

§71.119

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 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

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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.