Common Sense Initiative

Mike DeWine, *Governor*
Jon Husted, *Lt. Governor*
Joseph Baker, *Director*

MEMORANDUM

TO: Stephen Helmer, Ohio Department of Health

FROM: Michael Bender, Business Advocate

DATE: March 25, 2024

RE: **CSI Review – Radiation Generating Equipment Inspection (OAC 3701:1-66-01, 3701:1-66-03, 3701:1-66-04, 3701:1-66-05, 3701:1-66-07, and 3701:1-66-11)**

On behalf of Lt. Governor Jon Husted, and pursuant to the authority granted to the Common Sense Initiative (CSI) Office under Ohio Revised Code (ORC) section 107.54, the CSI Office has reviewed the abovementioned administrative rule package and associated Business Impact Analysis (BIA). This memo represents the CSI Office's comments to the Department as provided for in ORC 107.54.

Analysis

This rule package consists of six amended rules proposed by the Ohio Department of Health (ODH) as part of the statutory five-year review process. This rule package was submitted to the CSI Office on October 10, 2023, and the public comment period was held open through November 10, 2023. Unless otherwise noted below, this recommendation reflects the version of the proposed rules filed with the CSI Office on October 10, 2023. The rule package originally contained twelve amended rules, but six of the rules were withdrawn after the CSI public comment period to be submitted later for consideration in a separate rule package.

Ohio Administrative Code (OAC) 3701:1-66-01 lists definitions pertaining to radiation-generating equipment (RGE). The rule is amended to update language and clarify that medical purposes include dental purposes. OAC 3701:1-66-03 provides for the certification of radiation experts in the therapeutic, diagnostic (other than mammography), and mammography categories. The rule is amended to update language, add citations, remove roentgen-ray and gamma-ray physics as well as x-ray and radium physics as possible options for applicants for radiation expert certification in the

therapeutic category to fulfill the requirement for certification by the American Board of Radiology, increase the time required for applicants for radiation expert certification in the therapeutic category to obtain the necessary certification from within five years to within six years of qualifying, allow for international degrees to fulfill education requirements, and allow ODH to email notices and applications for renewal to certificate holders. OAC 3701:1-66-04 requires each registrant to develop, implement, and maintain a written quality assurance program in hard copy or electronic format for medical RGE. The rule is amended to update language and only require quality assurance committees to meet at least annually rather than quarterly.

OAC 3701:1-66-05 outlines standards for medical general purpose radiographic equipment. The rule is amended to update language and grammar, require mobile and portable RGE operators to be able to see a patient without leaving the protected barrier, and extend requirements for handlers of certified veterinary RGE designed to be hand-held to handlers of any certified RGE designed to be hand-held. OAC 3701:1-66-07 outlines standards for medical fluoroscopic equipment. The rule is amended to update language, allow handlers of fluoroscopic RGE to forgo the use of a protective barrier or lead apron under certain conditions, and no longer require the use of protective lead or lead equivalent gloves by individuals who have their hands simply near but not in the useful beam. OAC 3701:1-66-11 contains standards for medical bone densitometry RGE. The rule is amended to update language.

During early stakeholder outreach, ODH sent out announcements and agendas on September 1, 2023, via its radiation email listserv and its public affairs team notifying stakeholders that a Radiation-Generating Equipment Committee (Committee) meeting would be held on September 8, 2023, to consider input on the rules from radiation professionals, the public, and members of the Committee. The feedback received at the meeting led to ODH revising the rules to reflect current practices with a focus on radiation safety to the public. During the CSI public comment period, ODH received comments from the Ohio State University Wexner Medical Center (OSUWMC), two individuals affiliated with MetroHealth, Ohio Medical Physics Consulting (OMPC), the Cleveland Clinic, and OhioHealth Mansfield Hospital (OHMH).

The Cleveland Clinic asked for the rules to be revised to require anyone who puts a hand into a fluoroscopy beam for clinical purposes to receive and use an extremity monitoring device capable of measuring the radiation dose to the operator's fingers and hand, rather than requiring the use of lead equivalent gloves. ODH answered that this would not be aligned with radiation safety for the operator, as the operator should not have any hands continuously in the beam regardless of whether they are protected or not. Both commenters from MetroHealth asked what was meant by a "primary protective barrier" that must be used by handlers of dental equipment. ODH provided an excerpt from public guidance and assured the commenters that this rule would continue to be enforced as it had always been. OSUWMC recommended that fluoroscopic procedures be included in the list of exceptions for operators to be "entirely behind a protective barrier" when using RGE, while OMPC

and OHMH asked for the removal of the requirement for handlers of dental RGE in a hospital setting to conduct annual evaluations of x-ray operators. ODH determined to address these requests by withdrawing the aforementioned six rules for resubmission to CSI and separate consideration after proposing changes based on the comments received.

