

September 24, 2007

Ms. Melanie Rasmusson, MBA, Chief
Iowa Department of Public Health
Bureau of Radiological Health
Lucas State Office Building
321 E. 12th Street
Des Moines, Iowa 50319-0075

Dear Ms. Rasmusson:

We have reviewed the final revision to the Iowa regulations 641-38 "General Provisions for Radiation Machines and Radioactive Material," 641-39 "Registration of Radiation Machine Facilities, Licensure of Radioactive Materials and Transportation of Radioactive Materials," 641-40 "Standards for Protection Against Radiation," and 641-41 "Safety Requirements for the Use of Radiation Machines and Certain Uses of Radioactive Materials," received by our office on July 16, 2007. These regulations were reviewed by comparison to the equivalent Nuclear Regulatory Commission (NRC) rules in 10 CFR Parts 20, 30, 31, 32, 34, 35, 39, 40, 61, 70, and 71 and the requirements of the 13 amendments identified in the enclosed State Regulation Status (SRS) Data Sheet. We discussed our review of the regulations with Randy Dahlin on September 21, 2007.

As a result of our review, we have 11 comments that have been identified in the enclosure. Please note that we have limited our review to regulations required for compatibility and/or health and safety. We have determined that if these regulations are revised, incorporating our comments and without other significant change, they would meet the compatibility and health and safety categories established in the Office of Federal and State Materials and Environmental Management Programs (FSME) Procedure [SA-200](#).

We request that when you revise your regulations to address our comments, a copy of the "as published" regulations be provided to us for review. As requested in FSME Procedure [SA-201](#), "Review of State Regulatory Requirements," please highlight the location of any changes made by Iowa, in response to our comments, and provide a copy to Division of Materials Safety and State Agreements, FSME.

The SRS Data Sheet summarizes our knowledge of the status of other Iowa regulations, as indicated. Please let us know if you note any inaccuracies, or have any comments on the information contained in the SRS Data Sheet. This letter, including the SRS Data Sheet, is posted on the STP website: <http://www.hsr.gov/nrc/rulemaking.htm>.

If you have any questions regarding the comments, the compatibility and health and safety categories, or any of the NRC regulations used in the review, please contact me, Kathleen Schneider, State Regulation Review Coordinator at 301-415-2320 or by e-mail at KXS@nrc.gov, or Kim Lukes at 301-415-6701 or by e-mail at KXK2@nrc.gov.

Sincerely,

IRA By ADWhite For

Robert J. Lewis, Deputy Director
Division of Materials Safety and State Agreements
Office of Federal and State Materials and
Environmental Management Programs

Enclosures:
As stated

If you have any questions regarding the comments, the compatibility and health and safety categories, or any of the NRC regulations used in the review, please contact me, Kathleen Schneider, State Regulation Review Coordinator at 301-415-2320 or by e-mail at KXS@nrc.gov, or Kim Lukes at 301-415-6701 or by e-mail at KXK2@nrc.gov.

Sincerely,

IRA By ADWhite For

Robert J. Lewis, Deputy Director
Division of Materials Safety and State Agreements
Office of Federal and State Materials and
Environmental Management Programs

Enclosures:
As stated

Distribution:

DIR RF (7-55)

DCD (SP05)

Jim Lynch, RSAO

Aaron McCraw

SUNSI Review Complete

Publicly Available

Non-Publicly Available

Non-Sensitive

Sensitive

Iowa File

DOCUMENT NAME: D:\NRC\Regs\IA 7-55.wpd

ML of Incoming Document:ML071970162

To receive a copy of this document, indicate in the box: "C" = Copy without attachment/enclosure "E" = Copy with attachment/enclosure "N" = No copy

OFFICE	SAIS		SAIS		OGC		SAIS:BC		MSSA:DD	
NAME	KLukes		KSchneider		CCameron		DWhite		RLewis	
DATE	8/16/07*		8/20/07*		9/13 /07*		9/24/07*		9/24/07*	

