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|-----------------------|-------------|------------------|-------------|------------------------|----------|----------|
| | | | | R | C | A |
| Research Advisor | Dr. Simpson | | | | | |
| TERL Quality Engineer | Steve Bentz | | | | | |
| TERL Quality Manager | Jeff Morgan | | | | | |

Nomenclature

- R – Review
- C – Comment
- A – Approve

Quality Assurance (QA) Evaluation Procedures and Guidelines

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Nomenclature

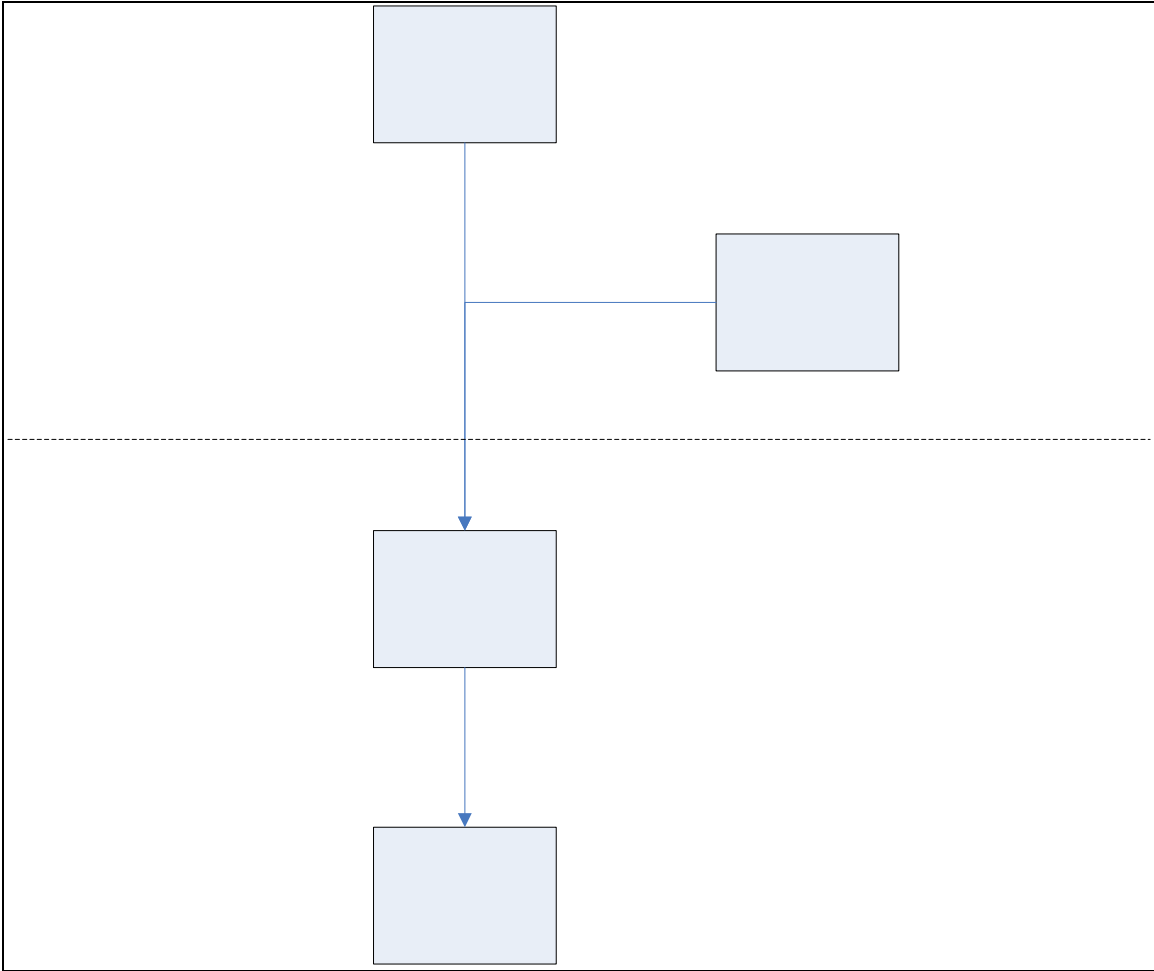
FDOT – Florida Department of Transportation
QA – Quality assurance
QRT – Quality Research Team
TERL – Traffic and Engineering Research Laboratory
APL – Approved product list

