

# EFCOG White Paper on Quality Engineer Roles and Responsibilities

## Introduction

The EFCOG ISM Working Group's Quality Assurance Subgroup Task Team on Quality Engineering was tasked with developing a document defining Qualifications, Roles and Responsibilities for a Quality Engineer. The impact of a standard set of Qualifications and Roles and Responsibilities will be especially beneficial to capital acquisition projects. The supplier base for material, services, and equipment at times is unfamiliar with nuclear quality standards, and is a particularly important target for Quality Engineering support.

## Purpose

The purpose of this white paper is to provide criteria to assist the DOE and contractors with the consistent application of guidance for Qualifications, Roles and Responsibilities for a Quality Engineer. This will help in implementation of DOE's QA Rule, 10 CFR 830, Subpart A, DOE's Project Management Order 413.3A and the DOE QA Order 414.1C.

## Definitions

A key to effective and consistent application of requirements is understanding and agreement of the primary terms and phrases used. Definitions such as quality specialist, quality analyst, quality lead, etc. have been used across the DOE complex to describe the Quality Engineer. The below listed definitions were identified as key to consistent interpretation and application of Qualifications, Roles and Responsibilities for a Quality Engineer. They were drawn from existing DOE orders, ASQ, NQA-1, ISO and other guidance documents.

### **Quality**

- The condition achieved when an item, service, or process meets or exceeds the user's requirements and expectations.

### **Quality Engineering**

- *Quality Engineering* is defined as "the branch of engineering which deals with the principles and practice of product and service quality assurance and quality control."

### **Quality Engineer**

- A *Quality Engineer* is a professional who understands the principles of product and service quality evaluation and control. This understanding of applied technologies includes, but is not limited to;
  - development and operation of quality control systems.
  - application and analysis of testing and inspection procedures.
  - ability to use metrology and statistical methods to diagnose and correct improper quality control practices.
  - understanding of human factors and motivation.
  - familiarity with quality cost concepts and techniques.

- knowledge and ability to develop and administer management information systems.
- ability to audit quality systems for deficiency identification and correction.
- understanding and familiarity with product quality.
- knowledge and familiarity with industry specifications/codes/standards.

The *Quality Engineer* would therefore be responsible for assuring the implementation of a Quality Management System in the company, as well as for the maintenance of the Quality Management System.

## **Discussion**

Quality Engineers (QE) are involved in developing and implementing systems to ensure products or services are designed and produced to meet or exceed customer requirements and expectations. The QE also participates in the change management process to assure the products or services continue to meet customer requirements. The QE is usually part of a cross-functional team with other business and engineering disciplines. Quality Engineers establish the principles of product and service quality evaluation and control for the system. The QE provides independent oversight and review of the project deliverables throughout the lifecycle.

## **Expectations of a Quality Engineer**

A Quality Engineer will;

- have a fundamental understanding of quality philosophies, principles, systems, methods, tools, standards, organizational and team dynamics, customer expectations and satisfaction, supplier relations and performance, leadership, training, interpersonal relationships, improvement systems, and professional ethics.
- have a fundamental understanding of a quality system and its development, documentation, and implementation with respect to domestic and international standards or requirements.
- have a basic understanding of the audit process including types of audits, planning, preparation, execution, reporting results, and follow-up.
- be able to develop and implement quality programs, including tracking, analyzing, reporting, and problem solving.
- be able to plan, control, and assure product and process quality in accordance with quality principles, which include planning processes, material control, acceptance sampling, and measurement systems.
- be able to plan, control, and assure product application, including design, manufacturing and construction.
- have basic knowledge of reliability, maintainability, and risk management, including key terms and definitions, modeling, systems design, assessment tools, and reporting.
- have a thorough understanding of problem-solving and quality improvement tools and techniques. This includes knowledge of management and planning tools, quality tools, preventive and corrective actions, and how to overcome barriers to quality improvements.
- be able to acquire and analyze data using appropriate standard quantitative methods across a spectrum of business environments to facilitate process analysis and improvements.

- Understand risk analysis philosophies and methodologies and their applications.
- Understand readiness processes and requirements.

## **Quality Engineer Qualifications**

**The Quality Engineer would be an individual who meets one or more of the following:**

- An ASQ certified Quality Engineer for positions involving hardware or an ASQ certified Software Quality Engineer for positions involving software.
- A Professional Quality Engineer licensed by the state.
- Has an engineering degree when required by HR policies for the particular site/company plus documented relevant experience in accordance with site/company requirements.
- Otherwise meets the minimum requirements for the position as defined by the particular site/company.

## **Quality Engineering Responsibilities**

**The Quality Engineer's responsibilities include:**

- Application of quality processes in a graded approach to the specific product or service.
- Participation in the development and review of project documentation.
- Direction and support for procurement activities.
- Application of testing and inspection activities to specific systems.
- Assessment of systems to identify deficiencies and participate in resolution of issues found.

**Typical duties include:**

### **Quality Management System Development**

- Assist management in with development of Quality Program Plan(s) and subsequent revisions.
- Perform adequacy reviews for flow down of QA requirements to implementing documents and quality affecting processes.
- Assist in defining/developing Quality Program status indicators, performance measurements and reporting requirements.
- Assist in development of quality system processes, i.e., records management and document control, control of electronic data, software development and control, etc.

### **Design Control:**

- Develop new/update existing Hazard Analysis and Quality Plans.
- Review and comment on drawings, calculations, specifications and other design inputs/outputs.
- Provide direction in developing inspection plans, First Article Inspection, In-Process and Final Product Inspection, Sampling Plans, inspection and acceptance criteria and Design Validation Testing.

