Fields of Opportunities

STATE OF IOWA

THOMAS J. VILSACK
GOVERNOR

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LT. GOVERNOR

DEPARTMENT OF PUBLIC HEALTH
JANE COLACECCHI, ACTING DIRECTOR

December 26, 2002

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STP

Josephine Piccone, Deputy Director
Office of State and Tribal Programs
U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001

Dear Ms. Piccone:

Enclosed is a copy of the proposed revision to the Iowa Radiation Machines and Radioactive Materials Rules. The proposed rules will be available for public comment after February 5, 2003, with a request for comments by February 25, 2003. We request NRC's comments by February 25, 2003. Proposed revisions are identified by item number and underlined/strikeout text. The corresponding NRC reference and RATS number is in bold italics. Amendments are in response to comments from amendments submitted in October, 2002, and an annual review of our rules for compatibility and errors.

We believe adoption of these revisions satisfies the compatibility and health and safety categories established in the Office of State and Tribal Programs (STP) procedure SA-200.

If you have any questions, please feel free to contact me at 515/725-0306 or Donald Flater at 515/281-3478 or email dflater@idph.state.ia.us or Fax 515/725-0318.

Sincerely,

Charlene Craig
Bureau of Radiological Health
515-725-0306; email: ccraig@idph.state.ia.us

cc: Jim Lynch, Regional 3

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 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 43, "Minimum Requirements for Radon Testing and Analysis"; Chapter 44, "Minimum Requirements for Radon Mitigation"; Chapter 45, "Radiation Safety Requirements for Industrial Radiographic Operations"; Iowa Administrative Code.

The following itemize the proposed changes.

Items 1, 6, 18, 25, 52, and 82 amend the rules to reflect current federal regulations.

Item 2 amends the definitions to meet NRC compatibility requirements and federal x-ray standards. The definition of "healing arts screening" was moved to Chapter 41. The definition of "recordable event" was rescinded because it is no longer used.

Item 3 corrects terminology.

Items 4 and 50 delete wording regarding effective dates since the effective dates are passed.

Item 5 adds wording to clarify who is a shipper of radioactive waste.

Item 7 adds wording to allow the agency to revoke a registration for facilities providing x-ray services.

Items 8, 53, 54, 58, 59, 84, 93, and 94 amend or add wording to reflect NRC compatibility requirements.

Item 9 adds language for general licensees who install generally licensed devices in order to reflect NRC compatibility requirements.

Item 10 adds language for industrial radiography license applicant in order to reflect NRC compatibility requirements.

Items 11, 12, 13, 14, 15, 16, and 17 add and correct language regarding the manufacture of radiopharmaceuticals and radiation sources. This is an NRC compatibility requirement.

Items 19, 21, and 51 correct references or misspellings.

Item 20 adds requirements for posting or labeling because of enforcement problems.

Items 22, 23, and 24 add and correct language regarding radiation protection. This is an NRC compatibility requirement.

Items 26, 30, 32, and 72 add a definition rescinded from Chapter 38 and change and add wording to reflect concerns of the Board of Medical Examiners and the agency legal staff regarding healing arts screening.

Item 27 clarifies the responsibilities in the use of x-ray equipment.

Items 28, 29, 31, 33, 34, 35, 37, 38, 39, 40, 41, 42, 43, 44, 45, 46, 47, and 48 amend wording to reflect federal or national standards in the operation of x-ray equipment.

Item 36 adds new language for retention of x-ray films to give guidance to the facilities.

Item 49 corrects the formulas.

Items 55 and 57 move posting and training requirements for operators to one subrule.

Item 56 adds new reporting requirements for an embryo/fetus or a nursing child. This is an NRC compatibility requirement.

Items 60, 61, 62, 63, 64, 65, 66, 67, 68, 69, 70, and 71 add or correct wording to reflect FDA compatibility for mammography.

Items 73, 74, 75, 76, 77, 78, 79, 80, and 81 reflect changes in testing for all individuals certified under Chapter 42 and training for limited diagnostic radiographers. These changes were in response to concerns raised by educators and agency staff and to resolve enforcement issues.

