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IOWA ADMINISTRATIVE MAR 1 5 2000 BULLETIN

Published Biweekly

VOLUME XXII January 26, 2000 NUMBER 15 Pages 1109 to 1188

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PREFACE

The Iowa Administrative Bulletin is published biweekly in pamphlet form pursuant to Iowa Code chapters 2B and 17A and contains Notices of Intended Action on rules, Filed and Filed Emergency rules by state agencies.

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 Public Hearings, Attorney General Opinions and Supreme Court Decisions.

The Bulletin may also contain Public Funds Interest Rates [12C.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.

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Iowa Administrative Bulletin

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Iowa Administrative Code

The Iowa Administrative Code and Supplements are sold in complete sets and subscription basis only. All subscriptions for the Supplement (replacement pages) must be for the complete year and will expire on June 30 of each year. Prices for the Iowa Administrative Code and its Supplements are as follows:

Iowa Administrative Code - \$1,163.76 plus \$58.19 sales tax

(Price includes 22 volumes of rules and index, plus a one-year subscription to the Code Supplement and the Iowa Administrative Bulletin.)

Iowa Administrative Code Supplement - \$409.24 plus \$20.46 sales tax (Subscription expires June 30, 2000) All checks should be made payable to the Iowa State Printing Division. Send all inquiries and subscription orders to:

Customer Service Center Department of General Services Hoover State Office Building, Level A Des Moines, IA 50319 Telephone: (515)242-5120

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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)	ŧ	(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).

IAB Vol. XII, No. 23 (5/16/90) p. 2050, ARC 872A

Schedule for Rule Making 2000

NOTICE SUBMISSION DEADLINE	NOTICE PUB. DATE	HEARING OR COMMENTS 20 DAYS	FIRST POSSIBLE ADOPTION DATE 35 DAYS	ADOPTED FILING DEADLINE	ADOPTED PUB. DATE	FIRST POSSIBLE EFFECTIVE DATE	POSSIBLE EXPIRATION OF NOTICE 180 DAYS
Dec. 24 '99	Jan. 12 '00	Feb. 1 '00	Feb. 16 '00	Feb. 18 '00	Mar. 8 '00	Apr. 12 '00	July 10 '00
Jan. 7	Jan. 26	Feb. 15	Mar. 1	Mar. 3	Mar. 22	Apr. 26	July 24
Jan. 21	Feb. 9	Feb. 29	Mar. 15	Mar. 17	Apr. 5	May 10	Aug. 7
Feb. 4	Feb. 23	Mar. 14	Mar, 29	Mar. 31	Apr. 19	May 24	Aug. 21
Feb. 18	Mar. 8	Mar. 28	Apr. 12	Apr. 14	May 3	June 7	Sept. 4
Mar. 3	Mar. 22	Apr. 11	Apr. 26	Apr. 28	May 17	June 21	Sept. 18
Mar. 17	Apr. 5	Apr. 25	May 10	May 12	May 31	July 5	Oct. 2
Mar. 31	Apr. 19	May 9	May 24	May 26	June 14	July 19	Oct. 16
Apr. 14	May 3	May 23	June 7	June 9	June 28	Aug. 2	Oct. 30
Apr. 28	May 17	June 6	June 21	June 23	July 12	Aug. 16	Nov. 13
May 12	May 31	June 20	July 5	July 7	July 26	Aug. 30	Nov. 27
May 26	June 14	July 4	July 19	July 21	Aug. 9	Sept. 13	Dec. 11
June 9	June 28	July 18	Aug. 2	Aug. 4	Aug. 23	Sept. 27	Dec. 25
June 23	July 12	Aug. 1	Aug. 16	Aug. 18	Sept. 6	Oct. 11	Jan. 8 '01
July 7	July 26	Aug. 15	Aug. 30	Sept. 1	Sept. 20	Oct. 25	Jan. 22 '01
July 21	Aug. 9	Aug. 29	Sept. 13	Sept. 15	Oct. 4	Nov. 8	Feb. 5 '01
Aug. 4	Aug. 23	Sept. 12	Sept. 27	Sept. 29	Oct. 18	Nov. 22	Feb. 19 '01
Aug. 18	Sept. 6	Sept. 26	Oct. 11	Oct. 13	Nov. 1	Dec. 6	Mar. 5 '01
Sept. 1	Sept. 20	Oct. 10	Oct. 25	Oct. 27	Nov. 15	Dec. 20	Mar. 19 '01
Sept. 15	Oct. 4	Oct. 24	Nov. 8	Nov. 10	Nov. 29	Jan. 3 '01	Apr. 2 '01
Sept. 29	Oct. 18	Nov. 7	Nov. 22	Nov. 24	Dec. 13	Jan. 17 '01	Apr. 16 '01
Oct. 13	Nov. 1	Nov. 21	Dec. 6	Dec. 8	Dec. 27	Jan. 31 '01	Apr. 30 '01
Oct. 27	Nov. 15	Dec. 5	Dec. 20	Dec. 22	Jan. 10 '01	Feb. 14 '01	May 14 '01
Nov. 10	Nov. 29	Dec. 19	Jan. 3 '01	Jan. 5 '01	Jan. 24 '01	Feb. 28 '01	May 28 '01
Nov. 24	Dec. 13	Jan. 2 '01	Jan. 17 '01	Jan. 19 '01	Feb. 7 '01	Mar. 14 '01	June 11 '01
Dec. 8	Dec. 27	Jan. 16 '01	Jan. 31 '01	Feb. 2 '01	Feb. 21 '01	Mar. 28 '01	June 25 '01
Dec. 22	Jan. 10 '01	Jan. 30 '01	Feb. 14 '01	Feb. 16 '01	Mar. 7 '01	Apr. 11 '01	July 9 '01
Jan. 5 '01	Jan. 24 '01	Feb. 13 '01	Feb. 28 '01	Mar. 2 '01	Mar. 21 '01	Apr. 25 '01	July 23 '01

	PRINTING SCHEDULE FOR IAB	· · · · · · · · · · · · · · · · · · ·
ISSUE NUMBER	SUBMISSION DEADLINE	ISSUE DATE
17	Friday, February 4, 2000	February 23, 2000
18	Friday, February 18, 2000	March 8, 2000
19	Friday, March 3, 2000	March 22, 2000

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.

PUBLICATION PROCEDURES

TO:	Administrative Rules Coordinators and Text Processors of State Agencies
FROM:	Kathleen K. Bates, Iowa Administrative Code Editor
SUBJECT:	Publication of Rules in Iowa Administrative Bulletin

The Administrative Code Division uses Interleaf 6 to publish the Iowa Administrative Bulletin and can import documents directly from most other word processing systems, including Microsoft Word, Word for Windows (Word 7 or earlier), and WordPerfect.

1. To facilitate the processing of rule-making documents, we request a 3.5" High Density (not Double Density) IBM PC-compatible diskette of the rule making. Please indicate on each diskette the following information: agency name, file name, format used for exporting, and chapter(s) amended. Diskettes may be delivered to the Administrative Code Division, 1st Floor, Lucas State Office Building or included with the documents submitted to the Governor's Administrative Rules Coordinator.

2. Alternatively, if you have Internet E-mail access, you may send your document as an attachment to an E-mail message, addressed to both of the following:

bcarr@legis.state.ia.us kbates@legis.state.ia.us

Please note that changes made prior to publication of the rule-making documents are reflected on the hard copy returned to agencies by the Governor's office, but not on the diskettes; diskettes are returned unchanged.

Your cooperation helps us print the Bulletin more quickly and cost-effectively than was previously possible and is greatly appreciated.

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Guide to Rule Making, June 1995 Edition, available upon request to the Iowa Administrative Code Division, Lucas State Office Building, First Floor, Des Moines, Iowa 50319.

AGENDA

The Administrative Rules Review Committee will hold a special meeting on Friday, February 4, 2000, at
9 a.m. in Room 118, State Capitol, Des Moines, Iowa. The following rules will be reviewed: Bulletin
AGRICULTURE AND LAND STEWARDSHIP DEPARTMENT[21] Prohibit movement of infested bees from designated states; inspection required for the sale of bees, comb, or used equipment, 22.10, 22.11, <u>Filed</u> ARC 9596A 1/12/00
ALCOHOLIC BEVERAGES DIVISION[185] COMMERCE DEPARTMENT[181]"umbrella" Waivers from rules, ch 19, <u>Notice</u> ARC 9621A
ECONOMIC DEVELOPMENT, IOWA DEPARTMENT OF [261] Uniform waiver and variance rules, ch 104, <u>Notice</u> ARC 9598A 1/12/00
EMERGENCY MANAGEMENT DIVISION[605] PUBLIC DEFENSE DEPARTMENT[601]"umbrella" Enhanced wireless 911 service plan, 10.7, Notice ARC 9632A, also Filed Emergency ARC 9633A
ENGINEERING AND LAND SURVEYING EXAMINING BOARD[193C] Professional Licensing and Regulation Division[193]
COMMERCE DEPARTMENT[181]"umbrella" Land surveys, 2.5(3), 2.6, 2.8, <u>Filed</u> ARC 9601A
ENVIRONMENTAL PROTECTION COMMISSION[567] NATURAL RESOURCES DEPARTMENT[561]"umbrella"
Animal feeding operations, 65.16(3), 65.19(6)"b"(1), <u>Filed Emergency</u> ARC 9599A
Disbursement of money from civil reparations trust fund, ch 12, Filed ARC 9634A 1/26/00
GENERAL SERVICES DEPARTMENT[401] Fees paid to newspapers, 5.21, <u>Filed</u> ARC 9602A
HUMAN SERVICES DEPARTMENT[441] Waivers of administrative rules, 1.8, Notice ARC 9597A Marce 1/12/00 Rent subsidy program, 53.2(2), 53.3(2), 53.4(2), Notice ARC 9612A Coverage of area education agency services under Medicaid, 78.32, Notice ARC 9613A Motice ARC 9613A Highly structured juvenile programs, 114.2, 185.83(4), Notice ARC 9614A Lifective date of rehabilitative treatment and supportive services contract, 152.8, 152.22(6), Notice ARC 9615A
INSPECTIONS AND APPEALS DEPARTMENT[481] Uniform waiver and variance rules, ch 6, Notice ARC 9625A Quality award for nursing facilities, ch 54, Notice ARC 9610A Collection of food stamp overpayments, 71.6(2), Notice ARC 9611A
INSURANCE DIVISION[191] COMMERCE DEPARTMENT[181]"umbrella" Reconstructive surgery; licensure requirement for health care professionals who are not medical professionals; community health management information system, 35.35, 71.23, 75.17, 76.9(1)"c," rescind ch 100, Notice ARC 9594A Valuation of life insurance policies, ch 47, Filed ARC 9609A Viatical settlement contracts, 50.120 to 50.124, Filed ARC 9616A
LABOR SERVICES DIVISION[875] WORKFORCE DEVELOPMENT DEPARTMENT[871]"umbrella" Waivers from administrative rules, ch 1 division VI, 1.100, ch 1 division VII, 1.101 to 1.109, Notice ARC 9631A Maivers from administrative rules, ch 1 division VI, 1.100, ch 1 division VII, 1.101 to 1.109, Notice ARC 9631A General industry safety and health, 10.20, Filed Emergency After Notice ARC 9619A Construction safety and health, 26.1, Filed Emergency After Notice ARC 9620A
LOTTERY DIVISION[705] REVENUE AND FINANCE DEPARTMENT[701]"umbrella" Suspension or revocation of a license, 2.12, <u>Filed</u> ARC 9624A
MEDICAL EXAMINERS BOARD[653] PUBLIC HEALTH DEPARTMENT[641]"umbreila"
Uniform waiver and variance; licensure application waivers, ch 3, 11.9(3), <u>Notice</u> ARC 9605A

NATURAL RESOURCE COMMISSION[571] NATURAL RESOURCES DEPARTMENT[561]"umbreila"	•
Shooting ranges located on game management areas, 51.3(1), <u>Filed Emergency</u> ARC 9628A	26/00
Waivers or variances from administrative rules, ch 10, <u>Notice</u> ARC 9627A	26/00
NURSING BOARD[655] PUBLIC HEALTH DEPARTMENT[641]"umbrella" Nursing education programs, 2.1, 2.10, 2.11, Notice ARC 9607A Nursing education programs, 2.1, 2.10, 2.11, Notice	12/00
PERSONNEL DEPARTMENT[581] Uniform rules for waivers and variances, ch 32, <u>Notice</u> ARC 9626A 1/2	26/00
PROFESSIONAL LICENSURE DIVISION[645] PUBLIC HEALTH DEPARTMENT[641]"umbrella" Dietetic examiners, 80.5(1), 80.5(4), 80.100(4), 80.101(1), 80.101(2)"d," 80.101(3), 80.101(8), 80.102(1), 80.104, Filed ARC 9606A	12/00
PUBLIC HEALTH DEPARTMENT[641] Radiation, ch 38 title, 38.1(2), 38.2, 38.3(1), 38.8(1)"a," 38.8(3)"a," 38.8(6), 38.10, 39.1(3), 39.3(2)"a," 39.3(3)"d," 39.3(10)"a," 39.4(24), 39.4(26)"e," 39.4(26)"f"(2) and (5), 39.4(27)"e," 39.4(33)"j"(2), 39.4(33)"k"(3), 39.4(90)"a"(3), 39.5, ch 39 appendices E, H, I, and J, 40.1(5), 40.2(2), 40.10(2), 40.15(1)"b"(1), 40.15(3), 40.20(1), 40.22, 40.36(1)"b"(1), 40.62(2), 40.62(5), 40.75, 40.80, ch 40 appendix D, 41.1(1), 41.1(2), 41.1(3)"a"(6), 41.1(3)"f"(1)"2," 41.1(3)"f"(2)"1," 41.1(3)"f"(4), 41.1(4)"i," 41.1(6), 41.1(6)"h"(1)"3," 41.1(7)"c"(5), 41.1(9)"e" to "g," 41.1(11)"a," 41.2(14)"c," 41.2(60)"a"(2)"1" and "2," 41.2(62), 41.3(1)"b," 41.3(2), 41.3(12), 41.3(13), 41.3(17)"a"(1)"3," 41.3(18)"a"(15), 41.3(18)"e," 41.3(18)"f"(1) and (3), 41.6(1), 41.6(2)"a"(8), 41.6(2)"c," 41.6(3), 41.6(4), 41.6(5)"a," "c," "h" to "o," 41.6(6), 41.6 appendix I, 41.7(1), ch 41 appendix B"3," 42.2(2)"f," 42.3(1)"a"(7), 45.1(2), 45.1(5)"c," 45.1(7), 45.1(9)"b," 45.1(10)"b"(1)"2," 45.1(10)"d," 45.1(10)"g"(1)"1," 45.1(11), 45.1(12)"b," 45.1(13), 45.3(1), 45.3(2)"a," 45.3(4)"c"(5) and (8), 45.3(4)"f" and "g," 45.3(5)"b," 45.3(6)"a"(9) to (12), 45.3(6)"c," 45.3(7)"b," 45.3(9)"a," 45.3(11), 45.4(2), 45.4(11)"c," 46.1, 46.5(1)"c," Notice ARC 9629A	26/00
45.4(11)°C, "46.1, 46.5(1)°C," <u>Notice</u> ARC 9629A	
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REVENUE AND FINANCE DEPARTMENT[701]	12/00
Individual income tax and withholding tax, 39.2(4)"b," 40.18(9), 42.2(6), 42.2(10), 43.8(2)"o," 46.3(3)"e," <u>Filed</u> ARC 9608A	
Local option sales and service tax; local option school infrastructure sales and service tax, 107.2, 107.8 to 107.10, 107.14, 108.2(3), 108.2(5), 108.2(6), 108.5, 108.7 to 108.9, Filed ARC 9636A	26/00
SECRETARY OF STATE[721] Election forms and instructions—plan III supervisor district candidate signatures after a change in the number of supervisors, 21.601, <u>Notice</u> ARC 9604A, also <u>Filed Emergency</u> ARC 9603A 1/2	12/00
TRANSPORTATION DEPARTMENT[761] Waiver of rules, 10.1(2), ch 11, 112.1(2), 115.1(2), 524.2(2), 529.3, Notice ARC 9617A Flashing lights and warning devices on slow-moving vehicles, ch 452 title, 452.1 to 452.3, Notice ARC 9622A Kail assistance program; railroad revolving loan fund, 830.2(2), 830.3(1), 830.3(2), 830.4(2), 830.4(4) "b," 830.6(4), 830.6(5), ch 831, Filed ARC 9593A	26/00
VOTER REGISTRATION COMMISSION[821] State registrar of voters, 1.2, Filed ARC 9595A 1/2	12/00

WORKFORCE DEVELOPMENT DEPARTMENT[871]

Extension of contribution surcharge to year 2001; request for waiver of administrative rule, 23.40(2)"a," ch 41,	
Notice ARC 9630A	.6/00

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 Chair at any place in the state and at any time. EDITOR'S NOTE: Terms ending April 30, 2003.

Senator H. Kay Hedge 3208 335th Street Fremont, Iowa 52561

Senator Merlin E. Bartz 2081 410th Street Grafton, Iowa 50440

Senator Patricia M. Harper 3336 Santa Maria Drive Waterloo, Iowa 50702

Senator John P. Kibbie P.O. Box 190 Emmetsburg, Iowa 50536

Senator Sheldon Rittmer 3539 230th Street DeWitt, Iowa 52742

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Representative Clyde Bradley 835 Blackhawk Lane Camanche, Iowa 52730

Representative Danny Carroll 244 400th Avenue Grinnell, Iowa 50112

Representative Minnette Doderer 2008 Dunlap Court Iowa City, Iowa 52245

Representative Geri Huser 213 7th Street NW Altoona, Iowa 50009

Brian Gentry Administrative Rules Coordinator Governor's Ex Officio Representative Capitol, Room 11 Des Moines, Iowa 50319

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 lowa Administrative Bulletin. HEARING LOCATION DATE AND TIME OF HEARING AGENCY **EMERGENCY MANAGEMENT DIVISION[605]** Conference Room-Level A February 15, 2000 Enhanced wireless 911 service plan, 10.7 Hoover State Office Bldg. 10 a.m. IAB 1/26/00 ARC 9632A Des Moines, Iowa (See also ARC 9633A herein) **INSPECTIONS AND APPEALS DEPARTMENT[481]** Quality award for nursing facilities, Director's Conference Room February 8, 2000 ch 54 Second Floor 10 a.m. IAB 1/12/00 ARC 9610A Lucas State Office Bldg. Des Moines, Iowa LABOR SERVICES DIVISION[875] Division of Labor Services February 15, 2000 Waivers from administrative rules, 1000 E. Grand Ave. 1:30 p.m. 1.101 to 1.109 IAB 1/26/00 ARC 9631A Des Moines, Iowa (If requested) MEDICAL EXAMINERS BOARD[653] Supervision of pharmacists who Auditorium February 15, 2000 administer prescription drugs, State Historical Building 1 p.m. 13.3 600 E. Locust St. IAB 1/26/00 ARC 9618A Des Moines, Iowa NURSING BOARD[655] Examinations, Ballroom March 1, 2000 2.10 Kirkwood Civic Center Hotel 7 p.m. IAB 1/12/00 ARC 9607A 4th and Walnut Des Moines, Iowa PERSONNEL DEPARTMENT[581] **IPERS** February 15, 2000 Uniform rules for waivers and variances, ch 32 600 E. Court Ave. 9 a.m. IAB 1/26/00 ARC 9626A Des Moines, Iowa PUBLIC HEALTH DEPARTMENT[641] Conference Room-5th Floor South February 29, 2000 Radiation, 8:30 a.m. amendments to chs 38 to 42, 45, 46 Side 1 IAB 1/26/00 ARC 9629A Lucas State Office Bldg. Des Moines, Iowa

PUBLIC HEALTH DEPARTMENT		
WIC program, 73.5, 73.8, 73.9, 73.12(1), 73.19, 73.20 IAB 1/26/00 ARC 9623A (ICN Network)	ICN Classroom 1, Room 0210 Scott Community College 500 Belmont Rd. Bettendorf, Iowa	February 15, 2000 12 noon to 1 p.m.
	ICN Classroom National Guard Armory 2500 Summer St. Burlington, Iowa	February 15, 2000 12 noon to 1 p.m.
	Schindler Education Center 130A UNI Hudson Rd. and 23rd St. Cedar Falls, Iowa	February 15, 2000 12 noon to 1 p.m.
	Jefferson High School 1243 20th St. SW Cedar Rapids, Iowa	February 15, 2000 12 noon to 1 p.m.
	ICN Classroom Clear Lake High School 125 N. 20th St. Clear Lake, Iowa	February 15, 2000 12 noon to 1 p.m.
	ICN Classroom 1 Southwestern Community College 1501 W. Townline Rd. Creston, Iowa	February 15, 2000 12 noon to 1 p.m.
	Room 115, Trade Industry Bldg. Northeast Iowa Community College 1625 Hwy. 150 Calmar, Iowa	February 15, 2000 12 noon to 1 p.m.
	Conference Room—6th Floor Lucas State Office Bldg. Des Moines, Iowa	February 15, 2000 12 noon to 1 p.m.
	Room 22, Library Bldg. Iowa Lakes Community College 300 S. 18th St. Estherville, Iowa	February 15, 2000 12 noon to 1 p.m.
	Army Aviation Support Facility 1649 Nelson Ave. Fort Dodge, Iowa	February 15, 2000 12 noon to 1 p.m.
	ICN Room National Guard Armory 2858 N. Court Rd. Ottumwa, Iowa	February 15, 2000 12 noon to 1 p.m.
	Forum Bldg.—2nd Floor Dubuque Community School District 2300 Chaney Dubuque, Iowa	February 15, 2000 12 noon to 1 p.m.
	Individual Learning Center Central Campus 1121 Jackson St. Sioux City, Iowa	February 15, 2000 12 noon to 1 p.m.

REAL ESTATE COMMISSION[193E]

Business conduct, 1.1, 1.27, 1.41, 1.42(6)	Conference Room—2nd Floor Commerce Bldg.	February 1, 2000 9 a.m.
IAB 1/12/00 ARC 9600A	1918 SE Hulsizer Ankeny, Iowa	

SECRETARY OF STATE[721]

Signature requirements for nomination petitions for	Office of the Secretary of State Second Floor	February 1, 2000 1:30 p.m.
supervisor candidates, 21.601	Hoover State Office Bldg.	•
IAB 1/12/00 ARC 9604A	Des Moines, Iowa	
(See also ARC 9603A)		

TRANSPORTATION DEPARTMENT[761]

Waiver of rules,	Commission Conference Room	February 17, 2000
10.1(2), ch 11, 112.1(2),	800 Lincoln Way	1 p.m.
115.1(2), 524.2(2), 529.3	Ames, Iowa	(If requested)
IAB 1/26/00 ARC 9617A		
Flashing lights and warning devices	Commission Conference Room	February 17, 2000
on slow-moving vehicles,	800 Lincoln Way	2 p.m.
ch 452	Ames, Iowa	(If requested)
IAB 1/26/00 ARC 9622A		

WORKFORCE DEVELOPMENT DEPARTMENT[871]

Request for waiver of	Unemployment Insurance Svcs. Div.	February 15, 2000
administrative rule,	1000 E. Grand Ave.	9:30 a.m.
23.40(2), ch 41	Des Moines, Iowa	
IAB 1/26/00 ARC 9630A		

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].

The following list will be updated as changes occur:

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] 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] ECONOMIC DEVELOPMENT, IOWA DEPARTMENT OF[261] City Development Board[263] Iowa Finance Authority[265] EDUCATION DEPARTMENT[281] Educational Examiners Board [282] College Student Aid Commission [283] Higher Education Loan Authority 284 Iowa Advance Funding Authority [285] Libraries and Information Services Division[286] Public Broadcasting Division[288] School Budget Review Committee[289] EGG COUNCIL[301] ELDER AFFAIRS DEPARTMENT[321] **EMPOWERMENT BOARD, IOWA[349]** ETHICS AND CAMPAIGN DISCLOSURE BOARD, IOWA[351] EXECUTIVE COUNCIL[361] FAIR BOARD[371] GENERAL SERVICES DEPARTMENT[401] HUMAN INVESTMENT COUNCIL[417] HUMAN RIGHTS DEPARTMENT[421] Community Action Agencies Division[427] Criminal and Juvenile Justice Planning Division[428] Deaf Services Division[429] Persons With Disabilities Division[431] Latino Affairs Division[433] Status of African-Americans, Division on the[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] State Public Defender[493] LAW ENFORCEMENT ACADEMY[501] LIVESTOCK HEALTH ADVISORY COUNCIL[521] MANAGEMENT DEPARTMENT[541] Appeal Board, State [543] City Finance Committee [545] County Finance Committee[547] NARCOTICS ENFORCEMENT ADVISORY COUNCIL[551] NATIONAL AND COMMUNITY SERVICE, IOWA COMMISSION ON[555] NATURAL RESOURCES DEPARTMENT[561] Energy and Geological Resources Division [565] Environmental Protection Commission[567] 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] Emergency Management Division[605] Military Division[611] PUBLIC EMPLOYMENT RELATIONS BOARD[621] PUBLIC HEALTH DEPARTMENT[641] Substance Abuse Commission[643] Professional Licensure Division[645] Dental Examiners Board [650] Medical Examiners Board[653] Nursing Board[655] Pharmacy Examiners Board [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] SEED CAPITAL CORPORATION, IOWA[727] SHEEP AND WOOL PROMOTION BOARD, IOWA[741] TELECOMMUNICATIONS AND TECHNOLOGY COMMISSION, IOWA[751] **TRANSPORTATION DEPARTMENT**[761] Railway Finance Authority[765] TREASURER OF STATE[781] TURKEY MARKETING COUNCIL, IOWA[787] UNIFORM STATE LAWS COMMISSION[791] VETERANS AFFAIRS COMMISSION[801] VETERINARY MEDICINE BOARD[811] VOTER REGISTRATION COMMISSION[821] WORKFORCE DEVELOPMENT DEPARTMENT[871] Labor Services Division[875] Workers' Compensation Division[876] Workforce Development Board and Workforce Development Center Administration Division[877]

NOTICE - AVAILABILITY OF PUBLIC FUNDS

AGENCY	PROGRAM	SERVICE DELIVERY AREA	ELIGIBLE APPLICANTS	SERVICES	APPLICATION DUE DATE	CONTRACT PERIOD
Public Health	Critical Access Hospital Grant Program	Statewide	Hospitals that are recognized as a necessary provider or that have a 1998 average daily census of 10.0 or lower	Grant funds for financial feasibility studies, system development, consultant studies, legal fees	March 1, 2000	March 15, 2000 to August 31, 2000

Faxed and electronic requests will be accepted. Request application packet from:

Marvin L. Firch Critical Access Hospital Program Coordinator Bureau of Rural Health & Primary Care Division of Family and Community Health Iowa Department of Public Health Lucas State Office Building, 5th Floor Des Moines, Iowa 50319-0075 Telephone: (515) 281-4808 FAX: (515) 242-6384 e-mail: mfirch@idph.state.ia.us

NOTICES

ALCOHOLIC BEVERAGES DIVISION[185]

Notice of Intended Action

Twenty-five interested persons, a governmental subdivision, an agency or association of 25 or more persons may demand an oral presentation hereon as provided in Iowa Code section 17A.4(1)^{*ab.*}

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 section 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 123.21, the Alcoholic Beverages Division hereby gives Notice of Intended Action to adopt Chapter 19, "Waivers from Rules," Iowa Administrative Code.

The purpose of proposed Chapter 19 is to satisfy the requirements of Executive Order Number 11 which requires state agencies to adopt a general waiver rule.

Consistent with Executive Order Number 9, the Division has considered the regulatory principles identified in this order and finds that this chapter will serve an important public need in making the rules of the Division more flexible in application to specific circumstances.

Proposed Chapter 19 provides for the general requirements for requesting a waiver and describes the procedure the Division will use to grant a waiver.

The Division will receive written comments on the proposed chapter until the close of business on February 16, 2000. Comments may be addressed to Judy K. Seib, Alcoholic Beverages Division, 1918 S.E. Hulsizer Road, Ankeny, Iowa 50021. Comments may be faxed to Judy K. Seib at (515)281-7375. Comments may be E-mailed to Judy K. Seib at Judy.Seib@comm2.state.ia.us.

This chapter is intended to implement Executive Order Number 11.

The following amendment is proposed.

Adopt the following new chapter:

CHAPTER 19 WAIVERS FROM RULES

185—19.1(123) Applicability. This chapter outlines a uniform process for the granting of waivers from rules adopted by the division.

19.1(1) Authority. A waiver from rules adopted by the alcoholic beverages division may be granted in accordance with this chapter if:

a. The division has exclusive rule-making authority to promulgate the rule from which a waiver is requested or has final decision-making authority over a contested case in which a waiver is requested; and

b. No statute or rule otherwise controls the granting of a waiver from the rule from which a waiver is requested.

19.1(2) Interpretive rules. This chapter shall not apply to rules that merely define the meaning of a statute or other provisions of law or precedent if the division does not possess delegated authority to bind the courts to any extent with its definition.

185—19.2(123) Compliance with statute. No waiver may be granted from a requirement that is imposed by statute. Any waiver must be consistent with statute.

185—19.3(123) Criteria for waiver. The division may issue an order, in response to a completed petition or on its own motion, granting a waiver from a rule adopted by the division, in whole or in part, as applied to the circumstances of a specified person if the division finds that:

1. Application of the rule to the person at issue would result in hardship or injustice to that person; and

2. Waiver on the basis of the particular circumstances relative to that specified person would be consistent with the public interest; and

3. Waiver in the specific case would not prejudice the substantial legal rights of any person.

In determining whether a waiver would be consistent with the public interest under "2," the division shall consider whether, if the waiver is granted, the public health and safety will be protected by other means that are substantially equivalent to full compliance with the rule.

19.3(1) Division discretion. The decision on whether the circumstances justify the granting of a waiver shall be made at the sole discretion of the division, upon consideration of all relevant factors.

19.3(2) Mandatory waivers. In response to the timely filing of a completed petition requesting a waiver, the division shall grant a waiver from a rule, in whole or in part, as applied to the particular circumstances of a specified person, if the division finds that the application of all or a portion thereof to the circumstances of that specified person would not, to any extent, advance or serve any of the purposes of the rule.

19.3(3) Burden of persuasion. The petitioner shall assume the burden of persuasion when a petition is filed for a waiver from a division rule.

19.3(4) Special waiver rules not precluded. This chapter shall not preclude the division from granting waivers in other contexts or on the basis of other standards if a statute or other division rule authorizes the division to do so, and the division deems it appropriate to do so.

19.3(5) Administrative deadlines. When the rule from which a waiver is sought establishes administrative deadlines, the division shall balance the special individual circumstances of the petitioner with the overall goal of uniform treatment of all licensees and license applicants.

185—19.4(123) Filing of petition. A petition for a waiver must be submitted in writing to the division as follows:

19.4(1) License application. If the petition relates to a license application, the petition shall be made in accordance with the filing requirements for the license in question.

19.4(2) Contested cases. If the petition relates to a pending contested case, the petition shall be filed in the contested case proceeding.

19.4(3) Other. If the petition does not relate to a license application or a pending contested case, the petition may be submitted to the division administrator.

185–19.5(123) Content of petition. A petition for waiver shall include the following information where applicable and known to the requester:

1. The name, address, and telephone number of the person or entity for whom a waiver is being requested and the license number or case number of any related contested case.

2. A description and citation of the specific rule from which a waiver is requested.

3. The specific waiver requested, including the precise scope and operative period that the waiver will extend.

4. The relevant facts that the petitioner believes would justify a waiver. This statement shall include a signed statement from the petitioner attesting to the accuracy of the facts

ALCOHOLIC BEVERAGES DIVISION[185](cont'd)

provided in the petition, and a statement of reasons that the petitioner believes will justify a waiver.

5. A history of any prior contacts between the division and the petitioner relating to the regulated activity or license affected by the proposed waiver, including:

• A description of each affected license held by the requester.

• Any notices of violation, contested case hearings, or investigative reports relating to the regulated activity or license.

6. Any information known to the requester regarding the division's treatment of similar cases.

7. The name, address, and telephone number of any public agency or political subdivision which also regulates the activity in question, or which might be affected by the granting of a waiver.

8. The name, address, and telephone number of any person or entity that would be adversely affected by the granting of a petition.

9. The name, address, and telephone number of any person with knowledge of the relevant facts relating to the proposed waiver.

10. Signed releases of information authorizing persons with knowledge regarding the request to furnish the division with information relevant to the waiver.

185—19.6(123) Additional information. Prior to issuing an order granting or denying a waiver, the division may request additional information from the petitioner relative to the petition and circumstances relating to the request for waiver. If the petition was not filed in a contested case, the division may, on its own motion or at the petitioner's request, schedule a telephonic or in-person hearing between the petitioner and the division administrator.

185—19.7(123) Notice. The division shall acknowledge a petition upon receipt. The division shall ensure that notice of the pendency of the petition and a concise summary of its contents have been provided to all persons to whom notice is required by any provision of law, within 30 days of the receipt of the petition. In addition, the division may give notice to other persons. To accomplish this notice provision, the division may require the petitioner to serve the notice on all persons to whom notice is required by any provision of law, and provide a written statement to the agency attesting that notice has been provided.

185—19.8(123) Hearing procedures. The provisions of Iowa Code sections 17A.10 to 17A.18A regarding contested case hearings shall apply to any petition for a waiver of a rule filed within a contested case and shall otherwise apply to division proceedings for a waiver only when the division so provides by rule or order or is required to do so by statute.

185—19.9(123) Ruling. An order granting or denying a waiver shall be in writing and shall contain a reference to the particular person and rule or portion thereof to which the order pertains, a statement of the relevant facts and reasons upon which the action is based, and a description of the precise scope and operative period of the waiver if one is issued.

19.9(1) Conditions. The division may condition the granting of the waiver on such reasonable conditions as appropriate to achieve the objectives of the particular rule in question through alternative means.

19.9(2) Time for ruling. The division shall grant or deny a petition for a waiver as soon as practicable but, in any event, shall do so within 120 days of its receipt, unless the petitioner agrees to a later date. However, if a petition is filed

in a contested case, the division shall grant or deny the petition no later than the time at which the final decision in that contested case is issued.

19.9(3) When deemed denied. Failure of the division to grant or deny a petition within the required time period shall be deemed a denial of that petition by the division.

19.9(4) Service of order. Within seven days of its issuance, any order issued under this chapter shall be transmitted to the petitioner or the person to whom the order pertains, and to any other person entitled to such notice by any provision of law.

185—19.10(123) Public availability. Subject to the provisions of Iowa Code section 17A.3(1)"e," the division shall maintain a record of all orders granting and denying waivers under this chapter. All final rulings in response to requests for waivers shall be indexed and available to members of the public at the division office.

185—19.11(123) Voiding or cancellation. A waiver is void if the material facts upon which the request is based are not true or if material facts have been withheld. The division may at any time cancel a waiver upon appropriate notice and hearing if the division finds:

1. The facts as stated in the request are not true.

2. Material facts have been withheld.

3. The alternative means of compliance provided in the waiver have failed to achieve the objectives of the statute.

4. The requester has failed to comply with the conditions of the order.

185—19.12(123) Violations. Violation of conditions in the waiver approval is the equivalent of violation of the particular rule for which the waiver is granted and is subject to the same remedies or penalties.

185—19.13(123) Defense. After the division issues an order granting a waiver, the order is a defense within its terms and the specific facts indicated therein for the person to whom the order pertains in any proceeding in which the rule in question is sought to be invoked. The order shall only be effective to the person to whom it is issued.

185—19.14(123) Appeals. Any request for an appeal from a decision granting or denying a waiver shall be in accordance with the procedures provided in Iowa Code chapter 17A and the division's rules. An appeal shall be taken within 30 days of the issuance of the ruling in response to the request unless a contrary time is provided by rule or statute.

These rules are intended to implement Iowa Code chapter 123.

ARC 9632A

EMERGENCY MANAGEMENT DIVISION[605]

Notice of Intended Action

Twenty-five interested persons, a governmental subdivision, an agency or association of 25 or more persons may demand an oral presentation hereon as provided in Iowa Code section 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 section 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 34A.7A, the Emergency Management Division proposes to

EMERGENCY MANAGEMENT DIVISION[605](cont'd)

amend Chapter 10, "Enhanced 911 Telephone Systems," Iowa Administrative Code.

The amendments reflect the formal adoption of the Wireless Enhanced 911 Implementation and Operation Plan, which is required by Iowa Code section 34A.7A and rule 605—10.7(34A).

Consideration will be given to all written suggestions or comments on the proposed amendments received on or before February 15, 2000. Such written materials should be sent to the E911 Program Manager, Emergency Management Division, Hoover State Office Building, Des Moines, Iowa 50319, or fax (515)281-7539.

Also, there will be a public hearing on February 15, 2000, at 10 a.m. in the Emergency Management Conference Room, Level A, Hoover 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.

Any persons who intend to attend the public hearing and have special requirements such as hearing or mobility impairments should advise the Emergency Management Division of specific needs.

These amendments are intended to implement Iowa Code chapter 34A.

These amendments were also Adopted and Filed Emergency and are published herein as ARC 9633A. The content of that submission is incorporated by reference.

ARC 9612A

HUMAN SERVICES DEPARTMENT[441]

Notice of Intended Action

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

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 section 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 217.6, the Department of Human Services proposes to amend Chapter 53, "Rent Subsidy Program," appearing in the Iowa Administrative Code.

The rent subsidy program is designed to provide rent assistance to persons who participate in a home- and community-based service (HCBS) waiver program and who were discharged from a medical institution in which they have resided, at risk of institutional placement, or able to leave a medical institution by use of services provided under an HCBS waiver upon turning 18 years of age during the last year of their institutional stay.

An eligible person may receive assistance in meeting rental expense and, in the initial two months of eligibility, in purchasing necessary household furnishings and supplies.

These amendments revise policy governing the rent subsidy program as follows:

• The basis of the maximum rental assistance payment is increased from 100 percent to 110 percent of the maximum prevailing fair market rent under guidelines of the applicable United States Department of Housing and Urban Development (HUD) low-rent housing program in the area where the person's residence is located, less 30 percent of the gross income of the individual consumer.

The Department of Housing and Urban Development (HUD) published interim regulations in the May 14, 1999, Federal Register at 24 CFR 982.503(b) and final regulations in the October 21, 1999, Federal Register allowing public housing authorities to establish the payment standard amount for a unit size at any level between 90 percent and 110 percent of the published Fair Market Rental for that unit size. The Department has decided to use the maximum guideline established by HUD to establish the amount of the rental assistance.

This change will, in most cases, result in increased monthly payments to participants. This increase is the same as would be experienced by participants in the federal rental assistance program, and makes the Department's program consistent with the federal program payment structure.

• Time-limited policy regarding eligibility criteria that is no longer in effect is deleted.

• The reference to one-bedroom homes is clarified.

• Statutory references are updated.

These amendments do not provide for waivers in specified situations because they only provide additional benefits, delete an outdated provision, clarify language, and update statutory references.

Consideration will be given to all written data, views, and arguments thereto received by the Office of Policy Analysis, Department of Human Services, Hoover State Office Building, Des Moines, Iowa 50319-0114, on or before February 16, 2000.

These amendments are intended to implement Iowa Code section 217.6 and 1999 Iowa Acts, chapter 203, section 11, subsection 3.

The following amendments are proposed.

ITEM 1. Amend the parenthetical implementation following each rule in 441—Chapter 53 as follows: (77GA,ch1218 78GA,ch203)

ITEM 2. Amend subrule 53.2(2) as follows:

53.2(2) Discharged from a medical institution. Except as provided in subrules 53.2(4) and 53.2(5), the person shall have been discharged from a medical institution on or after July 1, 1995, and immediately prior to receiving HCBS services. For a period of 60 days after April 1, 1999, persons who were discharged from a medical institution immediately prior to entering an HCBS program between July 1, 1995, and June 30, 1996, shall receive first consideration for eligibility and participation in this program if they demonstrate a need for rental assistance. These persons shall not replace anyone who is actively participating in this program at the time of their application. During this 60-day period, applications may be submitted by anyone, although first consideration will be given to the persons described above, whose applications will be acted upon in the order they are received. At the end of the 60-day period, all applications received during that time from persons not described above shall be considered in the chronological order that they were received and, if applicable, participation in the program shall be approved retroactive to the date that would have been allowed had an application been processed immediately on receipt.

