PUBLIC HEALTH DEPARTMENT [641]

Notice of Intended Action

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 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," Iowa Administrative Code.

The following itemize the proposed changes.

Items 1, 3, 5, and 24 amend the rules to reflect current federal regulations.

Item 2 deletes a definition of "mammogram" which is already defined in Chapter 41. It also adds to the definition of "mammography" a reference that directs the reader to Chapter 41 for additional information.

Item 4 is a compatibility issue with the U.S. Nuclear Regulatory Commission and place into rule a policy regarding federal facilities.

Item 6 changes a requirement for dental facilities. The commitment for this change was made to the dental community because the performance of the dental X-ray equipment does not change until after about four years.

Item 7 allows an exemption for X-ray equipment that is not manufactured with the audible signal and cannot be altered to include the audible signal. This allows the use of X-ray equipment manufactured before the federal requirements for audible signal.

Item 8 allows the facility to alter the procedures if it is pre-approved by the agency.

Item 9 allows the use of specific radioactive material in order to keep current with industry technology.

Items 10, 11, 12, 13, 14, 15, 16, 17, 18, and 19 correct references.

Item 20 is amended to include wording that was left out of the original amendment.

Item 21 changes time requirements that were in the original draft to match the final wording accepted by the regulating state bodies.

Item 22 expands the definition of "mammography" to exclude a procedure that is not for diagnostic purposes.

Item 23 shortens the time requirement for testing because the test is now scheduled upon demand instead of only three times a year.

Item 25 is changed to be consistent with the rule for retention of records for accelerators.

Item 26 is changed to exempt testing only.

Item 27 adds registration requirements to include all facilities producing radioactive material.

Item 28 adds training and testing requirements for operators not previously included except by policy.

Item 29 is changed to be consistent with the X-ray and sealed source rules.

Items 30 and 31 add a time frame not previously included.

Item 32 changes time frames to be consistent with other X-ray rules.

Items 33, 34, and 35 add wording to include all types of accelerator facilities.

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 April 24, 2001. Such written materials should be directed to Donald A. Flater, Chief, Bureau of Radiological Health, Department of Public Health, 401 S.W. 7th Street, Suite D, Des Moines, Iowa 50309; fax: (515)725-0318; or E-mail: dflater@idph.state.is.ua.

A public hearing will be held on April 24, 2001, at 8:30 a.m., in the Conference Room, Iowa Department of Public Health, 401 S.W. 7th Street, Suite D, Des Moines, Iowa, 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 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 ~~May 9, 2001~~July 4, 2001.

ITEM 2. Amend rule **641—38.2(136C)** by deleting the definition of "mammogram" and amending the definition of "mammography" as follows:

"Mammography" means the radiography of the breast except as defined in 41.6(1).

ITEM 3. 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 ~~May 9, 2001~~July 4, 2001.

ITEM 4. Adopt **new** subrule **39.1(4)** as follows:

39.1(5) In areas under exclusive federal jurisdiction, nothing in these rules apply to the extent that persons are subject to the regulation by the U.S. Nuclear Regulatory Commission (NRC) or other federal agencies.

ITEM 5. 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 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 ~~May 9, 2001~~July 4, 2001.

ITEM 6. Amend subrule **41.1(3)** as follows:

a. Registrant. The registrant shall be responsible for maintaining and directing the operation of the X-ray system(s) under the registrant's administrative control and for having the following minimum test performed ~~every two years~~ by a registered service facility according to the following schedule:

1. Medical/chiropractic: timer accuracy, exposure reproducibility, kVp accuracy as set forth in 41.1(6), and light field/X-ray field alignment as set forth in 41.1(6) every two years.

2. Dental/podiatry: timer accuracy, exposure reproducibility and kVp accuracy as set forth in 41.1(7) every four years.

3. Fluoroscopic: entrance exposure rate (641—41.1(5)"c"), and minimum SSD (641—41.1(5)"f") every two years.

ITEM 7. Amend subparagraph **41.1(7)"c"(2)** as follows:

(2) Exposure indication. Means shall be provided for visual indication observable at or from the operator's protected position whenever X-rays are produced. In addition, a signal audible to the operator shall indicate that the exposure has terminated except in X-ray systems that cannot be altered to meet this requirement.

ITEM 8. Amend subrule **41.2(22)** paragraph "**b**" as follows:

b. ~~A~~Unless otherwise approved by this agency, a licensee shall require each individual who prepares or administers radiopharmaceuticals to use a syringe radiation shield unless the use of the shield is contraindicated for that patient or human research subject.

