

**§71.111 Instructions, procedures, and drawings.**

The licensee, 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.

**§71.113 Document control.**

The licensee, certificate holder, and applicant for a CoC shall establish measures to control the issuance of documents such as instructions, procedures, and drawings, including changes, that 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.

**§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.

**§71.117 Identification and control of materials, parts, and components.**

The licensee, certificate holder, and applicant for a CoC shall establish measures for the identification and control of materials, parts, and components. These measures must assure that identification of the item is maintained by heat number, part 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.

**§71.119 Control of special processes.**

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

**§71.121 Internal inspection.**

The licensee, 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. Examination, measurements, or tests of material or products processed must be performed for each work operation where necessary to assure quality. If direct inspection of processed material or products is not carried out, indirect

## Nuclear Regulatory Commission

## § 71.133

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, which require witnessing or inspecting by the licensee'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.

### § 71.123 Test control.

The licensee, certificate holder, and applicant for a CoC shall establish a test program to assure that all testing required to demonstrate that the packaging 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 package approval. The test procedures must include provisions for assuring 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, certificate holder, and applicant for a CoC shall document and evaluate the test results to assure that test requirements have been satisfied.

### § 71.125 Control of measuring and test equipment.

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

### § 71.127 Handling, storage, and shipping control.

The licensee, certificate holder, and applicant for a CoC shall establish measures to control, in accordance with instructions, the handling, storage, shipping, cleaning, and preservation of materials and equipment to be

used in packaging to prevent damage or deterioration. When necessary for particular products, special protective environments, such as inert gas atmosphere, and specific moisture content and temperature levels must be specified and provided.

### § 71.129 Inspection, test, and operating status.

(a) The licensee, certificate holder, and applicant for a CoC shall establish measures to indicate, by the use of markings such as stamps, tags, labels, routing cards, or other suitable means, the status of inspections and tests performed upon individual items of the packaging. These measures must provide for the identification of items that have satisfactorily passed required inspections and tests, where necessary to preclude inadvertent bypassing of the inspections and tests.

(b) The licensee shall establish measures to identify the operating status of components of the packaging, such as tagging valves and switches, to prevent inadvertent operation.

### § 71.131 Nonconforming materials, parts, or components.

The licensee, certificate holder, and applicant for a CoC shall establish measures to control materials, parts, or components that do not conform to the licensee's requirements 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.

### § 71.133 Corrective action.

The licensee, certificate holder, and applicant for a CoC shall establish measures to assure that conditions adverse to quality, such as deficiencies, deviations, defective material and equipment, and nonconformances, are promptly identified and corrected. In the case of a significant condition adverse to quality, the measures must assure that the cause of the condition is determined and corrective action