

§ 830.121 Quality Assurance Program (QAP).

(a) Contractors conducting activities, including providing items or services, that affect, or may affect, the nuclear safety of DOE nuclear facilities must conduct work in accordance with the Quality Assurance criteria in § 830.122.

(b) The contractor responsible for a DOE nuclear facility must:

(1) Submit a QAP to DOE for approval and regard the QAP as approved 90 days after submittal, unless it is approved or rejected by DOE at an earlier date.

(2) Modify the QAP as directed by DOE.

(3) Annually submit any changes to the DOE-approved QAP to DOE for approval. Justify in the submittal why the changes continue to satisfy the quality assurance requirements.

(4) Conduct work in accordance with the QAP.

(c) The QAP must:

(1) Describe how the quality assurance criteria of § 830.122 are satisfied.

(2) Integrate the quality assurance criteria with the Safety Management System, or describe how the quality assurance criteria apply to the Safety Management System.

(3) Use voluntary consensus standards in its development and implementation, where practicable and consistent with contractual and regulatory requirements, and identify the standards used.

(4) Describe how the contractor responsible for the nuclear facility ensures that subcontractors and suppliers satisfy the criteria of § 830.122.

§ 830.122 Quality assurance criteria.

The QAP must address the following management, performance, and assessment criteria:

(a) Criterion 1—Management/Program.

(1) Establish an organizational structure, functional responsibilities, levels of authority, and interfaces for those managing, performing, and assessing the work.

(2) Establish management processes, including planning, scheduling, and providing resources for the work.

(b) Criterion 2—Management/Personnel Training and Qualification.

(1) Train and qualify personnel to be capable of performing their assigned work.

(2) Provide continuing training to personnel to maintain their job proficiency.

(c) Criterion 3—Management/Quality Improvement.

(1) Establish and implement processes to detect and prevent quality problems.

(2) Identify, control, and correct items, services, and processes that do not meet established requirements.

(3) Identify the causes of problems and work to prevent recurrence as a part of correcting the problem.

(4) Review item characteristics, process implementation, and other quality-related information to identify items, services, and processes needing improvement.

(d) Criterion 4—Management/Documents and Records.

(1) Prepare, review, approve, issue, use, and revise documents to prescribe processes, specify requirements, or establish design.

(2) Specify, prepare, review, approve, and maintain records.

(e) Criterion 5—Performance/Work Processes.

(1) Perform work consistent with technical standards, administrative controls, and other hazard controls adopted to meet regulatory or contract requirements, using approved instructions, procedures, or other appropriate means.

(2) Identify and control items to ensure their proper use.

(3) Maintain items to prevent their damage, loss, or deterioration.

(4) Calibrate and maintain equipment used for process monitoring or data collection.

(f) Criterion 6—Performance/Design.

(1) Design items and processes using sound engineering/scientific principles and appropriate standards.

(2) Incorporate applicable requirements and design bases in design work and design changes.

(3) Identify and control design interfaces.

(4) Verify or validate the adequacy of design products using individuals or groups other than those who performed the work.

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(5) Verify or validate work before approval and implementation of the design.

(g) Criterion 7—Performance/Procurement.

(1) Procure items and services that meet established requirements and perform as specified.

(2) Evaluate and select prospective suppliers on the basis of specified criteria.

(3) Establish and implement processes to ensure that approved suppliers continue to provide acceptable items and services.

(h) Criterion 8—Performance/Inspection and Acceptance Testing.

(1) Inspect and test specified items, services, and processes using established acceptance and performance criteria.

(2) Calibrate and maintain equipment used for inspections and tests.

(i) Criterion 9—Assessment/Management Assessment. Ensure managers assess their management processes and identify and correct problems that hinder the organization from achieving its objectives.

(j) Criterion 10—Assessment/Independent Assessment.

(1) Plan and conduct independent assessments to measure item and service quality, to measure the adequacy of work performance, and to promote improvement.

(2) Establish sufficient authority, and freedom from line management, for the group performing independent assessments.

(3) Ensure persons who perform independent assessments are technically qualified and knowledgeable in the areas to be assessed.

Subpart B—Safety Basis Requirements

§ 830.200 Scope.

This Subpart establishes safety basis requirements for hazard category 1, 2, and 3 DOE nuclear facilities.

§ 830.201 Performance of work.

A contractor must perform work in accordance with the safety basis for a hazard category 1, 2, or 3 DOE nuclear facility and, in particular, with the hazard controls that ensure adequate

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protection of workers, the public, and the environment.

§ 830.202 Safety basis.

(a) The contractor responsible for a hazard category 1, 2, or 3 DOE nuclear facility must establish and maintain the safety basis for the facility.

(b) In establishing the safety basis for a hazard category 1, 2, or 3 DOE nuclear facility, the contractor responsible for the facility must:

(1) Define the scope of the work to be performed;

(2) Identify and analyze the hazards associated with the work;

(3) Categorize the facility consistent with DOE-STD-1027-92 (“Hazard Categorization and Accident Analysis Techniques for compliance with DOE Order 5480.23, Nuclear Safety Analysis Reports,” Change Notice 1, September 1997);

(4) Prepare a documented safety analysis for the facility; and (5) Establish the hazard controls upon which the contractor will rely to ensure adequate protection of workers, the public, and the environment.

(c) In maintaining the safety basis for a hazard category 1, 2, or 3 DOE nuclear facility, the contractor responsible for the facility must:

(1) Update the safety basis to keep it current and to reflect changes in the facility, the work and the hazards as they are analyzed in the documented safety analysis;

(2) Annually submit to DOE either the updated documented safety analysis for approval or a letter stating that there have been no changes in the documented safety analysis since the prior submission; and

(3) Incorporate in the safety basis any changes, conditions, or hazard controls directed by DOE.

§ 830.203 Unreviewed safety question process.

(a) The contractor responsible for a hazard category 1, 2, or 3 DOE nuclear facility must establish, implement, and take actions consistent with a USQ process that meets the requirements of this section.

(b) The contractor responsible for a hazard category 1, 2, or 3 DOE existing nuclear facility must submit for DOE