

§ 72.142 Quality assurance organization.

(a) The licensee, applicant for a license, certificate holder, and applicant for a CoC shall be responsible for the establishment and execution of the quality assurance program. The licensee and certificate holder may delegate to others, such as contractors, agents, or consultants, the work of establishing and executing the quality assurance program, but the licensee and the certificate holder shall retain responsibility for the program. The licensee, applicant for a license, certificate holder, and applicant for a CoC shall clearly establish and delineate in writing the authority and duties of persons and organizations performing activities affecting the functions of structures, systems, and components which are important to safety. 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. The persons and organizations performing quality assurance functions shall have sufficient authority and organizational freedom to identify quality problems; to initiate, recommend, or provide solutions; and to verify implementation of solutions.

(c) The persons and organizations performing quality assurance functions shall report to a management level that ensures that the required authority and organizational freedom, including sufficient independence from cost and schedule considerations when these considerations are opposed to safety considerations, are provided. 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. 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.

§ 72.144 Quality assurance program.

(a) The licensee, applicant for a license, 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 which complies with the requirements of this subpart. The licensee, applicant for a license, 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 these procedures throughout the period during which the ISFSI or MRS is licensed or the spent fuel storage cask is certified. The licensee, applicant for a license, certificate holder, and applicant for a CoC shall identify the structures, systems, 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, applicant for a license, certificate holder, and applicant for a CoC, through their quality assurance program(s), shall provide control over activities affecting the quality of the identified structures, systems, and components to an extent commensurate with the importance to safety and, as necessary, to ensure conformance with the approved design of each ISFSI, MRS, or spent fuel storage cask. The licensee, applicant for a license, certificate holder, and applicant for a CoC shall ensure that activities affecting quality are accomplished under suitably controlled conditions. Controlled conditions include the use of