

Report From Agency

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**ADMINISTRATIVE RULES
REPORT TO LEGISLATURE
CLEARINGHOUSE RULE 06-021**

**By the Department of Health and Family Services
relating to Ch. HFS 157, Radiation Protection**

Basis and Purpose of Proposed Rule

Under s. 254.34 (1) (a), Stats., the department is responsible for developing and enforcing rules, including registration and licensing of sources of ionizing radiation to prohibit and prevent unnecessary radiation exposure to workers and members of the public. The department is also responsible for maintaining compliance with the agreement signed by Governor Doyle in July, 2003 and the Nuclear Regulatory Commission (NRC) that transferred regulatory authority over certain radioactive materials from the NRC to the state. Under the agreement, the department is responsible for licensing and inspecting radioactive materials commonly used in medicine, industry, research and education. NRC staff periodically evaluates the state regulatory program.

One of the requirements of this agreement is to revise the radioactive material portions of ch. HFS 157 within 3 years of any applicable changes in Titles 10 and 49, Code of Federal Regulations. Titles 10 and 49, CFR have been revised since ch. HFS 157 was last revised in 2002. Therefore, the department proposes to modify the radioactive material requirements in ch. HFS 157.

In addition, the department proposes to revise the portions of ch. HFS 157 pertaining to x-rays to reflect new diagnostic and therapeutic technologies, experience with implementing the current rule, changes in comparable federal regulations in 21 CFR Part 1020, and input provided by an advisory group that included representatives of academic and medical facilities, radioactive material users, x-ray users and large and small businesses.

Finally, the Department proposes to increase the annual site fee and the x-ray tube fee established under s. 254.35 (3), Stats., to address a projected operating deficit in the x-ray registration and inspection program for state fiscal year (SFY) 2006 and beyond. To maintain program revenue sufficient to operate the x-ray registration and inspection program, the department under s. 254.35 (3) (g), Stats., proposes to increase annual registration fees by increasing both the annual site fee and x-ray tube fee for installations required to be registered as follows:

- Increase the annual site fee from \$36 to \$50 for all required registrants, including sites serving physicians and clinics, osteopaths and clinics, chiropractors, hospitals, podiatrists, veterinarian, industrial, educational facilities, research projects, and dental sites, and other sites required to be registered.
- Increase the annual x-ray tube fee from \$44 to \$50 for all sites, except dental, serving physicians and clinics, osteopaths and clinics, chiropractors, hospitals, podiatrists, veterinarian, industrial sites, educational facilities, research projects, and other sites.
- Increase the annual x-ray tube fee from \$30 to \$35 for dental sites.

The proposed revisions to chapter HFS 157 accomplish the following:

- Update the radiation protection and regulatory requirements for radioactive materials to reflect changes in federal regulations in Title 10, Code of Federal Regulations Parts 19, 20, 31, 33-36, 39, 40, 70, 71 and 150 and applicable portions of Title 49 (transportation), Code of Federal Regulations.
- Update the radiation safety requirements for x-ray producing devices to reflect new technologies, current

- federal regulation and the input of an ad hoc advisory group representing a cross-section of regulated users.
- Revise 7 of the 42 radioactive material license fee categories to reflect lessons learned after 1.5 years as an Agreement state. There is no fee increase associated with the materials fee category revision.
 - Increase x-ray registration fees to ensure sufficient operating revenue for the x-ray registration and inspection program. The last fee increase occurred in 1996. The x-ray registration and inspection program helps to minimize unnecessary radiation exposure to the general public and device operators by verifying that devices are functioning according to radiation protection requirements in ch. HFS 157.

Responses to Legislative Council Rules Clearinghouse Recommendations

The department submitted the proposed rules to the Legislative Council Rules Clearinghouse for review on March 8, 2006. The department accepted most of the comments offered by the Rules Clearinghouse and, in response, modified the rule. The response to comments not accepted by the department is listed below:

