

CSI - Ohio

The Common Sense Initiative

Business Impact Analysis

Agency Name: Health

Regulation/Package Title: Chapter 3701:1-58 Medical Use of Radioactive Materials

Rule Number(s): 3701:1-40-16, 3701:1-46-43, 3701:1-58-01, -07, -08, -09, -10, -12, -15, -16, -18, -19, -20, -21, -26, -33, -35, -36, -37, -40, -41, -42, -43, -49, -51, -52, -53, -54, -55, -58, -69, -71, -73, -86, -100, -101, -104, -105.

Date: 08/12/2019

Rule Type:

☒ New

☒ Amended

☒ 5-Year Review

☐ Rescinded

The Common Sense Initiative was established by Executive Order 2011-01K and placed within the Office of the Lieutenant Governor. Under the CSI Initiative, agencies should balance the critical objectives of all regulations with the costs of compliance by the regulated parties. Agencies should promote transparency, consistency, predictability, and flexibility in regulatory activities. Agencies should prioritize compliance over punishment, and to that end, should utilize plain language in the development of regulations.

Regulatory Intent

1. Please briefly describe the draft regulation in plain language.

Please include the key provisions of the regulation as well as any proposed amendments.

These rules contain the requirements to possess and use radioactive material for medical use in Ohio. These rules establish the specific requirements for medical use of radioactive material including: definitions; license amendment procedures; notifications to the department; procedures for administering radioactive material; and training of personnel.

These rules are being amended to ensure Ohio rules are compatible with federal regulations.

The following rules were amended as follows:

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| 3701:1-40-16 | Adds reporting requirement for generator breakthrough or contamination. |
| 3701:1-46-43 | Clarifies labelling requirements for shipment of radioactive drugs. |
| 3701:1-58-01 | Adds definitions for "Associate Radiation Safety Officer" and "Ophthalmic Physicist". |
| 3701:1-58-07 | Clarifies information that must be provided on a radioactive material license application. |
| 3701:1-58-08 | Adds requirements for a license amendment prior to allowing a Associate Radiation Safety Officer to perform tasks and before a licensee receives a sealed source that is a different model than listed on a license. |
| 3701:1-58-09 | Adds notification requirement concerning Ophthalmic Physicists and certain sealed sources. |
| 3701:1-58-10 | Updates exemptions for broad scope licenses to include Ophthalmic Physicists. |
| 3701:1-58-12 | Allows a licensee to appoint multiple Associate Radiation Safety Officers. |
| 3701:1-58-15 | Updates information that must be included in written directives for brachytherapy treatments. |
| 3701:1-58-16 | Updates information that must be included in procedures for brachytherapy treatments. |
| 3701:1-58-18 | Adds training requirements for Associate Radiation Safety Officers. |
| 3701:1-58-19 | Updates training requirements for Authorized Medical Physicists. |
| 3701:1-58-20 | Updates training requirements for Authorized Nuclear Pharmacists. |
| 3701:1-58-21 | Updates training requirements for experienced personnel. |
| 3701:1-58-26 | Clarifies authorization for a licensee to possess certain radioactive material. |

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| 3701:1-58-33 | Clarifies who can provide an attestation for a radioactive material user. |
| 3701:1-58-35 | Adds reporting requirement for generator breakthrough. |
| 3701:1-58-36 | Clarifies who can provide an attestation for a radioactive material user. |
| 3701:1-58-37 | Clarifies rule language. |
| 3701:1-58-40 | Clarifies who can provide an attestation for a radioactive material user. |
| 3701:1-58-41 | Clarifies who can provide an attestation for a radioactive material user. |
| 3701:1-58-42 | Clarifies who can provide an attestation for a radioactive material user. |
| 3701:1-58-43 | Clarifies conditions for the use of manual brachytherapy sources. |
| 3701:1-58-49 | Adds requirements for the use of strontium-90 sources in ophthalmic treatments. |
| 3701:1-58-51 | Clarifies who can provide an attestation for a radioactive material user. |
| 3701:1-58-52 | Clarifies training requirements for the use of strontium-90 sources in ophthalmic treatments. |
| 3701:1-58-53 | Clarifies requirements on the use of sealed sources and medical devices for diagnosis. |
| 3701:1-58-54 | Allows an authorized user to be added to a licensee if they are listed on another radioactive material license with no further review. |
| 3701:1-58-55 | Clarifies requirements on the use of sealed sources and medical devices for therapy. |
| 3701:1-58-58 | Updates information that must be included in procedures for certain therapy devices. |
| 3701:1-58-69 | Updates the interval between inspections of teletherapy and gamma stereotactic units. |
| 3701:1-58-71 | Clarifies who can provide an attestation for a radioactive material user. |

