ARC 1470C

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 for Radiation Machines and Radioactive Materials," 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," and Chapter 45, "Radiation Safety Requirements for Industrial Radiographic Operations," Iowa Administrative Code.

The following paragraphs summarize the changes:

Items 1, 33, 43, 45 and 59 amend rules to reflect current federal regulations.

Items 42, 46, 52, 56, 57 and 61 amend rules to correct errors discovered by staff.

Items 47, 48, 49, 50, 51, 53, 54, 55, and 58 amend rules to reduce the regulatory burden on licensees.

The remaining items amend rules to meet U.S. Nuclear Regulatory Commission (USNRC) compatibility requirements pursuant to the stipulations of the state of Iowa's status as a USNRC agreement state.

Any interested person may make written suggestions or comments on these proposed amendments on or before June 17, 2014. Such written materials should be directed to Chief of Bureau of Radiological Health, Iowa Department of Public Health, Lucas State Office Building, Fifth Floor, 321 East 12th Street, Des Moines, Iowa 50319; fax (515)281-4529; or e-mail angela.leek@idph.iowa.gov.

After analysis and review of this rule making, no impact on jobs has been found.

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

The following amendments are proposed.

ITEM 1. Amend subrule 38.1(2) as follows:

38.1(2) All references to any Code of Federal Regulations (CFR) in this chapter are those in effect as of ~~September 15, 2010~~ [effective date of these amendments].

ITEM 2. Amend rule **641—38.2(136C)**, definition of "Unrefined and unprocessed ore," as follows:

"Unrefined and unprocessed ore" means ore in its natural form prior to any processing, such as grinding, roasting, beneficiating, or refining. Processing does not include sieving or encapsulation of ore or preparation of samples for laboratory analysis.

ITEM 3. Amend paragraph **39.4(2)"c,"** introductory paragraph, as follows:

c. Any person is exempt from the requirements for a license set forth in this chapter and from the rules in this chapter and 641—Chapter 40 to the extent that such person receives, possesses, uses, or transfers:

ITEM 4. Amend subparagraph **39.4(2)"c"(2)** as follows:

(2) Source material contained in the following products:

1. Glazed ceramic tableware manufactured before [effective date of these amendments], provided that the glaze contains not more than 20 percent by weight source material,

2. Glassware containing not more than ~~10~~ 2 percent by weight source material or, for glassware manufactured before [effective date of these amendments], 10 percent by weight source material, but not including commercially manufactured glass brick, pane glass, ceramic tile, or other glass or ceramic used in construction,

3. and 4. No change.

ITEM 5. Rescind and reserve numbered paragraph **39.4(2)"c"(5)"1."**

ITEM 6. Amend subparagraph **39.4(2)"c"(7)** as follows:

(7) Thorium or uranium contained in or on finished optical lenses and mirrors, provided that each lens or mirror does not contain more than ~~30~~ 10 percent by weight of thorium or uranium or, for lenses manufactured before [effective date of these amendments], 30 percent by weight of thorium; and that this exemption ~~shall~~ does not ~~be deemed to~~ authorize either:

1. The shaping, grinding, or polishing of such lens or mirror or manufacturing processes other than the assembly of such lens or mirror into optical systems and devices without any alteration of the lens or mirror, or

2. The receipt, possession, use, or transfer of uranium or thorium contained in contact lenses, or in spectacles, or in eyepieces in binoculars or other optical instruments.

ITEM 7. Rescind and reserve subparagraph **39.4(2)"c"(8)**.

ITEM 8. Adopt the following **new** paragraph **39.4(2)"f"**:

f. No person may initially transfer for sale or distribution a product containing source material to persons exempt under these rules, or equivalent regulations of an agreement state or the Nuclear Regulatory Commission, unless authorized by a license issued under 10 CFR 40.52 to initially transfer such products for sale or distribution.

(1) Persons initially transferring for sale or distributing source material in products covered by the exemptions in these rules before [effective date of these amendments] without specific authorization may continue such distribution for one year beyond this date. Initial distribution may also be continued until the Nuclear Regulatory Commission takes final action on a pending application for license or license amendment to specifically authorize distribution submitted no later than one year beyond this date.

(2) Persons authorized to manufacture, process, or produce these materials or products containing source material by the agency, an agreement state, or the Nuclear Regulatory Commission, and persons who import finished products or parts, for sale or distribution must be authorized by a license issued under 10 CFR 40.52 for distribution only and are exempt from the requirements of 641—Chapter 40 and 39.4(25)*"a"* and *"b."*

ITEM 9. Amend subparagraph **39.4(3)"c"(2)** as follows:

(2) Self-luminous products containing radioactive material.

1. Tritium, krypton-85, or promethium-147. Except for persons who manufacture, process, produce, or initially transfer for sale or distribution self-luminous products containing tritium, krypton-85, or promethium-147, any person is exempt from these rules to the extent that such person receives, possesses, uses, transfers, owns, or acquires tritium, krypton-85 or promethium-147 in self-luminous products manufactured, processed, produced, imported, or initially transferred in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission pursuant to Section 32.22 of 10 CFR Part 32, which license authorizes the initial transfer of the product for use under these rules. Any person who desires to manufacture, process, ~~or~~ produce or initially transfer for sale or distribution self-luminous products containing tritium, krypton-85, or promethium-147~~, or to transfer such products~~ for use according to this paragraph~~,~~ shall apply for a license ~~which states that the product may be transferred by the licensee to persons exempt from this paragraph~~ under 10 CFR 32.22 and for a certificate of registration in accordance with 10 CFR 32.210. The exemption in 39.4(3)*"c"*(2) does not apply to tritium, krypton-85, or promethium-147 used in products primarily for frivolous purposes or in toys or adornments.

