§ 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;
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§ 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 approval 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