



Iowa Department of Public Health
Advancing Health Through the Generations

Chester J. Culver
Governor

Patty Judge
Lt. Governor

Thomas Newton, MPP, REHS
Director

May 14, 2007

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

Dear Mr. Moore.

Enclosed is a copy of the adopted and final revision to the Iowa Radiation Machines and Radioactive Materials Rules. The final revision is effective May 16, 2007. The adopted revisions are identified by item number and underlined/strikeout text.

1. Item 6. 39.4(22)"d"(3)13. is amended to allow registration of devices approved in the Sealed Source Device Registry. In a letter dated September 30, 2004, to Jay Hyland, Josephine Piccone state, "...31.5(3)(13)(i) established the quantities of certain radioisotopes for which registration and a fee is required because 31.5(3)(13)(i) is classified as Compatibility Category B, states are prohibited from requiring the registration of smaller quantities, or for other radioisotopes than those established in 31.5(3)(13)(i)." 10 CFR 31.5(3)(13)(i) limits Iowa's ability to register and track isotopes not mentioned and activities lower than provided in 31.5(3)(13)(i). This prevents the state from protecting the health and safety of its citizens.
2. Item 7. 40.2(2) new definition is adopted to meet the requirements of FSME-06-110.
3. Item 8. 40.99 is adopted to meet the requirements of FSME-06-0110.
4. Item 9. Appendix H id adopted to meet the requirements of FSME-60-110.
5. Item 15. 41.2(11)"c"(1) adds "procedures for maintaining written directives" in order to meet eh H&S requirements of Part 35.27. "Quality management program" was deleted because this program was removed by NRC in approximately 1999-2000.
6. Item 16. 41.2(65) adds an omitted reference to meet requirements of Part 35.50.
7. Item 17. 41.2(67) adds an omitted reference to meet the requirements of Part 35.190.
8. Item 18. §1.2 (68) adds an omitted reference to meet requirements of Part 35.290.

We believe adoption of these revisions satisfy the compatibility and health and safety categories established in the Office of State and Tribal Programs (STP) procedures SA-200 except for number 1 above.

Rec'd 5/29/2007

May 14, 2007

Page 2

In your letter of February 23, 2007, to Melanie Rasmussen, Chief, certain items of compatibility were addressed.

1. 39.4(22)"d"(3)13 is addressed in number 1 above.
2. and 3. The reference to 41.2(76) will be removed from 41.2(67) and 41.2(68) in the proposed amendments forwarded to you on May 14, 2007.
4. 41.2(76) was rescinded.

Please let me know if you have any further questions.

Sincerely,



Charlene Craig
Bureau of Radiological Health
515/281-0415
FAX 515-281-4529
E-mail: ccraig@idph.state.ia.us

ITEM 6. Amend subrule 39.4(22), paragraph "d," subparagraph (3), numbered paragraph 13, as follows:

13. Shall register 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 labels approved in the Sealed Source Device Registry. 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;

ITEM 7. Amend subrule 40.2, paragraph (2), by adopting new definition in order:

"National tracked source" means a sealed source containing a quantity equal to or greater than Category 1 or Category 2 levels of any radioactive material listed in Appendix H of this chapter. In this context a sealed source is defined as radioactive material that is sealed in a capsule or closely bonded, in a solid form and which is not exempt from regulatory control. It does not mean material encapsulated solely for disposal, or nuclear material contained in any fuel assembly, subassembly, fuel rod, or fuel pellet. Category 1 nationally tracked sources are those containing radioactive material at a quantity equal to or greater than the Category 1 threshold. Category 2 nationally tracked sources are those containing radioactive material at a quantity equal to or greater than the Category 2 threshold but less than the Category 1 threshold.

ITEM 8. Amend rule 641—40.99 by removing the Reserved and replacing it with the following new rule:

641—40.99(136C) Reports of transactions involving nationally tracked sources. Each licensee who manufactures, transfers, receives, disassembles, or disposes of a nationally tracked source shall complete and submit a National Source Tracking Transaction Report as specified in paragraphs a. through e. of this rule for each type of transaction.

a. Each licensee who manufactures a nationally tracked source shall complete and submit a National Source Tracking Transaction Report. The report must include the following information:

- (1) The name, address, and license number of the reporting licensee;
- (2) The name of the individual preparing the report;
- (3) The manufacturer, model, and serial number of the source;
- (4) The radioactive material in the source;
- (5) The initial source strength in becquerels (curies) at the time of manufacture; and

- (6) the manufacture date of the source.

b. Each licensee that transfers a nationally tracked source to another person shall complete and submit a National Source Tracking Transaction Report. The report must include the following information:

- (1) the name, address, and license number of the reporting licensee;
- (2) The name of the individual preparing the report;

- (3) The name and license number of the recipient facility and the shipping address;
- (4) The manufacturer, model, and serial number of the source or, if not available, other information to uniquely identify the source.
- (5) The radioactive material in the source;
- (6) The initial or current source strength in becquerels (curies);
- (7) the date for which the source strength is reported;
- (8) The shipping date;
- (9) The estimated arrival date; and
- (10) For nationally tracked sources transferred as waste under a Uniform Low-Level Radioactive Waste Manifest, the waste manifest number and the container identification of the container with the nationally tracked source.

c. Each licensee that receives a nationally tracked source shall complete and submit a National Source Tracking Transaction Report. The report must include the following information:

- (1) The name, address, and license number of the reporting licensee;
- (2) The name of the individual preparing the report;
- (3) The name, address, and license number of the person that provided the source;
- (4) The manufacturer, model, and serial number of the source or, if not available, other information to uniquely identify the source;
- (5) The radioactive material in the source;
- (6) The initial or current source strength in becquerels (curies);
- (7) The date for which the source strength is reported;
- (8) The date of receipt; and
- (9) For material received under a Uniform Low-Level Radioactive Waste Manifest, the waste manifest number and the container identification with the nationally tracked source.

