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Rocketdyne Division, Rockwell International

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2627

TITLE: Quality Assurance Plan for Area IV Site Characterization, Monitoring & Surveillance

APPROVALS

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APPENDICES

FIGURES

1. INTRODUCTION

The quality assurance plan is defined in Quality Assurance Department Directive 9 (QADD-9). This plan is consistent with the ten quality criteria of DOE Order 5700.6C and has been approved by DOE. The plan identifies ETEC procedures used to assure compliance with applicable requirements of ASME NQA-1.

2. SCOPE

This plan augments the ETEC Quality Assurance Program Plan and defines the quality assurance program for validation that the collection, analysis and evaluation of radiological and chemical data for area IV site characterization and monitoring is defensible by objective evidence for purposes of regulatory compliance or safety. Elements of ASME NQA-1 applicable to this activity are defined herein.

2.1 Section 3.0 describes criteria to be considered in the application of the requirements of this plan.

2.2 Section 4.0 describes the quality assurance program which addresses the requirements of ASME NQA-1, "Quality Assurance Program Requirements," and is to be applied as applicable for the packaging and preparations for shipment of hazardous waste for subsequent transport to offsite waste disposal facilities.

NOTE: The second and third digits of Section 4.0 paragraph numbers correspond to each applicable section of NQA-1 (1 through 18).

2.3 Appendix I addresses the applicable requirements of ASME NQA-1 (1989) and corresponding ETEC Procedures, Rocketdyne Operating Policies (ROP), Advanced Power Programs (APP) Quality Assurance Operating Procedures and other supporting organizational procedures which address and implement quality assurance program criteria.

2.4 Appendix II lists separately the Rocketdyne Operating Policies (ROP), and supporting organizational procedures applicable to this program.

2.5 Engineering Documents Controlling Sampling, Survey, and Analysis

a) Area IV Radiological Characterization Plan A4CM-AN-0003

b) Area IV Environmental Monitoring Program Plan ER-AN-0006

c) Methods and Procedures for Radiological Monitoring, N0010P000033

d) Training Program for Radiation Protection and Health Physics (RP&HP) Personnel, N0010P000032

e) SSFL Analytical Chemistry Quality Assurance Manuals

f) Rocketdyne Chemistry Lab Procedures

3. APPLICATION

3.1 Application of the requirements of this plan to specific activities is based upon consideration of the following:

a) The need for controls of equipment/materials, and/or processing affecting an item.

b) The degree to which compliance to requirements can be verified/demonstrated by inspection, test, or surveillance/monitoring.

3.2 Quality requirements relative to procured materials/services shall be delineated in the procurement document. Supplier/ subcontractor quality assurance system/program shall be capable to provide controls to comply with Rocketdyne/DOE imposed requirements.

4. QUALITY ASSURANCE PROGRAM

4.1 The quality assurance program described herein addresses the requirements of Rockwell International policy, Rocketdyne Division policies and procedures, Department of Energy Quality Assurance requirements, and ASME NQA-1 basic criteria.

Activities affecting quality and responsibilities for assuring quality of performance relative to sample collecting, processing, packaging, and preparations for transport to the designated radiological/analytical laboratory site are conducted by the following organizations:

a) ETEC Engineering

b) Transportation - Hazardous Material Transportation and Distribution Management (Internal Trucking and Transportation Department)

c) Radiation Protection & Health Physics Service

d) ETEC Operations - General Programs

e) Health, Safety and Fire Protection

f) Environmental Protection

g) ETEC Quality Assurance and Training Department

h) Advanced Power Programs Assurance Department

i) SSFL Analytical Chemistry

Functions and responsibilities of these organizations shall include planning, controlling, auditing, inspection verification, surveillance, material review of nonconformances and corrective actions, data recording and quality records accumulation.

ETEC Organizational Functions:

The ETEC organizational structure is shown in Figure 1. The quality organizational structure is shown in Figure 2.

4.2 QA Functions and Responsibilities

4.2.1 Assurance shall be achieved as follows:

a) Provide resources for the accomplishment of identified quality assuring functions and responsibilities.

b) Provide written procedures and instructions for accomplishment of assigned tasks.

c) Provide necessary training of personnel in policy, procedures, regulations and instructions.

d) Assure effective execution to the requirements of the QA plan through independent QA oversight.

