Quality Management Manual

Revision 24

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Statement of Policy

This Manual describes Engineering Planning and Management's (EPM's) quality management system which is designed to (1) conform to the requirements of Title 10 Code of Federal Regulations Part 50 Appendix B as prescribed in NRC Regulatory Guide 1.28 when providing engineering services and computer software to nuclear power plants, (2) comply with the quality management principles described in ISO 9001:2015, and (3) comply with various Canadian quality assurance standards. The quality management system describes EPM's commitment to quality assurance requirements that ensure the highest levels of customer satisfaction.

This Manual and its implementing Quality Procedures define a quality management system that complies with the applicable requirements of the American National Standards ASME NQA-1-2022, ASQ/ANSI/ISO 9001:2015, CSA N299.1:19, and CSA N286.7-16.

The EPM quality management system ensures EPM's ability to consistently provide engineering and software services that meet the latest applicable regulatory as well as client requirements.

It is EPM's policy to enhance client satisfaction through effective implementation of EPM's Quality Management Manual and Quality Procedures for continued improvement of the EPM quality management system and to ensure conformity with client and applicable regulatory requirements.

The Manager of Quality Assurance has the overall responsibility for assuring the implementation of the EPM quality management system, and reports to the President on its status. He has the authority to initiate necessary corporate management action to resolve any deficiencies and assure that achieved solutions comply with client specifications and applicable regulatory requirements.

Proposed changes to this Manual and to the Quality Procedures are reviewed for compliance with applicable regulations, rules, codes, and standards prior to their approval.

Revision 24 of this Manual documents compliance to with the standards listed above, a reorganization, and the opening of a new office location. EPM will inform nuclear clients of any revisions to this Quality Manual.

Robert Kalantari

Robert Kalantari
President
EPM, Inc.

Proprietary Information Notice

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QUALITY MANAGEMENT MANUAL	Approved Robert J. Burg Manager, Quality Assurance Approved Robert Kalantari President Date April 1, 2025

Table of Contents

List of Figures

Record of Revision(s)		
Rev.	**Location**	**Change(s)**
19	Proprietary Information Notice	New
	List of Figures	New
	Quality Management System	Initial issue
	Attachment A	Indicated changes are from Revision 18 of the Quality Assurance Manual
	Attachment B	Initial issue
	Attachment C	Indicated changes are from Section 20.0 of Revision 18 of the Quality Assurance manual
20	Various	Updated company logo; not shown as change.
	Figure 3.1 Figure B4.1 Attach. B, Section 4.1 Attach. B, Section 4.2.1	Updated
	Attach. A, Section 10.2 Attach. A, Section 12.2 Attach. B, Section 7.1.5 Figure B7.1 Attach. B, Section 9.1.2	Clarified applicability
	Attach. A, Section 3.5.1	Replaced “project team” with “Project Manager”
	Attach. A, Section 4.5.6	Corrected spelling of title
	Attach. B, Section 2	Updated references
	Attach. B, Section 6.3	Updated review cycle to agree with other procedures
21	Various	Minor editorial and grammatical updates
	Figure 3.2	Added reference to new Quality Procedure EPM-QP-3.10
	Figure 3.2	Added reference to new Quality Procedure EPM-QP-17.3
	Section 6	Added references 10 CFR 50.55a, EPM-QP-5.0, EPRI Report 1025243; updated other references
	Attach. A, Section 2.3.1	Added advanced reactors to scope of services
	Figure B4.1	Updated Figure B4.1 organization chart
	Attach. B, Section 4.3	Added Chemical Process Safety as service
	Attach. B, Section 8.2	Removed reference to COO/CFO in organization
	Attach. C	Added definition of Staff Augmentation

Record of Revision(s)		
Rev.	**Location**	**Change(s)**
22	Statement of Policy	Updated for revision
	Various	Minor editorial and grammatical updates
	Section 5.7	Added description of Figure 3.2
	Figure 3.2	Revised some section titles
	Section 6	Added reference EPM-QP-17.2; updated references
	Figure A1.1	Updated
	Attachment A, Section 4.5.3	Added exclusion for commercial grade dedication
	Attachment A, Sections 7, 8	Revised section title
	Attachment A, Section 19	Added clarifications regarding to whom to report
	Figure B4.1	Deleted; referenced Figure A1.1; adjusted following figure numbers
	Attachment B, Section 4.1	Updated number of EPM offices
	Attachment B, Section 4.3	Clarified services
	Attachment B, Section 5.3.2	Replaced “Comptroller” with “Director of Administration”; updated responsibilities
	Attachment B, Section 7.1.4	Provided clarification regarding server rooms
	Attachment B, Section 8.4.2	Revised requirements for the evaluation of suppliers
23	Various	Revised reference from ASME NQA-1-2015 to ASME NQA-1-2022
	Various	Minor editorial and grammatical updates
	Statement of Policy	Removed reference to Canadian standards
	Figure 3.1	Remove Procedure 17.3 from table
	Attachment A, Section 2.2.1	Added date of review
	Attachment A, Section 2.3.3	Added Non-Q to consulting scope
	Attachment A, Section 2.4	Updated references
	Attachment A, Section 2.4 (d)	Removed reference to Canadian standards
	Attachment A, Section 3.7	Added discussion of third party software
	Attachment A, Section 12.2	Updated wording
	Attachment B, Section 2	Changed applicable date of Quality Procedures

Record of Revision(s)		
Rev.	**Location**	**Change(s)**
24	Statement of Policy Section 1, 3 Appendix A, Section 2.1	Added reference to Canadian standards
	Attachment A, Figure A1.1 Attachment B, Section 4.1	Revised organization structure
	Figure 3.1	Added CA Categories to Project Types
	Attachment B, Figure B4.1 Attachment B, Section 4.1	Added Toronto office
	Attachment B, Section 4.2.1	Added CSA, COG, and nuclear facilities as interested parties
	Attachment B, Section 4.3	Added inspections/audits to products
	Attachment B, Figure B7.1	Added EPM-QP-3.8
	Attachment C	Added definition of simple software
	Various	Minor editorial and grammatical updates

QUALITY MANAGEMENT SYSTEM

1. PURPOSE

This Manual describes EPM's Quality Management Program and how it fulfills the requirements and goals of the quality management system. This Manual also describes how the Quality Management Program conforms to the requirements of:

- 10 CFR 50 Appendix B [1]
- ISO 9001:2015 [2]
- CSA N299.1:19 [3] and
- CSA N286.7-16 [4]

2. RESPONSIBILITIES

2.1. President

The President, EPM is responsible for establishing the appropriate quality management system and establishing the quality goals for the company. Periodically the President reviews the implementation of the quality management system and the achievement of the quality goals and updates or modifies the system and goals as necessary.

The President, or his designee, is responsible for notifying the client, and the appropriate authorities, of any defect or nonconformance that may result in a substantial safety hazard.

The President delegates the Quality Assurance Manager with the responsibility to establish, administer, monitor, and improve as necessary the quality management system.

2.2. Quality Assurance Manager

The Quality Assurance (QA) Manager is responsible for establishing and administering the quality management system including assuring the adequacy of the system and verifying that activities affecting quality have been correctly performed.

3. REQUIREMENTS

The EPM quality management system shall meet the requirements of:

- 10 CFR 50 Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants" (10 CFR 50)

- ASME NQA-1-2022 [5], “Quality Assurance Requirements for Nuclear Facility Applications” (NQA-1)
- ASQ/ANSI/ISO 9001:2015, “Quality Management Systems – Requirements” (ISO 9001:2015)
- CSA N299.1:19, “Quality Assurance Program Requirements for the Supply of Items and Services for Nuclear Power Plants, Category 1”
- CSA N286.7-16, “Quality Assurance of Analytical, Scientific, and Design Computer Programs”

The quality management system shall establish, as necessary, categories of applicability of the quality management system.

A manual and set of implementing procedures shall be established to document and control quality management system.

4. DEFINITIONS

See Attachment C.

5. PROCEDURE

5.1. Conformance with 10 CFR 50 Appendix B

Conformance with 10 CFR 50 Appendix B and NQA-1 is described in Attachment A to this Manual.

5.2. Compliance with ISO 9001:2015

Compliance with ISO 9001:2015 is described in Attachment B to this Manual.

5.3. Precedence

In case of conflict between the requirements of Attachment A and Attachment B of this Manual, Attachment A will take precedence.

5.4. Quality Management Program

The Quality Management Program contains the structured, formal parts of the quality management system. The Quality Management Program is described in this Manual and is implemented by a set of Quality Procedures.

5.5. Quality Management Manual

This Quality Management Manual describes the controls establishing the Quality Management Program.

5.6. Quality Procedures

Quality Procedures are the highest level of procedures implementing the Quality Management Program. The Quality Procedures may be supplemented by lower tier procedures, guidelines, instructions, etc., as necessary.

5.7. Program Applicability

As described in Section 3.0 of Quality Procedure EPM-QP-1.1 [6], there are various categories of applicability for the Quality Management Program. These categories are:

- Safety-Related (Q)
- Augmented Quality (AQ)
- Nuclear Non-Safety-Related (Non-Q)
- ISO 9001
- Commercial Quality
- Staff Augmentation

The appropriate category is established during the procurement process.

Figure 3.1 provides the applicability of the Quality Management Program and Quality Procedures to the various EPM project categories.

Figure 3.2 provides supplemental guidance regarding the applicability of the Quality Management Program and Quality Procedures to various processes and actions.

PROCEDURE NUMBER	MANUAL / PROCEDURE TITLE	PROJECT TYPE					
		Safety Related (Q) CA Category 1 & 2	Augmented Quality (AQ) CA Category 3	Nuclear Non-Safety Related (Non-Q) CA Category 4	ISO 9001	Commercial Quality	Staff Augmentation
QM	Quality Management Manual	X	X	X	X	(3)	
1.0	Preparation, Issuance, and Control of Quality Procedures	X			X		
1.1	Project Planning	X	X	X	X	(3)	
1.2	Correspondence Control	X	X	(2)	X		
1.3	Preparation, Issuance, and Control of Project Procedures	X	X	(2)	X		
1.4	Preparation, Issuance, and Control of Division Procedures	X			X		
1.5	Management Quality Review	X			X		
1.6	Quality Monitoring, Measurement, Analysis, and Evaluation	X			X		
1.7	Risk Management	X			X		
1.8	Human Resources				X		
1.9	Information Technology				X		
2.0	Control of Quality Manual	X			X		
2.1	Control of Quality System Documents	X			X		
2.2	QA Indoctrination and Training	X	X	X	X		
3.0	Design Control	X	(1)	(2)	X		
3.1	Design Change Control	X	(1)	(2)	X		
3.2	Drawing Control	X			X		
3.3	Software Quality Assurance Plan	X			X		
3.4	Software Requirements Specification	X			X		
3.5	Software Design Description	X			X		
3.6	Software Verification and Validation	X	(1)	(2)	X		
3.7	Software Configuration Management	X			X		

Figure 3.1 – Quality Procedure Applicability

PROCEDURE NUMBER	MANUAL / PROCEDURE TITLE	PROJECT TYPE					
		Safety Related (Q) CA Category 1 & 2	Augmented Quality (AQ) CA Category 3	Nuclear Non-Safety Related (Non-Q) CA Category 4	ISO 9001	Commercial Quality	Staff Augmentation
3.8	Computer Media Library	X			X		
3.9	Control and Acceptance of Procured Software	X			X		
3.10	Verification and Validation of Non-EPM Developed Software		X	X	X	(2)	
4.0	Procurement Control	X	(1)		X		
4.1	Procurement	X	X	X	X	X	X
4.2	Project Risk Management	(3)	(3)	(3)	X	(3)	
5.0	Control of Client Drawings	X	X	(2)	X		
6.0	Document Control	X			X		
7-15	See Figure 3.2 below	X	(1)		X		
16.0	Corrective Action	X	X		X		
16.1	Open Item Tracking	X			X		
16.2	Quality Trend Analysis	X			X		
16.3	Control of Nonconformances	X	X	X	X	(3)	
17.0	Quality Assurance Records	X	X	X	X		
17.1	Records Management Document Retention System	X	X	X	X		
17.2	Changes to FAN Records	X	X	X	X		
18.0	Audits	X	X		X		
18.1	Auditor Training and Qualification	X					
19.0	Part 21 – Reporting of Defects and Noncompliance	X					

(1) See Quality Procedure 1.1 for applicability.
(2) Recommended but not required.
(3) At direction of Management

Figure 3.1 – Quality Procedure Applicability (Cont'd)

SUBJECT	GUIDANCE/CRITERIA
Control of Purchased Material, Items, and Services	Use Attachment A Section 7.0 and Quality Procedure Number EPM-QP-4.0
Identification And Control of Materials, Parts, and Components	Use Attachment A Section 8.0 and Quality Procedure Number EPM-QP-4.0
Control of Special Processes	Use Attachment A Section 9.0
Inspection	Use Attachment A Section 10.0 and Quality Procedure Number EPM-QP-4.0
Test Control	Use Attachment A Section 11.0 and for software Quality Procedure Number EPM-QP-3.6
Control of Measuring And Test Equipment	Use Attachment A Section 12.0
Handling, Storage, And Shipping	Use Attachment A Section 13.0
Inspection, Test, And Operating Status	Use Attachment A Section 14.0
Control of Nonconforming Items	Use Attachment A Section 15.0 and Quality Procedure Number EPM-QP-4.0

Figure 3.2 – Other Processes

6. REFERENCES

[1] United States of America, *Title 10 Code of Federal Regulations, Part 50 Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants".*

[2] International Organization for Standardization, *ISO 9001:2015, "Quality Management Systems"*, ASQ/ANSI.

[3] Canadian Standards Association, *CSA N299.1:19, "Quality Assurance Program Requirements for the Supply of Items and Services for Nuclear Power Plants, Category 1".*

[4] Canadian Standards Association, *CSA N286.7-16, "Quality Assurance of Analytical, Scientific, and Design Computer Programs".*

[5] ASME, *NQA-1-2022, "Quality Assurance Requirements for Nuclear Facility Applications".*

[6] EPM, Inc., *Quality Procedure EPM-QP-1.1, "Project Planning".*

[7] United States of America, *Title 10 Code of Federal Regulations Part 21, "Reporting of Defects and Noncompliances".*

[8] U.S. Nuclear Regulatory Commission, *Regulatory Guide 1.28, Rev. 6, "Quality Assurance Program Criteria (Design and Construction)"*, September 2023.

[9] EPM, Inc., *Quality Procedure EPM-QP-2.0, "Control Of Quality Management Manual".*

[10] EPM, Inc., *Quality Procedure EPM-QP-1.0, "Preparation, Issuance, And Control Of Quality System Documents".*

[11] American Society for Nondestructive Testing, Inc., *Recommended Proactice No. SNT-TC-1A, "Personnel Qualification and Certification in Nondestructive Testing".*

[12] U. S. Nuclear Regulatory Commission, *Title 10 Code of Federal Regulations, Part 50.55, "Conditions of Construction Permits, Early Site Permits, Combined Licenses, and Manufacturing Licenses", Section (e).*

[13] EPM, Inc., *Quality Procedure EPM-QP-16.0, "Corrective Action".*

[14] EPM, Inc., *Quality Procedure EPM-QP-17.0, "Quality Assurance Records".*

[15] ASME, *NQA-1-2008, "Quality Assurance Requirements for Nuclear Facility Applications".*

[16] ASME, *ASME NQA-1a-2009, "Addenda to ASME NQA-1-2008 Quality Assurance Requirements for Nuclear Facility Applications".*

[17] EPM, Inc., *Quality Procedure EPM-QP-4.1, "Procurement".*

[18] EPM, Inc., *Quality Procedure EPM-QP-1.7, "Risk Management".*

[19] EPM, Inc., *Quality Procedure EPM-QP-4.2, "Project Risk Management".*

[20] EPM, Inc., *Quality Procedure EPM-QP-18.0, "Audits".*

[21] EPM, Inc., *Quality Procedure EPM-QP-1.8, "Human Resources".*

[22] EPM, Inc., *Quality Procedure EPM-QP-1.9, "Information Technology".*

[23] EPM, Inc., *Quality Procedure EPM-QP-17.1, "Records Management Document Retention System".*

[24] EPM, Inc., *Quality Procedure EPM-QP-17.2, "Changes to FAN Records".*

[25] EPM, Inc., *Quality Procedure EPM-QP-1.5, "Management Quality Review".*

[26] EPM, Inc., *Quality Procedure EPM-QP-2.2, "QA Indoctrination and Training".*

[27] EPM, Inc., *Quality Procedure EPM-QP-1.4, "Preparation, Issuance, And Control Of Division Procedures".*

[28] EPM, Inc., *Quality Procedure EPM-QP-3.0, "Design Control".*

[29] EPM, Inc., *Quality Procedure EPM-QP-3.1, "Design Change Control".*

[30] EPM, Inc., *Quality Procedure EPM-QP-3.2, "Drawing Control".*

[31] EPM, Inc., *Quality Procedure EPM-QP-3.3, "Software Quality Assurance Plan".*

[32] EPM, Inc., *Quality Procedure EPM-QP-3.4, "Software Requirements Specification".*

[33] EPM, Inc., *Quality Procedure EPM-QP-3.5, "Software Design Description".*

[34] EPM, Inc., *Quality Procedure EPM-QP-3.6, "Software Verification and Validation".*

[35] EPM, Inc., *Quality Procedure EPM-QP-3.7, "Software Configuration Management".*

[36] EPM, Inc., *Quality Procedure EPM-QP-3.8, "Computer Media Library".*

[37] EPM, Inc., *Quality Procedure EPM-QP-16.1, "Open Item Tracking".*

[38] EPM, Inc., *Quality Procedure EPM-QP-4.0, "Procurement Control".*

[39] EPM, Inc., *Quality Procedure EPM-QP-3.9, "Control and Acceptance of Procured Software".*

[40] EPRI, *Technical Report 1025243, Plant Engineering: Guide for the Acceptance of Commercial-Grade Design and Analysis Computer Programs Used in Nuclear Safety-Related Applications, Rev. 1.*

[41] EPM, Inc., *Quality Procedure EPM-QP-5.0, "Control of Client Drawings".*

[42] EPM, Inc., *Quality Procedure EPM-QP-16.3, "Control of Nonconformances".*

[43] EPM, Inc., *Quality Procedure EPM-QP-1.6, "Quality Monitoring, Measurement, Analysis, and Evaluation".*

[44] EPM, Inc., *Quality Procedure EPM-QP-16.2, "Quality Trend Analysis".*

[45] Canadian Standards Association, *CSA/CAN3-Z299, "Quality Assurance Program".*

[46] Canadian Standards Association, *CSA N286.7, "Quality Assurance of Analytical, Scientific, and Design Computer Programs".*

[47] Canadian Standards Association, *CSA N286.2-86, "Design Quality Assurance for Nuclear Power Plants".*

7. ATTACHMENTS

1. Attachment A – Conformance with 10 CFR 50 Appendix B
2. Attachment B – Compliance with ISO 9001:2015
3. Attachment C – Definitions

ATTACHMENT A – CONFORMANCE WITH 10 CFR 50 APPENDIX B

1. ORGANIZATION

1.1. Purpose

To describe the organizational structure, functional responsibilities, levels of authority, and lines of communication within EPM for ensuring that EPM-provided engineering services and software products fully satisfy client and regulatory requirements.

