakage nor 0.05 percent for neutron leakage of the maximum absorbed dose in rads (grays) of the unattenuated useful beam measured at the point of intersection of the central axis of the beam and the circular plane specified in 41.1(9)"b"(1)"1.

- 2. The registrant shall determine or obtain from the manufacturer, the actual leakage radiation existing at the positions specified in 41.1(9)"b"(2)"1" for specified operating conditions. Radiation measurements excluding neutrons shall be averaged over an area up to but not exceeding 100 square centimeters. Neutron measurements shall be averaged over an area up to but not exceeding 200 square centimeters.
- (3) Beam-limiting devices. Adjustable or interchangeable beam-limiting devices shall be provided, and such devices shall transmit no more than 2 percent of the useful beam at the normal treatment distance for the portion of the useful beam which is to be attenuated by the beamlimiting device. The neutron component of the useful beam shall not be included in this requirement.

(4) Filters.

Each filter which is removable from the system shall be clearly marked with an identification number. Documentation available at the control panel shall contain a description of the filter. For wedge filters, the wedge angle shall appear on the wedge or wedge tray.

If the absorbed dose rate data required by 41.1(9)"b"(16) relates exclusively to operation with a field-flattening or beam-scattering filter in place, such fil-

ter shall be removable only by the use of tools.

- 3. For new equipment which utilizes a system of wedge filters, interchangeable field-flattening filters, or interchangeable beam-scattering filters: irradiation shall not be possible until a selection of a filter has been made at the treatment control panel; an interlock system shall be provided to prevent irradiation if the filter selected is not in the correct position; a display shall be provided at the treatment control panel showing the filter(s) in use; and an interlock shall be provided to prevent irradiation if any filter selection operation carried out in the treatment room does not agree with the filter selection operation carried out at the treatment control panel.
- (5) Beam quality. The registrant shall determine, or obtain from the manufacturer, data sufficient to ensure that the following beam quality requirements are met:
- 1. The absorbed dose resulting from X-rays in a useful electron beam at a point on the central axis of the beam 10 centimeters greater than the practical range of the electrons shall not exceed the values stated in Table III. Linear interpolation shall be used for values not stated.

TABLE III

Dose as a Fraction of Maximum Absorbed Dose
0.03 0.05
0.10 0.20

2. Compliance with 41.1(9)"b"(5)"1" shall be determined using: a measurement within a phantom with the incident surface of the phantom at the normal treatment distance and normal to the central axis of the beam; the largest field size available which does not exceed 15 by 15 centimeters; and a phantom whose cross-sectional dimensions exceed the measurement radiation field by at

least 5 centimeters and whose depth is sufficient to perform the required measurement.

3. The absorbed dose at a surface located at the normal treatment distance, at the point of intersection of that surface with the central axis of the useful beam during Xray irradiation, shall not exceed the limits stated in Table IV. Linear interpolation shall be used for values not stated.

Table IV

Maximum Photon Energy in MeV	Absorbed Dose at the Surface as a Fraction of the Maximum Absorbed Dose
1 2	0.80 0.70
5	0.60
15 35	0.50 0.40
50	0.20

- 4. Compliance with 41.1(9)"b"(5)"3" shall be determined by measurements made: within a phantom using an instrument which will allow extrapolation to the surface absorbed dose; using a phantom whose size and placement meet the requirements of 41.1(9)"b"(5)"2"; after removal of all beam-modifying devices which can be removed without the use of tools, except for beamscattering or beam-flattening filters; and using the largest field size available which does not exceed 15 by 15 centi-
- 5. The registrant shall determine, or obtain from the manufacturer, the maximum percentage absorbed dose in the useful beam due to neutrons, excluding stray neutron radiation, for specified operating conditions.
- (6) Beam monitors. All therapy systems shall be provided with radiation detectors in the radiation head.
- 1. New equipment shall be provided with at least two radiation detectors. The detectors shall be incorporated into two separate dose monitoring systems.

2. Existing equipment shall be provided with at least one radiation detector. This detector shall be incorporated

into a primary dose monitoring system.

- 3. The detector and the system into which that detector is incorporated shall meet the following requirements: each detector shall be removable only with tools and shall be interlocked to prevent incorrect positioning; each detector shall form part of a dose monitoring system from whose readings in dose monitor units the absorbed dose at a reference point in the treatment volume can be calculated; each dose monitoring system shall be capable of independently monitoring, interrupting, and terminating
- 4. For new equipment, the design of the dose monitoring systems shall ensure that the malfunctioning of one system shall not affect the correct functioning of the second system and the failure of any element common to both systems which could affect the correct function of both systems shall terminate irradiation.
- 5. Each dose monitoring system shall have a legible display at the treatment control panel. For new equipment, each display shall maintain a reading until intentionally reset to zero, have only one scale and no scale multiplying factors, utilize a design such that increasing dose is displayed by increasing numbers and shall be so

designed that, in the event of an overdose of radiation, the absorbed dose may be accurately determined and, in the event of power failure, the dose monitoring information required in 41.1(9)"b"(6)"3" displayed at the control panel at the time of failure shall be retrievable in at least one system for a 20-minute period of time.

- (7) Beam symmetry. In new equipment inherently capable of producing useful beams with asymmetry exceeding 5 percent, the asymmetry of the radiation beam in two orthogonal directions shall be monitored before the beam passes through the beam-limiting device. Facilities shall be provided so that, if the difference in dose rate between one region and another region symmetrically displaced from the central axis of the beam exceeds 5 percent of the central axis dose rate, indication of this condition is made at the control panel; and if this difference exceeds 10 percent, the irradiation is terminated.
 - (8) Selection and display of dose monitor units.
- 1. Irradiation shall not be possible until a selection of a number of dose monitor units has been made at the treatment control panel.

2. The preselected number of dose monitor units shall be displayed at the treatment control panel until reset

manually for the next irradiation.

3. After termination of irradiation, it shall be necessary to reset the dosimeter display to zero before subsequent treatment can be initiated.

- 4. For new equipment after termination of irradiation, it shall be necessary to manually reset the preselected dose monitor units before irradiation can be initiated.
- (9) Termination of irradiation by the dose monitoring system or systems during stationary beam therapy.
- 1. Each primary system shall terminate irradiation when the preselected number of dose monitor units has been detected by the system.
- 2. If original design of the equipment included a second dose monitoring system, that system shall be capable of terminating irradiation when not more than 15 percent or 40 dose monitor units above the preselected number of dose monitor units set at the control panel has been detected by the second dose monitoring system.
- 3. For new equipment, a second dose monitoring system shall be present. That system shall be capable of terminating irradiation when not more than 10 percent or 25 dose monitoring units above the preselected number of dose monitor units set at the control panel has been detected by the second dose monitoring system.

4. For new equipment, an indicator on the control panel shall show which dose monitoring system has termi-

nated irradiation.

- (10) Interruption switches. It shall be possible to interrupt irradiation and equipment movements at any time from the operator's position at the treatment control panel. Following an interruption, it shall be possible to restart irradiation by operator action without any reselection of operating conditions. If any change is made of a preselected value during an interruption, irradiation and equipment movements shall be automatically terminated.
- (11) Termination switches. It shall be possible to terminate irradiation and equipment movements, or go from an interruption condition to termination conditions, at any time from the operator's position at the treatment control panel.
 - (12) Timer.
- 1. A timer which has a display shall be provided at the treatment control panel. The timer shall have a preset time selector and an elapsed time indicator.

- 2. The timer shall be a cumulative timer which activates with the production of radiation and retains its reading after irradiation is interrupted or terminated. After irradiation is terminated and before irradiation can be reinitiated, it shall be necessary to reset the elapsed time indicator to zero.
- 3. For new equipment after termination of irradiation and before irradiation can be reinitiated, it shall be necessary to manually reset the preset time selector.
- 4. The timer shall terminate irradiation when a preselected time has elapsed if the dose monitoring systems have not previously terminated irradiation.
- (13) Selection of radiation type. Equipment capable of both X-ray therapy and electron therapy shall meet the following additional requirements:
- 1. Irradiation shall not be possible until a selection of radiation type has been made at the treatment control pan-
- An interlock system shall be provided to ensure that the equipment can emit only the radiation type which has been selected.
- 3. An interlock system shall be provided to prevent irradiation if any selected operations carried out in the treatment room do not agree with the selected operations carried out at the treatment control panel.
- 4. An interlock system shall be provided to prevent irradiation with X-rays except to obtain a port film when electron applicators are fitted.
- 5. An interlock system shall be provided to prevent irradiation with electrons when accessories specific for X-ray therapy are fitted.
- 6. The radiation type selected shall be displayed at the treatment control panel before and during irradiation.
- (14) Selection of energy. Equipment capable of generating radiation beams of different energies shall meet the following requirements:
- 1. Irradiation shall not be possible until a selection of energy has been made at the treatment control panel.
- 2. An interlock system shall be provided to prevent irradiation if any selected operations carried out in the treatment room do not agree with the selected operations carried out at the treatment control panel.
- The nominal energy value selected shall be displayed at the treatment control panel before and during irradiation.
- 4. For new equipment, an interlock system shall be provided to terminate irradiation if the energy of the electrons striking the X-ray target or electron window deviates by more than 20 percent or 3 MeV, whichever is smaller, from the selected nominal energy.
- (15)- Selection of stationary beam therapy or moving beam therapy. Equipment capable of both stationary beam therapy and moving beam therapy shall meet the following requirements:
- 1. Irradiation shall not be possible until a selection of stationary beam therapy or moving beam therapy has been made at the treatment control panel.
- 2. An interlock system shall be provided to ensure that the equipment can operate only in the mode which has been selected.
- 3. An interlock system shall be provided to prevent irradiation if any selected operations carried out in the treatment room do not agree with the selected operations carried out at the treatment control panel.
- 4. The mode of operation shall be displayed at the treatment control panel.

5. For new equipment, an interlock system shall be provided to terminate irradiation if movement of the gantry occurs during stationary beam therapy or movement of the gantry stops during moving beam therapy unless such stoppage is a preplanned function.

6. Moving beam therapy shall be controlled to obtain the selected relationships between incremental dose monitor units and incremental angle of movement. For new equipment, an interlock system shall be provided to terminate irradiation if the number of dose monitor units delivered in any 10 degrees of arc differs by more than 20 percent from the selected value. For new equipment, where gantry angle terminates the irradiation in arc therapy, the dose monitor units shall differ by less than 5 percent from the value calculated from the absorbed dose per unit angle relationship.

7. Where the dose monitor system terminates the irradiation in arc therapy, the termination of irradiation shall be as required by 41.1(9)"b"(9).

(16) Absorbed dose rate. For new equipment, a system shall be provided from whose readings the absorbed dose rate at a reference point in the treatment volume can be calculated. The radiation detectors specified in 41.1(9)"b"(6) may form part of this system. In addition:

1. The dose monitor unit rate shall be displayed at the

treatment control panel.

- 2. If the equipment can deliver under any conditions an absorbed dose rate at the normal treatment distance more than twice the maximum value specified by the manufacturer for any machine parameters utilized, a device shall be provided which terminates irradiation when the absorbed dose rate exceeds a value twice the specified maximum. The value at which the irradiation will be terminated shall be in a record maintained by the registrant...
- (17) Location of virtual source and beam orientation. The registrant shall determine, or obtain from the manufacturer, the location with reference to an accessible point on the radiation head of:
- 1. The X-ray target or the virtual source of X-rays; and

2. The electron window or the virtual source of electrons if the system has electron beam capabilities.

- (18) System checking facilities. Capabilities shall be provided so that all radiation safety interlocks can be checked for correct operation. When preselection of any of the operating conditions requires action in the treatment room and at the treatment control panel, selection at one location shall not give a display at the other location until the requisite selected operations in both locations have been completed.
- c. Facility and shielding requirements. In addition to 641—Chapter 40, the following design requirements shall apply:

(1) Protective barriers. All protective barriers shall be fixed except for entrance doors or beam interceptors.

(2) Control panel. The control panel shall be located outside the treatment room.

- (3) Viewing systems.

 1. Windows, mirrors, closed-circuit television, or an equivalent system shall be provided to permit continuous observation of the patient during irradiation and shall be so located that the operator may observe the patient from the control panel.
- 2. When the primary viewing system is by electronic means, an alternate viewing system, which may be electronic, shall be available for use in the event of failure of the primary viewing system.

- (4) Aural communications. Provision shall be made for two-way aural communication between the patient and the operator at the control panel. However, where excessive noise levels or treatment requirements make aural communication impractical, other methods of communication shall be used.
- (5) Room entrances. Treatment room entrances shall be provided with warning lights in readily observable positions near the outside of all access doors to indicate when the useful beam is "on."
- (6) Entrance interlocks. Interlocks shall be provided such that all entrance doors must be closed before treatment can be initiated or continued. If the radiation beam is interrupted by any door opening, it shall not be possible to restore the machine to operation without closing the door and reinitiating irradiation by manual action at the control panel.
- d. Surveys, calibrations, spot checks, and operating procedures.
 - (1) Surveys.
- 1. All new facilities, and existing facilities not previously surveyed, shall have a survey made by, or under the direction of, a qualified expert. In addition, such surveys shall be done after any change in the facility or equipment which might cause a significant increase in radiation hazard.
- 2. The registrant shall obtain a written report of the survey from the qualified expert, and a copy of the report shall be transmitted by the registrant to the agency within 30 days of receipt of the report.
- 3. The survey and report shall indicate all instances where the installation, in the opinion of the qualified expert, is in violation of applicable rules.
 - (2) Calibrations.
- 1. The calibration of systems subject to 41.1(9) shall be performed in accordance with an established calibration protocol acceptable to the agency before the system is first used for irradiation of a patient and thereafter at time intervals which do not exceed 12 months and after any change which might significantly alter the calibration, spatial distribution, or other characteristics of the therapy beam. The calibration protocol published by the American Association of Physicists in Medicine is accepted as an established protocol. For other protocols, the user shall submit that protocol to the agency for concurrence that the protocol is acceptable.
- 2. The calibration shall be performed under the direct supervision of a radiological physicist who is physically present at the facility during the calibration.
- 3. Calibration radiation measurements required by 41.1(9)"d"(2)"1" shall be performed using a dosimetry system having a calibration factor for cobalt-60 gamma rays traceable to a national standard, which has been calibrated within the previous two years and after any servicing that may have affected its calibration, which has been calibrated in such a fashion that an uncertainty can be stated for the radiation quantities monitored by the system, and which has had constancy checks performed on the system as specified by a radiological physicist.
- 4. Calibrations shall be in sufficient detail that the dose at a reference point in soft tissue may be calculated to within an uncertainty of 5 percent.
- 5. The calibration of the therapy beam shall include but not be limited to the following determinations: verification that the equipment is operating in compliance with the design specifications concerning the light localizer,

side light, and back-pointer alignment with the isocenter when applicable, variation in the axis of rotation for the table, gantry, and jaw system, and beam flatness and symmetry at the specified depth; the absorbed dose rate at various depths of water for the range of field sizes used, for each effective energy, that will verify the accuracy of the dosimetry of all therapy procedures utilized with that therapy beam; the uniformity of the radiation field and any dependency upon the direction of the useful beam; verification that existing depth-dose data and isodose charts applicable to the specific machine continue to be valid or are updated to existing machine conditions; verification of transmission and electron buildup factors for all accessories such as wedges, shadow trays, and compensators.

6. Records of calibration measurements under 41.1(9)"d"(2)"1" and dosimetry system calibrations under 41.1(9)"d"(2)"3" shall be maintained for five years after completion of the full calibration.

7. A copy of the latest calibration performed pursuant to 41.1(9)"d"(2)"1" shall be available in the area of the

control panel.

(3) Spot checks. Spot checks shall be performed on systems subject to 41.1(9) during calibrations and thereafter at intervals not to exceed one month. Such spot checks shall meet the following requirements:

1. The spot-check procedures shall be in writing and shall have been developed by a radiological physicist. A copy of the procedure shall be submitted to the agency prior to its implementation.

2. If a radiological physicist does not perform the spot-check measurements, the results of the spot-check measurements shall be reviewed by a radiological physician within 15 does

cist within 15 days.

- 3. The spot-check procedures shall specify the frequency at which tests or measurements are to be performed and the acceptable tolerance for each parameter measured in the spot check when compared to the value for that parameter determined in the calibration.
- 4. At intervals not to exceed one week, spot checks shall be made of absorbed dose measurements at a minimum of 2 depths in a phantom.
- 5. Where a system has built-in devices which provide a measurement of any parameter during irradiation, such measurement shall not be utilized as a spot-check measurement.
- 6. The cause for a parameter exceeding a tolerance set by the radiological physicist shall be investigated and corrected before the system is used for patient irradiation.
- 7. Whenever a spot check indicates a significant change in the operating characteristics of a system, as specified in the radiological physicist's spot-check procedures, the system shall be recalibrated as required in 41.1(9)"d"(2).

8. Records of spot-check measurements shall be maintained by the registrant for a period of two years after completion of the spot-check measurements and any necessary corrective actions.

- 9. Where a spot check involves a radiation measurement, such measurement shall be obtained using a system satisfying the requirements of 41.1(9)"d"(2)"3" or which has been intercompared with a system meeting those requirements within the previous year.
 - (4) Operating procedures.
- 1. No individual other than the patient shall be in the treatment room during treatment of a patient.

2. If a patient must be held in position during treatment, mechanical supporting or restraining devices shall be used.

3. The system shall not be used in the administration of radiation therapy unless the requirements of

41.1(9)"d"(1), (2), and (3) have been met. 41.1(10) Veterinary medicine radiographic installa-

a. Equipment.

(1) The protective tube housing shall be equivalent to

the requirements of 41.1(4)"c."

(2) Diaphragms or cones shall be provided for collimating the useful beam to the area of clinical interest and shall provide the same degree of protection as is required of the housing.

(3) The total filtration permanently in the useful beam shall not be less than 0.5 millimeters aluminum equivalent for machines operating up to 50 kVp, 1.5 millimeters aluminum equivalent for machines operating between 50 and 70 kVp, and 2.5 millimeters aluminum equivalent for machines operating above 70 kVp.

(4) A device shall be provided to terminate the expo-

sure after a preset time or exposure.

- (5) A dead-man type of exposure switch shall be provided, together with an electrical cord of sufficient length, so that the operator can stand out of the useful beam and at least 6 feet (1.83 m) from the animal during all X-ray exposures.
- b. Structural shielding. All wall, ceiling, and floor areas shall be equivalent to or provided with applicable protective barriers to ensure compliance 641—subrules 40.2(1), 40.2(4), and 40.2(5).

c. Operating procedures.

(1) The operator shall stand well away from the useful beam and the animal during radiographic exposures.

(2) No individual other than the operator shall be in the X-ray room while exposures are being made unless such individual's assistance is required.

(3) When an animal must be held in position during radiography, mechanical supporting or restraining devices should be used. If the animal must be held by an individual, that individual shall be protected with appropriate shielding devices, such as protective gloves and apron, and he shall be so positioned that no part of his body will be struck by the useful beam. The exposure of any individual used for this purpose shall be monitored.

41.1(11) Computed tomography X-ray systems.

a. Definitions. In addition to the definitions provided in 641—38.2(136C) and 41.1(2), the following definitions

shall be applicable to 41.1(11):

"Computed tomography dose index" means the integral from -7T to +7T of the dose profile along a line perpendicular to the tomographic plane divided by the product of the nominal tomographic section thickness and the number of tomograms produced in a single scan, that is:

$$CTDI = \frac{1}{nT} \int_{-7T}^{+7T} D(z) dz$$

where:

z = Position along a line perpendicular to the tomographic plane.

(z) = Dose at position z.

T = Nominal tomographic section thickness.

n = Number of tomograms produced in a single scan.

This definition assumes that the dose profile is centered around z = 0 and that, for a multiple tomogram system, the scan increment between adjacent scans is nT.

Contrast scale" means the change in the linear attenuation coefficient per CTN relative to water, that is:

$$CS = \frac{\mu_x - \mu_w}{(CTN)_x - (CTN)_x}$$

where:

 μ_{k} = Linear attenuation coefficient of the material of

 μ_{ω} = Linear attenuation coefficient of water.

 $(\tilde{C}TN)_{x} = CTN$ of the material of interest.

(CTN) = CTN of water.
"CS" (see "Contrast scale").

"CT conditions of operation" means all selectable parameters governing the operation of a CT X-ray system including, but not limited to, nominal tomographic section thickness, filtration, and the technique factors as defined in 41.1(2).

"CTDI" (see "Computed tomography dose index").
"CT gantry" means the tube housing assemblies, beam-limiting devices, detectors, and the supporting structures and frames which hold these components.

"CTN" (see "CT number").
"CT number" means the number used to represent the X-ray attenuation associated with each elemental area of the CT image.

$$CTN = \underbrace{\frac{k(\mu_x - \mu_w)}{\mu_w}}_{}$$

where:

k = A constant. (The constant has a normal value of 1,000 when the Houndsfield scale of CTN is used.)

μ = Linear attenuation coefficient of the material of interest.

 μ_{ω} = Linear attenuation coefficient of water.

"Dose profile" means the dose as a function of position along a line.

"Elemental area" means the smallest area within a tomogram for which the X-ray attenuation properties of a body are depicted (see also "Picture element").

"Multiple tomogram system" means a computed tomography X-ray system which obtains X-ray transmission data simultaneously during a single scan to produce more than one tomogram.

"Noise" means the standard deviation of the fluctuations in CTN expressed as a percentage of the attenuation coefficient of water. Its estimate (S_n) is calculated using the following expression:

$$S_n = \frac{100 \times CS \times s}{\mu}$$

where:

CS = Contrast scale.

 μ_{-} = Linear attenuation coefficient of water.

s = Estimated standard deviation of the CTN of picture elements in a specified area of the CT image.

"Nominal tomographic section thickness" means the full width at half-maximum of the sensitivity profile taken at the center of the cross-sectional volume over which Xray transmission data are collected.

"Picture element" means an elemental area of a tomo-

"Reference plane" means a plane which is displaced

from and parallel to the tomographic plane.

"Scan" means the complete process of collecting Xray transmission data for the production of a tomogram. Data can be collected simultaneously during a single scan for the production of one or more tomograms.

'Scan increment" means the amount of relative displacement of the patient with respect to the CT X-ray system between successive scans measured along the

direction of such displacement.

"Scan sequence" means a preselected set of two or more scans performed consecutively under preselected CT conditions of operation.

"Scan time" means the period of time between the beginning and end of X-ray transmission data accumulation

for a single scan.

'Single tomogram system" means a CT X-ray system which obtains X-ray transmission data during a scan to produce a single tomogram.

"Tomographic plane" means that geometric plane which is identified as corresponding to the output tomo-

gram.

"Tomographic section" means the volume of an object whose X-ray attenuation properties are imaged in a tomogram.

- b. Requirements for equipment.
- (1) Termination of exposure.
- 1. Means shall be provided to terminate the X-ray exposure automatically by either deenergizing the X-ray source or shuttering the X-ray beam in the event of equipment failure affecting data collection. Such termination shall occur within an interval that limits the total scan time to no more than 110 percent of its preset value through the use of either a backup timer or devices which monitor equipment function.

2. A visible signal shall indicate when the X-ray exposure has been terminated through the means required by

41.1(11)"b"(1)"1.

- 3. The operator shall be able to terminate the X-ray exposure at any time during a scan, or series of scans under CT X-ray system control, of greater than one-half second duration.
 - (2) Tomographic plane indication and alignment.
- 1. For any single tomogram system, means shall be provided to permit visual determination of the tomographic plane or a reference plane offset from the tomographic

2. For any multiple tomogram system, means shall be provided to permit visual determination of the location of a reference plane. This reference plane can be offset from

the location of the tomographic planes.

- 3. If a device using a light source is used to satisfy 41.1(11)"b"(2)"1" or "2," the light source shall provide illumination levels sufficient to permit visual determination of the location of the tomographic plane or reference plane under ambient light conditions of up to 500 lux.
- (3) Beam-on and shutter status indicators and control switches.
- The CT X-ray control and gantry shall provide visual indication whenever X-rays are produced and, if applicable, whether the shutter is open or closed.

- 2. Each emergency button or switch shall be clearly labeled as to its function.
- (4) Indication of CT conditions of operation. The CT X-ray system shall be designed such that the CT conditions of operation to be used during a scan or a scan sequence shall be indicated prior to the initiation of a scan or a scan sequence. On equipment having all or some of these conditions of operation at fixed values, this requirement may be met by permanent markings. Indication of CT conditions of operation shall be visible from any position from which scan initiation is possible.

(5) Extraneous radiation. When data are not being collected for image production, the radiation adjacent to the tube port shall not exceed that permitted by 41.1(4)"c."

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(6) Maximum surface CTDI identification. The angular position where the maximum surface CTDI occurs shall be identified to allow for reproducible positioning of a CT dosimetry phantom.

(7) Additional requirements applicable to CT X-ray systems containing a gantry manufactured after Septem-

ber 3, 1985.

- 1. The total error in the indicated location of the tomographic plane or reference plane shall not exceed 5
- 2. If the X-ray production period is less than one-half second, the indication of X-ray production shall be actuated for at least one-half second. Indicators at or near the gantry shall be discernible from any point external to the patient opening where insertion of any part of the human body into the primary beam is possible.
- The deviation of indicated scan increment versus actual increment shall not exceed plus or minus 1 millimeter with any mass from 0 to 100 kilograms resting on the support device. The patient support device shall be incremented from a typical starting position to the maximum incremented distance or 30 centimeters, whichever is less, and then returned to the starting position. Measurement of actual versus indicated scan increment may be taken anywhere along this travel.

4. Premature termination of the X-ray exposure by the operator shall necessitate resetting of the CT conditions of operation prior to the initiation of another scan.

Facility design requirements.

(1) Aural communication. Provision shall be made for two-way aural communication between the patient and the operator at the control panel.

(2) Viewing systems.

Windows, mirrors, closed-circuit television, or an equivalent shall be provided to permit continuous observation of the patient during irradiation and shall be so located that the operator can observe the patient from the control panel.

2. When the primary viewing system is by electronic means, an alternate viewing system (which may be electronic) shall be available for use in the event of failure of

the primary viewing system.

d. Surveys, calibrations, spot checks, and operating procedures.

(1) Surveys

1. All CT X-ray systems installed after the effective date of these rules and those systems not previously surveyed shall have a survey made by, or under the direction of, a qualified expert. In addition, such surveys shall be done after any change in the facility or equipment which might cause a significant increase in radiation hazard.

2. The registrant shall obtain a written report of the survey from the qualified expert, and a copy of the report shall be made available to the agency upon request.

(2) Radiation calibrations.

1. The calibration of the radiation output of the CT X-ray system shall be performed by, or under the direction of, a qualified expert who is physically present at the

facility during such calibration.

2. The calibration of a CT X-ray system shall be performed at intervals specified by a qualified expert and after any change or replacement of components which, in the opinion of the qualified expert, could cause a change in the radiation output.

3. The calibration of the radiation output of a CT Xray system shall be performed with a calibrated dosimetry system. The calibration of such system shall be traceable to a national standard. The dosimetry system shall have

been calibrated within the preceding two years.

- 4. CT dosimetry phantom(s) shall be used in determining the radiation output of a CT X-ray system. Such phantom(s) shall meet the following specifications and conditions of use: CT dosimetry phantom(s) shall be right circular cylinders of polymethyl methacrylate of density 1.19 plus or minus 0.01 grams per cubic centimeter. The phantom(s) shall be at least 14 centimeters in length and shall have diameters of 32.0 centimeters for testing CT X-ray systems designed to image any section of the body and 16.0 centimeters for systems designed to image the head or for whole body scanners operated in the head scanning mode; CT dosimetry phantom(s) shall provide means for the placement of a dosimeter(s) along the axis of rotation and along a line parallel to the axis of rotation 1.0 centimeter from the outer surface and within the phantom. Means for the placement of dosimeters or alignment devices at other locations may be provided; any effects on the doses measured due to the removal of phantom material to accommodate dosimeters shall be accounted for through appropriate corrections to the reported data or included in the statement of maximum deviation for the valobtained using the phantom; and all dose measurements shall be performed with the CT dosimetry phantom placed on the patient couch or support device without additional attenuation materials present.
- 5. The calibration shall be required for each type of head, body, or whole-body scan performed at the facility.
- 6. Calibration shall meet the following requirements: The dose profile along the center axis of the CT dosimetry phantom for the minimum, maximum, and midrange values of the nominal tomographic section thickness used by the registrant shall be measurable. Where less than three nominal tomographic thicknesses can be selected, the dose profile determination shall be performed for each available nominal tomographic section thickness; the CTDI along the two axes specified in 41.1(11)"d"(2)"4" shall be measured. (For the purpose of determining the CTDI, the manufacturer's statement as to the nominal tomographic section thickness for that particular system may be utilized.) The CT dosimetry phantom shall be oriented so that the measurement point 1.0 centimeter from the outer surface and within the phantom is in the same angular position within the gantry as the point of maximum surface CTDI identified. The CT conditions of operation shall correspond to typical values used by the registrant; and the spot checks specified in 41.1(11)"d"(3) shall be made.

- 7. Calibration procedures shall be in writing. Records of calibrations performed shall be maintained for inspection by the agency.
 - (3) Spot checks.

1. The spot-check procedures shall be in writing and shall have been developed by a qualified expert.

2. The spot-check procedures shall incorporate the use of a CT dosimetry phantom which has a capability of providing an indication of contrast scale, noise, nominal tomographic section thickness, the resolution capability of the system for low and high contrast objects, and measuring the mean CTN for water or other reference material.

All spot checks shall be included in the calibration required by 41.1(11)"d"(2) and at time intervals and under

system conditions specified by a qualified expert.

4. Spot checks shall include acquisition of images obtained with the CT dosimetry phantom(s) using the same processing mode and CT conditions of operation as are used to perform calibrations required by 41.1(11)"d"(2). The images shall be retained, until a new calibration is performed, in two forms as follows: photographic copies of the images obtained from the image display device; and images stored in digital form on a storage medium compatible with the CT X-ray system.

5. Written records of the spot checks performed shall

be maintained for inspection by the agency.

(4) Operating procedures.

The CT X-ray system shall not be operated except by an individual who has been specifically trained in its operation.

- 2. Information shall be available at the control panel regarding the operation and calibration of the system. Such information shall include the following: dates of the latest calibration and spot checks and the location within the facility where the results of those tests may be obtained; instructions on the use of the CT dosimetry phantom(s) including a schedule of spot checks appropriate for the system, allowable variations for the indicated parameters, and the results of at least the most recent spot checks conducted on the system; the distance in millimeters between the tomographic plane and the reference plane if a reference plane is utilized; and a current technique chart available at the control panel which specifies for each routine examination the CT conditions of operation and the number of scans per examination.
- 3. If the calibration or spot check of the CT X-ray system identifies that a system operating parameter has exceeded a tolerance established by the qualified expert, use of the CT X-ray system on patients shall be limited to those uses permitted by established written instructions of the qualified expert.

641—41.2(136C) Use of radionuclides in the healing

41.2(1) Purpose and scope. This rule establishes requirements and provisions for the use of radionuclides in the healing arts and for issuance of licenses authorizing the medical use of this material. These requirements and provisions provide for the protection of the public health and safety. The requirements and provisions of this rule are in addition to, and not in substitution for, others in these rules. The requirements and provisions of these rules apply to applicants and licensees subject to this rule unless specifically exempted.

41.2(2) Definitions. As used in this rule, the follow-

ing definitions apply:

"ALARA" (as low as reasonably achievable) means making every reasonable effort to maintain exposures to radiation as far below the dose limits as is practical:

(1) Consistent with the purpose for which the licensed

activity is undertaken;

- (2) Taking into account the state of technology, the economics of improvements in relation to benefits to the public health and safety, and other societal and socioeconomic considerations; and
- (3) In relation to utilization of nuclear energy in the public interest.

"Area of use" means a portion of a physical structure that has been set aside for the purpose of receiving, using,

or storing radioactive material.

*"Authorized user" means a practitioner of the healing arts who is identified as an authorized user on an agency [, agreement state, licensing state or U.S. Nuclear Regulatory Commission] license that authorizes the medical use of radioactive material.

"Brachytherapy" means a method of radiation therapy in which sealed sources are utilized to deliver a radiation dose at a distance of up to a few centimeters, by surface,

intracavitary, or interstitial application.

"Dedicated check source" means a radioactive source that is used to ensure the constant operation of a radiation detection or measurement device over several months or years. This source may also be used for other purposes.

"Management" means the chief executive officer or

that individual's designee.

"Medical institution" means an organization in which

several medical disciplines are practiced.

"Medical use" means the intentional internal or external administration of radioactive material, or the radiation therefrom, to humans in the practice of the healing arts.

"Misadministration" means the administration of:

- a. A radiopharmaceutical or radiation from a sealed source other than the one intended;
- b. A radiopharmaceutical or radiation to the wrong patient;
- c. A radiopharmaceutical or radiation by a route of administration other than that intended by the prescribing physician;
- d. A diagnostic dosage of a radiopharmaceutical differing from the prescribed dosage by more than 50 percent;
- e. A therapeutic dosage of a radiopharmaceutical differing from the prescribed dosage by more than 10 percent; or
- f. A therapeutic radiation dose from a sealed source such that errors in the source calibration, time of exposure, and treatment geometry result in a calculated total treatment dose differing from the final prescribed total treatment dose by more than 10 percent.

"Mobile nuclear medicine service" means the trans-

portation and medical use of radioactive material.
"Output" means the exposure rate, dose rate, or a quantity related in a known manner to these rates from a teletherapy unit for a specified set of exposure conditions.

"Teletherapy" means therapeutic irradiation in which the source of radiation is at a distance from the body.

"Teletherapy physicist" means an individual identified as the qualified teletherapy physicist on an agency li-

"Visiting authorized user" means an authorized user who is not identified on the license of the licensee being visited.

41.2(3) License required.

- a. No person shall manufacture, produce, acquire, receive, possess, use, or transfer radioactive material for medical use except in accordance with a specific license issued pursuant to these rules.
- b. Unless prohibited by license condition, an individual may receive, possess, use, or transfer radioactive material in accordance with these rules under the supervision of an authorized user as provided in 41.2(11).

41.2(4) License amendments. A licensee shall apply

for and receive a license amendment:

- a. Before using radioactive material for a method or type of medical use not permitted by the license issued under this rule;
- b. Before permitting anyone, except a visiting authorized user described in 41.2(12), to work as an authorized user under the license;
- c. Before changing a radiation safety officer or teletherapy physicist;
- d. Before receiving radioactive material in excess of the amount authorized on the license;
- e. Before adding to or changing the areas of use or address or addresses of use identified in the application or on the license; and

f. Before changing statements, representations, and procedures which are incorporated into the license.

- 41.2(5) Notifications. A licensee shall notify the agency in writing within 30 days when an authorized user, radiation safety officer, or teletherapy physicist permanently discontinues performance of duties under the license.
 - 41.2(6) Maintenance of records.
- a. Each record required by this rule must be legible throughout the retention period specified by each subrule. The record may be original or reproduced copy or a microform, provided that the copy or microform is authenticated by authorized personnel and that the microform is capable of producing a clear copy throughout the required retention period.
- b. The record may also be stored on electronic media with the capability for producing legible, accurate, and complete records during the required retention period. Records such as letters, drawings, and specifications must include all pertinent information such as stamps, initials, and signatures.
- c. The licensee shall maintain adequate safeguards against tampering with and loss of records specified in 41.2(6)"a" and "b."

41.2(7) ALARA program.

a. Each licensee shall develop and implement a written program to maintain radiation doses and releases of radioactive material in effluents to unrestricted areas as low as reasonably achievable in accordance with 641—subrule 40.1(2).

b. To satisfy the requirement of 41.2(7)"a":

(1) The management, radiation safety officer, and all authorized users shall participate in the establishment, implementation, and operation of the program as required by these rules or the radiation safety committee; or

(2) For licensees that are not medical institutions, management and all authorized users shall participate in the program as required by the radiation safety officer.

c. The ALARA program shall include an annual review by the radiation safety committee for licensees that are medical institutions, or management and the radiation safety officer for licensees that are not medical institu-

^{*}Brackets supplied by agency

tions, of summaries of the types and amounts of radioactive material used, occupational dose reports, and continuing education and training for all personnel who work with or in the vicinity of radioactive material. The purpose of the review is to ensure that individuals make every reasonable effort to maintain occupational doses, doses to the general public, and releases of radioactive material as low as reasonably achievable, taking into account the state of technology, and the cost of improvements in relation to benefits.

d. The licensee shall retain a current written description of the ALARA program for the duration of the license. The written description shall include:

(1) A commitment by management to keep occupational doses as low as reasonably achievable;

(2) A requirement that the radiation safety officer brief management once each year on the radiation safety program;

(3) Personnel exposure investigational levels as established in accordance with 41.2(9)"b"(8) that, when exceeded, will initiate an investigation by the radiation safety officer of the cause of the exposure; and

(4) Personnel exposure investigational levels that. when exceeded, will initiate a prompt investigation by the radiation safety officer of the cause of the exposure and a consideration of actions that might be taken to reduce the probability of recurrence.

41.2(8) Radiation safety officer.

- a. A licensee shall appoint a radiation safety officer responsible for implementing the radiation safety program. The licensee, through the radiation safety officer, shall ensure that radiation safety activities are being performed in accordance with approved procedures and regulatory requirements in the daily operation of the licensee's radioactive material program.
 - b. The radiation safety officer shall:
- Investigate overexposures, accidents, spills, losses, thefts, unauthorized receipts, uses, transfers, and disposals, and other deviations from approved radiation safety practice and implement corrective actions as neces-
 - (2) Implement written policy and procedures for:
 - 1. Authorizing the purchase of radioactive material:
- 2. Receiving and opening packages of radioactive material:
 - 3. Storing radioactive material;
- 4. Keeping an inventory record of radioactive materi-
 - 5. Using radioactive material safely:
- 6. Taking emergency action if control of radioactive material is lost;
 - 7. Performing periodic radiation surveys;
- 8. Performing checks and calibrations of survey instruments and other safety equipment;
 - 9. Disposing of radioactive material;
- 10. Training personnel who work in or frequent areas where radioactive material is used or stored; and
- 11. Keeping a copy of all records and reports required by the agency rules, a copy of these rules, a copy of each licensing request and license and amendments, and the written policy and procedures required by the rules; and
- (3) For medical use not sited at a medical institution. approve or disapprove radiation safety program changes with the advice and consent of management prior to submittal to the agency for licensing action; or

(4) For medical use sited at a medical institution, assist the radiation safety committee in the performance of its duties.

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- 41.2(9) Radiation safety committee. Each medical institution licensee shall establish a radiation safety committee to oversee the use of radioactive material.
- a. The committee shall meet the following administrative requirements:
- (1) Membership must consist of at least three individuals and shall include an authorized user of each type of use permitted by the license, the radiation safety officer, a representative of the nursing service, and a representative of management who is neither an authorized user nor a radiation safety officer. Other members may be included as the licensee deems appropriate.

(2) The committee shall meet at least once each calendar quarter.

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- To establish a quorum and to conduct business, one-half of the committee's membership shall be present, including the radiation safety officer and the management's representative.
- (4) The minutes of each radiation safety committee meeting shall include:
 - 1. The date of the meeting;
 - 2. Members present;
 - 3. Members absent:
 - 4. Summary of deliberations and discussions;
- 5. Recommended actions and the numerical results of all ballots; and
- 6. Document any reviews required in 41.2(7)"c" and 41.2(9)"b."
- (5) The committee shall provide each member with a copy of the meeting minutes and retain one copy until the agency authorizes its disposition.
- b. To oversee the use of licensed material, the committee shall:
- Be responsible for monitoring the institutional program to maintain occupational doses as low as reasonably achievable:
- (2) Review, on the basis of safety and with regard to the training and experience standards of this rule, and approve or disapprove any individual who is to be listed as an authorized user, the radiation safety officer, or teletherapy physicist before submitting a license application or request for amendment or renewal;
- (3) Review on the basis of safety and approve or disapprove each proposed method of use of radioactive material:
- (4) Review on the basis of safety, and approve with the advice and consent of the radiation safety officer and the management representative, or disapprove procedures and radiation safety program changes prior to submittal to the agency for licensing action;

(5) Review quarterly, with the assistance of the radiation safety officer, occupational radiation exposure records of all personnel working with radioactive material;

- (6) Review quarterly, with the assistance of the radiation safety officer, all incidents involving radioactive material with respect to cause and subsequent actions tak-
- (7) Review annually, with the assistance of the radiation safety officer, the radioactive material program; and
- (8) Establish a table of investigational levels for occupational dose that, when exceeded, will initiate inves-

tigations and considerations of action by the radiation safety officer.

41.2(10) Statement of authorities and responsibilities.

a. A licensee shall provide sufficient authority and organizational freedom to the radiation safety officer and the radiation safety committee to:

(1) Identify radiation safety problems;

(2) Initiate, recommend, or provide solutions; and

(3) Verify implementation of corrective actions.

- b. A licensee shall establish in writing the authorities, duties, responsibilities, and radiation safety activities of the radiation safety officer and the radiation safety committee.
 - **41.2(11)** Supervision.
- a. A licensee who permits the receipt, possession, use, or transfer of radioactive material by an individual under the supervision of an authorized user as allowed by 41.2(3) shall:
- (1) Instruct the supervised individual in the principles of radiation safety appropriate to that individual's use of radioactive material;
- (2) Review the supervised individual's use of radioactive material, provide reinstruction as needed and review records kept to reflect this use;

(3) Require the authorized user to be immediately available to communicate with the supervised individual;

- (4) Require the authorized user to be able to be physically present and available to the supervised individual on one hour's notice (the supervising authorized user need not be present for each use of radioactive material); and
- (5) Require that only those individuals specifically trained, and designated by the authorized user, shall be permitted to administer radionuclides or radiation to patients.
- b. A license shall require the supervised individual receiving, possessing, using or transferring radioactive material under 41.2(3) to:
- (1) Follow the instructions of the supervising authorized user:
- (2) Follow the procedures established by the radiation safety officer; and
- (3) Comply with these rules and the license conditions with respect to the use of radioactive material.

41.2(12) Visiting authorized user.

- a. A licensee may permit any visiting authorized user to use licensed material for medical use under the terms of the licensee's license for 60 days each year if:
- (1) The visiting authorized user has the prior written permission of the licensee's management and, if the use occurs on behalf of an institution, the institution's radiation safety committee;

(2) The licensee has a copy of an agency, agreement state, licensing state or U.S. Nuclear Regulatory Commission license that identifies the visiting authorized user by

name as an authorized user for medical use; and

- *(3) Only those procedures for which the visiting authorized user is specifically authorized by an agency [, agreement state, licensing state or U.S. Nuclear Regulatory Commission] license are performed by that individual.
- b. A licensee need not apply for a license amendment in order to permit a visiting authorized user to use licensed material as described in 41.2(12)"a."
- c. A licensee shall retain copies of the records specified in 41.2(12)"a" for five years from the date of the last visit.
- *Brackets supplied by agency

- 41.2(13) Mobile nuclear medicine service administrative requirements.
- a. The agency will only license mobile nuclear medicine services in accordance with this rule and other applicable requirements of these rules to serve clients who do not have an agency license.

b. Mobile nuclear medicine service licensees shall retain for the duration of service a letter signed by the management of each location where services are rendered that

authorizes use of radioactive material.

- c. If a mobile nuclear medicine service provides services that the client is also authorized to provide, the client is responsible for ensuring that services are conducted in accordance with the rules in this chapter while the mobile nuclear medicine service is under the client's direction.
- d. A mobile nuclear medicine service shall not have radioactive material delivered directly from the manufacturer or the distributor to the client's address of use.
 - 41.2(14) Records and reports of misadministrations.
- a. When a misadministration involves any therapy procedure, the licensee shall notify the agency by telephone. The licensee shall also notify the referring physician of the affected patient and the patient or a responsible relative or guardian, unless the referring physician agrees to inform the patient or believes, based on medical judgment, that telling the patient or the patient's responsible relative or guardian would be harmful to one or the other, respectively. These notifications must be made within 24 hours after the licensee discovers the misadministration. If the referring physician, patient, or the patient's responsible relative or guardian cannot be reached within 24 hours, the licensee shall notify them as soon as practicable. The licensee is not required to notify the patient or the patient's responsible relative or guardian without first consulting the referring physician; however, the licensee shall not delay medical care for the patient because of
- b. Within 15 days after an initial therapy misadministration report to the agency, the licensee shall report, in writing, to the agency and to the referring physician, and furnish a copy of the report to the patient or the patient's responsible relative or guardian if either was previously notified by the licensee as required by 41.2(14)"a." The written report shall include the licensee's name; the referring physician's name; a brief description of the event; the effect on the patient; the action taken to prevent recurrence; whether the licensee informed the patient or the patient's responsible relative or guardian, and if not, why not. The report shall not include the patient's name or other information that could lead to identification of the patient.
- c. When a misadministration involves a diagnostic procedure, the radiation safety officer shall promptly investigate its cause, make a record for agency review, and retain the record as directed in 41.2(14)"d." The licensee shall also notify the referring physician and the agency in writing on IDPH Form #588-2608 within 15 days if the misadministration involved the use of radioactive material not intended for medical use, administration of dosage five-fold different from the intended dosage, or administration of radioactive material such that the patient is likely to receive an organ dose greater than 2 rems (0.02 Sv) or a whole body dose greater than 500 millirems (5 mSv). Licensees may use dosimetry tables in package inserts, corrected only for amount of radioactivity administered,

to determine whether a report is required.

d. Each licensee shall retain a record of each misadministration for ten years. The record shall contain the names of all individuals involved in the event, including the physician, allied health personnel, the patient, and the patient's referring physician, the patient's social security number or identification number if one has been assigned, a brief description of the event, the effect on the patient, and the action taken, if any, to prevent recurrence.

e. Aside from the notification requirement, nothing in 41.2(14)"a" to 41.2(14)"d" shall affect any rights or duties of licensees and physicians in relation to each other, pa-

tients, or responsible relatives or guardians.

41.2(15) Suppliers. A licensee shall use for medical

use only:

- a. Radioactive material manufactured, labeled, packaged, and distributed in accordance with a license issued pursuant to these rules or the equivalent regulations of another agreement state, a licensing state or the U.S. Nuclear Regulatory Commission; and
- b. Reagent kits that have been manufactured, labeled, packaged, and distributed in accordance with an approval issued by the U.S. Food and Drug Administration.
- c. Teletherapy sources manufactured and distributed in accordance with a license issued pursuant to these rules, or the equivalent regulations of another agreement state, a licensing state, or the U.S. Nuclear Regulatory Commission.
- 41.2(16) Quality control of imaging equipment. Each licensee shall establish written quality control procedures for all equipment used to obtain images from radionuclide studies. As a minimum, the procedures shall include quality control procedures recommended by equipment manufacturers or procedures which have been approved by the agency. The licensee shall conduct quality control procedures in accordance with written procedures.

41.2(17) Possession, use, calibration, and check of dose calibrators.

- a. A medical use licensee authorized to administer radiopharmaceuticals shall possess a dose calibrator and use it to measure the amount of activity administered to each patient.
 - b. A licensee shall:
- Check each dose calibrator for constancy with a dedicated check source at the beginning of each day of use. To satisfy the requirement of this section, the check shall be done on a frequently used setting with a sealed source of not less than 10 microcuries (370 kBq) of radium-226 or 50 microcuries (1.85 MBq) of any other photon-emitting radionuclide with a half-life greater than 90 days;
- Test each dose calibrator for accuracy upon installation and at intervals not to exceed 12 months thereafter by assaying at least two sealed sources containing different radionuclides, the activity of which the manufacturer has determined within 5 percent of the stated activity, with minimum activity of 10 microcuries (370 kBq) for radium-226 and 50 microcuries (1.85 MBq) for any other photon-emitting radionuclide, and at least one of which has a principal photon energy between 100 keV and 500 keV;
- Test each dose calibrator for linearity upon installation and at intervals not to exceed three months thereafter over the range of use between 10 microcuries (370 kBq) and the highest dosage that will be administered; and
- (4) Test each dose calibrator for geometry dependence upon installation over the range of volumes and

- volume configurations for which it will be used. The licensee shall keep a record of this test for the duration of the use of the dose calibrator.
- c. A licensee shall mathematically correct dosage readings for any geometry or linearity error that exceeds 10 percent if the dosage is greater than 10 microcuries (370 kBq) and shall repair or replace the dose calibrator if the accuracy or constancy error exceeds 10 percent.
- d. A licensee shall also perform checks and tests required by 41.2(17)"b" following adjustment or repair of the dose calibrator.
- e. A licensee shall retain a record of each check and test required by 41.2(17) for three years. The records required by 41.2(17)"b" shall include:
- (1) For 41.2(17)"b"(1), the model and serial number of the dose calibrator, the identity and calibrated activity of the radionuclide contained in the check source, the date of the check, the activity measured, the instrument settings, and the initials of the individual who performed the check;
- (2) For 41.2(17)"b"(2), the model and serial number of the dose calibrator, the model and serial number of each source used and the identity of the radionuclide contained in the source and its activity, the date of the test, the results of the test, the instrument settings, and the signature of the radiation safety officer:

(3) For 41.2(17)"b"(3), the model and serial number of the dose calibrator, the calculated activities, the measured activities, the date of the test, and the signature of

the radiation safety officer; and

(4) For 41.2(17)"b"(4), the model and serial number of the dose calibrator, the configuration and calibrated activity of the source measured, the activity of the source, the activity measured and the instrument setting for each volume measured, the date of the test, and the signature of the radiation safety officer.

41.2(18) Calibration and check of survey instruments.

- a. A licensee shall ensure that the survey instruments used to show compliance with this rule have been calibrated before first use, annually, and following repair.
- b. To satisfy the requirements of 41.2(18)"a," the licensee shall:
- (1) Calibrate all required scale readings up to 1000 millirems (10 mSv) per hour with a radiation source;
- (2) For each scale that shall be calibrated, calibrate two readings separated by at least 50 percent of scale rat-

(3) Conspicuously note on the instrument the apparent dose rate from a dedicated check source as determined at

the time of calibration, and the date of calibration.

c. To satisfy the requirements of 41.2(18)"b," the licensee shall consider a point as calibrated if the indicated exposure rate differs from the calculated exposure rate by not more than 20 percent and shall conspicuously attach a correction chart or graph to the instrument.

- d. A licensee shall check each survey instrument for proper operation with the dedicated check source before each use. The licensee is not required to keep records of
- these checks.
- e. The licensee shall retain a record of each calibration required in 41.2(18)"a" for three years. The record shall include:
 - (1) A description of the calibration procedure; and
- (2) A description of the source used and the certified dose rates from the source, the rates indicated by the instrument being calibrated, the correction factors deduced

from the calibration data, the signature of the individual

who performed the calibration, and the date of calibration.

f. To meet the requirements of 41.2(18)"a," "b," and "c," the licensee may obtain the services of individuals licensed by the agency, the U.S. Nuclear Regulatory Commission, an agreement state, or a licensing state to perform calibrations of survey instruments. Records of calibrations which contain information required by 41.2(18)"e" shall be maintained by the licensee.

41.2(19) Assay of radiopharmaceutical dosages. A

licensee shall:

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- a. Assay, within 30 minutes before medical use, the activity of each radiopharmaceutical dosage that contains more than 10 microcuries (370 kBq) of a photon-emitting radionuclide:
- b. Assay, before medical use, the activity of each radiopharmaceutical dosage with a desired activity of 10 microcuries (370 kBq) or less of a photon-emitting radionuclide to verify that the dosage does not exceed 10 microcuries (370 kBq); and
- c. Retain a record of the assays required by 41.2(19)"a" for three years. To satisfy this requirement, the record shall contain the:
- (1) Generic name, trade name, or abbreviation of the radiopharmaceutical, its lot number, and expiration dates and the radionuclide:
- (2) Patient's name and identification number if one has been assigned;
- (3) Prescribed dosage and activity of the dosage at the time of assay, or a notation that the total activity is less than 10 microcuries (370 kBq);
 - (4) Date and time of the assay and administration; and(5) Initials of the individual who performed the assay.
- 41.2(20) Authorization for calibration and reference sources. Any person authorized by 41.2(3) for medical use of radioactive material may receive, possess, and use the following radioactive material for check, calibration and reference use:
- a. Sealed sources manufactured and distributed by persons specifically licensed pursuant to 641—Chapter 39 or equivalent provisions of the U.S. Nuclear Regulatory Commission, agreement state or licensing state and that do not exceed 15 millicuries (555 MBq) each;
- b. Any radioactive material listed in 41.2(32) or 41.2(34) with a half-life of 100 days or less in individual amounts not to exceed 15 millicuries (555 MBq);
- c. Any radioactive material listed in 41.2(32) or 41.2(34) with a half-life greater than 100 days in individual amounts not to exceed 200 microcuries (7.4 MBq) each; and
- d. Technetium-99m in individual amounts not to exceed 50 millicuries (1.85 GBq).
- 41.2(21) Requirements for possession of sealed sources and brachytherapy sources.
- a. A licensee in possession of any sealed source or brachytherapy source shall follow the radiation safety and handling instructions supplied by the manufacturer or equivalent instructions approved by the agency and shall maintain the instructions for the duration of source use in a legible form convenient to users.
- b. A licensee in possession of a sealed source shall ensure that:
- (1) The source is tested for leakage before its first use unless the licensee has a certificate from the supplier indicating that the source was tested within six months before transfer to the licensee: and

- (2) The source is tested for leakage at intervals not to exceed six months or at intervals approved by the agency, another agreement state, a licensing state or the U.S. Nuclear Regulatory Commission.
- c. To satisfy the leak test requirements of 41.2(21)"b," the licensee shall ensure that:
- (1) Leak tests are capable of detecting the presence of 0.005 microcurie (185 Bq) of radioactive material on the test sample or, in the case of radium, the escape of radon at the rate of 0.001 microcurie (37 Bq) per 24 hours;
- (2) Test samples are taken from the source or from the surfaces of the device in which the source is mounted or stored on which radioactive contamination might be expected to accumulate; and

(3) Test samples are taken when the source is in the "off" position.

- d. A licensee shall retain leak test records for five years. The records shall contain the model number, and serial number, if assigned, of each source tested, the identity of each source radionuclide and its estimated activity, the measured activity of each test sample expressed in microcuries (becquerels), a description of the method used to measure each test sample, the date of the test, and the signature of the radiation safety officer.
- e. If the leak test reveals the presence of 0.005 microcurie (185 Bq) or more of removable contamination, the licensee shall:
- (1) Immediately withdraw the sealed source from use and store it in accordance with the requirements of these rules; and
- (2) File a report with the agency within five days of receiving the leak test results with the agency describing the equipment involved, the test results, and the action taken.
- f. A licensee need not perform a leak test on the following sources:
- (1) Sources containing only radioactive material with a half-life of less than 30 days;
- (2) Sources containing only radioactive material as a
- *(3) Sources containing 100 microcuries (3.7 MBq) or less of beta or photon-emitting material or 10 microcuries (370 kBq) or less of alpha-emitting material; [and]
 - (370 kBq) or less of alpha-emitting material; [and]
 (4) Seeds of iridium-192 encased in hylon ribbon; and
- (5) Sources stored and not being used. The licensee shall, however, test each such source for leakage before any use or transfer unless it has been tested for leakage within six months before the date of use or transfer.
- g. A licensee in possession of a sealed source or brachytherapy source shall conduct a physical inventory of all such sources at intervals not to exceed three months. The licensee shall retain each inventory record for five years. The inventory records shall contain the model number of each source, and serial number if one has been assigned, the identity of each source radionuclide and its estimated activity, the location of each source, date of the inventory, and the signature of the radiation safety officer.
- h. A licensee in possession of a sealed source or brachytherapy source shall survey with a radiation survey instrument at intervals not to exceed three months all areas where such sources are stored. This does not apply to teletherapy sources in teletherapy units or sealed sources in diagnostic devices.
- i. A licensee shall retain a record of each survey required in 41.2(21)"h" for three years. The record shall include the date of the survey, a sketch of each area that

Brackets supplied by agency

was surveyed, the measured dose rate at several points in each area expressed in millirems (microsieverts) per hour, the model number and serial number of the survey instrument used to make the survey, and the signature of the radiation safety officer.

41.2(22) Syringe shields.

a. A licensee shall keep syringes that contain radioactive material to be administered in a radiation shield.

b. A licensee shall require each individual who prepares or administers radiopharmaceuticals to use a syringe radiation shield unless the use of the shield is contraindi-

cated for that patient.

- 41.2(23) Syringe labels. Unless utilized immediately, a licensee shall conspicuously label each syringe, or syringe radiation shield that contains a syringe with a radio-pharmaceutical, with the radiopharmaceutical name or its abbreviation, the type of diagnostic study or therapy procedure to be performed, or the patient's name.
- 41.2(24) Vial shields. A licensee shall require each individual preparing or handling a vial that contains a radiopharmaceutical to keep the vial in a vial radiation shield.
- 41.2(25) Vial shield labels. A licensee shall conspicuously label each vial radiation shield that contains a vial of a radiopharmaceutical with the radiopharmaceutical name or its abbreviation.
- 41.2(26) Surveys for contamination and ambient radiation dose rate.
- a. A licensee shall survey with a radiation detection survey instrument at the end of each day of use all areas where radiopharmaceuticals are routinely prepared for use or administered.
- b. A licensee shall survey with a radiation detection survey instrument at least once each week all areas where radiopharmaceuticals or radioactive wastes are stored.
- c. A licensee shall conduct the surveys required by 41.2(26)"a" and "b" so as to be able to measure dose rates as low as 0.1 millirem (1 μ Sv) per hour.
- d. A licensee shall establish dose rate action levels for the surveys required by 41.2(26)"a" and "b" and shall require that the individual performing the survey immediately notify the radiation safety officer if a dose rate exceeds an action level.
- e. A licensee shall survey for removable contamination each day of use all areas where radiopharmaceuticals are routinely prepared for use or administered and each week where radioactive materials are stored.
- f. A licensee shall conduct the surveys required by 41.2(26)"e" so as to be able to detect contamination on each wipe sample of 2000 disintegrations per minute (33.3 Bq).
- g. A licensee shall establish removable contamination action levels for the surveys required by 41.2(26)"e" and shall require that the individual performing the survey immediately notify the radiation safety officer if contamination exceeds action levels.
- h. A licensee shall retain a record of each survey required by 41.2(26)"a," "b," and "e" for two years. The record must include the date of the survey, a sketch of each area surveyed, action levels established for each area, the measured dose rate at several points in each area expressed in millirems (microsieverts) per hour or the removable contamination in each area expressed in disintegrations per minute (becquerels) per 100 square centimeters, the serial number and the model number of the instrument used to make the survey or analyze the

samples, and the initials of the individual who performed the survey.

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- 41.2(27) Release of patients containing radiopharmaceuticals or permanent implants.
- a. A licensee shall not authorize release from confinement for medical care any patient administered a radio-pharmaceutical until either:
- (1) The dose rate from the patient is less than 5 millirems (50 μSv) per hour at a distance of 1 meter; or
- (2) The activity in the patient is less than 30 millicuries (1.11 GBq).
- b. A licensee shall not authorize release from confinement for medical care any patient administered a permanent implant until the dose rate from the patient is less than 5 millirems (50 μ Sv) per hour at a distance of 1 meter
- 41.2(28) Mobile nuclear medicine service technical requirements. A licensee providing mobile nuclear medicine service shall:
- a. Transport to each address of use only syringes or vials containing prepared radiopharmaceuticals or radiopharmaceuticals that are intended for reconstitution of radiopharmaceutical kits;
- b. Bring into each location of use all radioactive material to be used and, before leaving, remove all unused radioactive material and associated radioactive waste;
- c. Secure or keep under constant surveillance and immediate control all radioactive material when in transit or at a location of use;
- d. Check survey instruments and dose calibrators as required in 41.2(17)"b"(1)"d" and "e" and 41.2(18)"d" and check all other transported equipment for proper function before medical use at each location of use;
- e. Carry a calibrated survey meter in each vehicle that is being used to transport radioactive material and, before leaving a client location of use, survey all areas of radiopharmaceutical use with a radiation detection survey instrument to ensure that all radiopharmaceuticals and all associated radioactive waste have been removed; and
- f. Retain a record of each survey required by 41.2(28)"e" for three years. The record must include the date of the survey, a plan of each area that was surveyed, the measured dose rate at several points in each area of use expressed in millirems (microsieverts) per hour, the model and serial number of the instrument used to make the survey, and the initials of the individual who performed the survey.

41.2(29) Storage of volatiles and gases.

- a. A licensee shall store volatile radiopharmaceuticals and radioactive gases in the shippers' radiation shield and container.
- b. A licensee shall store and use a multidose container in a properly functioning fume hood.

41.2(30) Decay-in-storage.

- a. A licensee shall hold radioactive material for decay-in-storage before disposal in ordinary trash and is exempt from the requirements of 641—subrule 40.4(1) if the licensee:
- (1) Holds radioactive material for decay a minimum of ten half-lives;
- (2) Monitors radioactive material at the container surface before disposal as ordinary trash and determines that its radioactivity cannot be distinguished from the background radiation level with a radiation detection survey instrument set on its most sensitive scale and with no interposed shielding;

(3) Removes or obliterates all radiation labels; and

(4) Separates and monitors each generator column individually with all radiation shielding removed to ensure that its contents have decayed to background radiation

level before disposal.

- For radioactive material disposed in accordance with 41.2(30)"a," the licensee shall retain a record of each disposal for three years. The record must include the date of the disposal, the date on which the radioactive material was placed in storage, the radionuclides disposed, the model and serial number of the survey instrument used, the background dose rate, the radiation dose rate measured at the surface of each waste container, and the name of the individual who performed the disposal.
- 41.2(31) Use of radiopharmaceuticals for uptake,

dilution, or excretion studies.

- a. A licensee may use the following prepared radiopharmaceuticals for diagnostic studies involving the measurement of uptake, dilution, or excretion:
- (1) Iodine-131 as sodium iodide, iodinated human serum albumin (IHSA), labeled rose bengal, or sodium iodohippurate;

(2) Iodine-125 as sodium iodide or iodinated human

serum albumin (IHSA);

- (3) Cobalt-57 as labeled cyanocobalamin;
- (4) Cobalt-58 as labeled cyanocobalamin;
- (5) Cobalt-60 as labeled cyanocobalamin;
- (6) Chromium-51 as sodium chromate or labeled human serum albumin;
 - (7) Iron-59 as citrate;

(8) Technetium-99m as pertechnetate;

(9) Any radioactive material in a radiopharmaceutical for a diagnostic use involving measurements of uptake, dilution, or excretion for which the Food and Drug Administration (FDA) has accepted a "Notice of Claimed Investigational Exemption for a New Drug" (IND) or approved a "New Drug Application" (NDA).

b. A licensee using a radiopharmaceutical specified in 41.2(31)"a" for a clinical procedure other than one specified in the product label or package insert instructions shall comply with the product label or package insert instructions regarding physical form, route of administration

and dosage range.

- 41.2(32) Possession of survey instrument. A licensee authorized to use radioactive material for uptake, dilution, and excretion studies shall possess a portable radiation detection survey instrument capable of detecting dose rates over the range 0.1 millirem (1.0 μ Sv) per hour to 50 millirems (500 µSv) per hour. The instrument shall be operable and calibrated in accordance with 41.2(18).
- 41.2(33) Use of radiopharmaceuticals, generators, and reagent kits for imaging and localization studies.
- a. A licensee may use the following radiopharmaceuticals, generators, and reagent kits for imaging and localization studies:
- (1) Molybdenum-99/technetium-99mm generators for the elution or extraction of technetium-99m as pertechnetate:
 - (2) Technetium-99m as pertechnetate;
- Prepared radiopharmaceuticals and reagent kits for the preparation of the following technetium-99m labeled radiopharmaceuticals:
 - 1. Sulfur colloid.
 - Penetrate sodium.
 - Human serum albumin microspheres,
 - 4. Polyphosphate,
 - 5. Macroaggregated human serum albumin,

- 6. Etidronate sodium,
- 7. Stannous pyrophosphate,
- 8. Human serum albumin,
- Medronate sodium.
- 10. Gluceptate sodium,
- 11. Oxidronate sodium,
- 12. Disofenin, and
- 13. Succimer;
- (4) Iodine-131 as sodium iodide, iodinated human serum albumin, macroaggregated iodinated human serum albumin, colloidal (macroaggregated) iodinated human serum albumin, rose bengal, or sodium iodohippurate;
 - (5) Iodine-125 as sodium iodide or fibrinogen;
 - (6) Chromium-51 as human serum albumin;
 - (7) Gold-198 in colloidal form;
 - (8) Mercury-197 as chlormerodrin;
 - (9) Selenium-75 as selenomethionine;
 - (10) Strontium-85 as nitrate;
 - (11) Ytterbium-169 as Penetrate sodium;
 - (12) Gallium-67 as citrate;
 - (13) Indium-111 as chloride or DTPA;
- (14) Tin-113/indium-113m generators for the elution of indium-113m as chloride;
- (15) Yttrium-87/strontium-87m generators for the elution of strontium-87m;
 - (16) Thallium-201 as chloride;
 - (17) Iodine-123 as sodium iodide or iodohippurate;
- (18) Any radioactive material in a diagnostic radiopharmaceutical, except aerosol or gaseous form, or any generator or reagent kit for preparation and diagnostic use of a radiopharmaceutical containing radioactive material for which the Food and Drug Administration has accepted a "Notice of Claimed Investigational Exemption for a New Drug" (IND) or approved a "New Drug Application"
- b. A licensee using radiopharmaceuticals specified in 41.2(33)"a" for clinical procedures shall comply with the product label or package insert regarding physical form, route of administration, and dosage range.
- c. A licensee shall elute generators in compliance with 41.2(34) and prepare radiopharmaceuticals from kits in accordance with the manufacturer's instructions.
- d. Technetium-99m Penetrate as an aerosol for lung function studies is not subject to the restrictions in 41.2(33)"b."
- e. Provided the conditions of 41.2(35) are met, a licensee shall use radioactive aerosols or gases only if specific application is made to and approved by the agency.
 - 41.2(34) Permissible molybdenum-99 concentration.
- a. A licensee shall not administer a radiopharmaceuticontaining more than 0.15 microcurie molybdenum-99 per millicurie of technetium-99m (0.15 kilobecquerel of molybdenum-99 per megabecquerel of technetium-99m).
- b. A licensee preparing technetium-99m radiopharmaceuticals from molybdenum-99/technetium-99m generators shall measure the molybdenum-99 concentration in each eluate or extract.
- c. A licensee who must measure molybdenum concentration shall retain a record of each measurement for three years. The record shall include, for each elution or extraction of technetium-99m, the measured activity of the technetium expressed in millicuries (megabecquerels), the measured activity of molybdenum expressed in microcuries (kilobecquerels), the ratio of the measures expressed as microcuries of molybdenum per millicurie of technetium (kilobecquerels of molybdenum per megabec-

querel of technetium), the date of the test, and the initials of the individual who performed the test.

- d. A licensee shall report immediately to the agency each occurrence of molybdenum-99 concentration exceeding the limits specified in 41.2(32)"a."
 - 41.2(35) Control of aerosols and gases.
- a. A licensee who administers radioactive aerosols or gases shall do so with a system that will keep airborne concentrations within the limits prescribed by 641—subrule 40.2(1) and 641—subrule 40.2(6) of these rules.
- b. The system shall either be directly vented to the atmosphere through an air exhaust or provide for collection and decay or disposal of the aerosol or gas in a shielded container.
- c. A licensee shall only administer radioactive gases in rooms that are at negative pressure compared to surrounding rooms.
- d. Before receiving, using, or storing a radioactive gas, the licensee shall calculate the amount of time needed after a release to reduce the concentration in the area of use to the occupational limit listed in Appendix A of 641—Chapter 40. The calculation shall be based on the highest activity of gas handled in a single container and the measured available air exhaust rate.
- e. A licensee shall post the time calculated in 41.2(35)"a" at the area of use and require that, in case of a gas spill, individuals evacuate the room until the posted time has elapsed.
- f. A licensee shall check the operation of collection systems monthly and measure the ventilation rates in areas of use at intervals not to exceed six months. Records of these checks and measurements shall be maintained for three years.
- g. A copy of the calculations required in 41.2(35)"d" shall be recorded and retained for the duration of the license.
- 41.2(36) Possession of survey instruments. A licensee authorized to use radioactive material for imaging and localization studies shall possess a portable radiation detection survey instrument capable of detecting dose rates over the range of 0.1 millirem (1 μ Sv) per hour to 50 millirems (500 μ Sv) per hour, and a portable radiation measurement survey instrument capable of measuring dose rates over the range of 1 millirem (10 μ Sv) per hour to 1000 millirems (10 μ Sv) per hour. The instruments shall be operable and calibrated in accordance with 41.2(18).
- 41.2(37) Use of radiopharmaceuticals for therapy. A licensee may use the following prepared radiopharmaceuticals:
- a. Iodine-131 as iodide for treatment of hyperthyroidism, cardiac dysfunction, and thyroid carcinoma;
- b. Phosphorus-32 as soluble phosphate for treatment of polycythemia vera, leukemia, and bone metastases;
- c. Phosphorus-32 as colloidal chromic phosphate for intracavitary treatment of malignant effusions;
- d. Gold-198 as colloid for intracavitary treatment of malignant effusions;
- e. Any radioactive material in a radiopharmaceutical and for a therapeutic use for which the Food and Drug Administration has accepted a "Notice of Claimed Investigational Exemption for a New Drug" (IND) or approved a "New Drug Application" (NDA). The licensee shall comply with the package insert instructions regarding indications and method of administration.
 - 41.2(38) Safety instruction.

- a. A licensee shall provide oral and written radiation safety instruction for all personnel caring for patients undergoing radiopharmaceutical therapy. Refresher training shall be provided at intervals not to exceed one year.
- b. To satisfy 41.2(38)"a," the instruction shall describe the licensee's procedures for:
 - (1) Patient control;
 - (2) Visitor control;
 - (3) Contamination control;
 - (4) Waste control;
- (5) Notification of the radiation safety officer or authorized user in case of the patient's death or medical emergency; and
- (6) Training requirements specified in 641— subrule 40.6(136C).
- c. A licensee shall keep a record of individuals receiving instruction required by 41.2(38)"a," a description of the instruction, the date of instruction, and the name of the individual who gave the instruction. Such record shall be maintained for inspection by the agency for three years.
 - 41.2(39) Safety precautions.
- a. For each patient receiving radiopharmaceutical therapy and hospitalized for compliance with 41.2(27), a licensee shall:
- (1) Provide a private room with a private sanitary facility;
- (2) Post the patient's door with a "Caution: Radioactive Material" sign and note on the door or on the patient's chart where and how long visitors may stay in the patient's room:
- (3) Authorize visits by individuals under 18 years of age only on a case-by-case basis with the approval of the authorized user after consultation with the radiation safety officer:
- (4) Promptly after administration of the dosage, measure the dose rates in contiguous restricted and unrestricted areas with a radiation measurement survey instrument to demonstrate compliance with the requirements of 641—subrule 40.2(5) and retain for three years a record of each survey that includes the time and date of the survey, a plan of the area or list of points surveyed, the measured dose rate at several points expressed in millirems per hour, the instrument used to make the survey, and the initials of the individual who made the survey;
- (5) Either monitor material and items removed from the patient's room to determine that any contamination cannot be distinguished from the natural background radiation level with a radiation detection survey instrument set on its most sensitive scale and with no interposed shielding, or handle these materials and items as radioactive waste;
- (6) Provide the patient with radiation safety guidance that will help to keep radiation dose to household members and the public as low as reasonably achievable before authorizing release of the patient;
- (7) Survey the patient's room and private sanitary facility for removable contamination with a radiation detection survey instrument before assigning another patient to the room. The room must not be reassigned until removable contamination is less than 2 disintegrations per minute (3.33 Bq) per 100 square centimeters; and
- (8) Measure the thyroid burden of each individual who helped prepare or administer a dosage of iodine-131 within three days after administering the dosage, and retain for the period required by 641—subparagraph 40.5(1)"c"(1) a record of each thyroid burden measure-

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ment, date of measurement, the name of the individual whose thyroid burden was measured, and the initials of the individual who made the measurements.

b. A licensee shall notify the radiation safety officer or the authorized user immediately if the patient dies or

has a medical emergency.

- 41.2(40) Possession of survey instruments. A licensee authorized to use radioactive material for radiopharmaceutical therapy shall possess a portable radiation detection survey instrument capable of detecting dose rates over the range of 0.1 millirem (1 μ Sv) per hour to 50 millirems (500 μ Sv) per hour, and a portable radiation measurement survey instrument capable of measuring dose rates over the range of 1 millirem (10 μ Sv) per hour to 1000 millirems (10 mSv) per hour. The instruments shall be operable and calibrated in accordance with 41.2(18).
- 41.2(41) Use of sealed sources for diagnosis. A licensee shall use the following sealed sources in accordance with the manufacturer's radiation safety and handling instructions:
- a. Iodine-125 as a sealed source in a device for bone mineral analysis;
- b. Americium-241 as a sealed source in a device for bone mineral analysis;
- c. Gadolinium-153 as a sealed source in a device for bone mineral analysis; and

d. Iodine-125 as a sealed source in a portable device

for imaging.

- 41.2(42) Availability of survey instrument. A licensee authorized to use radioactive material as a sealed source for diagnostic purposes shall have available for use a portable radiation detection survey instrument capable of detecting dose rates over the range of 0.1 millirem (1 μ Sv) per hour to 50 millirems (500 μ Sv) per hour or a portable radiation measurement survey instrument capable of measuring dose rates over the range of 1 millirem (10 μ Sv) per hour to 1000 millirems (10 mSv) per hour. The instrument shall be operable and calibrated in accordance with 41.2(18).
- 41.2(43) Use of sources for brachytherapy. A licensee shall use the following sources in accordance with the manufacturer's radiation safety and handling instructions:
- a. Cesium-137 as a sealed source in needles and applicator cells for topical, interstitial, and intracavitary treatment of cancer;
- b. Cobalt-60 as a sealed source in needles and applicator cells for topical, interstitial, and intracavitary treatment of cancer;
- c. Gold-198 as a sealed source in seeds for interstitial treatment of cancer;
- d. Iodine-125 as a sealed source in seeds for interstitial treatment of cancer;
- e. Iridium-192 as seeds encased in nylon ribbon for interstitial treatment of cancer;
- f. Radium-226 as a sealed source in needles or applicator cells for topical, interstitial, and intracavitary treatment of cancer;
- g. Radon-222 as seeds for interstitial treatment of cancer;
- h. Strontium-90 as a sealed source in an applicator for treatment of superficial eye conditions; and
- i. Palladium-103 as a sealed source in seeds for the interstitial treatment of cancer.
 - 41.2(44) Safety instruction.
- a. The licensee shall provide oral and written radiation safety instruction to all personnel caring for a patient re-

ceiving implant therapy. Refresher training shall be provided at intervals not to exceed one year.

- b. To satisfy 41.2(44)"a," the instruction shall describe:
 - (1) Size and appearance of the brachytherapy sources;
- (2) Safe handling and shielding instructions in case of a dislodged source;
 - (3) Procedures for patient control;
 - (4) Procedures for visitor control;
- (5) Procedures for notification of the radiation safety officer or authorized user if the patient dies or has a medical emergency; and
- (6) Training requirements specified in 641—

40.6(136C).

c. A licensee shall maintain a record of individuals receiving instruction required by 41.2(44)"a," a description of the instruction, the date of instruction, and the name of the individual who gave the instruction for three years.

41.2(45) Safety precautions.

- a. For each patient receiving implant therapy a licensee shall:
- (1) Not place the patient in the same room with a patient who is not receiving radiation therapy unless the licensee can demonstrate compliance with the requirement of 641—paragraph 40.2(5)"a" at a distance of 1 meter from the implant;
- (2) Post the patient's door with a "Caution: Radioactive Materials" sign and note on the door or the patient's chart where and how long visitors may stay in the patient's room;
- (3) Authorize visits by individuals under 18 years of age only on a case-by-case basis with the approval of the authorized user after consultation with the radiation safety officer:
- (4) Promptly after implanting the sources, survey the dose rates in contiguous restricted and unrestricted areas with a radiation measurement survey instrument to demonstrate compliance with 641—paragraph 40.2(5)"a" and retain for three years a record of each survey that includes the time and date of the survey, a sketch of the area or list of points surveyed, the measured dose rate at several points expressed in millirems (μSv) per hour, the instrument used to make the survey, and the initials of the individual who made the survey; and
- (5) Provide the patient with radiation safety guidance that will help keep the radiation dose to household members and the public as low as reasonably achievable before releasing the patient if the patient was administered a permanent implant.
- b. A licensee shall notify the radiation safety officer or authorized user immediately if the patient dies or has a medical emergency.

41.2(46) Brachytherapy sources inventory.

- a. Each time brachytherapy sources are returned to an area of storage from an area of use, the licensee shall immediately count or otherwise verify the number returned to ensure that all sources taken from the storage area have been returned.
- b. A licensee shall make a record of brachytherapy source utilization which includes:
- (1) The names of the individuals permitted to handle the sources;
- (2) The number and activity of sources removed from storage, the room number of use and patient's name, the time and date they were removed from storage, the number and activity of sources in storage after the removal,

and the initials of the individual who removed the sources from storage; and

- (3) The number and activity of sources returned to storage, the room number of use and patient's name, the time and date they were returned to storage, the number and activity of sources in storage after the return, and the initials of the individual who returned the sources to storage.
- c. Immediately after implanting sources in a patient and immediately after removal of sources from a patient, the licensee shall make a radiation survey of the patient and the area of use to confirm that no sources have been misplaced. The licensee shall make a record of each survey.
- d. A licensee shall maintain the records required in 41.2(46)"b" and "c" for three years.
- 41.2(47) Release of patients treated with temporary implants.
- a. Immediately after removing the last temporary implant source from a patient, the licensee shall perform a radiation survey of the patient with a radiation detection survey instrument to confirm that all sources have been removed. The licensee shall not release from confinement for medical care a patient treated by temporary implant until all sources have been removed.
- b. A licensee shall maintain a record of patient surveys which demonstrate compliance with 41.2(47)"a" for three years. Each record shall include the date of the survey, the name of the patient, the dose rate from the patient expressed as millirems (microsieverts) per hour and measured within 1 meter from the patient, and the initials of the individual who made the survey.
- 41.2(48) Possession of survey instruments. A licensee authorized to use radioactive material for implant therapy shall possess a portable radiation detection survey instrument capable of detecting dose rates over the range of 0.1 millirem (1 μ Sv) per hour to 50 millirems (500 μ Sv) per hour, and a portable radiation measurement survey instrument capable of measuring dose rates over the range of 1 millirem (10 μ Sv) per hour to 1000 millirems (10 mSv) per hour. The instruments shall be operable and calibrated in accordance with 41.2(18).
- 41.2(49) Use of a sealed source in a teletherapy unit. A licensee shall use cobalt-60 or cesium-137 as a sealed source in a teletherapy unit for medical use in accordance with the manufacturer's radiation safety and operating instructions.
- 41.2(50) Maintenance and repair restrictions. Only a person specifically licensed by the agency, the U.S. Nuclear Regulatory Commission, or an agreement state to perform teletherapy unit maintenance and repair shall install, relocate, or remove a teletherapy sealed source or a teletherapy unit that contains a sealed source or maintain, adjust, or repair the source drawer, the shutter or other mechanism of a teletherapy unit that could expose the source, reduce the shielding around the source, or result in increased radiation levels.
- 41.2(51) Amendments. In addition to the requirements specified in 41.2(4), a licensee shall apply for and receive a license amendment before:
- a. Making any change in the treatment room shielding;
- b. Making any change in the location of the teletherapy unit within the treatment room;
- c. Using the teletherapy unit in a manner that could result in increased radiation levels in areas outside the teletherapy treatment room;

- d. Relocating the teletherapy unit; or
- e. Allowing an individual not listed on the licensee's license to perform the duties of the teletherapy physicist.
 - 41.2(52) Safety instruction.
- a. A licensee shall conspicuously post written instructions at the teletherapy unit console. These instructions shall inform the operator of:
- (1) The procedure to be followed to ensure that only the patient is in the treatment room before turning the primary beam of radiation "on" to begin a treatment or after a door interlock interruption;
- (2) The procedure to be followed if the operator is unable to turn the primary beam of radiation "off" with controls outside the treatment room or any other abnormal operation occurs; and
- (3) The names and telephone numbers of the authorized users and radiation safety officer to be immediately contacted if the teletherapy unit or console operates abnormally.
- b. A licensee shall provide instruction in the topics identified in 41.2(52)"a" to all individuals who operate a teletherapy unit and shall provide appropriate refresher training to individuals at intervals not to exceed one year.
- c. A licensee shall maintain a record of individuals receiving instruction required by 41.2(52)"b," a description of the instruction, the date of instruction, and the name of the individual who gave the instruction for three years.
 - 41.2(53) Doors, interlocks, and warning systems.
- a. A licensee shall control access to the teletherapy room by a door at each entrance.
- b. A licensee shall equip each entrance to the teletherapy room with an electrical interlock system that shall:
- (1) Prevent the operator from turning the primary beam of radiation "on" unless each treatment room entrance door is closed;
- (2) Turn the beam of radiation "off" immediately when an entrance door is opened; and
- (3) Prevent the primary beam of radiation from being turned "on" following an interlock interruption until all treatment room entrance doors are closed and the beam "on-off" control is reset at the console.
- c. A licensee shall equip each entrance to the teletherapy room with a conspicuously visible beam condition indicator light.
- 41.2(54) Possession of survey instrument. A licensee authorized to use radioactive material in a teletherapy unit shall possess either a portable radiation detection survey instrument capable of detecting dose rates over the range of 0.1 millirem (1 μ Sv) per hour to 50 millirems (500 μ Sv) per hour or a portable radiation measurement survey instrument capable of measuring dose rates over the range of 1 millirem (10 μ Sv) per hour to 1000 millirems (10 mSv) per hour. The instruments shall be operable and calibrated in accordance with 41.2(18).
 - 41.2(55) Radiation monitoring device.
- a. A licensee shall have in each teletherapy room a permanent radiation monitor capable of continuously monitoring beam status.
- b. Each radiation monitor shall be capable of providing visible notice of a teletherapy unit malfunction that results in an exposed or partially exposed source. The visible indicator of high radiation levels shall be observable by an individual entering the teletherapy room.
- c. Each radiation monitor shall be equipped with a backup power supply separate from the power supply to

the teletherapy unit. This backup power supply may be a battery system.

d. A radiation monitor shall be checked with a dedicated check source for proper operation each day before the teletherapy unit is used for treatment of patients.

e. A licensee shall maintain a record of the check required by 41.2(55)"d" for three years. The record shall include the date of the check, notation that the monitor indicates when the source is exposed, and the initials of

the individual who performed the check.

- f. If a radiation monitor is inoperable, the licensee shall require any individual entering the teletherapy room to use a survey instrument or audible alarm personal dosimeter to monitor for any malfunction of the source exposure mechanism. The instrument or dosimeter shall be checked with a dedicated check source for proper operation at the beginning of each day of use. The licensee shall keep a record as described in 41.2(55)"e."
- g. A licensee shall promptly repair or replace the radiation monitor if it is inoperable.
- 41.2(56) Viewing system. A licensee shall construct or equip each teletherapy room to permit continuous observation of the patient from the teletherapy unit console during irradiation.

41.2(57) Dosimetry equipment.

a. A licensee shall have a calibrated dosimetry system available for use. To satisfy this requirement, one of the

following two conditions shall be met:

- (1) The system shall have been calibrated by the National Institute of Standards and Technology or by a calibration laboratory accredited by the American Association of Physicists in Medicine. The calibration shall have been performed within the previous two years and after any servicing that may have affected system calibration; or
- (2) The system shall have been calibrated within the previous four years; 18 to 30 months after that calibration, the system shall have been intercompared at an intercomparison meeting with another dosimetry system that was calibrated within the past 24 months by the National Institute of Standards and Technology or by a calibration laboratory accredited by the American Association of Physicists in Medicine. The intercomparison meeting shall be sanctioned by a calibration laboratory or radiologic physics center accredited by the American Association of Physicists in Medicine. The results of the intercomparison meeting must have indicated that the calibration factor of the licensee's system had not changed by more than 2 percent. The licensee shall not use the intercomparison result to change the calibration factor. When intercomparing dosimetry systems to be used for calibrating cobalt-60 teletherapy units, the licensee shall use a teletherapy unit with a cobalt-60 source. When intercomparing dosimetry systems to be used for calibrating cesium-137 teletherapy units, the licensee shall use a teletherapy unit with a cesium-137 source.
- b. The licensee shall have available for use a dosimetry system for spot-check measurements. To meet this requirement, the system may be compared with a system that has been calibrated in accordance with 41.2(57)"a."

 This comparison shall have been performed within the previous year and after each servicing that may have affected system calibration. The spot-check system shall be the same system used to meet the requirement in 41.2(57)"a."
- c. The licensee shall maintain a record of each calibration, intercomparison, and comparison for the dura-

tion of the license. For each calibration, intercomparison, or comparison, the record shall include the date, the model numbers and serial numbers of the instruments that were calibrated, intercompared, or compared as required by 41.2(57)"a" and "b," the correction factors that were determined, the names of the individuals who performed the calibration, intercomparison, or comparison, and evidence that the intercomparison meeting was sanctioned by a calibration laboratory or radiologic physics center accredited by the American Association of Physicists in Medicine.

41.2(58) Full calibration measurements.

- a. A licensee authorized to use a teletherapy unit for medical use shall perform full calibration measurements on each teletherapy unit:
 - (1) Before the first medical use of the unit;
- (2) Before medical use under the following conditions:
- 1. Whenever spot-check measurements indicate that the output differs by more than 5 percent from the output obtained at the last full calibration corrected mathematically for radioactive decay;

2. Following replacement of the source or following reinstallation of the teletherapy unit in a new location;

and

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- Following any repair of the teletherapy unit that includes removal of the source or major repair of the components associated with the source exposure assembly; and
 - (3) At intervals not exceeding one year.

b. To satisfy the requirement of 41.2(58)"a," full calibration measurements shall include determination of:

- (1) The output within 3 percent for the range of field sizes and for the distance or range of distances used for medical use;
- (2) The coincidence of the radiation field and the field indicated by the light beam localizing device;
- (3) The uniformity of the radiation field and its dependence on the orientation of the useful beam;
 - (4) Timer accuracy, constancy, and linearity;

(5) "On-off" error; and

- (6) The accuracy of all distance measuring and localization devices in medical use.
- c. A licensee shall use the dosimetry system described in 41.2(57) to measure the output for one set of exposure conditions. The remaining radiation measurements required in 41.2(58)"b"(1) may then be made using a dosimetry system that indicates relative dose rates.
- d. A licensee shall make full calibration measurements required by 41.2(58)"a" in accordance with either the procedures recommended by the Scientific Committee on Radiation Dosimetry of the American Association of Physicists in Medicine that are described in Physics in Medicine and Biology, Vol. 16, No. 3, 1971, pp. 379-396, or by Task Group 21 of the Radiation Therapy Committee of the American Association of Physicists in Medicine that are described in Medical Physics, Vol. 10, No. 6, 1983, pp. 741-771, and Vol. 11, No. 2, 1984, p. 213.
- e. A licensee shall correct mathematically the outputs determined in 41.2(58)"b"(1) for physical decay for intervals not exceeding one month for cobalt-60 and intervals not exceeding six months for cesium-137.
- f. Full calibration measurements required by 41.2(58)"a" and physical decay corrections required by 41.2(58)"e" shall be performed by a teletherapy physicist named on the licensee's license or authorized by a license

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issued by the U.S. Nuclear Regulatory Commission or an agreement state to perform such services.

g. A licensee shall maintain a record of each calibration for the duration of the license. The record shall include the date of the calibration, the manufacturer's name, model number, and serial number for both the teletherapy unit and the source, the model numbers and serial numbers of the instruments used to calibrate the teletherapy unit, tables that describe the output of the unit over the range of field sizes and for the range of distances used in radiation therapy, a determination of the coincidence of the radiation field and the field indicated by the light beam localizing device, the measured timer accuracy for a typical treatment time, the calculated "on-off" error, the estimated accuracy of each distance measuring or localization device, and the signature of the teletherapy physicist.

41.2(59) Periodic spot checks.

a. A licensee authorized to use teletherapy units for medical use shall perform output spot checks on each teletherapy unit at intervals not to exceed one month.

To satisfy the requirement of 41.2(59)"a," spot checks shall include determination of:

Timer constancy and timer linearity over the (1) range of use;

(2) "On-off" error;

- (3) The coincidence of the radiation field and the field indicated by the light beam localizing device:
- (4) The accuracy of all distance measuring and localization devices used for medical use;
- (5) The output for one typical set of operating conditions; and
- (6) The difference between the measurement made in 41.2(59)"b"(5) and the anticipated output, expressed as a percentage of the anticipated output (i.e., the value obtained at last full calibration corrected mathematically for physical decay).

c. A licensee shall use the dosimetry system described in 41.2(57) to make the spot check required in 41.2(59)"b"(5).

- d. A licensee shall perform spot checks required by 41.2(59)"a" in accordance with procedures established by the teletherapy physicist. The teletherapy physicist does not need to actually perform the output spot-check measurements.
- e. A licensee shall have the teletherapy physicist review the results of each output spot check within 15 days. The teletherapy physicist shall promptly notify the licensee in writing of the results of each output spot check. The licensee shall keep a copy of each written notification for
- f. A licensee authorized to use a teletherapy unit for medical use shall perform safety spot checks of each teletherapy facility at intervals not to exceed one month.
- g. To satisfy the requirement of 41:2(59)"f," safety spot checks shall ensure proper operation of:
- (1) Electrical interlocks at each teletherapy room entrance:
- Electrical or mechanical stops installed for the purpose of limiting use of the primary beam of radiation restriction of source housing angulation or elevation, carriage or stand travel, and operation of the beam "on-off" mechanism;
- (3) Beam condition indicator lights on the teletherapy unit, on the control console, and in the facility;
 - (4) Viewing systems;

- (5) Treatment room doors from inside and outside the treatment room: and
- (6) Electrically assisted treatment room doors with the teletherapy unit electrical power turned "off."
- h. A licensee shall lock the control console in the "off" position if any door interlock malfunctions. No licensee shall use the unit until the interlock system is repaired unless specifically authorized by the agency.

i. A licensee shall promptly repair any system identified in 41.2(59)"g" that is not operating properly. The teletherapy unit shall not be used until all repairs are com-

j. A licensee shall maintain a record of each spot check required by 41.2(59)"a" and "f" for three years. The record shall include the date of the spot check, the manufacturer's name, model number, and serial number for both the teletherapy unit and source, the manufacturer's name, model number and serial number of the instrument used to measure the output of the teletherapy unit, the timer constancy and linearity, the calculated "on-off" error, a determination of the coincidence of the radiation field and the field indicated by the light beam localizing device, the timer constancy and linearity for a typical treatment time, the calculated "on-off" error, the estimated accuracy of each distance measuring or localization device, the difference between the anticipated output and the measured output, notations indicating the operability of each entrance door electrical interlock, each electrical or mechanical stop, each beam condition indicator light, the viewing system and doors, and the signature of the individual who performed the periodic spot check.

41.2(60) Radiation surveys for teletherapy facilities.

- Before medical use, after each installation of a teletherapy source, and after making any change for which an amendment is required by 41.2(51), the licensee shall perform radiation surveys with an operable radiation measurement survey instrument calibrated in accordance with 41.2(18) to verify that:
- The maximum and average radiation levels at 1 meter from the teletherapy source with the source in the "off" position and the collimators set for a normal treatment field do not exceed 10 millirems (100 µSv) per hour and 2 millirems (20 µSv) per hour, respectively; and
- (2) With the teletherapy source in the "on" position with the largest clinically available treatment field, and with a scattering phantom in the primary beam of radiation, that:
- 1. Radiation levels in restricted areas are not likely to cause personnel exposures in excess of the limits specified in 641—subrule 40.2(1); and
- Radiation levels in unrestricted areas do not exceed the limits specified in 641—paragraph 40.2(5)"a."
- b. If the results of the surveys required in 41.2(60)"a" indicate any radiation levels in excess of the respective limit specified in that paragraph, the licensee shall lock the control in the "off" position and not use the unit:
- (1) Except as may be necessary to repair, replace, or test the teletherapy unit, the teletherapy unit shielding, or the treatment room shielding; or
- (2) Until the licensee has received a specific exemption from the agency.
- c. A licensee shall maintain a record of the radiation measurements made following installation of a source for the duration of the license. The record shall include the date of the measurements, the reason the survey is required, the manufacturer's name, model number and serial

number of the teletherapy unit, the source, and the instrument used to measure radiation levels, each dose rate measured around the teletherapy source while in the "off" position and the average of all measurements, a plan of the areas surrounding the treatment room that were surveyed, the measured dose rate at several points in each area expressed in millirems (microsieverts) per hour, the calculated maximum level of radiation over a period of one week for each restricted and unrestricted area, and the signature of the radiation safety officer.

41.2(61) Safety spot checks for teletherapy facilities.

a. A licensee shall promptly check all systems listed in 41.2(59)"g" for proper function after each installation of a teletherapy source and after making any change for which an amendment is required by 41.2(51).

b. If the results of the safety spot checks required in 41.2(61)"a" indicate the malfunction of any system specified in 41.2(59), the licensee shall lock the control console in the "off" position and not use the unit except as may be necessary to repair, replace, or check the malfunc-

tioning system.

c. A licensee shall maintain a record of the safety spot checks following installation of a source for three years. The record shall include notations indicating the operability of each entrance door interlock, each electrical or mechanical stop, each beam condition indicator light, the viewing system, doors, and the signature of the radiation safety officer.

41.2(62) Modification of teletherapy unit or room before beginning a treatment program. If the survey required by 41.2(60) indicates that an individual in an unrestricted area may be exposed to levels of radiation greater than those permitted by 641—paragraph 40.2(5)"a," before beginning the treatment program the

licensee shall:

a. Either equip the unit with stops or add additional radiation shielding to ensure compliance with 641—paragraph 40.2(5)"a";

b. Perform the survey required by 41.2(60) again; and

- c. Include in the report required by 41.2(63) the results of the initial survey, a description of the modification made to comply with 41.2(62)"a," and the results of the second survey; or
- d. Request and receive a license amendment under 641—paragraph 40.2(5)"b" that authorizes radiation levels in unrestricted areas greater than those permitted by 641—subrule 40.2(5).
- 41.2(63) Reports of teletherapy surveys, checks, tests, and measurements. A licensee shall furnish a copy of the records required in 41.2(60), 41.2(61), and 41.2(62) and the output from the teletherapy source expressed as rems (sieverts) per hour at 1 meter from the source as determined during the full calibration required in 41.2(58) to the agency within 30 days following completion of the action that initiated the record requirement.

41.2(64) Five-year inspection.

- a. A licensee shall have each teletherapy unit fully inspected and serviced during teletherapy source replacement or at intervals not to exceed five years, whichever comes first, to ensure proper functioning of the source exposure mechanism.
- b. This inspection and servicing shall be performed only by persons specifically licensed to do so by the agency, an agreement state, or the U.S. Nuclear Regulatory Commission.
- c. A licensee shall maintain a record of the inspection and servicing for the duration of the license. The record

shall contain the inspector's name, the inspector's license number, the date of inspection, the manufacturer's name and model number and serial number for both the teletherapy unit and source, a list of components inspected, a list of components serviced and the type of service, a list of components replaced, and the signature of the inspector.

41.2(65) Radiation safety officer. Except as provided in 41.2(66), an individual fulfilling the responsibilities of the radiation safety officer as provided in 41.2(8) shall:

a. Be certified by the:

(1) American Board of Health Physics in comprehensive health physics;

(2) American Board of Radiology in radiological physics, therapeutic radiological physics, or medical nuclear physics;

(3) American Board of Nuclear Medicine;

- (4) American Board of Science in Nuclear Medicine, or
- (5) Board of Pharmaceutical Specialties in Nuclear Pharmacy or Science; or
- b. Have had 200 hours of classroom and laboratory training as follows:
 - (1) Radiation physics and instrumentation;

(2) Radiation protection;

(3) Mathematics pertaining to the use and measurement of radioactivity;

(4) Radiation biology;

(5) Radiopharmaceutical chemistry; and

- (6) One year of full-time experience in radiation safety at a medical institution under the supervision of the individual identified as the radiation safety officer on an agency, agreement state, licensing state, or U.S. Nuclear Regulatory Commission license that authorizes the medical use of radioactive material;
- c. Be an authorized user for those radioactive material uses that come within the radiation safety officer's responsibilities.
- 41.2(66) Training for experienced radiation safety officer. An individual identified as a radiation safety officer on an agency, agreement state, licensing state, or U.S. Nuclear Regulatory Commission license on September 1, 1992, who oversees only the use of radioactive material for which the licensee was authorized on that date need not comply with the training requirements of 41.2(65).

41.2(67) Training for uptake, dilution, or excretion studies. Except as provided in 41.2(75) and 41.2(76), the licensee shall require the authorized user of a radiopharmaceutical listed in 41.2(31) to be a physician who:

a. Is certified in:

- (1) Nuclear medicine by the American Board of Nuclear Medicine;
- (2) Diagnostic radiology by the American Board of Radiology;
- (3) Diagnostic radiology or radiology within the previous five years by the American Osteopathic Board of Radiology; or

(4) Nuclear Medicine by the American Osteopathic Board of Nuclear Medicine; or

b. Has completed 40 hours of instruction in basic radionuclide handling techniques applicable to the use of prepared radiopharmaceuticals, and 20 hours of supervised clinical experience.

(1) To satisfy the basic instruction requirement, 40 hours of classroom and laboratory instruction shall in-

clude:

Radiation physics and instrumentation;

- 2. Radiation protection;
- 3. Mathematics pertaining to the use and measurement of radioactivity;
 - 4. Radiation biology; and

5. Radiopharmaceutical chemistry.

- (2) To satisfy the requirement for 20 hours of supervised clinical experience, training must be under the supervision of an authorized user at a medical institution and shall include:
- 1. Examining patients and reviewing their case histories to determine their suitability for radionuclide diagnosis, limitations, or contraindications;

2. Selecting the suitable radiopharmaceuticals and

calculating and measuring the dosages;

- Administering dosages to patients and using syringe radiation shields;
- 4. Collaborating with the authorized user in the interpretation of radionuclide test results; and

5. Patient follow-up; or

- c. Has successfully completed a six-month training program in nuclear medicine as part of a training program that has been approved by the Accreditation Council for Graduate Medical Education and that included classroom and laboratory training, work experience, and supervised clinical experience in all the topics identified in 41.2(67)"b."
- 41.2(68) Training for imaging and localization studies. Except as provided in 41.2(75) and 41.2(76), the licensee shall require the authorized user of a radiopharmaceutical, generator, or reagent kit specified in 41.2(33) to be a physician who:

a. Is certified in:

- (1) Nuclear medicine by the American Board of Nuclear Medicine;
- (2) Diagnostic radiology by the American Board of Radiology;
- (3) Diagnostic radiology or radiology within the previous five years by the American Osteopathic Board of Radiology; or
- (4) Nuclear medicine by the American Osteopathic Board of Nuclear Medicine; or
- b. Has completed 200 hours of instruction in basic radionuclide handling techniques applicable to the use of prepared radiopharmaceuticals, generators, and reagent kits, 500 hours of supervised work experience, and 500 hours of supervised clinical experience.
- (1) To satisfy the basic instruction requirement, 200 hours of classroom and laboratory training shall include:
 - 1. Radiation physics and instrumentation;

2. Radiation protection;

- 3. Mathematics pertaining to the use and measurement of radioactivity;
 - 4. Radiopharmaceutical chemistry; and

Radiation biology.

- (2) To satisfy the requirement for 500 hours of supervised work experience, training shall be under the supervision of an authorized user at a medical institution and shall include:
- Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;
- Calibrating dose calibrators and diagnostic instruments and performing checks for proper operation of survey meters;
 - 3. Calculating and safely preparing patient dosages;
- 4. Using administrative controls to prevent the misadministration of radioactive material;

- 5. Using emergency procedures to contain spilled radioactive material safely and using proper decontamination procedures; and
- 6. Eluting technetium-99m from generator systems, assaying and testing the eluate for molybdenum-99 and alumina contamination, and processing the eluate with reagent kits to prepare technetium-99m labeled radiopharmaceuticals.
- (3) To satisfy the requirement for 500 hours of supervised clinical experience, training shall be under the supervision of an authorized user at a medical institution and shall include:
- 1. Examining patients and reviewing their case histories to determine their suitability for radionuclide diagnosis, limitations, or contraindications;
- 2. Selecting the suitable radiopharmaceuticals and calculating and measuring the dosages;
- Administering dosages to patients and using syringe radiation shields;
- 4. Collaborating with the authorized user in the interpretation of radionuclide test results; and

5. Patient follow-up: or

- c. Has successfully completed a six-month training program in nuclear medicine that has been approved by the Accreditation Council for Graduate Medical Education and that included classroom and laboratory training, work experience, and supervised clinical experience in all the topics identified in 41.2(68)"b."
- 41.2(69) Training for the apeutic use of radiopharmaceuticals. Except as provided in 41.2(75), the licensee shall require the authorized user of a radiopharmaceutical listed in 41.2(37) for the rapy to be a physician who:
 - a. Is certified by:
 - (1) The American Board of Nuclear Medicine; or

(2) The American Board of Radiology in radiology, therapeutic radiology, or radiation oncology; or

- b. Has completed 80 hours of instruction in basic radionuclide handling techniques applicable to the use of therapeutic radiopharmaceuticals, and has had supervised clinical experience.
- (1) To satisfy the requirement for instruction, 80 hours of classroom and laboratory training shall include:
 - 1. Radiation physics and instrumentation;

2. Radiation protection;

3. Mathematics pertaining to the use and measurement of radioactivity; and

4. Radiation biology;

- (2) To satisfy the requirement for supervised clinical experience, training shall be under the supervision of an authorized user at a medical institution and shall include:
- Use of iodine-131 for diagnosis of thyroid function and the treatment of hyperthyroidism or cardiac dysfunction in ten individuals:
- 2. Use of soluble phosphorus-32 for the treatment of ascites, polycythemia vera, leukemia, or bone metastases in three individuals;
- 3. Use of iodine-131 for treatment of thyroid carcinoma in three individuals; and
- 4. Use of colloidal chromic phosphorus-32 or of colloidal gold-198 for intracavitary treatment of malignant effusions in three individuals.
- 41.2(70) Training for therapeutic use of brachytherapy sources. Except as provided in 41.2(75), the licensee shall require the authorized user using a brachytherapy source specified in 41.2(43) for therapy to be a physician who:

a. Is certified in:

(1) Radiology, therapeutic radiology, or radiation oncology by the American Board of Radiology;

(2) Radiation oncology by the American Osteopathic

Board of Radiology;

(3) Radiology, with a specialization in radiotherapy, as a British "Fellow of the Faculty of Radiology" or "Fellow of the Royal College of Radiology"; or

(4) Therapeutic radiology by the Canadian Royal Col-

lege of Physicians and Surgeons; or

- b. Is in the active practice of therapeutic radiology, has completed 200 hours of instruction in basic radionuclide handling techniques applicable to the therapeutic use of brachytherapy sources and 500 hours of supervised work experience and a minimum of three years of supervised clinical experience.
- (1) To satisfy the requirement for instruction, 200 hours of classroom and laboratory training shall include:

1. Radiation physics and instrumentation;

2. Radiation protection;

3. Mathematics pertaining to the use and measurement of radioactivity; and

4. Radiation biology.

- (2) To satisfy the requirement for 500 hours of supervised work experience, training shall be under the supervision of an authorized user at a medical institution and shall include:
- 1. Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

2. Checking survey meters for proper operation;

- 3. Preparing, implanting, and removing sealed sources:
- 4. Using administrative controls to prevent the misadministration of radioactive material; and

Using emergency procedures to control radioactive material.

