

QUALITY ASSURANCE MANUAL



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*PREPARED AND MAINTAINED
BY*

FDE CORPORATION
QUALITY ASSURANCE MANAGER

MANUAL SERIAL NO: _____

ISSUED TO: _____

DATE: _____

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GENERAL

0.1 PURPOSE AND SCOPE

The purpose of this manual is to set forth easy to use procedures covering all company quality assurance functions. The manual reflects official company policy and represents a total commitment of FDE management to conduct operations in accordance with established procedures to support customer needs. It is the responsibility of each department head to make certain that all phases of the system are operating efficiently and effectively in accordance with this manual which has been modeled in accordance with ISO 9001:2000 guidelines and requirements.

0.2 STATEMENT OF APPLICABILITY

This Quality Assurance Manual (QA Manual) has been written with the idea of future growth of Future Design & Engineering (FDE). Consequently, some sections of this manual may be labeled "Inactive" and will be implemented as needed. This manual depicts the controlled quality system established for marketing, purchasing, document control, engineering design, assembly, testing, and final inspection of services, products, and components. This QA Manual is applicable to all FDE Corporation facilities.

0.3 QUALITY GOALS

The QA Manual will be used as a tool to achieve the following goals of the FDE Quality Assurance Program:

- Meet or exceed customer requirements on every job.
- Continuously improve the quality systems which affect our quality, efficiency, and productivity.
- Deliver quality products and services at competitive prices.
- Stimulate creativity, innovation, and a sense of responsibility among our employees.
- Provide a work environment which promotes a spirit of pride, workmanship, and teamwork.

0.4 EXCLUSIONS

At present, manufacturing will be sub-contracted. Qualification of a subcontractor under the FDE quality program will include review of subcontractor manufacturing QA procedures.

0.5 QUALITY ASSURANCE MANUAL – DOCUMENT CONTROL

0.5.1 PURPOSE

This subsection describes the document control process for the FDE QA Manual.

0.5.2 APPLICATION

The QA manual is maintained and distributed on a controlled copy basis, with manual holders receiving copies of new or revised procedures as they are issued. In the event Quality Bulletins are issued, they are to be inserted in Appendix 1 of the Quality Procedures manual in chronological (serial number) sequence.

0.5.3 RESPONSIBILITY

The President of FDE is responsible to ensure that the Quality policy is consistent with company objectives.

This manual is published, distributed, and maintained by the QA Manager. The QA Manager is responsible for processing revisions, additions, and deletions to the QA Manual to maintain it in a current condition.

Assigned holders of the QA Manual are responsible for maintaining these controlled copies and for the update, familiarization, and training required as a result of new revisions to the manual.

0.5.4 REVIEW/APPROVAL

Initial Review/Approval – The QA Manager approves the QA Manual. The President approves the Quality Policy

Review/Approval of Revisions – Revisions to the QA Manual are subject to the same review and approval process as the original.

0.5.5 REFERENCE DOCUMENTS

The following reference documents form a basis for this manual:

| | |
|---------------|---|
| ISO-9001:2000 | Quality Systems |
| MIL-STD-1916 | DoD Preferred Methods for Acceptance of Product |
| MIL-HDBK-1916 | DoD Preferred Methods for Acceptance of Product |

Other reference documents may be incorporated by procurement documents.

1 QUALITY MANAGEMENT SYSTEM

1.1 GENERAL

FDE has implemented Quality System documentation that is continuously maintained for effectiveness. This documentation will reflect the needs of the company as it grows. The Quality System documentation will consist of the following four (4) levels;

LEVEL I - Quality Assurance Manual: The QA Manual establishes requirements and guidelines for the overall Quality System. These requirements and guidelines are applicable to all operations of Future Design & Engineering Corporation.

LEVEL II - Quality Procedures Manual: The Quality Procedures Manual is a collection of Standard Operating Procedures which are documented in conformance with and in support of the Quality Assurance Manual's requirements and guidelines. The Standard Operating Procedures will be labeled "QPM-xxx". The Quality Procedures Manual details the implementation of requirements and guidelines for FDE operations.

LEVEL III - Work Instructions: Work Instructions are documented as necessary to support each applicable Quality Procedure. They detail specific quality or inspection information and specific instructions for performance of individual tasks.

LEVEL IV Records & Forms: Records and Forms complete the system and provide objective evidence of compliance.

Supplemental to these documents are specific program Inspection and Test Plans and Master Lists.

1.2 RESPONSIBILITY AND AUTHORITY

It is the responsibility of the QA Manager to implement and maintain the Quality System defined in the QA Manual.

1.3 QUALITY SYSTEM CONTROL

The QA Manager is responsible for the issuance and control of the QA Manual.

A record is maintained by the QA Manager of all controlled copies of the QA Manual. Uncontrolled copies of the QA manual may be available for reference and training but FDE personnel shall use only controlled copies in the exercise of their responsibilities unless otherwise authorized.

Quality System documents are subject to document control requirements as defined in Section: 1.5.7 [QUALITY ASSURANCE DOCUMENTATION REVIEW](#)

Only sections containing revisions are reissued. Changes in the manual are identified by the method described in Section: 0.5 [QUALITY ASSURANCE MANUAL – DOCUMENT CONTROL](#) of this manual.

The Quality Assurance Manager maintains a historical record of all quality related documentation in accordance with Section: 1.5.5 - [CONTROL OF QUALITY ASSURANCE RECORDS / REPORTS](#) .

1.4 QUALITY PROCEDURES AND BULLETINS

1.4.1 PURPOSE

This section describes a method for the generation, maintenance, and control of Quality Procedures and Quality Bulletins. Quality procedures and bulletins related to company standards for providing customer products and services may be generated as part of future contractual planning and analysis.

1.4.2 APPLICATION

This procedure applies to the Quality Assurance, Purchasing, Receiving, and other departments requiring Quality Procedures, Bulletins, or other contractual quality elements.

1.4.3 ASSOCIATED MATERIALS

- A. Quality Procedures, Quality Procedure Manual, [QPM-001](#)
- B. Quality Form, Quality Procedure Template, [QP-006](#)
- C. Quality Form, Quality Bulletins, [QP-007](#)
- D. Quality Planning, Quality Procedure, [QPM-006](#)

1.4.4 PROCEDURE

- A. Quality Procedures or instructions shall be generated, maintained and utilized in accordance with [QUALITY PROCEDURES](#), Section No. 1.4.5.
- B. Quality Bulletins shall be generated, maintained, distributed and utilized in accordance with [QUALITY BULLETINS](#), Section No. 1.4.6.
- C. Quality Planning shall be conducted at periodic intervals or when new contractual requirements arise and shall be addressed in accordance with [QUALITY SYSTEM PLANNING](#) Section No. 2.5.

1.4.5 QUALITY PROCEDURES

1.4.5.1 PURPOSE

Quality Procedures are to provide instructions for completion of standard operational processes and procedures.

1.4.5.2 APPLICATION

This subsection applies to all FDE personnel that may effect customer satisfaction.

