

January 9, 2007

Mr. Paul Schmidt, Chief
Radiation Protection Section, Division of Public Health
Department of Health and Family Services
PO Box 2659
Madison, WI 53701-2659

Dear Mr. Schmidt:

We have reviewed the final revision to the Wisconsin radiation protection rules, Chapter HFS 157, "Radiation Protection," and the changes you made to address the letter we sent you on November 27, 2002, received by our office on November 13, 2006. These regulations were reviewed by comparison to the equivalent Nuclear Regulatory Commission (NRC) rules in 10 CFR Parts 20, 30, 32, 34, 35, 36, 39, 61, and 71 and the requirements of the five amendments identified in the enclosed State Regulation Status (SRS) Data Sheet. We discussed our review of the regulations with Cheryl Rogers on January 8, 2007.

As a result of our review, we have 10 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 State and Tribal Programs (STP) 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 STP Procedure [SA-201](#), "Review of State Regulatory Requirements," please highlight the location of any changes made by Wisconsin, in response to our comments, and provide a copy to Division of Materials Safety and State Agreements, Office of Federal and State Materials and Environmental Management Programs (FSME) (see letter [FSME 06-94](#) dated October 6, 2006 for further information).

The SRS Data Sheet summarizes our knowledge of the status of other Wisconsin 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 FSME website: <http://www.hsrd.ornl.gov/nrc/rulemaking.htm>.

Mr. Paul Schmidt, Chief

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January 9, 2007

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 Kathleen Schneider, State Regulation Review Coordinator at 301-415-2320 (e-mail: kxs@nrc.gov), or Cardelia H. Maupin at 301-415-2312 (e-mail: chm1@nrc.gov).

Sincerely,

Scott W. Moore, 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 Kathleen Schneider, State Regulation Review Coordinator at 301-415-2320 (e-mail: kxs@nrc.gov,) or Cardelia H. Maupin at 301-415-2312 (e-mail: chm1@nrc.gov).

Sincerely,

Scott W. Moore, Deputy Director
Division of Materials Safety and State Agreements
Office of Federal and State Materials and
Environmental Management Programs

Enclosures: As stated

DIR RF 6-283
DCD (SP05)
JLynch, RSAO MOrandi
LBolling, ASPO

SUNSI Review Complete
 Publicly Available Non-Publicly Available
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Wisconsin File

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COMPATIBILITY COMMENTS ON WISCONSIN FINAL REGULATION

STATE SECTION		NRC SECTION	RATS ID	CATEGORY	SUBJECT and COMMENTS
1	157.09(2)(a)(2)	30.14	N/A	B	<p>Exempt Concentrations</p> <p>Wisconsin omits the paragraph “This exemption does not apply to the transfer of byproduct material contained in any food, beverage, cosmetic, drug, or other commodity or product designed for ingestion or inhalation by, or application to, a human being,” from HFS 157.09(2)(a)(2).</p> <p>Wisconsin needs to add this paragraph to HFS 157.09(2)(a)(2) to meet the Compatibility Category B designation assigned to 10 CFR 30.14.</p>
2	157.09(2)(g)	30.21	N/A	B	<p>Radioactive drug: Capsules containing carbon-14 urea for “in vivo” diagnostic use for humans</p> <p>Wisconsin references HFS 157.13(4)(i) in HFS 157.09(2)(g)(3). This reference to HFS 157.13 (4)(i) does not match the reference to 10 CFR 32.21. Either the correct reference needs to be inserted or HFS 157.09(g) should reference 10 CFR 32.21.</p> <p>Wisconsin needs to revise HFS 157.09(2)(g) to reference 10 CFR 32.21 to meet the Compatibility Category B designation assigned to 10 CFR 30.21.</p>
3	157.53(1)(a)(2)	39.61	N/A	B	<p>Requirements for Personnel Safety</p> <p>The Wisconsin regulation includes the requirement to completed a course recognized by the department, the NRC, another agreement state or a licensing state. This requirement makes HFS 157.53(1)(a)(2) more restrictive than 10 CFR 39.61.</p> <p>Wisconsin needs to omit the requirements for completion of a course in order to meet the Compatibility Category B designation assigned to 10 CFR 39.61.</p>
4	157.03(197m, 198, 199, 200)	71.4	2004-1	B	<p>Definition- Low Specific Activity</p> <p>The definition of LSA-III omits the reference to meet requirements of 10 CFR 71.77 ‘Qualification of LSA-III material’.</p> <p>Wisconsin needs to add the appropriate reference</p>

