

[COMPANY NAME]

Quality Assurance Manual

10 CFR 50 Appendix B and ASME NQA-1

Approved By:

[Enter date]

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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 Program requirements implemented by:

Company Name
Address/Location

These requirements are applicable 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)
- American Society of Mechanical Engineers (ASME) NQA-1-1994 (95 addenda) and 2008 editions.

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

Certain requirements may not be applicable to current capabilities but have been included to ensure program inclusion should they become relevant with the expansion of capabilities and contract requirements.

3 Definitions

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

4 Quality Assurance Criteria

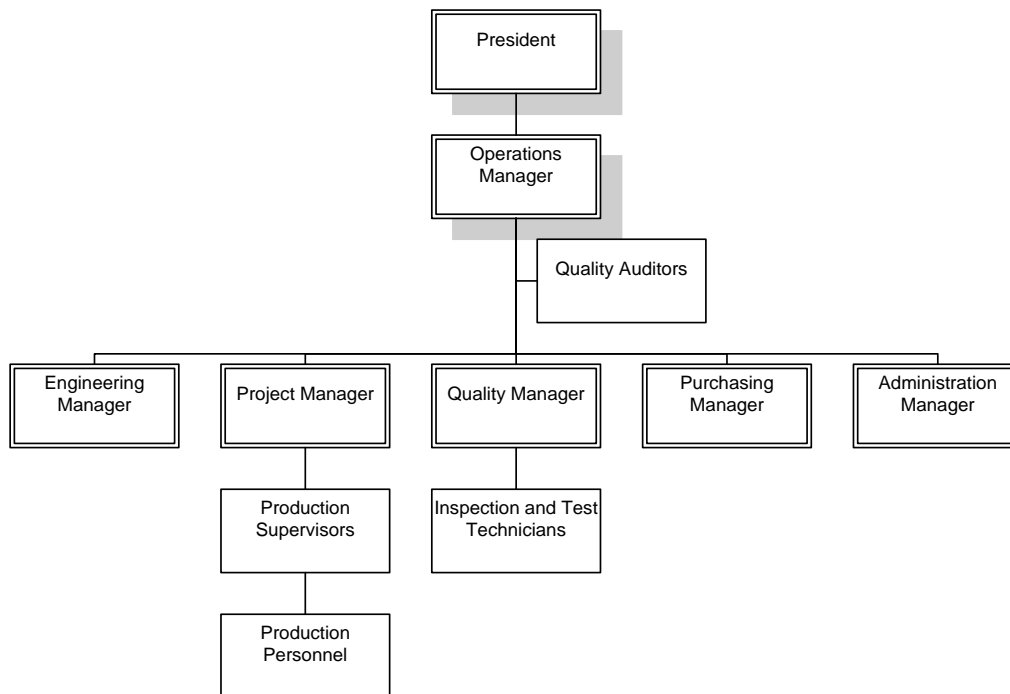
4.1 Organization

4.1.1 BASIC

Responsibilities for the establishment and implementation of the quality assurance program are defined. The organizational structure, functional responsibilities, levels of authority, and lines of communications for activities affecting quality are documented.

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

Organizational Chart



4.1.2 STRUCTURE AND RESPONSIBILITY

The organizational structure and responsibility of assignments is 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.
- Quality achievement is verified by those not directly responsible for performing the work.
- Those responsible for assuring that an appropriate quality assurance program have 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. These verification functions include the following:

(1) identifying quality problems

(2) initiating, recommending, or providing solutions to quality problems through designated channels

(3) verifying implementation of solutions

(4) assuring that further processing, delivery, installation, or use is controlled until proper disposition of a nonconformance, deficiency, or unsatisfactory condition has occurred.

Delegation of Work

The individual or organization responsible for establishing and executing a quality assurance program may delegate any or all of the work to others but shall retain responsibility.

4.1.3 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.

Reference Documents

QP 01-02 Order Entry and Contract Review

Job Descriptions

4.2 Quality Assurance Program

4.2.1 BASIC

A documented quality assurance program shall be planned, implemented, and maintained. The program shall identify the activities and items to which it applies. 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.

Structure of Quality Assurance Program Documentation

A four-tier documentation system is implemented to structure documentation. This allows for information to be presented in an organized manner and available to those who need it.