1.4.5.3 USAGE

- A. Quality Procedures are the directives issued by Quality Assurance for communicating the established methods for performing and administering the work relative to assuring and controlling the Quality of the company's products and services.
- B. Quality Procedures provide the summary level information required on a given subject. If this information must be described in further detail for a specific application, this detail is to be recorded in Work Instructions and may utilize Work Orders or other Quality System forms to provide process control.

1.4.5.4 ASSOCIATED MATERIALS

A. Quality Procedure Template, [QP-006](#)

1.4.5.5 PROCEDURE

A. New Quality Procedures may be requested by any company employee. A rough draft should be prepared using the Quality Procedures Template, Form [QP-006](#). The draft should outline the purpose and steps associated with the procedure and should be submitted through the applicable manager to the QA Manager for review and approval.

B. Revisions to existing Quality Procedures may be requested by any company employee. The existing procedure should be clearly marked as to the recommended change. It should be submitted through the appropriate manager to the QA Manager for review and approval.

C. The QA Manager shall assign reference numbers to new procedures and maintain records of all procedure development or revision work in process.

1.4.6 QUALITY BULLETINS

1.4.6.1 PURPOSE

This subsection describes the preparation and distribution of the Quality Bulletin.

1.4.6.2 APPLICATION

Quality Bulletins are used to provide:

- Emergency changes to existing quality procedures.
- Expedient interim applications of new, pending quality procedures
- One time or limited use instructions or information relative to the quality assurance program.

1.4.6.3 ASSOCIATED MATERIALS

A. Quality Bulletin, Form [QP-007](#)

1.4.6.4 PROCEDURE

A. Bulletins may be submitted by any employee to the QA Manager.

B. If distribution is appropriate beyond the Quality Assurance Manual holders, a recommended distribution list should be submitted by the requester to the Quality Manager.

C. The Quality Bulletin form is to be prepared with the following information:

- Control number of the bulletin (QA Manager),
- Bulletin's release date (QA Manager),
- Page number of the bulletin, starting with "1". If the bulletin supersedes a previously issued bulletin, the old Control No. and release date should be cited,
- Subject,
- Complete text of the bulletin in the outlined form.

The form should be checked and date entered, where applicable, relative to one of these four statements:

- Retain this bulletin until further notice.
- Discard this bulletin after noting contents.
- This bulletin will be invalid after (date).
- This bulletin will be incorporated into Procedure Number by date.

When the information on the form is complete, it should be submitted to the QA Manager for an approval signature. If the bulletin's instructions or information crosses department lines, other appropriate signatures may be required.

D. When the bulletin has been signed, it is to be reproduced and distributed. Distribution is to all Quality Assurance Procedure Manual holders, and others whose names are cited on the distribution list.

1.5 DOCUMENT CONTROL

1.5.1 PURPOSE

This section sets forth methods for review and control of documents related to contractual requirements for services or products delivered to customers.

1.5.2 APPLICATION

In addition to deliverable documents, this procedure applies to documents utilized by the Quality Assurance, Procurement, Receiving, and other departments required to provide quality related documents.

1.5.3 ASSOCIATED MATERIAL

N/A

1.5.4 PROCEDURE

A. Verification of completeness and correctness of documentation shall be performed in accordance with [DELIVERABLE DOCUMENTATION REVIEW](#), Section No. 1.5.6 and [QUALITY ASSURANCE DOCUMENTATION REVIEW](#), Section No. 1.5.7.

B. Procurement Documents shall be reviewed and approved in accordance with [PROCUREMENT DOCUMENT QUALITY REQUIREMENT REVIEW](#), Section No. 1.5.8.

1.5.5 CONTROL OF QUALITY ASSURANCE RECORDS / REPORTS

1.5.5.1 PURPOSE

This subsection describes a system for maintaining and using complete, reliable quality program records and data. The purpose of the quality assurance records system is documentation, data analysis, and reporting.

1.5.5.2 APPLICATION

This subsection applies to all quality program records and data.

1.5.5.3 PROCEDURE

A. The data to be included in this system includes, but is not limited to, Inspection Reports, Receiving Inspection Reports, Calibration History Forms, Work Orders, Certifications, Traceability, Acceptance Test Reports, Quality Assurance Audit Reports, Corrective Action Requests, and other QA Records as applicable.

B. QA information is to be accumulated, organized, analyzed, and reported in a manner that will enable convenient search and retrieval of specific data.

C. Unless otherwise specified, data is to be maintained in active files in accordance with the Records Retention Chart, shown in Figure No. 1. At the end of the active retention period, data is to be destroyed or packaged, indexed, and archived for a specified length of time.

| Records Retention Chart | | |
|--------------------------------|------------------------------|-------------|
| Record | Active File Retention Period | Disposition |
| Deliverable Document Checklist | 12 Months | Archive |
| Purchase Orders/Subcontracts | 12 Months | Archive |
| QA Audit Plan and Report | 36 Months | Destroy |
| Inspection Reports | 12 Months | Destroy |
| Receiving Inspection Reports | 12 Months | Destroy |
| Calibration History Forms | 36 Months | Destroy |
| Work Orders | 12 Months | Destroy |
| Certifications | 12 Months | Destroy |
| Traceability Forms | 12 Months | Destroy |
| Acceptance Test Reports | 12 Months | Archive |
| QA Audit Reports | 12 Months | Archive |
| Corrective Action Requests | 12 Months | Destroy |
| | | |

Figure 1: Records Retention Chart

D. Document storage containers are to be clearly marked as to contents, retention dates, and department ownership.

1.5.6 DELIVERABLE DOCUMENTATION REVIEW

1.5.6.1 PURPOSE

This subsection describes a system for verifying the completeness and correctness of deliverable documentation.

1.5.6.2 APPLICATION

This subsection applies to all programs and projects which require deliverable documentation either as the end product or as an item of supportive, certifying, or explanatory documentation included with a product.

1.5.6.3 ASSOCIATED MATERIALS

- A. Deliverable Documentation Checklist, Form [QP-008](#)
- B. Document Final Acceptance Processing, Quality Procedure, [QPM-007](#)

1.5.6.4 PROCEDURE

- A. The QA Manager or his appointed representative is responsible for verifying the completeness and correctness of deliverable documentation.
- B. This verification is to be done in conjunction with final acceptance processing, as described in Quality Procedure [QPM-007](#).
- C. Applicable contracts, purchase orders, and other agreements shall be examined to determine all deliverable documentation. This information is to be compiled into the Deliverable Document Checklist, Form [QP-008](#).

D. Documentation shall be examined for completeness and compliance with document type specifications if applicable.

1.5.7 QUALITY ASSURANCE DOCUMENTATION REVIEW

1.5.7.1 PURPOSE

This subsection describes the system for review and critique of Quality Assurance related documentation for adequacy, completeness, and correctness.

1.5.7.2 APPLICATION

This subsection applies to all documentation including, but not limited to engineering drawings, specifications, calibration instructions, Quality Procedures, quality related procurement documents, and change orders.

1.5.7.3 ASSOCIATED MATERIALS

N/A

1.5.7.4 PROCEDURE

- A. The QA Manager has the primary responsibility for documentation review and control.
- B. Program documentation is to be reviewed by the QA Manager or his representative and corrective action initiated for any discrepancies noted in adequacy, completeness, or relevance.
- C. Random audits are to be conducted periodically to see that only current QA documentation is being used and that obsolete material has been discarded.
- D. QA Technicians will review Quality Procedures and related maintenance instructions and initiate corrective action for any discrepancies in adequacy, completeness, and relevance.