2. No change.

ITEM 10. Amend subparagraph **39.4(3)"c"(3)** as follows:

(3) Gas and aerosol detectors containing radioactive material.

1. Except for persons who manufacture, process, produce, or initially transfer for sale or distribution gas and aerosol detectors containing radioactive material, any person is exempt from the requirements for a license set forth in this chapter and from the requirements contained in 641—Chapters

38, 40, and 41 to the extent that such person receives, possesses, uses, transfers, owns, or acquires radioactive material in gas and aerosol detectors designed to protect ~~life~~ health, safety or property ~~from fires and airborne hazards~~ and manufactured, processed, produced, or initially transferred in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission pursuant to Section 32.26 of 10 CFR Part 32, ~~; or a licensing state pursuant to 39.4(29)*"c,"*~~ which license authorizes the initial transfer of the product for use under this rule. This exemption also covers gas and aerosol detectors manufactured or distributed before November 20, 2007, in accordance with a specific license issued by a state under comparable provisions to 10 CFR 32.26 authorizing distribution to persons exempt from regulatory requirements.

~~2. Gas and aerosol detectors previously manufactured and distributed to general licensees in accordance with a specific license issued by an agreement state shall be considered exempt under 39.4(3)*"c"*(3)"1," provided that the device is labeled in accordance with the specific license authorizing distribution of the generally licensed device, and provided further that they meet the requirements of 39.4(29)*"c."*~~

~~3. Gas and aerosol detectors containing NARM previously manufactured and distributed in accordance with a specific license issued by a licensing state shall be considered exempt under 39.4(3)*"c"*(3)"1," provided that the device is labeled in accordance with the specific license authorizing distribution, and provided further that they meet the requirements of 39.4(29)*"c."*~~

~~4.~~ 2. Any person who desires to manufacture, process, or produce gas and aerosol detectors containing radioactive material, or to initially transfer such products for use pursuant to 39.4(3)*"c"*(3)"1," shall apply for a license ~~which states that the product may be initially transferred by the licensee to persons exempt from these rules, the regulations of the U.S. Nuclear Regulatory Commission, or equivalent rules of an agreement state~~ under 10 CFR 32.26 and for a certificate of registration in accordance with 10 CFR 32.210

ITEM 11. Adopt the following **new** subparagraph **39.4(3)"c"(4)**:

(4) 1. Static elimination devices which contain, as a sealed source or sources, by-product material consisting of a total of not more than 18.5 MBq (500 μCi) of polonium-210 per device.

2. Ion generating tubes designed for ionization of air that contain, as a sealed source or sources, by-product material consisting of a total of not more than 18.5 MBq (500 μCi) of polonium-210 per device or of a total of not more than 1.85 GBq (50 mCi) of hydrogen-3 (tritium) per device.

3. Such devices authorized before [effective date of these amendments] for use under the general license that was provided in 39.4(22)*"a"* and equivalent regulations of an agreement state or the Nuclear Regulatory Commission and manufactured, tested and labeled by the manufacturer in accordance with the specifications contained in a specific license issued by the agency.

ITEM 12. Adopt the following **new** subparagraph **39.4(3)"c"(6)**:

(6) Certain industrial devices. Except for persons who manufacture, process, produce, or initially transfer for sale or distribution industrial devices containing radioactive material designed and manufactured for the purpose of detecting, measuring, gauging or controlling thickness, density, level, interface location, radiation, leakage, or qualitative or quantitative chemical composition, or for producing an ionized atmosphere, any person is exempt from the requirements for a license set forth in this chapter to the extent that such person receives, possesses, uses, transfers, owns, or acquires radioactive material, in these certain detecting, measuring, gauging, or controlling devices and certain devices for producing an ionized atmosphere, and manufactured, processed, produced, or initially transferred in accordance with a specific license issued under 10 CFR 32.30, which license authorizes the initial transfer of the device for use under these rules. This exemption does not cover sources not incorporated into a device, such as calibration and reference sources. Any person who desires to manufacture, process, produce, or initially transfer for sale or distribution industrial devices containing by-product material for use under these rules should apply for a license under 10 CFR 32.30 and for a certificate of registration in accordance with 10 CFR 32.210.

ITEM 13. Amend paragraph **39.4(21)"a"** as follows:

a. A general license is hereby issued authorizing commercial and industrial firms, research, educational and medical institutions, and federal, state and local government agencies to receive, possess, use and transfer ~~not more than 15 pounds (6.82 kg) of source material at any one time~~ uranium and thorium, in their natural isotopic concentrations and in the form of depleted uranium, for research, development, educational, commercial, or operational purposes~~.~~ in the following forms and quantities: ~~A person authorized to use or transfer source material, pursuant to this general license, may not receive more than a total of 150 pounds (68.2 kg) of source material in any one calendar year.~~