1.0 Introduction

The manual serves as the central document for procedures related to the TERL’s QA evaluation of vendors seeking to have their product placed on FDOT’s APL. This document provides a general outline of the procedures used by the QRT to evaluate a vendor’s QA system. More detailed guidelines for specific subsections of the QA evaluation are referenced. This document also outlines the structure of the QRT and its relationship with the TERL and FDOT. It also outlines the responsibilities and purpose of each member of the QRT.

2.0 QRT Management Structure

2.1 QRT Organization Chart



2.2 Position Description and Responsibilities

The following is a summary of the responsibilities of all positions within the QRT.

Qualification Program Manager

- Final decision maker on all evaluations
- Spokesperson and representative of the QRT at the FDOT
- Meeting chairman

Technical Advisor

- Manages research associates
- Consults QA manager
- Consultant/Advisor for improving quality assurance procedures at TERL lab

QA Engineer

- Manages and updates database
- Communication representative with all vendors
- Performs evaluations
- Participate in teleconferences
- Initiate internal corrective & preventive actions

QA Research Associates

- Research and development
- Manages and updates database
- Perform evaluations
- Participate in teleconferences

3.0 Documents Control

3.1 Files naming convention

All the documents that are part of this system must be named in the following format (Names must appear in the upper right hand side of the document):

Department - Description – Release/Revision Date

Table 1: Document List

| Document Name | Status |
|--|---------------|
| Report Template | |
| VQA-PreEval-Pass~Fail-Vendor Name-yyyy-mm-dd | Auto Create |
| VQA-Eval-Pass-Vendor Name-yyyy-mm-dd | Operational |
| VQA-Eval-Fail-Vendor Name-yyyy-mm-dd | Operational |
| VQA-ReEval-Pass-Vendor Name-yyyy-mm-dd | Draft |
| VQA-ReEval-Fail-Vendor Name-yyyy-mm-dd | Draft |
| Forms | |
| VQA-Eval Survey-2006-04 | Operational |
| VQA-Eval WS-2006-06 | Operational |
| VQA-ReEval RFI-2006-06 | Draft |
| VQA-Field Audit CL-2006-06 | Draft |
| Reference Documents | |
| VQA-OPS Manual-2006-06 | Operational |
| VQA-PreEval Pro-2006-06 | Operational |
| VQA-Eval Pro-2006-06 | Operational |
| VQA-Eval GL-2006-06 | Operational |
| VQA-ReEval GL-2006-06 | Draft |

Nomenclature for document names:

- VQA - Vendor Quality Assurance
- Eval - Evaluation
- WS - Work Sheet
- RFI – Request for Information
- CL – Check List
- OPS – Operations
- Pro – Process
- GL - Guidelines

3.2. Filing

There exists a central location for all QA documents on the TERL file server (currently the directory is named “quality”). The following table lists the sub-directories that exist within the quality directory and their purposes.

| Folder Name | Descriptions |
|---------------------------|---|
| 1Operations | Contains files of documents created for each company that submitted material for an evaluation, and all active documents. |
| 2Administration | Contains newsletters, progress reports, presentations, meeting minutes and notes. |
| 3Research and Development | Contains all archived, obsolete and outdated documents as well as personnel folders and future works in progress. |

4.0 Evaluation Procedures

4.1 Overview

The QA evaluation consists of three loops, the pre-evaluation, evaluation and re-evaluation loops. With the pre-evaluation, the evaluator makes sure the vendor has submitted enough material to start a complete quality evaluation. If not, a report will be sent to the vendor asking for additional information. If the company passes the pre-evaluation loop, it enters the evaluation loop. In the evaluation, the vendor’s quality system is thoroughly reviewed by the evaluator, who determines whether to recommend vendor qualification. The Qualification Program Manager, however, makes the ultimate decision as to whether to qualify or not qualify the vendor.