ITEM 3. Amend subrule 53.3(2) as follows:

53.3(2) Date of application. The date of the application shall be the date the application, including written verification of income and written verification of application to other rental assistance programs, is received by the division of

HUMAN SERVICES DEPARTMENT[441](cont'd)

mental health and developmental disabilities. Applications received through June 30, 1999, on behalf of persons who would have met all of the qualifying criteria between July 1, 1998, and their date of application will be assessed for payment consideration retroactive to July 1, 1998, or the date between July 1, 1998, and the date of application on which the applicant would have met all eligibility criteria.

ITEM 4. Amend subrule 53.4(2) as follows:

53.4(2) Maximum monthly payment for rent. Assistance for rent shall be equal to the rent paid, not to exceed 110 percent of the maximum prevailing fair market rent under guidelines of the applicable United States Department of Housing and Urban Development (HUD) low-rent housing program in the area where the person's residence is located, less 30 percent of the gross income of the individual consumer. The fair market rent used shall be that for a one-bedroom home or a proportionate share of rental costs in living units containing more than one bedroom.

ITEM 5. Amend 441—Chapter 53, implementation clause, as follows:

These rules are intended to implement Iowa Code section 217.6 and 1998 1999 Iowa Acts, chapter 1218 203, section 11, subsection 3.

ARC 9613A

HUMAN SERVICES DEPARTMENT[441]

Notice of Intended Action

Twenty-five interested persons, a governmental subdivision, an agency or association of 25 or more persons may demand an oral presentation hereon as provided in Iowa Code section 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 section 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 expands the coverage of area education agency services under Medicaid to include social work, nursing, and vision services. This change was requested by the area education agencies.

This change will not impact the Medicaid budget as the area education agencies provide the state match for these services. Federal funding is available for 75 percent of the cost of the services billed.

This amendment does not provide for waivers in specified situations because the amendment only provides additional benefits.

Consideration will be given to all written data, views, and arguments thereto received by the Office of Policy Analysis, Department of Human Services, Hoover State Office Building, Des Moines, Iowa 50319-0114, on or before February 16, 2000.

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

The following amendment is proposed.

Amend rule 441—78.32(249A) as follows:

441—78.32(249A) Area education agencies. Payment will be made for physical therapy, occupational therapy, psychological evaluations and counseling, psychotherapy, speechlanguage therapy, and audiological, nursing, and vision services provided by an area education agency (AEA). These services shall be provided by personnel who meet standards as set forth in department of education rules 281— 41.8(256B,34CFR300) and to 281—41.9(256B,273, 34CFR300) 41.10(256B) to the extent that their certification or license allows them to provide these services. Services shall be provided directly by the AEA or through contractual arrangement with the AEA.

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

ARC 9614A

HUMAN SERVICES DEPARTMENT[441]

Notice of Intended Action

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

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 section 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 234.6, the Department of Human Services proposes to amend Chapter 114, "Licensing and Regulation of All Group Living Foster Care Facilities for Children," and Chapter 185, "Rehabilitative Treatment Services," appearing in the Iowa Administrative Code.

These amendments revise the placement criteria in Chapter 185 for children to be served in a highly structured residential facility and establish criteria for readmission to the program. An exception process is also added for children who do not meet the placement criteria. The definition of "highly structured juvenile program" in Chapter 114 is revised to remove duplicative policy.

Highly structured juvenile programs, more commonly known as boot camps, are programs lasting 90 days, which have a high degree of structure that stresses discipline, physical activity, and education.

Current policy requires that young men admitted to highly structured group foster care be 15 to 17 years old; be adjudicated delinquent on a charge that is at least an aggravated misdemeanor, but is not a forcible felony; be unable to live in a family situation due to severe social, emotional, and behavioral disabilities; and not be entering the program within 60 days of another residential placement.

Young men who do not meet these criteria enter the program by a Director's exception to policy as set forth at rule 441—1.8(217). There has been a substantial volume of admission by exceptions, particularly for boys who have been adjudicated delinquent for crimes less serious than aggravated misdemeanors.

These amendments maintain the age criteria. A requirement that the adjudicated crime be at least a serious misdemeanor has been substituted for the current requirement of an aggravated misdemeanor. In addition, the prohibition against entering the program within 60 days of another residential setting has been deleted and a requirement is added that youth not be able to benefit from further community-

HUMAN SERVICES DEPARTMENT[441](cont'd)

based services at the time of placement, but be able to successfully return to the community following intensive short-term residential treatment.

These amendments also change the process by which exceptions are granted. Young men who meet the criteria for admission will be deemed part of the target population for admission. Candidates for admission who are not part of the target population may be admitted with the approval of a Department regional administrator or designee. A regional administrator or designee may delegate this authority to the chief juvenile court officers or designees. The Department and juvenile court services will be required to keep data on the children placed who lack one or more of the target population characteristics.

The proposed target populations better identify the categories of young men most likely to benefit from the rigor and structure of these programs. The new process for exceptions to policy will have two benefits: it will translate into policy current best practice in providing this type of residential program to those most likely to benefit from it, and it will save caseworker time in processing exceptions.

The Department has also had several requests for exceptions to policy to allow readmission to the programs. These amendments provide that program participants may be readmitted to the program for an additional 30, 60, or 90 days. A readmission shall be decided upon and processed in the same manner as the original admission, using the same criteria. A readmission should be a rare occurrence, used only when troublesome behaviors, diagnoses or problems arise late in the original placement, and more time in the program will benefit the child.

The Department and juvenile court services are required to keep data on the children placed who lack one or more of the target population characteristics and on the children who are readmitted to a program.

These amendments do provide a process for waiver of the highly structured program admission criteria by Department regional administrators or their designees or, if so delegated, by chief juvenile court officers or their designees. Individuals may request a waiver of other criteria under the Department's general rule on exceptions at rule 441—1.8(217).

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 February 16, 2000.

These amendments are intended to implement Iowa Code sections 234.38 and 237.3.

The following amendments are proposed.

ITEM 1. Amend rule 441—114.2(237), definition of "Highly structured juvenile program," as follows:

"Highly structured juvenile program" means a short-term treatment program for adjudicated delinquent youth, aged 15 to 17, who are unable to live in a family situation due to severe social, emotional, and behavioral disabilities, who have not experienced a residential placement in the last 60 days, have a prior adjudication of delinquency, have committed a public offense that is an aggravated misdemeanor or above, and have not committed a forcible felony. These programs have lasting 90 days and having a high degree of structure that stresses discipline, physical activity, and education, and are short-term placements with a length of stay of 90 days. Program participants are assembled in cohorts (groups of youth adjudicated delinquent as to the criteria listed above) which are managed by the juvenile court. Each cohort is a number that is one-third of the program, with a cohort scheduled to finish the 90-day program every 30 days. Discharge planning must be started within the first 30 calendar days of placement. Specialized behavior management techniques are used several times per day. In addition, youth receiving the highly structured juvenile program shall require and receive treatment several times daily to enhance their social skills. In addition to the intensive programming and structure, the youth are provided 24-hour awake supervision.

These programs must be licensed as either community residential facilities under this chapter or as comprehensive residential facilities under 441—Chapter 115 and certified to provide rehabilitative treatment services under 441— Chapter 185. Programs shall have the ability to use a physically secure setting dependent upon the level of the license.

ITEM 2. Amend subrule 185.83(4) as follows:

185.83(4) Highly structured juvenile program. A highly structured juvenile program provides treatment in a facility licensed under 441—Chapter 114 or 115 for adjudicated delinquent youth from the ages of 15 to 17 years who are unable to live in a family situation due to severe social, emotional and behavioral disabilities and who have not experienced a residential placement in the last 60 days must meet the following requirements for licensing, admissions, readmission and discharge, and program and services. The youth require a high degree of supervision, and a structure that stresses discipline, physical activity, education, and social skill development due to their aggressive behavior which includes a prior adjudication of delinquency and commitment of a public offense that is an aggravated misdemeanor or above, but not a forcible felony.

a. Licensing. Facilities shall be licensed under 441— Chapter 114 or 115.

b. Admission criteria. Characteristics of the target population to be served by this program include young men who:

(1) Are aged 15, 16, or 17.

(2) Have been adjudicated delinquent for a public offense that is a serious misdemeanor or above, but is not a forcible felony.

(3) Are not able to benefit further from community-based services at the time of placement, but would be able to successfully return to the community following intensive shortterm residential treatment.

Regional administrators for the department, in consultation with juvenile court services, shall have authority to place youth that lack one or more target population characteristics on a case-by-case basis. A regional administrator or designee may delegate this authority to the chief juvenile court officers or their designees. The department and juvenile court services shall keep data on the children placed who lack one or more of the target population characteristics.

c. Readmission and discharge. Program participants may be readmitted to the program for an additional 30, 60, or 90 days. A readmission shall be decided upon and processed in the same manner as the original admission, using the same criteria. A readmission should be a rare occurrence, used only when troublesome behaviors, diagnoses or problems arise late in the original placement, and more time in the program will benefit the child. The department and juvenile court services shall keep data on the children readmitted to the program.

There are no temporary discharges from the highly structured program to detention or other placement for discipline purposes.

d. Program and services. This program is a short-term treatment program with a length of stay of 90 days. Program participants are assembled in cohorts (groups of youth adju-

HUMAN SERVICES DEPARTMENT[441](cont'd)

dicated delinquent as to the criteria listed above that advance through the program together) which are managed by the juvenile court. Each cohort is a number that is one-third of the program, with a cohort scheduled to finish the 90-day program in 30 days. Discharge planning must be started within the first 30 calendar days of placement.

Specialized behavior management techniques are used several times per day. In addition, youth receiving the highly structured juvenile program shall require and receive treatment several times daily to enhance their social skills. In addition to the intensive programming and structure, the youth are provided 24-hour awake supervision.

a. (1) Youth in the highly structured juvenile program shall receive the following services: restorative living skills development as needed and social skill development several times per day.

(2) One hour of therapy and counseling services shall be provided every week to each youth.

b. (3) The prime programming time hours and staff-toclient ratio shall meet the treatment and supervision needs of the youth served as specified in 185.10(8)"c"(4).

 ϵ_r (4) The payment for the daily rate shall be calculated based on a 30-day month. If, however, the department is able to provide payment based on the actual number of days in a month, rates shall be adjusted accordingly.

 d_{τ} (5) The unit of service for highly structured juvenile residential treatment shall be one day.

 $e_{\tau}(6)$ Services shall be provided on a face-to-face basis with the child.

 $f_{-}(7)$ Duration shall not exceed three calendar months.

(8) Youth shall have supervision 24 hours a day by awake staff.

ARC 9615A

HUMAN SERVICES DEPARTMENT[441]

Notice of Intended Action

Twenty-five interested persons, a governmental subdivision, an agency or association of 25 or more persons may demand an oral presentation hereon as provided in Iowa Code section 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 section 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 234.6, the Department of Human Services proposes to amend Chapter 152, "Contracting," appearing in the Iowa Administrative Code.

These amendments allow the effective date of a rehabilitative treatment and supportive services contract to be the day following the final signing by the Department Director or designee unless a later effective date is agreed upon by the provider and the Department. Current policy requires the contract to be effective the first day of the month following signature.

The Department is seeking to shorten time frames for approving contracts in order to facilitate access to services. This change may reduce the time from final signature of a contract by the Director to the effective date by up to 30 days.

These amendments do not provide for waivers in specified situations because providers may request a waiver of the contract effective date under the Department's general rule on exceptions at rule 441—1.8(217). Consideration will be given to all written data, views, and arguments thereto received by the Office of Policy Analysis, Department of Human Services, Hoover State Office Building, Des Moines, Iowa 50319-0114, on or before February 16, 2000.

These amendments are intended to implement Iowa Code section 234.6.

The following amendments are proposed.

ITEM 1. Amend rule 441—152.8(234) as follows:

441—152.8(234) Term of contract. The term of the contract shall be for not more than two years, effective the first day of the month following the signature of the director of the department or the director's designee, unless the provider and department agree to a later specified date.

ITEM 2. Amend subrule 152.22(6) as follows:

152.22(6) Contract effective date. When the agreed-upon contract conditions have been met, the effective date of the *a* new contract, a renewed contract or an amendment to add a new service code to the contract is the first day of an agreed-upon month following signature of the director of the department or the director's designee, unless the provider and the department agree to a later specified date. A contract can only be effective if signed by all parties as required in subrule 152.22(4).

ARC 9625A

INSPECTIONS AND APPEALS DEPARTMENT[481]

Notice of Intended Action

Twenty-five interested persons, a governmental subdivision, an agency or association of 25 or more persons may demand an oral presentation hereon as provided in Iowa Code section 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 section 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 chapter 10A and Executive Order Number 11, the Department of Inspections and Appeals hereby gives Notice of Intended Action to adopt Chapter 6, "Uniform Waiver and Variance Rules," Iowa Administrative Code.

The rules in Chapter 6 describe the procedures for applying for, issuing or denying waivers and variances from Department rules. The purpose of these rules is to comply with Executive Order Number 11, which requires state agencies to adopt a uniform waiver rule.

Public comments concerning the proposed rules will be accepted until 4:30 p.m. on February 15, 2000. Interested persons may submit written comments by contacting Jennifer Komos, Department of Inspections and Appeals, Second Floor, Lucas State Office Building, 321 East 12th Street, Des Moines, Iowa 50319, or fax to (515)242-6863. E-mail may be sent to <u>jkomos@dia.state.ia.us</u>.

These rules are intended to implement Executive Order Number 11.

The following <u>new</u> chapter is proposed.

CHAPTER 6

UNIFORM WAIVER AND VARIANCE RULES

481—6.1 (ExecOrd11) Applicability. This chapter outlines a uniform process for the granting of waivers or variances

INSPECTIONS AND APPEALS DEPARTMENT[481](cont'd)

from rules adopted by the department. The intent of this chapter is to allow persons to seek exceptions to the application of rules issued by the department.

481—6.2(ExecOrd11) Definitions.

"Attached units" means units attached to the department and includes the employment appeal board, hospital licensing board, Iowa citizens foster care review board, racing and gaming commission and state public defender's office.

"Department" means the department of inspections and appeals, authorized by Iowa Code chapter 10A, which is comprised of the administrative hearings division, audits division, health facilities division, inspections division and investigations division. Pursuant to Iowa Code section 7E.2(5), five attached units are included in the department.

"Director" means the director of the department of inspections and appeals or the director's designee.

"Director/board" means the director, board, commission or state public defender depending on which one has the decision-making authority pursuant to Iowa Code chapter 10A or 7E.

"Person" means an individual, corporation, limited liability company, government or governmental subdivision or association, or any legal entity.

481—6.3(ExecOrd11) Interpretive rules. This uniform waiver and variance rule shall not apply to rules that merely define the meaning of a statute or other provisions of law or precedent if the department does not possess delegated authority to bind the courts to any extent with its definition.

481—6.4(ExecOrd11) Compliance with statute. No waiver or variance may be granted from a requirement which is imposed by statute. Any waiver or variance must be consistent with statute.

481—6.5(ExecOrd11) Criteria for waiver or variance. The director/board may issue an order, in response to a completed petition or on the department's own motion, granting a waiver or variance from a rule adopted by the department, in whole or in part, as applied to the circumstances of a specified person if the director/board finds that:

1. Application of the rule to the person at issue would result in hardship or injustice to that person; and

2. Waiver or variance on the basis of the particular circumstances relative to that specified person would be consistent with the public interest; and

3. Waiver or variance in the specific case would not prejudice the substantial legal rights of any person.

In determining whether waiver or variance would be consistent with the public interest under "2," the director/board shall consider whether, if the waiver or variance is granted, the public health and safety will be protected by other means that are substantially equivalent to full compliance with the rule.

6.5(1) Director/board discretion. The decision on whether the circumstances justify the granting of a waiver or variance shall be made at the discretion of the director upon consideration of all relevant factors, except for the below-listed programs, for which the applicable board, commission or state public defender shall make the decision, upon consideration of all relevant factors:

1. Employment Appeal Board, 486-Chapter 1.

2. Hospital Licensing Board, 481-Chapter 51.

3. Iowa Citizens Foster Care Review Board, 489-Chapter 1.

4. Racing and Gaming Commission, 491-Chapter 1.

5. State Public Defender's Office, 493—Chapter 1.

6.5(2) Mandatory waivers or variances. In response to the timely filing of a completed petition requesting a waiver or variance, the director/board shall grant a waiver or variance from a rule, in whole or in part, as applied to the particular circumstances of a specified person, if the director/board finds that the application of all or a portion thereof to the circumstances of that specified person would not, to any extent, advance or serve any of the purposes of the rule.

6.5(3) Burden of persuasion. The petitioner shall assume the burden of persuasion when a petition is filed for a waiver or variance from a department rule.

6.5(4) Special waiver or variance rules not precluded. This uniform waiver and variance rule shall not preclude the department from granting waivers or variances in other contexts or on the basis of other standards if a statute or other department rule authorizes the department to do so, and the department deems it appropriate to do so.

6.5(5) Administrative deadlines. When the rule from which a waiver or variance is sought establishes administrative deadlines, the director/board shall balance the special individual circumstances of the petitioner with the overall goal of uniform treatment of all persons similarly situated.

481—6.6(ExecOrd11) Filing of petition. A petition for a waiver or variance must be submitted in writing to the Department of Inspections and Appeals, Office of the Director, Lucas State Office Building, 321 East 12th Street, Des Moines, Iowa 50319. If the petition relates to a pending contested case, the petition shall also be filed in the contested case proceeding.

481—6.7(ExecOrd11) Content of petition. A petition for waiver or variance shall include the following information where applicable and known to the requester:

1. The name, address, and telephone number of the person or entity for whom a waiver or variance is being requested, and the case number of any related contested case.

2. A description and citation of the specific rule from which a waiver or variance is requested.

3. The specific waiver or variance requested, including the precise scope and operative period that the waiver or variance will extend.

4. The relevant facts that the petitioner believes would justify a waiver or variance. This statement shall include a signed statement from the petitioner attesting to the accuracy of the facts provided in the petition, and a statement of reasons that the petitioner believes will justify a waiver or variance.

5. A history of any prior contacts between the department and the petitioner relating to the regulated activity, license, appeal, hearing, audit, investigation, inspection, representation or other assigned function of the department that would be affected by the proposed waiver or variance, including a description of each regulated activity, license, appeal, hearing, audit, investigation, inspection, representation or other assigned function of the department, any notices of violation, contested case hearings, or investigative reports relating to the regulated activity, license, appeal, hearing, audit, investigation, inspection, representation or other assigned function of the department within the last five years.

6. Any information known to the requester regarding the department's treatment of similar cases.

7. The name, address, and telephone number of any public agency or political subdivision which also regulates

INSPECTIONS AND APPEALS DEPARTMENT[481](cont'd)

the activity in question, or which might be affected by the grant of a waiver or variance.

8. The name, address, and telephone number of any person or entity that would be adversely affected by the grant of a petition.

9. The name, address, and telephone number of any person with knowledge of the relevant facts relating to the proposed waiver or variance.

10. Signed releases of information authorizing persons with knowledge regarding the request to furnish the department with information relevant to the waiver or variance.

481—6.8(ExecOrd11) Additional information. Prior to issuing an order granting or denying a waiver or variance, the department may request additional information from the petitioner relative to the petition and surrounding circumstances. If the petition was not filed in a contested case, the department may, on its own motion or at the petitioner's request, schedule a telephonic or in-person meeting between the petitioner and the department or department's designee.

481—6.9(ExecOrd11) Notice. The department shall acknowledge a petition upon receipt. The department shall ensure that notice of the pendency of the petition and a concise summary of its contents have been provided to all persons to whom notice is required by any provision of law, within 30 days of the receipt of the petition. In addition, the department may give notice to other persons. To accomplish this notice provision, the department may require the petitioner to serve the notice on all persons to whom notice is required by any provision of law, and provide a written statement to the department attesting that notice has been provided.

481—6.10(ExecOrd11) Hearing procedures. The provisions of Iowa Code sections 17A.10 to 17A.18A regarding contested case hearings shall apply to any petition for a waiver or variance of rule filed within a contested case, and shall otherwise apply to agency proceedings for a waiver or variance only when the department so provides by rule or order or is required to do so by statute.

481—6.11(ExecOrd11) Ruling. An order granting or denying a waiver or variance shall be in writing and shall contain a reference to the particular person and rule or portion thereof to which the order pertains, a statement of the relevant facts and reasons upon which the action is based, and a description of the precise scope and operative period of the waiver if one is issued.

6.11(1) Conditions. The director/board may condition the grant of the waiver or variance on such reasonable conditions as appropriate to achieve the objectives of the particular rule in question through alternative means.

6.11(2) Time for ruling. The director/board shall grant or deny a petition for a waiver or variance as soon as practicable but, in any event, shall do so within 120 days of its receipt, unless the petitioner agrees to a later date. However, if a petition is filed in a contested case, the director/board has the discretion to wait until the contested case is resolved before entering an order on the petition for waiver or variance.

6.11(3) When deemed denied. Failure of the director/board to grant or deny a petition within the required time period shall be deemed a denial of that petition by the director/board.

6.11(4) Service of order. Within seven days of its issuance, any order issued under this uniform rule shall be transmitted to the petitioner or the person to whom the order pertains, and to any other person entitled to such notice by any provision of law.

481—6.12(ExecOrd11) Public availability. Subject to the provisions of Iowa Code section 17A.3(1e), the department shall maintain a record of all orders granting and denying waivers and variances under this uniform rule. All final rulings in response to requests for waivers or variances shall be indexed and available to members of the public at the director's office.

481—6.13(ExecOrd11) Voiding or cancellation. A waiver or variance is void if the material facts upon which the request is based are not true or if material facts have been withheld. The director/board may at any time cancel a waiver or variance upon appropriate notice and hearing if the director/ board finds that the facts as stated in the request are not true, material facts have been withheld, the alternative means of compliance provided in the waiver or variance have failed to achieve the objectives of the statute, or the requester has failed to comply with the conditions of the order.

481—6.14(ExecOrd11) Violations. Violation of conditions in the waiver or variance approval is the equivalent of violation of the particular rule for which the waiver or variance is granted and is subject to the same remedies or penalties.

481—6.15(ExecOrd11) Defense. After the director/board issues an order granting a waiver or variance, the order is a defense within its terms and the specific facts indicated therein for the person to whom the order pertains in any proceeding in which the rule in question is sought to be invoked.

481—6.16(ExecOrd11) Appeals. Any request for an appeal from a decision granting or denying a waiver or variance shall be in accordance with the procedures provided in Iowa Code chapter 17A and department rules. An appeal shall be taken within 30 days of the issuance of the ruling in response to the request unless a contrary time is provided by rule or statute.

481—6.17(ExecOrd11) Sample petition for waiver or variance.

BEFORE THE DEPARTMENT OF INSPECTIONS AND APPEALS

Petition by (insert name of petitioner) for the waiver of (insert rule citation) relating to (insert the subject matter).	PETITION FOR WAIVER
(insert the subject matter).	

Include the following information in the petition for waiver where applicable and known:

1. Provide the petitioner's (the person that is asking for the waiver or variance) name, address and telephone number.

2. Describe and cite the specific rule from which a waiver or variance is requested.

3. Describe the specific waiver or variance requested, include the exact scope and time period that the waiver or variance will extend.

4. Explain the important facts that the petitioner believes justify the waiver or variance. Include in your explanation (1) why application of the rule would result in hardship or injustice to the petitioner; and (2) why granting a waiver or variance to the petitioner would be consistent with the public interest; and (3) why granting the waiver or variance would not prejudice the substantial legal rights of any person.

INSPECTIONS AND APPEALS DEPARTMENT[481](cont'd)

5. Provide history of prior contacts between the department and the petitioner relating to regulated activity, license, audit, investigation, inspection or representation that would be affected by the waiver or variance. In that history, include a description of each affected regulated activity, license, appeal, hearing, audit, investigation, inspection, representation or other assigned function of the department, any notices of violation, contested case hearings, or investigative reports relating to the regulated activity, license, appeal, hearing, audit, investigation, inspection, representation or other assigned function of the department within the last five years.

6. Provide information known to the petitioner regarding the department's treatment of similar cases.

7. Provide the name, address and telephone number of any public agency or political subdivision which also regulates the activity in question, or which might be affected by the grant of a waiver or variance.

8. Provide the name, address and telephone number of any person or entity that would be adversely affected or disadvantaged by the grant of the waiver or variance.

9. Provide signed releases of information authorizing persons with knowledge regarding the request to furnish the department with information relevant to the waiver or variance.

I hereby attest to the accuracy and truthfulness of the above information.

Petitioner's signature

Date

These rules are intended to implement Executive Order Number 11.

ARC 9611A

INSPECTIONS AND APPEALS DEPARTMENT[481]

Notice of Intended Action

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

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 section 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 10A.104(5), the Department of Inspections and Appeals proposes to amend Chapter 71, "Overpayment Recovery Unit," Iowa Administrative Code.

The proposed amendment brings rules into conformity with the DHS rules by deleting language that permitted unemployment compensation as one of the methods used for the collection of food stamp overpayments.

The proposed amendment modifies an existing rule and will be of benefit to the recipients of unemployment compensation. Therefore, it is the opinion of the Department that a waiver is not necessary.

Interested persons may make written comments or suggestions on the proposed amendment on or before February 15, 2000. Written materials should be addressed to the Director, Department of Inspections and Appeals, Lucas State Office Building, East 12th and Grand Avenue, Des Moines, Iowa 50319-0083, or faxed to (515)242-6863. E-mail may be sent to <u>csmith@dia.state.ia.us</u>. This amendment is intended to implement Iowa Code section 10A.402(5).

The following amendment is proposed.

Amend subrule 71.6(2) as follows:

71.6(2) For food stamp overpayments. In addition to the actions in subrule 71.6(1), the following may be used for the collection of food stamp overpayments.

a. Federal income tax refund offset in accordance with Iowa Administrative Code rule 441-11.5(234).

b. Federal payments (i.e., wages) withholding in accordance with Iowa Administrative Code rule 441-11.5(234).

c. Unemployment compensation withholding in accordance with Iowa Administrative Code rule 441-11.5(234).

The recovery unit may use one or more of the above actions listed for any overpayment that has occurred.

ARC 9631A

LABOR SERVICES DIVISION[875]

Notice of Intended Action

Twenty-five interested persons, a governmental subdivision, an agency or association of 25 or more persons may demand an oral presentation hereon as provided in Iowa Code section $17A.4(1)^{\mu}b.^{n}$

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 section 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 chapter 17A and section 91.6, the Labor Commissioner hereby gives Notice of Intended Action to amend Chapter 1, "Description of Organization and Procedures before the Division," Iowa Administrative Code.

These rules establish procedures for waiver of Division rules and are being adopted to implement Executive Order Number 11.

If requested no later than February 11, 2000, by 25 interested persons, a governmental subdivision, the Administrative Rules Review Committee, an agency, or an association having not less than 25 members, a public hearing will be held on February 15, 2000, at 1:30 p.m. at 1000 East Grand Avenue, Des Moines, Iowa. Interested persons will be given the opportunity to make oral statements and file documents concerning the proposed rules. The facility for the oral presentations is accessible to and functional for persons with physical disabilities. Persons who have special requirements should call (515)242-5869 in advance to arrange access or other needed services.

Written data, views, or arguments to be considered in adoption shall be submitted by interested persons no later than February 15, 2000, to Division of Labor Services, 1000 East Grand Avenue, Des Moines, Iowa 50319-0209.

The Division of Labor Services will issue a regulatory analysis as provided by 1998 Iowa Acts, chapter 1202, section 10, if a written request is submitted no later than February 28, 2000, to Division of Labor Services, 1000 East Grand Avenue, Des Moines, Iowa 50319. The request may be made by the Administrative Rules Review Committee, the Administrative Rules Coordinator, at least 25 persons who each qualify as a small businesse, or an organization representing at least 25 small businesses. The organization shall list the names, addresses and telephone numbers of not less than 25 small businesses it represents.

These rules will not necessitate combined expenditures exceeding \$100,000 by all political subdivisions or agencies

and entities that contract with political subdivisions to provide services.

These rules are intended to implement Executive Order Number 11.

The following rules are proposed.

ITEM 1. Reserve rule 875-1.100 in Division VI.

ITEM 2. Amend 875—Chapter 1 by adopting the following <u>new</u> Division VII:

DIVISION VII

WAIVERS FROM ADMINISTRATIVE RULES

875-1.101(17A,91) Scope.

1.101(1) These rules provide general procedures for waivers from division rules. Specific waiver or variance procedures must be followed when applicable. No waiver may be granted from a requirement or duty imposed by statute or when granting a waiver would cause a denial of federal funds or be inconsistent with federal statute or regulation. Any waiver must be consistent with statute. These waiver procedures do not apply to rules that merely define the meaning of a statute or other provision of law unless the division possesses delegated authority to bind the courts with its rules.

1.101(2) Waivers of rules may be granted either upon the division's own motion, in response to a petition for waiver filed within a contested case proceeding, or in response to a petition filed in the absence of a contested case proceeding.

875—1.102(17A,91) Petitions. If the petition for waiver relates to a pending contested case, the petition shall be filed in the contested case proceeding. Other petitions must be submitted in writing to Byron K. Orton, Labor Commissioner, 1000 E. Grand Avenue, Des Moines, Iowa 50319. In either case, the petition shall include the following information where applicable:

1.102(1) The name, address, case file number or state identification number, and telephone number of the person requesting the waiver and the person's representative, if any.

1.102(2) A description and citation of the specific rule to which the petition applies.

1.102(3) The specific waiver requested, including the precise scope and time period for the waiver.

1.102(4) The relevant facts the petitioner believes justify a waiver.

1.102(5) A description of any prior contacts between the division and the petitioner relating to the subject matter of the proposed waiver, including but not limited to a list or description of division licenses, registrations, or permits held by the petitioner, and any notices of violation, citations, contested case hearings, or investigative reports relating to the subject matter of the proposed waiver within the last five years.

1.102(6) The name, address, and telephone number of any public agency or political subdivision which also regulates the activity in question or which might be affected by the grant of a waiver.

1.102(7) Any information known to the petitioner regarding the division's treatment of similar cases.

1.102(8) The name, address, and telephone number of all persons inside or outside state government who would be adversely affected by the grant of the petition or who possess knowledge of relevant facts.

1.102(9) A signed release of information authorizing persons with knowledge regarding the request to furnish the division with information pertaining to the waiver.

1.102(10) A signed statement from the petitioner attesting to the accuracy of the facts provided in the petition.

875—1.103(17A,91) Notice and acknowledgment. The division will acknowledge petitions upon receipt. The division shall ensure that notice of the pendency of the petition and a concise summary of its contents have been provided to all persons to whom notice is required by any provision of law within 30 days of receipt of the petition. The division may require the petitioner to serve the notice and a concise summary on all persons to whom notice is required by any provision of law, and provide a written statement to the division attesting that notice has been provided. Notice and a concise summary may also be provided to others.

875—1.104(17A,91) Review. Discretion to grant or deny a waiver petition rests with the labor commissioner or the labor commissioner's designee. The burden of persuasion shall be upon the petitioner. The division may request additional information relating to the requested waiver from the petitioner and may conduct any necessary and appropriate investigation.

1.104(1) A waiver under these rules may be granted upon a showing that:

a. Application of the rule to the person at issue would result in hardship or injustice to that person;

b. Waiver of the rule in the specific circumstances would be consistent with the public interest; and

c. Waiver of the rule in the specific circumstances would not prejudice the substantial legal rights, health, or safety of any person.

1.104(2) A waiver shall be granted in whole or in part upon a finding that the application of all or a portion of a rule to the circumstances of the petitioner would not advance or serve any of the purposes of the rule to any extent.

875-1.105(17A,91) Ruling.

1.105(1) The division shall grant or deny all requests as soon as practicable, but no later than 120 days from receipt without consent of the petitioner. However, waiver petitions filed in contested cases shall be granted or denied no later than the date of the decision in the contested case proceeding. Failure to grant or deny a petition within the required time period shall be deemed a denial.

1.105(2) The ruling shall be in writing and shall include the reasons for granting or denying the petition and, if approved, the time period during which the waiver is effective. The division may condition the grant of a waiver on such reasonable conditions as appropriate to achieve the objectives of the particular rule in question through alternative means.

1.105(3) Within seven days of issuance of the ruling, a copy shall be mailed to the petitioner or the petitioner's representative, and to any other person(s) entitled to such notice by any provision of law or rule.

875—1.106(17A,91) Public availability. Subject to the provisions of Iowa Code section 17A.3(1)"e," orders granting and denying waivers shall be indexed by rule and available for public inspection.

875—1.107(17A,91) Cancellation. The division may cancel a waiver upon appropriate notice and hearing if the facts alleged in the petition or supplemental information provided were not true, material facts were withheld or have changed, the alternative means of compliance provided in the waiver have failed to achieve the objectives of the statute, the requester has failed to comply with conditions set forth in the

LABOR SERVICES DIVISION[875](cont'd)

waiver approval, or the rule or enabling act has been amended.

875-1.108(17A.91) Violations. Violation of conditions in the waiver approval is the equivalent of violation of the particular rule for which the waiver is granted and is subject to the same remedies or penalties.

875-1.109(17A,91) Appeals. Appeal from a decision granting or denying a waiver shall be in accordance with the procedures provided in Iowa Code chapter 17A. An appeal shall be taken within 30 days of the ruling. However, any appeal from a decision on a petition for waiver in a contested case proceeding shall be in accordance with the procedures for appeal of the contested case decision.

ARC 9618A

MEDICAL EXAMINERS **BOARD**[653]

Notice of Intended Action

Twenty-five interested persons, a governmental subdivision, an agency or association of 25 or more persons may demand an oral presentation hereon as provided in Iowa Code section 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 section 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 147.76 and 272C.3, the Board of Medical Examiners hereby gives Notice of Intended Action to amend Chapter 13, "Standards of Practice and Professional Ethics," Iowa Administrative Code.

The Board approved proposed rule 653-13.3(147), supervision of pharmacists who administer prescription drugs, during a meeting held via telephone conference call on January 5, 2000.

The proposed rule permits physicians to prescribe two vaccines (influenza and pneumococcal) to prepared pharmacists for administration to adults via written protocol. It forbids physicians from prescribing other drugs for administration by a pharmacist. The rule defines for the physician the preparatory process that a pharmacist must complete to be considered prepared. It also itemizes the elements needed in a written protocol for a physician to prescribe these two vaccines for pharmacist administration to patients. Finally, the rule describes the supervisory relationship between a prescribing physician and an administering pharmacist.

Any interested person may present written comments, data, views, and arguments on the proposed rule not later than 4 p.m. on February 15, 2000. Such written materials should be sent to Ann E. Mowery, Executive Director, Board of Medical Examiners, 400 S.W. 8th Street, Suite C, Des Moines, Iowa 50309-4686.

There will be a public hearing on February 15, 2000, at 1 p.m. in the Auditorium of the new State Historical Building, 600 East Locust Street, Des Moines, Iowa, at which time persons may present their views either orally or in writing.

This rule is intended to implement Iowa Code sections 147.76 and 272C.3.

The following rule is proposed.

Adopt the following new rule:

653-13.3(147) Supervision of pharmacists who administer prescription drugs. A physician may prescribe influenza virus vaccine and pneumococcal vaccine via written protocol for a prepared pharmacist to administer to adults if the physician meets the following rules for supervising the pharmacist. The physician may not prescribe, or delegate the prescription of, any other prescription drugs for administration by a pharmacist.

13.3(1) Definitions.

"Prepared pharmacist" means an Iowa-licensed phara. macist who provides to the physician documentation of successful completion of a 20-hour course on vaccine administration provided by an ACPE-approved provider that:

(1) Requires documentation by the pharmacist of current certification in the American Heart Association's Basic Cardiac Life Support for Health-Care Providers;

(2) Is an evidence-based course that includes study material and hands-on training in techniques for administering vaccines, requires testing with a passing score, meets current Centers for Disease Control and Prevention training guidelines, and provides instruction and experiential training in the following content areas:

Standards for immunization practices; 1.

2. Basic immunology and vaccine protection;

3. Vaccine-preventable diseases;

4. Recommended immunization schedules;

5. Vaccine storage and management;

6. Informed consent:

7. Physiology and techniques for vaccine administration;

8. Pre- and post-vaccine assessment and counseling;

9. Immunization record management; and

10. Management of adverse events, including identification, appropriate response, documentation, and reporting. b. "Vaccine" means a specially prepared antigen which,

upon administration to a person, will result in immunity.

c. "Written protocol" means a physician's order for one or more patients that contains, at a minimum, the following:

(1) A statement identifying the individual physician authorized to prescribe drugs and responsible for the delegation of administration of influenza virus vaccine and pneumococcal vaccine:

(2) A statement identifying the individual pharmacist authorized to administer influenza virus vaccine and pneumococcal vaccine as delegated by the physician;

(3) A statement that forbids the pharmacist from delegating the administration of influenza virus vaccine and pneumococcal vaccine to anyone other than a prepared pharmacist or a registered nurse;

(4) A statement identifying by address the location(s) at which the pharmacist may administer influenza virus vaccine and pneumococcal vaccine;

(5) A statement identifying the vaccines that may be administered by the pharmacist, the dosage, and the route of administration;

(6) A statement identifying the activities the pharmacist shall follow in the course of administering influenza virus vaccine and pneumococcal vaccine, including:

1. Procedures for determining if a patient is eligible to receive the vaccine;

2. Procedures for determining the appropriate scheduling and frequency of drug administration in accordance with applicable guidelines;

Procedures for record keeping and long-term record storage;

4. Procedures to follow in the case of life-threatening reactions; and

5. Procedures for the pharmacist and patient to follow in case of reactions following administration.

(7) A statement that describes how the pharmacist must report the administration of influenza virus vaccine and pneumococcal vaccine to the physician issuing the written protocols and the patient's primary care physician within 72 hours, including the content of the report. A standard protocol may be used or the physician may develop an immunization or vaccination protocol for an individual patient. If a standard protocol is used, the physician shall record what deviations, if any, from the standard protocol are ordered for an individual patient.

13.3(2) Supervision. A physician who prescribes influenza virus vaccine or pneumococcal vaccine to a pharmacist for administration shall adequately supervise that pharmacist. Physician supervision shall be considered adequate if the delegating physician:

1. Ensures that the pharmacist meets the definition of a "prepared pharmacist" in paragraph 13.3(1)"a";

2. Provides a written protocol that is updated at least annually;

3. Is geographically located so as to be easily accessible, i.e., within 30 miles of the pharmacist administering influenza virus vaccine or pneumococcal vaccine;

4. Is available through direct telecommunication for consultation, assistance, and direction or provides physician backup to provide these services when the physician supervisor is not available; and

5. Receives from the pharmacist a faxed, E-mailed, voice, or voice-recorded report and any other appropriate follow-up on any patient with any problem or complication encountered within two hours of the pharmacist's becoming aware of it.

ARC 9627A

NATURAL RESOURCES DEPARTMENT[561]

Notice of Intended Action

Twenty-five interested persons, a governmental subdivision, an agency or association of 25 or more persons may demand an oral presentation hereon as provided in Iowa Code section 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 section 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(1)"b" and 455A.4, the Director of the Department of Natural Resources hereby gives Notice of Intended Action to adopt a new Chapter 10, "Waivers or Variances from Administrative Rules," Iowa Administrative Code.

The proposed rules implement Executive Order Number 11, signed by Governor Vilsack on September 14, 1999. The Executive Order establishes uniform rules for waivers or variances from administrative rules. The other rule-making agencies within the Department are or will be adopting this chapter by reference, through concurrent or subsequent rulemaking proceedings.

Any interested persons may make written suggestions or comments on the proposed amendment on or before February 15, 2000. Written comments should be directed to Anne Preziosi, Department of Natural Resources, Air Quality Bureau, 7900 Hickman, Urbandale, Iowa 50322; (515) 281-6243; fax (515)242-5094. Requests for a public hearing regarding this rule making must be submitted in writing to the above address by that date.