(1) No more than 1.5 kg (3.3 lb) of uranium and thorium in dispersible forms (e.g., gaseous, liquid, powder, etc.) at any one time. Any material processed by the general licensee that alters the chemical or physical form of the material containing source material must be accounted for as a dispersible form. A person authorized to possess, use, and transfer source material under this paragraph may not receive more than a total of 7 kg (15.4 lb) of uranium and thorium in any one calendar year. Persons possessing source material in excess of these limits as of [effective date of these amendments] may continue to possess up to 7 kg (15.4 lb) of uranium and thorium at any one time for one year beyond this date, or until the agency takes final action on a pending application submitted on or before [date one year from effective date of these amendments] for a specific license for such material; and receive up to 70 kg (154 lb) of uranium or thorium in any one calendar year until [date of end of calendar year after effective date of these amendments], or until the agency takes final action on a pending application submitted on or before [date one year from effective date of these amendments] for a specific license for such material; and

(2) No more than a total of 7 kg (15.4 lb) of uranium and thorium at any one time. A person authorized to possess, use, and transfer source material under this paragraph may not receive more than a total of 70 kg (154 lb) of uranium and thorium in any one calendar year. A person may not alter the chemical or physical form of the source material possessed under this paragraph unless it is accounted for under the limits of 39.4(21)*"a"*(1); or

(3) No more than 7 kg (15.4 lb) of uranium, removed during the treatment of drinking water, at any one time. A person may not remove more than 70 kg (154 lb) of uranium from drinking water during a calendar year under this paragraph; or

(4) No more than 7 kg (15.4 lb) of uranium and thorium at laboratories for the purpose of determining the concentration of uranium and thorium contained within the material being analyzed at any one time. A person authorized to possess, use, and transfer source material under this paragraph may not receive more than a total of 70 kg (154 lb) of source material in any one calendar year.

ITEM 14. Amend paragraph **39.4(21)"b"** as follows:

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

(1) Is prohibited from administering source material, or the radiation therefrom, either externally or internally, to human beings except as may be authorized by the agency in a specific license.

(2) Shall not abandon such source material. Source material may be disposed of as follows:

1. A cumulative total of 0.5 kg (1.1 lb) of source material in a solid, nondispersible form may be transferred each calendar year, by a person authorized to receive, possess, use, and transfer source material under this general license to persons receiving the material for permanent disposal. The recipient of source material transferred under the provisions of this paragraph is exempt from the requirements to obtain a license under this chapter to the extent the source material is permanently disposed. This provision does not apply to any person who is in possession of source material under a specific license issued under this chapter; or

2. In accordance with 641—40.70(136C).

(3) Is subject to the provisions in 641—38.4(136C), 641—38.9(136C), 39.4(21), 39.4(32)*"a"* through *"d"* and *"f,"* 39.4(41), 39.4(51), 39.4(52), 641—40.95(136C), 641—40.96(136C), and 641—40.97(136C).

(4) Reserved.

(5) Shall not export such source material except in accordance with 10 CFR Part 110.

ITEM 15. Amend paragraph **39.4(21)"c"** as follows:

c. ~~Persons who receive, possess, use, or transfer source material pursuant to the general license in 39.4(21)*"a"* are prohibited from administering source material, or the radiation therefrom, either externally or internally, to human beings except as may be authorized by the agency in a specific license.~~ Any person who receives, possesses, uses, or transfers source material in accordance with 39.4(21)*"a"* shall conduct activities so as to minimize contamination of the facility and the environment. When activities involving such source material are permanently ceased at any site, if evidence of significant contamination is identified, the general licensee shall notify the agency about such contamination and may consult with the agency as to the appropriateness of sampling and restoration activities to ensure that any contamination or residual source material remaining at the site where source material was used under this general license is not likely to result in exposures that exceed the limits in 641—40.29(136C).

ITEM 16. Adopt the following **new** paragraph **39.4(21)"f"**:

f. Any person who receives, possesses, uses, or transfers source material in accordance with the general license granted in 39.4(21)*"a"* is exempt from the provisions of 641—Chapter 40 to the extent that such receipt, possession, use, and transfer are within the terms of this general license, except that such person shall comply with the provisions of 641—40.29(136C) and 641—40.70(136C) to the extent necessary to meet the provisions of 39.4(21)*"b"*(2) and 39.4(21)*"c."* However, this exemption does not apply to any person who also holds a specific license issued under this chapter.

ITEM 17. Adopt the following **new** paragraph **39.4(21)"g"**:

g. No person may initially transfer or distribute source material to persons generally licensed under 39.4(21)*"a"*(1) and (2), or equivalent regulations of the Nuclear Regulatory Commission or an agreement state, unless authorized by a specific license issued in accordance with 39.4(39) or equivalent provisions of the Nuclear Regulatory Commission or an agreement state. This prohibition does not apply to analytical laboratories returning processed samples to the client who initially provided the sample. Initial distribution of source material to persons generally licensed by 39.4(21)*"a"* before [effective date of these amendments] without specific authorization may continue for one year beyond this date. Distribution may also be continued until the agency takes final action on a pending application for license or license amendment to specifically authorize distribution submitted on or before [date one year from effective date of these amendments].

ITEM 18. Rescind and reserve paragraph **39.4(22)"a."**

ITEM 19. Amend paragraph **39.4(24)"g"** as follows:

g. ~~An~~ (1) Except as provided in 39.4(24)*"g"*(2), (3), and (4), an application for a specific license to use radioactive material in the form of a sealed source or in a device that contains the sealed source must either:

~~(1)~~ 1. Identify the source or device by manufacturer and model number as registered with the Nuclear Regulatory Commission under 10 CFR 32.210 or with an agreement state, or for a source or a device containing radium-226 or accelerator-produced radioactive material as registered with a state under provisions comparable to 10 CFR 32.210; or

~~(2)~~ 2. Contain the information identified in 10 CFR 32.210(c)~~; or~~.

