Ohio Administrative Code

Rule 3701:1-68-02 Quality assurance.

Effective: August 15, 2017

(A) Each handler of non-medical radiation-generating equipment shall develop, implement and maintain a written quality assurance program in the form of a readily available manual or manuals, either in hard copy, printed format or electronic format. For the purpose of this chapter, quality assurance program means written policies and procedures such as testing, auditing and inspection to assure compliance with applicable rules of the Administrative Code. The written quality assurance program shall at least address the following:

(1) The evaluation and maintenance of non-medical radiation-generating equipment in accordance with the manufacturer's recommendations;

(2) Radiation monitoring requirements such as, surveys, occupational exposure limits and procedures regarding the use of area and personnel monitoring;

(3) Facility compliance with occupational, pregnant worker and public exposure limits, to include notifying the director when individuals are occupationally over-exposed to radiation, pursuant to rule 3701:1-38-12 and rule 3701:1-38-21 of the Administrative Code;

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

(5) Radiation safety training for ancillary personnel, to include:

(a) Potential hazards of being present in a restricted area;

(b) Location, boundaries and purpose of restricted areas; and

(c) The identification of all radiation areas, warning signs, and warning lights;

(6) Prohibiting the use of non-medical radiation-generating equipment to intentionally irradiate human beings for any purpose;

(7) Prohibiting the operation of non-medical radiation-generating equipment if the provisions set forth in this rule or any other applicable requirements of Chapter 3701:1-68 of the Administrative Code are not met;

(8) Requiring operators of permanent radiographic installations and cabinet systems that are designed to admit humans to verify no individual is present in the room during radiation exposure;

(9) A current listing of all non-medical radiation-generating equipment, including the location and description of each system;

(10) Data and test results of the evaluation of the shielding and surroundings of all non-medical radiation-generating equipment;

(11) Maintenance logs and incident reports for each non-medical radiation-generating equipment system;

(12) Current copies of valid certification identification cards, issued by the independent program referenced in paragraph (C)(2)(a) of this rule, for each radiographer;

(13) Maintaining records required by this chapter, according to the following provisions:

(a) Determination of an individual's radiation exposure following an event where that individuals pocket dosimeter was found off-scale, or that individual's electronic personnel dosimeter read greater than two millisieverts (two hundred millirem) shall be maintained until the director terminates the registration;

(b) Calculation of an individuals radiation exposure from the time of issuance to the time of damage or loss of a personnel dosimeter shall be maintained until the director terminates the registration;

(c) In accordance with rule 3701:1-38-20 of the Administrative Code, dosimetry reports received

from accredited NVLAP personnel dosimeter processors shall be kept until the director terminates the registration;

(d) Area radiation surveys conducted at any site other than a temporary job site shall be maintained until the director terminates the registration;

(e) Operator training and refresher training shall be maintained until the employment of the operator has been terminated or three years, whichever is longer;

(f) All other records generated pursuant to the requirements of this chapter shall be maintained for no less than three years;

(g) Check, test or evaluation records shall include the date of the check or test, the name of the inspector, the equipment involved, any problems found, and what repair and/or maintenance, if any, was performed; and

(h) Each record must be legible throughout the specified retention period. The record may be the original or a reproduced copy or a microform provided that the copy or microform is authenticated by authorized personnel and that the microform is capable of reproducing a clear copy throughout the required retention period. The record may also be stored in electronic media with the capability for producing legible, accurate, and complete records during the required retention period. Records, such as letters, drawings, and specifications, must include all pertinent information, such as stamps, initials, and signatures. The registrant shall maintain adequate safeguards against tampering with and loss of records.

(14) Requiring non-medical radiation-generating equipment to be kept locked at all times, to prevent tampering or removal by unauthorized personnel, except when under the direct surveillance of the operator, or as may be otherwise authorized pursuant to this rule.

