

Quality Assurance Manual

Company Name
Company Address
City, ST ZIP

Approved By:

Signature

Top Manager's Name, Title

Date:

Copy#: _____

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1 INTRODUCTION

Use this section to provide general information about the company... history, products, services and other information about what the customer can buy from you can be added here.

2 PURPOSE and SCOPE

This manual provides the Quality Assurance requirements implemented by **Company Name** for purchase orders or contracts that invoke regulatory requirements or specifically require compliance to this manual. Each contract will be reviewed to determine regulated activities and the appropriate measures to be implemented.

This Quality Assurance Manual meets or exceeds the requirements of:

- Title 10, U.S. Code of Federal Regulations, Appendix B to Part 50 (10 CFR 50 Appendix B) and,
- American Society of Mechanical Engineers (ASME) NQA-1-2004.

The requirements of these documents shall be complied with as applicable to the services provided. Additionally, the requirements for reporting of defects and noncompliance according 10 CFR Part 21 will be accepted when invoked on contract documents.

Certain requirements may not be applicable to current capabilities but have been included and by become relevant with the expansion of capabilities and contract requirements.

3 TERMS AND DEFINITIONS

For the purposes of this document and associated contracts, terms and definitions as designated by Paragraph 400 of the current revision of ASME NQA-1 are applicable.

4 Quality Assurance Criteria

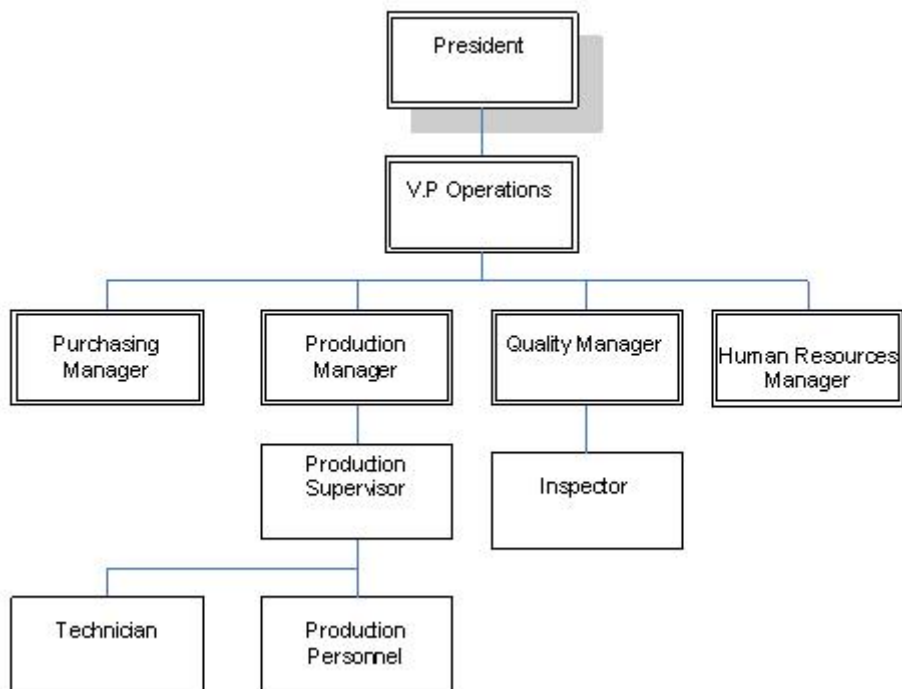
4.1 Organization

4.1.1 Basic

The organizational structure, functional responsibility, authority and duties of persons and organizations performing activities affecting the safety-related functions of structures, systems, and components shall be clearly established and delineated.

The organization chart provides an outline of the organizational structure. Additional information such as job descriptions, procedures, etc. may be designated to provide guidance where needed.

Organizational Chart



4.1.2 Structure and Responsibility

The organizational structure and responsibility assignments shall be such that:

- senior management establishes overall expectations for effective implementation of the quality assurance program and is responsible for obtaining the desired end result;
- quality is achieved and maintained by those assigned responsibility for performing work; and
- quality achievement is verified by those not directly responsible for performing the work.

Those responsible for verifying quality achievement shall have:

- sufficient authority, direct access to management, organizational freedom, and access to work to perform their function
- authority to identify quality problems; to initiate, recommend, or provide solutions; and to verify implementation of solutions.

Such persons and organizations perform their function by verifying, such as by checking, auditing, and inspection, that activities affecting the safety-related functions have been correctly performed.

Such persons and organizations performing quality assurance functions shall report to a management level such that this required authority and organizational freedom, including sufficient independence from cost and schedule when opposed to safety considerations, are provided. Because of the many variables involved, such as the number of personnel, the type of activity being performed, and the location or locations where activities are performed, the organizational structure for executing the quality assurance program may take various forms provided that the persons and organizations assigned the quality assurance functions have this required authority and organizational freedom. Irrespective of the organizational structure, the individual(s) assigned the responsibility for assuring effective execution of any portion of the quality assurance program at any location where activities subject to this document are being performed shall have direct access to such levels of management as may be necessary to perform this function.

4.1.3 Delegation of Work

Company Name may delegate to others, such as contractors, agents, or consultants, the work of establishing and executing the quality assurance program, or any part thereof, but shall retain responsibility.

4.1.4 Interface Control

Where 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 changes thereto, shall be documented.

Related Documents

QP 01-01 Quality Planning

QP 01-02 Contract Review

4.2 Quality Assurance Program

4.2.1 Basic

Company Name has established this documented quality assurance program which complies with the requirements of ASME NQA-1 and 10CFR50 Appendix B. This quality assurance program shall be planned, implemented, and maintained in accordance with the requirements identified in these documents. The program shall provide control over activities affecting quality to an extent consistent with their importance. The program shall include monitoring activities against acceptance criteria in a manner sufficient to provide assurance that the activities affecting quality are performed satisfactorily. The program shall be established at the earliest time consistent with the schedule for accomplishing the activities.

