Ohio | Common Sense Initiative

Mike DeWine, Governor
Jon Husted, Lt. Governor

Carrie Kuruc, Director

Business Impact Analysis

Agency, Board, or Commission Name: Health

Rule Contact Name and Contact Information:

Michael Snee – Michael.Snee@odh.ohio.gov 614-644-2732

Regulation/Package Title (a general description of the rules' substantive content):

Rule 3701:1-37-01 and rules in Chapter 3701:1-58

Rule Number(s): Appendix to rule 3701:1-37-01, 3701:1-58-18, 58-20, 58-21, 58-101, 58-102

Date of Submission for CSI Review: _____

Public Comment Period End Date: _____

Rule Type/Number of Rules:

New/_0__ rules

No Change/__0__ rules (FYR? ___)

Amended/__6__ rules (FYR? _0__)

Rescinded/__0__ rules (FYR? ___)

The Common Sense Initiative is established in R.C. 107.61 to eliminate excessive and duplicative rules and regulations that stand in the way of job creation. Under the Common Sense Initiative, agencies must balance the critical objectives of regulations that have an adverse impact on business with the costs of compliance by the regulated parties. Agencies should promote transparency, responsiveness, predictability, and flexibility while developing regulations that are fair and easy to follow. Agencies should prioritize compliance over punishment, and to that end, should utilize plain language in the development of regulations.

Reason for Submission

1. **R.C. 106.03 and 106.031 require agencies, when reviewing a rule, to determine whether the rule has an adverse impact on businesses as defined by R.C. 107.52. If the agency determines that it does, it must complete a business impact analysis and submit the rule for CSI review.**

   Which adverse impact(s) to businesses has the agency determined the rule(s) create?

   The rule(s):

   a. ☐ **Requires a license, permit, or any other prior authorization to engage in or operate a line of business.**

   b. ☐ **Imposes a criminal penalty, a civil penalty, or another sanction, or creates a cause of action for failure to comply with its terms.**

   c. ☐ **Requires specific expenditures or the report of information as a condition of compliance.**

   d. ☒ **Is likely to directly reduce the revenue or increase the expenses of the lines of business to which it will apply or applies.**

Regulatory Intent

2. **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 radioactive sealed sources used for medical procedures, training of personnel and release of patients administered radioactive material during treatment.

   The appendix to rule 3701:1-37-01 was reviewed due to changes in federal rules that corrected a mathematical formula.
   Rules 3701:1-58-18, 58-20, and 58-21 were reviewed due to changes in federal rules that corrects administrative errors in the rules.
   Rules 3701:1-58-101 and 58-102 were reviewed due to changes in federal rules that removes a requirement to submit social security numbers when reporting medical events.

   The draft rules do not require insurance and/or surety products as a condition of compliance.

3. **Please list the Ohio statute(s) that authorize the agency, board or commission to adopt the rule(s) and the statute(s) that amplify that authority.**

   Authorized by RC 3748.02, 3748.04

   Amplifies RC 3748.04, 3748.06

4. **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. Pursuant to RC 3748.04(A)(1)(a), and as condition of the agreement between the State of Ohio and the NRC, under which Ohio became an agreement state and assumed regulatory control of the possession and use of radioactive material in Ohio, the department is required to adopt administrative rules that are at least equivalent to those adopted by the NRC.

5. **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

6. **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 specific radiation protection requirements that are needed to ensure the safe use of radioactive material possessed by licensees for the medical use of radioactive materials.

7. **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.

8. **Are any of the proposed rules contained in this rule package being submitted pursuant to R.C. 101.352, 101.353, 106.032, 121.93, or 121.931?**
   If yes, please specify the rule number(s), the specific R.C. section requiring this submission, and a detailed explanation.
   No.

Development of the Regulation

9. **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 (RAC), 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 Ohio Department of Health (ODH). The council provides significant technical input to the Bureau of Environmental Health and Radiation Protection's Agreement State Program on all rulemaking actions proposed.

The RAC formed the Radioactive Material Committee (RMC) which is further comprised of experts in the field of radiation safety who represent stakeholders in industrial, academic, medical and research facilities. The RAC and RMC meetings are open to the public to encourage even more stakeholder participation. Next the proposed rules and amendments are posted for public comment on the ODH website. These rules were reviewed and approved for public comment by the RMC on June 15, 2022.

10. **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 June 15, 2022

11. **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 and in accordance with RC 3748.04(A)(1)(a), 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.

12. **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 must be compatible with the Code of Federal Regulations requirements in accordance with the regulatory agreement between Ohio and the NRC and RC 3478.04(A)(1)(a)

13. **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

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

    The 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.

15. **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 system and inspection processes of users of radioactive material. Health Physicists in the ODH Agreement State Program are given extensive training and use appropriate guidance documents to ensure that regulations are applied consistently and predictably.

Adverse Impact to Business

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

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

       Potential impacts on affected licensees include training of personnel and reporting medical events involving the use of radioactive material.

    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.

It is estimated that verification of personnel training will take 0.5 to 1 hour per staff at $36.19 per hour* and preparing required reports concerning medical events involving radioactive material will take 1-2 hours per event at $36.19 per hour*.

***All figures from United States Department of Labor, Bureau of Labor Statistics, Occupational Employment and Wages for the State of Ohio, May 2021, using the code for Nuclear Medicine Technologists (29-2033).**

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

    These rules establish the specific requirements for the medical use of radioactive material in a manner that protects workers and the public from excess exposure to radiation.

Regulatory Flexibility

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

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

19. **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 ODH statutory authority to waive fines and penalties. However, the ODH 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 ODH does not assess fines or penalties for paperwork violations.

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

    Health Physicists in the ODH Agreement State Program are available to provide technical advice to licensees.