The Department has determined that the proposed rules will have a favorable impact on small businesses within the meaning of Iowa Code section 17A.4A(2)"b."

The proposed amendment is intended to implement Iowa Code chapter 17A.

The following new chapter is proposed.

Adopt the following <u>new</u> chapter:

CHAPTER 10 WAIVERS OR VARIANCES FROM ADMINISTRATIVE RULES

561—10.1(17A,455A) Applicability. This chapter outlines a uniform process for the granting of waivers or variances from rules adopted by the department. As used in this chapter, the term "director" includes the director's designee.

561—10.2(17A,455A) Authority. A waiver or variance from rules adopted by the department may be granted in accordance with this chapter if:

10.2(1) The department has exclusive rule-making authority to promulgate the rule from which waiver or variance is requested or has final decision-making authority over a contested case in which a waiver or variance is requested; and

10.2(2) No statute or rule otherwise controls the granting of a waiver or variance from the rule from which waiver or variance is requested.

561—10.3(17A,455A) Interpretive rules. These uniform waiver and variance rules shall not apply to rules that merely define the meaning of a statute or other provisions of law or precedent if the department does not possess delegated authority to bind the courts to any extent with its definition.

561—10.4(17A,455A) Compliance with statute. No waiver or variance may be granted from a requirement imposed by statute. Any waiver or variance must be consistent with statute.

561—10.5(17A,455A) Criteria for waiver or variance. The director may issue an order, in response to a petition or on its own motion, granting a waiver or variance from a rule adopted by the department, in whole or in part, as applied to the circumstances of a specified person if the director finds that:

10.5(1) Application of the rule to the person would result in hardship or injustice to that person;

10.5(2) Waiver or variance on the basis of the particular circumstances of that specified person would be consistent with the public interest; and

10.5(3) Waiver or variance in the specific case would not prejudice the substantial legal rights of any person.

In determining whether waiver or variance would be consistent with the public interest the director shall consider whether, if the waiver or variance is granted, the public health and safety will be protected by other means that are substantially equivalent to full compliance with the rule.

561—10.6(17A,455A) Discretion. The decision regarding whether the circumstances justify the granting of a waiver or variance shall be made at the discretion of the director, upon consideration of all relevant factors.

NATURAL RESOURCES DEPARTMENT[561](cont'd)

561—10.7(17A,455A) Mandatory waivers or variances. In response to the timely filing of a completed petition requesting a waiver or variance, the director shall, except to the extent prohibited by statute, grant a waiver or variance from a rule, in whole or in part, as applied to the particular circumstances of a specified person, if the director finds that the application of all or a portion of the rule in question to the circumstances of that specified person would not, to any extent, advance or serve any of the purposes of the rule.

561—10.8(17A,455A) Burden of persuasion. The petitioner shall assume the burden of persuasion when a petition is filed for a waiver or variance from a department rule.

561—10.9(17A,455A) Special waiver or variance rules not precluded. This chapter shall not preclude the department from granting waivers in other contexts or on the basis of other standards if a statute or other department rule authorizes the director to do so, and the director deems it appropriate to do so.

561—10.10(17A,455A) Administrative deadlines. When the rule from which a waiver or variance is sought establishes administrative deadlines, the director shall balance the special individual circumstances of the petitioner with the overall goal of uniform treatment of all persons governed by the particular rule.

561—10.11(17A,455A) Filing of petition. A petition for a waiver or variance shall be submitted in writing to the department, as follows:

10.11(1) Contested cases. If the petition relates to a pending contested case, the petition shall be filed in the contested case proceeding. The director may elect not to rule on the waiver petition until the resolution of the contested case proceeding.

10.11(2) Other. If the petition does not relate to a pending contested case, the petition may be submitted to the director.

561—10.12(17A,455A) Contents of petition. A petition for waiver or variance shall include the following information when applicable and known to the petitioner:

10.12(1) The name, address, and telephone number of the person or entity for whom a waiver or variance is being requested, and the case number of any related contested case.

10.12(2) A description and citation of the specific rule from which a waiver or variance is requested.

10.12(3) The specific waiver or variance requested, including the precise scope and operative period that the waiver or variance will extend.

10.12(4) The relevant facts that the petitioner believes would justify a waiver or variance. This statement shall include a signed statement from the petitioner attesting to the accuracy of the facts provided in the petition and a statement of reasons that the petitioner believes will justify a waiver or variance.

10.12(5) A history of any prior contacts between the department and the petitioner for the past five years, including a description of each affected permit held by the petitioner, and any notices of violation, administrative orders, contested case proceedings, and lawsuits involving the department and the petitioner.

10.12(6) Any information known to the petitioner regarding the department's treatment of similar cases.

10.12(7) The name, address, and telephone number of any public agency or political subdivision of the state or federal government which also regulates the activity in question, or which might be affected by the grant of a waiver or variance.

10.12(8) The name, address, and telephone number of any person or entity who would be adversely affected by the grant of a petition.

10.12(9) The name, address, and telephone number of any person with knowledge of relevant facts relating to the proposed waiver or variance.

10.12(10) Signed releases of information authorizing persons with knowledge regarding the request to furnish the department with information relevant to the waiver or variance.

561—10.13(17A,455A) Additional information. Prior to issuing an order granting or denying a waiver or variance, the director may request additional information from the petitioner relative to the petition and surrounding circumstances. If the petition was not filed in a contested case, the director may, on the director's own motion or at the petitioner's request, schedule a telephonic or in-person meeting between the petitioner and the director.

561—10.14(17A,455A) Notice. The petitioner shall serve by certified mail notice of the pending petition and a concise summary of its contents upon all persons to whom notice is required by any provision of law, within 30 days of submission of the petition. The petitioner shall provide a written statement to the department attesting that the required notice has been provided. The department shall acknowledge a petition upon receipt and, in addition, the department may give notice to other persons.

561–10.15(17A,455A) Hearing procedures. The provisions of Iowa Code sections 17A.10 to 17A.18A regarding contested case hearings shall apply to any petition for a waiver or variance of rule filed within a contested case and shall otherwise apply to department proceedings for a waiver or variance only when the department so provides by rule or order or is required to do so by statute.

561—10.16(17A,455A) Ruling. An order granting or denying a waiver or variance shall be in writing and shall contain a reference to the particular person and rule or portion thereof to which the order pertains, a statement of the relevant facts and reasons upon which the action is based, and a description of the precise scope and operative period of the waiver if one is issued.

561—10.17(17A,455A) Conditions. The director may condition the grant of the waiver or variance on such reasonable conditions as appropriate to achieve the objectives of the particular rule in question through alternative means.

561—10.18(17A,455A) Time for ruling. The director shall grant or deny a petition for a waiver or variance as soon as practicable but, in any event, shall do so within 120 days of receipt of the petition, unless the petitioner agrees to a later date. However, if a petition is filed in a contested case, the director shall grant or deny the petition no later than the time at which the final decision in that contested case is issued.

561—10.19(17A,455A) When deemed denied. Failure of the director to grant or deny a petition within the required time period shall be deemed a denial of that petition by the department.

561—10.20(17A,455A) Service of order. Within seven days of its issuance, any order issued under this chapter shall be transmitted to the petitioner or the person to whom the order pertains and to any other person entitled to such notice by any provision of law.

561—10.21(17A,455A) Public availability. Subject to the provisions of Iowa Code section 17A.3(1)"e," the department shall maintain a record of all orders granting and denying waivers and variances under this chapter. All final rulings in response to requests for waivers or variances shall be indexed and available to members of the public.

561—10.22(17A,455A) Voiding or cancellation. A waiver or variance is void if the material facts upon which the request is based are not true or if material facts have been withheld. The director may at any time cancel a waiver or variance if the director finds that the facts as stated in the request are not true, material facts have been withheld, the alternative means of compliance provided in the waiver or variance have failed to achieve the objectives of the statute, or the requester has failed to comply with the conditions of the order.

561—10.23(17A,455A) Violations. Violation of conditions of the waiver or variance approval is the equivalent of violation of the particular rule for which the waiver or variance is granted and is subject to the same remedies or penalties.

561—10.24(17A,455A) Defense. After the director issues an order granting a waiver or variance, the order is a defense within its terms and the specific facts indicated therein for the person to whom the order pertains in any proceeding in which the rule in question is sought to be invoked.

These rules are intended to implement Iowa Code chapters 17A, 21, 22, and 455A.

ARC 9626A

PERSONNEL DEPARTMENT[581]

Notice of Intended Action

Twenty-five interested persons, a governmental subdivision, an agency or association of 25 or more persons may demand an oral presentation hereon as provided in Iowa Code section 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 section 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 19A.9 and 97B.15, the Department of Personnel gives Notice of Intended Action to adopt new Chapter 32, "Uniform Rules for Waivers and Variances," Iowa Administrative Code.

Proposed Chapter 32 outlines a uniform process for the granting of waivers and variances from rules. Executive Order Number 11 directs state rule-making authorities to adopt uniform rules regarding waivers and variances from rules of the authority. These proposed rules are in response to that order.

Any interested person may present written comments, data, views, and arguments on the proposed chapter not later than February 15, 2000. Such written comments should be sent to Michael Prey, Department of Personnel, East 14th and Grand Avenue, Des Moines, Iowa 50319, or to Kelly Lovell, Iowa Public Employees' Retirement System, 600 East Court Avenue, Des Moines, Iowa 50309. Persons who wish to present their comments orally may contact Michael Prey at (515)281-4168 or Kelly Lovell at (515)281-0089.

There will be a public hearing on February 15, 2000, at 9 a.m. at IPERS, 600 East Court Avenue, 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 names and addresses for the record and to confine their remarks to the proposed chapter.

These rules are intended to implement Iowa Code chapters 17A, 19A and 97B.

The following amendment is proposed.

Adopt the following new chapter:

CHAPTER 32

UNIFORM RULES FOR WAIVERS AND VARIANCES

581—32.1(17A,19A,97B) Applicability. This chapter outlines a uniform process for the granting of waivers or variances from rules adopted by the department.

32.1(1) Department authority. A waiver or variance from rules adopted by the department may be granted in accordance with this rule if:

a. The department has exclusive rule-making authority to promulgate the rule from which waiver or variance is requested or has final decision-making authority over a contested case in which a waiver or variance is requested; and

b. No statute or rule otherwise controls the grant of a waiver or variance from the rule for which waiver or variance is requested.

32.1(2) Interpretive rules. This chapter shall not apply to rules that merely define the meaning of a statute or other provisions of law or precedent if the department does not possess delegated authority to bind the courts to any extent with its definition.

32.1(3) Compliance with statute. No waiver or variance may be granted from a requirement that is imposed by statute. Any waiver or variance must be consistent with statute.

581—32.2(17A,19A,97B) Criteria for waiver or variance. The department may issue an order granting a waiver or variance, as applied to the circumstances of a specified person, if:

1. Application of the rule to that person would result in hardship or injustice; and

2. Granting the waiver or variance on the basis of the particular circumstances of that specified person would be consistent with the public interest; and

3. Granting the waiver or variance in that case would not prejudice the substantial legal rights of any other person.

In determining whether a waiver or variance would be consistent with the public interest under paragraph "2," the department shall consider whether, if the waiver or variance is granted, the public interest will be protected by other means that are substantially equivalent to full compliance with the rule.

32.2(1) The department may condition the grant of a proposed waiver or variance on such reasonable conditions as are appropriate to achieve the objectives of the particular rule in question through alternative means.

32.2(2) This rule shall not preclude the department from granting waivers or variances in other contexts or on the basis of other standards if the department deems it appropriate to do so and is not prohibited by state or federal statute, federal regulations, this rule, or any other rule adopted under Iowa Code chapter 17A from issuing such waivers or variances.

32.2(3) The inadvertent granting of a waiver or variance by the department shall not be deemed to be a waiver or variance to which the provisions of this rule apply but, depending on the facts and circumstances, the department may limit enforcement of the affected rule(s) on a prospective basis.

PERSONNEL DEPARTMENT[581](cont'd)

32.2(4) The petitioner shall bear the burden of proof when a petition for waiver or variance from a department rule is filed.

32.2(5) When the rule from which a waiver or variance is sought establishes administrative deadlines, the department shall balance the special individual circumstances of the petitioner with the overall goal of uniform treatment of all similarly situated persons.

581—32.3(17A,19A,97B) Filing of petition. Any person may file a petition with the department requesting a waiver or variance, in whole or in part, from a rule of the department on the ground that the application of the rule to the particular circumstances of that person would qualify for a waiver or variance.

A petition for a waiver or variance must be submitted in writing to the administrative rules coordinator of the division of the department having jurisdiction over the particular issue. For IPERS issues, such petitions shall be directed to Administrative Rules Coordinator, Iowa Public Employees' Retirement System, 600 East Court Avenue, Des Moines Iowa 50309. For all other department matters, such petitions shall be directed to Administrative Rules Coordinator, Department of Personnel, East 14th and Grand Avenue, Des Moines, Iowa 50319. If the request relates to a pending contested case, the request shall also be filed in the contested case proceeding. Waiver and variance rulings shall be made by department staff having jurisdiction over the particular issue and having the authority to issue final rulings on appeals regarding such issues, provided that the director shall have final authority with respect to all waiver and variance rulings.

581—32.4(17A,19A,97B) Contents of petition. A petition for waiver or variance does not have to be in a particular format, but must contain the following elements.

1. The name, address, social security number, and telephone number of the petitioner and the name, address, and telephone number of the petitioner's representative, if any.

2. The specific rule or rules for which a waiver or variance is requested.

3. The precise scope and operative period of the waiver or variance requested, including any alternative means or other condition or modification proposed to achieve the purposes of the rule.

4. An explanation of the reasons for the waiver or variance, including all material facts relevant to the waiver or variance in question.

5. A description of any prior contacts between the department and the petitioner relating to the proposed waiver or variance including, but not limited to, a list or description of prior notices, investigative reports, advice, negotiations, consultations or conferences, contested case rulings, and penalties relating to the proposed waiver or variance.

6. The name, address, and telephone number of any person inside or outside of state government who would be adversely affected by or who possesses material information related to the waiver or variance in question.

7. Any information known to the petitioner regarding the department's treatment of similar cases.

8. The name, address, and telephone number of any person with knowledge of the relevant facts relating to the proposed waiver or variance.

9. Any signed releases required to obtain relevant information from persons with knowledge of such information.

581—32.5(17A,19A,97B) Additional information. Prior to issuing an order granting or denying a petition for waiver

or variance, the department may request additional information from the petitioner relating to the petition and surrounding circumstances. If the petition was not filed in a contested case, the department may, on its own motion or at the petitioner's request, schedule a telephonic or in-person meeting between the petitioner and department representatives.

581—32.6(17A,19A,97B) Notices. Within 30 business days after receipt of a petition for waiver or variance from a rule, the department shall give notice of the pendency of the petition and a concise summary of its contents to all persons to whom notice is required by any provision of law. In addition, the department may give notice to other persons.

581—32.7(17A,19A,97B) Intervenors. Persons who qualify as intervenors under any provision of law may intervene in proceedings for waiver or variance from a rule if they file timely petitions for intervention according to department rules governing such intervention.

581-32.8(17A,19A,97B) Hearing procedures. The provisions of 581-Chapter 26 shall apply to proceedings under this chapter if the petition for waiver or variance is filed in a contested case proceeding. Prior to issuing an order granting or denying a proposed waiver or variance, the department shall determine whether or not the facts alleged in the proposed waiver are accurate and complete.

581—32.9(17A,19A,97B) Ruling. An order granting or denying a proposed waiver or variance shall be in writing and shall contain a reference to the particular person and rule or portion thereof to which the order pertains, a statement of the relevant facts and reasons on which that action is based, and a description of the precise scope (including any conditions) and operative period of the waiver or variance, if one is granted.

32.9(1) Time for ruling. The department shall grant or deny a petition for the waiver or variance as soon as practicable but, in any event, shall do so within 120 days of its receipt, unless petitioner agrees to a later date or the department, specifying good cause, extends this time period with respect to a particular petition for an additional 30 days. However, if a petition for waiver or variance has been filed in a contested case proceeding, the department shall grant or deny the petition no later than the time at which the final decision in that contested case is issued.

32.9(2) When deemed denied. Failure of the department to grant or deny a petition for waiver or variance within the required time period shall be deemed a denial of that petition by the department.

32.9(3) Service of order. Within seven days of its issuance, any order issued under this chapter shall be transmitted to the petitioner or the person to whom the order pertains and to any other person entitled to such notice by any provision of law.

581—32.10(17A,19A,97B) Defense. After an order granting a waiver or variance is issued, the order is a defense within its terms and the specific facts indicated therein for the person to whom the order pertains in any proceeding in which the rule in question is sought to be invoked.

581—32.11(17A,19A,97B) Public availability. Subject to the provisions of Iowa Code section 17A.3(1)"e," each division of the department shall maintain a record of all orders granting and denying waivers or variances under this chapter. All final rulings in response to requests for waivers or variances shall be indexed and available to members of the public at the offices of the applicable division of the department.

581—32.12(17A,19A,97B) Rules from which the department shall not grant waivers or variances. The department shall not grant waivers or variances from the following rules, except as otherwise indicated in the following list.

1. Rules which implement state or federal law, if the waiver could affect the taxability of pension, tax-sheltered annuity, deferred compensation, or health and dependent care benefits under the Internal Revenue Code and regulations thereunder or the Iowa Code and rules adopted thereunder;

2. Rules which set forth the formulas used to calculate IPERS monthly retirement benefits, actuarial equivalents, dividends, amounts to be credited to supplemental accounts of active members, refunds, death benefits, and service purchase costs;

3. Rules which implement contribution rates set and actuarial assumptions recommended by the Iowa public employees' retirement system's actuary;

4. Rules which limit the release of confidential information;

5. Rules which implement contracts between the department and its vendors (except as permitted in such contracts);

6. Rules governing separations, disciplinary actions and reductions in force under 581—Chapter 11, and grievances and appeals under 581—Chapter 12 (except as permitted by statute and applicable department rules).

581—32.13(17A,19A,97B) Voiding or cancellation. A waiver or variance is void if the material facts upon which the petition is based are not true or if material facts have been withheld or omitted. The department may at any time cancel a waiver or variance upon appropriate notice and hearing if the department finds that the facts as stated in the request are not true, material facts have been withheld or omitted, the alternative means of compliance provided in the waiver have failed to achieve the objectives of the statute, or the petitioner has failed to comply with conditions set forth in the order.

581—32.14(17A,19A,97B) Violation of conditions. Violations of the conditions precedent to a waiver's or variance's approval shall be deemed to be violations of the particular rule for which the waiver or variance was granted and will be subject to the same remedies or penalties.

581—32.15(17A,19A,97B) Appeals. Appeals of the department's decisions regarding proposed waivers or variances shall be filed in writing within 30 days after notice of the decision is mailed to the petitioner.

These rules are intended to implement Iowa Code chapters 17A, 19A, and 97B.

ARC 9629A

PUBLIC HEALTH DEPARTMENT[641]

Notice of Intended Action

Twenty-five interested persons, a governmental subdivision, an agency or association of 25 or more persons may demand an oral presentation hereon as provided in Iowa Code section 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 section 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 Department of Public Health hereby gives Notice of Intended Action to amend Chapter 38, "General Provisions"; Chapter 39, "Registration of Radiation Machine Facilities, Licensure of Radioactive Materials and Transportation of Radioactive Materials"; Chapter 40, "Standards for Protection Against Radiation"; Chapter 41, "Safety Requirements for the Use of Radiation Machines and Certain Uses of Radioactive Materials"; Chapter 42, "Minimum Certification Standards for Diagnostic Radiographers, Nuclear Medicine Technologists, and Radiation Therapists"; Chapter 45, "Radiation Safety Requirements for Industrial Radiographic Operations"; and Chapter 46, "Minimum Requirements for Tanning Facilities," Iowa Administrative Code.

The following itemizes the proposed changes.

Item 1 changes the title of Chapter 38 to clarify that these general provisions apply to radiation machines and radioactive materials.

Items 2, 9, 24, 37, and 103 amend the rules to reflect current federal codes.

Items 3, 25, 39, 40, 56, 64, and 65 move definitions from Chapter 39 to 45 to Chapter 38 because they apply to and are used in more than one chapter. Some of the definitions are amended or new definitions are proposed because of agreements with the Nuclear Regulatory Commission (NRC) and Food and Drug Administration (FDA) that require that the agency adopt certain language.

Items 4, 38, 50, 55, 63, 75, and 100 apply language that will allow the rules to apply to all chapters for which the agency is responsible.

Item 5 adds fees for food sterilization and bone densitometry which are new categories. Bone densitometry was previously included in Category 1 of the annual fee schedule. The fee for food sterilization is based on the time required to review the approval requests and oversee testing.

Item 6 increases examination fees to allow the Bureau of Radiological Health to recover the cost of administering the examination.

Item 7 ties certification fees to chapter 42 only.

Items 8, 14, 15, 16, 17, 18, 19, 21, 22, 23, 27, 28, 29, 30, 31, 32, 33, 34, 35, 36, 51, 52, 53, 58, 59, 79, 80, 81, 82, 83, 84, 85, 86, 87, 88, 89, 90, 91, 92, 94, 95, 96, 97, 101, and 102 are amended or proposed because of an agreement with the NRC that requires that the Bureau adopt certain language.

Item 10 changes the registration of facilities that are required to register with the agency from personnel dosimetry services to processor services. Personnel dosimetry services are already regulated by the federal government but processor services are not. Many of the problems with poor quality X-ray films are the result of processors.

Item 11 requires a permanent location with a non-wireless telephone for persons in order to obtain a registration or license. The term "non-wireless" is from federal language. This will allow the department to distinguish between instate and out-of-state businesses in order to determine regular versus reciprocity fees.

Items 12 and 20 change the number of days to match other references allowing three working days.

Item 13 corrects references and deletes a procedure that has not been used for several years.

Items 26, 41, 54, 55, and 98 correct language or references.

Items 42 and 43 have portions stricken because the manufacturers provide the information required.

Items 44 and 46 are for clarification.

Item 45 places a portion of the law into the rules to allow easier enforcement.

• Items 48, 49, 60, 61, 62, and 76 correct language that is accepted nationally and published by the Conference of

Radiation Control Program Directors, Inc. (CRCPD) and on which the Bureau's X-ray compliance program is based.

Items 66, 67, 68, 69, 70, 71, 72, 73, and 74 are proposed or amended because of an agreement with the FDA that requires the department to adopt certain language.

Item 77 adds grounds for discipline to the operator certification rules when an operator performs exposures that the operator is not trained or authorized to perform. This is important in preventing unnecessary patient exposure and misdiagnosis.

Item 78 corrects the name of the national accrediting body.

In Item 99, a subrule is rescinded because the information required is included on the application form.

Item 104 adds language that was omitted when the rules were amended in 1998; it is important that the warnings are read by the customer annually in order to remind the customer about the possible hazards of tanning.

These rules are subject to waiver pursuant to the Department's exemption provision contained at 641—38.3(136C). For this reason, the Department has not provided a specific provision for waiver of these particular rules.

Any interested person may make written suggestions or comments on these proposed amendments prior to the close of business on March 1, 2000. Such written materials should be directed to Donald A. Flater, Chief, Bureau of Radiological Health, Department of Public Health, Lucas State Office Building, Des Moines, Iowa 50319; fax: (515)242-6284; or E-mail: <u>dflater@idph.state.ia.us</u>.

A public hearing will be held on February 29, 2000, at 8:30 a.m., Conference Room, Fifth Floor South, Side 1, Lucas State Office Building, Des Moines, Iowa 50319, at which time persons may present their views 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.

Any person who plans to attend a public hearing and has special requirements such as hearing or mobility impairments should contact the Department of Public Health to advise of specific needs.

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

The following amendments are proposed.

ITEM 1. Amend the title of 641—Chapter 38 as follows:

CHAPTER 38

GENERAL PROVISIONS FOR RADIATION MACHINES AND RADIOACTIVE MATERIALS

ITEM 2. Amend subrule 38.1(2) as follows:

38.1(2) All references to Code of Federal Regulations (CFR) in this chapter are those in effect as of July 1, 1999 May 10, 2000.

ITEM 3. Amend rule **641—38.2(136C)** as follows: Amend the following definitions:

"Background radiation" means radiation from cosmic sources₇; naturally occurring radioactive materials, including radon₇ (except as a decay product of source or special nuclear material₇); and including global fallout as it exists in the environment from the testing of nuclear explosive devices or from past nuclear accidents such as Chernobyl that contribute to background radiation and are not under the control of the licensee. "Background radiation" does not include sources of radiation from radioactive materials regulated by the agency.

"Beam monitoring system" means a system designed and installed in the radiation head to detect and measure the radiation present in the useful beam.

"High radiation area" means an area, accessible to individuals, in which radiation levels from radiation sources external to the body could result in an individual's receiving a dose equivalent in excess of 1 mSv (0.1 rem) in 1 hour at 30 centimeters from any source of radiation or 30 centimeters from any surface that the radiation centrates.

"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 preventing the start or continued operation of equipment unless certain predetermined conditions prevail.

"Irradiation" means the exposure of *a living being or* matter to ionizing radiation.

"Misadministration" means the administration of:

1. to 3. No change.

4. Radiation doses received from teletherapy, linear accelerator therapy, deep X-ray machine therapy or superficial therapy; involving the wrong patient or human research subject, wrong mode of treatment or wrong treatment site;

When the treatment consists of three or fewer fractions or and the calculated total administered dose differs from the total prescribed dose by more than 10 percent of the total prescribed dose;

When the calculated weekly administered dose is 30 percent greater than the weekly prescribed dose; or

When the calculated total administered dose differs from the total prescribed dose by more than 20 percent of the total prescribed dose.

5. and 6. No change.

"Occupational dose" means the dose received by an individual in the course of employment in which the individual's assigned duties involve exposure to radiation from licensed or unlicensed and registered or unregistered sources of radiation, whether in the possession of the licensee, registrant, or other person. Occupational dose does not include dose received from background radiation, as a patient from medical practices, from any medical administration the individual has received, from exposure to individuals administered sources of radiation and released in accordance with 41.2(27), from voluntary participation in medical research programs, or as a member of the public.

"Public dose" means the dose received by a member of the public from exposure to sources of radiation possessed by a licensee, registrant, or other person, or to any other source of radiation under the control of a licensee, registrant, or other person. It does not include occupational dose or doses received from background radiation, as a patient from medical practices, from any medical administration the individual has received, from exposure to individuals administered sources of radiation and released in accordance with 41.2(27) or from voluntary participation in medical research programs.

Adopt the following <u>new</u> definitions in alphabetical order:

"Barrier" (see "Protective barrier").

"Beam axis" means the axis of rotation of the beamlimiting device.

"Beam-limiting device" means a field defining collimator, integral to the system, which provides a means to restrict the dimensions of the X-ray field or useful beam.

"Bone densitometry unit" means a medical device which uses electronically produced ionizing radiation to determine the density of bone structures of human patients.

"Critical group" means the group of individuals reasonably expected to receive the greatest exposure to residual radioactivity for any applicable set of circumstances.

"Decommission" means to remove a facility or site safely from service and reduce residual radioactivity to a level that permits:

1. Release of the property for unrestricted use and termination of the license; or

2. Release of the property under restricted conditions and termination of the license.

"Detector" (see "Radiation detector").

"Distinguishable from background" means that the detectable concentration of a radionuclide is statistically different from the background concentration of that radionuclide in the vicinity of the site or, in the case of structures, in similar materials using adequate measurement technology, survey, and statistical techniques.

"Kilovolt (kV) (kilo electron volt (keV))" means the energy equal to that acquired by a particle with one electron charge in passing through a potential difference of 1000 volts in a vacuum.

"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:

1. The useful beam, and

2. Radiation produced when the exposure switch or timer is not activated.

"Lens dose equivalent (LDE)" applies to the external exposure of the lens of the eye and is taken as the dose equivalent at a tissue depth of 0.3 centimeter (300 mg/cm^2).

"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.

"mA" means milliampere.

"Mammogram" means an image produced through radiography of the breast.

"Mammography" means radiography of the breast.

"Mammography unit" means an assemblage of components for the production of X-rays for use during mammography, including, at a minimum: an X-ray generator, an Xray control, a tube housing assembly, a beam-limiting device, and the supporting structures for these components.

"Primary protective barrier" (see "Protective barrier").

"Protective barrier" means a barrier used to reduce radiation exposure. The types of protective barriers are as follows:

1. "Primary protective barrier" means the material, excluding filters, placed in the useful beam, for protection purposes, to reduce the radiation exposure.

2. "Secondary protective barrier" means a barrier sufficient to attenuate the stray radiation to the required degree.

"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 incident radiation.

"Radiographic imaging system" means any system whereby a permanent or semipermanent image is recorded on an image receptor by the action of ionizing radiation. "Residual radioactivity" means radioactivity in structures, materials, soils, groundwater, and other media at a site resulting from activities under the licensee's control. This includes radioactivity from all licensed and unlicensed sources used by the licensee, but excludes background radiation. It also includes radioactive materials remaining at the site as a result of radioactive material at the site and previous burials at the site, even if those burials were made in accordance with the provisions of 641—Chapter 40 or any previous state or federal licenses, rules or regulations.

"Secondary dose monitoring system" means a system which will terminate irradiation in the event of failure of the primary dose monitoring system.

"Secondary protective barrier" (see "Protective barrier").

"Shutter" means a device attached to the tube housing assembly which can intercept the entire cross-sectional area of the useful beam and which has a lead equivalency not less than that of the tube housing assembly.

"Simulator (radiation therapy simulation system)" means any X-ray system intended for localizing the volume to be exposed during radiation therapy and reproducing the position and size of the therapeutic irradiation field.

"SSD" means the distance between the source and the skin entrance plane of the patient (see "Target-to-skin distance (TSD)").

"Stray radiation" means the sum of leakage and scattered radiation.

"Target-to-skin distance (TSD)" means the distance measured along the beam axis from the center of the front surface of the X-ray target or electron scattering foil to the surface of the irradiated object or patient.

"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.

"Tube housing assembly" means the tube housing with tube installed. It includes high-voltage or filament transformers, or both, and other appropriate elements when such are contained within the tube housing.

"Very high radiation area" means an area, accessible to individuals, in which radiation levels from radiation sources external to the body could result in an individual's receiving an absorbed dose in excess of 500 rad (5 Gy) in 1 hour at 1 meter from a source of radiation or 1 meter from any surface that the radiation penetrates.

Rescind the following definition:

"Eye dose equivalent" means the external dose equivalent to the lens of the eye at a tissue depth of 0.3 centimeter (300 mg/cm²).

ITEM 4. Amend subrule 38.3(1) as follows:

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 the rules in 641—Chapters 38 to 46 as it determines are authorized by law and will not result in undue hazard to public health and safety or property. Application for exemptions or exceptions should be made in accordance with 641—Chapter 178.

ITEM 5. Amend subrule **38.8(1)**, paragraph "a," as follows:

a. Each registrant shall, at the time of registration and the anniversary date thereafter, as long as the registrant owns the radiation machine, remit to the agency a fee sufficient to defray the cost of registering the equipment with the department. All fees shall be paid annually in the form of a check

or money order made payable to the Iowa Department of Public Health. The fees to be paid shall be in the amount computed by the following schedule:

ANNUAL FEE SCHEDULE

AUTOALTELSCHEDULL							
	Type of	Fee	Maximum				
	X-ray machine	per tube	fee				
1.	Medical	\$51	\$1500				
2.	Osteopathy	\$51	\$1500				
3.	Chiropractic	\$51	\$1500				
4.	Dentistry	\$39	\$1000				
5.	Podiatry	\$39	\$1000				
6.	Veterinary Medicine	\$25					
7.	(Industrial/ Nonmedical Use)	\$50					
8.	Food Sterilization	\$80 <i>\$1000</i>					
9.	Accelerators	\$100					
10.	Electron Microscope	\$20					
11.	Bone Densitometry	\$25					

ITEM 6. Amend subrule 38.8(3), paragraph "a," as follows:

a. A nonrefundable fee of 100 \$125 shall be submitted with each application for taking an industrial radiography examination to become certified by the agency.

ITEM 7. Amend subrule 38.8(6), introductory paragraph, as follows:

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

ITEM 8. Adopt <u>new</u> rule 641—38.10(136C) as follows:

641-38.10(136C) Deliberate misconduct.

38.10(1) Any licensee, registrant, applicant for a license or certificate of registration, employee of a licensee, registrant or applicant; or any contractor (including a supplier or consultant), subcontractor, employee of a contractor or subcontractor of any licensee or registrant or applicant for a license or certificate of registration, who knowingly provides to any licensee, applicant, registrant, contractor, or subcontractor any components, equipment, materials, or other goods or services that relate to a licensee's, registrant's or applicant's activities in this rule, may not:

a. Engage in deliberate misconduct that causes or would have caused, if not detected, a licensee, registrant, or applicant to be in violation of any rule, regulation, or order; or any term, condition, or limitation of any license or registration issued by the agency; or

b. Deliberately submit to the agency, a licensee, registrant, an applicant, or a licensee's, registrant's, or applicant's contractor or subcontractor, information that the person submitting the information knows to be incomplete or inaccurate in some respect material to the agency.

38.10(2) A person who violates paragraph 38.10(1)"a" or "b" may be subject to enforcement action in accordance with the procedures in 641—38.9(136C).

38.10(3) For the purposes of paragraph 38.10(1)"a," deliberate misconduct by a person means an intentional act or omission that the person knows:

a. Would cause a licensee, registrant, or applicant to be in violation of any rule, regulation, or order; or any term, condition, or limitation of any license issued by the agency; or

b. Constitutes a violation of a requirement, procedure, instruction, contract, purchase order, or policy of a licensee, registrant, applicant, contractor, or subcontractor.

ITEM 9. Amend subrule 39.1(3) as follows:

39.1(3) All references to any Code of Federal Regulations (CFR) in this chapter are those in effect as of July 1, 1999 May 10, 2000.

ITEM 10. Amend subrule **39.3(2)**, paragraph "a," as follows:

a. Apply for registration of such facility with the agency prior to the operation of a radiation machine facility. In order to register equipment, the person must have a permanent office located in Iowa that has a *non-wireless* telephone, employee and equipment, and storage for records regarding the equipment and operator certification. Application for registration shall be completed on forms furnished by the agency and shall include the appropriate fee from 641—38.8(136C).

ITEM 11. Amend subrule **39.3(3)**, paragraph **"d,"** as follows:

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. Processor or processor servicing, or both.

ITEM 12. Amend subrule **39.3(10)**, paragraph "a," introductory paragraph, as follows:

a. 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 three working days before such machine is to be used in the state. The notice shall include:

ITEM 13. Amend subrule 39.4(24) as follows:

39.4(24) Filing applications for specific licenses.

a. to d. No change.

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 e. 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.

g f. (1) Each application to possess radioactive materials in unsealed form, on foils or plated sources, or sealed in glass in excess of the quantities in Appendix G of this chapter, must contain either:

1. and 2. No change.

(2) One or more of the following factors may be used to support an evaluation submitted under 39.4(24)"g"(1)"1" 39.4(24)"f"(1)"1" of this subrule:

1. to 7. No change.

(3) An emergency plan for responding to a release of radioactive material submitted under 39.4(24)"g"(1)"2" 39.4(24)"f"(1)"2" must include the following information:

1. to 13. No change.

(4) No change.

ITEM 14. Amend subrule **39.4(26)**, paragraph "e," as follows:

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. The decommissioning funding plan must also contain a certification by the licensee that financial assurance for decommissioning has been provided in the amount of the cost estimate and a signed original of the financial instrument obtained to satisfy the requirements of 39.4(26)"f."

ITEM 15. Amend subparagraph 39.4(26)"f"(2) as follows:

(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. For commercial corporations that issue bonds, a guarantee of funds by the applicant or licensee for decommissioning costs based on a financial test may be used if the guarantee and test are as contained in Appendix H of this chapter. For commercial companies that do not issue bonds, a guarantee of funds by the applicant or licensee for decommissioning costs may be used if the guarantee and test are as contained in Appendix I of this chapter. For nonprofit entities, such as colleges, universities, and nonprofit hospitals, a guarantee of funds by the applicant or licensee may be used if the guarantee and test are as contained in Appendix J of this chapter. A guarantee by the applicant or licensee may not be used in combination with any other financial methods used to satisfy the requirements of paragraph 39.4(26) "f" or in any situation where the applicant or licensee has a parent company holding majority control of the voting stock of the company. Any surety method or insurance used to provide financial assurance for decommissioning must contain the following conditions:

ITEM 16. Amend subrule **39.4(26)**, paragraph "**f**," by adopting <u>new</u> subparagraph (**5**) as follows:

(5) When a governmental entity assumes custody and ownership of a site, an arrangement that is deemed acceptable by such governmental entity.

ITEM 17. Rescind subrule **39.4(27)**, paragraph "e," and adopt the following <u>new</u> paragraph in lieu thereof:

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 the application contains:

(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 of 641—Chapter 45;

(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 of the following applies to the location:

1. Non-wireless 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 641 subrule 45.1(8) and 641—Chapter 45, Appendix A); and

(7) If a license application includes underwater radiography, a description of:

1. Radiation safety procedures and radiographer responsibilities unique to the performance of underwater radiography;

2. 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.

ITEM 18. Amend subparagraph **39.4(33)**"j"(2), introductory paragraph, as follows:

(2) Conduct a radiation survey of the premises where the licensed activities were carried out and submit a report of the results of this survey unless the licensee demonstrates that the premises are suitable for release in some other manner in some other manner that the premises are suitable for release in accordance with the criteria for decommissioning in 641—40.28(136C) through 641—40.31(136C). The licensee shall, as appropriate:

ITEM 19. Amend subparagraph **39.4(33)**"k"(3) as follows:

(3) A radiation survey has been performed which demonstrates that the premises are suitable for release in accordance with state of Iowa requirements; or other information submitted by the licensee is sufficient to demonstrate that the premises are suitable for release in accordance with state of Iowa requirements the criteria for decommissioning in 641-40.28(136C) through 641-40.31(136C).

ITEM 20. Amend subparagraph **39.4(90)**"a"(3) as follows:

(3) The out-of-state licensee shall notify the agency in writing at least three *working* 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 receipt of the initial notification from a person engaging in activities under the general license provided by 39.4(90)"a."

ITEM 21. Rescind rule 641—39.5(136C) and adopt the following <u>new</u> rule in lieu thereof:

641-39.5(136C) Transportation of radioactive material.

All persons who transport radioactive material or deliver radioactive material to a carrier for transport must comply with the provision contained in 10 CFR Part 71 as it applies to the state of Iowa.

ITEM 22. Rescind and reserve 641—Chapter 39, Appendix E.

ITEM 23. Amend **641—Chapter 39** by adopting the following <u>new</u> Appendices H, I and J:

Appendix H

Criteria Relating to Use of Financial Tests and Self-Guarantees for Providing Reasonable Assurance of

Funds for Decommissioning

I. Introduction

An applicant or licensee may provide reasonable assurance of the availability of funds for decommissioning based on furnishing its own guarantee that funds will be available for decommissioning costs and on a demonstration that the company passes the financial test of Section II of this appendix. The terms of the self-guarantee are in Section III of this appendix. This appendix establishes criteria for passing the financial test for the self-guarantee and establishes the terms for a self-guarantee.

II. Financial Test

A. To pass the financial test, a company must meet all of the following criteria:

1. Tangible net worth at least ten times the total current decommissioning cost estimate for the total of all facilities or parts thereof (or the current amount required if certification is used).

2. Assets located in the United States amounting to at least 90 percent of total assets or at least ten times the total current decommissioning cost estimate for the total of all facilities or parts thereof (or the current amount required if certification is used).

3. A current rating for its most recent bond issuance of AAA, AA, or A as issued by Standard and Poor's (S&P) or Aaa, Aa, or A as issued by Moody's.

B. To pass the financial test, a company must meet all of the following additional requirements:

1. The company must have at least one class of equity securities registered under the Securities Exchange Act of 1934.

2. The company's independent certified public accountant must have compared the data used by the 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 the agency within 90 days of any matters coming to the attention of the auditor that cause the auditor to believe that the data specified in the financial test should be adjusted and that the company no longer passes the test.