Rules Clearinghouse Comment	Department Response
2d. In s. HFS 157.03 (124m), the second and third sentences are substantive in nature and should be placed in another section of the rule.	No change. This definition is required by federal law to be identical to the NRC definition in 10 CFR 71.4.
2h. In s. HFS 157.61 (7) (a) 2. b., the use of the notation and/or should be avoided.	No change. This language is consistent with federal regulations in 10 CFR and preferred to ensure the same interpretation of requirements.
2i. In s. HFS 157.61 (12 (a), in the cross reference, the first comma should be replaced by the word 'and'.	No change. The suggested revision would change the intent of the existing language and be inconsistent with 10 CFR.
5f. In s. HFS 157.03 (198), it is not clear what amendment is being made. If it is intended that the third quotation mark be deleted, the amendment should not be made.	No change. The definition of "Low-specific activity-I" contains four paragraphs (a-d). Paragraph (d) is being repealed and recreated to be consistent with a change in the definition in 10 CFR.
5w. In HFS 157.61 (10) (a), it appears that the second use of 'medical physicist' after the word 'authorized' should be replaced with the word 'user' to correspond with the title of the paragraph and the first sentence of sub. (10) (b). Also, in sub. (10) (b), 'were' should be replaced with 'are'. Finally, in sub. (10) (a) and (b), the comma following the acronym 'NRC' should be replaced by the word 'or'.	The department agrees with the final two suggestions and has modified the rule, as suggested. The department is unable to accept the first recommendation since the existing language is consistent with federal regulations in 10 CFR 35.
5oo. In s. HFS 157.76 (7) (a), 'Irradiation' should not be capitalized. Also, in sub. (7) (c) 2. d., an 's' should be added to the end of 'second'.	The department agrees with the second recommendation and has modified the rule, as suggested. The department is unable to accept the first suggestion since the word 'Irradiation' is part of the title and should be capitalized.
5uu. In s. HFS 157.92 (2) (c), 'Fissile materials' meeting one of the following requirements ...' should be replaced with 'The following fissile materials ...'. The introduction should conclude with a colon.	The department agrees with the second recommendation and has modified the rule, as suggested. The department is unable to accept the first recommendation since the sentence refers to a list of requirements and not fissile materials. The original language is correct.

Final Regulatory Flexibility Analysis

The Department is the state's radiation control agency and is required under ss. 254.34 (1) (a), 254.365 (4), and 254.37 (3), Stats., to promulgate rules pertaining to the use of radiation in Wisconsin. Specifically, the Department is required to promulgate and enforce rules pertaining to sources of ionizing radiation and for registration and licensing sources of ionizing radiation, and enforcement as may be necessary to prohibit and prevent unnecessary radiation exposure. Sites of ionizing radiation (x-ray devices) are required under s. 254.35 (3), Stats., to register and pay annual registration fees, which consist of a site fee and a fee for each x-ray tube upon registration. The current registration fee is \$66 for dental sites (\$36 site fee; \$30 for each x-ray tube) and \$80 (\$36 site fee; \$44 for each x-ray tube) for all other required registrants, including sites serving physicians and clinics, osteopaths and clinics, chiropractors, hospitals, podiatrists, veterinarians, industrial sites, educational facilities, research projects, and other sites. These industries are represented in the North American Industry Classification System sectors 33-Manufacturing; 42- Wholesale Trade; 44-45-Retail Trade; 54-Professional Scientific, and Technical Services; 61-Educational Services; 62-Health Care and Social Assistance; 71- Arts, Entertainment, and Recreation; and 92-Correctional Facilities.

The Department's x-ray registration and inspection program is 100% fee supported by the annual registration fees authorized under s. 254.35 (3), Stats. At current fee levels, the Department projects a program deficit of \$27, 770 in SFY 06 that will increase to \$135, 310 in SFY 07 and continue to increase each subsequent fiscal year if fees are not increased. To maintain program revenue sufficient to operate the x-ray registration and inspection program, the Department under s. 254.35 (3) (g), Stats., proposes to increase annual registration fees by increasing both the annual site fee and x-ray tube fee for installations required to be registered as follows:

- Increase the annual site fee from \$36 to \$50 for all required registrants, including sites serving physicians and clinics, osteopaths and clinics, chiropractors, hospitals, podiatrists, veterinarians, industrial, educational facilities, research projects, and dental sites, and other sites.
- Increase the annual x-ray tube fee from \$44 to \$50 for all sites, except dental, serving physicians and clinics, osteopaths and clinics, chiropractors, hospitals, podiatrists, veterinarians, industrial sites, educational facilities, research projects, and other sites.
- Increase the annual x-ray tube fee from \$30 to \$35 for dental sites.

An analysis of the Department's facility registration data shows that the 2,152 registered dental facilities average 4 x-ray tubes per site at a current cost of \$120 (\$30 x 4) in annual x-ray tube fees and \$36 in site fees for an approximate total of \$156 per year (or \$13 per month) in annual registration fees. Under the proposed fees increase, dental facilities with 4 x-ray tubes per site will pay \$140 (\$35 x 4) in annual x-ray tube fees and \$50 in site fees for an approximate total of \$190 per year (or \$16 per month) in annual registration fees; an increase of \$34 per year. Dental sites account for over 45% of the registered facilities and over 58% of the x-ray tubes, and at least 85% of these facilities may be considered small businesses.

