§ 71.103 Quality assurance organization.

(a) 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 shall identify the program by date of submittal to the Commission, Docket Number, and date of Commission approval.

(b) The quality assurance functions are—

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

(2) Obtaining Commission approval of quality assurance programs.

(c) The provisions of paragraph (b) of this section are applicable to the establishment and execution of the quality assurance program.

(d) Existing package designs. The provisions of this paragraph deal with packages that have been approved for use in accordance with this part before January 1, 1979, and which have been designed in accordance with the provisions of this part in effect at the time of application for package approval. Those packages will be accepted as having been designed in accordance with a quality assurance program that satisfies the provisions of paragraph (b) of this section.

(e) Existing packages. The provisions of this paragraph deal with packages that have been approved for use in accordance with this part before January 1, 1979, have been at least partially fabricated before that date, and for which the fabrication is in accordance with the provisions of this part in effect at the time of application for approval of package design. These packages will be accepted as having been fabricated and assembled in accordance with a quality assurance program that satisfies the provisions of paragraph (b) of this section.

(f) Previously approved programs. A Commission-approved quality assurance program that satisfies the applicable criteria of subpart H of this part, Appendix B of part 50 of this chapter, or subpart G of part 72 of this chapter, and that is 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 §§34.33(b) of this chapter or equivalent Agreement State requirement, is deemed to satisfy the requirements of §§71.17(b) and 71.101(b).
(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 used. The licensee, certificate holder, and applicant for a CoC 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.

(b) The licensee, certificate holder, and applicant for a CoC, 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 CoC 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 CoC 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.

(c) The licensee, certificate holder, and applicant for a CoC 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.

(d) The licensee, certificate holder, and applicant for a CoC shall provide for indoctrination and training of personnel performing activities affecting quality, as necessary to assure that