

CSI - Ohio

The Common Sense Initiative

Business Impact Analysis

Agency Name: Ohio Department of Health

Regulation/Package Title: Therapy Radiation-Generating Equipment

Rule Number(s): Ohio Administrative Code 3701-72-01, 3701-72-02, 3701-72-03 and 3701-72-04.

Date: 3/18//2016

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Rescinded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.

These regulations require individuals who medically expose human beings to ionizing radiation to meet education and examination to be licensed as radiographer, radiation therapist, nuclear medicine technologist or General X-ray Machine Operator (GXMO).

Please see attachment for a listing of the specific changes.

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

Revised Code 4773.

2. Does the regulation implement a federal requirement? **Yes** 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

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 require individuals who medically expose humans to ionizing radiation to meet education and examination requirements in order to minimize radiation exposure to the patient and themselves. This reduces the likelihood of radiation induced health issues and injury to the patient and operator. These regulations are in-line with the Federal requirements of the “Consumer-Patient Radiation Health and Safety Act of 1981” and are necessary for the radiation safety and protection of Ohio citizens.

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

The Agency measures success of individuals and facilities meeting compliance through inspection of facilities with radiation-generating equipment to assure operators are licensed. In turn, educated operators perform radiologic procedures with less radiation due to proper exposure technique, appropriate shielding and fewer retakes resulting in less exposure to the overall public to help reduce 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.

On October 28, 2015 and January 19, 2016 announcements and agendas were sent out through public affairs and BRadiation list serve emails identifying that Radiation-Generating Equipment Committee (REC) meetings would be held on November 6, 2015

77 SOUTH HIGH STREET | 30TH FLOOR | COLUMBUS, OHIO 43215-6117

CSIOhio@governor.ohio.gov

and January 29, 2016. The REC is formed by the Governor appointed Radiation Advisory Council and is composed of Ohio experts in the field of radiation to include medical physicists, radiologists, physicians, technologists and educators. The Ohio Society of Radiologic Technology, public radiation experts and the Radiation-Generating Committee (REC) provided input in the review and development of these rules.

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 included technical and clinical expertise to help make the regulations representative of current practices while focusing on radiation safety to the public.

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.

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.

These regulations are mostly performance based because they define the acceptable results with minimal description of the processes for achieving compliance.

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

A review of Ohio regulations found reference but no duplication in regulation. Also, 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 possession and use of radiation-generating equipment.

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 addressed by radiologic license applications and enforcement through registration and inspection of facilities with radiation-generating equipment. The application reviewers and inspectors of radiation-generating equipment are given extensive training to ensure that the 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;

These cost are mainly for individuals obtaining a license. There are currently 13,296 radiographers, 858 radiation therapists, 1,416 nuclear medicine technologists and 1,199 General X-ray Machine Operators (GXMO) in Ohio affected by these regulations.

Educational and continuing education courses accredited by the national accreditation body American Registry of Radiologic Technologists (ARRT) are accepted by the Ohio Department of Health (Department). Therefore, only 19 educational courses for GXMO and 193 continuing education courses have been approved by the Department.

Suggested revisions to rule result in:

CT certification American Registry of Radiologic Technologists (ARRT)

- **Post certification to ARRT Radiographer, Nuclear Medicine Technologist and Radiation Therapist certifications**
- **125 individual examinations**
- **Examination Fee \$200.00**

CT certification Nuclear Medicine Technology Certification Board (NMTCB)

- **During NMTCB certification for Nuclear Medicine Technologist or post certification to NMTCB Nuclear Medicine Technology certification.**
- **500 Clinical Hour and 35 contact hours**
- **Examination Fee \$180.00**

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

The adverse impact of a small fee for application processing and enforcing licensure is far outweighed by the radiation safety benefits to the public.

- 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.

The initial licensing fee is \$65.00 and renewal fee is \$45.00 every two years for each license category held.

There is a one-time fee of \$500.00 to conduct an educational course and a one-time fee of \$75.00 to provide a continuing education course.

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

These regulations are necessary to assure that individuals who deliver radiation to human beings know how to control radiation to obtain high quality radiographs and treat cancer while minimizing radiation exposure to the patient and themselves. Ultimately reducing the likelihood of radiation induced health effects or death.

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 license.

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?

N/A, there are no fines or penalties associated with an individual license.

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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 licensees. The X-ray Program website at the Ohio Department of Health provides instruction for licensing requirements and completing applications.