Veterinary services (431 facilities); chiropractors (901 facilities), and podiatrists (119 facilities) average 1 x-ray tube per site at a current cost of \$44 (\$44 x 1) in annual x-ray tube fees and \$36 in site fees for an approximate total of \$80 per year (or \$7 per month) in annual registration fees. Under the proposed fees increase, these facilities will pay \$50 (\$50 x 1) in annual x-ray tube fees and \$50 site fee for an approximate total of \$100 per year (or approximately \$8 per month) in annual registration fees; an increase of approximately \$20 per year. Veterinarians, chiropractors, and podiatrists account for 30% of the registered facilities and 10.5% of the x-ray tubes and at least 85% of these facilities may be considered small business.

Industrial applications; sites serving physicians and clinics and osteopaths and clinics; hospitals; educational facilities; research projects; and other sites including those with security installations, account for the remaining 25% of the registered facilities and 31% of the x-ray tubes. Some or all of these facilities are not small businesses as defined in s. 227.114 (1), Stats.

Based on an analysis of the average gross annual revenues (as given in the 2002 Economic Census) of dental facilities, chiropractic facilities, veterinary facilities, and podiatry facilities, the proposed increase in annual registration fees represents a less than 1% decrease in gross annual revenues of these small businesses.

Annual registration fees have not been increased since SFY 1997. The proposed increase in fees will increase program revenues by approximately \$140,614 if implemented in SFY 07 and ensure adequate program funding thru at least SFY 10. Adequate funding of the x-ray registration and inspection program is important because this program helps to minimize unnecessary radiation exposure to the general public and device operators by verifying that devices are functioning according to the radiation protection requirements in ch. HFS 157, state statutes, federal statutes and regulations, and the radiation protection policy stated in s. 254.33, Stats. If the annual registration fees are not increased the Department would be forced to terminate staff and reduce the frequency with which x-ray inspections are conducted. Reduced inspection frequency is linked to higher rates of non-compliance with radiation safety requirements. Faulty x-ray equipment or x-ray equipment not used as required increases the risk of injuries to skin and organ tissue, and cancer.

Effect on small business:

Pursuant to the foregoing analysis, the proposed increase in annual site registration fees will affect a substantial number of the small businesses that have x-ray devices, but will not have a significant economic impact on those businesses.

There were no issues raised by or alternatives suggested by small businesses during the public hearings.

Changes to the Analysis or Fiscal Estimate

Analysis

Corrections in clarity, grammar, punctuation or use of plain language were made in response to suggestions made by the Legislative Council Rules Clearinghouse. A change was also made to the analysis of Minnesota rules to indicate that Minnesota is now a Nuclear Regulatory Commission Agreement State, and to the plain language analysis to indicate that the Attorney General granted the department's request to incorporate standards by reference.

Fiscal Estimate

No changes were made to the rule's fiscal estimate.

Public Hearing Summary

Public Hearing Locations

The department held three public hearings on the proposed revisions to ch. HFS 157, as follows:

- * April 18, 2006 Milwaukee, WI
- * April 20, 2006 Madison, WI
- * April 27, 2006 Wausau, WI

Staff in Attendance

Paul Schmidt, Chief, Radiation Protection Section, Bureau of Environmental and Occupational Health (all)
Mark Bunge, X-ray Unit Supervisor, Radiation Protection Section (all)
Cheryl Rogers, Radioactive Materials Program Supervisor, Radiation Protection Section (April 18, 20)
Susan Hagstrom, Office Operations Associate, Radiation Protection Section (April 18)
Priscilla Sarow, License Permit Program Associate, Radiation Protection Section, (April 20, 27)
Leola Dekock, Nuclear Engineer Senior, Radiation Protection Section (April 20)
Jason Hunt, Nuclear Engineer Senior, Radiation Protection Section (April 18)
Megan Shober, Nuclear Engineer, Radiation Protection Section (April 20)
Rashid Salikhdjabnov, Nuclear Engineer Senior, Radiation Protection Section (April 20)
Michael Welling, Nuclear Engineer Senior, Radiation Protection Section (April 27)

Participation in the Hearings

Participation is summarized below. The indication of support and opposition reflect the positions indicated on the registrations or written statements filed by the hearing participants.