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| 3701:1-58-73 | Adds retention requirements for documents pertaining to Associate Radiation Safety Officers. |
| 3701:1-58-86 | Adds retention requirements for operational and safety instructions pertaining to teletherapy and gamma stereotactic units. |
| 3701:1-58-100 | Clarifies what documentation must be retained pertaining to inspections of teletherapy and gamma stereotactic units. |
| 3701:1-58-101 | Revises the criteria for medical events. |
| 3701:1-58-104 | Clarifies who can provide an attestation for a radioactive material user. |
| 3701:1-58-105 | Adds new rule for reporting of generator breakthrough. |

2. Please list the Ohio statute authorizing the Agency to adopt this regulation.

RC 3748.02 and RC 3748.04

3. Does the regulation implement a federal requirement? Is the proposed regulation being adopted or amended to enable the state to obtain or maintain approval to administer and enforce a federal law or to participate in a federal program?

If yes, please briefly explain the source and substance of the federal requirement.

Yes. These rules are similar to federal regulations found in Title 10, Code of Federal Regulations, Part 35 (10 CFR 35). As a condition of the agreement with the U. S. Nuclear Regulatory Commission (NRC), under which Ohio became an Agreement State and assumed regulatory control of the possession and use of radioactive material in the state, Ohio must maintain regulations compatible with applicable federal regulations for the use of radioactive materials as specified in Ohio Revised Code Section 3748.03.

4. If the regulation includes provisions not specifically required by the federal government, please explain the rationale for exceeding the federal requirement.

These regulations do not exceed federal regulations.

5. What is the public purpose for this regulation (i.e., why does the Agency feel that there needs to be any regulation in this area at all)?

These regulations give the requirements for the possession and use of radioactive material for medical purposes. The rules are needed to ensure the safe handling and use of radioactive material and to ensure that the radiation dose to workers, the public and the environment is kept as low as reasonably achievable.

6. How will the Agency measure the success of this regulation in terms of outputs and/or outcomes?

The success of these regulations is measured during inspections of radioactive material licensees, which includes observation of licensee operations and performance of surveys to evaluate radiation levels and potential exposure to workers and the public.

Development of the Regulation

7. Please list the stakeholders included by the Agency in the development or initial review of the draft regulation.

If applicable, please include the date and medium by which the stakeholders were initially contacted.

The Governor appointed Radiation Advisory Council, required by Revised Code 3748.20, serves as an influential and active body in advising the Director of Health on key radiological issues facing the ODH.

The council provides significant technical input on all radioactive material related rulemaking actions proposed by the ODH. Since the council members represent key stakeholder groups for radiological issues, ODH receives crucial input from stakeholders from the council. This input ensures that proposed rulemaking serves to protect workers, the public, and the environment without unduly burdening businesses.

There is also a public participation process whereby all proposed rules or changes in rules are posted on the ODH website for public comment. The council has formed the Radioactive Material Committee (RMC) which is comprised of experts in the field of radiation safety who represent industrial, academic, medical, research and development, and environmental licensees of radioactive materials.

The draft rules were reviewed by the RMC in a public meeting held on March 12, 2019.

8. What input was provided by the stakeholders, and how did that input affect the draft regulation being proposed by the Agency?

The RMC assisted health physics staff in the review of these regulations and approved the draft rules for public comment at their meeting on March 12, 2019.

9. What scientific data was used to develop the rule or the measurable outcomes of the rule? How does this data support the regulation being proposed?

