

## Report From Agency

### RULEMAKING REPORT TO LEGISLATURE

#### CLEARINGHOUSE RULE 22-015

Ch. DHS 157, relating to radiation protection requirements for radiation producing machines and radioactive materials.

#### **Basis and Purpose of Proposed Rule**

Under s. 254.34 (1) (a) and (b) Stats., the Department of Health Services (“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. Section 254.33, Stats., further directs the department to “conform as nearly as possible to nationally accepted standards in the promulgation and enforcement of rules.” The department is also responsible for maintaining compliance with the Agreement Between The United States Nuclear Regulatory Commission (“NRC”) and The State of Wisconsin for Discontinuance of Certain Commission Regulatory Authority and Responsibility Within the State pursuant to Section 274 of the Atomic Energy Act of 1954 (“the agreement”), signed by Governor Doyle and the NRC in 2003. The agreement 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. The state regulatory program is periodically evaluated by NRC staff. The agreement provides that the state will revise the radioactive material provisions of ch. DHS 157 within three years of any applicable changes to Title 10 CFR. Title 10 CFR was revised as recently as 2019, whereas ch. DHS 157 was last revised in 2016. The department proposes to revise the radioactive material requirements in ch. DHS 157 in order to comply with the agreement. No reasonable alternative exists to revising provisions in ch. DHS 157 pertaining to radioactive material, because the agreement remains in effect. The proposed revisions are anticipated to bring the state into compliance with the agreement.

In addition, the department proposes to revise provisions of ch. DHS 157 pertaining to x-rays. These revisions are necessary to prohibit and prevent unnecessary radiation exposure, and to conform to nationally accepted standards for technologies employing x-rays. Revisions reflect new diagnostic and therapeutic technologies, the department’s experience with implementing and administering the current rule, changes in comparable federal regulations, suggested national standards from the Conference of Radiation Control Program Directors, 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. No reasonable alternative exists to revising the provisions of ch. DHS 157 pertaining to x-rays, because pursuant to ss. 254.33 and 254.34, Stats., the department must promulgate and enforce rules, including registration and licensing of sources of ionizing radiation, as may be necessary to prohibit and prevent unnecessary radiation exposure. The proposed revisions are anticipated to accomplish this purpose.

Entities that may be affected by the proposed revisions to ch. DHS 157 are hospitals, academic facilities, medical clinics, dental facilities, chiropractic offices, veterinary facilities and industrial facilities that use radioactive materials or x-ray devices.

The proposed revisions to ch. DHS 157 would accomplish the following:

1. Update the radiation protection and regulatory requirements for radioactive materials to ensure compatibility with current applicable regulations of the federal NRC in 10 CFR pp. 19, 20, 31-37, 39, 40, 70, 71, and 150 and 49 CFR, relating to notices, instructions and reports to workers regarding inspections and investigations; standards for protection against radiation; general domestic licenses for byproduct material, specific domestic licenses to manufacture or transfer certain items containing byproduct material; specific domestic licenses of broad scope for byproduct material; licenses for industrial radiography and radiation safety requirements for industrial radiographic operations; physical protection of byproduct material; medical use of byproduct material; licenses and radiation safety requirements for irradiators; licenses and radiation safety requirements for well logging; domestic licensing of special nuclear material; packaging and transportation of radioactive material; and exemptions and continued regulatory authority in agreement states and in offshore waters.

2. Add one radioactive material license fee category and modify one fee category to reflect the difference in program effort and cost for licensees that use large amounts vs smaller amount of radioactive material in research and development.
3. Add one additional fee category for radioactive materials licenses that are authorized for three or more sites of locations of use or storage. There have been no fee increases or category changes since 2003. The number of licensees authorized for multiple sites under the same license has increased since 2003. This site fee category reflects the additional operating revenue needed for the radioactive materials program to sufficiently license and inspect licensees with multiple sites.
4. Achieve compatibility with current applicable regulations of the federal Food and Drug Administration (“FDA”) in 21 CFR pp. 900, 1020, 1030, and 1040, relating to mammography quality standards, performance standards for ionizing radiation emitting products; microwave and radio frequency emitting products; and light-emitting products for the protection against hazards of radiation.
5. Codify 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.
6. Correct outdated, imprecise, and inconsistent rule language based on the department’s experience administering the current rule.