The quality assurance program shall provide control over activities affecting the quality of the identified structures, systems, and components, to an extent consistent with their importance to safety. Activities affecting quality shall be accomplished under suitably controlled conditions. Controlled conditions include the use of appropriate equipment; suitable environmental conditions for accomplishing the activity, such as adequate cleanliness; and assurance that all prerequisites for the given activity have been satisfied.

This program shall be documented by written policies, procedures, or instructions and shall be carried out throughout plant life in accordance with those policies, procedures, or instructions. **Company Name** shall identify the services to be covered by the quality assurance program and the major organizations participating in the program, together with the designated functions of these organizations. The program shall take into account the need for special controls, processes, test equipment, tools, and skills to attain the required quality, and the need for verification of quality by inspection and test.

Management of other organizations participating in the quality assurance program shall regularly review the status and adequacy of that part of the quality assurance program which they are executing.

4.2.2 Indoctrination and Training

The program shall provide for indoctrination and training of personnel performing activities affecting quality as necessary to assure that suitable proficiency is achieved and maintained. **Company Name** shall regularly review the status and adequacy of the quality assurance program.

Personnel performing or managing activities affecting quality shall receive indoctrination in their job responsibilities and authority; general criteria, including applicable codes and standards, regulatory commitment, company procedures, and quality assurance program requirements.

The need for a formal training program for personnel performing or managing activities affecting quality shall be determined. Training shall be provided, if needed, to achieve initial proficiency, maintain proficiency, and adapt to changes in technology, methods, or job responsibilities.

4.2.3 Qualification Requirements

The responsible organization shall designate those activities that require qualification of personnel and the minimum requirements for such personnel. The responsible organization shall establish written procedures for the qualification of personnel, and for the assurance that only those personnel who meet the requirements are permitted to perform these activities.

Specific qualification requirements for personnel performing nondestructive testing examination inspection and tests to verify quality and auditing are specified in the following.

4.2.3.1 Nondestructive Examination (NDE)

This section specifies requirements for the qualification of personnel who perform radiographic (RT), magnetic particle (MP), ultrasonic (UT), liquid Penetrant (PT), electromagnetic (ET), and visual testing (VT) to verify conformance to the specified requirements. The American Society of Nondestructive Testing Recommended Practice No. SNT-TC-1A, and its applicable supplements shall apply as requirements to NDE.

4.2.3.2 Inspection and Test

The initial capabilities of a candidate shall be determined by an evaluation of the candidate's education, experience, training, and either test results or capability demonstration. The job performance of inspection and test personnel shall be reevaluated at periodic intervals not to exceed 3 years. Reevaluation shall be by evidence of continued satisfactory performance or redetermination of capability in accordance with the requirements of section 4.2.2. If during this evaluation or at any other time, it determined by the responsible organization that the capabilities of an individual are not in accordance with the qualification requirements specified for the job, that person shall be removed from that activity until such time as the required capability has been demonstrated. Any person who has not performed inspection or testing activities in the qualified area for a period of 1 year shall be reevaluated.

4.2.2.3 Lead Auditor

The lead auditor organizes and directs audits, reports audit findings, and evaluates corrective action. An individual shall meet the following requirements prior to being designated a Lead Auditor.

Communication Skills – The prospective Lead Auditor shall be capable of communicating effectively, both in writing and orally. These skills shall be attested to in writing by the Lead Auditor's employer.

Training – Prospective Lead Auditors shall receive training to the extent necessary to assure auditing competence including:

- Knowledge and understanding of this standard and other nuclear-related codes, standards, regulations, and regulatory guides, as applicable.
- General structure of quality assurance programs as a whole and applicable elements
- Auditing techniques of examining, questioning, evaluating, and reporting; methods of identifying and following up on corrective action items; and closing out audit findings.
- Planning audits of activities affecting quality
- On-the-job training to include applicable elements of the audit program

Audit Participation – Prospective Lead Auditors shall participate in a minimum of five quality assurance audits within a period of time not to exceed 3 years prior to the date of qualification, one audit of which shall be a nuclear quality assurance audit within the year prior to qualification.

Examination – Prospective Lead Auditors shall pass an examination which shall evaluate comprehension of and ability to apply the body of knowledge identified above. The examination may be oral, written, practical, or any combination thereof.

Maintenance of Proficiency – Lead auditors shall maintain their proficiency through one or more of the following: regular and active participation in the audit process; review and study of codes, standards, procedures, instructions, and other documents related to quality assurance program and program auditing; or participation in training programs. Based on annual assessment, management may extend the qualification, require retraining, or require requalification.

Requalification – Lead Auditors who fail to maintain tier proficiency for a period of 2 years or more shall require requalification. Requalification shall include retraining in accordance with the requirements of this section and participation as an Auditor in at least one nuclear quality assurance audit.

4.2.5 Auditors

Auditors are participants in an audit. Auditors shall have, or be given, appropriate training or orientation to develop their competence for performing audits. Competence of personnel for performance of the various auditing functions shall be developed by one or more of the following methods:

- Orientation to provide a working knowledge and understanding of this Standard and the auditing organization's procedures for implementing audits and reporting results.
- General and specialized training in audit performance where the general training shall include fundamentals, objectives, characteristics, organization, performance, and results of quality auditing and the specialized training shall include methods of examining, questioning, evaluating, and documenting specific audit items and methods of closing out audit findings.