Items 83, 85, 86, 87, 88, 89, 90, 91, 92, and 95 change the term "radiographer trainee" to "radiographer's assistant" to meet NRC compatibility requirements.

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 February 25, 2003. Such written materials should be directed to Donald A. Flater, Chief, Bureau of Radiological Health, Department of Public Health, 401 SW 7th Street, Suite D, Des Moines, Iowa 50309-4611; fax (515)725-0318; or E-mail: dflater@idph.state.ia.us.

A public hearing will be held on February 25, 2003, at 8:30 a.m. in the Conference Room, Department of Public Health, 401 SW 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 the public hearing and has special requirements such as those related to hearing or mobility impairments should contact the Department 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 ~~January~~ May 1, 2003.

ITEM 2. Amend rule **641—38.2(136C)** as follows:

Rescind the definitions of "Healing arts screening" and "Recordable event."

Amend the following definitions:

"Beam axis" means ~~the axis of rotation of the beam-limiting device~~ a line from the source through the centers of the x-ray fields.

"Diagnostic X-ray imaging system" means an assemblage of components for the generation, emission and reception of X-rays and the transformation, storage and visual display of the resultant X-ray image which are designed and used for irradiation of any part of the human or animal body for the purpose of diagnosis or visualization.

"Extremity" means hand, elbow, arm below the elbow, foot, knee, and leg below the knee. See 42.1(2) definitions of lower extremities and upper extremities for purposes of certification standards.

"Half-value layer (HVL)" means the thickness of a specified material which attenuates X-radiation or gamma radiation to an extent such that the air kerma rate, exposure rate or absorbed dose rate is reduced to one-half of the value measured without the material at the same point. The contribution of all scattered radiation, other than any which might be present initially in the beam concerned, is deemed to be excluded.

"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)~~ 0.1 rem (1 mSv) in 1 hour at 30 centimeters from any source of radiation or 30 centimeters from any surface that the radiation penetrates.

"Licensed practitioner" means a person licensed or otherwise authorized by law to practice medicine, osteopathy, chiropractic, podiatry, or dentistry in Iowa, or certification as a physician assistant as defined in Iowa Code section 148C.1, subsection 6, and is authorized to prescribe X-ray tests for the purpose of diagnosis or treatment.

20.1003 compatibility A

"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 or to radioactive material 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, from any medical administration the individual has received, from exposure to individuals administered sources of radiation or radioactive material and released in accordance with 41.2(27), from voluntary participation in medical research programs, or as a member of the public.

Compatibility C

"Person" means:

(1) ~~any~~ Any individual, corporation, partnership, firm, association, trust, estate, public or private institution, group, government agency other than the NRC or the Department of Energy (except that the agency shall be considered a person within the meaning of the regulations in 10 CFR Part 1 to the extent that its facilities and activities are subject to the licensing and related regulatory authority of the NRC under section 202 of the Energy Reorganization Act of 1974 (88 Stat. 1244), the Uranium Mill Tailings Radiation Control Act of 1978 (92 Stat. 3021), the Nuclear Waste Policy Act of 1982 (96 Stat. 2201), and section 3(b)(2) of the Low-Level Radioactive Waste Policy Amendments Act of 1985 (99 Stat. 1842)), any state or political subdivision of ~~this state, any other state or political subdivision or agency thereof,~~ or any political entity within a state, any foreign government or nation or any political subdivision of any such government or nation, or other entity; and

(2) ~~any~~ Any legal successor, representative, agent, or agency of the foregoing~~, but shall not include federal government agencies~~.

"Prescribed dosage" means the specified activity or range of activity of unsealed by-product material as documented:

1. In a written directive; or

2. ~~Either in the diagnostic clinical procedures manual or in any appropriate record in accordance with the directions of the authorized user for diagnostic procedures~~ In accordance with the directions of the authorized user for procedures performed in 41.2(31) and (33).

