

Report From Agency

DEPARTMENT OF HEALTH SERVICES REPORT TO THE LEGISLATURE

CLEARINGHOUSE RULE 16-078 Ch. DHS 157 Radiation Protection

Basis and Purpose of Proposed Rule

As specified under s. 254.34 (1), Stats., the department is the state 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. The department's rules for by-product material, source material, and special nuclear material are required to be in accordance with 42 USC 2021 (o) and be otherwise compatible with the requirements under 42 USC 2011 to 2114 and regulations adopted under 42 USC 2011 to 2114.

The department is also responsible for maintaining compliance with the Agreement signed by Governor Doyle in 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 Wisconsin's assurance that it will revise the radioactive material portions of ch. DHS 157 within three years of any applicable changes in Title 10 Code of Federal Regulations. Title 10 CFR has been revised since ch. DHS 157 was last revised in 2010. Therefore, the department proposes to update the radioactive material requirements in ch. DHS 157 to those in Title 10 CFR.

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

The proposed revisions to ch. DHS 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, 31-37, 39, 40, 70, 71 and 150.

- Update the radiation safety requirements for x-ray producing devices to reflect changes in Title 21, Code of Federal Regulations Parts 900, 1020, 1030, and 1040.
- Incorporate suggested national standards for x-ray device imaging from the Conference of Radiation Control Program Directors in the *Suggested State Regulations for the Control of Radiation*.
- Ensure conformity with ch. 462, Stats., relating to licensing and the practice of radiographers and limited x-ray machine operators, or rules promulgated thereunder by the radiography examining board.
- Incorporate minor corrections to rule language based on the Department’s experience administering the current rule.

Department Response to Legislative Council Rules Clearinghouse Recommendations

The department accepts the recommendations made by the Legislative Council Rules Clearinghouse and has modified the proposed rule where suggested except as follows:

Clearinghouse Comment	Department Response
2h. <i>Section DHS 157.03 (221m) (Note) appears to include a substantive provision on the applicability of the provision. Is the applicability adequately stated elsewhere? Review other Notes in the proposed rule for similar substantive provisions.</i>	The proposed language in DHS 157.03 (Note) and other Notes is not substantive but meant to be explanatory or informational.
2j. <i>Consider removing Section 12 of the proposed rule. Renumbering to replace a repealed provision can lead to confusion and is unnecessary.</i>	The Department is proposing renumbering to be consistent with the overall rule format.
5a. <i>Consider reviewing ch. DHS 157 for the use of slashed alternatives and replacing that phrasing with the alternative that is intended for the context. For example, s. DHS 157.61 (7) (a) 2. b. uses the slashed alternative “and/or” in two instances; it appears that in both instances the word “or” may be the appropriate word.</i>	The proposed language is consistent with the Suggested State Regulations for the Control of Radiation (basis document for the rule) approved by the Nuclear Regulatory Commission as compatible with federal regulations. Replacing the slashed alternative “and/or” with “or” may change the intent of a specific provision in 10 CFR and be incompatible with federal requirements.

Final Regulatory Flexibility Analysis

The issues raised by each small business during the public hearing(s):

There was one issue raised at the public hearing, and one issue raised as a separate written comment. Although the commenters were not representatives of small business, the issues may be applicable to small business. The issues are as follows:

- DHS 157.72(2)(a)5. Revision of radiation monitoring requirement for any individual working within 6 feet of operating fluoroscopic equipment.
- DHS 157.78(10) Proposed requirement for operators of hand held x-ray devices to wear protective lead aprons and thyroid collars while using the device.

Any changes in the rule as a result of an alternative suggested by a small business and the reasons for rejecting any of those alternatives:

The department response to the issues raised during the public hearing/public comment period is as follows:

- DHS 157.25(2)(a)5. A comment at the public hearing to eliminate DHS 157.25(2)(a)5. rather than revise it would remove the requirement for radiation monitoring of any individual working within 6 feet of operating medical fluoroscopic equipment, and all mention of time and distance requirements. The department is aware of fluoroscopy operators receiving substantial exposure from use of fluoroscopic devices. As a result, the department partially accepted the comment and has revised DHS 157.25(2)(a)5. to only require monitoring of device operators and remove time and distance requirements. This change will provide regulatory relief and potentially reduce monitoring costs for any impacted business while protecting operator safety.
- DHS 157.78(10). In a separate written comment, a representative of the Wisconsin Dental Association advised the department to a) remove the proposed requirement for operators of hand-held x-ray devices to wear lead aprons and thyroid collars while using the device, and replace with b) language allowing doctors and operators to determine the need for protection. The department is proposing no change to the rule order as a result of this comment. DHS 157.78(10) only requires an operator to wear a lead apron and thyroid collar for devices with no back scatter radiation shield. To the department's knowledge, the vast majority of portable x-ray devices used in the state incorporate a back scatter shield and would not require the operator to wear a lead apron and thyroid collar. As a result, the Department anticipates minimal fiscal impact on any facility, including small business.

