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Approved by:	Name	Signature	Date	Action Required		
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Nomenclature

R – Review

C – Comment

A – Approve

**State of Florida
Department of Transportation**

**QUALITY ASSURANCE PROGRAM EVALUATION SURVEY
GRADING GUIDELINES**

**Traffic Engineering Research Lab (TERL)
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1.0 General information

1.1 Purpose and Scope

Purpose of this section: This section states the purpose of the QA evaluation survey and also encourages a vendor of additional steps that would be required to complete the evaluation.

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 vendor's quality assurance (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 Manufacturer Information

Purpose of this section: This section requires the vendor to provide the general information about the organization. The size of the organization and the product type manufactured could influence the passing level. For example a company that manufactures dynamic message signs (DMS) will be held to a higher standard than one that makes pull boxes. For a detailed description of what are the passing levels for a particular type of vendor refer to the QA Evaluation Manual, section 4.3.

Please complete the following information about your company.

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 Required Manufacturer Documentation and Information

Purpose of this section: Vendors must provide **ALL** the information requested in this section in order for the evaluation to proceed. Vendors that perform poorly in this section should be rigorously examined or refused evaluation (i.e. fail pre-evaluation) until all required info is obtained. This section provides an incredible amount of information on the state of the company and their QA system.

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"/>	<p>a. A copy of the vendor's quality assurance / quality control manual.</p> <p>Why do we ask: Without a manual there is no quality assurance system! Therefore it is mandatory that a vendor provide one. Pay attention to the format of the QA manual. If it is unsatisfactory be sure to include appropriate comments in the report.</p>
<input type="checkbox"/>	<p>b. An organization chart showing the functional responsibilities of all key quality assurance personnel including names and positions.</p> <p>Why do we ask: This provides good insight on how many people are involved in the quality system, who they report to, and is an indication of how well the company is organized. This chart will be used later to help grade future questions.</p> <p><i>NOTE: If the chart seems too short and non-descriptive this maybe a red flag to investigate further.</i></p>
<input type="checkbox"/>	<p>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.</p> <p>Why do we ask: Videotape presentation is required as a substitute for an on-site visit. The video presentation shall include all the requirements stipulated in section 2. A properly produced video can provide great insight on the company and its QA system.</p>
<input type="checkbox"/>	<p>d. For products being considered for FDOT approval, list any principal customers who have purchased these products in the last two years.</p> <p>Why do we ask: We want to find out who purchases the products they manufacture. If the list is short we should pay particular attention to them. We are also interested to find out if the other customers have similar operations as FDOT. Combined with the info asked for in section 1.2 we can determine if we are dealing with an upstart company or one that is firmly established in making such a product. Upstarts may still have some issues to work out in their QA system therefore we should pay particular attention to them.</p>
<input type="checkbox"/>	<p>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.</p> <p>Why do we ask: We wish to find out if someone else has done an evaluation similar to</p>

	<p>ours. If yes, it is a definite plus and we may also ask to see the information of their evaluation.</p>
<input type="checkbox"/>	<p>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.</p> <p>Why do we ask: We want to see their approved vendor list. We will ask later about the procedures they used to determine which vendors get on their list. Also we may be able to obtain information on some of their vendors’ quality programs.</p>
<input type="checkbox"/>	<p>g. List all industry certifications and National Quality Standards (NQS) met. Provide a copy of registration and the latest assessment audit report. Include registrar’s name and registration number, if applicable.</p> <p>Why do we ask: Want to find out if they are ISO registered or have obtain any other certifications. It is a plus if they are. This can be (but not always) a substitute for evidence in answering questions in section 3. Please note that certain certifications may be referring to product quality only and not to the quality assurance system.</p>

Section 2: Manufacturing Process Video Requirements

Purpose of this section: This section is a replacement for an on-site visit. The video presentation serves a tool that would indicate how well a company is organized and how knowledgeable their personnel are. Like section 1.3, a good video presentation provides an incredible amount of general information on the state of the company and their QA system. Companies must provide **ALL** the information requested in this section. Again, companies that perform poor in this section should be rigorously examined or refused evaluation until all required info is obtained.

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. This presentation and quality does not have to be of high-grade professional quality, but must be of adequate audio and video quality that it can 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.

3.0 Quality System Questions

Purpose of this section: This section is where the actual grading or evaluation begins. The evaluator must be satisfied (vendor passed pre-evaluation) with the information provided in the previous sections before proceeding to grade questions in this section. These questions are used to determine whether the manufacturer has an appropriate and adequate quality system in place. The manufacturer's responses **MUST** have specific details and evidence substantiating their claims in order to receive a passing score.

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 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.

