



State of Florida
Department of Transportation
QUALITY ASSURANCE EVALUATION SURVEY

Traffic Engineering and Operations Office
Traffic Engineering Research Laboratory (TERL)
April 2006
(This survey replaces previous survey dated October 2004)

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Contact Information

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Section 1: General Information

1.1 Purpose and Scope

The ultimate goal of the quality assurance evaluation is to raise and maintain a high level of quality for transportation products bought and used by the Florida Department of Transportation (FDOT). Vendors requesting a device to be listed on the APL are queried to determine the maturity of their existing quality assurance programs for designing, manufacturing and testing their product. Only vendors whose quality system meets the department's minimum quality assurance (QA) standards are allowed to have their device evaluated and placed on the APL.

The purpose of this survey is to collect information regarding the vendors QA program. The documentation and responses provided by the vendor will be used to perform an off-site audit of the vendor's QA program. In addition to this quality survey, vendors may be required to:

1. Allow an on-site audit visit to their facilities.
2. Conduct a teleconference meeting with a TERL QA evaluator.
3. Present information on their QA program at the TERL facility.

Vendors are advised to assign personnel with a quality management background, or an outside quality consultant to prepare the following survey and accompanied document submittal.

1.2 Vendor Information

Please complete the following information about the vendor company. This information will be used to contact the vendor during the evaluation for clarification or any questions.

Company name:	
Date established:	
Products proposed to be listed on the APL: Product Name(s): Model Number(s): Number of years product has been manufactured:	
Physical address where products are manufactured:	
Name of point of contact:	
Phone and fax number:	
E-mail address:	
Company website:	
Current number of employees	
Engineering	
Manufacturing	
Quality Assurance	
Other	
Total	

1.3 Vendor Documentation and Information

The following checklist describes some of the required documents and information needed to perform the QA evaluation. Be sure to address each of the below items along with the remaining sections of the survey or your submittal will be incomplete.

<input type="checkbox"/>	a. A copy of the vendor's quality assurance / quality control manual.
<input type="checkbox"/>	b. An organization chart showing the functional responsibilities of all key quality assurance personnel including names and positions.
<input type="checkbox"/>	c. A video recording (VHS or DVD) describing the manufacturing, assembly and test processes, capabilities and experience for product to be listed on the APL. Please refer to section 2 for a description of the video requirements.
<input type="checkbox"/>	d. For products being considered for FDOT approval, list any principal customers who have purchased these same products within the last two years.
<input type="checkbox"/>	e. List any companies that have performed quality audits and/or source inspections at your facilities. Include the month and year of inspection and provide documented findings.
<input type="checkbox"/>	f. Provide your "approved vendor list", (a list of principal vendors you use as a source of material, processes, or services). Provide this list from your existing vendor rating system.
<input type="checkbox"/>	g. List all industry certifications and National Quality Standards (NQS) met. Provide a copy of registration or certification, and the latest assessment audit report. Include registrar's name and registration number, if applicable.

Section 2: Manufacturing Process Video Requirements

Provide a video, no more than 25 minutes in length, of the manufacturing process used to produce the submitted product. The video must be in VHS or DVD format, and while not requiring professional-grade quality, it must be of adequate audio and video quality to be easily viewed and understood. A transcript may be required. Produce this video as a virtual tour of the manufacturing and quality process for the device in question. This video should also be used as a supplement in answering questions throughout this QA evaluation survey, **primarily to demonstrate that your documented quality system is being implemented.** The following list describes the minimum requirements for the video. Each area below must be addressed or your submittal may be incomplete.

1. A real-time video **during a typical workday** of the:
 - a. Manufacturing plant,
 - b. Plant equipment, machinery, special tooling and relevant documents used in work stations,
 - c. Support/test equipment, and relevant documents used in work stations,
 - d. Manufacturing work and quality assurance testing in progress.
2. A description of the process and documents that will provide and maintain your quality system. For example the video should answer questions like:
 - a. When and how are corrective action reports generated?
 - b. What quality system documents accompany the product throughout the manufacturing cycle?
 - c. A description of the inspections and tests necessary to ensure conformance with FDOT specifications. Show and discuss the facilities and equipment used to perform these inspections.
 - d. A description of statistical sampling and testing required by the quality system, if performed.
3. Interviews with quality assurance personnel and discussions concerning:
 - a. Qualifications, and
 - b. Job functions.

Section 3: Quality System Questions

Instructions: A response **must** be provided for all questions. Each response is evaluated by assessing one or more of the following factors:

1. The written explanation of your quality system approach.
2. Evidence of documented policies and procedures. These documents should be referenced by quoting the appropriate sections from the QA manual in your written explanation of the system.
3. Evidence of the procedural implementation (e.g. filled out corrective action reports, meeting minutes, etc.). This evidence must also be referenced in your written explanation of the system.

Each question below is followed by a check list of required information. Please include each item in your survey submittal. You can use this column as a checklist. Failure to provide each of these requirements may result in an incomplete submittal.

3.1 Management Responsibilities	
a. What system is in place for ensuring that the quality policy is understood throughout all levels of the organization? Who is responsible for this?	<input type="checkbox"/> Written Explanation <input type="checkbox"/> Referenced Documents <input type="checkbox"/> Evidence of Implementation
b. Describe the positions and number of internal personnel responsible for performing quality program reviews/audits. Address the following in your explanation: <ol style="list-style-type: none"> 1. How often are these reviews/audits performed? 2. Provide records of your last two internal reviews/audits? 	<input type="checkbox"/> Written Explanation <input type="checkbox"/> Referenced Documents <input type="checkbox"/> Evidence of Implementation
3.2 Design Control	
a. Describe the general procedure used for design and development of a product. Include the following: <ol style="list-style-type: none"> 1. Who is responsible for the planning of each design and development activity? 2. What positions make up the design development team? 3. How is design input requirements related to the product identified and documented? 4. How are designs outputs documented and reviewed? 5. Describe the role quality management plays in product design reviews. 6. Provide copies of documents generated from such activities. 	<input type="checkbox"/> Written Explanation <input type="checkbox"/> Referenced Documents <input type="checkbox"/> Evidence of Implementation

3.3 Purchasing	
<p>a. What criteria are used to evaluate and select subcontractors or suppliers? Are they required to meet any quality standards? Provide the documents that describe the type and extent of control exercised by your company over subcontractors or suppliers?</p>	<p><input type="checkbox"/> Written Explanation</p> <p><input type="checkbox"/> Referenced Documents</p>
<p>b. Do you have a "Supplier Rating System"? If so, please explain the system and show where it is defined and documented. Address the following in your explanation:</p> <ol style="list-style-type: none"> 1. How do different evaluation/selection criteria apply for different types of subcontractors or suppliers? 2. What types of training and certification has a person undergone in order to be qualified as an auditor in your facilities? 3. How can a subcontractor or supplier become disqualified? 	<p><input type="checkbox"/> Written Explanation</p> <p><input type="checkbox"/> Referenced Documents</p> <p><input type="checkbox"/> Evidence of Implementation</p>
<p>c. Do you have an "Approved Supplier List"? If so, provide the list and describe how the list is maintained and updated? Who is responsible for maintaining this list?</p>	<p><input type="checkbox"/> Written Explanation</p> <p><input type="checkbox"/> Referenced Documents</p> <p><input type="checkbox"/> Evidence of Implementation</p>
3.4 Product Identification and Traceability	
<p>a. Describe how product identification and traceability are established and maintained throughout receiving, production, delivery, and installation? Address the following in your explanation:</p> <ol style="list-style-type: none"> 1. What documentation system has been established for this purpose? 2. Are parts, lot, or batch numbers used? How are these identification numbers assigned? 3. Provide examples (e.g. pictures, labels) showing the product identification and traceability information on the finished product. 	<p><input type="checkbox"/> Written Explanation</p> <p><input type="checkbox"/> Referenced Documents</p> <p><input type="checkbox"/> Evidence of Implementation</p>