The proposed revision to ch. DHS 157 will have the following economic impact on radioactive material regulated entities:

1. Increase the annual and application fee from \$1800 to \$3600 for licensees that are authorized to use a total of 5 curies or more of radioactive material for research and development.

2. The annual fee for each noncontiguous site listed on a license, starting at three, has a fee equal to 25% of the applicable fee category of use per each additional site. For example:

- licensee A has 2 sites with an applicable fee category of \$1000, there is no change and the total fee is \$1000;

- licensee B has 3 sites with an applicable fee category of \$1000, the fee increases 25% per site greater than 2 and the total fee is \$1250;

- licensee C has 3 sites with an applicable fee category of \$1000 and 1 site with an applicable fee category of \$500, a total of 4 sites and two different applicable fee categories. The total fee is \$1750 (\$1000 for sites one and two + \$250 for site three + \$500 for site four).

These fee changes apply to a small percentage of current licensees and is proportional to their operations.

### **Department Response to Legislative Council Rules Clearinghouse Recommendations**

The department accepts the recommendation(s) made by the Legislative Council Rules Clearinghouse and has modified the proposed rules were suggested except as follows:

Comment 2. hh. The rulemaking order proposes to repeal and recreate Appendices A, F, H, L, O, and T. However, these treatments may perhaps be more appropriately accomplished by amending these appendices, given that the changes to the appendices appear to be limited.

#### **Department Response**

The formatting of the referenced appendices makes individual amendments difficult to visually identify and maintain the desired formatting. During past rulemaking, changes were not published correctly when the amending treatment was used. At that time, it was suggested that repeal and recreate be used in future rulemaking orders.

## **Final Regulatory Flexibility Analysis**

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

None. The proposed rules will not have an economic impact on small businesses.

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:

Not applicable. The proposed rules will not have an economic impact on small businesses.

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

Not applicable. The proposed rules will not have an economic impact on small businesses.

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

Not applicable. The proposed rules will not have an economic impact on small businesses.

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 proposed rules will not have an impact on small businesses.

## **Changes to the Rule Analysis or Fiscal Estimate/Economic Impact Analysis**

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Rule Analysis:

In addition to general punctuation and grammar corrections, a change was made to the example provided under the annual fee for each noncontiguous site listed on a license. The example provided for "licensee C" did not calculate the total fee correctly for the given circumstance. This error was limited to the example and did not affect any other rule analysis or fiscal estimate/economic impact analysis. The example was changed to reflect the correct calculation of total fee, "-licensee C has 3 sites with an applicable fee category of \$1000 and 1 site with an applicable fee category of \$500, a total of 4 sites and two different applicable fee categories. The total fee is \$1750 (\$1000 for sites one and two + \$250 for site three + \$500 for site four)."

Fiscal Estimate/Economic Impact Analysis:

A change was made to the example provided under the annual fee for each noncontiguous site listed on a license. The example provided for "licensee C" did not calculate the total fee correctly for the given circumstance. This error was limited to the example and did not affect the calculations performed for the fiscal estimate/economic impact analysis. The example was changed to reflect the correct calculation of total fee, "-licensee C has 3 sites with an applicable fee category of \$1000 and 1 site with an applicable fee category of \$500, a total of 4 sites and two different applicable fee categories. The total fee is \$1750 (\$1000 for sites one and two + \$250 for site three + \$500 for site four)."