~~(3)~~ (2) For sources or devices ~~containing naturally occurring or accelerator-produced radioactive material~~ manufactured prior to ~~November 30, 2007~~ [effective date of these amendments], that are not registered with the Nuclear Regulatory Commission under 10 CFR 32.210 or with an agreement state, and for which the applicant is unable to provide all the categories of information specified in 10 CFR 32.210(c), the ~~applicant must provide~~ application must include:

1. All available information identified in 10 CFR 32.210(c) concerning the source and, if applicable, the device; and

2. Sufficient additional information to demonstrate that there is reasonable assurance that the radiation safety properties of the source or device are adequate to protect health and minimize danger to life and property. Such information must include a description of the source or device, a description of radiation safety features, the intended use and associated operating experience, and the results of a current leak test.

(3) For sealed sources and devices allowed to be distributed without registration of safety information in accordance with 10 CFR 32.210(g)(1), the applicant may supply only the manufacturer, model number, and radionuclide and quantity.

(4) If it is not feasible to identify each sealed source and device individually, the applicant may propose constraints on the number and type of sealed sources and devices to be used and the conditions under which they will be used, in lieu of identifying each sealed source and device.

ITEM 20. Adopt the following **new** subparagraph **39.4(26)"c"(6)**:

(6) If, in surveys made under 641—subrule 40.36(1), residual radioactivity in the facility and the environment, including the subsurface, is detected at levels that would, if left uncorrected, prevent the site from meeting the 641—40.29(136C) criteria for unrestricted use, the licensee must submit a decommissioning funding plan within one year of when the survey is completed.

ITEM 21. Amend paragraph **39.4(26)"e"** as follows:

e. (1) Each decommissioning funding plan must be submitted for review and approval and 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. Cost estimates must be adjusted at intervals not to exceed three years. 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."~~*

1. A detailed cost estimate for decommissioning, in an amount reflecting:

- The cost of an independent contractor to perform all decommissioning activities;
- The cost of meeting the 641—40.29(136C) criteria for unrestricted use, provided that, if the applicant or licensee can demonstrate its ability to meet the provisions of 641—40.30(136C), the cost estimate may be based on meeting the 641—40.30(136C) criteria;
- The volume of onsite subsurface material containing residual radioactivity that will require remediation to meet the criteria for license termination; and
- An adequate contingency factor;

2. Identification of and justification for using the key assumptions contained in the decommissioning cost estimate (DCE);

3. A description of the method of assuring funds for decommissioning from 39.4(26)*"f,"* including means for adjusting cost estimates and associated funding levels periodically over the life of the facility;

4. A certification by the licensee that financial assurance for decommissioning has been provided in the amount of the cost estimate for decommissioning; and

5. A signed original of the financial instrument obtained to satisfy the requirements of 39.4(26)*"f"* (unless a previously submitted and accepted financial instrument continues to cover the cost estimate for decommissioning).

(2) At the time of license renewal and at intervals not to exceed three years, the decommissioning funding plan must be resubmitted with adjustments as necessary to account for changes in costs and the extent of contamination. If the amount of financial assurance will be adjusted downward, this cannot be done until the updated decommissioning funding plan is approved. The decommissioning funding plan must update the information submitted with the original or prior approved plan, and must specifically consider the effect of the following events on decommissioning costs:

1. Spills of radioactive material producing additional residual radioactivity in onsite subsurface material;

2. Waste inventory increasing above the amount previously estimated;
3. Waste disposal costs increasing above the amount previously estimated;
4. Facility modifications;
5. Changes in authorized possession limits;
6. Actual remediation costs that exceed the previous cost estimate;
7. Onsite disposal; and
8. Use of a settling pond.

ITEM 22. Amend paragraph **39.4(26)"f,"** introductory paragraph, as follows:

f. The financial instrument must include the licensee's name, license number, and the name, address, and other contact information of the issuer, and, if a trust is used, the trustee. When any of the foregoing information changes, the licensee must, within 30 days, submit financial instruments reflecting such changes. The financial instrument submitted must be a signed original or signed original duplicate, except where a copy of the signed original is specifically permitted. Financial assurance for decommissioning must be provided by one or more of the following methods:

ITEM 23. Amend subparagraph **39.4(29)"d"(1)** as follows:

(1) An application for a specific license to manufacture or initially transfer devices containing radioactive material, excluding special nuclear material, to persons generally licensed under 39.4(22)*"d"* or equivalent regulations of the NRC, an agreement state, or a licensing state will be approved if:

1. to 3. No change.

4. Each device having a separable source housing that provides the primary shielding for the source also bears, on the source housing, a durable label containing the device model number and serial number, the isotope and quantity, the words "Caution—Radioactive Material," the radiation symbol described in 641—subrule 40.60(1), and the name of the manufacturer or initial distributor; ~~and~~

5. Each device meeting the criteria of 39.4(22)*"d"*(3)"13" bears a permanent (e.g., embossed, etched, stamped, or engraved) label affixed to the source housing if separable, or the device if the source housing is not separable, that includes the words, "Caution—Radioactive Material," and, if practicable, the radiation symbol described in 641—subrule 40.60(1)~~.~~; and

6. The device has been registered in the Sealed Source and Device Registry.

ITEM 24. Amend subparagraph **39.4(29)"e"(2)** as follows:

(2) The applicant satisfies the requirements of Sections 32.53, 32.54, 32.55, and 32.56~~, and 32.101~~ of 10 CFR Part 32, or their equivalent.