As a condition of Ohio maintaining its “Agreement State” status, these regulations are compatible with federal regulations for the medical use of radioactive material, which are designed to ensure that radiation exposure to members of the public and the environment remains less than the prescribed limits.

10. What alternative regulations (or specific provisions within the regulation) did the Agency consider, and why did it determine that these alternatives were not appropriate? If none, why didn't the Agency consider regulatory alternatives?

Alternative regulations were not considered. These regulations are required to be compatible with federal regulations (10 CFR 35) in accordance with the regulatory agreement between Ohio and the NRC.

11. Did the Agency specifically consider a performance-based regulation? Please explain.
Performance-based regulations define the required outcome, but don't dictate the process the regulated stakeholders must use to achieve compliance.

These regulations are performance based, which is a requirement of the regulatory agreement between Ohio and the NRC. They define the acceptable results without describing the processes for achieving compliance.

12. What measures did the Agency take to ensure that this regulation does not duplicate an existing Ohio regulation?

The Ohio Department of Health (ODH) is designated as Ohio's radiation control agency in RC 3748.02 and implements and administers all Ohio regulations concerning the possession and use of radioactive material.

13. Please describe the Agency's plan for implementation of the regulation, including any measures to ensure that the regulation is applied consistently and predictably for the regulated community.

The regulations are implemented through the licensing and inspection processes of licensed users of radioactive material. Radioactive material license reviewers and inspectors are given extensive training and use appropriate guidance documents to ensure that regulations are applied consistently and predictably.

Adverse Impact to Business

14. Provide a summary of the estimated cost of compliance with the rule. Specifically, please do the following:

- a. Identify the scope of the impacted business community;

There are currently three hundred (300) radioactive material licensees in Ohio that are affected by these regulations.

- b. Identify the nature of the adverse impact (e.g., license fees, fines, employer time for compliance); and

Potential impacts on affected licensees include payment of license fees, developing quality assurance programs and procedures and time needed for the licensee to conduct oversight for safe handling and medical use of radioactive material.

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- c. Quantify the expected adverse impact from the regulation.

The adverse impact can be quantified in terms of dollars, hours to comply, or other factors; and may be estimated for the entire regulated population or for a “representative business.” Please include the source for your information/estimated impact.

There are currently three hundred (300) radioactive material licensees in Ohio that are affected by these regulations.

Most of the amendments in this package will provide flexibility to the licensees in the operation of their radioactive material program. Some amendments in the package provide clarity to existing regulations. These amendments will not have a financial impact on licensees. The amendments that add reporting and notification requirements will have an impact. It is estimated that reporting and notifications will take 2 to 4 hours per event at \$33.70 per hour*.

***All figures from United States Department of Labor, Bureau of Labor Statistics, Occupational Employment and Wages for the State of Ohio, May 2017, using the code for Nuclear Medicine Technologists (29-2033).**

15. Why did the Agency determine that the regulatory intent justifies the adverse impact to the regulated business community?

The regulations are needed to ensure the safe handling and licensing of radioactive material and to keep Ohio’s Agreement State program compatible with federal requirements. Safe and handling of radioactive material is necessary to protect the public health and the environment from unnecessary radiation exposure.

Regulatory Flexibility

16. Does the regulation provide any exemptions or alternative means of compliance for small businesses? Please explain.

The rules in Chapter 3701:1-58 do not provide exemptions for small businesses; however, OAC rule 3701:1-38-02(J) provides for reduced license fees for small businesses.

17. How will the agency apply Ohio Revised Code section 119.14 (waiver of fines and penalties for paperwork violations and first-time offenders) into implementation of the regulation?

Chapter 3748 of the Revised Code does not grant the Department of Health statutory authority to waive fines and penalties. However, the Department of Health may utilize settlements facilitated by the Ohio Attorney General’s office to effectuate the intent of section 119.14 of the Revised Code. As a matter of course, the Ohio Department of Health does not assess fines or penalties for paperwork violations.

18. What resources are available to assist small businesses with compliance of the regulation?

Health Physicists at the Ohio Department of Health are available to provide technical advice to licensees.