

February 4, 2004

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 December 30, 2003. In addition, we reviewed your response to our letter dated September 30, 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, 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 February 4, 2004.

As a result of our review, we have six comments that relate to the changes made in response to our comments from the September 30, 2003 letter and three editorial suggestions. Comments 1-5 relate to the wording of the retention periods for records. There were also three comments from our September 30 letter that were not addressed, and we have included them in a separate chart. We understand that you will address these in a future rulemaking. Comment 6 relates to 10 CFR Part 35, Medical Training and Experience (T&E), which is currently undergoing revision. The State has adopted the requirements of Part 35, Subpart J in place of the requirements of Part 35.390. Although the State is currently compatible with this requirement, the NRC is currently revising the Medical T&E sections and when finalized, will rescind Part 35 Subpart J. Once this occurs, the State will no longer be compatible with the NRC unless the State adopts the new Medical T&E requirements. 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 meets 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,

IRA by KNSneider for

Josephine Piccone, Deputy Director
Office of State and Tribal Programs

Enclosures:
As stated

EDITORIAL SUGGESTIONS

1. In Appendix C of Chapter 45, the specific section listed for leak test record holding requirements is listed as 45.3(4). The specific section for leak test record holding requirements is 45.3(5). Appendix C should be updated to reflect this.
2. In Appendix C of Chapter 45, the record retention interval for utilization logs is listed as “until disposal is authorized by the agency.” In 641-45.1(7), utilization log records are required to be held for three years. Appendix C should be updated to reflect this.
3. In Appendix C of Chapter 45, the record retention interval for training and testing records is listed as “until the agency authorizes disposal.” The State has made changes to 641-45.1 (10) e. to reflect the minimum of three years retention interval, as found in 10 CFR 34.83. Appendix C should be updated to reflect this change.

**COMPATIBILITY COMMENTS ON
IOWA FINAL REGULATIONS**

| STATE SECTION | NRC SECTION | RATS ID | CATEGORY | SUBJECT and COMMENTS |
|---------------|-------------|---------|----------|---|
| 1 | 45.1(4) | 34.63 | 1997-5 | <p>Records of receipt and transfer of sealed sources.</p> <p>The State uses the words “shall be maintained for agency inspection until disposal is authorized by the agency” There is no minimum record retention length stated.</p> <p>The State needs to change their record retention requirements to three years, as stated in 34.63 to meet compatibility.</p> |
| 2 | 45.1(12) | 34.83 | 1997-5 | <p>Records of personnel monitoring procedures.</p> <p>The State’s requirements for retention of records of pocket dosimeter readings allows records to be disposed of when the agency authorizes disposal, if the dosimeter readings were used to determine external dose. The phrase “until the agency authorizes disposal” does not meet the same intent as the language in 10 CFR 34.83. As stated in 34.83, records need to be maintained for a period of three years after they are recorded, regardless of the status of the license or State approval for disposal.</p> <p>The State needs to add additional language to ensure that records are maintained for a minimum of three years to meet compatibility.</p> |
| 3 | 45.1(12) | 34.83 | 1997-5 | <p>Records of personnel monitoring procedures.</p> <p>The State’s requirements for retention of pocket dosimeter calibrations and alarming rate meter calibrations is two years which is less than the NRC requirement of three years.</p> <p>The State needs to adopt the retention requirements of Part 34.83 to meet compatibility.</p> |

| STATE SECTION | | NRC SECTION | RATS ID | CATEGORY | SUBJECT and COMMENTS |
|---------------|------------------------|-------------|---------|----------|--|
| 4 | 45.1(12) | 34.83 | 1997-5 | C | <p>Records of personnel monitoring procedures.</p> <p>The State requirements for record retention associated with OSL's TLD's and Film Badges are "until the agency authorizes disposal." This statement does not meet the same intent as the language in 10 CFR 34.83. As stated in 34.83, records associated with OSL's TLD's and Film Badges need to be maintained until termination of the license.</p> <p>The State needs to adopt the retention requirements of Part 34.83 to meet compatibility.</p> |
| 5 | 45.1(19) Appendix C | 34.81 | 1997-5 | C | <p>Copies of operating and emergency procedures.</p> <p>The State uses the phrase "until disposal is authorized by the agency." The phrase does not meet the same intent as the language in 10 CFR 34.81. This phraseology is different in meaning than the NRC's requirement of "until the Commission terminates the license and three years after a change is made."</p> <p>The State needs to adopt similar wording to 34.81 to meet compatibility.</p> |
| 6 | N/A | 35.390 | 2002-2 | B | <p>Training for use of unsealed byproduct material for which a written directive is required</p> <p>The State has adopted the training requirements of 10 CFR Part 35 Subpart J in place of Part 35.390.</p> <p>Although the State is currently compatible, the State will have to adopt Part 35.390 after Subpart J is rescinded.</p> |