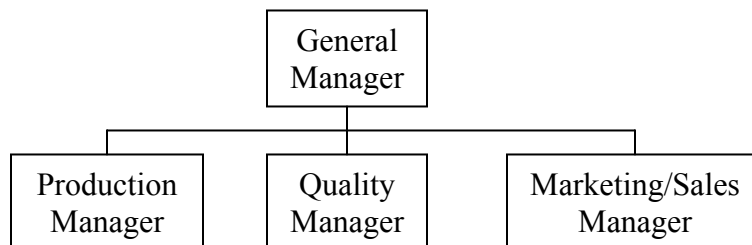
Each question below is followed by a check list of required information. Please include each item in your survey submittal. You can use this column as a checklist. Failure to provide each of these requirements may result in an incomplete submittal.

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?

What to look for

The person responsible for QA should have access to the highest level of management i.e. a member of executive management. Check the organization chart that company should have provided. An example of what to look for is:



Note: This is only an example. Small companies may not have a full-time quality manager. It is common for someone in production to also handle quality.

In addition, look for indications of any practices exercised in the organization for transmitting quality related policies, knowledge, information or updates through out the organization (i.e. memos, trainings, daily briefings etc.).

Importance: High

b) Describe the positions and number of internal personnel responsible for performing quality program reviews/audits. In doing so, please address the following:

1. How often are these reviews/audits performed?
2. Provide records of your last two internal reviews/audits?

What to look for

We wish to see if there is a dedicated person (at least half time if not full time – apply to small vendors) in the organization that ensures the quality assurance system is fully implemented. Look for documentation that clearly states who has the authority and responsibility to do this. This person should be a member of the executive branch. Independent of company influences.

Quality system reviews should be at defined intervals sufficient enough to ensure effectiveness a general rule of thumb is at least once a year. Review the records to get an idea of the extensiveness and effectiveness of the review. Also check to see if they are sticking to the predetermined intervals.

This question should be used to give the company comment for improvement if the current practice is not sufficient. The video should be a good source of evidence for this question.

Importance: High

3.2 Design Control

A company should do the following:

- Have procedures in place that ensure that the design of products meet specified requirements.
- Have procedures in place for planning design activities.

Note: This section may not apply to all companies. Some companies do not design new products rather imply manufacture a product for someone else. Evaluator must determine relevancy.

a) Describe the general procedure used for design and development of a product. Include the following:

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.

What to look for

Look for documentation that clearly states who has the authority and responsibility to do this. Look for documentation that shows that there is a clearly defined design and development process is in place. Look for evidence of documentation and implementation.

Importance: Medium

3.3 Purchasing

A company should do the following:

- Have procedures in place to ensure the quality of purchased products.
 - Have a documented evaluation system in place to select subcontractors based on their ability to meet specific requirements, including quality requirements.
 - Have monitoring records on these subcontractors.
-

a) What criteria are used to evaluate and select subcontractors, suppliers and vendors? What quality standards are they required to meet? Also provide the documents that describe the type and extent of control exercised by your company over subcontractors, suppliers and vendors?

What to look for

Look for policies and documentation that clearly states the procedures for vendor selection and the type of control they should have. Find out if the vendor specifies who determines the necessary level of control if the control level varies between vendors.

Importance: Medium

b) Do you have a "Supplier/Vendor Rating System"? If so, please explain the system and show where it is defined and documented. In explaining, please address the following:

1. How do different evaluation/selection criteria apply for different types of vendors?
2. What types of training and certification does a person undergo in order to become qualified as an auditor in your facilities?
3. How does a vendor become disqualified, or re-qualified under your rating system?

What to look for

Look for documented procedures that specify the above. Some companies tryout certain suppliers for an evaluation period only due to price factor. We want vendors to avoid doing this. In addition to cost the vendor should also consider other factors such as material specification, customer service, health and safety etc.

Importance: Medium

c) Do you have an "Approved Supplier/Vendor List"? If so, provide the list and describe how the list is maintained and updated? Who is responsible for maintaining this list?

What to look for

Look for an established system that maintains an approved supplier list. Also look for information that outlines the criteria for selecting a supplier. The policy related to this item should also be clearly defined in the QA manual. As far as evidence is concerned; expect a supplier list print-out from their current system. However some vendors (small businesses usually) may maintain a non computerized list which is sufficient as far as fulfilling this requirement.

Importance: High

3.4 Product Identification and Traceability

a) Describe how product identification and traceability are established and maintained throughout receiving, production, delivery, and installation? In explaining, be sure to address the following:

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 and/or forms.

What to look for

A company must have documented procedures identifying the product from receiving, throughout production, delivery, and installation. The company should also have documented procedures for unique identification of individual product or batches. Due to the nature of product or process (i.e. sand for concrete mixing, cast products) certain requirements may not apply. Use your own judgment to verify if these requirements have been fulfilled to the best of their ability.

Importance: High

3.5 Process Control

A company should do the following:

- Identify and plan processes that affect quality
- Identify the need for statistical techniques for controlling and stabilizing production processes.
- Establish documented procedures to implement statistical techniques.
- Have procedures in place to ensure that these planned processes are being carried out.

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.

What to look for

There can be various methods used for process control and not necessarily involved full pledge statistical techniques. In some cases it can be partial. To evaluate the method vendors use is quite subjective and therefore should not be given much weight. It is good if vendors apply these techniques, however if they do not this is an opportunity to make suggestions on how they can take advantage of these techniques.