The evaluator will have 45 days to evaluate the submittal and respond to the TERL director with their recommendation. A negative recommendation in either the pre-evaluation or evaluation loop stops the 45-day evaluation period. A new submittal resets this 45-day evaluation period.

4.2 Pre-evaluation

See **VQA-PreEval Pro-2006-06** for the pre-evaluation process.

Handling of Materials Received:

All vendor submittals are sent to the Qualification Program Manager who in turn delivers the submittal to the evaluator. The evaluator will update the QA database inputting the vendor’s information and the date the submittal was officially received by the evaluator. The evaluator will have 10 working days to perform the pre-evaluation. The pre-evaluation is considered complete once a report is generated and sent to the QA Manager

for review and release. It is the QA manager's responsibility to insure that the pre-evaluation is completed and released within this period.

Passing pre-evaluation:

A vendor that passes pre-evaluation is sent an e-mail with **VQA-PreEval-Pass~Fail-Vendor Name-yyyy-mm-dd** attached. The vendor is then placed in the evaluation queue where the submittal will be fully evaluated and the vendor will be notified of the results before the remaining time in the 45-day evaluation period are up.

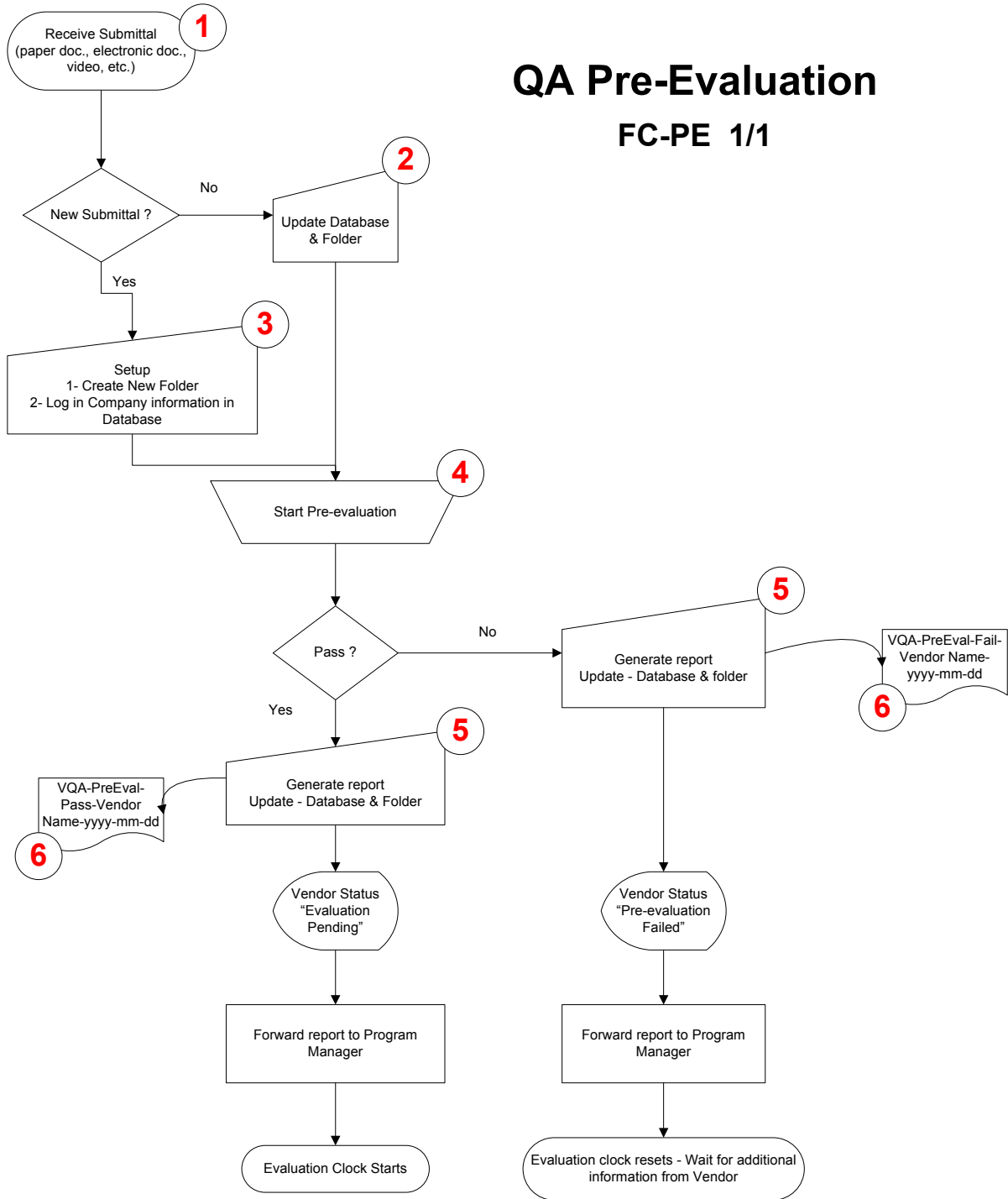
Failing pre-evaluation:

A vendor that fails pre-evaluation is sent an e-mail with **VQA-PreEval-Pass~Fail-Vendor Name-yyyy-mm-dd** attached. This report explains what the vendor was lacking and requests the additional information needed before starting a full evaluation. The evaluation is considered on hold at this point and any new submittal will restart the 45-day evaluation period. A vendor remains in this loop until they provide all required information to pass pre-evaluation.



QA Pre-Evaluation

FC-PE 1/1



4.3 Evaluation

A vendor's QA system proficiency is graded using form **VQA-Eval WS-2006-06**. Each question from the survey is evaluated on three factors:

- 1) The written explanation of the vendor's QA system.
- 2) Proof of documentation (this should have been referenced in the vendor's explanation of the QA system).
- 3) Proof of procedure implementation (this should have been referenced in the vendor's explanation of the QA system).

Each question has a certain amount of points associated with it based on its importance. Satisfying each of the three factors listed above results in the vendor receiving full credit (all points) on that question. Once each response has been reviewed, all points are summed and the submittals grade is determined using the following grading scale:

A: 100-90
B: 89-80
C: 79-70
F: 69-below

See **VQA-Eval Pro-2006-06** for the evaluation process.
See **VQA-Eval GL-2006-06** for the evaluation grading guidelines.

Requirements for passing evaluation are based on the type of device being manufactured:

DMS device: Vendors are required to get a grade of A and also to be ISO registered.
Traffic control devices: Vendors are required to get a grade of at least B.
Non-traffic control devices: Vendors are required to get a grade of at least C.

Passing the evaluation:

A vendor that passes the evaluation is sent an e-mail with **VQA-Eval-Pass-Vendor Name-yyyy-mm-dd** attached. The vendor is then placed in the re-evaluation loop where the date of their re-evaluation is based on the date of qualification. Re-evaluation of the company's quality assurance system is required two years from the date of qualification.

