

November 12, 2002

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

Dear Mr. Flater:

As requested, we have reviewed the proposed regulations in the Iowa Public Health Department, Notice of Intended Action, enclosed in your August 23, 2002 letter. The proposed regulations are in response to the amendments identified in the enclosed State Regulation Status (SRS) Data Sheet. The regulations were reviewed by comparison to the equivalent NRC regulations in 10 CFR Parts 20, 30, 31, 32, 34, 35 and 39. We discussed our review of the regulations with George Johns on September 27, 2002.

As a result of our review, we have 14 comments and 27 editorial suggestions that have been identified in the enclosures. Please note that we have limited our review to regulations required for compatibility and/or health and safety. Under our current procedure, a finding that a State regulation meets the compatibility and health and safety categories of the equivalent NRC regulation may only be made based on a review of the final State regulation. However, we have determined that if your proposed regulations were adopted incorporating the comments and without other significant change, they would meet the compatibility and health and safety categories established in Office of State and Tribal Programs (STP) Procedure SA-200.

We request that when the proposed regulations are adopted and published as final regulations, a copy of the "as published" regulations be provided to us for review. As requested in STP Procedure SA-201, *Review of State Regulations* (November 10, 1998), please highlight the final changes and send one copy in a computer readable format, if possible.

The SRS Data Sheet summarizes our knowledge of the status of other Iowa regulations. 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 Web Site: <http://www.hsrdrn.gov/nrc/rulemaking.htm>.

If you have any questions regarding the comments, the compatibility and health categories, or any of the NRC regulations used in the review, please contact me or James Lynch at (630) 829-9661 or JLL2@NRC.GOV.

Sincerely,

*/RA/*

Josephine M. Piccone, Deputy Director  
Office of State and Tribal Programs

Enclosures:  
As stated

Distribution:

DIR RF (2-204)

LBolling, ASPO

DCD (SP07) PDR (YES)

Iowa File

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OFFICE	RSAO	STP	OGC	STP:DD	
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DATE	10/10/02	10/16/02	11/05/02	10/17/02 11/12/02	

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**COMMENTS ON PROPOSED IOWA REGULATIONS  
AGAINST COMPATIBILITY AND HEALTH AND SAFETY CATEGORIES**

State Regulation	NRC Regulation	RATS ID	Category	Subject and Comments
39.4(22)d (3)13	31.5(c) 13(i)	2001-1	B	<p><b>Certain detecting, measuring gauging or controlling devices and certain devices for producing light or ionized atmospheres.</b></p> <p>The State rule requires a more restrictive registration of devices with .01 mCi of transuranic elements rather than 1 mCi as required by 31.5.</p> <p>The State needs to use the same requirement as found in 31.5</p>
39.4(22)d (3)13	31.5(c) 13(iv)	2001-1	B	<p><b>Certain detecting, measuring gauging or controlling devices and certain devices for producing light or ionized atmospheres.</b></p> <p>This NRC regulation allows the temporary use (less than 180 days per year) of generally-licensed devices in NRC jurisdiction without the requirement to register the devices. The State rule should reflect that generally-licensed devices from another jurisdiction do not require registration with Iowa, if used on a temporary basis.</p> <p>The State needs to include this statement to achieve compatibility</p>
39.4(29)d (4)	32.51a	2001-1	B	<p><b>Certain detecting, measuring gauging or controlling devices and certain devices for producing light or ionized atmospheres.</b></p> <p>This rule needs references to NRC general licensees and should be restated from the Iowa point of view, that is if the device is transferred from Iowa to another jurisdiction.</p>
39.4(29)d (5)	32.52(a) and (b)	2001-1	B	<p><b>Same: Material Transfer Reports and Records</b></p> <p>The State rule is missing the equivalent of 32.52(b).</p> <p>The State needs to include this requirement to meet compatibility.</p>

State Regulation	NRC Regulation	RATS ID	Category	Subject and Comments
41.2(58)	35.632	2002-2	B	<p><b>Full Calibrations Measurements on Remote Afterloader Units</b></p> <p>The State does not require the signature of the medical physicist who performed the full calibration on teletherapy units as per 35.632.</p> <p>The State needs to include this to meet compatibility.</p>
41.2(66)	35.57(a)	2002-2	B	<p><b>Training for Experienced Radiation Safety Officer, Teletherapy or Medical Physicist, Authorized User and Nuclear Pharmacist</b></p> <p>The rule does not include the language of 10 CFR 35.57(a).</p> <p>The State needs to include this section to meet compatibility.</p>
41.2(67)	35.190	2002-2	B	<p><b>Training for Uptake, Dilution and Excretion Studies</b></p> <p>It appears that references in 41.2(67)a and c(3) should read "41.2(67)c" not "41.2(67)b" as stated. If the State intended to reference this section as written it is incorrect.</p> <p>The State needs to reference this section correctly to meet compatibility.</p>
41.2 (68)	35.290	2002-2	B	<p><b>Training for Imaging and Localization Studies</b></p> <p>The State has omitted section 35.290 (b).</p> <p>The State needs to include this section to achieve compatibility.</p>

