

WAC 246-231-170 Quality assurance program. (1) The licensee, certificate holder, and applicant for a certificate of compliance 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 10 C.F.R. 71.101 through 71.137. The licensee, certificate holder, and applicant for a certificate of compliance 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, certificate holder, and applicant for a certificate of compliance 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.

(2) The licensee, certificate holder, and applicant for a certificate of compliance, 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, certificate holder, and applicant for a certificate of compliance 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, certificate holder, and applicant for a certificate of compliance 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.

(3) The licensee, certificate holder, and applicant for a certificate of compliance 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:

- (a) The impact of malfunction or failure of the item to safety;
- (b) The design and fabrication complexity or uniqueness of the item;
- (c) The need for special controls and surveillance over processes and equipment;
- (d) The degree to which functional compliance can be demonstrated by inspection or test; and
- (e) The quality history and degree of standardization of the item.

(4) The licensee, certificate holder, and applicant for a certificate of compliance shall provide for indoctrination 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 certificate of compliance 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.

[Statutory Authority: RCW 70.98.050. WSR 14-09-017, § 246-231-170, filed 4/7/14, effective 5/8/14; WSR 08-09-093, § 246-231-170, filed 4/18/08, effective 5/19/08.]