(B) Survey instruments and dosimeter requirements:

(1) Radiation survey instruments shall be calibrated:

(a) For the type of radiation to be monitored;

(b) Within the preceding six months for radiographic operations conducted at temporary job sites and twelve months for all other operations;

(c) After each instrument servicing other than battery replacement;

(d) Such that accuracy within plus or minus twenty per cent can be demonstrated;

(e) At two points located approximately one third and two thirds of full-scale on each scale for linear scale instruments;

(f) At midrange of each decade, and at two points of at least one decade for logarithmic scale instruments; and

(g) At appropriate points for digital instruments.

(2) Direct reading dosimeters shall:

(a) Have a range from zero to two millisieverts (two hundred millirem);

(b) Read within plus or minus twenty per cent of the true radiation exposure; and

(c) Be checked for correct response to radiation at periods not to exceed twelve months.

(3) Personnel dosimeters, except for direct and indirect reading dosimeters used to measure the dose to any extremity, that require processing to determine the radiation dose shall be processed and evaluated by a dosimetry processor that holds a current personnel dosimetry accreditation from the "National Voluntary Laboratory Accreditation Program" (NVLAP) of the national institute of standards and technology.

(4) The results of all survey instrument and direct reading dosimeter calibration shall be recorded.

(C) Radiographic systems shall be operated by radiographers and radiographer's assistants who meet the following:

(1) No individual shall act as a radiographer or radiographer's assistant unless such individual has received copies of, been instructed in, and has demonstrated understanding by successful completion of a written examination and competency by successful completion of a practical examination in the subjects identified in this paragraph. Training shall be presented on a formal basis and shall include the following subjects:

(a) Fundamentals of radiation safety and methods of controlling radiation;

(i) Time;

(ii) Distance;

(iii) Shielding; and

(iv) Collimation;

(b) Characteristics of radiation;

(c) Units of radiation dose;

(i) Significance of radiation dose; and

(ii) Radiation protection standards;

(d) Biological effects of radiation;

(e) Levels of radiation from sources of radiation;

(f) Applicable requirements of state regulations;

(g) Registrant's written operating and emergency procedures;

(h) Operation, inspection, maintenance and control of non-medical radiation-generating equipment to be used;

(i) Use of radiation survey instruments;

(i) Operation;

(ii) Calibration; and

(iii) Limitations;

(j) Survey techniques;

(k) Use of personnel monitoring equipment, to include;

(i) Distribution, wearing and exchange procedures;

(ii) Typically expected exposure levels; and

(iii) Methods to keep exposure levels as low as reasonably achievable; and

(l) Case histories of non-medical radiation-generating equipment accidents.

(2) Certification requirements for radiographers:

(a) Radiographers shall be certified through an independent program approved by the United States nuclear regulatory commission, the "Conference of Radiation Control Program Directors Inc.," or equivalent certification approved by the director in accordance with the requirements in the appendix to this rule; and

(b) Prior to any individual acting as a radiographer, he or she shall demonstrate one month of prior

on-the-job experience.

(D) The handler shall provide refresher training for operators of radiographic systems at intervals not to exceed twelve months.

(1) The training shall include, as a minimum:

(a) Any results of internal inspections;

(b) New procedures or equipment;

(c) New or revised regulations;

(d) Any accidents or errors that have been observed; and

(e) Opportunities for attendees to ask safety questions.

(2) The training shall be recorded and include, as a minimum:

(a) A list of the topics discussed during the refresher training;

(b) The dates the training was conducted; and

(c) The names of the instructors and attendees.

(E) Requirements for the individual responsible for radiation protection (IRRP) for radiographic systems shall include, as a minimum:

(1) Complete training requirements of paragraphs (C)(1) and (C)(2) of this rule;

(2) Two thousand hours of hands-on experience as a qualified radiographer in radiographic operations;

(3) Formal education in the establishment and maintenance of a radiation protection program; and

(4) The director will consider alternatives to paragraphs (E)(2) of this rule when the IRRP for radiography has appropriate training and/or experience in the field of ionizing radiation.