STATE SECTION		NRC SECTION	RATS ID	CATEGORY	SUBJECT and COMMENTS
					corresponding to 10 CFR 71.77 to the definition of LSA-III to meet the Compatibility Category B designation assigned to Low Specific Activity in 10 CFR 71.4.
5	157.92 (3)(a)	71.5(a)	2004-1	B	<p>Transportation of Licensed Material</p> <p>Wisconsin omits the reference to "DOT regulations 49 CFR parts 107, 171 through 180, and 390 through 397" from HFS 157.92(3)(a)(1).</p> <p>The State has not adequately address the comment regarding the inclusion in the introductory paragraph, provisions that the licensee shall comply with the applicable requirements of DOT regulations in 49 CFR Parts 107, 171 through 180, and 390 through 397, appropriate to the mode of transport, and the licensee shall particularly note DOT regulations in the following areas. Wisconsin needs to include the revisions noted above to meet the Compatibility Category B designation assigned to 10 CFR 71.5.</p> <p>Wisconsin needs to add the above reference to this section to meet the Compatibility Category B designation assigned to 10 CFR 71.5(a).</p>
6	157.92 (3)(b)	71.5(b)	2004-1	B	<p>Transportation of Licensed Material</p> <p>Wisconsin incorrectly references the DOT regulations in HFS 157.92(3)(b). The reference should be changed to read "...49 CFR parts 107, 171 through 180, and 390 through 397...".</p> <p>Wisconsin needs to revise the DOT reference in HFS 157.92(3)(b) to read 49 CFR parts 107, 171 through 180, and 390 through 397 to meet the Compatibility Category B designation assigned to 10 CFR 71.5(b).</p>
7	157 Appendix O	Appendix A Part 71	2004-1	B	<p>Determination of A1 and A2</p> <p>It was stated in a May 2006 letter that in Appendix O, Subsection II, Wisconsin makes reference to values in Table VII for values that may be used without department approval. The correct table is Table VIII. Also Wisconsin did not include equivalent provisions for the following 10 CFR Part 71, Appendix A Subsections: II(b), II(c), III(e) and III(f). Wisconsin indicated that they will be correcting these items in their next rule making.</p>

STATE SECTION		NRC SECTION	RATS ID	CATEGORY	SUBJECT and COMMENTS
					Wisconsin needs to change HFS 157 Appendix O to correct the Table reference in subsection II and add subsections equivalent to 10 CFR 71 Appendix A II(b), II(c), III(e), and III(f) to meet the Compatibility Category B designation assigned to 10 CFR 71 Appendix A.
8	157.03(294)	35.2	2005-2	B	<p>Definition - Radiation Safety Officer</p> <p>Wisconsin's definition of Radiation Safety officer omits the requirements of paragraph (2) in the 10 CFR 35.2 definition of Radiation Safety Officer.</p> <p>Wisconsin needs to add this paragraph to its definition of Radiation Safety Officer to meet the Compatibility Category B designation assigned to this definition in 10 CFR 35.2.</p>
9	157.61(10)(a)	35.57 (a)(1)	2005-2	B	<p>Training for Experienced Radiation Safety Officer, Teletherapy or Medical Physicist, Authorized Medical Physicist, Authorized User, Nuclear Pharmacist, and Authorized Nuclear Pharmacist</p> <p>Wisconsin adds "...authorized medical physicist..." to paragraph (a). Also Wisconsin does not include the phrasing "before October 24, 2002" in 157.61(10)(a).</p> <p>Wisconsin needs to change 157.61(10)(a) to remove the phrase "authorized medical physicist" and add "before October 24, 2002" to meet the Compatibility Category B designation assigned to 10 CFR 35.57(a)(1).</p>

STATE SECTION		NRC SECTION	RATS ID	CATEGORY	SUBJECT and COMMENTS
10	157.61(10)	35.57 (a)(2)	2005-2	B	<p>Training for Experienced Radiation Safety Officer, Teletherapy or Medical Physicist, Authorized Medical Physicist, Authorized User, Nuclear Pharmacist, and Authorized Nuclear Pharmacist</p> <p>Wisconsin omits 10 CFR 35.57(a)(2) from its regulations.</p> <p>Wisconsin needs to add this section to HFS 157.61(10) to meet the Compatibility Category B designation assigned to 10 CFR 35.57.</p>

STATE REGULATION STATUS

State: Wisconsin

Tracking Ticket Number: 6-283

[5 Amendments reviewed identified by a ★
at the beginning of the equivalent NRC requirement.]