ML072670007

OFFICIAL RECORD COPY

COMPATIBILITY COMMENTS ON IOWA FINAL REGULATIONS

STATE SECTION		NRC SECTION	RATS ID	CATEGORY	SUBJECT and COMMENTS
1	641-39.4 (33)	§70.38 (c)(d)(e) (f)(g)(h)(i)(j)& (k)(1),(2),(3)	1994-3	H&S	<p>Expiration and termination of licenses and decommissioning of sites and separate buildings or outdoor areas</p> <p>State regulation 39.4(33) is missing the wording under 10 CFR 70.38(g)(4)(vi) on a description of the physical security plan and material control and accounting plan provisions. The State needs to add this provision in order to meet the Compatibility Category H&S designation assigned to 10 CFR 70.38.</p>
2	641-Chapter 40 Appx. D	Part 20 Appendix G	1995-3	B	<p>Requirements for Transfers of Low-Level Radioactive Waste Intended for Disposal at Licensed Land Disposal Facilities and Manifests</p> <p>State regulation Chapter 40, Appendix D, Section I.(c) reflects the organizational unit that was in existence in 1995. The State needs to revise the references to NRC to reflect the current organizational changes and website reference in order to meet the Compatibility Category B designation assigned to 10 CFR 20.2006.</p>
3	641-41.2(69)	§ 35.390	2002-2	B	<p>Training for use of unsealed byproduct material for which a written directive is required</p> <p>State regulation 41.2(69) incorrectly references "10 CFR 35.930" instead of "10 CFR 35.390." The State needs to revise the references to 10 CFR 35.390 in order to meet the Compatibility Category B designation assigned to 10 CFR 35.390.</p>

STATE SECTION		NRC SECTION	RATS ID	CATEGORY	SUBJECT and COMMENTS
4	641-41.2(81)	§35.392	2002-2	B	<p>Training for the oral administration of sodium iodide I-131 requiring a written directive in quantities less than or equal to 1.22 Gigabecquerels (33 millicuries)</p> <p>State regulation 41.2(81) incorrectly references "10 CFR 35.930, 35.932, and 35.934." The State needs to revise the references to 10 CFR 35.390, 35.392, and 35.394 in order to meet the Compatibility Category B designation assigned to 10 CFR 35.392.</p>
5	641-41.2(82)	§35.394	2002-2	B	<p>Training for the oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 1.22 Gigabecquerels (33 millicuries)</p> <p>State regulation 41.2(82) incorrectly references "10 CFR 35.930 and 35.934." The State needs to revise these references to 10 CFR 35.390 and 35.394 in order to meet the Compatibility Category B designation assigned to 10 CFR 35.394.</p>
6	641-41.2(73)	§35.690	2002-2	B	<p>Training for use of remote afterloader units teletherapy units, and gamma stereotactic radiosurgery units</p> <p>State regulation 41.2(73) incorrectly references "10 CFR 35.960." The State needs to revise this reference to 10 CFR 32.690 in order to meet the Compatibility Category B assigned to 10 CFR 35.690.</p>
7	641-39.4 (29)l.	§ 32.74	2006-1	B	<p>Manufacture and distribution of sources or devices containing byproduct material for medical use</p> <p>State regulation 39.4 (29)l. is missing the equivalent reference to 10 CFR 35.600, as indicated under 10 CFR 32.74(a). The State needs to reference the equivalent regulation to 10 CFR 35.600 in order to meet the Compatibility Category B assigned to 10 CFR 32.74.</p>

STATE SECTION	NRC SECTION	RATS ID	CATEGORY	SUBJECT and COMMENTS
8	641-41.2(74), 641-41.2(31), 641-41.2(67), 641-41.2(68), 641-41.2(69), 641-41.2(81), 641-41.2(82), 641-41.2(89), 641-41.2(70), 641-41.2(71), and 641-41.2(73)	§ 35.51, § 35.100, § 35.190, § 35.290, § 35.390, § 35.392, § 35.394, § 35.396, § 35.490, § 35.491, and § 35.690	2006-1	<p>B, H&S, B, B, B, B, B, B, B, B</p> <p>Training for an authorized medical physicist</p> <p>Use of unsealed byproduct material for uptake, dilution, and excretion studies for which a written directive is not required</p> <p>Training for uptake, dilution, and excretion studies</p> <p>Training for imaging and localization studies</p> <p>Training for use of unsealed byproduct material for which a written directive is required</p> <p>Training for the oral administration of sodium iodide I-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries)</p> <p>Training for the oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 1.22 gigabecquerels (33 millicuries)</p> <p>Training for the parenteral administration of unsealed byproduct material requiring a written directive</p> <p>Training for use of manual brachytherapy sources</p> <p>Training for ophthalmic use of strontium-90</p> <p>Training for use of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units</p>

