Section 5

APL QUALITY MANAGEMENT SYSTEM EVALUATION PROCESS

5.1 PURPOSE

The objective of this section is to describe the process for evaluating and accepting/re-accepting the QMS of vendors of official traffic control signals and devices and ancillary devices seeking APL listing. The QMS of applicants/suppliers shall be evaluated using the Department's minimum quality assurance (QA) standards for QMS based on the ISO 9001 standard and 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 means for assessing conformity of a QMS to the Department's QA standards: 1) an applicant/supplier's declaration of conformity, and 2) second-party assessment.

5.2 EVALUATION PROCESS

(1) To begin the QMS evaluation process, a completed AQSL application, organization chart, 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/designers and customer service providers, 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/designer or customer service provider may each need to have their QMS evaluated and accepted.

(3) Vendors of official traffic control signals and devices shall submit *an* ***Official Device 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 QMS audit by TERL staff at the facility of the applicant/supplier or its contract manufacturer/designer or customer service provider to assess compliance with the QMS specification listed in ***Section 6***. All applicants/suppliers and their contract manufacturer/designer or customer service provider 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, organization chart, compliance matrix, and all supporting documentation must be provided in English.

(6) The TERL will evaluate all information and determine the company's QMS compliance with the specification listed in ***Section 6***. The TERL will communicate any deficiencies to the applicant/supplier via an evaluation report. Upon meeting the ***Section 6*** specification, the applicant/supplier will receive a final evaluation report and be listed on the AQSL. Specific conditions that may apply to the QMS acceptance will be detailed in the 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 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 QMS specification listed in ***Section 6***.

(3) When a facility relocates (assuming APL-listed products move to the relocated facility), depending on the significance of changes to its QMS.

(4) When there is a change of contract manufacturer/designer or customer service provider, 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 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-party assessment is required of the supplier's facility.

5.4 RE-EVALUATION PROCESS (SURVEILLANCE)

(1) To begin the re-evaluation process under the surveillance program, a completed AQSL application, organization chart 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/designers and customer service providers, 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/designer or customer service provider may each need to have their QMS re-evaluated and re-accepted.

(3) Suppliers of official traffic control signals and devices shall submit an ***Official Device 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 QMS audit by TERL staff at the facility of the supplier or its contract manufacturer/designer or customer service provider to assess compliance with the QMS specification listed in ***Section 6***. All suppliers and their contract manufacturer/designer or customer service provider 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, organization chart, compliance matrix, and all supporting documentation must be provided in English.

(6) The TERL will evaluate all information and determine the company's QMS compliance with the QMS specification listed in ***Section 6***. The TERL will communicate any deficiencies to the supplier via an evaluation report. Upon meeting the ***Section 6*** specification, the supplier will receive a final evaluation report and continue to be listed on the AQSL***.*** Specific conditions that may apply to the QMS re-acceptance will be detailed in the final evaluation report to the supplier.

5.5 RE-EVALUATION TIMING (SURVEILLANCE)

(1) Re-evaluation of the QMS under the surveillance program is typically performed every four years. A corresponding submittal must be received by the TERL no later than the QMS re-evaluation due date indicated in the TERL's evaluation report for QMS acceptance/re-acceptance. Upon showing good cause, the supplier may be granted an extension deadline.

(2) The TERL will notify the supplier of the upcoming QMS re-evaluation, typically at least 30 calendar days prior to the QMS re-evaluation due date. The supplier shall deliver a QMS 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 TERL actions as described in ***Section 3.6***.

5.6 DOCUMENT HISTORY

Rev	Description	Authored and Checked	Reviewed	Approved	Approval Date
1.0	New Product Certification Handbook section	A. Burleson	D. Vollmer R. Meyer J. Morgan T. Tillander	M. Wilson	08/14/2012
2.0	Comments from FDOT Legal Office addressed.	J. Morgan A. Burleson	J. Morgan	M. Wilson	03/12/2013
3.0	Modified evaluation process requirements for facilities located in Florida.	A. Burleson	J. Morgan	M. Wilson	01/23/2014
4.0	Clarified evaluation trigger related to facility relocation.	A. Burleson	J. Morgan	M. Wilson	08/19/2014
5.0	Updated position title for Mark Wilson in document control panel.	A. Burleson	J. Morgan	M. Wilson	03/04/2015
6.0	Removed requirement to have the applicant/supplier's quality system re-evaluated/re-accepted within six months of the re-evaluation due date. Revised names of quality system compliance matrices. Removed section specific to Florida vendors.	A. Burleson K. Moser	J. Morgan E. Birriel	M. Wilson	12/08/2015
7.0	Added term 'management' to 'quality system' for terminology consistency with other sections of the PCH. Updated names of compliance matrices. Removed use of compliance matrices for ISO 9001 certified vendors and eliminated reliance on ISO 9001 certification.	A. Burleson	D. Vollmer M. DeWitt	J. Easterling	07/01/2022