1.5.8 PROCUREMENT DOCUMENT QUALITY REQUIREMENT REVIEW

1.5.8.1 PURPOSE

This subsection will set forth a method for reviewing quality related procurement documents to assure that contractual and internal quality requirements have been properly and completely specified.

1.5.8.2 APPLICATION

This subsection applies to the procurement of all services, materials, parts, and assemblies that will be used in deliverables to FDE customers as related to contractual quality requirements. It involves specifications of the Quality Assurance and Purchasing functions.

1.5.8.3 ASSOCIATED MATERIALS

- A. Purchase Order, Form [QP-025](#)

1.5.8.4 PROCEDURE

- A. Purchase Orders and Subcontracts are submitted for approval using Form [QP-025](#). Once approved they are entered and maintained on the FDE electronic accounting system. Purchase Orders and Subcontracts will be prepared and printed from this system as part of the approval process. Signed purchase orders and subcontracts are filed and retained according to the Records Retention Chart, Figure 1.
- B. Prior to issuance, the Purchasing Department will forward Purchase Orders, Reprinted Purchase Orders (modified), and Subcontracts, as applicable, to the QA Manager for review.
- C. Purchasing is to review procurement documents to determine if all contractual and internal quality requirements have been adequately specified.
- D. Each procurement document is to be augmented with the appropriate technical and quality requirements being imposed on the supplier/subcontractor.
- E. If appropriate, the procurement document is to specify that FDE procurement and quality assurance personnel will require access to the supplier and subcontractor premises.
- F. If test reports and/or certifications are to be provided by the supplier or subcontractor, those items are to be specified in the procurement document.
- G. If the supplier or subcontractor is to maintain inspection, test, or other records as to functional, chemical and/or physical properties, this fact is to be specified in the procurement document.
- H. If the procurement document is for calibration/repair of M&TE or measurement standards, the part number and serial number shall be utilized to specify identification of the item.
- I. If there are discrepancies in the procurement document, it shall be returned to the Purchasing Department accompanied by documentation describing the discrepancies.
- J. If the procurement document is determined to be adequate from a technical and quality requirements standpoint, it is to be signed as reviewed by the QA Manager and returned to the Purchasing Department.
- K. Procurement documents shall be approved by the President of FDE or his authorized representative. An individual's purchasing approval authority and the level of that authority will be documented.
- L. The Quality Assurance Department is to maintain records as to the review and disposition of applicable procurement documents in accordance with the Records Retention Chart.

1.6 QUALITY AUDITS

1.6.1 PURPOSE

This section describes the process for independent reviews and evaluations in order to improve customer satisfaction. This includes evaluation of the suitability of applicable requirements as well as compliance with those requirements. Audits, as described in this section, are not surveillance or inspection type activities performed for the sole purpose of process control or product acceptance. Quality Audits are frequently carried out on a periodic basis with written procedures and checklists used as a guide in performing and documenting quality audits, but the audit may involve additional elements beyond these.

1.6.2 APPLICATION

In general, these quality system audits are an independent (unbiased) assessment of the effectiveness of the FDE Corporation quality system. The findings should be clearly reported so that the operation being audited can implement any required corrective action.

1.6.3 QUALITY ASSURANCE AUDITS OF INTERNAL SYSTEMS

1.6.3.1 PURPOSE

This subsection sets forth the method for periodically examining the adequacy and effectiveness of the overall Quality Assurance Program and for determining compliance with applicable requirements.

1.6.3.2 APPLICATION

This subsection applies to the following internal functions: Receiving Inspection, Procurement, Metrology, Inspection, Outside Services, Shipping, and other areas that affect quality. The quality auditing of supplier and subcontractor activities is covered by another procedure (see [QUALITY ASSURANCE AUDITS OF SUBCONTRACTORS AND SUPPLIERS FOR CALIBRATION REQUIREMENTS](#)).

1.6.3.3 ASSOCIATED MATERIALS

- A. Quality Assurance Audit Plan and Report, Form [QP-009](#)
- B. Corrective Action Request, Quality Procedure [QPM-005](#)
- C. Audit Committee Designation, Form [QP-004](#)

1.6.3.4 PROCEDURE

- A. The president of FDE has the responsibility for directing planning and conducting of quality audits.
- B. An audit plan is first prepared, using the Quality Assurance Audit Plan and Report Form, [QP-009](#). The plan section of this form is filled out as follows:
 - Assigned number of the audit plan and report.
 - Name and address of the facility being audited.
 - Planned audit date
 - Audit subject / department.
 - Detailed description of the audit plan.
 - Signature of the person who has prepared the plan.

C. An audit committee is established under direction of the president to carry out specific audits of the FDE quality system. The audit committee is named and authorized using the Audit Committee Designation Form, [QP-004](#).

D. The originator will contact the Audit Committee members 7 days prior to the audit to confirm availability.

E. The Audit Committee proceeds with the audit in accordance with the audit plan. At any time during the audit, an audit committee member may request that an item or procedure be selected from the production cycle at random and re-inspected or re-tested to evaluate the adequacy of the inspection/test processes as well as the effectiveness of the inspectors/testers.

F. At the conclusion of the audit, the lead auditor completes the report section of the Quality Assurance Audit Plan and Report ([QP-009](#)) as follows:

- Name of the person(s) contacted.
- Actual date of the audit.
- Audit findings.
- Indication of Corrective Action Request issuance.
- Signature of the auditor and the date.
- Other comments as necessary.

G. The report is reviewed, corrected if necessary, and approved with the president's dated signature.

H. The auditors will periodically follow-up on Corrective Action Requests to verify compliance, in accordance with the Corrective Action Request Quality Procedure, [QPM-005](#).

I. Records of Quality Assurance Audits shall be maintained in accordance with the Records Retention Chart, as shown in Figure No. 1.

1.6.4 QUALITY ASSURANCE AUDITS OF SUBCONTRACTORS AND SUPPLIERS

1.6.4.1 PURPOSE

This subsection sets forth the method for periodically and randomly examining the quality performance of subcontractors and suppliers to verify compliance with applicable contractual requirements as specified in FDE procurement documents.

1.6.4.2 APPLICATION

This subsection applies to subcontractors and suppliers that have quality requirements specifically established through procurement documents.

1.6.4.3 ASSOCIATED MATERIALS

- A. Audit Plan and Report, Form [QP-009](#)
- B. Corrective Action Report, Quality Procedure [QPM-005](#)
- C. Corrective Action Request, Form [QP-016](#)

1.6.4.4 PROCEDURE

A. When M&TE calibration and/or repair work is to be subcontracted, there must be assurance that this work will be done by capable subcontractors and with M&TE or measurement standards that are certified and traceable to the National Institute of Standards and Technology (NIST). The Quality Assurance Department is

responsible for evaluating calibration/repair subcontractors as to their conformance to traceability and procedural requirements. This evaluation, inspection, or audit is to be conducted on a random but periodic basis of no longer than three year intervals. Results of Government inspections or audits conducted within the last 12 months may be used in determining subcontractor compliance.

