

3701:1-50-24 Quality assurance requirements.

- (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. The licensee, certificate holder, and applicant for a CoC are responsible for the quality assurance requirements as they apply to design, fabrication, testing, and modification of packaging. Each licensee is responsible for the quality assurance provision which applies to its use of a packaging for the shipment of licensed material subject to this rule.
- (B) Each licensee, certificate holder, and applicant for a CoC shall establish, maintain, and execute a quality assurance program satisfying each of the applicable criteria of 10 C.F.R. 71.101 to 71.137 (as published in the January 1, 2014 Code of Federal Regulations) and satisfying any specific provisions that are applicable to the licensee's activities including procurement of packaging. The licensee, certificate holder, and applicant for a CoC 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 United States nuclear regulatory commission approval of its quality assurance program.
- (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, certificate holder, and applicant for a CoC shall be responsible for the establishment and execution of the quality assurance program. The licensee, certificate holder, and applicant for a CoC 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. The licensee shall clearly establish and delineate, in writing, the authority and duties of persons and organizations performing activities affecting the safety-related functions of structures, systems, and components. These activities include performing the functions associated with attaining quality objectives and the quality assurance functions. While the term licensee is used in these criteria, the requirements are applicable to whatever design, fabrication, assembly, and testing of the package is accomplished with respect to a package before the time a package approval is issued.
- (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 safety-related functions have been performed correctly.
- (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 licensee, certificate holder, and applicant for a CoC 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, certificate holder, and applicant for a CoC 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.

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Certification

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Date

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