Date: January 9, 2007

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)
Safety Requirements for Radiographic Equipment-Part 34	55 FR 843; (1/10/94)	1991-1			08/01/02 ⁶
ASNT Certification of Radiographers-Part 34	56 FR 11504; (none)	1991-2			08/01/02 ⁶
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			08/01/02 ⁶
Notification of Incidents-Parts 20, 30, 31, 34, 39, 40, 70	56 FR 64980; (10/15/94)	1991-4			08/01/02 ⁶
Quality Management Program and Misadministrations-Part 35	56 FR 34104; (1/27/95)	1992-1			08/01/02 ⁶
Eliminating the Recordkeeping Requirements for Departures from Manufacturer's Instructions-Parts 30, 35	57 FR 45566; (none)	1992-2			08/01/02 ⁶
Decommissioning Recordkeeping and License Termination: Documentation Additions [Restricted areas and spill sites]-Parts 30, 40	58 FR 39628; (10/25/96)	1993-1			08/01/02 ⁶
Licensing and Radiation Safety Requirements for Irradiators-Part 36	58 FR 7715; (7/1/96)	1993-2			08/01/02 ⁶
Definition of Land Disposal and Waste Site QA Program-Part 61	58 FR 33886; (7/22/96)	1993-3			08/01/02 ⁶
Self-Guarantee as an Additional Financial Mechanism-Parts 30, 40, 70	58 FR 68726; 59 FR 1618; (none)	1994-1			08/01/02 ⁶
Uranium Mill Tailings Regulations: Conforming NRC Requirements to EPA Standards-Part 40	59 FR 28220; (7/1/97)	1994-2			Not required ³
Timeliness in Decommissioning Material Facilities-Parts 30, 40, 70	59 FR 36026; (8/15/97)	1994-3			08/01/02 ⁶

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)
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			08/01/02 ⁶
Frequency of Medical Examinations for Use of Respiratory Protection Equipment-Part 20	60 FR 7900; (3/13/98)	1995-2			08/01/02 ⁶
Low-Level Waste Shipment Manifest Information and Reporting-Parts 20, 61	60 FR 15649; 60 FR 25983; (3/1/98)	1995-3			08/01/02 ⁶
Performance Requirements for Radiography Equipment-Part 34	60 FR 28323; (6/30/98)	1995-4			08/01/02 ⁶
Radiation Protection Requirements: Amended Definitions and Criteria-Parts 19, 20	60 FR 36038; (8/14/98)	1995-5			08/01/02 ⁶
Clarification of Decommissioning Funding Requirements-Parts 30, 40, 70	60 FR 38235; (11/24/98)	1995-6			08/01/02 ⁶
Medical Administration of Radiation and Radioactive Materials-Parts 20, 35	60 FR 48623; (10/20/98)	1995-7			08/01/02 ⁶
10 CFR Part 71: Compatibility with the International Atomic Energy Agency-Part 71	60 FR 50248; 61 FR 28724; (4/1/99)	1996-1			08/01/02 ⁶
One Time Extension of Certain Byproduct, Source and Special Nuclear Materials Licenses-Parts 30, 40, 70	61 FR 1109; (none)	1996-2			08/01/02 ⁶
Termination or Transfer of Licensed Activities: Recordkeeping Requirements-Parts 20, 30, 40, 61, 70	61 FR 24669; (6/17/99)	1996-3			08/01/02 ⁶
Resolution of Dual Regulation of Airborne Effluents of Radioactive Materials; Clean Air Act-Part 20	61 FR 65120; (1/9/00)	1997-1			08/01/02 ⁶
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			08/01/02 ⁶
Criteria for the Release of Individuals Administered Radioactive Material-Parts 20, 35	62 FR 4120; (5/29/00)	1997-3			08/01/02 ⁶
Fissile Material Shipments and Exemptions-Part 71	62 FR 5907; (none)	1997-4			08/01/02 ⁶