4.2.2 Quality Assurance requirements applicable to subcontractor/ supplier shall be communicated through procurement documents. The requesting organization shall communicate through the Rocketdyne Purchasing with the subcontractor/ supplier as necessary to provide a timely resolution of quality related matters.

4.2.3 A listing of procedures cross referenced to each applicable criterion of ASME NQA-1 is delineated in Appendix I.

4.2.4 The safety requirements applicable to the methods and activities utilized in the packaging and transport of samples shall be defined in applicable engineering documents.

4.2.5 An indoctrination and training program shall be established to assure that:

a) Personnel responsible for performing quality-affecting activities are instructed as to the purpose, scope, and implementation of the quality-related manuals, instructions, procedures, and this plan.

b) Personnel performing quality-affecting activities are indoctrinated, trained and, as required, are qualified in the principles and techniques of the activity being performed.

c) The scope, objective, and method of implementing the indoctrination and training program are documented.

d) Proficiency of personnel performing quality-affecting activities is maintained.

4.2.6 Activities affecting quality shall be performed in accordance with specified procedures which delineate equipment, environmental conditions, and other applicable prerequisites.

4.3 Design Control - Not Applicable

4.4 Procurement Document Control

4.4.1 The ETEC procedures manual delineates the sequence of actions to be accomplished in the preparation, review, approval, and control of procurement documents. APP support organizations shall control procurements in accordance with the APP QA manual.

4.4.2 A review and concurrence of the adequacy of quality requirements stated in procurement documents shall be performed by ETEC Quality Assurance Engineering personnel. This review shall verify that quality requirements are correctly stated, inspectable, and controllable; there are adequate acceptance and rejection criteria; and the procurement document has been prepared, reviewed, and approved in accordance with QA program requirements.

4.4.3 Procurement documents shall stipulate the procuring agency's right to access to supplier's facilities and records for inspection and audit.

4.4.4 Changes to procurement documents shall be subject to the same review and approval by Quality Assurance as the original document.

4.5 Instructions and Procedures

4.5.1 Activities affecting quality shall be prescribed and accomplished in accordance with documented instructions or procedures.

4.5.2 The ETEC Procedures Manual provides requirements for the preparation, review, approval, and control of instructions and procedures. APP procedures shall be prepared and approved in accordance with requirements established in the APP QA manual.

4.6 Document Control

4.6.1 The review, approval, issuance, change and control of documents shall be in accordance with established procedures i.e., ETEC procedures manual/APP QA manual.

4.7 Control of Purchased Materials, Equipment, and Services

4.7.1 When required, and prior to award of a purchase order/ contract, the capability of the potential supplier to provide acceptable quality services and/or products shall be evaluated by Quality Assurance.

4.7.2 Evaluation of suppliers shall be based on one or more of the following:

a) The supplier's capability to comply with the elements of QA contract requirements that are applicable to the type of material, equipment, or service being procured.

b) A review of previous records and performance of supplier's who have provided similar articles or services of the type being procured.

c) A survey of the supplier's facilities and QA program to determine his capability to supply a product which meets the design, manufacturing, and quality requirements.

4.7.3 The results of supplier evaluations shall be documented and controlled by the Quality Assurance group and distributed to the management of involved functions.

4.7.4 Surveillance of suppliers during fabrication, inspection, testing, and shipment of materials, equipment, and components shall be planned and performed in accordance with written procedures to assure conformance to the purchase order requirements.

4.7.5 The effectiveness of the control of quality by suppliers

shall be assessed through audits, surveillance, and the reporting of noncompliances.

4.8 Identification and Control of Materials and Items

4.8.1 Procedures shall be established to identify and control hazardous sample materials.

4.8.2 The identification requirements shall be determined as specified in the Procedures and Instructions.

4.8.3 Process control and inspection procedures shall specify that identification be maintained on the item and on associated records traceable to the item.

4.9 Control of Special Processes

4.9.1 Special processes used for analysis of sample materials shall be controlled in accordance with approved procedures.

