(2) For any violation for which a license may be revoked under section 186 of the Atomic Energy Act of 1954, as amended.

§ 71.100 Criminal penalties.

(a) Section 223 of the Atomic Energy Act of 1954, as amended, provides for criminal sanctions for willful violation of, attempted violation of, or conspiracy to violate, any regulation issued under sections 161b, 161i, or 161o of the Act. For purposes of section 223, all the regulations in part 71 are issued under one or more of sections 161b, 161i, or 161o, except for the sections listed in paragraph (b) of this section.

(b) The regulations in part 71 that are not issued under sections 161b, 161i, or 161o for the purposes of section 223 are as follows: §§ 71.0, 71.2, 71.4, 71.6, 71.7, 71.10, 71.31, 71.33, 71.35, 71.37, 71.38, 71.39, 71.40, 71.41, 71.43, 71.45, 71.47, 71.51, 71.55, 71.59, 71.65, 71.71, 71.73, 71.74, 71.75, 71.77, 71.99, and 71.100.

[60 FR 50264, Sept. 28, 1995, as amended at 69 FR 3796, Jan. 26, 2004]

Subpart H—Quality Assurance

SOURCE: 69 FR 3796, Jan. 26, 2004, unless otherwise noted.

§ 71.101 Quality assurance requirements.

(a) *Purpose.* This subpart 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 subpart, ''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 subpart.

(b) *Establishment of program.* 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 §§ 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 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) *Approval of program.* (1) Before the use of any package for the shipment of licensed material subject to this subpart, each licensee shall obtain Commission approval of its quality assurance program. Using an appropriate method listed in § 71.1(a), each licensee shall file a description of its quality assurance program, including a discussion of which requirements of this subpart are applicable and how they will be satisfied, by submitting the description to: ATTN: Document Control Desk, Director, Spent Fuel Project Office, Office of Nuclear Material Safety and Safeguards.

(2) Before the fabrication, testing, or modification of any package for the shipment of licensed material subject to this subpart, each licensee, certificate holder, or applicant for a CoC shall obtain Commission approval of its quality assurance program. Each certificate holder or applicant for a CoC shall, in accordance with § 71.1, file a description of its quality assurance program, including a discussion of which requirements of this subpart are applicable and how they will be satisfied.

(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 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

(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

[2] 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.