ITEM 9. Amend subrule **41.2(41)** by adopting **new** paragraph as follows:

e. Germanium-68 in imaging systems.

ITEM 10. Amend subrule **41.2(67)** as follows:

41.2(67) Training for uptake, dilution, or excretion studies. Except as provided in ~~41.2(75) and~~ 41.2(76), the licensee shall require the authorized user of a radiopharmaceutical listed in 41.2(31) to be a physician who:

ITEM 11. Amend subrule **41.2(68)** as follows:

41.2(68) Training for imaging and localization studies. Except as provided in ~~41.2(75) and~~ 41.2(76), the licensee shall require the authorized user of a radiopharmaceutical, generator, or reagent kit specified in 41.2(33) to be a physician who:

ITEM 12. Amend subrule **41.2(69)** as follows:

41.2(69) Training for therapeutic use of radiopharmaceuticals. ~~Except as provided in 41.2(75), the~~ The licensee shall require the authorized user of a radiopharmaceutical listed in 41.2(37) for therapy to be a physician who:

ITEM 13. Amend subrule **41.2(70)** as follows:

41.2(70) Training for therapeutic use of brachytherapy sources. ~~Except as provided in 41.2(75), the~~ The licensee shall require the authorized user using a brachytherapy source specified in 41.2(43) for therapy to be a physician who:

ITEM 14. Amend subrule **41.2(71)** as follows:

41.2(71) Training for ophthalmic use of strontium-90. ~~Except as provided in 41.2(75), the~~ The licensee shall require the authorized user using only strontium-90 for ~~opthalmic~~ophthalmic radiotherapy to be a physician who:

ITEM 15. Amend subrule **41.2(72)** as follows:

41.2(72) Training for use of sealed sources for diagnosis. ~~Except as provided in 41.2(75), the~~ The licensee shall require the authorized user using a sealed source in a device specified in 41.2(41) to be a physician, dentist, or podiatrist who:

ITEM 16. Amend subrule **41.2(73)** as follows:

41.2(73) Training for teletherapy. ~~Except as provided in 41.2(75), the~~ The licensee shall require the authorized user of a sealed source specified in 41.2(49) in a teletherapy unit to be a physician who:

ITEM 17. Amend subrule **41.3(2)** by amending the definition of "radiation therapy physicist" as follows:

"Radiation therapy physicist" means an individual qualified in accordance with ~~41.3(4)"d."~~41.3(6).

ITEM 18. Amend numbered subparagraph **41.3(18)"a"(4)"2"** as follows:

2. If the absorbed dose rate information required by ~~41.3(18)"a"(8)~~41.3(18)"a"(9) relates exclusively to operation with a field-flattening or beam-scattering filter in place, such filter shall be removable only by the use of tools;

ITEM 19. Amend numbered subparagraph **41.3(18)"a"(7)"2"** as follows:

2. The device(s) referenced in 41.3(18)"a"(7)"1" shall be able to detect field asymmetry greater than 10 percent, and shall be configured to terminate irradiation if ~~the specifications in 41.3(18)"a"(7)"2"~~field asymmetry cannot be maintained at 10 percent or less.

ITEM 20. Amend numbered subparagraph **41.3(18)"e"(1)"3"** as follows:

3. Before medical use under the following conditions:

- Whenever quality assurance check measurements indicate that the radiation output differs by more than 5 percent from the value obtained at the last full calibration and the difference cannot be reconciled. Therapeutic radiation machines with multi-energy and/or multi-mode capabilities shall only require measurements for those modes and/or energies that are not within their acceptable range; and
- Following any component replacement, major repair, or modification of components that could significantly affect the characteristics of the radiation beam. 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."

ITEM 21. Amend numbered subparagraph **41.3(18)"f"(5)"2"** and**"3"** as follows:

2. If all quality assurance parameters appear to be within their acceptable range, the quality assurance check shall be reviewed and signed by either the authorized user or radiation therapy physicist within ~~two weeks of treatment~~ seven working days; and

3. The radiation therapy physicist shall review and sign the results of each radiation output quality assurance check within ~~two weeks~~ 20 working days of completion.

ITEM 22. Amend subrule **41.6(1)** by amending the definition of "mammography" as follows:

"Mammography" means radiography of the breast but, for the purposes of 641—41.6(136C), does not include:

1. Radiography of the breast performed during invasive interventions for localization or biopsy procedures; or

2. Radiography of the breast performed with an investigational mammography device as part of a scientific study conducted in accordance with FDA investigational device exemption regulations; or

3. Radiography of the breast performed as part of either a breast localization procedure or a post stereotactic clip placement localization procedure.