**COMPATIBILITY COMMENTS ON IOWA FINAL REGULATIONS
FROM NRC LETTER DATED SEPTEMBER 30, 2003**

| | | | | | |
|---|-----------|--------|--------|---|---|
| 1 | 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> |
| 2 | 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>The 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> |
| 3 | 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>The State does not fully meet the training requirements of 10 CFR 35.690. The requirements of 35.690 (b)(3) are missing.</p> <p>The State needs to adopt all the training requirements of 10 CFR 35.690 to achieve compatibility.</p> |

STATE REGULATION STATUS

State: IOWA

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

Tracking Ticket Number: 4-05

Date: February 4, 2004

| 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 | |

| 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) |
|---|--|------------|--|---|---|
| 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 ML03640452 | N 2/04/04 ML040360241 | |
| 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 ML03640452 | N 2/04/04 ML040360241 | 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 ML03640452 | N 2/04/04 ML040360241 | |
| ★Criteria for the Release of Individuals Administered Radioactive Material-Parts 20, 35 | 62 FR 4120; (5/29/00) | 1997-3 | F ML03640452 | N 2/04/04 ML040360241 | |
| ★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 ML03640452 | Y 2/04/04 ML040360241 | |
| ★Radiological Criteria for License Termination-Parts 20, 30, 40, 70 | 62 FR 39057; (8/20/00) | 1997-6 | F ML03640452 | N 2/04/04 ML040360241 | |
| 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 ML03640452 | N 2/04/04 ML040360241 | |
| ★Self-Guarantee of Decommissioning Funding by Nonprofit and Non-Bond-Issuing Licensees- Parts 30, 40, 70 | 63 FR 29535; (none) | 1998-2 | F ML03640452 | 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 | P | N 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 ML03640452 | N 2/04/04 ML040360241 | |
| ★Transfer for Disposal and Manifests: Minor Technical Conforming Amendment-Part 20 | 63 FR 50127; (11/20/01) | 1998-6 | F ML03640452 | N 2/04/04 ML040360241 | |

| NRC Chronology Identification | FR Notice (State Due Date) | RATS ID | Proposed (P) / Final (F)¹ Rule / ML #⁵ | NRC Review / Y, N² / Date / ML #⁵ | Final State Regulation¹ (Effective Date) |
|--|---------------------------------------|--------------------|---|--|--|
| 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 ML03640452 | N 2/04/04 ML040360241 | |
| ★Energy Compensation Sources for Well Logging and Other Regulatory Clarifications-Part 39 | 65 FR 20337; (5/17/03) | 2000-1 | F ML03640452 | N 2/04/04 ML040360241 | |
| ★New Dosimetry Technology-Parts 34, 36, 39 | 65 FR 63750; (1/8/04) | 2000-2 | F ML03640452 | N 2/04/04 ML040360241 | |
| ★Requirements for Certain Generally Licensed Industrial Devices Containing Byproduct Material - Parts 30, 31, 32 | 65 FR 79162; (2/16/04) | 2001-1 | F ML03640452 | N 2/04/04 ML040360241 | |
| ★Revision of the Skin Dose Limit - Part 20 | 67 FR 16298; (4/5/05) | 2002-1 | F ML03640452 | N 2/04/04 ML040360241 | |
| ★Medical Use of Byproduct Material - Parts 20, 32, and 35 | 67 FR 20249; (4/24/05) | 2002-2 | F ML03640452 | Y 2/04/04 ML040360241 | |
| Financial Assurance for Materials Licensees – Parts 30, 40, 70 | 68 FR 57327 12/3/06 | 2003-1 | | | |

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