## **Public Hearing Summary**

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The department began accepting public comments on the proposed rule via the Wisconsin Legislature Administrative Rules website, and the Department's Administrative Rules Website on May 2, 2022. A public hearing was held on June 16, 2022, in Madison and virtually via Zoom. Public comments on the proposed rule were accepted until July 11, 2022

**List of the persons who appeared or registered for or against the Proposed Rule at the Public Hearing.**

<b>Registrant</b>	<b>Position Taken (Support or Opposed)</b>
Brady Smith via zoom	None provided
Todd Senglaub via zoom	None provided

**Summary of Public Comments to the Proposed Rule and the Agency’s response to those comments, and an explanation of any modification made in the proposed rule as a result of public comments or testimony received at the Public Hearing.**

Rule Provision	Public Comment	Department Response
General	The document entitled "Guidance for Portable Gauges or XFR Devices" (WISREG -1566 Vol.1, Rev. 2) is a concise, easy-to- understand, and very helpful resource. It was issued in May 2010. The commenter requested that the document be reviewed for pertinent updates and either re-confirmed or revised.	This comment is not relevant to the proposed rule order. No response necessary.
General	The testing of Mini C-arms should be conducted ‘on-site’ before being used on patients.	The proposal to require testing of equipment “on-site” before patient use is not within the scope of the approved statement of scope. No change was made to the proposed rule order in response to this comment.
157.03 (30m)	<p>Definitions</p> <p>Wisconsin omits the phrase, “A medical use permit issued by a Commission master material licensee” under the definition of Associate Radiation Safety Officer.</p> <p>Wisconsin needs to include the phrase noted above to meet the Compatibility Category B designation assigned to 10 CFR 35.2.</p>	A change was made to the table in DHS 157.03 (30m) to include the wording related to permits issued by NRC master material licensee suggested in the comment.
157.13 (4) (i)	<p>Manufacture, preparation, or transfer for commercial distribution of radioactive drugs containing byproduct material for medical use under part 35.</p> <p>Wisconsin omits the equivalent of 32.72(b)(5)(i) which states, “A copy of each individual’s certification by a specialty board whose certification process has been recognized by the Commission or an Agreement State as specified in § 35.55(a) of this chapter; or.”</p> <p>Wisconsin needs to add the provision noted above to meet the Compatibility Category B designation assigned to 10 CFR 32.72(b)(5)(i).</p>	The equivalent statement to 32.72 (b) (5) (i) is in DHS 157.68 (2) (a). No change was made to the proposed rule order in response to this comment.
157.13 (17) and 157.32 (1)	Wisconsin omits the equivalent of 10 CFR 30.50 (c) (1). Wisconsin omits the equivalent of 10 CFR 40.60 (c) (1). Wisconsin omits the equivalent of 10 CFR 70.50 (c) (1). Wisconsin needs to include the equivalent of 10 CFR 30.50 (c) (1), 10 CFR 40.60 (c) (1), and 10 CFR 70.50 (c) (1).	The equivalent requirements of 10 CFR 30.50 (c) (1), 10 CFR 40.60 (c) (1), and 10 CFR 70.50 (c) (1). already exist in DHS 157.13 (17) and 157. 32 (1). No change was made to the proposed rule order in response to this comment.