"Reportable medical event"

c. A dose to the skin or an organ or tissue other than the treatment site that exceeds by 50 rem (0.5 Sv) to an organ or tissue and 50 percent or more of the dose expected from the administration defined in the written directive (excluding, for permanent implants, seeds that were implanted in the correct site but migrated outside the treatment site).

ITEM 5. Amend subrule **38.8(11)**, paragraph "**a**," subparagraph **(3)**, as follows:

(3) $50 for each shipment by truck or by rail paid by the shipper for low-level radioactive waste shipped in or across Iowa. The department may accept an annual shipment fee as negotiated with a shipper or accept payment per shipment. This fee applies to waste shipped to a site authorized by a government agency to receive low level radioactive waste or is shipped to a storage site to be held for future disposal.

ITEM 6. 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 ~~January~~ May 1, 2003.

ITEM 7. Amend subrule **39.3(3)**, by adopting **new** paragraph "**f**," as follows:

f. A registration may be revoked for violating or causing a facility to violate any of the rules in 641—Chapters 38 through 45.

31.5(a)(13compatibility D)

ITEM 8. Amend subrule **39.4(22)**, paragraph "**d**," subparagraph **(3)**, numbered paragraph 13, first bulleted paragraph as follows:

- Shall register devices containing at least 10 mCi (370 MBq) of cesium-137, 0.1 mCi (3.7 MBq) of strontium-90, 1 mCi (37 MBq) of cobalt-60, 1 mCi (37 MBq) of americium-241, .01 mCi (.37 MBq) of radium-226, or 1 mCi (37 MBq) of any other transuranic (i.e., element with atomic number greater than uranium (92)), or 1000 times the activity indicated in Appendix B of 641—Chapter 39 (excluding hydrogen-3), based on the activity indicated on the label. Each address for a location of use, as described in 39.4(22)"d"(3)"13," represents a separate general licensee and requires a separate registration and fee;

RATS 2001-1, 31.6, compatibility B

ITEM 9. Amend subrule **39.4(22)**, paragraph "**d**," by adopting **new** subparagraph **(5)**, as follows:

(5) General license to install devices generally licensed in 39.4(22)"d." Any person who holds a specific license issued by an agreement state authorizing the holder to manufacture, install, or service a device described in 39.4(22)"d" within such agreement state is hereby granted a general license to install and service such device in any non-agreement state and a general license to install and service such device in offshore waters, as defined in 641—45.1(136C), provided that:

1. The device has been manufactured, labeled, installed, and serviced in accordance with the applicable provision of the specific license issued to such person by the agreement state, and

2. Such person assures that any labels required to be affixed to the device under regulations of the agreement state which licensed manufacture of the device bear a statement that removal of the label is prohibited.

34.13 compatibility C

ITEM 10. Amend subrule **39.4(31)** by adopting **new** paragraph "**c**," as follows:

c. Specific license for industrial radiography. An application for a specific license for the use of licensed material in industrial radiography will be approved if the applicant meets the following requirements:

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

(2) The applicant submits an adequate program for training radiographers and radiographers' assistants that meets the requirements of 45.1(10)

(3) The applicant submits procedures for verifying and documenting the certification status of radiographers and for ensuring that the certification of individuals acting as radiographers remains valid.

(4) The applicant submits written operating and emergency procedures as described in 45.2(4).

(5) The applicant submits a description of a program for inspections of the job performance of each radiographer and radiographers' assistant at intervals not to exceed 6 months as described in 45.1(11).

(6) The applicant submits a description of the applicant's overall organizational structure as it applies to the radiation responsibilities in industrial radiography, including specified delegation of authority and responsibility.

(7) The applicant identifies and lists the qualifications of the individual(s) designated as the RSO (45.1(10)"d") and potential designees responsible for ensuring that the licensee's radiation safety program is implemented in accordance with approved procedures.

(8) If an applicant intends to perform leak testing of sealed sources or exposure devices containing depleted uranium (DU) shielding, the applicant must describe the procedures for performing and the qualifications of the person(s) authorized to do the leak testing. If the applicant intends to analyze its own wipe samples, the application must include a description of the procedures to be followed. The description must include the instruments to be used, methods of performing the analysis, and pertinent experience of the person who will analyze the wipe samples.

