

CSI - Ohio

The Common Sense Initiative

Business Impact Analysis

Agency Name: Ohio Department of Health

Regulation/Package Title: Certification of Radiation Experts

Rule Number(s): Ohio Administrative Code 3701:1-66-03.

Date: 4/24/2017

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Rescinded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.

This regulation sets forth the educational, training and experience requirements necessary for certification as a radiation expert to oversee and maintain a hospital's radiation safety and quality assurance program.

Please see the attachment for specific changes.

77 SOUTH HIGH STREET | 30TH FLOOR | COLUMBUS, OHIO 43215-6117
CSIOhio@governor.ohio.gov

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

RC 3748.04

2. Does the regulation implement a federal requirement? **NO** 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? **NO**

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

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

N/A – While the federal government does not require the State of Ohio to regulate certified radiation experts, Ohio law (RC 3748.04) given the potential health and safety issues, does require the Ohio Department of Health, as the radiation control agency (RC 3748.02), to set forth the requirements governing entities using radiation-generating equipment.

4. 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 are in place to assure that certified radiation experts meet educational, training and experience standards to test radiation-generating equipment and oversee quality assurance programs for delivery of controlled doses of radiation to patients for diagnostic and radiation treatment purposes. In turn, this reducing unnecessary radiation and the likelihood of radiation induced health issues and injury to patients in Ohio.

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

The Agency measures success of certified radiation experts through inspecting radiation area surveys, radiation-generating equipment tests and quality assurance programs that radiation experts oversee. In turn, facilities meeting and maintaining compliance demonstrate few incidents of radiation induced health effects.

Development of the Regulation

6. 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 active body in advising the Director of Health on key radiological issues. The council provides significant technical input on rulemaking actions

regarding radiation protection. The Radiation-Generating Equipment Committee (REC)

formed by the Governor appointed RAC addresses items involving radiation-generating equipment. This committee is comprised of experts in the field of radiation who represent medical, nonmedical, academic and dental stakeholders of radiation-generating equipment. The REC meetings are open to the public for further stakeholder input. The stakeholders involved in drafting amendments to the rule are medical physicists, physicians, oncologists, radiographers and other members of the public attending the REC meetings on March 10, 2017.

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

The input provided by the medical physicists, physicians, radiographers and other members of the public included technical and clinical expertise to help make the regulations representative of current practices while focusing on radiation safety.

8. 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?

The regulations are comparable with the State Suggested Regulations from the Conference of Radiation Control Program Directors and the Code of Federal Regulations developed by scientific professionals in the field of radiation safety. This includes having medical physicists, physicians, oncologists, and radiographers at the REC meetings to support and further provide scientific input regarding radiation safety.

9. 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?

These regulations are devised around the national standards from the Conference of Radiation Control Program Directors and the Code of Federal Regulations which are developed by professionals in the field. There are no alternative provisions with as much profession knowledge behind them.

10. 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 regulation identifies the educational, training and experience requirements necessary for certification as a radiation expert to oversee and maintain a hospital's radiation safety and quality assurance program, but does describe the process for obtaining the education, training and experience.

11. 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 solely implements and administers all Ohio regulations concerning the radiation-generating equipment as it pertains to radiation protection and safety.

12. 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 tracking and maintaining all certified radiation experts in a computer database; and through inspecting facilities where radiation experts are required to test radiation-generating equipment and oversee quality assurance and radiation safety programs. The inspectors of medical facilities are given extensive training to ensure that regulations are applied consistently and predictably to the regulated community.

Adverse Impact to Business

13. 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 251 active certified radiation experts in Ohio affected by these regulations. These regulations provide educational standards that these individuals must meet to assure radiation safety to all members of the public.

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

There are certification fees used to support processing of applications.

- 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 three categories of certification: Mammography, Diagnostic, and Therapeutic. The initial certification fee is \$100.00 per category. Renewal is \$100.00 per category and is required every two years. The amendments to this rule do not establish any additional fees.

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

These regulations assure individuals meet educational and training standards to perform oversight and maintenance of a hospital's radiation quality assurance and safety program to reduce the likelihood of radiation induced health issues and injury.

Regulatory Flexibility

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

No, these regulations are for an individual's certification.

16. 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 penalty fees. However, the Department of Health may and often does utilize settlements facilitated by the Ohio Attorney General's office to effectuate the intent of section 119.14 of the Revised Code. Additionally, the Bureau of Environmental Health and Radiation Protection does not, as a matter of course assess fines and penalties for paperwork violations.

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

Health Physicists and administrative staff at the Ohio Department of Health are available to provide technical advice to certified radiation experts. The Ohio Department of Health, X-ray Program's website provides instruction for certification requirements and frequently asked questions for completing applications.