4.9.2 Procedures, equipment, and personnel controlling special processes shall be qualified in accordance with applicable codes, standards, and specifications.

4.9.3 Special processes performed by qualified personnel and accomplished in accordance with written process sheets or equivalent shall have recorded evidence of verification.

4.9.4 Qualification records of procedures, equipment, and personnel associated with special processes shall be established, filed, and maintained. The technical and skills development function shall maintain the records associated with inspectors, and other special processes and operators.

4.10 Inspection

4.10.1 Procedures prepared for control of special processes may have QA hold points to verify adherence to procedural requirements of the method of sampling, sample quantity and identification.

4.11 Test Control - Not Applicable

4.12 Control of Measuring and Test Equipment

4.12.1 Control of measuring and test equipment shall be in accordance with ETEC Procedure 6-06. Procedures established by Radiation Protection and Health Physics Services (RP&HPS) and Nuclear Operations shall be in accordance with the requirements established in the APP QA manual. SSFL Analytical Chemistry shall meet the requirements established in SSFL Analytical Chemistry Quality Assurance Manuals.

4.13 Handling, Storage, and Shipping

4.13.1 Special handling, preservation, storage, cleaning, packaging, and shipping requirements shall be established and accomplished in accordance with predetermined work instructions.

4.14 Inspection, Test, and Operating Status

4.14.1 Identification of sample material containers shall be in accordance with ETEC Approved Instructions or Procedures.

The identification of all sample containers shall be maintained from the accumulation date throughout analysis and required storage time.

4.14.2 The application and/or removal of inspection, stamps, and status indicators such as tags, markings, labels, and stamps shall be procedurally controlled.

4.14.3 Required inspections, tests, or hold points shall be procedurally controlled under the cognizance of the QA organization.

4.14.4 The status of nonconforming items shall be documented and identified.

4.15 Control of Nonconforming Items

4.15.1 The identification, documentation, segregation, review, and disposition of nonconforming items shall be controlled.

4.15.2 The documentation shall identify the nonconforming item, describe the nonconformance, the disposition of the nonconformance and signature approvals of the disposition.

4.15.3 Nonconforming items shall be segregated from acceptable items and identified as discrepant until properly dispositioned.

4.15.4 Nonconformance reports shall be periodically analyzed to determine quality trends, and the results reported to management for review and assessment.

4.16 Corrective Action

4.16.1 Evaluation of conditions adverse to quality (such as nonconformances, failures, malfunctions, deficiencies, deviations, and defective material, processes and equipment) shall be performed in accordance with approved procedures to determine the need for corrective action.

4.16.2 Corrective action shall be initiated following the

determination of a condition adverse to quality to preclude recurrence.

4.16.3 Follow-up reviews shall be conducted to verify proper implementation of corrective actions and to close out the corrective action documentation.

4.16.4 Significant conditions adverse to quality, the cause of the conditions, and the corrective action taken shall be reported to cognizant levels of management for review and assessment.

4.17 Quality Assurance Records

4.17.1 Records shall be maintained to provide retrievable documentary evidence of compliance to requirements bearing upon the quality of items, services, and the activities affecting quality.

4.17.2 QA records shall include operating logs; results of reviews, inspections, tests audits, and material analyses; monitoring of work performance; qualification of personnel, procedures, and equipment; and other documentation such as specifications, procurement documents, calibration procedures, and reports; nonconformance reports; and corrective action reports.

4.17.3 Requirements and responsibilities for record transmittals, retention (such as duration, location, fire protection, and assigned responsibilities) and maintenance subsequent to completion of work shall be consistent with applicable codes, standards, and procurement documents.

4.17.4 Record storage facilities shall be constructed, located, and secured to prevent destruction of the records by fire, flooding, theft, and deterioration or damage by environmental or physical conditions.

4.18 Audits

4.18.1 Audits shall be performed to pre-established written audit plans and checklists and conducted by trained personnel in accordance with established quality assurance procedures. Knowledgeable personnel, not having direct responsibilities in the areas being audited, shall be utilized in performance of audits.

4.18.2 Audit results shall be documented and reviewed with management having responsibility in the area audited.

4.18.3 Responsible management are to take the necessary actions to correct the deficiencies revealed by the audit.

4.18.4 Audits will include an objective evaluation of quality-related practices, procedures, and instructions and the effectiveness of implementation.

4.18.5 Audits will include the objective evaluation of work areas, activities, processes, and items, and the review of documents and records.

4.18.6 Audits to assure that procedures and activities are meaningful and comply with the overall QA program shall be performed by Quality Assurance to provide a comprehensive, independent verification and evaluation of quality-related procedures and activities.

4.18.7 Audits shall be regularly scheduled on the basis of the status and safety importance of the activities being performed.

4.18.8 Audit data shall be analyzed and the reports, which indicated quality trends and the effectiveness of the QA program, are reported to management for review and assessment.

APPENDIX I

ASME NQA-1 REQUIREMENTS	IMPLEMENTING DOCUMENTS	
BASIC 1. Organization	---	ETEC Procedures Manual
	A-500	Rocketdyne Operating Policies and Procedures
	A-577	Program Management
	Figure 1	ETEC Organization Chart (R.D.O.M.)
	Figure 2	QA Department Organization Chart
BASIC 2. Quality Assurance Program	QADD #9	Preparation and Maintenance of the Quality Assurance Program Index
	E-02	Hazard Communication Program
	N1.01	Quality Assurance Department Functions
	N1.05	Qualification of Audit Personnel
	N1.24	Training and Indoctrination
BASIC 3. Design Control		NOT APPLICABLE
BASIC 4. Procurement Document Control	3-04	Preparation and Control of ETEC Procurement Specifications
	4-06	Preparation, Review, Approval, and Control of Purchase Requisitions
	4-08	Receiving, Inspection, and Identification of Incoming Inspectable Material and Equipment
	G-503	Procurement of Material and Services
	G-552	Procurement Policy

ASME NQA-1 REQUIREMENTS	IMPLEMENTING DOCUMENTS	
	G-552	Procurement Policy
	N4.00	Procurement Documents
	QADD #12	Source Inspection/ Surveillance
	QADD #22	Quality Assurance Engineering Work Description
BASIC 5. Instructions, Procedures, and Drawings	1-01	Content, Preparation, and Use ETEC Procedures and Manuals
	1-02	Training Programs
	1-04	Correspondence & Commitment Control System
	1-15	ETEC Quality Assurance Audits
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	2-20	Control of Nonconforming Items
	2-24	Utilization of Rocketdyne Machine Shop for ETEC Construction & Modifications
	2-43	Corrective Action Request
	3-04	Preparation and Control of ETEC Procurement Specifications
	4-10	Supplier Corrective Action Request
	6-03	Preparation and Control of Test & Operating Procedures
	6-08	Occurrence Report (UOR)

ASME NQA-1 REQUIREMENTS	IMPLEMENTING DOCUMENTS	
	E-01	Hazardous Materials Program
	E-02	Hazard Communication Program
	E-530	Human Resources Testing and Job Demonstration
	EC 04.00	Hazardous Waste Identification and Characterization
	EC 04.10	Hazardous Waste Management
	EC 04.20	Hazardous Waste Minimization
	EC 04.40	Waste Analysis Plan
	F-539	Certification or Licensing of Employees
	M-500	Rocketdyne Safety Program
	M-508	Special Safety Precautions for Radiological Areas
	M-514	Hazardous Substances
	N1.21	Quality Assurance Plans
	N1.22	Quality Assurance Acceptance Procedures
	N13.13	Engineering Work Request
	QADD #9	Preparation and Maintenance of the Quality Assurance Program Index
	QADD #22	Quality Assurance Engineering Work Description
BASIC 6. Document Control	2-13	ETEC Document Release
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	2-15	Technical Document Change

ASME NQA-1 REQUIREMENTS	IMPLEMENTING DOCUMENTS	
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	3-01	Document Number Assignment
	3-03	Technical Reviews
	N1.02	Quality Assurance Manual, Procedures & Instructions
	N1.21	Quality Assurance Plans
	N1.22	Quality Assurance Acceptance Procedures
	N2.02	Document Review
	QADD #22	Quality Assurance Engineering Work Description
BASIC 7. Control of Purchased Items and Services	2-14	Recording & Control of Non-ETEC-Originated Documents
	2-20	Control of Nonconforming Items
	3-04	Preparation and Control of ETEC Procurement Specifications
	4-06	Preparation, Review, Approval, and Control of Purchase Requisitions
	4-07	Evaluation and Approval of Procurement Sources
	4-08	Receiving, Inspection, and Identification of Incoming New Material & Equipment
	4-10	Supplier Corrective Action Request

ASME NQA-1 REQUIREMENTS	IMPLEMENTING DOCUMENTS	
	G-503	Procurement of Material and Services
	G-552	Procurement Policy
	N4.00	Procurement Documents
	N4.01	Supplier Evaluation and Approval
	N4.02	Procurement Quality Verification Instructions
	N4.03	Source Quality Verification
	N4.04	Receiving Inspection
	QADD #12	Source Inspection/ Surveillance
	QADD #22	Quality Assurance Engineering Work Description
	QADD #23	Quality Assurance Procurement Review and Inspection Procedure Requirements
BASIC 8. Identification & Control of Items	2-14	Recording & Control of Non-ETEC-Originated Documents
	3-04	Preparation and Control of ETEC Procurement Specification
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	2-35	Utilization of Rocketdyne Plant Services for the Maintenance of ETEC Real Property
	3-04	Preparation and Control of ETEC Procurement Specifications
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	4-08	Receiving, Inspection, and Identification of Incoming Inspectable Material and Equipment
	E-01	Hazardous Materials Program
	E-530	Human Resources Testing and Job Demonstration
	EC 04.00	Hazardous Materials Identification and Characterization
	EC 04.10	Hazardous Waste Management
	EC 04.20	Hazardous Waste Minimization
	EC 04.40	Waste Analysis Plan

ASME NQA-1 REQUIREMENTS	IMPLEMENTING DOCUMENTS	
	F-539	Certification or Licensing of Employees
	M-500	Rocketdyne Safety Program
	N1.03	Vision Requirements for Quality Assurance Personnel
	N13.13	Engineering Work Request
	QADD #5	Use, Control, and Meaning of QA Stamps
	QADD #7	Vision Requirements for Quality Assurance Department Personnel
	QADD #22	Quality Assurance Engineering Work Description
BASIC 10. Inspection	2-24	Utilization of Rocketdyne Machine Shop for ETEC Construction & Modifications
	4-08	Receiving, Inspection, and Identification of Incoming Inspectable Material and Equipment
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BASIC 11. Test Control		NOT APPLICABLE
BASIC 12. Control of Measuring and Test Equipment	2-14	Recording & Control of Non-ETEC-Originated Documents
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	N3.00	Calibration of Measuring and Test Equipment
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	4-01	Storage & Control of Shipping Material
	4-05	Procurement and Handling of Hazardous Materials
	4-06	Preparation and Control of Purchase Requisitions
	4-08	Receiving, Inspection, and Identification of Incoming Inspectable Material and Equipment
	B-03	Department of Energy (DOE) Approvals for Radioactive Material Shipping Containers
	E-01	Hazardous Materials Program
	E-02	Hazard Communication Program
	EC 04.00	Hazardous Waste Identification and Characterization

ASME NQA-1 REQUIREMENTS	IMPLEMENTING DOCUMENTS	
	EC 04.10	Hazardous Waste Management
	EC 04.20	Hazardous Waste Minimization
	EC 04.40	Waste Analysis Plan
	M-514	Hazardous Substances
	N-501	Shipping Radioactive Materials
	N9.02	Serialization of Hardware
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	QADD #22	Quality Assurance Engineering Work Description
BASIC 14. Inspection, Test, & Operating Status	2-24	Utilization of Rocketdyne Machine Shop for ETEC Construction & Modifications
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	4-10	Supplier Corrective Action Request
	N10.00	Nonconforming Material and Items
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	J-500.1	Quality Program Audits
	N1.04	Quality Assurance Internal Audits
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APPENDIX II