State Regulation	NRC Regulation	RATS ID	Category	Subject and Comments
41.2(69)	35.390	2002-2	B	<p><b>Training for Use of Unsealed Byproduct Material for Which a Written Directive Is Required</b></p> <p>41.2(69)b(3)3 does not allow the use of an NRC licensed preceptor.</p> <p>The State needs to include this section to achieve compatibility.</p>
41.2(73)	35.690	2002-2	B	<p><b>Training for Use of Remote Afterloader Units, Teletherapy Units and Gamma Sterotatic Radiosurgery Units</b></p> <p>41.2(73)b(2) and b(3) do not recognize experience gained under an NRC license.</p> <p>The State need to include the language included in 35.690 (a) to achieve compatibility.</p>
41.2(74)	35.51	2002-2	B	<p><b>Training for an Authorized Medical Physicist</b></p> <p>The State adds the words “and teletherapy physicist” to this section. There is no teletherapy physicist authorized by the NRC regulations nor is this position defined in the States definition.</p> <p>The State needs to remove the reference to teletherapy physicist to achieve compatibility.</p>
41.2 (87)	35.40	2002-2	H&S	<p><b>Written Directives</b></p> <p>The State has omitted the requirements of 35.40(6)(ii)(c).</p> <p>The State needs to include these requirements to achieve compatibility.</p>

State Regulation	NRC Regulation	RATS ID	Category	Subject and Comments
41.2(85)	35.433	2002-2	H&S	<p><b>Decay of Strontium-90 Sources for Ophthalmic Treatments</b></p> <p>The regulatory reference in this rule appears to be incorrect and should be 41.2(84). As written, this reference makes the section non-compatible.</p> <p>The State needs to reference this section correctly to achieve compatibility.</p>
45.6 (17)	39.65	None	C	<p><b>Personnel Monitoring</b></p> <p>The State has omitted the requirement for bioassays as stated in 39.65 (b).</p> <p>The State needs to include these requirements to achieve compatibility.</p>

### Editorial Suggestions

State Section	NRC Section	Comment

38.2	20.1003	<p>“atmosphere-supplying respirator” definition</p> <p>The abbreviation for supplied-air respirators should be “SARs” not “SRAs.”</p>
38.2	20.1003	<p>“supplied-air respirator” definition</p> <p>The abbreviation for supplied-air respirators should be “SAR” not “SRA.”</p>
38.2	35.3045	<p>“reportable medical event” definition</p> <p>“prescribed” is misspelled in paragraph a(1).</p> <p>The text should read “...to an organ <u>or</u> tissue...” in paragraph c.</p>
39.4(22)d (2)	31.5(b)1	The rule uses the term “manufacturer” rather than “manufactured”
39.4(22)d (3)	31.5(c)	The rule uses the term “acquired” rather than “acquires”
39.4(22)d (3)7	31.5(c)7	The rule uses the term “CFR 10 Part 110” rather than “10 CFR Part 110”
39.4(29)d (1)3	32.51(a) 3(iii)	The term “distributor” was not changed to “initial transferor” on the label example.
40.26(6)	20.1301(c)	The rule uses the term “received” rather than “receive”
40.50(1)	20.1703	40.50(1)c(1) uses the term “exposures” rather than “doses”
40.117	30.7	40.117(1)a(4) should read “...any provision ( <u>or</u> proposed provision...”
41.2(10)	35.24	41.2(10)b should read “...Radiation Safety Officer...”
41.2(50)	35.605	<p>In 41.2(50)a, the term “...or repair remote an afterloader unit...” should be revised to “...or repair a remote afterloader unit...”</p> <p>Additionally, the word “reduce” is missing from the reference to shielding in 41.2(50)a.</p> <p>Also, the word “afterloader” is missing from the last part of 41.2(50)b.</p>
41.2(50)d	35.2605	The rule should read “...remote afterloader <u>units</u> ”
41.2(52)	35.610	41.2(52)a(4) should use the term “shielded” rather than “shielding” and should have the word “radiation” inserted before “field.”
41.2(53)	35.615	41.2(53)d should read “...each treatment room with <u>viewing and</u> intercom systems...”
41.2(57)a	35.630	The word “meeting” should be deleted from the second sentence of 41.2(57)a(2) and the word “calibrating” should be restored to the last sentence of the section.
41.2(58)	35.632	The term “the output within” is repeated in 41.2(58)a.