3. After the initial financial test, the company must repeat passage of the test within 90 days after the close of each succeeding fiscal year.

C. If the licensee no longer meets the requirements of Section II.A. of this appendix, the licensee must send immediate notice to the agency of its intent to establish alternate financial assurance as specified in these rules within 120 days of such notice.

III. Company Self-Guarantee

The terms of a self-guarantee which an applicant or licensee furnishes must provide that:

A. The guarantee will remain in force unless the licensee sends notice of cancellation by certified mail, return receipt requested, to the agency. Cancellation may not occur, however, during the 120 days beginning on the date of receipt of the notice of cancellation by the agency, as evidenced by the return receipt.

B. The licensee shall provide alternative financial assurance as specified in these rules within 90 days following receipt by the agency of a notice of cancellation of the guarantee.

C. The guarantee and financial test provisions must remain in effect until the agency has terminated the license or until another financial assurance method acceptable to the agency has been put in effect by the licensee.

D. The licensee will promptly forward to the agency and the licensee's independent auditor all reports covering the latest fiscal year filed by the licensee with the Securities and Exchange Commission pursuant to the requirements of Section 13 of the Securities and Exchange Act of 1934.

E. If, at any time, the licensee's most recent bond issuance ceases to be rated in any category of "A" or above by either Standard and Poor's or Moody's, the licensee will provide notice in writing of such fact to the agency within 20 days after publication of the change by the rating service. If the licensee's most recent bond issuance ceases to be rated in any category of A or above by both Standard and Poor's and Moody's, the licensee no longer meets the requirements of Section II.A. of this appendix.

F. The applicant or licensee must provide to the agency a written guarantee (a written commitment by a corporate officer) which states that the licensee will fund and carry out the required decommissioning activities or, upon issuance of an order by the agency, the licensee will set up and fund a trust in the amount of the current cost estimates for decommissioning.

Appendix I

Criteria Relating to Use of Financial Tests and Self-Guarantee for Providing Reasonable Assurance of Funds for Decommissioning by Commercial Companies

That Have No Outstanding Rated Bonds

I. Introduction

An applicant or licensee may provide reasonable assurance of the availability of funds for decommissioning based on furnishing its own guarantee that funds will be available for decommissioning costs and on a demonstration that the company passes the financial test of Section II of this appendix. The terms of the self-guarantee are in Section III of this appendix. This appendix establishes criteria for passing the financial test for the self-guarantee and establishes the terms for a self-guarantee.

II. Financial Test

A. To pass the financial test, a company must meet the following criteria:

1. Tangible net worth greater than \$10 million, or at least ten times the total current decommissioning cost estimate (or the current amount required if certification is used), whichever is greater, for all decommissioning activities for which the company is responsible as self-guaranteeing licensee and as parent-guarantor.

2. Assets located in the United States amounting to at least 90 percent of total assets or at least ten times the total current decommissioning cost estimate (or the current amount required if certification is used) for all decommissioning activities for which the company is responsible as self-guaranteeing licensee and as parent-guarantor.

3. A ratio of cash flow divided by total liabilities greater than 0.15 and a ratio of total liabilities divided by net worth less than 1.5.

B. In addition, to pass the financial test, a company must meet all of the following requirements:

1. The company's independent certified public accountant must have compared the data used by the company in the financial test, which is required to be derived from the independently audited year-end financial statement based on United States generally accepted accounting practices for the latest fiscal year, with the amounts in such financial statement. In connection with that procedure, the licensee shall inform the agency within 90 days of any matters that may cause the auditor to believe that the data specified in the financial test should be adjusted and that the company no longer passes the test.

2. After the initial financial test, the company must repeat passage of the test within 90 days after the close of each succeeding fiscal year.

3. If the licensee no longer meets the requirements of Section II.A. of this appendix, the licensee must send notice to the agency of intent to establish alternative financial assurance as specified in these rules. The notice must be sent by certified mail, return receipt requested, within 90 days after the end of the fiscal year for which the year-end financial data show that the licensee no longer meets the financial test requirements. The licensee must provide alternative financial assurance within 120 days after the end of such fiscal year.

III. Company Self-Guarantee

The terms of a self-guarantee which an applicant or licensee furnishes must provide that:

A. The guarantee shall remain in force unless the licensee sends notice of cancellation by certified mail, return receipt requested, to the agency. Cancellation may not occur until an alternative financial assurance mechanism is in place.

B. The licensee shall provide alternative financial assurance as specified in these rules within 90 days following receipt by the agency of a notice of cancellation of the guarantee.

C. The guarantee and financial test provisions must remain in effect until the agency has terminated the license or until another financial assurance method acceptable to the agency has been put in effect by the licensee.

D. The applicant or licensee must provide to the agency a written guarantee (a written commitment by a corporate officer) which states that the licensee will fund and carry out the required decommissioning activities or, upon issuance of an

order by the agency, the licensee will set up and fund a trust in the amount of the current cost estimates for decommissioning.

Appendix J

Criteria Relating to Use of Financial Tests and Self-Guarantee for Providing Reasonable Assurance of Funds for Decommissioning by Nonprofit Colleges, Universities, and Hospitals

I. Introduction

An applicant or licensee may provide reasonable assurance of the availability of funds for decommissioning based on furnishing its own guarantee that funds will be available for decommissioning costs and on a demonstration that the applicant or licensee passes the financial test of Section II of this appendix. The terms of the self-guarantee are in Section III of this appendix. This appendix establishes criteria for passing the financial test for the self-guarantee and establishes the terms for a self-guarantee.

II. Financial Test

A. For colleges and universities to pass the financial test, a college or university must meet either the criteria in Section II.A.1. or the criteria in Section II.A.2. of this appendix.

1. For applicants or licensees that issue bonds, a current rating for its most recent uninsured, uncollateralized, and unencumbered bond issuance of AAA, AA, or A as issued by Standard and Poor's (S&P) or Aaa, Aa, or A as issued by Moody's.

2. For applicants or licensees that do not issue bonds, unrestricted endowment consisting of assets located in the United States of at least \$50 million, or at least 30 times the total current decommissioning cost estimate (or the current amount required if certification is used), whichever is greater, for all decommissioning activities for which the college or university is responsible as a self-guaranteeing licensee.

B. For hospitals to pass the financial test, a hospital must meet either the criteria in Section II.B.1. or the criteria in Section II.B.2. of this appendix:

1. For applicants or licensees that issue bonds, a current rating for its most recent uninsured, uncollateralized, and unencumbered bond issuance of AAA, AA, or A as issued by Standard and Poor's (S&P) or Aaa, Aa, or A as issued by Moody's.

2. For applicants or licensees that do not issue bonds, all the following tests must be met:

(a) (Total revenues less total expenditures) divided by total revenues must be equal to or greater than 0.04.

(b) Long-term debt divided by net fixed assets must be less than or equal to 0.67.

(c) (Current assets and depreciation fund) divided by current liabilities must be greater than or equal to 2.55.

(d) Operating revenues must be at least 100 times the total current decommissioning cost estimate (or the current amount required if certification is used) for all decommissioning activities for which the hospital is responsible as a self-guaranteeing licensee.

C. In addition, to pass the financial test, a licensee must meet all the following requirements:

1. The licensee's independent certified public accountant must have compared the data used by the licensee in the financial test, which is required to be derived from the independently audited year-end financial statements, based on United States generally accepted accounting practices, for the latest fiscal year, with the amounts in such financial statement. In connection with that procedure, the licensee shall inform this agency within 90 days of any matters coming to

the attention of the auditor that cause the auditor to believe that the data specified in the financial test should be adjusted and that the licensee no longer passes the test.

2. After the initial financial test, the licensee must repeat passage of the test within 90 days after the close of each succeeding fiscal year.

3. If the licensee no longer meets the requirements of Section I of this appendix, the licensee must send notice to this agency of its intent to establish alternative financial assurance as specified in these rules. The notice must be sent by certified mail, return receipt requested, within 90 days after the end of the fiscal year for which the year-end financial data show that the licensee 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. Self-Guarantee

The terms of a self-guarantee which an applicant or licensee furnishes must provide that:

A. The guarantee shall remain in force unless the licensee sends notice of cancellation by certified mail, return receipt requested, to the agency. Cancellation may not occur unless an alternative financial assurance mechanism is in place.

B. The licensee shall provide alternative financial assurance as specified in these rules within 90 days following receipt by the agency of a notice of cancellation of the guarantee.

C. The guarantee and financial test provisions must remain in effect until the agency has terminated the license or until another financial assurance method acceptable to the agency has been put in effect by the licensee.

D. The applicant or licensee must provide to the agency a written guarantee (a written commitment by a corporate officer or officer of the institution) which states that the licensee will fund and carry out the required decommissioning activities or, upon issuance of an order by the agency, the licensee will set up and fund a trust in the amount of the current cost estimates for decommissioning.

E. If, at any time, the licensee's most recent bond issuance ceases to be rated in any category of "A" or above by either Standard and Poor's or Moody's, the licensee shall provide notice in writing of such fact to the agency within 20 days after publication of the change by the rating service.

ITEM 24. Amend subrule 40.1(5) as follows:

40.1(5) All references to Code of Federal Regulations (CFR) in this chapter are those in effect on or before July 1, 1999 May 10, 2000.

ITEM 25. Amend subrule 40.2(2), definitions of "Declared pregnant woman" and "Very high radiation area," as follows:

"Declared pregnant woman" means a woman who has voluntarily informed her employer, in writing, of her pregnancy and the estimated date of conception. *The declaration remains in effect until the declared pregnant woman with draws the declaration in writing or is no longer pregnant.*

"Very high radiation area" means an area, accessible to individuals, in which radiation levels could result in an individual receiving an absorbed dose in excess of 500 rad (5 Gy) in 1 hour at 1 meter from a source of radiation or from any surface that the radiation penetrates.

ITEM 26. Amend subrule 40.10(2) as follows:

40.10(2) The licensee or registrant shall use, to the extent practicable practical, procedures and engineering controls based upon sound radiation protection principles to achieve

occupational doses and public doses that are as low as is reasonably achievable (ALARA).

ITEM 27. Amend subparagraph 40.15(1)"b"(1) as follows:

(1) An eye A lens dose equivalent of 15 rem (0.15 Sv), and

ITEM 28. Amend subrule 40.15(3) as follows:

40.15(3) The assigned deep dose equivalent and shallow dose equivalent shall be for the portion of the body receiving the highest exposure determined as follows:

The deep dose equivalent, eye lens dose equivalent and shallow dose equivalent may be assessed from surveys or other radiation measurements for the purpose of demonstrating compliance with the occupational dose limits, if the individual monitoring device was not in the region of highest potential exposure, or the results of individual monitoring are unavailable.

ITEM 29. Amend subrule 40.20(1) as follows:

40.20(1) The licensee or registrant authorizes a planned special exposure only in an exceptional situation when alternatives that might avoid the higher exposure dose estimated to result from the planned special exposure are unavailable or impractical.

ITEM 30. Amend rule 641—40.22(136C) as follows:

641-40.22(136C) Dose equivalent to an embryo/fetus.

40.22(1) The licensee or registrant shall ensure that the dose *equivalent* to an embryo/fetus during the entire pregnancy, due to occupational exposure of a declared pregnant woman, does not exceed 0.5 rem (5 mSv). See 40.86(136C) for record-keeping requirements.

40.22(2) No change.

40.22(3) The dose *equivalent* to an embryo/fetus shall be taken as the sum of:

a. The deep dose equivalent to the declared pregnant woman; and

b. The dose *equivalent* to the embryo/fetus from radionuclides in the embryo/fetus and radionuclides in the declared pregnant woman.

40.22(4) If by the time the woman declares pregnancy to the licensee or registrant, the dose *equivalent* to the embryo/ fetus has exceeded 0.45 rem, (4.5 mSv), the licensee or registrant shall be deemed to be in compliance with 40.22(1) if the additional dose *equivalent* to the embryo/fetus does not exceed 0.05 rem (0.5 mSv) during the remainder of the pregnancy.

ITEM 31. Amend subparagraph **40.36(1)"b"(1)** as follows:

(1) Radiation The magnitude and extent of radiation levels; and

ITEM 32. Amend subrule 40.62(2) as follows:

40.62(2) Rooms or other areas in hospitals that are occupied by patients are not required to be posted with caution signs pursuant to 40.61(136C) provided that the patient could be released from confinement licensee control pursuant to 641-41.27(136C) 641-subrule 41.2(27).

ITEM 33. Amend rule 641—40.62(136C) by adopting <u>new</u> subrule 40.62(5) as follows:

40.62(5) Rooms in hospitals or clinics that are used for teletherapy are exempt from the requirement to post caution signs under 40.61(136C) if:

a. Access to the room is controlled pursuant to 641—subrule 41.2(53); and

b. Personnel in attendance take necessary precautions to prevent an inadvertent exposure of workers, other patients, and members of the public to radiation in excess of the limits established in this chapter.

ITEM 34. Rescind rule 641—40.75(136C) and adopt the following <u>new</u> rule in lieu thereof:

641-40.75(136C) Transfer for disposal and manifests.

40.75(1) Any licensee shipping radioactive waste intended for ultimate disposal at a licensed land disposal facility must document the information required on the Uniform Low-Level Radioactive Waste Manifest and transfer this recorded manifest information to the intended consignee in accordance with Appendix D of this chapter.

40.75(2) Each shipment manifest must include a certification by the waste generator as specified in Section II of Appendix D of this chapter.

40.75(3) Each person involved in the transfer for disposal and disposal of waste, including the waste generator, waste collector, waste processor, and disposal facility operator, shall comply with the requirements specified in Section III of Appendix D of this chapter.

ITEM 35. Amend rule 641-40.80(136C) as follows:

641-40.80(136C) General provisions.

40.80(1) Each licensee or registrant shall use the special units curie, rad, rem and roentgen, counts per minute (cpm), disintegrations per minute (dpm), or the SI units becquerel, gray, sievert and coulomb per kilogram, including multiples and subdivisions, and shall clearly indicate the units of all quantities on records required by this chapter.

40.80(2) The licensee or registrant shall make a clear distinction among the quantities entered on the records required by this chapter, such as, total effective dose equivalent, total organ dose equivalent, shallow dose equivalent, eye lens dose equivalent, deep dose equivalent, or committed effective dose equivalent.

40.80(3) In the records required by this chapter, the licensee may record quantities in SI units in parentheses following each of the units specified in 40.80(1). However, all quantities must be recorded as stated in 40.80(1).

40.80(4) Notwithstanding the requirements of 40.80(1), when recording information on shipment manifests, as required in 641—40.75(136C), information must be recorded in the International System of Units (SI) or in SI and units as specified in 40.80(1).

ITEM 36. Rescind 641—Chapter 40, Appendix D, and adopt <u>new</u> Appendix D as follows:

Appendix D

Requirements for Transfers of Low-Level Radioactive Waste Intended for Disposal at Licensed Land Disposal Facilities and Manifests

As used in this appendix, the following definitions apply: "Chelating agent" means amine polycarboxylic acids (e.g., EDTA, DTPA), hydroxycarboxylic acids, and polycarboxylic acids (e.g., citric acid, carbolic acid, and glucinic acid).

"Chemical description" means a description of the principal chemical characteristics of a low-level radioactive waste.

"Computer-readable medium" means that the regulatory agency's computer can transfer the information from the medium into its memory.

"Consignee" means the designated receiver of the shipment of low-level radioactive waste. "Decontamination facility" means a facility operating under an Agreement State or Nuclear Regulatory Commission license whose principal purpose is decontamination of equipment or materials to accomplish recycle, reuse, or other waste management objectives and, for purposes of this appendix, is not considered to be a consignee for LLW shipments.

"Disposal container" means a container principally used to confine low-level radioactive waste during disposal operations at a land disposal facility (also see "high integrity container"). Note that for some shipments, the disposal container may be the transport package.

"EPA identification number" means the number received by a transporter following application to the administrator of EPA as required by 40 CFR Part 263.

"Forms 540, 540A, 541, 541A, 542, and 542A" are official forms referenced in this appendix. Licensees need not use originals of these forms as long as any substitute forms are equivalent to the original documentation in respect to content, clarity, size, and location of information. Upon agreement between the shipper and consignee, Forms 541 (and 541A) and Forms 542 (and 542A) may be completed, transmitted, and stored in electronic media. The electronic media must have the capability for producing legible, accurate, and complete records in the format of the uniform manifest.

"Generator" means a licensee operating under an Agreement State or Nuclear Regulatory Commission license who (1) is a waste generator as defined in this appendix, or (2) is the licensee to whom waste can be attributed within the context of the Low-Level Radioactive Waste Policy Amendments Act of 1985 (e.g., waste generated as a result of decontamination or recycle activities).

"High integrity container (HÍC)" means a container commonly designed to meet the structural stability requirements of 10 CFR 61.56, and to meet United States Department of Transportation requirements for a Type A package.

"Land disposal facility" means the land, buildings and structures, and equipment which are intended to be used for the disposal of radioactive wastes. For purposes of this appendix, a "geologic repository" as defined in 10 CFR 60 is not considered a land disposal facility.

"Package" means the assembly of components necessary to ensure compliance with the packaging requirements of United States Department of Transportation regulations, together with its radioactive contents, as presented for transport.

"Physical description" means the items called for on Form 541 to describe a low-level radioactive waste.

"Residual waste" means low-level radioactive waste resulting from processing or decontamination activities that cannot be easily separated into distinct batches attributable to specific waste generators. This waste is attributable to the processor or decontamination facility, as applicable.

"Shipper" means the licensed entity (i.e., the waste generator, waste collector, or waste processor) who offers lowlevel radioactive waste for transportation, typically consigning this type of waste to a licensed waste collector, waste processor, or land disposal facility operator.

"Shipping paper" means Form 540 and, if required, Form 540A which includes the information required by United States Department of Transportation in 49 CFR Part 172.

"Uniform Low-Level Radioactive Waste Manifest" or "uniform manifest" means the combination of Forms 540, 541 and, if necessary, 542, and their respective continuation sheets as needed, or equivalent.

"Waste collector" means an entity, operating under an Agreement State or Nuclear Regulatory Commission license, whose principal purpose is to collect and consolidate waste generated by others, and to transfer this waste, without processing or repackaging the collected waste, to another licensed waste collector, licensed waste processor, or licensed land disposal facility.

"Waste description" means the physical, chemical and radiological description of a low-level radioactive waste as called for on Form 541.

"Waste generator" means an entity, operating under an Agreement State or Nuclear Regulatory Commission license, who (1) possesses any material or component that contains radioactivity or is radioactively contaminated for which the licensee foresees no further use, and (2) transfers this material or component to a licensed land disposal facility or to a licensed waste collector or processor for handling or treatment prior to disposal. A licensee performing processing or decontamination services may be a "waste generator" if the transfer of low-level radioactive waste from its facility is defined as "residual waste."

"Waste processor" means an entity, operating under an Agreement State or Nuclear Regulatory Commission license, whose principal purpose is to process, repackage, or otherwise treat low-level radioactive material or waste generated by others prior to eventual transfer of waste to a licensed low-level radioactive waste land disposal facility.

"Waste type" means a waste within a disposal container having a unique physical description (i.e., a specific waste descriptor code or description; or a waste sorbed on or solidified in a specifically defined media).

I. Manifest

A waste generator, collector, or processor who transports, or offers for transportation, low-level radioactive waste intended for ultimate disposal at a licensed low-level radioactive waste land disposal facility must prepare a manifest reflecting information requested on applicable Forms 540 (Uniform Low-Level Radioactive Waste Manifest (Shipping Paper)) and 541 (Uniform Low-Level Radioactive Waste Manifest (Container and Waste Description)) and, if necessary, on an applicable Form 542 (Uniform Low-Level Radioactive Waste Manifest (Manifest Index and Regional Compact Tabulation)). Forms 540 and 540A must be completed and must physically accompany the pertinent lowlevel waste shipment. Upon agreement between shipper and consignee, Forms 541 and 541A and 542 and 542A may be completed, transmitted, and stored in electronic media with the capability for producing legible, accurate, and complete records on the respective forms. Licensees are not required by this agency to comply with the manifesting requirements of this part when they ship:

(a) LLW for processing and expect its return (i.e., for storage under their license) prior to disposal at a licensed land disposal facility;

(b) LLW that is being returned to the licensee who is the "waste generator" or "generator," as defined in this part; or

(c) Radioactively contaminated material to a "waste processor" that becomes the processor's "residual waste."

For guidance in completing these forms, refer to the instructions that accompany the forms. Copies of manifests required by this appendix may be legible carbon copies, photocopies, or computer printouts that reproduce the data in the format of the uniform manifest.

Forms 540, 540A, 541, 541A, 542 and 542A, and the accompanying instructions, in hard copy, may be obtained from the Information and Records Management Branch, Office of Information Resources Management, U.S. Nuclear Regulatory Commission, Washington, DC 20555, teephone (301)415-7232.

This appendix includes information requirements of the United States Department of Transportation, as colified in 49 CFR Part 172. Information on hazardous, medical, or other waste required to meet Environmental Potection Agency regulations, as codified in 40 CFR Parts 259, 261, or elsewhere, is not addressed in this section, and must be provided on the required EPA forms. However, the required EPA forms must accompany the Uniform Low-Level Radioactive Waste Manifest required by this chapter.

Information Requirements

A. General Information

The shipper of the radioactive waste shall provide the following information on the uniform manifest:

1. The name, facility's address, and telephone number of the licensee shipping the waste;

2. An explicit declaration indicating whether the shipper is acting as a waste generator, collector, processor, or a combination of these identifiers for purposes of the manifested shipment; and

3. The name, address, and telephone number, or the name and EPA identification number, for the carrier transporting the waste.

B. Shipment Information

The shipper of the radioactive waste shall provide the following information regarding the waste shipment on the uniform manifest:

1. The date of the waste shipment;

2. The total number of packages/disposal containers;

3. The total disposal volume and disposal weight in the shipment;

4. The total radionuclide activity in the shipment;

5. The activity of each of the radionuclides, H-3, C-14, Tc-99, and I-129 contained in the shipment; and

6. The total masses of U-233, U-235, and plutonium in special nuclear material, and the total mass of uranium and thorium in source material.

C. Disposal Container and Waste Information

The shipper of the radioactive waste shall provide the following information on the uniform manifest regarding the waste and each disposal container of waste in the shipment:

1. An alphabetic or numeric identification that uniquely identifies each disposal container in the shipment;

2. A physical description of the disposal container, including the manufacturer and model of any high integrity container;

3. The volume displaced by the disposal container;

4. The gross weight of the disposal container, including the waste;

5. For waste consigned to a disposal facility, the maximum radiation level at the surface of each disposal container;

6. A physical and chemical description of the waste;

7. The total weight percentage of chelating agent for any waste containing more than 0.1 percent chelating agent by weight, plus the identity of the principal chelating agent;

The approximate volume of waste within a container;
 The sorbing or solidification media, if any, and the identity of the solidification media vendor and brand name;

10. The identities and activities of individual radionuclides contained in each container, the masses of U-233, U-235, and plutonium in special nuclear material, and the masses of uranium and thorium in source material. For discrete waste types (i.e., activated materials, contaminated equipment, mechanical filters, sealed source/devices, and wastes in solidification/stabilization media), the identities and activities of individual radionuclides associatd with or contained in these waste types within a disposal container shall be reported;

11. The total radioactivity within each container; and

12. For wastes consigned to a disposal facility, the classification of the waste pursuant to 10 CFR 61.55. Waste not meeting the structural stability requirements of 10 CFR 61.56(b) must be identified.

D. Uncontainerized Waste Information

The shipper of the radioactive waste shall provide the following information on the uniform manifest regarding a waste shipment delivered without a disposal container:

1. The approximate volume and weight of the waste;

2. A physical and chemical description of the waste;

3. The total weight percentage of chelating agent if the chelating agent exceeds 0.1 percent by weight, plus the identity of the principal chelating agent;

4. For waste consigned to a disposal facility, the classification of the waste pursuant to 10 CFR 61.55. Waste not meeting the structural stability requirements of 10 CFR 61.56(b) must be identified;

5. The identities and activities of individual radionuclides contained in the waste, the masses of U-233, U-235, and plutonium in special nuclear material, and the masses of uranium and thorium in source material; and

6. For wastes consigned to a disposal facility, the maximum radiation levels at the surface of the waste.

E. Multigenerator Disposal Container Information

This section applies to disposal containers enclosing mixtures of waste originating from different generators. (Note: The origin of the LLW resulting from a processor's activities may be attributable to one or more "generators" (including "waste generators") as defined in this appendix.) It also applies to mixtures of wastes shipped in an uncontainerized form, for which portions of the mixture within the shipment originate from different generators.

1. For homogeneous mixtures of waste, such as incinerator ash, provide the waste description applicable to the mixture and the volume of the waste attributed to each generator.

2. For heterogeneous mixtures of waste, such as the combined products from a large compactor, identify each generator contributing waste to the disposal container and, for discrete waste types (i.e., activated materials, contaminated equipment, mechanical filters, sealed source/devices, and wastes in solidification/stabilization media), the identities and activities of individual radionuclides contained in these waste types within the disposal container. For each generator, provide the following:

(a) The volume of waste within the disposal container;

(b) A physical and chemical description of the waste, including the solidification agent, if any;

(c) The total weight percentage of chelating agents for any disposal container containing more than 0.1 percent chelating agent by weight, plus the identity of the principal chelating agent;

(d) The sorbing or solidification media, if any, and the identity of the solidification media vendor and brand name if the media is claimed to meet stability requirements in 10 CFR 61.56(b); and

(e) Radionuclide identities and activities contained in the waste, the masses of U-233, U-235, and plutonium in special nuclear material, and the masses of uranium and thorium in source material if contained in the waste.

II. Certification

An authorized representative of the waste generator, processor, or collector shall certify by signing and dating the shipment manifest 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 United States Department of Transportation and this agency. A collector in signing the certification is certifying that nothing has been done to the collected waste that would invalidate the waste generator's certification.

III. Control and Tracking

A. Any licensee who transfers radioactive waste to a land disposal facility or a licensed waste collector shall comply with the requirements in paragraphs A.1. through A.9. of this appendix. Any licensee who transfers waste to a licensed waste processor for waste treatment or repackaging shall comply with the requirements of paragraphs A.4. through A.9. of this appendix. A licensee shall:

1. Prepare all wastes so that the waste is classified according to 10 CFR 61.55 and meets the waste characteristics requirements in 10 CFR 61.56;

2. Label each disposal container (or transport package if potential radiation hazards preclude labeling of the individual disposal container) of waste to identify whether it is Class A waste, Class B waste, Class C waste, or greater than Class C waste, in accordance with 10 CFR 61.55;

3. Conduct a quality assurance program to ensure compliance with 10 CFR 61.55 and 61.56 (the program must include management evaluation of audits);

4. Prepare the Uniform Low-Level Radioactive Waste Manifest as required by this appendix;

5. Forward a copy or electronically transfer the Uniform Low-Level Radioactive Waste Manifest to the intended consignee so that either (1) receipt of the manifest precedes the LLW shipment or (2) the manifest is delivered to the consignee with the waste at the time the waste is transferred to the consignee. Using both (1) and (2) is also acceptable;

6. Include Form 540 (and Form 540A, if required) with the shipment regardless of the option chosen in paragraph A.5. of this section;

7. Receive acknowledgment of the receipt of the shipment in the form of a signed copy of Form 540;

8. Retain a copy of or electronically store the Uniform Low-Level Radioactive Waste Manifest and documentation of acknowledgment of receipt as the record of transfer of licensed material as required by 641—subrule 39.4(41); and

9. For any shipments or any part of a shipment for which acknowledgment of receipt has not been received within the times set forth in this appendix, conduct an investigation in accordance with paragraph E of this appendix.

B. Any waste collector licensee who handles only prepackaged waste shall:

1. Acknowledge receipt of the waste from the shipper within one week of receipt by returning a signed copy of Form 540;

2. Prepare a new manifest to reflect consolidated shipments that meet the requirements of this appendix. The waste collector shall ensure that, for each container of waste in the shipment, the manifest identifies the generator of that container of waste;

3. Forward a copy or electronically transfer the Uniform Low-Level Radioactive Waste Manifest to the intended consignee so that either: (1) receipt of the manifest precedes the LLW shipment or (2) the manifest is delivered to the con-

signee with the waste at the time the waste is transferred to the consignee. Using both (1) and (2) is also acceptable;

4. Include Form 540 (and Form 540A, if required) with the shipment regardless of the option chosen in paragraph B.3. of this section;

5. Receive acknowledgment of the receipt of the shipment in the form of a signed copy of Form 540;

6. Retain a copy of or electronically store the Uniform Low-Level Radioactive Waste Manifest and documentation of acknowledgment of receipt as the record of transfer of licensed material as required by 641—subrule 39.4(41);

7. For any shipments or any part of a shipment for which acknowledgment of receipt has not been received within the times set forth in this appendix, conduct an investigation in accordance with paragraph E of this appendix; and

8. Notify the shipper and this agency when any shipment, or part of a shipment, has not arrived within 60 days after receipt of an advance manifest, unless notified by the shipper that the shipment has been canceled.

C. Any licensed waste processor who treats or repackages waste shall:

1. Acknowledge receipt of the waste from the shipper within one week of receipt by returning a signed copy of Form 540;

2. Prepare a new manifest that meets the requirements of this appendix. Preparation of the new manifest reflects that the processor is responsible for meeting these requirements. For each container of waste in the shipment, the manifest shall identify the waste generators, the preprocessed waste volume, and the other information as required in paragraph E.1. of this appendix;

3. Prepare all wastes so that the waste is classified according to 10 CFR 61.55 and meets the waste characteristics requirements in 10 CFR 61.56;

4. Label each package of waste to identify whether it is Class A waste, Class B waste, or Class C waste, in accordance with 10 CFR 61.55 and 61.57;

5. Conduct a quality assurance program to ensure compliance with 10 CFR 61.55 and 61.56 (the program shall include management evaluation of audits);

6. Forward a copy or electronically transfer the Uniform Low-Level Radioactive Waste Manifest to the intended consignee so that either: (1) receipt of the manifest precedes the LLW shipment or (2) the manifest is delivered to the consignee with the waste at the time the waste is transferred to the consignee. Using both (1) and (2) is also acceptable;

7. Include Form 540 (and Form 540A, if required) with the shipment regardless of the option chosen in paragraph C.6. of this section;

8. Receive acknowledgment of the receipt of the shipment in the form of a signed copy of Form 540;

9. Retain a copy of or electronically store the Uniform Low-Level Radioactive Waste Manifest and documentation of acknowledgment of receipt as the record of transfer of licensed material as required by 641—subrule 39.4(41);

10. For any shipment or any part of a shipment for which acknowledgment of receipt has not been received within the times set forth in this appendix, conduct an investigation in accordance with paragraph E of this appendix; and

11. Notify the shipper and this agency of any shipment, or part of a shipment, that has not arrived within 60 days after receipt of an advance manifest, unless notified by the shipper that the shipment has been canceled.

D. The land disposal facility operator shall:

1. Acknowledge receipt of the waste within one week of receipt by returning, as a minimum, a signed copy of Form

540 to the shipper. The shipper to be notified is the licensee who last possessed the waste and transferred the waste to the operator. If any discrepancy exists between materials listed on the Uniform Low-Level Radioactive Waste Manifest and materials received, copies or electronic transfer of the affected forms must be returned indicating the discrepancy;

2. Maintain copies of all completed manifests and electronically store the information required by 10 CFR 61.80(l) until the license is terminated; and

3. Notify the shipper and this agency when any shipment, or part of a shipment, has not arrived within 60 days after receipt of an advance manifest, unless notified by the shipper that the shipment has been canceled.

E. Any shipment or part of a shipment for which acknowledgment is not received within the times set forth in this section must:

1. Be investigated by the shipper if the shipper has not received notification or receipt within 20 days after transfer; and

2. Be traced and reported. The investigation shall include tracing the shipment and filing a report with this agency. Each licensee who conducts a trace investigation shall file a written report with this agency within two weeks of completion of the investigation.

ITEM 37. Amend subrule 41.1(1) as follows:

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, any other applicable provisions of these rules. The provisions of Chapter 41 are in addition to, and not in substitution for, any other applicable portions of 641—Chapters 38 to 42. All references to any Code of Federal Regulations (CFR) in this chapter are those in effect as of July 1, 1999 May 10, 2000.

ITEM 38. Amend subrule 41.1(2), introductory paragraph, as follows:

41.1(2) Definitions. For the purpose of this chapter, the definitions of 641—Chapter Chapters 38 and 40 may also apply. The following are specific to rule 41.1(136C) 641—Chapter 41.

ITEM 39. Amend subrule 41.1(2) as follows:

Adopt the following <u>new</u> definitions in alphabetical order:

"Base density" means the optical density due to the supporting base of the film alone. The base density of a film is the optical density that would result if an unexposed film were processed through the fixer, wash, and dryer, without first passing through the developer.

"Base plus fog density" means the optical density of a film due to its base density plus any action of the developer on the unexposed silver halide crystals. The base plus fog density can be measured by processing an unexposed film through the entire processing cycle and measuring the resultant optical density.

"Cassette" means a light-tight case, usually made of thin, low X-ray absorption plastic, for holding X-ray film. One or two intensifying screens for the conversion of X-rays to visible light photons are mounted inside the cassette so that they are in close contact to the film.

"Control chart" means a chart used to record (and control) the results of quality control testing as a function of time.

"Control limit" means the range of variation on a control chart beyond which action must be taken to correct the results of quality control testing.

"Dedicated mammography equipment" means X-ray systems designed specifically for breast imaging, providing optimum imaging geometry, a device for breast compression and low dose exposure that can generate reproducible images of high quality.

"Densitometer" means an instrument which measures the degree of blackening (or radiographic density) of film due to radiation or light by measuring the ratio of the light intensity incident on the film to the light intensity transmitted by the film.

"Detents" means mechanical settings that limit or prevent the motion or rotation of an X-ray tube, cassette assembly, or image receptor system.

"Developer" means a chemical solution (alkaline) that changes the latent image (exposed silver halide crystals) on a film to a visible image composed of minute masses of black metallic silver.

"Developer replenishment" means the process, occurring as film travels past a certain point in the processor, triggering the activation of a pump, whereby fresh developer is added in small amounts to the solution in the developer tank of the processor. The purpose is to maintain the proper alkalinity, chemical activity, and level of solution in the developer tank.

"Diagnostic mammography" means mammography performed on an individual who, by virtue of symptoms or physical findings, is considered to have a substantial likelihood of having breast disease.

"Fixer" means a chemical solution (acidic) which removes the unexposed and undeveloped silver halide crystals from film so it will not discolor or darken with age or exposure to light. Fixer also hardens the gelatin containing the black metallic silver so film may be dried and resist damage from abrasions.

"Fixer retention" means the inadequate removal of fixer from the film by the water in the wash tank of the processor. Retained fixer causes eventual brown discoloration of the radiograph.

"Focal spot size" means the area of the target or anode that is bombarded by electrons from the cathode of the X-ray tube to produce X-rays. The smaller the focal spot, the better the limited spatial resolution of the X-ray system, especially in magnification mammography.

"Fog" means the density added to a radiograph due to unwanted action of the developer on the unexposed silver halide crystals or by light, radiation, chemical, or heat exposure during storage, handling, and processing.

"Image contrast" means the amount of radiographic density difference between adjacent areas resulting from a fixed amount of attenuation difference or light exposure difference.

"Image noise." See "Radiographic noise."

"Image quality" means the overall clarity and detail of a radiographic image. Limiting spatial resolution (or resolving power), image sharpness, and image contrast are three common measures of image quality.

"Image sharpness" means the overall impression of detail and clarity in a radiographic image.

"Processor" means an automated device which transports film in a controlled manner by a system of rollers through specialized sections where developing, fixing, washing, and drying of the film occur. "Quality assurance" means the overall program of testing and maintaining the highest possible standards of quality in the acquisition and interpretation of radiographic images.

"Quality control" means the actual process of testing and maintaining the highest possible standards of quality in equipment performance and the acquisition and interpretation of radiographic images.

"Radiographic contrast" means the magnitude of optical density difference between structures of interest and their surroundings, or between areas of film receiving different amounts of X-ray or visible light exposure.

"Radiographic noise" means unwanted fluctuations in optical density on the screen-film image.

"Repeat (or reject) analysis" means a systematic approach to determine the causes for radiographs being discarded or repeated, or both.

"Replenishment rate" means the amount of chemicals added in order to maintain the proper chemical activity of developer and fixer solutions.

"Safelight" means a source of minimal visible light in a darkroom, produced at frequencies (colors) to which the film is insensitive, protecting the film from unwanted exposure (fog) while allowing personnel to function more efficiently and safely.

"Screen" means microscopic phosphor crystals on a plastic support and used in conjunction with either single or double emulsion film; the screen emits visible light when exposed to X-radiation, creating a latent image on X-ray film.

posed to X-radiation, creating a latent image on X-ray film. "Screen-film combination" means a particular intensifying screen used with a particular type of film. Care must be taken to match the number of screens (one or two) to the number of emulsions coating the film and to match the light output spectrum of the screen to the light sensitivity of the film.

"Screen-film contact" means the close proximity of the intensifying screen to the emulsion of the film, necessary in order to achieve a sharp image on the film.

"Sensitometer" means a device used to reproducibly expose a piece of film to a number of different levels of light intensity.

"Sensitometric strip" means a sheet of film exposed by a sensitometer, resulting in a gray scale range. Such strips are used to measure the range of densities, from minimum to maximum, resulting from a reproducible set of exposures.

"Sensitometry" means a quantitative measurement of the response of film to exposure and development. Sensitometry is used to test the processor setup and stability.

try is used to test the processor setup and stability. "Viewbox" means a device by which a uniform field of white light is transmitted through an X-ray so that the image on the film may be seen.

Amend the following definition:

"X-ray *exposure* control" means a device, switch, button or similar means by which an operator initiates or terminates the radiation exposure. The X-ray exposure control may include such associated equipment as timers and backup timers.

ITEM 40. Amend subrule **41.1(2)** by rescinding the following definitions: "barrier," "beam-limiting device," "detector," "kV," "lead equivalent," "leakage radiation," "light field," "mA," "primary protective barrier," "protective barrier," "radiation detector," "secondary protective barrier," "shutter," "SSD," "stray radiation," "termination of irradiation," and "tube housing assembly."

ITEM 41. Amend subparagraph 41.1(3)"a"(6) as follows:

(6) Gonad shielding of not less than 0.250. 50 millimeter lead equivalent shall be used for human 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.

ITEM 42. Amend 41.1(3)"f"(1)"2" as follows:

2. The temperature of solutions in the tanks shall be maintained within the range of 60° F to 80° F (16° C to 27° C). Film shall be developed in accordance with the time-temperature relationships recommended by the film manufacturer or, in the absence of such recommendations, with the time-temperature chart available from the agency.

ITEM 43. Amend 41.1(3)"f"(2)"1" as follows:

 Films shall be developed in accordance with the timetemperature relationships recommended by the film manufacturer; in the absence of such recommendations, the film shall be developed using the chart available from the agency.

ITEM 44. Amend paragraph **41.1(3)**"f" by adopting <u>new</u> subparagraph (4) as follows:

(4) Records shall be maintained to verify that the items in 41.1(3)"f" are performed according to the requirements. Records may be discarded only after an agency inspection has been completed and the facility determined to be in compliance.

ITEM 45. Amend paragraph 41.1(4)"i" as follows:

i. Locks. All position locking, holding, and centering devices on X-ray system components and systems shall function as intended. All X-ray systems shall be maintained in good mechanical repair and comply with all state and local electrical code requirements.

ITEM 46. Amend subrule 41.1(6), catchwords, as follows:

41.1(6) Radiographic systems, *including veterinary*, other than fluoroscopic, dental intraoral, or computed tomography X-ray systems.

ITEM 47. Rescind 41.1(6)"h"(1)"3."