B. The Quality Assurance Department is responsible for verifying compliance with contractually specified quality requirements imposed on subcontractors. This is achieved through period, random audits.

C. The auditor prepares a plan using the Audit Plan and Report Form ([QP-009](#)).

D. At the conclusion of each audit, the QA Department is to prepare a report which presents the results of the audit and offers any recommendations.

E. The QA Department is to create and continually maintain a list of qualified subcontractors for M&TE calibration and repair work.

F. The auditor will periodically follow-up on Corrective Action Requests to verify compliance.

1.6.5 SUBCONTRACTOR/SUPPLIER APPROVAL

1.6.5.1 PURPOSE

This subsection provides a system for approving specific suppliers / subcontractors for services and capabilities when such approval is required.

1.6.5.2 APPLICATION

This subsection applies to all services performed by suppliers / subcontractors.

1.6.5.3 ASSOCIATED MATERIALS

A. Supplier Approval, Form [QP-019](#)

1.6.5.4 PROCEDURE

A. A memo requesting approval of a supplier or subcontractor's services can be originated by the Quality Assurance or any other department requiring such services.

B. Upon receipt of an approval request, the Quality Assurance Department will visit the supplier and conduct a detailed Quality Audit in accordance with [QUALITY ASSURANCE AUDITS OF SUBCONTRACTORS AND SUPPLIERS](#).

C. If the supplier's capabilities cannot be approved, the Quality Assurance Department prepares a memo to this effect and transmits it to the original requester.

D. If the supplier's capabilities can be approved, the Supplier Approval Form ([QP-019](#)) is filled out as follows:

- Approval date.
- Approval's expiration date (normally three years after approval).
- Name, address and phone number of the supplier.
- Date when the survey was made.
- Name and/or description of the process or system being approved.

- Specifications to which the system(s) comply.
- Dated signature of the person who has prepared the approval form.
- Dated signature of the person who approved the supplier or subcontractor.

E. The approval is maintained in a master record by the Quality Assurance Department. A copy of the approval is to be transmitted to the requester and the organization being approved.

F. A copy of the approval is to be maintained by expiration date in a tickler file in the Quality Assurance Department. This file is to be continually reviewed by Quality Assurance for the purpose of activating a re-approval survey of suppliers or subcontractors.

2 MANAGEMENT RESPONSIBILITY

2.1 PURPOSE

Future Design & Engineering defines and documents the corporation policy for quality. The Quality Policy is relevant to the company's goals and the expectations of its customers.

2.2 APPLICATION

This section applies to all FDE Corporation personnel whose duties and responsibilities include Quality Assurance functions. Personnel and departments whose activities involve quality processes or procedures as outlined in this Quality Assurance Manual shall follow those procedures as applicable. Any areas of deficiencies shall be reported directly to the QA Manager or President of FDE.

2.3 STATEMENT OF AUTHORITY

The administration and responsibilities of the Quality Assurance function shall rest upon the QA Manager and his/her designated representatives. The QA Manager reports directly to the President of FDE Corporation and has the full authority and responsibility for the implementation and enforcement of the system described in this QA Manual. A simplified FDE organizational chart is presented in Figure No. 2. The QA Manager has the authority to access all work areas and has organizational freedom to: (1) identify quality problems; (2) initiate, recommend, or provide solutions to quality problems through designated channels; (3) verify implementation of solutions; and (4) assure that further processing, delivery, installation, or use is controlled until proper disposition of a non-conformance, deficiency, or unsatisfactory condition has occurred. The successful operation of this controlled system requires complete communication and full cooperation of all personnel. If major problems or differences of opinion cannot be resolved within the organization, they shall be brought to the President of FDE Corporation for final resolution.

2.4 MANAGEMENT REVIEW

The President and QA Manager, with company staff, will conduct a management review of the Quality System annually (at a minimum) to assess its continued suitability, effectiveness, and future direction.

Management review process – The President, QA Manager, and staff shall review all appropriate Quality System documentation.

Management reviews records – The QA Manager records/documents a summary of each management review.

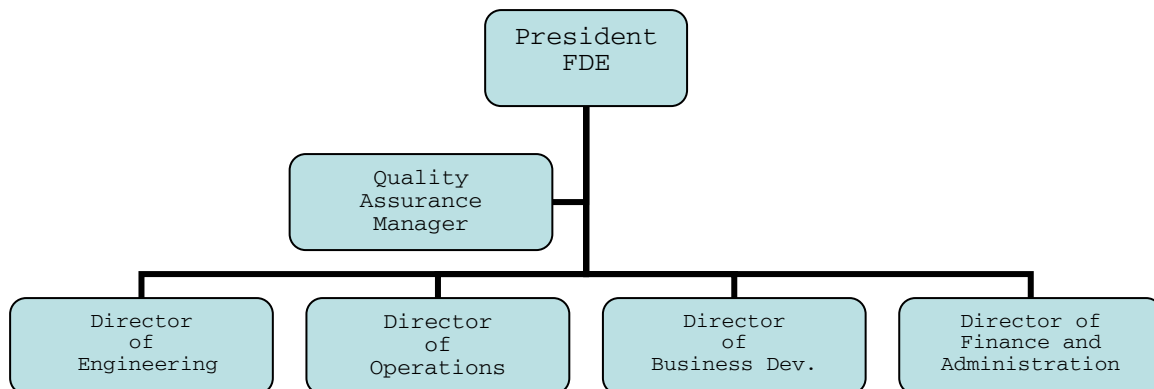


Figure 2: FDE Simplified Organizational Chart

2.5 QUALITY SYSTEM PLANNING

The Director of Operations is responsible for identifying and implementing the processes, equipment (including test equipment), and controls needed to achieve the required quality.

It is the responsibility of the Director of Operations and the QA Manager to ensure the compatibility of all system components.

The Engineering and QA Managers are responsible for Quality Assurance inspection and test techniques, including the development of new techniques.

The Engineering Manager is responsible for identifying, in a timely manner, any test measurement requirement(s) beyond current industry availability. This will allow sufficient time for developing test equipment/techniques.

The QA Manager is responsible for the identification of suitable verification stages appropriate in the production process.

The QA Manager is responsible for clarification of standards of acceptability for all features and requirements, including those that contain a subjective element.

2.5.1 NEW/PENDING CONTRACT QUALITY REQUIREMENTS ANALYSIS

2.5.1.1 PURPOSE

This subsection provides a means for quickly determining and planning for the quality requirements of a new contract or a potential contract as a first step in the Quality Planning function.

2.5.1.2 APPLICATION

This subsection relates to new and pending business.

2.5.1.3 ASSOCIATED MATERIALS

A. Quality Planning, Procedure [QPM-006](#)

2.5.1.4 PROCEDURE

A. The Business Development Department is responsible for providing the QA Manager with copies of new or pending contract information.

B. The Quality Manager analyzes the new/pending contract information to determine the impact of the new business on Quality Assurance functions. A Quality Plan is established for new business using the Quality Planning Procedure ([QPM-006](#)) and actions taken to implement any new requirements.

C. The QA Manager is responsible for monitoring compliance to the tasks, assignments, and dates related to acquiring the new contracts.

