Section 3

APL CERTIFIED PROCESS

3.1 PURPOSE

The objective of this section is to describe the Department's APL product certification process to applicants, suppliers, and end-users. Products certified under this process are listed on the APL (Certified Process) as defined in **Section 2**. Conditions for granting, maintaining, extending, suspending, and withdrawing certification are also included.

3.2 GRANTING CERTIFICATION

All official traffic control signals and devices, and ancillary devices (listed in **Section 4**) shall be evaluated by the TERL and certified by the Director, Office of Traffic Engineering and Operations or their delegate (TERL Manager). Granting certification of the applicant's product is based on meeting applicable specifications. In addition, during the course of a product evaluation, issues concerning safety/use/maintenance of a product, failure to meet common industry standards, or other issues may arise that are not explicitly addressed in the specifications. In such cases, the TERL may require that these issues be resolved prior to product certification.

An overview of the granting certification process can be found at: <u>https://www.fdot.gov/traffic/traf-sys/traf-sys.shtm</u>

Applicants wishing to have products listed on the APL for the **first time** shall follow the three-step process outlined below. The TERL responsibilities are also described for each step.

(1) Step 1: Initial PATH Application Submittal and Review: To begin the process, the applicant shall submit via the <u>PATH portal</u> product information including the applicable APL product type and product specification from the SSRBC. The information shall include a completed <u>Request for Product Consideration (RFPC)</u> <u>application</u>. The TERL will review the provided information to determine whether the product has benefit to the state, it requires APL listing, and the correct APL product type and product specification are selected.

The applicant can expect a response within 14 calendar days following receipt of the information. If the product requires listing on the APL, the applicant will be instructed to proceed to Step 2 and will be provided with the name of the assigned QMS point of contact. Note that other possible outcomes of Step 1 may

include following the traffic control device permit process (described in **Section 8**) or the APL developmental process (described in **Section 9**). If the product is out of the APL scope or is within scope but clearly not meeting standards, the applicant will be notified that certification is refused and be given reasons for the decision.

(2) Step 2: AQSL Application Submittal and Review: The applicant shall first submit a completed Acceptable Quality System List (AQSL) application (application form only) and organization chart. The application form will be provided by the assigned QMS evaluator to the applicant and is used to determine the extent of additional documentation required. The additional documentation depends on the product category (official traffic control signal and device, or ancillary device) and is specified in **Section 5.2**.

Contract manufacturers/designers and customer service providers, utilized by applicants may be required to follow the same evaluation process depending on the extent of their activities. The applicant can expect a response within 30 calendar days following receipt of the submittal (including the additional documentation). A vendor of official traffic control signals and devices will receive an evaluation report (including deficiencies, as applicable). Acceptance of the QMS is based on meeting the QMS specification listed in **Section 6**.

An applicant must have its QMS accepted before products can be evaluated. Upon QMS acceptance, the applicant will be notified and instructed to proceed to Step 3A, and its QMS will be listed on the AQSL. A vendor of official traffic control signals and devices will also receive a final evaluation report. The QMS evaluation process is detailed in **Section 5**.

- (3) Step 3A: Product Compliance Information Submittal and Review: The applicant will be provided with web links to the applicable <u>product compliance</u> <u>matrices</u> to complete. The applicant shall submit the following documentation:
 - (a) All required compliance matrices;
 - (b) Third-party or first-party test data stipulated in matrices (refer to Section 7 for test laboratory and test reporting requirements);
 - (c) Manufacturer's product specifications;
 - (d) Product drawings or cut sheets;
 - (e) Parts list; and
 - (f) Assembly and installation instructions.

Depending on the product, the following additional documentation may be required:

- (g) Operation manual;
- (h) Troubleshooting and service manual; and

(i) Circuit board schematics or block diagrams (refer to **Section 10.3** for how to handle confidential information).

