

September 30, 2003

Mr. Donald A. Flater, Chief
Bureau of Radiological Health
Iowa Department of Public Health
401 SW 7th Street, Suite D
Des Moines, IA 50309

Dear Mr. Flater:

We have reviewed the final revisions to the Iowa Administrative Code received by our office on August 8, 2003. In addition, we reviewed your responses to our letters, dated March 22, 2002; November 12, 2002 and February 12, 2003, which contained our comments on your proposed version of these rules. These regulations were reviewed by comparison to the equivalent Nuclear Regulatory Commission (NRC) regulations in 10 CFR Part 20, 30, 31, 32, 34, 35, 36, 39, 40, 50, 52, 60, 61, 70, 71, 72 and 150 and the requirements of the sixteen amendments identified in the enclosed States Regulation Status Data Sheet (SRS). We discussed our review of the regulations with Charlene Craig on September 10, 2003.

As a result of our review, we have 11 comments and four editorial suggestions. Comments 6-10 relate to the Part 35, Medical Training and Experience sections, which is currently undergoing revision. If the State did not incorporate these sections, due to this revision of Part 35, it would be acceptable for the State to wait until after the revision is published to make these corrections. Please provide an amended, final version of your rules showing the location of any changes made, by the State, in response to our comments. If there are any comments which the State believes are in error, the State should identify the section of their regulations that meet the designated compatibility category. 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 adopted, incorporating our comments and without significant change, they would meet the compatibility and health and safety categories established in the Office of State and Tribal Programs (STP) Procedure SA-200.

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.hrsd.ornl.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, or Aaron McCraw of my staff at (301) 415-1277 or ATM@NRC.GOV.

Sincerely,

/RA By C. Maupin for J. Piccone/

Josephine Piccone, Deputy Director
Office of State and Tribal Programs

Enclosures: As stated

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As a result of our review, we have 11 comments and four editorial suggestions. Comments 6 - 10 relate to the Part 35, Medical Training and Experience sections, which is currently undergoing revision. If the State did not incorporate these sections, due to this revision of Part 35, it would be acceptable for the State to wait until after the revision is published to make these corrections. Please provide an amended, final version of your rules showing the location of any changes made, by the State, in response to our comments. If there are any comments which the State believes are in error, the State should identify the section of their regulations that meet the designated compatibility category. 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 adopted, incorporating our comments and without significant change, they would meet the compatibility and health and safety categories established in the Office of State and Tribal Programs (STP) Procedure SA-200.

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Office of State and Tribal Programs

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EDITORIAL SUGGESTIONS

1. In 641-39.4(29) j., the State should change the phrase “for material use” in the title to “for medical use.”
2. In 641—45.1(136C), definitions section, In the definition of “certifying entity” and “independent certifying organization” Iowa’s appendix E to Chapter 45 is referenced. This reference should be removed because Iowa adopted the certifying entity requirement of 10 CFR 34 by reference and this makes this reference obsolete. Also Appendix E to this chapter is the radiographer certification training requirements. (Also see comment next editorial suggestion)
3. Appendix E to Chapter 45 is labeled incorrectly. It should be labeled as the “subjects to be included in training courses for radiographers” not “subjects to be included in training courses for logging supervisors.
4. In 641-45.1 (10) e., after “until disposal is authorized by the Agency”, the State should add “but in no case for less than three years” or similar wording for clarity.

**COMPATIBILITY COMMENTS ON
IOWA FINAL REGULATIONS**

STATE SECTION		NRC SECTION	RATS ID	CATEGORY	SUBJECT and COMMENTS
1	45.3 (5) c.	34.67	1997-5	C	<p>Records of leak testing of sealed sources and devices containing depleted uranium</p> <p>State rules require leak testing records to be held for six months after the next leak test is performed. 10 CFR 34.67 requires the records to be held for three years.</p> <p>The State needs to change their requirements for holding records to three years as specified in 34.67 to meet compatibility.</p>
2	45.1 (6) 45.1 (8) 45.1 (10)c	34.69 34.73 34.83	1997-5	C	<p>-Records of quarterly inventory -Records of inspection and maintenance of radiographic exposure devices, transport and storage containers, associated equipment, source changers, and survey instruments -Records of personnel monitoring Procedures</p> <p>State requires records to be held for two years. 10 CFR Parts 34.69, 34.73, and 34.83 require a three year holding period.</p> <p>The State needs to adopt the three year holding period as specified in Parts 34.67, 34.73, and 34.83 to meet compatibility.</p>
3	45.1 (8)	34.73 (b)	1997-5	C	<p>Records of inspection and maintenance of radiographic exposure devices, transport and storage containers, associated equipment, source changers, and survey instruments</p> <p>State omitted the requirements of 34.73 (b), which define what information must be listed on the records.</p> <p>The State needs to adopt requirements similar to 34.73 (b) for information on the records to meet compatibility.</p>