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A-500	Rocketdyne Operating Policy and Procedures
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A-577	Program Management
E-530	Human Resources, Testing and Job Demonstration
F-539	Certification or Licensing of Employees
G-503	Procurement of Materials and Services
G-552	Procurement Policy
J-500.1	Quality Program Audits
J-500.3	Calibration of Measuring and Test Equipment
M-500	Rocketdyne Safety Program
M-508	Areas Requiring Special Safety Precautions
M-514	Hazardous Substances
N-501	Shipping Radioactive Materials

Environmental Control Procedure

EC 04.00	Hazardous Waste Identification & Characterization
	Appendix A to EC 04.00
EC-04.10	Hazardous Waste Management and Disposal
	Appendix A to EC 04.10
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EC 04.20	Hazardous Waste Minimization
EC 04.40	Waste Analysis Plan

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Rocketdyne SSFL Analytical Chemistry

Laboratory QA/QC Plan

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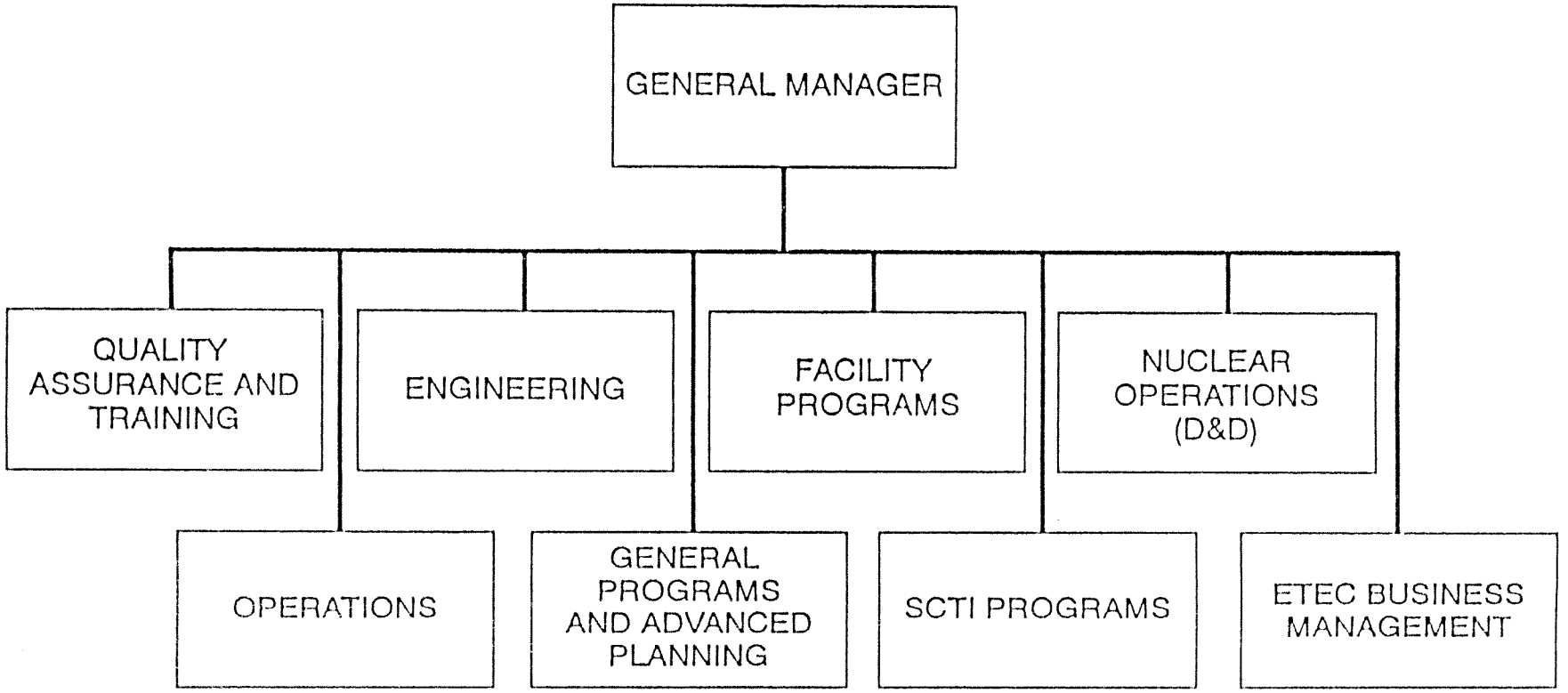

