

CSI - Ohio

The Common Sense Initiative

Business Impact Analysis

Agency Name: Health

Regulation/Package Title: Rule 3701:1-38-01 "Definitions"

Rule Number(s) 3701:1-38-01

Date: 12/28/15

Rule Type:

New

5-Year Review

Amended

Rescinded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.

This rule defines terms used in Chapters 3701:1-38, -40, -43, -44, -46, -48, -49, -50, -52, -54, -56, -58, -66, -67, and -68 of the Administrative Code. The rule was reviewed in accordance with 5-year rule review requirement. The rule was amended to update rule references in paragraphs (A)(11), (94), (95), (111), (112), and (159).

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

Ohio Revised Code (ORC) 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. This rule defines terms that are defined in federal regulations found in Title 10, Code of Federal Regulations. 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.

This rule does 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)?

This rule defines terms used in radiation protection rules found in other OAC Chapters.

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 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 (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

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industrial, academic, medical and research facilities. The RAC and RMC meetings are open to the public to encourage even more stakeholder participation. The proposed rule will also be posted for public comment on the ODH website.

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 this rule and approved the draft rule for public comment at their meeting on December 9, 2015.

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?

Not applicable.

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. The definitions in this rule must be compatible with Code of Regulations requirements 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.

This fee rule is not a performance based regulation.

12. 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.

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 review of license applications, application forms and guidance documents are provided by ODH, and the inspection 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

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 780 licensees in Ohio that are affected by this rule. In addition, there are currently 74 businesses that are licensed by other Agreement States or the NRC that operate in Ohio under reciprocity authorizations that would also be affected by this rule.

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

Potential impacts on affected licensees by this rule include the time spent reading the rule and ensuring that the definitions are understood.

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.

In general, these rules do not represent costs that are independent of those already obligated to the licensee by the virtue of their participation in the industry. Those costs include, but are not limited to, the costs associated with the purchase or lease of real estate, equipment, and personnel. There are also time and manpower costs associated with administrative requirements, including, but not limited to, policy development/implementation and quality assurance and performance improvement. The similar requirements set forth in Ohio’s rules are unlikely to require a significant amount of time or costs in addition to that which is already expended by the service and the services will, more likely than not, already meet or exceed the state requirements.

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

The rule defines radiation terms used in other OAC Chapters. The rule does not adversely impact the regulated business community.

Regulatory Flexibility

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

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 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.

ODH is committed to the goal of ensuring that regulated customers have the opportunity to achieve compliance with ODH's procedural requirements. ODH's Regulatory Ombudsman has developed a policy implementing section 119.14 of the Revised Code. This policy is available online at:

<http://www.odh.ohio.gov/rules/ombudsman/regulatoryombudsman.aspx>.

18. 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.