- (3) To satisfy the requirement for a period of supervised clinical experience, training shall include one year in a formal training program approved by the Residency Review Committee for Radiology of the Accreditation Council for Graduate Medical Education or the Committee on Postdoctoral Training of the American Osteopathic Association, and an additional two years of clinical experience in therapeutic radiology under the supervision of an authorized user at a medical institution. The supervised clinical experience shall include:
- 1. Examining individuals and reviewing their case histories to determine their suitability for brachytherapy treatment, and any limitations or contraindications;

2. Selecting the proper brachytherapy sources, dose, and method of administration;

3. Calculating the dose; and

4. Postadministration follow-up and review of case histories in collaboration with the authorized user.

41.2(71) Training for ophthalmic use of strontium-90. Except as provided in 41.2(75), the licensee shall require the authorized user using only strontium-90 for opthalmic radiotherapy to be a physician who:

a. Is certified in radiology, therapeutic radiology, or radiation oncology by the American Board of Radiology;

b. Is in the active practice of therapeutic radiology or ophthalmology, and has completed 24 hours of instruction in basic radionuclide handling techniques applicable to the use of strontium-90 for ophthalmic radiotherapy, and a period of supervised clinical training in ophthalmic radiotherapy.

- (1) To satisfy the requirement for instruction, the classroom and laboratory training shall include:
 - 1. Radiation physics and instrumentation:

2. Radiation protection;

Mathematics pertaining to the use and measurement of radioactivity; and

4. Radiation biology.

- (2) To satisfy the requirement for a period of supervised clinical training in ophthalmic radiotherapy, training shall be under the supervision of an authorized user at a medical institution and shall include the use of strontium-90 for the ophthalmic treatment of five individuals that includes:
 - 1. Examination of each individual to be treated;

2. Calculation of the dose to be administered;

3. Administration of the dose; and

4. Follow-up and review of each individual's case his-

tory.

41.2(72) Training for use of sealed sources for diagnosis. Except as provided in 41.2(75), the licensee shall require the authorized user using a sealed source in a device specified in 41.2(41) to be a physician, dentist, or podiatrist who:

a. Is certified in:

(1) Radiology, diagnostic radiology with special competence in nuclear radiology, therapeutic radiology, or radiation oncology by the American Board of Radiology;

(2) Nuclear medicine by the American Board of Nu-

clear Medicine; or

(3) Diagnostic radiology or radiology by the Ameri-

can Osteopathic Board of Radiology; or

b. Has completed eight hours of classroom and laboratory instruction in basic radionuclide handling techniques specifically applicable to the use of the device.

(1) To satisfy the requirement for instruction, the

training shall include:

- 1. Radiation physics, mathematics pertaining to the use and measurement of radioactivity, and instrumentation;
 - 2. Radiation biology; and
- 3. Radiation protection and training in the use of the device for the purposes authorized by the license.

(2) Reserved.

41.2(73) Training for teletherapy. Except as provided in 41.2(75), the licensee shall require the authorized user of a sealed source specified in 41.2(49) in a teletherapy unit to be a physician who:

a. Is certified in:

(1) Radiology, therapeutic radiology, or radiation oncology by the American Board of Radiology;

(2) Radiation oncology by the American Osteopathic

Board of Radiology;

(3) Radiology, with specialization in radiotherapy, as a British "Fellow of the Faculty of Radiology" or "Fellow of the Royal College of Radiology"; or

(4) Therapeutic radiology by the Canadian Royal Col-

lege of Physicians and Surgeons; or

- b. Is in the active practice of therapeutic radiology, and has completed 200 hours of instruction in basic radionuclide techniques applicable to the use of a sealed source in a teletherapy unit, 500 hours of supervised work experience, and a minimum of three years of supervised clinical experience.
- (1) To satisfy the requirement for instruction, the classroom and laboratory training shall include:
 - 1. Radiation physics and instrumentation;
 - 2. Radiation protection;

- 3. Mathematics pertaining to the use and measurement of radioactivity; and
 - 4. Radiation biology.
- (2) To satisfy the requirement for supervised work experience, training shall be under the supervision of an authorized user at an institution and shall include:
- 1. Review of the full calibration measurements and periodic spot checks;
- 2. Preparing treatment plans and calculating treatment times;
- 3. Using administrative controls to prevent misadministrations:
- 4. Implementing emergency procedures to be followed in the event of the abnormal operation of a teletherapy unit or console; and
 - 5. Checking and using survey meters.
- (3) To satisfy the requirement for a period of supervised clinical experience, training shall include one year in a formal training program approved by the Residency Review Committee for Radiology of the Accreditation Council for Graduate Medical Education or the Committee on Postdoctoral Training of the American Osteopathic Association and an additional two years of clinical experience in therapeutic radiology under the supervision of an authorized user at a medical institution. The supervised clinical experience shall include:
- 1. Examining individuals and reviewing their case histories to determine their suitability for teletherapy treatment and any limitations or contraindications;
- 2. Selecting the proper dose and how it is to be administered;
- Calculating the teletherapy doses and collaborating with the authorized user in the review of patients' progress and consideration of the need to modify originally prescribed doses as warranted by patients' reaction to radiation; and
- 4. Postadministration follow-up and review of case histories.
- 41.2(74) Training for teletherapy physicist. The licensee shall require the teletherapy physicist to:
- a. Be certified by the American Board of Radiology in:
 - (1) Therapeutic radiological physics;
 - (2) Roentgen-ray and gamma-ray physics;
 - (3) X-ray and radium physics; or
 - (4) Radiological physics; or
- b. Hold a master's or doctor's degree in physics, biophysics, radiological physics, or health physics, and have completed one year of full-time training in therapeutic radiological physics and also one year of full-time work experience under the supervision of a teletherapy physicist at a medical institution. To meet this requirement, the individual shall have performed the tasks listed in 41.2(21), 41.2(58), 41.2(59), and 41.2(60) under the supervision of a teletherapy physicist during the year of work experience.
- 41.2(75) Training for experienced authorized users. Practitioners of the healing arts identified as authorized users for the human use of radioactive material on an agency, NRC or agreement state or licensing state license on September 1, 1992, who perform only those methods of use for which they were authorized on that date need not comply with the training requirements of 41.2(65) to 41.2(77).
- 41.2(76) Physician training in a three-month program. A physician who, before July 1, 1984, began a three-month nuclear medicine training program approved by the

Accreditation Council for Graduate Medical Education and has successfully completed the program, is exempted from the requirements of 41.2(67) or 41.2(68).

41.2(77) Recentness of training. The training and experience specified in 41.2(65) to 41.2(74) shall have been obtained within the five years preceding the date of application or the individual shall have had continuing applicable experience since the required training and experience was completed.

641—41.3(136C) Radiation safety requirements for particle accelerators.

41.3(1) Purpose and scope.

a. This rule establishes procedures for the registration

or licensing and the use of particle accelerators.

- b. In addition to the requirements of this rule, all registrants or licensees are subject to the requirements of 641—Chapter 38, 39.1(136C) to 39.4(136C), and Chapter 40. Registrants and licensees engaged in industrial radiographic operations are subject to the requirements of 641—Chapter 45, and registrants and licensees engaged in the healing arts are subject to the requirements of 641—41.1(136C) and 41.2(136C). Registrants or licensees whose operations result in the production of radioactive material are subject to the requirements of 641—39.4(136C).
- 41.3(2) Registration or license requirements. No person shall receive, possess, use, transfer, own, or acquire a particle accelerator except as authorized in a registration or license issued pursuant to 641—39.1(136C) to 39.4(136C).
- 41.3(3) General requirements for the issuance of a registration or license for particle accelerators. In addition to the requirements of 641—39.1(136C) to 39.4(136C), a registration or license application for use of a particle accelerator will be approved only if the agency determines that:
- a. The applicant is qualified by reason of training and experience to use the accelerator in question for the purpose requested in accordance with this rule and 641—Chapter 40 in such a manner as to minimize danger to public health and safety or property;

b. The applicant's proposed or existing equipment, facilities, and operating and emergency procedures are adequate to protect health and minimize danger to public health and safety or property;

c. The issuance of the registration or license will not be inimical to the health and safety of the public, and the applicant satisfies any applicable special requirement in 41.3(4);

d. The applicant has appointed a radiation safety offi-

e. The applicant and the applicant's staff have substantial experience in the use of particle accelerators and training sufficient for application to its intended uses;

f. The applicant has established a radiation safety committee to approve, in advance, proposals for uses of particle accelerators, whenever deemed necessary by the agency; and

g. The applicant has an adequate training program for

operators of particle accelerators.

- 41.3(4) Human use of particle accelerators. In addition to the requirements of 641—39.1(136C) to 39.4(136C), a registration or license for use of a particle accelerator in the healing arts will be issued only if:
- a. The applicant has appointed a medical committee of at least three members to evaluate all proposals for re-

search, diagnostic, and therapeutic use of a particle accelerator whenever deemed necessary by the agency. Membership of the committee should include physicians expert in internal medicine, hematology, therapeutic radiology, and a person experienced in depth dose calculations and protection against radiation;

b. The individuals designated on the application as the users have substantial training and experience in deep therapy techniques or in the use of particle accelerators to

treat humans; and

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- c. The individual designated on the application as the user is a physician.
 - 41.3(5) Reserved. 41.3(6) Limitations.
- a. No registrant or licensee shall permit any individual to act as an operator of a particle accelerator until such individual:
- (1) Has been instructed in radiation safety and shall have demonstrated an understanding thereof;
- (2) Has received copies of and instruction in this rule and the applicable requirements of 641—Chapter 40, pertinent registration or license conditions and the registrant's or licensee's operating and emergency procedures, and shall have demonstrated understanding thereof; and

(3) Has demonstrated competence to use the particle accelerator, related equipment, and survey instruments

which will be employed.

- The radiation safety committee or the radiation safety officer shall have the authority to terminate the operations at a particle accelerator facility if such action is deemed necessary to minimize danger to public health and safety or property.
 - 41.3(7) Shielding and safety design requirements.
- a. A qualified expert, acceptable to the agency, shall be consulted in the design of a particle accelerator installation and called upon to perform a radiation survey when the accelerator is first capable of producing radiation.
- b. Each particle accelerator installation shall be provided with such primary and secondary barriers as are necessary to ensure compliance with 641—subrule 40.2(1) and 641—subrule 40.2(5).
- 41.3(8) Particle accelerator controls and interlock sys-
- a. Instrumentation, readouts, and controls on the particle accelerator control console shall be clearly identified and easily discernible.
- b. Each entrance into a target room or other high radiation area shall be provided with a safety interlock that shuts down the machine under conditions of barrier penetration.
- c. Each safety interlock shall be on a circuit which shall allow it to operate independently of all other safety interlocks.
- d. All safety interlocks shall be designed so that any defect or component failure in the safety interlock system prevents operation of the accelerator.
- e. When a safety interlock system has been tripped, it shall only be possible to resume operation of the accelerator by manually resetting controls at the position where the safety interlock has been tripped and, lastly, at the main control console.
- f. A scram button or other emergency power cutoff switch shall be located and easily identifiable in all high radiation areas. Such a cutoff switch shall include a manual reset so that the accelerator cannot be restarted

from the accelerator control console without resetting the cutoff switch

41.3(9) Warning devices.

a. Each location designated as high radiation area. and each entrance to such location, shall be equipped with easily observable warning lights that operate when, and only when, radiation is being produced.

- b. Except in facilities designed for human exposure, each high radiation area shall have an audible warning device which shall be activated for 15 seconds prior to the possible creation of such high radiation area. Such warning device shall be clearly discernible in all high radiation
- c. Barriers, temporary or otherwise, and pathways leading to high radiation areas shall be posted in accordance with 641—subrule 40.3(3).

41.3(10) Operating procedures.

- a. Particle accelerators, when not in operation, shall be secured to prevent unauthorized use.
- b. The safety interlock system shall not be used to turn off the accelerator beam except in an emergency
- c. All safety and warning devices, including interlocks, shall be checked for proper operation at intervals not to exceed three months. Results of such tests shall be maintained at the accelerator facility for inspection by the agency

d. Electrical circuit diagrams of the accelerator and the associated safety interlock systems shall be kept current and maintained for inspection by the agency and shall be available to the operator at each accelerator facility.

- e. If, for any reason, it is necessary to intentionally bypass a safety interlock or interlocks, such action shall
- (1) Authorized by the radiation safety committee or radiation safety officer:
- (2) Recorded in a permanent log and a notice posted at the accelerator control console; and

(3) Terminated as soon as possible.

f. A copy of the current operating and the emergency procedures shall be maintained at the accelerator control panel.

41.3(11) Radiation monitoring requirements.

- a. There shall be available at each particle accelerator facility appropriate portable monitoring equipment which is operable and has been appropriately calibrated for the radiations being produced at the facility. Such equipment shall be tested for proper operation daily and calibrated at intervals not to exceed one year and after each servicing and repair.
- b. A radiation protection survey shall be performed and documented by a qualified expert, acceptable to the agency, when changes have been made in shielding, operation, equipment, or occupancy of adjacent areas.
- c. Radiation levels in all high radiation areas shall be continuously monitored. The monitoring devices shall be electrically independent of the accelerator control and safety interlock systems and capable of providing a readout at the control panel.
- d. All area monitors shall be calibrated at intervals not to exceed one year and after each servicing and repair.
- Whenever applicable, periodic surveys shall be made to determine the amount of airborne particulate radioactivity present.
- f. Whenever applicable, periodic smear surveys shall be made to determine the degree of contamination.

g. All surveys shall be made in accordance with the written procedures established by a qualified expert, acceptable to the agency, or the radiation safety officer.

h. Records of all radiation protection surveys, calibrations, and instrumentation tests shall be maintained at the accelerator facility for inspection by the agency.

41.3(12) Ventilation systems.

- a. Ventilation systems shall be provided to ensure that personnel entering any area where airborne radioactivity may be produced will not be exposed to airborne radioactive material in excess of those limits specified in 641—Chapter 40.
- b. A registrant or licensee, as required by 641—subrule 40.2(6), shall not vent, release, or otherwise discharge airborne radioactive material to an unrestricted area which exceeds the limits specified in 641—Chapter 40, Appendix A, Table II, except as pursuant to 641—40.4(2) or 641—40.2(6)"b." For purposes of 41.3(12)"b," concentrations may be averaged over a period not greater than one year. Every effort should be made to maintain releases of radioactive material to unrestricted areas as far below these limits as is reasonably achievable.

641—41.4(136C) Radiation safety requirements for analytical X-ray equipment.

41.4(1) Purpose and scope. This rule provides special requirements for analytical X-ray equipment. The requirements of this rule are in addition to, and not in substitution for, applicable requirements of these rules.

41.4(2) Definitions. As used in this rule, the follow-

ing definitions apply:

"Analytical X-ray equipment" means equipment used

for X-ray diffraction or fluorescence analysis.

"Analytical X-ray system" means a group of components utilizing X- or gamma-rays to determine the elemental composition or to examine the microstructure of materials.

"Fail-safe characteristics" means a design feature which causes beam port shutters to close, or otherwise prevents emergence of the primary beam, upon the failure

of a safety or warning device.

"Local components" means part of an analytical X-ray system and includes X-ray areas that are struck by X-rays such as radiation source housings, port and shutter assemblies, collimators, sample holders, cameras, goniometers, detectors, and shielding, but does not include power supplies, transformers, amplifiers, readout devices, and control panels.

"Normal operating procedures" means step-by-step instructions necessary to accomplish the analysis. These procedures shall include sample insertion and manipulation, equipment alignment, routine maintenance by the registrant or licensee, and data recording procedures,

which are related to radiation safety.

"Open-beam configuration" means an analytical X-ray system in which an individual could accidentally place some part of his body in the primary beam path during normal operation.

"Primary beam" means radiation which passes through an aperture of the source housing by a direct path from the X-ray tube or a radioactive source located in the radiation source housing.

41.4(3) Equipment requirements.

a. Safety device. A device which prevents the entry of any portion of an individual's body into the primary X-ray beam path or which causes the beam to be shut off upon entry into its path shall be provided on all open-

beam configurations. A registrant or licensee may apply to the agency for an exemption from the requirement of a safety device. Such application shall include:

(1) A description of the various safety devices that

have been evaluated;

- (2) The reason each of these devices cannot be used; and
- (3) A description of the alternative methods that will be employed to minimize the possibility of an accidental exposure, including procedures to ensure that operators and others in the area will be informed of the absence of safety devices.

b. Warning devices.

- (1) Open-beam configurations shall be provided with a readily discernible indication of:
- 1. X-ray tube "on-off" status located near the radiation source housing, if the primary beam is controlled in this manner; or
- 2. Shutter "open-closed" status located near each port on the radiation source housing, if the primary beam is controlled in this manner.
- (2) An easily visible warning light labeled with the words "X-RAY ON", or words having a similar intent, shall be located:
- 1. Near any switch that energizes an X-ray tube and shall be illuminated only when the tube is energized; or
- 2. In the case of a radioactive source, near any switch that opens a housing shutter and shall be illuminated only when the shutter is open.
- (3) Warning devices shall be labeled so that their purpose is easily identified. On equipment installed after the effective date of these rules, warning devices shall have fail-safe characteristics.
- c. Ports. Unused ports on radiation source housings shall be secured in the closed position in a manner which will prevent casual opening.
- d. Labeling. All analytical X-ray equipment shall be labeled with a readily discernible sign or signs bearing the radiation symbol and the words:

radiation symbol and the words:

(1) "CAUTION—HIGH INTENSITY X-RAY
BEAM," or words having a similar intent, on the X-ray

source housing; and

- (2) "CAUTION RADIATION—THIS EQUIPMENT PRODUCES RADIATION WHEN ENERGIZED," or words having a similar intent, near any switch that energizes an X-ray tube if the radiation source is an X-ray tube; or
- (3) "CAUTION—RADIOACTIVE MATERIAL," or words having a similar intent, on the source housing in accordance with 641—subrule 40.3(3) if the radiation source is a radionuclide.
- e. Shutters. On open-beam configurations installed after the effective date of these rules, each port on the radiation source housing shall be equipped with a shutter that cannot be opened unless a collimator or a coupling has been connected to the port.

f. Radiation source housing. Each radiation source housing shall be subject to the following requirements:

- (1) Each X-ray tube housing shall be equipped with an interlock that shuts off the tube if it is removed from the radiation source housing or if the housing is disassembled.
- (2) Each radioactive source housing or port cover or each X-ray tube housing shall be so constructed that, with all-shutters closed, the radiation measured at a distance of 5 centimeters from its surface is not capable of producing a dose in excess of 2.5 millirems (0.025 mSv) in one hour.

For systems utilizing X-ray tubes, this limit shall be met at any specified tube rating.

g. Generator cabinet. Each X-ray generator shall be supplied with a protective cabinet which limits leakage radiation measured at a distance of 5 centimeters from its surface such that it is not capable of producing a dose in excess of 0.25 millirem (2.5 µSv) in one hour.

41.4(4) Area requirements.

a. Radiation levels. The local components of an analytical X-ray system shall be located and arranged and shall include sufficient shielding or access control such that no radiation levels exist in any area surrounding the local component group which could result in a dose to an individual present therein in excess of the dose limits given in 641—subrule 40.2(5). For systems utilizing X-ray tubes, these levels shall be met at any specified tube rating.

b. Surveys.

(1) Radiation surveys, as required by 641—subrule 40.3(1), of all analytical X-ray systems sufficient to show compliance with 41.4(4)"a" shall be performed:

1. Upon installation of the equipment, and at least

once every 12 months thereafter;

2. Following any change in the initial arrangement, number, or type of local components in the system;

3. Following any maintenance requiring the disassem-

bly or removal of a local component in the system:

- 4. During the performance of maintenance and alignment procedures if the procedures require the presence of a primary X-ray beam when any local component in the system is disassembled or removed;
- 5. Any time a visual inspection of the local components in the system reveals an abnormal condition; and
- Whenever personnel monitoring devices show a significant increase over the previous monitoring period or the readings are approaching the limits specified in 641—subrule 40.2(1).

(2) Radiation survey measurements shall not be required if a registrant or licensee can demonstrate compliance with 41.4(4)"a" to the satisfaction of the agency.

c. Posting. Each area or room containing analytical X-ray equipment shall be conspicuously posted with a sign or signs bearing the radiation symbol and the words "CAUTION-X-RAY EQUIPMENT" or words having a similar intent in accordance with 641—subrule 40.3(3).

41.4(5) Operating requirements.

- a. Procedures. Normal operating procedures shall be written and available to all analytical X-ray equipment workers. No individual shall be permitted to operate analytical X-ray equipment in any manner other than that specified in the procedures unless such individual has obtained written approval of the radiation safety officer.
- b. Bypassing. No individual shall bypass a safety device or interlock unless such individual has obtained the approval of the radiation safety officer. Such approval shall be for a specified period of time. When a safety device or interlock has been bypassed, a readily discernible sign bearing the words "SAFETY DEVICE NOT WORK-ING," or words having a similar intent, shall be placed on the radiation source housing.
- c. Repair or modification of X-ray tube systems. Except as specified in 41.4(5)"b," no operation involving removal of covers, shielding materials or tube housings or modifications to shutters, collimators, or beam stops shall be performed without ascertaining that the tube is off and

will remain off until safe conditions have been restored. The main switch, rather than interlocks, shall be used for routine shutdown in preparation for repairs.

d. Radioactive source replacement, testing, or repair. Radioactive source housings shall be opened for source replacement, leak testing, or other maintenance or repair procedures only by individuals authorized to specifically conduct such procedures under a license issued by the U.S. Nuclear Regulatory Commission, an agreement state, or a licensing state.

41.4(6) Personnel requirements.

a. Instruction. No individual shall be permitted to operate or maintain analytical X-ray equipment unless such individual has received instruction in and demonstrated competence as to:

(1) Identification of radiation hazards associated with

the use of the equipment;

- (2) Significance of the various radiation warning, safety devices, and interlocks incorporated into the equipment, or the reasons they have not been installed on certain pieces of equipment and the extra precautions required in such cases;
 - (3) Proper operating procedures for the equipment;

(4) Recognition of symptoms of an acute localized exposure; and

(5) Proper procedures for reporting an actual or suspected exposure.

b. Personnel monitoring.

- (1) Finger or wrist dosimetric devices shall be provided to and shall be used by:
- 1. Analytical X-ray equipment workers using systems having an open-beam configuration and not equipped with a safety device; and
- 2. Personnel maintaining analytical X-ray equipment if the maintenance procedures require the presence of a primary X-ray beam when any local component in the analytical X-ray system is disassembled or removed.

(2) Reported dose values shall not be used for the purpose of determining compliance with 641—subrule 40.2(1) unless evaluated by a qualified expert.

641-41.5(136C) Radiation safety requirements for wireline service operations and subsurface tracer studies.

41.5(1) Purpose. This rule establishes radiation safety requirements for using sources of radiation for wireline service operations including mineral-logging, radioactive markers, and subsurface tracer studies. The requirements of this rule are in addition to, and not in substitution for, the requirements of 641—Chapters 38, 39, and 40.

41.5(2) Scope. This rule applies to all licensees or registrants who use sources of radiation for wireline service operations including mineral-logging, radioactive

markers, or subsurface tracer studies.

41.5(3) Definitions. As used in this rule, the follow-

ing definitions apply:

'Field station" means a facility where radioactive sources may be stored or used and from which equipment is dispatched to temporary job sites.

"Injection tool" means a device used for controlled

subsurface injection of radioactive tracer material.

"Logging assistant" means any individual who, under the personal supervision of a logging supervisor, handles sealed sources or tracers that are not in logging tools or shipping containers or who performs surveys required by 41.5(22).

"Logging supervisor" means the individual who uses sources of radiation or provides personal supervision of the utilization of sources of radiation at the well site.

"Logging tool" means a device used subsurface to per-

form well-logging.

"Mineral-logging" means any logging performed for the purpose of mineral exploration other than oil or gas.

"Personal supervision" means guidance and instruction by the supervisor who is physically present at the job site and watching the performance of the operation in such proximity that contact can be maintained and immediate assistance given as required.

"Radioactive marker" means radioactive material placed subsurface or on a structure intended for subsurface use for the purpose of depth determination or direc-

tion orientation.

"Source holder" means a housing or assembly into which a radioactive source is placed for the purpose of facilitating the handling and use of the source in well-

logging operations.

"Subsurface tracer study" means the release of a substance tagged with radioactive material for the purpose of tracing the movement or position of the tagged substance in the well-bore or adjacent formation.

"Temporary job site" means a location where radioactive materials are present for the purpose of performing wireline service operations or subsurface tracer studies.

"Uranium sinker bar" means a weight containing depleted uranium used to pull a logging tool down toward the bottom of a well.

"Well-bore" means a drilled hole in which wireline service operations or subsurface tracer studies are performed.

"Well-logging" means all operations involving the lowering and raising of measuring devices or tools which may contain sources of radiation into well-bores or cavities for the purpose of obtaining information about the well or adjacent formations.

"Wireline" means a cable containing one or more electrical conductors which is used to lower and raise logging

tools in the well-bore.

"Wireline service operation" means any evaluation or mechanical service which is performed in the well-bore

using devices on a wireline.

- 41.5(4) Prohibition. No licensee shall perform wireline service operations with a sealed source(s) unless, prior to commencement of the operation, the licensee has a written agreement with the well operator, well owner, drilling contractor, or landowner that:
- a. In the event a sealed source is lodged downhole, a reasonable effort at recovery will be made; and
- b. In the event a decision is made to abandon the sealed source downhole, the requirements of 41.5(25)"c" and the name of any other state agency having applicable regulations shall be met.
- 41.5(5) Limits on levels of radiation. Sources of radiation shall be used, stored, and transported in such a manner that the transportation requirements of 641—39.5(136C) and the dose limitation requirements of 641—Chapter 40 are met.

41.5(6) Storage precautions.

a. Each source of radiation, except accelerators, shall be provided with a storage or transport container. The container shall be provided with a lock, or tamper seal for calibration sources, to prevent unauthorized removal of, or exposure to, the source of radiation.

- b. Sources of radiation shall be stored in a manner which will minimize danger from explosion or fire.
- 41.5(7) Transport precautions. Transport containers shall be physically secured to the transporting vehicle to prevent accidental loss, tampering, or unauthorized removal.

41.5(8) Radiation survey instruments.

- a. The licensee or registrant shall maintain sufficient calibrated and operable radiation survey instruments at each field station to make physical radiation surveys as required by this subrule and by 641—subrule 40.3(1). Instrumentation shall be capable of measuring 0.1 milliroentgen (25.8 nanocoulombs/kg) per hour through at least 50 milliroentgens (12.9 microcoulombs/kg) per hour. Survey instruments acquired before the effective date of this rule and capable of measuring 0.1 milliroentgen (25.8 nanocoulombs/kg) per hour through at least 20 milliroentgens (5.16 microcoulombs/kg) per hour also satisfies this requirement five years after the effective date of this rule.
- b. Each radiation survey instrument shall be cali-

brated:

- (1) At intervals not to exceed six months and after each instrument servicing;
- (2) For linear scale instruments, at two points located approximately and of full-scale on each scale; for logarithmic scale instruments, at midrange of each decade, and at two points of at least one decade; and for digital instruments, at appropriate points; and
- (3) So that accuracy within 20 percent of the true radiation level can be demonstrated on each scale.
- c. Calibration records shall be maintained for a period of two years for inspection by the agency.

41.5(9) Leak testing of sealed sources.

- a. Requirements. Each licensee using sealed sources of radioactive material shall have the sources tested for leakage. Records of leak test results shall be kept in units of microcuries (Bq) and maintained for inspection by the agency for six months after the next required leak test is performed or until transfer or disposal of the sealed source.
- b. Method of testing. Tests for leakage shall be performed only by persons specifically authorized to perform such tests by the agency, the U.S. Nuclear Regulatory Commission, an agreement state, or a licensing state. The test sample shall be taken from the surface of the source, source holder, or from the surface of the device in which the source is stored or mounted and on which one might expect contamination to accumulate. The test sample shall be analyzed for radioactive contamination, and the analysis shall be capable of detecting the presence of 0.005 microcurie (185 Bq) of radioactive material on the test sample.
- c. Interval of testing. Each sealed source of radioactive material shall be tested at intervals not to exceed six months. In the absence of a certificate from a transferor indicating that a test has been made prior to the transfer, the sealed source shall not be put into use until tested. If, for any reason, it is suspected that a sealed source may be leaking, it shall be removed from service immediately and tested for leakage as soon as practical.
- d. Leaking or contaminated sources. If the test reveals the presence of 0.005 microcurie (185 Bq) or more of leakage or contamination, the licensee shall immediately withdraw the source from use and shall cause it to be decontaminated, repaired, or disposed of in accordance with these rules. A report describing the equipment in-

volved, the test results, and the corrective action taken shall be filed with the agency within five days of receiving the test results.

- e. Exemptions. The following sources are exempted from the periodic leak test requirements of 41.5(9)"a" to "d".
 - (1) Hydrogen-3 sources;
- (2) Sources of radioactive material with a half-life of 30 days or less:
- (3) Sealed sources of radioactive material in gaseous form:
- (4) Sources of beta- or gamma-emitting radioactive material with an activity of 100 microcuries (3.7 MBq) or less; and

(5) Sources of alpha-emitting radioactive material with an activity of 10 microcuries (0.370 MBq) or less.

- 41.5(10) Quarterly inventory. Each licensee or registrant shall conduct a quarterly physical inventory to account for all sources of radiation. Records of inventories shall be maintained for two years from the date of the inventory for inspection by the agency and shall include the quantities and kinds of sources of radiation, the location where sources of radiation are assigned, the date of the inventory, and the name of the individual conducting the inventory.
- 41.5(11) Utilization records. Each licensee or registrant shall maintain current records, which shall be kept available for inspection by the agency for two years from the date of the recorded event, showing the following information for each source of radiation:
- a. Make, model number, and a serial number or a description of each source of radiation used;
- b. The identity of the well-logging supervisor or field unit to whom assigned;
 - c. Locations where used and dates of use; and
- d. In the case of tracer materials and radioactive markers, the utilization record shall indicate the radionuclide and activity used in a particular well.
- 41.5(12) Design, performance, and certification criteria for sealed sources used in downhole operations.
- a. Each sealed source, except those containing radioactive material in gaseous form, used in downhole operations and manufactured after the date one year after the effective date of this subrule shall be certified by the manufacturer, or other testing organization acceptable to the agency, to meet the following minimum criteria:
 - (1) Be of doubly encapsulated construction;
- (2) Contain radioactive material whose chemical and physical forms are as insoluble and nondispersible as practical; and
- (3) Has been individually pressure tested to at least 24,656 pounds per square inch absolute (170 MN/m²) without failure.
- b. For sealed sources, except those containing radioactive material in gaseous form, acquired after the date one year after the effective date of this rule, in the absence of a certificate from a transferor certifying that an individual sealed source meets the requirements of 41.5(12)"a," the sealed source shall not be put into use until such determinations and testing have been performed.
- c. Each sealed source, except those containing radioactive material in gaseous form, used in downhole operations after the date two years after the effective date of this rule shall be certified by the manufacturer, or other testing organization acceptable to the agency, as meeting the sealed source performance requirements for oil welllogging as contained in the American National Standard

- N43.6, "Classification of Sealed Radioactive Sources," (formerly N542, ANSI/NBS 126) in effect on the effective date of this rule.
- d. Certification documents shall be maintained for inspection by the agency for a period of two years after source disposal. If the source is abandoned downhole, the certification documents shall be maintained until the agency authorizes disposition.

41.5(13) Labeling.

a. Each source, source holder, or logging tool containing radioactive material shall bear a durable, legible, and clearly visible marking or label, which has, as a minimum, the standard radiation caution symbol, without the conventional color requirement, and the following wording:

DANGER 1/ RADIOACTIVE

This labeling shall be on the smallest component trans-

ported as a separate piece of equipment.

b. Each transport container shall have permanently attached to it a durable, legible, and clearly visible label which has, as a minimum, the standard radiation caution symbol and the following wording:

DANGER¹ RADIOACTIVE

NOTIFY CIVIL AUTHORITIES [OR NAME OF COMPANY]

41.5(14) Inspection and maintenance.

a. Each licensee or registrant shall conduct, at intervals not to exceed six months, a program of inspection and maintenance of source holders, logging tools, source handling tools, storage containers, transport containers, and injection tools to ensure proper labeling and physical condition. Records of inspection and maintenance shall be maintained for a period of two years for inspection by the agency.

b. If any inspection conducted pursuant to 41.5(14)"a" reveals damage to labeling or components critical to radiation safety, the device shall be removed from service un-

til repairs have been made.

c. If a sealed source is stuck in the source holder, the licensee shall not perform any operation, such as drilling, cutting, or chiseling, on the source holder unless the licensee is specifically approved by the U.S. Nuclear Regulatory Commission, an agreement state, or a licensing state to perform this operation.

d. The repair, opening, or modification of any sealed source shall be performed only by persons specifically authorized to do so by the agency, the U.S. Nuclear Regulatory Commission, an agreement state, or a licensing state.

41.5(15) Training requirements.

- a. No licensee or registrant shall permit any individual to act as a logging supervisor as defined in this rule until such individual has:
- (1) Received, in a course recognized by the agency, the U.S. Nuclear Regulatory Commission, an agreement state, or a licensing state, instruction in the subjects outlined in Appendix D of this chapter and demonstrated an understanding thereof:

(2) Read and received instruction in the rules contained in this chapter and the applicable sections of

¹ or CAUTION

641—Chapters 38, 39, and 40 or their equivalent, conditions of appropriate license or certificate of registration, and the licensee's or registrant's operating and emergency procedures, and demonstrated an understanding thereof; and

NOTICES

- (3) Demonstrated competence to use sources of radiation, related handling tools, and radiation survey instruments which will be used on the job.
- b. No licensee or registrant shall permit any individual to assist in the handling of sources of radiation until such individual has:
- (1) Read or received instruction in the licensee's or registrant's operating and emergency procedures and demonstrated an understanding thereof; and
- (2) Demonstrated competence to use, under the personal supervision of the logging supervisor, the sources of radiation, related handling tools, and radiation survey instruments which will be used on the job.

c. The licensee or registrant shall maintain employee training records for inspection by the agency for two years following termination of the individual's employment.

- 41.5(16) Operating and emergency procedures. The licensee's or registrant's operating and emergency procedures shall include instructions in at least the following:
- a. Handling and use of sources of radiation to be employed so that no individual is likely to be exposed to radiation doses in excess of the standards established in 641—Chapter 40;
- b. Methods and occasions for conducting radiation surveys:
- c. Methods and occasions for locking and securing sources of radiation:
- d. Personnel monitoring and the use of personnel monitoring equipment;
- e. Transportation to temporary job sites and field stations, including the packaging and placing of sources of radiation in vehicles, placarding of vehicles, and securing sources of radiation during transportation;
- f. Minimizing exposure of individuals in the event of an accident;
- g. Procedure for notifying proper personnel in the event of an accident;
 - h. Maintenance of records;
- i. Use, inspection and maintenance of source holders, logging tools, source handling tools, storage containers, transport containers, and injection tools;
- j. Procedure to be followed in the event a sealed source is lodged downhole;
- k. Procedures to be used for picking up, receiving, and opening packages containing radioactive material;
- 1. For the use of tracers, decontamination of the environment, equipment, and personnel;
- m. Maintenance of records generated by logging personnel at temporary job sites;
- n. Notifying proper persons in the event of an accident; and
- o. Actions to be taken if a sealed source is ruptured, including actions to prevent the spread of contamination and minimize inhalation and ingestion of radioactive material and actions to obtain suitable radiation survey instruments as required by 41.5(8).
 - 41.5(17) Personnel monitoring.
- a. No licensee or registrant shall permit any individual to act as a logging supervisor or to assist in the handling of sources of radiation unless each such individual wears either a film badge or a thermoluminescent dosimeter (TLD). Each film badge or TLD shall be assigned to

- and worn by only one individual. Film badges must be replaced at least monthly and TLDs replaced at least quarterly. After replacement, each film badge or TLD must be promptly processed.
- b. Personnel monitoring records shall be maintained for inspection until the agency authorizes disposition.
- 41.5(18) Security. During each logging or tracer application, the logging supervisor or other designated employee shall maintain direct surveillance of the operation to protect against unauthorized or unnecessary entry into a restricted area, as defined in 641—Chapter 38.
- 41.5(19) Handling tools. The licensee shall provide and require the use of tools that will ensure remote handling of sealed sources other than low activity calibration sources.
 - 41.5(20) Subsurface tracer studies.
- a. Protective gloves and other appropriate protective clothing and equipment shall be used by all personnel handling radioactive tracer material. Precautions shall be taken to avoid ingestion or inhalation of radioactive material.
- b. No licensee shall cause the injection of radioactive material into potable aquifers without prior written authorization from the agency and any other appropriate state agency.
- 41.5(21) Particle accelerators. No licensee or registrant shall permit above-ground testing of particle accelerators, designed for use in well-logging, which results in the production of radiation, except in areas or facilities so controlled or shielded that the requirements of 641—subrule 40.2(1) and 641—subrule 40.2(5), as applicable, are met.
 - 41.5(22) Radiation surveys.
- a. Radiation surveys or calculations shall be made and recorded for each area where radioactive materials are used and stored.
- b. Radiation surveys shall be made and recorded for the radiation levels in occupied positions and on the exterior of each vehicle used to transport radioactive material. Such surveys shall include each source of radiation or combination of sources to be transported in the vehicle.
- c. If the sealed source assembly is removed from the logging tool before departing the job site, the logging tool detector shall be energized, or a survey meter used, to ensure that the logging tool is free of contamination.
- d. Radiation surveys shall be made and recorded at the job site or wellhead for each tracer operation, except those using hydrogen-3, carbon-14, and sulfur-35. These surveys shall include measurements of radiation levels before and after the operation.
- e. Records required pursuant to 41.5(22)"a" to "d" shall include the dates, the identification of individual(s) making the survey, the identification of survey instrument(s) used, and an exact description of the location of the survey. Records of these surveys shall be maintained for inspection by the agency for two years after completion of the survey.
- 41.5(23) Documents and records required at field stations. Each licensee or registrant shall maintain, for inspection by the agency, the following documents and records for the specific devices and sources used at the field station:
- a. Appropriate license, certificate of registration, or equivalent document(s);
 - b. Operating and emergency procedures;
 - c. Applicable regulations;

- d. Records of the latest survey instrument calibrations pursuant to 41.4(8);
- e. Records of the latest leak test results pursuant to 41.5(9);
- f. Records of quarterly inventories required pursuant to 41.5(10);
 - g. Utilization records required pursuant to 41.5(11);
- h. Records of inspection and maintenance required pursuant to 41.5(14);
 - i. Survey records required pursuant to 41.5(22); and
 - j. Training records required pursuant to 41.5(15).
- 41.5(24) Documents and records required at temporary job sites. Each licensee or registrant conducting operations at a temporary job site shall have the following documents and records available at that site for inspection by the agency:
 - a. Operating and emergency procedures;
- b. Survey records required pursuant to 41.5(22) for the period of operation at the site;
- c. Evidence of current calibration for the radiation survey instruments in use at the site;
- d. When operating in the state under reciprocity, a copy of the appropriate license, certificate of registration, or equivalent document(s); and
- e. Shipping papers for the transportation of radioactive material.
- 41.5(25) Notification of incidents, abandonment, and lost sources.
- a. Notification of incidents and sources lost in other than downhole logging operations shall be made in accordance with appropriate provisions of 641—Chapter 40.
- b. Whenever a sealed source or device containing radioactive material is lodged downhole, the licensee shall:
- (1) Monitor at the surface for the presence of radioactive contamination with a radiation survey instrument or logging tool during logging tool recovery operations; and
- (2) Notify the agency immediately by telephone and subsequently, within 30 days, by confirmatory letter if the licensee knows or has reason to believe that a sealed source has been ruptured. This letter shall identify the well or other location, describe the magnitude and extent of the escape of radioactive material, assess the consequences of the rupture, and explain efforts planned or being taken to mitigate these consequences.
- c. When it becomes apparent that efforts to recover the radioactive source will not be successful, the licensee shall:
- (1) Advise the well operator of the regulations of the appropriate state agency regarding abandonment and an appropriate method of abandonment, which shall include:
- 1. The immobilization and sealing in place of the radioactive source with a cement plug;
- 2. The setting of a whipstock or other deflection device; and
- 3. The mounting of a permanent identification plaque at the surface of the well, containing the appropriate information required by 41.5(25)"d."
- (2) Notify the agency by telephone, giving the circumstances of the loss, and request approval of the proposed abandonment procedures; and
- (3) File a written report with the agency within 30 days of the abandonment. The licensee shall send a copy of the report to the appropriate state agency that issued permits or otherwise approved of the drilling operation. The report shall contain the following information:
 - 1. Date of occurrence;

- 2. A description of the well-logging source involved, including the radionuclide and its quantity, chemical, and physical form;
 - 3. Surface location and identification of the well;
- 4. Results of efforts to immobilize and seal the source in place;
- 5. A brief description of the attempted recovery effort:
 - 6. Depth of the source;
 - 7. Depth of the top of the cement plug;
 - 8. Depth of the well;
- Any other information, such as a warning statement, contained on the permanent identification plaque; and
- 10. The names of state agencies receiving a copy of this report.
- d. Whenever a sealed source containing radioactive material is abandoned downhole, the licensee shall provide a permanent plaque² for posting the well or wellbore. This plaque shall:
- (1) Be constructed of long-lasting material, such as stainless steel or monel; and
- (2) Contain the following information engraved on its face:
 - 1. The word "CAUTION";
- 2. The radiation symbol without the conventional color requirement;
 - 3. The date of abandonment;
 - 4. The name of the well operator or well owner;
- The well name and well identification number(s) or other designation;
 - 6. The sealed source(s) by radionuclide and activity;
- 7. The source depth and the depth to the top of the plug; and
- 8. An appropriate warning, depending on the specific circumstances of each abandonment.³
- e. The licensee shall immediately notify the agency by telephone and subsequently by confirming letter if the licensee knows or has reason to believe that radioactive material has been lost in or to an underground potable aquifer. Such notice shall designate the well location and shall describe the magnitude and extent of loss of radioactive material, assess the consequences of such loss, and explain efforts planned or being taken to mitigate these consequences.

CHAPTER 41—APPENDIX A

INFORMATION ON RADIATION SHIELDING REQUIRED FOR PLAN REVIEWS

In order for the agency to provide an evaluation, technical advice, and official approval on shielding requirements for a radiation installation, the following information shall be submitted.

- 1. The plans should show, as a minimum, the following:
- (a) The normal location of the X-ray system's radiation port; the port's travel and traverse limits; general direction(s) of the useful beam; locations of any windows

² An example of a suggested plaque is shown in Appendix E of this chapter.

Appropriate warnings may include: (a) "Do not drill below plug-back depth"; (b) "Do not enlarge easing"; or (c) "Do not re-enter the hole", followed by the words, "before contacting the Iowa Department of Public Health."

and doors; the location of the operator's booth; and the location of the X-ray control panel.

- (b) The structural composition and thickness or lead equivalent of all walls, doors, partitions, floor, and ceiling of the room(s) concerned.
 - (c) The dimensions of the room(s) concerned.
- (d) The type of occupancy of all adjacent areas inclusive of space above and below the room(s) concerned. If there is an exterior wall, show distance to the closest area(s) where it is likely that individuals may be present.
- (e) The make and model of the X-ray equipment and

the maximum technique factors.

- (f) The type of examination(s) or treatment(s) which will be performed with the equipment.
- 2. Information on the anticipated workload of the X-ray system(s).
- 3. If the services of a qualified expert have been utilized to determine the shielding requirements, a report, including all basic assumptions used, shall be submitted with the plans.

CHAPTER 41—APPENDIX B

DESIGN REQUIREMENTS FOR AN OPERATOR'S BOOTH

1. Space requirements:

- (a) The operator shall be allotted not less than 7.5 square feet (0.697 m²) of unobstructed floor space in the booth.
- (b) The operator's booth may be any geometric configuration with no dimension of less than 2 feet (0.61 m).
- (c) The space shall be allotted excluding any encumbrance by the X-ray control panel, such as overhang, cables, or other similar encroachments.
- (d) The booth shall be located or constructed such that unattenuated direct scatter radiation originating on the examination table or at the wall cassette not reach the operator's station in the booth.

2. Structural requirements:

- (a) The booth walls shall be permanently fixed barriers of at least 7 feet (2.13 m) high.
- (b) When a door or movable panel is used as an integral part of the booth structure, it must have an interlock which will prevent an exposure when the door or panel is not closed.
- (c) Shielding shall be provided to meet the requirements of 641—Chapter 40.

3. X-ray control placement:

The X-ray control for the system shall be fixed within the booth; and:

- (a) Shall be at least 40 inches (1.02 m) from any open edge of the booth wall which is nearest to the examining table.
- (b) Shall allow the operator to use the majority of the available viewing windows.

4. Viewing system requirements:

- (a) Each booth shall have at least one viewing device which will:
- (1) Be so placed that the operator can view the patient

during any exposure, and

(2) The device shall be so placed that the operator can have full view of any occupant of the room and should be so placed that the operator can view any entry into the room. If any door which allows access to the room cannot be seen from the booth, then that door must have an interlock controlling the exposure which will prevent the exposure if the door is not closed.

- (b) When the viewing system is a window, the following requirements also apply:
- (1) The viewing area shall be at least 1 square foot (0.0929 m²).
- (2) The design of the booth shall be such that the operator's expected position when viewing the patient and operating the X-ray system is at least 18 inches (0.457 m) from the edge of the booth.
- (3) The material constituting the window shall have the same lead equivalence as that required in the booth's wall in which it is mounted.
- (c) When the viewing system is by mirrors, the mirror(s) shall be so located as to accomplish the general requirements of Appendix B, 4(a).
 - (d) When the viewing system is by electronic means:
- (1) The camera shall be so located as to accomplish the general requirements of Appendix B,4(a), and
- (2) There shall be an alternate viewing system as a backup for the primary system.

CHAPTER 41—APPENDIX C

INFORMATION TO BE SUBMITTED BY PERSONS PROPOSING TO CONDUCT HEALING ARTS SCREENING

Persons requesting that the agency approve a healing arts screening program shall submit the following information and evaluation:

- 1. Name and address of the applicant and, where applicable, the names and addresses of agents within this
- 2. Diseases or conditions for which the X-ray examinations are to be used in diagnoses.
- 3. A detailed description of the X-ray examinations proposed in the screening program.

4. Description of the population to be examined in the screening program, i.e., age, sex, physical condition, and other appropriate information.

5. An evaluation of any known alternate methods not involving ionizing radiation which could achieve the goals of the screening program and why these methods are not used instead of the X-ray examinations.

- 6. An evaluation by a qualified expert of the X-ray system(s) to be used in the screening program. The evaluation by the qualified expert shall show that such system(s) do satisfy all requirements of these regulations.
- 7. A description of the diagnostic film quality control program.
- 8. A copy of the technique chart for the X-ray examination procedures to be used.
- 9. The qualifications of each individual who will be operating the X-ray system(s).
- 10. The qualifications of the individual who will be supervising the operators of the X-ray system(s). The extent of supervision and the method of work performance evaluation shall be specified.

11. The name and address of the individual who will interpret the radiograph(s).

12. A description of the procedures to be used in advising the individuals screened and their private practitioners of the healing arts of the results of the screening procedure and any further medical needs indicated.

13. A description of the procedures for the retention or disposition of the radiographs and other records pertaining to the X-ray examinations.

CHAPTER 41—APPENDIX D

SUBJECTS TO BE INCLUDED IN TRAINING COURSES FOR LOGGING SUPERVISORS

- I. Fundamentals of radiation safety.
 - A. Characteristics of radiation.
 - B. Units of radiation dose and quantity of radioactiv-

ity.

- C. Significance of radiation dose.
 - 1. Radiation protection standards.
 - 2. Biological effects of radiation dose.
- D. Levels of radiation from sources of radiation.
- E. Methods of minimizing radiation dose.
 - 1. Working time.
 - 2. Working distances.
 - 3. Shielding.
- F. Radiation safety practices including prevention of contamination and methods of decontamination.
 - II. Radiation detection instrumentation to be used.
 - A. Use of radiation survey instruments.
 - 1. Operation.
 - 2. Calibration.
 - 3. Limitations.
 - B. Survey techniques.
 - C. Use of personnel monitoring equipment.
 - III. Equipment to be used.
 - A. Handling equipment.
 - B. Sources of radiation.
 - C. Storage and control of equipment.
 - D. Operation and control of equipment.
- IV. The requirements of pertinent federal and state regulations.
- V. The licensee's or registrant's written operating and
- emergency procedures.

 VI. The licensee's or registrant's record-keeping procedures.

The following total revision is proposed.

CHAPTER 41—APPENDIX E

EXAMPLE OF PLAQUE FOR IDENTIFYING WELLS CONTAINING SEALED SOURCES CONTAINING RADIOACTIVE MATERIAL ABANDONED DOWNHOLE

(WELL IDENTIFICATION)



CAUTION



0

ONE 2 CURIE CS-137 RADIOACTIVE SOURCE ABANDONED 3-3-75 AT 8400 FT. PLUG BACK DEPTH 8200 FT. DO NOT RE-ENTER THIS WELL BEFORE CONTACTING

[RADIATION CONTROL AGENCY]

0

The size of the plaque should be convenient for use on active or inactive wells, e.g., a 7-inch square. Letter size of the word "CAUTION" should be approximately twice the letter size of the rest of the information, e.g., 1/2-inch and 1/4-inch letter size, respectively.

These rules are intended to implement Iowa Code

chapter 136C.

ARC 3050A

PUBLIC HEALTH DEPARTMENT[641]

Notice of Intended Action

Twenty-five interested persons, a governmental subdivision, an agency or an association of 25 or more persons may demand an oral presentation hereon as provided in Iowa Code §17A.4(1)"b."

Notice is also given to the public that the Administrative Rules Review Committee may, on its own motion or on written request by any individual or group, review this proposed action under \$17A.860 at a regular or special meeting where the public or interested persons may be heard.

Pursuant to the authority of Iowa Code section 136C.3, the Iowa Department of Public Health hereby gives Notice of Intended Action to adopt a new Chapter 45, "Radiation Safety Requirements for Industrial Radiographic Operations," Iowa Administrative Code.

The action taken is appropriate in order to keep current with the standards set forth by the Conference of Radiation Control Program Directors' "Suggested State Regulations for the Control of Radiation" (SSRCRs) and to remain compatible with the U.S. Nuclear Regulatory Commission (NRC) pursuant to the Agreement State Program between the Governor and the NRC.

The proposed Chapter 45 will require persons engaged in industrial radiography in the state to be credentialed. These requirements were formerly contained in 641—41.4(136C); however, the Department has determined that it is necessary to develop a separate chapter to consolidate all rules for industrial radiography. This chapter also delineates requirements for industrial radiography using sealed radioactive sources and X-ray units, since the requirements for each use are in many instances unique to the type of use.

Any interested person may make written suggestions or comments on the proposed Chapter 45 on or before close of business June 17, 1992. Such written material should be directed to Donald A. Flater, Chief, Bureau of Environmental Health, Iowa Department of Public Health, Lucas State Office Building, Des Moines, Iowa 50319, FAX (515)242-5284.

A public hearing will be held on June 17, 1992, at 9 a.m. in the Third Floor Conference Room, Lucas State Office Building, at which time persons may present their views orally or in writing. At the hearing, persons will be asked to give their name, address, and whom they represent. Presenters will also be asked to confine their remarks to the subject of the rules.