STATE SECTION		NRC SECTION	RATS ID	CATEGORY	SUBJECT and COMMENTS
4	N/A	34.81	1997-5	C	<p>Copies of operating and emergency procedures</p> <p>The State has omitted specific guidance on maintaining and holding copies of operating and emergency procedures as required by 34.81.</p> <p>The State needs to adopt the requirements of 34.81 for the maintenance of operating and emergency procedures to meet compatibility.</p>
5	45.6 (9)	39.35	2000-1	C	<p>Leak testing of sealed sources</p> <p>State omitted the exception for neutron-emitters in 39.35(e)(5).</p> <p>The State needs adopt the exception for neutron-emitters in 39.35(e)(5) to meet compatibility.</p>
6	41.2 (74)	35.51	2002-2	B	<p>Training for an authorized medical physicist</p> <p>State omitted requirements for an authorized medical physicist. The requirements for a teletherapy physicist are not adequate to cover the requirements of 10 CFR 35.51.</p> <p>The State needs to adopt the essential requirements of 10 CFR 35.51 to meet compatibility.</p>
7	N/A	35.390	2002-2	B	<p>Training for use of unsealed byproduct material for which a written directive is required</p> <p>State omitted the training requirements of Part 35.390.</p> <p>The State needs to adopt the training requirements of Part 35.390 to meet compatibility.</p>

STATE SECTION		NRC SECTION	RATS ID	CATEGORY	SUBJECT and COMMENTS
8	N/A	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 omitted the training requirements of Part 35.392.</p> <p>The State needs to adopt the training requirements of Part 35.392 to meet compatibility.</p>
9	N/A	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 omitted the training requirements of Part 35.394.</p> <p>The State needs to adopt the training requirements of Part 35.394 to meet compatibility.</p>
10	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 does not fully meet the training requirements of 10 CFR 35.690.</p> <p>The State needs to adopt all the training requirements of 10 CFR 35.690 to achieve compatibility.</p>
11	41.2 (14)	35.3045	2002-2	C	<p>Report and notification of a medical event</p> <p>State has omitted essential elements of Part 35.3045(a)(1-3) regarding medical events that warrant reporting.</p> <p>The State needs to include specific guidance on reporting medical events to meet all essential objectives of Part 35.3045. Particularly the State should include the limits that trigger reporting in 35.3045(a)(1-3).</p>

STATE REGULATION STATUS

State: IOWA

[Sixteen Amendments reviewed are identified by a ★ at the beginning of each equivalent NRC regulation.]