1.2. Scope

This section applies to all Safety-Related (Q) and Augmented-Quality (AQ) engineering services and software products provided to EPM clients.

1.3. Requirements

The organizational structure, functional responsibilities, levels of authority, and lines of communication for activities affecting quality shall be documented. The organizational structure and the responsibility assignments shall be such that:

(a) Senior management establishes overall expectations for effective implementation of the quality management program and is responsible for obtaining the desired end result;
(b) Quality is achieved and maintained by those who have been assigned responsibility;
(c) Quality achievement is verified by persons or organizations not directly responsible for performing the work; and
(d) Those responsible for assuring that an appropriate quality management program has been established and those verifying activities affecting quality have sufficient authority, direct access to responsible levels of management, organizational freedom, and access to work to perform this function, including sufficient independence from cost and schedule when opposed to safety function considerations.

1.4. Responsibilities

The EPM organization is shown on the Organization Chart (Figure A1.1) in this section. The President and the QA Manager are responsible for assuring that work

performed by EPM is in compliance with this Manual and client requirements. The responsibilities of corporate key functions are as follows:

1.4.1. President

The President, as the senior management official at EPM, has ultimate responsibility for all corporate plans and policies, including the establishment of this Manual. The President is responsible for assuring that an appropriate quality management program has been established and personnel who verify activities that affect quality have sufficient authority, direct access to responsible levels of management, organizational freedom, and access to work to perform this function. The President is responsible for reviewing the implementation of the requirements set forth in the EPM Quality Management Manual and EPM Quality Procedures. The President has delegated the Manager of Quality Assurance with the responsibility for establishing the EPM quality management system. The President has delegated the Manager of Quality Assurance to remain independent of the pressures of cost and schedule in assuring the implementation of EPM's quality management system.

1.4.2. Manager of Quality Assurance

The Manager of Quality Assurance is responsible for establishing and administering the EPM quality management system. He is responsible for assuring the adequacy of the EPM quality management system and verifying that activities affecting quality have been correctly performed. He reports directly to the President and is independent from operational cost, scheduling, and production restraints. He has been delegated with authority and organizational freedom to:

(a) Identify quality problems.
(b) Initiate, recommend, or provide solutions to quality problems through designated channels.
(c) Verify implementation of solutions.
(d) Assure that further processing, delivery, installation, or use of nonconforming, deficient, or unsatisfactory condition is controlled until proper disposition has occurred.
(e) Develop and schedule a system of quality audits.
(f) Establish and conduct a quality training and indoctrination program for EPM personnel.

(g) Maintain the EPM Quality Management Manual and Quality Procedures; and
(h) Interface with client quality representatives, and coordinate client audits of EPM.

1.4.3. Division Directors

Division Directors provide services and qualified personnel to project teams. Division Directors are responsible for:

(a) Directing the quality affecting activities of the Division;
(b) Approving Project Plans and Division Procedures;
(c) Providing sufficient and appropriate resources for the Division to ensure that the project work is accomplished as required; and
(d) Determining the required qualifications of Division personnel, as applicable.

1.4.4. Field Service Contractors

Safety-related activities performed by field service contractors are normally conducted under the client's Quality Management Program. However, per client's request or contract, application of the EPM quality management system may apply to all safety-related activities performed by field service contractors.

1.4.5. Project Managers

Within EPM, each project is assigned to a Project Manager who reports to the appropriate Division Director for coordination, compliance with contract/project scope commitments, internal and external interfaces, and technical matters.

Managers are responsible for direction, control, and coordination of their projects. Their responsibilities include:

(a) Develop the Project Plan to provide direction to project personnel for planning, organizing, and executing project activities;
(b) Interface with EPM Division Directors for the necessary support in executing project activities outlined in the Project Plan; and
(c) Maintain liaison with clients, evaluate project performance, and resolve conflicts in schedule and resource commitments.

1.4.6. Project Engineers

The appropriate Division Director, upon consultation with the cognizant Project Manager, appoints a Project Engineer for the project, as needed. The Project Engineer reports to the Project Manager for coordination, compliance with contract/project scope commitments, and technical matters. The Project Engineer is responsible for the technical aspects of the project.

The Project Engineer is responsible for directly supervising the work performed by Engineers, and for implementing prescribed quality-related functions of the project. Within the scope of quality responsibilities, the Project Engineer:

(a) Supervises engineering activities required for the project task;
(b) Assigns independent Engineering Checkers to review design documents;
(c) Approves design documents as authorized by the Project Plan;
(d) Schedules and supervises internal design reviews; and
(e) Interfaces with the client and other project participants and assures that contract/project commitments are met.

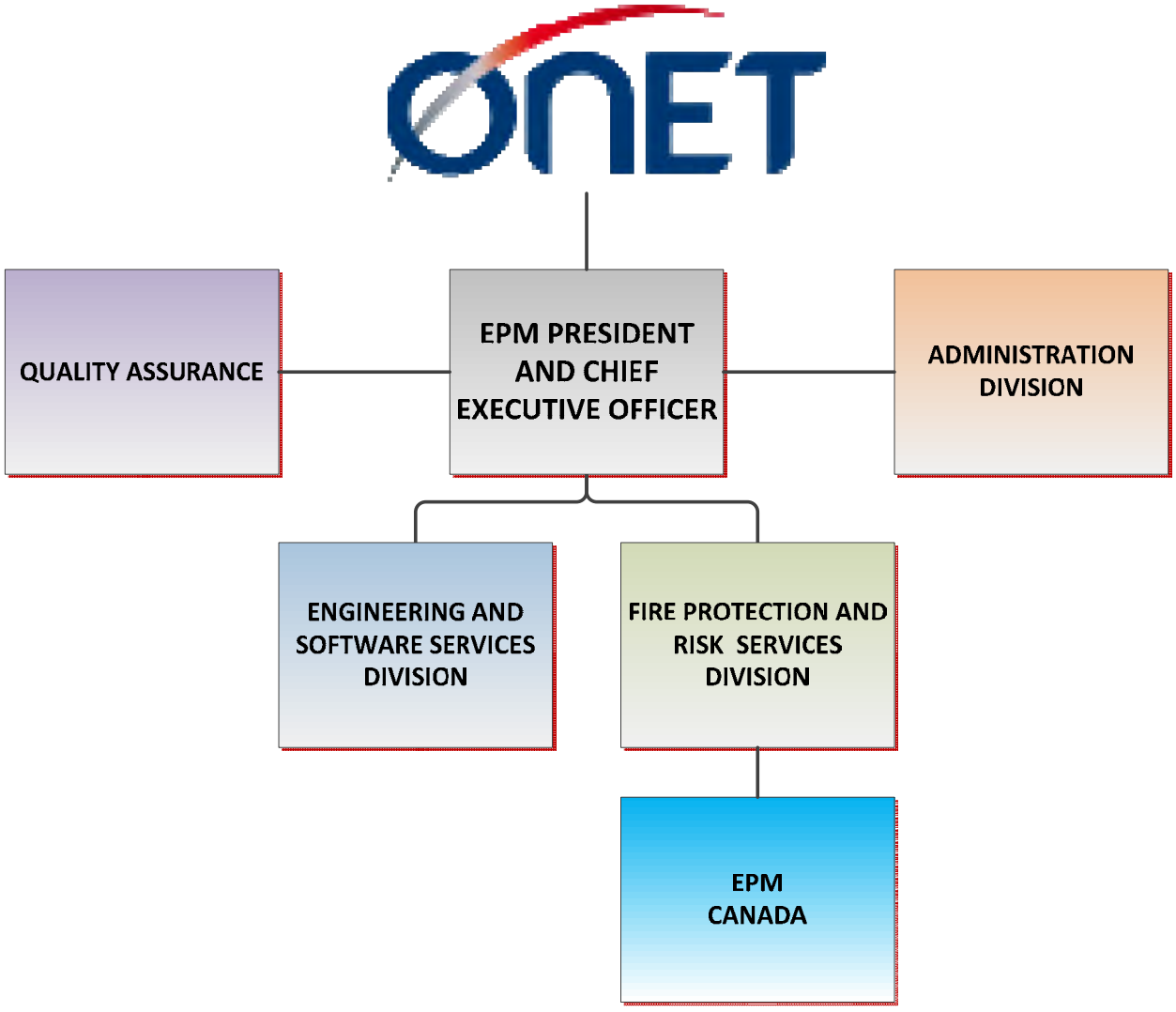
When the designation of a Project Engineer is not deemed necessary for a project, the Project Manager will assume the Project Engineer's responsibilities, also.

1.5. Interface Controls

When more than one organization is involved in the execution of activities, the responsibilities, interfaces, and authority of each organization shall be clearly defined and documented.

The external interfaces between organizations and the internal interfaces between organizational units, and the changes thereto, shall be documented.

Figure A1.1 – Organization



2. QUALITY MANAGEMENT PROGRAM

2.1. Purpose

To describe planning, implementing, and maintaining the EPM Quality Management Program for compliance with the applicable requirements of Title 10 Code of Federal Regulations Part 50 Appendix B, 10 CFR Part 21 [7], applicable regulatory guides, ASME NQA-1, ISO 9001, CSA N299.1:19, CSA N286.7-16, and client requirements. This section describes the EPM Quality Management Program contained in this Manual.

2.2. Quality System

Activities affecting quality are documented in accordance with written procedures, instructions, specifications, and drawings that contain appropriate criteria for determining that the required activities have been satisfactorily accomplished. The documentation of the performed work is established in the following three distinct categories that integrate EPM policies, procedures, and working documents:

(a) Category Q - nuclear power plant safety-related activities and/or items.

(b) Category AQ – nuclear power plant non-safety-related activities and/or items to which specified, graded quality requirements have been applied.

(c) Category Non-Q - nuclear power plant non-safety-related activities and/or items, and other nuclear related commercial services and/or items.

2.2.1. Quality Category Q

Quality category Q applies to nuclear power plant safety-related activities and/or items. Implementation of the EPM Quality Management Manual and Quality Procedures ensures that client quality assurance requirements and related quality standards are met. The EPM Quality Management Manual and Quality Procedures are structured to the requirements of 10 CFR Part 50 Appendix B, 10 CFR Part 21, and ASME NQA-1. An 2010 evaluation of the EPM Quality Assurance Manual determined compliance with the applicable requirements of Canadian Standard Z299.2 and applicable elements of CSA N286.2 (Engineering) and N286.7 (Software) standards.

2.2.2. Quality Category AQ (Augmented Quality)

Quality Category AQ applies to nuclear power plant non-safety-related activities and/or items for which the utility/client has made a regulatory or design commitment to implement special controls. These special controls are included in the EPM Quality Management Program as Category AQ (Augmented Quality) and the specific requirements of this Category are contained in Quality Procedure EPM-QP-1.1.

2.2.3. Quality Category Non-Q

Quality Category Non-Q applies to nuclear power plant non-safety-related activities and/or items and nuclear related commercial grade products. Implementation of the EPM Quality Management Manual and Quality Procedures is not mandatory. Non-nuclear commercial grade products, services, or items are not within the scope of this Manual.

2.3. Scope

EPM is a company that provides engineering services, software products, and consulting services to Architect/Engineers, NSSS organizations, and owners of nuclear power plants and other nuclear related facilities. The EPM Quality Management Manual and Quality Procedures ensure that appropriate controls are provided over EPM activities that affect quality. The EPM Quality Management Program is applicable to all phases of nuclear safety-related activities in the scope of EPM contracts from initial planning to completion of all contractual responsibilities. The scope of EPM activities consists of:

2.3.1. Engineering Services

Engineering services provided by EPM include design, design reviews, design analysis, and technical direction pertaining to safety-related systems, structures, and components, requiring the application of the EPM Quality Management Program. Such services encompass (1) plants under construction, (2) modification, maintenance, and testing for operating plants, (3) advanced reactors and other nuclear-related facilities, and (4) chemical processing facilities.

The design review and design analysis services are provided by EPM to evaluate the work performed by others. These services include checking

calculations, drawings, flow diagrams, and related design software against the requirements of design specifications and design criteria.

2.3.2. Software Products and Services

EPM develops software products for use internally in support of Engineering Services and Consulting Services. EPM also develops software products for its clients in support of maintaining configuration management and performing database-related calculations that assist in performing specific engineering functions.

In addition, EPM provides software services in the areas of database integrity, data migration, data scrubbing, software design reviews, and review of the software life cycle as it pertains to governing procedures and software quality assurance.

2.3.3. Consulting Services

EPM performs feasibility studies, conceptual design and design reviews, and provides advice and counsel to its clients. The EPM Quality Management Program will be applied to this category of service when the task or the activity is identified as Q, safety-related, as AQ, Augmented Quality, or as Non-Q, non-safety-related, as defined in this Manual.

2.4. Requirements

The Quality Management Program of EPM shall comply with the current applicable requirements of:

(a) Code of Federal Regulations, Title 10, Part 50, Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," and NRC Regulatory Guides

(b) ASME NQA-1-2022, "Quality Assurance Requirements for Nuclear Facility Applications"

(c) NRC Regulatory Guide 1.28, Rev. 6, “Quality Assurance Program Criteria (Design and Construction)” [8]

2.5. Responsibilities

2.5.1. President

The President is the Chief Executive Officer of EPM. He is responsible for establishing policy and approving the issuance of the EPM Quality Management Manual and Quality Procedures. The President establishes overall expectations for effective implementation of the Quality Management Program.

2.5.2. Quality Assurance Manager

The Quality Assurance Manager, who reports to the President, has been delegated the responsibility for establishing, maintaining, and administering the EPM quality management system.

2.5.3. Division Directors

Division Directors are responsible for ensuring that EPM quality requirements are communicated, understood, and implemented at all levels.

2.5.4. EPM Personnel

Implementation of the EPM Quality Management Manual and Quality Procedures is the responsibility of all EPM personnel.

2.6. Indoctrination and Training

Under the direction of the Quality Assurance Manager, periodic training sessions are held and documented for indoctrination of all personnel in the effective implementation of the EPM Quality Management Program.

Division Directors are responsible for conducting technical indoctrination and training, as necessary, of personnel within their functional disciplines to assure that suitable proficiency is achieved and maintained.

2.7. Program Evaluation and Management Review

The Quality Assurance Manager, through internal audits, shall regularly assess the adequacy of the EPM Quality Management Program and shall assure its effective implementation. The President is responsible for annual review of the implementation of the EPM quality management system. These reviews are conducted to ensure continued suitability, adequacy, and effectiveness of the EPM quality management system. These reviews include assessing opportunities for improvement and the need for changes to the quality management system, quality policy, and quality objectives.

The reviews include audit performance data, customer satisfaction feedback, and other key performance indicators.

2.8. Purchase Order/Contract Review

Client purchase orders and specifications and subsequent changes regarding technical, administrative, and quality requirements are reviewed by the Project Manager and other designated functional groups to ensure that client requirements are adequately defined and documented, and that EPM could meet client requirements. Requirements that differ from those in the final proposal are communicated with the client and resolved. EPM project quality plans shall reflect/reference client requirements. Documentation of purchase order/contract review is maintained in accordance with EPM Quality Procedures.

2.9. Quality Management Manual Revision and Approval

The preparation and revision of all sections of this Manual and the Quality Procedures are the responsibility of the Quality Assurance Manager.

EPM personnel are encouraged to submit suggestions for revision of the Quality Management Manual/Procedures by utilizing the Quality Management Manual/Procedure Change Request Form per the requirements given in Quality Procedure EPM-QP-2.0 [9]. The QA Manager shall review all suggested changes to the Quality Management Manual/Procedures for compliance with applicable regulations, rules, codes, and standards prior to their approval.

The President shall approve all revisions thereof by signing and dating the Table of Contents page.

Revisions to the pages of the Quality Management Manual/Procedures shall be identified by annotating the revised text and placing the revision number at the top of the page.

2.10. Distribution

The Quality Assurance Manager shall distribute on-line electronic copies of the latest revisions of the Quality Management Manual/Procedures. The latest revision of the Quality Management Manual shall be submitted to the NUPIC web site for download by NUPIC members. Procedural controls for hard copy distribution shall be exercised for Quality Management Manual accountability and receipt acknowledgement per the requirements given in Quality Procedure EPM-QP-2.0. Procedural controls for hard copy distribution shall be exercised for Quality Procedures accountability and receipt

acknowledgement per the requirements given in Quality Procedure EPM-QP-1.0 [10]. Revisions to the Quality Management Manual need not be sent to holders of uncontrolled copies.

3. DESIGN CONTROL

3.1. Purpose

To provide appropriate control measures on all design activities for which EPM is responsible, and to describe requirements and responsibilities for the translation of design requirements into design documents.

3.2. Scope

EPM is responsible for its design activities in accordance with client purchase order requirements and/or contracts accepted by EPM. The requirements of this section apply to all design activities for safety-related structures, systems, and components. The Augmented Quality Requirements as detailed in Quality Procedure EPM-QP-1.1 Appendix 1.1-A shall apply for non-safety-related projects classified as AQ.

3.3. Requirements

The design of safety-related structures, systems, and components shall be defined, controlled, and verified. Design inputs shall be specified on a timely basis and translated into design documents. Design interfaces shall be identified and controlled. Individuals other than those who designed the item or computer program shall verify design adequacy. Design changes shall be governed by control measures commensurate with those applied to the original design.

3.4. Responsibilities

3.4.1. Division Directors

The Division Directors are responsible for attaining quality of design activities in compliance with the EPM Quality Management Manual and Quality Procedures.

3.4.2. Project Managers/Project Engineers

Project Managers/Project Engineers are responsible for reviewing design contract documents to assure that applicable procedures have been prepared and followed, appropriate quality standards are specified and included in the design, design activities including independent verification of design adequacy are properly documented, and applicable contractual requirements have been met.

3.5. Design Control Process

The key elements of the EPM design control process consist of:

3.5.1. Project Planning

The Project Plan document is the primary vehicle for identifying the requirements for control of the project, including the contractual, technical, administrative, and quality assurance requirements.