(9) If the applicant intends to perform "in-house" calibrations of survey instruments the applicant must describe the methods to be used and the relevant experience of the person(s) who will perform the calibrations. All calibrations must be performed according to the procedures described and at the intervals prescribed in 45.1(5).

(10) The applicant identifies and describes the location(s) of all field stations and permanent radiographic installations.

(11) The applicant identifies the locations where all records required by 641—Chapters 38, 39, 40, and 45.

32.72, compatibility B

ITEM 11. Amend subrule **39.4(29)**, paragraph "**j**," subparagraph (**1**), the second numbered paragraph, by adopting an additional **new** bulleted paragraph, as follows:

- Operating as a nuclear pharmacy within a federal medical institution.

ITEM 12. Amend subrule **39.4(29)**, paragraph "**j**," subparagraph (**1**), the third numbered paragraph, as follows:

3. The applicant submits ~~the following~~ information on the radionuclide: the chemical and physical form ~~of the radionuclide~~; the maximum activity per vial, syringe, generator, or other container of the radioactive drug; the shielding provided by the packaging to show it is appropriate for the safe handling and storage of the radioactive drugs by medical use licensees; and

32.72, compatibility B

ITEM 13. Amend subrule **39.4(29)**, paragraph "**j**," subparagraph (**2**), the second numbered paragraph, as follows:

2. May allow a pharmacist to work as an authorized nuclear pharmacist if:

- ~~the~~ This individual qualifies as an authorized nuclear pharmacist as defined in 641—subrule 41.2(2),
- This individual meets the requirements specified in 41.2(77) and 41.2(78) and the licensee has received an approved license amendment identifying this individual as an authorized nuclear pharmacist, or
- This individual is designated as an authorized nuclear pharmacist in accordance with 39.4(29)"j"(2)"4."

ITEM 14. Amend subrule **39.4(29)**, paragraph "**j**," subparagraph (**2**), by adopting new numbered paragraphs:

4. The actions authorized in 39.4(29)"j"(2)"1" and "2" are permitted in spite of more restrictive language in license conditions.

5. Shall provide to the agency a copy of each individual's certification by the Board of Pharmaceutical Specialties, the NRC, or agreement state license, or the permit issued by a licensee of broad scope, and a copy of the state pharmacy licensure or registration, no later than 30 days after the date that the licensee allows, pursuant to 39.4(20)"j"(2)"2," bulleted paragraphs one and three, the individual to work as an authorized nuclear pharmacist.

ITEM 15. Amend subrule **39.4(29)**, paragraph "**j**," subparagraph (**3**), introductory paragraph, as follows:

(3) A licensee shall possess and use instrumentation to measure the radioactivity of radioactive drugs. The licensee shall have procedures for use of the instrumentation ~~to measure the radioactivity of radioactive drugs. The licensee shall have procedures for use of the instrumentation~~. The licensee shall measure, by direct measurement or by combination of measurements and calculations, the amount of radioactivity in dosages of alpha-,beta-, or photon-emitting radioactive drugs prior to transfer for commercial distribution. In addition, the licensee shall:

32.74, compatibility B

ITEM 17. Amend subrule **39.4(29)**, paragraph "**l**," subparagraph (**3**), as follows:

(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 ~~is licensed by the agency for distribution~~ to persons licensed ~~pursuant~~ to use by-product material identified in 641—41.2(136C) and 641—subrules 41.2(41) and 41.2(43), as appropriate, ~~or under~~ and to persons who hold an equivalent licenses ~~of the U.S. Nuclear Regulatory Commission,~~ issued by an agreement state~~, or a licensing state, provided that such labeling for sources which do not require long-term storage may be on a leaflet or brochure which accompanies the source~~;

ITEM 18. 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 ~~January~~ May 1, 2003.

ITEM 19. Amend subrule **40.32(1)**, subparagraph "**a**," as follows:

a. Each sealed source, except as specified in ~~40.34(2)~~ 40.32(2). is tested for leakage or contamination and the test results are received before the sealed source is put into use unless

the licensee has a certificate from the transferor indicating that the sealed source was tested within six months before transfer to the licensee.