These rules are intended to implement Iowa Code chapter 136C.

The following new chapter is proposed.

CHAPTER 45

RADIATION SAFETY REQUIREMENTS FOR INDUSTRIAL RADIOGRAPHIC OPERATIONS

641-45.1(136C) General requirements.

45.1(1) Purpose and scope. The rules in this chapter establish radiation safety requirements for using sources of radiation for industrial radiography. The requirements of this chapter are in addition to, and not in substitution for, other applicable requirements of 641-Chapter 38, 39, 40, or 41. The rules in this chapter apply to all licensees or registrants who use sources of radiation for industrial radiography. All references to any Code of Federal Regulations (CFR) in this chapter are those in effect as of September 1, 1992.
45.1(2) Definitions. As used in this chapter, the fol-

lowing definitions apply:

"Cabinet radiography" means industrial radiography conducted in an enclosure or cabinet shielded so that radiation levels at every location on the exterior meet the lim-

itations specified in 641—subrule 40.2(5).

'Cabinet X-ray system" means an X-ray system with the X-ray tube installed in an enclosure independent of existing architectural structures except the floor on which it may be placed. The cabinet X-ray system is intended

- 1. Contain at least that portion of a material being irradiated:
 - 2. Provide radiation attenuation; and
- 3. Exclude personnel from its interior during generation of radiation. Included are all X-ray systems designed primarily for the inspection of carry-on baggage at airline, railroad, and bus terminals, and in similar facilities. An X-ray tube used within a shielded part of a building, or X-ray equipment which may temporarily or occasionally incorporate portable shielding, is not considered a cabinet X-ray system.

"Certifiable cabinet X-ray system" means an existing uncertified X-ray system that has been modified to meet certification requirements specified in 21 CFR 1020,40.

"Certified cabinet X-ray system" means an X-ray system which has been certified in accordance with 21 CFR 1010.2 as being manufactured and assembled pursuant to

the provisions of 21 CFR 1020.40.

Collimator" means a small radiation shield of lead or other heavy metal that is placed on the end of a guide tube or directly onto a radiographic exposure device to restrict the size of the radiation beam when the sealed source is cranked into position to make a radiographic exposure.

'Crank-out device" means the cable, protective sheath, and handcrank used to move the sealed source from the shielded to the unshielded position to make an industrial radiographic exposure.

"Enclosed radiography" means industrial radiography conducted in an enclosed cabinet or room and includes cabinet radiography and shielded-room radiography.

"Fluoroscopic imaging assembly" means a subsystem in which X-ray photons produce a fluoroscopic image. It includes the image receptors such as the image intensifier and spot-film device, electrical interlocks, if any, and structural material providing linkage between the image receptor and source assembly.

GED" means general educational development.

"I.D. card" means the document issued by the agency to industrial radiographers following completion of requirements stated in 45.1(10)"b."

"Industrial radiography" means a nondestructive testing method using ionizing radiation, such as gamma rays or X-rays, to make radiographic images for the purpose of detecting flaws in objects without destroying them.

"Lay-barge radiography" means industrial radiography

performed on any water vessel used for laying pipe.

"Lixiscope" means a portable light-intensified imaging device using a sealed source.

'Lock-out survey" means a radiation survey performed to verify that a sealed source is in its shielded position. The lock-out survey is performed before moving the radiographic exposure device or source changer to a new location or when securing the radiographic exposure device or source changer.

'Minimal threat" means that during the operations of electronic devices capable of generating or emitting fields

of radiation:

a. No deliberate exposure of an individual occurs:

- b. The radiation is not emitted in an open beam configuration; and
- c. No known physical injury to an individual has occurred.

"Offshore" means within the territorial waters of the United States.

"Permanent radiographic installation" shielded installation or structure designed or intended for performing enclosed radiography and in which radiogra-

phy is regularly performed.

'Personal supervision" means guidance and instruction provided to a radiographer trainee by a radiographer instructor who is present at the site, in visual contact with the trainee while the trainee is using sources of radiation, and in such proximity that immediate assistance can be given if required.

"Platform radiography" means industrial radiography

performed on an offshore platform or other structure.

"Radiation machine" means any device capable of producing ionizing radiation except those which produce radiation only from radioactive material.

"Radiation safety officer" means an individual named by the licensee or registrant who has a knowledge of, responsibility for, and authority to enforce appropriate radiation protection rules, standards, and practices on behalf of the licensee or registrant and who meets the requirements of 45.1(10)"d.

"Radiographer" means any individual who has successfully completed the training, testing, and documentation requirements of 45.1(10)"b" and who performs or personally supervises industrial radiographic operations.

"Radiographer trainee" means any individual who has successfully completed the training, testing, and documentation requirements of 45.1(10)"a" and who uses sources of radiation and related handling tools or radiation survey instruments under the personal supervision of a radiographer trainer.

'Radiographer trainer (instructor)" means any individual who instructs and supervises radiographer trainees during on-the-job training and who meets the require-

ments of 45.1(10)"c."

"Radiographic exposure device" means any instrument containing a sealed source fastened or contained therein. in which the sealed source or shielding thereof may be moved or otherwise changed from a shielded to unshielded position for purposes of making a radiographic exposure (e.g., camera).

"Radiographic personnel" means any radiographer or

radiographer trainee.

"Residential location" means any area where structures in which people lodge or live are located, and the grounds on which such structures are located including, but not limited to, houses, apartments, condominiums, and garages.

"Sealed source" means radioactive material that is permanently bonded or fixed in a capsule or matrix designed to prevent release and dispersal of the radioactive material under the most severe conditions likely to be encountered

in normal use and handling (pill).

"Shielded position" means the location within the radiographic exposure device or storage container which, by manufacturer's design, is the proper location for the sealed source during storage.

"Shielded-room radiography" means industrial radiography conducted in a room shielded so that radiation levels at every location on the exterior meet the limitations

specified in 641—subrule 40.2(5).

"Source assembly" means a component to which the sealed source is affixed or in which the sealed source is contained. The source assembly includes the sealed source (pigtail).

"Source changer" means a device designed and used for replacement of sealed sources in radiographic exposure devices, including those source changers also used for transporting and storage of sealed sources.

"Source container" means a shielded device in which

sealed sources are secured and stored.

"Storage area" means any location, facility, or vehicle which is used to store, to transport, or to secure a radiographic exposure device, a storage container, or a sealed source when it is not in use and which is locked or has a physical barrier to prevent accidental exposure, tampering with, or unauthorized removal of the device, container, or source.

"Storage container" means a shielded device in which

sealed sources are secured and stored.

"Temporary job site" means any location where industrial radiography is performed other than the location(s) listed in a specific license or certificate of registration.

"Trainee status card" means the document issued by the agency following completion of the requirements of

45.1(10)"a"(1) and (2).

"Transport container" means a package that is designed to provide radiation safety and security when sealed sources are transported and which meets all applicable requirements of the U.S. Department of Transportation.

"Underwater radiography" means industrial radiography performed when the radiographic exposure device and related equipment are beneath the surface of the water.

45.1(3) Exemptions.

- a. Uses of certified and certifiable cabinet X-ray systems designed to exclude individuals exempt from the requirements of this chapter, except for the requirements of 45.2(7)"b" and "c."
- b. Industrial uses of lixiscopes are exempt from the requirements in this chapter.
- c. Radiation machines determined by the agency to constitute a minimal threat to human health and safety in accordance with 641—subrule 38.3(1) are exempt from the rules in this chapter, except for the requirements of this subrule.

45.1(4) Receipt, transfer, and disposal of sources of radiation. Each licensee and registrant shall maintain records showing the receipt, transfer, and disposal of sources of radiation. These records shall include the date the individual made the record, the radionuclide, number of curies, and the make, model, and serial number of each source of radiation and device, as appropriate. Records shall be maintained for agency inspection until disposal is authorized by the agency.

45.1(5) Radiation survey instruments.

- a. The licensee or registrant shall maintain sufficient calibrated and operable radiation survey instruments to make physical radiation surveys as required by this chapter and 641—subrule 40.3(1). Instrumentation required by this subrule shall have a range such that 2 milliroentgens (5.16 x 10⁻⁷ C/kg) per hour through 1 roentgen (2.58 x 10⁻⁴ C/kg) per hour can be measured.
- b. Each radiation survey instrument shall be calibrated:
- (1) At energies appropriate for use and at intervals not to exceed three months and after each instrument servicing;

(2) Such that accuracy within plus or minus 20 per-

cent can be demonstrated;

(3) At 2 points located approximately 1/3 and 2/3 of full-scale on each scale for linear scale instruments; at midrange of each decade, and at 2 points of at least 1 decade for logarithmic scale instruments; and at appropriate points for digital instruments; and

(4) By a person licensed or registered by the agency, another agreement state, or the U.S. Nuclear Regulatory

Commission to perform such service.

c. Records of these calibrations shall be maintained for two years after the calibration date for inspection by

d. Each radiation survey instrument shall be checked with a radiation source at the beginning of each day of use and at the beginning of each work shift to ensure it is op-

erating properly.

45.1(6) Quarterly inventory. Each licensee shall conduct a physical inventory at intervals not to exceed three months to account for all sealed sources and radiography exposure devices received and possessed by the licensee. Sources of radiation include radiographic exposure devices containing depleted uranium. The records of the inventories shall be maintained for two years from the date of the inventory for inspection by the agency and shall include: the manufacturer, model number, serial number, radionuclide, number of curies, and location of each source of radiation; number of kilograms of depleted uranium shielding; date of the inventory; and name of the individual making the inventory.

45.1(7) Utilization logs.

- a. Each licensee or registrant shall maintain current logs of the use of each source of radiation. The logs shall include:
- (1) A unique identification, such as a serial number, of each radiation machine, each radiographic exposure device containing a sealed source, and each sealed source;

(2) The identity of the radiographer using the source of radiation;

(2) I acc

- (3) Locations where each source of radiation is used; and
- (4) The date(s) each source of radiation is removed from storage and returned to storage. For fixed installa-

tions, the date(s) each source of radiation is energized or used and the number of exposures made.

- b. Utilization logs may be kept on IDPH Form 588-2693, Utilization Log, or on clear, legible records containing all the information required by 45.1(7)"a." Copies of utilization logs shall be maintained for agency inspection for two years from the date of the recorded event. The records shall be kept at the location specified by the license or certificate of registration.
 - 45.1(8) Inspection and maintenance.

a. Each licensee or registrant shall ensure that checks for obvious defects in radiation machines, radiographic exposure devices, storage containers, and source changers

are performed prior to each day or shift of use.

- b. Each licensee or registrant shall conduct a program, at intervals not to exceed three months, or prior to the first use thereafter, of inspection and maintenance of radiation machines, radiographic exposure devices, storage containers, and source changers to ensure proper functioning of components important to safety. All appropriate parts shall be maintained in accordance with manufacturer's specifications. Records of inspection and maintenance shall be maintained for inspection by the agency for two years from the date of the recorded event. This program shall cover, as a minimum, the items in Appendix B.
- c. If any inspection conducted pursuant to 45.1(8)"a" or "b" reveals damage to components critical to radiation safety, the device shall be removed from service and labeled as defective until repairs have been made.
- 45.1(9) Permanent radiographic installations. Permanent radiographic installations having high radiation area entrance controls of the type described in 641—40.3(3)"c"(2)"2" and "3" shall also meet the following requirements:
- a. Each entrance that is used for personnel access to the high radiation area shall have both visible and audible warning signals to warn of the presence of radiation. The visible signal shall be activated by radiation. The audible signal shall be activated when an attempt is made to enter the installation while the source is exposed.
- b. The control device or alarm system shall be tested for proper operation at the beginning of each day of equipment use. If a control device or alarm system is operating improperly, it shall be immediately labeled as defective and repaired before industrial radiographic operations are resumed. Records of these tests shall be maintained for inspection by the agency for two years from the date of the event.
- **45.1(10)** Training and testing for radiographic personnel.
- a. Radiographer trainee requirements. No licensee or registrant shall permit any individual to act as a radiographer trainee, as defined in this chapter, until:
- (1) It has been documented on the appropriate agency form or equivalent that such individual has received copies of and has demonstrated an understanding of:
- 1. The subjects outlined in Appendix A, presented in a course approved by the agency, another agreement state, or the U. S. Nuclear Regulatory Commission;
- 2. The rules contained in this chapter and the applicable sections of 641—Chapters 38, 39, and 40;
- 3. The appropriate conditions of license(s) or certificate(s) of registration; and
- 4. The licensee's or registrant's operating and emergency procedures.

- (2) The individual possesses a current agency-issued trainee status card issued after completion of 45.1(10)"a"(1).
- b. Radiographer requirements. No licensee or registrant shall permit any individual to act as a radiographer:
- (1) Until it has been documented to the agency that such individual:
 - 1. Has completed the requirements of 45.1(10)"a"(1);
- 2. Has completed at least two months of on-the-job training as a radiographer trainee supervised by one or more radiographic trainers authorized on a license or registration certificate. The on-the-job training shall be documented on the appropriate agency form or equivalent and shall include at least 360 hours of active participation in industrial radiographic operations and does not include safety meetings or classroom training (this requirement does not apply to individuals designated as radiographers prior to January 1, 1992);

3. Has demonstrated competence in the use of sources of radiation, radiographic exposure devices, related handling tools, and radiation survey instruments which may be employed in industrial radiographic assignments;

(2) The individual has successfully completed within the last five years the appropriate agency-administered examination prescribed in 45.1(10)"f"(2) or equivalent examination; and

(3) The individual possesses a current I.D. card issued pursuant to 45.1(10)"g"(1) or issued by the U.S. Nuclear Regulatory Commission, another agreement state, or a licensing state.

c. Radiographer trainer. No individual shall act as a

radiographer trainer unless such individual:

(1) Has met the requirements of 45.1(10)"a"(1) and "b";

(2) Has one year of documented experience as an industrial radiographer; and

- (3) Is named on the specific license or certificate of registration issued by the agency and under which an individual is acting as a radiographer trainer.
 - d. Radiation safety officer.
- (1) A radiation safety officer (RSO) shall be designated for every industrial radiography license and certificate of registration issued by the agency.

(2) The RSO's qualifications shall include:

 Possession of a high school diploma or a certificate of high school equivalency based on the GED test;

2. Completion of the training and testing requirements of 45.1(10)"a"(1) and 45.1(10)"b"(1)"3," (2), and (3); and

- 3. Two years of documented radiation protection experience, including knowledge of industrial radiographic operations with at least 40 hours of active participation in industrial radiographic operations.
- (3) The specific duties of the RSO include, but are not limited to, the following:
- 1. To establish and oversee operating, emergency, and ALARA procedures and to review them regularly to ensure that the procedures are current and conform with these rules;
- 2. To oversee and approve all phases of the training program for radiographic personnel so that appropriate and effective radiation protection practices are taught;
- To ensure that required radiation surveys and leak tests are performed and documented in accordance with these rules, including any corrective measures when levels of radiation exceed established limits;

4. To ensure that personnel monitoring devices are calibrated and used properly by occupationally exposed personnel, that records are kept of the monitoring results, and that timely notifications are made as required by 641—Chapter 40.5. To ensure that any required interlock switches and

warning signals are functioning and that radiation signs, ropes, and barriers are properly posted and positioned;

- 6. To investigate and report to the agency each known or suspected case of radiation exposure to an individual or radiation level detected in excess of limits established by these rules and each theft or loss of source(s) of radiation, to determine the cause, and to take steps to prevent its recurrence;
- 7. To have a thorough knowledge of management policies and administrative procedures of the licensee or registrant;
- 8. To assume control and have the authority to institute corrective actions including shutdown of operations when necessary in emergency situations or unsafe conditions;
- 9. To maintain records as required by these rules (see Appendix C);
- 10. To ensure the proper storing, labeling, transport, and use of exposure devices and sources of radiation;
- 11. To ensure that quarterly inventory and inspection and maintenance programs are performed in accordance with 45.1(6), 45.1(8), 45.2(3), and 45.3(6)"b"; and
- 12. To ensure that personnel are complying with these rules, the conditions of the license or the registration, and the operating and emergency procedures of the licensee or registrant.
- e. Training and testing records. Each licensee and registrant shall maintain, for agency inspection, training and testing records which demonstrate that the applicable requirements of 45.1(10)"a" and "b" are met for all industrial radiographic personnel. Records shall be kept on IDPH Form 588-2692 or on clear, legible records containing all the information required by IDPH Form 588-2692. Records shall be maintained until disposal is authorized by the agency.
 - f. Applications and examinations.
 - (1) Application.
- 1. An application for taking the examination shall be on forms prescribed and furnished by the agency.
- 2. A nonrefundable fee of \$100 to cover the cost of the examination shall be submitted with each application.
- 3. The application and the nonrefundable fee shall be submitted to the agency by the date specified by the agency.
- 4. An individual whose I.D. card has been suspended or revoked shall obtain prior approval from the agency to apply to take the examination.
- (2) Examination. The examination shall be given for the purpose of determining the qualifications of applicants.
- 1. A written examination shall be held at such times and places as the agency shall determine. The scope of the examination and the methods of procedure, including determination of the passing score, shall be prescribed by the agency. The examination will emphasize the applicant's ability to safely use sources of radiation and related equipment and the applicant's knowledge of these rules.
- A candidate failing an examination may apply for reexamination in accordance with 45.1(10)"f"(1) and will be reexamined. A candidate shall not retake the same version of the agency-administered examination.

- 3. The examination will be held at locations designated by the agency. The examination shall normally be offered quarterly. Dates, times, and locations of the examinations will be provided by the agency.
 - 4. The examination will be in the English language.
- 5. To take the examination, an individual shall have a picture identification card (such as an Iowa driver's license) at the time of the examination.
- 6. Calculators will be permitted during the examination; however, calculators or computers with preprogrammed data or formulas, including exposure calculations, will not be permitted.
- 7. The examination will be a "closed book" examination.
- Examination material shall be returned to the agency at the end of the examination. No photographic or other copying of examination questions or materials shall be permitted. Disclosure by any individual of the contents of any examination prior to the administration is prohibited.
- 9. Any individual observed by an agency proctor to be compromising the integrity of the examination shall be required to surrender the examination, the answer sheet, and any work paper. Such individual will not be allowed to complete the examination, will forfeit the examination fee, and will leave the examination site to avoid disturbing other examinees. Such individual may resubmit an application and an additional examination fee to take the examination not earlier than three months later.
- 10. The names and scores of individuals taking the examination shall be a public record.
 - g. Identification procedures.(1) I.D. card.
- 1. An I.D. card shall be issued to each person who successfully completes the requirements of 45.1(10)"b" and the examination prescribed in 45.1(10)"f"(2) or equivalent exam.
 - 2. Each person's I.D. card shall contain the person's
- 3. The I.D. card remains the property of the state of Iowa and may be revoked or suspended under the provisions of 45.1(10)"h.'
- 4. Any individual who wishes to replace the I.D. card shall submit to the agency a written request for a replacement I.D. card, stating the reason a replacement I.D. card is needed. A nonrefundable fee of \$25 shall be paid to the agency for each replacement of a lost I.D. card. The individual shall maintain in possession a copy of the request while performing industrial radiographic operations until a replacement I.D. card is received from the agency.
- (2) Expiration of I.D. card. Each I.D. card expires at the end of the day, in the month and year stated on the I.D. card.
 - (3) Renewal of I.D. card.
- 1. Applications for examination to renew an I.D. card shall be filed in accordance with 45.1(10)"f"(1).
- 2. The examination for renewal of an I.D. card shall be administered in accordance with 45.1(10)"f"(2).
- 3. A renewed I.D. card shall be issued in accordance with 45.1(10)"g"(1).
 - h. Revocation or suspension of an I.D. card.
- (1) Any radiographer who violates these rules may be required to show cause at a formal hearing why the I.D. card should not be revoked or suspended.
- (2) When an agency order has been issued for an industrial radiographer to cease and desist from the use of radioactive material or revoking or suspending the I.D.

card, the industrial radiographer shall surrender the I.D. card to the agency until such time as the order is changed or the suspension expires.

- (3) An agency's inspector may, in certain instances, confiscate any radiographer's I.D. card on the spot while conducting an inspection or investigation. If the inspector determines that the activities being conducted by the radiographer are significant enough to be classified as severity I, II, or III, as specified in Appendix A to Chapter 38, Supplement I, II, III, IV or VII, and after obtaining the approval of agency management, the inspector may take any radiographer's I.D. card. The agency will then issue a cease and desist order to the radiographer's employer, forward the I.D. card(s) to the issuing entity, and notify the U.S. Nuclear Regulatory Commission and other agreement states.
- 45.1(11) Internal audits. Each licensee or registrant shall conduct an internal audit program to ensure that the agency's radioactive material license conditions and the licensee's or registrant's operating and emergency procedures are followed by each radiographer. These internal audits shall be performed at least quarterly, and each radiographer shall be audited at least quarterly. Records of internal audits shall be maintained for inspection by the agency for two years from the date of the audit.
 - 45.1(12) Personnel monitoring control.
- a. The personnel monitoring program shall meet the applicable requirements of 641—Chapter 40.
- b. When performing industrial radiographic operations:
- (1) No licensee or registrant shall permit an individual to act as a radiographer, radiographer trainee, or radiographer trainer unless the individual wears a direct-reading pocket dosimeter, an alarm ratemeter, and either a film badge or a thermoluninescent dosimeter (TLD) at all times during the radiographic operations. For permanent radiographic installations where other appropriate alarming or warning devices are in routine use, the wearing of an alarm ratemeter is not required.
- (2) Pocket dosimeters shall meet the criteria in ANSI N322-1977 and shall have a range of zero to at least 200 milliroentgens.
- (3) Pocket dosimeters shall be recharged at the start of each work shift.
- (4) Pocket dosimeters shall be read and exposures recorded at least once daily, at the end of each work shift, and before each recharging.
- (5) If an individual's pocket dosimeter is discharged beyond its range (i.e., goes "off scale"), industrial radiographic operations by that individual shall cease and the individual's film badge or TLD shall be immediately sent for processing. The individual shall not return to work with sources of radiation until a determination of the radiation exposure has been made.
- (6) Each film badge or TLD shall be assigned and worn by only one individual.
- (7) Film badges and TLDs must be replaced at least monthly. After replacement, each film badge or TLD must be returned to the supplier for processing within 14 calendar days of the exchange date specified by the personnel monitoring supplier.
- (8) If a film badge or TLD is lost or damaged, the worker shall cease work immediately until a replacement film badge or TLD is provided and the exposure is calculated for the time period from issuance to loss or damage of the film badge or TLD.

c. Records of pocket dosimeter readings of personnel exposures shall be maintained for two years by the licensee or registrant for agency inspection. If the dosimeter readings were used to determine external radiation dose (i.e., no TLD or film badge exposure records exist), the records shall be maintained until the agency authorizes disposal.

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- d. Pocket dosimeters shall be checked for correct response to radiation at periods not to exceed one year. Acceptable dosimeters shall read within plus or minus 30 percent of the true radiation exposure. Records of this check shall be maintained for inspection by the agency for two years from the date of the event.
- e. Reports received from the film badge or TLD processor shall be kept for inspection by the agency until the agency authorizes disposition.
 - f. Each alarm ratemeter must:
- (1) Be checked to ensure that the alarm functions properly (sounds) prior to use at the start of each shift. Records of alarm function checks shall be maintained for two years by the licensee or registrant for agency inspection:
- (2) Be set to give an alarm signal at a preset dose rate of 500 mR/hr;
- (3) Require special means to change the preset alarm function; and
- (4) Be calibrated at periods not to exceed one year for correct response to radiation: Acceptable ratemeters must alarm within plus or minus 20 percent of the true radiation dose rate. Records of the alarming ratemeter calibrations shall be maintained for two years by the licensee or registrant for agency inspection.
- 45.1(13) Supervision of radiographer trainee. Whenever a radiographer trainee uses radiographic exposure devices, sealed sources or related source handling tools or conducts radiation surveys required by 45.2(5) or 45.3(7) to determine that the sealed source has returned to the shielded position after an exposure, the radiographer trainee shall be under the personal supervision of a radiographer instructor.
 - 45.1(14) Access control.
- a. During each industrial radiographic operation, a radiographer shall maintain visual surveillance of the operation to protect against unauthorized entry into a radiation area or high radiation area, except:
- (1) Where the high radiation area is equipped with a control device or an alarm system as described in 641—40.3(3)"c"(2); or
- (2) Where the high radiation area is locked to protect against unauthorized or accidental entry.
- b. Radiographic exposure devices shall not be left unattended except when in storage or physically secured against unauthorized removal.
 - 45.1(15) Posting.
- a. Notwithstanding any provisions in 641—40.3(4)"c," areas in which radiography is being performed shall be conspicuously posted as required by 641—40.3(3)"b" and "c"(1).
- b. Whenever practicable, ropes or barriers shall be used in addition to appropriate signs to designate radiation areas and to help prevent unauthorized entry.
- c. During pipeline industrial radiography operations, sufficient radiation signs and other barriers shall be posted to prevent unmonitored individuals from entering the radiation area.

d. Notwithstanding the requirements of 45.1(15)"a," each radiation area may be posted in accordance with 40.3(3)"b" and "c"(1), i.e., both signs may be posted at the same location at the boundary of the radiation area.

45.1(16) Temporary job site requirements.

- a. Documents and records. Each licensee or registrant conducting industrial radiography at a temporary job site shall have the following records available at that site for inspection by the agency:
- (1) Appropriate license or certificate of registration or equivalent document;
- (2) The appropriate operating and emergency procedures:

(3) The applicable agency rules;

- (4) Survey records required pursuant to 45.2(5)"d" and 45.3(7)"j" for the period of operation at the site;
- (5) Daily pocket dosimeter records for the period of operation at the site;

(6) The daily alarming ratemeter records for the peri-

od of operation at the site; and

- (7) The latest radiation survey instrument calibration and leak test records for specific devices and sealed sources in use at the site. Acceptable records include tags or labels which are affixed to the device or survey meter and decay charts for sources which have been manufactured within the last six months.
 - b. Reserved.
- **45.1(17)** Specific requirements for radiographic personnel performing industrial radiography.
- a. At a job site, the following shall be supplied by the licensee or registrant:
- (1) At least one operable, calibrated radiation survey instrument;
- (2) A current whole body personnel monitor (TLD or film badge) for each individual;
- (3) An operable, calibrated pocket dosimeter with a range of 0 to 200 milliroentgens (5.16 x 10⁻⁵ C/kg) for each worker; and
- (4) An operable, calibrated alarm ratemeter for each worker; and

(5) The appropriate barrier ropes and signs.

- b. Each radiographer at a job site shall possess a valid I.D. card issued by the agency.
- c. Each radiographer trainee at a job site shall possess a valid trainee status card issued by the agency.
- d. Industrial radiographic operations shall not be performed if any of the items in 45.1(17)"a," "b," and "c" are not available at the job site or are inoperable.

e. No individual other than a radiographer or a radiographer trainee who is under the personal supervision of a radiographer instructor shall manipulate controls or operate equipment used in industrial radiographic operations.

- f. During an inspection by the agency, the agency inspector may terminate an operation if any of the items in 45.1(17)"a" are not available and operable or if the required number of radiographic personnel are not present. Operations shall not be resumed until such conditions are met.
 - 45.1(18) Notification of incidents.
- a. The agency shall be notified of thefts or losses of sources of radiation, overexposures, and excessive levels in accordance with 641—subrule 40.5(3).
- b. Each licensee or registrant shall submit a written report within 30 days to the agency whenever one of the following events occurs:
- (1) The source assembly cannot be returned to the fully shielded position and properly secured;

- (2) The source assembly becomes disconnected from the drive cable;
- (3) The failure of any component (critical to safe operation of the radiographic exposure device) to properly perform its intended function; or
- (4) An indicator on a radiation-producing machine fails to show that radiation is being produced or an exposure switch fails to terminate production of radiation when turned to the off position.
- c. The licensee or registrant shall include the following information in each report submitted in accordance with 45.1(18)"b":

(1) A description of the equipment problem;

(2) Cause of each incident, if known;

- (3) Manufacturer and model number of equipment involved in the incident;
 - (4) Location, time, and date of the incident;
 - (5) Actions taken to establish normal operations;
- (6) Corrective actions taken or planned to prevent recurrence; and
 - (7) Names of personnel involved in the incident.

641—45.2(136C) Radiation safety requirements for the use of radiation machines in industrial radiography

- 45.2(1) Locking of sources of radiation. The control panel of each radiation machine shall be equipped with a locking device that will prevent the unauthorized use of an X-ray system or the accidental production of radiation. The radiation machine shall be kept locked and the key removed at all times except when under the direct visual surveillance of a radiographer.
- 45.2(2) Permanent storage precautions. Radiation machines shall be secured while in storage to prevent tampering or removal by unauthorized individuals.

45.2(3) Requirements for radiation machines used in

industrial radiographic operations.

- a. Equipment used in industrial radiographic operations involving radiation machines manufactured after January 1, 1992, shall be certified at the time of manufacture to meet the criteria set forth by ANSI N537-1976.
- b. The registrant's name and city or town where the main business office is located shall be prominently displayed with a durable, clearly visible label(s) on all vehicles used to transport radiation machines for temporary job site use.

45.2(4) Operating and emergency procedures.

- a. The registrant's operating and emergency procedures shall include instructions in at least the following:
- (1) Operation and safety instruction on the radiation machine(s) to be used;
- (2) Methods and occasions for conducting radiation surveys;
- (3) Methods for controlling access to radiographic areas;
- (4) Methods and occasions for locking and securing sources of radiation;
- (5) Personnel monitoring and the use of personnel monitoring equipment, including steps that must be taken immediately by radiography personnel in the event a pocket dosimeter is found to be off-scale;
- (6) Minimizing exposure of individuals in the event of an accident;
- (7) The procedure for notifying proper personnel in the event of an accident;
 - (8) Maintenance of records; and
- (9) Inspection and maintenance of radiation machines.

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PUBLIC HEALTH DEPARTMENT[641](cont'd)

b. Each registrant shall provide, as a minimum, two radiographic personnel when radiation machines are used for any industrial radiography conducted other than at a permanent radiographic installation (shielded room, bay, or bunker). If one of the personnel is a radiographer trainee the other shall be a radiographer trainer authorized by the certificate of registration.

c. No individual other than a radiographer or a radiographer trainee who is under the personal supervision of a radiographer trainer shall manipulate controls or operate equipment used in industrial radiographic operations.

- d. Each registrant shall conduct an internal audit program to ensure that these rules, the conditions of the registration, and the registrant's operating and emergency procedures are followed by radiographic personnel. Each radiographer's and radiographer trainee's performance during an actual radiographic operation shall be audited at intervals not to exceed three months. If a radiographer or a radiographer trainee has not participated in a radiographic operation for more than three months since the last audit, that individual's performance shall be observed and recorded the next time the individual participates in a radiographic operation. Records of audits shall be maintained by the registrant for agency inspection for two years from the date of the audit.
 - 45.2(5) Radiation surveys and survey records.
- a. No radiographic operation shall be conducted unless calibrated and operable radiation survey instrumentation, as described in 45.1(5), is available and used at each site where radiographic exposures are made.

b. A physical radiation survey shall be made after each radiographic exposure using radiation machines to

determine that the machine is "off.

- c. All potential radiation areas where industrial radiographic operations are to be performed shall be posted in accordance with 45.1(15), based on calculated dose rates, before industrial radiographic operations begin. An area survey shall be performed during the first radiographic exposure to confirm that 45.1(15) requirements have been met and that unrestricted areas do not have radiation levels in excess of the limits specified in 641—subrule 40.2(5).
- d. Records shall be kept of the surveys required by 45.2(5)"b" and "c." Such records shall be maintained for inspection by the agency for two years after completion of the survey. If the survey was used to determine an individual's exposure, however, the records of the survey shall be maintained until the agency authorizes their disposi-

45.2(6) Special requirements and exemptions for enclosed radiography.

a. Systems for enclosed radiography, including shielded-room radiography and cabinet radiography, designed to allow admittance of individuals shall:

- (1) Comply with all applicable requirements of this chapter and 641—subrule 40.2(5). If such a system is a certified cabinet X-ray system, it shall comply with all applicable requirements of this chapter and 21 CFR
- (2) Be evaluated at intervals not to exceed one year to ensure compliance with the applicable requirements as specified in 641—subrule 40.2(5). Records of these evaluations shall be maintained for inspection by the agency for a period of two years after the evaluation.
- b. Certified and certifiable cabinet X-ray systems designed to exclude individuals from the interior of the cabi-

net are exempt from the requirements of this chapter except that:

(1) Operating personnel must be provided with either a film badge or a thermoluminescent dosimeter, and reports of the results shall be maintained for inspection by

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(2) No registrant shall permit any individual to operate a cabinet X-ray system until such individual has received a copy of and instruction in the operating procedures for the unit and has demonstrated competence in its use. Records which demonstrate compliance with this subparagraph shall be maintained for inspection by the agency until disposition is authorized by the agency.

(3) Tests for proper operation of interlocks used to control entry to the high radiation area or alarm systems, where applicable, shall be conducted and recorded. Records of these tests shall be maintained for agency inspec-

tion until disposal is authorized by the agency.

(4) The registrant shall perform an evaluation, at intervals not to exceed one year, to determine conformance with 641—subrule 40.2(5). If such a system is a certified cabinet X-ray system, it shall be evaluated at intervals not to exceed one year to determine conformance with 21 CFR 1020.40. Records of these evaluations shall be maintained for inspection by the agency for a period of two years after the evaluation.

c. Certified cabinet X-ray systems shall be maintained in compliance with 21 CFR 1020.40 unless prior approval has been granted by the agency pursuant to 641—38.3(136C).

45.2(7) Registration for industrial radiographic opera-

- a. Radiation machines used in industrial radiographic operations shall be registered in accordance with 641—Chapter 39.
- In addition to the registration requirements in 641—Chapter 39, an application for a certificate of registration shall include the following information:
- (1) A schedule or description of the program for training radiographic personnel which specifies:

1. Initial training,

Periodic training,

3. On-the-job training, and

4. Methods to be used by the registrant to determine the knowledge, understanding, and ability of radiographic personnel to comply with agency rules, registration requirements, and the operating and emergency procedures of the applicant.

(2) Written operating and emergency procedures, including all items listed in Appendix D.

(3) A description of the internal inspection system or other management control to ensure that radiographic personnel follow registration provisions, rules of the agency, and the applicant's operating and emergency procedures

(4) A list of permanent radiographic installations and descriptions of permanent storage and use locations.

- (5) A description of the organization of the industrial radiographic program, including delegations of authority and responsibility for operation of the radiation safety program.
- c. A certificate of registration will be issued if the requirements of 641—Chapter 39 and this subrule are met.
- 641-45.3(136C) Radiation safety requirements for use of sealed sources of radiation in industrial radiography.

45.3(1) Equipment control.

a. Limits on levels of radiation for radiographic exposure devices, source changers and transport containers.

(1) Radiographic exposure devices and all storage containers manufactured prior to January 10, 1992, shall

meet the following minimum criteria:

- 1. Radiographic exposure devices measuring less than 4 inches (10 cm) from the sealed source storage position to any exterior surface of the device shall have no radiation level in excess of 50 milliroentgens (1.29 x 10⁵ C/kg) per hour at 6 inches (15 cm) from any exterior surface of the device.
- 2. Radiographic exposure devices measuring a minimum of 4 inches (10 cm) from the sealed source storage position to any exterior surface of the device and all storage containers for sealed sources or outer containers for radiographic exposure devices, including source changers, shall have no radiation level in excess of 200 milliroentgens (5.16 x 10⁵ C/kg) per hour at any exterior surface, and 10 milliroentgens (2.58 x 10⁶ C/kg) per hour at 39.4 inches (1 m) from any exterior surface.

3. The radiation levels specified are with the sealed

source in the shielded position.

(2) After January 10, 1992, radiographic equipment other than storage containers and source changers shall meet the limits on radiation levels specified in American National Standard (ANSI) N432-1980.

b. Reserved.

- 45.3(2) Locking of sources of radiation.
- a. Each source of radiation shall be provided with a lock or lockable outer container designed to prevent unauthorized or accidental removal or exposure of a sealed source and shall be kept locked at all times except when under the direct surveillance of a radiographer or radiographer trainee, or as may be otherwise authorized pursuant to 45.3(6). Each storage container and source changer likewise shall be provided with a lock and shall be kept locked when containing sealed sources except when the container is under the direct surveillance of a radiographer or radiographer trainee.
- b. Radiographic exposure devices, source changers, and storage containers, prior to being moved from one location to another and also prior to being secured at a given location, shall be locked and surveyed to ensure that the sealed source is in the shielded position.
- c. The sealed source shall be secured in its shielded position by locking the exposure device or securing the remote control each time the sealed source is returned to its shielded position. Then a survey shall be performed to determine that the sealed source is in the shielded position pursuant to 45.3(7)"b."

45.3(3) Storage precautions.

- a. Locked radiographic exposure devices, source changers, and storage containers shall be physically secured to prevent tampering or removal by unauthorized personnel.
- b. Radiographic exposure devices, source changers, or storage containers that contain radioactive material shall not be stored in residential locations. This requirement does not apply to storage of radioactive material in a vehicle in transit for use at temporary job sites, if the licensee complies with 45.1(15), and if the vehicle does not constitute a permanent storage location as described in 45.1(9).
- c. If a vehicle is to be used for storage of radioactive material, a vehicle survey shall be performed after securing radioactive material in the vehicle and before trans-

port to ensure that radiation levels do not exceed the limits specified in 641—subrule 40.2(5) at the exterior surface of the vehicle.

d. A storage or use location is permanent if radioactive material is stored at the location for more than 90 days and any one or more of the following applies to the location:

(1) Telephone service is established by the licensee;

(2) Industrial radiographic services are advertised for or from the location;

(3) Industrial radiographic operations are conducted at other sites due to arrangements made from the location.

45.3(4) Performance requirements for radiography equipment. Equipment used in industrial radiographic operations must meet the following minimum criteria:

- a. Each radiographic exposure device and all associated equipment must meet the requirements specified in American National Standard N432-1980 "Radiological Safety for the Design and Construction of Apparatus for Gamma Radiography" (published as NBS Handbook 136, issued January 1981). This publication has been approved for incorporation by reference by the Director of the Federal Register in accordance with 5 U.S.C. 552(a). This publication may be purchased from the Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402, and from the American National Standards Institute, Inc., 1430 Broadway, New York, New York 10018, telephone (212)642-4900. Copies of the document are available for inspection at the Iowa Department of Public Health, Bureau of Radiological Health, Lucas State Office Building, Des Moines, Iowa 50319.
- b. In addition to the requirements specified in paragraph "a" of this subrule, the following requirements apply to radiographic exposure devices and associated equipment.
- (1) Each radiographic exposure device must have attached to it by the user a durable, legible, clearly visible label bearing the:
- 1. Chemical symbol and mass number of the radionuclide in the device;
- 2. Activity and the date on which this activity was measured:
- 3. Model number and serial number of the sealed source;
 - [°]4. Manufacturer of the sealed source: and
 - 5. Licensee's name, address, and telephone number.
- (2) Radiographic exposure devices intended for use as Type B transport containers must meet the applicable requirements of 641—39.5(136C).
- (3) Modification of any exposure devices and associated equipment is prohibited, unless the design of any replacement component, including source holder, source assembly, controls or guide tubes would not compromise the design safety features of the system.
- c. In addition to the requirements specified in paragraphs "a" and "b" of this subrule, the following requirements apply to radiographic exposure devices and associated equipment that allow the source to be moved out of the device for routine operation:
- (1) The coupling between the source assembly and the control cable must be designed in such a manner that the source assembly will not become disconnected if cranked outside the guide tube. The coupling must be such that it cannot be unintentionally disconnected under normal and reasonably foreseeable abnormal conditions;
- (2) The device must automatically secure the source assembly when it is cranked back into the fully shielded

position within the device. This securing system may only be released by means of a deliberate operation on the exposure device;

- (3) The outlet fittings, lock box, and drive cable fittings on each radiographic exposure device must be equipped with safety plugs or covers which must be installed during storage and transportation to protect the source assembly from water, mud, sand, or other foreign matter;
- (4) Each sealed source or source assembly must have attached to it or engraved in it, a durable, legible, visible label with the words: "DANGER—RADIOACTIVE." The label must not interfere with safe operation of the exposure device or associated equipment;
- (5) The guide tube must have passed the crushing tests for the control tube as specified in ANSI N432 and a kinking resistance test that closely approximates the kinking forces likely to be encountered during use;
- (6) Guide tubes must be used when moving the source out of the device;
- (7) An exposure head or similar device designed to prevent the source assembly from passing out of the end of the guide tube must be attached to the outermost end of the guide tube during radiographic operations;

(8) The guide tube exposure head connection must be able to withstand the tensile test for control units specified in ANSI N432:

- (9) Source changers must provide a system for ensuring that the source will not be accidentally withdrawn from the changer when connecting or disconnecting the drive cable to or from a source assembly.
- d. All newly manufactured radiographic exposure devices and associated equipment acquired by licensees after January 10, 1992, must comply with the requirements of this subrule.
- e. All radiographic exposure devices and associated equipment in use after January 10, 1992, must comply with the requirements of this subrule.
- 45.3(5) Leak testing, repair, tagging, opening, modification, and replacement of sealed sources.
- a. The replacement of any sealed source fastened to or contained in a radiographic exposure device and leak testing, repair, tagging, opening, or any other modification of any sealed source shall be performed only by persons specifically authorized to do so by the agency, the U.S. Nuclear Regulatory Commission, or an agreement state.
- b. Each sealed source shall be tested for leakage at intervals not to exceed six months. In the absence of a certificate from a transferor indicating that a test has been made within the six-month period prior to the transfer, the sealed source shall not be put into use until tested.
- c. The leak test shall be capable of detecting the presence of 0.005 microcurie (185 Bq) of removable contamination on the sealed source. An acceptable leak test for sealed sources in the possession of a radiography licensee would be to test at the nearest accessible point to the sealed source storage position, or other appropriate measuring point, by a procedure to be approved pursuant to 641—39.4(27)"e"(5). Records of leak test results shall be kept in units of microcuries (becquerels) and maintained for inspection by the agency for six months after the next required leak test is performed or until the sealed source is transferred or disposed.
- d. Any test conducted pursuant to 45.3(5)"b" and "c" which reveals the presence of 0.005 microcurie (185 Bq)

- or more of removable radioactive material shall be considered evidence that the sealed source is leaking. The licensee shall immediately withdraw the equipment involved from use and shall cause it to be decontaminated and repaired or to be disposed of in accordance with rules of the agency. Within five days after obtaining results of the test, the licensee shall file a report with the agency describing the equipment involved, the test results, and the corrective action taken.
- e. Each radiographic exposure device shall have permanently attached to it a durable label which has, as a minimum, the instruction: "Danger—Radioactive Material—Do Not Handle—Notify Civil Authorities if Found."

45.3(6) Operating and emergency procedures.

- a. The licensee's operating and emergency procedures shall include instructions in at least the following:
- (1) Handling and use of sources of radiation to be employed such that no individual is likely to be exposed to radiation doses in excess of the limits established in 641—Chapter 40;
- (2) Methods and occasions for conducting radiation surveys;
- (3) Methods for controlling access to radiographic areas;
- (4) Methods and occasions for locking and securing sources of radiation;
- (5) Personnel monitoring and the use of personnel monitoring equipment, including steps that must be taken immediately by radiography personnel in the event a pocket dosimeter is found to be off-scale;
- (6) Transportation to field locations, including packing of sources of radiation in the vehicles, posting of vehicles, and control of sources of radiation during transportation:
- (7) Minimizing exposure of individuals in the event of an accident;
- (8) The procedure for notifying proper personnel in the event of an accident;
 - (9) Maintenance of records; and
- (10) The inspection and maintenance of radiographic exposure devices, source changers, storage containers, and radiation machines.
- b. Each licensee shall conduct an internal audit program to ensure that these rules, the conditions of license(s) and the licensee's operating and emergency procedures are followed by radiographic personnel. Each individual radiographer's performance during an actual radiographic operation shall be audited at intervals not to exceed three months. If a radiographer has not participated in a radiographic operation for more than three months since the last audit, that individual's performance shall be observed and recorded the next time the individual participates in a radiographic operation. Records of audits shall be maintained by the licensee or agency inspection for three years from the date of the audit.
- c. Each licensee shall provide, as a minimum, two radiographic personnel when sources of radiation are used for any industrial radiography conducted other than at a permanent radiographic installation (shielded room, bay, bunker). If one of the personnel is a radiographer trainee, the other shall be a radiographer trainer authorized by the license.
- d. Collimators shall be used in industrial radiographic operations which use crank-out devices except when physically impossible.

- e. No individual other than a radiographer or a radiographer trainee who is under the personal supervision of a radiographer trainer shall manipulate controls or operate equipment used in industrial radiographic operations.
 - 45.3(7) Radiation surveys and survey records.
- a. No radiographic operation shall be conducted unless calibrated and operable radiation survey instrumentation, as described in 45.1(5), is available and for each exposure device used at each site where radiographic exposures are made.
- b. A survey with a calibrated and operable radiation survey instrument shall be made after each radiographic exposure to determine that the sealed source has been returned to its shielded position. The entire circumference of the radiographic exposure device shall be surveyed. If the radiographic exposure device has a source guide tube, the survey shall also include the entire length of the guide tube and collimator.
- c. (1) All potential radiation areas where industrial radiographic operations are to be performed shall be posted in accordance with 641—subrule 40.3(3), based on calculated dose rates, before industrial radiographic operations begin. An area survey shall be performed during the first radiographic exposure (i.e., with the sealed source in the exposed position) to confirm that 641—subrule 40.3(3) requirements have been met and that unrestricted areas do not have radiation levels in excess of the limits specified in 641—40.2(136C).
- (2) Each time the exposure device is relocated or the exposed position of the sealed source is changed, the requirements of 45.3(7)"c"(1) shall be met.
- (3) The requirements of 45.3(7)"c"(2) do not apply to pipeline industrial radiographic operations when the conditions of exposure including, but not limited to, the radiographic exposure device, duration of exposure, source strength, pipe size, and pipe thickness remain constant.
- d. A lock-out survey, in which all accessible surfaces of the radiographic exposure device or source changer are surveyed, shall be made to determine that each sealed source is in its shielded position before securing the radiographic exposure device or source changer.
- e. The sealed source shall be secured in its shielded position by locking the radiographic exposure device or source changer each time the sealed source is returned to its shielded position.
- f. Each radiographic exposure device and source changer shall be locked and the key removed from any keyed lock prior to being moved or transported from one location to another and also prior to being stored at a given location.
- g. If a vehicle is to be used for storage of radioactive material, a vehicle survey shall be performed after securing radioactive material in the vehicle and before transport to ensure that radiation levels do not exceed the limits specified in 641—40.2(136C) at the exterior surface of the vehicle.
- h. Surveys shall be performed on storage containers to ensure that radiation levels do not exceed the limits specified in 641—40.2(136C). These surveys shall be performed initially with the maximum amount of radioactive material present in the storage location and thereafter at the time of the quarterly inventory and whenever storage conditions change.
- i. A survey meeting the requirements of 45.3(7)"b" shall be performed on the radiographic exposure device

and the source changer after every sealed source exchange. A survey shall be made of the storage area as defined in 641—45.2(136C) whenever a radiographic exposure device is being placed in storage.

j. Records shall be kept of the surveys required by 45.3(7)"c," "d," "g," "h," and "i." Such records shall be maintained for inspection by the agency for two years after completion of the survey. If the survey was used to determine an individual's exposure, however, the records of the survey shall be maintained until the agency authorizes their disposition.

45.3(8) Requirements for enclosed radiography.

- a. Systems for enclosed radiography, including shielded-room radiography designed to allow admittance of individuals shall comply with all applicable requirements of this chapter.
- b. Be evaluated at intervals not to exceed one year to ensure compliance with the applicable requirements as specified in 641—subrule 40.2(5). Records of these evaluations shall be maintained for inspection by the agency for a period of two years after the evaluation.
- c. Tests for proper operation of high radiation area control devices or alarm systems, where applicable, shall be conducted, recorded, and maintained in accordance with 45.1(9)"b."
- **45.3(9)** Underwater, offshore platform, and lay-barge radiography.
- a. Underwater, offshore platform, or lay-barge radiography shall not be performed unless specifically authorized in a license issued by the agency in accordance with 45.3(11).
- b. In addition to the other rules of this chapter, the following rules apply to the performance of lay-barge or offshore platform radiography:
- offshore platform radiography:

 (1) Cobalt-60 sources with activities in excess of 20 curies (nominal) and iridium-192 sources with activities in excess of 100 curies (nominal) shall not be used in the performance of lay-barge or offshore platform industrial radiography.
- (2) Collimators shall be used for all industrial radiographic operations performed on lay-barge or offshore platforms.
- 45.3(10) Prohibitions. Industrial radiography performed with a sealed source which is not fastened to or contained in a radiographic exposure device (fishpole technique) is prohibited unless specifically authorized in a license issued by the agency.
- 45.3(11) Licensing for industrial radiographic operations.
- a. Sealed sources used in industrial radiographic operations shall be licensed in accordance with 641—Chapter 39.
- b. In addition to the licensing requirements in 641—Chapter 39, an application for a license shall include the following information:
- (1) A schedule or description of the program for training radiographic personnel which specifies:
 - 1. Initial training,
 - 2. Periodic training,
 - 3. On-the-job training, and
- 4. Methods to be used by the licensee to determine the knowledge, understanding, and ability of radiographic personnel to comply with agency rules, licensing requirements, and the operating and emergency procedures of the applicant;

(2) Written operating and emergency procedures, including all items listed in Appendix D;

(3) A description of the internal inspection system or

other management control to ensure that radiographic personnel follow license provisions, rules of the agency, and the applicant's operating and emergency procedures;

- (4) A list of permanent radiographic installations and descriptions of permanent storage and use locations. Radioactive material shall not be stored at a permanent storage location or used at a permanent use location unless such storage or use location is specifically authorized by the license. A storage or use location is permanent if radioactive material is stored at the location for more than 90 days and any one or more of the following applies to the location:
 - 1. Telephone service is established by the licensee:
- 2. Industrial radiographic services are advertised for or from the location;
- 3. Industrial radiographic operations are conducted at other sites due to arrangements made from the location;
- (5) A description of the organization of the industrial radiographic program, including delegations of authority and responsibility for operation of the radiation safety program;
- (6) A description of the program for inspection and maintenance of radiographic exposure devices and transport and storage containers (including applicable items in 45.1(8) and Appendix A); and

(7) If a license application includes underwater radi-

ography, a description of:

1. Radiation safety procedures and radiographer responsibilities unique to the performance of underwater radiography;

Radiographic equipment and radiation safety equipment unique to underwater radiography; and

3. Methods for gas-tight encapsulation of equipment; (8) If a license application includes offshore platform

or lay-barge radiography, a description of: 1. Transport procedures for radioactive material to be

used in industrial radiographic operations; 2. Storage facilities for radioactive material; and

3. Methods for restricting access to radiation areas.

CHAPTER 45—APPENDIX A

SUBJECTS FOR INSTRUCTION OF RADIOGRAPHER TRAINEES

Training provided to qualify individuals as radiographer trainees in compliance with 45.1(10) shall be presented on a formal basis. The training shall include the following subjects:

- I. Fundamentals of radiation safety
 - A. Characteristics of radiation
 - B. Units of radiation dose and quantity of radioactivity
 - C. Significance of radiation dose
 - 1. Radiation protection standards
 - 2. Biological effects of radiation
 - 3. Case histories of radiography accidents
 - D. Levels of radiation from sources of radiation
 - E. Methods of controlling radiation dose
 - 1. Working time
 - 2. Working distances
 - 3. Shielding
- II. Radiation detection instrumentation to be used
 - A. Use of radiation survey instruments

- 1. Operation
- 2. Calibration
- 3. Limitations
- B. Survey techniques
- C. Use of personnel monitoring equipment

 - Film badges
 Thermoluminescent dosimeters (TLDs)
 - Pocket dosimeters
- III. The requirements of pertinent federal and state regulations

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- IV. The licensee's or registrant's written operating and emergency procedures
- V. Radiographic equipment to be used
 - A. Remote handling equipment
 - B. Operation and control of radiographic exposure devices and sealed sources, including pictures or models of source assemblies (pigtails)
 - Storage and transport containers, source changers
 - Operation and control of X-ray equipment
 - Collimators

CHAPTER 45—APPENDIX B

GENERAL REQUIREMENTS FOR INSPECTION OF INDUSTRIAL RADIOGRAPHIC EQUIPMENT

- I. Panoramic devices (devices in which the sealed source) is physically removed from the shielded container during exposure) shall be inspected for:
 - A. Radiographic exposure unit
 - Abnormal surface radiation levels anywhere on camera, collimator, or guide tube;

 - Condition of safety plugs; Proper operation of locking mechanism;
 - 4. Condition of pigtail connector;
 - Condition of carrying device (straps, handle, 5. etc.);
 - 6. Proper labeling.
 - B. Source tube
 - Rust, dirt, or sludge buildup inside the source
 - Condition of source tube connector:
 - 3. Condition of source stop;
 - Kinks or damage that could prevent proper operation:
 - 5. Presence of radioactive contamination.
 - C. Control cables and drive mechanism
 - Proper drive mechanism with camera, as appropriate:
 - Changes in general operating characteristics;
 - Condition of connector on drive cable; 3.
 - Drive cable flexibility, wear, and rust;
 - 5. Excessive wear or damage to crank assembly
 - Damage to drive cable conduit that could prevent the cable from moving easily;
 - Connection of the control cable connector with the pigtail connector for proper mating;
 - Proper operation of source position indicator, if applicable:
 - Presence of radioactive contamination.
- II. Directional beam devices shall be inspected for:
 - A. Abnormal surface radiation;
 - Changes in the general operating characteristics of the unit;
 - Proper operation of shutter mechanism;
 - D. Chafing or binding of shutter mechanism;

E.	Damage to the	device	that r	night in	npair its	opera-
	tion;			-		

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F. Proper operation of locking mechanism;

- G. Proper drive mechanism with camera, as appropriate;
- H. Condition of carrying device (strap, handle, etc.);

I. Proper labeling.

III. X-ray equipment shall be inspected for:

- A. Change in the general operating characteristics of the unit;
- B. Wear of electrical cables and connectors;

C. Proper labeling of console:

- D. Proper console with machine, as appropriate;
- E. Proper operation of locking mechanism;

F. Timer run-down cutoff;

G. Damage to tube head housing that might result in excessive radiation levels.

CHAPTER 45—APPENDIX C

TIME REQUIREMENTS FOR RECORD KEEPING

Specific Section	Name of Record	Time Interval Required for Record Keeping
45.1(4)	Receipt, transfer and disposal.	Until disposal is authorized by the agency.
45.1(5)	Survey instrument calibrations.	2 years.
45.3(4)	Leak tests.	2 years.
45.1(6)	Quarterly inventory.	2 years.
45.1(7)		Until disposal is
45.1(7)	Utilization logs.	
		authorized by the
45 1(0)	Ó	agency.
45.1(8)	Quarterly inspection	•
	and maintenance.	2 years.
45.1(9)	High radiation area	Until disposal is
•	control devices or	authorized by the
	alarm systems.	agency.
45.1(10)	Training and testing	Until disposal is
	records.	authorized by the
		agency.
45.1(12)	Pocket dosimeter	2 years or until
	readings.	disposal is author-
	•	ized by the agency
		if dosimeters were
		used to determine
		external radiation
		dose.
	Pocket dosimeter	uose.
	calibrations.	2 vaora
		2 years.
	Alarming ratemeter	2 110000
	calibrations.	2 years.
	Alarming ratemeter	2
15 2(6)	functions.	2 years.
45.3(6)	Internal audit program.	3 years.
45.0(5)	Radiographer audits.	2 years.
45.2(5)	Radiation surveys.	2 years or until
and	•	disposal is author-
45.3(7)		ized by the agency if
		a survey was used to
		determine an individ-
		ual's exposure.
45.1(16)	Records at temporary	During temporary job
-	inh sites	cite operations

site operations.

job sites.