3 RESOURCE MANAGEMENT

3.1 QUALITY ASSURANCE PERSONNEL TRAINING

3.1.1 PURPOSE

This section sets forth a method for initial and refresher training of employees in Quality Assurance (QA) policies and procedures.

3.1.2 APPLICATION

This section applies to all Quality Assurance and Technical personnel whose duties and responsibilities lie within Quality Assurance functions.

3.1.3 ASSOCIATED MATERIALS

- A. FDE Quality Assurance Manual
- B. Quality Assurance Training Notice, Form [QP-002](#)
- C. Certificate of Completion, Form [QP-003](#)
- D. QA Technical Library / Bibliography

3.1.4 PROCEDURE

A. The Quality Assurance Manager is responsible for creating, maintaining, and presenting a Quality Assurance Training Course suitable for familiarizing new quality assurance and technical employees in QA policies and methods of operation.

B. Periodically, the same or a similar course is to be presented to all QA personnel to reinforce their knowledge of QA policies and procedures and to acquaint personnel with any changes to the QA Manual or Quality Procedures Manual.

C. Course material is to cover, but not be limited to:

- Quality Assurance functions,
- Objectives of the Quality Assurance functions,
- Quality Planning System and QP instructions,
- Inspection and test processes,
- Measuring and test equipment calibration and control systems,
- Roles of records and reports.

D. All Quality Assurance employees will be notified of training sessions through the use of the Quality Assurance Training Notice Form, [QP-002](#).

E. Employees who have been certified are to receive a Certificate of Completion, Form [QP-003](#).

F. The QA Manager is responsible for maintaining records of Quality Assurance employees in terms of training sessions attended.

4 PRODUCT REALIZATION

4.1 PURCHASING

4.1.1 PROCUREMENT OF PARTS OR MATERIAL

4.1.1.1 PURPOSE

This subsection sets forth a method for the procurement of parts that may be used in providing services or products.

4.1.1.2 APPLICATION

This subsection applies to all parts, components, assemblies, or devices procured for the express use in providing customer services or products.

4.1.1.3 ASSOCIATED MATERIAL

- A. Parts Requisition, Form [QP-010](#)
- B. Static Sensitive Devices, Quality Procedure [QPM-003](#)

4.1.1.4 PROCEDURE

A. A Parts Requisition Form, [QP-010](#), shall be completed along with any special requirements and forwarded to the Purchasing Department for procurement.

B. The Purchasing Department shall order the part, device, component, assembly, product, or service as approved on the Parts Requisition Form and in accordance with [PROCURING, HANDLING, AND STORAGE OF ESD SENSITIVE DEVICES](#) as applicable.

C. In the event Purchasing can not procure the requisitioned item(s), the annotated requisition is returned to the appropriate department and originator.

D. Receiving Inspection as outlined under [RECEIVING INSPECTION](#) is to be performed on all incoming parts, devices, components, and assemblies.

E. Specific quality requirements shall be specified and imposed in procurement documents as applicable, and in accordance with [PROCUREMENT DOCUMENT QUALITY REQUIREMENT REVIEW](#).

4.1.2 RECEIVING INSPECTION

4.1.2.1 PURPOSE

This subsection prescribes the system for visually inspecting parts or materials received from suppliers and subcontractors.

4.1.2.2 APPLICATION

This subsection applies to the visual inspection of all parts, materials, and equipment received by FDE as a result of purchase actions.

4.1.2.3 ASSOCIATED MATERIALS

- A. Receiving Inspection, Quality Procedure [QPM-002](#)
- B. Receiving Inspection Check List, Form [QP-020](#)
- C. Non-Conforming Material, Form [QP-021](#)
- D. Rejection and Disposition Tag/Stamp, Form [QP-022](#)
- E. Accepted Tag/Stamp, Form [QP-023](#)
- F. Material Handling and Storage Quality Procedure, [QPM-009](#).

PROCEDURE

A. All parts, material, and equipment are to be inspected upon receipt and are to be handled in accordance with Material Handling and Storage Quality Procedure, [QPM-009](#). Receiving Inspection shall inspect these items in terms of visual compliance to specified requirements, completeness, and transit damage. Applicable paper work and documentation shall be verified complete and correct

B. Parts or materials that have been sent out for special processing are to be inspected upon return only for the processing performed.

C. M&TE and measurement standards received from calibration or repair shall be forwarded to the Quality Assurance Department for inspection.

D. M&TE or measurement standards that have been source inspected, upon receipt, are to be examined only for transit damage and the completeness/correctness of the accompanying paper work/documentation (such as certificates of calibration and test reports).

E. All incoming items are to be processed in a date required priority sequence.

F. As a prelude to inspecting received materials, the inspector is to obtain all appropriate drawings, specifications, and inspection instructions. For the Receiving Inspection Check List, see Form [QP-020](#).

G. The materials are to be inspected for conformance to requirements, checking the results in accordance with the Receiving Inspection Check List. The data to be checked and verified are as follows:

- Name and address of the vendor, supplier or subcontractor
- Purchase order or contract number
- Invoice number
- Certificate or test report date, as applicable
- Each item number, item description, item part number, quantity ordered, quantity cited on the packing slip, quantity received, quantity inspected, quantity accepted, and quantity rejected

Accepted items shall be tagged/stamped with an Accepted tag/stamp as shown on Form [QP-023](#).

H. Descriptions of discrepancies found are recorded as follows:

- Handling/shipping defects
- Discrepancy between quantities shipped and received
- Improper paper work
- Incomplete and/or incorrect documentation
- Discrepancies regarding functional characteristics

I. Parts or materials that have been accepted as a result of Receiving Inspection should be routed to their appropriate department for disposition or secured in the proper storage location in accordance with the Material Handling and Storage Quality Procedure, [QPM-009](#).

J. Parts or materials that have been rejected should be tagged/stamped with the Rejection and Disposition tag/stamp, as shown on Form [QP-022](#). For items in assembly, the inspector may designate rework as the disposition but must refer the material to the Material Review Board on a second rejection. Purchased or

customer supplied items should be returned by purchasing directly to the customer, vendor, supplier or subcontractor.

4.1.3 DISCREPANT MATERIAL RETURN

4.1.3.1 PURPOSE

This subsection describes the system for returning vendor parts and materials found to be discrepant.

4.1.3.2 APPLICATION

This subsection applies to all company functions which use purchased parts and materials.

4.1.3.3 ASSOCIATED MATERIALS

A. Non-Conforming Material Report, Form [QP-021](#)

4.1.3.4 PROCEDURE

A. A material return request can be initiated by any organizational unit representative who has reason to believe that certain parts or materials are discrepant and should be returned to the vendor or purged from the system.

B. Requests are initiated by completing the Non-Conforming Material Report as shown on Form [QP-021](#).

C. The request is forwarded to the QA Department for analysis and disposition. The QA Department investigates the request and completes the applicable sections.

E. Instructions on the Non-Conforming Material Report will be carried out by the assigned person.

F. When the report is complete, a Material Review Board which includes QA and Purchasing representatives decides on the proper disposition of the material.

