

Section 6

QUALITY SYSTEM REQUIREMENTS

6.1 DESCRIPTION

This section provides minimum Department quality management system (QMS) requirements for vendors of traffic control products listed on the Department's Acceptable Quality System List (AQSL). Listing on the AQSL is mandatory before a product can be evaluated and listed on the Department's Approved Product List (APL). These requirements pertain to the acceptance and periodic re-acceptance of the quality system. Re-acceptance of the quality system is part of an on-going surveillance program. Re-acceptance is mandatory for vendors to continue listing of their quality system on the AQSL and their traffic control products on the APL. For definitions, refer to **Section 2**.

6.2 ACCEPTANCE OF QUALITY SYSTEM

6.2.1 Quality Manual

The QMS shall comply with the requirements of clause 4.2.2 of the International Organization for Standardization (ISO) 9001:2008 for the ISO elements stipulated within this specification.

6.2.2 Control of Documents

The QMS shall comply with the requirements of clause 4.2.3 of ISO 9001:2008.

6.2.3 Control of Records

The QMS shall comply with the requirements of clause 4.2.4 of ISO 9001:2008.

6.2.4 Management Review

The QMS shall comply with the requirements of clause 5.6 of ISO 9001:2008.

6.2.5 Competence, Training and Awareness

The QMS shall comply with the requirements of clause 6.2.2 of ISO 9001:2008.

6.2.6 Planning of Product Realization

The QMS shall comply with the requirements of clause 7.1 of ISO 9001:2008.

6.2.7 Customer-Related Processes

The QMS shall comply with the requirements of clause 7.2 of ISO 9001:2008.

6.2.8 Design and Development

The QMS shall comply with the requirements of clause 7.3 of ISO 9001:2008.

6.2.9 Purchasing

The QMS shall comply with the requirements of clause 7.4 of ISO 9001:2008.

6.2.10 Production and Service Provision

The QMS shall comply with the requirements of clause 7.5 of ISO 9001:2008.

6.2.11 Control of Monitoring and Measuring Devices

The QMS shall comply with the requirements of clause 7.6 of ISO 9001:2008.

6.2.12 Internal Audit

The QMS shall comply with the requirements of clause 8.2.2 of ISO 9001:2008 for the ISO elements stipulated within this specification.

6.2.13 Monitoring and Measurement of Product

The QMS shall comply with the requirements of clause 8.2.4 of ISO 9001:2008.

6.2.14 Control of Nonconforming Product

The QMS shall comply with the requirements of clause 8.3 of ISO 9001:2008.

6.2.15 Corrective Action

The QMS shall comply with the requirements of clause 8.5.2 of ISO 9001:2008.

6.2.16 Preventive Action

The QMS shall comply with the requirements of clause 8.5.3 of ISO 9001:2008.

6.2.17 ISO Certification

A current ISO 9001 registration certificate and the most recent ISO 9001 registrar's audit report (in English) shall be provided for companies with a QMS registered through the ISO.

6.2.18 Virtual Tour of Manufacturing Facility

A real-time audio-video presentation of the manufacturing facility (duration: 10-30 minutes) shall be provided. The material shall be formatted for viewing in standard Windows® Media Player software and shall be stored on digital video disc or flash drive media. The audio-video shall be in English and of sufficient quality to allow adequate viewing and understanding of the narrator. The following items shall be shown and described in the audio-video:

- (1) All major departments in the manufacturing plant (including, at a minimum: receiving, production, testing/ inspection, quarantine and shipping areas, quality assurance/quality control [QA/QC]); and
- (2) Manufacturing and inspection/testing equipment (in use) and associated documents used at work stations for all products to be listed on the APL.

The QMS shall be described in the audio-video with an emphasis on documents accompanying products throughout the production cycle starting at receiving and ending in the shipping departments. Interviews with QA/QC staff, including management, describing qualifications and job-related functions shall be included in the audio-video.

6.3 RE-ACCEPTANCE OF QUALITY SYSTEM

6.3.1 Continued Compliance with this Specification

The QMS shall comply with the current requirements listed in this specification.

6.3.2 Complaints Received by Suppliers

All complaints received about APL listed products concerning conformance with the Department's certification or product requirements shall be recorded. Appropriate action shall be taken and documented with respect to (a) complaints received and (b) any deficiencies found in these products that affect compliance with such requirements.

6.3.3 ISO Certification

A current ISO 9001 registration certificate and the most recent ISO 9001 registrar's audit report (in English) shall be provided for companies with a QMS registered through the ISO.

6.3.4 Changes to Previously Accepted QMS

All records requested in this sub-section shall be provided and be reflective of the previous quality system's acceptance period.

Updates concerning:

- (1) Company ownership,
- (2) Company management,
- (3) Quality manual,
- (4) Facilities listed in the last Department quality system evaluation report, and
- (5) Original equipment manufacturers/subcontractors.

6.3.5 Changes to APL Listing

Updates concerning the APL listing shall be provided, and be reflective of the previous quality system's acceptance period.