45.2(6) and 45.3(8)	Annual evaluation of enclosed X-ray systems. Film badge or TLD records.	2 years. Until disposal is authorized by the agency.
45.1(9)	Tests of Chapter 45 high radiation control devices and alarm	Until disposal is authorized by the agency.
45.2(6)	systems. Evaluation of certified cabinet X-ray systems.	2 years.

CHAPTER 45—APPENDIX D

OPERATING AND EMERGENCY PROCEDURES

The licensee's or registrant's operating and emergency procedures shall include instructions in at least the following:

A. Handling and use of sources of radiation for industrial radiography such that no individual is likely to be exposed to radiation doses that exceed the limits established in 641—Chapter 40;

B. Methods and occasions for conducting radiation sur-

veys, including lock-out survey requirements;

C. Methods for controlling access to industrial radiography areas;

D. Methods and occasions for locking and securing sources or radiation;

E. Personnel monitoring and the use of personnel monitoring equipment, including steps to be taken immediately by industrial radiographic personnel in the event a pocket dosimeter is found to be off-scale;

F. Methods of transporting equipment to field locations, including packing of sources of radiation in the vehicles, placarding of vehicles, and controlling of sources of radiation during transportation (including applicable U.S. Department of Transportation requirements);

G. Methods or procedures for minimizing exposure of individuals in the event of an accident, including procedures for a disconnect accident, a transportation accident, and loss of a sealed source;

H. Procedures for notifying proper personnel in the event of an accident;

I. Specific posting requirements;

J. Maintenance of records (Appendix C); and

K. Inspection and maintenance of radiographic exposure devices, source changers, storage containers, transport containers, source guide tubes, crank-out devices, and radiation machines.

These rules are intended to implement Iowa Code chapter 136C.

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PUBLIC SAFETY DEPARTMENT[661]

Notice of Intended Action

Twenty-five interested persons, a governmental subdivision, an agency or an association of 25 or more persons may demand an oral presentation hereon as provided in Iowa Code §17A.4(1)"b."

Notice is also given to the public that the Administrative Rules Review Committee may, on its own motion or on written request by any individual or group, review this proposed action under §17A.8(6) at a regular or special meeting where the public or interested persons may be heard.

Pursuant to the authority of the Iowa Code section 103A.7, the Building Code Commissioner hereby gives Notice of Intended Action to amend Chapter 16, "State of Iowa Building Code," Iowa Administrative Code, with the approval of the Building Code Advisory Council.

These amendments update the State of Iowa Building Code to include the latest editions of the nationally recognized model codes which are adopted by reference and

amended as necessary.

Public hearings regarding these amendments will be held before the Building Code Advisory Council on June 25, 1992, at 10 a.m. and at 1 p.m. Both hearings will be held in the Wallace State Office Building, second floor conference room.

Persons may present their views concerning these amendments at either public hearing orally or in writing. Persons who wish to make oral presentations at either hearing should contact the Building Code Bureau, Fire Marshal Division, Iowa Department of Public Safety, Wallace State Office Building, Des Moines, Iowa 50319-0047; or by telephone at (515)281-5132 at least one day prior to the hearings. Any interested person may make oral or written comments concerning these proposed amendments to the Building Code Bureau by mail, telephone, or in person at the above address prior to June 25, 1992.

These amendments are intended to implement Iowa Code sections 103A.7, 103A.8 and 103A.9.

The following amendments are proposed.

ITEM 1. Amend rule 661—16.110(103A) as follows: Amend subrule 16.110(1), second and third unnum-

bered paragraphs, to read as follows:

The Iowa state building code (ISBC) 100.0 was adopted by the advisory council and became effective on February 1, 1973. ISBC 100.0 contained the 1970 editions of the national model codes. Upon adoption of the 1973 editions of the model codes, the number was changed to ISBC 200.0, which became effective March 1, 1975. ISBC 300.0 designates the adoption of the 1976 editions of the model codes and became effective on September 1, 1977. ISBC 400.0 is the adoption of the 1979 editions of the model codes and became effective on March 1, 1981. ISBC 500.0 is the adoption of the 1982 editions of the model codes and became effective on August 12, 1983. ISBC 600.0 is the adoption of the 1985 editions of the model codes and became effective on January 1, 1987. ISBC 700.0 is the adoption of the 1988 editions of the model codes which became effective on January 1, 1989.

These revisions will adopt the 1988 1991 editions of the model codes and will be designated as ISBC 700.0 800.0. Future minor revisions or additions will be indi-

cated by changes in the designation as ISBC 700.1, 700.2 800.1, 800.2, etc.

Amend subrule 16.110(3) as follows:

16.110(3) Title. These administrative and construction rules and regulations (ISBC 700.0 800.0) promulgated by the commissioner and approved by the building code advisory council, shall be known as the state building code, may be cited as such and will be referred to herein as this code.

ITEM 2. Amend rule 661—16.120(103A) as follows: Amend subrule 16.120(2) to read as follows:

16.120(2) The Uniform Building Code and appendices, 1988 1991 edition, the Uniform Building Code Standards, 1988 1991 edition, as published by the International Conference of Building Officials.

Amend subrule 16.120(4) to read as follows:

16.120(4) The Uniform Mechanical Code, 1988 1991 edition, as published by the International Conference of Building Officials and the International Association of Plumbing and Mechanical Officials.

Amend subrule 16.120(5) to read as follows:

16.120(5) The Uniform Plumbing Code, 1988 1991 edition, as published by the International Association of Plumbing and Mechanical Officials.

ITEM 3. Amend rule 661—16.121(103A) as follows: Amend subrule 16.121(1) to read as follows:

16.121(1) The CABO One and Two Family Dwelling Code, 1986 1989 edition, as published by the Council of American Building Officials.

Amend subrule 16.121(3) to read as follows:

16.121(3) Any governmental subdivision which has by ordinance or resolution adopted the state building code as their building code may delete chapter 44 or chapter 45 of the Uniform Building Code, 1988 1991, and substitute their own specific requirements as deemed necessary by those in authority.

ITEM 4. Amend subrule 16.130(14) as follows:

16.130(14) Use or occupancy. No building or structure of A, E, I, H, B or R, occupancy classifications as defined by the Uniform Building Code, 1988 1991 edition, shall be used or occupied, and no change in the existing occupancy classification of a building or structure or portion thereof shall be made until the building official has issued a certificate of occupancy, if so required by local laws or ordinances.

ITEM 5. Amend Rule 661—16.131(103A) to read as follows:

661—16.131(103A) Plans and specifications review. Plans Architectural technical submissions, engineering documents or plans and specifications for all state-owned buildings, and other buildings covered by Iowa Code chapters 103A and 104A shall be filed with submitted to and approved by the commissioner before construction is commenced begun. Such plans and specifications submittals shall be filed by the owner or an authorized agent, agency or the responsible design architect or engineer whose seal shall appear on each page of the drawings and on the title page of the specifications; said architect or engineer-shall be legally qualified to practice such profession in the state of Iowa. Submittals to the commissioner shall be certified or stamped and signed as required by Iowa Code chapters 114 and 118 unless the applicant has certified on the submittal to the applicability of a specific

PUBLIC SAFETY DEPARTMENT[661](cont'd)

exception under Iowa Code section 118.18 and the submittal does not constitute the practice of professional engineering as defined by Iowa Code section 114.2.

EXCEPTION EXCEPTIONS:

1. Plans and specifications reviewed by a local building official or other duly authorized person or agency in accord with as provided in Iowa Code chapters 103A and 104A shall be exempt from filing said documents being filed with the commissioner.

2. Preliminary or intermediate documents may be submitted for informal review or general discussion concerning compliance with the appropriate regulations if the documents are labeled "preliminary," "not for construction" or similar wording indicating that the documents are not being filed for final approval.

ITEM 6. Amend subrule 16.140(1) as follows:

Rescind the introductory paragraph and insert in lieu

thereof the following:

16.140(1) Adoption. Chapters 4 to 30 and 32 to 56 and Chapter 60 on standards with all appendices of the Uniform Building Code, 1991 edition, and all standards except 31-1 of the Uniform Building Code standards, 1991 edition, as published by the International Conference of Building Officials, 5360 South Workman Mill Road, Whittier, California 90601, are hereby adopted by reference as the construction rules and regulations Division I, Part 4 of the Iowa state building code, administration section, with the following deletions, revisions and amendments:

Rescind paragraph "b" and insert in lieu thereof the

following:

b. Delete appendix Chapters 1, 7, 12 Divisions I and III, 23 Divisions II and III, 26, 31, 32, 51, 53 and 70.

Amend the NOTE in paragraph "d" to read as follows: The requirements of the American National Standard ANSI A117.1 - 1980 1986 may also be used for toilet facilities which are accessible to the physically handicapped.

Amend paragraph "e" to read as follows:

e. Delete the second third paragraph of Section 1204

and insert in lieu thereof the following:

Access to, and egress from, buildings required to be accessible shall be provided as specified in Division VII

Every sleeping room below the fourth story, and dwelling unit basements which have habitable rooms, shall have at least one operable window or door approved for emergency escape or rescue which shall open directly into a public street, public alley, yard or exit court. The units shall be operable from the inside to provide a full, clear opening without the use of separate tools.

Rescind paragraph "f" and insert in lieu thereof an

additional section 1214 in U.B.C. 1991 to read as follows:

f. Section 1214. Buildings containing four or more individual dwelling units and all hotels and motels shall comply with the applicable provision of Division VII of the Iowa state building code.

ITEM 7. Amend subrule 16.300(1), introductory paragraph, to read as follows:

16.300(1) Adoption. Chapters 4 to 20, and appendices A, B, and C of the Uniform Mechanical Code, 1988 1991 edition, and published by the International Conference of Building Officials, 5360 South Workman Mill Road, Whittier, California 90601, are hereby adopted as the Mechanical Rules and Regulations, Division III of the state building code with amendments as follows:

ITEM 8. Amend subrule 16.400(1) as follows:

Amend the introductory paragraph to read as follows: 16.400(1) Adoption. Chapters 1 to 13 and appendix D of the Uniform Plumbing Code, 1988 1991 edition, as published by the International Association of Plumbing and Mechanical Officials, 20001 South Walnut Drive South, Walnut, California 91789, are hereby adopted by reference as the Plumbing Rules and Regulations, Division IV, of the Iowa state building code, with amendments

as follows:

Rescind paragraph "j," subparagraph (c), and insert in

lieu thereof the following:

(c) In single- and two-family dwellings, no vent will be required on a two-inch basement P trap provided that it drains into a properly vented house drain or branch which is three inches or larger in diameter (except for a water closet branch) on the sewer side at a distance of five feet or more from the base of the stack and the branch to the P trap is not more than eight feet in length. In buildings of one story, where only a lavatory or a urinal empties into the stack, the five-foot distance from the base of the stack does not apply.

Rescind paragraph "k."

Rescind paragraph "r" and insert in lieu thereof the

r. Section 1003. Delete subsection 1003(b) and re-

place as follows:

(b) The premise owner or responsible person shall have the backflow prevention assembly tested by a person competent in that particular field at the time of installation, repair, or relocation and at least on an annual schedule thereafter or as required by the authority having iurisdiction.

Rescind paragraph "s" and insert in lieu thereof the

following:

s. All water service yard piping shall, whenever feasible, be no less than five feet below the surface of the ground.

Amend paragraph "y" to read as follows:

y. Appendices. Except as provided in amendment "z" the The appendices in this code are not approved as rules. although those other than E (mobile home parks), G (swimming pools), and I (private sewage disposal systems) may be used as a point of reference when circumstances warrant. The Iowa Administrative Code (IAC) 641—Chapter 15 provides the requirements for swimming pools and spas, and (IAC) 567—Chapters 49 and 69 provide the requirements for private water well and sewage disposal systems.

Rescind paragraph "z."

ITEM 9. Rescind the table entitled "Minimum Plumbing Fixtures" in rule 661-16.401(104B) and replace with the following:

PUBLIC SAFETY DEPARTMENT[661](cont'd)

MINIMUM PLUMBING FIXTURES

Type of Building or Occupancy	Water Closets (Fixtures per occupants)		Urinals** (Fixtures per occupants)	Lavatories (Fixtures per occupants)	
Places of Assembly for Public Use, including but not limited to Theaters, Auditoriums, and Convention Halls	Male Female 3:1-50 4:51-100 3:201-400 8:101-200 11:201-400 Over 400, add one fixture for each additional 500 males and two for each 300 females		1:1-100 2:101-200 3:201-400 4:401-600 Over 600 add one fixture for each additional 500 males	Male 1:1-200 2:201-400 3:401-750 Over 750, add one	Female 1:1-201 2:201-400 3:401-750
				fixture for each additional 500 persons	
Restaurants, Pubs and Lounges*	Male 1:1-50 2:51-150 3:151-300	Female 1:1-50 2:51-150 4:151-300	1:1-150 Over 150, add one	Male 1:1-150 2:151-200 3:201-400	Female 1:1-150 2:151-200 3:201-400
	Over 300, add one fixture for each additional 200 persons		fixture for each additional 150 males	Over 400, add one fixture per each additional 400 persons	

^{*}Restrooms in restaurants which have occupancies of 50 or less comply with these requirements if they have one water closet and one lavatory.

** Urinal requirements apply only to male-only restrooms.

1. The division of occupancy is to be based upon one half being male and one half being female. The number of occupants shall be determined by use and the occupancy class of the state building code or the local building code which is in effect.

2. The number of fixtures may be graduated within the group,

Example: 8:101-200

- 4 fixtures are required for 100 persons.
- 5 fixtures are required for 101-125 persons.
- 6 fixtures are required for 126-150 persons.
- 7 fixtures are required for 151-175 persons.
- 8 fixtures are required for 176-200 persons.
- 3. Accessibility for the physically disabled shall be provided as required by Division VII of the State Building Code.

ITEM 10. Amend subrule 16.500(1) as follows:

Amend the introductory paragraph to read as follows:

16.500(1) Adoption. The CABO One and Two Family Dwelling Code, Parts II to VIII, Appendices A and B, 1986 1989 Edition, published by the Council of American Building Officials, 5203 Leesburg Pike, Falls Church, Virginia 22041, under the auspices of the code group listed in Division I, Part 2 subrule 16.121(1) of this code is adopted as an optional alternate for one- and twofamily dwellings, with the following deletions and amendments:

Amend paragraph "c" to read as follows:

c. Revise the first sentence of Section R-211.2 R-210.2 to read as follows:

Basements which have habitable rooms and every sleeping room below the fourth story shall have at least one operable window or exterior door approved for emergency egress or rescue.

Amend paragraph "d" to read as follows:

d. Add a note to Table No. R-304.4.2 R-304.3b on page 26 29 to read as follows:

NOTE: The provisions of amendment $\frac{m+1}{2}$ "k" or of subrule 16.140(1) of Part 4 of Division I of this code may be used as an acceptable method of reinforcement for masonry and concrete foundations.

Rescind paragraph "i" and insert in lieu thereof the following:

i. Delete Part VI (page 247) and insert in lieu thereof the following:
PART VI—Electrical

The electrical requirements shall conform to the provisions of the National Electrical Code 1990 Edition (National Fire Protection Association 70-1991) adopted by rule 661-16.200(103A) which apply to one- and twofamily dwellings.

Delete subheading "Part VI Electrical" and the introductory paragraph under that subheading.

Amend paragraph "j" as follows:

j. Delete the requirements of Part VII (page 195 249)

and insert in lieu thereof the following:

The energy conservation requirements shall conform to the provisions of Division VIII rule 661-16.800(103A) of this code which apply to one- and two-family dwellings.

NOTICES

REVENUE AND FINANCE DEPARTMENT[701]

Notice of Intended Action

Twenty-five interested persons, a governmental subdivision, an agency or an association of 25 or more persons may demand an oral presentation hereon as provided in Iowa Code §17A.4(1)"b."

Notice is also given to the public that the Administrative Rules Review Committee may, on its own motion or on written request by any individual or group, review this proposed action under §17A.8(6) at a regular or special meeting where the public or interested persons may be heard.

Pursuant to the authority of Iowa Code sections 17A.22 and 421.14, the Iowa State Board of Tax Review, an administrative and budgetary unit created by statute within the Department of Revenue and Finance, hereby gives Notice of Intended Action to amend Chapter 2, "Conduct of Appeals, Rules of Practice and Procedure," Iowa Administrative Code.

The amendment to Chapter 2 is proposed to authorize the Chairperson of the Board or designee to simplify the issues to be decided upon hearing by ordering a prehearing conference to clarify the issues in dispute; to grant a continuance under rule 701—2.14(421,17A); to enter orders resolving discovery disputes; and to order the parties to make a better statement of the claim or defense under rule 701—2.10(421,17A). The State Board of Tax Review as a whole has this authority at the present time. This amendment to the rules will save the time and expense of a special meeting of the entire Board called for the sole purpose of entering routine orders preliminary to the hearing of the appeal on its merits.

The State Board of Tax Review has determined that the proposed amendment will not have an impact on small businesses as defined in Iowa Code section 17A.31(1).

The proposed amendment will not necessitate additional expenditures by political subdivisions or agencies and entities which contract with political subdivisions.

Any interested person may make written suggestions or comments on this proposed amendment on or before June 26, 1992. Such written comments should be directed to the State Board of Tax Review, Iowa Department of Revenue and Finance, Hoover State Office Building, P. O. Box 10460, Des Moines, Iowa 50306.

Persons who want to orally convey their views should contact Peggy Christian, Secretary, State Board of Tax Review, Iowa Department of Revenue and Finance, telephone (515)281-3417, or at the State Board of Tax Review offices on the fourth floor of the Hoover State Office Building.

Requests for a public hearing must be received by June 19, 1992.

This amendment is intended to implement Iowa Code chapters 17A and 421.

The following amendment is proposed.

Amend 701—Chapter 2 by adding the following new rule to be designated 701—2.12(421) and renumbering present rules 701—2.12(421,17A) through 2.22(421, 17A) accordingly:

701—2.12(421) Authority of chairperson to enter prehearing and procedural orders. During periods when the board is not in session, the chairperson, or other member designated by the chairperson, may enter preliminary orders for a party to file a better statement of the nature of a claim or defense under rule 701-2.10(421,17A) or a continuance under rule 701-2.14(421,17A) or order a prehearing conference before the board to be conducted under rule 701—2.13(421,17A). The chairperson, or other member designated by the chairperson, may also enter preliminary orders on discovery disputes or other prehearing matters which should be timely resolved in order to assist the progress of the appeal toward final hearing before the board. The secretary shall immediately mail a copy of any preliminary order entered under this rule to the two members of the board who did not participate in the order. All orders entered under this rule shall become the action of the board unless both members of the board who did not participate in the order notify the secretary of their objection within five days of its receipt by them. In case both members of the board who did not participate in the order object, then the order shall be null and void. The secretary shall notify the parties of the order entered under this rule, when it becomes the order of the board. The chairperson, or other member designated by the chairperson, may grant a continuance of the hearing on appeal for just cause even though there is insufficient time before the scheduled hearing for other members of the board to object to the continuance.

This rule is intended to implement Iowa Code sections 17A.15 and 421.1(4).

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REVENUE AND FINANCE DEPARTMENT[701]

Notice of Intended Action

Twenty-five interested persons, a governmental subdivision, an agency or an association of 25 or more persons may demand an oral presentation hereon as provided in Iowa Code §17A.4(1)"b."

Notice is also given to the public that the Administrative Rules Review Committee may, on its own motion or on written request by any individual or group, review this proposed action under \$17A.8(6) at a regular or special meeting where the public or interested persons may be heard.

Pursuant to the authority of Iowa Code sections 421.14, 422.35(11) and 422.68(1), the Iowa Department of Revenue and Finance hereby gives Notice of Intended Action to amend Chapter 53, "Determination of Net Income," Chapter 54, "Allocation and Apportionment," and Chapter 59, "Determination of Net Income," Iowa Administrative Code.

The amendments to rules 701—53.2(422) and 701—59.2(422) are made to adopt a long-standing policy of the Department to look at and apply the federal limitation on the carryover of a net operating loss after reorganizations and mergers.

The amendments to subrule 54.6(3) change the attribution of gross receipts from financial services from where the service is performed to the location of the consumer of the service.

New subrule 54.6(6) attributes the gross receipts from the rental of real property to the situs of the property. Also, new subrule 54.6(6) attributes the gross receipts

from rental of tangible personal property to this state if the property is utilized wholly in this state or to this state based on the extent of usage in this state.

The amendment to rule 701—54.9(422) clarifies tax a taxpayer may petition the Director of Revenue and Finance for an alternative method of apportionment if the taxpayer is of the opinion the method of apportionment required by Chapter 54 of the Department's rules creates an injustice.

The proposed amendments will not necessitate additional expenditures by political subdivisions or agencies and entities which contract with political subdivisions.

The Department has determined that these proposed amendments may have an impact on small business. The Department has considered the factors listed in Iowa Code section 17A.31(4). The Department will issue a regulatory flexibility analysis as provided in Iowa Code sections 17A.31 to 17A.33 if a written request is filed by delivery or by mailing postmarked no later than June 16, 1992, to the Policy Section, Technical Services Division, Iowa Department of Revenue and Finance, Hoover State Office Building, P.O. Box 10457, Des Moines, Iowa 50306. The request may be made by the Administrative Rules Review Committee, the Governor, a political subdivision, at least 25 persons who qualify as a small business under Iowa Code sections 17A.31 to 17A.33, or an organization of small businesses representing at least 25 persons which is registered with this agency under Iowa Code sections 17A.31 to 17A.33.

Any interested person may make written suggestions or comments on these proposed amendments on or before June 26, 1992. Such written comments should be directed to the Policy Section, Technical Services Division, Iowa Department of Revenue and Finance, Hoover State Office Building, P.O. Box 10457, Des Moines, Iowa 50306.

Persons who want to orally convey their views should contact the Policy Section, Technical Services Division, Iowa Department of Revenue and Finance, at (515)281-4250 or at Department of Revenue and Finance offices on the fourth floor of the Hoover State Office Building.

Requests for a public hearing must be received by June 19, 1992.

The amendments are intended to implement Iowa Code chapter 422.

The following amendments are proposed.

ITEM 1. Amend rule 701—53.2(422) by adding the following new subrule 53.2(6):

53.2(6) The carryover of Iowa net operating losses after reorganizations or mergers is limited to the same extent as the carryover of a net operating loss is limited under the provisions of sections 381 through 386 of the Internal Revenue Code and regulations thereunder or any other section of the Internal Revenue Code or regulations thereunder. Where the taxpayer files as a part of a consolidated income tax return for federal income tax purposes, but a separate return for Iowa income tax purposes, the limitation on an Iowa net operating loss carryover must be determined as though a separate income tax return was filed for federal income tax purposes.

ITEM 2. Amend the implementation clause of rule 701—53.2(422) to read as follows:

This rule is intended to implement Iowa Code section 422.35 as amended by 1990 Iowa Acts, Senate File 2114.

ITEM 3. Amend subrule 54.6(3) to read as follows:

54.6(3) Business income of a financial organization, excepting a financial institution exempted from the corporation income tax under Iowa Code section 422.34(1) attributable to Iowa shall be:

a. In the case of taxable income of a taxpayer whose income-producing activities are confined solely to this

state, the entire net income of such taxpayer.

- b. In the case of taxable income of a taxpayer who conducts income-producing activities as a financial organization partially within and partially without this state, that portion of its net income as its gross business in this state is to its gross business everywhere during the period covered by its return, which portion shall be determined as the sum of:
- (1) Fees, commission or other compensation for financial services rendered for a customer located in this state or an account maintained within this state;
- (2) Gross profits from trading in stocks, bonds or other securities managed within this state;
- (3) Interest income from a loan on real property located in this state. It will be presumed that interest on loans on personal property is allocable to the office making the loan. Other interest and income from service charges, fees, gains from the sale of assets and other miscellaneous carnings will be presumed allocable to the office charging for the services or carning the income. For tax years beginning on or after January 1, 1989, the following rules shall apply. Interest income from a loan on real property located in this state. Interest and other receipts from assets in the nature of loans and installment obligations if the borrower is located within this state. Other fees and other miscellaneous earnings if connected with loans to borrowers within this state.
- (4) Interest charged to customers within this state or to accounts at places of business maintained within this state for carrying debit balances of margin accounts, without deduction of any costs incurred in carrying such accounts; and
- (5) Interest, lease payments, or other receipts from financing leases, installment sales contracts, leases or other financing instruments received from customers within this state; and

(5) (6) Any other gross income resulting from the operation as a financial organization within this state.

A "financial organization" means an association, joint stock company or corporation a substantial part of whose assets consist of intangible personal property and a substantial part of whose gross income consists of dividends or interest or other charges resulting from the use of money or credit.

ITEM 4. Rescind subrule 54.6(6) and insert the following in lieu thereof:

54.6(6) Gross receipts from rent or royalties or other fees received for the use of real property are attributable to this state if the real property is located in this state.

Gross receipts from rent, royalties, license fees, or other fees received for the use of tangible personal property are attributable to this state to the extent that the property is utilized in this state. The extent of utilization of tangible personal property in this state is determined by multiplying the rents, royalties, license fees or other fees by a fraction, the numerator of which is number of days or other measure of physical location of the property in the state during the rental period in the taxable year and the de-

nominator of which is the number of days or other measure of physical location of the property everywhere during all rental periods in the taxable year. If the physical location of property during the rental period is unknown or not ascertainable by the taxpayer, tangible personal property is utilized in the state in which the property was located at the time the rental payer obtained possession.

An example of another measure of physical location of property is where a lessee of transportation equipment is required to report to the lessor miles traveled by state.

a. A lessee takes possession of a rental car in this state. Six days later after driving 1,500 miles, the rental car is returned to the lessor in this state. Absent evidence to the contrary, the rental receipts are attributable to this state.

b. A lessee takes possession of a rental car in this state. Six days later after driving 1,500 miles, the rental car is returned to the lessor in an adjacent state. Absent evidence to the contrary, it is assumed that 50 percent of the rental receipts are attributable to this state.

c. A lessee takes possession of a rental semi truck in another state. The lessee is required to maintain mileage records by state for purposes of special fuel tax. The lessee provides copies of these records to the lessor. The lessor must use these records to determine the portion of the rental receipts that are attributable to this state.

ITEM 5. Amend rule 701—54.9(422), introductory paragraph, to read as follows:

701—54.9(422) Allocation and apportionment of income in special cases. If a taxpayer feels that the allocation and apportionment method as prescribed by Iowa Code section 422.33, subsection 2, or Chapter 54 of the department's rules, in its case results in an injustice, such the taxpayer may petition the department for permission to determine the taxable net income, both allocable and apportionable, to the state on some other basis.

ITEM 6. Amend rule 701—59.2(422) by adding the fol-

lowing new subrule 59.2(6):

59.2(6) The carryover of Iowa net operating losses after reorganizations or mergers is limited to the same extent as the carryover of a net operating loss is limited under the provisions of sections 381 through 386 of the Internal Revenue Code and regulations thereunder or any other section of the Internal Revenue Code or regulations thereunder. Where the taxpayer files as a member of a consolidated income tax return for federal income tax purposes, but is required to file a separate franchise tax return, the limitation on an Iowa net operating loss carryover must be determined as though a separate income tax return was filed for federal income tax purposes.

ARC 3034A

REVENUE AND FINANCE DEPARTMENT[701]

Notice of Intended Action

Twenty-five interested persons, a governmental subdivision, an agency or an association of 25 or more persons may demand an oral presentation hereon as provided in Iowa Code §17A.4(1)"b."

Notice is also given to the public that the Administrative Rules Review Committee may, on its own motion or on written request by any individual or group, review this proposed action under \$174.860 at a regular or special meeting where the public or interested persons may be heard.

Pursuant to the authority of Iowa Code sections 421.14, 422.33(2)"b"(3) and 422.68(1), the Iowa Department of Revenue and Finance hereby gives Notice of Intended Action to amend Chapter 54, "Allocation and Apportionment," Iowa Administrative Code.

Rule 701—54.6 and subrule 54.6(1) are being amended so that the apportionment of income by service companies is consistent with the apportionment of income by manufacturers and sellers of tangible personal property. Current subrule 54.6(1) uses person hours to attribute gross receipts from the performance of services to Iowa where the service is performed partly within and partly without the state, without consideration of the location where the recipient of the service receives benefit of the service.

The amended subrule 54.6(1) creates equality with manufacturers and sellers of tangible personal property for providers of service in that it establishes a destination basis for determination of where the recipient of the services receives the benefit of the service.

In addition, the subrule provides a method for a taxpayer to present evidence that the apportionment method set forth in the subrule is inappropriate and request the use of an alternative method of apportionment. If the Department agrees that the taxpayer's alternative method of apportionment more reasonably attributes income to business activities in Iowa, the taxpayer will be authorized to use that method of apportionment until the factual situation changes or the Department prospectively notifies the taxpayer that the alternative method of apportionment may no longer be used.

The method of apportionment in revised subrule 54.6(1) may, at the taxpayer's election, be applied to tax years beginning on or after January 1, 1991; however, revised subrule 54.6(1) must be used for all tax years beginning on or after January 1, 1992.

The proposed amendments will not necessitate additional expenditures by political subdivisions or agencies and entities which contract with political subdivisions.

The Department has determined that the proposed amendments may have an impact on small business. The Department has considered the factors listed in Iowa Code section 17A.31(4). The Department will issue a regulatory flexibility analysis as provided in Iowa Code sections 17A.31 to 17A.33 if a written request is filed by delivery or by mailing postmarked no later than June 16, 1992, to the Policy Section, Technical Services Division, Iowa Department of Revenue and Finance, Hoover State Office Building, P.O. Box 10457, Des Moines, Iowa 50306. The request may be made by the Administrative Rules Review Committee, the Governor, a political subdivision, at least

25 persons who qualify as a small business under Iowa Code sections 17A.31 to 17A.33, or an organization of small businesses representing at least 25 persons which is registered with this agency under Iowa Code sections 17A.31 to 17A.33.

Any interested person may make written suggestions or comments on the proposed amendments on or before June 26, 1992. Such written comments should be directed to the Policy Section, Technical Services Division, Iowa Department of Revenue and Finance, Hoover State Office Building, P.O. Box 10457, Des Moines, Iowa 50306.

Persons who want to orally convey their views should contact the Policy Section, Technical Services Division, Iowa Department of Revenue and Finance, at (515)281-4250 or at Department of Revenue and Finance offices on the fourth floor of the Hoover State Office Building.

Requests for a public hearing must be received by June 19, 1992.

These amendments are intended to implement Iowa Code section 422.33.

The following amendments are proposed.

ITEM 1. Amend rule 701—54.6(422), introductory paragraph, to read as follows:

701—54.6(422) Apportionment of income derived from business other than the manufacture or sale of tangible personal property. Income derived from business other than the manufacture or sale of tangible personal property shall be attributed to Iowa in the proportion which the Iowa gross receipts bear to the total gross receipts. Gross receipts are attributable to this state includable in the numerator of the apportionment factor in the proportion which the income-producing activity which gave rise to the receipts is performed within recipient of the service receives benefit of the service in this state.

ITEM 2. Rescind subrule 54.6(1) and adopt the following in lieu thereof:

54.6(1) Services other than those set forth in subrules 54.6(3), 54.6(4) and 54.6(5), and rule 701—54.7(422). With respect to a specific contract or item of income, all gross receipts from the performance of services are includable in the numerator of the apportionment factor if the recipient of the service receives all of the benefit of the service in Iowa. If the recipient of the service receives some of the benefit of the service in Iowa with respect to a specific contract or item of income, the gross receipts are includable in the numerator of the apportionment factor in proportion to the extent the recipient receives benefit of the service in Iowa.

The following are noninclusive examples of the application of this subrule.

- a. A real estate development firm from State A is developing a tract of land in Iowa. The real estate development firm from State A engages a surveying company from State B to survey the tract of land in Iowa. The survey work is completed and the plats are drawn in Iowa. The gross receipts from this survey work are attributable to Iowa and included in the numerator of the apportionment factor because the recipient of the service received all of the benefits of the service in Iowa.
- b. A corporation headquartered in State Y is building an office complex in Iowa. The corporation from State Y contracts with an engineering firm from State X to oversee construction of the buildings on the site. The engi-

neering firm performs some of their service in Iowa at the building site and also some of their service in State X. The gross receipts from the engineering service are attributable to Iowa and included in the numerator of the apportionment factor because the recipient of the service received all of the benefit of the service in Iowa.

- c. A corporation from State A contracts with a computer software company from State D to develop and install a custom software application in a business office in Iowa of the company from State A. The software firm does consulting work on the project in State A and in Iowa. The software development is done in State D and Iowa. The software package is delivered to the corporation from State A in Iowa. The gross receipts from the software development are attributable to Iowa and included in the numerator of the apportionment factor because the recipient of the service received all of the benefit of the service in Iowa.
- d. A corporation located in Iowa performs direct mail activities for a customer located in State X. The direct mail activities include the preparation and mailing of materials to households located throughout the United States. The corporation located in Iowa performed some activities related to the direct mail contract in State X. One percent of the direct mailings went to addresses within Iowa. One percent of the gross receipts related to this direct mail contract are attributable to Iowa and included in the numerator of the apportionment factor because the recipient of the service received the 1 percent of the benefit of the service in Iowa.
- e. A corporation located in State A performs direct mail activities for a customer located in State X. The corporation has nexus with Iowa due to other activities of the unitary business. The direct mail activities include the preparation and mailing of materials to households throughout the United States. The corporation located in State A printed and mailed the direct mail materials to households on a mailing list prepared by the direct mailing company in State A. Five percent of the direct mailings went to addresses within Iowa. Five percent of the gross receipts related to this direct mail contract are attributable to Iowa and included in the numerator of the apportionment factor.
- f. A company which owns apartments in Iowa and State A contracts with a pest control corporation for pest control activities. One contract is entered into which covers 100 apartment units in Iowa and 400 apartment units in State A. Twenty percent (100/500) of the gross receipts from the pest control contract are attributable to Iowa and are included in the numerator of the apportionment factor as 20 percent of the apartment units are located in Iowa and in the absence of more accurate records, it is presumed that the number of apartment units is the best measure of the extent the recipient of the service received benefit of the service in Iowa.

If a taxpayer does not believe that the method of apportionment set forth in this subrule reasonably attributes income to business activities within Iowa, the taxpayer may request the use of an alternative method of apportionment. The request must be filed at least 60 days before the due date of the return, considering any extensions of time to file, in which the taxpayer wishes to use an alternative method of apportionment. The request should be filed with Policy Section, Technical Service Division, P.O. Box 10457, Des Moines, Iowa 50306. The taxpayer must set forth in detail the extent of the taxpayer's business opera-

tions within and without the state, along with the reasons why the apportionment method set forth in this subrule is inappropriate. In addition, the taxpayer must set forth a proposed method of apportionment and the reasons why the proposed method of apportionment more reasonably attributes income to business activities in Iowa.

If the department agrees that the proposed method of apportionment more reasonably attributes income to business activities in Iowa, the taxpayer may continue to use the proposed method of apportionment until the taxpayer's factual situation changes or the department prospectively informs the taxpayer that the method of apportionment

may no longer be used.

If the taxpayer's factual situation changes and under the new factual situation the taxpayer still believes that the method of apportionment set forth in this subrule still is not appropriate, then the taxpayer must submit a new request for the use of an alternative method of apportionment.

If the taxpayer disagrees with the determination of the department, the taxpayer may file a protest within 60 days of the date of the letter setting forth the department's determination and the reasons therefor in accordance with rule 701—7.8(17A), Iowa Administrative Code. The department's determination letter shall set forth the taxpayer's rights to protest the department's determination.

ARC 3014A

SECRETARY OF STATE[721]

Notice of Intended Action

Twenty-five interested persons, a governmental subdivision, an agency or an association of 25 or more persons may demand an oral presentation hereon as provided in Iowa Code §17A.4(1)"b."

Notice is also given to the public that the Administrative Rules Review Committee may, on its own motion or on written request by any individual or group, review this proposed action under §17A.8(6) at a regular or special meeting where the public or interested persons may be heard.

Pursuant to the authority of Iowa Code section 17A.3(1)"b," the Secretary of State hereby gives Notice of Intended Action to amend Chapter 21, "Election Forms and Instructions," Iowa Administrative Code.

The purpose of the proposed amendment is to provide voters and other interested persons with the opportunity to review the summary to be printed on the ballot for a proposed constitutional amendment that is to be voted upon at the November 3, 1992, general election.

Written suggestions or comments regarding this amendment will be considered if they are received not later than June 16, 1992. Written comments or suggestions should be sent to the Director of Elections, Office of the Secretary of State, Second Floor, Hoover State Office Building, Des Moines, Iowa 50319.

A public hearing will be held on Thursday, June 18, 1992, at 1:30 p.m. at the office of the Secretary of State, Second Floor, Hoover State Office Building, Des Moines. Anyone wishing to present oral comments at the public

hearing should notify the Director of Elections by 4:30 p.m. on Tuesday, June 16, 1992. Notice of intention to present oral comments at the hearing may be made by telephone: (515)281-5865.

This amendment is intended to implement Iowa Code sections 47.1 and 49.44.

The following amendment is proposed.

Amend rule 721—21.1(49) by adding the following new subrule:

21.1(4) One proposed constitutional amendment was passed by the 73rd General Assembly as 1989 Iowa Acts, chapter 325, and by the 74th General Assembly in 1992 as House Joint Resolution 4. This proposed amendment will be voted upon at the general election to be held on November 3, 1992. The summary that is proposed by the secretary of state appears below:

The amendment repeals the disqualification from public office for parties to a duel.

NOTICE—USURY

In accordance with the provisions of Iowa Code section 535.2, subsection 3, paragraph "a," the Superintendent of Banking has determined that the maximum lawful rate of interest shall be:

November 1, 1989 – November 30, 1989	10.25%
December 1, 1989 – December 31, 1989	10.00%
January 1, 1990 – January 31, 1990	9.75%
February 1, 1990 – February 28, 1990	9.75%
March 1, 1990 – March 31, 1990	10.25%
April 1, 1990 – April 30, 1990	10.50%
May 1, 1990 – May 31, 1990	10.50%
June 1, 1990 – June 30, 1990	10.75%
July 1, 1990 – July 31, 1990	10.75%
August 1, 1990 – August 31, 1990	10.50%
September 1, 1990 – September 30, 1990	10.50%
October 1, 1990 – October 31, 1990	10.75%
November 1, 1990 – November 30, 1990	11.00%
December 1, 1990 – December 31, 1990	10.75%
January 1, 1991 – January 31, 1991	10.50%
February 1, 1991 – February 28, 1991	10.00%
March 1, 1991 – March 31, 1991	10.00%
April 1, 1991 – April 30, 1991	9.75%
May 1, 1991 – May 31, 1991	10.00%
June 1, 1991 – June 30, 1991	10.00%
July 1, 1991 – July 31, 1991	10.00%
August 1, 1991 – August 31, 1991	10.25%
September 1, 1991 – September 30, 1991	10.25%
October 1, 1991 – October 31, 1991	10.00%
November 1, 1991 – November 30, 1991	9.75%
December 1, 1991 – December 31, 1991	9.50%
January 1, 1992 – January 31, 1992	9.50%
February 1, 1992 – February 29, 1992	9.00%
March 1, 1992 – March 31, 1992	9.00%
April 1, 1992 – April 30, 1992	9.25%
May 1, 1992 – May 31, 1992	9.50%
June 1, 1992 – June 30, 1992	9.50%

ARC 3016A

LABOR SERVICES DIVISION[347]

Adopted and Filed Emergency After Notice

Pursuant to the authority of Iowa Code sections 88.5, 17A.3(1) and 17A.5(2), the Labor Commissioner adopts an amendment to Chapter 10, "General Industry Safety and Health Rules," Iowa Administrative Code.

This amendment relates to process safety management of highly hazardous chemicals; explosives and blasting agents; and a correction; and occupational exposure to asbestos, tremolite, anthophyllite and actinolite, amendment.

The Notice of Intended Action was published in the Iowa Administrative Bulletin on April 1, 1992, as ARC 2932A. In compliance with Iowa Code section 88.5(1)"b," a public hearing was scheduled for April 23, 1992. No comments were received. This amendment is identical to the Notice.

Pursuant to Iowa Code section 17A.5(2)"b"(2) and (3), this amendment shall become effective upon publication on May 27, 1992. The Commissioner finds that this amendment confers a benefit on employees by permitting them to be provided with safety and health equal those found in states under federal OSHA's jurisdiction and is necessary because of the safety and health of employees in this state.

This rule is intended to implement Iowa Code section 88.5.

The following amendment is adopted.

Amend rule 347—10.20(88) by inserting at the end thereof:

57 Fed. Reg. 6403 (February 24, 1992) 57 Fed. Reg. 7847 (March 4, 1992)

57 Fed. Reg. 7878 (March 5, 1992)

[Filed Emergency After Notice 5/6/92, effective 5/27/92] [Published 5/27/92]

EDITOR'S NOTE: For replacement pages for IAC, see IAC Supplement 5/27/92.

ARC 3017A

LABOR SERVICES DIVISION[347]

Adopted and Filed Emergency After Notice

Pursuant to the authority of Iowa Code sections 88.5, 17A.3(1) and 17A.5(2), the Labor Commissioner adopts an amendment to Chapter 26, "Construction Safety and Health Rules," Iowa Administrative Code.

The amendment relates to occupational exposure to asbestos, tremolite, anthophyllite and actinolite.

The Notice of Intended Action was published in the Iowa Administrative Bulletin on April 1, 1992, as ARC 2933A. In compliance with Iowa Code section 88.5(1)"b," a public hearing was scheduled for April 23, 1992. No comments were received. This amendment is identical to the Notice.

Pursuant to Iowa Code section 17A.5(2)"b"(2) and (3). this amendment shall become effective upon publication on May 27, 1992. The Commissioner finds that this amendment confers a benefit on employees by permitting them to be provided with safety and health equal those found in states under federal OSHA's jurisdiction and is necessary because of the safety and health of employees in this state.

This rule is intended to implement Iowa Code section 88.5

The following amendment is adopted.

Amend rule 347-26.1(88) by inserting at the end thereof:

57 Fed. Reg. 7878 (March 5, 1992)

[Filed Emergency After Notice 5/6/92, effective 5/27/92] [Published 5/27/92]

EDITOR'S NOTE: For replacement pages for IAC, see IAC Supplement 5/27/92.

ARC 3011A

PERSONNEL DEPARTMENT[581]

Adopted and Filed Emergency

Pursuant to the authority of Iowa Code section 19A.9, the Iowa Department of Personnel hereby adopts an amendment to Chapter 11, "Separations, Disciplinary Actions and Reduction in Force," Iowa Administrative Code.
The purpose of these amendments is to correct an over-

sight in rule making published in the April 15, 1992, Iowa Administrative Bulletin as ARC 2948A in which new rules were adopted concerning the issuance of recall certificates, but the old rules were not rescinded.

In compliance with Iowa Code section 17A.4(2), the Department finds that notice and public participation are impracticable because the intent of this change was already addressed to the public in ARC 2948A.

The Department also finds, pursuant to Iowa Code section 17A.5(2)"b"(2), that the normal effective date of these amendments should be waived and the amendments should be made effective on May 20, 1992, so that two different rules on the same subject are not in effect at the same time.

These amendments are intended to implement Iowa Code section 19A.9.

The following amendments are adopted.

ITEM 1. Rescind the second unnumbered paragraph under paragraph 11.3(6)"c."

ITEM 2. Rescind paragraph 11.3(6)"d" and adopt the following:

d. The following provisions shall apply to the issuance and use of recall certificates:

(1) When one or more names are on the recall list for a class in which a vacancy exists, the agency filling that vacancy must first offer the position to former employees on that list who were laid off by that agency. Recall offers shall be in descending order according to retention points.

PERSONNEL DEPARTMENT[581](cont'd)

If no one is available on such a recall certificate, the agency filling the vacancy shall next request the recall

certificate provided for in 11.3(6)"d"(2).

(2) An agency shall consider recalling former employees on the recall list who were laid off by agencies other than the one filling the vacancy. If no one from such a recall certificate is selected, the agency shall justify that decision to the director before the position may be filled otherwise.

(3) Recall alternatives shall be exhausted before other

eligible lists may be used to fill vacancies.

Former employees listed in subrule 11.3(6), paragraph "a," subparagraphs (4) and (5), having received a medical release to perform the duties of a position, shall be considered and their medically related work restrictions shall be reasonably accommodated.

[Filed Emergency 4/29/92, effective 5/20/92] [Published 5/27/92]

EDITOR'S NOTE: For replacement pages for IAC, see IAC Supplement 5/27/92.

ARC 3035A

REVENUE AND FINANCE DEPARTMENT[701]

Adopted and Filed Emergency

Pursuant to the authority of Iowa Code sections 421.14 and 422.68(1), the Iowa Department of Revenue and Finance hereby amends Chapter 40, "Determination of Net

Income," Iowa Administrative Code.

In the Iowa Administrative Bulletin of February 5, 1992, rules were Adopted and Filed under ARC 2749A which rescinded prior rule 701—40.15(422) and replaced that rule with a revised version of rule 701—40.15(422). The rescission of prior rule 701—40.15(422) inadvertently and erroneously deleted subrules 40.15(1), 40.15(2), 40.15(3) and 40.15(4) which should not have been affected by the revision of rule 701—40.15(422).

Subrules 40.15(1), 40.15(2), 40.15(3) and 40.15(4) were longstanding rules which clarified how incomes of married taxpayers were to be allocated between spouses under different circumstances when those spouses elected to file either separate Iowa returns or separately on the combined Iowa return form. The subrules included in this filing are identical to the four subrules that were inadvertently deleted except for revision of some possibly sexist language in paragraph "e" under subrule 40.15(4).

Subrule 40.15(1) specifies that when property that is not used in a business is owned by one spouse the income from that property is to be reported by that spouse.

Subrule 40.15(2) covers reporting of income from property which is owned by both spouses of a married

couple.

Subrule 40.15(3) deals with the reporting of salaries and wages paid for personal services or professional services performed in the course of employment and how those wages are to be reported when married taxpayers file separate returns or file separately on the combined return form. This subrule also covers reporting of salaries

or wages in situations when one spouse is employed by the other spouse.

Subrule 40.15(4) covers reporting of incomes from businesses in which both a husband and wife have an ownership interest. The rule also covers allocation of incomes between spouses from partnerships and other businesses in which both spouses have an ownership interest. The rule sets out three factors that should be considered for purposes of allocation of incomes between spouses from a business owned by the spouses which is not a partnership.

In compliance with Iowa Code section 17A.4(2), the Department finds that notice and public participation are impracticable because these were longstanding subrules inadvertently rescinded and the statute to which these subrules are applicable will apply before subrules can be adopted and become effective by way of the usual procedure.

In compliance with Iowa Code section 17A.5(2)"b"(2), the Department finds that the normal effective date of this amendment, 35 days after publication, should be waived and the amendment be made effective upon filing with the Administrative Rules Coordinator on May 8, 1992.

This amendment is intended to implement Iowa Code Supplement section 422.7.

The following amendment is adopted.

Amend rule 701—40.15(422) by adding the following subrules:

40.15(1) Income from property in which only one spouse has an ownership interest but which is not used in business. If ownership of property not used in a business is in the name of only one spouse and each files a separate state return, income derived from such property may not be divided between husband and wife but must be reported by only that spouse possessing the ownership interest.

40.15(2) Income from property in which both husband and wife have an ownership interest but which is not used in a business. A husband and wife who file a joint federal return and elect to file separate Iowa returns must each report the share of income from jointly or commonly owned real estate, stocks, bonds, bank accounts, and other property not used in a business in the same manner as if their federal adjusted gross incomes had been determined separately. The rules for determining the manner of reporting this income depend upon the nature of the ownership interest and, in general, may be summarized as follows:

a. Joint tenants. A husband and wife owning property as joint tenants with the right of survivorship, a common example of which is a joint savings account, should each report on separate returns one-half of the income from the savings account held by them in joint tenancy.

b. Tenants in common. Income from property held by husband and wife as tenants in common is reportable by them in proportion to their legally enforceable ownership

interests in the property.