The nature of any reports and estimated cost of their preparation by small businesses that must comply with the rule:

No additional reports are being required of small business.

The nature and estimated costs of other measures and investments that will be required by small businesses in complying with the rule:

The department anticipates there may be a small cost associated with training requirements, but little to no cost associated with radiation safety requirements, including to small business.

The reason for including or not including in the proposed rule any of the following methods for reducing the rule's impact on small businesses, including additional cost, if any, to the department for administering or enforcing a rule which includes methods for reducing the rule's impact on small businesses and the impact on public health, safety and welfare, if any, caused by including methods in rules:

The methods specified in s. 227.114 (2), Stats., for reducing a rule's impact on small business were considered by the department, but have not been adopted in the proposed rules because they are not feasible and would be contrary to statutory objectives stated in s. 254.33, Stats., federal requirements, and the agreement between the state and the NRC, which are the basis for the proposed rule.

Changes to the Analysis or Fiscal Estimate/Economic Impact Analysis

Analysis

No changes were made to the rule's analysis.

Fiscal Estimate/Economic Impact Analysis

No changes were made to the fiscal estimate/economic impact analysis.

Public Hearing Summary

The department began accepting public comments on the proposed rule via the Wisconsin Administrative Rules website on December 19, 2016. A public hearing was held on February 8, 2017 in Madison, WI. Four persons attended the hearing. Public comments on the proposed rule were accepted until February 22, 2017.

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 during the public comment period, the position taken by the commenter and whether or not the individual provided written or oral comments.

Commenter #	Name and Address	Position Taken	Method of Commenting
1.	Robert Allman 14 Basil Ct. Madison, WI 53704	Opposes	Observed only
2	Sandra Helinski, rep. WI Society of Radiologic Technologists E-mail: irezn82000@aol.com	Supports	Written
3.	Pamela J. Henderson Office of Nuclear Material Safety and Safeguards U.S. Nuclear Regulatory Commission Washington, D.C. 20555-0001	No position taken	Written
4.	Rebecca Kitchen Aurora Baycare Medical Center 2845 Green Brier Rd. Green Bay, WI 54311	Supports	Written
5.	Matt Labron 30 East Campus Mall Madison, WI 53715	No position taken	Observed only
6.	Daniel Miron W176S8019 Joel Drive Muskego, WI 53750	No position taken	Written
7.	Matt Rosetto Wisconsin Dental Association 122 W. Washington Ave., Ste 600 Madison, WI 53703	Supports in part Opposes in part	Written
8.	Jason Rusch U.W. Madison 30 East Campus Mall Madison, WI 53715	No position taken	Written

Summary of Public Comments and Department Responses

The number(s) following each comment corresponds to the number assigned to the individual listed in the Public Hearing Attendees and Commenters section of this document.

Rule Provision	Public Comment	Department Response
General	Agree with all the changes. 4	No response necessary.
General	No objections to the proposed rule changes to DHS 157. 2	No response necessary.
General	No quarrel with the proposed training requirements for hand held dental x-ray units. 7	No response necessary
General	Capitalize “Nuclear Regulatory Commission” and “Commission” 3	No change. The department capitalized words as required by the Legislative Reference Bureau.
DHS 157.03 (166m)	Capitalize the word “Tribe”. Correct the reference “25 W.S.C. 479a” to “25 U.S.C. 479a”. 3	Accepted. The department has capitalized ‘Tribe’ and corrected the reference as suggested in the comment.
DHS 157.03(404)	Modify definition of “unrefined and processed ore” to be consistent with 10 CFR 40.4. 3	Accepted. The department has modified the definition as suggested in the comment.
DHS 157.09(1)(a)10.	Include mirrors to be consistent with 10 CFR 40.13(c)(7). 3	Accepted. The department has added wording as suggested in the comment.
DHS 157.09 (2)(c)9.-11.	Modify the phrase “equivalent regulations of agreement states to read “equivalent	Accepted. The department has modified the wording as suggested in the comment.

