Ohio Administrative Code

Rule 3701:1-50-24 Quality assurance requirements.

Effective: February 15, 2021

(A) This rule describes quality assurance requirements applying to design, purchase, fabrication, handling, shipping, storing, cleaning, assembly, inspection, testing, operation, maintenance, repair, and modification of components of packaging that are important to safety. As used in this rule, "quality assurance" comprises all those planned and systematic actions necessary to provide adequate confidence that a system or component will perform satisfactorily in service. Quality assurance includes quality control, which comprises those quality assurance actions related to control of the physical characteristics and quality of the material or component to predetermined requirements. Each licensee is responsible for satisfying the quality assurance requirements that apply to its use of a packaging for the shipment of licensed material subject to this rule.

(B) Each licensee shall establish, maintain, and execute a quality assurance program satisfying each of the applicable criteria of this chapter and satisfying any specific provisions that are applicable to the licensee's activities including procurement of packaging. The licensee shall execute the applicable criteria in a graded approach to an extent that is commensurate with the quality assurance requirement's importance to safety.

(C) Before the use of any package for the shipment of licensed material subject to this rule, each licensee shall obtain the director's approval of its quality assurance program. Each licensee shall file a description of its quality assurance program, including a discussion of which requirements of this chapter are applicable and how they will be satisfied, by submitting the description to the address in rule 3701:1-50-03 of the Administrative Code.

(D) A program for transport container inspection and maintenance limited to radiographic exposure devices, source changers, or packages transporting these devices and meeting the requirements of paragraph (B) of rule 3701:1-48-11 of the Administrative Code or equivalent United States nuclear regulatory commission or agreement state requirements, is deemed to satisfy the requirements of paragraph (B) of rule 3701:1-50-07 of the Administrative Code and paragraph (B) of this rule.

(E) The licensee shall be responsible for the establishment and execution of the quality assurance program. The licensee may delegate to others, such as contractors, agents, or consultants, the work of establishing and executing the quality assurance program, or any part of the quality assurance program, but shall retain responsibility for the program. These activities include performing the functions associated with attaining quality objectives and the quality assurance functions.

(F) The quality assurance functions are:

(1) Assuring that an appropriate quality assurance program is established and effectively executed; and

(2) Verifying, by procedures such as checking, auditing, and inspection, that activities affecting the functions that are important to safety have been correctly performed.

(G) The persons and organizations performing quality assurance functions must have sufficient authority and organizational freedom to:

(1) Identify quality problems;

(2) Initiate, recommend, or provide solutions; and

(3) Verify implementation of solutions.

(H) The persons and organizations performing quality assurance functions shall report to a management level that assures that the required authority and organizational freedom, including sufficient independence from cost and schedule, when opposed to safety considerations, are provided.

(I) Because of the many variables involved, such as the number of personnel, the type of activity being performed, and the location or locations where activities are performed, the organizational structure for executing the quality assurance program may take various forms, provided that the persons and organizations assigned the quality assurance functions have the required authority and organizational freedom.

(J) Irrespective of the organizational structure, the individual(s) assigned the responsibility for assuring effective execution of any portion of the quality assurance program, at any location where activities subject to this chapter are being performed, must have direct access to the levels of management necessary to perform this function.

(K) The licensee shall establish, at the earliest practicable time consistent with the schedule for accomplishing the activities, a quality assurance program that complies with the requirements of this chapter. The licensee shall document the quality assurance program by written procedures or instructions and shall carry out the program in accordance with those procedures throughout the period during which the packaging is used. The licensee shall identify the material and components to be covered by the quality assurance program, the major organizations participating in the program, and the designated functions of these organizations.