Project planning is performed by designating the Project Manager/Project Engineer, defining the project scope, and identifying the design activities to the level of detail necessary to permit the design process to be carried out in a correct manner and permit verification that the design meets the requirements. The Project Plan shall identify the Project Manager, determine the EPM Quality Management Program's applicability, and establish applicable technical and quality requirements for the project.

3.5.2. Design Interface Control

Based on the client purchase order or contract, design interface is established and implemented to identify and control design interfaces among participating organizations or groups. Design interfaces are documented, reviewed, and approved by the participants. Design interface controls include the assignment of responsibility and the process for the review, approval, distribution, and revision of documents involving safety-related and Augmented Quality design interfaces. Transmittal of design information is documented and controlled.

3.5.3. Design Input

Applicable design inputs, such as client specifications, functional requirements, design bases, performance requirements, codes and standards, and technical requirements, are identified and documented, and their selection reviewed and approved by the Project Manager. Design input is obtained or specified and approved in a timely manner and to the level of detail to permit design activities to proceed in a correct manner. Design decisions, design verifications, and evaluation of design changes are measured against design input requirements. Changes from approved design inputs are submitted for client approval as appropriate.

Changes from specified design inputs, including the reasons for the changes, shall be identified, reviewed for suitability, approved, documented, and controlled. Design methods, materials, parts, equipment, and processes that are essential to the function of the structure, system, or component shall be selected and reviewed for suitability of application.

3.5.4. Design Process

At the project level, design activities are prescribed and documented. Design information is reviewed and coordinated among interfacing design engineers and client organizations. Design actions are verified for meeting requirements and suitability for the intended service. Final designs (approved design output documents and changes thereto) are verified against design input. Completed detailed design documents are reviewed by the cognizant Project Engineer or his designee. Approved documents are submitted to clients in accordance with purchase order or contract requirements.

3.5.5. Design Analysis

When applicable, design analysis is performed in a controlled and documented manner. Design analyses are sufficiently detailed as to purpose, method, assumptions, design input, and references such that a person technically qualified in the subject can review and understand the analyses and verify the adequacy of the results without recourse to the originator. Documentation of design analysis includes:

(a) The objective of the analysis

(b) Design inputs and their sources

(c) Results of literature searches or other reference data

(d) Assumptions, and identification of those that must be verified during design

(e) Identification of any computer calculations, including computer type, computer program name and revision, inputs, outputs, and verification that the computer software is controlled, verified, and validated in accordance with established procedures

(f) Review and approval.

3.5.6. Design Output

The Project Manager is responsible for design output, including computer software, in the form that meets client requirements. Typical design output

includes analyses, design calculations and reports, drawings, and specifications. The Project Manager is responsible for ensuring that the design output complies with design input requirements, client requirements, and regulatory requirements, and for ensuring suitability of application.

3.5.7. Design Verification

The Project Manager is responsible for ensuring that design verification is performed and documented prior to releasing/submitting to the client. EPM's design control measures are applied to verify the adequacy of design by one or more of the following methods:

(a) Performance of design reviews;
(b) Use of alternate calculations; or
(c) Performance of qualification tests.

The Project Manager/Engineer identifies and documents the particular design verification method(s) used. Design verification is performed by any competent individual(s) or group(s) other than those who performed the original design, but who may be from the same organization. This verification may be performed by the originator's supervisor, provided that:

(a) the supervisor did not specify a singular design approach or rule out certain design considerations, and did not establish the design inputs used in the design; or
(b) the supervisor is the only individual in the organization competent to perform the verification.

Cursory supervisory reviews do not satisfy the intent of design verification.

Extent of design verification is subject to the importance of safety of the item, complexity of the design, and other valid considerations.

When design verification by the qualification test method is selected, applicable procedures are prepared. These procedures, upon internal review and approval, are submitted to the client in accordance with contract requirements.

Results of design verification are documented.

3.5.8. Design Change Control

Changes to final designs need to be justified and subjected to design control measures commensurate with those applied to the original design. For EPM-

originated designs, review and approval of changes are performed by the same organization and/or individual that reviewed and approved the original design document. Where a significant design change is necessary because of an incorrect design, the design process and verification procedure shall be reviewed and modified as necessary.

Per client request and delegation, EPM may accept to be the new responsible organization to perform design changes where the organization that was originally responsible for approving a particular design document is no longer responsible.

3.6. Software Design Control

The requirements of ASME NQA-1 (Part I, Requirement 3, paragraph 800 and Part II, Subpart 2.7) pertaining to computer software design control are incorporated into the EPM software quality procedures. EPM software quality procedures include provisions for validation and acceptance of computer software developed by EPM or obtained from external sources. EPM-developed computer software encompasses the activities associated with software design requirements, software design, software design verification, computer program testing, and software configuration management. Functional requirements, design documents, test requirements, and test results are verified in accordance with written procedures. Verification is performed at the completion of each phase to ensure that the output of a given phase fulfills the requirements established by previous phases. Validation is performed upon completion of software development to ensure that the final product satisfies all identified requirements and produces correct results.

3.6.1. Computer Software Change Control

Changes to software are documented, approved, and controlled by authorized personnel in accordance with established Quality Procedures.

3.6.2. Computer Software Testing

Software is tested for all intended applications. The degree of testing is dependent on the complexity of the program and prior documented performance. Acceptance criteria may be based on hand calculations, documented results from other validated computer programs, empirical data, published data in technical literature, or performance standards established through use. Testing is conducted in accordance with written test plans, and test results are documented. Testing is independently verified.

3.6.3. Computer Hardware Systems

Platform testing will be run whenever the computer software is installed on a different computer, or when significant hardware or operating system configuration changes are made.

3.7. Third Party Software

Third party developed software used for safety-related design analysis shall be accepted for use and controlled or the computer program's results shall be independently verified with the design analysis for each application. Third party software includes procured software and otherwise acquired software[1].

3.8. Documentation and Records

Design documents and records, which provide evidence that the design verification processes were performed in accordance with the requirements of this Manual, shall be collected, stored, and maintained in accordance with Project Plans and EPM Quality Procedures.

The documentation shall include not only final design documents, such as drawings and specifications, and revisions thereto, but also documentation that identifies design inputs and design calculations that support the final design.

[1] For "otherwise acquired software", see definition, ASME-NQA-1-2022, Part II, Subpart 2.7, Section 302.

4. PROCUREMENT DOCUMENT CONTROL

4.1. Purpose

To ensure that procured items and services conform to specified requirements, and that selected suppliers are evaluated on their ability to supply products in accordance with EPM's technical and quality requirements.

4.2. Scope

This section applies to all EPM procurement documents for safety-related items and services.

4.3. Requirements

Applicable design bases and other requirements necessary to ensure adequate quality shall be included or referenced in EPM documents for procurement of items and services. To the extent necessary, EPM procurement documents shall require suppliers to have a quality assurance program consistent with the applicable requirements of 10 CFR 50 Appendix B as evaluated in accordance with ASME NQA-1, or alternate requirements invoked by client requirements.

4.4. Responsibilities

4.4.1. Project Manager

The Project Manager or his designee is responsible for preparing the procurement document and for including the applicable technical and quality requirements.

4.4.2. Quality Assurance Manager

The Quality Assurance Manager is responsible for reviewing and approving procurement documents for quality contents and to evaluate suppliers' quality assurance programs prior to placement of EPM purchase orders.

4.5. Procurement Documents

EPM procurement documents for safety-related items or services shall contain the following as deemed necessary:

4.5.1. Scope of Work

A statement of the scope of work to be performed by the supplier shall be described in the procurement documents.

4.5.2. Technical Requirements

Technical requirements shall be specified in the procurement documents. These requirements shall be specified, as appropriate, by reference to specific drawings, specifications, codes, standards, regulations, procedures or instructions, including revisions thereto, that describe the items or services to be furnished. The procurement documents shall identify appropriate test, inspection, and acceptance criteria for determining acceptability of the item or service

4.5.3. Quality Assurance Program Requirements

EPM procurement documents shall require that the supplier have a documented quality assurance program that implements applicable elements of 10 CFR 50 Appendix B and 10 CFR Part 21 requirements unless commercial grade dedication of items or services is pursued. The extent of the program required shall depend upon the type and use of the item or service being procured. The EPM procurement documents shall require the supplier to incorporate appropriate quality assurance program management system requirements in sub-tier procurement documents.

4.5.4. Right of Access

The procurement document shall provide for access to the supplier's and sub-tier supplier's facilities and records for surveillance, inspection, or audit by EPM and/or other parties authorized by EPM.

4.5.5. Documentation Requirements

The procurement documents at all tiers shall identify the documentation required to be submitted for information, review, or approval by EPM. The time of submittal shall also be established. When EPM requires the supplier to maintain specific quality assurance records, the retention times and disposition requirements shall be prescribed.

4.5.6. Nonconformances

Procurement documents shall include EPM requirements for reporting and approving disposition of nonconformances.

4.5.7. Spare and Replacement Parts

The procurement documents shall specify the supplier's requirements to identify spare and replacement parts or assemblies and the related data required for ordering these parts or assemblies.

4.6. Procurement Document Review

4.6.1. Review

A review of the procurement documents and changes thereto shall be made and documented by the Project Manager or his designee to assure that documents transmitted to the prospective supplier include appropriate provisions to ensure that items or services will meet the specified requirements. The reviews shall be accomplished prior to contract awards and shall be documented.

4.6.2. Changes

Changes made in the procurement requests as a result of bid evaluations or pre-contract negotiations shall be incorporated into the procurement documents.

4.6.3. QA Manager

The Quality Assurance Manager shall review and approve all safety-related EPM procurement documents to assure that they have been prepared, reviewed, and approved in accordance with EPM quality requirements and client requirements.

4.7. Procurement Document Changes

Procurement document changes affecting technical requirements or quality program requirements shall be subject to the same degree of control as utilized in the preparation of the original documents.

4.8. Purchasing Activities

Purchasing activities shall be controlled through documented EPM procedures and instructions, which include requirements of selection of supplier, evaluation of supplier performance and resolution of nonconformances. As appropriate, EPM will conduct surveillances of suppliers during fabrication, inspection, testing, and release of items as specified in procurement documents.

Documents submitted by suppliers are reviewed/evaluated against acceptance criteria defined in the procurement documents for technical correctness, completeness of inspection test data, and acceptability of test results.

EPM's acceptance of quality assurance releases of EPM-procured items shall be documented prior to being shipped to EPM clients. A statement of conformance shall be documented for items or services in accordance with client requirements.

5. INSTRUCTIONS, PROCEDURES, AND DRAWINGS

5.1. Purpose

To provide appropriate control measures for ensuring that activities affecting quality are prescribed by and performed in accordance with documented instructions, procedures, or drawings of a type appropriate to the circumstances.

5.2. Scope

The requirements of this section are mandatory for EPM activities affecting the quality of safety-related items or services.

5.3. Requirements

All EPM activities affecting quality shall be prescribed by and performed in accordance with documented instructions, procedures, or drawings that include or reference appropriate quantitative or qualitative acceptance criteria for determining that prescribed activities have been satisfactorily accomplished.

The activity shall be described to a level of detail commensurate with the complexity of the activity and the need to ensure consistent and acceptable results. The need for, and level of detail in, written procedures or instructions shall be determined based upon the complexity of the task, the significance of the item or activity, work environment, and worker proficiency and capability (education, training, experience).

5.4. Responsibilities

5.4.1. Division Directors

The Division Directors are responsible for prescribing appropriate documented instructions, procedures, or drawings for EPM safety-related activities for their functional disciplines. Division Directors are responsible for assuring that EPM quality requirements are communicated, understood, and implemented at all levels.

5.4.2. Quality Assurance Manager

The Quality Assurance Manager is responsible for reviewing EPM-originated instructions and procedures for EPM safety-related activities.

5.4.3. Project Manager/Project Engineer

The Project Manager/Project Engineer is responsible for reviewing and approving EPM-originated project procedures, instructions, specifications, calculations, and drawings, and for assuring that the adequacy of such documents has been verified by persons other than those who prepared them.

5.5. Control Process

The preparation, review and approval of EPM-issued instructions, procedures, and drawings shall be subject to the following controls:

5.5.1. Instructions

Instructions for performing safety-related activities shall be documented. At the project level, the documentation shall be via the Project Plan. Written instructions shall be issued only when written procedures do not exist or provide adequate coverage.

Such documented instructions, prepared and issued by the Project Manager/Project Engineer, shall be reviewed by the Quality Assurance Manager for incorporation into Project Procedures or EPM Quality Procedures, as appropriate.

5.5.2. Quality Procedures

EPM Quality Procedures shall be designed to address EPM activities for compliance with the EPM quality management system and client requirements.

The President is responsible for reviewing and approving EPM Quality Procedures and their revisions prior to issuance for implementation.

The Quality Assurance Manager is responsible for coordinating the preparation, issuance, and control of EPM Quality Procedures and revisions thereto.

5.5.3. Drawings

The Project Engineer/Project Manager is responsible for reviewing and approving EPM-originated drawings and assuring that the adequacy of drawings is verified by persons other than those who prepared them.

6. DOCUMENT CONTROL

6.1. Purpose

To describe the EPM measures for ensuring that documents related to quality activities are appropriately controlled.

6.2. Scope

EPM is responsible for all incoming technical documents and EPM-generated technical documents for receipt, processing, revising, maintaining, and distributing in accordance with client purchase order and/or contract requirements. The requirements of this section apply to all documents concerning safety-related structures, systems, and components. These documents include:

(a) EPM Quality Management Manual
(b) EPM Quality Procedures
(c) EPM-issued Purchasing/Contract Documents
(d) EPM-generated Specifications
(e) Project Calculations
(f) EPM-generated Drawings
(g) Other per Project Requirements

6.3. Requirements

The preparation, issuance, and change of EPM documents that specify quality requirements or prescribe activities affecting quality, such as instructions, procedures, and drawings, shall be controlled to ensure that correct documents are being employed. Such documents, including changes thereto, shall be reviewed for adequacy and approved for release by authorized personnel.

6.4. Responsibilities

6.4.1. Division Director

The Division Director is responsible for identification of personnel, positions, or organizations responsible for preparing, reviewing, approving, and issuing documents.

6.4.2. Quality Assurance Manager

The Quality Assurance Manager is responsible for the control of the Quality Management Manual and Quality Procedures.

6.4.3. Project Manager/Project Engineer

The Project Manager/Project Engineer is responsible for assuring that the correct revisions of applicable codes and standards are used, in accordance with client requirements, and is responsible for:

(a) Identification of documents to be controlled
(b) Review of documents for adequacy, completeness, and correctness prior to approval and issue
(c) Receiving, distributing, and filing project documents received by or generated by EPM

6.4.4. Records Coordinator

The Records Coordinator is responsible for reviewing and accepting document submittals to the EPM document retention system.

6.5. Document Control Process

The EPM document control process is addressed in EPM Quality Procedures. Technical documents include all written or pictorial technical information such as drawings, design criteria, design description, design requirements, specifications, installation, and/or operational requirements for a plant or a project. Such documents, including changes thereto, are reviewed for adequacy and approved for release by authorized personnel.

EPM Quality Procedures provide necessary controls applied to documents and changes thereto, such as:

(a) the identification of controlled documents
(b) the specified distribution of controlled documents for use at the appropriate location
(c) the identification of individuals responsible for the preparation, review, approval, and distribution of controlled documents
(d) the review of controlled documents for completeness, and approval prior to distribution
(e) a method to ensure the correct documents are being used.

6.6. Computer Software Control

Computer software control is addressed in EPM Quality Procedures. EPM Quality Procedures are established to control changes to the approved configuration of

computer software used in safety-related activities. The development and maintenance of EPM safety-related software includes appropriate documentation of software requirements, software design descriptions, testing, verification and validation, configuration control, and error reporting and resolution.

6.7. Document Changes

Changes to documents, other than those defined as minor changes, are reviewed and approved by the same organizations that performed the original review and approval unless other organizations are specifically designated. The reviewing organizations have access to pertinent background data or information upon which to base their approval.

Minor changes to documents, such as inconsequential editorial corrections, shall not require that the revised documents receive the same review and approval as the original documents. The Project Manager can authorize such decisions on technical documents, and the Quality Assurance Manager can authorize such decisions on Quality Management-related documents.

6.8. Retention of Technical Documents

EPM will retain technical documents for the duration of the contract. When such documents are categorized as quality records, their retention shall comply with Quality Procedure requirements.

7. CONTROL OF PURCHASED MATERIAL, ITEMS, AND SERVICES

7.1. Purpose

To describe the control measures for EPM procured safety-related items and services for ensuring that applicable technical and quality requirements are met.

7.2. Scope

This section applies to all safety-related items and services procured by EPM.

7.3. Requirements

The procurement of items and services shall be controlled to ensure conformance with specified requirements. Such EPM control shall provide for the following as appropriate:

(a) Supplier evaluation and selection,
(b) Evaluation of objective evidence of quality furnished by the supplier,
(c) Source inspection,
(d) Audit, and
(e) Examination of items or services upon delivery or completion.

7.4. Responsibilities

7.4.1. Quality Assurance Manager

The Quality Assurance Manager is responsible for establishing necessary control measures on all EPM safety-related procurements. He is responsible for establishing EPM's Approved Supplier List based on his evaluation of suppliers. He shall review the acceptability of supplier deviations from procurement documents in accordance with Section 15.0, Attachment A of this Manual.

7.4.2. Project Manager/Engineer

The Project Manager/Engineer who normally initiates the purchasing requisition is responsible for selecting suppliers from the EPM Approved Supplier List.

7.5. Procurement Process

Preparation, review, and change control of procurement documents are described under Section 4.0, Attachment A of this Manual. This Section addresses the procurement planning for the integration of items (a) through (g) below:

(a) Supplier evaluation and selection
(b) Bid evaluation
(c) Control of supplier-generated documents
(d) Acceptance of item or service
(e) Control of supplier non-conformances
(f) Commercial grade items and services
(g) Records

7.5.1. Supplier Evaluation and Selection

Prior to award of contract, the selection of suppliers shall be based on EPM evaluation of suppliers' capability to provide items or services in accordance with the requirements of the EPM procurement document. Suppliers of safety-related items and services are selected from the EPM Approved Supplier List.

7.5.1.1. Approved Supplier List

An Approved Supplier List shall be prepared and issued by the Quality Assurance Manager, as needed. Inclusion on this list shall be based upon evaluation and documentation of one or more of the measures described below:

(a) Supplier's history of providing an identical or similar product that performs satisfactorily in actual use. The supplier's history shall reflect current capability.

(b) Supplier's current quality records supported by documented qualitative and quantitative information that can be objectively evaluated.

(c) Supplier's technical and quality capability as determined by a direct evaluation of his facilities, personnel, and the implementation of the supplier’s quality assurance program.