	Wisconsin needs to make the changes noted above to meet the Compatibility Category C designation assigned to 10 CFR 30.50 (c) (1), 10 CFR 40.60 (c) (1), and 10 CFR 70.50 (c) (1).	
157.29 (6)	<p>The equivalent to 10 CFR 20.1906(d) is omitted. Wisconsin needs to include the equivalent of 10 CFR 20.1906(d).</p> <p>Wisconsin needs to make the change noted above to meet the Compatibility Category H&amp;S designation assigned to 10 CFR 20.1906 (d).</p>	The equivalent requirements of 10 CFR 20.1906 (d) already exist in DHS 157.29 (6) (e). No change was made to the proposed rule order in response to this comment.
157.32 (1)	<p>Wisconsin omits the equivalent of 10 CFR 20.2201 (a) (2) (ii). Wisconsin needs to include the equivalent of 10 CFR 20.2201 (a) (2) (ii).</p> <p>Wisconsin needs to make the change noted above to meet the Compatibility Category C designation assigned to 10 CFR 20.2201 (a) (2) (ii).</p>	The equivalent requirements of 10 CFR 20.2201 (a) (2) (ii) already exist in DHS 157.32 (1) (a). No change was made to the proposed rule order in response to this comment.
157.32 (2)	<p>Wisconsin omits the equivalent of 10 CFR 20.2202 (d) (2). Wisconsin needs to include the equivalent of 10 CFR 20.2202 (d) (2).</p> <p>Wisconsin needs to make the change noted above to meet the Compatibility Category C designation assigned to 10 CFR 20.2202 (d) (2).</p>	The equivalent requirements of 10 CFR 20.2202 (d) (2) (ii) already exist in DHS 157.32 (2) (c). No change was made to the proposed rule order in response to this comment.
157.61 (4) (b) 6.	<p>Written directives</p> <p>In the equivalent of § 35.40(b)(7), Wisconsin needs to replace the word afterloading with the word afterloaders.</p> <p>Wisconsin needs to revise the phrase noted above to meet the Compatibility Category H&amp;S designation assigned to 10 CFR 35.40.</p>	A change was made to 157.61(4) (b) 6. to use the wording suggested in the comment.
157.61 (7)	<p>Training for Radiation Safety Officer and Associate Radiation Safety Officer</p> <p>In the equivalent of 10 CFR 35.50(c)(1), Wisconsin omits the phrase “and meets the requirements in paragraph (d) of this section; or”</p> <p>In the equivalent of 10 CFR 35.50(c)(2), Wisconsin omits the phrase “by a Commission master material licensee, a permit issued by a Commission or an Agreement State licensee of broad scope, or a permit issued by a</p>	<p>The equivalent statement to 10 CFR 35.50 (d) and reference, “and meets the requirements in paragraph (d)” in 10 CFR 35.50 (c) (1) is in DHS 157.61 (7) (intro.). No change was made to the proposed rule order in response to this part of the comment.</p> <p>A change was made to DHS 157.61 (7) (c) 2. to include the wording related to “permits issued by NRC master material licensee” to be equivalent to 10 CFR 35.50 (c) (2), as suggested in the comment.</p> <p>The reference to “new medical use permit issued by a Commission master material license” in DHS 157.61 (7) (c) 3. was omitted on purpose.</p>

	<p>Commission master material license broad scope permittee.”</p> <p>In the equivalent of 10 CFR 35.50(c)(2), Wisconsin omits the phrase “and meets the requirements in paragraph (d) of this section;” after the phrase, “has experience with the radiation safety aspects of similar types of use of byproduct material for which the licensee seeks the approval of the individual as the Radiation Safety Officer or Associate Radiation Safety Officer.”</p> <p>In the equivalent of 10 CFR 35.50(c)(3), Wisconsin omits the phrase “license or new medical use permit issued by a Commission master material license. The individual must also meet the requirements in paragraph (d) of this section.”</p> <p>Wisconsin needs to make the changes noted above to meet the Compatibility Category B designation assigned to 10 CFR 35.50.</p>	<p>The department has no authority to issue master materials licenses and thus the circumstance involving issuance of a new permit by a master materials license is not applicable. No change was made in response to this part of the comment.</p>
157.61 (8)	<p>Training for an authorized medical physicist.</p> <p>In the equivalent of 10 CFR 35.51(a), Wisconsin omits the phrase, “and who meets the requirements in paragraph (c) of this section.” after the phrase, “Is certified by a specialty board whose certification process has been recognized by the Commission or an Agreement State.”</p> <p>Wisconsin needs to make the change noted above to meet the Compatibility Category B designation assigned to 10 CFR 35.51.</p>	<p>The equivalent statement to 10 CFR 35.51(c) and reference, “and meets the requirements in paragraph (c)” in 10 CFR 35.51(a), is in DHS 157.61(8) (intro.) No change was made to the proposed rule order in response to this comment.</p>
157.61 (10)	<p>Training for experienced Radiation Safety Officer, teletherapy or medical physicist, authorized medical physicist, authorized user, nuclear pharmacist, and authorized nuclear pharmacist.</p> <p>In the equivalent of 10 CFR 35.57(a)(1), Wisconsin omits the phrase, “on a Commission or an Agreement State license or a permit issued by a Commission or an Agreement State broad scope licensee or master material license permit or by a master material license permittee of broad scope”</p>	<p>A change was made to DHS 157.61 (10) (a) 1. to include the wording related to “permits issued by NRC master material licensee” to be equivalent to 10 CFR 35.57 (a)(1), as suggested in the comment.</p>

