

WAC 246-231-160 Quality assurance organization. (1) The licensee, certificate holder, and applicant for a certificate of compliance shall be responsible for the establishment and execution of the quality assurance program. The licensee, certificate holder, and applicant for a certificate of compliance 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.

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.

(2) The quality assurance functions are:

(a) Assuring 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 functions that are important to safety have been correctly performed.

(3) 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.

(4) 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.

(5) 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.

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

[Statutory Authority: RCW 70.98.050 and 70.98.110. WSR 17-01-034, § 246-231-160, filed 12/12/16, effective 1/12/17. Statutory Authority: RCW 70.98.050. WSR 08-09-093, § 246-231-160, filed 4/18/08, effective 5/19/08.]