ITEM 48. Amend subparagraph 41.1(7)"c"(5) as follows:

(5) Each X-ray exposure switch 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 exposure switch so that the operator is required to remain in the protected area during the entire exposure; and Stationary X-ray systems shall be required to have the X-ray exposure switch located in a protected area or have an exposure switch cord of sufficient length to permit the operator to activate the unit while in a protected area, e.g., corridor outside the operatory. The procedures required under 41.1(3) "a"(4) must instruct the operator to remain in the protected area during the entire exposure.

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)"c"(5)"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 foot (1.98 m) high protective barrier or means to allow the operator to be at least 9 feet (2.7 meters) from the tube housing assembly while making exposure. ITEM 49. Amend subrule 41.1(9) by adopting the following <u>new</u> paragraphs:

e. Bone densitometry on human patients shall be conducted only under a prescription of a licensed physician, a licensed physician assistant as defined in Iowa Code section 148C.1, subsection 6, or a licensed registered nurse who is registered as an advanced registered nurse practitioner pursuant to Iowa Code chapter 152.

f. During the operation of the bone densitometry system:

(1) The operator, ancillary personnel, and members of the general public shall be positioned at least one meter from the patient and bone densitometry system during the examination.

(2) The operator shall advise the patient that the bone densitometry examination is a type of X-ray procedure.

g. Equipment shall be maintained and operated in accordance with the manufacturer's specifications. Records of the maintenance shall be kept for inspection by the agency.

ITEM 50. Amend subrule 41.1(11), paragraph "a," introductory paragraph, as follows:

a. Definitions. In addition to the definitions provided in 641-38.2(136C), 641-40.2(136C), and 41.1(2), the following definitions shall be applicable to 41.1(11):

ITEM 51. Amend subrule 41.2(14), paragraph "c," as follows:

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 or equivalent 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 or human research subject 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) a dose exceeding 5 rem (0.05 Sv) effective dose equivalent or 50 rem (0.5 Sv) dose equivalent to any individual organ. Licensees may use dosimetry tables in package inserts, corrected only for amount of radioactivity administered, to determine whether a report is required.

ITEM 52. Amend subparagraph 41.2(60)"a"(2), numbered paragraphs "1" and "2," as follows:

1. Radiation levels dose rates in restricted areas are not likely to cause personnel exposures any occupationally exposed individual to receive a dose in excess of the limits specified in 641-40.15(136C); and

2. Radiation levels dose rates in controlled or unrestricted areas do not exceed are not likely to cause any individual member of the public to receive a dose in excess of the limits specified in 641—40.26(136C).

ITEM 53. Amend subrule 41.2(62), introductory paragraph, as follows:

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 any individual member of the public is likely to receive a dose greater than those permitted by 641—40.26(136C) before beginning the treatment program the licensee shall:

ITEM 54. Amend subrule 41.3(1), paragraph "b," as follows:

b. The use of therapeutic radiation machines shall be by, or under the supervision of, a physician who meets the training/experience criteria established by 41.3(4)"c." 41.3(5).

ITEM 55. Amend subrule 41.3(2), introductory paragraph, as follows:

41.3(2) Definitions. In addition to the definitions provided in 641-38.2(136C) and 641-40.2(136C), The the following definitions are specific to 641-41.3(136C).

ITEM 56. Amend subrule **41.3(2)** by rescinding the following definitions: "beam axis," "kilo electron volt (keV)," "radiation detector," and "target-to-skin distance (TSD)."

ITEM 57. Amend subrule **41.3(2)**, definition of "filter," as follows:

"Filter" means material placed in the useful beam to change beam quality in therapeutic radiation machines subject to subrule 41.3(6).

ITEM 58. Amend subrule 41.3(12) as follows:

41.3(12) Records retention. All records required by 641-41.3(136C) shall be retained until disposal is authorized by the agency unless another retention period is specifically authorized in 41.3(136C). All required records shall be retained in an active file from at least the time of generation until the next agency inspection. Any required record generated before the last agency inspection may be microfilmed or otherwise archived as long as a complete copy can be retrieved until such time the agency authorizes final disposal.

ITEM 59. Rescind and reserve subrule 41.3(13).

ITEM 60. Amend subparagraph **41.3(17)**"a"(1) by adopting <u>new</u> numbered paragraph "3" as follows:

3. For each therapeutic machine, the registrant shall determine, or obtain from the manufacturer, the leakage radiation existing at positions specified in 41.3(17)"a"(1)"1" and 41.3(17)"a"(1)"2" for the specified operating conditions. Records on leakage radiation measurements shall be maintained at the facility for inspection by the agency.

ITEM 61. Amend subparagraph 41.3(18)"a"(15) as follows:

(15) 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. The nominal energy value selected shall be displayed at the treatment control panel before and during irradiation; until reset manually for the next irradiation. After termination of irradiation, it shall be necessary to reset the nominal energy value selected before subsequent treatment can be initiated; and

3. Irradiation shall not be possible until the appropriate flattening filter or scattering foil for the selected energy is in its proper location.

ITEM 62. Amend subrule 41.3(18) as follows:

Amend paragraph "e" as follows:

e. Full calibration measurements.

(1) Full calibration of a therapeutic radiation machine subject to 41.3(18) shall be performed by, or under the direct supervision of, a radiation therapy physicist:

1. Before the first medical use following installation or reinstallation of the therapeutic radiation machine;

2. At intervals not to exceed 12 months; and

2. Full calibration shall include measurement of all parameters listed in Appendix D of 641—Chapter 41. Although it shall not be necessary to complete all elements of a full calibration at the same time, all parameters (for all energies) shall be completed at intervals not to exceed 12 calendar months, unless a more frequent interval is required by this agency.

3. No change.

4. Notwithstanding the requirements of 41.3(18)"e"(1)"3":

• Full calibration of therapeutic radiation machines with multienergy or multimode capabilities is required only for those modes or energies that are not within their acceptable range; and

If the repair, replacement or modification does not affect all modes or energies, full calibration shall be performed on the effected mode/energy that is in most frequent clinical use at the facility. The remaining energies/modes may be validated with quality assurance check procedures against the criteria in 41.3(18)"e"(1)"3."

(2) To satisfy the requirement of 41.3(18)"e"(1), full calibration shall include all measurements required for annual calibration by Appendix D of 641—Chapter 41.

(3) (2) The registrant shall use the dosimetry system described in 41.3(16)"c" to measure the radiation output for one set of exposure conditions. The remaining radiation measurements required in 41.3(18)"e"(2) may then be made using a dosimetry system that indicates relative dose rates; and

(4) (3) The registrant shall maintain a record of each calibration for the duration of the registration. The record shall include the date of the calibration, the manufacturer's name, model number, and serial number for the therapeutic radiation machine, the model numbers and serial numbers of the instruments used to calibrate the therapeutic radiation machine, and the signature of the radiation therapy physicist responsible for performing the calibration.

sponsible for performing the calibration. Amend paragraph "f," subparagraphs (1) and (3), as follows:

(1) Periodic quality assurance checks shall be performed on all therapeutic radiation machines subject to 41.3(18) at intervals not to exceed one week; as specified in Appendix D of 641—Chapter 41;

(3) The registrant shall use a dosimetry system which has been compared intercompared within the previous 12 months with the dosimetry system described in 41.3(16)"c"(1) to make the periodic quality assurance checks required in 41.3(18)"f"(2);

ITEM 63. Amend subrule 41.6(1), introductory paragraph, as follows:

41.6(1) Definitions. In addition to the definitions provided in 641—38.2(136C), 641—40.2(136C), and 641—41.1(136C), the following definitions shall be applicable to this rule.

ITEM 64. Amend subrule **41.6(1)** by rescinding the following definitions: "base density," "base plus fog density," "cassette," "control chart," "control limit," "densitometer," "detents," "developer," "developer replenishment," "diagnostic mammography," "fixer," "fixer retention," "focal spot size," "fog," "half-value layer (HVL)," "image contrast," "image quality," "image sharpness," "kilovoltage peak (kVp)," "milliampere (mA) setting," "milliampere seconds (mAs)," "phantom," "physician consultant," "processor," "quality assurance," "quality control," "quali-

ty control technologist," "radiographic contrast," "radiographic noise," "radiographic sharpness," "repeat (or reject) analysis," "replenishment rate," "safelight," "screen," "screen-film combination," "screen-film contact," "sensitometer," "sensitometric strip," "sensitometry," "thermoluminescent dosimeter (TLD)," and "viewbox."

ITEM 65. Amend subrule **41.6(1)** by adopting the following <u>new</u> definitions in alphabetical order:

"Category 1" means medical education activities that have been designated as Category 1 by the Accreditation Council for Continuing Medical Education (ACCME), the American Osteopathic Association (AOA), a state medical society, or an equivalent organization.

"MQSA" means the Mammography Quality Standards Act of 1992.

"Positive mammogram" means a mammogram that has an overall assessment of findings that are either "suspicious" or "highly suggestive" of malignancy.

"Serious complaint" means a report of a serious adverse event. This means an event that may significantly compromise clinical outcomes, or an adverse event for which a facility fails to take appropriate corrective action in a timely manner.

ITEM 66. Amend subrule **41.6(2)**, paragraph "**a**," by adopting the following <u>new</u> subparagraph (**8**):

(8) Provisional authorization. A new facility beginning operation after September 30, 1994, is eligible to apply for a provisional authorization. This will enable the facility to perform mammography and to obtain the clinical images needed to complete the authorization process. To apply for and receive a provisional certificate, a facility must meet the requirements of 641-41.6(136C). A provisional authorization shall be effective for up to six months from the date of issuance and cannot be renewed. The facility may apply for a 90-day extension.

ITEM 67. Amend subrule **41.6(2)**, paragraph "c," as follows:

c. Withdrawal or denial of mammograph f authorization.

(1) Mammography authorization may be withdrawn with cause if any *facility or* machine does not meet one or more of the standards of these rules, will not permit inspections or provide access to records or information in a timely fashion, or has been guilty of misrepresentation in obtaining the authorization.

(2) The facility shall have opportunity for a hearing in connection with a denial or withdrawal of mammography authorization *in accordance with 641—Chapter 173*.

(3) An emergency order withdrawing authorization may be issued in accordance with 641—173.31(17A) if the agency finds the radiation unit or facility violates rules that seriously affect the health, safety, and welfare of the public. An opportunity for hearing shall be held within five working days after the issuance of the order. The order shall be effective during the proceedings.

(4) If authorization is withdrawn, the radiation machine shall not be used for mammography until reinstated.

(5) If a facility's authorization is revoked, no person who owned or operated that facility at the time the act occurred may own or operate a mammography facility within two years of the date of revocation.

ITEM 68. Amend subrule 41.6(3) as follows: 41.6(3) Mammography personnel. a. Physician consultant. (1) Must be available either on staff or through arrangement.

(2) Must document in writing annually completion of:

1. Review of the procedural manuals to determine that they are adequate.

 Verification that equipment and personnel meet applicable state requirements and are performing properly.

3. Verification that the safety procedures are being followed.

4. Verification that all other requirements of these rules are being met.

a. Reserved.

b. Interpreting physician. All mammograms must be interpreted by a radiologist who meets All radiologists qualifying before October 1, 1994, must meet the requirements in effect as of October 1, 1994. All radiologists qualifying after April 28, 1999, must meet MQSA rules effective on that date or meet the following certification, experience, continuing education, and written report requirements:

(1) Be certified in diagnostic radiography by the American Board of Radiology, the American Osteopathic Board of Radiology, or Royal College of Physicians and Surgeons of Canada in Radiology or have had at least two three months of documented full-time mammographic training from a person recognized by this agency. The training must include interpretation of mammograms and topics in mammography, including instructions in radiation physics specific to mammography, radiation effects and radiation protection. Mammography interpretation shall be under the direct supervision of a physician who already meets the requirements as an interpreting physician.

(2) Has interpreted or multi-read an average of ten-or more mammograms per workweek in the prior six months 960 mammograms in the prior 24 months or has completed a radiology residency within the past two years. The multireading shall be under the direct supervision of an interpreting physician who meets the qualifications of these rules.

(3) Has successfully completed or taught a minimum of 40 60 hours (includes radiology residency) of postgraduate instruction in mammography interpretation, basic breast anatomy, pathology, physiology, technical aspects of mammography, and quality assurance and quality control in mammography. All 60 of these hours shall be Category 1 and at least 16 of the Category 1 hours shall have been acquired within the last 36 months immediately prior to the date that the physician qualifies as an interpreting physician. Before beginning to independently interpret mammograms produced by a new mammographic modality in which the interpreting physician shall have at least 8 hours of training in the new mammographic modality.

(4) Has successfully completed or taught a minimum of 15 Category 1 hours of postgraduate instruction in mammography interpretation every 36 months thereafter. This training shall include at least 6 Category 1 continuing medical education credits in each mammographic modality used by the interpreting physician in practice. Credits earned through teaching a specific course can be counted only once towards the 15 required even if the course is taught multiple times during the previous 36 months.

(5) Continues to interpret or multi-read an average of ten or more mammograms per workweek 960 mammograms in 24 months.

(6) and (7) No change.

(8) Provides a written statement to the patient, either through a referring physician or designee or, if a referring

physician is not available, directly to the patient. The statement must:

1. to 3. No change.

4. Indicate that the original images of films are being provided to the mammographic supplier facility, for inclusion in the patient's medical record.

(9) Reestablishing qualifications.

1. Interpreting physicians who fail to maintain the required continuing interpreting experience or continuing education requirements of 41.6(3) "b" (5) shall reestablish their qualifications before resuming the independent interpretation of mammograms by:

• Interpreting or multi-reading at least 240 mammographic examinations under the direct supervision of an interpreting physician who meets the qualifications of these rules, or

• Interpreting or multi-reading a sufficient number of mammographic examinations, under the direct supervision of an interpreting physician who meets the qualifications of these rules, to bring the physician's total up to 960 examinations for the prior 24 months, whichever is less.

2. The interpretations required shall be done within the 6 months immediately prior to resuming independent interpretation.

3. Interpreting physicians who fail to meet the continuing education requirements of 41.6(3) "b"(4) shall obtain a sufficient number of additional Category 1 continuing medical education credits in mammography to bring their total up to the required 15 credits in the previous 36 months before resuming independent interpretation.

c. Mammography imaging medical physicist. All mammography imaging medical physicists conducting surveys of mammography facilities and providing oversight of the facility quality assurance program under the federal Mammography Quality Standards Act of 1992 (MQSA) shall meet the requirements for initial qualifications as well as the requirements for continuing qualifications.

(1) Initial qualifications. All mammography imaging medical physicists shall be state-approved of and be certified in diagnostic radiation physics or radiation physics by the American Board of Radiology in Radiological Physics/ Diagnostic Radiological Physics, the American Board of Medical Physics in Diagnostic Imaging Physics, or the Canadian College of Physicists in Medicine as a Fellow in Diagnostic Radiological Physics or any other body approved by FDA to certify medical physicists; and

1. Have a master's or higher degree in a physical science from a college or university accredited by one of the regional accreditation bodies of the Commission on Higher Education with not less than 30 20 semester hours or 30 quarter hours or equivalent of college level physics or radiation science, have two years of experience in conducting performance evaluations of mammography facilities, have experience in conducting surveys of at least one mammography facility and a total of at least ten mammography units (no more than one survey of a specific unit within a period of 60 days can be counted towards this requirement), and 20 contact hours of documented specialized training in conducting performance evaluations of mammography facilities. Complete surveys of five mammography units shall be equal to one year of experience. Two or more years of training while pursuing a master's or higher degree in medical physics may be accepted in lieu of one year of experience. After April 28, 1999, the experience shall be acquired under the direct supervision of a mammography imaging medical physicist who meets the requirements in 41.6(3) "c"(1) and 41.6(3) "c"(2), or

2. Prior to October 27, 1997, have a bachelor's degree in a physical science from a college or university accredited by one of the regional accreditation bodies of the Commission on Higher Education with not less than 15 semester hours or equivalent-college level physics or radiation sciences and five years of experience in conducting performance evaluations of mammography facilities. The individual shall have surveyed at least five mammography units in each of the five years and have at least 40 hours of documented specialized training in conducting performance evaluations of mammography facilities to comply with the requirements of MQSA.

2. Have a letter of approval from the FDA.

3. Before a medical physicist may begin independently performing mammographic surveys of a new mammographic modality other than one for which the physicist received initial training, the physicist must receive at least 8 hours of training in surveying units of the new mammographic modality.

4. Apply and receive approval from this agency.

(2) Continuing qualifications.

1. Continuing education. After the third anniversary of completion of the requirements of 41.6(3)"c"(1), the individual shall have taught or completed at least 15 continuing education units in mammographic imaging over the three previous years previous 36 months. This shall include training, if available, appropriate to each mammographic modality evaluated by the mammography imaging medical physicist during the surveys or oversights of quality assurance programs for which the medical physicist is responsible. Units earned through teaching a specific course can be counted only once towards the required 15 units in a 36-month period, even if the course is taught multiple times during the 36-month period.

2. Continuing experience. After the first anniversary of completion of the requirements of 41.6(3)"c"(1), and each year thereafter, the individual shall have surveyed at least three Iowa mammography units facilities within the last 12 months. No more than one survey of a specific facility within a 10-month period or a specific unit within a period of 60 days can be counted towards the total mammography unit survey requirement. This requirement does not apply to an individual who is employed full-time at a single facility as a diagnostic medical physicist.

(3) and (4) No change.

5) Mammography imaging medical physicists who fail to maintain the required continuing qualifications stated in 41.6(3)"c"(2) shall reestablish their qualifications before independently surveying another facility. To reestablish their qualifications, mammography imaging medical physicists who fail to meet the continuing education requirement of 41.6(3)"c"(2) must obtain a sufficient number of continuing education units to bring their total up to the required 15 in the previous three years. Mammography imaging medical physicists who fail to meet the continuing experience requirement of 41.6(3)"c"(1) must obtain experience by surveying one mammography unit for each year of not meeting the continuing experience requirements under the supervision of a mammography-imaging-medical-physicist who-meets-the qualifications stated in 41.6(3)"c"(1) and 41.6(3)"c"(2). After five years of not meeting the continuing experience requirements, the mammography imaging medical physicist must requalify under 41.6(3)"c"(1).

(5) Reestablishing qualifications. Medical physicists who fail to maintain the required continuing qualifications of this subrule shall obtain a sufficient number of continuing education units to bring their total units up to the required 15 in the previous 36 months. Those failing to meet the continuing experience requirements of this subrule must complete a sufficient number of surveys under the direct supervision of a medical physicist who meets the qualifications of this subrule to bring the total surveys up to the required three Iowa facilities in the previous 12 months. No more than one survey of a specific unit within a period of 60 days can be counted towards the total mammography unit survey requirement.

d. Equipment operators. Any individual operating mammography equipment must be a physician as defined in 641—Chapter 38 or must be credentialed as a general radiographer as set forth in 641—Chapter 42.

(1) Each general radiographer must meet one of the following:

1. No change.

2. Have successfully completed a formal training program in radiologic technology that is approved by the Council on Allied Health Education and Accreditation Joint Review Committee on Education on Radiologic Technology; or 3. No change.

(2) Each general radiographer must have completed successfully 40 hours of specialized training, approved by the agency, to include a minimum of one hour of hands-on mammographic positioning compression, quality assurance/control, technique factor settings, imaging of patients with breast implants, and other areas pertinent to mammography prior to the time the individual begins performing mammography. and an average of five hours of specialized training every 12 months thereafter to be averaged over no more than a 36-month period. Training shall include the performance of a minimum of 25 examinations under the direct supervision of an individual already qualified under this subrule and at least 8 hours of training in each mammography modality to be used by the technologist in performing mammography examinations.

Training programs shall be submitted to the agency for approval and shall include demonstrations and practical evaluation by the instructor of the student's performance and documentation describing training, date and length of training, and evaluation of student's performance to be signed and dated by the instructor, and the business address of the supplier of the training.

(3) Continuing education. Each general radiographer shall have completed or taught an average of 5 hours of specialized mammographic training every 12 months thereafter to be averaged over no more than a 36-month period. Units earned through teaching a specific course can be counted only once towards the 15 required hours even if the course is taught multiple times during the previous 36 months to a maximum of 7.5 hours. Beginning April 28, 1999, at least 6 of the continuing education hours shall be related to each mammographic modality used by the radiographer.

(4) Beginning April 28, 1999, each general radiographer shall have performed a minimum of 200 mammography examinations during each 24-month period thereafter.

(5) Requalification.

1. General radiographers who fail to meet the continuing education requirements of this subrule shall obtain a sufficient number of continuing education hours in mammography to bring their total up to at least 15 in the previous 36 months, at least 6 of which shall be related to each modality used by the radiographer. The general radiographer may not resume performing unsupervised mammography examinations until the continuing education requirements are completed.

2. General radiographers who fail to meet the continuing experience requirements of this subrule shall perform a minimum of 25 mammography examinations under the direct supervision of a qualified radiologic technologist before resuming the performance of unsupervised mammography examinations.

(6) Before a general radiographer may begin independently performing mammographic examinations using a mammographic modality other than the one for which the radiographer received training under this subrule, the radiographer shall have at least 8 hours of continuing education hours in the new modality.

e. No change.

f. Personnel records. Records must be maintained to indicate that each employee is qualified for a specific position by means of appropriate state or other certification, license, training, and experience. Records of personnel no longer employed by the facility should not be discarded until the next annual inspection has been completed and it has been determined that the facility is in compliance.

ITEM 69. Amend subrule 41.6(4) as follows:

41.6(4) Obtaining and preserving records.

a. No change.

b. The supplier must make, for each patient, a record of the mammography services it provides, including:

(1) The date the mammography procedure was performed, and the date of the interpretation, and the name of the interpreting physician.

(2) The name of the patient and an additional patient identifier.

(3) The name of the operator of the equipment and the interpreting physician.

(4) to (6) No change.

(7) The overall final assessment of findings, classified in one of the following categories:

1. "Negative": Nothing to comment upon (if the interpreting physician is aware of clinical findings or symptoms, despite the negative assessment, these shall be explained).

2. "Benign": Also a negative assessment.

3. "Probably benign": Finding(s) has a high probability of being benign.

4. "Suspicious": Finding(s) without all the characteristic morphology of breast cancer but indicating a definite probability of being malignant.

5. "Highly suggestive of malignancy": Finding(s) has a high probability of being malignant.

(8) In cases where no final assessment category can be assigned due to incomplete work-up, "Incomplete: Need additional imaging evaluation" shall be assigned as an assessment, and reasons why no assessment can be made shall be stated by the interpreting physician.

(9) Recommendations made to the health care provider about what additional actions, if any, should be taken. All clinical questions raised by the referring health care provider shall be addressed in the report to the extent possible, even if the assessment is negative or benign.

c. Preservation of records.

(1) and (2) No change.

(3) If the supplier should cease to exist before the end of the 60-month period, the records must be transferred to the patient or patient's physician or other mammographic facility.

(4) The supplier shall upon request by, or on behalf of, the patient, permanently or temporarily, transfer the original mammograms and copies of the patient's reports to a medical institution, or to a physician or health care provider of the patient, or to the patient directly.

(5) Any fee charged to the patients for providing the services in subparagraph (4) above shall not exceed the documented costs associated with this service.

d. Communication of results to the patient. Each facility shall maintain a system to ensure that the results of each mammographic examination are communicated to the patient in a timely manner. If assessments are "Suspicious" or "Highly suggestive of malignancy" and the patient has not named a health care provider, the facility shall make reasonable attempts to ensure that the results are communicated to the patient as soon as possible.

(1) As soon as possible, but no later than 30 days from the date of the mammography examination, patients who do not name a health care provider to receive the mammography report shall be sent the report described in 41.6(4) "e"(1) in addition to a written notification of results in lay terms.

(2) Each facility that accepts patients who do not have a primary care provider shall maintain a system for referring such patients to a health care provider when clinically indicated.

e. Communication of results to health care providers. When the patient has a referring health care provider or the patient has named a health care provider, the facility shall:

(1) Provide a written report of the mammography examination, including the items listed in 41.6(4) "b"(7), to the health care provider as soon as possible, but no later than 30 days from the date of the examination, and

(2) If the assessment is "Suspicious" or "Highly suggestive of malignancy," make reasonable attempts to communicate with the health care provider as soon as possible or, if the health care provider is unavailable, to a responsible designee of the health care provider.

f. Mammographic image identification. Each mammographic image shall have the following information indicated on it in a permanent, legible, and unambiguous manner and placed so as not to obscure anatomic structures:

(1) Name of patient and an additional patient identifier.

(2) Date of examination.

(3) View and laterality. This information shall be placed on the image in a position near the axilla. Standardized codes specified by the accreditation body and approved by FDA shall be used to identify view and laterality.

(4) Facility name and location. At a minimum, the location shall include the city, state, and ZIP code of the facility. (5) Technologist identification.

(6) Cassette/screen identification.

(7) Mammography unit identification, if there is more than one unit in the facility.

ITEM 70. Amend subrule 41.6(5), paragraphs "a" and "c," as follows:

a. The supplier shall ensure that the facility has an equipment quality assurance program specific to mammography and covering all components of the system, to ensure consistently high-quality images with minimum patient exposure. Responsibility for the quality assurance program and for each of its elements shall be assigned to individuals who are qualified for their assignments and who shall be allowed adequate time to perform these duties.

(1) Lead interpreting physician. The facility shall identify a lead interpreting physician who shall have the general responsibility of ensuring that the quality assurance program meets all requirements of these rules. No other individual shall be assigned or shall retain responsibility for quality assurance tasks unless the lead interpreting physician has determined that the individual's qualifications for, and performance of, the assignment are adequate.

(2) Interpreting physicians. All interpreting physicians interpreting mammograms for the facility shall:

1. Follow the facility procedures for corrective action when the images they are asked to interpret are of poor quality, and

2. Participate in the facility's medical outcomes audit program.

(3) Medical physicist. Each facility shall have the services of a medical physicist available to survey mammography equipment and oversee the equipment-related quality assurance practices of the facility. At a minimum, the medical physicist(s) shall be responsible for performing the surveys and mammography equipment evaluations and providing the facility with the applicable reports.

(4) Quality control technologist. Responsibility for all individual tasks within the quality assurance program not assigned to the lead interpreting physician or the medical physicist shall be assigned to a quality control technologist(s). The tasks are to be performed by the quality control technologist or by other personnel qualified to perform the tasks. When other personnel are utilized for these tasks, the quality control technologist shall ensure that the tasks are completed in such a way as to meet the requirements of 41.6(5) "e" through "k."

c. Under the direction of the *lead interpreting* physician consultant, the radiation physicist shall have responsibility for establishing and conducting the equipment quality assurance program. The program shall include:

(1) to (3) No change.

ITEM 71. Amend subrule **41.6(5)**, paragraph **"h,"** as follows:

h. Retake analysis program.

(1) A program shall be established as a further aid in detecting and correcting problems affecting image quality or exposure.

(2) All retakes shall be logged including date, technologist's name and reason for retake. A retake analysis shall be performed every 250 patients or quarterly, whichever comes first.

(3) If the total repeat or reject rate changes from the previously determined rate by more than 2.0 percent of the total films included in the analysis, the reason(s) for the change shall be determined. Any corrective actions shall be recorded and the results of these corrective actions shall be assessed.

ITEM 72. Amend subrule **41.6(5)** as follows:

Amend paragraph "i" as follows:

i. Medical outcomes audit. Each facility shall establish a system for reviewing outcome data from all mammography performed, including follow-up on the disposition of positive mammograms and correlation of surgical biopsy results with mammogram reports the interpreting physician's findings. This program shall be designed to ensure the reliability, clarity, and accuracy of the interpretation of mammograms.

(1) Analysis of these outcome data shall be made individually and collectively for all interpreting physicians at the facility. In addition, any cases of breast cancer among women imaged at the facility that subsequently become known to the facility shall prompt the facility to initiate

follow-up on surgical or pathology results, or both, and review of the mammograms taken prior to the diagnosis of a malignancy. Responsibility for each requirement for monitoring shall be assigned to qualified personnel and documented in the supplier's records.

(2) Frequency of audit analysis. The facility's first audit analysis shall be initiated no later than 12 months after the date the facility becomes certified, or 12 months after April 28, 1999, whichever date is the latest. This audit analysis shall be completed within an additional 12 months to permit completion of diagnostic procedures and data collection. Subsequent audit analyses will be conducted at least once every 12 months.

(3) Reviewing interpreting physician. Each facility shall designate at least one interpreting physician to review the medical outcomes audit data at least once every 12 months. This individual shall record the dates of the audit period(s) and shall be responsible for analyzing results based on this audit. This individual shall also be responsible for documenting the results, notifying other interpreting physicians of their results and the facility aggregate results. If follow-up actions are taken, the reviewing interpreting physician shall also be responsible for documenting the responsible for documenting the nature of the follow-up.

Rescind paragraph "j" and adopt the following <u>new</u> paragraph in lieu thereof:

j. Quality assurance records. The lead interpreting physician, quality control technologist, and medical physicist shall ensure that records concerning employee qualifications to meet assigned quality assurance tasks, mammography technique and procedures, quality control (including monitoring data, problems detected by analysis of that data, corrective actions, and the effectiveness of the corrective actions), safety, and protection are properly maintained and updated. These quality control records shall be kept for each test specified in these rules until the next annual inspection has been completed and the facility is in compliance with the quality assurance requirements or until the test has been performed two additional times at the required frequency, whichever is longer.

Adopt new paragraphs "k" to "o" as follows:

k. Quality assurance-equipment.

(1) Daily quality control tests. Film processors used to develop mammograms shall be adjusted and maintained to meet the technical development specifications for the mammography film in use. A processor performance test shall be performed on each day that examinations are performed before any clinical films are processed that day. The test shall include an assessment of base plus fog density, mid-density, and density difference, using the mammography film used clinically at the facility.

1. The base plus fog density shall be within plus or minus 0.03 of the established operating level.

2. The mid-density shall be within plus or minus 0.15 of the established operating level.

3. The density difference shall be within plus or minus 0.15 of the established operating level.

(2) Weekly quality control tests. Facilities with screenfilm systems shall perform an image quality evaluation test, using an FDA-approved phantom, at least weekly.

1. The optical density of the film at the center of an image of a standard FDA-accepted phantom shall be at least 1.20 when exposed under a typical clinical condition.

2. The optical density of the film at the center of the phantom image shall not change by more than plus or minus 0.20 from the established operating level.

3. The phantom image shall achieve at least the minimum score established by the accreditation body and accepted by FDA.

4. The density difference between the background of the phantom and an added test object used to assess image contrast shall be measured and shall not vary by more than plus or minus 0.05 from the established operating level.

(3) Quarterly quality control tests. Facilities with screenfilm systems shall perform the following quality control tests at least quarterly:

• Fixer retention in film. The residual fixer shall be no more than 5 micrograms per square centimeter.

(4) Semiannual quality control tests. Facilities with screen-film systems shall perform the following quality control tests at least semiannually:

1. Darkroom fog. The optical density attributable to darkroom fog shall not exceed 0.05 when a mammography film of the type used in the facility, which has a mid-density of no less than 1.2 OD, is exposed to typical darkroom conditions for two minutes while such film is placed on the countertop emulsion side up. If the darkroom has a safelight used for mammography film, it shall be on during this test.

2. Screen-film contact. Testing for screen-film contact shall be conducted using 40 mesh copper screen. All cassettes used in the facility for mammography shall be tested.

3. Compression device performance. A compression force of at least 25 pounds (111 newtons) for 15 seconds shall be provided. Effective October 28, 2002, the maximum compression force for the initial power drive shall be between 25 pounds (111 newtons) and 47 pounds (209 newtons).

(5) Annual quality control tests. Facilities with screenfilm systems shall perform the following quality control tests at least annually:

1. Automatic exposure control (AEC) performance.

The AEC shall be capable of maintaining film optical density within plus or minus 0.30 of the mean optical density when thickness of a homogeneous material is varied over a range of 2 to 6 centimeters and the kVp is varied appropriately for such thicknesses over the kVp range used clinically in the facility. If this requirement cannot be met, a technique chart shall be developed showing appropriate techniques (kVp and density control settings) for different breast thicknesses and compositions that must be used so that optical densities within plus or minus 0.30 of the average under phototimed conditions can be produced.
 After October 28, 2002, the AEC shall be capable of

• After October 28, 2002, the AEC shall be capable of maintaining film optical density (OD) within plus or minus 0.15 of the mean optical density when thickness of a homogenous material is varied over a range of 2 to 6 centimeters and the kVp is varied appropriately for such thicknesses over the kVp range used clinically in the facility.

• The optical density of the film in the center of the phantom image shall not be less than 1.20.

2. kVp accuracy and reproducibility.

• The kVp shall be accurate within plus or minus 5 percent of the indicated or selected kVp at the lowest clinical kVp that can be measured by a kVp test device, the most commonly used clinical kVp, and the highest available clinical kVp.

• At the most commonly used clinical settings of kVp, the coefficient of variation of reproducibility of the kVp shall be equal to or less than 0.02.

3. Focal spot condition. Until October 28, 2002, focal spot condition shall be evaluated either by determining system resolution or by measuring focal spot dimensions. On

and after October 28, 2002, facilities shall evaluate focal spot condition only by determining the system resolution.

• Each X-ray system used for mammography, in combination with the mammography screen-film combination used in the facility, shall provide a minimum resolution of 11 cycles/millimeters (mm) (line-pairs/mm) when a high contrast resolution bar test pattern is oriented with the bars perpendicular to the anode-cathode axis, and a minimum resolution of 13 line-pairs/mm when the bars are parallel to that axis.

• The bar pattern shall be placed 4.5 centimeters above the breast support surface, centered with respect to the chest wall edge of the image receptor, and with the edge of the pattern within 1 centimeter of the chest wall edge of the image receptor.

• When more than one target material is provided, the measurement above shall be made using the appropriate focal spot for each target material.

• When more than one SID is provided, the test shall be performed at the SID most commonly used clinically.

• Test kVp shall be set at the value used clinically by the facility for a standard breast and shall be performed in the AEC mode, if available. If necessary, a suitable absorber may be placed in the beam to increase exposure times. The screen-film cassette combination used by the facility shall be used to test for this requirement and shall be placed in the normal location used for clinical procedures.

• Focal spot dimensions. Measured values of the focal spot length (dimension parallel to the anode-cathode axis) and width (dimension perpendicular to the anode-cathode axis) shall be within tolerance limits specified in Table 1.

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Focal Spot Tolerance Limit Nominal Focal Spot Size (mm)	Maximum Measured Dimensions Width (mm)	Length (mm)
0.10	0.15	0.15
0.15	0.23	0.23
0.20	0.30	0.30
0.30	0.45	0.65
0.40	0.60	0.85
0.60	0.90	1.30

4. Beam quality and half-value layer (HVL). The HVL shall meet the specification of 41.1(4) and 41.1(6) for the minimum HVL. These values, extrapolated to the mammographic range, are shown in Table 2. Values not shown in Table 2 may be determined by linear interpolation or extrapolation.

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X-ray Tube Voltage (kilovolt peak) and Minimum HVL Designed Operating Range (kV) Below 50		
Measured Operating Voltage (kV)	Minimum HVL (millimeters of aluminum)	
20	0.20	
25	0.25	
30	0.30	

5. Breast entrance air kerma and AEC reproducibility. The coefficient of variation for both air kerma and mAs shall not exceed 0.05.

6. Dosimetry. The average glandular dose delivered during a single cranio-caudal view of an FDA-accepted phantom simulating a standard breast shall not exceed 0.3

rad (3.0 milligray (mGy)) per exposure. The dose shall be determined with technique factors and conditions used clinically for a standard breast.

7. X-ray field/light field/image receptor/compression paddle alignment.

• All systems shall have beam-limiting devices that allow the useful X-ray beam to extend to or beyond the edges of the image receptor but by no more than 2 percent of the SID at the chest wall side.

• If a light field that passes through the X-ray beam limitation device is provided, it shall be aligned with the X-ray field so that the total of any misalignment of the edges of the light field and the X-ray field along either the length or the width of the visually defined field at the plane of the breast support surface shall not exceed 2 percent of the SID.

• The chest wall edge of the compression paddle shall not extend beyond the chest wall edge of the image receptor by more than 1 percent of the SID when tested with the compression paddle placed above the breast support surface at a distance equivalent to standard breast thickness. The shadow of the vertical edge of the compression paddle shall be not be visible on the image.

8. Uniformity of screen speed. Uniformity of screen speed of all the cassettes in the facility shall be tested and the difference between the maximum and minimum optical densities shall not exceed 0.30. Screen artifacts shall also be evaluated during this test.

9. System artifacts. System artifacts shall be evaluated with a high-grade, defect-free sheet of homogeneous material large enough to cover the mammography cassette and shall be performed for all cassette sizes used in the facility using a grid appropriate for the cassette size being tested. System artifacts shall also be evaluated for all available focal spot sizes and target filter combinations used clinically.

10. Radiation output.

• The system shall be capable of producing a minimum output of 513 milliRoentgen (mR) per second (4.5 mGy air kerma per second) when operating at 28 kVp in the standard mammography (moly/moly) mode at any SID where the system is designed to operate and when measured by a detector with its center located 4.5 centimeters above the breast support surface with the compression paddle in place between the source and the detector. After October 28, 2002, the system, under the same measuring conditions, shall be capable of producing a minimum output of 800 mR per second (7.0 mGy air kerma per second) when operating at 28 kVp in the standard (moly/moly) mammography mode at any SID where the system is designed to operate.

• The system shall be capable of maintaining the required minimum radiation output averaged over a 3.0 second period.

11. Decompression. If the system is equipped with a provision for automatic decompression after completion of an exposure or interruption of power to the system, the system shall be tested to confirm that it provides:

• An override capability to allow maintenance of compression;

• A continuous display of the override status; and

• A manual emergency compression release that can be activated in the event of power or automatic release failure.

(6) Quality control tests—other modalities. For systems with image receptor modalities other than screen-film, the quality assurance program shall be substantially the same as the quality assurance program recommended by the image receptor manufacturer, except that the maximum allowable dose shall not exceed the maximum allowable dose for screen-film systems in 41.6(5)"k"(6).

(7) Mobile units. The facility shall verify that mammography units used to produce mammograms at more than one location meet the requirements in 41.6(5)"k." In addition, at each examination location, before any examinations are conducted, the facility shall verify satisfactory performance of such units using a test method that establishes the adequacy of the image quality produced by the unit.

(8) Use of test results.

1. After completion of the tests specified in 41.6(5)"k," the facility shall compare the test results to the corresponding specified action limits; or, for non-screen-film modalities, to the manufacturer's recommended action limits; or, for postmove, preexamination testing of mobile units, to the limits established in the test method used by the facility.

2. If the test results fall outside of the action limits, the source of the problem shall be identified, and corrective actions shall be taken:

• Before any further examinations are performed or any films are processed using the component of the mammography system that failed the test, if the failed test was that described in 41.6(5)"k"(1) through (7);

• Within 30 days of the test date for all other tests described in 41.6(5)"k."

(9) Surveys.

1. At least once a year, each facility shall undergo a survey by a medical physicist or by an individual under the direct supervision of a medical physicist. At a minimum, this survey shall include the performance of tests to ensure that the facility meets the quality assurance requirements of the annual tests described in 41.6(5)"k"(5) and (6) and the weekly phantom image quality test described in 41.6(5)"k"(2).

2. The results of all tests conducted by the facility in accordance with 41.6(5)"k"(1) through (7), as well as written documentation of any corrective actions taken and their results, shall be evaluated for adequacy by the medical physicist performing the survey.

3. The medical physicist shall prepare a survey report that includes a summary of this review and recommendations for necessary improvements.

4. The survey report shall be sent to the facility within 30 days of the date of the survey.

5. The survey report shall be dated and signed by the medical physicist performing or supervising the survey. If the survey was performed entirely or in part by another individual under the direct supervision of the medical physicist, that individual and the part of the survey that individual performed shall also be identified in the survey report.

(10) Mammography equipment evaluations. Additional evaluations of mammography units or image processors shall be conducted whenever a new unit or processor is installed, a unit or processor is disassembled and reassembled at the same or a new location, or major components of a mammography unit or processor equipment are changed or repaired. These evaluations shall be used to determine whether the new or changed equipment meets the requirements of applicable standards in 41.6(5). All problems shall be corrected before the new or changed equipment is put into service for examinations or film processing. The mammography equipment evaluation shall be performed by a medical physicist or by an individual under the direct supervision of an Iowa-approved medical physicist.