ITEM 20. Amend rule **641—40.60(136C)** by adopting the following new subrule:

(4) The licensee or registrant shall ensure that adequate measures are taken to prevent deceptive posting or labeling.

ITEM 21. Amend subrule **40.65(4)**, paragraph "**a**," as follows:

a. Removable radioactive surface contamination exceeds the limits of ~~641—paragraph 39.5(15)"h"~~ 49 CFR 173.443; or

ITEM 22. Amend rule **641—40.80(136C)** by adopting new subrule **40.80(5)** as follows:

40.80(5) Notwithstanding the requirements of 40.80(1), records of removable radioactive surface contamination on packages shall be recorded in disintegrations per minute (dpm).

ITEM 23. Amend subrule **40.97(1)**, paragraph "**b**," by rescinding subparagraph **(3)** and renumbering the subsequent subparagraphs.

Appendix a to part 20, compatibility B

ITEM 24. Rescind rule **641—Chapter 40, Appendix A**, and adopt the following new Appendix A in lieu thereof:

APPENDIX A
PROTECTION FACTORS FOR RESPIRATORS[a]

	Operating Mode	Assigned Protection Factor
I. Air Purifying Respirators (Particulate 1A[b] only) 1A[c]:		
Filtering facepiece disposable[d]	Negative Pressure	([d])
Facepiece, half[e]	Negative Pressure	10
Facepiece, full	Negative Pressure	100
Facepiece, half	Powered air-purifying respirators	50
Facepiece, full	Powered air-purifying respirators	1000
Helmet/hood	Powered air-purifying respirators	1000
Facepiece, loose-fitting	Powered air-purifying respirators	25
II. Atmosphere supplying respirators (particulate, gases and vapors1A[f]):		
1. Air-line respirator:		
Facepiece, half	Demand	10
Facepiece, half	Continuous Flow	50
Facepiece, half	Pressure Demand	50
Facepiece, full	Demand	100
Facepiece, full	Continuous Flow	1000
Facepiece, full	Pressure Demand	1000
Helmet/hood	Continuous Flow	1000
Facepiece, loose-fitting	Continuous Flow	25

Suit	Continuous Flow	([g])
2. Self-contained breathing Apparatus (SCBA):		
Facepiece, full	Demand	[h]100
Facepiece, full	Pressure Demand	[i]10,000
Facepiece, full	Demand, Recirculating	[h]100
Facepiece, full	Positive Pressure Recirculating	[i]10,000
III. Combination Respirators:		
Any combination of air-purifying and atmosphere-supplying respirators	(1) Assigned protection factor for type and mode of operation as listed above.	

[a] These assigned protection factors apply only in a respiratory protection program that meets the requirement of this 641—Chapter 40. They are applicable only to airborne radiological hazards and may not be appropriate to circumstances when chemical or other respiratory hazards exist instead of, or in addition to, radioactive hazards. Selection and use of respirators for such circumstances must also comply with Department of Labor regulations.

Radioactive contaminants for which the concentration values in Table 1, Column 3 of Appendix B to 641—Chapter 40 are based on internal dose due to inhalation may, in addition, present external exposure hazards at higher concentrations. Under these circumstances, limitations on occupancy may have to be governed by external dose limits.

[b] Air purifying respirators with APF <100 must be equipped with particulate filters that are at least 95 percent efficient. Air purifying respirators with APF=100 must be equipped with particulate filters that are at least 99 percent efficient. Air purifying respirators with APFs>100 must be equipped with particulate filters that are at least 99.97 percent efficient.

[c] The licensee may apply to the agency for the use of an APF greater than 1 for sorbent cartridges as protection against airborne radioactive gases and vapors (e.g., radiodine).