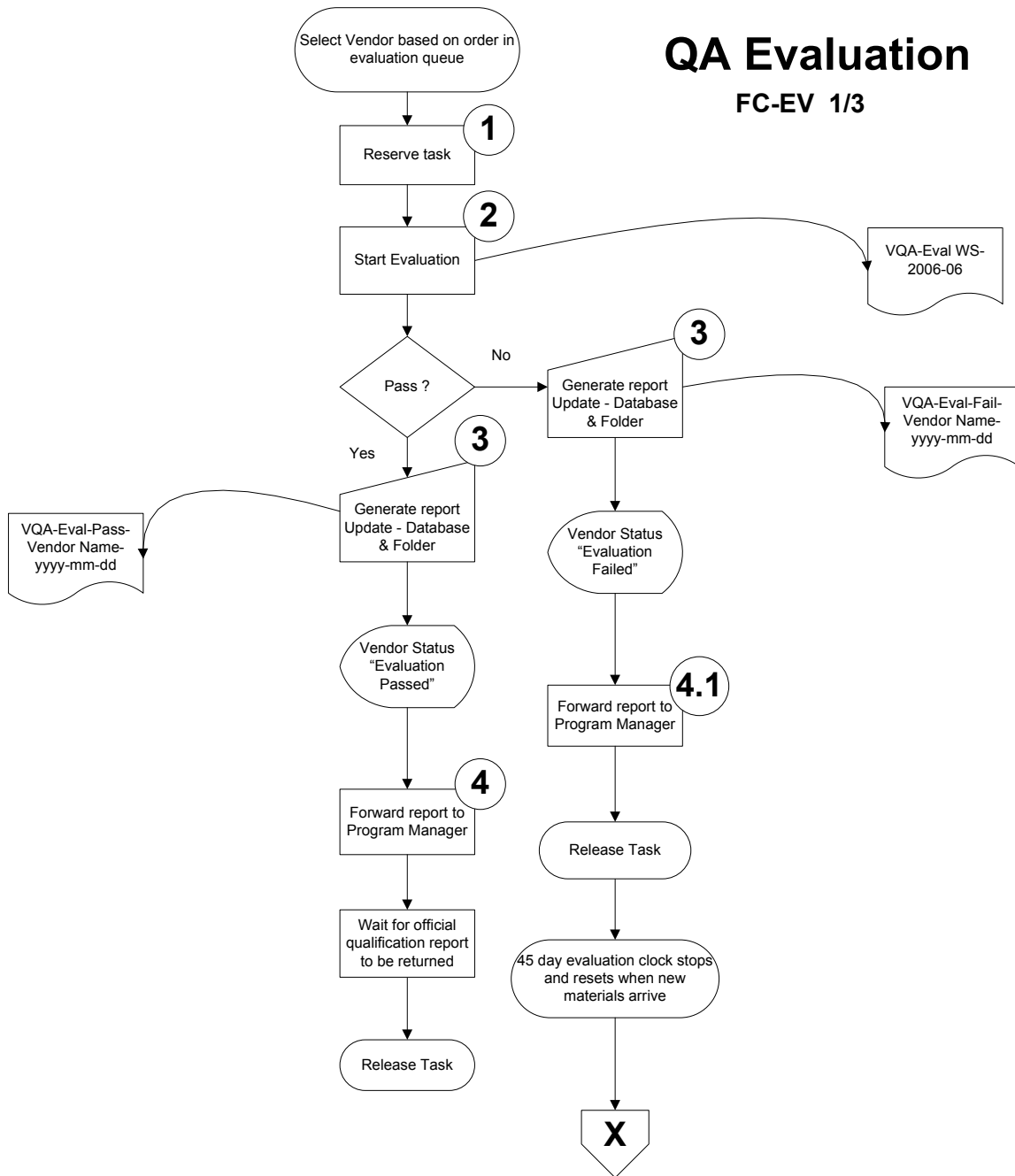
Failing the evaluation:

If a vendor fails the evaluation, the 45-day evaluation period ends. Any subsequent submittal restarts a new 45-day evaluation period, and moves the vendor back into the "evaluation pending" queue. A vendor that fails evaluation the first time is sent an e-mail with **VQA-Eval-Fail-Vendor Name-yyyy-mm-dd** attached, which explains what was

lacking and requests additional information in order to continue the evaluation. For a second failure, an e-mail is again sent with an updated evaluation report attached. A teleconference or in-person meeting is also requested in order to clearly specify evaluation requirements. The vendor will be asked to submit written notes (or an equivalent) to the TERL after the meeting to confirm they understand what was discussed and what is being asked of them. The third time a vendor fails the evaluation they will be suspended from the evaluation loop and given a final updated evaluation report. The vendor will be notified that they cannot re-submit for 6 months and to use this time to implement the necessary changes to their quality system in order to satisfy TERL requirements.

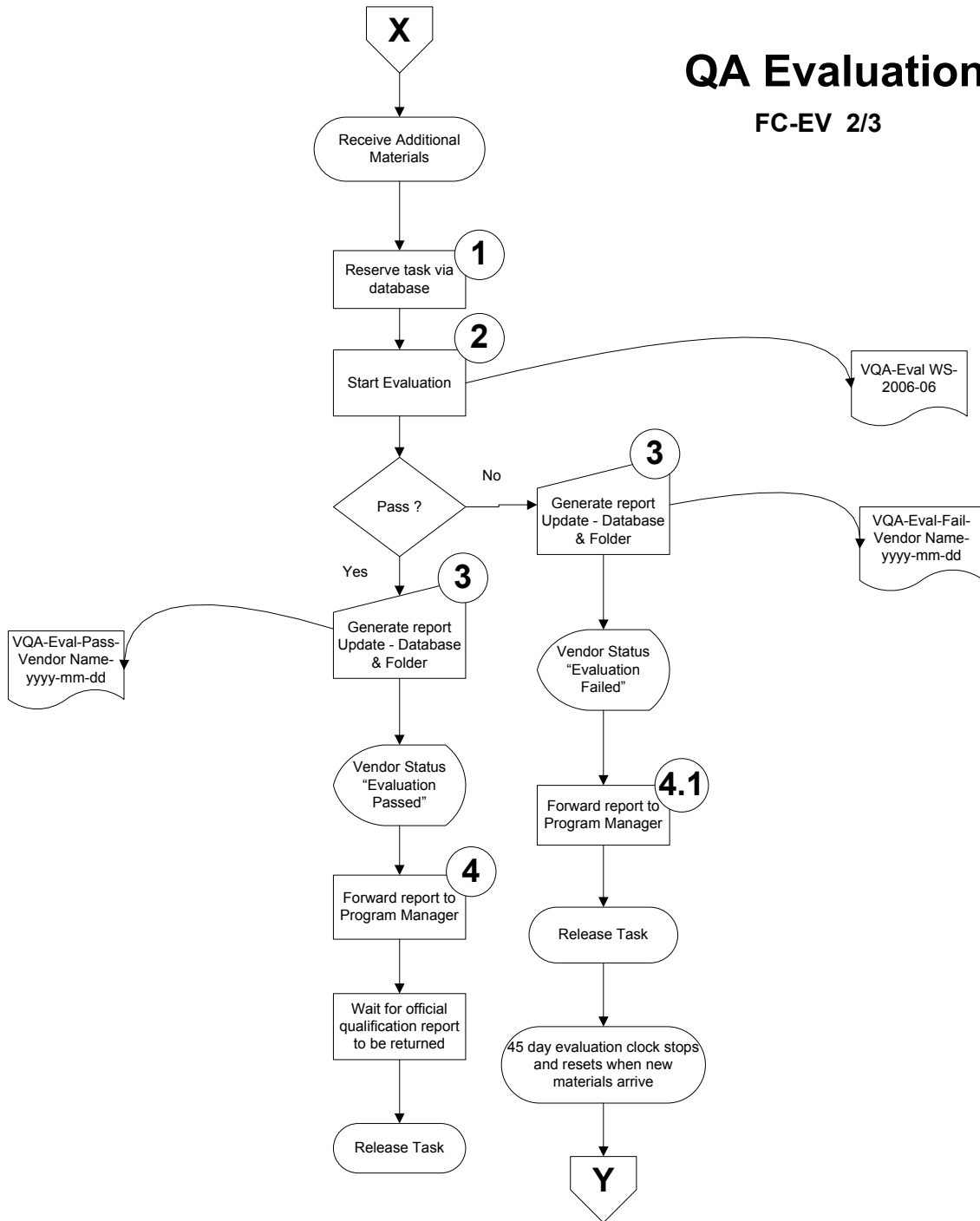
QA Evaluation

FC-EV 1/3



QA Evaluation

FC-EV 2/3



4.4 Re-evaluation

See **VQA-ReEval GL-2006-06** for the re-evaluation grading guidelines. (Draft)

INSERT:

Introduction:

Passing evaluation:

Failing evaluation:

Flow Chart:

5.0 Training

Training is mandatory for all new evaluators. The purpose of the training is to provide all new evaluators adequate information on the operations of the TERL in general and QA activities in specific. Currently the training program is intended to equip the evaluator with the necessary guidelines on handling pre-evaluation and evaluation activities. Training consists of attending 3 sessions over a span of one week. However, it is the responsibility of the QA Engineer and the Qualification Program Manager to guide the new evaluator whenever assistance is required.

Frequency of training is determined by the QA Engineer based on the evaluators' performance and when a new evaluator joins the organization. The QA Engineer may decide to conduct individual training if determined necessary. A mandatory training shall be conducted at 6 month intervals. During the mandatory training session all evaluators, regardless of seniority, shall participate.

5.1 Pre-requisite

