

ADMINISTRATIVE RULES
Fiscal Estimate & Economic Impact Analysis

1. Type of Estimate and Analysis

Original Updated Corrected

2. Administrative Rule Chapter, Title and Number

DHS 157, Radiation Protection

3. Subject

Radiation Protection

4. Fund Sources Affected

GPR FED PRO PRS SEG SEG-S

5. Chapter 20, Stats. Appropriations Affected

N/A

6. Fiscal Effect of Implementing the Rule

No Fiscal Effect

Increase Existing Revenues

Increase Costs

Indeterminate

Decrease Existing Revenues

Could Absorb Within Agency's Budget

Decrease Cost

7. The Rule Will Impact the Following (Check All That Apply)

State's Economy

Specific Businesses/Sectors

Local Government Units

Public Utility Rate Payers

Small Businesses

8. Would Implementation and Compliance Costs Be Greater Than \$20 million?

Yes

No

9. Policy Problem Addressed by the 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. The Department is also responsible for maintaining compliance with an Agreement signed by the Governor 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 3 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 modify the radioactive material requirements in ch. DHS 157.

In addition, the Department proposes to revise the portions of ch. DHS 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, 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.

The proposed revisions to chapter 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, 33-36, 39, 40, 70, 71 and 150 and applicable portions of Title 49 (transportation), Code of Federal Regulations.

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- Incorporate new security requirements for certain radioactive materials published in the new Title 10, Code of Federal Regulations, Part 37 published in 2013.
- Update the radiation safety requirements for x-ray producing devices to reflect new diagnostic and therapeutic technologies, 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, current federal regulation and the input of an ad hoc advisory group representing a cross-section of regulated users.
- Incorporate minor corrections to rule language based on the Department's experience administering the current rule.
- Ensure conformance with ch. 462, Stats., relating to licensing and the practice of radiographers and limited x-ray machine operators by removing any conflicts with ch. 462, Stats., or rules promulgated thereunder by the radiography examining board.

There are no fee increases in the proposed rule.

10. 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 of members approved by the Governor's Office of Regulatory Compliance. 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. In addition, the department solicited public comments on the rule's economic impact from September 26 to October 17, 2016. The department received one comment from the Wisconsin Dental Association that was unrelated to economic impact.

11. Identify the local governmental units that participated in the development of this EIA.
None.

12. 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)
None.

13. Benefits of Implementing the Rule and Alternative(s) to Implementing the Rule
The proposed rule revision will ensure that DHS 157 is compatible with federal regulations in Titles 10 and 49, Code of Federal Regulations as required by an agreement signed by the Governor in 2003.

14. Long Range Implications of Implementing the Rule
The proposed rule revision will ensure compatibility with recent changes in federal regulations in 10 CFR for radioactive materials and 21 CFR for radiation producing devices.

15. Compare With Approaches Being Used by Federal Government
The proposed rule revision is consistent with regulations of the Nuclear Regulatory Commission in Title 10, Code of Federal Regulations for radioactive materials; and Food and Drug Administration regulations for radiation producing devices in Title 21, Code of Federal Regulations, parts 900, 1020, 1030 and 1040.

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16. Compare With Approaches Being Used by Neighboring States (Illinois, Iowa, Michigan and Minnesota)
Illinois, Iowa and Minnesota are Agreement States with the Nuclear Regulatory Commission. As a result, their respective state laws contain regulatory requirements very similar to those in DHS 157. Michigan is not an agreement state with the Nuclear Regulatory Commission. However, Michigan law contains some of the regulations equivalent to DHS 157. The Nuclear Regulatory Commission is currently responsible for regulating the majority of radioactive material use in Michigan under federal regulations.

17. Contact Name Paul Schmidt	18. Contact Phone Number (608) 267-4792
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