- Review and/or document Design Control activities for Project Reviews.
- Provide input for design-for-quality issues.
- Perform internal audits to assess compliance to Standards and to the internal Quality System, including investigation, presentation of observations and findings, and reporting.
- Apply sound systematic problem-solving methodologies in identifying, prioritizing, communicating, and resolving quality issues.
- Provide trending analysis on quality issues and performance metrics.

#### **Procurement Quality Engineering:**

- Review procurements documents for flowdown and inclusion of quality requirements.
- Provide direction in implementing Incoming Inspection plans, First Article Inspection, In-Process and Final Product Inspection, Sampling Plans, inspection and test acceptance criteria, and resolve nonconformances.
- Coordinate supplier deviation request process.
- Perform vendor audits and qualifications.
- Provide input for fabrication issues.
- Apply sound systematic problem-solving methodologies in identifying, prioritizing, communicating, and resolving vendor quality issues.
- Provide trending analysis on vendor quality issues and performance metrics.

#### **Construction Quality Engineering:**

- Develop and update Quality Plans.
- Provide direction in implementing Work Packages/Inspection plans, Receipt Inspection, Witness and Hold Points, In-Process and Final Product Inspection, Sampling Plans, inspection and acceptance criteria and Startup Testing.
- Review and/or document Field Change activities.
- Provide input for construction quality issues.
- Perform internal audits to assess compliance to Standards and to the internal Quality System, including investigation, presentation of observations and findings, and reporting.
- Apply sound systematic problem-solving methodologies in identifying, prioritizing, communicating, and resolving construction quality issues.
- Provide trending analysis on quality issues and performance metrics.
- Provide guidance on treatment of punchlist items vs. nonconformances.

#### **Regulatory Compliance:**

- Assist in maintaining Rule/Order and Program Quality compliance.
- Review and document Rule/Order changes for Projects/Programs.
- Perform product and process evaluations to identify areas for improvement. Recommend solutions to identified problems. Implement approved changes using sound quality engineering principles and fully document requirements on a timely basis.

- Assist Regulatory Affairs and Engineering personnel in new product/process design to assure effective control procedures are established. Participate actively in product and process start-ups. Design and write protocol and implement process validation procedures in accordance with Quality guides.
- Establish a basis for the application of quality.
- Assist in regulatory reporting activities.

**Qualitative and Quantitative data analysis:**

- Investigate product quality problems, determine root cause, gather and analyze data and implement corrective action to reduce or eliminate cause.
- Routinely review regular inspection data and prepare statistical and operational performance reports.
- Perform process capability studies or special studies necessary to increase control and lower total quality costs.
- Monitor and/or perform quality activities to support First Article Inspection.
- Use quality tools and practices to establish approval criteria to ensure the identification of quality failure concerns for both internal and external manufactured parts and assemblies.

**Complaint investigation and analysis:**

- Support Customer Service to ensure fulfillment of customer requirements.
- Coordinate and participates in elements of investigations regarding customer complaints.
- Perform all responsibilities with the achievement of Customer-Focused Quality as the primary priority and goal.
- Establish a basis for the application of quality.

**Operations and Production Support:**

- Actively participate in definition of test requirements, justification of acceptance limits and sampling plans to assure compliance with requirements.
- Perform product and process evaluations to identify areas for improvement. Recommend solutions to identified problems. Implement approved changes using sound quality engineering principles and fully document requirements on a timely basis.
- Represent Quality on the Project/Program Core Team.
- Provide lessons learned and issues management support.
- Establish a basis for the application of quality.
- Monitor and/or perform quality activities for part acceptance including First Article Inspection.
- Work closely with Manufacturing Operations to Identify and resolve production and quality system deficiencies.
- Assist in development, review and approval of process and equipment validation/qualifications.
- Participate in the improvement of the manufacturing process for existing products. Review and approve work instructions, inspection documents, Bills of Material and drawings.

**Training:**

- Help facilitate continuous improvement and learning across all functional areas through training and communication of quality initiatives.
- Monitor training/certification activities for Quality/Project personnel.
- Assist in the development and delivery of specific Quality training.
- Conduct oversight of training activities and report to Management.

**Metrology and Gage Replace & Repair activities include:**

- Verify recall database entries for correct input of identification and calibration data.
- Review and verify procedures developed for the calibration and control of M&TE.
- Validate “return to service” activities after replace or repair of M&TE.
- Monitor training/certification activities for Metrology personnel.

## 1. REQUIREMENTS/REFERENCES

10 CFR 830.120, Subpart A, “Quality Assurance Requirements.” *Code of Federal Regulations*, as amended.

ASME-NQA-1- *Quality Assurance Requirements for Nuclear Facility Applications*, American Society of Mechanical Engineers, New York, New York.

DOE O 413.3A, 7-28-2006, Program and Project Management For The Acquisition of Capital Assets, U.S. Department of Energy

DOE G 414.1-2A, 2005, *Quality Assurance Management System Guide for Use With 10 CFR 830 Subpart A, Quality Assurance Requirements, and DOE O 414.1C, Quality Assurance*, U.S. Department of Energy, Office of Environment, Safety and Health Washington, D.C.

DOE O 414.1C, 2005, *Quality Assurance*, U.S. Department of Energy, Office of Environment, Safety and Health Washington, D.C.

ISO 9001, *Quality Management Systems*, International Organization for Standardization, Geneva, Switzerland.

American Society for Quality - ASQ *Certification requirements CQE*