

## § 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.

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