ITEM 23. Amend subrule **42.3(3)** as follows:

a. All individuals seeking to perform diagnostic radiography must, in addition to subrule 42.3(1), take and satisfactorily pass a written examination within ~~one year~~ six months of the date of the initial certification. Examination must include the following subject matter for each category of radiographer:

ITEM 24. Amend subrule **45.1(1)**, introductory paragraph, as follows:

45.1(1) Purpose and scope. The rules in this chapter establish radiation safety requirements for using sources of radiation for industrial radiography. The requirements of this chapter are in addition to, and not in substitution for, other applicable requirements of 641—Chapters 38, 39, and 40. The rules in this chapter apply to all licensees or registrants who use sources of radiation for industrial radiography. All references to any Code of Federal Regulations (CFR) in this chapter are those in effect as of ~~May 9, 2001~~ July 4, 2001.

ITEM 25. Amend subparagraph **45.2(6)"a"(2)** as follows:

(2)Be evaluated at intervals not to exceed one year to ensure compliance with the applicable requirements as specified in 641—subrule 40.26(1). Records of these evaluations shall be maintained for inspection by the agency for a period of ~~two~~three years after the evaluation.

ITEM 26. Amend subrule **45.4(1)** by amending paragraph "**b**" and adding **new** paragraph "**c**":

b. Unless specifically required otherwise by this rule, all registrants or licensees performing operations with a particle accelerator are subject to the requirements of 641—Chapters 38 to 40 and 641—45.1(136C). ~~The requirements of 45.1(10) do not apply.~~

c. The requirements of 45.1(10) do not apply to non-radiographic uses.

ITEM 27. Amend paragraph **45.4(3)"a"** as follows:

a. Accelerator facilities whose operations result in nuclear transformations that produce or are likely to produce radioactive material more than the exempt quantities and concentrations listed in Appendices A and B of 641—Chapter 39 shall be authorized by the issuance of a radioactive material license in accordance with 641—Chapter 39. Accelerator facilities that produce or are likely to produce radioactive material less than the exempt quantities and concentrations shall be authorized by registration.

ITEM 28. Amend subrule **45.4(6)** by adding the following the **new** paragraph:

d. Operators of particle accelerators used for industrial radiography shall meet the requirements of 45.1(10).

ITEM 29. Amend paragraph **45.4(6)"c"** as follows:

c. Along with the audit required in 641—subrule 40.10(3), each operator's performance during an actual accelerator operation shall be audited by the radiation safety officer or designee at intervals not to exceed ~~12~~six months. If an operator has not participated in an accelerator operation for more than ~~12~~six months since the last audit, the individual's performance shall be observed and recorded at the first opportunity the individual participates in an accelerator operation. Records of the audits shall be maintained by the registrant for the agency inspection for three years from the date of the audit.

ITEM 30. Amend paragraph **45.4(10)"c"** as follows:

c. All safety and warning devices, including interlocks, shall be checked for proper operation intervals not to exceed three months. Results of such tests shall be maintained at the accelerator facility for inspection by the agency for three years.

ITEM 31. Amend paragraph **45.4(10)"d"** as follows:

d. All incidents ~~whereby~~in which the interlock system fails to operate properly or where the operation is terminated by the interlock system shall be investigated and reported to the radiation safety officer or, if applicable, the radiation safety committee. Documentation shall be maintained for inspection by the agency for three years.

ITEM 32. Amend paragraph **45.4(11)"b"** as follows:

b. Accelerator facilities ~~registered pursuant to 45.4(3)"a"~~ shall survey with a radiation detection instrument at intervals not to exceed ~~three~~12 months. Records of this survey shall be maintained for agency review for three years.

ITEM 33. Amend paragraph **45.4(11)"c"** as follows:

c. Accelerator facilities registered or licensed pursuant to 45.4(3)"a" shall survey for removable contamination at intervals not to exceed six months to determine the degree of contamination.

ITEM 34. Amend paragraph **45.4(11)"e"** as follows:

e. Accelerator facilities registered or licensed pursuant to 45.4(3)"a" shall perform a survey with a radiation detection instrument and surveys for removable contamination before maintenance or servicing of its particle accelerator(s) or associated equipment located in the high radiation area.

ITEM 35. Amend paragraph **45.4(11)"h"** as follows:

h. Whenever applicable, accelerator facilities registered or licensed pursuant to 45.4(3)"a" shall perform surveys at intervals not to exceed six months to determine the amount of airborne particulate radioactivity present.

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Stephen C. Gleason, Director Date