7.5.2. Bid Evaluation

Bid evaluations shall be made by the Project Manager/Engineer and the Quality Assurance Manager to evaluate the supplier's capability to conform to the technical and quality assurance requirements. Prior to award of the contract, EPM shall resolve or obtain commitments to resolve unacceptable technical or quality assurance conditions resulting from the bid evaluation.

7.5.3. Control of Supplier-Generated Documents

EPM shall implement necessary controls to ensure that the submittal and evaluation of supplier-generated documents are accomplished in accordance with the procurement document requirements. These controls shall provide for the acquisition, processing, and recorded evaluation of the quality assurance, technical, inspection, and test documentation or data against acceptance criteria.

7.5.4. Acceptance of Item or Service

7.5.4.1. General

Prior to acceptance, the supplier shall verify that the item or service being furnished complies with the procurement requirements. The extent of the verification activities by EPM shall be a function of the importance, complexity, and quantity of the item or services procured and the supplier's quality performance. Where required by code, regulation, or contract requirements, documentary evidence that items conform to procurement requirements shall be available at the nuclear facility site prior to installation or use.

7.5.4.2. Method of Acceptance

Methods used to accept an item or service from a supplier shall be the supplier's Certificate of Conformance, source verification, receiving inspection, or post-installation testing at the nuclear facility site, or a combination of these methods.

When a Certificate of Conformance is used to accept an item, the following requirements shall be met:

(a) The Certificate shall identify the purchased material, equipment, or service by purchase order number.

(b) The Certificate shall identify the specific procurement requirements met by the purchased material, equipment, or service, such as codes and standards.
(c) The Certificate shall identify any procurement requirements that have not been met, with an explanation and the means for resolving the non-conformances.
(d) The Certificate shall be signed by a person who is responsible for this quality assurance function.
(e) The Certification system shall be described in the supplier's quality assurance program.
(f) The validity of supplier's certificates shall be verified by the Project Manager/Engineer.

When Source Verification is used, it shall be performed at intervals consistent with the importance and complexity of the item or service. Upon EPM's acceptance of source verification, documented evidence of acceptance shall be furnished to the nuclear facility site and to the supplier.

When Receiving Inspection is used, purchased items shall be inspected as necessary to verify conformance to specified requirements. Documented evidence of acceptance shall be furnished to the nuclear facility site and to the supplier.

When Post-Installation Testing is used at the nuclear facility site, acceptance documentation shall be mutually established by EPM and the supplier.

In cases involving procurement of Services Only, EPM shall accept the service by any or all of the following methods:

(a) technical verification of data produced
(b) surveillance and/or audit of the activity
(c) review of objective evidence for conformance to the procurement document requirements.

7.5.5. Control of Supplier Non-conformances

Methods for control and disposition of supplier non-conformances for items and services that do not meet procurement document requirements shall include the following:

(a) evaluation of non-conforming items
(b) submittal of nonconformance notice to EPM by supplier. The submittals shall include supplier-recommended disposition (e.g., use-as-is or repair) and technical justification. Non-conformances to the procurement requirements shall be submitted to EPM for approval of the recommended disposition:
    1. technical or material requirement is violated
    2. requirement in supplier documents, which has been approved by EPM, is violated
    3. non-conformance cannot be corrected by continuation of the original manufacturing process or by rework
    4. the item does not conform to the original requirement even though the item can be restored to a condition such that the capability of the item to function is unimpaired
(c) EPM's disposition of supplier recommendation
(d) verification of implementation of the disposition
(e) maintenance of records of supplier-submitted non-conformances.

7.5.6. Commercial Grade Items and Services

When commercial grade items or services are utilized, a detailed procedure shall be prepared, reviewed, and approved, as an acceptable alternative to Subsections 7.5.2 through 7.5.5 requirements. The procedure shall address the following:

(a) utilization
(b) critical characteristics
(c) dedication
(d) supplier deficiency correction

7.6. Quality Records

Records shall be established and maintained to indicate the performance of the following functions:

(a) supplier evaluation and selection
(b) acceptance of items or services
(c) supplier non-conformances to procurement document requirements, including their evaluation and disposition
(d) utilization and acceptance of commercial grade items.

Collection, storage, and maintenance of quality assurance records shall be in accordance with Section 17.0, Attachment A of this Manual.

8. IDENTIFICATION AND CONTROL OF MATERIALS, PARTS, AND COMPONENTS

8.1. Purpose

To describe the controls for ensuring proper identification and control of items.

8.2. Scope

EPM does not procure/provide safety-related items for nuclear power plants. However, if the client requests such a service, this section applies to all EPM-procured/provided safety-related items.

8.3. Requirements

Controls shall be established to ensure that only correct and accepted items are used or installed. Identification shall be maintained either on the items or in documents traceable to the items, or in a manner which ensures that identification is established and maintained.

8.4. Responsibilities

8.4.1. Project Manager/Project Engineer

The Project Manager/Engineer or his designee shall be responsible for specifying identification requirements of safety-related procured items.

8.4.2. Quality Assurance Manager

The Quality Assurance Manager or his designee shall be responsible for verifying conformance with EPM procurement document requirements.

8.5. Identification Methods

EPM procurement documents shall require that procured items be identified from the initial receipt and fabrication of the items up to and including installation and use when it is within the EPM scope of work. The identification on items shall relate to an applicable procurement/specifying document.

8.5.1. Physical Identification

Physical identification by marking or tagging shall be used to the maximum extent possible. Where physical identification on the item is either impractical or insufficient, physical separation, procedural control, or other appropriate means shall be employed.

Identification markings shall be applied using materials and methods that provide a clear and legible identification and do not degrade the function or service life of the item. Markings shall be transferred to each part of an identified item when subdivided and shall not be obliterated or hidden by surface treatment or coatings unless other means of identification are substituted.

8.5.2. Traceability of Items

When codes, standards, or specifications include specific identification or traceability requirements, applicable specification and grade of material (such as identification or traceability of the item to applicable specification and grade of material; heat, batch, lot, part or serial number; or specified inspection, test, or other records), the application shall provide such identification and traceability control.

8.5.3. Limited Life Items

Items having limited calendar or operating life or cycles shall be identified and controlled to preclude use of items whose shelf life or operating life has expired.

8.5.4. Maintaining Identification of Stored Items

Provisions shall be made for the control of items' identification consistent with the planned duration and conditions of storage, such as:

(a) provisions for maintenance or replacement of markings and identification records due to damage during handling or aging
(b) protection of identification on items subject to excessive deterioration due to environmental exposure
(c) provisions for updating existing plant records.

Any safety-related item received by EPM shall be inspected by the Quality Assurance Manager or his designee to verify conformance with EPM procurement document requirements. This inspection shall be documented and such documentation considered a quality record, to be treated in accordance with Section 17.0, Attachment A of this Manual.

Material accepted by the Quality Assurance Manager or his designee shall be tagged with a Quality Acceptance Tag. The item's acceptance shall be noted in the Safety-Related Items Receiving Log.

Unacceptable nonconforming items shall be documented per Section 15, Attachment A of this Manual.

9. CONTROL OF SPECIAL PROCESSES

9.1. Purpose

To describe the controls required for special processes affecting quality.

9.2. Scope

EPM does not procure/provide safety-related items to nuclear power plants. However, if the client requests such a service, this section applies to special processes performed by or for EPM.

9.3. Requirements

Special processes that control or verify quality, such as those used in welding, heat treating, and nondestructive examination, shall be performed by qualified personnel using qualified procedures in accordance with specified requirements.

9.4. Responsibilities

9.4.1. Project Manager/Project Engineer

The Project Manager/Engineer shall be responsible for specifying appropriate instructions that include or reference procedure, personnel, and equipment qualification requirements.

9.4.2. Quality Assurance Manager

The Quality Assurance Manager or his designee shall be responsible for verifying compliance of personnel performing special processes and for assuring qualification of special process procedures for compliance with specified requirements.

9.5. Welding and NDE Control

All welding and NDE procedures shall be qualified in accordance with applicable codes, standards, and specified requirements. All welders and welding operators shall be qualified to the applied welding procedures in compliance with the applicable codes and standards. NDE examiners shall be certified in accordance with the latest edition of SNT-TC-1A [11] and personnel shall be qualified by examination.

For EPM-contracted welding and NDE activities, contractors' welding and NDE procedures shall be reviewed by EPM's QA Manager or his designee prior to authorization for use.

9.5.1. Acceptance Criteria

The requirements of acceptable codes and standards, including acceptance criteria for the process, shall be specified or referenced in the EPM procurement documents or the implementing procedures.

9.5.2. Special Requirements

For special processes not covered by existing codes and standards or where quality requirements specified exceed those of existing codes and standards, the necessary requirements for qualification of personnel, procedures, or equipment shall be specified or referenced in procedures or instructions.

9.6. Records

Qualification records shall be obtained for the qualified personnel, processes, and equipment of each process applied. Collection, storage, and maintenance of records shall be in accordance with Section 17.0, Attachment A of this Manual.

10. INSPECTION

10.1. Purpose

To describe required inspections to verify conformance of an item or activity to specified requirements.

10.2. Scope

EPM does not inspect safety-related items for nuclear power plants. However, if the client requests such a service, this section applies to safety-related items or activities performed by or for EPM.

10.3. Requirements

Inspections required to verify conformance of an item or activity to specified requirements or continued acceptability of items in service shall be planned and executed. Characteristics subject to inspection and inspection shall be specified. Inspection results shall be documented. Inspection for acceptance shall be performed by qualified persons other than those who performed or directly supervised the work being inspected.

10.4. Responsibilities

10.4.1. Project Manager/Engineer

The Project Manager/Engineer shall be responsible for identifying in procurement documents the inspection requirements and specific hold points for EPM inspections.

10.4.2. Quality Assurance Manager

The Quality Assurance Manager or his designee shall be responsible for inspections required to verify conformance of an item or activity to specified requirements. The Quality Assurance Manager is responsible for documenting consent to waive specified hold points prior to continuation of work beyond the designated hold point.

10.5. Inspection Planning

Characteristics to be inspected, methods of inspection, and acceptance criteria shall be identified during the inspection planning process. Sampling procedures, when used, shall be based upon valid statistical methods.

10.6. In-Process Inspection

Inspection of items under construction or otherwise in-process shall be performed as necessary to verify quality. If inspection of processed items is impossible or disadvantageous, indirect control by monitoring of processed method, equipment, and personnel shall be provided. Process monitoring shall be performed by qualified personnel or qualified automatic means. Both inspection and process monitoring shall be provided when control is inadequate without both.

10.7. Final Inspections

Final inspections shall include a records review of results and resolution of nonconformances identified by prior inspections.

Completed items shall be inspected for completeness, markings, calibration, adjustments, protection from damage, or other characteristics as required to verify the quality and conformance of the item to specified requirements.

Any modifications, repairs, or replacements of items performed subsequent to final inspection shall require inspection or retest, as appropriate, to verify acceptability.

The acceptance of the item shall be approved by authorized personnel.

10.8. Inspection Records

Inspection records shall, as a minimum, identify the following:

(a) item inspected
(b) date of inspection
(c) inspector
(d) type of observation
(e) results or acceptability
(f) reference to information on action taken in connection with nonconformances.

11. TEST CONTROL

11.1. Purpose

To describe the planning and execution of tests required to verify conformance of an item or computer program to specified requirements.

11.2. Scope

This section applies to safety-related items procured by EPM and to demonstrate satisfactory performance of safety-related computer programs issued or used by EPM.

11.3. Requirements

Tests required to verify conformance of an item or computer program to specified requirements and to demonstrate that items will perform satisfactorily in service shall be planned and executed. Characteristics to be tested and test methods to be employed shall be specified. Test results shall be documented and their conformance with acceptance criteria shall be evaluated. Tests required to collect data shall be planned, executed, documented, and evaluated.

11.4. Responsibilities

11.4.1. Project Manager/Project Engineer

The Project Manager/Project Engineer shall be responsible for identifying test requirements and acceptance criteria based upon specified requirements contained in applicable design or other pertinent technical documents.

11.4.2. Quality Assurance Manager

The Quality Assurance Manager or his designee shall be responsible to review, evaluate, and witness tests at supplier shops, as necessary, to assure compliance with applicable codes, standards, and procurement document requirements.

11.5. Test Control Process

Test requirements and acceptance criteria shall be provided by the organization responsible for the design of the item to be tested unless otherwise designated. EPM shall review suppliers' test procedures for approval.

Required tests, including, as appropriate, prototype qualification tests, performance tests, preoperational and operational tests, shall be controlled. Test requirements and

acceptance criteria shall be based upon specified requirements of the procurement documents.

For computer program testing, such as software design verification, in conjunction with basic requirements as stated above in Section 11.3, test requirements and acceptance criteria shall be based upon specified requirements contained in applicable design, pertinent technical documents or software specifications.

11.5.1. Test Procedures

Test procedures for procured safety-related items (other than for computer programs) shall include or reference test objectives and provisions for ensuring that prerequisites for the given test have been met, that adequate instrumentation is available and used, that necessary monitoring is performed, and that suitable environmental conditions are maintained.

Test prerequisites shall include the following as applicable:

(a) Calibrated instrumentation
(b) Appropriate equipment
(c) Trained personnel
(d) Condition of test equipment and the item to be tested
(e) Suitable environmental conditions
(f) Provisions for data acquisition.

In lieu of specially prepared written test procedures, appropriate sections of related documents, such as ASTM methods, supplier manuals, approved drawings, or shop travelers with acceptance criteria, can be used. Such documents shall include adequate instructions to ensure the required quality of work.

11.5.2. Computer Program Test Procedures

For computer program testing, such as software design verification, in conjunction with basic requirements as stated above in Section 11.3, test requirements and acceptance criteria shall be based upon specified requirements contained in applicable design, pertinent technical documents, or software specifications.

Computer software shall be tested for all intended applications to ensure adherence to the requirements and to ensure that the software produces correct results for the test cases. Test procedures and instructions shall comply with

ASME NQA-1 Part II Subpart 2.7. Test procedures shall include provisions for the validation and acceptance of procured software. For software developed by EPM, functional requirements, test requirements, and test results shall be verified in accordance with written plans/procedures. Verification shall be performed at the completion of each phase to ensure the output at a given phase fulfills the requirements established by previous phases. Validation of the software shall be performed upon completion of the software development to ensure that the code satisfies all identified requirements and produces correct results.

In-use/platform test procedures shall be performed after the computer program is installed on a different computer, or when there are significant changes in the operating system. Periodic in-use manual or automatic self-check in-use tests shall be prescribed and performed for those computer programs in which computer program errors, data errors, computer hardware failures, or instrument drift can affect required performance.

11.6. Test Results

Test results shall be documented by the testing organization and evaluated by the EPM Project Manager/Project Engineer to ensure that test requirements have been satisfied. Test records vary depending on the test type, purpose, and application.

11.7. Test Records

Test records for procured items (other than for computer programs) shall, as a minimum, identify the following:

(a) Item tested
(b) Date tested
(c) Tester or data recorder
(d) Type of observation
(e) Results and acceptability
(f) Action taken in connection with any deviations noted
(g) Person evaluating test result

11.8. Computer Program Test Records

11.8.1. Verification Test Records

(a) Computer program tested
(b) Computer hardware tested

(c) Test equipment and calibration, where applicable
(d) Date of test
(e) Tester or data recorder
(f) Simulation models used, where applicable
(g) Test problems
(h) Results and applicability
(i) Action taken in connection with any deviations noted
(j) Person evaluating test results.

11.8.2. In-Use/Platform Test Records

(a) Computer program tested
(b) Computer hardware tested
(c) Test equipment and calibrations, when applicable
(d) Date of test
(e) Tester or data recorder
(f) Acceptability.

12. CONTROL OF MEASURING AND TEST EQUIPMENT

12.1. Purpose

To describe the control of measuring and test equipment.

12.2. Scope

EPM does not employ equipment to measure or test safety-related activities affecting quality at nuclear power plants. However, if the client requests such a service, this section applies to safety-related items or activities performed by or for EPM.

12.3. Requirement

Tools, gages, instruments, and other measuring and test equipment used for activities affecting quality shall be controlled, calibrated at specific periods, adjusted, and maintained to required accuracy limits.

12.4. Responsibilities

12.4.1. Project Manager/Project Engineer

The Project Manager/Project Engineer shall be responsible for specifying applicable technical requirements for the control of measuring and test equipment.

12.4.2. Quality Assurance Manager

The Quality Assurance Manager or his designee shall be responsible for verifying the implementation of EPM-required controls of measuring and test equipment.

12.5. Measuring and Test Equipment Control

12.5.1. Selection

Selection of measuring and test equipment shall be based on the type, range, accuracy, and tolerance needed to accomplish the required measurements for determining conformance to specified requirements.

12.5.2. Calibration

Measuring and test equipment shall be calibrated at prescribed times or intervals and whenever the accuracy of measuring and test equipment is suspect. Calibration shall be against and traceable to certified equipment or reference

standards having known valid relationships to nationally recognized standards, or to international standards known to be equivalent to corresponding nationally recognized standards. Where no such standards exist, the basis for selection of the standard in question shall be technically justified.

12.5.3. Control

The method and interval of calibration for each item shall be defined, based on the type of equipment stability characteristics, required accuracy, intended use, and other conditions affecting measurement control.

When measuring and test equipment is found to be out of calibration, an evaluation shall be made and documented of the validity of previous inspection or test results and of the acceptability of items previously inspected or tested. Out-of-calibration devices shall be tagged or segregated and not used until they have been recalibrated. If any measuring or test equipment is consistently found to be out of calibration, it shall be repaired or replaced. A calibration shall be performed when the accuracy of the equipment is suspect.

12.5.4. Commercial Devices

Calibration and control measures are not required for rulers, tape measures, levels, and other such devices if normal commercial equipment provides adequate accuracy.

12.6. Handling and Storage

Measuring and test equipment shall be properly handled and stored to maintain accuracy under environmental controls to the extent necessary to ensure that the required accuracy and precision is maintained.

Measuring and test equipment and reference standards submitted for calibration shall be checked and the results recorded before any required adjustments or repairs are made.

Measuring and test equipment shall be suitably marked, tagged, labeled, or otherwise identified to indicate calibration status and establish traceability to calibration records.

12.7. Records

Records shall be established and maintained to indicate calibration status and the capability of measuring and test equipment to satisfactorily perform its intended function.

13. HANDLING, STORAGE, AND SHIPPING

13.1. Purpose

To describe handling, storage, and shipping requirements for EPM-procured items.

13.2. Scope

EPM does not procure safety-related items for nuclear power plants. However, if the client requests such a service, this section applies to safety-related items procured by EPM.

13.3. Requirements

Handling, storage, cleaning, packaging, shipping, and preservation of items shall be controlled to prevent damage or loss and to minimize deterioration. These activities shall be conducted in accordance with established work and inspection instructions, drawings, specifications, shipment instructions, or other pertinent documents or procedures specified for use in conducting the activity.