41.2(60)	35.652	41.2(60)a should read "...of the main source <u>safe</u> with the source..."
41.2(65)	35.50	41.2(65)a uses the term "include" rather than "includes" 41.2(65)b(3) uses the term "complete" rather than "completed"
41.2(68)	35.290	41.2(68)b(1)3 uses the term "measurement or radioactivity" instead of "measurement of radioactivity."
41.2(69)	35.390	41.2(69)a(2)2(second bulleted paragraph) should read "...operation of <u>survey</u> meters;"
41.2(70)	35.490	41.2(70)b should read "...applicable to the <u>use of</u> manual brachytherapy..." 41.2(70)b(2) has the word "event" misspelled. 41.2(70)b(3) has the term "may be obtained" repeated.
41.2(79)	35.57	The rule title should read "experienced" not "experience"
41.2(83)	35.6	The word "subject" should be plural in two places. 41.2(83)c should read "...that has <u>implemented</u> the Federal..." 41.2(83)c should read "...licensee will, before <u>conducting</u> research..." 41.2(83)c(1) should read "...and described <u>in the</u> Federal..."
41.2(21) (2)	35.3067	In (2) the first sentence is confusing, the word order and use of the word "agency" should be revised for clarity.
41.2(74)	35.51	The first word in (b) should be "holds" not "hold."
45.6(12)	39.41	In (2) the State omitted the word "that" between the words "forms" and "are."

## STATE REGULATION STATUS

State: Iowa

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

Tracking Ticket Number: 2-204

Date: November 12, 2002

NRC Chronology Identification	FR Notice (State Due Date)	RATS ID	Proposed (P) / Final (F) <sup>1</sup> Rule / ML # <sup>5</sup>	NRC Review / Y, N <sup>2</sup> / Date / ML # <sup>5</sup>	Final State Regulation <sup>1</sup> (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 <sup>3</sup>
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 <sup>3</sup>
Licensing and Radiation Safety Requirements for Irradiators-Part 36	58 FR 7715; (7/1/96)	1993-2			Not applicable SECY-95-112 <sup>4</sup>
Definition of Land Disposal and Waste Site QA Program-Part 61	58 FR 33886; (7/22/96)	1993-3			Not applicable SECY-95-112 <sup>4</sup>
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 <sup>3</sup>
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	

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Radiation Protection Requirements: Amended Definitions and Criteria-Parts 19, 20	60 FR 36038; (8/14/98)	1995-5	F	N 1/14/00	
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	P P ML013470356	N 3/21/00 N 3/5/01 Y 3/22/02 ML020800579	
One Time Extension of Certain Byproduct, Source and Special Nuclear Materials Licenses- Parts 30, 40, 70	61 FR 1109; (none)	1996-2			Not required <sup>3</sup>
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	P	N 3/21/00	Not required <sup>3</sup>
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	P ML010750515	N 5/14/01 ML011350617	
Criteria for the Release of Individuals Administered Radioactive Material-Parts 20, 35	62 FR 4120; (5/29/00)	1997-3	F P	Y 1/14/00 N 3/21/00	
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	P P	Y 3/21/00 Y 3/5/01	
Radiological Criteria for License Termination-Parts 20, 30, 40, 70	62 FR 39057; (8/20/00)	1997-6	F P	Y 1/14/00 Y 3/21/00	
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	P	N 3/21/00	
Self-Guarantee of Decommissioning Funding by Nonprofit and Non-Bond-Issuing Licensees- Parts 30, 40, 70	63 FR 29535; (none)	1998-2	P	N 3/21/00	Not required <sup>3</sup>
License Term for Medical Use Licenses-Part 35	63 FR 31604; (none)	1998-3			Not required <sup>3</sup>
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	

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Minor Corrections, Clarifying Changes, and a Minor Policy Change-Parts 20, 35, 36	63 FR 39477; 63 FR 45393 (10/26/01)	1998-5	P	N 3/21/00	
Transfer for Disposal and Manifests: Minor Technical Conforming Amendment-Part 20	63 FR 50127; (11/20/01)	1998-6	P	N 3/21/00	
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 <sup>3</sup>
*Respiratory Protection and Controls to Restrict Internal Exposure-Part 20	64 FR 54543; 64 FR 55524 (2/2/03)	1999-3	P ML022550214	N 11/12/02 ML023170625	
*Energy Compensation Sources for Well Logging and Other Regulatory Clarifications-Part 39	65 FR 20337; (5/17/03)	2000-1	P ML022550214	N 11/12/02 ML023170625	
*New Dosimetry Technology-Parts 34, 36, 39	65 FR 63750; (1/8/04)	2000-2	P ML013470356  P ML022550214	Y 3/22/02 ML020800579  N 11/12/02 ML023170625	
*Requirements for Certain Generally Licensed Industrial Devices Containing Byproduct Material - Parts 30, 31, 32	65 FR 79162; (2/16/04)	2001-1	P ML022550214	Y 11/12/02 ML023170625	
*Revision of the Skin Dose Limit - Part 20	67 FR 16298; (4/5/05)	2002-1	P ML022550214	N 11/12/02 ML023170625	
*Medical Use of Byproduct Material - Parts 20, 32, and 35	67 FR 20249; (4/24/05)	2002-2	P ML022550214	Y 11/12/02 ML023170625	

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