

April 4, 2002

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

Dear Mr. Schmidt:

As requested, we have reviewed the proposed regulations in Wisconsin Administrative Code, Chapter HFS 157 entitled, "Radiation Protection," dated September, 2001 and transmitted by letter dated September 20, 2001. The proposed regulations will replace the referenced NRC regulations currently in place. The regulations were reviewed by comparison to the equivalent NRC regulations and the Suggested State Radiation Control Regulations of the Conference of Radiation Control Program Directors, Inc. We discussed our review of the regulations with you on January 8, 2002 and with Ms. Cheryl Rogers on January 22, 2002.

As a result of our review, we have 68 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. 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 the Office of State and Tribal Programs (STP) Procedure SA-200.

We request that when the proposed regulations are adopted and published as final, a copy of the "as published" regulations be provided to us for review. Please include a redline/strike-out version of the final document including indication of where the changes were incorporated. In your cover letter, please include justification for any alternate solutions to the comments showing how they meet compatibility with the NRC rules. We request that you submit the final regulations 60 days prior to any deadline needed by the State for this review and if possible, in an electronic format. If you have any questions about the regulation submission or review process, you may reference STP Procedure SA-201, *Review of State Regulations* (November 10, 1998); this document can be found on the STP Website:
<http://www.hsr.d.ornl.gov/nrc/procfrm.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 Lloyd Bolling at (301) 415-2327 or LAB@NRC.GOV.

Sincerely,

/RA Josephine M. Piccone Acting for/
Paul H. Lohaus, Director
Office of State and Tribal Programs

Enclosure:
As stated

Paul Schmidt

Distribution:

DIR RF (1-193)

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

State Regulation	NRC Regulation	RATS ID	Category	Subject and Comments
157.03	20.1003		A	<p>(3) Absorbed dose (D) means the mean energy imparted by ionizing radiation to matter. Absorbed dose is the quotient of dE by dM, where dE is the mean energy imparted by ionizing radiation to matter of mass dM. This does not change the definition. The SI unit of absorbed dose is joule per kilogram and is called the Gray. The special name of the unit of absorbed dose is the RAD. 1 Gy = 100 Rad. This definition needs to be changed to be essentially identical to the 10 CFR Part 20.1003 definition.</p>
			A	<p>(16) Airborne radioactivity area means a room, enclosure or area in which airborne radioactive materials exist in concentrations that meet either of the following criteria: Insert between materials and exist “, composed wholly or partly of licensed material,”</p>
			B	<p>(83) Critical group means the group of individuals reasonably expected to receive the greatest exposure to radiation residual radioactivity for any applicable set of circumstances. Delete “radiation” and add “residual radioactivity.”</p>
			B	<p>(139) Fit test means the use of a protocol to qualitatively or qualitatively evaluate the fit of a respirator on an individual. Insert “or quantitatively” between qualitatively and evaluate.</p>
			A	<p>(230) Nonstochastic effect means a health effect, the severity of which varies with the dose and for which a threshold is believed to exist. Radiation-induced cataract formation is an example of a nonstochastic effect. (Also called a deterministic effect) should be added to this definition, as in 10 CFR Part 20.1003.</p>

State Regulation	NRC Regulation	RATS ID	Category	Subject and Comments
			B	(294) Radiation safety officer - add "the individual identified as the radiation safety officer an agency license" and who meets the applicable Department requirements.
157.03	20.1003		A	(413) Very high radiation area means an area, accessible to individuals, in which radiation levels from radiation sources external to the body could result in an individual receiving an absorbed dose in excess of 5 Gy (500 rad) in one hour at one meter from a source of radiation or one meter from any surface that the radiation penetrates. Insert the 10 CFR Part 20 highlighted text.
157.03	40.4		B	(406) Unrefined and unprocessed ore means ore in its natural form prior to any processing, such as grinding, roasting or , beneficiating or refining. Insert " , beneficiating or" between roasting and refining. If it is not possible to use beneficiating, an alternative approach could be to use the phrase "altering the ore from its natural state."
157.03	20.1005		A	(87) Curie means a unit of quantity of radioactivity. One curie (Ci) is that quantity of radioactive material that decays at the rate of 3.7E+10 transformations per second (tps). The definition should be changed to be essentially identical to 10 CFR Part 20.1005.

