

4731.0421 QUALITY ASSURANCE ORGANIZATION.

Subpart 1. **Licensee duty.** A licensee is responsible for the establishment and execution of the quality assurance program. 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 prior to the time a package approval is issued.

Subp. 2. **Delegation permitted.** A licensee 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 must retain responsibility for the program.

Subp. 3. **Delegation requirements.** A licensee must clearly establish and delineate, in writing, the authority and duties of persons and organizations performing activities affecting the safety-related functions of structures, systems, and components. These activities include performing the functions associated with attaining quality objectives and the quality assurance functions.

Subp. 4. **Quality assurance functions.** The quality assurance functions are:

A. ensuring that an appropriate quality assurance program is established and effectively executed; and

B. verifying, by procedures such as checking, auditing, and inspection, that activities affecting the safety-related functions have been performed correctly.

Subp. 5. **Required authority.** The persons and organizations performing quality assurance functions must have sufficient authority and organizational freedom to:

A. identify quality problems;

B. initiate, recommend, or provide solutions; and

C. verify implementation of solutions.

Subp. 6. **Management.** The persons and organizations performing quality assurance functions must report to a management level that ensures that the required authority and organizational freedom, including sufficient independence from cost and schedule, when opposed to safety considerations, are provided.

Subp. 7. **Organizational structure.** Because of many variables involved, such as the number of personnel, the type of activity being performed, and the location 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.

Subp. 8. **Access to management.** Irrespective of the organizational structure, the individuals assigned the responsibility for ensuring effective execution of any portion of the quality assurance program, at any location where activities subject to parts 4731.0400 to 4731.0455 are being performed, must have direct access to the levels of management necessary to perform this function.

Statutory Authority: *MS s 144.1202; 144.1203*

History: *29 SR 755; 32 SR 831*

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