Rule Provision	Public Comment	Department Response
	regulations of the NRC and other agreement states”. 3	
DHS 157.09(2)(d)	Add the phrase “or initially transfer for sale or distribution” to the first sentence. 3	Accepted. The department has added the phrase as suggested in the comment.
DHS 157.09(2)(e)	Modify to be consistent with 10 CFR 30.20(b) 3	Accepted. The department has added wording to be consistent with federal regulations in 10 CFR 30.20(b).
DHS 157.09(2)(g)	Modify to be consistent with 10 CFR 30.22. 3	Accepted. The department has added wording to be consistent with federal regulations in 10 CFR 30.22.
DHS 157.13(1)(h)	Modify to be consistent with 10 CFR 30.32(g). 3	Accepted. The department has added wording to be consistent with federal regulations in 10 CFR 30.32(g).
DHS 157.13(4)(d)1.h.	Definition of SSSDR has inconsistent capitalization. 8	No change. The capitalization is consistent with federal regulations.
DHS 157.13(10)(b)1.	Missing close parentheses DHS 157.13(10)(b)1. 8	Accepted. The department has added the missing parentheses as suggested in the comment.
DHS 157.25(2)(a)5.	Eliminate the requirement of radiation monitoring for individuals working within 6 feet of operating fluoroscopy equipment. 6	Partially accepted. The department has revised DHS 157.25(2)(a) 5. to require only operator monitoring and remove any monitoring requirement based on time and distance.
DHS 157.36(1)(a)	Add the ANSI contact information for purchase of documents. 3	Accepted. The department has added the contact information as suggested in the comment.
DHS 157.78(10)	Remove requirement for a lead apron and thyroid collar for hand-held dental radiographic units and replace with language that allows doctor and operator	No change. A lead apron and thyroid collar are not required unless the device has no secondary protective barrier.

Rule Provision	Public Comment	Department Response
	to determine the need for protection. 7	
DHS 157.80(2) (a)1.	Missing open parentheses in the new text. 8	Accepted. The department has removed the single parentheses after the word 'exemptions' as suggested in the comment.
DHS 157.83(3) (b)4.	The word "were" is new and should be underlined. 8	Accepted. The department has underlined "were" as suggested in the comment.
DHS 157.92(2)(b)1.	Change the word "purpose" to "purposes". 3	Accepted. The department has changed the wording as suggested in the comment.
DHS 157.94(3)	Replace the word "irradiate" with "irradiated" in DHS 157.94(3)(5). Correct spelling of "irradiation" in DHS 157.94(3)(5)(b). Replace the phrase "and special controls" with "any special controls" in DHS 157.93(3)(7). 3	Accepted. The department has changed the wording as suggested in the comment.
DHS 157.94(5)(a) 1.	Add the phrase "within or across the boundary of the state" after "to a carrier for transport". Add the phrase "of a state" after "to the governor". 3	Accepted. The department has added wording as suggested in the comment.
DHS 157.94(5)(c) 4.	Add the phrase "or Tribal reservation boundaries" after "State boundaries". 3	Accepted. The department has added the phrase as suggested in the comment.
DHS 157.94(5)(d)	Revise the phrase "in writing to the office of the governor" to read "in writing to the office of each appropriate governor".	Accepted. The department has changed the wording as suggested in the comment.

Rule Provision	Public Comment	Department Response
	Revise the phrase “delivered by messenger of facsimile” to “delivered by any other means than mail”. 3	
DHS 157.94(5)(e)	Remove the option to use a facsimile rather than telephone. 3	Accepted. The department has removed the wording as suggested in the comment
DHS 157.94(5)(f)	Revise the phrase “to the governor, governor’s designee, Indian tribal official or Indian tribal official’s designee” to read “to the governor of each state, or governor’s designee previously notified, each tribal official or tribal official’s designee previously notified”. 3	Accepted. The department has changed the wording as suggested in the comment.
DHS 157.102 (1)	Replace the phrase “including but not limited to” with “e.g.” to be consistent with 10 CFR 37.25(a). 3	Accepted. The department has changed the wording to be consistent with federal regulations in 10 CFR 37.25(a).
DHS 157.103 (3) (a) and (b)	Modify to be consistent with 10 CFR 37.27(c)(1). 3	Accepted. The department has changed the wording to be consistent with federal regulations in 10 CFR 37.27(c)(1).
DHS 157.106	Modify DHS 157.106(1) to be consistent with 10 CFR 37.33. 3	Accepted. The department has added wording to be consistent with federal regulations in 10 CFR 37.33.
DHS 157.108 (3)	Replace the phrase “shall include all the following” with “all of the following”. 3	Accepted. The department has changed the wording as suggested in the comment.
DHS 157 Appendix O	Change appendix title to “Exempt consignment activity limit for mixture” to be consistent with 10 CFR 71, Appendix A. 3	Accepted. The department has changed the wording as suggested in the comment.

Rule Provision	Public Comment	Department Response
DHS 157 Appendix O, Table VI	Add Kr-79 to Table VI and footnotes to A1 columns for Ir-192. 3	Accepted. The department has added wording as suggested in the comment to be consistent with federal regulations in 10 CFR 30.20(b).
DHS 157 Appendix O, Table VII	Add Ag-108m to Table VII Note (a) list of parent nuclides and progeny. 3	Accepted. The department has added wording as suggested in the comment.
DHS 157 Appendix O, Table VIII	Correct spelling of word "emitting". 3	Accepted. The department has revised the wording as suggested in the comment.
DHS 157 Appendix O	Table VIII is missing the superscripts for two entries which read 2.7X10. They should read 2.7X10 ⁻² . 8	Accepted. The department has changed the wording as suggested in the comment.