Registered:	17
Support the rule:	1
Oppose the rule:	2
Position not indicated:	14
Oral testimony:	1
Written testimony:	3

The hearing record remained open until May 12, 2006 for receipt of written comments. In response to comments received during public review of the proposed rules, the department made numerous changes, as described in this report.

List of Public Hearing Attendees and Commenters

The following is a complete list of the persons who attended the public hearing or submitted comments on the proposed rule, the position taken by the commenter and whether or not the individual provided written or oral comments.

Name and Address	Position Taken (Support or Opposed)	Action (Oral or Written)
1. Daniel Hunt WE Energies 231 W. Michigan Ave. Milwaukee, WI 53203	Not indicated	None - observer
2. Tony Kaprelian Balestrieri Environmental PO Box 860 Elkhorn, WI 53121-0860	Not indicated	None - observer
3. Bela Piacsek 560 N. 16 th St. Milwaukee, WI 53201-1881	Not indicated	None - observer
4. Sandra Helinski 1213 S. 64 th St. W. Allis, WI 53214	Oppose	Oral and written
5. Dennis Koblenski Cardinal Health 11829 W. Ripley Ave. Wauwatosa, WI 53226	Not indicated	None – observer
6. Noelle Geier Community Memorial Hospital W180 N8085 Town Hall Rd. Menomonee Falls, WI 53051	Not indicated	None – observer
7. Dan Miron 11829 Ripley Wauwatosa, WI 53226	Not indicated	None – observer
8. Kimberly Knight-Wiegert Medical College of Wisconsin Milwaukee, WI	Not indicated	None - observer
9. Lynn Poker 6308 8 th Ave. Kenosha, WI 53143	Not indicated	None – observer
10. Marcum Martz Medical College of Wisconsin 8701 Watertown Plank Rd. Milwaukee, WI 53095	Support	Written
11. Terry Kidd 3305 W. Forest Home Milwaukee, WI 53215	Oppose	Written
12. Karen Andrusco Meriter Hospital 202 S. Park St. Madison, WI 53715	Not indicated	None – observer

13. Jeff Orwin U. W. Madison, Safety Dept. 30 N. Murray St. Madison, WI	Not indicated	None - observer
14. Ray Riddle Standard Imaging, Inc. 7601 Murphy Drive Middleton, WI 53562	Not indicated	None – observer
15. Daniel Hayes Blumenfeld and Associates 16 N. Carroll, Ste. 800 Madison, WI 53703	Not indicated	None – observed
16. Charles Chipurt Stora Enso North America PO Box 8050 Wisconsin Rapids, WI 5495	Not indicated	None – observer
17. Greg Owens American Engineering Testing, Inc. 4203 Schofield Ave., Ste. 1 Schofield, WI 54476	Not indicated	None – observer
18. Charles Wilson Froedtert Memorial Lutheran Hospital 9200 W. Wisconsin Ave. Milwaukee, WI 53226	Not indicated	Written (submitted separate from hearing)
19. Mary Ellen Jafari Gunderson Lutheran Medical Center LaCrosse, WI	Not indicated	Written (submitted separate from hearing)
20. Dennis Rathbun U.S. Nuclear Regulatory Commission Washington, DC 20555-0001	Not indicated	Written (submitted separate from hearing)
Rule Provision	Public Comment	Department Response
GENERAL	<p>Commenter 4: Request licensing of x-ray operators.</p> <p>Commenter 11: Request additional training requirements for limited scope x-ray device operators.</p>	<p>Commenter 4: No change. Nothing proposed in rule action. DHFS requires that x-ray registrants ensure that x-ray device operators be instructed in safe operating procedures and competent to use the equipment. However, DHFS does not have statutory authority to establish a license for x-ray operators, as requested by commenter 4. Currently, this could only be done by the Dept. of Regulation and Licensing.</p> <p>Commenter 11: No change. Nothing proposed in rule action. DHFS proposed training</p>

