

§71.103

10 CFR Ch. I (1–1–10 Edition)

Appendix B of part 50 of this chapter, or subpart G of part 72 of this chapter, and that is established, maintained, and executed regarding transport packages, will be accepted as satisfying the requirements of paragraph (b) of this section. Before first use, the licensee, certificate holder, and applicant for a CoC shall notify the NRC, in accordance with §71.1, of its intent to apply its previously approved subpart H, Appendix B, or subpart G quality assurance program to transportation activities. The licensee, certificate holder, and applicant for a CoC shall identify the program by date of submittal to the Commission, Docket Number, and date of Commission approval.

(g) *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 §34.31(b) of this chapter or equivalent Agreement State requirement, is deemed to satisfy the requirements of §§71.17(b) and 71.101(b).

§71.103 Quality assurance organization.

(a) The licensee,² 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. These activities include performing the functions associated with attaining quality objectives and the quality assurance functions.

(b) The quality assurance functions are—

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

²While 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.

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

(c) 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.

(d) 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.

(e) 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.

(f) 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 section are being performed, must have direct access to the levels of management necessary to perform this function.

§71.105 Quality assurance program.

(a) The licensee, certificate holder, and applicant for a CoC 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 §§71.101 through 71.137. The licensee, certificate holder, and applicant for a CoC 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