STATE SECTION		NRC SECTION	RATS ID	CATEGORY	SUBJECT and COMMENTS
8	(cont.)	(cont.)	(cont.)	(cont.)	In the sections identified, the State incorrectly references "10 CFR 35.961" in 41.2(74)(b)(2), "10 CFR 35.920" in 41.2(31)(b)(2), "10 CFR 35.910, 35.920, and 35.930" in 41.2(67), "10 CFR 35.920" in 41.2(68), "10 CFR 35.930" in 41.2(69), "10 CFR 35.930, 35.932, and 35.934" in 41.2(81), "10 CFR 35.35.930 and 35.934" in 41.2(82), "10 CFR 35.930, 35.940, and 35.960" in 41.2(89), "10 CFR 35.940" in 41.2(70), "10 CFR 35.940 and 35.941" in 41.2(71), and "10 CFR 35.960" in 41.2(73). The State needs to revise these various references to the correct 10 CFR regulations in order to meet the respective Compatibility Category designations assigned to these regulations.
9	641-41.2 (33)	§ 35.200	2006-1	H&S	<p>Use of unsealed byproduct material for imaging and localization studies for which a written directive is not required.</p> <p>State regulation 41.2(33)(b) is missing an equivalent reference to 10 CFR 35.390, as referenced under 10 CFR 35.200(b)(2). The State needs to reference 41.2(69), which is the equivalent regulation to 10 CFR 35.390, in order to meet the Compatibility Category H&S designation assigned to 10 CFR Part 35.200.</p>
10	641-41.2(68)	§ 35.290	2006-1	B	<p>Training for imaging and localization studies.</p> <p>State regulation 41.2 (68)(a)(1) states "...for uptake, dilution, and excretion studies..." The State needs to change this text to "...for imaging and localization studies..." as stated under 10 CFR 35.290(a)(1), in order to meet the Compatibility Category B designation assigned to 10 CFR 35.290.</p>

STATE SECTION		NRC SECTION	RATS ID	CATEGORY	SUBJECT and COMMENTS
11	641-40.2(2)	§20.1003	2006-3	B	<p>Definitions-Nationally tracked sources</p> <p>Appendix H of the States regulation 641 Chapter 40 states 15.0 as the Category 2 Curie value for Curium-244. Appendix E of 10 CFR Part 20 indicates 14 as the Category 2 Curie value for Curium-244. The State needs to revise this Curie value from 15 to 14 in order to meet the Compatibility Category B designation assigned to 10 CFR 20.1003.</p>