	<p>Wisconsin needs to make the change noted above to meet the Compatibility Category B designation assigned to 10 CFR 35.57.</p>	
157.64 (7) and (8)	<p>Training for the parenteral administration of unsealed byproduct material requiring a written directive</p> <p>The equivalent to 10 CFR 35.396(b)(2) omits the sentence, “A supervising authorized user who meets the requirements in 10 CFR 35.390, 35.396, or equivalent Agreement State requirements, must have experience in administering dosages in the same category or categories as the individual requesting authorized user status.”</p> <p>In the equivalent to 10 CFR 35.396(b)(2)(vi), Wisconsin subsection 157.64 (7) (c) (2)(f), Wisconsin is missing the phrase, “as specified in 10 CFR 35.390(b)(1)(ii)(G)(3),” including the reference to the equivalent of 10 CFR 35.390(b)(1)(ii)(G)(3).”</p> <p>The equivalent to 10 CFR 35.396 (b) (3) (i) omits the sentence, “A preceptor authorized user who meets the requirements in 10 CFR 35.390, 35.396, or equivalent Agreement State requirements, must have experience in administering dosages in the same category or categories as the individual requesting authorized user status;” Wisconsin needs to include the above sentence in their equivalent of 10 CFR 35.396 (b) (3) (i).</p> <p>Wisconsin needs to make the changes noted above to meet the Compatibility Category B designation assigned to 10 CFR 35.396.</p>	<p>A change was made to DHS 157.64 (7) (c) 2. to include the equivalent wording to, “A supervising authorized user who meets the requirements in §§ 35.390, 35.396, or equivalent Agreement State requirements, must have experience in administering dosages in the same category or categories as the individual requesting authorized user status.” as suggested by the comment.</p> <p>A change was made to DHS 157.64 (7) (c) 2. f. to included wording equivalent to 10 CFR 35.390 (b) (1) (ii) (G) (3) as suggested by the comment.</p> <p>A change was made to DHS 157.64 (8) (d) 1. To included wording equivalent to 10 CFR 35.396 (b) (3) (i) as suggested by the comment.</p>
157.66 (2)	<p>Training for use of sealed sources and medical devices for diagnosis.</p> <p>Wisconsin omits the equivalent to 10 CFR 35.590(d). Wisconsin needs to provide the equivalent to 10 CFR 35.590(d).</p> <p>Wisconsin needs to make the changes noted above to meet the Compatibility Category B designation assigned to 10 CFR 35.590.</p>	<p>The equivalent statement to 10 CFR 35.590 (d) is in DHS 157.66 (2). No change was made to the proposed rule order in response to this comment.</p>
157.67 (17) and (18)	<p>Training for use of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units</p>	<p>The equivalent statement to 10 CFR 35.590 (d) is in DHS 157.67 (17). No change was made to the proposed rule order in response to this comment.</p>



