§ 71.107 Package design control.

(a) The licensee, certificate holder, and applicant for a CoC shall establish measures to assure that applicable regulatory requirements and the package design, as specified in the license or CoC for those materials and components to which this section applies, are correctly translated into specifications, drawings, procedures, and instructions. These measures must include provisions to assure 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 materials, parts, and components of the packaging that are important to safety.

(b) The licensee, 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 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, certificate holder, and applicant for a CoC shall include suitable qualification testing of a prototype or sample unit under the most adverse design conditions. The licensee, certificate holder, and applicant for a CoC shall apply design control measures to the following:

1. Criticality physics, radiation shielding, stress, thermal, hydraulic, and accident analyses;
2. Compatibility of materials;
3. Accessibility for in-service inspection, maintenance, and repair;
4. Features to facilitate decontamination; and
5. Delineation of acceptance criteria for inspections and tests.

The licensee, 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 CoC require prior NRC approval.

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

(a) The licensee, certificate holder, and applicant for a CoC shall establish measures to assure 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 on delivery.

(b) The licensee, certificate holder, and applicant for a CoC shall have available documentary evidence that material and equipment conform to the procurement specifications before installation or use of the material and equipment. The licensee, certificate holder, and applicant for a CoC shall retain, or have available, this documentary evidence for the life of the package to which it applies. The licensee, certificate holder, and applicant for a CoC shall assure that the evidence is sufficient to identify the specific requirements met by the purchased material and equipment.

(c) The licensee, certificate holder, and applicant for a CoC 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.