State Regulation	NRC Regulation	RATS ID	Category	Subject and Comments
157.03	34.3		C	(153) Hands-on Experience - This definition adds a substantial amount of clarifying information to the definition. However, it does not include conducting surveys. The additional information does not apply to all of the places in the regulations that "hands-on experience" appears. The definition needs to be changed to match the definition in 10 CFR Part 34 with all of the additional information moved into the chapter, suggested part HFS 157.44 (3).
			C	(294) Radiation Safety Officer - This definition was written generically to describe the RSO for many different places sited in HFS 157. In order for this definition to meet compatibility as used for radiographic operations, the RSO must be defined as stated in 10 CFR 34.3, specifying "RSO for industrial radiography," due to the fact there is a difference in training between an industrial radiography RSO and other RSOs.
157.04(2)(a), (d)	30.12		B	Corrected text - exemptions granted to U.S. DOE and U.S. NRC prime contractors and sub-contractors for handling Atomic Energy Act material is a Commission only decision. In (a), delete "sources of radiation" and insert "byproduct material, source material and special nuclear material." In (d), delete "the state and" and "jointly," and make determine(s) plural.
157.09(2)(a)	30.14(b) & (c)		B	Exempt concentrations - paragraphs (b) on import ban and (c) on manufacturing restrictions are missing and should be added.
157.09(2)(c) (12)	30.19		B	Not essentially identical. Should follow 10 CFR 30.19.
157.09(2)(c) (13)	30.20		B	Not essentially identical. Should follow 10 CFR 30.20.
157.09(2)(c) (15)	30.21(d)		B	Not essentially identical. Should include 10 CFR 30.21(d).
157.11(1)(c) (1)	40.25		C	Insert between manufactured & either, "or initially transferred."

State Regulation	NRC Regulation	RATS ID	Category	Subject and Comments
157.13(4)	30.32(g)		C	Should require the use of registered SS&Ds.
157.13(4)(d)(1)	32.51		B	Insert "initially" between "or & distribute"
157.13(4)(d)(2)	32.51(a)(4), (5)		B	Text missing. Insert equivalent to 10 CFR 32.51(a)(4)&(5).
157.13(4)(d)(3)	32.51(b)		B	Text missing. Insert equivalent to 10 CFR 32.51(b)(1-10).
157.13(4)(d)(5)	32.51a		B	Due to recent substantive changes to Part 32, it is recommended that 10 CFR 32.51a be copied verbatim.
157.13(4)(d)(5)	32.52		B	Due to recent substantive changes to Part 32, it is recommended that 10 CFR 32.52 be copied verbatim.
157.13(4)(g)(5)	32.71(e)		B	Possible wrong reference "HFS 157.23(1)", should be "HFS 157.30(1)."
157.13(4)(i)	32.72(d)		B	Missing text. Insert a new paragraph, "Nothing in this section relieves the licensee from complying with applicable FDA, other Federal, and State requirements governing radioactive drugs."
157.13(4)(j)	32.72		B	Deleted this subsection and insert 10 CFR 32.72 text. In 10 CFR this subsection, HFS 157.13(j), has been subsumed into 10 CFR 32.72.
157.13(4)(k)(3)	32.74(a)(3)		B	Delete the following text, " provided that the labeling for sources that do not require long term storage may be on a leaflet or brochure that accompanies the source. "
157.13(4)(k)(4)	32.74(b)(2)(i-x)		B	Missing text. Insert 10 CFR 32.74(b)(2) text on acceptance testing for leakage of RAM.
157.13(4)(L)(4)(b)	40.35(b)		B	Missing text. Insert "or initial transferor," between manufacturer & of the. Insert "or initially transferred" between manufactured, & the fact.
157.13(6)(b)	34.13(b)		C	Missing text. Insert "and radiographers assistants" between radiographers & that.

