

ADMINISTRATIVE RULES Fiscal Estimate & Economic Impact Analysis

1. Type of Estimate and Analysis <input checked="" type="checkbox"/> Original <input type="checkbox"/> Updated <input type="checkbox"/> Corrected	2. Date 01/14/2022
3. Administrative Rule Chapter, Title and Number (and Clearinghouse Number if applicable) DHS 157	
4. Subject Radiation protection requirements for radiation producing machines and radioactive materials	
5. Fund Sources Affected <input type="checkbox"/> GPR <input type="checkbox"/> FED <input checked="" type="checkbox"/> PRO <input type="checkbox"/> PRS <input type="checkbox"/> SEG <input type="checkbox"/> SEG-S	6. Chapter 20, Stats. Appropriations Affected None
7. Fiscal Effect of Implementing the Rule <input type="checkbox"/> No Fiscal Effect <input checked="" type="checkbox"/> Increase Existing Revenues <input type="checkbox"/> Increase Costs <input type="checkbox"/> Decrease Costs <input type="checkbox"/> Indeterminate <input type="checkbox"/> Decrease Existing Revenues <input type="checkbox"/> Could Absorb Within Agency's Budget	
8. The Rule Will Impact the Following (Check All That Apply) <input type="checkbox"/> State's Economy <input checked="" type="checkbox"/> Specific Businesses/Sectors <input type="checkbox"/> Local Government Units <input type="checkbox"/> Public Utility Rate Payers <input checked="" type="checkbox"/> Small Businesses (if checked, complete Attachment A)	
9. Estimate of Implementation and Compliance to Businesses, Local Governmental Units and Individuals, per s. 227.137(3)(b)(1). \$50000 per year	
10. Would Implementation and Compliance Costs Businesses, Local Governmental Units and Individuals Be \$10 Million or more Over Any 2-year Period, per s. 227.137(3)(b)(2)? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	
11. Policy Problem Addressed by the 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 s. 2021 (o) and be otherwise compatible with laws and regulations under 42 USC ss. 2011 to 2114. As specified under s. 254.33, Stats., it is further the policy for the department to advise, consult and cooperate with other agencies of the state, the federal government, other states and interstate agencies and with affected groups, political subdivisions and industries; and, in general, to conform as nearly as possible to nationally accepted standards in the promulgation and enforcement of rules. The proposed rule revision will accomplish all of the following: <ul style="list-style-type: none">- Incorporate the newest federal radioactive material regulations in 10 CFR pts 19, 20, 31-37, 39, 40, 70, 71 and 150.- Update the x-ray requirements to reflect changes in 21 CFR. 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.	

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- 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 in the rule chapter.

12. Summary of the Businesses, Business Sectors, Associations Representing Business, Local Governmental Units, and Individuals that may be Affected by the Proposed Rule that were Contacted for Comments.

The department formed an Advisory Committee consisting stakeholders affected by the proposed rules. Advisory Committee membership included representatives of academic and medical facilities, radioactive materials users, x-ray users, and large and small businesses. The public was notified of Advisory Committee meetings pursuant to Wisconsin's Open Meetings Law. Committee members reviewed the initial draft and their comments guided the development of the proposed rule. Representatives of radioactive materials licensees affected by the proposed fee changes were advisory committee members. In addition, the department solicited public comments on the rule's economic impact from November 1 to November 15, 2021. The department received no comments related to the economic impact.

13. Identify the Local Governmental Units that Participated in the Development of this EIA.

None.

14. Summary of Rule's Economic and Fiscal Impact on Specific Businesses, Business Sectors, Public Utility Rate Payers, Local Governmental Units and the State's Economy as a Whole (Include Implementation and Compliance Costs Expected to be Incurred)

The proposed rule includes two categories of fee changes:

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. The total fee is \$1400 (\$1000 for sites one and two + \$250 for site three + \$125 for site four).

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

Other proposed rule changes have minimum implementation and compliance costs.

15. Benefits of Implementing the Rule and Alternative(s) to Implementing the Rule

The proposed changes to ch. DHS 157 ensure continued compatibility with new federal radioactive material regulations in 10 CFR pp.. 19, 20, 31, 33-36, 37, 39, 40, 70, 71 and 150, and 49 CFR as required by s. 254.34 (1), Stats. and an agreement signed by the Governor in 2003. 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.

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The proposed changes to ch. DHS 157 are equivalent to 21 CFR pp. 900, 1020, and 1040, which set quality standards for mammography, diagnostic, therapeutic, and cabinet x-ray devices. 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

The proposed fee changes in ch. DHS 157 will apply only to licensees that have increased risks or multiple locations of use authorized. These licensees inherently take more staff time and resources to license and inspect adequately. A fee increase is necessary to ensure the department has adequate program resources to license and inspect sources of ionizing as required under ss. 254.34 (1) (a), 254.365 (4), and 254.37 (3), Stats.

16. Long Range Implications of Implementing the Rule

The rule provides clear licensing and registration requirements for sources of ionizing radiation which in turn allows for the beneficial use of ionizing radiation in numerous sectors. The fee changes in the rule will help ensure the ongoing financial health of the DHS program that licenses and inspects radioactive materials licensees. The proposed changes will ensure the continued compatibility of ch. DHS 157 with federal law.

17. Compare With Approaches Being Used by Federal Government

Wisconsin's agreement with the Nuclear Regulatory Commission ("NRC") requires the department to incorporate relevant changes to federal radioactive material regulations into its radiation protection rules within three years of the effective date of the federal regulations. The proposed changes to ch. DHS 157 ensure continued compatibility with new federal radioactive material regulations in 10 CFR pp. 19, 20, 31, 33-36, 37, 39, 40, 70, 71 and 150, and 49 CFR as required by s. 254.34 (1), Stats.

The fee structure for federally licensed radioactive materials licensee include fees based on the licensed activity and number of licensed sites.

The proposed changes to ch. DHS 157 are equivalent to 21 CFR pp. 900, 1020, and 1040, which set quality standards for mammography, diagnostic, therapeutic, and cabinet x-ray devices.

18. Compare With Approaches Being Used by Neighboring States (Illinois, Iowa, Michigan and Minnesota)

Illinois, Iowa and Minnesota are Agreement States with the NRC. As a result, their respective state laws contain regulatory requirements very similar to those in ch. DHS 157. Michigan is not an agreement state with the NRC. However, Michigan law contains some of the regulations equivalent to ch. DHS 157. The radiation safety standards in all neighboring states are similar.

Except for Iowa, neighboring states have fee structures that include a per site fee ranging from 10% to 65% of a base fee depending on the number of sites. No neighboring state has a license fee category for research and development licensees based on the amount of radioactive authorization. However there is such a category for other types of licensees. Of note, neighboring states do not have a research and development licensee authorized for large quantities of radioactive material.

Illinois:

Illinois is an agreement state with the NRC. As a result, Illinois law contains radiation protection and regulatory requirements similar to those contained in ch. DHS 157 and compatible with equivalent federal regulations in Titles 10 and 49, CFR.

Illinois's annual fee structure for radioactive materials licenses includes an additional site fee for every site that isn't the main location of the licensee. The site fee is based on the category authorized at the site and ranges from 20-55% of the full cost of the fee category.

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Illinois does not have a fee category for research and development licensees based on the amount of radioactive authorization.

Reference: Illinois Regulation Title 32: Energy chapter II: Illinois emergency management agency Subchapter b: radiation protection Part 331 fees for radioactive material licensees

Iowa:

Iowa is an agreement state with the NRC. As a result, Iowa law contains radiation protection and regulatory requirements similar to those in ch. DHS 157 and compatible with equivalent federal regulations in Titles 10 and 49, CFR.

Iowa's annual fee structure for radioactive materials licenses includes an additional site fee for every additional license site. Licensees with more than two authorized locations are charged an additional 10% of the annual fee per location. Iowa does not have a license fee category for research and development licensees based on the amount of radioactive authorization.

Reference: Iowa Administrative Code 641-38.8(2)

Michigan:

Michigan is not an agreement state with the NRC. Michigan law in effect April 21, 2021 contains some regulatory requirements similar to those in ch. DHS 157. The Nuclear Regulatory Commission is currently responsible for regulating the majority of radioactive material use in Michigan under Titles 10 and 49 CFR.

The Nuclear Regulatory Commission determines license fees within Michigan. There are specific fee categories that limit the number of sites authorized under the license. The ranges are 1-5 locations, 6-20 locations, more than 20 locations. The fee for 6-20 locations and more than 20 locations is an additional 32% and 65% of the 1-5 location fee, respectively.

The Nuclear Regulatory Commission does not have a license fee category for research and development licensees based on the amount of radioactive authorization.

Reference; 10 CFR section 170.31 Table 1.

Minnesota:

Minnesota is an agreement state with the NRC. As a result, Minnesota law contains radiation protection and regulatory requirements similar to those in ch. DHS 157 and compatible with equivalent federal regulations in Titles 10 and 49, CFR.

Minnesota does not have a license fee structure that differs based on the number of sites.

Minnesota does not have a license fee category for research and development licensees based on the amount of radioactive authorization.

Reference: Minnesota Rules, Chapter 4731.

19. Contact Name Mark Paulson	20. Contact Phone Number 608-264-6516
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ATTACHMENT A

1. Summary of Rule's Economic and Fiscal Impact on Small Businesses (Separately for each Small Business Sector, Include Implementation and Compliance Costs Expected to be Incurred)

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. Adopting the methods specified in s. 227.114 (2), Stats., would be contrary to the state's public policy on radiation control stated in s. 254.33, Stats., as well as federal requirements, and the agreement between the state and the NRC, which are the basis for the proposed rule. The department's analysis of the effect of rulemaking on small businesses regulated by ch. DHS 157 is therefore confined to proposed revisions addressing x-ray regulatory requirements and fee changes.

The department's x-ray registration and inspection program, and radioactive materials licensing and inspection program, are both entirely supported by the annual fees authorized under ss. 254.35 (3) and 254.365 (5), Stats. The department applied the fee changes as proposed to current licensees. The site fee equal to 25% of the applicable use category would apply to 67 of the 442 licensed sites. This would affect 42 licensees and total \$48,075. There are five licensees that hold licenses for research and development purposes that authorize greater than 5 curies of radioactive material. The proposed fee change for those five licensees would total \$9,000. Out of the 285 current licensees, 47 would be subject to a fee change as proposed. Smaller businesses do not typically have large possession authorizations or more than two sites of use. Of the 47 licensed businesses affected by the proposed fee change, it is estimated that 26 do not meet the small business definition in s. 227.114(1) based on being a large health care provider, government entity, national company, or large publicly traded company. In the absence of further information, if it is assumed that the remaining affected business meet the small business definition, the proposed license fee changes would apply to 21 businesses and total \$22,750. This analysis conservatively shows that total impact on small business would be less than \$50,000.

There is expected to be little to no fiscal impact to x-ray registrants from proposed requirements.

The number of small business licensees that are expected to incur an annual fee increase by sector:

1. License for medical use: 3.
2. License for gauges used in construction and materials testing: 14.
3. License for research and development: 0.
4. License for gauges used in manufacturing (systems controls or quality assurance): 3.
5. License for other limited scope of radioactive material (water treatment): 1.

2. Summary of the data sources used to measure the Rule's impact on Small Businesses

1. The input of an advisory committee that included stakeholders affected by the proposed rules. These included representatives of academic and medical facilities, radioactive materials users, x-ray users, and large and small businesses.

2. An agreement state rule template called the "Suggested State Regulations for the Control of Radiation" (SSRCR) developed by the Conference of Radiation Control Program Directors, Inc. ("CRCPD"). The CRCPD is a national organization of primarily state radiation control staff that supports and represents state radiation control programs. The SSRCR is developed with the involvement of federal radiation agencies, such as the NRC, Food and Drug Administration, and the Environmental Protection Agency. The SSRCR is also continually updated and used by most of the existing agreement states to help meet federal requirements.

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3. Requirements of Titles 10, 21, and 49 CFR; 42 USC; Sections 254.31 to 254.45, Stats., and the 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.

4. The department maintains a database of all radioactive material licensees. This data includes the number sites, quantities of radioactive material, and categories of use. The department used this information as the bases to analyze the impact of the proposed license fee changes.

5. Section 227.114 (1) (a), Stats., which defines “small business” as a business entity, including its affiliates, which is independently owned and operated and not dominant in its field, and which employs 25 or fewer full-time employees or which has gross annual sales of less than \$5,000,000.

3. Did the agency consider the following methods to reduce the impact of the Rule on Small Businesses?

- Less Stringent Compliance or Reporting Requirements
- Less Stringent Schedules or Deadlines for Compliance or Reporting
- Consolidation or Simplification of Reporting Requirements
- Establishment of performance standards in lieu of Design or Operational Standards
- Exemption of Small Businesses from some or all requirements
- Other, describe:

The changes to the fee structure will be proportional to the operations of the licensed business

4. Describe the methods incorporated into the Rule that will reduce its impact on Small Businesses

The economic impact of the proposed rule is related to the fee schedule changes. To limit the impact on small businesses a tiered approach was used in the fee schedule. The fee schedule change for research and development licensees is based on the amount of radioactive materials authorized. The amount of material authorized reflects the size (employee count, revenue) of the business. Similarly, the fee schedule change for the number of permanent authorized sites is also proportional to the size of the business. There is no proposed fee change for the first two permanent authorized sites. The majority of licensees have fewer than two listed locations, regardless of small business status. Additionally, no fee change was proposed for the use of radioactive material at temporary jobsites. Temporary jobsite authorization is a common authorization for radioactive materials licensees using portable gauges in the construction and materials testing sectors. These sectors have the most licensees that would be considered small businesses.

5. Describe the Rule's Enforcement Provisions

The department has authority to inspect, including entering upon and inspecting any site where any radioactive materials are used, licensed activities and alleged violations of the rule. The department may interview individuals, review work practices, review and copy records, and perform other activities necessary to determine compliance with the rule as it relates to radiation safety. The department may initiate an action against a license to require for failure or refusal to comply with any provision of the rule. These actions may include orders of abatement; license revocation, suspension, modification, or denial; assessment of direct forfeiture between \$100 and \$100,000; and emergency orders to protect the public health or safety.

6. Did the Agency prepare a Cost Benefit Analysis (if Yes, attach to form)

- Yes No
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