G. Purged parts and materials, accompanied by a copy of the completed Nonconformance Report, are to be forwarded to the QA Manager for final disposition.

H. Quality Assurance is to initiate alternate or corrective actions, as required.

4.2 CONTROL OF CUSTOMER FURNISHED EQUIPMENT / PROPERTY

4.2.1 PURPOSE

This subsection describes the system for providing adequate inspection, handling, storage, and maintenance of equipment or property furnished by the customer.

4.2.2 APPLICATION

This subsection applies to all customer furnished equipment, property, or materials unless excluded from these requirements by contractual agreement.

4.2.3 ASSOCIATED MATERIAL

- A. Material Handling, and Storage, Quality Procedure [QPM-009](#).
- B. Receiving Inspection, Quality Procedure [QPM-002](#).
- C. Requisition and Invoice/Shipping Document, DD FORM 1149 and 1149c.
- D. Government Property Control Program, Work Instruction [WI-001](#).

4.2.4 PROCEDURE

A. Upon receipt, a Receiving Inspection of all customer furnished/owned items shall be conducted in accordance with the Receiving Inspection Quality Procedure [QPM-002](#). If material is government property, Work Instruction [WI-001](#) applies. Each item shall be examined for:

- Transit damage,
- Completeness and proper type,
- Proper identification,
- Correct quantity.

B. If appropriate and in accordance with contractual agreement, the items shall be functionally tested to determine satisfactory operation. The test result shall be included as part of the Receiving Inspection.

C. Quality Assurance is responsible for conducting periodic inspections to assure that the materials are being properly stored, adequately protected, subjected to periodic maintenance when/as required, and that precautions exist to protect them from improper use or disposition, as outlined under the Material Handling and Storage Quality Procedure [QPM-009](#) and Work Instruction [WI-001](#).

D. Quality Assurance is responsible for reporting to the customer incidence of damage, malfunction, or otherwise unsuitable customer-furnished materials. If the problem is detected after installation, then the report is to contain an indication of the probable cause.

E. Quality Assurance and the Director of Operations are responsible for maintaining complete and accurate records of all customer furnished/owned property and making these records available for review by the customer on request.

F. Customer furnished/owned property shall be inventoried and secured apart from other FDE parts and materials.

G. Government Furnished Equipment (GFE) will be received, verified, and documented using DD FORM 1149/1149c as detailed in the Government Property Control Work Instruction, [WI-001](#).

4.3 PRODUCT IDENTIFICATION AND TRACEABILITY

4.3.1 PURPOSE

This subsection describes a system for controlling the quality of products through managing the configuration of elements of these products.

4.3.2 APPLICATION

This subsection applies to all departments and personnel that design, procure, assemble, compile, organize, or document FDE hardware, software, or documentation products.

4.3.3 ASSOCIATED MATERIAL

Configuration Management Quality Procedure, [QPM-012](#)

4.3.4 PROCEDURE

Software, documentation, drawings, and associated lists will be controlled, tracked, and updated using configuration management procedures reviewed and approved by the QA Manager. These procedures will be in the form of Quality Procedures and Work Instructions.

Electronic configuration management systems will be utilized to the fullest extent possible and will meet customer requirements for such systems.

Electronic configuration management systems will be access controlled to ensure a disciplined, managed approach to revision updates and baseline establishment.

4.4 PROCESS CONTROL

4.4.1 PURPOSE

This subsection describes a system for controlling the quality of customer products and services through managing the processes involved..

4.4.2 APPLICATION

This subsection applies to all departments and personnel that design, assemble, compile, organize, or document FDE hardware, software, or documentation products and services.

4.4.3 ASSOCIATED MATERIAL

Work Order Form, [QP-029](#)

4.4.4 PROCEDURE

Software, documentation, and hardware production will be authorized and detailed through the use of Work Order and Work Instructions.

The Operations Manager will compile and issue Work Orders covering scheduled production activities.

The Operations Manager will ensure that Work Instructions are available and complete for any detailed operations involved in providing products or services.

The QA Manager will verify that Work Orders are complete, accurate, and are followed by those assigned production activities.

4.5 HANDLING, STORAGE, PACKAGING, PRESERVATION, AND DELIVERY

4.5.1 PURPOSE

This subsection describes a system for specifying and monitoring proper handling, preservation, storage, packaging, and transportation practices to protect the quality of deliverable products and to prevent their damage, deterioration, or degradation.

4.5.2 APPLICATION

This subsection applies to all M&TE, measurement standards, devices, components, parts, or assemblies that are transported, handled, or stored in the process of providing a service or product to the customer

4.5.3 ASSOCIATED MATERIALS

Government Property Control Program, Work Instruction [WI-001](#),

4.5.4 PROCEDURE

A. Devices shall be transported, stored, and handled in a manner to protect the calibration, condition, and operability of the equipment. Instructions for handling government owned property are detailed in Work Instruction [WI-001](#).

B. Products, devices, components, or assemblies that are static sensitive shall be handled and stored in accordance with section 4.5.5, [PROCURING, HANDLING, AND STORAGE OF ESD SENSITIVE DEVICES](#).

C. Receiving Inspection is responsible for monitoring subcontractor compliance to specifications designed to protect product quality as outlined under section 4.1.2, [RECEIVING INSPECTION](#).

D. Quality Assurance is responsible for periodically but randomly inspecting storage areas to determine if goods are being stored safely and if:

- specified environmental conditions are being maintained,
- goods are being properly rotated,
- obsolete and out-of-date goods are being removed,
- goods are properly identified,
- customer furnished items are maintain separately from FDE inventory.

E. The Shipping Department is responsible for overseeing the proper packaging of finished goods prior to shipment. This includes verifying compliance with packaging specifications including the use of dehydrating agents and humidity indicators if required, proper caution labeling, adequate and proper packaging material, and making certain that all interior and exterior containers are properly identified, labeled, and marked.

F. The Shipping Department is responsible for overseeing the proper shipping of goods including verification that shipping documents are correct and properly stamped, that containers are properly loaded and secured in shipping vehicles, and that the company is in compliance with Interstate Commerce Commission and other applicable regulations.

4.5.5 PROCURING, HANDLING, AND STORAGE OF ESD SENSITIVE DEVICES

4.5.5.1 PURPOSE

This subsection provides guidelines and instructions for procuring, handling, and storage of Electrostatic Discharge Sensitive (ESDS) devices and assemblies utilized in repair, modifications, products, or services.

4.5.5.2 APPLICATION

This subsection applies to all departments and personnel involved in procuring, handling, or storing devices, components, or assemblies identified as static sensitive.

4.5.5.3 ASSOCIATED MATERIALS

A. Static Sensitive Devices, Quality Procedure [QPM-003](#)

4.5.5.4 PROCEDURE

A. All ESD sensitive devices, components, or assemblies shall be ordered from vendors in proper protective containers, identifying the contents as static sensitive. The following terms and conditions shall be incorporated in all procurement documents which are known to include ESD sensitive devices, components, or assemblies:

"Static-sensitive (ESD) devices, components, or assemblies (PCB) included in this Purchase Order shall be properly handled, stored, packaged, and labeled in accordance with approved static-safe precautions, protection, and procedures. Items received without proper ESD packaging and labeling will be returned at the Vendor's expense."

