
Section 5

APL QUALITY SYSTEM EVALUATION PROCESS

5.1 PURPOSE

The objective of this section is to describe the process for evaluating and accepting/re-accepting quality management systems (QMS) of vendors of official traffic control signals and devices and ancillary devices. The QMS of applicants/suppliers shall be evaluated using the Department's minimum quality assurance (QA) standards for QMS and other requirements described in this section. Minimum QA standards for QMS are defined in **Section 6**. All applicants/suppliers shall have their QMS accepted before their products can be evaluated and listed on the APL. Applicants/suppliers must maintain their QMS acceptance status in order to continue selling products in the state. The Department conducts an ongoing surveillance program, including re-evaluation of the previously accepted QMS, to ensure continued compliance with minimum QA standards. The TERL has the responsibility for establishing and implementing the QMS evaluation program, which uses the following three means for assessing conformity of a QMS to the Department's QA standards: 1) an applicant/supplier's declaration of conformity, 2) second-party, and 3) third-party assessments.

5.2 EVALUATION PROCESS

- (1) To begin the QMS evaluation process, a completed AQSL application and Department-supplied QMS compliance matrix (with all supporting information) must be submitted to the TERL by the applicant/supplier. A compliance matrix must be completed for each facility involved in design, development, manufacturing, testing, or customer service activities as they relate to products proposed for APL listing.
- (2) Contract manufacturers, or designers utilized by applicants/suppliers, may be required to follow the same evaluation process depending on the extent of their activities. This means that both applicant/supplier and contract manufacturer or designer may each need to have their QMS evaluated and accepted.
- (3) Vendors of official traffic control signals and devices without an ISO 9001 certification shall submit a **Non-ISO Quality System Acceptance Compliance Matrix**. Vendors of official traffic control signals and devices with a current ISO 9001 certification shall submit an **ISO Quality System Acceptance Compliance Matrix**. Vendors of ancillary devices shall submit an **Ancillary Device Quality System Acceptance Compliance Matrix**.

- (4) The QMS evaluation may also involve an on-site audit by TERL staff of the applicant/supplier's facility to assess evidence of implementation of the QMS. All applicants/suppliers are required to allow on-site audits, and satisfactorily address any nonconformity identified during the audit within an agreed upon time frame. This may include providing root-cause analysis, corrective action reports showing how the issues were resolved, and any documentation that was generated as a result of corrective action activities.
- (5) The application, compliance matrix, and all supporting documentation must be provided in English.
- (6) Vendors of official traffic control signals or devices with facilities in the state shall complete the application. However, these vendors have the option to either (1) provide a completed compliance matrix (with all supporting information) as described above or (2) not provide the matrix, but allow an on-site audit of the facility so TERL staff can assess applicant/supplier conformance to matrix requirements. On-site auditing is only offered for facilities involved in design, development, manufacturing and testing activities.
- (7) The TERL will evaluate all information and determine the company's QA system compliance with the QMS specification listed in **Section 6**, and other aforementioned requirements. The TERL will communicate any deficiencies to the applicant/supplier via an evaluation report. Upon meeting the **Section 6** specification, the applicant/supplier will be listed on the AQSL along with a re-evaluation due date for future re-acceptance of the QMS. Specific conditions that may apply to the QMS acceptance will be detailed in a final evaluation report to the applicant/supplier.

5.3 EVALUATION TRIGGERS

The process described in **Section 5.2** shall be followed under the following scenarios:

- (1) For each facility where products proposed for APL listing are designed, developed, manufactured, or tested, and customer service activities are performed (such as, but not limited to: handling product orders, customer complaints, product-related corrective actions, and technical support).
- (2) When approved/certified product and/or supplier performance issues occur with a supplier, depending on the significance of the issues. For vendors of ancillary devices, a second-party assessment may be needed in place of a declaration of conformity to verify compliance to the Department's QA standards.
- (3) When a facility relocates (assuming APL-listed products move to the relocated facility).