(L) The licensee, through its quality assurance program, shall provide control over activities affecting the quality of the identified materials and components to an extent consistent with their importance to safety, and as necessary to assure conformance to the approved design of each individual package used for the shipment of radioactive material. The licensee shall assure that activities affecting quality are accomplished under suitably controlled conditions. Controlled conditions include the use of appropriate equipment; suitable environmental conditions for accomplishing the activity, such as adequate cleanliness; and assurance that all prerequisites for the given activity have been satisfied. The licensee shall take into account the need for special controls, processes, test equipment, tools, and skills to attain the required quality, and the need for verification of quality by inspection and test.

(M) The licensee shall base the requirements and procedures of its quality assurance program on the following considerations concerning the complexity and proposed use of the package and its components:

(1) The impact of malfunction or failure of the item to safety;

(2) The design and fabrication complexity or uniqueness of the item;

(3) The need for special controls and surveillance over processes and equipment;

(4) The degree to which functional compliance can be demonstrated by inspection or test; and

(5) The quality history and degree of standardization of the item.

(N) The licensee shall provide for orientation and training of personnel performing activities affecting quality, as necessary to assure that suitable proficiency is achieved and maintained. The licensee shall review the status and adequacy of the quality assurance program at established intervals. Management of other organizations participating in the quality assurance program shall review regularly the status and adequacy of that part of the quality assurance program they are executing.

(O) Each quality assurance program approval holder shall submit, in accordance with rule 3701:1-50-03 of the Administrative Code, a description of a proposed change to its director approved quality assurance program that will reduce commitments in the program description as approved by the director. The quality assurance program approval holder shall not implement the change before receiving director approval. The description of a proposed change to the director approved quality assurance program must identify the change, the reason for the change, and the basis for concluding that the revised program incorporating the change continues to satisfy the applicable requirements of this chapter.

(P) Each quality assurance program approval holder may change a previously approved quality assurance program without prior director approval, if the change does not reduce the commitments in the quality assurance program previously approved by the director. Changes to the quality assurance program that do not reduce the commitments shall be submitted to the director every twenty four months, in accordance with rule 3701:1-50-03 of the Administrative Code. In addition to quality assurance program changes involving administrative improvements and clarifications, spelling corrections, and non-substantive changes to punctuation or editorial items, the following changes are not considered reductions in commitment:

(1) The use of a quality assurance standard approved by the director that is more recent than the quality assurance standard in the licensee's current quality assurance program at the time of the

change. The use of a quality assurance standard approved by the director that is more recent than the quality assurance standard in the licensee's current quality assurance program at the time of the change;

(2) The use of generic organizational position titles that clearly denote the position function, supplemented as necessary by descriptive text, rather than specific titles, provided that there is no substantive change to either the functions of the position or reporting responsibilities;

(3) The use of generic organizational charts to indicate functional relationships, authorities, and responsibilities, or alternatively, the use of descriptive text, provided that there is no substantive change to the functional relationships, authorities, or responsibilities;

(4) The elimination of quality assurance program information that duplicates language in quality assurance regulatory guides and quality assurance standards to which the quality assurance program approval holder has committed to on record; and

(5) Organizational revisions that ensure that persons and organizations performing quality assurance functions continue to have the requisite authority and organizational freedom, including sufficient independence from cost and schedule when opposed to safety considerations.

(Q) Each quality assurance program approval holder shall maintain records of quality assurance program changes.

(R) The licensee shall maintain sufficient written records to describe the activities affecting quality. These records must include changes to the quality assurance program as required by this chapter, the instructions, procedures, and drawings required by 10 C.F.R. 71.111 (as in effect on the effective date of this rule) to prescribe quality assurance activities, and closely related specifications such as required qualifications of personnel, procedures, and equipment. The records must include the instructions or procedures that establish a records retention program that is consistent with applicable regulations and designates factors such as duration, location, and assigned responsibility. The licensee shall retain these records for three years beyond the date when the licensee last engage in the activity for which the quality assurance program was developed. If any portion of the quality assurance program, written procedures or instructions is superseded, the licensee shall retain the

superseded material for three years after it is superseded.