ITEM 25. Amend subparagraphs **39.4(29)"f"(1)** and **(2)** as follows:

(1) The applicant satisfies the general requirements of 39.4(25); and

(2) The applicant satisfies the requirements of Sections 32.57, 32.58, and 32.59 of 10 CFR Part 32, or their equivalent. ~~The applicant submits sufficient information regarding each type of calibration or reference source pertinent to evaluation of the potential radiation exposure, including:~~

~~1. Chemical and physical form and maximum quantity of americium-241 or radium-226 in the source;~~

~~2. Details of construction and design;~~

~~3. Details of the method of incorporation and binding of the americium-241 or radium-226 in the source;~~

~~4. Procedures for and the results of prototype testing of sources, which are designed to contain more than 0.005 microcuries of americium-241 or radium-226, to demonstrate that the americium-241 or radium-226 contained in each source will not be released or be removed from the source under normal conditions of use;~~

~~5. Details of quality control procedures to be followed in the manufacture of the source;~~

~~6. Description of labeling to be affixed to the source or storage container for the source;~~

~~7. Any additional information, including experimental studies and tests, required by the agency to facilitate a determination of the safety of the source.~~

ITEM 26. Rescind subparagraphs **39.4(29)"f"(3)** to **(6)**.

ITEM 27. Amend paragraph **39.4(29)"i"** as follows:

i. ~~Licensing the manufacture and distribution of ice detection devices.~~ An application for a specific license to manufacture or initially transfer ice detection devices containing strontium-90 to persons generally licensed under 39.4(22)*"j"* will be approved if the applicant satisfies the general requirements of 39.4(25) and the ~~criteria~~ requirements of Sections 32.61~~,~~ and 32.62~~, and 32.103~~ of 10 CFR Part 32, or their equivalent.

ITEM 28. Amend paragraph **39.4(29)"l"** as follows:

l. Manufacture and distribution of sources or devices containing radioactive material for medical use.

(1) An application for a specific license to manufacture and distribute sources and devices containing radioactive material to persons licensed pursuant to 641—41.2(136C) for use as a calibration, transmission, or reference source or for the uses listed in 641—subrules 41.2(41), 41.2(43), 41.2(49), and 41.2(88) will be approved if:

~~(1)~~ 1. The applicant satisfies the general requirements in 39.4(25);

~~(2)~~ 2. The applicant submits sufficient information regarding each type of source or device pertinent to an evaluation of its radiation safety, including:

~~1.~~ ● The radioactive material contained, its chemical and physical form, and amount,

~~2.~~ ● Details of design and construction of the source or device,

~~3.~~ ● Procedures for, and results of, prototype tests to demonstrate that the source or device will maintain its integrity under stresses likely to be encountered in normal use and accidents,

~~4.~~ ● For devices containing radioactive material, the radiation profile of a prototype device,

~~5.~~ ● Details of quality control procedures to ensure that production sources and devices meet the standards of the design and prototype tests,

~~6.~~ ● Procedures and standards for calibrating sources and devices,

~~7.~~ ● Legend and methods for labeling sources and devices as to their radioactive content, and

~~8.~~ ● Instructions for handling and storing the source or device from the radiation safety standpoint. These instructions are to be included on a durable label attached to the source or device or attached to a permanent storage container for the source or device, provided that instructions which are too lengthy for such label may be summarized on the label and printed in detail on a brochure which is referenced on the label;

~~(3)~~ 3. The label affixed to the source or device, or to the permanent storage container for the source or device, contains information on the radionuclide, quantity, and date of assay, and a statement that the NRC, agreement state, or this agency has approved distribution of the source or device to persons licensed to use by-product material identified in 641—41.2(136C) and 641—subrules 41.2(41) and 41.2(43), as appropriate, and to persons who hold an equivalent license issued by the NRC or an agreement state; and

4. The source or device has been registered in the Sealed Source and Device Registry.

~~(4)~~ (2) In the event the applicant desires that the source or device be required to be tested for leakage of radioactive material at intervals longer than six months, the applicant shall include in the application sufficient information to demonstrate that such longer interval is justified by performance characteristics of the source or device or similar sources or devices and by design features that have a significant bearing on the probability or consequences of leakage of radioactive material from the source~~; and~~.

~~(5)~~ (3) In determining the acceptable interval for test of leakage of radioactive material, the agency will consider information that includes, but is not limited to:

1. to 10. No change.

ITEM 29. Amend paragraph **39.4(32)"b"** as follows:

b. No license issued or granted under this chapter and no right to possess or utilize radioactive material granted by any license issued pursuant to this chapter shall be transferred, assigned, or in any manner disposed of, either voluntarily or involuntarily, directly or indirectly, through transfer of control

of any license to any person unless the agency shall, after securing full information, find that the transfer is in accordance with the provisions of the Iowa Code, now or hereafter in effect, and to all valid rules, regulations, and orders of the agency, and shall give its consent in writing. An application for transfer of license must include:

(1) The identity and technical and financial qualifications of the proposed transferee; and

(2) The financial assurance for decommissioning information required by 39.4(26).