40.15(3) Salary and wages derived from personal or professional services performed in the course of employment. A husband and wife who file a joint federal return and elect to file separate Iowa returns must report on each spouse's state return the salary and wages which are attributable to services performed pursuant to each individual's employment. The income must be reported on Iowa separate returns in the same manner as if their federal adjusted gross incomes had been determined separately. The man-

ner of reporting wages and salaries by spouses is dependent upon the nature of the employment relationship and is subject to the following rules:

a. Interspousal employment—salary or wages paid by one spouse to the other. Wages or compensation paid for services or labor performed by one spouse with respect to property or business owned by the other spouse may be reported on a separate return if the amount of the payment is reasonable for the services or labor actually performed. It is presumed that the compensation or wages paid by one spouse to the other is not reasonable nor allowable for purposes of reporting the income separately unless a bona fide employer-employee relationship exists. For example, unless actual services are rendered, payments are actually made, working hours and standards are set and adhered to, unemployment compensation and worker's compensation requirements are met, the payments may not be separately reported by the salaried spouse.

b. Wages and salaries received by a husband or wife pursuant to an employment agreement with an employer other than a spouse. Wages or compensation paid for services or labor performed by a husband or wife pursuant to an employment agreement with some other employer is presumed income of only that spouse that is employed and must be reported separately only by that spouse.

40.15(4) Income from a business in which both husband and wife have an ownership interest. Income derived from a business the ownership of which is in both spouses' names, as evidenced by record title or by the existence of a bona fide partnership agreement or by other recognized method of establishing legal ownership, may be allocated between spouses and reported on separate individual state income tax returns provided that the interest of each spouse is allocated according to the capital interest of each, the management and control exercised by each, and the services performed by each with respect to such business. Compliance with the conditions contained in paragraphs "a" or "b" of this subrule and consideration of paragraphs "c," "d," and "e" of this subrule must be made in allocating income from a business in which both husband and wife have an ownership interest.

a. Allocation of partnership income. Allocation of partnership income between spouses is presumed valid only if partnership information returns, as required for income tax purposes, have currently been filed with respect to the federal self-employment tax law. An oral understanding does not constitute a bona fide partnership implied merely from a common ownership of property.

b. Allocation of income derived from a business other than a partnership in which both husband and wife claim an ownership interest. In the case of a business owned by a husband and wife who filed a joint federal income tax return in which one of them claimed all of the income therefrom for federal self-employment tax purposes, it will be presumed for purposes of administering the state income tax law, unless expressly shown to the contrary by the taxpayer, that the spouse who claimed that income for federal self-employment tax purposes did, thereby, with the consent of the other spouse, claim all right to such income and that therefore such income must be included in

the state income tax return of the spouse who claimed it for federal self-employment tax purposes if the husband and wife file separate state income tax returns.

c. Capital contribution. In determining the weight to be attributed to the capital contribution of each spouse to a business, consideration may be given only to that invested capital which is legally traceable to each individual spouse. Capital existing under the right, dominion, and control of one spouse which is invested in the business is presumed to be a capital contribution of that spouse. Sham transactions which do not affect real changes of ownership in capital between spouses in that such transactions do not legally disturb the right, dominion, and control of the assignor or the donor over the capital must be disregarded in determining capital contribution of the recipient spouse.

d. Management and control. Participation in the control and management of a business must be distinguished from the regular performance of nonmanagerial services. Contribution of management and control with respect to the business must be of a substantial nature in order to accord it weight in making an allocation of income. Substantial participation in management does not necessarily involve continuous or even frequent presence at the place of business, but it does involve genuine consultation with respect to at least major business decisions, and it presupposes substantial acquaintance with an interest in the operations, problems, and policies of the business, along with sufficient maturity and background of education or experience to indicate an ability to grasp business problems that is appreciably commensurate with the demands of the enterprise concerned. Vague or general statements as to family discussions at home or elsewhere will not be accepted as a sufficient showing of actual consultation.

e. Services performed. The amount of services performed by each spouse is a factor to be considered in determining proper allocation of income from a business in which each spouse has an ownership interest. In order to accord weight to services performed by an individual spouse, the services must be of a beneficial nature in that they make a direct contribution to the business. For example, for a business operation, whether it is a retail sales enterprise, farming operation or otherwise, in which both husband and wife have an ownership interest, the services contributed by the spouses must be directly connected with the business operation. Services for the family such as planting and maintaining family gardens, domestic housework, cooking family meals, and routine errands and shopping, are not considered to be services performed or rendered as an incident of or a contribution to the particular business; such activities by a spouse must be disregarded in determining the allocable income attributable to that spouse.

This rule is intended to implement Iowa Code section 422.7.

[Filed Emergency 5/8/92, effective 5/8/92] [Published 5/27/92]

EDITOR'S NOTE: For replacement pages for IAC, see IAC Supplement 5/27/92.

ARC 3062A

ARC 3009A

AGRICULTURE AND LAND STEWARDSHIP DEPARTMENT[21]

Adopted and Filed

Pursuant to the authority of Iowa Code sections 159.5(11) and 190.2, the Iowa Department of Agriculture and Land Stewardship adopts an amendment to Chapter 71, "Standards for Dairy Products," Iowa Administrative Code.

Notice of Intended Action was published in the Iowa Administrative Bulletin on March 18, 1992, as ARC 2884A.

Interested persons were given until April 7, 1992, to submit comments. No comments were submitted. The rule is identical to the rule published under Notice of Intended Action.

This rule is in response to a petition received by the Department to establish a standard of identity for "light butter." Currently, no such standard exists under Iowa or federal law.

This rule is intended to implement Iowa Code chapter 190.

This rule will become effective July 1, 1992.

The following rule is adopted.

Amend 21—Chapter 71 by adding the following new rule:

21-71.6(190) Standard for light butter.

"Light butter" is the food defined in Iowa Code section 190.1(1) except:

- 1. The milkfat content of light butter shall be 52 percent.
- 2. Light butter shall have vitamin A added, if needed, to provide 15,000 international units per pound, within limits of good manufacturing practices.
- 3. Light butter may contain the following dairy ingredients: partially skimmed milk, skim milk, buttermilk, whey or whey-derived ingredients.
- 4. Other optional ingredients allowed in light butter are:
 - (1) Water:
 - (2) Salt or salt substitutes;
 - Bacterial cultures;
 - (4) Nutritive sweeteners:
 - (5) Emulsifiers and stabilizers;
 - (6) Safe and suitable color additives;
 - (7) Natural flavors; or

(8) Safe and suitable ingredients that improve texture, prevent syneresis, or extend the shelf life of the product.

5. Label declaration. The principal display panel of the label must include a comparative statement expressing the reduction in calories and fat relative to butter (i.e., one-third less fat and calories than regular butter).

This rule is intended to implement Iowa Code chapter 190.

[Filed 5/8/92, effective 7/1/92] [Published 5/27/92]

EDITOR'S NOTE: For replacement pages for IAC, see IAC Supplement 5/27/92.

ALCOHOLIC BEVERAGES DIVISION[185]

Adopted and Filed

Pursuant to the authority of Iowa Code section 123.21, the Alcoholic Beverages Commission, on March 26, 1992, amended Chapter 16, "Trade Practices," Iowa Administrative Code.

Notice of Intended Action was published in the Iowa Administrative Bulletin on December 11, 1991, as ARC 2581A.

The adopted amendments are substantially similar to the amendments published under Notice of Intended Action; however, certain changes were made to further clarify the rules.

Item 1 amends subrule 16.1(6) by further defining the term, "exclusion," as used in these rules to include consideration of an industry member's preferential treatment of a retailer which is not similarly offered to all retailers in the same market. After careful consideration, as well as industry comment, this paragraph was amended consistent with the objectives of the rule making.

Item 2 amends subrule 16.1(7) by requiring the Division to annually adjust the dollar limitations which may be expended by an industry member in a retail establishment to include retailer advertising utensils (defined and limited in 185—16.13(123), adopted in this rule making).

Item 3 amends subrule 16.1(8) by exempting "consumer souvenirs" from the definition of "furnishings, fix-

tures and equipment" as used in Chapter 16.

Item 4 adopts subrules prohibiting an industry member's purchase of advertising from a retailer. The subrule does not prohibit an industry member from purchasing advertising from a business affiliated with a retailer provided that other related trade practices rules are not violated as a result of the transaction. The subrules permit an industry member to give a spectacular sign or bill-board to a retailer subject to certain conditions. The adopted subrule regarding spectacular signs and billboards includes the element of "exclusion of a competitor's product" as part of the test used to determine whether a violation has occurred, in addition to other conditions. The additional conditions were added consistent with the purposes of the rule making after discussion with affected industry members and retailers.

Item 5 amends subrule 16.5(4) to permit an industry member to purchase advertising in publications owned by nonprofit retailer associations under certain conditions. The adopted subrule does not substantially vary from the

proposed subrule.

Item 6 adds a new rule which defines "retailer advertising utensils" and permits an industry member to furnish utensils to a retailer up to an annually imposed dollar limitation. The new rule also defines "consumer souvenirs" which may be furnished to a retailer for distribution to consumers. The rule permits an industry member to sell certain wearing apparel which bears substantial permanently affixed advertising identifying the industry member or the industry member's products. There are no dollar limitations on "consumer souvenirs" which may be given to a retailer or on wearing apparel which may be sold to a retailer.

ALCOHOLIC BEVERAGES DIVISION[185](cont'd)

Item 7 amends 185—16.20(123) to impose certain record-keeping requirements on industry members for "consumer souvenirs" and "retailer advertising utensils" given by industry members to retailers.

Interested persons were allowed to comment on the proposed amendments. An oral hearing was held on January 8, 1992. Written comments were received by the Division concerning the proposed amendments. The Division has fully considered the written and oral comments received in this rule making.

These amendments are intended to implement Iowa

Code sections 123.45 and 123.186.

These amendments will become effective on July 1, 1992.

The following amendments are adopted.

ITEM 1. Amend subrule 16.1(6), paragraph "g," as follows:

g. Any other special considerations or preferential treatment offered by the industry member and accepted by the retailer which were not similarly offered to all retailers in the same market.

ITEM 2. Amend subrule 16.1(7) as follows:

- 16.1(7) Cost adjustment factor. The division shall annually adjust the dollar limitations in 16.3(123) not to exceed the adjusted annual cost permitted by the federal Bureau of Alcohol, Tobacco, and Firearms contained in 27 CFR 6.83. The division shall annually adjust the dollar limitations in 16.13(123) not to exceed the adjusted annual cost permitted by the federal Bureau of Alcohol, Tobacco, and Firearms contained in 27 CFR 6.85. The division shall annually adjust the dollar limitations in 16.16(123) not to exceed the adjusted annual cost permitted by the federal Bureau of Alcohol, Tobacco, and Firearms contained in 27 CFR 6.100.
 - ITEM 3. Amend subrule 16.1(8) as follows:
- **16.1(8)** Furnishings, fixtures and equipment do not include the items identified in 16.3(123), 16.5(5), 16.5(6), 16.6(123), 16.10(123), 16.11(123), or 16.12(123), or 16.13(5).

ITEM 4. Amend rule 185—16.5(123) by adding the fol-

lowing new subrules:

- 16.5(2) An industry member is prohibited from purchasing advertising from a retailer on such things as, but not limited to, signs, scoreboards, programs, scorecards, and tote boards in ballparks, stadiums, auditoriums, racetracks, arenas, bowling alleys and all other retail establishments.
- 16.5(3) An industry member may furnish a billboard or "spectacular" sign to a retailer. The sign must bear conspicuous, permanently affixed advertising which identifies the industry member or the industry member's alcoholic beverages products. The sign may be displayed within the establishment or on a fence or similar enclosure facing into the establishment.

If the billboard or sign has secondary value (i.e., electronic, mechanical or manual message center, scorekeeping capabilities, menu board) other than mere advertising, an industry member may furnish a billboard or "spectacular" sign to a retailer provided:

lar" sign to a retailer provided:

a. The sign is not on a premises covered by a license or permit;

b. The sign is not owned by a retail licensee or permittee;

- c. The retailer is not compensated, directly or indirectly, in conjunction with the placement of the sign or advertising thereon;
- d. The furnishing of the "spectacular" sign by an industry member shall not result in exclusion (which includes, but is not limited to, preferential treatment), in whole or in part, of a competitor's alcoholic beverages products in the retail establishment; and
- e. The billboard or "spectacular" sign does not contain or show an advertisement naming or advertising any retailer, or provide any other secondary utility value for the retailer.

ITEM 5. Amend subrule 16.5(4) as follows:

16.5(4) An industry member is prohibited from purchasing advertising in retailer publications, as well as those publications sponsored by retailer organizations. An industry member may purchase advertising in a publication owned by an incorporated nonprofit trade association of retail members. The publication shall be disseminated to the membership of the association on a regular basis. No revenue derived from the advertising shall be used for the benefit or use of any individual member.

The fact that an industry member did not advertise in the publication shall not be used in any way by the membership jointly or severally to effect a restraint of trade of the brands carried by the industry member failing to ad-

vertise

ITEM 6. Amend 185—Chapter 16 by adding the following new rule:

185—16.13(123) Retailer advertising utensils, consumer souvenirs, wearing apparel. An industry member may furnish, give, or sell retailer advertising utensils which bear conspicuous advertising matter permanently affixed to the utensils and which are primarily valuable as point of sale advertising intended for use on the premises of the retail establishment. No advertising utensils with secondary value which constitute furnishings, fixtures, or equipment used in the storage, handling, serving, or dispensing of alcoholic beverages, wine, beer, or food within the place of the retail business of a licensee or permittee shall be given, furnished or sold by an industry member to a retailer.

16.13(1) The total value of all retailer advertising utensils which may be furnished, given or sold by an industry member to a retailer per brand per calendar year may not exceed \$76.

16.13(2) Industry members may not pool or combine their dollar limitations in order to provide a retailer with

retailer advertising utensils which exceed \$76.

16.13(3). Industry members may not pool or combine the dollar limitations for several brands in order to provide a retailer with retailer advertising utensils which exceed \$76.

16.13(4) The value of the retailer advertising utensil is

the industry member's original cost of the item.

16.13(5) An industry member may furnish, give or sell consumer souvenirs to a retailer for unconditional distribution by the retailer to consumers. Consumer souvenirs may include such items as printed recipes, matches, bottle or can openers, corkscrews, shopping bags, pamphlets, leaflets, blotters, postcards, pens or pencils.

Consumer souvenirs must bear conspicuous advertising matter which identifies the industry member or the industry member's alcoholic beverages product. The industry

ALCOHOLIC BEVERAGES DIVISION[185](cont'd)

member may not pay or credit the retailer, directly or indirectly, for distributing consumer souvenirs. There is no dollar limitation on consumer souvenirs.

Such souvenirs shall be offered to all retailers by the industry member within the industry member's marketing territory on as equal and equitable a basis as possible. In the event the souvenir also advertises a local event not sponsored by the retailer, the souvenir need only be offered by the industry member to the retailers within the local community where the event is held.

16.13(6) An industry member may sell wearing apparel, including sweatshirts, t-shirts, pants, shorts, hats, caps, polo type shirts, jackets, jerseys and other similar clothing, which bears substantial permanently affixed advertising identifying the industry member's name or products to a retailer at not less than the industry member's laid-in cost of the items. There is no dollar limitation on wearing apparel which may be sold by an industry member to a retailer.

ITEM 7. Amend rule 185—16.20(123) as follows:

185—16.20(123) Record keeping. Industry members are required to keep and maintain accurate records for a three-year period regarding each of the items which may be provided to retailers in rules 16.3(123) (product displays), 16.6(123) (glassware), 16.10(123) (tastings, samand trade spending), 16.13(123) (retailer advertising utensils, consumer souvenirs, wearing apparel), 16.16(123) (participation in seminars and retail association activities), and 16.17(123) (sponsorships and special events). Commercial records or invoices may be used to satisfy this record-keeping requirement if all the required information appears on the record or invoice. These records shall state the following: the name and address of the retailer receiving the item, the date furnished, sold, given, loaned, leased or rented, the item furnished, the industry member's laid-in cost of the item furnished, and charges to the retailer for the item. Such records shall be open to representatives of the division during normal business hours of the industry member, and may be subject to administrative subpoena issued by the division administrator.

[Filed 4/28/92, effective 7/1/92] [Published 5/27/92]

EDITOR'S NOTE: For replacement pages for IAC, see IAC Supplement 5/27/92.

ARC 3029A

ATTORNEY GENERAL[61]

DEPARTMENT OF JUSTICE

Adopted and Filed

Pursuant to the authority of Iowa Code section 912.2A(2), the Crime Victim Assistance Board hereby adopts amendments to Chapter 9, Division IV, "Sexual Abuse Examination Payment," Iowa Administrative Code.

These amendments delete reference to the state requirement that applications for payment be submitted within 90 days of service. Reference to the right of an ap-

plicant to appeal denial of payment to the Iowa Board of Appeals is also deleted.

These amendments require that the birth date of the sexual abuse victim be included in the application for payment.

The proposal to raise the maximum reimbursement for physician services from \$100 to \$150, made in the Notice of Intended Action, was deleted by action of the Crime Victim Assistance Board.

Notice of Intended Action was published in the Iowa Administrative Bulletin on November 27, 1991, as ARC 2570A.

Interested persons were allowed to comment on the proposed rules. No persons attended the public hearing held on December 17, 1991. One letter supporting the increase in maximum physician fees from \$100 to \$150 was received from a Cedar Rapids hospital.

The Crime Victim Assistance Board of the Department of Justice adopted these amendments on January 31, 1992.

These amendments will become effective on July 1, 1992.

These amendments are intended to implement Iowa Code section 709.10.

The following amendments are adopted.

ITEM 1. Amend subrule 9.82(2) as follows:

9.82(2) Application filing. Application for sexual abuse examination payment must be filed with the department within 90 days of the sexual abuse examination. To apply for payment under the sexual abuse examination program, the form or bill submitted must identify the sexual assault victim by name, birth date, and patient number, indicate that the claim is for a sexual abuse examination, and itemize all services rendered and the fee for each service.

ITEM 2. Amend rule 61—9.87(73GA, SF2413) as follows:

61—9.87(73GA, SF2413709) Right to appeal. An eligible claimant who disagrees with the department's decision concerning payment or amount of payment has the right to request reconsideration of that decision by the crime victim assistance board. The request for reconsideration must be received by the department within 60 days after the decision of the department is mailed. An applicant who is denied sexual abuse examination payment due to failure to submit the application within 90 days has the right to appeal to the Iowa board of appeals.

[Filed 5/8/92, effective 7/1/92] [Published 5/27/92]

EDITOR'S NOTE: For replacement pages for IAC, see IAC Supplement 5/27/92.

ARC 3031A

EDUCATION DEPARTMENT[281]

Adopted and Filed

Pursuant to the authority of Iowa Code section 256.7(5), the Iowa State Board of Education hereby amends Chapter 43, "Pupil Transportation," Iowa Administrative Code.

Notice of Intended Action was published in the Iowa Administrative Bulletin as ARC 2851A on March 4, 1992

FILED

Item 1 combines and clarifies into one rule the content of two separate rules dealing with the responsibility of employers to require that school bus drivers demonstrate their knowledge and ability to safely operate vehicles they will be required to drive during their employment. This item also includes a new rule describing the procedure to be used by the Department of Education for implementing Iowa Code subsection 321.376(3) dealing with the assessment of a fee for issuing annual school bus drivers' permits by the Department.

Item 2 establishes the procedure to be followed by the Department of Education for determining whether a school bus driver's permit should be denied or revoked based on an alleged violation of Iowa Code subsection 321.375(2) relating to: (1) the use of nonprescription controlled substances and alcoholic beverages by school bus drivers during working hours, (2) operation of a school bus while under the influence of controlled substances or alcoholic beverages, (3) fraud in the procurement or renewal of a school bus driver's permit, or (4) criminal code violations relevant to the operation of a school bus, including sexual involvement with a minor student with intent to commit acts and practices proscribed under Iowa Code sections 709.8 and 725.1 to 725.3.

Interested persons were allowed to comment on the proposed rules. A public hearing was held but no one appeared to comment. As a result of an oral comment which was received, the following change is made to the Notice:

Rule 43.21(285) is amended for clarification.

These rules will become effective on July 1, 1992.

These rules are intended to implement Iowa Code sections 285.8 and 321.375.

The following amendments are adopted.

ITEM 1. Rescind rules 281—43.21(285) and 281—43.22(285) and insert in lieu thereof the following:

281—43.21(285) Experience, traffic law knowledge and driving record. No driver applicant shall be employed or allowed to transport students until the board determines that the applicant has an acceptable driving record, demonstrates the ability to safely operate the vehicle(s) representative of the vehicle(s) required to be operated during employment and is knowledgeable of traffic laws and regulations pertaining to the operation of a school bus.

281—43.22(321) Annual permit fee collection and distribution of funds. The department of education, commencing with the issuing of school bus permits for the 1992-93 school year and each year thereafter, shall assess an annual fee for each school bus driver's permit issued by the department. The department shall present for payment a fee statement to the employer of each driver issued a school bus permit. The fee statement shall contain the name(s), school bus permit number(s) and total fees due. A school bus permit shall not be issued for any driver whose fee has not been paid for the preceding year.

The department of education shall submit an annual school bus driver training budget request for an amount equal to 100 percent of the total projected fees to be collected during the next fiscal year which shall be based on an amount equal to the number of school bus driver permits issued as of May 1 of the previous school year multiplied by the permit fee authorized by statute.

The department of education shall develop an annual "school bus driver and passenger safety education plan" which shall outline the projects and activities to be funded during each year. These projects and activities may include, but not be limited to, curriculum development costs, printing and distribution of safety literature and manuals, purchase of equipment used in conducting school bus safety education programs, and other expenditures deemed appropriate by the department of education.

ITEM 2. Rescind rule 281—43.24(285) and insert in lieu thereof the following:

281—43.24(321) Permit denials and revocations. A person who believes that a school bus driver who holds a permit issued by the department of education or who seeks a school bus permit has committed acts in violation of Iowa Code subsection 321.375(2) or rule 43.12(285) may file a complaint with the department against the permit holder or applicant. The department shall notify the permit holder or applicant that a complaint has been filed and shall provide a copy of the complaint to the driver. A hearing shall be set for the purpose of determining whether the bus driver's permit shall be denied or revoked. Hearing procedures in 281—Chapter 6 shall be applicable to permit revocation or denial proceedings.

[Filed 5/8/92, effective 7/1/92] [Published 5/27/92]

EDITOR'S NOTE: For replacement pages for IAC, see IAC Supplement 5/27/92.

ARC 3015A

INSPECTIONS AND APPEALS DEPARTMENT[481]

Adopted and Filed

Pursuant to the authority of Iowa Code section 10A.104(5) and Iowa Code Supplement section 68B.4(4), the Department of Inspections and Appeals hereby adopts a new Chapter 7, "Consent for the Sale of Goods and Services," Iowa Administrative Code.

The adopted rules specify the procedures by which an official of the agency may be granted agency consent to sell goods or services to individuals, associations, or corporations subject to the regulatory authority of the

The adopted rules are identical to those published under Notice of Intended Action in the Iowa Administrative Bulletin on April 1, 1992, as ARC 2900A. No comments were received on the amendments.

These rules will become effective July 1, 1992.

These rules are intended to implement Iowa Code Supplement section 68B.4.

EDITOR'S NOTE: Pursuant to recommendation of the Administrative Rules Review Committee published in the Iowa Administrative Bulletin, September 10, 1986, the text of these rules [Ch 7] is being omitted. These rules are identical to those published under Notice as ARC 2900A, IAB 4/1/92.

[Filed 5/6/92, effective 7/1/92] [Published 5/27/92]

[For replacement pages for IAC, see IAC Supplement 5/27/92.]

ARC 3057A

NATURAL RESOURCE COMMISSION[571]

Adopted and Filed

Pursuant to the authority of Iowa Code section 455A.5, the Natural Resource Commission hereby amends Chapter 15. "General License Regulations." Iowa Administrative Code.

New rule 15.8(110) establishes guidelines for Volunteer Hunter Education Instructor Certification and remov-

al of certification.

Notice of Intended Action was published in the Iowa Administrative Bulletin on March 4, 1992, as ARC 2843A. Thirty-two written comments were received during the comment period; no comments were received at the public hearing held March 25, 1992. The following are the significant changes from the Notice of Intended Action:

In 15.8(1), add "volunteer" preceding the word "instructors"

In 15.8(2), definition of certified instructor, delete "other than a department employee".

In 15.8(3)"c," add "and bows and arrows".
In 15.8(4)"a"(1), delete "Thirty hours of course" and add "in three courses"

In 15.8(4)"a"(2), delete "Fifteen hours of course participation and attendance at the department's annual instructor academy"

In 15.8(4)"c"(1), delete "hourly instruction" and add

"course"

In 15.8(5)"g," delete "30" and add "15".
In 15.8(6)"c," delete "five or more" and add "two".
In 15.8(7)"e," add "or bow or archery equipment".
In 15.8(7)"i" through "m," delete "i" and reletter remaining paragraphs.

In relettered 15.8(7)"1" add "directly or indirectly from

In 15.8(9), add "either directly or indirectly from students".

This rule as amended was adopted by the Natural Resource Commission on May 7, 1992, and will become effective July 1, 1992.

This rule is intended to implement the provisions of

Iowa Code section 110.27.

The following rule is adopted.

Amend 571—Chapter 15 by adding the following new rule:

571—15.8(110) Volunteer hunter education instructors.

15.8(1) Purpose. Pursuant to Iowa Code subsection 110.27(4), the department will certify volunteer instructors to teach the hunter education and ethics course as provided in this chapter.

15.8(2) Definitions. For the purposes of this rule:

"Certified instructor" means a person who has met all criteria in this rule.

'Course" means the department's hunter education and ethics course.

"Department" means the Department of Natural Resources, Wallace State Office Building, Des Moines, Iowa 50319-0034.

"Instructor applicant" means a person who has applied to become a certified volunteer hunter education instruc-

15.8(3) Minimum qualifications. The following conditions must be satisfied before any person can become a certified instructor. Failure to meet these conditions will result in the denial of the application. The instructor applicant will be notified of the denial by the recreational safety coordinator. An instructor applicant shall:

a. Submit an application as provided by the department to the local conservation officer or recreational safety of-

ficer.

b. Be at least 18 years of age.

- c. Have experience in handling firearms and bows and
- d. Have completed the course as defined in subrule 15.8(2).

e. Attend and pass an instructor's training and certifica-

tion course administered by the department.

- f. Submit to a background check. This check will include, but not be limited to, a criminal history check as provided by the department of public safety. A record of a felony conviction will disqualify the applicant.
- g. Be disqualified, even if involved in an apprenticeship, if that person has accumulated any habitual offender points pursuant to rule 571—15.6(109).

h. Successfully complete the apprenticeship as required

in subrule 15.8(4).

15.8(4) Instructor applicant apprenticeship. Once an instructor applicant has met all of the criteria, as provided in subrule 15.8(3), the applicant will apprentice with a certified instructor until such time as the instructor applicant can satisfactorily perform all facets required of a certified instructor.

a. The minimum amount of time for an instructor ap-

plicant to apprentice will be the following:

Participation in three courses and attendance at one local instructor workshop as conducted by the recreational safety officer.

b. The recreational safety officer will make the determination as to which certified instructor will be supervising the instructor applicant during the apprenticeship.

- c. The recreational safety officer will approve an instructor applicant for certification based upon the follow-
- (1) Successful completion of the minimum course requirements.
- (2) Recommendation for certification from the supervising certified instructor.
- (3) Lack of just cause objections from the local conservation officer(s), local chief instructor (if applicable), and the recreational safety coordinator.
- 15.8(5) Certified hunter education instructor responsibilities. A certified instructor has the following responsi-
- a. To complete all prerequisites to becoming an instructor as provided in subrules 15.8(3) and 15.8(4)
- b. To follow all policies and procedures as set forth in the current "Instructor Procedures Manual."
- c. To assist in the recruitment and training of additional volunteer instructors.
- d. To recruit and train students in the Iowa hunter education and ethics program.
- e. To actively promote the program in the instructor's county and to arrange for publicity on each new class.

- f. To maintain a file on all students that the instructor teaches.
- g. To accurately fill out all required forms and reports for each class and mail that material to the recreational safety coordinator within 15 days after the completion of the course.
 - h. To teach the course as prescribed by the department.
- i. To maintain order and discipline in the classroom, field, and firing line at all times.
 - j. To actively participate in one course every two years.
- k. To attend a minimum of one continuing education instructor workshop as provided by the department every three years.
- 15.8(6) Inactive instructors. If a certified instructor fails to comply with paragraphs 571-15.8(5)"j" and 571—15.8(5)"k," the certified instructor will be placed on inactive status.
- a. The inactive instructor will not be allowed to conduct a course and certify students as long as the instructor is on inactive status.
- b. The inactive instructor can be reactivated by attending an instructor certification workshop as provided by the
- c. If an instructor remains inactive for a period of two years, that instructor will be required to turn in the instructor card to the department and will no longer be considered a certified hunter education instructor. The inactive instructor will be notified by the department regarding the termination of the instructor's certification.

15.8(7) Grounds for revocation of instructor certification. The department may, at any time, seek to revoke the instructor certification of any person who:

- a. Fails to meet the instructor responsibilities as outlined in subrule 15.8(5).
- b. Fails to follow the policies and procedures as set forth in the current "Instructor Procedures Manual."
- c. Falsifies any information as may be required by the department.
- d. Fails, after two notices, to provide the department with the required records of students trained and certificates of competency issued.
- e. Handles any firearm or bow in an unsafe manner, or allows any other student or instructor to handle firearms or archery equipment in a reckless or unsafe manner.
- f. Is convicted of or forfeits bond for any fish and game violation of this state or any other state.
- g. Uses abusive or foul language while conducting a course.
- h. Participates in a course while under the influence of alcohol or any illegal drugs.
- i. Remains on the inactive instructor list for a period of five years or more.
- j. Has substantiated complaints filed against the instructor by the public, department personnel, or other certified instructor(s).
- k. Is convicted of a felony, aggravated or serious misdemeanor as defined in the statutes of this state. This would also include any felonies or comparable misdemeanors of any other state.
- 1. Receives compensation directly or indirectly from students for time spent on preparing for or participating in a course.
- 15.8(8) Termination of certification. Any certified instructor has the right, at any time, to voluntarily terminate certification. If an instructor terminates certification, voluntarily or is terminated by the department, that instructor

must return to the department the certification card and any and all materials that were provided.

15.8(9) Compensation for instructors. Instructor applicants and certified instructors shall not receive any compensation either directly or indirectly from students for their time while preparing for or participating in a course. However, instructor applicants and certified instructors may require students to pay for actual course-related expenses involving facilities and materials other than those provided by the department.

15.8(10) Hearing rights. If the department seeks to revoke an instructor certification pursuant to subrule 15.8(7), the department shall provide written notice of intent to revoke the certification as provided in 561-7.16(17A,455A). If the certified instructor requests a hearing, it shall be conducted in accordance with 561—Chapter 7.

> [Filed 5/8/92, effective 7/1/92] [Published 5/27/92]

EDITOR'S NOTE: For replacement pages for IAC, see IAC Supplement 5/27/92.

ARC 3054A

NATURAL RESOURCE COMMISSION[571]

Adopted and Filed

Pursuant to the authority of Iowa Code section 455A.5(6)"a," the Natural Resource Commission hereby adopts amendments to Chapter 61, "State Parks and Recreation Areas," Iowa Administrative Code.

Notice of Intended Action was published in the Iowa Administrative Bulletin on April 1, 1992, as ARC 2915A. A public hearing was held in Des Moines on April 21, 1992. No comments were received on the amendments. Except for a grammar correction in Item 7, there are no changes from the Notice of Intended Action.

The amendments make the following changes in the chapter:

- 1. Establish a winter season and procedures for rental of the new year-round cabins at Backbone State Park and Wilson Island State Recreation Area.
- Raise the damage deposit for cabin rental from \$25 to \$50 for all cabins except the sleeping-only structure at Wilson Island State Recreation Area.
- 3. Limit the number of persons that can occupy a rental cabin based on the cabin's safe carrying capacity.
- 4. Change procedures and time limits in making cabin and group camp reservations.

5. Place a time limit on completing registration for a

6. Lengthen the vessel storage season with no change in fee.

7. Allow swimming from vessels in state park and recreation area artificial lakes under certain conditions.

These rules are intended to implement Iowa Code section 111.35.

Except as noted, these amendments will become effective July 1, 1992.

EDITOR'S NOTE: Pursuant to recommendation of the Administrative Rules Review Committee published in the Iowa Administrative Bulletin, September 10, 1986, the text of these rules [61.2, 61.3(5)"a," 61.4(1)"a," 61.4(2), 61.4(3), 61.5(8)] is being omitted. With the exception of the change noted above, these rules are identical to those published under Notice as ARC 2915A, IAB 4/1/92.

[Filed 5/27/92, effective 7/1/92] [Published 5/27/92]

[For replacement pages for IAC, see IAC Supplement 5/27/92.]

ARC 3055A

NATURAL RESOURCE COMMISSION[571]

Adopted and Filed

Pursuant to the authority of Iowa Code sections 107.24, 109.38 and 109.39, the Natural Resource Commission, on May 7, 1992, adopted the following amendments to Chapter 94, "Nonresident Deer Hunting," Iowa Administrative Code.

Notice of Intended Action was published in the Iowa Administrative Bulletin on March 4, 1992, as ARC 2842A.

These amendments govern hunting of deer by nonresidents and include season dates, bag limits, possession limits, season limits, shooting hours, areas open to hunting, license quotas, licensing procedures, means and methods of take and transportation tag requirements.

Few comments were received concerning nonresident

deer hunting.

There are no changes from the Notice of Intended Action.

These amendments are intended to implement Iowa Code sections 110.1 and 110.8.

These amendments shall become effective July 6, 1992.

The following amendments are adopted.

ITEM 1. Amend rule 571—94.1(110) to read as follows:

571—94.1(110) Licenses. Every hunter must have in possession a valid 1991 1992 deer license and a 1991 1992 habitat stamp when hunting, possessing, or transporting deer. No person, while hunting deer, shall carry or have in possession any license or transportation tag issued to another person. No person shall obtain more than one nonresident deer hunting license.

94.1(1) Bow season license. Bow and arrow deer licenses shall be valid for any sex deer only during the bow season and zone designated.

94.1(2) Regular gun season license. Regular gun season licenses will be issued for any sex deer except paid gun licenses in Zones 1, 2, 7, 8, 9, and 10 will be buck only. Regular gun season licenses will be issued by zone and period and will be valid in the designated zone and for the designated period only. Any applicant who fails to designate the zone on the application form will not receive a license.

94.1(3) Special muzzleloader season. Special muzzleloader season licenses will be issued for any sex deer except licenses in Zones 1, 2, 7, 8, 9, and 10 will be buck only and shall be valid only during the special muzzle-

loader season and zone designated.

ITEM 2. Amend rule 571—94.2(110) to read as follows:

571—94.2(110) Season dates. Deer may be taken in 1991-1992 1992-1993 only during the following periods.

94.2(1) Bow season. Deer may be taken by bow and arrow only in accordance with the type, tenure, and zone of license issued from October 1 through December 6 4, 1991 1992, and December 23-21, 1991 1992, through January 10, 1992 1993.

94.2(2) Regular gun season. Deer may be taken with gun only in accordance with the type, tenure, and zone of license issued, from December 7.5 through December 14.9, or from December 14.12 through December 22.20, 1991.1992.

94.2(3) Special muzzleloader season. Deer may be taken by muzzleloader only in accordance with the type, tenure, and zone of license issued from December 23 21, 1991 1992, through January 10, 1992 1993.

ITEM 3. Amend rule 571—94.8(110) to read as follows:

571—94.8(110) Application procedures. All applications for regular gun season deer hunting licenses for 1991 1992 deer hunting season shall be made on forms provided by the department of natural resources and returned to the department of natural resources office in Des Moines, Iowa. Applications for nonresident deer hunting licenses must be accompanied by the appropriate license fee. The nonresident license fee shall be \$100 110. Party applications with no more than four individuals will be accepted. Applications will be received and accepted only from June 17 15 through July 2 17, 1991 1992, or if the application form bears a valid and legible U.S. Postal Service postmark during the same period. Any incomplete or improperly completed application, any application not meeting the above conditions, or any application received prior to the application period will not be considered as a valid application. Applications will be accepted and licenses will be issued in the order in which they are received.

ITEM 4. Amend the implementation clause at the end of Chapter 94 as follows:

These rules are intended to implement Iowa Code sections 109.38, 109.39, 109.48, 110.1 and 110.8.

[Filed 5/8/92, effective 7/6/92] [Published 5/27/92]

EDITOR'S NOTE: For replacement pages for IAC, see IAC Supplement 5/27/92.

ARC 3036A

ARC 3056A

NATURAL RESOURCE

NATURAL RESOURCE COMMISSION[571]

Adopted and Filed

Pursuant to the authority of Iowa Code sections 107.24, 109.38 and 109.39, the Natural Resource Commission, on May 7, 1992, adopted the following amendments to Chapter 97, "Common Snipe, Virginia Rail and Sora, Wood-cock and Ruffed Grouse Hunting Seasons," Iowa Administrative Code.

Notice of Intended Action was published in the Iowa Administrative Bulletin, on March 4, 1992, as ARC

These amendments govern hunting of common snipe, Virginia rail, sora, woodcock and ruffed grouse and include season dates, bag limits, possession limits, shooting hours, and areas open to hunting.

There are no changes from the Notice of Intended Ac-

tion.

These amendments are intended to implement Iowa Code sections 109.38, 109.39 and 109.48.

These amendments shall become effective August 3,

The following amendments are adopted.

ITEM 1. Rule 571—97.1(109) is amended to read as follows:

571—97.1(109) Common snipe season. Open season for hunting common snipe shall be from September 7 5 through December 22 20, 1991 1992. Shooting hours shall be from sunrise to sunset each day. Daily bag limit 8 birds; possession limit 16 birds. Entire state open.

ITEM 2. Rule 571—97.2(109) is amended to read as follows:

571—97.2(109) Virginia rail and sora season. Open season for hunting Virginia rail and sora shall be from September 75 through November 15 13, 1991 1992. Shooting hours shall be from sunrise to sunset each day. Daily bag limit 15 12 and possession limit 25 24 in aggregate of both species. Entire state open.

ITEM 3. Rule 571-97.3(109) is amended to read as follows:

571—97.3(109) Woodcock season. Open season for hunting woodcock shall be from September 14 12 through November 17 15, 1991 1992. Shooting hours shall be from sunrise to sunset each day. Daily bag limit 5; possession limit 10. Entire state open.

ITEM 4. Rule 571—97.4(109), introductory paragraph, is amended to read as follows:

571—97.4(109) Ruffed grouse season. Open season for hunting ruffed grouse shall be from October 12 10, 1991 1992, through January 31, 1992 1993. Shooting hours shall be from sunrise to sunset each day. Daily bag limit 3; possession limit 6.

[Filed 5/8/92, effective 8/3/92] [Published 5/27/92]

EDITOR'S NOTE: For replacement pages for IAC, see IAC Supplement 5/27/92.

COMMISSION[571]

Adopted and Filed

Pursuant to the authority of Iowa Code sections 107.24, 109.38 and 109.39, the Natural Resource Commission, on May 7, 1992, adopted Chapter 99, "Wild Turkey Fall Hunting," Iowa Administrative Code.

Notice of Intended Action was published in the Iowa Administrative Bulletin on March 4, 1992, as ARC

These amendments govern hunting of wild turkeys during the fall for resident and nonresident hunters and include season dates, bag limits, possession limits, shooting hours, areas open to hunting, licensing procedures, means and methods of take and transportation tag requirements.

There are no changes from the Notice of Intended Ac-

These amendments are intended to implement Iowa Code sections 109.38, 109.39, 109.48 and 110.7.

These amendments shall become effective July 6, 1992.

The following amendments are adopted.

ITEM 1. Amend 571—99.1(109), introductory paragraph, and subrules 99.1(1) and 99.1(2) as follows:

571-99.1(109) General. Wild turkey may be taken during the 1991 1992 fall season subject to the following:

99.1(1) License. All resident hunters must have in possession a valid 1991 1992 resident fall wild turkey hunting license, and additionally a 1991 1992 hunting license and 1991 1992 habitat stamp if normally required to have them, when hunting wild turkey. No person while hunting wild turkey shall carry or have in possession any license or transportation tag issued to another person. Licenses will be issued by zone and period and will be valid in the designated zone and for the designated period only. Except as provided in 99.4(1), no resident shall obtain more than one fall wild turkey gun hunting license and one fall wild turkey bow hunting license.

99.1(2) Seasons. Wild turkey of any age or sex may be taken only by the use of shotguns, muzzleloading shotguns, and bow and arrow during specified periods as

follows:

a. Combination shotgun-or-archery season. The open fall season for hunting wild turkey with shotguns, muzzleloading shotguns and bow and arrow shall be October 14 17 through November 30 29, 1991 1992, for residents.

b. Archery only. The open fall season for hunting wild turkey with bow and arrow only shall be October 1 through December 64, 1991 1992, and December 23 21, 1991 1992, through January 10, 1992 1993, for residents

ITEM 2. Amend subrule 99.3(1) as follows:

99.3(1) Permitted weapons. In accordance with the type of license issued, wild turkey may be taken only with shotguns and muzzleloading shotguns not smaller than 20-gauge and shooting 4, 5, 6, 7 1/2 or 8 shot only, or with recurve, compound or long bows with broadhead or blunt head (with a minimum diameter of 9/16 inch) arrows only, except as otherwise provided in 571—

15.5(110). Arrows with chemical or explosive pods are not permitted.

ITEM 3. Amend rule 571—99.4(109) as follows:

571—99.4(109) Application procedure. All applications for wild turkey hunting licenses for the 1991 1992 fall wild turkey hunting season must be made on forms provided by the department of natural resources and returned to the Department of Natural Resources, Des Moines, Iowa 50319, with the proper license fee. Individual applications only will be accepted.

99.4(1) Applications for combination shotgun-orarchery licenses. Applications for resident 1991 1992 fall wild turkey combination shotgun-or-archery hunting licenses shall be received and accepted from July 1 to July 26 24, 1991 1992, or if the application form bears a valid and legible U.S. Postal Service postmark during the same period. No person shall submit more than one application. At the end of the period, if applications have been received in excess of the license quota for any hunting zone and license type, the department of natural resources shall conduct a drawing to determine which applicants shall receive licenses. Incomplete or improperly completed applications, applications not meeting the above conditions, or applications received prior to or after the application period shall not be considered valid applications for the drawing. If the quota for any hunting period, zone or license type has not been filled by applications received during the application period, licenses shall then be issued in the order in which applications are received starting August 19 17 and shall continue to be issued until the quota has been met or until August 30 28, 1991 1992, whichever first occurs. Residents who have obtained one combination shotgun-or-archery license may obtain one additional combination shotgun-or-archery license between August 26 24, 1991 1992, and August 30 28, 1991 1992, if licenses are still available. dents may not apply for or obtain a 1991 1992 fall turkey

99.4(2) Applications for archery-only licenses. Residents may apply for 1991 1992 fall wild turkey archery-only hunting licenses at any time after July 1, 1991 1992. The number of archery-only licenses will not be restricted. Nonresidents may not apply for this type of license.

99.4(3) Special turkey hunting licenses. Applications for special wild turkey hunting licenses, as provided for in Iowa Code section 109.38, subsection 3, shall be on forms furnished by the department and shall be received at the department offices from July 1 to August 30 28, 1991 1992.

99.4(4) Landowner-tenant licenses. The application period for free landowner-tenant licenses shall be July 1 to August 30 28, 1991 1992. Free landowner-tenant shotgun-or-archery licenses are valid only for that portion of the farm unit that lies within Zone 6. Free landowner-tenant archery licenses are valid on farm units statewide. No resident landowner or tenant may obtain both a free combination shotgun-or-archery license and a paid shotgun-or-archery license except that persons obtaining a free landowner or tenant license may obtain a paid license in the same manner that a nonlandowner or tenant obtains a second paid license, as provided for in 99.4(1). Nonresident landowners are not eligible for free wild turkey hunting licenses.

ITEM 4. Amend rule 571—99.5(109) as follows:

571—99.5(109) License quotas. A limited number of wild turkey hunting licenses will be issued to residents in the zones as follows:

- 1. Zone 1. 0
- 2. Zone 2. 0
- 3. Zone 3. 50 30
- 4. Zone 4. 0
- 5. Zone 5. 0
- 6. Zone 6. 2,500 1,500
- 7. Zone 7. 0

These rules are intended to implement Iowa Code sections 109.38, 109.39, 109.48 and 110.7.

[Filed 5/8/92, effective 7/1/92] [Published 5/27/92]

EDITOR'S NOTE: For replacement pages for IAC, see IAC Supplement 5/27/92.

ARC 3037A

NATURAL RESOURCE COMMISSION[571]

Adopted and Filed

Pursuant to the authority of Iowa Code sections 107.24, 109.38 and 109.39, the Natural Resource Commission, on May 7, 1992, adopted the following amendments to Chapter 106, "Deer Hunting Regulations," Iowa Administrative Code.

Notice of Intended Action was published in the Iowa Administrative Bulletin on March 4, 1992, as ARC 2845A.

These amendments govern hunting of deer and include season dates, bag limits, possession limits, season limits, shooting hours, areas open to hunting, license quotas, licensing procedures, means and methods of take and transportation tag requirements.

Numerous comments were received regarding low deer numbers in northern and eastern Iowa. Some people wanted to reduce party size, and restrict party hunting. Most comments were addressing the youth deer season. Most people favored the idea but wanted the season shortened and placed later in the fall. Bow hunters objected to additional gun hunting of deer prior to the bow season.

The only changes from the Notice of Intended Action were to shorten the length of the youth deer season, to shorten the application period for special muzzleloader season licenses, and to clarify language.

These amendments are intended to implement Iowa Code sections 109.38, 109.39 and 109.48 and shall become effective July 6, 1992.

The following amendments are adopted.

ITEM 1. Amend rule 571—106.1(109) to read as follows:

571—106.1(109) Licenses. Every hunter must have in possession a valid 1991 1992 deer license when hunting, possessing, or transporting deer. No person, while hunting deer, shall carry or have in possession any license or transportation tag issued to another person.

ITEM 2. Amend rule 571-106.2(109) to read as fol-

571—106.2(109) Season dates. Deer may be taken in 1991 1992 only during the following periods:

106.2(1) Bow season. Deer may be taken by bow and arrow only in accordance with the type of license issued from October 1 through December 6 4, 1991 1992, and December 23 21, 1991 1992, through January 10, 1992 1993.

106.2(2) Regular gun season seasons. Deer may be taken with gun only in accordance with the type, tenure, and zone of license issued, from December 7 5 through December 11 9, or from December 14 12 through December 22 20, 1991 1992.

106.2(3) Special muzzleloader seasons. Deer may be taken by muzzleloader only in accordance with the type of license issued, from October 12 10 through October 20 18, or from December 23 21, 1991 1992, through January 10, 1992 *1993*.

106.2(4) No change.

ITEM 3. Amend rule 571—106.5(109) as follows:

Amend subrule 106.5(1) as follows:

106.5(1) Bow season. Any sex bow deer licenses will be valid over the entire state. Antlerless-only bow deer licenses will be valid only in Zones 3A, 4A, 5A and 6. Amend subrule 106.5(2), paragraph "i," as follows:

 Zone 9. Beginning at the point where state Highway 3 intersects with the Illinois-Iowa state line; thence along state Highway 3 to U.S. Highway 63; thence along U.S. Highway 63 to the Minnesota-Iowa state line; thence along the Minnesota-Iowa, Wisconsin-Iowa, and Illinois-Iowa state lines to the point of beginning. Zone 9A is that portion of Zone 9 lying in Allamakee, Howard and Winneshiek counties and 9B is that portion of Zone 9 lying in Chickasaw, Bremer, Fayette, Clayton, Delaware and Dubuque counties.

Amend subrule 106.5(3) as follows:

106.5(3) Special muzzleloader seasons. Early season muzzleloader deer licenses and any sex licenses licenses issued for the late season will be valid over the entire state. Antlerless-only late season deer licenses will be valid only in Zones 3A, 4A, 5A and 6.

ITEM 4. Amend subrules 106.6(1), 106.6(2) and

106.6(3) to read as follows:

106.6(1) Bow season. There will be no restrictions on the number of licenses issued for the bow deer season. A second antierless-only bow license may be purchased for \$20 25 from the county recorder's office. Second bow licenses will be valid for antlerless-only deer for Zones 3A, 4A, 5A and 6.

106.6(2) Regular gun season. Unlimited any sex licenses for both first and second periods will be available for all zones except first season paid gun licenses in Zones 1, 2, 7, 8, 9b and 10 will be buck only. All persons receiving a license for the second period will be eligible to apply for a second antierless permit for the second period that is valid for Zones 3A, 4A, 5A and 6. Persons purchasing only one regular gun season license may purchase an additional antierless-only late muzzleloader license valid in Zones 3A, 4A, 5A and 6. No person purchasing two regular gun season licenses is eligible for a late muzzleloader license. Those persons requesting an antlered deer only license and those failing to designate a zone on their application form will receive a license valid only for antiered deer. Antiered deer are defined as those deer having at least one three-inch antler.

106.6(3) Special muzzleloader seasons.

a. Early muzzleloader season. No more than 5,000 7500 any sex licenses will be issued for the period October 12 10 through October 20 18. If applications exceed that number, the department shall conduct a drawing to determine which applicants are to receive deer-licenses. Any person purchasing a special early muzzleloader license is not eligible to purchase any other gun license.

b. Late muzzleloader season. An unlimited number of any sex licenses will be issued for December 23 21, 1991 1992, through January 10, 1992 1993. Any person purchasing a late muzzleloader season license may purchase a second late antierless-only muzzleloader license valid in Zones 3A, 4A, 5A and 6. Any person purchasing two late season muzzleloader licenses may not purchase any other gun license.

ITEM 5. Amend subrule 106.7(1) to read as follows:

106.7(1) Bow season. Except as provided in 571— 15.5(109), only recurve, compound or longbows with broadhead arrows will be permitted in taking deer during the bow season. Arrows with chemical or explosive pods are not permitted.

ITEM 6. Amend subrules 106.8(2) and 106.8(3) to read as follows:

106.8(2) Regular gun season licenses. All applications for regular gun season deer hunting licenses for the 1991 1992 deer hunting season shall be made on forms provided by the department of natural resources and returned to the department of natural resources office in Des Moines, Iowa. No one shall submit more than one application. Applications for paid regular gun season deer hunting licenses must be accompanied by \$20 \$25 for each license. Only individual applications will be accepted. Applications will be received and accepted only from July 22 20 through August 30 28, 1991 1992, or if the application form bears a valid and legible U.S. Postal Service postmark prior to August 31 29, 1991 1992. Any incomplete or improperly completed application or any application not meeting the above conditions will not be considered as a valid application, except that any application for a gun license not showing the designated zone shall be presumed to be a valid application for an antlered deer only license provided it meets all other conditions.

106.8(3) Special muzzleloader season licenses. All applications for special muzzleloader season deer hunting licenses for the 1991 1992 season must be made on forms provided by the department of natural resources and returned to the department in Des Moines, Iowa. Applications must be accompanied by \$20 \$25 for each license. Only individual applications will be accepted. Applications will be received and accepted only from July 22 20 through August 30 14, 1991 1992, or if the application form bears a valid and legible U.S. Postal Service postmark prior to August 31 15, 1991, 1992. except any unsuccessful applicant for the early muzzleloader season may reapply for a regular gun or a second season muzzle-loader license through September 30, 1991. Any incomplete or improperly completed application, any application not meeting the above conditions, or any application received after the application period will not be considered as a valid application. If the quotas for special muzzleloader season deer licenses have not been filled, licenses Licenses shall then be issued in the order in which applications are received and shall continue to be issued until quotas have been met or until September 30 August 28, 1991 1992, whichever first occurs.

