

STATEMENT OF SCOPE

WISCONSIN DEPARTMENT OF HEALTH SERVICES

CHAPTER: DHS 157

RELATING TO: RADIATION PROTECTION REQUIREMENTS FOR RADIATION PRODUCING MACHINES AND RADIOACTIVE MATERIALS.

RULE TYPE: PERMANENT

SCOPE TYPE: ORIGINAL

FINDINGS OF EMERGENCY: NOT APPLICABLE

SUMMARY

1. Description of rule objective/s

The Department of Health Services proposes to amend ch. DHS 157 relating to radiation producing machines and radioactive materials. The proposed rule revision will accomplish the following:

- Incorporate the newest federal radioactive material regulations in 10 C.F.R. pts 19, 20, 31-37, 39, 40, 70, 71 and 150.
- Update the x-ray requirements to reflect changes in 21 C.F.R. pts 900, 1020 and 1040 and other nationally recognized standards.
- Revise the fee structure in s. DHS 157.10 to require that specific radioactive material licenses which authorize research and development are subject to fees based on the possession limits, and that licenses which authorize multiple facilities are subject to fees based on the number of facilities that are licensed.
- In order to reduce the regulatory burden on licensees and registrants, incorporate alternatives to rule requirements that are routinely accepted by the department.
- Incorporate minor corrections and clarification to rule definitions and language based on the department's experience administering the current rule and the input of an advisory group.
- Correct grammatical and other technical errors that have been identified.

2. Existing policies relevant to the rule

The department proposes to revise ch. DHS 157 to comply with applicable federal regulations in 10 and 21 C.F.R. Under s. 254.34 (1) Stats., the department is required to promulgate and enforce rules. Including the registration and licensing of sources of ionizing radiation, that are necessary to prevent unnecessary radiation exposure. Under the 2003 Agreement Between the United States Nuclear Regulatory Commission 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 as Amended (agreement), the department's rules must remain compatible with 42 U.S.C. 2011-2014 and the regulations adopted thereunder by the United States Nuclear Regulatory Commission (NRC) relating to radioactive materials, namely 10 C.F.R. In order to maintain compliance with the 2003 agreement, the requirements in ch. DHS 157 pertaining to radioactive materials must be updated within 3 years of any applicable changes to 10 C.F.R. 10 C.F.R is revised frequently. Each revision to 10 C.F.R. has a separate effective date, which requires the department to revise DHS 157 approximately every 3 years to meet the NRC requirement.

The department further proposes to revise the fee schedule in s. DHS 157.10 to better align the fee schedule with regulatory workload. The radioactive materials program is funded by licensing fees that are proportional to the work hours for a given license type. Changes in licensee business practices have resulted in licensees combining multiple locations under the same license. These changes in business practices are not reflected in the current fee category structure. In addition, research licensees are requesting to use larger quantities of radioactive materials that require increased regulatory review and inspection. With input from a dedicated advisory committee, the rule revision will modify the fee schedule in s. DHS 157.10 to account for multiple-site licenses, licenses authorizing larger quantities of radioactive materials for research purposes, multisite tiers set at a percent of the base fee category, and licenses for research and development based on possession limit.

Minor revision of DHS 157 is also needed to address changes in x-ray technology, rule variances and exemptions that are routinely granted by the department, editorial errors, changes in comparable federal regulation in 21 C.F.R. and other changes in nationally recognized quality control standards for x-ray device imaging.

3. Policies proposed to be included in the rule

The Department proposes to update the rule to: (1) incorporate the latest federal standards to maintain federal compatibility requirement for program rules; (2) change certain language that is ambiguous to

ensure clear consistent requirements; (3) fix known grammatical and technical errors; (4) incorporate rule exemptions that are common and are routinely approved through exemption requests; (5) update documentation and retention requirements to allow for modern business practices; (6) update licensing fees for applicability to certain research and multi-site licensees; and (7) make any other corrective changes identified throughout the rule promulgation process.

4. Analysis of policy alternative

There is no acceptable alternative to the rule revision. The existing rule is outdated under the agreement between the NRC and Wisconsin, which requires periodic revision of ch. DHS 157 to remain current with comparable federal regulations.

5. Statutory authority for the rule

a. Explanation of authority to promulgate the proposed rule

Under s. 254.34 (1) (a) and (b), Stats., the department is designated as the state radiation control agency and given statutory authority to promulgate, administer and enforce rules promulgated under the subchapter, which governs radiation protection. Section 254.33, Stats., authorizes the department to advise, consult and cooperate with other agencies of the state, federal government, and other jurisdictions. Section 254.365 (4), Stats., authorizes the department to promulgate rules related to the issuance, modification, suspension, and termination of specific and general licenses for radioactive materials. Section 254.37 (3), Stats., authorizes the department to promulgate and enforce rules pertaining to ionizing radiation. The department also has rule making authority under s. 227.11 (2) (a), Stats., which states that each agency may promulgate rules interpreting the provisions of any statute enforced by the agency, if the agency considers it necessary to effectuate the purpose of the statute.

b. Statute/s that authorize/s the promulgation of the proposed rule

- Section 227.11 (2)(a), Stats.
 - Section 254.34 (1)(a) and (b), Stats.
 - Section 254.365(4), Stats.
 - Section 254.37 (3), Stats.
- c. Statute/s or rule/s that will affect the proposed rule or be affected by it
- Ch. DHS 157
 - Ch. NR 809.833

6. Estimates of the amount of time that state employees will spend to develop the rule and other necessary resources

The Department will require approximately 250 hours of staff time to develop the rule. This includes the time required for research and analysis coordinating an advisory committee, drafting rule language, preparing related documents, holding a public hearing and communicating with stakeholders and other affected parties.

7. Description of all of the entities that may be affected by the rule, including any local governmental units, businesses, economic sectors, or public utility ratepayers who may reasonably be anticipated to be affected by the rule

The entities that may be affected by the proposed rule include entities that have or will apply for a radioactive materials license or x-ray machine registration. These entities include hospitals, academic institutions, medical clinics, dental facilities, chiropractic offices, veterinary facilities, facilities that perform research and development, and industrial facilities.

8. Summary and preliminary comparison of any existing or proposed federal regulation that is intended to address the activities to be regulated by the rule

The radiation protection requirements in ch. DHS 157 are based on or identical to the following federal regulations as required under state statute and the Agreement:

- 10 C.F.R. pts. 19, 20, 30, 31-37, 40, 70, 71 and 150, which provide standards for notices and licensing for, packaging and transporting of, and protection from radioactive materials.
- 21 C.F.R. pts. 900, 1020, and 1040, which set quality standards for mammography, diagnostic, therapeutic, and cabinet x-ray devices.

9. Anticipated economic impact, locally or statewide

If revisions to the fee schedule are promulgated, the proposed rule is anticipated to have moderate economic impact on large facilities with multiple sites under one license and research facilities requesting larger quantities of radioactive materials. If revisions are not made to the fee schedule then little to no economic impact is anticipated. The proposed rule will have minimal effect on small businesses.

10. Agency contacts

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