The applicant can expect a response on information completeness and conformance with applicable product specifications within 14 calendar days following receipt of the submittal. Conformance is initially based on a review of the "Item Comply? (Yes/No/NA)" information in the matrices and justification for any noncompliant item. Once the application is deemed complete and no apparent nonconformities are noted, the applicant will be instructed to proceed to Step 3B and will be provided with the name of the assigned product evaluator.

(4) Step 3B: Product Sample Submittal, Evaluation and Certification: After Steps 1 through 3A have been successfully completed, the applicant will be notified to provide a product sample to the TERL for evaluation. The applicant shall submit a product sample that is a production unit representative of the entire line or group of products to be certified, and with all accessory components necessary for full operation. All product shipping boxes must have the PATH application ID number and name of the assigned product evaluator on their shipping label. All costs of freight and shipping must be at the applicant's expense. The applicant can expect a response regarding product evaluation within 45 calendar days following receipt of the sample.

The product compliance information submitted in Step 3A will be reviewed for content and the product evaluated against all applicable specifications. The TERL will communicate any deficiencies to the applicant via an evaluation report. If the product fails the evaluation or is found to have numerous or serious specification violations, the product may not be re-submitted for up to 90 calendar days from the date of notification of such failure. Following the second product failure, the applicant may have to wait for up to one year before resubmitting the product.

Once the TERL product evaluation staff determine that a product meets applicable specifications and requirements, a recommendation will be made to the TERL Manager or Director, Office of Traffic Engineering and Operations to certify the product. If the recommendation is accepted, the applicant will receive a final evaluation report (uploaded to PATH); the Director, Office of Materials (or designee) will conduct an administrative review; and the applicant will be notified that the product is listed on the APL.

3.3 MAINTAINING CERTIFICATION

Maintaining certification shall be accomplished by the following:

(1) Maintaining compliance to the relevant product/QMS standards and certification requirements including re-certification under revised standards and specifications

(refer to **Section 3.5**). This involves successful and prompt resolution of any required actions from suppliers to maintain compliance. Examples of deficiencies requiring actions are listed in **Section 3.6**; and

(2) Utilizing a surveillance program, including a re-evaluation and re-acceptance of the supplier's QMS (typically performed every four years). To begin the re-evaluation process, the supplier shall first submit a completed AQSL application (application form only) and organization chart. The application form will be provided by the assigned QMS evaluator to the supplier and is used to determine the extent of additional documentation required. The additional documentation depends on the product category (official traffic control signal and device, or ancillary device) and is specified in **Section 5.4**.

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. The supplier can expect a response within 30 calendar days following receipt of the submittal (including the additional documentation). A vendor of official traffic control signals and devices will receive an evaluation report (including deficiencies, as applicable). Re-acceptance of the QMS is based on meeting the QMS specification listed in *Section 6*. Upon QMS re-acceptance, the supplier will be notified, and its QMS will continue to be listed on the AQSL. A vendor of official traffic control signals and devices will also receive a final evaluation report. The QMS re-evaluation process is detailed in *Section 5*.

3.4 EXTENDING CERTIFICATION

(1) Suppliers with products currently listed on the APL that wish to extend (add) new products or modify existing certified products shall follow the process outlined in *Section 3.2* beginning with Step 1 but with modifications described in this section. To begin the process, the applicant shall submit via the <u>PATH portal</u> APL product information for a new product or product change information for an existing APL product. The information shall include a completed <u>RFPC</u> application. Step 2 may be bypassed if the supplier's QMS has already been accepted in relation to the products proposed for extension or modification. Steps 3A and 3B requirements may be reduced for the supplier under certain conditions explained in this section. In all cases, conditions for maintaining product certification as defined in *Section 3.3* must also be met for granting an extension of product certification.

For modification of a certified product, the supplier shall document all product modifications in the RFPC application. The product change information will be reviewed to determine the significance of the proposed modifications to the certified product or the significance of the changes between the certified product and the new product submitted for extension. The supplier can expect a response within 14 calendar days following receipt of the information. The response may include a request for information to make a final determination of significance.

- (2) If differences between the existing certified product and the product submitted for extension or modification are deemed significant, suppliers shall follow the process outlined in Steps 3A and 3B within *Section 3.2*. The TERL responsibilities described in *Section 3.2* also apply. As an example, a complete product replacement or replacement of one/more components providing the functionality to be evaluated, is deemed significant. In this case, the supplier shall submit an application for an "APL" (e.g., new product) instead of a "ProductChange" application in PATH.
- (3) If differences between the existing certified product and the product submitted for extension or modification are not deemed significant, the supplier shall provide extension material which may include product test data or a product sample (meeting requirements outlined in Step 3B within **Section 3.2**). Following receipt of the requested extension material, the supplier can expect a response regarding the evaluation within 45 calendar days following receipt of the material. The TERL will communicate any deficiencies to the supplier via an evaluation report.

For product differences deemed non-significant, once the TERL product evaluation staff determine that a product meets applicable specifications and requirements, a recommendation will be made to the TERL Manager or Director, Office of Traffic Engineering and Operations to certify the product. If the recommendation is accepted, the applicant will receive a final evaluation report (uploaded to PATH) if there were deficiencies; the Director, Office of Materials (or designee) will conduct an administrative review; and the applicant will be notified that the product is listed on the APL.

(4) Suppliers with products currently listed on the APL wishing to extend (add) or modify accepted QMS/facilities handling product design/development, manufacturing/testing, or customer service shall follow the process outlined in Step 2 of Section 3.2 if the extension or modification involves scenarios described in Section 5.3. Conditions for maintaining product certification as defined in Section 3.3 must also be met for granting an extension of QMS acceptance.

3.5 RE-CERTIFICATION UNDER REVISED STANDARDS

The Department regularly revises specifications to keep pace with new product technology and revised standards.

(1) If the latest product specification revisions are deemed more stringent than earlier versions, the TERL and/or Office of Materials will notify suppliers of affected products and specific revisions. To begin the process, the applicant shall submit via the <u>PATH portal</u> APL product information for a product change corresponding to the affected APL product. The information shall include a completed <u>RFPC</u> application and compliance matrix only completed for the more stringent requirements along with applicable supporting information. A product sample representative of the entire line or group of products to be re-certified, may also be required depending on the significance of the specification revisions. The supplier shall indicate in the RFPC that it is submitted in response to a product recertification.

The TERL will communicate any deficiencies to the supplier via an evaluation report. Once the TERL product evaluation staff make a final determination of compliance (or lack thereof) to the more stringent specification, a recommendation will be made to the TERL Manager or Director, Office of Traffic Engineering and Operations to re-certify (or not re-certify) the product. If the recommendation is accepted, the supplier will receive a final evaluation report if there were deficiencies to resolve (uploaded to PATH); the Director, Office of Materials (or designee) will conduct an administrative review; and the supplier will be notified of the final outcome. The product will remain listed on the APL if it is deemed to meet the revised specification. If the product does not meet the revised specification, the product will continue to be listed on the APL with a limitation that it can no longer be used after the effective date of the revised specification).

(2) Compliance with revisions concerning the QMS specification listed in **Section 6** is evaluated as part of the surveillance program (see **Section 3.3**). This program includes a re-evaluation and re-acceptance of the supplier's QMS (typically performed every four years) based on meeting the latest specification requirements listed in **Section 6**.

3.6 TERMINATING, REDUCING, SUSPENDING AND WITHDRAWING CERTIFICATION

Alleged deficiencies in product and/or supplier performance, supplier's quality assurance and fabrication procedures, and lack of compliance with product certification requirements will be evaluated. Specific examples of deficiencies include, but are not limited to:

- (a) Failure of the product to perform satisfactorily or to meet current standards and specifications;
- (b) Failure of the supplier to cooperate with the ongoing surveillance program;
- (c) Failure of the supplier to address product deficiencies that TERL requested them to address;

- (d) Failure of the supplier to immediately notify the TERL of any modification, alteration, or obsolete nature of a listed product affecting its conformity to standards and specifications;
- (e) Failure of the supplier to resolve improper use of the APL certification (i.e., misleading publications or advertisement); and
- (f) Failure of the supplier to comply with supplier requirements listed in **Section 10**.

The degree of action taken by the TERL (i.e., halting evaluation; reducing, suspending, and withdrawing certification) will vary with the degree of deficiency confirmed and its effect on product safety and intended use of the product.

The halting evaluation policy consists of halting evaluations of products submitted for APL listing until the supplier resolves the deficiency of interest (e.g., supplier's quality management system is re-accepted, specific product issue is resolved). This policy is also referred to as placing the supplier on "QA Hold". Upon implementation, the TERL Manager (or delegate) will notify the supplier of the "QA Hold" status.

The reduction, suspension, and withdrawal process is typically escalated as follows. However, any of the below penalties can be applied independently of the typical sequence shown:

(1) 1st Action – Notice of Deficiency

The TERL Manager (in coordination with the Director, Office of Traffic Engineering and Operations) will issue a Notice of Deficiency to the supplier to resolve the deficiency. Under this action, product certification or supplier's QMS acceptance is not affected. Upon receipt, the TERL will review the supplier's response and supporting documentation and notify the supplier of any additional information or action needed.

(2) 2nd Action – Notice of Suspension

Failure to provide a satisfactory response to the Notice of Deficiency will lead to suspension. In this case, upon recommendation from (and agreement with) the Director, Office of Traffic Engineering and Operations, and the Director, Office of Materials, the Chief Engineer will issue a Notice of Suspension to the supplier. Under suspension, the deficient product is removed from the APL. In addition, the supplier's accepted QMS may be removed from the AQSL depending on the deficiency; QMS removal from the AQSL automatically results in all products under the supplier's name removed from the APL. The affected product(s) is/are ineligible for sale or installation within the state for the period of suspension. The supplier is given a minimum of 30 calendar days to provide a response to the suspension. Upon receipt, the TERL will review the supplier's response and supporting documentation and notify the supplier of any additional information or action needed. If the response to the Director, Office of Traffic Engineering and

Operations, to remove the suspension. If the recommendation is accepted, the supplier will be notified of the removal of suspension.

3rd Action – Notice of Revocation

Unless an extension is requested and approved, failure to meet the 30-day Notice of Suspension deadline or provide a satisfactory response will lead to revocation. In this case, upon recommendation from (and agreement with) the Director, Office of Traffic Engineering and Operations, and the Director, Office of Materials, the Chief Engineer will issue a Notice of Revocation to the supplier. Under revocation, the deficient product remains off the APL. In addition, the supplier's accepted QMS may be removed from the AQSL depending on the deficiency; QMS removal from the AQSL automatically results in all products under the supplier's name removed from the APL. The supplier shall follow the three-step certification process described in **Section 3.2** to re-apply for APL listing (beginning with Step 1) but wait for a minimum of one (1) year to do so.

Special cases include the following:

- (a) Certification will be terminated at the request of the supplier without formal documentation provided by the TERL if the supplier does not wish to continue the certification (involving product or QMS) or the product is no longer manufactured or sold by the supplier;
- (b) Certification will be reduced or withdrawn if a product is deemed to not meet revised standards and specifications (refer to Section 3.5), without formal documentation provided by the TERL (including above listed penalties);
- (c) Certification will be suspended if a product is deemed to pose an immediate threat to the general public. In this case, a Notice of Suspension (as described above) will be sent to the supplier;
- (d) Certification will be withdrawn if the supplier goes out of business, without formal documentation provided by the TERL;
- (e) The supplier's QMS will be removed from the AQSL without formal documentation provided by the TERL (including above listed penalties) if the supplier refuses to proceed to a required QMS re-evaluation and has no product listed on the APL.

3.7 ADDRESSING ALLEGED DEFICIENCIES

Alleged deficiencies of Section 316.0745, F.S., product/QMS standards or certification requirements should be reported. To do so, the complainant shall submit a completed Alleged Deficiency Report (ADR) (downloadable at https://www.fdot.gov/traffic/traf-sys/traf-sys.shtm). Supporting evidence must be provided in order for the TERL to process the ADR. If there is sufficient evidence of a deficiency and the deficiency is supplier related, a Notice of Deficiency will be sent to the supplier consistent with the process outlined in *Section 3.6*. If the deficiency is determined to present an immediate threat to the general public, the subject product will be immediately removed from the

APL. Upon resolution of the deficiency, the TERL will notify the supplier and originator of the deficiency. If action by the supplier is not deemed necessary, the TERL will document the resolution and notify the originator accordingly.

If the resolution of a deficiency affects other suppliers (e.g., other suppliers may use products removed from the APL), the TERL and/or Office of Materials will notify affected suppliers.

3.8 DOCUMENT HISTORY

Rev	Description	Authored and Checked	Reviewed	Approved	Approval Date
1.0	New Product Certification Handbook section created from transferring and revising section 7.1 of the Traffic Engineering Manual (excluding temporary permit section).	A. Burleson	D. Vollmer R. Meyer J. Morgan T. Tillander	M. Wilson	05/24/2012
2.0	Revisions of section/sub-section numbers, removal of definitions (since definitions now have their own section), and removal of unnecessary hyperlinks.	A. Burleson	J. Morgan	M. Wilson	06/12/2012
3.0	Revised section 3.1 and 3.4 to include additional details regarding steps 3a and 3b.	A. Burleson	J. Morgan	M. Wilson	08/17/2012
4.0	Comments from FDOT Legal Office addressed.	J. Morgan A. Burleson	J. Morgan	M. Wilson	01/30/2013
5.0	Revised to address additional requirements in the ISO 17065 standard (certification agreement, refusing certification). Added special cases for reduction, suspension, and withdrawal of certification/approval. Added use of certification letter and agreement when extending certification. Expanded section on extending certification. Added the latest revised URL.	A. Burleson	J. Morgan	M. Wilson	08/06/2013
6.0	Modified references to revised permit process. In section 3.6, added scenario where supplier has no product on the APL and does not want to go through a quality system re-evaluation, leading to removal from the AQSL. Indicated that completed APL application (form itself) was always required for extension of certification. Added that under suspension, removal of accepted quality system can occur.	A. Burleson	J. Morgan	M. Wilson	01/23/2014
7.0	Removed references to product certification agreement and included additional example of deficiency in section 3.6. Content of product certification agreement is being incorporated in section 9 of the PCH and will be referenced in the APL and AQSL applications.	A. Burleson	J. Morgan	M. Wilson	07/09/2014

8.0	Revised section 3.2 to indicate vendors are asked quality management system questions to determine extent of documentation required for evaluation before submitting AQSL application. Revised sections 3.6 and 3.7 to reference changed from nomenclature for reporting deficiencies and eliminate use of notice of corrective action. Updated position title for State Traffic Operations Engineer. Removed 'approval' terminology in section title and throughout document.	A. Burleson	J. Morgan	M. Wilson	11/27/2014
9.0	Added reference to Innovative Product List (IPL) as possible outcome of Step 1 in Granting Certification.	A. Burleson	J. Morgan	M. Wilson	03/04/2015
10.0	Added use of the PATH portal and process changes created due to PATH. Reflected current practice of product certification decision by the TERL Manager or Director, Office of Traffic Engineering and Operations.	A. Burleson	D. Vollmer M. DeWitt W. Geitz	T. Tillander	05/27/2022
11.0	Revised Step 2 process for ancillary device vendors. Removed most references to PATH. Clarified requirements for complete APL product replacements. Replaced references to Program Management Office with Office of Materials. Expanded re-certification process under revised standards. Added QA hold policy. Reverted back to using the Traffic Systems site for submitting ADRs (because of PATH issues). Updated PATH URL.	A. Burleson	D. Vollmer M. DeWitt W. Geitz	R. Powell	05/09/2024