ITEM 7. Amend 571—Chapter 106 by adding the following new rule:

571-106.10(109) Youth deer hunt.

106.10(1) Licenses. A special youth deer license will be issued to any Iowa resident that is 12 to 15 years of age by September 1 that possesses a valid hunter safety certificate. All persons participating must be accompanied by an adult possessing a regular hunting license and habitat stamp. Only one adult for each hunter may participate. The accompanying adult must not possess a firearm and must be in direct company of the youth at all times. Persons may obtain only one youth deer license which would not prohibit that individual from obtaining one additional regular bow or gun license.

106.10(2) Season dates. Any sex deer may be taken in 1992 statewide on September 12, 13, 19, 20, 26, and 27.

106.10(3) Shooting hours. Legal shooting hours for hunting deer will be sunrise to sunset each day regardless of weapon used.

106.10(4) Limits and license quotas. Daily bag and possession limit is one deer per licensed youth. The licensee can only shoot one deer during this season. An un-

limited number of licenses will be issued.

106.10(5) Method of take and other regulations. Deer may be taken with shotgun or muzzleloader rifles as permitted in 571—106.7(109). All participants must meet the hunter orange requirement in Iowa Code section 109.122. All other regulations for taking deer with a gun

shall apply.

106.10(6) Application procedures. All applications for youth gun deer hunting licenses for the 1992 season shall be made on forms provided by the department of natural resources and returned to the department of natural resources office in Des Moines, Iowa. No one shall submit more than one application. Applications for youth gun deer hunting licenses must be accompanied by \$25 for each license. Applications will be received and accepted only from June 22 through July 24, 1992, or if the application bears a valid and legible U.S. Postal Service postmark prior to July 25, 1992.

This rule is intended to implement Iowa Code sections

109.38, 109.39 and 109.48.

[Filed 5/8/92, effective 7/6/92] [Published 5/27/92]

EDITOR'S NOTE: For replacement pages for IAC, see IAC Supplement 5/27/92.

ARC 3046A

NATURAL RESOURCE COMMISSION[571]

Adopted and Filed

Pursuant to the authority of Iowa Code sections 107.24, 109.38 and 109.39, the Natural Resource Commission, on May 7, 1992, adopted the following amendments to Chapter 107, "Rabbit and Squirrel Hunting," Iowa Administrative Code.

Notice of Intended Action was published in the Iowa Administrative Bulletin on March 4, 1992, as ARC 2844A.

These amendments govern hunting of rabbits and squirrels and include season dates, bag limits, possession limits, shooting hours, and areas open to hunting.

There are no changes from the Notice of Intended Ac-

tion.

These amendments are intended to implement Iowa Code sections 109.38, 109.39 and 109.48 and shall become effective August 3, 1992.

The following amendments are adopted.

ITEM 1. Amend rule 571—107.1(109) to read as follows

571—107.1(109) Cottontail rabbit season. Open season for hunting cottontail rabbits shall be from August 31 September 5, 1991 1992, through February 29 28, 1992 1993. Bag limit shall be 10 per day; possession limit 20. Legal hunting hours shall be from sunrise to sunset. Entire state open.

ITEM 2. Amend rule 571—107.2(109) to read as fol-

571—107.2(109) Jackrabbit season. Open season for hunting jackrabbits shall be from October 26 31, 1991 1992, through December 8 6, 1991 1992. Bag limit shall be 3 2 per day; possession limit 6 4. Legal hunting hours shall be from sunrise to sunset. Entire state open.

ITEM 3. Amend rule 571—107.3(109) to read as fol-

571—107.3(109) Squirrel season. Open season for hunting squirrels (fox and gray) shall be from August 31 September 5, 1991 1992, through January 31, 1992 1993. Bag limit shall be 6 squirrels per day; possession limit 12. Entire state open.

These rules are intended to implement Iowa Code sec-

tions 109.38, 109.39, and 109.48.

These rules are based on the best biological data available as determined by research conducted by the department of natural resources.

> [Filed 5/8/92, effective 8/3/92] [Published 5/27/92]

EDITOR'S NOTE: For replacement pages for IAC, see IAC Supplement *5/27/92*.

ARC 3059A

NATURAL RESOURCE COMMISSION[571]

Adopted and Filed

Pursuant to the authority of Iowa Code sections 107.24, 109.38 and 109.39, the Natural Resource Commission, on May 7, 1992, adopted the following amendments to Chapter 108, "Mink, Muskrat, Raccoon, Badger, Opossum, Weasel, Striped Skunk, Fox (Red and Gray), Beaver, Coyote, Otter and Spotted Skunk Seasons," Iowa Administrative Code.

Notice of Intended Action was published in the Iowa Administrative Bulletin on March 4, 1992, as ARC

These amendments govern taking of furbearers (except groundhog) and include season dates, bag limits, possession limits, shooting hours, and areas open to hunting.

There are no changes from the Notice of Intended Ac-

These amendments are intended to implement Iowa Code sections 109.6, 109.38, 109.39, 109.87 and 109.90 and shall become effective August 3, 1992.

The following amendments are adopted.

ITEM 1. Amend rule 571—108.1(109), introductory paragraph and subrule 108.1(2), to read as follows:

571—108.1(109) Mink, muskrat and weasel. Open season for the taking of mink, muskrat and weasel shall be from 8 a.m., November 2 7, 1991 1992, through January 26 31, 1992 1993. Entire state open. No bag or possession limit.

108.1(2) Game management areas. Open season for taking muskrats on certain state game management areas, certain federal national wildlife refuges, and certain county conservation board areas, only where approved by the natural resource commission and posted accordingly, shall be from 8 a.m., February 29 27 through April 5 4, 1992 1993. The use of leghold traps during this season is prohibited unless each trap is placed completely inside a muskrat house. No bag or possession limit.

ITEM 2. Amend rule 571—108.2(109) to read as follows:

571—108.2(109) Raccoon, badger, opossum and striped skunk. Open season for the taking of raccoon, badger, opossum, and striped skunk shall be from 8 a.m., November 2 7, 1991 1992, through January 26 31, 1992 1993. Entire state open. No bag or possession limit.

ITEM 3. Amend rule 571—108.3(109) to read as follows:

571—108.3(109) Red and gray fox. Open season for the taking of red and gray fox shall be from 8 a.m., November 27, 1991 1992, through January 26 31, 1992 1993. Entire state open. No bag or possession limit.

ITEM 4. Amend rule 571—108.4(109) to read as follows:

571—108.4(109) Beaver. Open season for the taking of beaver shall be from 8 a.m., November 2 7, 1991 1992, through April 5 4, 1992 1993. No bag or possession limit.

ITEM 5. Amend rule 571—108.5(109) to read as follows:

571—108.5(109) Coyote.

108.5(1) Hunting. Continuous open season. Entire state

open. No bag or possession limit.

108.5(2) Trapping. Open season for trapping coyote shall be 8 a.m., November 2 7, 1991 1992, through January 26 31, 1992 1993. Entire state open. No bag or possession limit. Any conservation officer or wildlife biologist may authorize a landowner, tenant or designee to trap coyotes causing damage outside the established trapping season dates.

[Filed 5/8/92, effective 8/3/92] [Published 5/27/92]

EDITOR'S NOTE: For replacement pages for IAC, see IAC Supplement 5/27/92.

ARC 3023A

NURŚING BOARD[655]

Adopted and Filed

Pursuant to the authority of Iowa Code sections 17A.3, 147.76 and 258A.3, the Iowa Board of Nursing hereby amends Chapter 2, "Nursing Education Programs," Iowa Administrative Code.

These amendments specify the qualifications for heads of programs and faculty members of nursing education

programs and eliminate consultant requirements.

Notice of Intended Action was published in the Iowa Administrative Bulletin on April 1, 1992, as ARC 2891A. These amendments are identical in substance to those published as Notice of Intended Action. Two redundant sentences have been eliminated in subrule 2.3(2) because the content is included elsewhere.

These amendments are intended to implement Iowa Code section 152.5.

These amendments will become effective July 1, 1992.

EDITOR'S NOTE: Pursuant to recommendation of the Administrative Rules Review Committee published in the Iowa Administrative Bulletin, September 10, 1986, the text of these rules [2.3(2), 2.6(1), 2.6(2)] is being omitted. With the exception of the changes noted above, these rules are identical to those published under Notice as ARC 2891A, IAB 4/1/92.

[Filed 5/7/92, effective 7/1/92] [Published 5/27/92]

[For replacement pages for IAC, see IAC Supplement 5/27/92.]

ARC 3030A

PROFESSIONAL LICENSING AND REGULATION DIVISION[193]

Adopted and Filed Without Notice

Pursuant to the authority of Iowa Code section 546.10, the Professional Licensing and Regulation Division hereby amends Chapter 1, "Organization and Operation," appearing in the Iowa Administrative Code.

The Professional Licensing and Regulation Division was created by 1986 Iowa Acts, Chapter 1245, under the "umbrella" of the Department of Commerce [181]. The Division is amending rule 193—1.4(546) to reflect the agency number changes resulting in that organization and to add the Real Estate Appraiser Examining Board.

In accordance with Iowa Code subsection 17A.4(2), the Division finds that it is impracticable and unnecessary to provide Notice of Intended Action as the amendment to 193—4.1(546) merely adds the Real Estate Appraiser Examining Board to the professions within the Division and updates the rule to conform with the statute.

This amendment is intended to implement Iowa Code

section 546.10.

PROFESSIONAL LICENSING AND REGULATION DIVISION[193](cont'd)

This amendment will become effective July 1, 1992. The following amendment is adopted.

Amend rule 193—1.4(546) as follows:

193—1.4(546) Purpose of division. The division exists to coordinate the administrative support for the following

five six professional licensing boards.

1.4(1) The engineering and land surveying examining board is a seven-member board appointed by the governor and confirmed by the senate. It is composed of four professional engineers, one land surveyor, and two public members. The board administers Iowa Code chapter 114, Professional Engineers and Land Surveyors, and board rules published under agency number [390] [193C]—Chapters 1 to 45, Iowa Administrative Code.

1.4(2) The accountancy examining board is an eightmember board, seven appointed by the governor and confirmed by the senate, and one appointed from the accounting practitioner advisory council. The board is composed of five certified public accountants, two public members, and one *licensed* accounting practitioner. The board administers Iowa Code chapter 116, Public Accountants, and board rules published under agency number [10] [193A]—Chapters 1 to 15 16, Iowa Administrative Code.

- 1.4(3) The real estate examining board commission is a five-member board commission appointed by the governor and confirmed by the senate. It is composed of three members licensed under Iowa Code chapter 117 and two public members. The board commission administers Iowa Code chapters 117, Real Estate Brokers and Salespersons; 117A, Sales of Subdivided Land Outside of Iowa; 557A, Time-Share Act; and board commission rules published under agency number [700] [193E]—Chapters 1 to 4 6, Iowa Administrative Code.
- 1.4(4) The architectural examining board is a sevenmember board appointed by the governor and confirmed by the senate. It is composed of five registered architects, and two public members. The board administers Iowa Code chapter 118, Registered Architects, and board rules published under agency number [80] [193B]—Chapters 1 to 5 6, Iowa Administrative Code.
- 1.4(5) The landscape architectural examining board is a seven-member board appointed by the governor and confirmed by the senate. It is composed of five registered landscape architects and two public members. The board administers Iowa Code chapter 118A, Landscape Architects, and board rules published under agency number [540] [193D]—Chapters 1 to 4 5, Iowa Administrative Code.
- 1.4(6) The real estate appraiser examining board is a seven-member board appointed by the governor and confirmed by the senate. It is composed of five certified real estate appraisers and two public members. The board administers Iowa Code chapter 117B, Real Estate Appraisals and Appraisers, and board rules published under agency number [193D]—Chapters 1 to 10, Iowa Administrative Code.

[Filed Without Notice 5/8/92, effective 7/1/92] [Published 5/27/92]

EDITOR'S NOTE: For replacement pages for IAC, see IAC Supplement 5/27/92.

ARC 3019A

IAB 5/27/92

PROFESSIONAL LICENSURE DIVISION[645]

BOARD OF EXAMINERS FOR THE LICENSING AND REGULATION OF HEARING AID DEALERS

Adopted and Filed

Pursuant to the authority of Iowa Code section 154A.4, the Board of Examiners for the Licensing and Regulation of Hearing Aid Dealers hereby amends Chapter 120, "Board of Examiners for the Licensing and Regulation of Hearing Aid Dealers," and adopts Chapter 121, "Declaratory Rulings," Chapter 122, "Petitions for Rule Making," and Chapter 123, "Agency Procedure for Rule Making," Iowa Administrative Code.

The rules adopt definitions by reference as they appear in Iowa Code chapter 154A, clarify lapsed license, add an inactive status to comply with Iowa Code section 258A.2(2)"f," clarify settlement procedures and grounds for discipline of a licensee and adopt uniform rules on declaratory rulings, petitions for rule making and procedures for rule making.

Notice of Intended Action regarding these amendments was published in the March 4, 1992, Iowa Administrative Bulletin as ARC 2833A, and the amendments were adopted by the Board of Examiners for the Licensing and Regulation of Hearing Aid Dealers on May 3, 1992. These amendments become effective July 1, 1992.

No changes were made to the Notice of Intended Ac-

These amendments are intended to implement Iowa Code sections 17A.10, 17A.3(1)"b," and 17A.7 and chapters 154A and 258A.

The following amendments are adopted.

ITEM 1. Amend rule 645—120.1(154A), catchwords, as follows:

645—120.1(154A) Availability of information General information.

ITEM 2. Adopt a new subrule 120.1(3) as follows: 120.1(3) Definitions. The board adopts herein by reference the definitions set out in Iowa Code chapter 154A.

ITEM 3. Renumber existing subrule 120.5(4) as 120.5(5) and adopt a new subrule 120.5(4) as follows:

120.5(4) Hearing aid dealers who have not fulfilled the requirements for license renewal or an exemption by January 31 (odd year) of the licensure biennium will have a lapsed license and shall not engage in the practice of hearing aid dealer.

ITEM 4. Adopt new rules 120.7(258A) and 120.8(258A) as follows and renumber the existing rules 120.7(154A) through 120.11(154A) as 120.9(154A) through 120.13(154A).

645—120.7(258A) Exemptions for inactive practitioners. A licensee who is not engaged in the active practice of hearing aid dealer in the state of Iowa residing within or without the state of Iowa may be granted a certificate of exemption upon written application to the board. The application shall contain a statement that the applicant will not engage in the practice of hearing aid dealer in

PROFESSIONAL LICENSURE DIVISION[645](cont'd)

Iowa without first complying with all regulations governing reinstatement after exemption. See rule 645—120.8(258A). The application for a certificate of exemption shall be submitted upon the form provided by the board.

Individuals who fail to request reinstatement after a five-year period from the date the certificate of exemption was granted shall be considered to have a lapsed license.

645—120.8(258A) Reinstatement of exempted, inactive practitioners. Inactive practitioners who have been granted a waiver of compliance with these rules and obtained a certification of exemption shall, prior to engaging in the practice of hearing aid dealer in the state of Iowa, satisfy the following requirements for reinstatement:

120.8(1) Submit written application for reinstatement to the board upon forms provided by the board, pay rein-

statement fee and current renewal fee.

- 120.8(2) Furnish evidence of completion of 50 hours of accredited continuing education in the following categories, with a minimum of five hours in each category.
 - a. Anatomy and physiology of the auditory mechanism.

b. Acoustics of sound.

c. Types of hearing loss—disorders of hearing.

d. Puretone and speech audiometry—basic tympanometry.

e. Interpreting the audiogram.

- f. Hearing aids—types, characteristics, components, circuits, etc.
- g. Hearing aid selection, adaptation and fitting (to include earmold technology) with consideration for adult, geriatric, pediatric and special populations.

h. Aural rehabilitation, counseling the hearing-

impaired.

i. Office procedures, records, follow-up care.

j. Troubleshooting hearing aid fittings, making modifications.

The continuing education hours must be completed within the prior six months of date of application for reinstatement.

- ITEM 5. Rescind existing rule 120.12(17A) in its entirety.
- ITEM 6. Rescind and reserve rule 120.200(258A) in its entirety.
- ITEM 7. Rescind rule 120.204(258A) and insert the following in lieu thereof:

645—120.204(258A) Settlements.

120.204(1) Informal settlement—parties.

- a. A contested case may be resolved by informal settlement. Negotiation of an informal settlement may be initiated by the state of Iowa represented by the prosecuting attorney, the respondent, or the board. The board shall designate a board member with authority to negotiate on behalf of the board.
- b. The board is not involved in negotiation until presentation of a final, written form to the full board for approval.
- 120.204(2) Informal settlement—waiver of notice and opportunity to be heard. Consent to negotiation by the respondent constitutes a waiver of notice and opportunity to be heard pursuant to Iowa Code section 17A.17 during informal settlement negotiation. Thereafter, the prosecuting attorney is authorized to discuss informal settlement with the board's designee.

120.204(3) Informal settlement—board approval. All informal settlements are subject to approval by a majority of the full board. No informal settlement shall be presented to the board for approval except in final, written form executed by the respondent. If the board fails to approve the informal settlement, it shall be of no force or effect to either party.

120.204(4) Informal settlement—disqualification of designee. A board member who is designated to act in negotiation of an informal settlement is not disqualified from participating in the adjudication of the contested

case.

This rule is intended to implement Iowa Code section 17A.1 and chapter 258A.

ITEM 8. Rescind rule 120.212(258A) and insert the following in lieu thereof:

645—120.212(258A) Suspension, revocation or probation. The board may revoke or suspend a license or temporary permit permanently or for a fixed period, or impose a civil penalty which shall not exceed \$1000 for any of the following causes:

120.212(1) Willful or repeated violations of the provi-

sions of Iowa Code chapter 154.

120.212(2) Violation of the rules promulgated by the board.

120.212(3) Knowingly making misleading, deceptive, untrue or fraudulent representations in the practice of a profession or engaging in unethical conduct or practice harmful or detrimental to the public. Proof of actual injury need not be established.

120.212(4) Fraud in representations as to skill or abil-

ity.

120.212(5) Personal disqualifications:

a. Mental or physical inability reasonably related to and adversely affecting the licensee's ability to practice in a safe and competent manner.

b. Involuntary commitment for treatment of mental

illness, drug addiction or alcoholism.

120.212(6) Practicing the profession while license is suspended or lapsed.

120.212(7) Violating the terms of probation, settlement or decision and order.

120.212(8) Suspension or revocation of license by another state.

120.212(9) Negligence by the licensee in the practice of the profession, which is a failure to exercise due care including negligent delegation to or supervision of employees or other individuals, whether or not injury results; or any conduct, practice or conditions which impair the ability to safely and skillfully practice the profession.

120.212(10) Prohibited acts consisting of the follow-

ing:

 a. Permitting an unlicensed employee or person under the licensee's control to perform activities requiring a license.

b. Permitting another person to use the person's license for any purpose.

c. Practice outside the scope of a license.

d. Obtaining, possessing, or attempting to obtain or possess a controlled substance without lawful authority; or selling, prescribing, giving away, or administering controlled substances.

e. Verbally or physically abusing clients.

120.212(11) Unethical business practices, consisting of any of the following:

PROFESSIONAL LICENSURE DIVISION[645](cont'd)

a. Betrayal of a professional confidence.

b. Falsifying clients' records.

c. Advertising that hearing testing or hearing screening is for the purpose of detection of or diagnosis of medical problems or medical screening for referral to a physician.

120.212(12) Failure to report a change of name or ad-

dress within 30 days after it occurs.

120.212(13) Submission of a false report of continuing education or failure to submit the biannual report of con-

tinuing education.

120.212(14) Failure to notify the board within 30 days after occurrence of any judgment or settlement of a malpractice claim or action.

120.212(15) Failure to comply with a subpoena issued

by the board.

120.212(16) Failure to report to the board as provided in rule 645—120.201(258A) any violation by another licensee of the reasons for disciplinary action as listed in this rule.

This rule is intended to implement Iowa Code section 154A.24.

ITEM 9. Adopt a new 645—Chapter 121 as follows:

CHAPTER 121 DECLARATORY RULINGS

The board of examiners for the licensing and regulation of hearing aid dealers hereby adopts the declaratory rulings segment of the Uniform Rules which is printed in the first Volume of the Iowa Administrative Code, with the following amendments:

645—121.1(17A) Petition for declaratory ruling. In lieu of the words "(designate office)", insert "Board of Examiners for the Licensing and Regulation of Hearing Aid Dealers, Professional Licensure, Iowa Department of Public Health, Lucas State Office Building, Des Moines, Iowa 50319-0075".

In lieu of the words "(AGENCY NAME)", the heading on the petition should read:

BEFORE THE BOARD OF EXAMINERS FOR THE LICENSING AND REGULATION OF HEARING AID DEALERS

645—121.3(17A) Inquiries. In lieu of the words "(designate official by full title and address)", insert "the Hearing Aid Dealers Board Administrator, Professional Licensure, Lucas State Office Building, Des Moines, Iowa 50319-0075".

These rules are intended to implement Iowa Code section 17A.9.

ITEM 10. Adopt a new 645—Chapter 122 as follows:

CHAPTER 122 PETITIONS FOR RULE MAKING

The board of examiners for the licensing and regulation of hearing aid dealers hereby adopts the petitions for rule making segment of the Uniform Rules which is printed in the first Volume of the Iowa Administrative Code, with the following amendments:

645—122.1(17A) Petition for rule making. In lieu of the words "(Designate office)", insert "Board of Examiners for the Licensing and Regulation of Hearing Aid Dealers, Professional Licensure, Iowa Department of Public

Health, Lucas State Office Building, Des Moines, Iowa 50319-0075".

In lieu of the words "(AGENCY NAME)", the heading of the petition should read:

BEFORE THE BOARD OF EXAMINERS FOR THE LICENSING AND REGULATION OF HEARING AID DEALERS

645—122.3(17A) Inquiries. Inquiries concerning the status of a petition for rule making may be made to the Hearing Aid Dealers Board Administrator, Professional Licensure, Lucas State Office Building, Des Moines, Iowa 50319-0075.

These rules are intended to implement Iowa Code section 17A.7.

ITEM 11. Adopt a new 645—Chapter 123 as follows:

CHAPTER 123 AGENCY PROCEDURE FOR RULE MAKING

The board of examiners for the licensing and regulation of hearing aid dealers hereby adopts the agency procedure for rule making segment of the Uniform Rules which is printed in the first Volume of the Iowa Administrative Code, with the following amendments:

645—123.3(17A) Public rule-making docket.

123.3(2) Anticipated rule making. In lieu of the words "(commission, board, council, director)", insert "Board of Examiners for the Licensing and Regulation of Hearing Aid Dealers".

645—123.4(17A) Notice of proposed rule making.

123.4(3) Notices mailed. In lieu of the words "(specify time period)", insert "one year".

645—123.5(17A) Public participation.

123.5(1) Written comments. In lieu of the words "(identify office and address)", insert "Board of Examiners for the Licensing and Regulation of Hearing Aid Dealers, Professional Licensure, Iowa Department of Public Health, Lucas State Office Building, Des Moines, Iowa 50319-0075".

645—123.6(17A) Regulatory flexibility analysis.

123.6(3) Mailing list. In lieu of the words "(designate office)", insert "Board of Examiners for the Licensing and Regulation of Hearing Aid Dealers, Professional Licensure, Iowa Department of Public Health, Lucas State Office Building, Des Moines, Iowa 50319-0075".

645—123.10(17A) Exemptions from public rule-making procedures.

123.10(2) Categories exempt. In lieu of the words "(List here narrowly drawn classes of rules where such an exemption is justified and a brief statement of reasons for exempting each of them)", insert the following:

a. Rules which implement recent legislation, when a statute provides for an effective date which does not allow for the usual notice and public participation requirements.

b. Rules which confer a benefit or remove a restriction on licensees, the public, or some segment of the public.

c. Rules which are necessary because of imminent per-

il to the public health, safety or welfare.

d. Nonsubstantive rules intended to correct typographical errors, incorrect citation, or other errors in existing rules.

PROFESSIONAL LICENSURE DIVISION[645](cont'd)

645—123.11(17A) Concise statement reasons.

123.11(1) General. In lieu of the words "(specify the office and address)", insert "Board of Examiners for the Licensing and Regulation of Hearing Aid Dealers, Professional Licensure, Iowa Department of Public Health, Lucas State Office Building, Des Moines, Iowa 50319-0075".

645—123.13(17A) Agency rule-making record. 123.13(2) Contents.

c. In lieu of the words "(agency head)", insert "Board of Examiners for the Licensing and Regulation of Hearing Aid Dealers".

These rules are intended to implement Iowa Code sections 17A.3 to 17A.5.

[Filed 5/7/92, effective 7/1/92] [Published 5/27/92]

EDITOR'S NOTE: For replacement pages for IAC, see IAC Supplement 5/27/92.

ARC 3027A

PUBLIC HEALTH DEPARTMENT[641]

Adopted and Filed

Pursuant to the authority of Iowa Code sections 135.11(16) and 136C.3(4), the Iowa Department of Public Health hereby adopts amendments to Chapter 38, "General Provisions," and Chapter 42, "Operating Procedures and Standards for Use of Radiation Emitting Equipment," Iowa Administrative Code.

Amendments to Chapter 38 include radiation therapists and nuclear medicine technologists in fee and penalty requirements. The amendment to Chapter 42 clarifies operating procedures and standards for limited diagnostic radiographers, sets standards for recertification and expands disciplinary grounds and actions for all diagnostic radiographers.

Notice of Intended Action was published in the April 1, 1992, Iowa Administrative Bulletin as ARC 2923A.

These amendments are identical to those published under Notice of Intended Action.

The few comments received prior to the public hearing indicated support of the amendments. One comment was received at the public hearing held on April 21, 1992, and did not warrant any further changes.

The Board of Health adopted these amendments on May 6, 1992.

These amendments shall become effective July 1, 1992.

These amendments are intended to implement Iowa Code chapter 136C.

The following amendments are adopted.

ITEM 1. Amend subrule 38.13(5), introductory para-

graph, as follows:

38.13(5) Diagnostic radiographers. Fees for 641—Chapter 42 certification. General and limited diagnostic Diagnostic radiographers, radiation therapists, and nu-

clear medicine technologists, other than licensed practitioners of the healing arts, are required to pay fees sufficient to defray the cost of administering rule 42.1(136C) 641—Chapter 42. Fees are as follows:

ITEM 2. Amend subrule 38.13(6) by adding a new paragraph "c" as follows:

- c. Late fees for 641—Chapter 42 continuing education
- requirements.
- (1) For any individual who completes the required continuing education before the continuing education due date, but fails to submit the required proof within 30 days after the continuing education due date, the certification shall be terminated and the renewal fee will not be refunded.
- (2) For any individual who fails to complete the required continuing education before the continuing education due date, but submits a written plan of correction to obtain the required hours, that person shall be allowed no more than 60 days after the original continuing education due date to complete the plan of correction and submit the documentation of completion of continuing education requirements. After 60 days, the certification shall be terminated and the individual shall not function as a diagnostic radiographer, radiation therapist, or nuclear medicine technologist in Iowa.
- (3) Once terminated, any individual who requests permission to function within six months of the initial continuing education due date must submit proof of continuing education hours and shall submit a late fee of \$30 in addition to the annual fees in order to obtain reinstatement certification.

ITEM 3. Amend 641—Chapter 42 as follows:

641—42.1(136C) Minimum training standards for diagnostic radiographers.

42.1(1) Definitions.

"Approved course of study" means a curriculum and associated training and testing materials which the agency department has determined is adequate to train students to meet the requirements of 42.1(136C).

"Chest" is defined as the lung fields including the cardiac shadow, as taught in the approved limited radiography curriculum. Radiography of the shoulder, clavicle, scapula, ribs, thoracic spine and sternum for diagnostic evaluation of these body structures is not allowed under this body part classification.

"Clinical education" means the direct participation of the student in completion of diagnostic studies.

"Contrast media" means material intentionally administered to the human body to define a part(s) which is not

normally visualized radiographically.

"Diagnostic radiography" means the science and art of applying X-radiation to human beings for diagnostic purposes other than in dental radiography. It shall include adjustment or manipulation of X-ray equipment and appurtenances including image receptors, positioning of patients and processing of films so as to materially affect the radiation exposure of patients.

"Licensed practitioner" means a person licensed or otherwise authorized by law to practice medicine, osteopathy, chiropractic, podiatry, dentistry or dental hygiene or certification as a physician's physician assistant as defined in Iowa Code section 148C.1, subsection 6.

fined in Iowa Code section 148C.1, subsection 6.

"Lower extremities" refers to those body parts from the distal phalanges of the foot to the head of the femur and its articulation with the pelvic girdle as taught in the ap-

proved limited radiographer curriculum. True hip radiographs are prohibited under this limited category.

"Spine" refers to the cervical, thoracic (dorsal), lumbar vertebrae and their articulations. It may also include the sacrum or coccyx and the sacral articulation with the pelvic girdle. True pelvis radiographs performed with the image receptor positioned perpendicular to the long axis of the torso are prohibited under this limited category. Lumbo-pelvic or full spine radiography may be performed if the long axis of the image receptor is positioned parallel with the long axis of the spine as taught in the approved limited radiographer curriculum.

"Student" means a person enrolled in and participating

in an approved course of study.

"Supervision" means responsibility for and control of quality, radiation safety and protection, and technical aspects of the application of ionizing radiation to human be-

ings for diagnostic or therapeutic purposes.
"Upper extremities" refers to those body parts from the distal phalanges of the hand to the head of the humerus. These projections may include the acromioclavicular or glenoidhumeral areas as taught in the approved limited radiographer curriculum. True shoulder radiography that includes both distal and proximal ends of the clavicle is prohibited under this category.

"X-radiation" means penetrating electromagnetic radiation with energy greater than 0.1 kV produced by bombarding a metallic target with fast electrons in a high

42.1(2) Types of operators.

"General diagnostic radiographer" means a person, other than a licensed practitioner or dental radiographer, who applies X-radiation to any part of the human body for diagnostic purposes while under the supervision of a li-

censed practitioner.

b. "Limited diagnostic radiographer" means a person, other than a licensed practitioner or dental radiographer, who applies X-radiation to one not more than two specific body part parts while under the supervision of a licensed practitioner. Chest and extremity radiographic examinations are considered as one body part. The exceptions to the one body part restriction are:

(1) The limited diagnostic radiographer may perform both chest and extremity radiographic examinations if that individual has received appropriate clinical experience during the didactic training required under 42.1(4)"b" and

42.1(5)"b," and

(2) When an individual gains the status of a limited diagnostic radiographer as outlined in 42.1(4)"b"(2), (3) or (4), that individual may perform the permitted radio-

graphic procedures.

"Conditional diagnostic radiographer (hardship)" means a diagnostic X-ray machine operator who has minimal clinical competency but does not fully meet the appropriate requirements of 42.1(3) and 42.1(4) or is not otherwise covered under 42.1(5), 42.1(6) or 42.1(8), but in which case there is substantial evidence that the people in the locality of the state in which this exemption is sought would be denied adequate health care because of the unavailability of appropriately qualified persons under 42.1(136C). A conditional exemption shall be granted for limited periods of time to be prescribed by the agency department at the agency's department's discretion and in accordance with the purposes of 42.1(136C). A conditional diagnostic radiographer shall be limited by the agency department to those rights specified in the exemption notice and be under the direct supervision of a licensed practitioner.

42.1(3) Minimum eligibility requirements.

- a. Graduation from high school or its equivalent.
- b. Attainment of 18 years of age.
- c. Ability to adequately perform necessary duties without constituting a hazard to the health or safety of patients

42.1(4) Training requirements.

a. General diagnostic radiographer. Successful completion of a Committee on Allied Health Education and Accreditation approved course of study or equivalent to prepare the student to demonstrate competency in the following areas:

(1) Radiation protection of patients and workers, including monitoring, shielding, units of measurement and permissible levels, biological effects of radiation, and technical consideration in reducing radiation exposure and

frequency of retakes;

- (2) Technique and quality control to achieve diagnostic objectives with minimum patient exposure, including X-ray examinations, X-ray production, films, screens, holders and grids, technique conversions, film processing, artifacts, image quality, film systems and control of secondary radiation for the specified category;
- (3) Patient care including, but not limited to, aseptic techniques, emergency procedures and first aid, and con-

trast media;

(4) Positioning, including normal and abnormal anato-

my and projections;

(5) Radiographic equipment and operator maintenance to include X-ray tubes, grids, standardization of equipment, generators, preventive maintenance, basic electricity, film processors and maintenance, collimators, X-ray control consoles, tilt tables, ancillary equipment, fluoroscopes and electrical and mechanical safety;

(6) Special techniques, including stereo, body section radiography, pelvimetry, image intensification, photo tim-

ing and mobile units; and

(7) Clinical experience sufficient to demonstrate competency in the application of the above as specified in the revised 1978 1990 edition of the "Essentials and Guidelines of an Accredited Educational Program for the Radiographer" of the American Medical Association's Committee on Allied Health Education and Accreditation.

b. Limited diagnostic radiographer.

- (1) Completion of an approved course of study to prepare the student to demonstrate competency in the follow-
- 1. Radiation protection of patients and workers including monitoring, shielding, units of measurement and permissible levels, biological effects of radiation, and technical considerations in reducing radiation exposure and frequency of retakes;
- 2. Technique and quality control to achieve diagnostic objectives with minimum patient exposure to include Xray examination, X-ray production, films, screens, holders and grids, technique conversions, film processing, artifacts, image quality, film systems and control of secondary radiation for the specified category;
- 3. Patient care including, but not limited to, aseptic techniques, emergency procedures and first aid;
- 4. Positioning, including normal and abnormal anatomy and projections for the specific category;
- 5. Radiographic equipment and operator maintenance to include X-ray tubes, grids, standardization of equip-

ment, generators, preventive maintenance, basic electricity, film processors and maintenance, collimators, X-ray control consoles, tilt tables, ancillary equipment, fluoroscopes and electrical and mechanical safety;

6. Special techniques limited to those required by the

specific category; and

- 7. Clinical experience sufficient to demonstrate competency in the application of the above as specified in the revised 1978 edition of the "Essentials and Guidelines of an Accredited Educational Program for the Radiographer" of the American Medical Association's Committee on Allied Health Education and Accreditation. by the department. Clinical experience must be directly supervised by a two-year trained general radiographer or licensed physician who physically observes and critiques the actual X-ray procedures.
- (2) An individual may apply X-radiation to more than one specific part of the human body for diagnostic purposes if the individual meets the requirements of 42.1(4)"b"(1) and 42.1(5)"b" and receives a course of elinical training approved by the department from a radiologist who then certifies the individual's competency to perform certain specific radiographic procedures. The individual may only perform those diagnostic radiographic procedures certified by the radiologist. The following information and statements will need to be provided to the department:

1. The diagnostic radiographic procedures which the individual may perform;

2. The name and qualifications of the certifying radiologist and a list of the body part(s) and projection(s) they

have certified the individual to perform;

- 3. If the individual has not successfully completed a training program which meets the requirements set forth in 42:1(4)"b" and 42:1(5)"b," a letter from the institution providing didactic training which indicates the employee's enrollment status and course dates; and
- 4. 8. Permission for a representative of the Iowa department of public health to comprehensively evaluate whether the individual meets the training standard.
- (3) An individual employed in a diagnostic radiography facility which has a work load of less than five thousand (5000) examinations per year and which provides twenty-four 24-hour service in a hospital will be permitted to apply X-radiation to any part of the human body at that facility if the individual completes a training program recognized by the department, as outlined in 42.1(4)"b"(1) and 42.1(5)"b" and has received elinical training and submits a letter from a board-certified or board-eligible radiologist who then certifies verifies in writing the specific procedures the individual is competent to perform. The training program must cover the areas outlined in 42.1(4)"b," the anatomy and physiology of the entire body, positioning and techniques relative to the procedures to be performed, and appropriate clinical training which includes all parts of the human body. The certifying radiologist must be directly responsible for the individual's clinical training. Training received under this subrule is specific to the facility and must be reevaluated by the department before an individual may transfer to another facility.
- c. Certification by the American Registry of Radiologic Technologists or the American Registry of Clinical Radiography Technologists meets the minimum requirements of 42.1(136C).
 - 42.1(5) School accreditation.
- a. Graduates of schools accredited by the Committee on Allied Health Education and Accreditation who have

successfully completed an appropriate course of study in diagnostic radiography will be considered to meet the requirements of 42.1(2)"a."

b. Graduates of programs recognized by the Iowa department of public health in consultation with the professional societies and boards of examiners for appropriate course of study in diagnostic radiography will be considered to meet the requirements of 42.1(2)"b."

42.1(6) Exemptions.

- a. Students enrolled in and participating in an approved program or approved course of study for diagnostic radiography or an approved school of medicine, osteopathy, podiatry, and chiropractic, who as a part of their course of study, apply ionizing radiation to a human being while under the supervision of a licensed practitioner. The projected completion date of the clinical portion of the program or course of study shall be within a time period equal to or less than twice that required for a full-time student, the original program or course of study.
 - b. Licensed practitioners as defined in 42.1(1).

c. Conditional diagnostic radiographer as defined under 42.1(2)"c."

42.1(7) Enforcement. Disciplinary grounds and actions. The following shall be grounds for disciplinary action involving possible suspension or revocation of certification or levying of fines:

a. Any individual, except a licensed practitioner defined in subrule 42.1(1), who operates X-ray equipment in the practice of diagnostic radiography shall meet the re-

quirements of 42.1(136C).

b. Any person including a licensed practitioner defined in 42.1(1) who employs an individual in the practice of diagnostic radiography may do so only if that individual meets the requirements of 42.1(136C).

a. Operating as a diagnostic radiographer without

meeting the requirements of this rule.

b. Allowing any person, excluding a licensed physician, to operate as a diagnostic radiographer if that person cannot provide proof of certification by the department.

c. Failing to report to the department any person who the certificate holder knows is in violation of this rule.

- d. Submitting false information in order to obtain certification or renewal certification as a diagnostic radiographer.
- e. Any action that the department determines may jeopardize the public or therapist's health and safety.
- 42.1(8) Reciprocity. Any person who is the holder of a current certificate in diagnostic radiography issued by another state, jurisdiction, agency or recognized professional registry may be considered by the agency to meet the requirements of 42.1(136C), provided that the agency finds that the standards and procedures for certification in the state, jurisdiction, agency or recognized professional registry which issued the certificate, afford protection to the public equivalent to that afforded by 42.1(136C).

42.1(9) Technical advisory committee.

- a. The department shall establish a technical advisory committee made up of two radiologic technologists, two physicians, including one radiologist and one private practice practitioner, and a representative of the department.
- b. The advisory committee shall assist the department in developing and establishing criteria for continuing education and examinations.
 - 42.1(10) Examinations.
- a. All individuals, except licensed practitioners, seeking to perform diagnostic radiography must, in addition to

subrule 42.1(4), take and satisfactorily pass a written examination including within one year of the date of the initial certification. Examination must include the following subject matter for each category of radiographer:

(1) General radiographer and limited radiographer under provisions of 42.1(4)"b"(3)—radiation protection, radiation physics, radiographic and fluoroscopic techniques, special procedures, patient care, positioning, equipment maintenance, anatomy, contrast media, physiology, quality control, radiographic processing and clinical experience.

Limited radiographer under the provisions of 42.1(4)"b"(1) or 42.1(4)"b"(2)—radiation protection, radiation physics, radiographic techniques, patient care, positioning, equipment maintenance, anatomy, physiology, quality control, and radiographic processing and clinical experience for the specific permit to practice requested.

(3) Contents of the examinations will be established and periodically revised by the department in consultation with the technical advisory committee.

b. Examinations will be given by the department at least annually, or as necessary, at course of study location or other location determined by the department.

c. The department may accept, in lieu of its own examination, evidence of satisfactory performance in an examination given by an appropriate organization or testing service provided that the department finds the organization or service to be competent to examine applicants in the discipline of radiography. For purposes of this subrule, persons who are registered with the American Registry of Radiologic Technologists or American Registry of Clinical Radiography Technologists meet the testing requirements of 42.1(10).

42.1(11) Continuing education.

- a. Each individual, other than a licensed practitioner, who operates diagnostic X-ray equipment shall, during a two-year period, obtain continuing education credit as follows:
 - (1) General diagnostic radiographer—24 clock hours.
- (2) Limited diagnostic radiographer under the provisions of 42.1(4)"b"(3)—24 clock hours.
- (3) Limited diagnostic radiographer under the provision of 42.1(4)"b"(1) or 42.1(4)"b"(2)—12 clock hours.

b. Continuing education course approval.

Thirty days prior to conducting a continuing education course, the sponsoring person must submit the following:

1. The course objectives.

- 2. An outline of the course which sets forth the subject to be given, the course content, and the length of the course in clock hours.
- 3. The instructor's name and short resumé detailing qualifications.
- (2) Following its review, the department may, in consultation with or under predetermined guidance of the technical advisory committee, approve, disapprove, or request additional information on the proposed course.

(3) The department may, from time to time, audit the continuing education course to verify the adequacy of

program content and delivery.

- (4) The department will recognize continuing education courses approved for credit by the American Society of Radiologic Technologists or the American Registry of Clinical Radiography Technologists.
- c. Continuing education credit will be awarded under provisions of 42.1(11)"b" by the department to individu-

- (1) Who have successfully completed a continuing education course which has been approved by the department.
- Who present a continuing education course to diagnostic radiographers which has been approved by the department. Credit granted shall be at a rate of two times the amount of time it takes to present the course.

(3) Only once during a two-year period for the same

continuing education course.

d. All continuing education must be directly related to

diagnostic radiography.

- e. It is required that proof of receiving continuing education be retained at each individual's place of employment for review by representatives of this department. Proof of continuing education must be maintained for at least three years.
- f. All continuing education requirements shall be completed during the two-year period prior to the certification continuing education due date. Failure to complete the continuing education requirements prior to the due date may result in penalties or termination of certification as specified in 641—paragraph 38.13(6)"d.

42.1(12) Recertification.

a. If a person who performs as a diagnostic radiographer in Iowa allows the certification to expire for any reason or if any person voluntarily terminates certification, the following will apply:

(1) Any individual who wishes to regain certification and makes application within six months of the termination date will be allowed to do so with no additional

training or testing required.

- (2) Any individual who wishes to regain certification after the six-month period will need to meet the current educational and testing requirements as outlined in 641—42.1(136C). Proof of possession of a previous certification may satisfy the training portion of this requirement.
- (3) Any individual who has not renewed certification for at least five years and wants to regain certification, or who has not applied for certification within five years of the completion date of the radiography course, will need to complete a recertification program approved by the department of not less than 24 contact hours for general technologists and 12 contact hours for limited technologists which specifically applies to diagnostic radiography.

b. Recertification programs.

(1) The recertification program must review those basic principles necessary to ensure minimum competency in radiology and must also include the satisfactory completion of a written examination. Both the program and the examination must acquire prior approval from the department. Courses designed for use in the recertification program will not qualify for continuing education credit for those persons required to attend in order to recertify.

(2) If no approved programs are available, the department may require attendance for a minimum of 24 contact hours for general technologists and 12 hours for limited technologists at specific continuing education programs. The continuing education must be confined to subjects which apply to the area of certification limitation, if any, and would have to be completed within a specified time

c. Exemptions. Any or all of the above-mentioned requirements may be waived for a person who has been actively employed as a radiologic technologist in another state, country, or federal institution or who can prove cir-

cumstances above and beyond the norm. These cases will be reviewed on an individual basis and the decision of the department shall be final.

42.1(13) Fees. All diagnostic radiographers certified under this rule must pay fees as specified in 641—subrule

38.13(5).

[Filed 5/8/92, effective 7/1/92] [Published 5/27/92]

EDITOR'S NOTE: For replacement pages for IAC, see IAC Supplement 5/27/92.

ARC 3026A

PUBLIC HEALTH DEPARTMENT[641]

Adopted and Filed

Pursuant to the authority of Iowa Code sections 135.11(16) and 136C.3(4), the Iowa Department of Public Health hereby adopts amendments to Chapter 42, "Operating Procedures and Standards for Use of Radiation Emitting Equipment," Iowa Administrative Code.

Notice of Intended Action was published in the April 1, 1992, Iowa Administrative Bulletin as ARC 2924A.

This rule is identical to that published under Notice of Intended Action, with the exception of the following:

- 1. The definition of "nuclear medicine procedure" was revised to read "means any procedure utilizing radiopharmaceuticals for diagnosis or treatment of disease in human beings and any duties performed by the technologist during sealed source procedures, and includes, but is not limited to: " to include all procedures in which the technologist might participate.
- 2. Delete the language shown as paragraph "2" in the definition of "nuclear medicine procedure" to eliminate

inaccurate terminology.

3. In the definition of "quality control," change "potency" to "quantity" and delete "efficacy" to eliminate inac-

curate terminology.

4. In 42.2(3)"a," add "3. American Society of Clinical Pathologists." Delete this phrase from 42.2(5)"a." This group no longer offers testing but retains a certification

list of past registrants in nuclear medicine.

- 5. In 42.2(3)"c," change "the effective date of these rules" to "January 1, 1992" because of comments received from the regulated community and nuclear medicine technologists. With competency verified by the licensed physician, the technicians can continue to work without interruption of health care for patients requiring nuclear medicine procedures.
 - 6. In 42.2(4)"a"(2), change "toxicology" to "chemistry"

to eliminate inaccurate terminology.

- 7. Change 42.2(4)"a"(8) to read "Clinical application of radiopharmaceuticals used for diagnostic and therapeutic uses and duties performed by the technologist during sealed source procedures" to include all procedures in which the technologist might participate.
- 8. Change 42.2(5)"b" to read "shall be exempt from the examination requirements as long as the certificate re-

mains in effect" because of comments received from the regulated community and nuclear medicine technologists. With competency verified by the licensed physician, the technicians can continue to work without interruption of health care for patients requiring nuclear medicine procedures.

The adoption creates guidelines for any person wishing to operate as a nuclear medicine technologist in Iowa. These include training, examination, continuing educa-

tion, recertification and penalties.

Written comments and suggestions received from the public hearing on April 21, 1992, indicated support for the overall amendment. The majority of comments recommended the changes indicated above.

The State Board of Health adopted this rule on May 6,

1992.

This rule will become effective on July 1, 1992.

This rule is intended to implement Iowa Code section 136C.

The following rule is adopted.

Amend 641—Chapter 42 by adopting the following new rule:

641—42.2(136C) Minimum standards for nuclear medicine technologists.

42.2(1) Definitions.

"In vitro" means a procedure in which the radioactive material is not administered to a human being.

"In vivo" means a procedure in which the radioactive material is administered to a human being.

"NRC" means Nuclear Regulatory Commission.

"Nuclear medicine procedure" means any procedure utilizing radiopharmaceuticals for diagnosis or treatment of disease in human beings and any duties performed by the technologist during sealed source procedures, and includes, but is not limited to:

1. Administration of any radiopharmaceutical to hu-

man beings for diagnostic purposes.

2. Administration of radioactive material to human beings for therapeutic purposes.

3. Use of radioactive material for diagnostic purposes involving transmission or excitation.

4. Quality control and quality assurance.

"Nuclear medicine technologist" means a person, other than a licensed physician, who performs nuclear medicine procedures while under the supervision of a physician who is authorized by NRC or Iowa to possess and use radioactive materials.

"Quality assurance" means all aspects of a nuclear medicine program that ensure the quality of imaging and

therapy procedures.

"Quality control" means specific tests and measurements that ensure the purity, quantity, product identity, and biologic safety of radiopharmaceuticals.

"Radionuclide" means a radioactive element or a radio-

active isotope.

"Radiopharmaceutical" means a substance defined by the Food and Drug Administration as a radioactive drug.

42.2(2) Minimum eligibility requirements.

a. Graduation from high school or its equivalent.

b. At least 18 years of age.

c. Ability to adequately perform necessary duties without constituting a hazard to the health or safety of patients, self, other health care workers, or the general public.

42.2(3) Specific eligibility requirements.

- a. Any person who is registered in nuclear medicine technology with the following organizations may meet the education and testing requirements of this rule.
 - American Registry of Radiologic Technologists.
 Nuclear Medicine Technology Certification Board.

(3) American Society of Clinical Pathologists.

- b. Any person, other than a licensed physician, who has completed all educational requirements of this rule but has not yet successfully completed the required examination will be issued temporary certification valid for one year from completion of a training program approved by the department.
- c. Any person, other than a licensed physician, who has been employed as a nuclear medicine technologist in other than a student capacity before January 1, 1992, shall submit the following to the department:
- (1) Details of on-job training, to include the areas of 42.2(4)"a."

(2) Name and position of on-job instructor.

- (3) Date of initial employment as a nuclear medicine technologist.
- (4) A statement of competency from a licensed physician who is an authorized user of radioactive material on an Iowa or NRC license.
- (5) A statement of permission to allow a representative of the department to comprehensively evaluate whether the individual meets the training standard.

42.2(4) Training requirements.

a. General nuclear medicine technologist. Successful completion of a Committee on Allied Health Education and Accreditation (CAHEA) approved course of study or equivalent designed to prepare the student to demonstrate competency in the following:

(1) Basic anatomy, physiology, and pathology.

- (2) Intravenous injections and radiopharmaceutical chemistry.
 - (3) Radiation physics and mathematics.

(4) Nuclear instrumentation.

- (5) Radiation biology.
- (6) Radiation protection and radiation protection standards and codes.
- (7) Laboratory procedures and techniques (in vivo and in vitro).
- (8) Clinical application of radiopharmaceuticals used for diagnostic and therapeutic uses and duties performed by the technologist during sealed source procedures.

(9) Records and administrative procedures.

- (10) Medical ethics.
- (11) Patient care.
- b. Limited nuclear medicine technologist. Successful completion of a department-approved training program that prepares the student to demonstrate competency in a specified area. Each program shall include the items in 42.2(4)"a" that are specific to the limited area. Included are laboratory technologists who perform nuclear medicine procedures unless the material handled is regulated under 641—39.25(136C).
- c. Graduates of programs recognized by the department in consultation with the professional societies and others as being adequate and appropriate courses of study in nuclear medicine technology may be considered to meet the requirements of this subrule.
- d. Any person submitting a training program to the department for approval must provide the following:
- (1) An outline of the didactic and clinical studies to meet the requirements of this subrule.

(2) Proof that the instructor meets the requirements of this rule as a nuclear medicine technologist or is a licensed physician who is authorized to possess and use radioactive materials.

(3) A time schedule of the training program.

- (4) A description of the mechanism to be used to determine competency.
- e. Upon the completion of the training in 42.2(4)"d," the following must be submitted:
- A statement of competency from a licensed physician who is an authorized user on an Iowa or NRC radioactive materials license.
- (2) A statement of permission to allow a representative of the department to comprehensively evaluate whether the individual meets the training standard.

42.2(5) Examinations.

a. Any person, other than a licensed physician, seeking certification as a general nuclear medicine technologist shall, in addition to the requirements of 42.2(4)"a," successfully complete a written examination including the subject matter specified in 42.2(4)"a." The following organizations offer approved general examinations:

(1) American Registry of Radiologic Technologists.

- (2) Nuclear Medicine Technology Certification Board. b. Any person seeking to perform as a nuclear medicine technologist under 42.2(3)"c" shall be exempt from the examination requirements as long as the certification remains in effect.
- c. Any person, other than a licensed physician, seeking certification as a limited nuclear medicine technologist shall, in addition to the requirements of 42.2(4)"b," successfully complete a written examination approved by the department which includes the subject matter specified in 42.2(4)"b."
- d. Any person holding temporary certification must successfully complete an approved examination within one year of the issuance date of the certification.

