

3701:1-66-04 Quality assurance program.

- (A) Each registrant shall develop, implement and maintain a written quality assurance program. 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 shall 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 requirements 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) shall be instructed in the following:
 - (a) The location, boundaries, and purpose of restricted areas;
 - (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 required 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; and
 - (15) Policies regarding patient protection, including screening for pregnancy, exposure of pregnant patients, patient shielding, patient education, patient identity verification.
- (C) In addition to the requirements of paragraphs (A) and (B) of this rule the quality assurance program of hospital registrants shall comply with the following:
- (1) A certified radiation expert shall conduct oversight and maintenance of quality assurance programs for hospital registrants, by:
 - (a) Auditing the quality assurance program on an annual basis;
 - (b) Performing quarterly reviews;
 - (c) Completing and submitting all required 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 shall 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, shall be conspicuously posted in each area where radiation-generating equipment is used.
 - (3) Each hospital registrant shall establish a quality assurance committee for the management of the quality assurance program. The members of the quality assurance committee shall be approved by an executive administrator. Committee meetings may be attended by the members or similarly qualified, designated alternates. The quality assurance committee shall 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 shall meet as often as is deemed necessary to carry out its duties, but at least on a quarterly basis. To establish a quorum at least one-half of the committee's membership must be present either in person or by telecommunication means, and must include the individual responsible for radiation protection for the hospital, and the member of the executive administration of the hospital. In addition, each member must attend at least one quarterly meeting each calendar year. A record of each meeting shall be maintained and distributed to each member which shall 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 shall submit, to each appointed quality assurance committee member, a review of the quality assurance plan which shall 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) Radiation-generating equipment performance evaluation summaries to include a description of any issues found; and
 - (e) Any corrective actions recommended by the certified radiation expert necessary to comply with the requirements of this chapter.
 - (6) The quality assurance program shall be audited at least annually as defined in paragraph (A)(18) of rule 3701:1-38-01 of the Administrative Code by a certified radiation expert. The certified radiation expert shall 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 shall review the audit report and implement any corrective actions determined to be necessary. The certified radiation expert shall file the audit report with the director within ninety days of completing the audit. Every audit report shall 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 requirements of this chapter. The audit report shall become a part of the inspection record.
- (D) At the time of the state inspection the following items shall be readily available for review:
- (1) A complete listing of the inventory of radiation-generating equipment, including the location and description of each unit;

- (2) The written quality assurance program as required by this rule shall be maintained in the form of a readily available manual or manuals, either in hard copy printed format or electronic format;
- (3) Data and test results of the evaluation of each unit of radiation-generating equipment and its shielding and surroundings;
- (4) Maintenance logs and incident reports for each radiation-generating equipment system;
- (5) Current copies of department's licensure verification web page for each individual who is required to possess a license at the facility; and
- (6) Instrumentation used to perform area radiation surveys, calibrations and evaluations, as appropriate for each type of radiation-generating equipment, including at least biennial calibration certificates or cross-calibration documentation done within the biennium.

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Certification

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