ITEM 30. Amend subparagraph **39.4(32)"f"(2)** as follows:

(2) An entity (as that term is defined in 11 U.S.C. ~~101(14)~~ 101(15)) controlling the licensee or listing the license or licensee as property of the estate; or

ITEM 31. Adopt the following **new** subrule 39.4(39):

39.4(39) *Requirements for license to initially transfer source material for use under a general license.* An application for a specific license to initially transfer source material for use under 39.4(21), or equivalent regulations of an agreement state or the Nuclear Regulatory Commission, will be approved if:

a. The applicant satisfies the general requirements specified in 39.4(25); and

b. The applicant submits adequate information on, and the agency approves the methods to be used for, quality control, labeling, and providing safety instructions to recipients.

ITEM 32. Adopt the following **new** subrule 39.4(40):

39.4(40) *Conditions of licenses to initially transfer source material for use under general license: quality control, labeling, safety instructions, and records and reports.*

a. Each person licensed under 39.4(39) shall label the immediate container of each quantity of source material with the type of source material and quantity of material and the words "radioactive material."

b. Each person licensed under 39.4(39) shall ensure that the quantities and concentrations of source material are as labeled and indicated in any transfer records.

c. Each person licensed under 39.4(39) shall provide the information specified in this paragraph to each person to whom source material is transferred for use under 39.4(21) or equivalent provisions in agreement state or Nuclear Regulatory Commission regulations. This information must be transferred before the source material is transferred for the first time in each calendar year to the particular recipient. The required information includes:

(1) A copy of 39.4(21) and 39.4(41) or relevant equivalent regulations of the agreement state or Nuclear Regulatory Commission.

(2) Appropriate radiation safety precautions and instructions relating to handling, use, storage, and disposal of the material.

d. Each person licensed under 39.4(39) shall report transfers as follows:

(1) File a report with the Iowa Department of Public Health, 321 East 12th Street, Des Moines, Iowa 50319. The report shall include the following information:

1. The name, address, and license number of the person who transferred the source material;

2. For each general licensee under 39.4(21) or equivalent agreement state or Nuclear Regulatory Commission provisions to whom greater than 50 grams (0.11 lb) of source material has been transferred in a single calendar quarter, the name and address of the general licensee to whom source material is distributed; a responsible agent, by name or position, or both, and telephone number, of the general licensee to whom the material was sent; and the type, physical form, and quantity of source material transferred; and

3. The total quantity of each type and physical form of source material transferred in the reporting period to all such generally licensed recipients.

(2) File a report with each responsible agreement state agency or the Nuclear Regulatory Commission that identifies all persons, operating under provisions equivalent to 39.4(21), to whom greater than 50 grams (0.11 lb) of source material has been transferred within a single calendar quarter. The report shall include the following information specific to those transfers made to the agreement state or Nuclear Regulatory Commission jurisdiction:

1. The name, address, and license number of the person who transferred the source material; and

2. The name and address of the general licensee to whom source material was distributed; a responsible agent, by name or position, or both, and telephone number, of the general licensee to whom the material was sent; and the type, physical form, and quantity of source material transferred; and

3. The total quantity of each type and physical form of source material transferred in the reporting period to all such generally licensed recipients within the agreement state or Nuclear Regulatory Commission jurisdiction.

(3) Submit each report by January 31 of each year covering all transfers for the previous calendar year. If no transfers were made to persons generally licensed under 39.4(21) or equivalent agreement state or Nuclear Regulatory Commission provisions during the current period, a report shall be submitted to the agency indicating so. If no transfers have been made to general licensees in a particular agreement state or Nuclear Regulatory Commission jurisdiction during the reporting period, this information shall be reported to the responsible agreement state agency or Nuclear Regulatory Commission upon request.

e. Each person licensed under 39.4(39) shall maintain all information that supports the reports required by these rules concerning each transfer to a general licensee for a period of one year after the event is included in a report to the agency, the Nuclear Regulatory Commission or to an agreement state agency.

ITEM 33. Amend subrule 40.1(5) as follows:

40.1(5) All references to any Code of Federal Regulations (CFR) in this chapter are those in effect ~~on or before September 15, 2010~~ as of [effective date of these amendments].

ITEM 34. Amend subrule 40.28(6) as follows:

40.28(6) Minimization of contamination. Applicants for licenses, other than renewals, after July 1, 1999, shall describe in the application how facility design and procedures for operation will minimize, to the extent practicable, contamination of the facility and the environment, facilitate eventual decommissioning, and minimize, to the extent practicable, the generation of radioactive waste. Licensees shall, to the extent practical, conduct operations to minimize the introduction of residual radioactivity into the site, including the subsurface, in accordance with the existing radiation protection requirements in 641—40.10(136C) and radiological criteria for license termination in 40.28(1) through 40.28(5).