State Regulation	NRC Regulation	RATS ID	Category	Subject and Comments
157.13(6)(i)	34.13(i)		C	Survey meters require 6-month calibrations and for alarm ratemeters the requirement is 12 months.
157.13(11)(c)(1)	30.36(c)(1)		H&S	Insert "decommissioning" and delete "decontamination."
157.22(2)(a)	20.1202(a)		A	Missing text. Insert "by meeting one of the conditions in paragraph (b) of this section and the conditions of paragraph (c) and (d) of this section" between doses & under.
157.22(2)(d)	20.1202(d)		A	Corrected and missing text. Insert "and ,to the extent practical, account for intakes" Delete "estimate."
157.22(4)(a)	20.1204(a)		A	Missing text. Insert "suitable and timely" between "take & measurements."
157.22(8)	20.1208		A	This section requires a high degree of compatibility with 10 CFR Part 20. It is recommended that 20.1208 text be inserted and the existing text be deleted.
157.23(1)(b)	20.1301(b)		A	Corrected text. Delete " restricted " and insert "to controlled areas..."
157.23(2)(a)	20.1302(a)		H&S	Missing text. Insert "unrestricted and controlled areas.."
157.29(2)(c)	20.1902(c)		A	Corrected text. Delete "words Extreme Danger, Very High Radiation Area or"
	20.1403		C	<u>Criteria for License Termination under Restricted Conditions</u> - Wisconsin has chosen to omit this requirement due to potential State liability. The State believes that a facility and lands must be decontaminated to unrestricted use levels or the existing license should be maintained.
157.33	20.1406		C	Need to adopt 10 CFR 20.1406.

State Regulation	NRC Regulation	RATS ID	Category	Subject and Comments
157.36(1)(a), (1)(b)(9), & (2)	34.20		B	The ANSI reference N43.9-1991 does not match the ANSI reference in 10 CFR 34.20 stated as N432-1980. NRC has not accepted the newer guidance because there are endurance test requirements in the 1991 standard that are less restrictive than the 1980 standard.
157.36(1)(a)(3)	34.20(b)(3)		B	Does not allow for minor changes.
157.41(2)(a)	34.31(b)(1)		C	Does not address replacement components, see 10 CFR 34.31(b)(1).
157.45(11) & 157.44(6)	34.47 & 34.83		C	Needs to reflect the new requirements concerning dosimetry detailed in 34.47 and 34.83.
	34 App A		B	State did not cover Appendix "A"?
157.59	Part 35		Variable	It is recommended that Wisconsin follow the format of the draft final rule, since it is expected to be implemented at the time that the agreement becomes effective.
157.73(1)(a)	36.1 (b) & (c)		C	Subchapter VII is missing the quantitative values and irradiator types stated in 10 CFR 36.1 (b) and (c).
157.73(1)(a)1	36.21(a)(1)		B	Section HFS 157.73(1)(a)1 does not accurately state the requirement in 10 CFR 36.21(a)(1). Should add, "Must have a certificate of registration issued by NRC or an Agreement State."
157.73(7)	36.33		H&S	The effective date of July 1, 1993 needs to be inserted into HFS 157.73 (7), (a)&(c) as stated in 10 CFR 36.33(a).
157.51 (1)	39.15 (3)&(4)		C	Section HFS 157.51 (1) omits two requirements found in 10 CFR 39.15, (3) & (4). These requirements relate to the radiation monitoring and contamination control requirements necessary following the loss of a source.

