

November 27, 2002

Mr. Paul S. 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:

We have reviewed the final regulations in Wisconsin Administrative Code, Chapter HFS 157 entitled, "Radiation Protection," which became effective on August 1, 2002. The regulations were reviewed by comparison to the equivalent NRC regulations. We discussed our review of the regulations with you and with Ms. Cheryl Rogers on September 17, 2002.

As a result of the NRC review, we have identified 33 comments, as enclosed. These comments must be addressed to meet the compatibility and health and safety categories established in the Office of State and Tribal Programs (STP) Procedure SA-200.

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 at (301) 415-3340 or Lloyd Bolling at (301) 415-2327 or LAB@NRC.GOV.

Sincerely,

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

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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(13) Definitions	35.2		[C]	<u>(13) Agreement State</u> - Correct text- delete "42 USC 2201" & retain "subsection 274b of the atomic energy act of 1954, as amended."
157.03(294) Definitions	35.2		B	<u>(294) Radiation Safety Officer</u> - This definition should reference ss HFS 157.61(7) and (10).
157.09(2)(a)(2)	30.14		B	<u>Exemptions of radioactive material other than source material</u> - Delete current text and insert - A manufacturer, processor or producer of a product or material is exempt from the requirements of subch. II if he transfers radioactive material contained in a product or material in concentrations not in excess of those in Appendix A and introduced into the product or material by a licensee holding a specific license issued by the department, an agreement state, or the NRC expressly authorizing such introduction.
157.09(2)(c)	30.15(a)		B	<u>Exempt items</u> - Correct text - "Except for persons who apply radioactive material to the following products, or incorporate radioactive material into the following products, <u>or initially transfers for sale or distribution</u> the following products, a person is exempt from this subchapter if the person receives, possesses, uses, transfers, owns or acquires any of the following products:"
157.09(2)(c)(12)	30.19		B	<u>Self-luminous products.....</u> - Correct text - adopt text essentially identical to 10 CFR 30.19.
157.09(2)(c)(13) (a)	30.20(a)		B	<u>Gas and aerosol detectors.....</u> - Insert "or initially transfer for sale or distribution" between "produce" & "gas." Insert "processed, produced" between "manufactured" & "or"....
157.09(2)(c)(15)	30.21		B	<u>Radioactive drugs: Capsules containing carbon-14 urea for "in vivo" diagnostic use for humans</u> - correct text - adopt text essentially identical to 10 CFR 30.21.
157.13(4)(d)(1)	32.51		B	<u>Licensing the manufacture and distribution of devices to persons generally licensed under s. HFS 157.11(2)(b).1</u> - Insert "initially" between "or" & "distribute" . . & between "and" & "distribute"...
157.13(4)(d) (2)	32.51(a)(4), (5)		B	<u>Licensing the manufacture and distribution of devices to persons generally licensed under s. HFS 157.11(2)(b)</u> - Text missing. Insert equivalent to 10 CFR 32.51(a)(4)&(5).
157.13(4)(d)5.1.	32.51a(e)		B	<u>Licensing the manufacture and distribution of devices to persons generally licensed under s. HFS 157.11(2)(b)</u> - Correct text - 1. If a notification of bankruptcy has been made under s. HFS 157.13(10) or the license is to be terminated, a person licensed under this paragraph shall provide, upon request, to the department, and to the appropriate regulatory agency, NRC or other Agreement States, having jurisdiction at the devices location, records of final disposition required under subd. Par. 5. h.
157.22(8)(c)	20.1208		A	<u>Dose Equivalent to an embryo or fetus</u> - missing text - insert "equivalent" between "dose" and "to."