Rule Provision	Public Comment	Department Response
		requirements for a limited scope x-ray operator in a previous rule action. The department received many negative comments on the provision and subsequently removed it from the rule. DHFS is monitoring proposed federal legislation (CARE Act) that may establish federal minimum standards for x-ray device operators and address this area.
s. HFS 157.03	Commenter 20: HFS 157.03 omits the definition of the acronym "DOT" used in proposed revisions.	Accepted. Rule revised to remove acronym "DOT" and replace with "U.S. department of transportation".
s. HFS 157.03 (57r)	Commenter 20: Modify definition of "Certificate of compliance" to be consistent with 10 CFR 71.4.	Accepted. Rule revised.
s. HFS 157.03 (198)	Commenter 20: Modify definition of "Low specific activity" to be consistent with 10 CFR 71.4.	Accepted. Rule revised.
s. HFS 157.03 (210)	Commenter 20: Add definition of "Authorized medical physicist" to be consistent with 10 CFR 35.2.	Accepted. Rule revised.
s. HFS 157.03 (247m)	Commenter 19: Correct definition of "PACS" to read "Picture Archiving and Communication System".	Accepted. Rule revised.
s. HFS 157.03 (264m)	Commenter 19: Modify definition of PET/CT to incorporate SPECT/CT.	No change. SPEC/CT is not used in rule. PET/CT definition is accurate.
s. HFS 157.03 (398)	Commenter 20: Modify definition of "Type B package" to be consistent with 10 CFR 71.4.	Accepted. Rule revised.
s. HFS 157.13 (1) (i)	Commenter 20: Include the word "and" between design and procedures consistent with 10 CFR 20.1406.	Accepted. Rule revised.
s. HFS 157.53 (1) (a) 2.	Commenter 20: Delete the provision for oral examinations to demonstrate understanding of requirements for well-logging supervisors consistent with 10 CFR 39.61.	Accepted. Rule revised.
s. HFS 157.61 (7) (a) 2. c.	Commenter 19: Include therapeutic radiological physics as an option for meeting Radiation Safety Officer (RSO) training requirements.	No change. Proposed change is inconsistent with federal regulations in 10 CFR 35.50.
s. HFS 157.61 (7) (b) 2.	Commenter 20: Modify the specific training requirements in this subdivision paragraph for RSO's to be consistent with 10 CFR 35.50	Accepted. Rule revised.
s. HFS 157.61 (10)(b)	Commenter 19: Change the word 'perform' to 'performs'.	Accepted. Rule revised.

Rule Provision	Public Comment	Department Response
s. HFS 157.61 (10) (a) and (b)	Commenter 20: Modify language to be consistent with 10 CFR 35.50	Accepted. Rule revised.
s. HFS 157.61 (12) (a) and (b)	Commenter 20: Modify to be consistent with 10 CFR 35.50.	Accepted. Rule revised.
s. HFS 157.63 (5) (Note)	Commenter 19: Use Tc-99m (rather than Tc-99) and Rb-82 as examples.	Accepted. Rule revised.
s. HFS 157.63 (3)	Commenter 10: Modify to be consistent with CRCPD Suggested State Regulations, Part G, Section G.48.	Accepted. Rule revised.
s. HFS 157.64 (5) (c) 3.	Commenter 20: Modify to be consistent with 10 CFR 35.392.	Accepted. Rule revised.
s. HFS 157.71 (14)	Commenter 10: Modify to be consistent with CRCPD, Suggested State Regulations.	Accepted. Rule revised.
s. HFS 157.72 (1) (a) 3. and (h)	Commenter 20: Modify to be consistent with 10 CFR 35.3045.	Accepted. Rule revised.
s. HFS 157.74 (2) (b)	Commenter 19: Change requirements for posting technique charts.	Accepted. Rule revised.
s. HFS 157.74 (3) (c)	Commenter 18: Rule proposes new test of x-ray film processor performance. Rule should also require corrective action if test fails.	Accepted. Rule revised.
s. HFS 157.80 (2) (a)	Commenter 19: Modify requirements for qualifications of PET/CT personnel to perform diagnostic CT scans.	No change. Proposed training requirements for PET/CT systems (new technology) are based on a consensus recommendation of national organizations.
s. HFS 157.82 (2)	Commenter 10: Change title to "Training for Radiation Therapy Users" to broaden training requirements for new technologies such as x-ray brachytherapy devices.	Accepted. Rule revised.
s. HFS 157.92 (3) (a) 1.	Commenter 20: Modify language to be consistent with 10 CFR 71.5.	Accepted. Rule revised.
s. HFS 157.92 (3) (a) 3.	Commenter 20: Modify language to be consistent with 10 CFR 71.89.	Accepted. Rule revised.
s. HFS 157.93 (7) (c) 1.	Commenter 20: Modify language to be consistent with 10 CFR 71.22.	Accepted. Rule revised.
s. HFS 157.93 Table A	Commenter 20: Modify table value for U-233 to be consistent with 10 CFR 71.22, Table 71-1.	Accepted. Rule revised.
Appendix O, Subsection II	Commenter 20: - Correct reference from Table VII to VIII. - Modify Appendix O to be consistent with	Accepted. Rule revised.

Rule Provision	Public Comment	Department Response
	10 CFR 71, Appendix A.	