Tracking Ticket Number: 3-194

Date: SEPTEMBER 30, 2003

NRC Chronology Identification	FR Notice (State Due Date)	RATS ID	Proposed (P) / Final (F) ¹ Rule / ML # ⁵	NRC Review / Y, N ² / Date / ML # ⁵	Final State Regulation ¹ (Effective Date)
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 P	N 11/6/97 Y 3/5/01	10/6/96
Safety Requirements for Radiographic Equipment-Part 34	55 FR 843; (1/10/94)	1991-1			
ASNT Certification of Radiographers-Part 34	56 FR 11504; (none)	1991-2			Not required ³
Notification of Incidents-Parts 20, 30, 31, 34, 39, 40, 70	56 FR 64980; (10/15/94)	1991-4			
Quality Management Program and Misadministrations-Part 35	56 FR 34104; (1/27/95)	1992-1			
Eliminating the Recordkeeping Requirements for Departures from Manufacturer's Instructions-Parts 30,35	57 FR 45566; (none)	1992-2			Not required ³
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
Decommissioning Recordkeeping and License Termination: Documentation Additions [Restricted areas and spill sites]-Parts 30, 40	58 FR 39628; (10/25/96)	1993-1			
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			
Timeliness in Decommissioning Material Facilities-Parts 30, 40, 70	59 FR 36026; (8/15/97)	1994-3			
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 P	Y 1/14/00 N 3/21/00	
Frequency of Medical Examinations for Use of Respiratory Protection Equipment-Part 20	60 FR 7900; (3/13/98)	1995-2	F	Y 1/14/00	
Low-Level Waste Shipment Manifest Information and Reporting-Parts 20, 61	60 FR 15649; 60 FR 25983 (3/1/98)	1995-3	F	Y 1/14/00	
Performance Requirements for Radiography Equipment-Part 34	60 FR 28323; (6/30/98)	1995-4	F P	Y 1/14/00 N 3/21/00	
Radiation Protection Requirements: Amended Definitions and Criteria-Parts 19, 20	60 FR 36038; (8/14/98)	1995-5	F	N 1/14/00	

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Clarification of Decommissioning Funding Requirements-Parts 30, 40, 70	60 FR 38235; (11/24/98)	1995-6	F	N 1/14/00	
Medical Administration of Radiation and Radioactive Materials-Parts 20, 35	60 FR 48623; (10/20/98)	1995-7	F	N 1/14/00	
★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 ML032230070	N 9/30/03 ML032740187	
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	
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	
★Fissile Material Shipments and Exemptions-Part 71	62 FR 5907; (none)	1997-4	F ML	N 9/30/03 ML032740187	Not required ³
★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 ML032230070	N 9/30/03 ML032740187	
★Criteria for the Release of Individuals Administered Radioactive Material-Parts 20, 35	62 FR 4120; (5/29/00)	1997-3	F ML032230070	N 9/30/03 ML032740187	
★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 ML032230070	Y 9/30/03 ML032740187	
★Radiological Criteria for License Termination-Parts 20, 30, 40, 70	62 FR 39057; (8/20/00)	1997-6	F ML032230070	N 9/30/03 ML032740187	
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	
★Deliberate Misconduct by Unlicensed Persons-Parts 30, 40, 61, 70, 71, 150	63 FR 1890; 63 FR 13773 (2/12/01)	1998-1	F ML032230070	N 9/30/03 ML032740187	
★Self-Guarantee of Decommissioning Funding by Nonprofit and Non-Bond-Issuing Licensees- Parts 30, 40, 70	63 FR 29535; (none)	1998-2	F ML	N 9/30/03 ML032740187	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	P	Y 3/21/00	
★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 ML032230070	N 9/30/03 ML032740187	
★Transfer for Disposal and Manifests: Minor Technical Conforming Amendment-Part 20	63 FR 50127; (11/20/01)	1998-6	F ML032230070	N 9/30/03 ML032740187	

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Radiological Criteria for License Termination of Uranium Recovery Facilities-Part 40	64 FR 17506; (6/11/02)	1999-1			
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
★Respiratory Protection and Controls to Restrict Internal Exposure-Part 20	64 FR 54543; 64 FR 55524 (2/2/03)	1999-3	F ML032230070	N 9/30/03 ML032740187	
★Energy Compensation Sources for Well Logging and Other Regulatory Clarifications-Part 39	65 FR 20337; (5/17/03)	2000-1	F ML032230070	Y 9/30/03 ML032740187	
★New Dosimetry Technology-Parts 34, 36, 39	65 FR 63750; (1/8/04)	2000-2	F ML032230070	N 9/30/03 ML032740187	
★Requirements for Certain Generally Licensed Industrial Devices Containing Byproduct Material - Parts 30, 31, 32	65 FR 79162; (2/16/04)	2001-1	F ML032230070	N 9/30/03 ML032740187	
★Revision of the Skin Dose Limit - Part 20	67 FR 16298; (4/5/05)	2002-1	F ML032230070	N 9/30/03 ML032740187	
★Medical Use of Byproduct Material - Parts 20, 32, and 35	67 FR 20249; (4/24/05)	2002-2	F ML032230070	Y 9/30/03 ML032740187	

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