[d] Licensees may permit individuals to use this type of respirator who have not been medically screened or fit tested on the device provided that no credit be taken for their use in estimating intake or dose. It is also recognized that it is difficult to perform an effective positive or negative pressure pre-use user seal check on this type of device. All other respiratory protection program requirements listed in 641—40.50(136C) apply. An assigned protection factor has not been assigned for these devices. However, an APF equal to 10 may be used if the licensee can demonstrate a fit factor of at least 100 by use of a validated or evaluated, qualitative or quantitative fit test.

[e] Under-chin type only. No distinction is made in this Appendix between elastomeric half-masks with replaceable cartridges and those designed with the filter medium as an integral part of the facepiece (e.g., disposable or reusable disposable). Both types are acceptable so long as the seal area of the latter contains some substantial type of seal-enhancing material such as rubber or plastic, the two or more suspension straps are adjustable, the filter medium is at least 95 percent efficient, and all other requirements of this rule are met.

[f] The assigned protection factors for gases and vapors are not applicable to radioactive contaminants that present an absorption or submersion hazard. For tritium oxide vapor, approximately one-third of the intake occurs by absorption through the skin so that an overall protection factor of 3 is appropriate when atmosphere-supplying respirators are used to protect against tritium oxide. Exposure to radioactive noble gases is not considered a significant

respiratory hazard, and protective actions for these contaminants should be based on external (submersion) dose considerations.

[g] No NIOSH approval schedule is currently available for atmosphere supplying suits. This equipment may be used in an acceptable respiratory protection program as long as all the other minimum program requirements, with the exception of fit testing, are met.

[h] the licensee should implement institutional controls to assure that these devices are not used in areas immediately dangerous to life or health.

[i] This type of respirator may be used as an emergency device in unknown concentrations for protection against inhalation hazards. External radiation hazards and other limitations to permitted exposure such as skin absorption shall be taken into account in these circumstances. This device may not be used by any individual who experiences perceptible outward leakage of breathing gas while wearing the device.

ITEM 52. Amend subrule **41.2(1)**, paragraph "**b**," as follows:

b. All references to any Code of Federal Regulations (CFR) in this chapter are those in effect as of ~~January~~ May 1, 2003.

ITEM 53. Amend subrule **41.2(4)**, paragraph "**e**," as follows:

e. Before adding to or changing ~~the areas of use or~~ address or addresses of use identified in the application or on the license; and

correction to amendments effective January 15, 2003.

ITEM 54. Amend subrule **41.2(10)**, paragraph "**b**," as follows:

b. A licensee's management shall appoint a radiation safety officer, who agrees, in writing, to be responsible for implementing the radiation protection program. The licensee, through the radiation safety ~~office~~ officer, shall ensure that the radiation safety activities are being performed in accordance with licensee-approved procedures and regulatory requirements.

35.3047, compability C

ITEM 56. Amend subrule **41.2(14)**, by adopting new paragraph "**f**," as follows:

f. Report and notification of a dose to an embryo/fetus or a nursing child.

(1) A licensee shall report any dose to an embryo/fetus that is greater than 5 rem (50 mSv) dose equivalent that is a result of an administration of by-product material or radiation from by-product material to a pregnant individual unless the embryo/fetus was specifically approved, in advance, by the authorized user.

(2) A licensee shall report any dose to a nursing child that is a result of an administration of by-product material to a feeding individual that:

1. Is greater than 5 rem (50 mSv) total effective dose equivalent; or

2. Has resulted in unintended permanent functional damage to an organ or a physiological system of the child, as determined by a physician.

(3) The licensee shall notify by telephone this agency no later than the next calendar day after a dose to the embryo/fetus or nursing child that requires a report in 41.2(14)"f"(1) or (2).

(4) The licensee shall submit a written report to the agency 15 days after discovery of a dose to the embryo/fetus or nursing child that requires a report in 41.2(14)"f"(1) or (2).

1. The written report must include:

- The licensee's name;
- The name of the prescribing physician;
- A brief description of the event;
- Why the event occurred;

- The effect, if any, on the embryo/fetus or the nursing child;
- What actions, if any, have been taken or are planned to prevent recurrence; and
- Certification that the licensee notified the pregnant individual or mother (or the mother's or child's responsible relative or guardian), and it not, why not.