State Regulation	NRC Regulation	RATS ID	Category	Subject and Comments
157.52 (4)	39.33		C	Section HFS 157.52 (4) omits "...and temporary job sites." As written, the regulation allows work at temporary job sites to be conducted without proper survey equipment.
157.52(4)	39.33		C	Section HFS 157.52 (4) omits the requirement for having other available calibrated instruments capable of detecting low level radiation and contamination that may be encountered with a ruptured source, as per 10 CFR 39.33 (b).
157.52(5)(b)	39.35 (b)		C	Section HFS 157.52(5)(b) omits the requirement that the leak test must be "performed using a leak test kit or method approved by the NRC or State" as written 10 CFR 39.35 (b).
157.52(10)	39.41		B	Section HFS 157.52(10) is missing many elements of 10 CFR 39.41. This section is a compatibility B category and therefore must contain all of the essential objectives of 10 CFR 39.41. The section needs to be rewritten including all of these requirements.
Appendix J	39.61(e)(1)(iii) & (e)(5)		B	Appendix J is missing the subjects "hazzards of exposure to radiation" as stated in 10 CFR 39.61(e)(1)(iii) and "case histories of well logging accidents" in 39.61(e)(5).
157.53(1)(a)(1)	39.61(a)(4)		B	Should delete the allowance for an "oral" test.
157.53(1)(a)(3)	39.61(a)(3)		B	Section HFS 157.53(1)(a)(3) is missing the on the job training requirements.
157.92(3)(b)	71.5(b)		B	Missing Text. Insert "A request for modification, waiver, or exemption from those requirements, and any notification referred to in those requirements must be filed with the Department (Wisconsin)."

State Regulation	NRC Regulation	RATS ID	Category	Subject and Comments
157.94	71.87(g) & (k)		B	Missing text. Insert two new paragraphs, "For fissile material, any moderator or neutron absorber, if required, is present and in proper condition" and "Accessible package surface temperatures will not exceed the limits specified in 71.43(g) at any time during transportation."
Appendix B	30.71 Schedule B		B	<u>Exempt Quantities Table</u> - the following Appendix B radionuclides are not listed in either the Suggested State Regulations or 10 CFR: Cs-129, Co-57, Ga-67, Ge-68, Au-195, In-111, I-123, Fe-52, K-43, Rb-81, Na-22, Y-87, Y-88. What is the technical basis for adding these radionuclides to Appendix B? Delete "Note 1."
Appendix G	Appendix G Part 20		B	Missing definitions. Insert definitions for: "disposal, disposal site, land disposal facility." Section III(d)(2) - corrected text, delete "the department authorizes their disposal" and insert "license termination." Section III(d)(3) - corrected text, insert ", unless notified by the shipper that the shipment has been canceled."
Appendix G Section III (a)(2)	Appendix G Part 20 (3)(a)(2)		B	Missing "Greater than Class C."
Appendix H	61.55		B	Section I(b) <u>Classes of waste</u> - Missing text, insert new paragraph compatible with 10 CFR 61.55(a)(2)(iv).
Appendix I	Appendix B Part 30		B	Missing text, insert Gold-198 100 microcuries and Gold-199 100 microcuries. What is the technical basis for adding Sodium-22?

State Regulation	NRC Regulation	RATS ID	Category	Subject and Comments
Appendix O	Appendix A Part 71		B	<p>Section IV(a) & (b) corrected text, use NRC format for these formulae in order to maintain nationwide consistency.</p> <p>Table IV, corrected text - insert 1.5×10^{-3} for the specific activity of Bi-205. Delete the exponent "$\times 10^4$" for the specific activity of Cd-113m.</p>
Appendix P	Schedule C 30.72		H & S	<p>Corrected text - insert Carbon-14 (Non-CO₂).</p> <p>Insert Germanium-68 0.01 release fraction and 2,000 Ci quantity.</p> <p>Change Iodine-124 to Iodine-125.</p> <p>Insert mixed corrosion products 0.01 release fraction and 10,000 Ci quantity between mixed fission products and mixed radioactive waste.</p> <p>Insert Irradiated material, Solid non-combustible 0.001 release fraction and 10,000 Ci quantity.</p>
Appendix Q	30.32(i)(4)		H & S	<p><u>Contents of an Emergency Plan</u> - Section k. Corrected text - it is required that offsite response organizations be provided up to 60-days to review and comment on the licensee's emergency plan before it is submitted to the Department. Section k. should amended accordingly.</p>