(11) Facility cleanliness.

1. The facility shall establish and implement adequate protocols for maintaining darkroom, screen, and viewbox cleanliness.

2. The facility shall document that all cleaning procedures are performed at the frequencies specified in the protocols.

(12) Calibration of air kerma measuring instruments. Instruments used by medical physicists in their annual survey to measure the air kerma or air kerma rate from a mammography unit shall be calibrated at least once every two years and each time the instrument is repaired. The instrument calibration must be traceable to a national standard and calibrated with an accuracy of plus or minus 6 percent (95 percent confidence level) in the mammography energy range.

(13) Infection control. Facilities shall establish and comply with a system specifying procedures to be followed by the facility for cleaning and disinfecting mammography equipment after contact with blood or other potentially infectious materials. This system shall specify the methods for documenting facility compliance with the infection control procedures established and shall:

1. Comply with all applicable federal, state, and local regulations pertaining to infection control; and

2. Comply with the manufacturer's recommended procedures for the cleaning and disinfecting of the mammography equipment used in the facility; or

3. If adequate manufacturer's recommendations are not available, comply with generally accepted guidance on infection control, until such recommendations become available.

I. Mammography procedures and techniques for mammography of patients with breast implants.

(1) Each facility shall have a procedure to inquire whether or not the patient has breast implants prior to the actual mammographic examination.

(2) Except where contraindicated, or unless modified by a physician's directions, patients with breast implants undergoing mammography shall have mammographic views to maximize the visualization of breast tissue.

m. Consumer complaint mechanism. Each facility shall: (1) Establish a written and documented system for collecting and resolving consumer complaints;

(2) Maintain a record of each serious complaint received by the facility for at least three years from the date the complaint was received;

(3) Provide the consumer with adequate directions for filing serious complaints with the facility's accreditation body and any other appropriate regulatory entity if the facility is unable to resolve a serious complaint to the consumer's satisfaction.

(4) Report unresolved serious complaints to the accreditation body in a manner and time frame specified by the accreditation body.

n. Clinical image quality. Clinical images produced by any certified facility must continue to comply with the standards for clinical image quality established by that facility's accreditation body.

o. Additional mammography review and patient notification.

(1) If the agency believes that mammography quality at a facility has been compromised and may present a serious risk to human health, the facility shall provide clinical images and other relevant information, as specified by the agency, for review by the accreditation body or other entity designated by the agency. This additional mammography review will help the agency to determine whether the facility is in compliance with rule 641—41.6(136C) and, if not, whether there is a need to notify affected patients, their physicians, or

the public that the reliability, clarity, and accuracy of interpretation of mammograms has been compromised.

(2) If the agency determines that any activity related to the provision of mammography at a facility may present a serious risk to human health such that patient notification is necessary, the facility shall notify patients or their designees, their physicians, or the public of action that may be taken to minimize the effects of the risk. Such notification shall occur within a time frame and a manner specified by the agency.

ITEM 73. Amend subrule 41.6(6) as follows:

41.6(6) Equipment standards. The equipment used to perform mammography shall meet the following standards:

a. Be specifically designed for mammography. This prohibits systems that have been modified or equipped with special attachments for mammography.

b. Meet the Food and Drug Administration (FDA) performance standards for diagnostic X-ray systems and their major components found in 21 CFR 1020.30 and FDA standards for radiographic equipment in 21 CFR 1020.31 641— 41.1(136C).

c. Have image receptor systems and individual components which are appropriate for mammography and used according to the manufacturer's recommendations.

(1) Systems using screen-film image receptors shall provide, at a minimum, for operation for image receptors of 18×24 centimeters and 24×30 centimeters.

(2) Systems using screen-film image receptors shall be equipped with moving grids matched to all image receptor sizes provided.

(3) Systems used for magnification procedures shall be capable of operation with the grid removed from between the source and image receptor.

d. Have beam limitation which limits the useful beam so 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 source to image receptor distance (SID). However, the X-ray field may extend beyond the edge of the image receptor which is adjacent to the chest wall provided it does not extend beyond this edge by more than 2 percent of the SID.

d. Have beam-limiting devices that allow the useful beam to extend to or beyond the chest wall edge of the image receptor. For any system with a light beam that passes through the X-ray beam-limiting device, the light shall provide an average illumination of not less than 160 lux (15 foot candles) at 100 centimeters or the maximum source-image receptor distance (SID), whichever is less.

e. Magnification:

(1) Systems used to perform noninterventional problemsolving procedures shall have radiographic magnification capability available for use by the operator.

(2) Systems used for magnification procedures shall provide, at a minimum, at least one magnification value within the range of 1.4 to 2.0.

e f. Check Shall check film/screen contact when cassettes are first placed into use and semiannually thereafter.

f.—Have limits to provide kV-target-filter combinations appropriate for the image receptors which have met the requirements of 41.6(6)"c."

g. The focal spot size, magnification factor and source to image receptor distance (SID) are appropriate for mammography and in the ranges shown below:

SID	Nominal Focal Spot Size
> 65 cm	< or = to 0.6 mm

cm	< or $=$ to	0.6 mm

50 to 65 cm	< or = to 0.5 mm
< or = to 50 cm	< or = to 0.4 mm

(1) When more than one focal spot is provided, the system shall indicate, prior to exposure, which focal spot is selected.

(2) When more than one target material is provided, the system shall indicate, prior to exposure, the preselected target material.

(3) When the target material or focal spot, or both, is selected by a system algorithm that is based on the exposure or on a test exposure, the system shall display, after the exposure, the target material or focal spot, or both, actually used during the exposure.

h. Devices Shall have compression devices parallel to the imaging plane shall be available and able to immobilize and compress the breast with a force of at least 25 pounds per square inch and shall be capable of maintaining this compression for at least three seconds. Effective October 28, 2002, each system shall provide:

(1) An initial power-driven compression activated by hands-free controls operable from both sides of the patient; and

(2) Fine adjustment compression controls operable from both sides of the patient.

(3) Systems shall be equipped with different sized compression paddles that match the sizes of all full field image receptors provided for the system. Compression paddles for special purposes, including those smaller than the full size of the image receptor (for "spot compression"), may be provided. Such compression paddles for special purposes are not subject to 41.6(6) "h"(6) and (7).

(4) Except as provided in 41.6(6) "h" (5), the compression paddle shall be flat and parallel to the breast support table and shall not deflect from parallel by more than 1.0 cm at any point on the surface of the compression paddle when compression is applied.

(5) Equipment intended by the manufacturer's design not to be flat and parallel to the breast support table during compression shall meet the manufacturer's design specifications and maintenance requirements.

(6) The chest wall edge of the compression paddle shall be straight and parallel to the edge of the image receptor.

(7) The chest wall edge may be bent upward to allow for patient comfort but shall not appear on the image.

i. Shall have the capability for using antiscatter grids. j. Shall have the capability of automatic exposure control.

j. Shall have automatic exposure control such that:

(1) Each screen-film system shall provide an AEC mode that is operable in all combinations of equipment configuration provided, e.g., grid, nongrid; magnification, nonmagnification; and various target-filter combinations.

(2) The positioning or selection of the detector shall permit flexibility in the placement of the detector under the target tissue.

• The size and available positions of the detector shall be clearly indicated at the X-ray input surface of the breast compression paddle.

• The selected position of the detector shall be clearly indicated.

(3) The system shall provide means for the operator to vary the selected optical density from the normal (zero) setting.

k. Shall have a control panel that:

(1) Gives a positive indication when X-rays are being produced.

(2) Gives an audible signal indicating termination of exposure.

(3) Includes labeled control settings or appropriate indications that show the physical factors used for exposure such as kilovoltage potential (kVp), milliampere seconds (mAs), exposure time, and whether exposure termination is automatic.

(3) Has manual selection of milliampere seconds (mAs) or at least one of its component parts (milliampere (mA) or time, or both).

(4) Has the technique factors (peak tube potential in kilovolts (kV) and either tube current in mA and exposure time in seconds or the product of tube current and exposure time in mAs) to be used during an exposure indicated before the exposure begins, except when AEC is used, in which case the technique factors that are set prior to the exposure shall be indicated.

(5) Has a system that, following AEC mode use, shall indicate the actual kilovoltage peak (kVp) and mAs used during the exposure. The mAs may be displayed as mA and time.

1. Shall indicate, or provide a means of determining, the mAs resulting from each exposure made with automatic exposure control.

m. The viewbox shall be Shall have a viewbox that is checked periodically to ensure optimal conditions. When the mammogram is placed on the viewbox, the area surrounding the film must be masked to exclude extraneous light which may reduce image contrast.

n. Mobile units and vans.

(1) A phantom image shall be made and processed after each relocation.

(2) If processing is not available, a check of the radiation output shall be made.

Equipment shall be recalibrated as necessary to maintain quality of phantom image.

n. Shall use X-ray film that has been designated by the film manufacturer as appropriate for mammography and that is matched to the screen's spectral output as specified by the manufacturer.

o. Shall use intensifying screens that have been designated by the screen manufacturer as appropriate for mammography.

p. Shall use chemical solutions for processing mammography films that are capable of developing the films in a manner equivalent to the minimum requirements specified by the film manufacturer.

q. Shall make special lights for film illumination, i.e., hot-lights, capable of producing light levels greater than that provided by the viewbox, available to the interpreting physicians.

r. Shall ensure that film masking devices that can limit the illuminated area to a region equal to or smaller than the exposed portion of the film are available to all interpreting physicians interpreting for the facility.

s. For mobile units and vans.

(1) A phantom image shall be produced, processed, and evaluated after each relocation.

(2) If processing is not available, a check of the radiation output shall be made and compared to a preset standard for quality. Equipment shall be recalibrated as necessary to maintain quality of phantom image.

ITEM 74. Amend rule 641—41.6(136C), Appendix I, as follows:

RULE 41.6(136C)—APPENDIX I

Normally, the frequency of monitoring for each of the following should be no longer than the values given on the following table. The standards of image quality are also given on the table. The surveyor is expected to measure phantom image quality and calculate dose from a measured exposure to confirm that the guidelines meet the desired standards of image quality. The surveyor will determine if the other standards are met by checking the supplier's monitoring records.

<u>ITEMS</u>	FREQUENCY	STANDARDS OF IMAGE QUALITY
Processor	Daily	Mid-density step and density difference (contrast) < ± 0.1 OD of the optimized operating level and base + fog deviation ≤ 0.03 OD
HVL	Annually	Meas. HVL with compression device in field \geq (kVp/100) mm Al and < (kVp/100 + 0.1 mm Al)
Output reproducibility	*Quarterly	Coefficient of variation ≤ 0.05 with 4 exposures at the same technique
Output linearity	*Quarterly	mR/mAs values at any two consecutive tube current settings should not vary more than 0.1 times their sum.
Automatic exposure control reproducibility	Annually	The phantom used for measurements related to this and the two following automatic control parameters should be either acrylic or BR-12 and consist of at least three 2-cm-thick slabs to provide thicknesses of 2 cm, 4 cm, and 6 cm (each having linear dimensions of at least 8×10 cm). When a fixed kVp is used to produce four images of the 4-cm-thick phantom, the maximum value for the coefficient of variation for exposure at the center of the image should be ≤ 0.05 .
kVp response of automatic exposure	Annually	Film density maintained to ± 0.3 OD of the average optical density at the center of an exposure control phantom image over the range of kVp used in the facility. To obtain the average, at least four phantom images should be made, one each with the highest and lowest kVps commonly used in the facility and the other two at intermediate values.

<u>ITEMS</u>	FREQUENCY	STANDARDS OF IMAGE QUALITY
Thickness response of automatic exposure control	Annually	Film density maintained to ± 0.3 OD of the average optical density at the center of a phantom image at each kVp commonly used in the facility. To obtain the average, images with phantom thickness of at least 2 cm, 4 cm, and 6 cm should be used.
Adequacy of unexposed film storage	Quarterly	Increase in base + fog density over storage time maintained to < 0.02 OD
Availability and use of technique charts	Monthly	Ensure that charts are available and used
kVp/target/filter combination	Daily	Must be unchanged from that indicated on the technique charts
Darkroom integrity	Clean Daily Fog measured when bulbs or filter changed and semiannually	Minimum dust particles on film. Fog not greater than 0.05 OD with 2-minute test
Phantom image quality	At least monthly weekly	Phantom image scores not less than required ACR MAP (currently specified only using RMI phantoms) and that should not decrease more than one in any category between consecutive tests. Also, they should not have decreased by more than one in any category from the initial baseline phantom image.
Dose	Annually	See Appendix II

*If the supplier can document that the item has remained within limits for at least three consecutive monitoring periods, it may use a longer monitoring interval for any parameters except processor performance and phantom image quality. The period should not be longer than one year in any case. If during the longer monitoring interval the test results fall outside the "Standards of Image Quality" criteria, then the test frequency must revert to the original intervals for at least three consecutive quarters.

ITEM 75. Amend subrule 41.7(1) as follows:

41.7(1) Definitions. In addition to the definitions provided in rule 641-38.2(136C), 641-40.2(136C), and 641-41.1(136C), the following definitions are applicable to this rule.

ITEM 76. Amend 641—Chapter 41, Appendix B, "3," as follows:

3. <u>X-ray control placement</u>:

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 point subject to direct scatter, leakage or primary beam radiation.(b) Shall allow the operator to use the majority of the

available viewing windows or mirrors.

ITEM 77. Amend subrule **42.2(2)** by adopting <u>new</u> paragraph "f" as follows:

f. Performing procedures not allowed under the individual's current certification.

ITEM 78. Amend subparagraph 42.3(1)"a"(7) as follows:

(7) Clinical experience sufficient to demonstrate competency in the application of the above as specified in the revised 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. "Standards for an Accredited Education Program in Radiologic Sciences" as adopted by the Joint Review Committee on Education on Radiologic Technology.

ITEM 79. Amend subrule **45.1(2)** as follows:

Adopt the following <u>new</u> definitions in alphabetical order: "Annual refresher safety training" means a review conducted or provided by the licensee for its employees on radiation safety aspects of industrial radiography. The review may include, as appropriate, the results of internal inspections, new procedures or equipment, new or revised regulations, accidents or errors that have been observed, and should also provide opportunities for employees to ask safety questions.

"Associated equipment" means equipment that is used in conjunction with a radiographic exposure device to make radiographic exposures that drives, guides, or comes in contact with the source, e.g., guide tube, control tube, control (drive) cable, removable source stop, "J" tube and collimator when it is used as an exposure head.

"Certifying entity" means an independent certifying organization meeting the requirements in Appendix E of this chapter or Agreement State meeting the requirements of Appendix E or the requirements of Appendix A in 10 CFR Part 34.

"Control (drive) cable" means the cable that is connected to the source assembly and used to drive the source to and from the exposure location.

"Control drive mechanism" means a device that enables the source assembly to be moved to and from the exposure device.

"Control tube" means a protective sheath for guiding the control cable. The control tube connects the control drive mechanism to the radiographic exposure device.

"Exposure head" means a device that locates the gamma radiography sealed source in the selected working position. (An exposure head is also known as a source stop.)

"Field station" means a facility where licensed material may be stored or used and from which equipment is dispatched.

"Guide tube (projection sheath)" means a flexible or rigid tube (i.e., "J" tube) for guiding the source assembly and the attached control cable from the exposure device to the exposure head. The guide tube may also include the connections necessary for attachment to the exposure device and to the exposure head.

"Hands-on experience" means experience in all of those areas considered to be directly involved in the radiography process.

"Independent certifying organization" means an independent organization that meets all of the criteria of Appendix E to this chapter.

"Permanent radiographic installation" means an enclosed shielded room, cell, or vault, not located at a temporary job site, in which radiography is performed.

"Practical examination" means a demonstration through practical application of the safety rules and principles in industrial radiography including use of all appropriate equipment and procedures.

"Radiographer certification" means written approval received from a certifying entity stating that an individual has satisfactorily met certain established radiation safety, testing, and experience criteria.

"Radiographic operations" means all activities associated with the presence of radioactive sources in a radiographic exposure device during use of the device or transport (except when being transported by a common or contract transport), to include surveys to confirm the adequacy of boundaries, setting up equipment and any activity inside restricted area boundaries.

"S-tube" means a tube through which the radioactive source travels when inside a radiographic exposure device.

Amend the following definitions:

"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 source changer where the sealed source is secured and restricted from movement.

"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) an assembly that consists of the sealed source and a connector that attaches the source to the control cable. The source assembly may also include a stop ball used to secure the source in the shielded position.

ITEM 80. Amend subrule **45.1(5)**, paragraph "c," as follows:

c. Records of these calibrations shall be maintained for two three years after the calibration date for inspection by the agency.

ITEM 81. Amend subrule 45.1(7) as follows:

45.1(7) Utilization logs.

a. Each licensee or registrant shall maintain current logs of the use of each *sealed* source of radiation. The logs shall include:

(1) A unique identification, such as which includes the make, model and a serial number of each radiation machine, of each radiographic exposure device containing a sealed source, and each sealed source;

(2) The identity of the radiographer using the *sealed* source of radiation;

(3) Locations where each *sealed* source of radiation is used; and

(4) The date(s) each *sealed* source of radiation is removed from storage and returned to storage. For fixed installations, the date(s) each source of radiation is energized or used and the number of exposures made.

b. Each registrant shall maintain current logs of the use of each source of radiation. The logs shall include:

(1) A unique identification, which includes the make, model and serial number of each source of radiation;

(2) The identity of the radiographer using the source of radiation;

(3) The date(s) each source of radiation is energized or used and the number of exposures made.

b c. 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 three years from the date of the recorded event. The records shall be kept at the location specified by the license or certificate of registration.

ITEM 82. Amend subrule **45.1(9)**, paragraph **"b,"** as follows:

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 three years from the date of the event.

ITEM 83. Rescind 45.1(10)"b"(1)"2" and adopt the following <u>new</u> numbered paragraph "2" in lieu thereof:

2. Has completed on-the-job training as a radiographic trainee supervised by one or more radiographic trainers. The on-the-job training shall be documented on the appropriate agency form or equivalent and shall include a minimum of two months (320 hours) of active participation in the performance of industrial radiography utilizing radioactive material or one month (160 hours) of active participation in the performance of industrial radiography utilizing radiation machines, or both. Individuals performing industrial radiography utilizing radioactive materials and radiation machines must complete both segments of the on-the-job training (three months or 480 hours). Active participation does not include safety meetings or classroom training;

ITEM 84. Amend subrule **45.1(10)**, paragraph "d," introductory paragraph, as follows:

d. Radiation safety officer. 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 program.

ITEM 85. Amend 45.1(10)"g"(1)"1" as follows:

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 an equivalent exam examination. Certification by a certifying entity in accordance with 10 CFR 34.43(a)(1) meets the examination requirements of 45.1(10) "f"(2) but not the requirements of 45.1(10) "f"(2).

ITEM 86. Rescind subrule 45.1(11) and adopt the following <u>new</u> subrule in lieu thereof:

45.1(11) Internal audits. Except as provided in 45.1(11)"c," the RSO or designee shall conduct an inspection program of the job performance of each radiographer and radiographer trainee to ensure that these rules, license requirements, and the licensee's or registrant's operating and

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emergency procedures are followed. The inspection program must:

a. Include observation of the performance of each radiographer and radiographer trainee during an actual industrial radiographic operation, at intervals not to exceed six months; and

b. Provide that, if a radiographer or radiographer trainee has not participated in an industrial radiographic operation for more than six months since the last audit, the radiographer or radiographer trainee must demonstrate understanding of the subjects contained in Appendix A of this chapter by a practical examination before these individuals can next participate in a radiographic operation.

c. The agency may consider alternatives in those situations where the individual serves as both radiographer and RSO.

d. Records of audits shall be maintained by the licensee or registrant for agency inspection for three years from the date of the audit.

ITEM 87. Amend paragraph 45.1(12)"b" as follows:

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 at all times during radiographic operations the each individual wears, on the trunk of the body, a combination of a direct-reading pocket dosimeter, an operating alarm ratemeter, and either a film badge, an optically stimulated device (OSD) or a thermoluminescent 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 or *electronic personal dosimeters* shall meet the criteria in ANSI N322-1977 and shall have a range of zero to at least 200 milliRoentgens.

(3) Pocket dosimeters or *electronic personal dosimeters* shall be recharged at the start of each work shift.

(4) Pocket dosimeters or *electronic personal 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"), or if the electronic personal dosimeter reads greater than 200 millirem (2 millisievert), and the possibility of radiation exposure cannot be ruled out as the cause, industrial radiographic operations by that individual shall cease and the individual's film badge or TLD shall be within 24 hours sent for processing. The individual shall not return to work with sources of radiation until a determination of the radiation exposure has been made. This determination must be made by the RSO or the RSO's designee. The results of this determination must be included in the exposure records maintained in accordance with 641—Chapter 40.

(6) Each film badge, OSD or TLD shall be assigned to and worn by only one individual.

(7) Film badges, OSDs and TLDs must be replaced at least monthly. After replacement, each film badge, OSD 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, OSD or TLD is lost or damaged, the worker shall cease work immediately until a replacement film badge, OSD or TLD is provided and the exposure is calculated for the time period from issuance to loss or damage of the film badge, OSD or TLD.

ITEM 88. Amend subrule 45.1(13) as follows:

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. *The personal supervision must include:*

a. The radiographer's physical presence at the site where the source(s) of radiation is being used;

b. The availability of the radiographer to give immediate assistance if required; and

c. The radiographer's direct observation of the trainee's performance of the operations referred to in this subrule.

ITEM 89. Rescind subrule 45.3(1) and adopt the following <u>new</u> subrule in lieu thereof:

45.3(1) Limits on external radiation levels from storage containers and source changers. The maximum exposure rate limits for storage containers and source changers are 200 millirem (2 millisieverts) per hour at any exterior surface, and 10 millirem (0.1 millisievert) per hour at 1 meter from any exterior surface with the sealed source in the shielded position.

ITEM 90. Amend subrule **45.3**(2), paragraph "**a**," as follows:

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 *and*, *if applicable*, *the key removed*, 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.

ITEM 91. Amend subparagraph 45.3(4)"c"(5) as follows:

(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 be able to withstand a crushing test that closely approximates the crushing forces that are likely to be encountered during use, and be able to withstand a kinking resistance test that closely approximates the kinking forces that are likely to be encountered during use;

ITEM 92. Amend subparagraph 45.3(4)"c"(8) as follows:

(8) The guide tube exposure head connection must be able to withstand the tensile test for control units specified in ANSI N432-1980;

ITEM 93. Amend subrule **45.3**(4) by adopting <u>new</u> paragraphs "f" and "g" as follows:

f. Notwithstanding the requirements of 45.3(4)"a," equipment used in industrial radiographic operations need not comply with § 8.9.2© of the Endurance Test in American National Standards Institute N432-1980, if the prototype equipment has been tested using a torque value representative of the torque that an individual using the radiography equipment can realistically exert on the lever or crankshaft of the drive mechanism.

g. Engineering analysis may be submitted by an applicant or licensee to demonstrate the applicability of previously performed testing on similar individual radiography equipment components. Upon review, the agency may find this an acceptable alternative to actual testing of the component pursuant to the above referenced standard.

ITEM 94. Rescind paragraph 45.3(5)"b" and adopt the following <u>new</u> paragraph in lieu thereof:

b. Leak testing.

(1) Each sealed source shall be tested for leakage at intervals not to exceed 6 months. In the absence of a certificate from a transferor indicating that a test has been made within the 6-month period prior to the transfer, the sealed source shall not be put into use until tested.

(2) Each exposure device using depleted uranium (DU) shielding and an S-tube configuration must be tested for DU contamination at intervals not to exceed 12 months. Should the leak test reveal that the S-tube is worn through, the device may not be used again. DU shielded devices do not have to be tested for DU contamination while in storage and not in use. Before using or transferring such a device, however, the device must be tested for DU contamination if the interval of storage exceeded 12 months.

ITEM 95. Amend paragraph 45.3(6)"a," subparagraphs (9) and (10), and adopt <u>new</u> subparagraphs (11) and (12) as follows:

(9) Maintenance of records; and

(10) The inspection and maintenance of radiographic exposure devices, source changers, storage containers, and radiation machines,

(11) The procedure(s) for identifying and reporting defects and noncompliance in 10 CFR Part 21; and

(12) Source recovery procedure if the licensee will perform source recovery.

ITEM 96. Amend subrule **45.3**(6), paragraph "c," as follows:

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). Whenever radiography is performed at a location other than a permanent radiographic installation, the radiographer must be accompanied by at least one other qualified radiographer or a radiographer trainee. If one of the personnel is a radiographer trainee, the other shall be a radiographer trainer authorized by the license. The additional qualified individual shall observe the operations and be capable of providing immediate assistance to prevent unauthorized entry. Except for the situation of a radiographer trainer with a trainee, radiography may not be performed if only one qualified individual is present.

ITEM 97. Amend subrule **45.3**(7), paragraph **"b,"** as follows:

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. The survey required by this subrule must be done before exchanging films, repositioning the exposure head or dismantling the equipment. ITEM 98. Amend subrule 45.3(9), paragraph "a," as follows:

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). 641—paragraph 39.4(27) "e."

ITEM 99. Rescind and reserve subrule 45.3(11).

ITEM 100. Amend subrule 45.4(2), introductory paragraph, as follows:

45.4(2) Definitions. For purposes of this subrule, definitions in 641—Chapter Chapters 38 and 40 and subrule 45.1(2) may also apply. As used in this rule, the following definitions apply:

ITEM 101. Amend subrule **45.4(2)** by adopting the following <u>new</u> definition:

"Cold pasteurization" means the process of using radiation for destroying disease-causing microorganisms in commercial products.

ITEM 102. Amend subrule **45.4(11)**, paragraph "c," as follows:

c. Accelerator facilities registered pursuant to 45.4(3)"a" shall survey for removable contamination at intervals not to exceed three six months to determine the degree of contamination.

ITEM 103. Amend rule **641—46.1(136D)**, first unnumbered paragraph, as follows:

All references to Code of Federal Regulations (CFR) in this chapter are those in effect as of July 1, 1999 May 10, 2000.

ITEM 104. Amend subrule **46.5(1)**, paragraph "c," introductory paragraph, as follows:

c. A tanning facility shall provide each consumer with a written warning statement prior to the consumer's initial exposure *and annually thereafter* which includes at least the following information:

ARC 9623A

PUBLIC HEALTH DEPARTMENT[641]

Notice of Intended Action

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

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 section 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 135.11, the Department of Public Health hereby proposes to amend Chapter 73, "Special Supplemental Nutrition Program for Women, Infants, and Children (WIC)," Iowa Administrative Code.

The purpose of amending Chapter 73 is to update the language and definitions for consistency with the federal guidelines for the Special Supplemental Nutrition Program for Women, Infants and Children. The amendments include changes in terminology, clarification of the process for selecting approved WIC foods, and tougher penalties for vendor abuse and fraud.

Due to rapidly changing technology, there are now many alternatives to the WIC checks currently being utilized by the Iowa WIC Program to supply food and formula to participants. The United States Department of Agriculture (USDA) now uses the term "food instrument" to describe all devices used to obtain supplemental foods. Chapter 73 has been modified to reflect this change in terminology.

The process for determining whether a vendor has been overcharging WIC participants has also been clarified in this revision of Chapter 73, partly by defining the term "peer group" and explaining its use. The use of the term "peer group" is not a change in policy; it is simply a clarification of existing policy.

There has also been a change in the terminology used by dietitians to describe certain juice products. "Single-strength" is now used to describe what was previously known as "fluid" juice, and "frozen" juice is now called "concentrated" juice. Chapter 73 has been modified to reflect this change.

Another change in Chapter 73 regards formula and infant cereal stocking requirements for vendors. Due to a desire to improve participant services, grocery vendors will now be required to have the capability to supply participants with requested rebate contract formula within 48 hours, or 72 hours if a holiday is involved. This is a change from the previous policy, which did not specify how much time a vendor had to stock formula after a participant request was received. Also, the new policy will not require vendors to keep rare, expensive formulas in stock indefinitely, which is expected to attract more small-town vendors that previously could not meet the formula stocking requirements.

Chapter 73 is also being revised to clarify the process of choosing brands of cereal for inclusion in the list of approved foods. The total number of approved brands remains at 19, and the selection process is not being modified. The proposed amendments simply specify the steps in the existing process.

Chapter 73 is also being modified to reflect changes in the way juices are chosen for inclusion in the approved foods list. The number of approved brands for each type of juice has been decreased in order to eliminate confusion at the grocery store, both for the vendors and the participants. This will also assist staff in the administration of the program. Chapter 73 has been modified to reflect this policy change.

The USDA has also recently recognized that tougher sanctions are needed for vendors who commit violations of WIC program rules. The implementation of mandatory sanctions by the USDA is intended to curb vendor fraud in the WIC Program and to promote WIC and Food Stamp Program coordination in the disqualification of vendors who violate Program rules. Chapter 73 has been modified to implement the mandatory sanctions required by the USDA.

The Department has provided an opportunity for its local contractors, Medicaid staff of the Department of Human Services, and internal staff of the Department of Public Health to review the revised chapter prior to filing this Notice of Intended Action.

Any interested person may make written or oral suggestions or comments on the amendments on or before February 15, 2000. Comments should be directed to Mary L. Weaver, RN, MSN, Division Director, Family and Community Health, Department of Public Health, Lucas State Office Building, Fifth Floor, Des Moines, Iowa 50319-0075; telephone (515)281-4910 or fax (515)242-6384.

There will also be a public hearing on Tuesday, February 15, 2000, from 12 noon to 1 p.m. utilizing the Iowa Commu-

nications Network (ICN). The hearing will be conducted using 13 sites. Please telephone (515)281-8857 to schedule a time to speak at the hearing. The following ICN sites have been confirmed for the hearing:

Persons desiring to make oral presentations at the public hearing should contact Mary Weaver at least one day prior to the date of the public hearing. 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. Any person who plans to attend the hearing and who may have special requirements, such as hearing or mobility impairments, should contact the Department of Public Health and advise of specific needs.

These rules are subject to waiver pursuant to the Department's variance and waiver provisions contained at 641— Chapter 178. For this reason, the Department has not pro-

vided a specific provision for waiver of these particular rules.

These amendments are intended to implement Iowa Code section 135.11.

The following amendments are proposed.

ITEM 1. Amend rule 641—73.5(135) by adopting the following <u>new</u> definitions in alphabetical order:

"Food instrument" means a voucher, check, coupon, electronic benefits transfer (EBT) card or any other document used to obtain supplemental foods.

"Peer group" means a system of grouping WIC vendors according to structure, type, and number of cash registers. Peer groups are used to establish statistical norms that an individual store may be compared against and provide the numeric baselines for the process of determining what may be fraudulent behavior.

ITEM 2. Amend rule 641—73.8(135), introductory paragraph, as follows:

641—73.8(135) Food delivery. Food delivery refers to all aspects of the method by which WIC participants receive food benefits, i.e., printing, distribution, and processing of computerized personal food checks instruments redeemable through retail food markets and the statewide banking system. Food delivery shall be uniform throughout the state as provided for by these rules.

ITEM 3. Amend subrule 73.8(1) as follows:

73.8(1) Responsibilities of WIC participants.

a. Prompt redemption of food checks instruments. A WIC participant has 30 days from the date of issue in which to cash any WIC check food instrument through a vendor. The check food instrument becomes invalid after this time.

b. Claiming food checks instruments. Enrolled participants are required to appear in person to claim checks food instruments when they have appointments to certify or have nutrition education contacts. Missed attendance may entitle contract agencies to deny that month's benefit. If a written statement is provided to the contract agency, a proxy may pick up checks food instruments not more than twice during a single certification period. Under limited circumstances, a permanent proxy may be approved by the contract agency.

c. Adherence to standards for use of the food check instrument. The WIC participant in using the WIC check food instrument to obtain the specified foods shall:

(1) Sign each check food instrument at the time of receipt in the clinic.

(2) Present the blue ID folder to the vendor at point of purchase.

(3) Sign each check food instrument a second time in the appropriate box in the presence of the vendor.

(4) Write in the total amount of the purchase in the designated space.

(5) Not accept money in exchange for unused checks food instruments or portions of the food allotment.

(6) Attempt to redeem checks food instruments only with a WIC-contracted vendor.

ITEM 4. Amend subrule 73.8(2) as follows:

73.8(2) Responsibilities of contract agencies.

a. Loss or theft of checks food instruments. The contract agency is responsible for any financial loss due to theft or other loss of food checks instruments from clinics. Steps for minimizing the chances of theft or loss are followed in accord with the Iowa WIC Policy and Procedure Manual.

b. Mailing of WIC checks food instruments. Mailing of checks food instruments to participants is allowed when in-

clement weather prevents participants from coming to a distribution site. Any mailing of WIC checks food instruments on a clinicwide basis must have prior approval from the state.

c. Use of manual checks food instruments. Manually written checks food instruments shall be issued only when:

(1) Computer checks food instruments arrive damaged or mutilated, or are lost or stolen after being issued to participant.

(2) Computer checks food instruments are not available due to error in entering participant data, delay or loss in shipping, or a need to change the food package.

d. Training/monitoring of WIC vendors. The contract agency shall communicate information regarding the Iowa WIC program to vendors, as instructed by the department. Monitoring and training of vendors and annual biennial securement of contracts shall be carried out in accord with department directives outlined in the WIC Policy and Procedure Manual.

e. Check Food instrument distribution on nonclinic days. It is the policy of the Iowa WIC program to ensure maximum accessibility to program benefits by establishing alternate procedures for distributing WIC checks food instruments to participants on days other than regularly scheduled clinic days when the participant notified the contract agency on or before the clinic day of the participant's inability to appear at the clinic. Each contract agency shall establish written guidelines for assessing the adequacy of reasons presented for inability to appear and shall establish written procedures for alternative means of check food instrument distribution when a participant timely presents adequate reasons for inability to appear on a regularly scheduled clinic day. These written guidelines and procedures shall be subject to review and approval by the department.

ITEM 5. Amend subrule 73.8(4) as follows:

73.8(4) Responsibilities of WIC vendors. A potential vendor shall make application to the Iowa department of public health WIC program and shall accept the obligations imposed by signing of a WIC Vendor Agreement prior to acceptance of any WIC eheck food instrument. The two categories for which any potential vendor may apply are grocery vendors and special purpose vendors.

a. Grocery vendor agreement. To qualify for a grocery vendor agreement with the Iowa WIC program, a retail outlet shall meet all of the following criteria:

(1) The vendor must be primarily a retailer of groceries rather than of other merchandise such as gasoline, beverages, or snack foods. A grocery retailer is defined as a business which stocks at least four of the following categories of items: fresh produce (e.g., raw fruits and vegetables), fresh or frozen meats and poultry (prepackaged luncheon meats do not qualify), canned and frozen vegetables, dairy products, cereals and breadstuffs.

(2) The vendor must maintain regular business hours. This shall include a minimum of two 4-hour blocks of time on each of five days per week. Daily operating hours shall be consistent from week to week, and shall be posted.

(3) The vendor must stock the following varieties and minimum quantities of WIC approved foods:

1. A minimum of two boxes of each of six varieties of cold, ready-to-eat cereals and two boxes of one variety of hot cereal from the current WIC approved food list.

2. A minimum of fifteen 46-ounce containers of 100 percent fruit or vegetable juice and ten 12-ounce containers of frozen concentrated 100 percent fruit or vegetable juice from the current WIC approved food list. This shall include an assortment of at least three approved canned or bottled

(plastic only) varieties of orange, pineapple, grapefruit, apple, grape, vegetable, or tomato, and two frozen concentrated varieties of orange, pineapple, grapefruit, grape or apple.

3. A minimum of four gallons of whole fluid milk and four gallons of either low-fat, reduced fat, or fat-free fluid milk, and two 1-pound packages each of two approved varieties of cheese. two pounds each of at least two different varieties of approved cheese in packages weighing one pound or less.

4. A minimum of two 1-pound bags of edible dried beans or peas, any variety.

5. A minimum of two containers, 18-ounce size or less, of 100 percent peanut butter.

6. A minimum of five dozen large fresh eggs, white or brown.

7. A minimum of four pounds of raw full-size or baby carrots.

8. A minimum of eight cans of tuna, 6-ounce minimum size.

9. Upon request by a participant, a minimum of 31 cans of 13-ounce concentrated infant formula as specified, or the equivalent amount of powdered formula, plus 24 ounces of dry infant cereal.

9. A minimum of six cans of any current rebate contract powdered formula.

10. A minimum of twenty-four 13-ounce cans of any current rebate contract concentrated formula.

11. A minimum of 24 ounces of WIC approved dry infant cereal.

The specific brands of products that are included on the WIC approved food list shall be made available to the vendor at the time of application and prior to renewal of each agreement.

The variety and quantity in stock are defined as including both inventory on display and in on-premises storage, but not inventory on order from suppliers.

(4) A vendor shall charge a price to WIC participants that is equal to or less than the price charged to all other customers. The prices charged to WIC participants for the average of all WIC items, as reported on the application, at the time of on-site review, and throughout the agreement period, shall not exceed 105 percent of the average prices of all other WIC vendors in the same city or metropolitan area. For purposes of the comparison, a metropolitan area is defined as including the principal city or cities and all contiguous incorporated areas peer group. The vendor's average price for any category of WIC items, as reported on the application, at the time of the on-site review, and throughout the agreement period, shall not exceed 115 percent of the average for the same category by all other WIC vendors in the city or metropolitan area same peer group. Categories refer to the groupings of items identified in subparagraph (3), "1" to "9 11." For purposes of making the price comparisons, the average price for all other WIC vendors in the area peer group shall be computed from the most recent Price Assessment Reports on file from those vendors. If a vendor intends to comply with this provision by charging WIC participants a lower price than the price charged to other customers, the WIC price for each approved item must be identified on the package or shelf front.

(5) There must be a minimum of five current WIC participants residing in the same ZIP code area as the vendor.

(6) The vendor must not have had a food stamp program disqualification or civil monetary penalty imposed within

the 12 months preceding the date of the application or reauthorization.

(7) The vendor must not have had a WIC program suspension imposed or a WIC application denied within the sixmonth period preceding the date of the application.

(8) The vendor must accept training on WIC program regulations prior to signing an agreement and must agree to provide training to all employees who will handle WIC food checks instruments prior to accepting any checks food instruments.

(9) The vendor must agree to adhere to all provisions of the WIC Grocery Vendor Instructions and Agreement and Instruction Booklet.

b. Special purpose vendor. To qualify as a special purpose vendor, a retail outlet shall meet all of the following criteria:

(1) The vendor may be primarily a retailer of any type of merchandise but shall be authorized to provide only specified infant formula in exchange for WIC food checks instruments.

(2) The vendor must be able to provide the specified formula within 48 hours; 72 hours if a weekend or holiday is involved.

(3) The prices charged WIC participants must be equal to or less than the prices charged all other customers. The average price of each brand of infant formula sold to WIC participants as reported must not exceed the average price of the same brands of infant formula charged by all authorized WIC grocery vendors in the same city or metropolitan area, as defined above peer group.

(4) The vendor shall meet the criteria in *paragraph "a,"* subparagraphs (2), (5), (6), (7), and (8), for grocery vendors as specified above.

(5) The vendor must agree to adhere to applicable provisions of the WIC Special Purpose Vendor Instructions and Agreement and Instruction Booklet.

The department shall review each vendor application within five working days of receipt and determine if the information provided indicates that the retail outlet meets the selection criteria. If the application shows that the vendor does not meet one or more of the criteria, the department shall deny the application. If the vendor's application indicates that the vendor would qualify, the department or contract agency shall make an on-site visit to verify that the information provided in the application is correct, to provide training, and sign the agreement. If the department or contract agency finds that the vendor has two or more types of out-of-date, stale, or moldy WIC foods in stock during the on-site visit, the vendor's application may be denied. If the contract agency or department determines during the on-site visit that the vendor does not qualify, the contract agency or department shall not sign the agreement. Within five working days of disapproving an application or agreement, the department will advise the vendor in writing of the reasons for denial of the application and the procedure for appeal. During the on-site visit, the contract agency representative is acting as an agent of the department and has the authority to approve or deny an application.