The business community impacted by the rules includes approximately 9,000 businesses with medical RGE in Ohio. These businesses vary from small doctor offices to large medical facilities. The adverse impacts created by the rules include inspection fees and the time required for the inspection itself to ensure that facilities are complying with the established standards. Hospital inspections occur every two years, with inspections fees of $960 for one to ten x-ray units, $1,800 for eleven to twenty-five x-ray units, and $2,640 for more than twenty-five x-ray units. Non-medical facility inspections occur every three years, with inspection fees of $120 for each cabinet, gauging, or analytical x-ray unit, $240 for each non-medical x-ray unit other than a cabinet, gauging, or analytical unit, $610 for x-ray units greater than 250 kilovoltage peak, and $380 for assembler-maintainers. ODH states that the adverse impacts to business are justified to ensure that medical RGE functions properly to deliver controlled doses of radiation to patients for diagnosing injury and disease as well as to reduce the likelihood of radiation-induced health effects and injury.

Recommendations

Based on the information above, the CSI Office has no recommendations on this rule package.

Conclusion

The CSI Office concludes that ODH should proceed in filing the proposed rules with the Joint Committee on Agency Rule Review.

Common Sense Initiative

Mike DeWine, *Governor* Joseph Baker, *Director*
Jon Husted, *Lt. Governor*

MEMORANDUM

TO: Stephen Helmer, Ohio Department of Health

FROM: Michael Bender, Business Advocate

DATE: March 25, 2024

RE: **CSI Review – Radiation Generating Equipment Inspection – Amendments (OAC 3701:1-66-02, 3701:1-66-06, 3701:1-66-08, 3701:1-66-10, 3701:1-66-16, and 3701:1-66-17)**

On behalf of Lt. Governor Jon Husted, and pursuant to the authority granted to the Common Sense Initiative (CSI) Office under Ohio Revised Code (ORC) section 107.54, the CSI Office has reviewed the abovementioned administrative rule package and associated Business Impact Analysis (BIA). This memo represents the CSI Office's comments to the Department as provided for in ORC 107.54.

Analysis

This rule package consists of six amended rules proposed by the Ohio Department of Health (ODH) as part of the statutory five-year review process. This rule package was submitted to the CSI Office on February 13, 2024, and the public comment period was held open through March 5, 2024. Unless otherwise noted below, this recommendation reflects the version of the proposed rules filed with the CSI Office on February 13, 2024.

Ohio Administrative Code (OAC) 3701:1-66-02 outlines general standards for radiation-generating equipment (RGE). The rule is amended to update language, update the rule title, add a citation, remove a provision requiring gonadal shielding of less than 0.5 millimeter lead equivalent material for young human patients during radiologic procedures in which gonads are in the useful beam, clarify who can determine whether a radiation worker does not need to wear an individual monitoring device during a procedure, require RGE operators to be able to see a patient without leaving the protected barrier, and remove the exemption for fluoroscopy facilities from completing image quality

evaluations of RGE at least annually. OAC 3701:1-66-06 06 contains standards for dental RGE. The rule is amended to update language, clarify that handlers of dental intraoral and panoral equipment are exempt from certain shielding requirements, exempt operators of dental equipment in hospitals from the annual evaluation requirement, and provide certain exceptions for handlers of dental cone-beam computed tomography RGE from the protective barrier requirement. OAC 3701:1-66-08 contains standards for mammography RGE. The rule is amended to update language. OAC 3701:1-66-10 outlines standards for medical computed tomography RGE. The rule is amended to update language and make a technical correction. OAC 3701:1-66-16 outlines standards for security screening systems. The rule is amended to update language. OAC 3701:1-66-17 contains standards for medical screening and research. The rule is amended to update language and make a technical correction.

During early stakeholder outreach, ODH sent out announcements and agendas on September 1, 2023, via its radiation email listserv and its public affairs team. The notices informed stakeholders that a Radiation-Generating Equipment Committee (Committee) meeting would be held on September 8, 2023, to consider input on the rules from radiation professionals, the public, and members of the Committee. The feedback received at the meeting led to ODH revising the rules to reflect current practices with a focus on radiation safety to the public. The rules were originally submitted as part of a related rule package in October 2023 but were subsequently withdrawn for further consideration after ODH determined to make additional changes in response to the public comments received. No comments were received during the 2024 CSI public comment period for the revised version of these rules, although ODH made an additional technical correction to the rule.

The business community impacted by the rules includes approximately 9,000 businesses with medical RGE in Ohio. These businesses vary from small doctor offices to large medical facilities. The adverse impacts created by the rules include inspection fees and the time required for the inspection itself to ensure that facilities are complying with the established standards. Hospital inspections occur every two years, with inspections fees of $960 for one to ten x-ray units, $1,800 for eleven to twenty-five x-ray units, and $2,640 for more than twenty-five x-ray units. Non-medical facility inspections occur every three years, with inspection fees of $120 for each cabinet, gauging, or analytical x-ray unit, $240 for each non-medical x-ray unit other than a cabinet, gauging, or analytical unit, $610 for x-ray units greater than 250 kilovoltage peak, and $380 for assembler-maintainers. ODH states that the adverse impacts to business are justified to ensure that medical RGE functions properly to deliver controlled doses of radiation to patients for diagnosing injury and disease as well as to reduce the likelihood of radiation-induced health effects and injury.

Recommendations

Based on the information above, the CSI Office has no recommendations on this rule package.

Conclusion

The CSI Office concludes that ODH should proceed in filing the proposed rules with the Joint Committee on Agency Rule Review.