

WAC 246-231-150 Quality assurance requirements. (1) Purpose.

This section describes quality assurance requirements that apply 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 chapter, "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 and applicant for a package approval is responsible for satisfying the quality assurance requirements that apply to design, fabrication, testing, and modification of packaging subject to this chapter. Each licensee is responsible for satisfying the quality assurance requirements that apply to its use of packaging for the shipment of licensed material subject to this chapter.

(2) Establishment of program. Each licensee, certificate holder, and applicant for a certificate of compliance shall establish, maintain, and execute a quality assurance program satisfying each of the applicable criteria in 10 C.F.R. 71.101 through 71.137 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 certificate of compliance shall execute the applicable criteria in a graded approach to an extent that is commensurate with the quality assurance requirement's importance to safety.

(3) Approval of program. Before the use of any package for the shipment of licensed material subject to this chapter, each licensee shall obtain the department's approval of its quality assurance program. Using an appropriate method listed in 10 C.F.R. 71.1(a), each licensee shall file a description of its quality assurance program, including a discussion of which requirements of 10 C.F.R. 71 Subpart H are applicable and how they will be satisfied, by submitting the description to the department.

(4) Radiography containers. 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 WAC 246-243-120(2), 10 C.F.R. 34.31(b), or equivalent agreement state requirements, is deemed to satisfy the requirements of WAC 246-231-060(2) and 246-231-150(2).

[Statutory Authority: RCW 70A.388.040 and 70A.388.110. WSR 22-11-063, § 246-231-150, filed 5/16/22, effective 6/16/22. Statutory Authority: RCW 70.98.050 and 70.98.110. WSR 17-01-034, § 246-231-150, filed 12/12/16, effective 1/12/17. Statutory Authority: RCW 70.98.050. WSR 14-09-017, § 246-231-150, filed 4/7/14, effective 5/8/14; WSR 08-09-093, § 246-231-150, filed 4/18/08, effective 5/19/08.]