	<p>Wisconsin omits the equivalent to 10 CFR 35.690 (a). Wisconsin needs to provide the equivalent to 10 CFR 35.690(a).</p> <p>Wisconsin needs to make the changes noted above to meet the Compatibility Category B designation assigned to 10 CFR 35.690.</p>	
157.72 (2)	<p>Wisconsin omits the provision in 10 CFR 35.3045 (g) (1) (ii).</p> <p>Wisconsin needs to include this provision to meet the Compatibility Category C designation assigned to 10 CFR 35.3045.</p>	No change was made. The proposed change to DHS 157.72 (2) (f) 1. b. is equivalent to 10 CFR 35.3045 (g) (1) (ii).
Table 157.75	Table 157.75 - recommend changing wording from this table to be consistent with 21 CFR 1020.30.	A change was made to the table in DHS 157.75 to match the wording in 21 CFR 1020.30 as suggested in the comment.
157.76(8)	DHS 157.76(8) should be modified to be consistent with 21 CFR 1020.32. There are mobile and portable fluoroscopes that are not an image intensifier but rather digital image receptors.	An image intensifier is not required for digital image receptor. The department changed DHS 157.76 (intro.) and (8) to use the wording "image-intensification or a direct-digital receptor" to reflect current technology and 21 CFR as suggested in the comment.
157.81 (4)	Correct DHS 157.81(4) to 'mrem' from 'mRem'	A change was made to the table in DHS 157.81 (4) as suggested in the comment.
157.87 (1) (c)	DHS157.87(1)(c) should be 'Radiation source housing' not 'Radiation source sousing'.	A change was made to the table in DHS 157.87 (1) (c) as suggested in the comment.
157.94 (3) (a)	DHS 157.94(3)(a) doesn't have an exemption equivalent to 10 CFR 71.14(b) for the equivalent 10 CFR 71.91(a). The commenter questioned if an exemption exists for type A packages and if not, why that is the case.	There is currently no exemption for type A packages. The referenced 10 CFR 71.14(b) is designated compatibly category "NRC" and cannot be adopted by agreements states under that current designation. The equivalent 10 CFR 10 CFR 71.91(a) is found in DHS 157.92(2). No change was made to the proposed rule order in response to this comment.
157.94(5)(d) and 157.9719	<p>Advance notification of shipment of irradiated reactor fuel and nuclear waste</p> <p>DSH 157.94 (5) (d) omits the requirements of 10 CFR 71.97 (c), that notifications need to be provided to The Director, Office of Nuclear Security and Incident Response.</p> <p>DHS 157.9719 omits requirements in 10 CFR 71.97 (c) (3).</p> <p>Wisconsin needs to include the equivalent of 10 CFR 71.97 (c) and 10 CFR 71.97 (c) (3).</p>	<p>A change was made to DHS 157.94 (5) (d) to be equivalent to 10 CFR 71.97(c)(2) and (3) regarding providing notification The Director, Office of Nuclear Security and Incident Response as suggested by the comment</p> <p>No change was made to DHS 157.9719 as it is equivalent to 10 CFR 37.77 (a) (3).</p>

	Wisconsin needs to make the changes noted above to meet the Compatibility Category B designation assigned to 10 CFR 71.97.	
157.9721	<p>Reporting of Events</p> <p>Wisconsin omits the equivalent of 10 CFR 37.81(c) and (d). Wisconsin needs to provide the equivalent of 10 CFR 37.81(c) and (d) to meet the Compatibility Category B designation assigned to 10 CFR 37.81.</p>	<p>The equivalent to 10 CFR 37.81(c) and (d) are in DHS 157.9721 (3) and (4). No change was made to the proposed rule order in response to this comment.</p>



## Summary of Items Submitted with this Report to the Legislature

Below is a checklist of the items that are attached to or included in this report to the legislature under s. 227.19 (3), Stats.

Documents/Information	Included in Report	Attached	Not Applicable
Final proposed rule -- Rule Summary and Rule Text		x	
Department response to Rules Clearinghouse recommendations	x		
Final Regulatory Flexibility Analysis	x		
Changes to the Analysis or Fiscal Estimate/Economic Impact Analysis	x		
Public Hearing Summary	x		
List of Public Hearing Attendees and Commenters	x		
Summary of Public Comments and Department Responses	x		
Fiscal Estimate/Economic Impact Analysis		x	
Revised Fiscal Estimate/Economic Impact Analysis		x	
Small Business Regulatory Review Board (SBRRB) statement, suggested changes, or other material, and reports made under s. 227.14 (2g), Stats. and Department's response			x
Department of Administration (DOA) report under s. 227.115 (2), Stats., on rules affecting housing			x
DOA report under s. 227.137 (6), Stats., on rules with economic impact of \$20 MM or more			x
Public Safety Commission (PSC) energy impact report under s. 227.117 (2), Stats. and the Department's response, including a description of changes made to the rule			x