ITEM 35. Amend paragraph **40.30(3)"a"** as follows:

a. Funds placed into ~~an account~~ a trust segregated from the licensee's assets and outside the licensee's administrative control ~~as described in 641—subparagraph 39.4(26)~~*"f"*~~(1)~~ and in which the adequacy of the trust funds is to be assessed based on an assumed annual 1 percent real rate of return on investment;

ITEM 36. Rescind and reserve paragraph **40.30(3)"b."**

ITEM 37. Amend subrule 40.31(1) as follows:

40.31(1) The agency may terminate a license using alternate criteria greater than the dose criterion of 641—40.29(136C), 40.30(2) and 40.30(4)*"a"*(1) if the licensee:

a. and *b.* No change.

c. Reduces doses to ALARA levels taking into consideration any detriments such as traffic accidents expected to potentially result from decontamination and waste disposal; ~~and~~

d. Has submitted a decommissioning plan or license termination plan (LTP) to the agency indicating the licensee's intent to decommission in accordance with 641—paragraph 39.4(33)*"d,"* and specifying that the licensee proposes to decommission by use of alternate criteria. The licensee shall document in the decommissioning plan or LTP how the advice of individuals and institutions in the community, who may be affected by the decommissioning, has been sought and addressed, as appropriate, following analysis of that advice. In seeking such advice, the licensee shall provide for:

(1) and (2) No change.

(3) A publicly available summary of the results of all such discussions, including a description of the individual viewpoints of the participants on the issues and the extent of agreement and disagreement among the participants on the issues.; and

e. Has provided sufficient financial assurance in the form of a trust fund to enable an independent third party, including a governmental custodian of a site, to assume and carry out responsibilities for any necessary control and maintenance of the site.

ITEM 38. Amend paragraphs **40.32(1)"b"** and **"c"** as follows:

b. Each sealed source that is not designed to emit alpha particles is tested for leakage or contamination at intervals not to exceed six months or at alternative intervals approved by the agency, after evaluation of information specified by 641—subparagraphs 39.4(29)*"l"*(4)(2) and 39.4(29)*"l"*(5)(3) of these rules, an agreement state, a licensing state, or the U.S. Nuclear Regulatory Commission.

c. Each sealed source that is designed to emit alpha particles is tested for leakage or contamination at intervals not to exceed three months or at alternative intervals approved by the agency, after evaluation of information specified by 641—subparagraphs 39.4(29)*"l"*(4)(2) and 39.4(29)*"l"*(5)(3) of these rules, an agreement state, a licensing state, or the Nuclear Regulatory Commission.

ITEM 39. Amend subrule 40.36(1) as follows:

40.36(1) Each licensee or registrant shall make, or cause to be made, surveys of areas, including the subsurface, that:

a. No change.

b. Are necessary under the circumstances to evaluate:

(1) No change.

(2) Concentrations or quantities of ~~radioactive material~~ residual radioactivity; and

(3) The potential radiological hazards ~~that could be present~~ of the radiation levels and residual radioactivity detected.

ITEM 40. Renumber subrules **40.36(2)** to **40.36(5)** as **40.36(3)** to **40.36(6)**.

ITEM 41. Adopt the following **new** subrule 40.36(2):

40.36(2) Notwithstanding 641—40.82(136C), records from surveys describing the location and amount of subsurface residual radioactivity identified at the site must be kept with records important for decommissioning, and such records must be retained in accordance with 641—subrule 39.4(26) as applicable.

ITEM 42. Amend paragraph **40.37(1)"b"** as follows:

b. Minors likely to receive, in 1 year from sources external to the body, a deep dose equivalent in excess of 0.1 rem (1 mSv), a lens dose equivalent in excess of 0.15 rem (1.5 mSv), or a shallow dose equivalent to the skin or to the extremities in excess of 0.5 rem (~~1~~ 5 mSv);

ITEM 43. Amend paragraph **41.1(1)"b"** as follows:

b. All references to any Code of Federal Regulations (CFR) in this chapter are those in effect as of ~~July 9, 2008~~ [effective date of these amendments].

ITEM 44. Amend subparagraph **41.1(3)"a"(10)**, introductory paragraph, as follows:

(10) All individuals who are associated with the operation of an X-ray system are subject to the requirements of 641—subrule ~~40.36(3)~~ 40.36(4) and rules 641—40.15(136C) and 641—40.37(136C). In addition:

ITEM 45. Amend paragraph **41.2(1)"b"** as follows:

b. All references to any Code of Federal Regulations (CFR) in this chapter are those in effect as of ~~September 15, 2010~~ [effective date of these amendments].

ITEM 46. Amend paragraphs **41.2(4)"b"** and **"c"** as follows:

b. Before permitting anyone, except a visiting authorized user or visiting authorized nuclear pharmacist described in 41.2(12), to work as an authorized user or authorized nuclear pharmacist under the license;

c. Before changing a radiation safety officer, ~~or~~ teletherapy physicist or authorized medical physicist;

ITEM 47. Rescind and reserve subparagraph **41.2(9)"a"(3)**.

ITEM 48. Amend subparagraphs **41.2(17)"b"(2)** and **(3)** as follows:

(2) Test each dose calibrator for accuracy upon installation and at 12-month intervals ~~not to exceed 12 months~~ thereafter by assaying at least two sealed sources containing different radionuclides, the activity of which the manufacturer has determined within 5 percent of the stated activity, with minimum activity of 10 microcuries (370 kBq) for radium-226 and 50 microcuries (1.85 MBq) for any other photon-emitting radionuclide, and at least one of which has a principal photon energy between 100 keV and 500 keV;

(3) Test each dose calibrator for linearity upon installation and at 3-month intervals ~~not to exceed three months~~ thereafter over the range of use between 30 microcuries (1.1 megabequerels) and the highest dosage that will be administered; and