13.4. Responsibilities

13.4.1. Project Manager/Project Engineer

The Project Manager/Project Engineer shall be responsible for identifying applicable technical requirements for handling, storage, and shipping of EPM-procured items.

13.4.2. Quality Assurance Manager

The Quality Assurance Manager or his designee shall be responsible for verifying the implementation of EPM-specified handling, storage, and shipping requirements.

13.5. Handling, Storage, and Shipping Process

Handling, storage, and shipping of items shall be conducted in accordance with established instructions, drawings, specifications, or other pertinent documents or procedures specified or approved by EPM.

When required, special equipment (such as containers, shock absorbers, and accelerometers) and special protective environments (such as inert gas atmosphere, specific moisture content levels, and temperature levels) shall be specified and the implementation verified. When required for critical, sensitive, or high-value items,

specific procedures for handling, storage, packaging, shipping, and preservation shall be used.

Special handling tools and equipment shall be utilized and controlled where necessary to ensure safe and adequate handling. Special handling tools and equipment shall be inspected and tested in accordance with procedures and specified time intervals or prior use. Operators of special handling and lifting equipment shall be experienced or trained in the use of the equipment.

13.6. Marking

Instructions for marking or labeling for packaging, shipment, special handling, and storage of items shall be included in EPM procurement documents as necessary to adequately identify, maintain, and preserve the item, including indication of the presence of special environments or the need for special controls.

14. INSPECTION, TEST, AND OPERATING STATUS

14.1. Purpose

To describe EPM requirements for identifying the status of inspection, test, and operating status of EPM-procured/provided items.

14.2. Scope

Other than developing software, EPM does not procure/provide safety-related items for nuclear power plants. However, if the client requests such a service, this section applies to safety-related items procured or provided by EPM.

14.3. Requirements

The organization responsible for a work scope shall ensure that the status of inspection and test activities is identified either on the items or in documents traceable to the items where it is necessary to ensure that (1) required inspections and tests are performed, and (2) items that have not passed the required inspections and tests are not inadvertently installed, used, or operated.

Status shall be maintained through indicators such as physical location, tags, markings, shop travelers, stamps, inspection records, or other suitable means. The authority for application and removal of tags, markings, labels, and stamps shall be specified. Status indicators shall also provide for indicating the operating status of systems and components of the nuclear facility, such as by tagging valves and switches to prevent inadvertent operation.

14.4. Responsibilities

14.4.1. Project Manager/Project Engineer

The Project Manager/Project Engineer shall be responsible for identifying in EPM procurement documents applicable requirements for inspection, test, and operating status.

14.4.2. Quality Assurance Manager

The Quality Assurance Manager or his designee shall be responsible for verifying the implementation of EPM-specified requirements.

14.5. Inspection, Test, and Operating Status

On engineered items built to EPM specifications, the organization responsible for the work scope shall ensure that the status of inspections, tests, and operations can be determined at any point throughout the process. Use of "shop travelers" indicating the required step-by-step fabrication, inspection, assembly, and tests would provide appropriate documentation.

Shop travelers or other appropriate documentation indicating the status of inspections and tests shall be reviewed by the Quality Assurance Manager for EPM acceptance.

On standard off-the-shelf catalog items, appropriate tagging, marking, or inspection records that indicate the required and performed inspections and tests will be acceptable.

15. CONTROL OF NONCONFORMING ITEMS

15.1. Purpose

To describe the measures used to control nonconforming items.

15.2. Scope

Other than developing software, EPM does not procure/provide safety-related items for nuclear power plants. However, if the client requests such a service, this section applies to the control of nonconforming safety-related items procured or provided by EPM.

15.3. Requirements

Items that do not conform to specified requirements shall be controlled to prevent inadvertent installation or use. Controls shall provide for identification, documentation, evaluation, segregation when practical, and disposition of nonconforming items, and for notification to affected organizations and to the client.

15.4. Responsibilities

15.4.1. EPM Personnel

Any EPM employee, upon observing a nonconforming EPM-procured/provided item, shall inform the Quality Assurance Manager or his designee to prevent inadvertent installation or use of the item.

15.4.2. Project Manager/Project Engineer

The Project Manager/Project Engineer shall be responsible for review and evaluation of nonconforming items procured or provided by EPM.

15.4.3. The Quality Assurance Quality Assurance Manager

The Quality Assurance Manager is responsible for the disposition of nonconforming items.

The Quality Assurance Manager or his designee shall prepare a Nonconformance Report and affix a Nonconformance Tag to the nonconforming item, and report to the client as appropriate.

15.5. Control of Nonconforming Items

15.5.1. Identification

Nonconforming items shall be identified by legible marking, tagging, or other methods not detrimental to the item, on either the item, the container, or the package containing the item. If identification of each nonconforming item is not practical, the container, package, or segregated storage area, as appropriate, shall be identified.

15.5.2. Segregation

Nonconforming items shall be segregated, when practical, by placing them in a designated hold area until properly dispositioned. When segregation is impractical or impossible due to physical conditions, such as size, weight, or access limitations, other precautions shall be employed to preclude inadvertent use of a nonconforming item.

15.5.3. Disposition Control

Nonconforming items shall be evaluated and recommended dispositions shall be proposed and approved in accordance with documented Nonconformance Reports. The Quality Assurance Manager is responsible for the control of further processing, delivery, installation, or use of a nonconforming item. For items procured by EPM, the Project Manager/Project Engineer is responsible for the evaluation and the Quality Assurance Manager is responsible for the disposition of nonconforming items.

15.5.4. Final Disposition

The final disposition, such as use-as-is, repair, rework, or reject, of nonconforming items shall be identified and documented.

Acceptability of a nonconforming item dispositioned repair or use-as-is shall be documented by the Project Manager/Project Engineer. The quality verification records shall reflect the Quality Assurance Manager's acceptance of the deviation.

Repaired or reworked items shall be reexamined in accordance with approved procedures and with the original acceptance criteria unless the disposition has established alternate acceptance criteria.

Approval of the final disposition of the nonconformance report with supporting quality verification records shall be submitted to the client prior to or with shipment of the item.

16. CORRECTIVE ACTION

16.1. Purpose

To describe the measures to ensure that conditions adverse to quality are promptly identified and corrected.

16.2. Scope

This section applies to all conditions adverse to quality identified by EPM on work performed by EPM.

16.3. Requirements

During the course of EPM work, conditions adverse to quality shall be identified promptly and corrected as soon as practicable.

In the case of significant conditions adverse to quality, the cause of the condition shall be determined and corrective action taken to preclude recurrence. The identification, cause, and corrective action for significant conditions adverse to quality shall be documented and reported to the cognizant Division Director. Follow-up action shall be taken to verify implementation of corrective action.

16.4. Responsibilities

16.4.1. Quality Assurance Manager

The Quality Assurance Manager or his designee shall be responsible for issuing all Corrective Action Requests. The Quality Assurance Manager has the authority, where conditions warrant, to stop any work until conditions adverse to quality have been corrected. The Quality Assurance Manager maintains a Log for Corrective Action Requests.

16.4.2. Project Manager/Project Engineer

The Project Manager/Project Engineer shall be responsible for promptly initiating the required action to process Corrective Action Requests in a timely manner. When work has been stopped by the Quality Assurance Manager, the Project Manager/Project Engineer shall be responsible for correcting the identified problem and for stopping work until the Quality Assurance Manager rescinds the stop-work directive.

16.5. Corrective Action Process

During the course of EPM work, EPM shall take action to eliminate the cause of conditions adverse to quality and to prevent recurrence. Corrective action shall be taken on observed conditions adverse to quality and on noncompliances. The EPM Quality Procedure on corrective action shall define requirements for reviewing, determining the cause, evaluating the need for action to ensure that the reported adverse condition does not recur, determining and implementing action needed, and maintaining records of the results of corrective action taken. The EPM Quality Procedures shall address the method of reporting 10 CFR 50.55(e) [12] and 10 CFR Part 21 [7] defects and noncompliance.

For EPM work scopes, the following actions will be implemented to ensure that conditions adverse to quality are identified, corrected, verified, and documented:

(a) Any individual who suspects that an existing condition is adverse to EPM's established quality requirements shall notify the Quality Assurance Manager.

(b) The Quality Assurance Manager shall review suspect conditions adverse to quality and shall initiate a Corrective Action Request in accordance with Quality Procedure EPM-QP-16.0 [13] as warranted. Also, Quality Assurance personnel in the course of their audits shall initiate Corrective Action Requests as warranted. If the condition is severe, and if temporary measures cannot overcome the condition, the Quality Assurance Manager shall issue a written directive to stop work in the affected area. Directives to stop work shall include the Corrective Action Request.

(c) The Project Manager/Project Engineer receiving the Corrective Action Request shall promptly investigate the reported condition and take the necessary action to correct the situation and preclude recurrence. The Corrective Action Request form shall be utilized to indicate the corrective actions taken and the form shall be returned to the Quality Assurance Manager.

(d) The Quality Assurance Manager shall review the response and, as warranted, will verify the corrective actions taken prior to approving the closeout. Any disagreement in the method or implementation of required corrective actions will be referred to the cognizant Division Director or to the President of EPM for final decision.

16.6. Preventive Action Process

Reported Corrective Action Requests are reviewed by the Quality Assurance Manager for trends in EPM performance that may require preventive action to eliminate the cause of potential conditions adverse to quality. Preventive action is an inherent part of EPM's corrective action process to document:

(a) determining potential nonconformities and their causes
(b) evaluating the need for corrective action to prevent occurrence of nonconformities
(c) determining and implementing action needed
(d) reviewing results of action taken and approval.

16.7. Documentation

All completed Corrective Action Requests, upon receipt, verification, and acceptance by the Quality Assurance Manager, will be part of Quality Management Records.

17. QUALITY ASSURANCE RECORDS

17.1. Purpose

To describe the applied measures for ensuring that pertinent quality assurance records obtained by EPM, and those generated during the course of EPM activities, are reviewed, approved, classified, and stored in compliance with ASME NQA-1 requirements.

17.2. Scope

This section applies to all EPM-generated and EPM-obtained quality records for safety-related activities and/or items identified as "Lifetime (Permanent)" and "Nonpermanent" per ASME NQA-1.

17.3. Requirements

Records that furnish documentary evidence of quality shall be specified, prepared, and maintained. Records shall be legible, identifiable, and retrievable.

The control of quality records shall be consistently established with the schedule for accomplishing work activities. Quality records shall furnish documentary evidence that items or activities meet quality requirements.

Records shall be protected against damage, deterioration, or loss. Requirements and responsibilities for record identification, generation, authentication, transmittal, distribution, retention, maintenance, and disposition shall comply with EPM Quality Procedures.

17.4. Responsibilities

17.4.1. Project Manager/Project Engineer

The Project Manager/Project Engineer shall follow the established procedural requirements of EPM Quality Procedures for the identification, generation and processing of quality records.

17.4.2. Records Administrator

The Records Administrator shall be responsible for maintaining the EPM quality records in compliance with Quality Procedure requirements.

17.4.3. Quality Assurance Manager

The Quality Assurance Manager or his designee is responsible for ensuring that the records management system is maintained to the requirements of this program. The QA Manager is responsible for auditing the quality records management system.

17.5. Control of Quality Assurance Records

The term "quality records" used throughout the EPM Quality Management Manual and Quality Procedures is to be interpreted as "Quality Management Records."

Quality records are completed documents that furnish documentary evidence of the quality of the items, services, and/or activities affecting quality, and are objective evidence of compliance with applicable client and EPM Quality Procedure requirements. Quality records shall comply with Quality Procedure requirements for administration, identification, and classification as Permanent or Nonpermanent, legibility, collection, filing, and indexing per EPM Generic Q Project File Outline. In addition, storage, retention, retrieval, and disposition of quality assurance records shall comply with EPM Quality Procedure requirements.

Each project shall follow the EPM Generic Q Project File Outline, as established in EPM's Quality Procedures, for identification and classification of project quality records. Records administration shall be conducted in compliance with EPM Quality Procedure and client requirements.

The applicable Project Plans, procurement documents, or other documents shall specify the records to be generated, supplied to the client, or maintained by EPM. Documents that are designated quality records shall be legible, accurate, and completed appropriate to the work accomplished.

17.5.1. Classification of QA Records

Records shall be classified as lifetime (Q-Permanent) or nonpermanent (Q-Nonpermanent) as described in Quality Procedure EPM-QP-17.0 [14].

17.5.2. Dual Storage Facilities

Quality records are protected against deterioration, damage, and loss in accordance with EPM Quality Procedures, and duplicate copies are maintained at storage facilities that are remote from each other to eliminate the chance of exposure to a simultaneous hazard.

Records may be stored in either hard copy printed form or authenticated electronic copies where the content and context of the records are identical with comparable information to hard copies.

17.5.3. Record Validation

Documents shall be considered valid records only if stamped, initialed, or signed and dated by authorized personnel or otherwise authenticated. This authorization may take the form of a statement by the responsible individual or organization. Handwritten signatures are not required if the document is clearly identified as a statement by the reporting individual or organization.

17.5.4. Disposition of Quality Assurance Records

Records classified as "Q-Permanent" or "Q-Nonpermanent" may be transferred to the client upon completion of the project when client requirements are satisfied. The transfer shall be by client's consent and properly documented. When permanent records are not transferred to the client at the completion of the project, lifetime records shall be maintained by EPM for the Plant Owner for the life of any particular item while it is installed in the plant or stored for future use.

18. AUDITS

18.1. Purpose

To establish the requirements for the planning, scheduling, and conducting of audits to verify compliance with all aspects of the EPM Quality Management Program and to determine its effectiveness.

18.2. Scope

This section applies to internal and external audits.

18.3. Requirements

Planned and scheduled audits shall be performed to verify compliance with all aspects of the EPM Quality Management Program and to determine its effectiveness. EPM audits shall be performed in accordance with written procedures or checklists by personnel who do not have direct responsibility for performing the activities being audited.

Audit results shall be documented and reported to the President, the cognizant Division Director, and the Project Manager/Project Engineer. Follow-up action shall be taken where indicated.

18.4. Responsibilities

18.4.1. President

The President of EPM is responsible for annual evaluation of EPM's Quality Management Program to determine its effectiveness.

18.4.2. Quality Assurance Manager

The Quality Assurance Manager is responsible for planning, conducting, and documenting internal audits. He is responsible for establishing a qualification program for Lead Auditors. The qualification program shall be in accordance with ASME NQA-1, Requirement 2, Section 303.

18.4.3. Division Directors/Project Managers

The cognizant Division Director/Project Manager is responsible for responding to audit findings within 30 days of issue of the audit report or the Corrective Action Request.

18.5. Audit Process

The major elements of the audit process are:

18.5.1. Planning and Scheduling

18.5.1.1. Internal Audits

EPM internal audits shall be planned and scheduled to verify compliance with all aspects of the Quality Management Program and to determine its effectiveness.

All aspects of the EPM Quality Management Program shall be audited annually to provide coverage and coordination with ongoing quality program activities.

The Lead Auditor shall prepare an audit plan for each audit. The plan shall identify the audit scope, requirements, audit personnel, activities to be audited, organization(s) to be notified, applicable documents, schedule, and written checklists or procedure.

Audit personnel shall have sufficient authority and organizational freedom to make the audit process meaningful and effective.

18.5.1.2. External Audits

EPM may procure safety-related items or services for nuclear power plants. If the client requests or the project requires such an item or service, then EPM will schedule external audits at a frequency commensurate with the status and importance of the activity.

External audits, after the award of contract, are not necessary for procurement actions when the purchased items or services are:

(a) Relatively simple and of standard design, manufacture, and test;

(b) Adaptable to receiving inspection or test to verify quality after delivery to EPM; and

(c) Such that receiving inspection does not require operations that could adversely affect the integrity or cleanliness of the item.

18.5.1.3. Supplemental Audits

Regularly scheduled internal and external audits shall be supplemented by audits for one or more of the following conditions:

(a) When significant changes are made in functional areas of the Quality Management Program such as significant reorganization or procedure revisions.

(b) When it is suspected that the quality of the item is in jeopardy due to deficiencies in the Quality Management Program.

(c) When a systematic, independent assessment of program effectiveness is considered necessary.

(d) When necessary, to verify implementation of required corrective action.

18.5.2. Preparation for Auditing

The Quality Assurance Manager will select qualified personnel who do not have direct responsibility for performing the activities being audited, for audit assignments. Pertinent information, including policies, procedures, client purchase order requirements and prior audit reports, should be made available for review by the auditors for preparation of audit checklists. For internal audits, the cognizant Project Manager and Project Engineer should be notified of the upcoming audit, except for unannounced audits. For external audits, the cognizant QA Manager shall be notified of the upcoming audit.

18.5.3. Performance

A pre-audit conference should be conducted with the Project Manager/Project Engineer for internal audits or the cognizant QA Manager for external audits to confirm the audit scope per an agreed-to agenda as given below:

(a) Review of procedures and work instructions for completeness and adequacy.

(b) Examination in work areas for evidence of implementation of procedures and instructions.

(c) Examination of personnel training and qualification records.

(d) Examination of selected work that has been completed for conformance with client contractual/procurement requirements.

(e) Examination of administrative controls and prepared records to determine conformance with project requirements.

A post-audit conference should be held by the audit team with the audited personnel to present audit results and clarify misunderstandings.

Conditions requiring prompt corrective action shall be reported immediately to management of the audited organization.

18.5.4. Reporting

The audit report, per EPM Quality Procedures, shall be submitted within 30 days.

The audited Project Manager/Project Engineer and/or the cognizant QA Manager should respond to the reported Corrective Action Request stating the corrective action to prevent recurrence. In the event that corrective action cannot be taken immediately, the auditee's response should include a scheduled date for completion of the identified corrective action.

Follow-up action shall be taken to verify whether the required corrective action is accomplished as scheduled.

18.6. Records

Audit records shall include audit plans, audit reports, written replies, and the record of completion of corrective action.

19. PART 21 REPORTING

19.1. Purpose

To describe Part 21 to Title 10 of the Code of Federal Regulations reporting requirements.

19.2. Scope

This section applies to all safety-related EPM-procured items or EPM-provided services and all Augmented Quality activities and/or items if specified as applicable by the client/utility.

19.3. Requirements

As contained in the Notice of Reporting of Defects and Noncompliance and Part 21 to Title 10 of the Code of Federal Regulations, the Nuclear Regulatory Commission shall be made aware of all defects or nonconformances that may result in substantial safety hazards.

The Notice of Reporting of Defects and Noncompliance shall be posted.

19.4. Responsibilities

19.4.1. EPM Employees

Any EPM employee, upon observation of a defect that could create a substantial safety hazard, shall report it immediately to the EPM Project Manager/Project Engineer or directly to the NRC.

