

permanently attached to the top of the cylinder.

(ii) On the footring permanently attached to the cylinder, provided the water capacity of the cylinder does not exceed 30 pounds.

(2) Embossing the cylinder head or side wall is not permitted.

(o) *Inspector's report.* In addition to the information required by § 178.35, the record of chemical analyses must also include applicable information on iron, titanium, zinc, and magnesium used in the construction of the cylinder.

[Amdt. 178-114, 61 FR 25942, May 23, 1996, as amended at 62 FR 51561, Oct. 1, 1997; 66 FR 45386, Aug. 28, 2001; 67 FR 51654, Aug. 8, 2002; 68 FR 75748, Dec. 31, 2003; 69 FR 54046, Sept. 7, 2004; 74 FR 16143, Apr. 9, 2009; 85 FR 85431, Dec. 27, 2020]

§ 178.69 Responsibilities and requirements for manufacturers of UN pressure receptacles.

(a) Each manufacturer of a UN pressure receptacle marked with "USA" as a country of approval must comply with the requirements in this section. The manufacturer must maintain a quality system, obtain an approval for each initial pressure receptacle design type, and ensure that all production of UN pressure receptacles meets the applicable requirements.

(1) *Quality system.* The manufacturer of a UN pressure receptacle must have its quality system approved by the Associate Administrator. The quality system will initially be assessed through an audit by the Associate Administrator or his or her representative to determine whether it meets the requirements of this section. The Associate Administrator will notify the manufacturer in writing of the results of the audit. The notification will contain the conclusions of the audit and any corrective action required. The Associate Administrator may perform periodic audits to ensure that the manufacturer operates in accordance with the quality system. Reports of periodic audits will be provided to the manufacturer. The manufacturer must bear the cost of audits.

(2) *Quality system documentation.* The manufacturer must be able to demonstrate a documented quality system. Management must review the adequacy

of the quality system to assure that it is effective and conforms to the requirements in § 178.70. The quality system records must be in English and must include detailed descriptions of the following:

(i) The organizational structure and responsibilities of personnel with regard to design and product quality;

(ii) The design control and design verification techniques, processes, and procedures used when designing the pressure receptacles;

(iii) The relevant procedures for pressure receptacle manufacturing, quality control, quality assurance, and process operation instructions;

(iv) Inspection and testing methodologies, measuring and testing equipment, and calibration data;

(v) The process for meeting customer requirements;

(vi) The process for document control and document revision;

(vii) The system for controlling non-conforming material and records, including procedures for identification, segregation, and disposition;

(viii) Production, processing and fabrication, including purchased components, in-process and final materials; and

(ix) Training programs for relevant personnel.

(3) *Maintenance of quality system.* The manufacturer must maintain the quality system as approved by the Associate Administrator. The manufacturer shall notify the Associate Administrator of any intended changes to the approved quality system prior to making the change. The Associate Administrator will evaluate the proposed change to determine whether the amended quality system will satisfy the requirements. The Associate Administrator will notify the manufacturer of the findings.

(b) *Design type approvals.* The manufacturer must have each pressure receptacle design type reviewed by an IIA and approved by the Associate Administrator in accordance with § 178.70. A cylinder is considered to be of a new design, compared with an existing approved design, as stated in the applicable ISO design, construction and testing standard.

§ 178.70

49 CFR Ch. I (10–1–23 Edition)

(c) *Production inspection and certification.* The manufacturer must ensure that each UN pressure receptacle is inspected and certified in accordance with § 178.71.

[71 FR 33885, June 12, 2006]

§ 178.70 Approval of UN pressure receptacles.

(a) *Initial design-type approval.* The manufacturer of a UN pressure receptacle must obtain an initial design type approval from the Associate Administrator. The initial design type approval must be of the pressure receptacle design as it is intended to be produced. The manufacturer must arrange for an IIA, approved by the Associate Administrator in accordance with subpart I of part 107 of this chapter, to perform a pre-audit of its pressure receptacle manufacturing operation prior to having an audit conducted by the Associate Administrator or his designee.

(b) *IIA pre-audit.* The manufacturer must submit an application for initial design type approval to the IIA for review. The IIA will examine the manufacturer's application for initial design type approval for completeness. An incomplete application will be returned to the manufacturer with an explanation. If an application is complete, the IIA will review all technical documentation, including drawings and calculations, to verify that the design meets all requirements of the applicable UN pressure receptacle standard and specification requirements. If the technical documentation shows that the pressure receptacle prototype design conforms to the applicable standards and requirements in § 178.70, the manufacturer will fabricate a prototype lot of pressure receptacles in conformance with the technical documentation representative of the design. The IIA will verify that the prototype lot conforms to the applicable requirements by selecting pressure receptacles and witnessing their testing. After prototype testing has been satisfactorily completed, showing the pressure receptacles fully conform to all applicable specification requirements, the certifying IIA must prepare a letter of recommendation and a design type approval certificate. The design type ap-

proval certificate must contain the name and address of the manufacturer and the IIA certifying the design type, the test results, chemical analyses, lot identification, and all other supporting data specified in the applicable ISO design, construction and testing standard. The IIA must provide the certificate and documentation to the manufacturer.

(c) *Application for initial design type approval.* If the pre-audit is found satisfactory by the IIA, the manufacturer will submit the letter of recommendation from the IIA and an application for design type approval to the Associate Administrator. An application for initial design type approval must be submitted for each manufacturing facility. The application must be in English and, at a minimum, contain the following information:

(1) The name and address of the manufacturing facility. If the application is submitted by an authorized representative on behalf of the manufacturer, the application must include the representative's name and address.

(2) The name and title of the individual responsible for the manufacturer's quality system, as required by § 178.69.

(3) The designation of the pressure receptacle and the relevant pressure receptacle standard.

(4) Details of any refusal of approval of a similar application by a designated approval agency of another country.

(5) The name and address of the production IIA that will perform the functions prescribed in paragraph (e) of this section. The IIA must be approved in writing by the Associate Administrator in accordance with subpart I of part 107 of this chapter.

(6) Documentation on the manufacturing facility as specified in § 178.69.

(7) Design specifications and manufacturing drawings, showing components and subassemblies if relevant, design calculations, and material specifications necessary to verify compliance with the applicable pressure receptacle design standard.

(8) Manufacturing procedures and any applicable standards that describe in detail the manufacturing processes and control.