STATE REGULATION STATUS

State: IOWA

Tracking Ticket Number: 7-55

13 Amendments reviewed identified by a ★ at the beginning of the equivalent NRC requirement]

Date: September 24, 2007

NRC Chronology Identification	FR Notice (State Due Date)	RATS ID	Proposed (P) / Final (F)¹ Rule / License Condition (LC) ML #⁵	NRC Review / Y, N² / Date / ML #⁵	Final State Regulation¹ (Effective Date)
Safety Requirements for Radiographic Equipment-Part 34	55 FR 843; (1/10/94)	1991-1			superceded by 1997-5
ASNT Certification of Radiographers-Part 34	56 FR 11504; (none)	1991-2			Not required ³
Standards for Protection Against Radiation-Part 20	56 FR 23360; 56 FR 61352; 57 FR 38588; 57 FR 57877; 58 FR 67657; 59 FR 41641; 60 FR 20183; (1/1/94)	1991-3	F	N 11/6/97	10/6/96
★Notification of Incidents-Parts 20, 30, 31, 34, 39, 40, 70	56 FR 64980; (10/15/94)	1991-4	F ML071970162	N 9/24/07 ML072670007	9/7/94
Quality Management Program and Misadministrations-Part 35	56 FR 34104; (1/27/95)	1992-1			superceded by 2002-2
Eliminating the Recordkeeping Requirements for Departures from Manufacturer's Instructions-Parts 30,35	57 FR 45566; (none)	1992-2			Not required ³
★Decommissioning Recordkeeping and License Termination: Documentation Additions [Restricted areas and spill sites]-Parts 30, 40	58 FR 39628; (10/25/96)	1993-1	F ML071970162	N 9/24/07 ML072670007	7/12/95
Licensing and Radiation Safety Requirements for Irradiators-Part 36	58 FR 7715; (7/1/96)	1993-2			Not applicable SECY-95-112 ⁴
Definition of Land Disposal and Waste Site QA Program-Part 61	58 FR 33886; (7/22/96)	1993-3			Not applicable SECY-95-112 ⁴
Self-Guarantee as an Additional Financial Mechanism-Parts 30, 40, 70	58 FR 68726; 59 FR 1618 (none)	1994-1			Not required ³
Uranium Mill Tailings Regulations: Conforming NRC Requirements to EPA Standards-Part 40	59 FR 28220; (7/1/97)	1994-2			Not applicable SECY-95-112 ⁴
★Timeliness in Decommissioning Material Facilities-Parts 30, 40, 70	59 FR 36026; (8/15/97)	1994-3	F ML071970162	Y 9/24/07 ML072670007	7/12/95

NRC Chronology Identification	FR Notice (State Due Date)	RATS ID	Proposed (P) / Final (F) ¹ Rule / License Condition (LC) ML # ⁵	NRC Review / Y, N ² / Date / ML # ⁵	Final State Regulation ¹ (Effective Date)
★Preparation, Transfer for Commercial Distribution, and Use of Byproduct Material for Medical Use-Parts 30, 32, 35	59 FR 61767; 59 FR 65243 60 FR 322; (1/1/98)	1995-1	F ML071970162	N 9/24/07 ML072670007	5/10/00
★Frequency of Medical Examinations for Use of Respiratory Protection Equipment-Part 20	60 FR 7900; (3/13/98)	1995-2	F ML071970162	N 9/24/07 ML072670007	5/8/02
★Low-Level Waste Shipment Manifest Information and Reporting-Parts 20, 61	60 FR 15649; 60 FR 25983 (3/1/98)	1995-3	F ML071970162	Y 9/24/07 ML072670007	5/10/00
Performance Requirements for Radiography Equipment-Part 34	60 FR 28323; (6/30/98)	1995-4	P ML003692594	Y 3/21/00 ML003694911	5/10/00
Radiation Protection Requirements: Amended Definitions and Criteria-Parts 19, 20	60 FR 36038; (8/14/98)	1995-5	F	N 1/14/00 ML003683660	5/10/00
Clarification of Decommissioning Funding Requirements-Parts 30, 40, 70	60 FR 38235; (11/24/98)	1995-6	F	N 1/14/00 ML003683660	5/10/00
Medical Administration of Radiation and Radioactive Materials-Parts 20, 35	60 FR 48623; (10/20/98)	1995-7	F	N 1/14/00 ML003683660	5/10/00
10 CFR Part 71: Compatibility with the International Atomic Energy Agency-Part 71	60 FR 50248; 61 FR 28724 (4/1/99)	1996-1	F ML033640452	N 2/04/04 ML040360241	5/5/04
One Time Extension of Certain Byproduct, Source and Special Nuclear Materials Licenses-Parts 30, 40, 70	61 FR 1109; (none)	1996-2			Not required ³
Termination or Transfer of Licensed Activities: Recordkeeping Requirements-Parts 20, 30, 40, 61, 70	61 FR 24669; (6/17/99)	1996-3	F	N 1/14/00 ML003683660	5/10/00
Resolution of Dual Regulation of Airborne Effluents of Radioactive Materials; Clean Air Act-Part 20	61 FR 65120; (1/9/00)	1997-1	F	N 1/14/00 ML003683660	5/10/00
Recognition of Agreement State Licenses in Areas Under Exclusive Federal Jurisdiction Within an Agreement State-Part 150	62 FR 1662; (2/27/00)	1997-2	F ML033640452	N 2/04/04 ML040360241	5/5/04

NRC Chronology Identification	FR Notice (State Due Date)	RATS ID	Proposed (P) / Final (F) ¹ Rule / License Condition (LC) ML # ⁵	NRC Review / Y, N ² / Date / ML # ⁵	Final State Regulation ¹ (Effective Date)
Criteria for the Release of Individuals Administered Radioactive Material-Parts 20, 35	62 FR 4120; (5/29/00)	1997-3	F ML033640452	N 2/04/04 ML040360241	5/5/04
Fissile Material Shipments and Exemptions-Part 71	62 FR 5907; (none)	1997-4	F ML033640452	N 2/04/04 ML040360241	Not required ³
Licenses for Industrial Radiography and Radiation Safety Requirements for Industrial Radiography Operations-Parts 30, 34, 71, 150	62 FR 28947; (6/27/00)	1997-5	F ML050320039	N 4/06/05 ML050960431	5/4/05
Radiological Criteria for License Termination-Parts 20, 30, 40, 70	62 FR 39057; (8/20/00)	1997-6	F ML033640452	N 2/04/04 ML040360241	5/5/04
Exempt Distribution of a Radioactive Drug Containing One Microcurie of Carbon-14 Urea-Part 30	62 FR 63634; (1/02/01)	1997-7	F	N 1/14/00 ML003683660	5/5/04
Deliberate Misconduct by Unlicensed Persons-Parts 30, 40, 61, 70, 71, 150	63 FR 1890; 63 FR 13773 (2/12/01)	1998-1	F ML033640452	N 2/04/04 ML040360241	5/5/04
Self-Guarantee of Decommissioning Funding by Nonprofit and Non-Bond-Issuing Licensees- Parts 30, 40, 70	63 FR 29535; (none)	1998-2	F ML033640452	N 2/04/04 ML040360241	Not required ³
License Term for Medical Use Licenses-Part 35	63 FR 31604; (none)	1998-3			Not required ³
Licenses for Industrial Radiography and Radiation Safety Requirements for Industrial Radiographic Operations-Part 34	63 FR 37059; (7/9/01)	1998-4	R ⁸ ML003692594	N 3/21/00 ML003694911	5/10/00
Minor Corrections, Clarifying Changes, and a Minor Policy Change-Parts 20, 35, 36	63 FR 39477; 63 FR 45393 (10/26/01)	1998-5	F ML033640452	N 2/04/04 ML040360241	5/5/04
Transfer for Disposal and Manifests: Minor Technical Conforming Amendment-Part 20	63 FR 50127; (11/20/01)	1998-6	F ML033640452	N 2/04/04 ML040360241	5/5/04
Radiological Criteria for License Termination of Uranium Recovery Facilities-Part 40	64 FR 17506; (6/11/02)	1999-1			Not applicable SECY-95-112 ⁴
Requirements for Those Who Possess Certain Industrial Devices Containing Byproduct Material to Provide Requested Information-Part 31	64 FR 42269; (none)	1999-2			Not required ³