19.4.2. EPM Project Manager/Project Engineer

The EPM Project Manager/Project Engineer shall evaluate the reported condition without delay to determine if the condition is a potential reportable defect or a nonconformance and report it to the Division Director and to the President of EPM.

19.4.3. President

The President of EPM, in consultation with the Quality Assurance Manager, shall promptly and formally report to the client any condition adjudged to be a Part 21 reportable item or condition. Upon discussion with the client, if it is determined that said condition is indeed a Part 21 reportable item or condition, the President shall notify the Commission within two days.

19.5. Part 21 Reporting Procedure

Each EPM employee, upon observation of a defect that could create a substantial safety hazard, shall report it immediately to the EPM Project Manager/Project Engineer or directly to the NRC. The reporting could be verbal/phone followed by an office memorandum.

The Project Manager/Project Engineer shall evaluate the reported condition without delay to determine if the condition is a potential reportable defect or nonconformance that could create a substantial safety hazard. Upon this determination, he will report it to the cognizant Division Director and to the President of EPM.

The President, in consultation with the Quality Assurance Manager, shall promptly notify the client of any defect or nonconformance that could create a substantial safety hazard. Upon discussion with the client, the President shall notify the Commission within two days. Initial notification by facsimile, which is the preferred method of notification, shall be made to the NRC Operations Center at (301) 816-5151, or by telephone at (301) 816-5100 within two days following receipt of information by the EPM President or designee.

19.6. Formal Report

Within five days of the initial notification, the President shall prepare a formal report to the client and to the Commission that will address the following as applicable:

(a) Description of the defect or nonconformance

(b) System, structure or component affected

(c) Cause of defect or nonconformance

(d) Date of observation and notification.

19.7. Interfaces

Correspondence, discussions, and meetings among EPM, the client, and the Commission concerning the Part 21 reportable item shall be documented and filed in the Project QA Records.

ATTACHMENT B – COMPLIANCE WITH ISO 9001:2015

1. SCOPE

Attachment B to this Quality Management Manual (QMM) describes the Quality Management Program applicable to Engineering Planning and Management, Inc. (EPM) projects performed in accordance with ISO 9001:2015 and processes relied upon to support those projects. Projects in support of nuclear production and utilization facilities shall also be performed in accordance with the EPM Q Management Program.

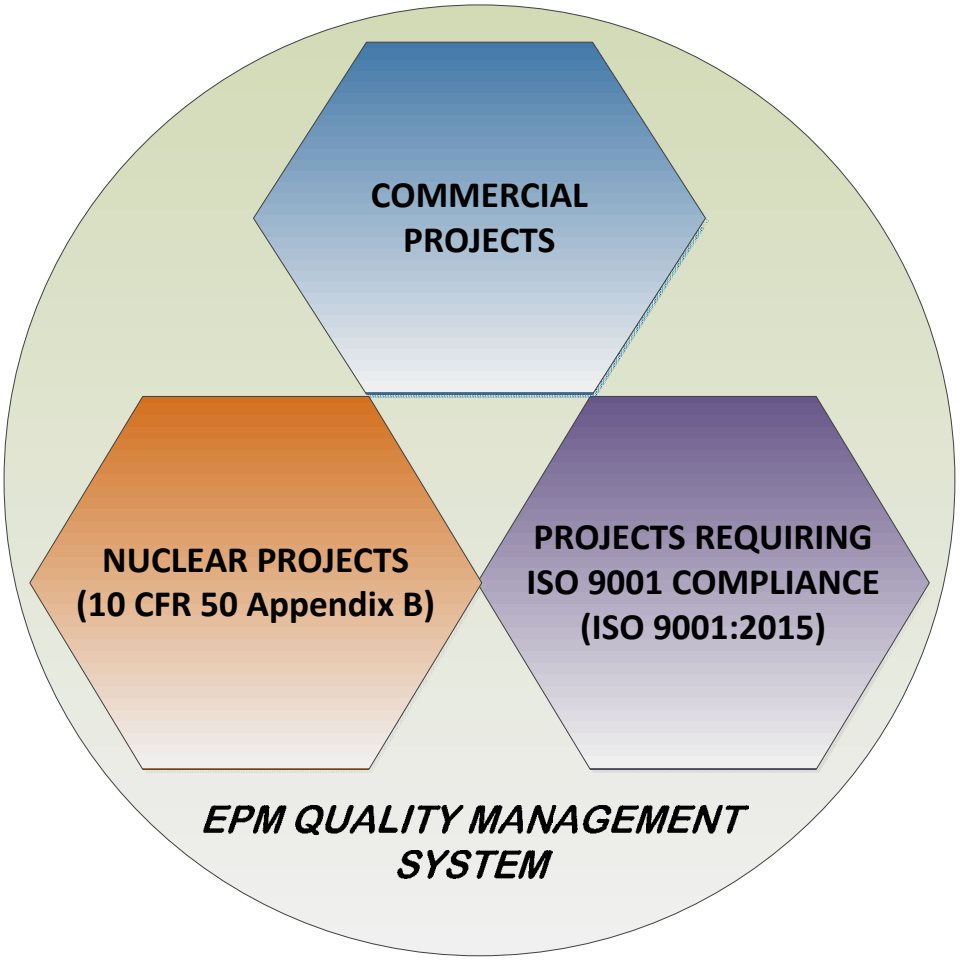


Figure B1.1 – Quality Management System Application

2. REFERENCES

This QMM is based on ISO 9001:2015. The following records were also used in the development of this Quality Management Program:

- 10 CFR 50 Appendix B, “Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants”
- ASME NQA-1-2008 [15], “Quality Assurance Requirements for Nuclear Facility Applications”
- ASME NQA-1a-2009 [16], “Addenda to ASME NQA-1-2008 Quality Assurance Requirements for Nuclear Facility Applications"
- ASME NQA-1-2022, “Quality Assurance Requirements for Nuclear Facility Applications”
- U.S. Nuclear Regulatory Commission Regulatory Guide 1.28, “Quality Assurance Program Criteria (Design and Construction)”, Revision 6, September 2023
- U.S. Nuclear Regulatory Commission Regulatory Guide 1.33, “Quality Assurance Program Requirements (Operation)”, Revision 3 June 2013
- EPM Quality Assurance Procedures dated prior to December 31, 2023

3. TERMS AND DEFINITIONS

In addition to the definitions provided in Attachment C of this Manual, the following definitions are provided:

3.1. Tender

Proposal or quotation for services or products.

3.2. DMAIC Process[2]

- **Define** the problem, improvement activity, opportunity for improvement, the project goals, and customer (internal and external) requirements
- **Measure** process performance
- **Analyze** the process to determine root causes of variation, poor performance (defects)
- **Improve** process performance by addressing and eliminating the root causes
- **Control** the improved process and future process performance

[2] Excerpted from The Certified Quality Engineer Handbook, Third Edition, ed. Connie M. Borror, ASQ Quality Press, 2009, pp. 321–332.

4. ORGANIZATION

See Figure A1.1

Figure B4.1 - EPM Offices

4.1. Understanding the Organization and Its Context

EPM is a leading provider of fire protection, risk analysis, risk management, engineering solutions, and software to nuclear utility customers throughout the world. EPM also provides services in commercial fire protection and chemical process safety. EPM has delivered high-quality, cost-effective solutions to assist our customers addressing complex regulatory compliance and to improve and reduce the risk at their nuclear power plants for the past 40 years.

EPM provides a full spectrum of services in support of utility engineering programs and offer state of the art software tools for performing Automated Safe Shutdown Analysis, Cable and Raceway Management, Cable Aging Management and Environmental Qualification Analysis. EPM's team of Engineering, PRA, and Information Technology personnel have developed innovative methods to achieve practical, comprehensive, and cost-effective solutions using a combination of creative strategies, time-tested engineering methods, and an experienced staff.

EPM is owned by the ONET Groupe (ONET). ONET, with home offices in Marseilles, France, is an international engineering and services group. ONET's diversified offerings extend to 10 countries and is based on the expertise of 66,000 employees found within the six brands, which includes ONET Technologies, a leading provider of creative solution to its French and international customers throughout the entire life cycle of their industrial installations, supporting them in meeting their objectives in terms of safety, performance, and competitiveness.

EPM is organized into the following Divisions (see Figure A1.1) including two technical Divisions:

- Engineering and Software Services (ESS) Division
- Fire Protection and Risk Services (FPRS) Division

These Divisions are supported by the Administration Division comprised of:

- Accounting
- Information Technology (IT)
- Human resources (HR)
- Records Administration

Independent of these Divisions is Quality Assurance.

EPM has three offices and occasionally places personnel at customer facilities.

EPM's strategic direction is established by the EPM Board of Directors which includes representatives of ONET, EPM, and the nuclear industry. The Board of Directors meets quarterly.

4.2. Understanding the Needs and Expectations of Interested Parties

4.2.1. Interested Parties

Parties interested in EPM include:

- Customers
- Commercial partners including contracted agents
- Electric utilities worldwide
- Nuclear facilities
- Industry organizations such as NEI, ANS, ASME, IEEE, ANSI, CSA, COG, and NFPA
- Federal and state regulators
- Employees
- ONET

Note: This list may change depending on future diversification of EPM services or products.

4.2.2. Needs and Expectations

An analysis of the needs and expectations of parties interested in EPM reveals the following main areas:

- Technical abilities
- Compliance with and knowledge of code, standards, and regulations
- Worker health and safety

- Personal relationships
- Communication
- Financial

Stakeholder requirements are defined and taken into account through defined procedures and documentation. Any specific request from an external interested party is recorded and processed. (For requests in the form of a tender see Quality Procedure EPM-QP-4.1 [17].)

4.3. Determining the Scope of the Quality Management Program

The EPM Quality Management (QM) Program is applicable to EPM and its subcontractors for all projects required to be in conformance with ISO 9001.

EPM's activities include services to the commercial and nuclear industries in the areas of:

- Fire protection
- Chemical process safety
- Systems analysis
- Risk assessment
- Software
- Licensing support

EPM's products include:

- Design
- Analyses
- Calculations
- Software
- Oversight/reviews
- Inspections/audits
- Consultation
- Training

EPM rarely supplies a physical product and does not perform special processes such as welding, inspections, calibrations, etc. EPM may subcontract for analytical services but will rarely purchase, inspect, or store products for customers.

Based on the above, all major sections of ISO 9001:2015 have some applicability to EPM however some subsections, those related to "products" for example, may not be applicable.

4.4. Quality Management Program and its Processes

EPM's QM Program relies on:

- This QMM to define the QM Program goals, organization, and structure
- Procedures listed in this document and elsewhere
- Various administrative systems (e.g., the FAN System, contract review system)

See Figure B4.2 below.

5. LEADERSHIP

5.1. Leadership and Commitment

5.1.1. General

The leadership and commitment of EPM's management is documented in the Statement of Policy presented at the beginning of this Manual. It is the responsibility of management to ensure that statutory and regulatory requirements applicable to EPM's product and to customer satisfaction are met while assessing risk and opportunities.

5.1.2. Customer Focus

Customer and applicable statutory and regulatory requirements are determined and taken into account. For example, Quality Procedure EPM-QP-4.1 [17] provides a structured evaluation of customer specification and contractual requirements as well as the risks and opportunities that can affect conformity of products and services and the ability to enhance customer satisfaction. Statutory and regulatory requirements may also be reflected in records such as the Project Plan, project procedures, schedule, referenced codes and standards, etc.

Project risk analyses are carried out before project implementation and monitored and updated as necessary throughout project implementation. Risk analyses are described in Quality Procedures EPM-QP-1.7 [18], "Risk Management" and EPM-QP-4.2 [19], "Project Risk Management".

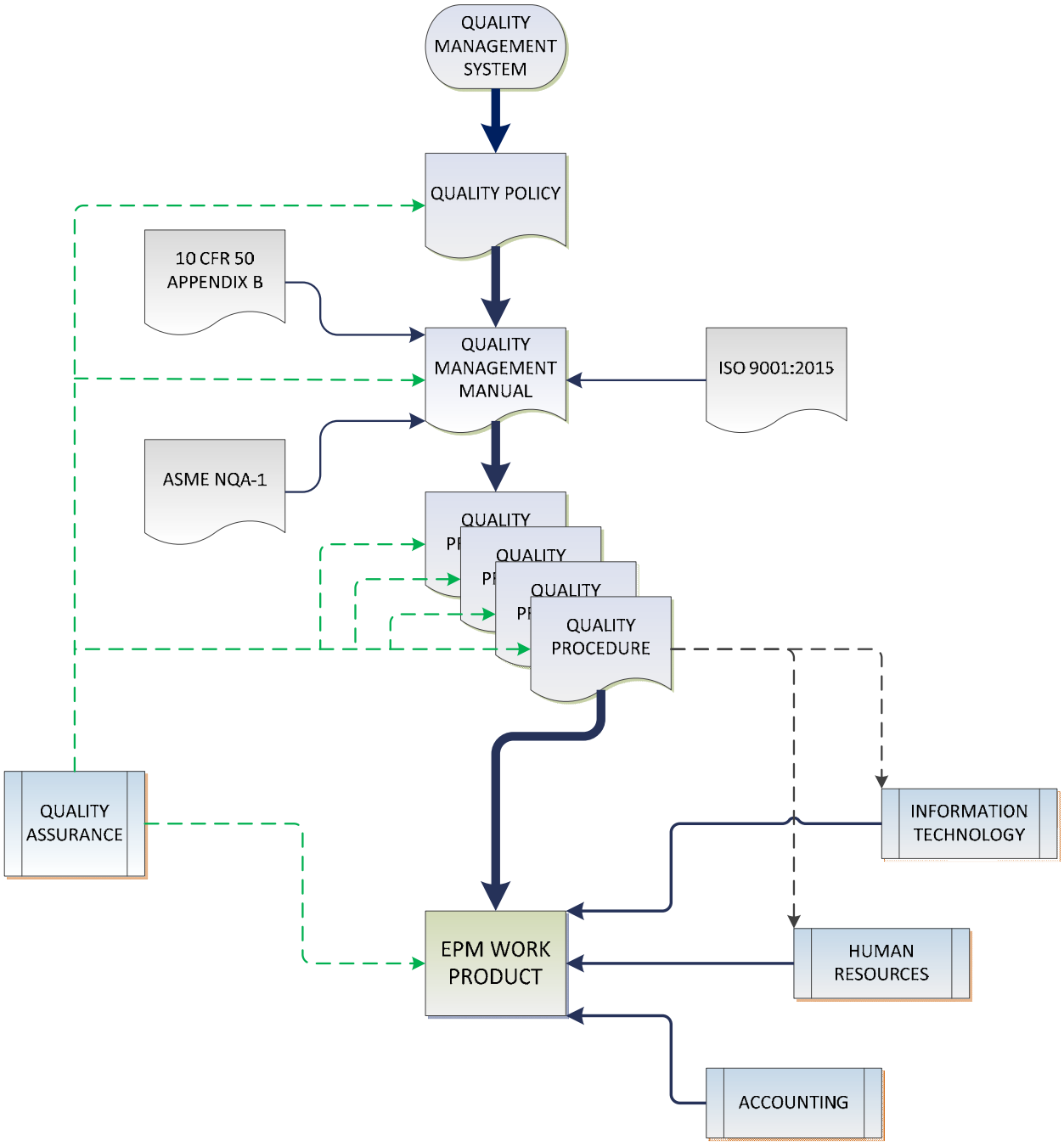


Figure B4.2 – Quality Management System Structure

To maintain focus on increasing customer satisfaction, performance indicators are monitored and actions implemented with the goals of anticipation, adaptation, and improvement.

Verification that customer specification and contractual requirements have been addressed is accomplished through the use of Quality Procedure EPM-QP-4.1 as well as during the performance of internal project audits (see Quality Procedure EPM-QP-18.0 [20]) and with the review of the Project Plan document and use of the Project Closing Form (see Quality Procedure EPM-QP-1.1 [6]).

5.2. Policy

5.2.1. Establishing the Quality Policy

The Quality Policy and the associated objectives are defined each year at the time of the Management Review and in the determination of the annual strategic objectives. The annual Management Review is used to provide continual improvement to the Quality Management Program.

5.2.2. Communicating the Quality Policy

The Quality Policy is published on EPM's Employee Intranet Site and is available to all employees. The Quality Policy is also available to interested external parties through a link provided on the EPM website.

5.3. Organizational Roles, Responsibilities and Authorities

5.3.1. President of EPM

The President of EPM is responsible for the Quality Management Program as a whole.

5.3.2. Administration

5.3.2.1. Director of Administration

The Director of Administration is responsible for the implementation of the Quality Management Program in the Accounting, Human Resources, Information Technology (IT), and Records Administration.

5.3.2.2. Manager, Human Resources

The responsibilities of the Manager, Human Resources are detailed in Quality Procedure EPM-QP-1.8 [21], "Human Resources".

5.3.2.3. Manager, IT

The responsibilities of the Manager, IT are detailed in Quality Procedure EPM-QP-1.9 [22], "Information Technology".

5.3.2.4. Records Administrator

The responsibilities of the Records Administrator are detailed in Quality Procedures EPM-QP-17.0 [14], "Quality Assurance Records", Quality Procedures EPM-QP-17.1 [23], "Records Management Document Retention System", and Quality Procedures EPM-QP-17.2 [24], "Changes to FAN Records". (Also see Attachment A, Section 17.4.2.)

5.3.3. Division Directors

The Division Directors are responsible for the implementation of the Quality Management Program for their Division and in accordance with Division specific procedures and processes. In particular, Division Directors:

- Promote the goal of customer focus throughout the Division and company
- Ensure and/or verify compliance with Quality Management Program requirements
- Ensure that processes deliver expected results
- Report to the President annually on the performance of the Quality Management Program and identify opportunities for improvement (see Quality Procedure EPM-QP-1.5 [25])
- Follow-up regarding customer satisfaction and complaints
- Ensure that the integrity of the Quality Management Program is maintained when changes to the Program are planned and implemented

5.3.4. Quality Assurance Manager

The Manager of Quality Assurance (QA Manager) is responsible for establishing and administering the EPM Quality Management Program. He is responsible for assuring the adequacy of the Program and verifying that activities affecting quality have been correctly performed and that changes to the Program are planned, implemented, and effective.

6. PLANNING

6.1. Actions to Address Risks and Opportunities

This Quality Management Program addresses risks and opportunities taking into account the requirements of stakeholders and the goal of continuous improvement in proportion to the potential impact on the Program to provide assurance that the Program can achieve the expected results, prevent or reduce risk, and improve and increase desired effects.

This is accomplished through:

- Management attention
- Documented processes
- Operational awareness at the project level

See Quality Procedure EPM-QP-1.7, “Risk Management” [18].

Annual progress plans are prepared by each Division and group which include actions to be taken in response to the risks and opportunities identified in the previous year’s annual Division assessment. (See §5.3 above.)

6.2. Quality Objectives and Planning To Achieve Them

Annual quality objectives are defined following the Management Review (see §9.3 below) and are promulgated as is the Quality Policy document issued annually. (See §5.2 above.)

Division progress plans include actions to be taken following the definition of the annual quality objectives for the current year.

Quality objectives shall be:

- Consistent with the Quality Policy
- Measurable
- Relevant to the goal of increased customer satisfaction
- Monitored
- Communicated
- Updated as appropriate

When planning how to achieve the quality objectives, the following shall be documented:

- What will be done
- What resources will be required
- Who will be responsible
- What is the schedule
- How will the results be evaluated

6.3. Planning Of Changes

Changes to the Quality Management Program are planned and completed based on the annual quality objectives following a risk and opportunity analysis.

The following list of Quality Management Program related records has been put in place to describe and control the Program. These records are updated as necessary however, unless otherwise specified, these records will be reviewed at a frequency not exceeding annually to verify continued effectiveness and efficiency.

- Quality Policy
- Quality Management Manual
- Quality Procedures

7. SUPPORT

7.1. Resources

7.1.1. General

Resources are managed through the Division Directors and the Human Resources Department (HR).

7.1.2. People

See § 5.3 above.

7.1.3. Infrastructure

Most EPM employees work in one of EPM's three offices. Employees occasionally work at a customer's site.

7.1.3.1. Customer Site

In general, the needs of an EPM employee working at a customer's facility are the responsibility of the customer. Particular needs of EPM personnel working at a customer's facility are negotiated with the customer at the

time of contract award and may be supplied by EPM. This includes such things as computers, cameras, safety equipment, etc.

EPM employees working at the customer's facility shall verify access to critical records or software available only on EPM's network and not available on the customer's network. The records may include procedures, forms, etc. required by EPM's Quality Management Program.

7.1.3.2. EPM Office

EPM offices are leased spaces. These spaces are climate controlled providing a comfortable working environment.

EPM personnel are provided with an office or cubicle, computer, software, phone, etc. necessary to work efficiently and effectively. (See EPM Policies and Procedures Section 5 as well as Quality Procedures EPM-QP-1.8 [21] and EPM-QP-1.9 [22].)

7.1.4. Environment for the Operation of Processes

7.1.4.1. Record Retention Locations

EPM maintains important technical records and software records in redundant, physically separate locations. (See Quality Procedure EPM-QP-17.0 [14].)

Records are stored electronically on computer servers maintained in the Framingham and Raleigh EPM offices. The servers in the Framingham and Raleigh offices are in a climate-controlled area as discussed below.

Physical records consisting of CDs, DVDs, and computer tapes, are maintained in Framingham and Raleigh in the same area as the computer servers.

7.1.4.2. Computer Servers

In EPM's Framingham and Raleigh offices, computer servers are located in an access controlled rooms with a dedicated environmental control system. (See Quality Procedure EPM-QP-1.9.) The server rooms also function as one of the redundant locations for physical records.

The environment in these server rooms is constantly monitored and alarmed to EPM's Information Technology Department if the environment exceeds preset values.

7.1.5. Monitoring and Measuring Resources

Monitoring and measuring equipment may be used by EPM's FPRS Division. Valid and reliable results when using the monitoring and measuring equipment will be ensured by an EPM Division Procedure.

7.1.6. Organizational Knowledge

Organizational awareness includes knowledge specific to EPM gained through experience and shared inside EPM to achieve conformity of products and services.

Organizational knowledge begins at hiring with required training in EPM's Quality Management Program. (See Quality Procedure EPM-QP-2.2 [26].) EPM's Training Matrix provides guidelines regarding technical training for new hires. The Training Matrix is periodically updated as new training resources are identified. (See Quality Procedure EPM-QP-1.8.)

Daily EPM engineers are provided with industry information. Lunch time seminars regarding technical and administrative issues are held periodically to allow subject matter experts to share knowledge and experience. Participation in professional organizations is encouraged and subsidized. (See EPM Policies and Procedures Section 4.)

Certain specific technical methodologies are contained and controlled in Division Procedures. The Division Procedures are updated as necessary as methodologies, standards, or regulations change. Training and qualification on Division Procedures is documented. Division Procedures are available on EPM's Employee Intranet Site. (See Quality Procedure EPM-QP-1.4 [27].)

7.2. Competence

Upon hire, the EPM HR Department:

- Collects and maintains a personal resume
- Verifies previous employment
- Performs background check (see EPM Policies and Procedures Section 5)

As part of the review of experience and in questioning during the interview process, skills are evaluated. Upon hire, the Training Matrix is used to develop an individual training syllabus. (See §7.1.6 above.)

Training on Division Procedures is documented. (See Quality Procedure EPM-QP-1.4.) Periodic specialized training is performed and documented.

The Project Manager is responsible for assessing project needs and ensuring personnel assigned to the project have the appropriate knowledge, training, certification, etc. required by the work and the contract. (See Quality Procedure EPM-QP-1.1, §5.5.2.) EPM's Skills Matrix is available to Project Managers and Division Directors in selecting the appropriate personnel for a task. (See Quality Procedure EPM-QP-1.8.)

At times it may be necessary to employ subcontractors when EPM personnel do not have the requisite skill, experience, certification, etc. The Project Manager is responsible for identifying the need to employ subcontractors.

7.3. Awareness

At the time of hiring, all technical employees are provided with Quality Indoctrination Training (see Quality Procedure EPM-QP-2.2). This training includes:

- The Quality Policy
- Relevant quality objectives
- The impact of actions on the effectiveness of quality and the benefits of improved performance
- The implications of not conforming to Quality Management Program requirements
- Actions to be taken if technical/regulatory requirements or quality goals are not being met

When available, the quality policy and quality objectives of customers are also available to EPM personnel.

7.4. Communication

Internal communication relevant to the Quality Management Program by EPM management and the QA Manager is accomplished by:

- Maintaining the Quality Policy and quality objectives on the EPM's Employee Intranet Site
- Indoctrination training for all employees

- Periodic emails to all employees regarding quality, quality initiatives, quality failures, etc.
- Periodic meetings for all employees where quality performance is stressed
- Periodic targeted emails concerning quality challenges or weaknesses

External communication includes the project end customer satisfaction questionnaire used to gather the opinions of customers regarding the services provided by EPM. Analysis of the results of this questionnaire allows for measurement of overall satisfaction, for the identification of strengths and weaknesses in EPM's performance, and for development of improvements in the Quality Management Program. (See Quality Procedure EPM-QP-4.1.)

The provisions for dealing with customer complaints are defined in § 10.2 below.

7.5. Documented Information

7.5.1. General

Quality Management Program records are controlled and disseminated by the EPM QA Manager. Implementing procedures are controlled and disseminated by the Division or group responsible for the action(s) described in the procedure.

7.5.2. Creating and Updating

All records identified in this manual associated with the Quality Management Program are created under the guidance and/or approval of the QA Manager. Each record is uniquely identified and revisions are controlled. The format, available media, and review and approval of the records are procedurally controlled.

7.5.3. Control of Documented Information

Records required by the Quality Management Program are controlled by a number of procedures as shown in the Figure B7.1.

PROCEDURE	Quality Management Manual	Quality Management Procedures	Division Procedures	Project Procedures
EPM-QP-1.0 – Preparation, Issuance, and Control of Quality System Documents	X	X		
EPM-QP-1.3 – Preparation, Issuance, and Control of Project Procedures				X
EPM-QP-1.4 – Preparation, Issuance, and Control of Division Procedures			X	
EPM-QP-2.0 – Control of Quality Management Manual	X			
EPM-QP-2.1 – Control of QA Program Documents and Procedures	X	X		
EPM-QP-3.8 – Computer Media Library	X	X		
EPM-QP-17.0 – Quality Assurance Records	X	X	X	X

Figure B7.1 – Control of Quality Documents

7.5.4. Procedures

For quality records, the controlling procedures address the following:

- Distribution, access, retrieval, and use
- Storage and preservation
- Control of changes
- Retention

If external documentation is defined as necessary for the planning and operation of the Quality Management Program, the information will be identified as such

and maintained in EPM's document retention (FAN) system. (See Quality Procedure EPM-QP-17.1 [23].)

8. OPERATION

8.1. Operational Planning and Control

As described herein and in referenced documents, the Quality Management Program provides for the planning, implementation, and control of processes (see §4.4 above) necessary to provide products and services by:

- Determining the requirements for the products and services
- Establishing criteria for:
  - The processes
  - The acceptance of products and services
  - Actions to address risks and opportunities
  - Control of outsourced products and services
- Determining the resources needed to achieve conformity to the requirements of the products and services
- Implementing control of the processes in accordance with criteria
- Determining, maintaining, and retaining documentation to the extent necessary
  - To have confidence that the processes have been carried out as planned
  - To demonstrate conformity of products and services to their requirements

The Quality Management Program provides for the control of planned changes, for the review of the consequences of unintended changes, and for the actions required to mitigate any adverse impacts, as necessary.

8.2. Requirements for Products and Services

8.2.1. Customer Communication

As part of the standard project lifecycle, EPM's communication with customers can take several forms including:

- Marketing meetings to present products and services
- Communication during the request for tender (RFT) or tender process including pre-bid meetings and questions and clarifications required on the RFT or tender
- Contract acceptance or negotiation including contract changes

- Identification of the preferred mechanisms for communication and identification of stakeholders during the performance phase of the project
- Periodic meetings either contractually established or on an as needed basis
- Access to and control of customer property, e.g., design information
- Periodic progress reports, including technical and monetary status, as directed by the customer
- Identification and resolution of open items
- Presentation of project results and training of customer personnel
- Audits by the customer or customer representatives
- Obtaining customer feedback, including customer complaints
- Establishing specific requirements for contingency actions, if relevant

8.2.2. Determining the Requirements for Products and Services

EPM's process for proposal preparation, verification, contract review, and contract approval are described in Quality Procedure EPM-QP-4.1 [17]. This process includes the definition of the product or service including any applicable statutory, regulatory, or customer requirement.

8.2.2.1. Proposal Preparation

EPM's Marketing Database is used to track opportunities from initial identification through contract award. This database is available to EPM employees who are encouraged to maintain it up to date on a weekly basis.

Receipt of a RFT is communicated to EPM management including the President and the Division Directors. Depending on the scope and technical requirements, a person or team is assigned the responsibility by a Division Director to assess and, if decided, prepare a bid package in response to the tender.

The bid team determines whether:

- The RFT adequately and clearly establishes the customer's needs
- Regulatory requirements, both technical and quality, have been clearly defined
- EPM has the means internally to meet the requirements of the tender or needs additional resources

Based on input from the bid team, EPM management directs the preparation of a tender. The Marketing Database is updated and generates a tender number.

During the preparation of the proposal, the bid team completes the appropriate portions of the Tender Checklist (see Quality Procedure EPM-QP-4.1).

The proposal is reviewed by the President prior to issuance.

Revisions to tender documents receive the same review as the original proposal.

8.2.2.2. Contract Review

Upon receipt of a contract, after preliminary review by the Project Manager to identify any obvious concerns, the Project Manager completes a Project Number Request Form and submits it to the Accounting Department. This form identifies the quality requirements imposed by the contract or imposed by the Quality Management Program (see Quality Procedure EPM-QP-4.1).

8.2.3. Review of the Requirements for Products and Services

Upon receipt of the project number, the contract is entered into EPM's contract review software and is reviewed by Accounting and the technical Division Director prior to acknowledging acceptance of the contract to the customer. Depending on the complexity of the contract, the opinion of a legal expert may be requested.

Any identified concerns regarding the contents of the contract are resolved prior to accepting and returning the contract to the customer. Negotiations regarding contract requirements or content are carried out by the Accounting and the assigned Project Manager as required.

Documentation of the review and acceptance of the contract is retained in the FAN System.

8.2.4. Changes to Requirements for Products and Services

Revisions to contracts are processed in the same manner as the original contract. Revisions to contracts must be in writing from the appropriate person or department of the customer.

8.3. Design and Development of Products and Services

8.3.1. General

EPM maintains the processes necessary to ensure the quality of products and services. For engineering services see Quality Procedure EPM-QP-3.0 [28] Exhibit 3.0-1.

EPM provides engineering services and software. Controls for engineering services are contained in a number of procedures including EPM-QP-3.0 [28], "Design Control", QP-3.1 [29], "Design Change Control", and EPM-QP-3.2 [30], "Drawing Control".

Controls for the development and control of software are found primarily in the following procedures:

- EPM-QP-3.3 [31], "Software Quality Assurance Plan"
- EPM-QP-3.4 [32], "Software Requirements Specification"
- EPM-QP-3.5 [33], "Software Design Description"
- EPM-QP-3.6 [34], "Software Verification and Validation"
- EPM-QP-3.7 [35], "Software Configuration Management"
- EPM-QP-3.8 [36], "Computer Media Library"

8.3.2. Design and Development Planning

For each project, EPM develops a Project Plan (see Quality Procedure EPM-QP-1.1 [6]). As appropriate, the Project Plan establishes and records the:

- Quality requirements
- Customer contact and contract number
- EPM Project Manager
- Specific scope including requirements regarding applicable procedures, training, and other contract requirements
- Design input description, location, and method to obtain, if applicable (e.g., walk down, drawings, etc.)
- Technical approach
- Required external resources, e.g., specific software
- Special verification or validation requirements
- Required deliverables
- Communication methods

- Schedule

8.3.3. Design and Development Inputs

Requirements essential to products and services are documented by EPM as necessary:

- For the initial development of software, EPM prepares a Software Requirements Specification.
- Critical requirements essential to engineering services are discussed in Quality Procedure EPM-QP-3.0 and if necessary documented in the Project Plan.

The Software Requirements Specification and the Project Plan are retained in the FAN System.

As applicable, the Software Requirements Specification and the Project Plan contain:

- Project goals
- Description of the work to be performed
- Functional and performance requirements
- Information derived from previous similar efforts
- Statutory and regulatory requirements, standards, and codes
- Applicable Division and project specific (incl. customer) procedures

Technical design inputs such as drawings, specifications, etc. are controlled and maintained in EPM's FAN System in accordance with Quality Procedure EPM-QP-17.0 [14].

8.3.4. Design and Development Controls

Engineering services are controlled though a series of procedures including:

- EPM-QP-3.0, "Design Control"
- EPM-QP-3.1, "Design Change Control"
- EPM-QP-3.2, "Drawing Control"
- EPM-QP-16.1 [37], "Open Item Tracking"
- EPM-QP-17.0, "Quality Assurance Records"

Development of software is controlled using the procedures listed in §8.3.1 above and Quality Procedure EPM-QP-16.1 and EPM-QP-17.0.

The procedures discussed above include the requirements for review of engineering services and software verification and validation. Review and verification and validation activities are performed by qualified personnel who are different from the preparers of the work being reviewed (see Quality Procedure EPM-QP-3.0, §2.3).

Documentation of the review or verification and validation effort is controlled and maintained in EPM's FAN System in accordance with Quality Procedure EPM-QP-17.0.

8.3.5. Design and Development Outputs

Project outputs can be either interim, draft, or final. Final outputs are approved by the Project Manager (see Quality Procedure EPM-QP-3.0, §2.3 and §2.6) who verifies that the work:

- Complies with contractual requirements
- Has been prepared and reviewed or verified and validated properly by qualified personnel
- Is complete and suitable to send to the customer

Record of outputs is controlled and maintained in EPM's FAN System in accordance with Quality Procedure EPM-QP-17.0.

8.3.6. Design and Development Changes

Changes required to products or services during or subsequent to the initial effort are incorporated using generally the same controls as the initial effort.

Design changes are evaluated by the Project Manager for impact including whether the contract needs to be amended. Design changes are addressed in accordance with Quality Procedure EPM-QP-3.1.

Changes to developed software are addressed in accordance with Quality Procedure EPM-QP-3.7.

8.3.7. In-Process Reviews

Figure B8.1 shows the various stages of review performed during a typical engineering project.

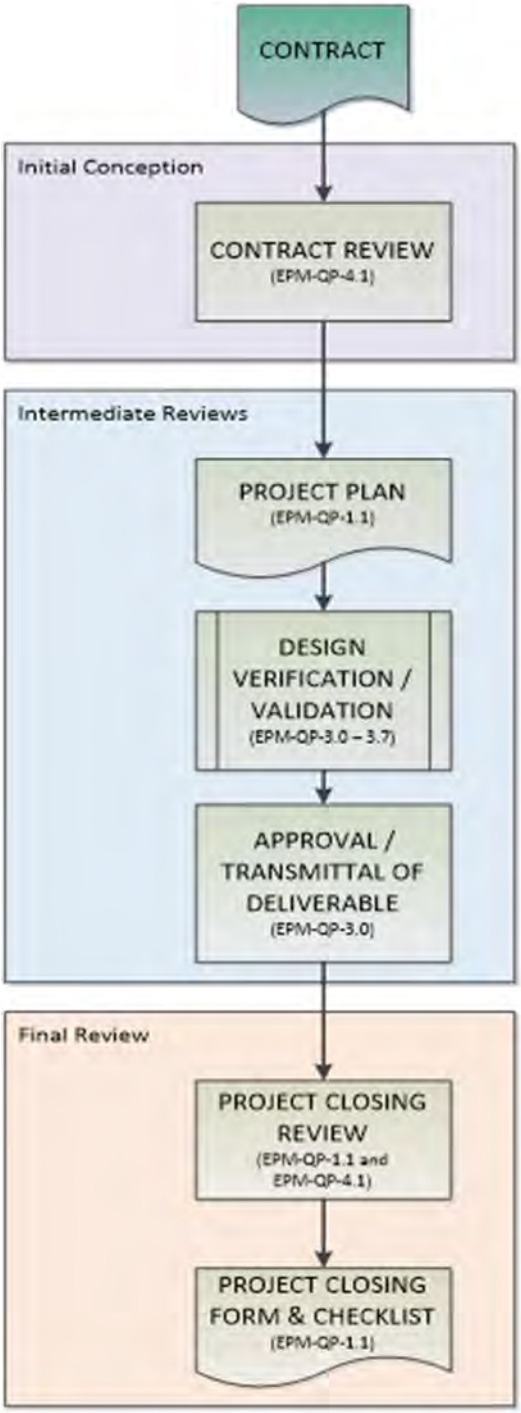


Figure B8.1 – Project Reviews

8.4. Control of Externally Provided Processes, Products and Services

8.4.1. General

Quality Procedure EPM-QP-4.0 [38] provides control for the procurement of items or services.

Quality Procedure EPM-QP-3.9 [39] provides general control for the procurement of software however for safety related applications EPM has committed to develop a commercial grade software dedication procedure using the guidance of EPRI Report 1025243 [40]. (See Quality Procedure EPM-QP-4.0, §1.0.) At this time, EPM is not using commercial grade software on safety related projects.

Evaluations of suppliers of items or services are performed to establish the ability of the supplier to provide the items or services in accordance with requirements.

8.4.2. Type and Extent of Control

To maintain a supplier as acceptable as providers of safety-related items or services, suppliers are audited on an interval not to exceed three (3) years and evaluated annually. Evidence of the supplier evaluations is maintained in EPM's FAN System.

Quality Procedure EPM-QP-4.0, §5.5 and §5.6 discuss the methods of acceptance for procured items or services.

Quality Procedure EPM-QP-4.0, §5.7 and §5.8 provide for the disposition of nonconforming items or services and for the reporting of certain serious defects or nonconformance.

8.4.3. Information for External Providers

Quality Procedure EPM-QP-4.0, §5.0 specifies

- The information to be provided to suppliers
- The review and approval process for procurement records
- Monitoring of the supplier's performance

8.5. Production and Service Provision

8.5.1. Control of Production and Service Provision

The items and services provided by EPM are controlled by a set of procedures, plans, forms, etc. established to provide the control and monitoring of EPM's efforts.

Quality Procedures are used as discussed in this document to provide the required structure and control to EPM activities. Project Plans establish the project specific scope of services, deliverables, quality and technical requirements, restraints, etc. necessary to meet customer requirements.

8.5.2. Identification and Traceability

EPM provides engineering and software services. EPM is not a manufacturer of goods or products.

Software traceability is controlled in accordance with Quality Procedure EPM-QP-3.7 using a unique numbering system. Identification and traceability of procured software is controlled by Quality Procedure EPM-QP-3.9.

Identification and traceability of services is provided by unique numbering of deliverables based on the project number. The status of records is clearly designated.

Identification and traceability are contained in the FAN System.

8.5.3. Property Belonging to Customers or External Providers

Controlled drawings supplied by the customer are controlled by Quality Procedure EPM-QP-5.0 [41].

Customer information required to prepare services and software is maintained. This information may be drawings, databases, reports, studies, etc. This information is primarily in electronic format. If requested by the customer, safeguards are placed on this information while in the possession of EPM to prevent loss, inappropriate access, or distribution. Similar safeguards regarding customer information are placed on subcontractors if information is supplied by EPM to the subcontractor.

8.5.4. Preservation

The product of engineering services is generally a report. Each report is uniquely numbered, including revisions. Reports may be delivered as hard copies or electronic files. A copy of any final report or revision is maintained in the FAN System.

Software programs and large electronic files and databases may be supplied on CDs or DVDs or posted to an access controlled internet site. Customer receipt is generally confirmed by a signed and returned document/data transmittal. Copies of final software programs or electronic files and databases sent to the client are maintained in the FAN System. Handling and shipping of CDs and DVDs are also addressed in Attachment A, Section 13.0, “Handling Storage and Shipping”.

8.5.5. Post-delivery Activities

EPM’s software license contains details of the warranty provided for the software.

Final reports, software programs, contracted electronic files and other critical information are maintained in the FAN System per Quality Procedure EPM-QP-17.0.

Customer feedback is solicited in compliance with ISO 9001:2015 (see Quality Procedure EPM-QP-4.1).

8.5.6. Control of Changes

Quality Procedure EPM-QP-3.1 describes control of changes to final engineering designs, analyses, calculations, etc.

Quality Procedure EPM-QP-3.7 controls changes to delivered software including notification of changes to the customer.

Documentation of changes is contained in the FAN System.

8.6. Release of Products and Services

The Project Manager approval signature on an EPM deliverable is indication that the deliverable is ready for release.

For software, completion and signing of all required development or change records is indication that the deliverable is ready for release. Software release is frequently

accompanied by a Certificate of Conformance (see Quality Procedure EPM-QP-1.1, Exhibit 1.1-2).

8.7. Control of Nonconforming Outputs

Quality Procedure EPM-QP-16.3 [42] addresses the control of nonconformances. Significant nonconformances as defined in EPM-QP-16.3 may become Corrective Action Requests (see Quality Procedure EPM-QP-16.0).

The following procedures also define the handling of specific sources of nonconformances.

8.7.1. Software

Software Change Requests (SCRs) (Quality Procedure EPM-QP-3.7, §5.2.1 and Exhibit 3.7-1) are initiated by EPM software users when a user discovers an error or is informed about an error by a customer.

8.7.2. From Suppliers

Methods for control and disposition of supplier nonconformance for items and services that do not meet procurement document requirements are addressed in Quality Procedure EPM-QP-4.0.

9. PERFORMANCE EVALUATION

9.1. Monitoring, Measurement, Analysis and Evaluation

9.1.1. General

The role of the Quality Management Program is to monitor the system by measuring, analyzing, and evaluating the elements of the system. As part of quality management, in addition to other Quality Management Program targeted actions, this monitoring is carried out through:

- Internal and external audits
- Evaluations of external providers
- External Audits
- Customer satisfaction surveys
- Monitoring of performance indicators
- Follow-up of complaints and non-conformities
- Process reviews

The EPM monitoring program is described in Quality Procedure EPM-QP-1.6 [43].

9.1.2. Customer Satisfaction

Customer satisfaction may be evaluated using a number of sources such as:

- Customer surveys
- Supplier ratings by customers
- Repeat business
- Continued presence on customer's approved suppliers list
- Lost business analysis
- Customer compliments
- Customer referrals

A customer satisfaction survey is carried out for most projects in compliance with ISO 9001:2015 at the end of the project or generally at an interval not exceeding yearly if the project continues for that time period (see Quality Procedure EPM-QP-4.1).

Customer complaints may be documented in the nonconformance process (see Quality Procedure EPM-QP-4.1).

9.1.3. Analysis and Evaluation

Performance monitoring analyses are compiled at least annually and distributed to the interested parties. (See Quality Procedures EPM-QP-1.5 and EPM-QP-16.2 [44])

Process reviews are conducted annually. This allows process owners to review the process for drift or change and to implement corrective measures if necessary.

9.2. Internal Audit

A series of internal audits is performed annually to assess all aspects of the Quality Management Program (see Quality Procedure EPM-QP-18.0 [20]).

9.3. Management Review

9.3.1. General

A management review is conducted annually by the President of EPM. (See Quality Procedures EPM-QP-1.5 and EPM-QP-18.0.)

Division Directors conduct annual assessments of the effectiveness of the Quality Management Program in their Division. (See Quality Procedures EPM-QP-1.5 and EPM-QP-18.0.)

9.3.2. Management Review Inputs

See Quality Procedures EPM-QP-1.5 and EPM-QP-18.0.

9.3.3. Management Review Outputs

See Quality Procedures EPM-QP-1.5 and EPM-QP-18.0.

The management review includes as appropriate decisions and actions related to:

- Opportunities for improvement
- Any recommended changes to the Quality Management Program
- Resource needs

Management assessments are retained in EPM's FAN System.

10. IMPROVEMENT

10.1. General

Through the implementation of this Quality Management Program, EPM has established the mechanism to identify and implement opportunities for improvement necessary to meet customer requirements and enhance customer satisfaction. Improvement can be effected reactively (e.g., corrective action), incrementally (e.g., continual improvement), by step change (e.g., breakthrough), creatively (e.g., innovation) or by re-organization (e.g., transformation).

It is the goal of this Quality Management Program to:

- Improve products and services to meet requirements as well as address future needs and expectations
- Correct, prevent, or reduce undesired effects

- Improve the performance and effectiveness of the Quality Management Program

To realize this goal, EPM uses the "DMAIC" process shown in Figure 10.1.

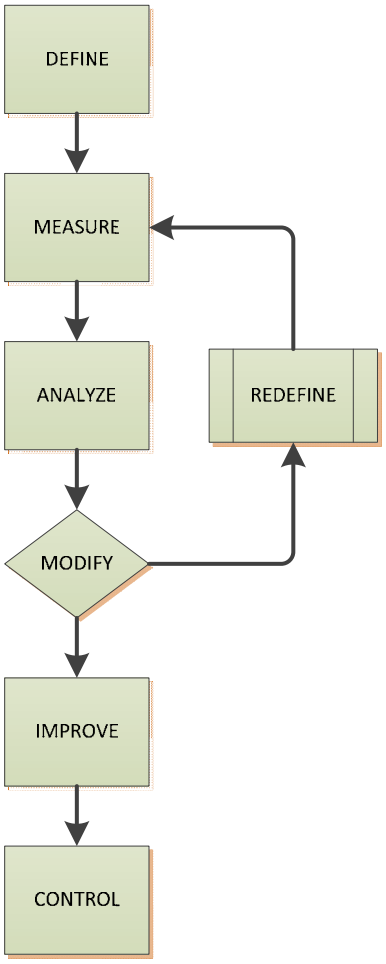


Figure B10.1 – DMAIC Process

10.2. Nonconformity and Corrective Action

As described in this Manual, when confronted with a nonconformity or complaint, EPM:

- Takes the necessary actions to identify and correct the nonconformity including any appropriate corrective actions
- Review the effectiveness of corrective actions

- Evaluate and eliminate the cause of the nonconformity to prevent reoccurrence
- Make necessary changes to the Quality Management Program

10.3. Continual Improvement

At least annually, EPM evaluates the Quality Management Program with the aim of improving the suitability, adequacy, and effectiveness of the Program.

11. REFERENCES

See Section 6 of main body of this document.

ATTACHMENT C – DEFINITIONS

Acceptance Criteria

Specified limits placed on the performance, results, or other characteristics of an item, process, or service defined in codes, standards, or other requirement documents.

Audit

A planned and documented activity performed to determine by investigation, examination, or evaluation of objective evidence the adequacy of and compliance with established procedures, instructions, drawings, and other applicable documents, and the effectiveness of implementation. An audit should not be confused with surveillance or inspection activities performed for the sole purpose of process control or product acceptance.

Audit – External

An audit of those portions of another organization's quality assurance program not under the direct control or within the organizational structure of the auditing organization.

Audit – Internal

An audit of those portions of an organization's quality assurance program retained under its direct control and within its organizational structure.

Augmented Quality

Quality classification applied to non-safety-related activities, items, services, etc. where graded quality assurance requirements have been decided or directed to be applicable.

Basic Component

A structure, system, component, or part thereof that affects its safety function, that was designed and manufactured in accordance with the requirements of NQA-1, or commercial grade items which have successfully completed the dedication process.

Certificate of Conformance

A document signed or otherwise authenticated by an authorized individual certifying the degree to which items or services meet specified requirements.

Certification

The act of determining, verifying, and attesting in writing to the qualifications of personnel, processes, procedures, or items in accordance with specified requirements.

Characteristic

Any property or attribute of an item, process, or service that is distinct, describable, and measurable.

Commercial Grade Item

A structure, system, or component, or part thereof, that affects a safety function that was not designed and manufactured in accordance with the requirements of ASME NAQ-1 standard.

Commercial Grade Service

A service to a nuclear related facility or organization that was not provided in accordance with the requirements of ASME NQA-1.

Computer Program

A combination of computer instructions and data definitions that enables computer hardware to perform computational or control functions.

Condition Adverse to Quality

An all-inclusive term used in reference to any of the following: failures, malfunctions, deficiencies, defective items, and nonconformances. A significant condition adverse to quality is one that, if uncorrected, could have a serious effect on safety or operability.

Configuration

The physical, functional, and operational characteristics of the structures, systems, components, or parts of the existing facility.

Configuration Item (software)

A collection of hardware or software elements treated as a unit for the purpose of configuration control.

Configuration Management

The process that controls the activities, and interfaces, among design, construction, procurement, training, licensing, operations, and maintenance to ensure that the configuration of the facility is established, approved, and maintained.

Corrective Action

Measures taken to rectify conditions adverse to quality and, where necessary, to preclude repetition.

Critical Characteristics

Important design, material, and performance characteristics of a commercial grade item or service that, once verified, will provide reasonable assurance that the item or service will perform its intended safety function.

Dedication

An acceptance process performed in accordance with ASME NQA-1 to provide reasonable assurance that a commercial grade item or service will successfully perform its intended safety function and, in this respect, is deemed equivalent to an item or service provided under the requirements of ASME NQA-1 standard.

Dedicating Entity

The organization that performs the dedication process.

Design Authority

The organization having the responsibility and authority for approving the design bases, the configuration, and changes thereto.

Design Bases

That information which identifies the specific functions to be performed by a structure, system, or component of a facility, and the specific values or ranges of values chosen for controlling parameters as reference bounds for design. These values may be (1) restraints desired from generally accepted “state-of-the-art” practices for achieving functional goals, or (2) requirements derived from analysis (based on calculations and/or experiments) of the effects of a postulated accident for which a structure, system, or component must meet its functional goals.

Design - Change

Any revision or alternation of the technical requirements defined by approved and issued design output documents and approved and issued changes thereto.

Design - Final

Approved design output documents and approved changes thereto.

Design Input

Those criteria, performance requirements, codes and standards, design bases, regulatory requirements, or other design requirements upon which detailed final design is based.

Design Output

Drawings, specifications, and other documents used to define technical requirements of structures, systems, and components, and computer programs.

Design Process

Technical and management processes that commence with identification of design input and that lead to and include the issuance of design output documents.

Design Review

A critical review to provide assurance that the final design is correct and satisfactory.

Deviation

A departure from specified requirements.

Document

Any written or pictorial information describing, defining, specifying, reporting, or certifying activities, requirements, procedures, or results. A document is not considered to be a Quality Assurance Record until it satisfies the definition of a Quality Assurance Record as defined in this section.

Document Control

The act of assuring that documents are reviewed for adequacy, approved for release by authorized personnel, and distributed to and used at the location where the prescribed activity is performed.

Document - Electronic

A document stored in a form (i.e., magnetic or optical media) that is typically accessible only by a computer.

FAN System

EPM proprietary records management, storage, and retention interactive software system.

Guideline

A suggested practice that is not mandatory in programs intended to comply with a standard. The word ‘should’ denotes a guideline; the word ‘shall’ denotes a requirement.

Inspection

Examination or measurement to verify whether an item or activity conforms to specified requirements.

Inspector

A person who performs inspection activities to verify conformance to specific requirements.

Item

An all-inclusive term used in place of any of the following: appurtenance, assembly, component, equipment, material, module, part, structure, subassembly, subsystem, system, or unit.

Measuring and Test Equipment

Devices or systems used to calibrate, gage, test, or inspect in order to control or to acquire data to verify conformance to specified requirements.

Nonconformance

A deficiency in characteristic, documentation, or procedure that renders the quality of an item or activity unacceptable or indeterminate.

Non-Nuclear Commercial Grade

Activities, products, services, or items supplied to or performed for non-nuclear related facilities or organizations.

Objective Evidence

Any documented statement of fact, other information, or record, either quantitative or qualitative, pertaining to the quality of an item or activity, based on observations, measurements, or tests which can be verified.

Owner

The organization legally responsible for the construction and/or operation of a nuclear facility including but not limited to one who has applied for, or who has been granted, a construction permit or operating license by the regulatory authority having lawful jurisdiction.

Employee Intranet Site

EPM internal network site containing general technical and administrative information including:

- Quality Policy document
- Quality Management Manual
- Quality procedures
- Division technical procedures
- Company organization chart
- Employee Policies and Procedures
- Information Technology information
- Links to the EPM contracts and records management systems
- Ability to record and approve time spent on assignments
- Ability to review project performance

Procedure

A document that specifies or describes how an activity is to be performed.

Procurement Document

Purchase requisitions, purchase orders, drawings contracts, specifications, or instructions used to define requirements for purchase.

Purchaser

The organization responsible for establishment of procurement requirements and for issuance or administration or both of procurement documents.

Qualification (Personnel)

The characteristics or abilities gained through education, training, or experience, as measured against established requirements such as standards or tests that qualify an individual to perform a required function.

Qualified Automated Means

Automated methods of controlling or monitoring processes that have been demonstrated to produce required quality within controlled limits.

Qualified Procedure

An approved procedure that has been demonstrated to meet the specified requirements for its intended purpose.

Quality Assurance (QA)

All those planned and systematic actions necessary to provide adequate confidence that a structure, system, or component will perform satisfactorily in service.

Quality Assurance Record

A completed document that furnishes evidence of the quality of items and/or activities affecting quality. Records may also include specially processed documents such as radiographs, photographs, negatives, or microforms.

Quality Standard

A code or standard that provides design inputs, acceptance criteria, or other criteria necessary to assure the quality of the designated item.

Receiving

Taking delivery of an item at a designated location.

Repair

The process of restoring a nonconforming characteristic to a condition such that the capability of an item to function reliably and safely is unimpaired, even though that item still does not conform to the original requirement.

Request for Tender

A formal, structured invitation to suppliers to submit a bid to supply products or services.

Rework

The process by which an item is made to conform to original requirements by completion or correction.

Safety Function

The performance of an item or service necessary to achieve safe, reliable, and effective utilization of nuclear energy and nuclear material processing.

Service

The performance of activities such as design, fabrication, inspection, nondestructive examination, repair, or installation.

Shall

The word “shall” denotes a requirement.

Should

The word “should” denotes guidance.

Simple Software

Software such as Microsoft Access© or Excel© where the results of any manipulation of data by the software can be easily verified as correct by external means.

Site Activities

Those onsite activities (i.e., described by procedures, task descriptions, project plans, etc.) that are controlled by the Site Projects Division Director, or designee. Onsite activities that are quality-related are subject to Quality Assurance requirements.

Software

Computer programs and associated documentation and data pertaining to the operation of a computer system.

Special Process

A process, the results of which are highly dependent on the control of the process or the skill of the operators, or both, and in which the specified quality cannot be readily determined by inspection or test of the product.

Staff Augmentation

Situation where an EPM employee is under the direct supervision of the client, is working under the client's QA Program and procedures, and does not issue anything as an EPM product.

Supplier

Any individual or organization that furnishes items or services to a procurement document. An all-inclusive term used in place of any of the following: vendor, seller, contractor, subcontractor, fabricator, consultant, and their sub-tier levels.

Surveillance

Monitoring or observing processes, activities, or items to assess adequacy and effectiveness and to verify conformance to specified requirements.

Testing

An element of verification for the determination of the capability of an item to meet specified requirements by subjecting the item to a set of physical, chemical, environmental, or operating conditions.

Traceability

The ability to trace the history, application, or location of an item and like items or activities by means of recorded identification.

Use-as-is

A disposition permitted for a nonconforming item when it can be established that the item is satisfactory for its intended use.

Waiver

Documented authorization to depart from specified requirements.