ITEM 49. Amend paragraphs **41.2(20)"a"** to **"d"** as follows:

a. Sealed sources manufactured and distributed by persons specifically licensed pursuant to 641—Chapter 39 or equivalent provisions of the U.S. Nuclear Regulatory Commission, agreement state or licensing state and that do not exceed ~~15~~ 30 millicuries (~~555 MBq~~ 1.11 GBq) each;

b. Any radioactive material listed in 41.2(31) or 41.2(33) with a half-life of ~~100~~ 120 days or less in individual amounts not to exceed 15 millicuries (555 MBq);

c. Any radioactive material listed in 41.2(31) or 41.2(33) with a half-life greater than ~~100~~ 120 days in individual amounts not to exceed 200 microcuries (7.4 MBq) each; and

d. Technetium-99m ~~in individual~~ amounts ~~not to exceed 50 millicuries (1.85 GBq)~~ as needed.

ITEM 50. Amend paragraph **41.2(21)"d"** as follows:

d. A licensee shall retain leak test records for five years. The records shall contain the model number, and serial number, if assigned, of each source tested, the identity of each source radionuclide and its estimated activity, the measured activity of each test sample expressed in microcuries (becquerels), a description of the method used to measure each test sample, the date of the test, ~~and~~ the signature of the radiation safety officer and the signature of the individual performing the leak test.

ITEM 51. Amend paragraph **41.2(21)"g"** as follows:

g. A licensee in possession of a sealed source or brachytherapy source shall conduct a physical inventory of all such sources at 6-month intervals ~~not to exceed three months~~. The licensee shall retain each inventory record for five years. The inventory records shall contain the model number of each source, and serial number if one has been assigned, the identity of each source radionuclide and its estimated activity, the location of each source, date of the inventory, ~~and~~ the signature of the radiation safety officer and the signature of the individual performing the physical inventory.

ITEM 52. Amend subparagraph **41.2(34)"a"(2)** as follows:

(2) More than 0.02 microcurie of strontium-82 per millicurie of rubidium-82 chloride injection (0.02 kilobecquerel strontium-82 per megabecquerel rubidium-82 chloride); or more than ~~0.02~~ 0.2 microcurie of strontium-85 per millicurie of rubidium-82 chloride injection (~~0.02~~ 0.2 kilobecquerel strontium-85 per megabecquerel rubidium-82 chloride).

ITEM 53. Amend paragraph **41.2(38)"a"** as follows:

a. A licensee shall provide oral and written radiation safety instruction for all personnel caring for patients or human research subjects undergoing radiopharmaceutical therapy and hospitalized for compliance with 41.2(27). Refresher training shall be provided initially and at 12-month intervals ~~not to exceed one year~~ or as required for patient care.

ITEM 54. Rescind and reserve subparagraph **41.2(39)"a"(8)**.

ITEM 55. Amend paragraph **41.2(44)"a"** as follows:

a. The licensee shall provide oral and written radiation safety instruction to all personnel caring for a patient or human research subject receiving implant therapy. Refresher training shall be provided initially and at 12-month intervals ~~not to exceed one year~~ or as required for patient care.

ITEM 56. Adopt the following **new** subparagraph **41.3(6)"b"(5)**:

(5) Therapeutic medical physics; or

ITEM 57. Amend subrule 41.3(7) as follows:

41.3(7) Qualifications of operators. Individuals who will be operating a therapeutic radiation machine for medical use shall be adequately instructed in the safe operating procedures and hold a current permit to practice in radiation therapy as a radiation therapist under the provisions of 641—Chapter 42. The permit holder shall make the permit available at the individual's place of employment. If the permit holder works at more than one facility, a duplicate of the permit shall be kept at each facility.

ITEM 58. Amend subparagraph **41.3(18)"f"(6)** as follows:

(6) Therapeutic radiation machines subject to 41.3(18) shall have safety quality assurance checks of each external beam radiation therapy machine performed at intervals ~~not to exceed one week~~ recommended by the manufacturer;

ITEM 59. Amend paragraph **45.1(1)"b"** as follows:

b. All references to any Code of Federal Regulations (CFR) in this chapter are those in effect as of ~~September 15, 2010~~ [effective date of these amendments].

~~The provisions of 641—Chapter 38 are in addition to, and not in substitution for, any other applicable portions of 641—Chapters 39 to 45.~~

ITEM 60. Amend paragraph **45.1(5)"b,"** introductory paragraph, as follows:

b. Notwithstanding the requirements of 641—subrule ~~40.36(2)~~ 40.36(3) each radiation survey instrument shall be calibrated:

ITEM 61. Amend subparagraph **45.1(7)"a"(3)** as follows:

(3) The plant or site where each sealed source is used and the date of use; and

ITEM 62. Amend paragraph **45.3(4)"a"** as follows:

a. Each radiographic exposure device, source assembly or sealed source, and all associated equipment must meet the requirements specified in American National Standard N432-1980, "Radiological Safety for the Design and Construction of Apparatus for Gamma Radiography" (published as NBS Handbook 136, issued January 1981). This publication has been approved for incorporation by reference by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR Part 51. This publication may be purchased from the American National Standards Institute, Inc., ~~1430 Broadway~~ 25 West 43rd Street, New York, New York ~~10018~~ 10036, telephone (212)642-4900. ~~Copies of the document are available for inspection at the Iowa Department of Public Health, Bureau of Radiological Health, Lucas State Office Building, Des Moines, Iowa 50319.~~