A vendor that is denied an agreement, either at the application review level or at the on-site review, is required to wait six months prior to submitting a new application. The department may, at its discretion, request a vendor to resubmit an application prior to completing its review if the application has not been completed to the extent that a determination of eligibility can be made.

c. Reauthorization. If ownership of an authorized vendor changes during the agreement period, the agreement becomes void. The new owner must file an application and be approved prior to accepting WIC checks food instruments. Vendor agreements are valid only for the period of time specified, and a vendor may not continue accepting checks food instruments past the expiration date unless a new agreement is signed. When a currently authorized vendor makes application for a subsequent agreement, an agreement shall be signed only if the vendor has a score of at least 40 review points. A vendor that meets the minimum qualifications for new vendors is awarded 100 review points. Points assessed during the previous 24 months for administrative and procedural violations under 73.19(2)"b" are then subtracted to determine the final score. has been assessed less than 60 violation points under paragraph 73.19(2)"b" within the previous 24 months.

Vendors with a current WIC agreement are not required to complete a new written application each year if the information in their original application is substantially unchanged. The department may request a new application from any vendor prior to offering a new agreement if it has reason to believe the information in the original is no longer correct or the vendor may no longer be eligible for an agreement.

The department shall send the vendor written notice at least 30 days prior to the expiration of the agreement that it does not intend to offer the vendor a new agreement if the minimum review points are not met or if any of the following conditions are in effect:

1. The vendor has failed to submit any of the preceding year's Price Assessment Reports by the specified dates.

2. The vendor has not cashed any WIC checks food instruments for at least two consecutive months. This provision does not apply to special purpose vendors.

3. Any of the selection criteria listed in 73.8(4)"a" and "b" above are no longer met.

Expiration of a WIC agreement is not subject to appeal. A vendor who is not offered a new agreement by the department has the right to file a new application. If that application is denied, the vendor has the right to appeal.

Contract agencies are responsible for providing training regarding all changes in program regulations and determining that all of the selection criteria are still met prior to signing a new agreement. If the contract agency denies a new agreement, the vendor has the right to appeal without first submitting an application.

d. Training. Vendors shall accept training in program policies and procedures at the on-site review prior to becoming an authorized vendor and shall be responsible for training all employees who will be handling WIC enecks food instruments. The manager and person responsible for staff training must allow time at this visit for training; the agreement will not be signed until training is completed. Vendors shall be responsible for all actions of their employees in conducting WIC transactions.

If violations of program policies and procedures are documented, either through on-site monitoring or other indirect means, the vendor shall implement a corrective action training plan developed jointly by the vendor and the department or contract agency.

e. Validity of checks food instruments. The WIC vendor shall be responsible for ensuring that:

(1) The participant countersignature required on the food check instrument is completed in the vendor's presence, and that both signatures on the food check instrument match;

(2) The participant presents a WIC identification card prior to redeeming checks food instruments for food;

(3) The type and quantity of food to be purchased is as indicated on the checks food instrument;

(4) The amount of money written onto the check food instrument for repayment does not exceed the maximum amount as designated by the department and printed on the check food instrument;

(5) The expiration date is present on the check food instrument and is equal to or no later than the date of usage;

(6) WIC checks food instruments are never exchanged for cash or credit;

(7) Substitutions of foods different from those listed on the check food instrument in type or amount are not made;

(8) Checks Food instruments are presented to the state's agent (bank) for payment within 15 days of the date of receipt;

(9) The costs of foods purchased by WIC participants do not exceed charges to other customers for the same foods;

(10) The vendor's authorizing number is stamped with the state-issued vendor stamp on the face of the check food instrument prior to its being presented for payment.

f. and g. No change.

ITEM 6. Amend subrule 73.8(5) as follows:

73.8(5) Vendor monitoring. To maintain program integrity and accountability for federal or state program funds, the department and contract agencies shall conduct ongoing monitoring of authorized vendors, both through on-site visits and through indirect means. A random sample of 10 percent of *currently authorized* vendors receives on-site monitoring every year. Vendors that change ownership during the year, or apply during the contract period, receive an on-site visit prior to signing an agreement. The types of on-site monitoring are defined as follows:

a. Routine or representative monitoring is used for vendors for which there is no record of violations or complaints or other indication of problems. It may include any or all of the following: use of a check food instrument or observation of a participant, educational buys, review of inventory levels, examination of redeemed WIC food checks instruments on hand, review of store policies on return items, and review of employee training procedures. The results of the monitoring are reviewed with the owner or manager on duty, and a follow-up letter confirming the findings is sent from the department. Routine monitoring may be performed by the department or by contract agency staff under the direction of the department. Depending on the nature and severity of violations noted, the department may schedule additional visits, initiate a compliance investigation, or apply sanctions.

Educational buy monitoring is a specialized type of routine monitoring and may include gathering the same information. In addition, department or contract agency staff attempt to use a WIC check food instrument to purchase unauthorized types or brands of foods to test the level of training of store employees. At the conclusion of the transaction, the results of the buy are discussed with the store owner or manager on duty. The transaction is then voided, and the merchandise returned to the shelves. Educational buys are used on authorized vendors, selected by the department. If unauthorized items are allowed to be purchased, the vendor shall agree to a corrective action training plan. A follow-up educational buy is scheduled within 30 to 90 days. A letter is sent from the department documenting the violation. By signing a WIC agreement, a vendor gives consent for educational buys by the department or contract agency. Vendors are not notified in advance that an educational buy is sched-

uled. The protocol for educational buys, including procedures, appropriate items to purchase, and forms to be used, is specified in the Iowa WIC Policy and Procedure Manual.

b. No change.

c. High-risk monitoring is used for vendors that have a documented record of problems such as previous violations, participant complaints, or high volume of WIC food check redemption been identified as high-risk according to the Iowa WIC Policy and Procedure Manual. It includes, but is not limited to, any or all of the following: review of inventory levels, examination of redeemed WIC food checks instruments on hand, examination of electronic monitoring indicators, volume of WIC redemptions, number of identified errors, participant complaints, and review of store policies on returned items. High-risk monitoring may be performed by the department or by contract agency staff under the direction of the department. Educational buying shall be included whenever possible.

d. Compliance buys may be used for any vendors. Compliance buys include covert activities used to document grounds for suspension from the program and may include purchase attempted purchases of unauthorized items. Compliance buys may be performed by the department or another state agency or private company under contract with the department. The department is responsible for identifying the vendors to be investigated and for approving the protocol to be used by the other agency or company during the investigation. Upon completion of a compliance buy documenting program violations, the department shall issue the vendor a notice of violation points assessed or suspension.

The department also monitors vendor performance through in-office review of information. Such information, specifically the total amount of WIC redemptions, is confidential as provided for in Iowa Code section 22.7(6). This business information could provide an advantage to competitors and would serve no public purpose if made available.

ITEM 7. Amend subparagraph 73.9(2)"c"(1) as follows:

(1) Administrative adjustments. No sliced, shredded, or grated, or string cheese is provided due to cost and possible confusion with imitation or processed cheese products. Approved fluid single-strength juice shall be packaged in a 46-ounce container. Approved frozen concentrated juice shall be packaged in a 11.5- or 12-ounce container container container s.

The food package is adjusted to accommodate the special needs of homeless and transient participants. Nonrefrigerated orange or grapefruit juice in small serving containers may be provided. The reason for providing single-serving containers must be documented in the nutrition care plan. No tuna in cans containing less than six ounces is allowed due to cost. No frozen or canned carrots will be allowed in the enhanced food package for breast-feeding women. Fresh carrots will be provided due to their widespread availability and acceptability.

ITEM 8. Amend subrule 73.9(3), paragraph "c," as follows:

c. Changes to the approved food list are made once a year biennially, taking effect on October 1 in years when new vendor contracts are signed. Inquiries from food companies about new and continuing products must be received annually between November 1 and prior to February 1 of the year vendor contracts expire to be guaranteed consideration.

ITEM 9. Amend paragraph 73.9(3)"d," subparagraph (4), as follows:

(4) Ready-to-eat cold cereals are ranked by the six major distributors to Iowa WIC vendors based on volume of total sales. Hot cereals are ranked in the same way. Multiple varieties of a single brand of cereal shall be considered as one brand for the purposes of constructing this ranking. The state office compiles data from all distributors to develop an overall ranking or ranked list. The top 19 16 name-brand cold cereals, the top 3 varieties of private-label (store) brand cold cereals, and the top 2 hot cereals that qualify are selected. This process includes both name-brand and private-label cereals.

ITEM 10. Amend paragraph 73.9(3)"e" as follows:

e. Juices shall meet the federal guidelines for vitamin C content and all of the following conditions:

(1) Juices shall be 100 percent juice and contain no added sugar, sweeteners or artificial sweeteners.

(2) Fluid Single-strength juice shall be packaged in a 46-ounce container. Frozen Concentrated juice shall be marketed in 11.5- or 12-ounce containers.

(3) The brand shall be carried by one of the six largest distributors in the state. Juices are ranked by the six major distributors to Iowa WIC vendors based on volume of total sales. The top two name brands of each flavor of juice (e.g., tomato, orange, grapefruit, grape, apple, or blended) and form of juice (single-strength or concentrated) that meet the selection criteria will be approved. Any private-label (store) brands from the six major distributors that meet the selection criteria will also be approved.

(4) The product form and marketing approach shall be consistent with the promotion of good nutrition and education.

(5) If a group of juices from one manufacturer have similar names and package designs and some do not qualify, the department reserves the right to not approve those types that would otherwise qualify, to reduce the potential for confusion by retail vendors and participants. <u>Canned Singlestrength</u> and frozen concentrated varieties of juice with the same brand name will be evaluated separately.

(6) Calcium-fortified juices shall not be approved.

(7) Product shall have been available in retail stores in Iowa for one year prior to the effective date of inclusion in the approved food list.

(8) Frozen Concentrated juices must be single flavors of juice.

ITEM 11. Amend paragraph 73.9(3)"f," subparagraph (3), as follows:

(3) All brands of natural cheese qualify. The cheese shall be in block or string form (not shredded, sliced, or grated or string) and shall have no added flavors (e.g., smoke flavoring, peppers, or wine).

ITEM 12. Amend subrule 73.12(1) as follows:

73.12(1) Right of appeal. A local agency or a vendor shall have a right to appeal when a local agency's or vendor's application to participate is denied. The right to appeal shall be granted when a local agency's or a vendor's application to participate is denied. The right to appeal shall also be granted when, during the course of the contract or agreement period, a local agency or vendor is disqualified or any other action which affects participation is taken. For participating vendors, a minimum of 30 days' advance notice will be given before the effective date of the action. For participating contract agencies, a minimum of 60 days' advance notice will be given before the effective date of the action. The right to appeal shall not be granted in the following circumstances:

a. When a vendor's contract expires.

b. When the department makes a determination regarding participant access.

c. When a vendor is disqualified from the WIC program as a result of a food stamp program disqualification.

ITEM 13. Amend subrule **73.19(1)** by replacing the word "check" or "checks" with "food instrument" or "food instruments," respectively.

ITEM 14. Amend subrule 73.19(2) as follows:

73.19(2) Vendor violations. There are three types of sanctions that are applied to vendors for violations of program regulations: nonpayment of checks food instruments, issuance of violation points, and suspensions.

a. Nonpayment of checks food instruments.

(1) As a result of prepayment reviews conducted by the state's bank, improperly completed food items are refused payment and returned to the vendor. Items screened during prepayment are authorized vendor stamp not present or legible in the "Pay to the Order of:" box on face of check food instrument, missing or mismatched signature and countersignature, price exceeds maximum printed on face of check food instrument.

(2) If the violation can be corrected by applying the authorized stamp, obtaining the proper countersignature, or reducing the price, the item may be resubmitted for payment. Federal banking regulations prohibit a financial instrument from being sent through the federal reserve system more than twice. If an improperly completed WIC check food instrument is received by the state's bank a second time, it is voided and may not be redeposited.

b. Administrative and procedural violation points. Administrative and procedural violations are offenses to the provisions of the WIC vendor agreement that do not rise to the level of fraud against the program or its participants.

These violations are an indication of a vendor's inattention to or disregard of the requirements of a WIC vendor agreement. It is in the department's interest to record and consider these violations when considering whether to continue its contractual relationship with the vendor.

Vendors are assessed violation points, which are applied as demerits against the vendor's score in the subsequent procurement for WIC vendor agreements in the vendor's area.

In addition, the accumulation of 45 violation points within the first year or 90 violation points within a single agreement period is a major violation subject to a one-year suspension of the WIC agreement for that vendor.

The assignment of violation points does not limit the department's right to effect stronger penalties and sanctions, in cases in which there is evidence of an intentional or systematic practice of abusing or defrauding the Iowa WIC program.

Vio	lation	Points Per Event
1.	Accepting five checks food instruments over 30 days old within the agreement period.	5
2.	Redeeming five checks food instruments	

more than 15 days after receipt within the agreement period.

5

matching signatures.

Vio	lation	Points Per Event
3.	Accepting five checks food instruments	Lieni
	with no date stamp within the agreement	
	period.	5
4.	Refusal to accept valid WIC checks food	
	instruments from participants.	10
5.		
	WIC participants, such as requiring WIC	
	participants to use special checkout lanes or	
	provide extra identification.	10
6.	Insufficient number of brands or types in a	-
_	single food group.	5
7.	Insufficient quantity of a single food group.	5
8.	No stock in a single food group.	5
9.	Insufficient number of brands or types in	
	two food groups.	10
10.	Insufficient quantity in two food groups.	10
11.	8 F	10
12.	Insufficient number of brands or types in	
	three or more food groups.	10
13.	Insufficient quantity in three or more food	
	groups.	15
14.	01	
	(For 6 to 14, food groups are as	15
4.5	defined in 73.8(4)"a"(3).)	15
15.	Failure to carry out corrective action plan	10
10	developed as a result of monitoring visit.	10
16.	0 1	10
17	approved foods.	10
17.	Failure to reimburse department for poten-	
	tially overpaid check food instrument or provide reasonable explanation for the cost	
	of the check food instrument.	5
18.		5
10.	with WIC checks food instruments for cash	
	or credit toward other purchases.	10
19.	Using a WIC vendor stamp other than the	10
17.	one issued by the Iowa WIC program.	5
20.	Providing a brand of formula other than the	•
20.	one specified on the check food instrument.	10
21.	Issuing "rain checks" or credit in exchange	
	for WIC checks food instruments.	10
22.	Stocking out-of-date, stale, or moldy WIC	
	foods, per type.	10
23.	Failure to submit vendor price assessment	
	reports as requested.	10
24.	For vendors that have special WIC prices,	-
	failure to post WIC prices on the shelf or	
	on the package.	15
25.	Failure to complete check food instrument	
	properly, including filling in correct	
	amount and date of purchase, and verifying	

15

Points

PUBLIC HEALTH DEPARTMENT[641](cont'd)

Violation		Per
		Event
	Contacting WIC participants in an attempt to recover funds not paid by WIC.	15
	Charging prices to WIC participants that	
	are more than 105 percent of the	
i	average prices of all other WIC vendors in	
1	the same city or metropolitan area peer	
Į	group.	15
28. I	Providing false information on the price	
ä	assessment report.	15
29. I	Failure to train all employees and ensure	
	their knowledge regarding WIC	
	program procedures set forth in the ven-	
	dor's current agreement and in the	
(current publication of the Iowa WIC pro-	
	gram's vendor instruction booklet.	10
	Requiring WIC participant to purchase a	
1	particular brand when other WIC approved	
1	brands are available.	10
31 . I	Not allowing WIC participants to use dis-	
Ċ	count coupons or promotional	
5	specials to reduce the WIC check food in-	
2	strument amount.	10
32 . 1	Requiring other cash purchases to redeem	
	WIC checks food instruments.	15
33. 1	Failure to allow purchase of up to the full	
á	amount of WIC foods authorized on the	
ę	check food instrument if such foods are	
2	available and desired by the WIC partici-	
I	pant.	20
<u> </u>	Suspensions for chronic violations fraud	or shuse

c. Suspensions for chronic violations, fraud, or abuse. With an administrative finding of the following violations, the vendor will be suspended for one year.

Items 1 to 6 are Class I offenses and result in a one-year suspension. Items 7 to 14 are Class II offenses and result in a two-year suspension. Items 15 to 17 are Class III offenses and result in a three-year suspension.

1. Accumulation of 45 or more violation points within the first year or 90 or more violation points within a single agreement period.

2. Allowing purchase of nonapproved and nonsimilar food items in exchange for WIC checks food instruments.

3. Failure to provide access to store premises or in any manner to hinder, impede or misinform authorized WIC personnel in the act of conducting an on-site education, monitoring or investigation visit.

4. Loss of Iowa department of inspections and appeals license.

5. Violation of the rules and provisions of the USDA Food Stamp Program or other state WIC program, resulting in a loss of vendor authorization or in a civil monetary penalty. The suspension period for such offenses shall equal the time period of disqualification from the other USDA program or one full year, whichever is greater.

6 5. Submitting for payment a WIC check food instrument redeemed by another authorized vendor.

7. Charging WIC participants more than non-WIC customers or charging WIC participants more than the current shelf price.

8. Charging for items not received by the WIC participant or for foods provided in excess of those listed on the check.

9. Allowing-purchase of nonfood items with a WIC check.

10. Receiving, transacting or redeeming WIC checks outside of authorized channels.

11. Claiming reimbursement for the sale of a quantity of a specific food item which exceeds the store's documented inventory of that food item for a specified period of time.

12. Accepting WIC food checks from unauthorized per-

13.6. Threatening or verbally abusing WIC participants or authorized WIC program personnel in the conduct of legitimate WIC program transactions.

14. Two or more incidents of Class I violations within a single agreement period (whether or not the first instance resulted in a sanction).

15. Trafficking or exchanging cash or credit for WIC checks.

16. Submission for payment of WIC checks known to have been lost or stolen.

17. Participation with other individuals including but not limited to WIC employees, vendors, and participants, in systematic efforts to submit false claims for reimbursement of improper WIC checks.

d. With an administrative finding of the following violations, the vendor will be suspended for three years.

1. A pattern of charging WIC participants more than non-WIC customers or charging WIC participants more than the current shelf price.

2. A pattern of charging for items not received by the WIC participant or for foods provided in excess of those listed on the WIC food instrument.

3. A pattern of providing credit or nonfood items, except for alcohol, alcoholic beverages, or tobacco products, in exchange for WIC food instruments.

4. One incidence of allowing the purchase of alcohol, alcoholic beverages, or tobacco products with a WIC food instrument.

5. A pattern of receiving, transacting, or redeeming WIC food instruments outside authorized channels, including through unauthorized vendors or persons.

6. A pattern of claiming reimbursement for the sale of a quantity of a specific food item which exceeds the store's documented inventory of that food item for a specified period of time.

7. Submission for payment of WIC food instruments known by the vendor to have been lost or stolen.

e. With an administrative finding of the following violations, the vendor will be suspended for six years.

1. One incidence of buying or selling food instruments for cash (trafficking).

2. Participating with other individuals including but not limited to WIC employees, vendors, and participants, in systematic efforts to submit false claims for reimbursement of improper WIC food instruments.

3. One incidence of selling firearms, ammunition, explosives, or controlled substances (as defined in Section 102 of the Controlled Substances Act (21 U.S.C. 802)), in exchange for WIC food instruments.

f. With a conviction in a criminal court of law for trafficking in WIC food instruments or selling firearms, ammuni-

tion, explosives, or controlled substances (as defined in Section 102 of the Controlled Substances Act (21 U.S.C. 802)) in exchange for WIC food instruments, the vendor will be permanently disqualified from the Iowa WIC program. The department may impose a civil money penalty (CMP) in lieu of a disqualification when it determines, in its sole discretion, that:

1. Disqualification of the vendor would result in inadequate participant access; or

2. The vendor had, at the time of the violation, an effective policy and program in effect to prevent trafficking; and the ownership of the vendor was not aware of, did not approve of, and was not involved in the conduct of the violation.

d g. The following items do not have a point value, but shall result in or extend a suspension period:

1. Failure to return WIC vendor stamp(s) to the WIC program within ten days of effective date of suspension, or expiration of agreement following denial of subsequent application, shall result in a 30-day extension of a suspension period.

2. Failure to submit a WIC price assessment report after the second request will result in termination of the agreement.

3 2. For each month in which a vendor accepts WIC checks food instruments during a suspension period, the suspension period shall be extended by 30 days.

eh. The above sanctions notwithstanding, the state of Iowa reserves the right to seek civil and criminal prosecution of WIC vendors for any and all instances of dealing in stolen or lost checks food instruments, trading cash and other inappropriate commodities for checks food instruments, or cases in which there exists evidence of a clear business practice to improperly obtain WIC funds, or other practices meeting the definition of fraud as defined in 7 CFR 246 or the Iowa Code.

i. A vendor shall not be entitled to receive any compensation for revenues lost as a result of any suspension or permanent disqualification.

f j. A minimum of 15 days' notice is provided prior to all suspensions, except for permanent disqualifications assessed under paragraph 73.19(2) "f," which are effective on the date of receipt of the notice of administrative action. When the department determines that a Class I, II, or III an offense has occurred, a suspension letter with supporting documentation is prepared for the WIC director's signature. The suspension letter identifies the specific offense offenses from paragraph "c" of this subrule that the vendor is charged with and the procedures for filing an appeal.

g k. The department is responsible for issuing all warning and suspension letters. Contract agencies are informed of all vendor correspondence regarding violations. In situations where participant violations are also involved, the contract agency is responsible for follow-up, as detailed in subrule 73.19(1).

h l. Federal food stamp regulations require automatic disqualification from the food stamp program for vendors suspended by the WIC program for certain types of violations. When a vendor is suspended from the WIC program, the suspension letter to the vendor will include the following statement: "This disqualification from WIC may result in disqualification as a retailer in the food stamp program. Such disqualification may not be subject to administrative or judicial review under the food stamp program." For offenses numbered 7, 8, 9, 10, 11, 12, and 15 in paragraph "c" above, all vendor disqualifications from the WIC program, notice will be sent to the United States Department of Agriculture for appropriate action. im. The department shall disqualify a vendor who has been disqualified from the food stamp program. The disqualification shall be for the same length of time as the food stamp program disqualification, may begin at a later date than the food stamp program disqualification, and shall not be subject to administrative or judicial review under the WIC program. If the department determines that disqualification of a vendor would result in inadequate participant access, it will impose a civil money penalty (CMP) in lieu of disqualification.

j. The department shall permanently disqualify a vendor convicted of trafficking in food instruments or selling firearms, ammunition, explosives, or controlled substances (as defined in Section 102 of the Controlled Substances Act (21 U.S.C. 802)) in exchange for food instruments. A vendor shall not be entitled to receive any compensation for revenues lost as a result of such violation. The department may impose a civil money penalty (CMP) in lieu of a disqualification for this violation when it determines, in its sole discretion, and documents in accordance with the Federal Register, Volume 64, Number 52, Thursday, March 8, 1999, paragraph 246.12(k)(8) that:

(1) Disqualification of the vendor would result in inadequate participant access; or

(2) The vendor had, at the time of the violation, an effective policy and program in effect to prevent trafficking; and the ownership of the vendor was not aware of, did not approve of, and was not involved in the conduct of the violation.

k n. Civil money penalties.

1. The department When the department determines that a civil money penalty (CMP) shall be imposed in lieu of disqualification for reasons specified under paragraph 73.19(2) "f" or 73.19(2) "m," it shall use the civil money penalty formula in accordance with the Federal Register, Volume 64, Number 52, Thursday, March 8, 1999, paragraph 246.12(k)(8) Title 7 CFR Subpart 246.12(k)(1)(x) to determine the CMP.

2. If a vendor does not pay, only partially pays, or fails to timely pay a CMP, the department will disqualify the vendor for the length of the disqualification corresponding to the violation for which the CMP was assessed. "Failure to timely pay a CMP" includes the failure to pay a CMP in accordance with an installment plan approved by the department.

13. Money received by the state WIC agency as a result of civil money penalties or fines assessed against a vendor and any interest charged in the collection of these penalties and fines shall be considered as program income.

ITEM 15. Amend rule 641-73.20(135) as follows:

641—73.20(135) Data processing. All contract agencies shall comply with the instructions outlined in the Iowa WIC Policy and Procedure Manual for use of the automated data processing system in provision of WIC checks food instruments and monitoring of WIC services. No contract agency is exempted from adherence to any portion of these instructions.

PUBLIC SAFETY DEPARTMENT[661]

Public Notice

Pursuant to the authority of Iowa Code section 13.10 and 61 IAC 8.6(13), the Department of Public Safety hereby gives public notice that the Division of Criminal Investigation Criminalistics Laboratory is prepared to process samples of DNA collected pursuant to Iowa Code section 13.10 and 61—Chapter 8. Therefore, 61—Chapter 8 is effective immediately upon publication of this notice in the Iowa Administrative Bulletin, as provided in 61 IAC 8.6(13).

ARC 9617A

TRANSPORTATION DEPARTMENT[761]

Notice of Intended Action

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 section 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 307.10 and 307.12, the Department of Transportation hereby gives Notice of Intended Action to amend Chapter 10, "Administrative Rules and Declaratory Orders," Chapter 112, "Primary Road Access Control," Chapter 115, "Utility Accommodation," Chapter 524, "For-Hire Intrastate Motor Carrier Authority," and Chapter 529, "For-Hire Interstate Motor Carrier Authority," and to adopt Chapter 11, "Waiver of Rules," Iowa Administrative Code.

These amendments adopt the waiver rule required by Executive Order Number 11 and make coordinating amendments.

Any person or agency may submit written comments concerning these proposed amendments or may submit a written request to make an oral presentation. The comments or request shall:

1. Include the name, address, and telephone number of the person or agency authoring the comments or request.

2. Reference the number and title of the proposed rule, as given in this Notice, that is the subject of the comments or request.

3. Indicate the general content of a requested oral presentation.

4. Be addressed to the Department of Transportation, Director's Staff Division, 800 Lincoln Way, Ames, Iowa 50010; fax (515)239-1639; Internet E-mail address: <u>rules@</u> <u>iadot.e-mail.com</u>.

5. Be received by the Director's Staff Division no later than February 15, 2000.

A meeting to hear requested oral presentations is scheduled for Thursday, February 17, 2000, at 1 p.m. in the Commission Conference Room of the Department of Transportation, 800 Lincoln Way, Ames, Iowa.

The meeting will be canceled without further notice if no oral presentation is requested.

These amendments are intended to implement Iowa Code chapter 17A and Executive Order Number 11, dated September 14, 1999. Proposed rule-making actions:

ITEM 1. Amend subrule **10.1(2)**, definition of "Written criticisms," numbered paragraph **"2,"** as follows:

2. Petitions for waiver of a rule tendered to the department or granted by the department *under 761—Chapter 11*.

ITEM 2. Adopt the following new chapter:

CHAPTER 11 WAIVER OF RULES

761—11.1(17A) Purpose and scope.

11.1(1) The purpose of this chapter is to establish generally applicable standards for granting waivers of department rules, the form for petitioning the department to grant waivers using these standards, and the procedure for acting upon such petitions.

11.1(2) This chapter does not preclude the granting of waivers using other standards, forms and procedures if a statute or other department rule so provides. If the rule for which a waiver is sought has a specific waiver provision of its own, this chapter is applicable only when it is specifically cited.

11.1(3) This chapter does not apply to contested case proceedings.

11.1(4) This chapter does not apply to rules that merely define the meaning of a statute or other provision of law if the department does not possess the delegated authority to bind the courts to any extent with its definition.

761—11.2(17A) Standards.

11.2(1) The director of transportation may, on the director's own motion, issue an order granting a waiver of a rule, in whole or in part, for a class of persons if the director finds that the waiver would confer a benefit or remove a restriction on that class of persons and that the waiver would be consistent with the public interest.

11.2(2) The director of transportation may, on the director's own motion or in response to a written petition, issue an order granting a waiver of a rule, in whole or in part, as applied to the circumstances of a specified person, if the director finds that:

a. Application of the rule to that person would result in undue hardship or injustice to that person,

b. Waiver of the rule on the basis of the circumstances of that person would be consistent with the public interest, and

c. Waiver of the rule would not prejudice the substantial legal rights of any person.

11.2(3) In response to a written petition requesting a waiver, the director of transportation shall issue an order granting a waiver of a rule, in whole or in part, as applied to the circumstances of a specified person, if the director finds that application of all or a portion of the rule to the circumstances of that person would not to any extent advance or serve any of the purposes of the rule.

761—11.3(17A) Waiver considerations and limitations.

11.3(1) In determining whether a waiver would be consistent with the public interest, the director shall consider whether, if the waiver were granted, the public health and safety will be protected by other means that are substantially equivalent to full compliance with the rule.

11.3(2) When the rule for which a waiver is sought establishes an administrative deadline, the director shall balance the special individual circumstances of the petitioner with the overall goal of uniform treatment of all applicants or licensees.

TRANSPORTATION DEPARTMENT[761](cont'd)

11.3(3) A requirement created or duty imposed by statute shall not be waived.

11.3(4) Any waiver granted must be consistent with statute.

11.3(5) A rule may be waived only if the department has exclusive rule-making authority to promulgate that rule.

761—11.4(17A) Petition for waiver.

11.4(1) Petitioner. A person may petition the department for waiver of a rule only on the ground that application of that rule to the circumstances of that person would justify a waiver under subrule 11.2(2) or 11.2(3). The petitioner must have a real and direct interest in the matter. The petitioner has the burden of persuasion.

11.4(2) Form of petition.

a. A petition for waiver of a rule must be in writing and state clearly at the top of the petition that it is a petition for waiver of a rule.

b. The body of a petition for waiver of a rule shall contain the following information where applicable and known to the petitioner:

(1) The name, address and telephone number of the petitioner.

(2) A description of and citation to the specific rule from which a waiver is requested.

(3) The specific waiver requested, including its precise scope and operative period.

(4) The reasons for the requested waiver.

(5) The relevant facts supporting the requested waiver, and a statement attesting to the accuracy of these facts.

(6) A history of the department's actions relative to the petitioner.

(7) Whether the petitioner is currently a party to a rulemakine leclaratory order, contested case or judicial proceeding related to the requested waiver.

(8) Information regarding the department's treatment of similar situations.

(9) The name, address and telephone number of any public agency or political subdivision that also regulates the activity in question or that may be affected if the waiver were granted.

(10) The name, address and telephone number of any person or entity who may be adversely affected if the waiver were granted.

(11) The name, address and telephone number of any person inside or outside the department who has knowledge of the relevant facts related to the requested waiver.

(12) The name, address and telephone number of the individual who is the petitioner's authorized representative regarding the petition.

c. A petition for waiver of a rule shall be signed and dated by the petitioner or the petitioner's authorized representative.

d. If applicable, a petition for waiver of a rule shall be accompanied by a separate release signed by the petitioner or the petitioner's authorized representative authorizing specific persons with knowledge of the relevant facts related to the requested waiver to furnish that information to the department.

11.4(3) Submission of petition. A petition for waiver of a rule shall be submitted to the Director's Staff Division, Department of Transportation, 800 Lincoln Way, Ames, Iowa 50010.

761—11.5(17A) Procedure. Following is the procedure for granting or denying a waiver upon petition:

11.5(1) The department shall acknowledge receipt of a petition for waiver of a rule immediately.

11.5(2) Before a waiver is granted or denied, the department may request a petitioner to furnish additional information related to the petition.

11.5(3) The director shall issue a written order granting or denying a waiver within 120 days after the department receives the petition for waiver unless the petitioner agrees to a later time. However, if the matter is also the subject of a contested case proceeding, the order need not be issued until after the final decision in that contested case is issued.

11.5(4) An order granting or denying a waiver shall contain:

a. The name of the person to whom the order pertains.

b. A citation to the rule or portion thereof to which the order pertains.

c. The relevant facts upon which the decision is based.

d. The reason(s) for granting or denying the waiver.

e. The precise scope and operative period of the waiver if one is granted. The director may condition the granting of a waiver upon such reasonable conditions as are appropriate to achieve the objectives of the rule in question.

11.5(5) Within seven days after an order is issued, the department shall transmit it to the petitioner.

11.5(6) Failure to grant or deny a waiver within the required time is deemed a denial.

11.5(7) The director's decision on a waiver is final agency action.

11.5(8) A petition for waiver of a rule is independent of a contested case proceeding. A petition for waiver of a rule does not delay the time to request a contested case hearing, to appeal a proposed decision in a contested case, or to file a petition for judicial review of a final decision in a contested case.

11.5(9) A petition for waiver of a rule is not required to exhaust administrative remedies before judicial review of a department action under Iowa Code section 17A.19.

761—11.6(17A) Validity.

11.6(1) An order granting a waiver is a defense within its terms for the person to whom the order pertains in any proceeding in which the rule in question is sought to be invoked.

11.6(2) A waiver is void if the relevant facts upon which the waiver is based are not true, if relevant facts have been withheld, or if the petitioner has failed to comply with the conditions set forth in the order granting the waiver.

761-11.7(17A) Records.

11.7(1) All orders issued under this chapter are open records. However, if an order contains personal information that is confidential, that information shall be deleted before the order is made available for public inspection.

11.7(2) The department shall retain orders denying waivers for five years. The department shall retain orders granting waivers for five years or until there is no longer any need to retain them, whichever is later. The orders are indexed by rule chapter.

These rules are intended to implement Iowa Code chapter 17A and Executive Order Number 11, dated September 14, 1999.

ITEM 3. Amend subrule 112.1(2) as follows:

112.1(2) The department reserves the right to may make exceptions to these rules this chapter where the exercise of sound and reasonable judgment indicates that the literal enforcement of the rules this chapter would cause an undue hardship to any interested party affected person, the community or the state. 761—Chapter 11 is not applicable except

TRANSPORTATION DEPARTMENT[761](cont'd)

for rules 761—11.6(17A) and 761—11.7(17A). When submitting an application, the applicant may submit a written request for an exception. The request shall include an explanation of and justification for the requested exception. The requested exception shall be evaluated as part of the application.

ITEM 4. Amend subrule 115.1(2) as follows:

115.1(2) The department reserves the right to may make exceptions to this chapter where the exercise of sound and reasonable judgment indicates that the literal enforcement of this chapter would defeat its objectives. 761—Chapter 11 is not applicable except for rules 761—11.6(17A) and 11.7(17A). When submitting an application, the applicant may submit a written request for an exception. The request shall include an explanation of and justification for the requested exception. The requested exception shall be evaluated as part of the application.

ITEM 5. Amend subrule 524.2(2) as follows:

524.2(2) Waiver of rules. The director of the motor vehicle division transportation may, in accordance with 761— Chapter 11, waive provisions of this chapter. In lieu of the standards in rule 761—11.2(17A), the director may issue a waiver if the director determines after determining that special or emergency circumstances exist or that the waiver is in the best interest of the public.

a. "Special or emergency circumstances" means one or more of the following:

(1) 1. Circumstances where the movement is necessary to cooperate with cities, counties, other state agencies or other states in response to a national or other disaster.

(2) 2. Circumstances where the movement is necessary to cooperate with national defense officials.

(3) 3. Circumstances where the movement is necessary to cooperate with public or private utilities in order to maintain their public services.

(4) 4. Circumstances where the movement is essential to ensure safety and protection of any person or property due to events such as, but not limited to, pollution of natural resources, a potential fire or an explosion.

(5) 5. Circumstances where weather or transportation problems create an undue hardship for citizens of the state of Iowa.

(6) 6. Circumstances where movement involves emergency-type vehicles.

(7) 7. Uncommon and extraordinary circumstances where the movement is essential to the existence of an Iowa business and the move may be accomplished without causing undue hazards to the safety of the traveling public or undue damage to private or public property.

b. A request for a waiver must be submitted in writing to the Director of the Motor Vehicle Division, Department of Transportation, P.O. Box 9204, Des Moines, Iowa 50306-9204.

c. The request should include the following information where applicable and known to the requester;

(1) The name, address and motor carrier permit or certificate number.

(2) The specific rule from which a waiver is requested.

(3) The specific waiver requested.

(4) The reasons for the request.

(5) The relevant facts supporting the request.

d. The request shall be acknowledged immediately and shall be responded to in writing within 60 days of receipt.

e. The decision on the waiver is the final decision of the department.

ITEM 6. Amend rule 761—529.3(327B) as follows:

761—529.3(327B) Waiver of rules. The director of the motor vehicle division transportation may, in accordance with 761—Chapter 11, waive provisions of this chapter. In lieu of the standards in rule 761—11.2(17A), the director may issue a waiver if the director determines after determining that special or emergency circumstances exist or the waiver is in the best interest of the public for interstate travel through Iowa.

529.3(1) "Special or emergency circumstances" means one or more of the following:

a 1. Circumstances where the movement is necessary to cooperate with cities, counties, other state agencies or other states in response to a national or other disaster.

b 2. Circumstances where the movement is necessary to cooperate with national defense officials.

e 3. Circumstances where the movement is necessary to cooperate with public or private utilities in order to maintain their public services.

 $d \dot{4}$. Circumstances where the movement is essential to ensure safety and protection of any person or property due to events such as, but not limited to, pollution of natural resources, a potential fire or explosion.

e-5. Circumstances where weather or transportation problems create an undue hardship for citizens of the state of Iowa.

f 6. Circumstances where movement involves emergency-type vehicles.

g 7. Uncommon and extraordinary circumstances where the movement is essential to the existence of an Iowa business and the move may be accomplished without causing undue hazard to the safety of the traveling public or undue damage to private or public property.

529.3(2) A request for a waiver must be submitted in writing to the Director of the Motor Vehicle Division, Department of Transportation, P.O. Box 9204, Des Moines, Iowa 50306-9204.

529.3(3) The request should include the following information where applicable and known to the requester:

a. The name, address and motor carrier-permit or certificate number.

b. The specific waiver requested.

c. The reasons for the request.

d. The relevant facts supporting the request.

529.3(4) The request shall be acknowledged immediately and shall be responded to in writing within 60 days of receipt.

529.3(5) The decision on the waiver is the final decision of the department.

ARC 9622A

TRANSPORTATION DEPARTMENT[761]

Notice of Intended Action

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 section 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 307.10 and 307.12, the Department of Transportation hereby gives Notice of Intended Action to amend Chapter 452, "Flashing Lights and Warning Devices on Slow-Moving Vehicles," Iowa Administrative Code.

TRANSPORTATION DEPARTMENT[761](cont'd)

These amendments delete two obsolete rules and adopt a new rule providing standards for an alternative reflective device for use on horse- or mule-drawn vehicles. 1999 Iowa Acts, chapter 102, section 2, provides that an alternative reflective device may be used if the individual operating the horse- or mule-drawn vehicle objects for religious reasons to using a reflective device that complies with the standards of the American Society of Agricultural Engineers. The alternative reflective device must be in compliance with rules adopted by the Department.

The new rule provides for an alternative reflective device of one-inch-wide reflective strips that outline the rear of the vehicle. This new rule does not provide a waiver. Rather, the rule implements a statutory waiver.

Any person or agency may submit written comments concerning these proposed amendments or may submit a written request to make an oral presentation. The comments or request shall:

1. Include the name, address, and telephone number of the person or agency authoring the comments or request.

2. Reference the number and title of the proposed rule, as given in this Notice, that is the subject of the comments or request.

3. Indicate the general content of a requested oral presentation.

4. Be addressed to the Department of Transportation, Director's Staff Division, 800 Lincoln Way, Ames, Iowa 50010; fax (515)239-1639; Internet E-mail address: <u>rules@iadot.e-mail.com</u>.

5. Be received by the Director's Staff Division no later than February 15, 2000.

A meeting to hear requested oral presentations is scheduled for Thursday, February 17, 2000, at 2 p.m. in the Commission Conference Room of the Department of Transportation, 800 Lincoln Way, Ames, Iowa.

The meeting will be canceled without further notice if no oral presentation is requested.

These amendments are intended to implement Iowa Code Supplement section 321.383(2).

Proposed rule-making actions:

ITEM 1. Amend the title of **761—Chapter 452** as follows:

FLASHING LIGHTS AND WARNING REFLECTIVE DEVICES ON SLOW-MOVING VEHICLES

ITEM 2. Rescind and reserve rules 761-452.1(321) and 761-452.2(321).