The training procedures do not include technical knowledge of QA systems. Therefore, all evaluators are required to have at least basic level skill and knowledge related to quality assurance systems. Proficiency in QA systems for a potential evaluator candidate is to be determined by the Qualification Program Manager and the technical advisor during interviewing period.

5.2 Associated Documents

The document associated with the pre-evaluation process is **VQA-PreEval Pro-2006-06**

The document associated with the evaluation process is **VQA-Eval Pro-2006-06**

The document associated with evaluation grading guideline is **VQA-Eval GL-2006-06**

6.0 Evaluator Inspections

6.1 Audits

The QA Manager is in charge of performing all internal audits on evaluation procedures. Database audits will be performed at least once a week. The audits consist of checking the status of every vendor within the pre-evaluation and evaluation loops to ensure that all information is up to date and all new submittals are recorded and properly queued. It is also the responsibility of the QA Manager to insure that all due dates are met. The QA Manager is in charge of reviewing all forms and reports sent out to vendors. All reports must be grammatically correct and must be in compliance with the procedures documented herein.

6.2 Corrective Action

Nonconformance with the procedures outlined within these documents will trigger a corrective action form, QRT2. The form will state:

- What the nonconformance was.
- The date corrective action was requested.
- Who is in charge of implementing the corrective action.
- Due date for corrective action to take place.

The evaluator assigned to implement the corrective action will update the QRT2 form to indicate when corrective action was implemented. The QA Manager will verify that the corrective action was achieved and note it on the form. All corrective actions will be reviewed and addressed at the evaluators' weekly meetings.

6.3 Preventative Action

Preventative actions are those that can improve procedures over current methods. Any evaluator can suggest preventative actions by filling out a QRT2 form, stating:

- Change requested.
- Benefits of implementing changes.

Requests will be reviewed at the evaluators' weekly meetings and a decision will be made by the QA Manager. Adopted changes will be incorporated into the affected procedures or forms and a log of these changes will appear in the front cover to these procedures and forms.

- Change approved? (Yes or No)
- Date to implement changes.
- Who is assigned to implement changes?

The QA Manager is responsible for insuring all approved preventative action items are implemented by the assigned due date.