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)
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			08/01/02 ⁶
Radiological Criteria for License Termination-Parts 20, 30, 40, 70	62 FR 39057; (8/20/00)	1997-6			08/01/02 ⁶
Exempt Distribution of a Radioactive Drug Containing One Microcurie of Carbon-14 Urea-Part 30	62 FR 63634; (1/02/01)	1997-7			08/01/02 ⁶
Deliberate Misconduct by Unlicensed Persons-Parts 30, 40, 61, 70, 71, 150	63 FR 1890; 63 FR 13773; (2/12/01)	1998-1			08/01/02 ⁶
Self-Guarantee of Decommissioning Funding by Nonprofit and Non-Bond-Issuing Licensees- Parts 30, 40, 70	63 FR 29535; (none)	1998-2			08/01/02 ⁶
License Term for Medical Use Licenses-Part 35	63 FR 31604; (none)	1998-3			08/01/02 ⁶
Licenses for Industrial Radiography and Radiation Safety Requirements for Industrial Radiographic Operations-Part 34	63 FR 37059; (7/9/01)	1998-4			08/01/02 ⁶
Minor Corrections, Clarifying Changes, and a Minor Policy Change-Parts 20, 35, 36	63 FR 39477; 63 FR 45393; (10/26/01)	1998-5			08/01/02 ⁶
Transfer for Disposal and Manifests: Minor Technical Conforming Amendment-Part 20	63 FR 50127; (11/20/01)	1998-6			08/01/02 ⁶
Radiological Criteria for License Termination of Uranium Recovery Facilities-Part 40	64 FR 17506; (6/11/02)	1999-1			08/01/02 ⁶
Requirements for Those Who Possess Certain Industrial Devices Containing Byproduct Material to Provide Requested Information-Part 31	64 FR 42269; (none)	1999-2			08/01/02 ⁶
Respiratory Protection and Controls to Restrict Internal Exposure-Part 20	64 FR 54543; 64 FR 55524; (2/2/03)	1999-3			08/01/02 ⁶
Energy Compensation Sources for Well Logging and Other Regulatory Clarifications-Part 39	65 FR 20337; (5/17/03)	2000-1			08/01/02 ⁶

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)
New Dosimetry Technology-Parts 34, 36, 39	65 FR 63750; (1/8/04)	2000-2			08/01/02 ⁶
Requirements for Certain Generally Licensed Industrial Devices Containing Byproduct Material - Parts 30, 31, 32	65 FR 79162; (2/16/04)	2001-1	P ⁸ ML012770029	Y 8/31/06 ML062410002	08/01/02 ⁶
★Revision of the Skin Dose Limit-Part 20	67 FR 1629; (4/5/05)	2002-1	F ML063120323	N 1/09/07 ML070090076	08/01/02 ⁶
Medical Use of Byproduct Material-Parts 20, 32, 36	67 FR 20249; (10/24/05)	2002-2	P ML060740270	Y 05/11/06 ML061310350	
★Financial Assurance for Materials Licensees – Parts 30, 40, 70	68 FR 57327; (12/3/06)	2003-1	F ML063120323	N 1/09 /07 ML070090076	
★Compatibility with IAEA Transportation Safety Standards and Other Transportation Safety Amendments - Part 71	69 FR 3697; (10/01/07)	2004-1	F ML063120323	Y 1/09/07 ML070090076	
★Security Requirements for Portable Gauges Containing Byproduct Material - Part 30	70 FR 2001; (7/11/08)	2005-1	F ML063120323	N 1/09/07 ML070090076	
★Medical Use of Byproduct Material - Recognition of Specialty Boards - Part 35	70 FR 16336; 71 FR 1926 (4/29/08)	2005-2	F ML063120323	Y 1/09/07 ML070090076	
Increased Controls for Risk-Significant Radioactive Sources (NRC Order EA-05-090) ⁷	70 FR 72128; (12/1/05)	2005-3	LC ML052560315	N 09/14/05 ML052580010	
Minor Amendments - Parts 20, 30, 32, 35, 40, and 70	71 FR 15005 (3/27/09)	2006-1			

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 the regulation. See: "Final Policy Statement on Adequacy and Compatibility of Agreement State Programs," III.1.Time From For Adoption of Compatible State Regulations, p. 6, SECY-95-112, May 3, 1995.
5. ADAMS ML Number.
6. Wisconsin became an Agreement State effective 08/11/03. The State incorporated NRC regulations 08/01/02 and these regulations were found compatible.
7. 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
8. A re-review was completed on this item due to the change in compatibility category of 31.5 and 31.6. More information can be found in the All Agreement States letter STP 05-072.