3.5 Process Control	
<p>a. What statistical techniques are used to monitor and verify manufacturing process capability and stability? Estimate the number of processes statistically monitored in your system. Provide examples of control charting if used.</p>	<p><input type="checkbox"/> Written Explanation</p> <p><input type="checkbox"/> Referenced Documents</p> <p><input type="checkbox"/> Evidence of Implementation</p>
<p>b. What quality related trainings and certification programs has upper management arranged and provided for personnel? Address the following in your explanation:</p> <ol style="list-style-type: none"> 1. What type of personnel is required to participate in these events? 2. How often do these events take place? 3. Is there any statistical process control specialist available in the organization? If so, please describe their responsibilities. 4. Has anyone within the organization received Six-Sigma training? If so, please describe their responsibilities. 	<p><input type="checkbox"/> Written Explanation</p> <p><input type="checkbox"/> Referenced Documents</p> <p><input type="checkbox"/> Evidence of Implementation</p>
3.6 Inspection and Testing	
<p>a. Describe your receiving inspection and testing procedures of raw materials or components. Address the following in your explanation:</p> <ol style="list-style-type: none"> 1. What statistical sampling technique is used (e.g. 100% testing, random testing, etc.)? 2. How are the damaged materials handled? 3. What data is maintained to provide feedback to your purchasing procedures? 	<p><input type="checkbox"/> Written Explanation</p> <p><input type="checkbox"/> Referenced Documents</p> <p><input type="checkbox"/> Evidence of Implementation</p>
<p>b. Who is authorized to perform in-process and final inspection testing of the manufactured products? Include names and position descriptions.</p>	<p><input type="checkbox"/> Written Explanation</p> <p><input type="checkbox"/> Referenced Documents</p>
<p>c. Describe the procedure for in-process or final inspection product failure. Address the following in your explanation:</p> <ol style="list-style-type: none"> 1. How and where are inspection and testing results recorded? 2. Provide examples of the test records showing whether the product passed or failed inspection and identify the inspector. 	<p><input type="checkbox"/> Written Explanation</p> <p><input type="checkbox"/> Referenced Documents</p> <p><input type="checkbox"/> Evidence of Implementation</p>

3.7 Controlling Measuring and Test equipment	
<p>a. Describe the procedures used for inspection and calibration of tools, gauges, and test equipment. Address the following in your explanation:</p> <ol style="list-style-type: none"> 1. Who ensures that measuring and test equipment is calibrated and adjusted at predetermined intervals? 2. How are un-calibrated items identified, recalled and managed? 3. What certifications of calibration are on file? Provide the latest copy of certificates of all equipments that require calibration. 	<p><input type="checkbox"/> Written Explanation</p> <p><input type="checkbox"/> Referenced Documents</p> <p><input type="checkbox"/> Evidence of Implementation</p>
3.8 Controlling Nonconforming Products	
<p>a. Describe the procedures established for the identification, marking and segregation of discrepant material? Where are these procedures defined and documented? Provide examples (e.g. pictures, labels) of the identification and/or marking of discrepant material.</p>	<p><input type="checkbox"/> Written Explanation</p> <p><input type="checkbox"/> Referenced Documents</p> <p><input type="checkbox"/> Evidence of Implementation</p>
3.9 Corrective and Preventative Action	
<p>a. Describe the procedures for implementing corrective action. Address the following in your explanation:</p> <ol style="list-style-type: none"> 1. What triggers corrective action? 2. Who is responsible for investigating the causes of nonconformities and recording the results of the investigation? Include names and position descriptions. 3. How do records indicate the nature of deficiencies and the positive corrective action taken? Provide an example copy of these records. 	<p><input type="checkbox"/> Written Explanation</p> <p><input type="checkbox"/> Referenced Documents</p> <p><input type="checkbox"/> Evidence of Implementation</p>
<p>b. Describe the procedures for implementing preventative action. Address the following in your explanation:</p> <ol style="list-style-type: none"> 1. Who is responsible for determining and implementing the necessary steps to deal with problems requiring preventive action? Include names and position descriptions. 2. How is the effectiveness of preventative action measured? 	<p><input type="checkbox"/> Written Explanation</p> <p><input type="checkbox"/> Referenced Documents</p> <p><input type="checkbox"/> Evidence of Implementation</p>
<p>c. Describe the procedure for handling customer complaints and reports of product nonconformities.</p>	<p><input type="checkbox"/> Written Explanation</p> <p><input type="checkbox"/> Referenced Documents</p> <p><input type="checkbox"/> Evidence of Implementation</p>

Section 4: Statement of Authenticity

The FDOT will not consider any vendor for qualification until this form is completed and signed by an authorized official of the device vendor/manufacturer and received at the address on the first page of this survey.

I have read this application and attest that the information submitted within and attached for qualification evaluation is true and correct.

Signed:	
Printed Name:	
Position:	
E-mail:	
Date Signed:	
Company:	
Address:	