B. Approved static protective containers, bags, tote boxes, and labels shall be made available for packaging and storage of static sensitive devices.

C. The QA Manager will periodically evaluate FDE facilities and procedures to determine their suitability under the company ESD Protection Program. The company areas listed in Table 1 will be evaluated to determine their compliance with or need for ESD safeguards.

COMPANY ESD SENSITIVE AREAS

Receiving/Inspection
Stores
Assembly
Test and inspection
Research and development
Packaging
Field Installation or Repair
Offices and laboratories

Table 1. Typical facility areas requiring ESD protection

D. Procedures, materials, and safeguards as outlined in the Quality Procedure for Static Sensitive Devices, [QPM-003](#), shall be utilized to reduce costs and improved reliability of products and equipment.

5 MEASUREMENT, ANALYSIS, AND IMPROVEMENTS

5.1 PURPOSE

This section provides a system to ensure conformance, compliance, and verification of documentation, products or services prior to the delivery of the product or service to the customer.

5.2 APPLICATION

Applicable to all Quality Assurance personnel who are responsible for the inspection or testing of products, services, documentation, or material relative to quality factors.

5.3 ASSOCIATED MATERIALS

- A. Final Inspection and Test, Quality Procedure [QPM-011](#)
- B. Statistical Sampling Inspection, Quality Procedure [QPM-008](#)
- C. Final Inspection Checklist, Form [QP-024](#)

5.4 PROCEDURE

A. Inspection/test procedures utilized during the inspection and verification of products or services shall be the same as existing applicable performance verification procedures, i.e. manufacturer's manual, DOD or published standard practices.

B. Prior to delivery, shippable items shall be placed in an area, station, or shelf, labeled "HOLD FOR INSPECTION". At this time the following inspection process shall take place:

Visual Inspection Visual inspection shall consist of verification of certain details and characteristics, including, but not limited to, Cleanliness, Exterior Finish, Workmanship, Hardware, Batteries, Accessories, and appropriate Protective Covers, Calibration Decals and Calibration Seals affixed.

Shipping Documentation Inspection Shipping documentation inspection shall consist of verification of completeness and correctness of all documentation, including, but not limited to, Customer Billing/Shipping Address, Purchase Order Number, Type of Service Requested/Performed, Unit-Under-Test (UUT) Problems Verified /Corrected, and Calibration Documentation included as applicable.

C. An Inspection Report, Form [QP-027](#), shall be completed on all items requiring final performance verification inspection.

D. The QA Manager or QA Representative shall be responsible for completing the final performance verification inspection as outlined under the Final Inspection and Test Quality Procedure, [QPM-011](#).

E. The QA Manager shall review, with the appropriate personnel, all Inspection Reports that indicate failures.

F. Completed Inspection Reports shall be filed in accordance with the [CONTROL OF QUALITY ASSURANCE RECORDS / REPORTS](#), section 1.5.5.

5.5 IN-PROCESS INSPECTION

5.5.1 PURPOSE

This subsection establishes the method for monitoring and controlling the quality of services or products throughout the various intermediate steps involved in the development/production process.

5.5.1.1 APPLICATION

This subsection applies to the In-Process Inspection, and excludes source and receiving inspection, random audit inspections, and final inspection.

5.5.1.2 ASSOCIATED MATERIALS

A. Inspection Report, Form [QP-027](#)

5.5.1.3 PROCEDURE

A. The QA Department shall be responsible for periodic inspection of services or products throughout their intermediate stages of development. These inspections are to take place periodically, upon request by the QA Manager, as requested by the customer, or when there is a situation that indicates that a special inspection is appropriate.

B. Inspection methods employed can include inspections by appropriate technicians and witnessed by inspection personnel, inspections performed solely by the QA Manager or qualified QA inspection personnel.

C. Inspections are to be made using applicable performance verification procedures, inspection instructions, drawings, specifications, and other appropriate reference materials.

E. The inspection is to include an examination of the accompanying paper work for completeness and correctness in addition to reviewing the workmanship, physical and functional characteristics, and cleanliness of the item.

F. An Inspection Report, Form [QP-027](#), is to be completed on items that FAIL an inspection and routed to the QA Manager for oversight.

5.6 FINAL INSPECTION

5.6.1 PURPOSE

This subsection establishes the methods and responsibilities for the final performance verification inspection of completed services or products to ensure that they comply with company standards and customer requirements.

5.6.2 APPLICATION

This subsection applies to the inspection of all deliverables, finished products, or services.

5.6.3 ASSOCIATED MATERIALS

A. Inspection Report, Form [QP-027](#)

B. Accepted Tag/Stamp, Form [QP-023](#)

C. Rejection and Disposition Tag/Stamp, Form [QP-022](#)

5.6.4 PROCEDURE

- A. All finished products are to be inspected in accordance with the Final Inspection and Test, Quality Procedure [QPM-011](#).
- B. Items will not be accepted for final inspection unless all operations called out on the work order or integration and test document are identified as complete.
- C. The inspection is to include an examination of workmanship, physical and functional characteristics, and the proper markings on items and assemblies as indicated in the Engineering Drawing Package. The accompanying paper work shall also be examined for completeness and correctness.
- D. A Discrepancy Report, Form [QP-028](#), is to be filled out when items are found to be discrepant. These reports will be maintained in a database to facilitate analysis and reporting.
- E. Rejected hardware/documentation items needing rework are to be routed to the appropriate department and engineer/technician together with rework instructions included in the Discrepancy Report.
- F. Completed Inspection Reports are to be forwarded to the QA Manager for review and disposition.

5.7 CUSTOMER IN-PLANT INSPECTIONS

5.7.1 PURPOSE

This subsection describes the system for accommodating customer source inspections.

5.7.2 APPLICATION

This subsection applies to services or products produced under contract for specific customers.

5.7.3 PROCEDURE

- A. When the customer wishes to conduct source inspections of systems or products, a statement to this effect is to be incorporated into the original purchase agreement.
- B. When contractual, the Purchasing Department is to pass on the source inspection requirement to subcontractors and vendors to permit customer inspections. Under no circumstances will a customer's source inspection relieve FDE nor its subcontractors and vendors from their basic responsibilities for complete inspections.
- C. When a customer source inspection is appropriate, proper and adequate personnel and records will be made available for customer inspection and review. Customers are not allowed to make copies of privileged or confidential information or records, unless authorized by the QA Manager or the President of FDE.
- D. When the customer detects nonconformance as a result of a source inspection, this fact is to be communicated to the QA Manager together with a request for corrective action.

5.8 CONTROL OF INSPECTION, MEASURING AND TEST EQUIPMENT

5.8.1 PURPOSE

This subsection establishes a system for maintenance and control regarding the calibration and "Traceability" of all measurement and test equipment (M&TE) and measurement standards used in the fulfillment of contractual requirements.

5.8.2 APPLICATION

This subsection applies specifically to measurement and test equipment (M&TE), measurement standards, and all FDE personnel utilizing these items for production and delivery of customer products or services.

