AUTHENTICATED
U.S. GOVERNMENT
INFORMATION
GPO

(1) The standard material component requirements of part 160 of this chapter with which the component complies; or

(2) The Use Code(s) of the component.

(g) A statement indicating the specific provision(s) of this subchapter with which the component complies.

(h) A copy of the records of all required production tests performed on the component lots that are covered by the affidavit.

§ 164.019–13 Production quality control requirements.

(a) *General*. Each component manufacturer shall establish procedures for maintaining quality control of the materials used in production, manufacturing operations, and the finished product.

(b) *Recognized laboratory oversight*. Each manufacturer of non-standard components shall supplement its procedures for assuring production quality control with a program of oversight by a recognized laboratory, as described in the oversight procedures submitted to the Coast Guard in accordance with § 164.019–7(c)(9). The laboratory's oversight program must be performed at the place of manufacture unless alternate procedures have been accepted by the Commandant.

(c) *Production tests and inspections*. Production tests and inspections must be conducted in accordance with this section and subpart 159.007 of this chapter.

(d) *Responsibilities; component manufacturers*. Each component manufacturer shall—

(1) Perform all production tests and inspections required by the applicable subpart of this part;

(2) Adhere to the accepted quality control procedures for the component as submitted to the Coast Guard in accordance with § 164.019–7(c)(8); and

(3) Establish a continuing program of employee training and a program for maintaining production and test equipment.

(e) *Responsibilities; recognized laboratories*. The same recognized laboratory that performed the acceptance testing shall, at least quarterly, or more frequently if required by the applicable subpart of this part or by the oversight procedures submitted in accordance with § 164.019–7(c)(9)—

(1) Audit the component manufacturer's records required by § 164.019–15;

(2) Perform, or supervise the performance of, the tests required by this section, the applicable subpart of this part, and the accepted quality control and oversight procedures; and

(3) Verify, during each inspection, compliance by the manufacturer with the manufacturer's established quality control program and provide a summary report of any noncompliance to the Commandant at least annually.

(f) *Component lots*—(1) *Lot numbers*. The manufacturer shall assign a lot number to each group of components manufactured. A new lot must be started whenever any change is made in materials, design, or production method, and whenever any substantial discontinuity in the manufacturing process (such as a change in shift) occurs. Changes in lots of incoming materials must be treated as changes in materials. Lots must be numbered serially. The lot number assigned, in combination with the unique product name or identification, must enable the component manufacturer (or supplier), by referring to the records required by this subpart, to determine the source(s) of all raw materials used in that lot.

(2) *Lot size*. The maximum lot size for any particular component must be as defined in the applicable subpart of this part.

(g) *Samples*. (1) Procedures for selection of test samples, and required sample sizes, must be in accordance with the applicable subpart of this part.

(2) The inspector shall select different samples than were tested by the manufacturer.

(h) *Detailed product examination*—(1) *General*. In addition to the tests and inspections required by the applicable subpart of this part, the manufacturer or the inspector shall examine each sample component to determine that—

(i) The construction, markings, and workmanship conform to the information submitted in the request for acceptance; and

(ii) The component is not otherwise defective.

(2) *Inspection responsibility*. The manufacturer shall ensure that the inspection required by paragraph (h)(1) of this section is performed by a manufacturer's representative familiar with the performance requirements for the component, and all of the production quality control requirements. The manufacturer's representative must not be responsible for meeting production schedules, or be subject to supervision by someone responsible for meeting production schedules.

(i) [Reserved]

(j) *Accept/reject criteria*. (1) A component lot passes production testing and is therefore accepted if each sample tested passes each test.

(2) A lot having a production test failure may be accepted if it meets the following additional test requirements.

(i) When the basis of acceptability is an average result, a second sampling with an identical number of samples is taken. The results of this second sampling must be averaged with the initial results. If the average result passes the test, then the lot may be accepted.

(ii) When the basis of acceptability is individual sample results, a second sampling is taken. The size of the second sampling must be as specified in the subpart of this part which covers the component. If each sample in this sampling passes the test, the lot may be accepted.

(3) A rejected lot of components may be resubmitted for testing, examination, or inspection if—

(i) The manufacturer first removes each component having the same type of defect or;

(ii) After obtaining authorization from the Commandant or the recognized laboratory, the manufacturer reworks the lot to correct the defect.

(4) A rejected lot or rejected component may not be sold or offered for sale with the representation that it meets the requirements of this subpart or is accepted by the Coast Guard, and may not be used in the construction of Coast Guard-approved PFDs.

(k) *Facilities and equipment*—(1) *General*. The manufacturer shall provide the test equipment and facilities for performing production tests, examinations, and inspections described in the applicable subpart of this part and in the quality control and oversight procedures submitted in accordance with § 164.019–7(c) (8) and (9).

(2) *Calibration*. The manufacturer shall have the calibration of all test equipment checked at least every 6 months by a weights and measures agency or by the equipment manufacturer, distributor, or dealer.

(3) *Facilities for inspector's use*. The manufacturer shall provide a suitable place and the necessary apparatus for the inspector to use in conducting or supervising tests. For the detailed product examination, the manufacturer shall provide a suitable working environment and a smooth-top table for the inspector's use.

(4) *Access to facilities*. The manufacturer shall permit the inspector to have access to any place in the factory where work is being done on PFD components or where components are stored. The inspector may take samples of parts or materials entering into production or completed components, for further examinations, inspections, or tests.

(l) [Reserved]

(m) *Alternate procedures for standard components*. In lieu of the quality control procedures specified in this section, manufacturers of standard components may follow the quality control procedures in a Federal or military specification with which the component is required to comply by this subchapter, or equivalent procedures accepted by the Commandant.

(n) *Additional tests*. The Commandant may prescribe additional production tests and inspections to maintain quality control. A representative of the Commandant may conduct inspections for compliance with the requirements of this subpart.

[CGD 84–068, 58 FR 29494, May 20, 1993; 58 FR 32416, June 9, 1993]

§ 164.019–15 Component manufacturer records.

(a) Each component manufacturer shall retain records as required by § 159.007–13 of this chapter.

(b) The records required by paragraph (a) of this section must include the following information: