

(n) *Handling, storage, and shipping.* DOE shall establish measures to control the handling, storage, shipping, cleaning and preservation of material and equipment in accordance with work and inspection instructions to prevent damage or deterioration. When necessary for particular products, special protective environments, such as inert gas atmosphere, specific moisture content levels, and temperature levels, must be specified and provided.

(o) *Inspection, test, and operating status.* DOE shall establish measures to indicate the status of inspections and tests performed on individual items of the high-level waste repository by markings such as stamps, tags, labels, routing cards, or other suitable means. These measures must provide for the identification of items that have satisfactorily passed required inspections and tests, where necessary to preclude inadvertent bypassing of such inspections and tests. Measures must also be established for indicating the operating status of structures, systems, and components of the high-level waste repository, such as by tagging valves and switches, to prevent inadvertent operation.

(p) *Nonconforming materials, parts, or components.* DOE shall establish measures to control materials, parts, or components which do not conform to requirements in order to prevent their inadvertent use or installation. These measures must include, as appropriate, procedures for identification, documentation, segregation, disposition, and notification to affected organizations. Nonconforming items must be reviewed and accepted, rejected, repaired or reworked in accordance with documented procedures.

(q) *Corrective action.* DOE shall establish measures to assure that conditions adverse to quality, such as failures, malfunctions, deficiencies, deviations, defective material and equipment, and nonconformances are promptly identified and corrected. If significant conditions are adverse to quality, the measures must assure that the cause of the condition is determined and corrective action taken to preclude repetition. The identification of the significant condition adverse to quality, the cause of the condition, and the corrective ac-

tion taken must be documented and reported to appropriate levels of management.

(r) *Quality assurance records.* DOE shall maintain sufficient records to furnish evidence of activities affecting quality.

(1) The records must include at least the following: Operating logs and the results of reviews, inspections, tests, audits, monitoring of work performance, and materials analyses.

(2) The records must also include closely-related data such as qualifications of personnel, procedures, and equipment.

(3) Inspection and test records must, at a minimum, identify the inspector or data recorder, the type of observation, the results, the acceptability, and the action taken in connection with any deficiencies noted.

(4) Records must be identifiable and retrievable. Consistent with applicable regulatory requirements, the applicant shall establish requirements concerning record retention, such as duration, location, and assigned responsibility.

(s) *Audits.* DOE shall carry out a comprehensive system of planned and periodic audits to verify compliance with all aspects of the quality assurance program and to determine the effectiveness of the program. The audits must be performed in accordance with the written procedures or check lists by appropriately trained personnel not having direct responsibilities in the areas being audited. Audit results must be documented and reviewed by management having responsibility in the area audited. Followup action, including reaudit of deficient areas, must be taken where indicated.

#### **§ 63.143 Implementation.**

DOE shall implement a quality assurance program based on the criteria required by § 63.142.

#### **§ 63.144 Quality assurance program change.**

Changes to DOE's NRC-approved Safety Analysis Report quality assurance program description are processed as follows:

(a) DOE may change a previously accepted quality assurance program description included or referenced in the Safety Analysis Report without prior NRC approval, if the change does not reduce the commitments in the program description previously accepted by the NRC. Changes to the quality assurance program description that do not reduce the commitments must be submitted every 24 months, in accordance with paragraph (b)(1) of this section. In addition to quality assurance program changes involving administrative improvements and clarifications, spelling corrections, punctuation, or editorial items, the following changes are not considered reductions in commitment:

(1) The use of a quality assurance standard approved by the NRC which is more recent than the quality assurance standard in DOE's current quality assurance program at the time of the change;

(2) The use of generic organizational position titles that clearly denote the position function, supplemented as necessary by descriptive text, rather than specific titles;

(3) The use of generic organizational charts to indicate functional relationships, authorities, and responsibilities, or alternatively, the use of descriptive text;

(4) The elimination of quality assurance program information that duplicates language in quality assurance regulatory guides and quality assurance standards to which the licensee is committed; and

(5) Organizational revisions that ensure that persons and organizations performing quality assurance functions continue to have the requisite authority and organizational freedom, including sufficient independence from cost and schedule when opposed to safety considerations.

(b) DOE shall submit changes made to the NRC-accepted Safety Analysis Report quality assurance program description that do reduce the commitments to the NRC and receive NRC approval prior to implementation, as follows:

(1) By an appropriate method listed in §63.4 of this chapter, the signed document must be submitted to the Nu-

clear Regulatory Commission, addressed: ATTN: Document Control Desk; Director, Office of Nuclear Material and Safeguards; U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, and one copy to the appropriate NRC Resident Inspector, if one has been assigned to the site or facility.

(2) The submittal of a change to the Safety Analysis Report quality assurance program description must include all pages affected by that change and must be accompanied by a forwarding letter identifying the change, the reason for the change, and the basis for concluding that the revised program incorporating the change continues to describe how the requirements of §63.142 will be satisfied and continues to satisfy the criteria of §63.142 and the Safety Analysis Report quality assurance program description previously accepted by the NRC (the letter need not provide the basis for changes that correct spelling, punctuation, or editorial items).

(3) DOE shall maintain records of quality assurance program changes that do reduce commitments.

[66 FR 55792, Nov. 2, 2001, as amended at 68 FR 58816, Oct. 10, 2003]

## Subpart H—Training and Certification of Personnel

### § 63.151 General requirements.

Operations of systems and components that have been identified as important to safety in the Safety Analysis Report and in the license must be performed only by trained and certified personnel or by personnel under the direct visual supervision of an individual with training and certification in such operation. Supervisory personnel who direct operations that are important to safety must also be certified in such operations.

### § 63.152 Training and certification program.

DOE shall establish a program for training, proficiency testing, certification, and requalification of operating and supervisory personnel.