Ohio Administrative Code

Rule 3701:1-66-04 Quality assurance program for medical radiation-generating equipment.

Effective: December 13, 2024

(A) Each registrant will develop, implement and maintain a written quality assurance program in the form of a readily available manual or manuals, either in hard copy format or electronic format. For purposes of this chapter and Chapter 3701:1-67 of the Administrative Code, quality assurance program means a program providing for verification by written procedures such as testing, auditing, and inspection to ensure that deficiencies, deviations, defective equipment, or unsafe practices, or a combination thereof, relating to the use, disposal, management, or manufacture of radiation devices are identified, promptly corrected, and reported to the appropriate regulatory authorities.

(B) The written quality assurance program of each registrant will address and include records to verify implementation of at least the following:

(1) The intervals of and procedures for the evaluation of all radiation-generating equipment to ensure compliance with all applicable rules of this chapter;

(2) Procedures for maintaining compliance with occupational and public exposure limits;

(3) Procedures for notifying the director when individuals are occupationally over-exposed to radiation, pursuant to Chapter 3701:1-38 of the Administrative Code;

(4) Safe operating procedures for each type of radiation-generating equipment to be handled;

(5) Training of operators of each type of radiation-generating equipment to be handled in order to assure competency in the operating procedures;

(6) In addition to the obligations of paragraph (B)(1) of rule 3701:1-38-10 of the Administrative Code, individuals likely to receive an annual occupational dose in excess of one millisievert (one hundred millirem) will be instructed in the following:

(a) The location, boundaries, and purpose of restricted areas; and

(b) A description of the radiation-generating equipment and its location;

(7) The quality control tests to be performed, the frequency of the quality control tests to be performed and the personnel responsible for the performance of the quality control tests as applicable to the radiation-generating equipment type and use;

(8) Policies regarding the state licensure or certification of each person operating radiation-generating equipment as obligated by Chapters 4773. and 4715. of the Revised Code;

(9) The dissemination of quality assurance policies and a method to educate affected workers on those policies and any policy changes;

(10) Radiation workers' role and responsibility for following and supporting the quality assurance program;

(11) Policies regarding personnel protection, including time, distance, and shielding;

(12) Policies regarding occupational exposure of pregnant workers;

(13) Policies regarding radiation safety training for ancillary personnel;

(14) Policies regarding training for personnel with quality control responsibilities;

(15) Policies regarding human patient protection, including screening for pregnancy, exposure of pregnant patients, patient shielding, patient education;

(16) Policies regarding verification of human patient identity and exam to be performed, including identification of the appropriate body part;

(17) Policies to only permit licensed practitioners to order radiographic examinations;

(18) An inventory of radiation-generating equipment, including the location and description of each unit.

(C) In addition to the obligations of paragraphs (A) and (B) of this rule, the quality assurance program of hospital registrants will comply with the following:

(1) A certified radiation expert will conduct oversight and maintenance of quality assurance programs for hospital registrants, by:

(a) Auditing the quality assurance program on an annual basis;

(b) Performing reviews of the quality assurance program each quarter;

(c) Completing and submitting all necessary information with the annual audit form in accordance with paragraph (C)(6) of this rule; and

(d) Serving on the quality assurance committee;

(2) Employees working in the radiation areas will be made aware of the identity, scope of authority, and a method for contacting the certified radiation expert and the individual responsible for radiation protection. This information, or a specific location where this information may be obtained, will be conspicuously posted in each area where radiation-generating equipment is used;

(3) Each hospital registrant will establish a quality assurance committee for the management of the quality assurance program. The members of the quality assurance committee will be approved by an executive administrator. Committee meetings may be attended by the members or similarly qualified, designated alternates. The quality assurance committee will include at least the following members:

(a) A member of the hospital's executive administration;

(b) The individual responsible for radiation protection;

(c) A radiologist or radiation oncologist;

(d) A certified radiation expert representing each of the following as applicable in each hospital;

(i) Radiation therapy services,

(ii) Mammography, or

(iii) Diagnostic radiography other than mammography; and

(e) A management representative of each department of the hospital which has responsibilities involving the handling of radiation-generating equipment;

(4) The quality assurance committee will meet as often as is deemed necessary to carry out its duties, but at least annually. To establish a quorum at least one-half of the committee's membership will be present either in person or by telecommunication, and will include the individual responsible for radiation protection for the hospital, and the member of the executive administration of the hospital. A record of each meeting will be maintained and distributed to each member which will include the following:

(a) The date of the meeting;

(b) An indication of members present; and

(c) A summary of meeting including any recommended actions and ALARA reviews;

(5) Each quarter, the certified radiation expert will submit, to each appointed quality assurance committee member, a review of the quality assurance program, which will contain, as applicable:

(a) Radiation safety policy revisions proposed by the certified radiation expert;

(b) A review of occupational exposure records by the certified radiation expert;

(c) Radiation safety incidents;

(d) Performance evaluation summaries for radiation-generating equipment including a description of any issues found; and

(e) Any corrective actions recommended by the certified radiation expert that are necessary to comply with the obligations of this chapter;

(6) The quality assurance program will be audited at least annually by a certified radiation expert. The certified radiation expert will develop a written report of the audit findings on forms prescribed by the director and submit the report to the quality assurance committee within thirty days of completing the audit. The quality assurance committee will review the audit report and implement any corrective actions determined to be necessary. The certified radiation expert will file the audit report with the director within ninety days of completing the audit. Every audit report will include a determination of whether the quality assurance program properly addresses the matters described in this rule and whether it is being carried out in accordance with the written quality assurance program, and any corrective actions to be taken to comply with the obligations of this chapter. The audit report will become a part of the inspection record.

(D) In addition to the obligations of paragraphs (A) and (B) of this rule, the quality assurance program of registrants performing fluoroscopically-guided interventional other than veterinary procedures, and computed tomography (CT) other than veterinary and cone beam CT procedures will establish a radiation dose review committee in accordance with the following:

(1) The registrant may establish a system-wide committee if the registrant has more than one site;

(2) If the registrant is a subsidiary of a hospital, the obligations of paragraph (D) of this rule may be delegated to the hospital quality assurance committee provided its members meet the obligations of paragraph (D)(3) of this rule;

(3) The radiation dose review committee will include at least the following members:

(a) The individual responsible for radiation protection;

(b) A diagnostic radiation expert;

(c) As applicable, a physician that performs fluoroscopically-guided interventional and/or computed tomography procedures; and

(d) As applicable, a technologist that performs fluoroscopically-guided interventional and/or computed tomography procedures;

(4) A quorum of the radiation dose review committee will meet as often as necessary to carry out its duties, but at least annually. To establish a quorum at least one-half of the committee's membership will be present either in person or by telecommunication, and will include the individual responsible for radiation protection. A record of each meeting will be maintained and include the following:

(a) The date of the meeting;

(b) An indication of members present; and

(c) A summary of meeting including any recommended actions;

(5) The radiation dose review committee for fluoroscopically-guided interventional procedures will establish and implement written policies that include but are not limited to the following:

(a) Identification of individuals who are authorized to use fluoroscopic systems for interventional purpose;

(b) A method to be used to monitor patient radiation dose during fluoroscopically-guided interventional procedures;

(c) Dose notification levels, as appropriate, at which the physician is notified and appropriate actions are taken for patient safety;

(d) Substantial radiation dose level values following nationally recognized standards;

(e) Actions to be taken for cases when a substantial radiation dose level is exceeded which may include patient follow-up; and

(f) Reviewing policies identified in paragraphs (C)(5)(a) to (C)(5)(e) of this rule at least annually;

(6) The radiation dose review committee for computed tomography will determine and review written protocols to improve image quality and minimize patient dose. The review will include acquisition and reconstruction protocols, image quality, and radiation dose. At a minimum, the review will be performed annually and include the following clinical protocols, if performed:

(a) Pediatric head;

(b) Pediatric abdomen;

(c) Adult head;

(d) Adult abdomen;

(e) Adult chest; and

(f) Brain perfusion.

(E) Records obligated by this chapter and Chapter 3701:1-67 of the Administrative Code will be maintained in accordance with the following:

(1) Data and test results of evaluations and calibrations of all radiation-generating equipment for no less than five years;

(2) Data and test results of evaluations of shielding and surroundings of all radiation-generating equipment until the director terminates the registration or five years after the equipment is transferred or disposed;

(3) Maintenance logs for radiation-generating equipment for five years;

(4) Medical event reports involving radiation exposure to individuals for all radiation-generating equipment until the director terminates the registration;

(5) Copies of current licenses or the department's licensure verification web page for everyone who is obligated to possess a license at the facility; and

(6) Biennial calibration certificates or cross calibration documentation for all instruments used to perform area radiation surveys, calibrations, and evaluations for five years.