The program shall provide for the planning and accomplishment of activities affecting quality under suitably controlled conditions. Controlled conditions include the use of appropriate equipment, suitable environmental conditions for accomplishing the activity, and assurance that prerequisites for the given activity have been satisfied. The program shall provide for any special controls, processes, test equipment, tools, and skills to attain the required quality of activities and items and for verification of that quality. The organization shall establish and implement processes to detect and correct quality problems.

The program shall provide for indoctrination, training, and qualification as necessary of personnel performing or managing activities affecting quality to ensure that suitable proficiency is achieved and maintained.

Management shall regularly assess the adequacy and effective implementation of the quality assurance program.

4.2.2 INDOCTRINATION AND TRAINING

Indoctrination and training shall be commensurate with scope, complexity, importance of the activities, and the education, experience, and proficiency of the person.

Indoctrination

Personnel performing or managing activities affecting quality shall receive indoctrination in their job responsibilities and authority that includes general criteria, technical objectives, requirements of applicable codes and standards, regulatory commitments, company procedures, and quality assurance program requirements.

Training

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. On-the-job training shall be used if direct hands-on applications or experience is needed to achieve and maintain proficiency.

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 examination inspection and tests to verify quality and auditing are specified below.

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), neutron radiographic (NR), leak testing (LT), acoustic emission (AE), and visual testing (VT) to verify conformance to the specified requirements. The American Society of Nondestructive Testing (AS NT) Recommended Practices or Standards provide acceptable qualification

requirements for NDE personnel. Applicable Codes and Standards or design criteria controlling the qualification of NDE personnel shall be utilized to establish the applicable ASNT qualification requirement and edition or to specify an equivalent alternative requirement.

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 this section. If during this evaluation or at any other time, it is 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.

4.2.3.3 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.

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

- knowledge and understanding of nuclear-related codes, standards, regulations, and regulatory guides
- 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.

Participation in independent assessments including team assessment activities such as operations readiness reviews and regulatory inspections/surveys may be used to satisfy up to

four of the five required quality assurance audits, provided that the activities can demonstrate the following:

- independence from the functional areas being assessed
- planning that establishes the scope of the activities and associated evaluation criteria
- performance by technically qualified and experienced personnel
- results that are documented and reported to management
- appropriate corrective action initiated and tracked to resolution

Such participation shall be subject to review and acceptance by the organization responsible for quality assurance audits and/or the certifying authority prior to their use for qualification.

Examination - Prospective Lead Auditors shall pass an examination that 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
- participation in training program(s)

Based on annual assessment, management may extend the qualification, require retraining, or require requalification.

Requalification - Lead Auditors who fail to maintain their proficiency for a period of 2 years or more shall require requalification per this section including reexamination and participation as an auditor in at least one nuclear quality assurance audit.

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.

- on-the-job training, guidance, and counseling under the direct supervision of a Lead Auditor. Such training shall include planning, performing, reporting, and follow-up action involved in conducting audits.

Technical Specialists

The responsible auditing organization shall establish the qualifications and requirements for use of technical specialists to accomplish the auditing of quality assurance programs.

4.2.4 RECORDS OF QUALIFICATION

The qualification of inspection, test, and Lead Auditor personnel shall be certified in writing and include the following information:

- (1) employer's name
- (2) identification of person being certified
- (3) activities certified to perform
- (4) basis of qualification
 - (a) education, experience, indoctrination, and training
 - (b) test results, where applicable
 - (c) capability demonstration results
- (5) results of periodic evaluation
- (6) results of physical examinations, when required
- (7) signature of employer's designated representative who is responsible for such certification
- (8) date of certification or recertification and certification expiration.

The responsible organization shall identify any special physical characteristics needed in the performance of each activity, including the need for initial and subsequent physical examination. The employer may delegate qualification examination activities to an independent certifying agency, but shall retain responsibility for conformance of the examination and its administration. Integrity of the examination shall be maintained by the employer or certifying agency through appropriate confidentiality of files and, where applicable, proctoring of examinations. Copies of the objective evidence regarding the type and content of the examination shall be retained.

4.2.5 RECORDS

Records of the implementation for indoctrination and training may take the form of attendance sheets, training logs, or personnel training records. Records of indoctrination and training shall include one or more of the following:

- attendance sheets
- training logs
- personnel training records

The employer shall establish and maintain records for indoctrination and training; Auditor and Lead Auditor qualification and requalification; and inspection and test personnel qualification and requalification.

Reference Documents

QP 02-01 Annual Management Review

QP 02-02 Indoctrination and Training

QP 02-03 Lead Auditor Qualification and Certification

QP 02-04 Qualification and Certification of Inspection Personnel