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- (4) When there is a change of contract manufacturer or designer and such entities were previously required to have their QMS accepted/re-accepted.
 - (5) When a facility merges with other companies or changes ownership, depending on the significance of potential changes to its QMS.
 - (6) When a vendor of ancillary devices proposes APL-listing of official traffic control signals and devices. In this case, a second or third-party assessment is required depending on ISO 9001 certification (or lack thereof) of the supplier's facility.
 - (7) When a vendor of official traffic control signals and devices with a QMS accepted/re-accepted based on its ISO 9001 certification lets its ISO 9001 certification lapse. In this case, a second-party assessment is required.

Vendors with facilities in the state (not relocating out-of-state) can elect to postpone following the process described in **Section 5.2** (for scenarios (3)-(7) only) until the time of surveillance as described in **Sections 5.4** and **5.5** below.

5.4 RE-EVALUATION PROCESS (SURVEILLANCE)

- (1) To begin the re-evaluation process, a completed AQSL application and Department-supplied QMS compliance matrix (with all supporting information) must be submitted to the TERL by the supplier. A compliance matrix must be completed for each facility involved in design, development, manufacturing, testing, or customer service activities as they relate to products on the APL.
- (2) Contract manufacturers or designers utilized by suppliers may be required to follow the same re-evaluation process depending on the extent of their activities. This means that both supplier and contract manufacturer or designer may each need to have their QMS re-evaluated and re-accepted.
- (3) Suppliers of official traffic control signals and devices without an ISO 9001 certification shall submit a **Non-ISO Quality System Re-Acceptance Compliance Matrix**. Suppliers of official traffic control signals and devices with a current ISO 9001 certification shall submit an **ISO Quality System Re-Acceptance Compliance Matrix**. Suppliers of ancillary devices shall submit an **Ancillary Device Quality System Re-Acceptance Compliance Matrix**.
- (4) The QMS re-evaluation may also involve an on-site audit by TERL staff of the supplier's facility and a survey of the supplier's APL-listed products sold in the state to assess the level of customer satisfaction and product performance. All suppliers are required to allow on-site audits and satisfactorily address any potential nonconformity identified during the audit, or resulting from the survey within an agreed upon time frame. This may include providing root-cause-

analysis, corrective action reports showing how the issues were resolved, and any documentation that was generated as a result of corrective action activities.

- (5) The application, compliance matrix, and all supporting documentation must be provided in English.
- (6) The TERL will evaluate all information and determine the company's QA system compliance with the QMS specification listed in **Section 6**, and other aforementioned requirements. The TERL will communicate any deficiencies to the supplier via an evaluation report. Upon meeting the **Section 6** specification, the supplier will continue to be listed on the AQSL, along with a new re-evaluation due date for future re-acceptance of the QMS. Specific conditions that may apply to the QMS re-acceptance will be detailed in a final evaluation report to the supplier.

5.5 RE-EVALUATION TIMING

- (1) Re-evaluation of the QMS is typically performed every four years, and a corresponding submittal must be received by the TERL no later than the re-evaluation due date. Upon showing good cause, the supplier may be granted an extension deadline. The re-evaluation due date is indicated on the evaluation report for QMS acceptance/re-acceptance and on the web site at: http://www.dot.state.fl.us/trafficoperations/Traf_Sys/AcceptableQualitySystemList.shtm
- (2) The TERL will notify the supplier of the upcoming re-evaluation, typically at least 30 calendar days prior to the due date. The supplier shall deliver a re-evaluation submittal by the re-evaluation due date (or other agreed upon time frame). Failure to comply with the notification deadline may result in corrective actions as described in **Section 3.6**.
- (3) Re-acceptance of the QMS must occur within six months following the re-evaluation due date. Failure to meet this requirement may lead to corrective actions as described in **Section 3.6**.