

used to verify the adequacy of a specific design feature in lieu of other verifying or checking processes, the licensee and certificate holder shall include suitable qualification testing of a prototype or sample unit under the most adverse design conditions. The licensee, applicant for a license, certificate holder, and applicant for a CoC shall apply design control measures to items such as the following: criticality physics, radiation, shielding, stress, thermal, hydraulic, and accident analyses; compatibility of materials; accessibility for inservice inspection, maintenance, and repair; features to facilitate decontamination; and delineation of acceptance criteria for inspections and tests.

(c) The licensee, applicant for a license, certificate holder, and applicant for a CoC shall subject design changes, including field changes, to design control measures commensurate with those applied to the original design. Changes in the conditions specified in the license or CoC require prior NRC approval.

§ 72.148 Procurement document control.

The licensee, applicant for a license, certificate holder, and applicant for a CoC shall establish measures to assure that applicable regulatory requirements, design bases, and other requirements which are necessary to assure adequate quality are included or referenced in the documents for procurement of material, equipment, and services, whether purchased by the licensee, certificate holder, or by their contractors and subcontractors. To the extent necessary, the licensee, applicant for a license, certificate holder, and applicant for a CoC, shall require contractors or subcontractors to provide a quality assurance program consistent with the applicable provisions of this subpart.

§ 72.150 Instructions, procedures, and drawings.

The licensee, applicant for a license, certificate holder, and applicant for a CoC shall prescribe activities affecting quality by documented instructions, procedures, or drawings of a type appropriate to the circumstances and

shall require that these instructions, procedures, and drawings be followed. The instructions, procedures, and drawings must include appropriate quantitative or qualitative acceptance criteria for determining that important activities have been satisfactorily accomplished.

§ 72.152 Document control.

The licensee, applicant for a license, certificate holder, and applicant for a CoC shall establish measures to control the issuance of documents such as instructions, procedures, and drawings, including changes, which prescribe all activities affecting quality. These measures must assure that documents, including changes, are reviewed for adequacy, approved for release by authorized personnel, and distributed and used at the location where the prescribed activity is performed. These measures must ensure that changes to documents are reviewed and approved.

§ 72.154 Control of purchased material, equipment, and services.

(a) The licensee, applicant for a license, certificate holder, and applicant for a CoC shall establish measures to ensure that purchased material, equipment, and services, whether purchased directly or through contractors and subcontractors, conform to the procurement documents. These measures must include provisions, as appropriate, for source evaluation and selection, objective evidence of quality furnished by the contractor or subcontractor, inspection at the contractor or subcontractor source, and examination of products upon delivery.

(b) The licensee, applicant for a license, certificate holder, and applicant for a CoC shall have available documentary evidence that material and equipment conform to the procurement specifications prior to installation or use of the material and equipment. The licensee and certificate holder shall retain or have available this documentary evidence for the life of the ISFSI, MRS, or spent fuel storage cask. The licensee and certificate holder shall ensure that the evidence is sufficient to identify the specific requirements met by the purchased material and equipment.

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(c) The licensee, applicant for a license, certificate holder, and applicant for a CoC, or a designee of either, shall assess the effectiveness of the control of quality by contractors and sub-contractors at intervals consistent with the importance, complexity, and quantity of the product or services.

§ 72.156 Identification and control of materials, parts, and components.

The licensee, applicant for a license, certificate holder, and applicant for a CoC shall establish measures for the identification and control of materials, parts, and components. These measures must ensure that identification of the item is maintained by heat number, part number, serial number, or other appropriate means, either on the item or on records traceable to the item as required, throughout fabrication, installation, and use of the item. These identification and control measures must be designed to prevent the use of incorrect or defective materials, parts, and components.

§ 72.158 Control of special processes.

The licensee, applicant for a license, certificate holder, and applicant for a CoC shall establish measures to ensure that special processes, including welding, heat treating, and nondestructive testing, are controlled and accomplished by qualified personnel using qualified procedures in accordance with applicable codes, standards, specifications, criteria, and other special requirements.

§ 72.160 Licensee and certificate holder inspection.

The licensee, applicant for a license, certificate holder, and applicant for a CoC shall establish and execute a program for inspection of activities affecting quality by or for the organization performing the activity to verify conformance with the documented instructions, procedures, and drawings for accomplishing the activity. The inspection must be performed by individuals other than those who performed the activity being inspected. Examinations, measurements, or tests of material or products processed must be performed for each work operation where necessary to assure quality. If direct in-

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spection of processed material or products cannot be carried out, indirect control by monitoring processing methods, equipment, and personnel must be provided. Both inspection and process monitoring must be provided when quality control is inadequate without both. If mandatory inspection hold points that require witnessing or inspecting by the licensee's or certificate holder's designated representative, and beyond which work should not proceed without the consent of its designated representative, are required, the specific hold points must be indicated in appropriate documents.

§ 72.162 Test control.

The licensee, applicant for a license, certificate holder, and applicant for a CoC shall establish a test program to ensure that all testing, required to demonstrate that the structures, systems, and components will perform satisfactorily in service, is identified and performed in accordance with written test procedures that incorporate the requirements of this part and the requirements and acceptance limits contained in the ISFSI, MRS, or spent fuel storage cask license or CoC. The test procedures must include provisions to ensure that all prerequisites for the given test are met, that adequate test instrumentation is available and used, and that the test is performed under suitable environmental conditions. The licensee, applicant for a license, certificate holder, and applicant for a CoC shall document and evaluate the test results to ensure that test requirements have been satisfied.

§ 72.164 Control of measuring and test equipment.

The licensee, applicant for a license, certificate holder, and applicant for a CoC shall establish measures to ensure that tools, gauges, instruments, and other measuring and testing devices used in activities affecting quality are properly controlled, calibrated, and adjusted at specified periods to maintain accuracy within necessary limits.

§ 72.166 Handling, storage, and shipping control.

The licensee, applicant for a license, certificate holder, and applicant for a