42.2(6) Exemptions.

- a. Students enrolled in and participating in an approved program or approved course of study for nuclear medicine technology or an approved school of medicine, osteopathy, podiatry, or chiropractic who, as a part of their course of study, administer radioactive material to a human being while under the supervision of a licensed physician who appears as an authorized user on an Iowa or NRC radioactive materials license. Clinical experience must be directly supervised by a certified nuclear medicine technologist or by a physician who appears as an authorized user on an Iowa or NRC radioactive materials license.
- b. A licensed physician who appears as an authorized user on an Iowa or NRC radioactive materials license.

42.2(7) Continuing education.

a. Every two years a certificate holder shall complete a total of 24.0 continuing education hours and present proof of completion to the department at the time of renewal. Hours are to be distributed as follows:

(1) One clock hour in principles of radiation protection and exposure each year, a total of two hours each two-

year period.

(2) One clock hour in quality assurance each year, a total of two hours each two-year period.

(3) The remaining 20 clock hours of continuing education in each two-year period may be in any other subjects directly related to nuclear medicine and approved by the department.

b. Continuing education course approval.

- (1) Thirty days prior to conducting a continuing education course, the sponsoring person shall submit the following to the department:
 - 1. The course objectives.
- 2. An outline of the course which sets forth the subject, the course content, and the length of the course in clock hours.
- 3. The instructor's name and short resumé detailing qualifications.
- (2) Any program submitted within 30 days of presentation will not be guaranteed a complete review before the presentation date.
- (3) Following its review, the department may approve, disapprove, or request additional information on the proposed course.
- (4) The department may, from time to time, audit the continuing education course to verify the adequacy of program content and delivery.
- c. Continuing education credit will be awarded under provisions of 42.2(7) by the department to individuals who:
- (1) Successfully complete a continuing education course which has been approved by the department.
- (2) Attend an approved course only once during a twoyear period, except for those required in 42.2(7)"a"(1) and (2).
- (3) Present a continuing education course to nuclear medicine technologists which has been approved by the department. Credit granted shall be two times the amount of time it takes to present the course.
- d. All continuing education must be directly related to

the subject area stated in 42.2(4)"a."

- e. Proof of receiving continuing education is to be retained at each individual's place of employment for review by representatives of the department. Proof of continuing education hours must be maintained for at least three years.
- f. All continuing education requirements shall be completed during the two-year period prior to the certificate continuing education due date. Failure to complete the continuing education requirements prior to the due date may result in termination of certification as specified in 641—paragraph 38.13(6)"d."

42.2(8) Recertification.

- a. If a person who holds certification as a nuclear medicine technologist in Iowa allows the certification to expire for any reason or if any person voluntarily terminates certification, the following will apply:
- (1) Any individual who wishes to regain a valid certification and makes application within six months of the termination date will be allowed to do so with no additional training or testing required.
- (2) Any individual who wishes to regain certification after the six-month period will need to meet the current educational and testing requirements as outlined in this rule. Proof of possession of a previous certification may satisfy the training portion of this requirement.
- (3) Any individual who has not renewed certification for at least five years and wants to regain certification or who has not applied for certification within five years of the completion date of the nuclear medicine training shall complete a recertification program approved by the department of not less than 12 contact hours which specifically applies to nuclear medicine.
 - b. The recertification program.

- (1) Must review those basic principles necessary to ensure minimum competency in nuclear medicine technology.
- (2) Must include the satisfactory completion of a written examination.
- (3) Both the program and the examination must acquire prior approval from this department.
- (4) Courses designed for use in the recertification program will not qualify for continuing education credit for those persons required to attend in order to recertify.
- (5) If no approved programs are available, this department may require attendance for a minimum of 12 contact hours at continuing education programs specific to nuclear medicine.
- (6) Exemptions. Any or all of the above-mentioned requirements may be waived for an individual who has been actively employed as a nuclear medicine technologist in another state, country, or federal institution or who can prove circumstances above and beyond the norm. These cases will be reviewed on an individual basis and the decision of the department shall be final.
- 42.2(9) Disciplinary grounds and actions. The following shall be grounds for disciplinary action involving possible suspension or revocation of certification or levying of fines:
- a. Operating as a nuclear medicine technologist without meeting the requirements of this rule.
- b. Allowing any person to operate as a nuclear medicine technologist, excluding a licensed physician who is an authorized user, if that person cannot prove certification by the department.
- c. Failing to report to the department any person who the certificate holder knows is in violation of this rule.
- d. Submitting false information in order to obtain a certificate or renewal certificate as a nuclear medicine technologist.
- e. Any action that the department determines may jeopardize the public or technologist's health and safety.
- 42.2(10) Fees. All nuclear medicine technologists certified under this chapter shall pay fees as specified in 641—subrule 38.13(5).

This rule is intended to implement Iowa Code chapter 136C.

[Filed 5/8/92, effective 7/1/92] [Published 5/27/92]

EDITOR'S NOTE: For replacement pages for IAC, see IAC Supplement 5/27/92.

ARC 3044A

PUBLIC HEALTH DEPARTMENT[641]

Adopted and Filed

Pursuant to the authority of Iowa Code sections 135.11(16) and 136C.3(4), the Iowa Department of Public Health hereby adopts amendment to Chapter 42, "Operating Procedures and Standards for Use of Radiation Emitting Equipment," Iowa Administrative Code.

Notice of Intended Action was published in the April 1, 1992, Iowa Administrative Bulletin as ARC 2920A.

This rule is identical to that published under Notice of Intended Action, with the exception of the following:

In the definition of "Radiation therapist," "licensed physician" was changed to "radiation oncologist".

In the definition of "Radiation therapy technology,"

"(sealed sources, I131, P32)" was deleted.

42.3(3)"c" was changed to read, "...who has been employed in Iowa..." and "...before January 1, 1992, and does not qualify under 42.3(3)"a" or "b,"..."

In 42.3(3)"c"(4), "physician of oncology" was changed to "radiation oncologist"

to "radiation oncologist.

In 42.3(4)"d"(2) and 42.3(4)"e"(1), "...licensed physi-

cian...therapy" was changed to "radiation oncologist."
42.3(5)"b" was changed to read "...under 42.3(3)"c" is exempt from examination requirements as long as the initial certification remains in effect."

In 42.3(6)"a," "licensed physician" was changed to

"radiation oncologist".

"Radiation oncologist" is used instead of "physician of oncology" or "licensed physician" to designate a specific field of practice.

'Sealed sources..." was deleted in order to prevent re-

strictions of other radioactive materials.

42.3(3)"c" and 42.3(5)"b" were revised because of comments received from the regulated community and radiation oncologists. The affected technologists represent about 20 percent of the work force. With competency verified by the radiation oncologist, the technicians can continue to work without interruption of health care to the cancer patients.

The adoption creates the guidelines for any person wishing to operate as a radiation therapist in Iowa. These include training, examination, continuing education, recertification, and penalties.

Written comments and suggestions from the public hearing on April 21, 1992, indicated support for the overall amendment. The majority of comments recommended the changes indicated above.

The Board of Health adopted this rule on May 6, 1992.

This rule shall become effective July 1, 1992.

This rule is intended to implement Iowa Code section 136C.

The following new rule is adopted.

Amend 641—Chapter 42 by adopting the following new rule:

641—42.3(136C) Minimum standards for radiation therapists.

42.3(1) Definitions.

"Radiation therapist" means a person, other than a licensed physician, who performs radiation therapy technology under the supervision of a radiation oncolo-

"Radiation therapy technology" means the science and art of performing simulation radiography or applying ionizing radiation emitted from X-ray machines, particle accelerators, or radioactive materials to human beings for therapeutic purposes.

"Simulation radiography" means the science and art of applying X-radiation to human beings for the purpose of localizing treatment fields and isotopes and for treatment

planning.

"Simulation therapist" means a person, other than a physician, who applies X-radiation to human beings for the purpose of localizing treatment fields and isotopes and for treatment planning.

42.3(2) Minimum eligibility requirements.

a. Graduation from high school or its equivalent.

b. At least 18 years of age.

c. Ability to adequately perform necessary duties without constituting a hazard to the health or safety of patients, self, other health care workers and the general

42.3(3) Specific eligibility requirements. Each person

shall meet one of the following:

- a. Any person who is registered in radiation therapy with the American Registry of Radiological Technologists in radiation therapy meets the education and testing requirements of this rule.
- b. Any person, other than a licensed physician, who has completed all educational requirements of this rule but has not successfully completed the required examination will be issued temporary certification valid for one year from the date of completion of a training program approved by the department.
- c. Any person, other than a licensed physician, who has been employed in Iowa as a radiation therapist or simulation therapist in other than a student capacity before January 1, 1992, and does not qualify under 42.3(3)"a" or "b," shall submit the following to the depart-
- (1) Details of on-job training, to include the areas of 42.3(4)"a."
- (2) Name, position, and qualifications of on-job instructor.
 - (3) Date of initial employment as a radiation therapist. (4) A statement of competency from a radiation

(5) A statement of permission to allow a representative

oncologist.

of the department to comprehensively evaluate whether the individual meets the training standard.

42.3(4) Training requirements. a. General radiation therapist. Successful completion of a Committee on Allied Health Education and Accreditation (CAHEA)-approved course of study or equivalent designed to prepare the student to demonstrate didactic and clinical competency in radiation therapy including, but not limited to, anatomy, physiology, radiation physics, radiation protection and exposure, quality assurance, radiation oncology treatment techniques, dosimetry, radiation

b. Limited radiation therapist. Successful completion of a training program approved by the department to prepare the student to demonstrate competency in a specified area only. This includes the simulation therapist. Each program shall include the items in 42.3(4)"a" that are spe-

oncology and pathology, radiology, oncologic patient care

cific to the limited area.

and management.

c. Graduates of programs recognized by the department in consultation with the professional societies and others as being adequate and appropriate courses of study in radiation therapy technology may be considered to meet the requirements of this subrule.

d. Any person submitting a training program to the department for approval must include the following:

(1) An outline of the didactic and clinical studies to meet the requirements of 42.3(4)"a."

(2) Proof that the instructor meets the requirements of this rule as a radiation therapist or is a radiation oncologist.

- (3) An approximate time schedule of the training program.
- (4) A description of the mechanism to be used to determine competency.
- e. Upon completion of the training in 42.3(4)"d," the following must be submitted:
- A statement of competency from a radiation (1) oncologist.
- (2) A statement of permission to allow a representative of the department to comprehensively evaluate whether the individual meets the training standard.

42.3(5) Examinations.

- a. Any person, other than licensed physicians, seeking certification as a radiation therapist shall, in addition to the requirements of 42.3(4), satisfactorily complete a written examination in radiation therapy technology approved by the department. An approved examination is offered by the American Registry of Radiologic Technologists.
- b. Any person seeking to perform radiation therapy under 42.3(3)"c" is exempt from examination requirements as long as the initial certification remains in effect.
- c. Any person seeking to perform simulation radiography only must successfully complete an approved examination in either diagnostic radiography or radiation therapy.
- d. Any person holding a temporary certification must successfully complete an approved examination within one year of the date of completion of the training.

42.3(6) Exemptions.

- Students enrolled in and participating in an approved program or approved course of study for radiation therapy technology or an approved school of medicine, osteopathy, podiatry, or chiropractic who, as a part of their course of study, administer radiation therapy to a human being while under the supervision of a licensed physician in the state of Iowa. Clinical experience must be directly supervised by a radiation therapist or radiation oncologist who physically observes and critiques the actual radiation therapy procedure.
 - b. A licensed physician in the state of Iowa.

42.3(7) Continuing education.

- a. Every two years a certificate holder shall complete continuing education hours for submission at the time of
- (1) Radiation therapist: proof of 24.0 clock hours of continuing education courses in subjects directly related to radiation therapy.
- (2) Simulation therapist: proof of 24.0 clock hours of continuing education courses with at least 12.0 hours directly related to radiation therapy. 12.0 hours may be in specified diagnostic radiography courses.
 - b. Continuing education course approval.
- Thirty days prior to conducting a continuing education course, the sponsoring person must submit the following to the department:
 - 1. The course objectives.
- 2. An outline of the course which sets forth the subject, the course content, and the length of the course in clock hours.
- The instructor's name and short resumé detailing qualifications.
- (2) Any program submitted within 30 days of presentation will not be guaranteed a complete review before the presentation date.

- (3) Following its review, the agency may approve, disapprove, or request additional information on the proposed course.
- (4) The department may, from time to time, audit the continuing education course to verify the adequacy of program content and delivery.
- c. Continuing education credit will be awarded under provisions of 42.3(7) by the department to individuals who:
- Successfully complete a continuing education (1)course which has been approved by the department.
- (2) Present an approved continuing education course to radiation therapists. Credit granted shall be at a rate of two times the amount of time it takes to present the course.
- (3) Attend an approved course only once during each two-year period.
- d. All continuing education must be directly related to the subject area stated in 42.3(4)"a."
- e. Proof of receiving continuing education is to be retained at each individual's place of employment for review by representatives of the department. Proof of continuing education hours must be maintained for at least three years.
- f. All continuing education requirements shall be completed during the two-year period prior to the certificate continuing education due date. Failure to complete the continuing education requirements prior to the due date may result in termination of certification as specified in 641—paragraph 38.13(6)"d.' 42.3(8) Recertification.

- a. If a person who holds certification as a radiation therapist in Iowa allows the certification to expire for any reason or if any person voluntarily terminates certification, the following will apply:
- (1) Any individual who wishes to regain a valid certification and makes application within six months of the termination date will be allowed to do so with no additional training or testing required.
- (2) Any individual who wishes to regain certification after the six-month period will need to meet the current educational and testing requirements as outlined in this rule. Proof of possession of a previous certification may satisfy the training portion of this requirement.
- (3) Any individual who has not renewed the certification for at least five years and wants to regain certification or who has not applied for certification within five years of the completion date of the radiation therapy training shall complete a recertification program approved by the department of not less than 12 contact hours which specifically apply to radiation therapy.

b. Recertification programs.

- (1) The recertification program must review the basic principles necessary to ensure minimum competency in radiation therapy and must also include the satisfactory completion of a written examination. Both the program and the examination shall acquire prior approval from the department. Courses designed for use in the recertification program will not qualify for continuing education credit for those persons required to attend in order to recertify.
- (2) If no approved programs are available, the department may require attendance for a minimum of 12 contact hours at continuing education programs specific to radiation therapy.

E.P.A.'s RMPP,

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(3) Exemptions. Any or all of the above-mentioned requirements may be waived for an individual who has been actively employed as a radiation therapist in another state, country, or federal institution or who can prove circumstances above and beyond the norm. These cases will be reviewed on an individual basis and the decision of the department shall be final.

42.3(9) Disciplinary grounds and actions. The following shall be grounds for disciplinary action involving possible suspension or revocation of certification or levying

of fines:

a. Operating as a radiation therapist without meeting the requirements of this rule.

b. Allowing any person, excluding a licensed physician, to operate as a radiation therapist in the state of Iowa, if that person cannot prove certification by the department.

c. Failing to report to the department any person who the radiation therapist knows is in violation of this rule.

d. Submitting false information in order to obtain certification or renewal certification as a radiation therapist.

e. Any action that the department determines may jeopardize the public or radiation therapist's health and safety.

42.3(10) Fees. All radiation therapists certified under this chapter shall pay fees as specified in 641—subrule 38.13(5).

This rule is intended to implement Iowa Code chapter 136C.

[Filed 5/8/92, effective 7/1/92] [Published 5/27/92]

EDITOR'S NOTE: For replacement pages for IAC, see IAC Supplement 5/27/92.

ARC 3043A

PUBLIC HEALTH DEPARTMENT[641]

Adopted and Filed

Pursuant to the authority of Iowa Code section 136B.4, the Iowa Department of Public Health adopts an amendment to Chapter 43, "Minimum Requirements for Radon Testing and Analysis," Iowa Administrative Code.

Notice of Intended Action was published April 1, 1992,

Notice of Intended Action was published April 1, 1992, as ARC 2921A in the Iowa Administrative Bulletin. A public hearing was held on April 21, 1992. No comments were received. The revisions of Chapter 43 will clarify that certified radon testers must be listed on the United States (U.S.) Environmental Protection Agency (E.P.A.) on its radon measurement proficiency program.

There are no changes as a result of the public hearing and the amendment is identical to that published in the

Notice.

The Board of Health adopted this amendment on May 6, 1992.

This amendment is intended to implement Iowa Code chapter 136B.

This amendment will become effective July 1, 1992. The following amendment is adopted.

Amend subparagraph 43.3(3)"b"(1) to read as follows:
(1) Conduct testing in conformance with E.P.A. protocols—and—guidelines Be successfully enrolled in the

[Filed 5/8/92, effective 7/1/92] [Published 5/27/92]

EDITOR'S NOTE: For replacement pages for IAC, see IAC Supplement 5/27/92.

ARC 3024A

PUBLIC HEALTH DEPARTMENT[641]

Adopted and Filed

Pursuant to the authority of Iowa Code section 135.28, the Department of Public Health hereby amends Chapter 84, "State Emergency Medical Board," Iowa Administrative Code.

Notice of Intended Action was published in the Iowa Administrative Bulletin on March 18, 1992, as ARC 2868A. A public hearing was held on April 8, 1992. The State Board of Health adopted these amendments on May 6, 1992.

The changes are consistent with Iowa Code section

135.28. General changes include the following:

The title and references throughout have been changed from "emergency medical board" to "substitute medical decision-making board."

The responsibility for developing rules for local boards

is added.

The composition of the board is modified.

Language is added for the use of panels to act on cases appealed from local board decisions and cases submitted to the state board from counties which do not have local boards. New rule 84.7(135) references 641—Chapter 85 which was published under Notice in the Iowa Administrative Bulletin on February 19, 1992, as ARC 2804A, was adopted by the State Board of Health on May 6, 1992, and is published herein as ARC 3025A.

Responsibility for the review of local boards is added.

There are no changes as a result of the public hearing and this amendment is identical to that published under Notice of Intended Action.

The amendments are intended to implement Iowa Code section 135.28.

The amendments will become effective July 1, 1992.

EDITOR'S NOTE: Pursuant to recommendation of the Administrative Rules Review Committee published in the Iowa Administrative Bulletin, September 10, 1986, the text of these rules [amendments to Ch 84] is being omitted. These rules are identical to those published under Notice as ARC 2868A, IAB 3/18/92.

[Filed 5/8/92, effective 7/1/92] [Published 5/27/92]

[For replacement pages for IAC, see IAC Supplement 5/27/92.]

ARC 3025A

PUBLIC HEALTH DEPARTMENT[641]

Adopted and Filed

Pursuant to the authority of Iowa Code sections 135.11 and 135.28, the Department of Public Health hereby adopts a new Chapter 85, "Local Substitute Medical Decision-Making Boards," Iowa Administrative Code.

Notice of Intended Action was published in the Iowa Administrative Bulletin on February 19, 1992, as ARC 2804A. A public hearing was held on March 10, 1992. The State Board of Health adopted this rule on May 6.

These rules are intended to implement the mandate set by the 73rd General Assembly, both sessions. In that legislation, a State Substitute Medical Decision-Making Board was established which had the responsibility to develop rules for the appointment and operation of Local Substitute Medical Decision-Making Boards. The purpose of these boards is to assist people who are not able to understand the nature and consequences of proposed medical care and thus cannot give informed consent. If these individuals do not have guardians or family members and have not granted durable power of attorney for health care, this creates a procedure to make some medical care decisions for them.

As a result of public comments, several wording changes were made to improve clarity and consistency regarding the patient's expression of wishes and the panel voting.

These rules are intended to implement Iowa Code sections 135.28 and 135.29.

These rules will become effective July 1, 1992.

Adopt the following new chapter:

CHAPTER 85

LOCAL SUBSTITUTE MEDICAL DECISION-MAKING BOARDS

641—85.1(135) Purpose. The purpose of this chapter is to establish the requirements and procedures for local substitute medical decision-making boards. Counties may establish local substitute medical decision-making boards for patients who are incapable of making their own medical care decisions and who have no other surrogate decision maker available. If the patient has designated an individual to have durable power of attorney for health care or has a guardian or has family members who are reasonably available, willing and able to make medical care decisions, the case should not be submitted to the substitute medical decision-making board. If the patient has provided advance directives which cover the proposed care, the case should not be submitted to the board.

641—85.2(135) Definitions. For the purpose of these rules, the following definitions shall apply:

85.2(1) "Conflict of interest" means a standard which precludes the participation of a panel member in the proceedings with regard to a patient whenever the panel member is a relative of the patient, is a direct care provider of the patient or has a financial interest in the patient.

85.2(2) "Correspondent" means a person other than a relative of the patient who has demonstrated a genuine interest in promoting the best interest of a patient by having a personal relationship with the patient, by participating in the planning of a patient's care and treatment, by regularly visiting the patient, or by regularly communicating with the patient.

85.2(3) "Department" means Iowa department of pub-

lic health.

85.2(4) "Local board" means a local substitute medical decision-making board established under Iowa Code section 135.29.

85.2(5) "Medical care" means care a reasonably prudent person would consider to be medically necessary. It includes, but is not limited to, procedures which involve any significant invasion of bodily integrity requiring an incision or producing substantial pain, discomfort, debilitation or which has a potential for significant bodily harm. This includes, but is not limited to, any medical, surgical or diagnostic intervention or procedure for which a general anesthetic is used. Medical care may include placement decisions where there is inadequate time to obtain appointment of a guardian and the placement is a medical consideration or a medical necessity.

The definition does not include discontinuance of medical treatment which is sustaining life functions because the board does not have authority to make this deci-

The definition also does not include the following types of care which can ordinarily be provided without special approval and do not need to be submitted to the board for consideration:

a. Routine office-based care or routine dental care;

b. Routine diagnosis or treatment such as extraction of bodily fluids for analysis, administration of medications or routine activities of daily living support;

c. Any procedure which is provided under emergency

circumstances

"Other surrogate decision maker" means an 85.2(6) attorney-in-fact, guardian, spouse, adult child, parent or an adult sibling who is reasonably available, willing and able to make a medical care decision.

85.2(7) "Panel" means a group of three or more members of a local board or the state board who are appointed by the chairperson of that board to hear a case when an application has been filed with the board or when an appeal has been filed with the state board.

"Patient" means the person for whom the medical care decision is proposed. They may be in a hospital, long-term care facility, home, or other setting.

85.2(9) "Person incapable of making their own medical care decisions" means a patient who is unable to adequately understand and appreciate the nature and consequences of a proposed medical care decision, including the benefits and risks of the proposed medical care and of alternatives to such care, and cannot thereby reach an informed decision to consent or refuse such care in a knowing and voluntary manner that promotes the patient's well-being and autonomy. This incapability may be temporary or permanent.

85.2(10) "Physician" means any individual licensed

under Iowa Code chapter 148, 150, or 150A.

85.2(11) "State board" means the state substitute medical decision-making board established under Iowa Code section 135.28.

641-85.3(135) Appointment of local boards.

85.3(1) The county board of supervisors may establish and fund a local substitute medical decision-making

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board. The boards shall include one or more representatives from each of the three categories:

- a. Physicians, nurses, or psychologists licensed by the state of Iowa.
- Attorneys admitted to the practice of law in Iowa or social workers.
- c. Other individuals with recognized expertise or interest in persons unable to make their own medical care decisions not included in "a" and "b" above.
- 85.3(2) County boards of supervisors may join together to form a multicounty local substitute medical decision-making board pursuant to Iowa Code chapter 28E. If a multicounty board is established, the agreement shall specify the procedure for appointment of board members and the procedure for allocation of expenses.

85.3(3) Board members shall be appointed to terms of

three years with staggered terms.

85.3(4) The board shall elect a chairperson at the first meeting of each fiscal year.

641—85.4(135) Filing an application.

- 85.4(1) Any person having knowledge and concern may file the application on behalf of any patient residing within the geographic area served by the local board, when the person filing the application believes the patient is incapable of decision making, is in need of medical care, and has no other surrogate decision maker available.
- 85.4(2) The local board of the county of residence of the patient shall have jurisdiction except the local board may, by mutual consent, transfer jurisdiction to the local board in the county where the treatment is being considered.
- 85.4(3) The application shall be made in writing and shall include the following:
- a. The relationship of the person filing the application to the patient.
- b. A statement that the patient does not have an attorney-in-fact, guardian, spouse, adult child, parent or an adult sibling who is reasonably available, willing and able to make the medical care decision. The application shall provide the factual basis for such a statement, including the efforts made to contact such persons.
- c. The reasons for believing that the person lacks the capability to consent to or refuse medical care and the factual basis supported by an appropriate statement for this belief.
- d. The patient's opinion regarding the proposed care, if known, and the source(s) of the information regarding this opinion.
- e. If the patient's opinion regarding the proposed care is not known, the person filing the application shall include a stated opinion on whether the best interests of the patient would be promoted by such care and the basis for the opinion.
- f. Any other information that may be necessary to determine the need for such care, including a copy of a second medical or dental opinion which would be required by a prudent physician or dentist based on the nature of the proposed medical care.
- g. A statement, completed, signed and dated by a physician or dentist including:
- (1) A description of the proposed medical care and the patient's medical or dental condition which requires such treatment indicating the date of diagnosis;
- (2) The risks and benefits to the patient of the proposed care and any alternative treatments including consideration and consequences of nontreatment; and

- (3) A statement whether the patient has any medical or dental condition which would prevent the patient's travel to or presence at the panel meeting and including a description of such condition.
- h. The application shall be signed and dated by the person filing it stating that the information on the application is true to the best of that person's knowledge, except for any portion signed and dated by another person who shall make a similar statement as to that portion.

641—85.5(135) Review of application. The board chairperson or designee shall preliminarily review the application to ascertain whether additional information may be necessary to assist the board in determining the patient's need for surrogate decision making and in determining whether the patient's best interests will be served by consenting to or refusing medical care on the patient's behalf.

The board chairperson or designee may:

85.5(1) Request and shall, notwithstanding any other law to the contrary, be entitled to receive from any physician, hospital or health care facility or person licensed to render health care, any information which is relevant to the patient's need for surrogate decision making or for the proposed medical care. Such information may include, among other things: information regarding the patient's preferences regarding medical care; facts regarding the patient's attorney-in-fact, guardian, spouse, adult child, parent, or an adult sibling; facts and professional opinions regarding the patient's inability to consent to or refuse medical care; and facts and professional opinions regarding whether the proposed medical care is in the patient's best interests; the board chairperson or designee shall maintain the confidentiality of records as required by Iowa Code chapters 22, 141, and 228, and 42 Code of Federal Regulations Part 2, as of January 1, 1992, or any other applicable confidentiality law provision;

85.5(2) Consult with any other person who might assist in such a determination of the best interests of the patient, including ascertainment of the personal beliefs and

values of the patient;

85.5(3) Notify the patient that an application has been filed, a panel is being appointed, a hearing will be held, the patient has the right to express feelings to the panel orally or in writing and the patient has the right to designate someone to represent the patient before the panel.

641—85.6(135) Panel appointment and procedures.

85.6(1) When an application is filed, the chairperson shall appoint a panel to handle the case and designate a panel chairperson. The panel shall consist of at least three members with at least one from each category listed in rule 85.3(135). A person shall not participate on a panel for a case when that person has a conflict of interest. The panel may include the entire local board.

85.6(2) Upon appointment of the panel, the board chairperson or designee shall provide a copy of the application to each panel member accompanied by a notice of the time, place and date of the panel hearing on the application. The notice of the hearing shall also be provided to the patient, the person who filed the application, and any other interested party, if known. The notice shall inform the recipients of the procedures of the panel, including the opportunity for the recipient to be present and to be heard. The notice shall be given at least 48 hours prior to the scheduled time for the hearing except where medical circumstances require a more immediate hearing.

PUBLIC HEALTH DEPARTMENT[641](cont'd)

85.6(3) The general procedures of the hearing are as follows:

a. The panel shall be empowered to administer oaths and take testimony from any person who might assist the panel in making its decision. It shall also be empowered to conduct its proceeding via telephone conference calls in appropriate cases, unless someone objects and requests a face-to-face hearing.

b. A record of the deliberations and proceedings of the panel shall be made and retained for ten years. Such record shall include any information, record, assessment or consultation submitted to or considered by the panel.

c. The panel and each member of the local board shall maintain the confidentiality of records as required by Iowa Code chapters 22, 141, and 228 and 42 Code of Federal Regulations Part 2 or any other applicable confidentiality law provision.

d. The patient shall have the right to be present at the hearing and the right to express feelings to the panel orally or in writing and the right to designate someone to rep-

resent the patient before the panel.

- e. If at any time during the pendency or prior to initiation of treatment, an attorney-in-fact, guardian, spouse, adult child, parent or an adult sibling is reasonably available, willing and able to consent to or refuse such care on the patient's behalf, objects to the panel acting upon the application, the proceedings regarding such patient shall cease. A record of any such person's objection shall be included as part of the record as provided for by this section.
- f. The panel shall issue its written decision within 24 hours after the conclusion of the hearing. The decision shall state when the decision shall become effective and shall include a statement describing the right of appeal. The written decision shall be issued to the necessary persons, including the patient.
- g. If the decision is hand-delivered, it shall not be effective sooner than 24 hours after the written decision is delivered to the patient or the person designated by the patient in 85.6(3) "e." If the decision is sent by certified mail, return receipt requested, it shall not be effective sooner than 48 hours after it is mailed. The date, time, and method of delivery of the decision to the patient shall be noted in the record.
- h. A panel determination that a patient is in need of surrogate decision making for the proposed medical care shall not be valid for any future medical care and shall not be construed or deemed valid for any other purpose or for any other future medical care unless the determination explicitly applies to related or continuing treatment necessitated by the original treatment. No panel determination shall be valid after 60 days from its effective date unless the determination explicitly states otherwise.
- i. All information, records, assessments or consultations submitted to or considered by the panel or board and the panel and board deliberations are confidential as required by Iowa Code chapters 22, 141, and 228 and 42 Code of Federal Regulations Part 2 or any other applicable confidentiality law provision.
- 641—85.7(135) Panel determination of need for surrogate decision making. The panel's determination of the patient's need for surrogate decision making shall be made in accordance with the following provisions:
- 85.7(1) The panel shall decide based upon a preponderance of evidence whether the patient is in need of surrogate decision making by determining that the patient:

lacks the ability to consent to or refuse the proposed medical care and does not have an attorney-in-fact, guardian, spouse, adult child, parent, or an adult sibling who is reasonably available, willing and able to make such a decision.

The method of determining patient's capability to consent or refuse care shall include examination of patient by a licensed physician with a written report to the local board.

When practical, the panel members shall personally interview and observe the patient as a part of the hearing. If a personal appearance by the patient before the panel is not practical, then either the panel chairperson shall designate a member of the panel to interview and observe the patient prior to the hearing or the panel shall require one of the following:

- 1. Written report of examination by psychiatrist.
- 2. Written report of examination by psychologist.
- 3. Written report of examination by physician not involved in case.
- 4. Written report from a department of human services investigator involved with patient.
- 5. Written report from long-term care case management project.
- 85.7(2) In making the determination of whether the patient lacks the capacity to consent to or refuse the proposed medical care, the panel or board shall consider whether the patient is unable to adequately understand and appreciate the nature and consequences of the proposed medical care.
- 85.7(3) A majority of the panel members must vote in the affirmative that the patient is in need of surrogate decision making or the patient will be deemed not to need surrogate decision making.
- 85.7(4) A panel determination that a patient is in need of surrogate decision making shall not be construed or deemed to be a legal determination that such person is incompetent.
- 85.7(5) In the event the panel or board has determined the patient to be capable of decision making, then the patient's consent to or refusal of such treatment, if given, shall constitute valid consent or refusal. No other consent shall be required by a provider of health services.
- 641—85.8(135) Panel determination regarding proposed medical care decision. If a patient has been determined by the panel to be in need of surrogate decision making, the panel's determination regarding the proposed medical care shall be made in accordance with the following provisions:

85.8(1) The past or present expression of wishes by the patient will be presumed valid unless clearly overcome by other evidence. The patient's autonomy should always be respected.

- 85.8(2) If there is no clear preference by the patient, the panel shall make the determination whether the proposed medical care is in the best interests of the patient based upon a preponderance of the evidence by considering the following standards:
- a. The burdens of the treatment to the patient in terms of pain and suffering outweighing the benefits or whether the proposed treatment would merely prolong the patient's suffering and not provide any net benefit;
- b. The degree, expected duration, and constancy of pain with and without treatment, and the possibility that the pain could be mitigated by less intrusive forms of

PUBLIC HEALTH DEPARTMENT[641](cont'd)

medical treatment including the administration of medications:

c. The likely prognosis, expectant level of functioning, degree of humiliation and dependency with or without the proposed medical care; and

d. Evaluation of treatment options, including non-treatment, and their benefits and risks compared to those

of the proposed medical care.

85.8(3) A majority of the panel members must vote in the affirmative for a valid determination of consent to or

refusal of medical care on behalf of the patient.

85.8(4) The panel determination consenting to or refusing medical care shall constitute valid consent or refusal to such treatment in the same manner and to the same extent as if the patient were able to consent or refuse on the patient's own behalf.

85.8(5) The panel's consent to medical care shall state that any tissues or parts surgically removed may be disposed of or preserved by the provider of health services in

accordance with customary practice.

641—85.9(135) Right of appeal.

85.9(1) The patient, the person who filed the application, or a correspondent may appeal the local board's decision to the state board. The appeal must be made before the date and time that the consent becomes effective. The person appealing shall notify the local board or the department of the appeal. The notice of the appeal shall be in writing or by telephone followed by a written appeal to the department. If the appeal is initially made by telephone, the written appeal to the department shall be postmarked within 48 hours of the telephone notice. written appeal shall state the reason for the appeal. If the initial appeal is made to the local board, the local board representative shall immediately notify the department and the health care provider. If the initial appeal is made to the department, the department representative shall immediately notify the local board and the health care provider.

85.9(2) Upon receipt of the notice of appeal the local board shall immediately provide a copy of the record of the case to the state board. The state board chairperson shall appoint a panel to review the case. The panel shall consist of at least three members with the same composition requirements as the local panels as specified in rule 85.6(135). The panel shall review the record to determine whether the determination by the local panel is supported by substantial evidence. The state panel shall also review new information which is submitted regarding the case. The state panel's decision shall be based on a review of the record and a review of any new information and shall be made in accordance with the provisions for local panel determination in rules 85.7(135) and 85.8(135). The state panel's decision shall be promptly sent by certified mail, return receipt requested, or otherwise provided by any other means that will provide more timely or reliable written notice to the: patient, the person filing the appeal, the person who filed the application and the chairperson of the local board. If any of these persons are dissatisfied with the state panel's decision, an appeal may be taken in the manner provided by Iowa Code chapter 17A.

641—85.10(135) Procedure when there is no local board. If an application is filed on behalf of a patient residing in a county which does not have a local board, the application shall be submitted to the department. When an application is filed with the department, the chairperson of the state substitute medical decision-making board

shall appoint a panel to handle the case. The panel shall consist of at least three members with the same composition requirements as the local panels. The state panel shall follow the same procedures as the local board or panel. If a decision is made by a panel of the state board, it may be appealed as provided in rule 85.9(135). The appeal shall be heard by a second panel appointed by the chairperson of the state board.

641—85.11(135) Records and reports. Local boards shall submit a quarterly summary report to the state board on forms provided by the state board within 15 days after the end of each quarter. The report shall include information regarding the number, nature and disposition of applications filed with the local board and such other information as the state board may deem necessary. Members of the state board or authorized representatives of the department shall have access to all records of the local boards. All record information which is excluded from public access and inspection pursuant to Iowa Code chapter 22, 141 or 228 and 42 Code of Federal Regulations Part 2 or any other confidentiality law provision shall be respected by the state board members and department representatives.

641—85.12(135) Liability. The local substitute medical decision-making board and its members shall not be held liable, jointly or separately, for any actions or omissions taken or made in the official discharge of their duties, except those acts or omissions constituting willful or wanton misconduct.

These rules are intended to implement Iowa Code sections 135.28 and 135.29.

[Filed 5/7/92, effective 7/1/92] [Published 5/27/92]

EDITOR'S NOTE: For replacement pages for IAC, see IAC Supplement 5/27/92.

ARC 3058A

SECRETARY OF STATE[721]

Adopted and Filed

Pursuant to the authority of Iowa Code section 52.28, the Secretary of State hereby adopts amendments to Chapter 22, "Alternative Voting Systems," Iowa Administrative Code.

Notice of Intended Action was published in the Iowa Administrative Bulletin on April 1, 1992, as ARC 2886A. A public hearing was scheduled for April 23, 1992; however, no one attended. Written comments were received and the changes that have been made are in response to those comments.

The revision of Chapter 22 clarifies procedures for counties using central count voting systems.

The following changes have been made from the Notice:

In Item 3, amending subrule 22.53(2), paragraphs "a" and "g," the words "high" and "tall" are changed to "in height" for consistency.

SECRETARY OF STATE[721](cont'd)

In Item 4, amending subrule 22.53(5), paragraph "b," first unnumbered paragraph, add the words "voting target" after the words that are stricken. In paragraph "d," references are added to the use of secrecy envelopes which are necessary to conceal the voter's choices.

These amendments are intended to implement Iowa

Code chapter 52.

The amendments will become effective July 1, 1992.

EDITOR'S NOTE: Pursuant to recommendation of the Administrative Rules Review Committee published in the Iowa Administrative Bulletin, September 10, 1986, the text of these rules [22.53] is being omitted. With the exception of the changes noted above, these rules are identical to those published under Notice as ARC 2886A, IAB 4/1/92.

[Filed 5/8/92, effective 7/1/92] [Published 5/27/92]

[For replacement pages for IAC, see IAC Supplement 5/27/92.]

ARC 3022A

TRANSPORTATION DEPARTMENT[761]

Adopted and Filed

Pursuant to the authority of Iowa Code section 307.12, the Department of Transportation on May 6, 1992, adopted Chapter 26, "Consent for the Sale of Goods and Services," Iowa Administrative Code.

A Notice of Intended Action for these rules was published in the April 1, 1992, Iowa Administrative Bulletin

as **ARC 2889A**.

These rules implement Iowa Code Supplement section 68B.4, as it relates to sales by officials to individuals, associations or corporations subject to the regulatory authority of the Department of Transportation. Section 68B.4 requires each regulatory agency to adopt rules regarding the granting of consent to agency officials for such sales. Pursuant to Iowa Code section 68B.2, the Department of Transportation is a regulatory agency.

These rules are identical to the ones published under Notice except for the following: in subrule 26.4(2), the deputy director of transportation has been substituted for

the special assistant attorney general.

These rules are intended to implement Iowa Code Supplement section 68B.4. These rules will become effective July 1, 1992.

Rule-making action:

Adopt the following new chapter:

CHAPTER 26

CONSENT FOR THE SALE OF GOODS AND SERVICES

761—26.1(68B) Applicability and definitions.

26.1(1) Applicability. These rules apply to the sale of goods or services by officials to individuals, associations or corporations subject to the regulatory authority of the department.

26.1(2) Definitions.

"Individual," "association" and "corporation" do not include the United States, a state, or a political subdivision of a state.

"Official" means the director of transportation or a member of the transportation commission. The term "official" includes the individual's spouse and minor children, any firm of which the individual is a partner, and any corporation of which the individual holds 10 percent or more of the stock either directly or indirectly.

"Sale of goods or services" means the receipt of compensation for providing goods or services. The term does not include outside employment activities that constitute

an employer-employee relationship.

761—26.2(68B) Prohibitions and conditions.

26.2(1) General prohibition. An official shall not sell, either directly or indirectly, any good or service to an individual, association or corporation subject to the regulatory authority of the department except when consent is granted pursuant to rule 26.3(68B) or 26.4(68B).

26.2(2) Conditions for consent. Consent may be granted only when all of the following conditions are met:

- a. The official's job duties or functions are not related to the department's regulatory authority over the individual, association or corporation, or the selling of the good or service does not affect the official's job duties or functions.
- b. The selling of the good or service does not include acting as an advocate on behalf of the individual, association or corporation to the department.
- c. The selling of the good or service does not result in the official selling a good or service to the department on behalf of the individual, association or corporation.
- 761—26.3(68B) Consent granted by rule. The department finds that the sales described in this rule do not, as a class, constitute sales that affect an official's job duties or functions. Consent is hereby granted for these sales, and individual application and approval pursuant to rule 26.4(68B) are not required unless there are unique facts surrounding a particular sale which would cause that sale to affect the official's duties or functions, would give the buyer an advantage in its dealings with the department, or would otherwise present a conflict of interest.

Sales for which consent is granted by rule:

- 1. A sale in the ordinary course of business to a person subject to driver licensing laws unless the sale relates to driver licensing functions.
- 2. A sale in the ordinary course of business to a person subject to vehicle registration or titling laws unless the sale relates to vehicle registration or titling functions.
- 3. A sale in the ordinary course of business to a person subject to aircraft registration laws unless the sale relates to aircraft registration functions.

761—26.4(68B) Individual consent required. Except as provided in rule 26.3(68B), an official who wishes to sell a good or service to an individual, association or corporation subject to the regulatory authority of the department must have prior written consent for the sale.

26.4(1) Application for consent. Consent must be applied for and received in advance of the sale. To obtain consent, the official shall apply in writing, describing the good or service to be sold, the anticipated clientele, the approximate form and amount of compensation, and any other relevant facts concerning the sale.

TRANSPORTATION DEPARTMENT[761](cont'd)

26.4(2) Who may consent. The deputy director of transportation is authorized to consent to sales by the director of transportation. The director of transportation is authorized to consent to sales by a member of the transportation commission.

26.4(3) Consent. Consent must be in writing. Consent may be granted for a particular sale or for a class of sales

involving specified goods, services or clientele.

26.4(4) Effect of consent. Consent is valid only to the extent that all relevant facts relating to the sale have been disclosed and remain unchanged.

761—26.5(68B) Public records. An application for consent and the resultant consent granted or denial issued are public records and are open to examination and copying.

761—26.6(68B) Effect of other laws. These rules do not authorize any activity that constitutes a conflict of interest at common law or that violates any applicable statute or rule.

These rules are intended to implement Iowa Code Supplement section 68B.4.

> [Filed 5/7/92, effective 7/1/92] Published 5/27/921

EDITOR'S NOTE: For replacement pages for IAC. see IAC Supplement 5/27/92.

ARC 3018A

UTILITIES DIVISION[199]

Adopted and Filed

Pursuant to Iowa Code sections 17A.4, 476.1, 476.2, 476.76, and 476.77(4), the Utilities Board (Board) gives notice that on April 24, 1992, the Board issued an order in Docket No. RMU-91-2, In Re: Disposal of a Public Utility's Assets, "Order Adopting Rules.

On January 30, 1992, the Board issued an order in this docket commencing a rule making to consider amendments to 199 IAC 32.2(476). The proposed rule making was published in IAB Vol. XIV, No. 17 (2/19/92), p. 1480, as ARC 2788A. The subject of the Notice was an amendment to 199 IAC 32.2(476), relating to dollar threshold limits for applications for reorganization pursuant to Iowa Code Supplement sections 476.76 and 476.77. The amendments also related to exemptions for certain transactions from the reorganization filing requirements.

Comments in this rule making were filed by the Consumer Advocate Division of the Department of Justice (Consumer Advocate), Iowa-Electric Light and Power Company(Iowa Electric), the Iowa Telephone Association (ITA), U S West Communications, Inc. (U S West), Vista Telephone Company (Vista), GTE North Incorporated (GTE), Iowa-Illinois Gas and Electric Company (Iowa-Illinois), and Peoples Natural Gas Company (Peoples). An oral presentation was held on April 10, 1992.

The adopted rule replaces current 199 IAC 32.2(476). The adopted rule deletes the current definition of "substantial part of a public utility's assets" and the hypothetical examples. A definite dollar threshold below which an application for reorganization would not have to be filed is established. However, different thresholds are adopted for the acquisition or lease of assets and the sale or disposal of assets. The Board has less concern with an acquisition of assets by a utility than with disposal of assets by a utility, since the former brings assets into the Board's jurisdiction while the latter removes assets from the Board's jurisdiction.

The adopted rule sets the dollar thresholds at \$2 million for the acquisition or lease of assets, and \$1 million for the sale or disposal of assets. The dollar limits eliminate the need to file an application for reorganization or request a waiver with respect to relatively small transac-

tions.

In addition, adopted subrule 32.2(3) exempts from the filing requirements of Iowa Code Supplement section 476.77 many utility transactions which occur on a routine No such list can be exhaustive; and thus the adopted subrule exempts similar transactions which occur in the ordinary course of business, provided that the transaction does not involve more than 10 percent of a public utility's gross assets less depreciation.

In response to the comments, the Board is deleting the language in proposed subrule 32.2(3) relating to "essential or bottleneck facilities under federal antitrust law". The telephone companies in particular were concerned that this language would require Board approval for any improvements to local exchange facilities, which have been held to be essential facilities under federal antitrust law. The proposed rule was not intended to require telephone companies to file for all improvements made to local exchange facilities, and the Board will delete the antitrust language to clarify this intent. A reorganization proposal or request for waiver would only be required if the improvements made were outside the ordinary course of business or exceeded 10 percent of the utility's gross utility assets less depreciation.

Several commenters indicated their belief that the rule should apply only to transactions which occur in Iowa. Iowa Code Supplement sections 476.76 and 476.77 do not limit the Board's jurisdiction to Iowa transactions. This issue was addressed by the Board in a declaratory ruling issued February 1, 1991, in Union Electric Company, Docket No. DRU-91-1. Under the rule currently in effect, however, the Board in declaratory rulings has not required proposals for reorganization to be filed for transactions which have minimal or no impact on Iowa ratepayers. See "Declaratory Ruling," Union Electric Company, Docket No. DRU-92-2, March 27, 1992. The Board, under the adopted rule, intends to continue this policy by

liberally granting waivers for such transactions.

Vista in its comments indicated its belief that Board approval of any proposals for reorganization means that such investment or expense will conclusively be presumed reasonable for rate-making purposes. This is not correct. Under the Board's statutory authority, the Board has the authority to "disapprove" a merger, but not to approve a mergér. Merely allowing a reorganization to go forward is no indication of how the reorganization will be treated for rate-making purposes.

The only change in the adopted rule from the proposed rule is the elimination of the language dealing with essential or bottleneck facilities. The Board does not believe

UTILITIES DIVISION[199](cont'd)

additional public comment on the adopted rule is necessary because the change made to the rule is a logical outgrowth of the prior Notice and public hearing.

This rule is intended to implement Iowa Code Supplement sections 476.76 and 476.77. This rule will become effective on July 1, 1992, pursuant to Iowa Code section 17A.5.

The following amendment is adopted.

Rescind rule 199—32.2(476) and insert in lieu thereof the following:

199—32.2(476) Substantial part of a public utility's assets.

32.2(1) No public utility shall acquire or lease assets, directly or indirectly, with a value in excess of \$2 million, without first filing an application pursuant to Iowa Code section 476.77 and this chapter or obtaining a waiver under the provisions of rule 32.8(476).

32.2(2) No public utility shall sell or otherwise dispose of assets, directly or indirectly, with a value in excess of \$1 million, without first filing an application pursuant to Iowa Code section 476.77 and this chapter or obtaining a waiver under the provisions of rule 32.8(476).

32.2(3) Notwithstanding the provisions of subrules 32.2(1) and 32.2(2), board approval of the following types

of transactions is not necessary in the public interest and such transactions are exempt from the filing requirements of Iowa Code section 476.77 and this chapter: fuel purchases, energy and capacity purchases and sales, gas purchases, sale of accounts receivables, sale of bonds, claim and litigation payments, tax payments, regulatory fees and assessments, insurance premiums, payroll, stock dividends, financings, routine financial transactions, operation and maintenance expense, construction expense, or similar transactions which occur in the ordinary course of business; provided, however, that any transaction involving more than 10 percent of a public utility's gross utility assets less depreciation, or any transaction outside the ordinary course of business, shall not be exempt under this subrule. In addition, transactions where board approval is otherwise required in a contested case proceeding are exempt from the filing requirements of Iowa Code section 476.76 and this chapter.

This rule is intended to implement Iowa Code Supplement sections 476.76 and 476.77.

[Filed 5/6/92, effective 7/1/92] [Published 5/27/92]

EDITOR'S NOTE: For replacement pages for IAC, see IAC Supplement 5/27/92.



In The Name and By The Authority of The State of Iowa

EXECUTIVE ORDER NUMBER 44

- whereas, Executive Order Number 46 was enacted on December 21, 1982 to enhance the affirmative action efforts of the State of Iowa government by coordinating resources, assigning responsibilities, and requiring progress reviews;
- WHEREAS, Executive Order Number 46 created an Affirmative Action Task Force to be appointed annually by the Governor to review the progress made in complying with the Executive Order;
- WHEREAS, Iowa Code Section 19A.1(2), effective July 1, 1986, designated that the Iowa Department of Personnel be the central Executive Branch agency responsible for State personnel management, including equal employment opportunity and affirmative action programs;
- WHEREAS, Iowa Code Section 19A.1(3), designated that the Affirmative Action Task Force, created pursuant to Executive Order Number 46, or its successor, is an entity within the Iowa Department of Personnel;
- WHEREAS, Iowa Code Section 19B.3(1), effective July 1, 1986, designated that the Iowa Department of Personnel be responsible for the administration and promotion of equal employment opportunity and affirmative action efforts in all State agencies;
- WHEREAS, Iowa Code Section 198.5 further required that the Iowa Department of Personnel submit an annual report on the condition of affirmative action programs under its jurisdiction; and
- WHEREAS, Coordination of equal employment opportunity and affirmative action monitoring and reporting requirements would enhance the State's efforts and address inconsistencies that now exist between Executive Order Number 46 and Iowa Code Chapters 19A and 19B;

Now, Therefore, I, Terry E. Branstad, Governor of the State of Iowa, by the power and authority vested in me by the Constitution and the Laws of Iowa, do hereby reaffirm my commitment to maintaining a work force that provides equal

employment opportunity to all applicants and employees without regard to race, creed, color, religion, national origin, sex, age, marital status, or physical or mental disability.

To that end, I hereby rescind Executive Order Number 46, and recommit the efforts of the Executive Branch and all Department Directors, members of Governing Boards and Commissions, and other public officers and employees of the State of Iowa, as follows:

I. The Iowa Department of Personnel, through the State Affirmative Action Administrator, shall coordinate the affirmative action reporting of all State agencies within the Executive Branch. This shall be accomplished in concert with and through the Iowa Department of Management, and shall be in accordance with Iowa Code Section 19B.3(1).

In addition to the Chair, the Affirmative Action Task Force shall consist of persons appointed by the Governor. Appointments shall be for a term of one year commencing on July 1, 1992.

- II. The State Affirmative Action Administrator shall chair the Affirmative Action Task Force. The Affirmative Action Task Force shall provide recommendations on programs to the State Affirmative Action Administrator based on their expertise and program knowledge, and shall assist the State Affirmative Action Administrator in reviewing the annual affirmative action report.
- III. All management and supervisory employees of the Executive Branch and employees working in a capacity related to human resource management, as a condition of such employment, shall attend affirmative action, discriminatory harassment prevention, and cultural diversity training, and other related training provided through the Iowa Department of Personnel.
 - IV. Departments not included under this Executive Order are encouraged to adopt affirmative action efforts in accordance with affirmative action planning standards outlined in Iowa Code Section 19B.3 and administrative rules, as promulgated by the Iowa Department of Personnel.

OF THE SOUTH OF THE MAINTAIN TO SEE THE SECOND OF THE SECO

IN TESTIMONY WHEREOF, I have hereunto subscribed my name and caused the Great Seal of Iowa to be affixed. Done at Des Moines this 30th day of April in the year of our Lord, one-thousand nine hundred and ninety-two.

GOVERNOR

Secretary of State

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IOWA ADMINISTRATIVE BULLETIN

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