Importance: Low

b) What quality related trainings and certification programs has the top management arranged and provided for personnel? In answering this question, please address the following:

1. What type of personnel has to participate in these events?
2. How often do these events take place annually?
3. Is there any statistical process control specialist available in the organization? If so, please describe his or her responsibilities.
4. Has anyone within the organization received six-sigma training? If so, please describe his or her responsibilities.

What to look for

We want to see if the management has any awareness towards statistical techniques. It reflects positively on a company if the majority of management has received some kind of statistical training. We are also interested to see if they're using advance statistical techniques within their quality system. This

shows that they have carefully considered what tools are necessary to ensure the quality of their product as well as promoting continuous improvement. Grading the method they use is subjective and should not be given much weight. However, this is an opportunity to make suggestions on how they can improve it.

Importance: Low

3.6 Inspections and Testing

A company should do the following:

- Have documented procedures for inspection and testing in order to verify that the product meets specific requirements.
 - Ensure that incoming products are not used until they have been inspected or verified.
 - Have and maintain records that show that the product has been inspected and tested.
 - Records should show what test the product has passed and failed.
 - Records should show who inspected and released the product.
-

a) Describe your receiving inspection and testing procedures of raw materials or components. In doing so, address the following:

1. What statistical sampling technique is used (e.g. 100% testing, random testing, etc.) to determine what portion is inspected?
2. How are any damaged/failed material issues handled?
3. What data is maintained to provide feedback to your purchasing procedures?

What to look for

Documented procedures for inspection and testing in order to verify that purchased materials and components meet specific quality requirements. Check to see that procedures are in place to record problems with subcontractors that will be used in their vendor rating system (see "purchasing" questions) and procedures for handling of non conforming materials.

Importance: High

b) Who is authorized to perform in-process and final inspection testing of the manufactured products? Include names and position descriptions.

What to look for

Documented procedures that delegate this responsibility.

Importance: Medium

c) Describe the procedure for in-process or final inspection product failure. In doing so, please address the following:

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.
3. How is the inspection results used as part of a continuous improvement program?

What to look for

Look for documented procedures that list these required tests. In an ideal case (e.g. Vultron) each product will have its own checklist that indicates what inspection and test must be performed. In addition they also must provide documented evidence that substantiate it.

Importance: Medium

3.7 Controlling Measuring and Test equipment

A company should do the following:

-Have procedures in place to control, maintain and calibrate measuring and test equipment.

a) Describe the procedures used for inspection and calibration of tools, gauges, and test equipment. In doing so, address the following:

1. Who ensures that measuring and test equipment is calibrated and adjusted at predetermined intervals?
2. How are out-of-calibration and expired calibration instruments identified, recalled, and managed?
3. What certifications of calibration are on file? Provide the latest copy of certificates of all equipments that require calibration.

What to look for

Documented procedures that illustrate how the company will ensure that their measuring and testing equipment are calibrated (whether in house or outsource) and working properly. The equipment should be labeled such that date of calibration and due date for re-calibration is indicated. We are also interested to see the latest copy of certificate of calibration for all the equipments. Check to see if the dates in which the equipment was calibrated are consistent with the predetermined intervals indicated in their procedure

Importance: High

3.8 Controlling Nonconforming Products

A company should do the following:

- Establish procedures preventing products that do not conform to requirements from unintended use.
 - Provide for identification and segregation on nonconforming products.
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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, and the quarantine area.

What to look for

Documented procedures that clearly illustrate how a nonconforming product will be marked and segregated and required documentation filed in order to address the non conformance during review meetings. Procedures also should indicate how a product will be marked such that everyone knows that this is a nonconforming product. Pictures or video of labels or marking must be provided.

Importance: High

3.9 Corrective and Preventative Action

A company should do the following:

- Have documented procedures for implementing corrective and preventative action.
 - Implement and record any changes to the procedures that result from corrective and preventative action.
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a) Describe the procedures for implementing corrective action. In doing so, address the following:

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.

What to look for

Each point must be addressed with references to documented procedures. Make sure records indicate who requested, investigated and performed corrective action. Also, investigate how long it took to rectify the situation. This is a reflection of how seriously they take continuous improvement.

Importance: High

b) Describe the procedures for implementing preventative action. In doing so, address the following:

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?

What to look for: Each point must be addressed with references to documented procedures. Make sure records indicate who requested, investigated and performed corrective action. Also, investigate how long it took to rectify the situation. This is a reflection of how seriously they take continuous improvement.

Importance: High

c) Describe the procedure for handling customer complaints and reports of product nonconformities. In doing so, address the following:

1. Who is responsible for determining and implementing the necessary steps to deal with customer problems? Include names and position descriptions.
2. How is the effectiveness of the response action measured?
3. How are the results used as part of a continuous improvement program, or management review?

What to look for: These procedures should be intertwined with their corrective and preventative action procedure described in the previous question. Often bad companies do not monitor or have procedures for their product after it leaves their facilities.

Importance: High