2. The report must not contain the individual's or child's name or any other information that could lead to identification of the individual or child.

(5) The licensee shall provide notification of the event to the referring physician and also notify the pregnant individual or mother, both hereafter referred to as the mother, no later than 24 hours after discovery of an event that would require reporting under 41.2(14)"f"(1) or (2), unless the referring physician personally informs the licensee either that the physician will inform the mother or that, based on medical judgment, telling the mother would be harmful. The licensee is not required to notify the mother without first consulting with the referring physician. If the referring physician or mother cannot be reached within 24 hours, the licensee shall make the appropriate notifications as soon as possible thereafter. The licensee may not delay any appropriate medical care for the embryo/fetus or for the nursing child including any necessary remedial care as a result of the event, because of any delay in notification. To meet the requirements of this
subrule, the notification may be made to the mother's or child's responsible relative or guardian instead of the mother. If a verbal notification is made, the licensee shall inform the mother, or the mother's or child's responsible relative or guardian, that a written description of the even can be obtained from the licensee upon request. The licensee shall provide such a written description if requested.

(6) A licensee shall:

1. Annotate a copy of the report provided to the agency with the:

- Name of the pregnant individual or the nursing child who is the subject of the event; and
- Social security number or other identification number, if one has been assigned, of the pregnant individual or the nursing child who is the subject of the event; and

2. Provide a copy of the annotated report to the referring physician, if other than the licensee, no later than 15 days after the discovery of the event.

ITEM 57. Rescind and reserve subrule **41.2(80).**

RATS 2002-2, 35.40, compatibility H&S

ITEM 58. Amend subrule **41.2(87)** by adopting **new** paragraph "**h**," as follows:

h. A written revision to an existing written directive may be made if the revision is dated and signed by an authorized user before the administration of the dosage of unsealed by-product material, the brachytherapy dose, the gamma stereotactic radiosurgery dose, the teletherapy dose, or the next fractional dose.

35.1000, compatibility UK

ITEM 59. Adopt **new** subrule **41.2(88)** as follows:

41.2(88) Other medical uses of by-product material or radiation from by-product material. A licensee may use by-product material or a radiation source approved for medical use which is not specifically addressed in 641—41.2(136C)(example: Y-90 microspheres, liquid brachytherapy, intravascular brachytherapy) if:

a. The applicant or licensee has submitted the information required by the agency: and

b. The applicant or licensee has received written approval from the agency in a license or license amendment and uses the material in accordance with the regulations and specific conditions the agency considers necessary for the medical use of the material.

Compatibility B, items 83 through 95

ITEM 83. Amend subrule **45.1(2)**, definitions as follows:

"~~Radiographer trainee~~ Radiographer's assistant" means any individual who has successfully completed the training, testing and documentation requirements of 45.1(10)"a" and who uses sources of radiation and related handling tools or radiation survey instruments under the direct supervision of a radiographer trainer.

"Radiographer trainer (instructor)" means any individual who instructs and supervises ~~radiographer trainees~~ radiographer's assistants during on-the-job training and who meets the requirements of 45.1(10)"c."

"Radiographic personnel" means any radiographer or ~~radiographer trainee~~ radiographer's assistant.

ITEM 84. Amend subrule **45.1(6)**, the first sentence, as follows:

45.1(6) Quarterly inventory. Each licensee shall conduct a physical inventory at intervals not to exceed three months to account for all sealed sources and radiography exposure devices received and possessed ~~by the licensee~~.

ITEM 85. Amend subrule **45.1(10)**, paragraph "**a**," as follows:

a. Radiographer trainee requirements. No licensee or registrant shall permit any individual to act as a ~~radiographer trainee~~, radiographer's assistant as defined in this chapter, until:

ITEM 86. Amend subrule **45.1(11)**, introductory paragraph and paragraphs "**a**" and "**b**," as follows:

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~~ radiographer's assistant to ensure that these rules, license requirements, and the licensee's or registrant's operating and emergency procedures are followed. The inspection program must:

a. Include observation of the performance of each radiographer and ~~radiographer trainee~~ radiographer's assistant during an actual industrial radiographic operation, at intervals not to exceed six months; and

b. Provide that, if a radiographer or ~~radiographer trainee~~ radiographer's assistant has not participated in an industrial radiographic operation for more than six months since the last audit, the radiographer or ~~radiographer trainee~~ radiographer's assistant must demonstrate understanding of the subjects contained in Appendix A of this chapter by a practical examination before the individual can next participate in a radiographic operation.