ITEM 3. Adopt the following <u>new</u> rule:

761—452.3(321) Alternative reflective device. If a person operating a vehicle drawn by a horse or mule objects for religious reasons to using a reflective device that complies with the standards of the American Society of Agricultural Engineers, the vehicle may be identified by an alternative reflective device that is in compliance with the following:

452.3(1) The alternative reflective device shall consist of one-inch-wide strips applied to the rear of the vehicle. The combined length of the strips shall be at least 72 inches. The strips, when applied, shall approximate the outline of the vehicle.

452.3(2) The reflective material may be black, gray, silver or white in color, but must reflect white when illuminated by other vehicles' headlamps.

452.3(3) The reflective material shall be visible from a distance of not less than 500 feet from the rear of the vehicle when illuminated by other vehicles' headlamps.

452.3(4) The reflective material shall be kept free of dirt and debris.

This rule is intended to implement Iowa Code Supplement section 321.383(2).

NOTICE—PUBLIC FUNDS INTEREST RATES

In compliance with Iowa Code chapter 74A and section 12C.6, the committee composed of Treasurer of State Michael L. Fitzgerald, Superintendent of Credit Unions James E. Forney, Superintendent of Banking Holmes Foster, and Auditor of State Richard D. Johnson have established today the following rates of interest for public obligations and special assessments. The usury rate for January is 8.00%.

INTEREST RATES FOR PUBLIC OBLIGATIONS AND ASSESSMENTS

74A.2 Unpaid Warrants	Maximum 6.0%
74A.4 Special Assessments	

<u>RECOMMENDED</u> for 74A.3 and 74A.7: A rate equal to 75% of the Federal Reserve monthly published indices for U.S. Government securities of comparable maturities.

The rate of interest has been determined by a committee of the state of Iowa to be the minimum interest rate that shall be paid on public funds deposited in approved financial institutions. To be eligible to accept deposits of public funds of the state of Iowa, a financial institution shall demonstrate a commitment to serve the needs of the local community in which it is chartered to do business. These needs include credit services as well as deposit services. All such financial institutions are required to provide the committee with a written description of their commitment to provide credit services in the community. This statement is available for examination by citizens.

New official state interest rates, effective January 11, 2000, setting the minimums that may be paid by Iowa depositories on public funds are listed below.

TIME DEPOSITS

7-31 days	Minimum 5.00%
32-89 days	
90-179 days	
180-364 days	
One year	
Two years or more	

These are minimum rates only. The one year and less are four-tenths of a percent below average rates. Public body treasurers and their depositories may negotiate a higher rate according to money market rates and conditions.

Inquiries may be sent to Michael L. Fitzgerald, Treasurer of State, State Capitol, Des Moines, Iowa 50319.

ARC 9630A

WORKFORCE DEVELOPMENT DEPARTMENT[871]

Notice of Intended Action

Twenty-five interested persons, a governmental subdivision, an agency or association of 25 or more persons may demand an oral presentation hereon as provided in Iowa Code section 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 section 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 96.11, the Director of the Workforce Development Department hereby gives Notice of Intended Action to amend Chapter 23, "Employer's Contribution and Charges," and adopt Chapter 41, "Request for Waiver of Administrative Rule," Iowa Administrative Code.

Subrule 23.40(2), paragraph "a," is amended by extending the contribution surcharge to the year 2001.

871—Chapter 41 is adopted in compliance with IAPA and Executive Order Number 11.

Interested persons, governmental agencies and associations may present written comments or statements on the proposed amendments not later than 4:30 p.m., February 15, 2000, to Reynel Dohse, Department of Workforce Development, Unemployment Insurance Services Division, 1000 East Grand Avenue, Des Moines, Iowa 50319.

A public hearing will be held at 9:30 a.m., February 15, 2000, at the above address. The proposed amendments are subject to revision after the Division considers all written and oral presentations. Persons who want to convey their views orally should contact Reynel Dohse at (515)281-4986 or at the above address.

These proposed rules are intended to implement Iowa Code chapter 17A and Executive Order Number 11.

The following amendments are proposed.

ITEM 1. Amend subrule 23.40(2), paragraph "a," as follows:

a. For calendar years 1988 through $1998\ 2001$, each employer except a governmental entity and a 501(c)(3) non-profit organization will have an administrative contribution surcharge added to the contribution rate. The administrative contribution surcharge shall be a percentage, rounded to the next highest one-hundredth of 1 percent of the Federal Unemployment Tax Act (FUTA) taxable wage base in effect on the computation date.

ITEM 2. Adopt the following <u>new</u> chapter:

CHAPTER 41 REQUEST FOR WAIVER OF ADMINISTRATIVE RULE

871—41.1(17A,ExecOrd11) Requests for waiver of rules. Any person may file a request for waiver of an administrative rule of the Workforce Development Department[871], Iowa Administrative Code, by writing a proper request which is received by the Division Administrator, Division of Unemployment Insurance Services, 1000 East Grand Ave, Des Moines, Iowa 50319. All requests for waiver of an administrative rule must be in writing and meet all requirements set out in this chapter. A request is deemed filed when it is received by the division administrator. The agency shall provide the requester with a file-stamped copy of the request if the requester provides the agency an extra copy for this purpose. The request must be typewritten or legibly handwritten in ink and must substantially conform to the following form:

IOWA WORKFORCE DEVELOPMENT

(Name of person requesting	ing	Request for waiver of (Specify rule for
waiver).		which waiver is re- quested).

The petition must provide the following information:

1. The name and address of the person or entity for whom a waiver is requested.

2. A description and citation of the specific rule for which a waiver is requested.

3. The specific waiver requested, including the precise scope and operative period that the waiver will extend.

4. Relevant facts that the requester believes would justify a waiver. This statement shall include a signed statement from the petitioner attesting to the accuracy of the facts provided in the petition, and a statement of reasons the petitioner believes will justify a waiver.

5. A history of the agency's action relative to the requester.

6. Any information regarding the agency's treatment of similar cases, if known.

7. The name, address and telephone number of any person inside or outside state government who would be adversely affected by the grant of the request, or who otherwise possesses knowledge of the matter with respect to the waiver request.

8. Signed release of information authorizing persons with knowledge regarding requests to furnish the agency with information pertaining to the waiver, if necessary.

871-41.2(17A,ExecOrd11) Procedural requirements.

41.2(1) The department shall acknowledge a request upon receipt. Within 30 days after receipt of a request for waiver of an administrative rule, the agency shall ensure that the requester has provided a copy of the request to all persons who are required to receive one by provision of law. The agency may also require the requester to give notice to send a copy of the request to other persons who would have an interest in the subject matter.

41.2(2) The agency shall grant or deny a request for waiver of all or a portion of a rule as soon as practical, but in any event, shall do so within 120 days of its receipt, unless requester agrees to a later date. However, if a waiver request has been filed in a contested case proceeding, the agency shall grant or deny the request no later than the time at which the final decision in that contested case is issued. Failure of the agency to grant or deny such a request within the required time period shall be deemed a denial of that request by the agency. If the request for waiver relates to a time requirement of an administrative rule, the request must be received before the time specified in the rule has expired. Within seven days of its issuance, any response issued under this rule shall be transmitted, normally by depositing it in the mail, to the requester or the person to whom the response pertains and to any other person entitled to such notice by any provision of law.

871-41.3(17A,ExecOrd11) Criteria for waiver.

41.3(1) The director of the workforce development department shall make a decision as to whether circumstances justify the granting of a waiver. Waivers are granted at the

WORKFORCE DEVELOPMENT DEPARTMENT[871](cont'd)

discretion of the director after consideration of relevant facts. The requester shall assume the burden of persuasion with regard to a request for waiver of an administrative rule. The person requesting the waiver of the rule must provide clear and convincing evidence that compliance with the rule will create an undue hardship on the person for whom the waiver is requested; and the waiver of the rule on the basis of the particular circumstances relevant to that specified person would be consistent with public interest; and the waiver of the rule in the specific case would not prejudice the substantial legal rights of any person.

41.3(2) The agency shall deny a request for waiver of an administrative rule if the request waives any statute in whole or part. The agency shall deny any request if it does not comply with the provisions of this rule. The agency may grant waiver of a rule if it finds that application of all or a portion of the rule to the circumstances of the specified person would not, to any extent, advance or serve any purposes of the rule. The agency will deny a request unless there are exceptional circumstances justifying an exception to the general applica-

tion of the rule in otherwise similar circumstances. A waiver shall be denied if the material facts presented in the request are not true or material facts have been withheld. The agency may request additional information from the requesting party relative to the application and surrounding circumstances.

871—41.4(17A,ExecOrd11) Public inspection. All waiver requests and responses shall be indexed by administrative rule number and available to members of the public for inspection at the administrative office of the Workforce Development Department, 1000 East Grand Avenue, Des Moines, Iowa. Identifying information concerning individuals as unemployment benefit claimants and taxpayers and other identifying information may be withheld by the agency in order to protect the confidentiality of parties as required by Iowa Code chapter 96.

These rules are intended to implement Iowa Code chapter 17A and Executive Order Number 11.

FILED EMERGENCY

ARC 9633A

EMERGENCY MANAGEMENT DIVISION[605]

Adopted and Filed Emergency

Pursuant to the authority of Iowa Code sections 17A.3 and 34A.7A, the Emergency Management Division hereby amends Chapter 10, "Enhanced 911 Telephone Systems," Iowa Administrative Code.

The amendments reflect the formal adoption of the Wireless Enhanced 911 Implementation and Operation Plan, which is required by Iowa Code section 34A.7A and rule 605—10.7(34A).

In compliance with Iowa Code section 17A.4(2), the Emergency Management Division finds that notice and public participation are impracticable because of the immediate need to begin the implementation and operation of an enhanced wireless 911 phone system.

The Division also finds, pursuant to Iowa Code section 17A.5(2)"b"(2), that the normal effective date of these amendments should be waived and these amendments should be made effective on February 1, 2000, as they confer a benefit upon the citizens of Iowa, joint E911 service boards, the Iowa Department of Public Safety, and E911 service providers.

These amendments are also published herein under Notice of Intended Action as **ARC 9632A** to allow for public comment.

These amendments are intended to implement Iowa Code chapter 34A.

These amendments will become effective February 1, 2000.

The following amendments are adopted.

Amend rule 605—10.7(34A) to read as follows:

605—**10.7(34A)** Enhanced wireless 911 service plan. Each joint E911 service board, the department of public safety, the E911 communications council, and wireless service providers shall cooperate with the E911 program manager in preparing an enhanced wireless 911 service plan for statewide implementation of enhanced wireless 911 phase I and phase II implementation.

10.7(1) Plan specifications. The enhanced wireless 911 service plan shall include, at a minimum, the following information:

1. Maps showing geographic area to be served by each PSAP receiving enhanced wireless 911 telephone calls.

2. A list of all public and private safety agencies within the enhanced wireless 911 service area.

3. The geographic location of each PSAP receiving enhanced wireless 911 calls and the name of the person responsible for the management of the PSAP.

4. A set of guidelines for determining eligible cost for wireless service providers, wire-line service providers, and public safety answering points.

5. A statement of estimated charges for the implementation and operation of enhanced wireless 911 phase I and phase II service, detailing the equipment operated or needed to operate enhanced wireless 911 service, including any technology upgrades necessary to provide service. Charges must be directly attributable to the implementation and operation of enhanced wireless 911 service. Charges shall be detailed showing item(s) or unit(s) of cost, or both, and include estimated charges from:

• Wireless service providers.

• Wire-line service providers for implementation and operation of enhanced wireless 911 service.

• Public safety answering points.

6. A schedule for the implementation of enhanced wireless 911 phase I and phase II service.

10.7(2) Adoption by reference. The "Wireless Enhanced 911 Implementation and Operation Plan," effective February 1, 2000, and available from the Emergency Management Division, Hoover State Office Building, Des Moines, Iowa, or at the Law Library in the Capitol Building, Des Moines, Iowa, is hereby adopted by reference.

> [Filed Emergency 1/7/00, effective 2/1/00] [Published 1/26/00]

EDITOR'S NOTE: For replacement pages for IAC, see IAC Supplement 1/26/00.

ARC 9619A

LABOR SERVICES DIVISION[875]

Adopted and Filed Emergency After Notice

Pursuant to the authority of Iowa Code sections 88.5 and 17A.3(1), the Labor Commissioner amends Chapter 10, "General Industry Safety and Health Rules," Iowa Administrative Code.

The amendment relates to methylene chloride, CFR correction; dipping and coating operations; and powered industrial truck operator training, correction.

Notice of Intended Action was published in the Iowa Administrative Bulletin on August 25, 1999, as ARC 9288A.

In compliance with Iowa Code section 88.5(1)"b," a public hearing was scheduled for September 22, 1999. No comments were received.

This amendment is identical to the Notice of Intended Action.

Pursuant to Iowa Code section 17A.5(2)"b"(2) and (3), this amendment shall become effective upon publication on January 26, 2000. 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 amendment is intended to implement Iowa Code section 88.5.

The amendment will become effective January 26, 2000. The following amendment is adopted.

Amend rule 875—10.20(88) by inserting at the end thereof:

64 Fed. Reg. 13700 (March 22, 1999)

64 Fed. Reg. 13908 (March 23, 1999)

64 Fed. Reg. 22552 (April 27, 1999)

[Filed Emergency After Notice 1/5/00, effective 1/26/00] [Published 1/26/00]

EDITOR'S NOTE: For replacement pages for IAC, see IAC Supplement 1/26/00.

ARC 9620A

LABOR SERVICES DIVISION[875]

Adopted and Filed Emergency After Notice

Pursuant to the authority of Iowa Code sections 88.5 and 17A.3(1), the Labor Commissioner amends Chapter 26, "Construction Safety and Health Rules," Iowa Administrative Code.

The amendment relates to a correction to the powered industrial truck operator training rules previously adopted.

Notice of Intended Action was published in the Iowa Administrative Bulletin on August 25, 1999, as ARC 9290A.

In compliance with Iowa Code section 88.5(1)"b," a public hearing was scheduled for September 22, 1999. No comments were received.

This amendment is identical to the Notice of Intended Action.

Pursuant to Iowa Code section 17A.5(2)"b"(2) and (3), this amendment shall become effective upon publication on January 26, 2000. 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 amendment is intended to implement Iowa Code section 88.5.

The amendment will become effective January 26, 2000. The following amendment is adopted.

Amend rule **875—26.1(88)** by inserting at the end there-of:

64 Fed. Reg. 22552 (April 27, 1999)

[Filed Emergency After Notice 1/5/00, effective 1/26/00] [Published 1/26/00]

EDITOR'S NOTE: For replacement pages for IAC, see IAC Supplement 1/26/00.

ARC 9628A

NATURAL RESOURCE COMMISSION[571]

Adopted and Filed Emergency

Pursuant to the authority of Iowa Code subsection 455A.5(6), the Natural Resource Commission hereby gives Notice of Intended Action to amend Chapter 51, "Game Management Areas," Iowa Administrative Code.

This amendment establishes uniform regulations for shooting ranges located on game management areas. The language in this amendment was initially approved by the Natural Resource Commission in a rule making which became effective January 5, 2000, but was inadvertently omitted from the amendment as it was filed.

In compliance with Iowa Code section 17A.4(2), the Department finds that notice and public participation are impracticable because recent rule making on this same topic was noncontroversial and there was no public participation. The amendment adds language which does not create a hardship for the general public or significantly alter the intent of the rule. The Department also finds, pursuant to Iowa Code section 17A.5(2)"b"(2), that the normal effective date of the amendment should be waived and this amendment should be made effective upon filing with the Administrative Rules Coordinator, as it was initially approved in correct form by the Natural Resource Commission in the rule making which became effective January 5, 2000.

This amendment is intended to implement Iowa Code section 481A.6.

This amendment became effective January 7, 2000. The following amendment is adopted.

Amend subrule 51.3(1) as follows:

51.3(1) Restrictions. The use or possession of firearms on certain game management areas is restricted.

a. Target shooting, for the purposes of this rule, is defined as the discharge of a firearm for any reason other than the taking of, or attempting to take, any game birds, game animals, or furbearers. Target shooting with shotguns shooting shot is not restricted to a specific range, except as otherwise provided. Target shooters using shotguns with lead shot cannot discharge the shot over water.

b. to f. No change.

g. No alcoholic beverages are allowed on the shooting range or *adjacent* parking area.

h. and i. No change.

j. All requirements listed in this rule subrule shall apply to the following shooting ranges:

- (1) Badger Creek Area Madison County.
- (2) Banner Mine Area Warren County.
- (3) Bays Branch Area Guthrie County.
- (4) Hawkeye Wildlife Area Johnson County.
- (5) Hull Wildlife Area Mahaska County.
- (6) Mines of Spain Dubuque County.
- (7) Ocheyedan Wildlife Area Clay County.
- (8) Princeton Wildlife Area Scott County.
- (9) Spring Run Wildlife Area Dickinson County.

k. In addition to the requirements listed, the following shooting ranges have range has specific restrictions.

(1) Lake Darling Recreation Area -- Washington County. Hunting, trapping and the use of weapons of any kind, except for the use of bow and arrow to take rough fish and except as provided in 571-- subrule 61.6(3) and 571-- Chapter 105, are prohibited.

(2) McIntosh Wildlife Area - Cerro Gordo County. The use or possession of firearms, except shotguns shooting shot only, is prohibited.

(3) Oyens Shooting Range - Plymouth County. The range is closed to the public except between 9 a.m. and sunset. Law enforcement firearms training and qualification of local, county, state or federal officers shall have priority over general public use of the range. Shotguns shooting birdshot may be fired outside the firing tubes, but within the designated range area. General shooting by the public shall take place on a first-come, first-served basis.

I. McIntosh Wildlife Area - Cerro Gordo County. The use or possession of firearms, except shotguns shooting shot only, is prohibited.

[Filed Emergency 1/7/00, effective 1/7/00] [Published 1/26/00]

EDITOR'S NOTE: For replacement pages for IAC, see IAC Supplement 1/26/00.

FILED

ARC 9634A

EXECUTIVE COUNCIL[361]

Adopted and Filed

Pursuant to the authority of Iowa Code chapter 668A, the Executive Council hereby adopts Chapter 12, "Disbursement of Money from Civil Reparations Trust Fund," Iowa Administrative Code.

These are new rules for the disbursement of money from the Civil Reparations Trust Fund. The rules create a procedure for notice to the public of money in the fund and for applications from the public to the Executive Council for disbursement of the money from the fund.

Notice of Intended Action was published in the October 20, 1999, Iowa Administrative Bulletin as ARC 9438A. Written comments were due to the State Treasurer's office by November 9, 1999. No written comments were received.

Based on further consideration of the proposed rules, the Executive Council added language to subrule 12.3(3) to allow the agency to waive the deadline for submission of application for good cause and added language to rule 12.9(668A) to allow the Executive Council in its discretion to disburse money while a motion for reconsideration by an applicant is pending to the extent that resolution of any pending motion could not affect the disbursement of money to other applicants. The adopted rules have been changed to reflect these additions.

These rules will become effective March 1, 2000.

These rules are intended to implement Iowa Code chapter 17A as amended by 1998 Iowa Acts, chapter 1202, and Iowa Code chapters 7D and 668A.

The following **new** chapter is adopted.

CHAPTER 12 DISBURSEMENT OF MONEY FROM CIVIL REPARATIONS TRUST FUND

361—12.1(668A) Eligibility. Money in the civil reparations trust fund may be disbursed upon application for indigent civil litigation programs or insurance assistance programs.

361—12.2(668A) Notice of funds. The executive council shall provide notice of availability of money in the fund in the following ways:

12.2(1) Iowa Administrative Bulletin. The executive council shall publish notice of the balance in the fund in the Iowa Administrative Bulletin semiannually in January and July of each year and within 30 days of the deposit of any amount into the fund exceeding \$10,000. If the deposit of an amount exceeding \$10,000 would cause notice within 30 days of the deposit to be published in January or July, no additional publication is required.

12.2(2) First-class mail. The executive council shall maintain a mailing list of those persons who wish to receive notice of the balance in the fund. Notice shall be sent semiannually in January and July of each year and within 30 days of the deposit of any amount into the fund exceeding \$10,000 by first-class mail to all persons on the mailing list. If the deposit of an amount exceeding \$10,000 would cause notice within 30 days of the deposit to be mailed in January or July, no additional mailing is required. Any person may be added to the mailing list on request.

In the event that there is no money in the fund in January or July, no notice will be published or mailed.

361-12.3(668A) Applications. The executive council shall accept applications for money from the fund for a period of 30 days after notice has been published in the Iowa Administrative Bulletin or sent by first-class mail. Applications will be not be accepted in advance of this time period.

12.3(1) Forms. Application forms are available in the office of the state treasurer.

12.3(2) Filing. Applications shall be filed with the office of the state treasurer.

12.3(3) Timeliness. An application is timely if it is postmarked on the thirtieth day after the date of publication in the Iowa Administrative Bulletin or on the thirtieth day after the date affixed to the notice sent by first-class mail, whichever is later. The executive council may accept applications submitted after this deadline only for good cause upon motion in writing.

361-12.4(668A) Criteria. In determining whether to grant an application for money from the fund, the executive council shall consider the following factors:

1. The purpose for which the money will be utilized;

2. The number of people who will be served by the

money; 3. The availability to the applicant of alternative sources of money;

4. The degree to which the applicant complied with legal restrictions on the use of the money under any prior applications

361-12.5(668A) Disposition of applications. The executive council shall determine the disposition of all pending applications and notify all applicants of the decision by firstclass mail. Notice of disposition shall be sent to all applicants on the same date.

361-12.6(668A) Motion for reconsideration. Any applicant who is aggrieved or adversely affected by the disposition of the applicant's application must file a motion for reconsideration in the office of the state treasurer within 15 days of the date affixed to the notice of disposition. The motion is deemed filed when received and date-stamped by the treasurer.

361-12.7(668A) Grounds. The motion for reconsideration must delineate the specific grounds for reconsideration. An applicant may request a contested case hearing; however, any request for a contested case hearing must specifically delineate the facts in dispute to be contested and determined at the hearing.

361—12.8(668A) Procedure. The executive council shall rule on any pending motion for reconsideration, including a request for a contested case hearing. In the event that a request for a contested case hearing is granted, the proceeding shall be conducted as provided in 361 IAC 10.8(17A,68B) et seq. The burden of proof by a preponderance of the evidence shall be on the requester to establish grounds for reconsideration. The decision of the executive council shall be defended by the office of the attorney general.

361-12.9(668A) Disbursement of money. No money will be disbursed from the fund after disposition of all applications until the time period for filing a motion for reconsideration has expired. After the time period for filing a motion for reconsideration has expired but while a motion for reconsideration by any applicant is pending, the executive council in its discretion may disburse money from the fund to applicants who have not filed a motion for reconsideration. Money may be disbursed to applicants while a motion for reconsideration

EXECUTIVE COUNCIL[361](cont'd)

is pending only to the extent that resolution of any pending motion could not affect the disbursement of money to other applicants.

361-12.10(668A) Administrative costs. The costs of administering this fund, including any costs associated with the conduct of any contested case proceeding challenging the disbursement of money from the fund and costs for postage and copying, shall be billed to the fund after approval by the executive council.

These rules are intended to implement Iowa Code chapter 17A as amended by 1998 Iowa Acts, chapter 1202, and Iowa Code chapters 7D and 668A.

> [Filed 1/10/00, effective 3/1/00] [Published 1/26/00]

EDITOR'S NOTE: For replacement pages for IAC, see IAC Supplement 1/26/00.

ARC 9616A

INSURANCE DIVISION[191]

Adopted and Filed

Pursuant to the authority of Iowa Code section 502.607, the Insurance Division hereby amends Chapter 50, "Regulation of Securities Offerings and Those Who Engage in the Securities Business," Iowa Administrative Code.

These rules impose certain advertising, examination, and disclosure requirements upon issuers and agents who wish to sell viatical settlement contracts within the state of Iowa. A waiver provision is also included herein which applies specifically to these rules.

Notice of Intended Action was published in the August 11, 1999, Iowa Administrative Bulletin as ARC 9273A. Comments were received at a public hearing held on Wednesday, September 8, 1999. Five comments were received after the hearing. The administrator revised the proposed rules in light of those comments. The time period for submission of proposed advertising has been clarified as ten business days. The administrator may deem advertisements false and misleading.

These rules will become effective on March 1, 2000.

These rules are intended to implement Iowa Code section 502.201 and Iowa Code Supplement sections 502.102 and 502.202.

The following <u>new</u> rules are adopted.

VIATICAL SETTLEMENT CONTRACTS

191-50.120(502) Advertising of viatical settlement contracts.

50.120(1) Under this rule, the term "advertisement" includes any written, electronic or printed communication or any communication by means of recorded telephone messages or transmitted on radio, television, the Internet, or similar communications media, including film strips, motion pictures, and videos, published in connection with the offer or sale of a viatical settlement contract.

50.120(2) The issuer and agent shall file all viatical settlement contract advertisements with the administrator not less than ten business days prior to the date of use or a shorter period as the administrator may permit. The administrator shall mark the advertisements with allowance for use or expressly disapprove them during this time frame. The advertisements shall not be used in Iowa until a copy thereof, marked with allowance for use, has been received from the administrator.

50.120(3) Viatical settlement contract advertisements should contain no more than the following:

a. The name of the issuer;

b. The address and telephone number of the issuer;

c. A brief description of the security, including minimum purchase requirements and liquidity aspects;

d. If rate of return is advertised, it must be stated as the annual average rate of return, with a disclaimer that this is an annual average rate of return, that individual investor rates of return will vary based upon the viator's projected and actual date of death, and that an annual rate of return on a viatical settlement contract cannot be guaranteed;

e. The name, address and telephone number of the agent of the issuer authorized to sell the viatical settlement contracts;

f. A statement that the advertisement is neither an offer to sell nor a solicitation of an offer to purchase and that any offer or solicitation may only be made by providing a disclosure document; and

g. How a copy of the disclosure document may be obtained.

50.120(4) Notwithstanding the provisions of rule 191-50.25(502), certain viatical settlement advertisements may be deemed false and misleading on their face by the administrator and are prohibited under Iowa Code sections 502.401 and 502.602. False and misleading viatical settlement advertisements include, but are not limited to, the following representations:

a. "Fully secured," "100% secured," "fully insured," "secure," "safe," "backed by rated insurance company(ies)," "backed by federal law," "backed by state law," or similar representations;

b. "No risk," "minimal risk," "low risk," "no specula-

tion," "no fluctuation," or similar representations; c. "Qualified or approved for IRA, Roth IRA, 401K, SEP, 403B, Keogh plans, TSA, other retirement account rol-

lovers," "tax deferred," or similar representations; d. "Guaranteed fixed return," "guaranteed annual return,""guaranteed principal,""guaranteed earnings,""guaranteed profits," "guaranteed investment," or similar representations;

e. "No sales charges or fees," or similar representations;

f. "High yield," "superior return," "excellent return," "high return," "quick profit," or similar representations; g. "Perfect investment," "proven investment," or similar

representations;

h. Purported favorable representations or testimonials about the benefits of viaticals as an investment, taken out of context from newspapers, trade papers, journals, radio and television programs, and all other forms of print and electronic media.

This rule is intended to implement Iowa Code section 502.201 and Iowa Code Supplement sections 502.102 and 502.202.

191-50.121(502) Application by viatical settlement contract issuers and registration of agents to sell viatical settlement contracts.

50.121(1) Under this rule, the term "viatical settlement contract issuer" includes, but is not limited to, any individual, company, corporation or other entity that offers or sells, directly or indirectly, viatical settlement contracts to investors.

50.121(2) A viatical settlement contract issuer employing agents in Iowa must make prior application to the administrator for this authority. The application shall be made by letter and shall include:

a. A statement of the issuer's intent to employ agents for the sale of its viatical settlement contracts; and

b. Name, address, social security number and proof of satisfaction of subrule 50.121(3) for each agent.

50.121(3) An applicant for registration as an Iowalicensed agent of an issuer of viatical settlement contracts shall file with the administrator:

a. Proof of obtaining a passing grade on the NASD Series 7 examination;

b. Proof of obtaining a passing grade on the NASD Series 63 examination;

c. An accurate, complete and signed Form U-4; and

d. A \$30 filing fee.

This rule is intended to implement Iowa Code section 502.201 and Iowa Code Supplement sections 502.102 and 502.202.

191—50.122(502) Risk disclosure. Viatical settlement contract issuers and registered agents of issuers must provide specific, written disclosures of risk to Iowa investors at the time of the initial offer to sell a viatical settlement contract. These disclosures must be preceded by the following caption, which must be in bold, 16-point typeface:

IMPORTANT RISK DISCLOSURE INFORMATION-READ

BEFORE SIGNING ANY VIATICAL SETTLEMENT CONTRACT Certain items must be disclosed including, but not limited to, the following:

1. That the actual annual rate of return on any viatical settlement contract is dependent upon (a) an accurate projection of the viator's life expectancy, and (b) the actual date of the viator's death. An annual "guaranteed" rate of return is not possible;

2. Whether, after purchasing the viatical settlement contract, the investor will be responsible for payment of premiums on the contract if the viator lives longer than projected. If the investor will be responsible for such premiums, the amount of the premium payment and its negative effect on the investor's return must be disclosed to the investor;

3. Whether any premium payments on the contract have been escrowed. The investor must be provided the date upon which the escrowed funds will be depleted, informed whether the investor will be responsible for payment of premiums thereafter, and informed of the amount of such premiums;

4. Whether any premium payments on the contract have been waived. The investor must be informed whether the investor will be responsible for payment of the premiums if the insurer who wrote the policy terminates the waiver after purchase, and informed of the amount of such premiums;

5. Whether the investor is responsible for payment of premiums on the contract if the viator returns to health, and the amount of such premiums;

6. Whether the investor is entitled to all or part of the investor's investment under the contract if the viator's underlying policy is later determined to be null and void;

7. Whether the insurance policy is a group policy and, if so, the special risks associated with group policies including, but not limited to, whether the investor is responsible for payment of additional premiums if the policies are sold or converted;

8. Whether the insurance policy is term insurance and, if so, the special risks associated with term insurance includ-

ing, but not limited to, whether the investor is responsible for additional premium costs if the viator continues the term policy at the end of the current term;

9. Whether the investor will be the beneficiary or owner of the insurance policy and, if the investor is the beneficiary, the special risks associated with beneficiary status;

10. Whether the insurance policy is contestable and, if so, the special risks associated with contestability including, but not limited to, the risk that the investor will have no claim or only a partial claim to death benefits should the insurer cancel the policy within the contestability period;

11. Who is making the projection of the viator's life expectancy, the information this projection is based upon, and the relationship of the projection maker to the issuer;

12. Who is monitoring the viator's condition, how often the monitoring is done, how the date of death is determined, and how and when this information will be transmitted to the investor;

13. Whether the insurer who wrote the viator's underlying policy has any additional rights which could negatively affect or extinguish the investor's rights under the viatical settlement contract, what these rights are, and under what conditions these rights are activated;

14. That a viatical settlement contract is not a liquid investment and that there is no established secondary market for resale of these products by the investor;

15. That the investor will receive no returns (i.e., dividends and interest) until the viator dies; and

16. That the investor may lose all benefits or receive substantially reduced benefits if the insurer goes out of business during the term of the viatical investment.

This rule is intended to implement Iowa Code section 502.201 and Iowa Code Supplement sections 502.102 and 502.202.

191—50.123(502) Duty to disclose. Issuers and agents equally share an affirmative duty to disclose all relevant and material information to prospective investors in viatical settlement contracts. The required disclosure is the registration statement required by Iowa Code section 502.207 which has been reviewed and made effective by the administrator.

This rule is intended to implement Iowa Code section 502.201 and Iowa Code Supplement sections 502.102 and 502.202.

191—50.124(502) Waivers. The administrator may grant a waiver of a rule pertaining to issuer and agent applications for viatical licensure.

50.124(1) No waiver shall be granted from a requirement imposed by statute. Any waiver must be consistent with statutory requirements.

50.124(2) A waiver under this subrule may be granted only upon a showing of all the following:

a. Because of special circumstances, applying the rule would impose an undue burden or extreme hardship on the requester;

b. Granting the waiver would not adversely affect the public interest and the protection of investors; and

c. Granting the waiver would provide substantially equal protection of public health and safety as would compliance with the rule.

50.124(3) A request for waiver shall be made at any time within 60 days of the initial application and shall include the following information:

a. The name, address, and telephone number of the person requesting the waiver;

b. The specific rule from which a waiver is requested;

INSURANCE DIVISION[191](cont'd)

c. The nature of the waiver requested;

d. An explanation of all facts relevant to the waiver request, including all material facts necessary for the administrator to evaluate the criteria for granting a waiver as defined in subrule 50.124(2); and

e. A description of any prior communication between the administrator and the requester regarding the proposed waiver.

50.124(4) The administrator shall rule upon all waiver requests and transmit the ruling to the requester. The ruling shall include the reason for granting or denying the request. The administrator's ruling shall constitute final agency action for the purposes of Iowa Code chapter 17A.

50.124(5) The administrator may impose reasonable conditions when granting a waiver to achieve the objectives of the particular rule being waived.

50.124(6) If at any time the administrator finds the facts as stated in the waiver request are not true, that material facts have been withheld, or that the requester has failed to comply with conditions set forth in the waiver, the administrator may cancel the waiver and seek additional sanctions against the issuer and agent as provided by this chapter and Iowa Code chapter 502.

50.124(7) Any request for an appeal from a decision granting, denying, or canceling a waiver shall comply with the procedures provided in Iowa Code chapter 17A. An appeal shall be made within 30 days after the administrator's ruling in response to the waiver request.

50.124(8) All final rulings in response to waiver requests shall be indexed and available to members of the public at the administrator's office.

This rule is intended to implement Iowa Code section 502.201 and Iowa Code Supplement sections 502.102 and 502.202.

[Filed 1/5/00, effective 3/1/00] [Published 1/26/00]

EDITOR'S NOTE: For replacement pages for IAC, see IAC Supplement 1/26/00.

ARC 9624A

LOTTERY DIVISION[705]

Adopted and Filed

Pursuant to the authority of Iowa Code section 99E.9, the Iowa Lottery Board, for the Lottery Division of the Department of Revenue and Finance, amends Chapter 2, "Licensing," Iowa Administrative Code.

This amendment makes subrule 2.12(1) more readable by breaking a lengthy list of items in a single paragraph into a series of lettered paragraphs, and it adds a new provision clarifying and implementing a stepped penalty process governing penalties for failure to comply with the provisions of Iowa Code section 99E.18(2) regarding sales of lottery tickets to persons under 21 years of age.

Notice of Intended Action was published in the Iowa Administrative Bulletin on October 6, 1999, as ARC 9377A. The Lottery solicited comment by submitting copies of the amended rule, in the form noticed and ultimately adopted, to law enforcement agencies and associations, retailer associations and an anti-lottery spokesperson. No comment was received from any source, and no hearing was scheduled. This amendment is identical to that published under Notice of Intended Action.

The Iowa Lottery Board adopted this amendment on December 30, 1999.

This amendment will become effective on March 1, 2000. This amendment is intended to implement Iowa Code chapter 99E.

EDITOR'S NOTE: Pursuant to recommendation of the Administrative Rules Review Committee published in the Iowa Administrative Bulletin, September 10, 1986, the text of this amendment [2.12] is being omitted. This amendment is identical to that published under Notice as ARC 9377A, IAB 10/6/99.

[Filed 1/6/00, effective 3/1/00] [Published 1/26/00]

[For replacement pages for IAC, see IAC Supplement 1/26/00.]

ARC 9635A

REVENUE AND FINANCE DEPARTMENT[701]

Adopted and Filed

Pursuant to the authority of Iowa Code section 421.14, the Department of Revenue and Finance hereby adopts amendments to Chapter 71, "Assessment Practices and Equalization," Chapter 73, "Property Tax Credit and Rent Reimbursement," Chapter 74, "Mobile, Modular and Manufactured Home Tax," Chapter 75, "Property Tax Administration," Chapter 77, "Determination of Value of Utility Companies," Chapter 78, "Property Tax Exemptions," Chapter 79, "Real Estate Transfer Tax," and Chapter 80, "Property Tax Credits and Exemptions," Iowa Administrative Code.

Notice of Intended Action was published in IAB Volume XXII, Number 11, page 872, on December 1, 1999, as **ARC 9500A**.

The rule changes incorporate the provisions of 1999 Iowa Acts, Senate Files 53, 136, 392, 462, and 473 and House Files 417, 755, 757, 758, and 769.

These amendments are identical to those published under Notice of Intended Action.

These amendments will become effective March 1, 2000, after filing with the Administrative Rules Coordinator and publication in the Iowa Administrative Bulletin.

These amendments are intended to implement Iowa Code chapters 425, 426A, 427, 428A, 433, 435, 440, 443, 445, 446, 476, and 499B.

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 amendments [71.1, 71.25, 73.1, 73.10, 73.14, 73.27(3), 73.29, 74.4, 75.6, 75.7, 77.1, 78.1, 78.4, 79.1, 79.5, 80.2, 80.4, 80.14] is being omitted. These amendments are identical to those published under Notice as ARC 9500A, IAB 12/1/99.

[Filed 1/7/00, effective 3/1/00] [Published 1/26/00]

[For replacement pages for IAC, see IAC Supplement 1/26/00.]

ARC 9636A

REVENUE AND FINANCE DEPARTMENT[701]

Adopted and Filed

Pursuant to the authority of Iowa Code section 421.17, the Department of Revenue and Finance hereby amends Chapter 107, "Local Option Sales and Service Tax," and Chapter 108, "Local Option School Infrastructure Sales and Service Tax," Iowa Administrative Code.

Notice of Intended Action was published in IAB Volume XXII, Number 11, page 877, on December 1, 1999, as ARC 9499A.

Item 1 adopts new rule 701-107.2(422B) and Item 11 amends 701-108.5(422E) to provide that the sales of natural gas, electricity and electrical services that are subject to Iowa use tax are also subject to local option taxes. The new rule 701-107.2(422B) in Item 1 also restructures the rule and includes new repeal dates and the notice requirements by the county auditor to the director. Item 2 amends rule 701-107.8(422B) by restructuring the rule and adding a new subrule to include new nexus requirements for imposition of all local option taxes. Item 3 amends rule 701-107.9(422B) by providing that the sales of natural gas, electricity, and electrical services that are subject to Iowa use tax are also subject to local option taxes. This amendment also provides that the sales of certain equipment to contractors are exempt from local option tax. Items 4 and 13 amend rules 701-107.10(422B) and 701-108.7(422E) by providing the new date by which an adjustment for local option overpayment must be made. The amendment of 701107.10(422B) in Item 4 also provides that a certified census may be used in the distribution formula for local option tax. Item 5 amends rule 701—107.14(422B) by setting forth the new requirements of city residency for a county to qualify for imposing local option tax. Items 14 and 15 amend 701— Chapter 108 by adopting new rules 701—108.8(422E) and 701—108.9(422E) which implement the law governing construction contractor refunds and the authority granted under Iowa Code chapter 128E agreements, respectively. Item 8 amends subrules 108.2(3), 108.2(5), and 108.2(6) for the implementation of repeal dates and notice by county auditor requirements and sets forth that sales of natural gas, electricity and electrical services that are subject to Iowa use tax are also subject to local option taxes.

These amendments are identical to those published under Notice of Intended Action.

These amendments will become effective March 1, 2000, after filing with the Administrative Rules Coordinator and publication in the Iowa Administrative Bulletin.

These amendments are intended to implement Iowa Code chapters 422B and 422E as amended by 1999 Iowa Acts, chapters 151 and 156 which relate to local option taxes.

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 Chs 107 and 108] is being omitted. These rules are identical to those published under Notice as ARC 9499A, IAB 12/1/99.

[Filed 1/7/00, effective 3/1/00] [Published 1/26/00]

[For replacement pages for IAC, see IAC Supplement 1/26/00.]

IOWA ADMINISTRATIVE BULLETIN Customer Service Center Department of General Services Hoover State Office Building, Level A Des Moines, Iowa 50319

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