§ 72.146 Design control.

(a) The licensee, applicant for a license, certificate holder, and applicant for a CoC shall establish measures to ensure that applicable regulatory requirements and the design basis, as specified in the license or CoC application for those structures, systems, and components to which this section applies, are correctly translated into specifications, drawings, procedures, and instructions. These measures must include provisions to ensure that appropriate quality standards are specified and included in design documents and that deviations from standards are controlled. Measures must be established for the selection and review for suitability of application of materials, parts, equipment, and processes that are essential to the functions of the structures, systems, and components which are important to safety.

(b) The licensee, applicant for a license, certificate holder, and applicant for a CoC shall establish measures for the identification and control of design interfaces and for coordination among participating design organizations. These measures must include the establishment of written procedures among participating design organizations for the review, approval, release, distribution, and revision of documents involving design interfaces. The design control measures must provide for verifying or checking the adequacy of design by methods such as design reviews, alternate or simplified calculational methods, or by a suitable testing program. For the verifying or checking process, the licensee and certificate holder shall designate individuals or groups other than those who were responsible for the original design, but who may be from the same organization. Where a test program is 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,
§ 72.148 Procurement 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.

§ 72.150 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.

(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 subcontractors at intervals consistent with the importance, complexity, and quantity of the product or services.