Figure 1. ETEC Organization Chart

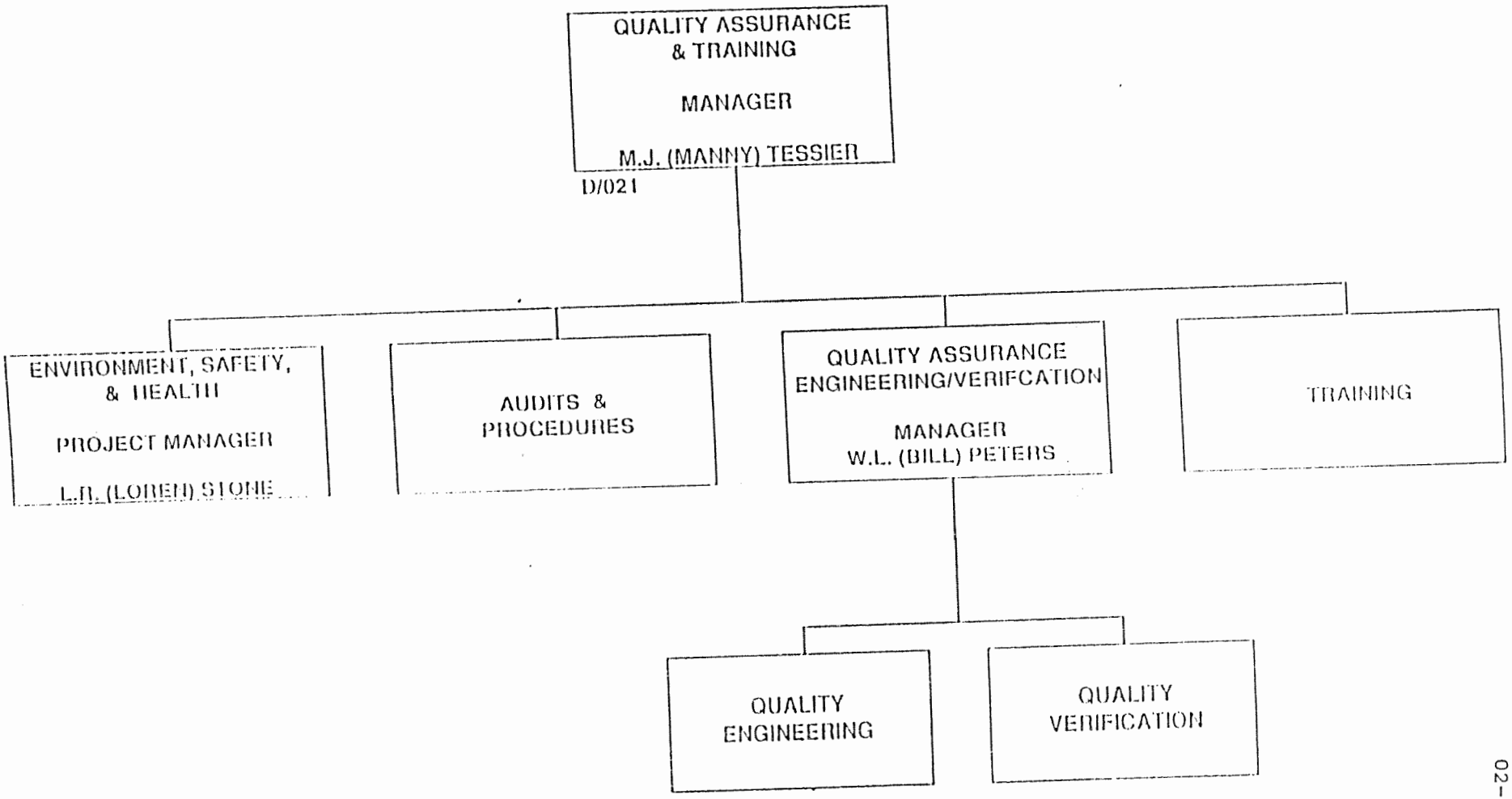

Figure 2. QA Organization Chart