§71.111

§ 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