NRC Chronology Identification	FR Notice (State Due Date)	RATS ID	Proposed (P) / Final (F)¹ Rule / License Condition (LC) ML #⁵	NRC Review / Y, N² / Date / ML #⁵	Final State Regulation¹ (Effective Date)
Respiratory Protection and Controls to Restrict Internal Exposure-Part 20	64 FR 54543; 64 FR 55524 (2/2/03)	1999-3	F ML033640452	N 2/04/04 ML040360241	5/5/04
Energy Compensation Sources for Well Logging and Other Regulatory Clarifications-Part 39	65 FR 20337; (5/17/03)	2000-1	F ML033640452	N 2/04/04 ML040360241	5/5/04
New Dosimetry Technology-Parts 34, 36, 39	65 FR 63750; (1/8/04)	2000-2	F ML033640452	N 2/04/04 ML040360241	5/5/04
Requirements for Certain Generally Licensed Industrial Devices Containing Byproduct Material - Parts 30, 31, 32	65 FR 79162; (2/16/04)	2001-1	F ⁷ ML071560559	Y 7/17/07 ML071930449	5/7/03
Revision of the Skin Dose Limit - Part 20	67 FR 16298; (4/5/05)	2002-1	F ML033640452	N 2/04/04 ML040360241	5/5/04
★Medical Use of Byproduct Material - Parts 20, 32, and 35	67 FR 20249; (10/24/05)	2002-2	F ML071970162	Y 9/24/07 ML072670007	5/5/04
★Financial Assurance for Materials Licensees – Parts 30, 40, 70	68 FR 57327 (12/3/06)	2003-1	F ML071970162	N 9/24/07 ML072670007	5/3/06
★Compatibility With IAEA Transportation Safety Standards and Other Transportation Safety Amendments – Part 71.	69 FR 3697; (10/01/07)	2004-1	F ML071970162	N 9/24/07 ML072670007	5/3/06
★Security Requirements for Portable Gauges Containing Byproduct Material - Part 30	70 FR 2001; (7/11/08)	2005-1	F ML071970162	N 9/24/07 ML072670007	5/4/05
Medical Use of Byproduct Material - Recognition of Speciality Boards - Part 35	70 FR 16336; 71 FR 1926 (4/29/08)	2005-2	F ML071560559	Y 7/17/07 ML071930449	5/3/06
Increased Controls for Risk-Significant Radioactive Sources (NRC Order EA-05-090) ⁶	70 FR 72128; (12/1/05)	2005-3	P ML053550019 LC ML052520149	N 01/19/06 ML060200518 N 09/14/05 ML052570342	9/3/05
★Minor Amendments - Parts 20, 30, 32, 35, 40, and 70	71 FR 15005 (3/27/09)	2006-1	F ML071970162	Y 9/24/07 ML072670007	5/3/06

NRC Chronology Identification	FR Notice (State Due Date)	RATS ID	Proposed (P) / Final (F) ¹ Rule / License Condition (LC) ML # ⁵	NRC Review / Y, N ² / Date / ML # ⁵	Final State Regulation ¹ (Effective Date)
★National Source Tracking System - Serialization Requirements - Part 32 with reference to Part 20 Appendix F	71 FR 65685 (2/6/07)	2006-2	F ML071970162	9/24/07 ML072670007	Not applicable SECY-95-112 ⁴
★National Source Tracking System - Part 20	71 FR 65865 (11/15/07) & (11/30/07)	2006-3 ⁹	F ML071970162	Y 9/24/07 ML072670007	5/10/07

1. Or other generic Legally Binding Requirements.
2. (Y/N) Y means "Yes," there are comments in the review letter that the State needs to address. N means "No," there are no comments in the review letter.
3. Not required means these regulations are not required for purposes of compatibility.
4. A State need not adopt a specific regulation if the State has no licensees that would be subject to that regulation. See: "Final Policy Statement on Adequacy and Compatibility of Agreement State Programs," III.1. Time Frame for Adoption of Compatible State Regulations, p. 6, SECY-95-112, May 3, 1995.
5. ADAMS ML Number
6. By letter dated September 2, 2005, from Paul H. Lohaus, Director, Office of State and Tribal Programs, Agreement States were given 90 days to issue legally binding requirements satisfying the requirements of NRC Order EA-05-090.
7. A re-review was completed on this item due to change in compatibility of 31.5 and 31.6. More information can be found in the All Agreement States letter STP 05-072.
8. R stands for proposed changes made to final regulations.
9. RATS ID 2006-3 will not be considered under the Non-Common Performance Indicator "Compatibility Requirements" for IMPEP reviews until such time as the National Source Tracking System is ready for use. Revisions in the implementation date for Agreement States will be provided to the States under separate correspondence and the SRS sheet will be revised as appropriate.