(F) The specific duties and authorities of the individual responsible for radiation protection (IRRP) include, but are not limited to:

(1) Overseeing and approving all phases of the training program for operators, ensuring that appropriate and effective radiation protection practices are taught; and

(2) Ensuring that operations are conducted safely and to assume control for instituting corrective actions when necessary.

(G) In addition to the requirements of paragraph (F) of this rule, the specific duties and authorities of the individual responsible for radiation protection (IRRP) of radiographic systems addressed in rule 3701:1-68-03 of the Administrative Code include, but are not limited to:

(1) Establishing and overseeing all operating, emergency, and ALARA procedures as required by Chapter 3701:1-38 of the Administrative Code, and reviewing them regularly to ensure that the procedures in use conform to current regulatory requirements, and to the registration conditions;

(2) Ensuring that required radiation surveys are performed and recorded in accordance with the Administrative Code, including any corrective measures when levels of radiation exceed established limits;

(3) Ensuring that personnel monitoring devices are calibrated and used properly by occupationally-exposed personnel, that records are kept of the monitoring results, and that timely notifications are made as required by paragraph (C) of rule 3701:1-38-21 of the Administrative Code; and

(4) Auditing each radiographer and radiographers assistant at intervals not to exceed six months to ensure that the applicable paragraphs of the Ohio Administrative Code and the registrant's operating and emergency procedures are followed.

(a) The audit must:

(i) Include observation of the performance of each radiographer and radiographer's assistant during an actual non-medical radiographic operation, and

(ii) Provide that, if a radiographer or a radiographer's assistant has not participated in a non-medical radiographic operation for more than six months since the last audit, the radiographer or radiographers assistant must demonstrate knowledge of the training requirements of paragraphs (C)(1)(h), (C)(1)(i) and (C)(1)(j) of this rule by a practical examination before the individual can participate in a radiographic operation.

(b) The director may consider alternatives in those situations where the individual serves as both radiographer and individual responsible for radiation protection.

(c) In those operations where a single individual serves as both radiographer and individual responsible for radiation protection, and performs all radiographic operations, an audit program is not required.

(d) A record of the audit shall include, as a minimum:

(i) The identity of the radiographer or radiographers assistant audited;

(ii) A list showing the items checked; and

(iii) Any non-compliance observed by the individual responsible for radiation protection.

(H) Operators of analytical, cabinet, hand-held and miniature radioscopic systems are exempt from the requirements of paragraphs (C), (D), and (E) of this rule, and shall be required to receive training and demonstrated competence in the following:

(1) The safe operation procedures for the equipment;

(2) Precautions and measures to take to minimize radiation exposure;

(3) Significance of the various radiation warning, safety devices, and interlocks incorporated into the systems, or the reasons they have not been installed on certain parts of the systems and the extra precautions required in such cases;

(4) Recognition of the potential hazards of use, biological effects of radiation, radiation risks, and recognition of signs and symptoms of an acute localized exposure;

(5) Procedures for reporting an actual or suspected accidental exposure or other radiation safety concerns, such as any unusual occurrence or malfunction that may involve exposure to radiation; and

(6) Performing surveys where applicable.

(I) Operators of permanent radiographic installations that meet the design requirements of rule 3701:1-68-06 of the Administrative Code and operators of radiographic particle accelerators, or bomb detection systems are required to meet the training topics of paragraph (C)(1) of this rule, but are exempt from the requirements of paragraphs (C)(2) and (E) of this rule.

(J) The director may, upon application thereof or upon his or her own initiative, grant a variance to the requirements of this chapter as he or she determines is authorized by law, provided that the registrant shows to the satisfaction of the director that there is good cause for the variance, and that the variance will not result in any undue hazard or effect on the public health and safety or environment. The terms, conditions, and expiration of the variance shall be set forth in writing by the director. Failure to comply with the terms of the variance may result in immediate revocation of the variance.