5.8.3 PROCEDURE

A. The accuracy of all M&TE and measurement standards utilized by FDE Corporation, in areas where they may impact quality of products or services, shall be maintained traceable according to the following definition:

Traceability: "The ability to relate individual measurements through an unbroken chain of calibrations to one or more of the following:

- U.S. National standards maintained by the U.S. National Institute of Standards and Technology (NIST), and the U.S. Naval Observatory.
- Fundamental or natural physical constants with values assigned or accepted by the U.S. NIST National Standards of other countries which are correlated with U.S. national standards; Ratio type of Calibrations; Comparison to Consensus standards." (Per MIL-STD 45662A, Par 3.5, 3.5.1, 3.5.2, 3.5.3, 3.5.4, and 3.5.5.).

B. Where appropriate, traditional methods of traceability may be achieved by means of an unbroken chain of calibrations from the National Standards to an individual M&TE or measurement standard, as shown in the Traceability Chart, Figure No. 3.

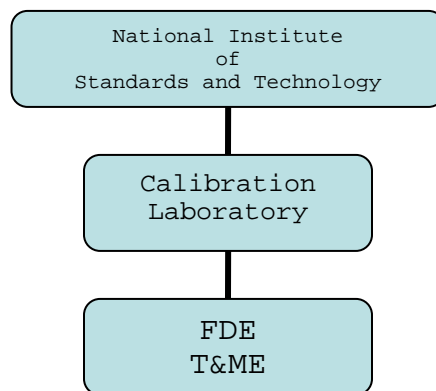


Figure 3: Traceability Chart

C. Procedures for maintaining the FDE metrology systems, as described in [QPM-004](#), shall be followed by all personnel and departments procuring, using, or monitoring items of this system.

5.9 REQUEST FOR DEVIATION OR WAIVERS

5.9.1 PURPOSE

This subsection provides instruction for requesting from the customer advance permission to deviate from specified requirements or a waiver of prescribed technical requirements.

5.9.2 APPLICATION

This subsection applies to the customer and to the Quality Assurance, Receiving Inspection, Procurement, and Business Development Departments.

Deviation Permission: Permission, in writing and in advance of performance, to deviate from specified requirements for individual units or for a specified period of time.

Waiver Permission: Permission, in writing, to accept for use a completed but nonconforming item either "as is" or upon completion of rework. This is applicable to an individual unit or for a specific period of time.

5.9.3 ASSOCIATED MATERIALS

Request for Deviation or Waiver, Form [QP-015](#)

5.9.4 PROCEDURE

A. The QA Manager provides a request serial number and prepares the Request for Deviation or Waiver form, [QP-015](#), as follows:

- Number of the request, and date the request form is filled out
- Customer to whom the request is directed
- Name, address and telephone number of the requesting function
- Type of request
- Priority
- Purchase order or contract number
- Model number, drawing or specification number
- Affected unit(s) or dates of the deviation or waiver
- Explanation of the reason for the deviation or waiver
- Appropriate requesting signatures

B. The completed form is next presented to the customer for approval. The request is returned approved or disapproved with the authorized customer signature and date.

C. The QA Manager forwards the returned request to the appropriate department for disposition.

5.10 CORRECTIVE AND PREVENTATIVE ACTION

5.10.1 PURPOSE

This subsection specifies a system for informing appropriate personnel of instances of nonconformance to quality requirements and to initiate corrective actions.

5.10.2 APPLICATION

This system encompasses the activities of all departments in the company. Its operation is the responsibility of the Quality Assurance Department.

5.10.3 ASSOCIATED MATERIALS

- A. Corrective Action Request Procedure, [QPM-005](#)
- B. Corrective Action Request, Form [QP-016](#)

5.10.4 PROCEDURE

A. A Corrective Action Request (CAR) is used to initiate an investigation to determine the cause of a discrepancy. CAR recommendations for corrective actions are used to avoid the recurrence of a discrepancy.

B. The generation of a CAR can come about as a result of Random Inspection activity (see [QUALITY ASSURANCE AUDITS OF INTERNAL SYSTEMS](#)) or upon receipt of an Inspection Report. Detailed procedures for taking corrective actions are specified in Quality Procedure Manual, Section [QPM-005](#).

C. The Corrective Action Request (CAR) form, [QP-016](#), is to be filled out as follows:

- Number of the CAR
- Name, address, and telephone number of the department or organization responsible for investigating the cause and for taking corrective action
- Name of the person and organization requesting the action, the date of the request, the date when a reply to the request is due
- Name of the program or project
- Part name, and part number
- Inspection report number if applicable
- Description of the condition, and the apparent cause of the condition if known

D. The CAR is forwarded to the assigned organization or department where an investigation is done to detect the cause of the discrepancy and action is taken to prevent recurrence. This information is recorded on the CAR form as follows:

- Actual cause of the discrepancy
- Action taken to prevent recurrence
- Signature and title of the person responsible for the corrective action
- Date of the signature

E. The completed CAR is returned to the QA Manager. The Corrective Action Request is updated to reflect the date of the actual response and remarks pertinent to the action.

APPENDIX 2 - FORMS INDEX

| Number | Name | Number | Name |
|------------------------|--|------------------------|---|
| QP-001 | Log, QA Manual Distribution | QP-002 | Quality Assurance Training Notice |
| QP-003 | Certification of Completion | QP-004 | Audit Committee Designation |
| | Customer Profile and Special Instruction Sheet | QP-006 | Quality Procedures Template |
| QP-007 | Quality Bulletin | QP-008 | Deliverable Document Checklist |
| QP-009 | QA Audit Plan and Report | QP-010 | Parts Requisition |
| QP-011 | ESD Symbols | QP-012 | Calibration History |
| QP-013 | Calibration, decals | QP-014 | Calibration Recall Notice/ Extension Request |
| QP-015 | Request For Deviation or Waiver | QP-016 | Corrective Action Request (CAR) |
| QP-017 | Log, Corrective Action | QP-018 | Log, Request for Deviation/Waiver |
| QP-019 | Supplier Approval | QP-020 | Receiving Inspection Checklist/Receiver |
| QP-021 | Non-Conforming Material | QP-022 | Rejection and Disposition Tag/Stamp |
| QP-023 | Acceptance Tag/Stamp | QP-024 | Final Inspection Check List |
| QP-025 | Purchase Order | QP-026 | Packing Slip |
| QP-027 | Inspection Report | QP-028 | Discrepancy Report |
| QP-029 | Work Order | QP-030 | Metrology System Evaluation Checklist |
| QP-031 | Material Requisition/Turn-In | QP-032 | GFP Equipment Usage Log |
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APPENDIX 3 – QUALITY PROCEDURES INDEX

| Number | Name | Number | Name |
|-------------------------|--------------------------------------|-------------------------|------------------------------------|
| QPM-001 | Quality Procedures | QPM-002 | Receiving Inspection |
| QPM-003 | Static Sensitive Devices | QPM-004 | Metrology System Maintenance |
| QPM-005 | Corrective Action Report | QPM-006 | Quality Planning |
| QPM-007 | Document Final Acceptance Processing | QPM-008 | Statistical Sampling Inspection |
| QPM-009 | Material Handling and Storage | QPM-010 | Nonconforming Material Disposition |
| QPM-011 | Final Inspection and Test | QPM-012 | Configuration Management |
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