State Regulation	NRC Regulation	RATS ID	Category	Subject and Comments
157.33(3)(a)3.a. & b.	20.1404		C	<u>Alternate Criteria for a Decommissioning Possession-Only License Termination</u> - Correct text - (3)(a) "A licensee may decommission a facility and maintain a decommissioning possession only license using alternate criteria greater than the dose criterion specified in sub. (2) of this rule, provided that the licensee:" Missing text - between (3)(a)3. a. & b. insert a new sentence "Has employed, to the extent practical, restrictions on site use in minimizing exposures at the site;" This is needed since Wisconsin does not allow restricted site release.
157.33	20.1406		C	<u>Radiological criteria for license termination</u> - Need to adopt 10 CFR 20.1406.
157.36(1)(a), (1)(b)(9), & (2)	34.20		B	<u>Performance requirements for industrial radiography equipment</u> - 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)(1)	34.20(b)(1)		B	<u>Performance requirements for industrial radiography equipment</u> - correct text - delete " source changer or source assembly, " this section pertains only to radiographic exposure devices.
157.36(1)(a)(3)	34.20(b)(3)		B	<u>Performance requirements for industrial radiography equipment</u> - Does not allow for minor changes. Should use 10 CFR 34.20(b)(3) text.
157.41(2)(a)	34.31(b)(1)		C	<u>Procedures</u> - Does not address replacement components, see 10 CFR 34.31(b)(1).
157.44(3)(c)(2)	34.43(c)(3)		B	<u>Training</u> - correct text - delete "or oral."
157.45(11)(c) & 157.44(6)	34.47 & 34.83		C	<u>Records of personnel monitoring</u> - Needs to reflect the new requirements concerning dosimetry detailed in 34.47 and 34.83 re: NAVLAP.
157.52(10)	39.41		B	<u>Design, performance and certification criteria for sealed sources used in well-bore operations</u> - Section HFS 157.52(10) is missing many elements of 10 CFR 39.41. This section is a compatibility B category and therefore must be essentially identical to 10 CFR 39.41. The section needs to be rewritten including all of these requirements.
157.53(1)	39.61(c)		B	<u>Training</u> - missing text - add requirement for annual safety reviews for logging supervisors and logging assistants.
157.53(1)(a)(1) & (2)	39.61(a)(4)		B	<u>Training</u> - delete text - oral examinations are not allowed for logging supervisors.
157.55(1)(d)	39.67(e)		C	<u>Radiation surveys</u> - correct text - delete ", except those using hydrogen-3, carbon-14 and sulfur-35."
157.61(8)(b) (1) & (2)	35.51		B	<u>Training for authorized medical physicist</u> - Add new lead sentence - "Except as provided in HFS 157.61(10), the licensee shall require the authorized medical physicist to be an individual who:" Delete text - "or an equivalent training program approved by the NRC," in (b)(1). Missing text - add 35.51(b)(2) equivalent text.
157.61(9)(a)	35.55		B	<u>Training for authorized nuclear pharmacist</u> - Missing text - after NRC, add "or an Agreement State, or;"

State Regulation	NRC Regulation	RATS ID	Category	Subject and Comments
157.61(10)(b)	35.57		B	<u>Training for experienced Radiation Safety Officer, Teletherapy or medical Physicist, authorized user and nuclear pharmacist</u> - Correct text - change "and" to "thru" between ss. HFS 157.63 & 157.67.
157.62 (3)(b)(2)(a)	35.63		H&S	<u>Determination of dosages of unsealed radioactive material for medical use</u> - Missing text - add "or NRC or another Agreement State."
No equivalent Sections	Subpart J 35.900 thru 35.981		D	<u>Training and experience requirements</u> - These requirements are compatibility category D; however, they should be adopted for consistency and uniformity either through regulations or legally binding requirements.
157.72(2)	35.3047		C	<u>Report of a dose to an embryo or fetus or a nursing child</u> - Correct text - as written this section is not compatible with Part 35. The State should adopt 35.3047 in its entirety.
157.73(1)(a)	36.1 (b) & (c)		C	<u>Performance criteria for sealed sources</u> - Subchapter VII is missing the quantitative values and irradiator types stated in 10 CFR 36.1 (b) and (c).
Appendix G Section III (a)(2)	Appendix G Part20(3)(a)(2)		B	<u>Requirements for transfer of low-level radioactive waste for disposal at land disposal facilities and manifests</u> - Missing "Greater than Class C."
Appendix H Section I(b)(4)	61.55(a)(2) (iv)		B	<u>Classification and characterization of low-level radioactive waste</u> - Section I(b) <u>Classes of waste</u> - Missing text, "Waste that is <u>not</u> generally..."
Appendix P	Schedule C 30.72		H&S	<u>Quantities of radioactive materials requiring consideration of the need for a contingency plan for responding to a release</u> - Insert "-68" after Germanium