ITEM 87. Amend subrule **45.1(12)**, paragraph "**b**," subparagraph **(1)**, the first sentence, as follows:

(1) No licensee or registrant shall permit an individual to act as a radiographer, ~~radiographer trainee~~ radiographer's assistant, or radiographer trainer unless at all times during radiographic operations each individual wears, on the trunk of the body, a combination of direct-reading pocket dosimeter, an operating alarm ratemeter, and a film badge, an optically stimulated luminescent device (OSL device) or a thermoluminescent dosimeter (TLD).

ITEM 88. Amend subrule **45.1(13)**, introductory paragraph, as follows:

45.1(13) Supervision of ~~radiographer trainee~~ radiographer's assistant. Whenever a ~~radiographer trainee~~ radiographer's assistant 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~~ radiographer's assistant shall be under the direct supervision of a radiographer instructor. The direct supervision must include:

ITEM 89. Amend subrule **45.1(17)**, paragraphs "**c**" and "**e**," as follows:

c. Each ~~radiographer trainee~~ radiographer's assistant at a job site shall possess a valid trainee status card issued by the agency.

e. No individual other than a radiographer or a ~~radiographer trainee~~ radiographer's assistant who is under the direct supervision of a radiographer trainer shall manipulate controls or operate equipment used in industrial radiographic operations.

ITEM 90. Amend subrule **45.2(4)**, paragraphs "**b**" and "**c**," as follows:

b. Each registrant shall provide, as a minimum, two radiographic personnel when radiation machines are used for any industrial radiography conducted other than at a permanent radiographic installation (shielded room, bay, or bunker). If one of the personnel is a ~~radiographer trainee~~ radiographer's assistant the other shall be a radiographer trainer authorized by the certificate of registration.

c. No individual other than a radiographer or a ~~radiographer trainee~~ radiographer's assistant who is under the direct supervision of a radiographer trainer shall manipulate controls or operate equipment used in industrial radiographic operations.

ITEM 91. 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~~ radiographer's assistant, 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~~ radiographer's assistant.

ITEM 92. Amend subrule **45.3(6)**, paragraph "**c**" and "**e**," as follows:

c. 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~~ radiographer's assistant. If one of the personnel is a ~~radiographer trainee~~ radiographer's assistant, 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 shall not be performed if only one qualified individual is present.

e. No individual other than a radiographer or a ~~radiographer trainee~~ radiographer's assistant who is under the direct supervision of a radiographer trainer shall manipulate controls or operate equipment used in industrial radiographic operations.

ITEM 93. Amend subrule **45.6(12)**, paragraph "**a**," subparagraph (2), as follows:

(2) The sealed source contains chemical and physical forms that are as insoluble and nondispersible as practical; and

39.65

ITEM 94. Amend subrule **45.6(17)**, paragraph "**b**" and "**c**," as follows:

b. The licensee shall provide bioassay services to individuals using licensed materials in subsurface tracer studies if required by the license.

~~b~~ c. Personnel monitoring records and bioassay results shall be maintained for inspection until the agency authorizes disposition.

ITEM 95. Amend rule **641—Chapter 45, Appendix A**, the title and the first sentence of the introductory paragraph, as follows:

CHAPTER 45—APPENDIX A
SUBJECTS FOR INSTRUCTION OF
~~RADIOGRAPHER TRAINEES~~ RADIOGRAPHER'S ASSISTANT

Training provided to qualify individuals as ~~radiographer trainees~~ radiographer's assistants in compliance with 45.1(10) shall be presented on a formal basis.

Jane Colacecchi, Acting Director
Department of Public Health

Date