d. Each licensee that disassembles a nationally tracked source shall complete and submit a National Source Tracking Transaction Report. The report must include the following information:

- (1) The name, address, and license number of the reporting licensee;
- (2) The name of the individual preparing the report;
- (3) The manufacturer, model, and serial number of the source or, if not available, other information to uniquely identify the source;
- (4) The radioactive material in the source;
- (5) The initial or current source strength in becquerels (curies);
- (6) The date for which the source strength is reported;
- (7) The disassemble date of the source.

e. Each licensee who disposes of a nationally tracked source shall complete and submit a National Source Tracking Transaction Report. The report must include the following information:

- (1) The name, address, and license number of the reporting licensee;
- (2) The name of the individual preparing the report;
- (3) The waste manifest number;
- (4) The container identification with the nationally tracked source;

- (5) The date of disposal; and
 - (6) The method of disposal.
- f. Reports discussed in paragraphs a. through e. of this rule must be submitted by the close of the next business day after the transaction. A single report may be submitted for multiple sources and transactions. The reports must be submitted to the National Source Tracking System by using:
- (1) The on-line National Source Tracking system;
 - (2) Electronically using a computer-readable format;
 - (3) By facsimile;
 - (4) By mail to the address on the National Source Tracking Transaction Report Form (NRC Form 748); or

(5) by telephone with follow-up by facsimile or mail;

g. Each licensee shall correct any error in previously filed reports or file a new report for any missed transaction within 5 business days of the discovery of the error or missed transaction. Such errors may be detected by a variety of methods such as administrative reviews or by physical inventories required by regulation. In addition, each licensee shall reconcile the inventory of nationally tracked sources possessed by the licensee against that licensee's data in the National Source Tracking System. The reconciliation must be conducted during the month of January in each year. The reconciliation process must include resolving any discrepancies between the National Source Tracking system and the actual inventory by filing the reports identified by paragraphs a. through e. of this rule. By January 31 of each year, each licensee must submit to the National Source Tracking System confirmation that the data in the National Source Tracking System is correct.

h. Each licensee that possesses Category 1 nationally tracked sources shall report its initial inventory of Category 1 nationally tracked sources to the National Source Tracking System by November 15, 2007. Each licensee that possesses Category 2 nationally tracked sources shall report its initial inventory of Category 2 nationally tracked sources to the National Source Tracking System by November 30, 2007. The information may be submitted by using any of the methods identified in 40.99" f"(1) through (4) of this rule. The initial inventory report must include the following information:

- (1) The name, address, and license number of the reporting licensee;
- (2) The name of the individual preparing the report;
- (3) The manufacturer, model, and serial number of each nationally tracked source or, if not available, other information to uniquely identify the source;
- (4) The radioactive material in the sealed source;
- (5) The initial or current source strength in becquerels (curies); and
- (6) The date for which the source strength is reported.

ITEM 9. Amend 641—Chapter 40, by adopting new Appendix H:
Nationally Tracked Source Thresholds

The Terabecquerel (TBq) values are the regulatory standard. The curie (Ci) values specified are obtained by converting from the TBq value. The curie values are provided for practical usefulness only and are rounded after conversion.

Radioactive material	Category 1	Category 1	Category 2	Category 2
----------------------	------------	------------	------------	------------

	(TBq)	(Ci)	(TBq)	(Ci)
Actinium-227	20	540	0.2	5.4
Americium-241	60	1,600	0.6	16
Americium-24/Be	60	1,600	0.6	16
Californium-252	20	540	0.2	5.4
Cobalt-60	30	810	0.3	8.1
Curium-244	50	1,400	0.5	15
Cesium-137	100	2,700	1	27
Gadolinium-153	1,000	27,000	10	270
Iridium-192	80	2,200	0.8	22
Plutonium-238	60	1,600	0.6	16
Plutonium-239/Be	60	1,600	0.6	16
Polonium-210	60	1,600	0.6	16
Promethium-147	40,000	1,100,000	400	11,000
Radium-226	40	1,100	0.4	11
Selenium-75	200	5,400	2	54
Strontium-90	1,000	27,000	10	270
Thorium-228	20	540	0.2	5.4
Thorium-229	20	540	0.2	5.4
Thulium-170	20,000	540,000	200	5,400
Ytterbium-169	300	8,100	3	81

ITEM 15. Amend subrule 41.2(11), paragraph "c," subparagraph (1), as follows:

(1) Instruct the supervised individual in the preparation of radioactive material for medical use and the principles of and procedures for radiation safety and in the licensee's written ~~quality management program~~ procedures for maintaining written directives, as appropriate to that individual's use of radioactive material;

ITEM 16. Amend subrule 41.2(65), introductory paragraph, as follows:

41.2(65) Training for radiation safety officer. Except as provided in ~~41.2(66)~~41.2(75), the licensee shall require an individual fulfilling the responsibilities of the radiation safety officer as provided in 41.2(8) to be an individual who:

ITEM 17. Amend subrule 41.2(67), introductory paragraph, as follows:

41.2(67) Training for uptake, dilution, and excretion studies. Except as provided in 41.2(75) and (76), the licensee shall require an authorized user of unsealed radioactive material for the uses authorized under 41.2(31) to be a physician who:

ITEM 18. Amend subrule 41.2(68), introductory paragraph, as follows:

41.2(68) Training for imaging and localization studies. Except as provided in 41.2(75) and (76), the licensee shall require the authorized user of unsealed radioactive material specified in 41.2(33) to be a physician who: