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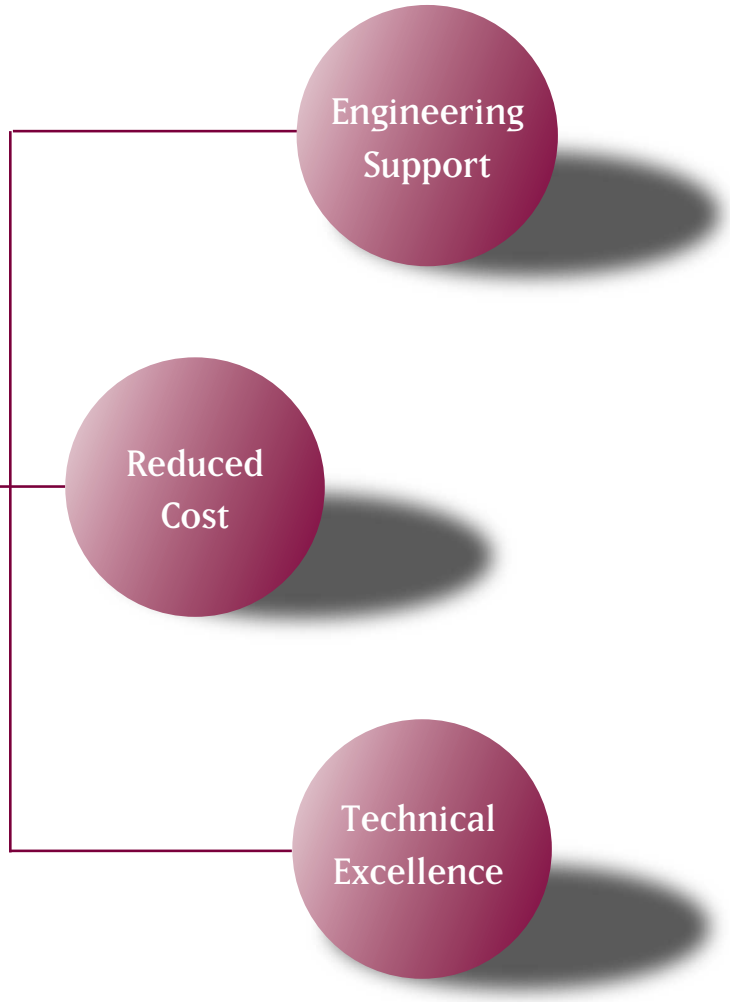
Analysis and Comparison of ANSI/ISO/ASQ Q9001:2000 with 10CFR50, Appendix B

ISO 9000 Gap Analysis

Technical Report



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PLANT SUPPORT ENGINEERING

Analysis and Comparison of ANSI/ISO/ASQ Q9001:2000 with 10CFR50, Appendix B

ISO 9000 Gap Analysis

1007937

Final Report, December 2003

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PRODUCT DESCRIPTION

The purpose of this report is to analyze, through comparison, the quality requirements described in the American National Standards Institute/International Organization for Standardization/ American Society for Quality (ANSI/ISO/ASQ) Q9001:2000 with those of 10 Code of Federal Regulations Part 50 (10CFR50), Appendix B, as those requirements apply to suppliers/manufacturers/ service providers to the nuclear power industry. The objective of this analysis is to determine whether a supplier, satisfactorily complying with the quality requirements of ISO Q9001:2000, also meets the quality requirements of 10CFR50, Appendix B.

Results and Findings

The analysis determined that there is one definitive "gap" between the current requirements of ANSI/ISO/ASQ Q9001:2000 and 10CFR, Appendix B relative to independent inspection. Additionally, the analysis determined that 10CFR50, Appendix B has more explicit requirements regarding the independence of design verification than defined in ANSI/ISO/ASQ Q9001:2000.

Challenges and Objectives

The development of this report was challenging because of the need to analyze the quality requirements from the perspective of a supplier, and not from the perspective of the licensee. In doing so, it became apparent how individual suppliers might interpret and subsequently implement the requirements differently to meet the needs of their customers and to achieve their specific business objectives.

Applications, Values, and Use

In 2001, an EPRI Plant Support Engineering (PSE) task group completed an assessment of key processes associated with the administration and implementation of the International Organization for Standardization's (ISO's) family of standards known as ISO 9000. The task group's observations and conclusions were published in EPRI Report 1003104, *Assessment of the ISO 9000 Quality Management System Registrar Accreditation and Supplier Certification Processes*. This report also included background information to familiarize the user with the ISO 9000 QMS. The results of the assessment were used to develop guidance on how to dedicate commercial-grade items procured from ISO 9000 suppliers within the existing regulatory framework and within the context of the dedication process as described in EPRI Report NP-5652, *Guidelines for the Utilization of Commercial-Grade Items in Nuclear Safety-Related Applications (NCIG-07)*. This guidance was published in EPRI Report 1003105, *Dedicating Commercial-Grade Items Procured from ISO 9000 Suppliers.*

In 2002, the task group began Phase Two of the project—to pursue a broader acceptance of supplier ISO 9000 quality programs when procuring items intended for nuclear safety-related applications. This phase of the project included developing guidance to assist licensees with the programmatic implementation of two proposed procurement options. This guidance is documented in EPRI Report 1002976, *An In-Depth Review of Licensee Procurement Options for Use with ISO 9000 Suppliers,* which draws upon the gap analysis described in the current report.

Also in 2002, the task group studied industry-wide experience with ISO 9000 suppliers and their respective products as well as the development of numerous sector-specific ISO 9000 QMSs. The results of this study have been published in EPRI Report 1008258, *An Overview of Other Industry Experience with the ISO 9000 Quality Management System.*

EPRI Perspective

This report is valuable to plant personnel at several levels. At the management level, it provides valuable information regarding the similarities between ANSI/ISO/ASQ Q9001:2000 and 10CFR50, Appendix B, and how those similarities might affect certain procurement processes. At the quality assurance (QA) (supplier evaluation) level, the report is valuable to auditors because it provides a better understanding of how ISO 9000 requirements apply to an organization in the nuclear supply chain, and how those organizations interpret the requirements to achieve high quality. At the engineering level, the report enhances familiarity with the quality requirements of ISO 9000 certified organizations, and subsequently could improve the specification of quality procurement requirements to those organizations.

Approach

The goal of this report was to provide comprehensive analysis of two major QA programs/ systems employed by many organizations in the nuclear supply chain. To accomplish this goal, each criterion of 10CFR50, Appendix B was evaluated against applicable requirements in ANSI/ISO/ASQ Q9001:2000. Each of the 18 criteria of 10CFR50, Appendix B was broken down into individual sentences or phrases to facilitate analysis and comparison at the most appropriate level of detail. In most cases, there was not a one-for-one or direct correlation between the requirements of ISO Q9001:2000 and 10CFR50, Appendix B. This was primarily due to the different layout, grouping, and organization of quality requirements between the two quality standards. As such, there are often several requirements from ISO Q9001:2000 that apply to, correlate with, and meet the stated requirement of 10CFR50, Appendix B.

Keywords

ISO 9000
Quality assurance (QA)
10CFR50
Procurement
Commercial grade
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INTRODUCTION

1.1 Purpose and Objective

The purpose of this report is to analyze, through comparison, the quality requirements described in the American National Standards Institute/International Organization for Standardization/ American Society for Quality (ANSI/ISO/ASQ) Q9001:2000 with those of 10 Code of Federal Regulations Part 50 (10CFR50), Appendix B, as those requirements apply to suppliers/manufacturers/ service providers to the nuclear power industry. The term "organization" is used to describe the parties (that is, suppliers/manufacturers/service providers) certified to the International Standard.

The objective of this analysis is to determine whether a supplier satisfactorily complying with the quality requirements of ISO Q9001:2000 also meets the quality requirements of 10CFR50, Appendix B. In those cases where the ISO Q9001:2000 requirements do not meet those of 10CFR50, Appendix B, an analysis was required and was performed to determine the extent of the "gap."

1.2 Scope and Method of Analysis

1.2.1 General

Each criterion of 10CFR50, Appendix B was evaluated against applicable requirements described in ANSI/ISO/ASQ Q9001:2000. Each of the eighteen criteria of 10CFR50, Appendix B, has been broken down into individual sentences or phrases to facilitate analysis and comparison at the most appropriate level of detail. In most cases, there was not a one-for-one or direct correlation between the requirements of ISO Q9001:2000 and 10CFR50, Appendix B. This was primarily due to the different layout, grouping, and organization of quality requirements between the two quality standards. As such, there are often several requirements from ISO Q9001:2000 that apply, correlate, and meet the stated requirement of 10CFR50, Appendix B.

In some cases the requirements of ANSI/ISO/ASQ Q9001:2000 are clarified by providing definitions of certain terms as provided in ANSI/ISO/ASQ Q9000:2000, "Quality management systems - Fundamentals and vocabulary."

1.2.2 Basic Premises

1.2.2.1 Licensee Retention of Supplier Control

This analysis assumes that each licensee will retain control of supplier qualification and product acceptance activities to the extent deemed appropriate by each licensee under their 10CFR50, Appendix B quality assurance (QA) program. Each licensee's use of the results of this analysis is optional, and the extent to which these results are incorporated into quality program requirements will vary from licensee to licensee.

The extent to which a licensee takes credit for the results of this analysis will directly impact the means selected for qualifying and accepting products from ISO 9000 certified suppliers. In general, this report anticipates that each licensee will take the appropriate measures to modify/enhance product specification/purchase documents and acceptance activities, as deemed necessary to maintain the level of quality from each supplier and their respective scope of products.

1.2.2.2 Applicable Version of ISO 9000

This analysis does not include comparisons of previous versions of ISO 9000 with 10CFR50, Appendix B. As such, the analysis applies only to programs of organizations who have transitioned from the 1994 version to ISO 9000:2000.

1.2.2.3 Comparison of Supplier Quality Programs and Systems

As shown on Figure 1-1, the analysis compares the requirements of ANSI/ISO/ASQ Q9001:2000 with those of 10CFR50, Appendix B as they would be implemented by a supplier. It does not compare the requirements of ANSI/ISO/ASQ Q9001:2000 with those of 10CFR50, Appendix B as they would be implemented by a licensee. The general intent and purpose of this task does not propose the re-licensing of nuclear power plants by replacing 10CFR50, Appendix B, with the ISO 9000 Quality Management System (QMS) at the licensee level.

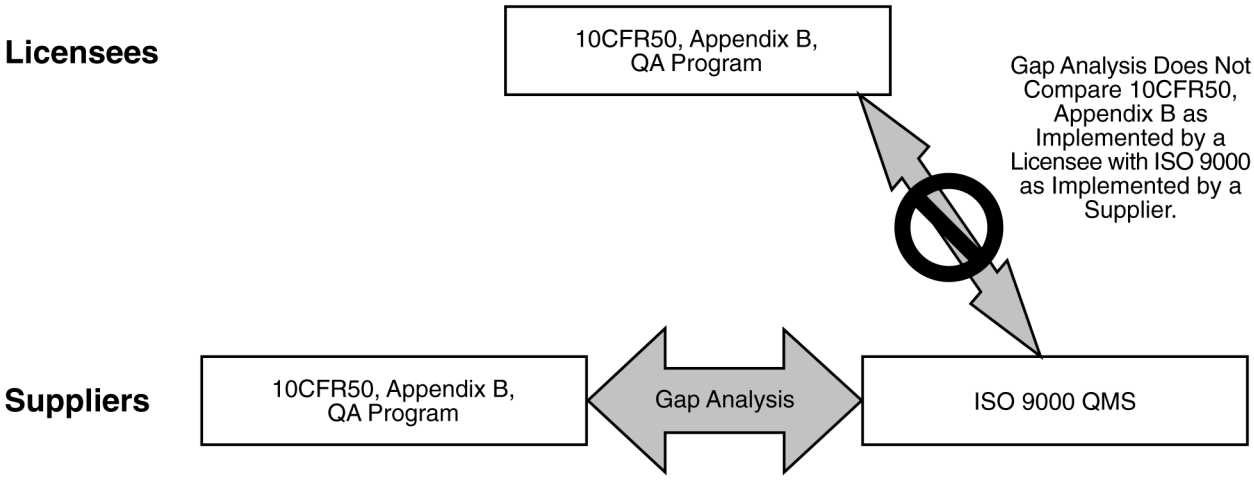

Figure 1-1
Comparison of Supplier Quality Programs and Systems

1.2.2.4 Level of Comparison of Supplier Quality Programs and Systems

As depicted in Figure 1-2, the methodology used to perform this comparison of quality requirements does not attempt to interject the requirements, intent, or merit of any implementing standards (for example, ANSI N45.2, ISO 10011) or implementation tools (that is, quality program documents, licensee-specific procedures, and the like) into the analysis.

The primary reason why analysis is limited to the quality program/system level is because implementing documents vary significantly among suppliers based on the type and scope of items being supplied. This wide variation of implementing documents is evident not only between ISO 9000 certified suppliers and 10CFR50, Appendix B suppliers, but among suppliers in either major category.

For example, some nuclear suppliers have structured a quality program around ANSI N45.2, but have done so as a result of a business decision and not as a means to comply with a regulatory commitment. Other nuclear suppliers have simply adapted the 18 quality criteria of 10CFR50, Appendix B to fit their respective business model and product lines. Each quality program will result in different implementing tools and procedures and, as such, there is no effective means for comparing these requirements with those employed by ISO 9000 certified suppliers.

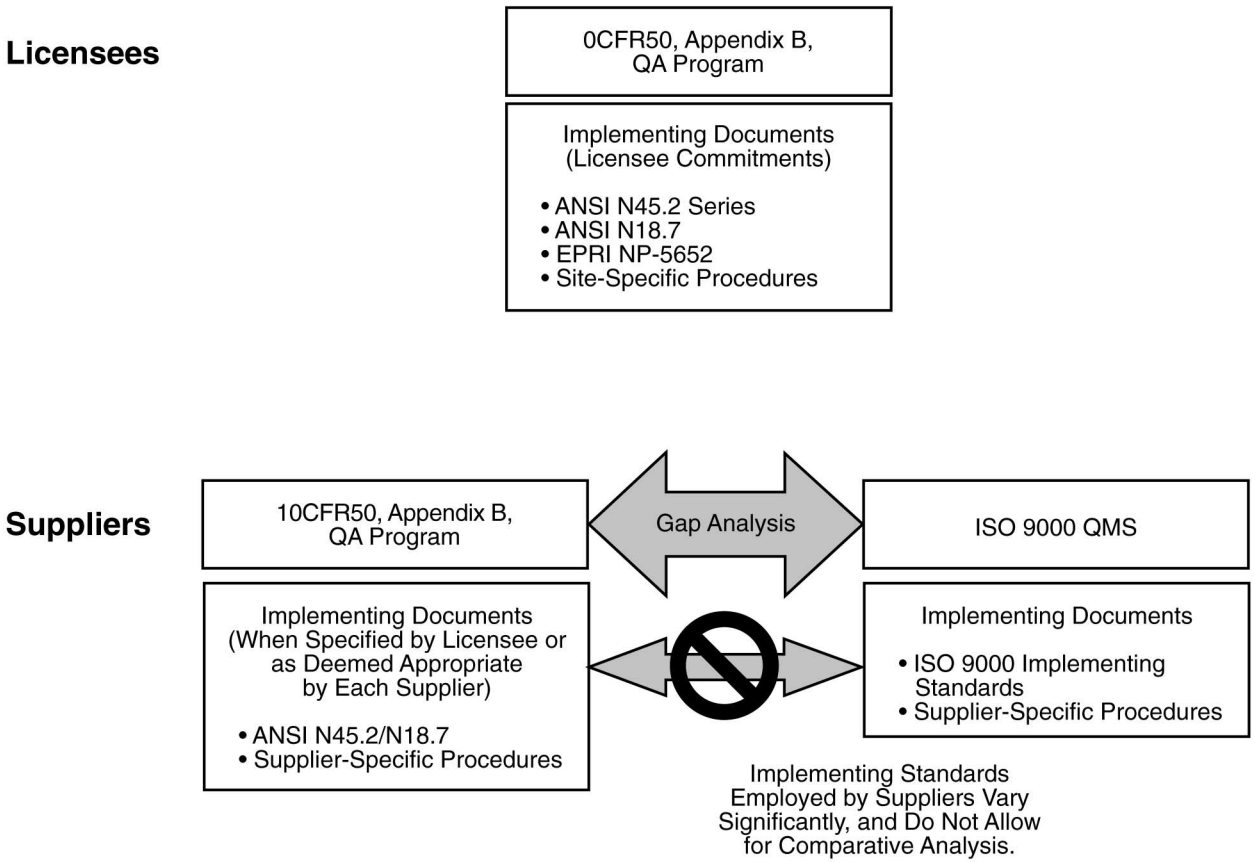

Figure 1-2
Level of Comparison of Supplier Quality Programs and Systems

1.2.2.5 Comparison of Implementing Procedures

This analysis does not speculate on the extent to which an organization effectively implements their QA program/system requirements through their respective procedures. As such, this analysis does not attempt to compare the resulting quality of products or services provided under the ISO 9000 QMS with those of 10CFR50, Appendix B.

The user of this report should recognize that implementation practices can vary significantly from one supplier to the next, although both could be committed to the same QA program/system requirements. As such, this report does not advocate any generic change to how the licensee is currently ensuring proper implementation of a given supplier's QA program/system.

1.2.2.6 Types of Gaps Identified and Analyzed

This analysis does not examine the gaps between 10CFR50, Appendix B, and ANSI/ISO/ASQ Q9001:2000 in those instances where the ISO 9000 requirements exceed those of 10CFR50, Appendix B. Although there were instances where this was the case, further analysis of these gaps was not deemed relevant to the purpose of this task, and further discussion of these gaps is not provided in this report.

1.2.3 Tools Used to Perform the Analysis

The most current version of the Nuclear Utility Procurement Issues Committee (NUPIC) checklist was used as a tool during the analysis of the quality requirements. The NUPIC checklist is employed to perform joint audits of 10CFR50, Appendix B suppliers, and for the purposes of this task, it provided a means for understanding how the requirements of 10CFR50, Appendix B are interpreted and applied to a nuclear supplier in today's procurement environment.

1.3 General Comparison of the Quality Assurance Requirements

1.3.1 Overview of Quality Assurance Requirements

Table 1-1 provides an overview of the requirements inherent to the two QA systems. 10CFR50, Appendix B consists of 18 criteria comprising approximately 69 specific quality requirements. ANSI/ISO/ASQ Q9001:2000 consists of 4 general areas of quality comprising approximately 89 specific quality requirements.

Table 1-1
Overview of the Requirements Inherent to 10CFR50, Appendix B, and ANSI/ISO/ASQ Q9001:2000

10CFR50, Appendix B	ANSI/ISO/ASQ Q9001:2000
18 criteria	4 general areas of quality
69 specific quality requirements	89 specific quality requirements

1.3.2 Fundamental Differences Between 10CFR50, Appendix B, and ANSI/ISO/ASQ Q9001:2000

1.3.2.1 Primary Users of the Quality Assurance Requirements

10CFR50, Appendix B was primarily developed as a QA program for licensees (that is, applicants of nuclear power plant licenses) approximately 30 years ago. The wording of the 18 quality criteria most directly applies to a nuclear power plant licensee/operator and not a manufacturer/supplier. However, licensees have and continue to specify this program to certain suppliers and manufacturers on a regular basis. Many suppliers through the years have developed

QA programs that meet the applicable requirements of 10CFR50, Appendix B for their products and type of business. Through various means, licensees gain assurance that the applicable 10CFR50, Appendix B requirements are effectively implemented by each supplier to the extent that they apply to their product/service line of business.

ISO 9000 was primarily developed as a QMS for suppliers/manufacturers of products and services. Development of the ISO QMS began in the 1980s; the ISO QMS has been revised/updated on a regular basis. The wording of the quality criteria in ISO 9000 most directly applies to organizations providing goods and services. Through various means, both licensees and the organization's registrar can gain assurance that the applicable ISO 9000 quality requirements are effectively implemented by each supplier to the extent that they apply to their product/service line of business.

1.3.2.2 Scope of Items/Products Controlled Under Each Quality System

Another primary difference between 10CFR50, Appendix B and ANSI/ISO/ASQ Q9001:2000 is how the two quality systems define the scope of items/products controlled under each respective system. Inherent in 10CFR50, Appendix B is the requirement for the applicant/licensee to determine which structures, systems, and components (SSC) must be controlled under the requirements of the program. The fundamental basis for inclusion of a SSC under 10CFR50, Appendix B is its safety function. 10CFR50, Appendix B applies to those SSCs determined to have a safety-related function by each licensee.

This inherent requirement found in 10CFR50, Appendix B for each licensee to define the scope of applicable SSCs is not characteristic of ANSI/ISO/ASQ Q9001:2000. The organization certified to ISO 9000 applies quality measures as necessitated by each customer's specified requirements.

Thus, in summary, the applicability of 10CFR50, Appendix B is primarily determined upon each licensee's classification of their SSCs, based on the safety function of each item. The applicability of ANSI/ISO/ASQ Q9001:2000 is primarily determined based on each customer's specified requirements.

1.3.2.3 Evolving Quality Principles and Philosophy

The requirements inherent to 10CFR50, Appendix B are indicative of the quality philosophy that was prevalent at the time the requirements were written (1970). At that time, inspection and independent review/verification (or, in a broader sense, "error detection"), were viewed as the most effective ways to ensure quality of items and processes. Given that the primary users of the CFR requirements were the applicants of nuclear power plant licenses embarking on the design and construction of nuclear facilities, heavy reliance on independent inspection/verification of items and processes was appropriate at the time. As such, Criteria I, II, III, VII, X, XIII, XIV, and XVII of 10CFR50, Appendix B all include requirements relating to the inspection of processes and items; and Criteria III and X include requirements relating to independent verification.

Beginning in the mid-1980s, the total quality management (TQM) philosophy began to gain acceptance in the United States, which in part relies on "error prevention" in addition to "error detection." The current requirements of ANSI/ISO/ASQ Q9001:2000 reflect this philosophy and do not rely solely on independent inspection/verification of product or processes to achieve quality. Instead, the requirements reflect individual responsibility for quality, establishing performance measures for both individuals and the processes they work to, and methods to ensure the processes are controlled.

1.3.2.4 Applicability of 10CFR50, Appendix B, and ANSI/ISO/ASQ Q9001:2000

10CFR50, Appendix B is applicable only to the nuclear power industry. As such, the areas of concern addressed, and the language used to address these concerns, is unique to the nuclear industry in general, and more specifically to licensees who designed/constructed nuclear power plants.

Although ANSI/ISO/ASQ Q9001:2000 envelopes the same areas of concern as does 10CFR50, Appendix B, they are addressed with more general language. This is the case because ANSI/ISO/ASQ Q9001:2000 is not specific to any one industry sector, but can be implemented by a wide array of organizations. This impacts the QMS in two ways. It allows each organization some latitude in determining appropriate controls when those controls are not specifically defined. But likewise, it puts additional responsibility on the customer to specify controls when they are not specifically defined in the standard.

1.3.3 Application of QA Requirements at the Supplier/Manufacturer Level

The comparison of the two QA programs was performed in terms of how each program would apply to a supplier/manufacturer of products/services to the nuclear power industry. This approach takes into account that each supplier/manufacturer is responsible for demonstrating to their respective customers how they meet the requirements of either 10CFR50, Appendix B and/or ANSI/ISO/ASQ Q9001:2000.

1.4 Results

The detailed results of the analysis are provided in Section 3 of this report. The section is divided into the 18 criteria and further broken down into the level of detail most appropriate for performing the comparison of requirements. For each sub-criteria examined, applicable requirements of ANSI/ISO/ASQ Q9001:2000 are noted in full. Following each comparison is an explanation of the requirements, supporting definitions, and how the ANSI/ISO/ASQ Q9001:2000 requirements either satisfy or do not satisfy the corresponding requirement(s) of 10CFR50, Appendix B.

The analysis determined that there is one definitive "gap" between the current requirements of ANSI/ISO/ASQ Q9001:2000 and 10CFR50, Appendix B, which will be described in more detail in Section 1.5 of this report. Additionally, the analysis determined one other area that could or could not be a definitive gap between the requirements, but is presented for discussion and licensee interpretation.

This does not mean that an ISO 9000 certified supplier meets all of the other requirements of 10CFR50, Appendix B verbatim. In practice, not all suppliers are required to implement every element of 10CFR50, Appendix B. For example, a supplier that has been contracted to perform materials testing will not have the same scope of quality requirements as a full scope architect-engineering company. 10CFR50, Appendix B provides latitude to the licensee when specifying quality requirements as stated in the following excerpt from Criterion IV:

> "To the extent necessary, procurement documents shall require … a quality assurance program consistent with the pertinent provisions of this appendix."

1.4.1 Gap – Need for Independent Inspectors

As noted earlier in this section, the analysis determined that there is one definitive "gap" between the current requirements of ANSI/ISO/ASQ Q9001:2000 and 10CFR50, Appendix B. One of the requirements of Criterion X of 10CFR50, Appendix B (Inspection), states the following:

> "such inspection shall be performed by individuals other than those who performed the activity being inspected."

This requirement is not specifically addressed in the requirements of ANSI/ISO/ASQ Q9001:2000.

1.4.2 Gap – Independence of Design Verification

One of the requirements of Criterion III of 10CFR50, Appendix B (Design Control), states the following:

> "The design control measures shall provide for verifying or checking the adequacy of design, such as by the performance of design reviews, by the use of alternate or simplified calculational methods, or by the performance of a suitable testing program.
>
> The verifying or checking process **shall be performed by individuals or groups other than those who performed the original design**, but who may be from the same organization." (**emphasis added**)

Although the requirement for design verification is adequately defined in ANSI/ISO/ASQ Q9001:2000, the requirements regarding the independence of the verifier(s) are less definitive and not as explicit.

2
DEFINITIONS AND TERMINOLOGY

2.1 Key Definitions

The following definitions are provided because they are used in Section 3 of this report to clarify certain requirements from ANSI/ISO/ASQ Q9001:2000.

Audit - systematic, independent, and documented process for obtaining audit evidence and evaluating it objectively to determine the extent to which audit criteria are fulfilled.

Characteristic - a distinguishing feature.

Note 1: A characteristic can be inherent or assigned.

Note 2: A characteristic can be qualitative or quantitative.

Note 3: There are various classes of characteristic, such as the following:

- Physical (for example, mechanical, electrical, chemical, or biological characteristics)
- Sensory (for example, related to smell, touch, taste, sight, or hearing)
- Behavioral (for example, courtesy, honesty, or veracity)
- Temporal (for example, punctuality, reliability, or availability)
- Ergonomic (for example, physiological characteristic, or related to human safety)
- Functional (for example, maximum speed of an aircraft)

Design and Development - a set of processes that transforms requirements into specified characteristics or into the specification of a product or system.

Inspection - conformity evaluation by observation and judgment accompanied as appropriate by measurement, testing or gauging.

Organization - a group of people and facilities with an arrangement of responsibilities, authorities, and relationships (for example, company, corporation, firm, enterprise, institution, charity, sole trader, association, or parts or combination thereof).

Note 1: The arrangement is generally orderly.

Note 2: An organization can be public or private.

Note 3: This definition is valid for the purposes of the QMS standards.

User's Note: For the purposes of this comparative analysis, the term "organization" refers to the organization certified to ISO 9000 that is furnishing products/services to the nuclear licensee.

Quality - the degree to which a set of inherent characteristics fulfills requirements.

Validation - confirmation, through the provision of objective evidence, that the requirements for a specific intended use or application have been fulfilled.

Note 1: The term "validated" is used to designate the corresponding status.

Note 2: The use conditions for validation can be real or simulated.

Verification - confirmation, through the provision of objective evidence, that specified requirements have been fulfilled.

Note 1: The term "verified" is used to designate the corresponding status.

Note 2: Confirmation can comprise activities such as:

- Performing alternative calculations
- Comparing a new design specification with a similar proven design specification
- Undertaking tests and demonstrations
- Reviewing documents prior to issue

2.2 Terminology Used in this Comparative Analysis

As previously noted, 10CFR50, Appendix B was not necessarily developed for implementation by suppliers, whereas the ISO 9000 QMS was developed for a wide range of organizations, including suppliers of products/services to nuclear licensees. To assist the user of this comparative analysis, the following table is provided to clarify terminology and to put the analysis in the proper context.

Table 2-1
Terminology Used in This Comparative Analysis

10CFR50, Appendix B		ANSI/ISO/ASQ Q9001-2000	
Verbatim Terminology	**Refers to:**	**Verbatim Terminology**	**Refers to:**
Applicant	A 10CFR50, Appendix B, supplier	Organization	An ISO 9000 certified supplier
Contractor or sub-contractor	A sub-supplier of the 10CFR50, Appendix B, supplier	Supplier	A sub-supplier of the ISO 9000 certified supplier

Note: The reference indicates how the corresponding terminology is used within the context of the comparative analysis of ISO 9000 requirements with 10CFR50, Appendix B requirements *as implemented by suppliers of products/services* to nuclear licensees.

3
COMPARISON AND ANALYSIS

As noted in Section 1 of this report, the comparison described in this report is between the requirements of 10CFR50, Appendix B, *as implemented by a supplier,* and the requirements of ANSI/ISO/ASQ Q9001:2000 *as implemented by a supplier*. Therefore, the terminology referring to the licensee/applicant actually applies to the supplier/organization within the context of this analysis.

Table 3-1A
10CFR50, Appendix B, Criterion I – Organization

10CFR50, Appendix B, Criterion I	ISO Q9001:2000 - 5.1 and 5.3 and 5.4.1 and 4.1
The applicant[1] shall be responsible for the establishment and execution of the quality assurance program. The applicant 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 therefor. [1] While the term "applicant" is used in these criteria, the requirements are, of course, applicable after such a person has received a license to construct and operate a nuclear powerplant or a fuel reprocessing plant. These criteria will also be used for guidance in evaluating the adequacy of quality assurance programs in use by holders of construction permits and operating licenses.	5.1 Management commitment Top management shall provide evidence of its commitment to the development and implementation of the quality management system and continually improving its effectiveness by a) communicating to the organization the importance of meeting customer as well as statutory and regulatory requirements, b) establishing the quality policy, c) ensuring that quality objectives are established, d) conducting management reviews, and e) ensuring the availability of resources. 5.3 Quality policy Top management shall ensure that the quality policy a) is appropriate to the purpose of the organization b) includes a commitment to comply with requirements and continually improve the effectiveness of the quality management system, c) provides a framework for establishing and reviewing quality objectives, d) is communicated and understood within the organization, and e) is reviewed for continuing suitability.

Table 3-1A (cont.)
10CFR50, Appendix B, Criterion I – Organization

	5.4.1 Quality objectives Top management shall ensure that quality objectives, including those needed to meet requirements for product (see 7.1a), are established at relevant functions and levels within the organization. The quality objectives shall be measurable and consistent with the quality policy. 4.1 Quality management system – General requirements The organization shall establish, document, implement and maintain a quality management system and continually improve its effectiveness in accordance with the requirements of this International Standard. The organization shall a) identify the processes needed for the quality management system and their application throughout the organization (see 1.2) b) determine the sequence of and interaction of these processes, c) determine criteria and methods needed to ensure that both the operation and control of these processes are effective, d) ensure the availability of resources and information necessary to support the operation and monitoring of these processes, e) monitor, measure and analyze these processes, f) implement actions necessary to achieve planned results and continual improvement of these processes. These processes shall be managed by the organization in accordance with the requirements of this International Standard. Where an organization chooses to outsource any process that affects product conformity with requirements, the organization shall ensure control over such processes. Control of such outsourced processes shall be identified within the quality management system. Note: Processes needed for the quality management system referred to above should include processes for management activities, provision of resources, product realization and measurement.

Fundamental Objective of the Quality Element:

Assigns responsibility and execution of the QA program with the organization (that is, the supplier in the context of this comparative analysis) but allows for delegation of its execution to others.

ISO Q9001:2000 Provisions:

Criterion 5.1 requires the organization's top management to provide evidence of its commitment to the development and implementation of the QMS and continually improving its effectiveness by:

a) Communicating to the organization the importance of meeting customer as well as statutory and regulatory requirements
b) Establishing the quality policy
c) Ensuring that quality objectives are established
d) Conducting management reviews
e) Ensuring the availability of resources

Criterion 5.3 requires the organization's top management to ensure that the quality policy:

a) Is appropriate to the purpose of the organization
b) Includes a commitment to comply with requirements and continually improve the effectiveness of the quality management system
c) Provides a framework for establishing and reviewing quality objectives
d) Is communicated and understood within the organization
e) Is reviewed for continuing suitability

Criteria 5.4.1 requires the organization's top management to ensure that quality objectives, including those needed to meet requirements for product realization, are established at relevant functions and levels within the organization, and that quality objectives are measurable and consistent with the quality policy.

Criterion 4.1 requires that when the organization opts to outsource any process that affects product conformity with requirements, the organization must ensure control over such processes. Control of such outsourced processes must be identified within the QMS.

Result:

The requirements of ANSI/ISO/ASQ Q2001:9000 meet the fundamental requirements of this sub-criterion of 10CFR50, Appendix B, to the extent the quality requirements apply to an organization furnishing products and services to the nuclear power industry.

Table 3-1B
10CFR50, Appendix B, Criterion I – Organization

10CFR50, Appendix B, Criterion I	ISO Q9001:2000 – 5.5.1
The 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 in writing. These activities include both the performing functions of attaining quality objectives and the quality assurance functions. The quality assurance functions are those of (a) assuring that an appropriate quality assurance program is established and effectively executed and (b) verifying, such as by checking, auditing, and inspection, that activities affecting the safety-related functions have been correctly performed.	5.5.1 Responsibility and authority Top management shall ensure that responsibilities and authorities are defined and communicated within the organization.

Fundamental Objective of the Quality Element:

Requires the identification and documentation of persons/organizations affecting safety-related functions.

ISO Q9001:2000 Provisions:

The requirements in 10CFR50, Appendix B, that define the scope and applicability of the requirements based upon the safety functions of certain SSCs do not apply to an ISO 9000 certified organization furnishing products/services to the nuclear power industry.

The applicability of the 10CFR50, Appendix B, QA requirements is dependent upon the safety classification of SSCs. Those SSCs that have been classified as safety-related must be controlled under the requirements of 10CFR50, Appendix B, and those that are not classified as safety-related need not be controlled under the requirements of 10CFR50, Appendix B.

Suppliers generally do not perform a safety-classification of SSCs because, in most cases, they do not know the end use application(s) of the item.

The requirements of ANSI/ISO/ASQ Q2001:9000 require the organization to define quality in terms of consistently meeting customer expectations. Criterion 5.5.1 requires the organization to define and communicate responsibilities and authorities to the extent that these functions affect the quality of products/services rendered.

Result:

The requirements of ANSI/ISO/ASQ Q2001:9000 meet the fundamental requirements of this sub-criterion of 10CFR50, Appendix B, to the extent the quality requirements apply to an organization furnishing products and services to the nuclear power industry.

Table 3-1C
10CFR50, Appendix B, Criterion I – Organization

10CFR50, Appendix B, Criterion I	ISO Q9001:2000 – 5.5.2 and 5.1 and 5.3 and 5.4.1 and 5.5.1 and 6.1 and 6.2.1 and 5.6.1 and 8.5.1
The persons and organizations performing quality assurance functions shall have sufficient authority and organizational freedom to identify quality problems; to initiate, recommend, or provide solutions; and to verify implementation of solutions. 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 appendix are being performed shall have direct access to such levels of management as may be necessary to perform this function.	5.5.2 Management representative Top management shall appoint a member of management who, irrespective of other responsibilities, shall have responsibility and authority that includes a) ensuring that processes needed for the quality management system are established, implemented and maintained, b) reporting to top management on the performance of the quality management system and any need for improvement, and c) ensuring the promotion of awareness of customer requirements throughout the organization. Note: The responsibility of a management representative can include liaison with external parties on matters relating to the quality management system. 5.1 Management commitment Top management shall provide evidence of its commitment to the development and implementation of the quality management system and continually improving its effectiveness by a) communicating to the organization the importance of meeting customer as well as statutory and regulatory requirements, b) establishing the quality policy, c) ensuring that quality objectives are established, d) conducting management reviews, and e) ensuring the availability of resources. 5.3 Quality policy Top management shall ensure that the quality policy a) is appropriate to the purpose of the organization b) includes a commitment to comply with requirements and continually improve the effectiveness of the quality management system, c) provides a framework for establishing and reviewing quality objectives, d) is communicated and understood within the organization, and e) is reviewed for continuing suitability.

Table 3-1C (cont.)
10CFR50, Appendix B, Criterion I – Organization

	5.4.1 Quality objectives Top management shall ensure that quality objectives, including those needed to meet requirements for product (see 7.1a), are established at relevant functions and levels within the organization. The quality objectives shall be measurable and consistent with the quality policy. 5.5.1 Responsibility and authority Top management shall ensure that responsibilities and authorities are defined and communicated within the organization. 6.1 Provision of resources The organization shall determine and provide the resources needed a) to implement and maintain the quality management system and continually improve its effectiveness, and b) to enhance customer satisfaction by meeting customer requirements. 6.2.1 Human resources – general Personnel performing work affecting product quality shall be competent on the basis of appropriate education, training, skills and experience. 5.6.1 Management review – general Top management shall review the organization's quality management system, at planned intervals, to ensure its continuing suitability, adequacy and effectiveness. This review shall include assessing opportunities for improvement and the need for changes to the quality management system, including the quality policy and quality objectives. 8.5.1 Continual improvement The organization shall continually improve the effectiveness of the quality management system through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions and management review.

Fundamental Objective of the Quality Element:

Addresses the need for persons and organizations performing QA functions to have the appropriate authority and organizational freedom to identify problems; initiate, recommend or provide solutions; and verify implementation.

ISO Q9001:2000 Provisions:

Criterion 5.5.2 requires that the organization's top management appoint a member of management who, irrespective of other responsibilities, has responsibility and authority that includes:

a) Ensuring that processes needed for the QMS are established, implemented and maintained
b) Reporting to top management on the performance of the QMS and any need for improvement
c) Ensuring the promotion of awareness of customer requirements throughout the organization

The responsibility of a management representative can include liaison with external parties on matters relating to the QMS.

The other Criteria that are noted all support this objective and provide an overall level of assurance that appropriate individuals can identify quality problems; initiate, recommend, or provide solutions; and verify implementation of those solutions.

Result:

The requirements of ANSI/ISO/ASQ Q2001:9000 meet the fundamental requirements of this sub-criterion of 10CFR50, Appendix B to the extent the quality requirements apply to an organization furnishing products and services to the nuclear power industry.

Table 3-2A
10CFR50, Appendix B, Criterion II – Quality Assurance Program

10CFR50, Appendix B, Criterion II	ISO Q9001:2000 – 4.1 and 4.2.2 and 8.2.1
The applicant shall establish at the earliest practicable time, consistent with the schedule for accomplishing the activities, a quality assurance program which complies with the requirements of this appendix. 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.	4.1 Quality management system – General requirements The organization shall establish, document, implement and maintain a quality management system and continually improve its effectiveness in accordance with the requirements of this International Standard. The organization shall a) identify the processes needed for the quality management system and their application throughout the organization (see 1.2) b) determine the sequence of and interaction of these processes, c) determine criteria and methods needed to ensure that both the operation and control of these processes are effective, d) ensure the availability of resources and information necessary to support the operation and monitoring of these processes, e) monitor, measure and analyze these processes, f) implement actions necessary to achieve planned results and continual improvement of these processes. These processes shall be managed by the organization in accordance with the requirements of this International Standard. Where an organization chooses to outsource any process that affects product conformity with requirements, the organization shall ensure control over such processes. Control of such outsourced processes shall be identified within the quality management system. Note: Processes needed for the quality management system referred to above should include processes for management activities, provision of resources, product realization and measurement. 4.2.2 Quality manual The organization shall establish and maintain a quality manual that includes a) the scope of the quality management system, including details of and justification for any exclusions (see 1.2) b) the documented procedures established for the quality management system, or reference to them, and c) a description of the interaction between the processes of the quality management system.

Table 3-2A (cont.)
10CFR50, Appendix B, Criterion II – Quality Assurance Program

	8.2.1 Customer satisfaction As one of the measurements of the performance of the quality management system, the organization shall monitor information relating to customer perception as to whether the organization has met customer requirements. The methods for obtaining and using this information shall be determined.

Fundamental Objective of the Quality Element:

To establish a QA program (that complies with the requirements of this appendix), documented by written policies, procedures, or instructions, and implemented in accordance with those policies, procedures, or instructions.

ISO Q9001:2000 Provisions:

Criterion 4.1 requires that the organization establish, document, implement, and maintain a QMS and continually improve its effectiveness in accordance with the requirements of ISO Q9001:2000.

Criterion 4.2.2 further requires the organization to establish and maintain a quality manual that must describe the scope of the QMS (including details of and justification for any exclusions), documented procedures established for the QMS (or reference to them), and a description of the interaction between the processes of the QMS.

Criterion 8.2.1 requires the organization to monitor information relating to customer perception as to whether the organization has met customer requirements. This is established as one of the measurements of the performance of the QMS. The methods for obtaining and using this information must also be determined.

Result:

The requirements of ANSI/ISO/ASQ Q2001:9000 meet the fundamental requirements of this sub-criterion of 10CFR50, Appendix B, to the extent the quality requirements apply to an organization furnishing products and services to the nuclear power industry.

Table 3-2B
10CFR50, Appendix B, Criterion II – Quality Assurance Program

10CFR50, Appendix B, Criterion II	ISO Q9001:2000 – 5.5.1 and 6.1 and 6.2.1 and 7.2.1 and 8.2.4
The applicant shall identify the structures, systems, and components to be covered by the quality assurance program and the major organizations participating in the program, together with the designated functions of these organizations.	5.5.1 Responsibility and authority Top management shall ensure that responsibilities and authorities are defined and communicated within the organization. 6.1 Provision of resources The organization shall determine and provide the resources needed a) to implement and maintain the quality management system and continually improve its effectiveness, and b) to enhance customer satisfaction by meeting customer requirements. 6.2.1 Human resources – general Personnel performing work affecting product quality shall be competent on the basis of appropriate education, training, skills and experience. 7.2.1 Determination of requirements related to the product The organization shall determine a) requirements specified by the customer, including the requirements for delivery and post-delivery activities, b) requirements not stated by the customer but necessary for specified or intended use, where known, c) statutory and regulatory requirements related to the product, and d) any additional requirements determined by the organization. 8.2.4 Monitoring and measurement of product The organization shall monitor and measure the characteristics of the product to verify that product requirements have been met. This shall be carried out at appropriate stages of the product realization process in accordance with the planned arrangements. (see 7.1). Evidence of conformity with the acceptance criteria shall be maintained. Records shall indicate the person(s) authorizing release of product (see 4.2.4). Product release and service delivery shall not proceed until the planned arrangements (see 7.1) have been satisfactorily completed, unless otherwise approved by a relevant authority and, where applicable, by the customer.

Fundamental Objective of the Quality Element:

To define the scope of the program in terms of SSCs; and participating organizations and their functions.

ISO Q9001:2000 Provisions:

As discussed with regard to Criterion I, the requirements in 10CFR50, Appendix B, that define the scope and applicability of the requirements based upon the safety functions of certain SSCs do not apply to an ISO 9000 certified organization furnishing products/services to the nuclear power industry.

The applicability of the 10CFR50, Appendix B, QA requirements is dependent upon the safety classification of SSCs. Those SSCs that have been classified as safety-related must be controlled under the requirements of 10CFR50, Appendix B, and those that are not classified as safety-related need not be controlled under the requirements of 10CFR50, Appendix B.

Suppliers generally do not perform a safety-classification of SSCs because, in most cases, they do not know the end use application(s) of the item.

The requirements of ANSI/ISO/ASQ Q2001:9000 require the organization to define quality in terms of consistently meeting customer expectations. Criterion 5.5.1 requires the organization to define and communicate responsibilities and authorities to the extent that these functions affect the quality of products/services rendered.

Criteria 6.1 and 6.2.1 also require the organization to clearly provide appropriate resources and to demonstrate the competency of those resources.

Criterion 7.2.1 requires the organization to determine the following:

a) Requirements specified by the customer, including the requirements for delivery and post-delivery activities
b) Requirements not stated by the customer but necessary for specified or intended use, where known
c) Statutory and regulatory requirements related to the product
d) Any additional requirements determined by the organization

Criterion 8.2.4 then requires the organization to monitor and measure the characteristics of the product to verify that product requirements are met.

Comparison and Analysis

Result:

The requirements of ANSI/ISO/ASQ Q2001:9000 meet the fundamental requirements of this sub-criterion of 10CFR50, Appendix B, to the extent the quality requirements apply to an organization furnishing products and services to the nuclear power industry.

Table 3-2C
10CFR50, Appendix B, Criterion II – Quality Assurance Program

10CFR50, Appendix B, Criterion II	ISO Q9001:2000 – 5.4.2 and 7.1
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.	5.4.2 Quality management system planning Top management shall ensure that a) the planning of the quality management system is carried out in order to meet the requirements given in 4.1, as well as the quality objectives, and b) the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented. 7.1 Planning of product realization The organization shall plan and develop the processes needed for product realization. Planning of product realization shall be consistent with the requirements of the other processes of the quality management system (see 4.1) In planning product realization, the organization shall determine the following, as appropriate: a) quality objectives and requirements for the product; b) the need to establish processes, documents, and provide resources specific to the product; c) required verification, validation, monitoring, inspection and test activities specific to the product and the criteria for product acceptance; d) records needed to provide evidence that the realization processes and resulting product meet requirements (see 4.2.4) The output of this planning shall be in a form suitable for the organization's method of operations. Note 1: A document specifying the processes of the quality management system (including the product realization processes) and the resources to be applied to a specific product, project or contract, can be referred to as a quality plan. Note 2: The organization may also apply the requirements given in 7.3 to the development of product realization processes.

Fundamental Objective of the Quality Element:

To exercise control over activities affecting quality of certain SSCs, to the degree consistent with each item's importance to safety.

ISO Q9001:2000 Provisions:

As already noted, the requirements in 10CFR50, Appendix B, that define the scope and applicability of the requirements based upon the safety functions of certain SSCs do not apply to an ISO 9000 certified organization furnishing products/services to the nuclear power industry.

The applicability of the 10CFR50, Appendix B, QA requirements is dependent upon the safety classification of SSCs. Those SSCs that have been classified as safety-related must be controlled under the requirements of 10CFR50, Appendix B, and those that are not classified as safety-related need not be controlled under the requirements of 10CFR50, Appendix B.

Suppliers generally do not perform a safety-classification of SSCs because, in most cases, they do not know the end use application(s) of the item.

The requirements of ANSI/ISO/ASQ Q2001:9000 require the organization to define quality in terms of consistently meeting customer expectations.

Criterion 5.4.2 requires the organization's top management to ensure proper controls exist through the planning process to ensure the QMS is implemented to meet the requirements given in 4.1, as well as the quality objectives, and the integrity of the QMS is maintained when changes to the QMS are planned and implemented.

The degree to which the controls are exercised is not necessarily a function of the item's importance to safety, but rather in a broader sense its overall performance of design functions and its conformity to design requirements. This is captured in the concept of product realization.

Criterion 7.1 requires that the organization plan and develop the processes needed for product realization. Planning of product realization must be consistent with the requirements of the other processes of the QMS described in Criterion 4.1.

In planning product realization, the organization must determine the following, as appropriate:

a) Quality objectives and requirements for the product
b) The need to establish processes, documents, and provide resources specific to the product
c) Required verification, validation, monitoring, inspection, and test activities specific to the product and the criteria for product acceptance
d) Records needed to provide evidence that the realization processes and resulting product meet requirements (see 4.2.4)

Result:

The requirements of ANSI/ISO/ASQ Q2001:9000 meet the fundamental requirements of this sub-criterion of 10CFR50, Appendix B, to the extent the quality requirements apply to an organization furnishing products and services to the nuclear power industry.

Table 3-2D
10CFR50, Appendix B, Criterion II – Quality Assurance Program

10CFR50, Appendix B, Criterion II	ISO Q9001:2000 – 6.3 and 6.4 and 7.5.1 and 7.5.2
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 cleanness; and assurance that all prerequisites for the given activity have been satisfied.	6.3 Infrastructure The organization shall determine, provide and maintain the infrastructure needed to achieve conformity to product requirements. Infrastructure includes, as applicable a) buildings, workspace and associated utilities, b) process equipment (both hardware and software), and c) supporting services (such as transport or communication) 6.4 Work environment The organization shall determine and manage the work environment needed to achieve conformity to product requirements. 7.5.1 Control of production and service provision The organization shall plan and carry out production and service provision under controlled conditions. Controlled conditions shall include, as applicable a) the availability of information that describes the characteristics of the product, b) the availability of work instructions, as necessary, c) the use of suitable equipment, d) the availability and use of monitoring and measuring devices, e) the implementation of monitoring and measurement, and f) the implementation of release, delivery and post-delivery activities. 7.5.2 Validation of processes for production and service provision The organization shall validate any processes for production and service provision where the resulting output cannot be verified by subsequent monitoring or measurement. This includes any processes where deficiencies become apparent only after the product is in use of the service has been delivered. Validation shall demonstrate the ability of these processes to achieve planned results.

Table 3-2D (cont.)
10CFR50, Appendix B, Criterion II – Quality Assurance Program

	The organization shall establish arrangements for these processes including, as applicable a) defined criteria for review and approval of the processes, b) approval of equipment and qualification of personnel, c) use of specific methods and procedures, d) requirements for records, (see 4.2.4) e) revalidation.

Fundamental Objective of the Quality Element:

To ensure activities affecting quality shall be accomplished under suitably controlled conditions. Examples constituting controlled conditions are provided and may include the use of appropriate equipment; suitable environmental conditions for accomplishing the activity, such as adequate cleanness; and assurance that all prerequisites for the given activity have been satisfied.

ISO Q9001:2000 Provisions:

Criteria 6.3 and 6.4 require the organization to establish the appropriate infrastructure and work environment necessary to achieve conformity to product requirements.

Criterion 7.5.1 requires the organization to plan and carry out production and service provisions under controlled conditions that include, as applicable, the availability of work instructions (that is, procedures), as well as the availability of information that describes the characteristics of the product, the use of suitable equipment, the availability and use of monitoring and measuring devices, and the implementation of release, delivery, and post-delivery activities.

Criterion 7.5.2 requires the organization to validate any processes for production and service provisions where the resulting output cannot be verified by subsequent monitoring or measurement. This includes any (special) processes where deficiencies become apparent only after the product is in use or the service has been delivered. Validation must demonstrate the ability of these processes to achieve planned results. The organization must also establish arrangements for these processes including the approval of equipment and qualification of personnel, as well as other requirements.

Result:

The requirements of ANSI/ISO/ASQ Q2001:9000 meet the fundamental requirements of this sub-criterion of 10CFR50, Appendix B, to the extent the quality requirements apply to an organization furnishing products and services to the nuclear power industry.

Table 3-2E
10CFR50, Appendix B, Criterion II – Quality Assurance Program

10CFR50, Appendix B, Criterion II	ISO Q9001:2000 – 5.4.2 and 7.1
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.	5.4.2 Quality management system planning Top management shall ensure that a) the planning of the quality management system is carried out in order to meet the requirements given in 4.1, as well as the quality objectives, and b) the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented. 7.1 Planning of product realization The organization shall plan and develop the processes needed for product realization. Planning of product realization shall be consistent with the requirements of the other processes of the quality management system (see 4.1) In planning product realization, the organization shall determine the following, as appropriate. a) quality objectives and requirements for the product; b) the need to establish processes, documents, and provide resources specific to the product; c) required verification, validation, monitoring, inspection and test activities specific to the product and the criteria for product acceptance; d) records needed to provide evidence that the realization processes and resulting product meet requirements (see 4.2.4)

Fundamental Objective of the Quality Element:

Acknowledges the need for special controls and verification of quality by inspection and test.

ISO Q9001:2000 Provisions:

Criterion 7.1 requires the organization to establish processes needed for product realization, and the need for verification, validation, monitoring, inspection, and test activities, and the criteria for product acceptance.

Result:

The requirements of ANSI/ISO/ASQ Q2001:9000 meet the fundamental requirements of this sub-criterion of 10CFR50, Appendix B, to the extent the quality requirements apply to an organization furnishing products and services to the nuclear power industry.

Table 3-2F
10CFR50, Appendix B, Criterion II – Quality Assurance Program

10CFR50, Appendix B, Criterion II	ISO Q9001:2000 – 6.2.2
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.	6.2.2 Competence, awareness and training The organization shall a) determine the necessary competence for personnel performing work affecting product quality, b) provide training or take other actions to satisfy these needs, c) evaluate the effectiveness of the actions taken, d) ensure that its personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the quality objectives, and e) maintain appropriate records of education, training , skills and experience (see 4.2.4).

Fundamental Objective of the Quality Element:

Requires appropriate indoctrination and training of personnel performing activities affecting quality, and the maintenance of this proficiency among effected personnel.

ISO Q9001:2000 provisions:

Criterion 6.2.2 requires the organization to determine the need for proficiency (competence), training, a means for evaluating the effectiveness of the actions taken to achieve a given level of proficiency, and maintaining a documented proficiency level among effected personnel.

Result:

The requirements of ANSI/ISO/ASQ Q2001:9000 meet the fundamental requirements of this sub-criterion of 10CFR50, Appendix B, to the extent the quality requirements apply to an organization furnishing products and services to the nuclear power industry.

Table 3-2G
10CFR50, Appendix B, Criterion II – Quality Assurance Program

10CFR50, Appendix B, Criterion II	ISO Q9001:2000 – 5.6.1 and 5.6.2 and 5.6.3 and 8.5.1 and 5.5.3 and 8.2.2 and 8.2.3 (for internal organizations participating in the QA program) ISO Q9001:2000 – 7.4.1 and 7.4.3 and 8.2.4 (for external organizations (i.e., sub-suppliers) participating in the QA program)
The applicant shall regularly review the status and adequacy of the quality assurance program. 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.	5.6.1 Management review – General Top management shall review the organization's quality management system, at planned intervals, to ensure its continuing suitability, adequacy and effectiveness. This review shall include assessing opportunities for improvement and the need for changes to the quality management system, including the quality policy and quality objectives. 5.6.2 Review input The input to management review shall include information on a) results of audits, b) customer feedback, c) process performance and product conformity, d) status of preventive and corrective actions, e) follow-up actions from previous management reviews, f) changes that could affect the quality management system, and g) recommendations for improvement. 5.6.3 Review output The output from the management review shall include any decisions and actions related to a) improvement of the effectiveness of the quality management system b) improvement of product related to customer requirements, and c) resource needs. 8.5.1 Continual improvement The organization shall continually improve the effectiveness of the quality management system through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions and management review.

Table 3-2G (cont.)
10CFR50, Appendix B, Criterion II – Quality Assurance Program

	5.5.2 Internal communication Top management shall ensure that appropriate communication processes are established within the organization and that communication takes place regarding the effectiveness of the quality management system. 8.2.2 The organization shall conduct internal audits of planned intervals to determine whether the quality management system a) conforms to the planned arrangements (see 7.1), to the requirements of this International Standard and to the quality management system requirements established by the organization, and b) is effectively implemented and maintained. An audit programme shall be planned, taking into consideration the status and importance of the processes and areas to be audited, as well as the results of previous audits. The audit criteria, scope, frequency and methods shall be defined. Selection of auditors and conduct of audits shall ensure objectivity and impartiality of the audit process. Auditors shall not audit their own work. The responsibilities and requirements for planning and conducting audits, and for reporting results and maintaining records (see 4.2.4) shall be defined in a documented procedure. The management responsible for the area being audited shall ensure that actions are taken without undue delay to eliminate detected nonconformities and their causes. Follow-up activities shall include the verification of the actions taken and the reporting of verification results (see 8.5.2). Note See ISO 10011-1, ISO 10011-2 and ISO 10011-3 for guidance. 8.2.3 Monitoring and measurement of processes The organization shall apply suitable methods for monitoring and, where applicable, measurement of the quality management system processes. These methods shall demonstrate the ability of the processes to achieve planned results. When planned results are not achieved, correction and corrective action shall be taken, as appropriate, to ensure conformity of the product.

Table 3-2G (cont.)
10CFR50, Appendix B, Criterion II – Quality Assurance Program

	7.4.1 Purchasing process The organization shall ensure that purchased product conforms to specified purchase requirements. The type and extent of control applied to the supplier and the purchased product shall be dependent upon the effect of the purchased product on subsequent product realization or the final product. The organization shall evaluate and select suppliers based on their ability to supply product in accordance with the organization's requirements. Criteria for selection, evaluation, and re-evaluation shall be established. Records of the results of evaluations and any necessary actions arising from then evaluation shall be maintained (see 4.2.4). 7.4.3 Verification of purchased product The organization shall establish and implement the inspection or other activities necessary for ensuring that purchased product meets specified purchase requirements. Where the organization or its customer intends to perform verification at the supplier's premises, the organization shall state the intended verification arrangements and method of product release in the purchasing information. 8.2.4 Monitoring and measurement of product The organization shall monitor and measure the characteristics of the product to verify that product requirements have been met. This shall be carried out at appropriate stages of the product realization process in accordance with the planned arrangements. (see 7.1). Evidence of conformity with the acceptance criteria shall be maintained. Records shall indicate the person(s) authorizing release of product (see 4.2.4). Product release and service delivery shall not proceed until the planned arrangements (see 7.1) have been satisfactorily completed, unless otherwise approved by a relevant authority and, where applicable, by the customer.

Fundamental Objective of the Quality Element:

To review the adequacy and status of the QA program at both management and implementation levels, and for all organizations participating in the QA program.

ISO Q9001:2000 Provisions:

Criterion 5.6.1 requires the organization's top management to review the organization's QMS, at planned intervals, to ensure its continuing suitability, adequacy, and effectiveness. This review must include assessing opportunities for improvement and the need for changes to the QMS, including the quality policy and quality objectives.

Criteria 5.6.2 and 5.6.3 require the organization's top management to meet defined criteria for the input and output of the review respectively.

Criterion 8.2.2 requires the organization to conduct internal audits of planned intervals to determine whether the QMS:

a) Conforms to the planned arrangements (see 7.1), to the requirements of this International Standard, and to the QMS requirements established by the organization
b) Is effectively implemented and maintained

The audit program must be planned, taking into consideration the status and importance of the processes and areas to be audited, as well as the results of previous audits. The audit criteria, scope, frequency, and methods must all be defined. Selection of auditors and conduct of audits must ensure objectivity and impartiality of the audit process, and auditors cannot audit their own work.

The management responsible for the area being audited must ensure that actions are taken without undue delay to eliminate detected nonconformities and their causes. ISO 10011-1, ISO 10011-2, and ISO 10011-3 provide implementation guidance.

Criterion 8.2.3 requires the organization to apply suitable methods for monitoring and, where applicable, measurement of the QMS processes. These methods must demonstrate the ability of the processes to achieve planned results. When planned results are not achieved, correction and corrective action must be taken, as appropriate, to ensure conformity of the product.

With regard to other organizations participating in the QA program, this analysis assumes for conservatism that a sub-supplier may be considered as one of these "other" organizations. As such, Criteria 7.4.1, 7.4.3, and 8.2.4 require the organization to regularly review the status and adequacy of that part of the QA program which those sub-suppliers are executing (that is, furnishing purchased items and services). These criteria are discussed in more detail as they relate to the requirements of Criterion VII of 10CFR50, Appendix B.

Result:

The requirements of ANSI/ISO/ASQ Q2001:9000 meet the fundamental requirements of this sub-criterion of 10CFR50, Appendix B, to the extent the quality requirements apply to an organization furnishing products and services to the nuclear power industry.

Table 3-3A
10CFR50, Appendix B, Criterion III – Design Control

10CFR50, Appendix B, Criterion III	ISO Q9001:2000 – 7.3.1 and 7.2.1 and 7.3.2
Measures shall be established to assure that applicable regulatory requirements and the design basis, as defined in §50.2 and as specified in the license application, for those structures, systems, and components to which this appendix applies are correctly translated into specifications, drawings, procedures, and instructions. These measures shall include provisions to assure that appropriate quality standards are specified and included in design documents and that deviations from such standards are controlled.	7.3.1 Design and development planning The organization shall plan and control the design and development of product. During the design and development planning, the organization shall determine a) the design and development stages b) the review, verification and validation that are appropriate to each design and development stage, and c) the responsibilities and authorities for design and development. The organization shall manage the interfaces between different groups involved in design and development to ensure effective communication and clear assignment of responsibility. Planning output shall be updated, as appropriate, as the design and development progresses. 7.2.1 Determination of requirements related to the product The organization shall determine a) requirements specified by the customer, including the requirements for delivery and post-delivery activities, b) requirements not stated by the customer but necessary for specified or intended use, where known, c) statutory and regulatory requirements related to the product, and d) any additional requirements determined by the organization. 7.3.2 Design and development inputs Inputs relating to product requirements shall be determined and records maintained (see 4.2.4). These inputs shall include a) functional and performance requirements, b) applicable statutory and regulatory requirements, c) where applicable, information derived from previous similar designs, and d) other requirements essential for design and development. These inputs shall be reviewed for adequacy. Requirements shall be complete, unambiguous and not in conflict with each other.

Fundamental Objective of the Quality Element:

To include appropriate and applicable regulatory requirements and design bases into working documents. To ensure appropriate standards are specified and included in design documents.

ISO Q9001:2000 Provisions:

Criterion 7.2.1 requires the organization to determine:

a) Requirements specified by the customer, including the requirements for delivery and post-delivery activities
b) Requirements not stated by the customer but necessary for specified or intended use, where known
c) Statutory and regulatory requirements related to the product
d) Any additional requirements determined by the organization

Criterion 7.3.2 requires inputs relating to product requirements are determined and records maintained (see 4.2.4). These inputs shall include:

a) Functional and performance requirements
b) Applicable statutory and regulatory requirements
c) Information derived from previous similar designs, where applicable
d) Other requirements essential for design and development

These inputs shall be reviewed for adequacy. Requirements shall be complete, unambiguous, and not in conflict with each other.

These requirements noted include design bases and regulatory requirements. Criterion 4.2.4 is referenced to ensure the requirements are properly, identified, documented as records, and properly maintained.

Result:

The requirements of ANSI/ISO/ASQ Q2001:9000 meet the fundamental requirements of this sub-criterion of 10CFR50, Appendix B, to the extent the quality requirements apply to an organization furnishing products and services to the nuclear power industry.

Table 3-3B
10CFR50, Appendix B, Criterion III – Design Control

10CFR50, Appendix B, Criterion III	ISO Q9001:2000 –7.3.1 and 7.3.3 and 7.3.4 and 7.3.6
Measures shall also be established for the selection and review for suitability of application of materials, parts, equipment, and processes that are essential to the safety-related functions of the structures, systems and components.	7.3.1 Design and development planning The organization shall plan and control the design and development of product. During the design and development planning, the organization shall determine a) the design and development stages b) the review, verification and validation that are appropriate to each design and development stage, and c) the responsibilities and authorities for design and development. The organization shall manage the interfaces between different groups involved in design and development to ensure effective communication and clear assignment of responsibility. Planning output shall be updated, as appropriate, as the design and development progresses. 7.3.3 Design and development outputs The outputs of design and development shall be provided in a form that enables verification against the design and development input and shall be approved prior to release. Design and development outputs shall a) meet the input requirements for design and development, b) provide appropriate information for purchasing, production and for service provision, c) contain or reference product acceptance criteria, and d) specify the characteristics of the product that are essential for its safe and proper use.

Table 3-3B (cont.)
10CFR50, Appendix B, Criterion III – Design Control

	7.3.4 Design and development review At suitable stages, systematic reviews of design and development shall be performed in accordance with planned arrangements (see 7.3.1) a) to evaluate the ability of the results of design and development to meet requirements, and b) to identify any problem and propose necessary actions. Participants in such reviews shall include representatives of functions concerned with the design and development stage(s) being reviewed. Records of the results of the reviews and any necessary actions shall be maintained (see 4.2.4). 7.3.6 Design and development validation Design and development validation shall be performed in accordance with planned arrangements (see 7.3.1) to ensure that the resulting product is capable of meeting the requirements for the specified application or intended use, where known. Wherever practicable, validation shall be completed prior to the delivery or implementation of the product. Records of the results of validation and any necessary actions shall be maintained (see 4.2.4).

Fundamental Objective of the Quality Element:

To select and review for suitability of the application any material, parts, equipment, and processes necessary for the item to perform its safety functions.

ISO Q9001:2000 Provisions:

Criterion 7.3.3 requires the organization to demonstrate that the outputs of design and development are provided in a form that enables verification against the design and development input, and are approved prior to release.

Design and development outputs must meet the input requirements for design and development, provide appropriate information for purchasing, production and for service provision, contain or reference product acceptance criteria, and specify the characteristics of the product that are essential for its safe and proper use (that is, performance).

Criterion 7.3.6 requires the organization to demonstrate that the resulting product is capable of meeting the requirements for the specified application or intended use, where known.

Result:

The requirements of ANSI/ISO/ASQ Q2001:9000 meet the fundamental requirements of this sub-criterion of 10CFR50, Appendix B, to the extent the quality requirements apply to an organization furnishing products and services to the nuclear power industry.

Table 3-3C
10CFR50, Appendix B, Criterion III – Design Control

10CFR50, Appendix B, Criterion III	ISO Q9001:2000 – 7.3.1 and 7.3.4
Measures shall be established for the identification and control of design interfaces and for coordination among participating design organizations.	7.3.1 Design and development planning The organization shall plan and control the design and development of product. During the design and development planning, the organization shall determine a) the design and development stages b) the review, verification and validation that are appropriate to each design and development stage, and c) the responsibilities and authorities for design and development. The organization shall manage the interfaces between different groups involved in design and development to ensure effective communication and clear assignment of responsibility. Planning output shall be updated, as appropriate, as the design and development progresses. 7.3.4 Design and development review At suitable stages, systematic reviews of design and development shall be performed in accordance with planned arrangements (see 7.3.1) a) to evaluate the ability of the results of design and development to meet requirements, and b) to identify any problem and propose necessary actions. Participants in such reviews shall include representatives of functions concerned with the design and development stage(s) being reviewed. Records of the results of the reviews and any necessary actions shall be maintained (see 4.2.4).

Fundamental Objective of the Quality Element:

To identify and control design interfaces and to ensure appropriate coordination among design organizations.

ISO Q9001:2000 Provisions:

Criterion 7.3.1 requires that the organization plan and control the design and development of product, including the delineation of the responsibilities and authorities for design and development. The organization must also manage the interfaces between different groups involved in design and development to ensure effective communication and clear assignment of responsibility.

Planning output must be updated, as appropriate, as the design and development progresses.

Result:

The requirements of ANSI/ISO/ASQ Q2001:9000 meet the fundamental requirements of this sub-criterion of 10CFR50, Appendix B, to the extent the quality requirements apply to an organization furnishing products and services to the nuclear power industry.

Table 3-3D
10CFR50, Appendix B, Criterion III – Design Control

10CFR50, Appendix B, Criterion III	ISO Q9001:2000 – 7.3.1 and 4.2.3
These measures shall include the establishment of procedures among participating design organizations for the review, approval, release, distribution, and revision of documents involving design interfaces.	7.3.1 Design and development planning The organization shall plan and control the design and development of product. During the design and development planning, the organization shall determine a) the design and development stages b) the review, verification and validation that are appropriate to each design and development stage, and c) the responsibilities and authorities for design and development. The organization shall manage the interfaces between different groups involved in design and development to ensure effective communication and clear assignment of responsibility. Planning output shall be updated, as appropriate, as the design and development progresses. 4.2.3 Control of documents Documents required by the quality management system shall be controlled. Records are a special type of document and shall be controlled according to the requirements given in 4.2.4. A documented procedure shall be established to define the controls needed a) to approve documents for adequacy prior to issue, b) to review and update as necessary and re-approve documents, c) to ensure that changes and the current revision status of documents are identified, d) to ensure that relevant versions of applicable documents are available at points of use, e) to ensure that documents remain legible and readily identifiable, to ensure that documents of external origin are identified and their distribution controlled, and f) to prevent the unintended use of obsolete documents, and to apply suitable identification to them if they are retained for any purpose.

Fundamental Objective of the Quality Element:

To establish procedures controlling the review, approval, release, distribution, and revision of design documents among organizations participating in the design process.

ISO Q9001:2000 Provisions:

ISO Q9001:2000 requires processes related to the design of products (that is, development of design inputs, design outputs, design verification and validation, and design reviews) be documented by cross-referencing Criteria 4.2.3 and 4.2.4.

Criterion 4.2.3 requires the organization to demonstrate that documents required by the QMS are controlled. The criterion further defines the need for procedures to address approval, review, revision, availability (that is, distribution), maintenance, identification, and obsolescence of applicable documents and records.

Result:

The requirements of ANSI/ISO/ASQ Q2001:9000 meet the fundamental requirements of this sub-criterion of 10CFR50, Appendix B, to the extent the quality requirements apply to an organization furnishing products and services to the nuclear power industry.

Table 3-3E
10CFR50, Appendix B, Criterion III – Design Control

10CFR50, Appendix B, Criterion III	ISO Q9001:2000 – 7.1 and 7.3.1 and 7.3.3 and 7.3.4 and 7.3.5 and 7.3.6
The design control measures shall provide for verifying or checking the adequacy of design, such as by the performance of design reviews, by the use of alternate or simplified calculational methods, or by the performance of a suitable testing program. The verifying or checking process shall be performed by individuals or groups other than those who performed the original design, but who may be from the same organization. Where a test program is used to verify the adequacy of a specific design feature in lieu of other verifying or checking processes, it shall include suitable qualifications testing of a prototype unit under the most adverse design conditions. Design control measures shall be applied to items such as the following: reactor physics, stress, thermal, hydraulic, and accident analyses; compatibility of materials; accessibility for inservice inspection, maintenance, and repair; and delineation of acceptance criteria for inspections and tests.	7.1 Planning of product realization The organization shall plan and develop the processes needed for product realization. Planning of product realization shall be consistent with the requirements of the other processes of the quality management system (see 4.1) In planning product realization, the organization shall determine the following, as appropriate: a) quality objectives and requirements for the product; b) the need to establish processes, documents, and provide resources specific to the product; c) required verification, validation, monitoring, inspection and test activities specific to the product and the criteria for product acceptance; d) records needed to provide evidence that the realization processes and resulting product meet requirements (see 4.2.4) 7.3.1 Design and development planning The organization shall plan and control the design and development of product. During the design and development planning, the organization shall determine a) the design and development stages b) the review, verification and validation that are appropriate to each design and development stage, and c) the responsibilities and authorities for design and development. The organization shall manage the interfaces between different groups involved in design and development to ensure effective communication and clear assignment of responsibility. Planning output shall be updated, as appropriate, as the design and development progresses. 7.3.3 Design and development outputs The outputs of design and development shall be provided in a form that enables verification against the design and development input and shall be approved prior to release.

Table 3-3E (cont.)
10CFR50, Appendix B, Criterion III – Design Control

	Design and development outputs shall a) meet the input requirements for design and development, b) provide appropriate information for purchasing, production and for service provision, c) contain or reference product acceptance criteria, and d) specify the characteristics of the product that are essential for its safe and proper use. 7.3.4 Design and development review At suitable stages, systematic reviews of design and development shall be performed in accordance with planned arrangements (see 7.3.1) a) to evaluate the ability of the results of design and development to meet requirements, and b) to identify any problem and propose necessary actions. Participants in such reviews shall include representatives of functions concerned with the design and development stage(s) being reviewed. Records of the results of the reviews and any necessary actions shall be maintained (see 4.2.4). 7.3.5 Design and development verification Verification shall be performed in accordance with planned arrangements (see 7.3.1) to ensure that the design and development outputs have met the design and development input requirements. Records of the results of the verification and any necessary actions shall be maintained (see 4.2.4). 7.3.6 Design and development validation Design and development validation shall be performed in accordance with planned arrangements (see 7.3.1) to ensure that the resulting product is capable of meeting the requirements for the specified application or intended use, where known. Wherever practicable, validation shall be completed prior to the delivery or implementation of the product. Records of the results of validation and any necessary actions shall be maintained (see 4.2.4).

Fundamental Objective of the Quality Element:

To verify and check design adequacy via design reviews, calculation, or testing using individuals other than those who performed the actual design.

ISO Q9001:2000 Provisions:

Criterion 7.1 requires the organization to establish a plan for achieving product realization. This plan must begin during the design of the product and continue through product verification, validation, monitoring, inspection, and test activities specific to the product, and must identify the criteria for product acceptance.

Criterion 7.3.5 requires the organization to demonstrate that design verification is planned and employs personnel with the appropriate assigned responsibilities and authority. Verification, as defined in ANSI/ISO/ASQ 9000:2000, is the confirmation through the provision of objective evidence, that specified requirements have been fulfilled. The definition notes that confirmation can comprise activities such as performing alternate calculations, comparing a new design specification with a similar proven design specification, undertaking tests and demonstrations, and reviewing documents prior to issue.

Criterion 7.3.6 requires the organization to plan and implement an independent process defined as design and development validation. Validation, as defined in ANSI/ISO/ASQ 9000:2000, is the confirmation through the provision of objective evidence, that the requirements for a specific intended use or application have been fulfilled. The criterion does not preclude the use of independent verifiers and, in certain cases, the use of independent verifiers may be appropriate. However, the use of independent verifiers in all cases is not a requirement described in ISO Q9001:2000. The design and development validation process is required in lieu of employing independent verifiers.

Result:

The requirements of ANSI/ISO/ASQ Q2001:9000 may not meet the fundamental requirements of this sub-criterion of 10CFR50, Appendix B, to the extent the quality requirements apply to an organization furnishing products and services to the nuclear power industry.

Table 3-3F
10CFR50, Appendix B, Criterion III – Design Control

10CFR50, Appendix B, Criterion III	ISO Q9001:2000 – 7.3.7
Design changes, including field changes, shall be subject to design control measures commensurate with those applied to the original design and be approved by the organization that performed the original design unless the applicant designates another responsible organization.	7.3.7 Control of design and development changes Design and development changes shall be identified and records maintained. The changes shall be reviewed, verified and validated, as appropriate, and approved before implementation. The review of design and development changes shall include evaluation of the effect of the changes on constituent parts and product already delivered. Records of the results of the review of changes and any necessary actions shall be maintained (see 4.2.4).

Fundamental Objective of the Quality Element:

To control design changes made by the organization in a manner commensurate with those applied to the original design.

ISO Q9001:2000 Provisions:

Design changes made by the licensee would not be applicable to or within the scope of quality controls implemented by an organization certified to ISO 9000:2000.

Criterion 7.3.7 requires the organization to control design changes. The criterion states that design and development changes must be reviewed, verified, and validated, as appropriate, and approved before implementation. Therefore the design change must be made in a manner commensurate with the original design and development plan that inherently includes review, verification, and validation. The criterion also requires review of design changes on constituent parts and product already delivered.

Result:

The requirements of ANSI/ISO/ASQ Q2001:9000 meet the fundamental requirements of this sub-criterion of 10CFR50, Appendix B, to the extent the quality requirements apply to an organization furnishing products and services to the nuclear power industry.

Table 3-4A
10CFR50, Appendix B, Criterion IV – Procurement Document Control

10CFR50, Appendix B, Criterion IV	ISO Q9001:2000 – 7.4.2
Measures shall be established to assure that applicable regulatory requirements, design bases, and other requirements which are necessary to assure adequate quality are suitably included or referenced in the documents for procurement of material, equipment, and services, whether purchased by the applicant or by its contractors or subcontractors.	7.4.2 Purchasing information Purchasing information shall describe the product to be purchased, including where appropriate a) requirements for approval of product, procedures, processes and equipment, b) requirements for qualification of personnel, and c) quality management system requirements. The organization shall ensure the adequacy of specified purchase requirements prior to their communication to the supplier.

Fundamental Objective of the Quality Element:

To include purchase requirements necessary to ensure adequate quality in purchase documents, and to extend these requirements throughout the supply chain.

ISO Q9001:2000 Provisions:

Criterion 7.4.2 requires the organization to ensure purchasing information describes the product to be purchased, including requirements for approval of product, procedures, processes and equipment, requirements for qualification of personnel, and QMS requirements.

The criterion also requires the organization to ensure the adequacy of specified purchase requirements prior to their communication to a supplier.

Result:

The requirements of ANSI/ISO/ASQ Q2001:9000 meet the fundamental requirements of this sub-criterion of 10CFR50, Appendix B, to the extent the quality requirements apply to an organization furnishing products and services to the nuclear power industry.

Table 3-4-B
10CFR50, Appendix B, Criterion IV – Procurement Document Control

10CFR50, Appendix B, Criterion IV	ISO Q9001:2000 – 7.4.2 and 7.4.1
To the extent necessary, procurement documents shall require contractors or subcontractors to provide a quality assurance program consistent with the pertinent provisions of this appendix.	7.4.2 Purchasing information Purchasing information shall describe the product to be purchased, including where appropriate a) requirements for approval of product, procedures, processes and equipment, b) requirements for qualification of personnel, and c) quality management system requirements. The organization shall ensure the adequacy of specified purchase requirements prior to their communication to the supplier. 7.4.1 Purchasing process The organization shall ensure that purchased product conforms to specified purchase requirements. The type and extent of control applied to the supplier and the purchased product shall be dependent upon the effect of the purchased product on subsequent product realization or the final product. The organization shall evaluate and select suppliers based on their ability to supply product in accordance with the organization's requirements. Criteria for selection, evaluation, and re-evaluation shall be established. Records of the results of evaluations and any necessary actions arising from then evaluation shall be maintained (see 4.2.4).

Fundamental Objective of the Quality Element:

To require to the extent necessary, that suppliers and sub-suppliers provide a QA program meeting the intent of 10CFR50, Appendix B.

ISO Q9001:2000 Provisions:

Criterion 7.4.2 requires the organization to specify the appropriate quality requirements including QMS requirements. As such, the organization must "pass on" the appropriate requirements of the QMS to their sub-suppliers to the extent each of these sub-suppliers has the capability to comply and to the extent that customer requirements will be met.

Criterion 7.4.1 requires the organization to ensure that purchased product conforms to specified purchase requirements. The type and extent of control applied to the supplier and the purchased product is dependent upon the effect of the purchased product on subsequent product realization activities or the final product. The organization must evaluate and select suppliers based on their ability to furnish product in accordance with the organization's requirements. Criteria for selection, evaluation, and re-evaluation must be established by the organization.

Discussion:

The requirement in this Criterion provides each licensee latitude to specify the appropriate technical and quality requirements based upon the type of supplier and their respective scope of supply. In practice, the specification of 10CFR50, Appendix B, to suppliers able to comply with these requirements has become more difficult because the number of nuclear suppliers maintaining this QA program has decreased over time. As such, it has become much more difficult to simply "pass on" the entire complement of 10CFR50, Appendix B, requirements to a supplier. To compensate for this situation, licensees typically specify the required activity required for a given vendor/situation. These activities are specified within one or more criteria of 10CFR50, Appendix B. However, it may not be necessary to specify 10CFR50, Appendix B, in its entirety.

Like licensees, suppliers are also given latitude when determining the degree to which their QA program requirements need to be specified to their sub-suppliers. In practice, rarely can a nuclear supplier maintaining a 10CFR50, Appendix B, QA program procure raw materials or parts from sub-suppliers who also maintain 10CFR50, Appendix B, QA programs. In most cases, items procured from sub-suppliers are procured as commercial grade items. The nuclear supplier, like the licensee, specifies and subsequently accepts these products, as they deem necessary to ensure their products meet customer/licensee requirements.

In either case, ANSI/ISO/ASQ Q2001:9000 allows the supplier the latitude to specify or "pass on" the appropriate technical/quality requirements as deemed necessary. However while providing latitude, ANSI/ISO/ASQ Q2001:9000 also requires that the organization identify "the type and extent of control applied (that is, specified) to the supplier," and that purchasing information describe the product to be purchased. This includes where appropriate:

a) Requirements for approval of product, procedures, processes and equipment
b) Requirements for qualification of personnel
c) QMS requirements.

Result:

The requirements of ANSI/ISO/ASQ Q2001:9000 meet the fundamental requirements of this sub-criterion of 10CFR50, Appendix B, to the extent the quality requirements apply to an organization furnishing products and services to the nuclear power industry.

Table 3-5A
10CFR50, Appendix B, Criterion V – Instructions, Procedures, and Drawings

10 CFR50, Appendix B, Criterion V	ISO Q9001:2000 – 4.1 and 4.2.2 and 4.2.1
Activities affecting quality shall be prescribed by documented instructions, procedures, or drawings, of a type appropriate to the circumstances and shall be accomplished in accordance with these instructions, procedures, or drawings.	4.1 Quality management system – General requirements The organization shall establish, document, implement and maintain a quality management system and continually improve its effectiveness in accordance with the requirements of this International Standard. The organization shall a) identify the processes needed for the quality management system and their application throughout the organization (see 1.2) b) determine the sequence of and interaction of these processes, c) determine criteria and methods needed to ensure that both the operation and control of these processes are effective, d) ensure the availability of resources and information necessary to support the operation and monitoring of these processes, e) monitor, measure and analyze these processes, f) implement actions necessary to achieve planned results and continual improvement of these processes. These processes shall be managed by the organization in accordance with the requirements of this International Standard. Where an organization chooses to outsource any process that affects product conformity with requirements, the organization shall ensure control over such processes. Control of such outsourced processes shall be identified within the quality management system. Note: Processes needed for the quality management system referred to above should include processes for management activities, provision of resources, product realization and measurement.

Table 3-5A (cont.)
10CFR50, Appendix B, Criterion V – Instructions, Procedures, and Drawings

	4.2.2 Quality manual The organization shall establish and maintain a quality manual that includes a) the scope of the quality management system, including details of and justification for any exclusions (see 1.2) b) the documented procedures established for the quality management system, or reference to them, and c) a description of the interaction between the processes of the quality management system. 4.2.1 Documentation requirements – General The quality management system documentation shall include a) documented statements of a quality policy and quality objectives, b) quality manual, c) documented procedures required by this International Standard d) documents needed by the organization to ensure the effective planning, operation and control of its processes, and e) records required by the International Standard (see 4.2.4). Note 1 Where the term “documented procedure” appears within this International Standard, this means that the procedure is established, documented, implemented and maintained. Note 2 The extent of the quality management system documentation can differ from on organization to another due to a) the size organization and type of activities, b) the complexity of processes and their interactions, and c) the competence of personnel. Note 3 The documentation can be in any form or type of medium.

Fundamental Objective of the Quality Element:

To require documented instructions, procedures, and drawings, detailed as appropriate to the circumstance, for accomplishing activities affecting quality.

ISO Q9001:2000 Provisions:

Criterion 4.2.1 requires the organization to provide documentation of activities needed to ensure the effective planning, operation, and control of its processes. The documented procedures must be documented, implemented, and maintained. The procedures may be detailed as appropriate to the circumstance by taking into account the size of the organization, the type of activities described, the complexity of the processes and their interactions, and the competence of personnel.

Result:

The requirements of ANSI/ISO/ASQ Q2001:9000 meet the fundamental requirements of this sub-criterion of 10CFR50, Appendix B, to the extent the quality requirements apply to an organization furnishing products and services to the nuclear power industry.

Table 3-5B
10CFR50, Appendix B, Criterion V – Instructions, Procedures, and Drawings

10CFR50, Appendix B, Criterion V	ISO Q9001:2000 – 4.2.1 and 5.4.2 and 7.1
Instructions, procedures, or drawings shall include appropriate quantitative or qualitative acceptance criteria for determining that important activities have been satisfactorily accomplished.	4.2.1 Documentation requirements – General The quality management system documentation shall include a) documented statements of a quality policy and quality objectives, b) a quality manual, c) documented procedures required by this International Standard d) documents needed by the organization to ensure the effective planning, operation and control of its processes, and e) records required by the International Standard (see 4.2.4). 5.4.2 Quality management system planning Top management shall ensure that a) the planning of the quality management system is carried out in order to meet the requirements given in 4.1, as well as the quality objectives, and b) the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented. 7.1 Planning of product realization The organization shall plan and develop the processes needed for product realization. Planning of product realization shall be consistent with the requirements of the other processes of the quality management system (see 4.1) In planning product realization, the organization shall determine the following, as appropriate. a) quality objectives and requirements for the product; b) the need to establish processes, documents, and provide resources specific to the product; c) required verification, validation, monitoring, inspection and test activities specific to the product and the criteria for product acceptance; d) records needed to provide evidence that the realization processes and resulting product meet requirements (see 4.2.4)

Fundamental Objective of the Quality Element:

To require inclusion of either qualitative and/or quantitative acceptance criteria for determining that important activities have been satisfactorily accomplished.

ISO Q9001:2000 Provisions:

In general, Criterion 4.2.1 requires the organization to provide evidence of documentation associated with the establishment and implementation of their QMS. Documentation must include the following:

a) Documented statements of a quality policy and quality objectives
b) A quality manual
c) Documented procedures required by this International Standard
d) Documents needed by the organization to ensure the effective planning, operation, and control of its processes
e) Records required by the International Standard

Criterion 7.1 requires that the organization determine quality objectives and requirements for the product, the need to establish processes, documents, and provide resources specific to the product, and required verification, validation, monitoring, inspection, and test activities specific to the product and the criteria for product acceptance. The criterion also requires the organization to maintain records to provide evidence that the processes and resulting product meet requirements.

Both criteria also require the organization to define certain documents as records and to maintain them in accordance with the requirements of Criterion 4.2.4.

Result:

The requirements of ANSI/ISO/ASQ Q2001:9000 meet the fundamental requirements of this sub-criterion of 10CFR50, Appendix B, to the extent the quality requirements apply to an organization furnishing products and services to the nuclear power industry.

Table 3-6
10CFR50, Appendix B, Criterion VI – Document Control

10CFR50, Appendix B, Criterion VI	ISO Q9001:2000 – 4.2.3
Measures shall be established to control the issuance of documents, such as instructions, procedures, and drawings, including changes thereto, which prescribe all activities affecting quality. These measures shall assure that documents, including changes, are reviewed for adequacy and approved for release by authorized personnel and are distributed to and used at the location where the prescribed activity is performed. Changes to documents shall be reviewed and approved by the same organizations that performed the original review and approval unless the applicant designates another responsible organization.	4.2.3 Control of documents Documents required by the quality management system shall be controlled. Records are a special type of document and shall be controlled according to the requirements given in 4.2.4. A documented procedure shall be established to define the controls needed a) to approve documents for adequacy prior to issue, b) to review and update as necessary and re-approve documents, c) to ensure that changes and the current revision status of documents are identified, d) to ensure that relevant versions of applicable documents are available at points of use, e) to ensure that documents remain legible and readily identifiable, f) to ensure that documents of external origin are identified and their distribution controlled, and g) to prevent the unintended use of obsolete documents, and to apply suitable identification to them if they are retained for any purpose.

Fundamental Objective of the Quality Element:

To control the issuance, change, review, and approval of documents such as instructions, procedures, or drawings affecting quality.

ISO Q9001:2000 Provisions:

Criterion 4.2.3 requires that the organization control documents required by the QMS that could include instructions, procedures, or drawings. Certain documents that are considered records are controlled in accordance with Criterion 4.2.4 that is cross-referenced. Document controls include document approval prior to issue, updating, change control, availability (that is, issuance/distribution), identification, and obsolescence.

Result:

The requirements of ANSI/ISO/ASQ Q2001:9000 meet the fundamental requirements of this sub-criterion of 10CFR50, Appendix B, to the extent the quality requirements apply to an organization furnishing products and services to the nuclear power industry.

Table 3-7A
10CFR50, Appendix B, Criterion VII – Control of Purchased Material, Equipment, and Services

10CFR50, Appendix B, Criterion VII	ISO Q9001:2000 – 7.4.1
Measures shall be established to assure that purchased material, equipment, and services, whether purchased directly or through contractors and subcontractors, conform to the procurement documents.	7.4.1 Purchasing process The organization shall ensure that purchased product conforms to specified purchase requirements. The type and extent of control applied to the supplier and the purchased product shall be dependent upon the effect of the purchased product on subsequent product realization or the final product. The organization shall evaluate and select suppliers based on their ability to supply product in accordance with the organization's requirements. Criteria for selection, evaluation, and re-evaluation shall be established. Records of the results of evaluations and any necessary actions arising from then evaluation shall be maintained (see 4.2.4).

Fundamental Objective of the Quality Element:

To assure that purchased products and services conform to the procurement document.

ISO Q9001:2000 Provisions:

Criterion 7.4.1 requires that the organization ensure that purchased product conforms to specified purchase requirements.

Result:

The requirements of ANSI/ISO/ASQ Q2001:9000 meet the fundamental requirements of this sub-criterion of 10CFR50, Appendix B, to the extent the quality requirements apply to an organization furnishing products and services to the nuclear power industry.

Table 3-7B
10CFR50, Appendix B, Criterion VII – Control of Purchased Material, Equipment, and Services

10CFR50, Appendix B, Criterion VII	ISO Q9001:2000 – 7.4.1 and 7.4.3 and 8.2.4
These measures shall include provisions, as appropriate, for source evaluation and selection, objective evidence of quality furnished by the contractor or subcontractor, inspection at the contractor or subcontractor source, and examination of products upon delivery.	7.4.1 Purchasing process The organization shall ensure that purchased product conforms to specified purchase requirements. The type and extent of control applied to the supplier and the purchased product shall be dependent upon the effect of the purchased product on subsequent product realization or the final product. The organization shall evaluate and select suppliers based on their ability to supply product in accordance with the organization's requirements. Criteria for selection, evaluation, and re-evaluation shall be established. Records of the results of evaluations and any necessary actions arising from then evaluation shall be maintained (see 4.2.4). 7.4.3 Verification of purchased product The organization shall establish and implement the inspection or other activities necessary for ensuring that purchased product meets specified purchase requirements. Where the organization or its customer intends to perform verification at the supplier's premises, the organization shall state the intended verification arrangements and method of product release in the purchasing information. 8.2.4 Monitoring and measurement of product The organization shall monitor and measure the characteristics of the product to verify that product requirements have been met. This shall be carried out at appropriate stages of the product realization process in accordance with the planned arrangements. (see 7.1). Evidence of conformity with the acceptance criteria shall be maintained. Records shall indicate the person(s) authorizing release of product (see 4.2.4). Product release and service delivery shall not proceed until the planned arrangements (see 7.1) have been satisfactorily completed, unless otherwise approved by a relevant authority and, where applicable, by the customer.

Fundamental Objective of the Quality Element:

To describe provisions for assurance of product acceptability that include source evaluation and selection, objective evidence of quality furnished by the supplier, inspection at the source, and examination of products upon delivery.

ISO Q9001:2000 Provisions:

Criteria 7.4.1, 7.4.3, and 8.2.4 all require the organization to demonstrate and document that procured products meet specified requirements. Criterion 7.4.1 provides flexibility to the organization for accomplishing this process by stating that the type and extent of control applied to the supplier and the purchased product should be dependent upon the effect of the purchased product on subsequent product realization activities or the final product. The criterion requires the organization to evaluate and select suppliers based on their ability to supply product in accordance with the organization's requirements. Criteria for selection, evaluation, and re-evaluation must be established by the organization prior to planning and implementing procurement.

Criterion 7.4.3 allows the organization to establish and implement inspections or other activities necessary for ensuring that purchased product meets specified purchase requirements. Where the organization or its customer intends to perform verification at the source, the organization must state the intended verification arrangements and method of product release in the purchasing information.

Criterion 8.2.4 requires the organization, when applicable, to monitor and measure the characteristics of the product to verify that product requirements have been met. This allows the organization to carry out the measurement (for example, testing and/or inspection) at appropriate stages of the product realization process in accordance with the planned arrangements (see Criterion 7.1).

Discussion:

Although this analysis does not attempt to compare implementation practices among suppliers or between the licensee and the supplier, a discussion of this requirement is provided. In practice, a licensee often maintains what is commonly known as an "approved suppliers list" to designate those suppliers whose quality programs/systems have been audited/surveyed and found acceptable in whole or in part. As such, the list represents those suppliers whose products are accepted based on the merits of their quality program as verified by audit/commercial grade survey. Suppliers appearing on this list are often referred to as "qualified suppliers". This acceptance practice is one of four methods allowed in this Criterion. When licensees purchase products from a supplier who has not undergone an audit or commercial grade survey, then the other acceptance methods should be used as deemed appropriate by each licensee. These "un-audited" suppliers are typically not noted on the licensees "approved suppliers list" however. This should not be interpreted that only audited/surveyed suppliers are capable of furnishing quality and acceptable products. Each licensee is provided latitude in the regulation as to how to most cost-effectively accept products/services, and when each method is deemed the most appropriate.

Like licensees, a supplier adapting a 10CFR50, Appendix B, program has the same latitude to select the most appropriate means for accepting products purchased from sub-suppliers. Like licensees, a supplier would not be expected to audit/survey every sub-supplier with whom items are procured, but rather employ the most effective combination of acceptance activities to ultimately meet their customer's needs. As a result, the practice of maintaining an approved suppliers list may be interpreted differently by a supplier versus a licensee, and the criteria established by each supplier for listing a sub-supplier on their approved supplier's list may also be different.

Result:

The requirements of ANSI/ISO/ASQ Q2001:9000 meet the fundamental requirements of this sub-criterion of 10CFR50, Appendix B, to the extent the quality requirements apply to an organization furnishing products and services to the nuclear power industry.

Table 3-7C
10CFR50, Appendix B, Criterion VII – Control of Purchased Material, Equipment, and Services

10CFR50, Appendix B, Criterion VII	ISO Q9001:2000 – 7.4.2 and 7.4.3 and 8.2.4
Documentary evidence that material and equipment conform to the procurement requirements shall be available at the nuclear powerplant or fuel reprocessing plant site prior to installation or use of such material and equipment.	7.4.2 Purchasing information Purchasing information shall describe the product to be purchased, including where appropriate a) requirements for approval of product, procedures, processes and equipment, b) requirements for qualification of personnel, and c) quality management system requirements. The organization shall ensure the adequacy of specified purchase requirements prior to their communication to the supplier. 7.4.3 Verification of purchased product The organization shall establish and implement the inspection or other activities necessary for ensuring that purchased product meets specified purchase requirements. Where the organization or its customer intends to perform verification at the supplier's premises, the organization shall state the intended verification arrangements and method of product release in the purchasing information. 8.2.4 Monitoring and measurement of product The organization shall monitor and measure the characteristics of the product to verify that product requirements have been met. This shall be carried out at appropriate stages of the product realization process in accordance with the planned arrangements. (see 7.1). Evidence of conformity with the acceptance criteria shall be maintained. Records shall indicate the person(s) authorizing release of product (see 4.2.4). Product release and service delivery shall not proceed until the planned arrangements (see 7.1) have been satisfactorily completed, unless otherwise approved by a relevant authority and, where applicable, by the customer.

Fundamental Objective of the Quality Element:

That conformity of material and equipment to procurement requirements is documented prior to installation.

ISO Q9001:2000 Provisions:

Criterion 7.4.2 requires the organization to ensure purchasing information describes the product to be purchased, thus providing assurance that the item is specified correctly and the appropriate technical and quality procurement requirements are communicated in the purchase document. The purchase document then becomes the basis for ensuring the procured items/services are conforming.

Criterion 7.4.3 requires the organization to establish and implement the inspection or other activities necessary for ensuring that purchased product meets specified purchase requirements.

Criterion 8.2.4 requires the organization to monitor, measure, and maintain evidence of the conformity of product characteristics to verify that product requirements have been met. This must be carried out at appropriate stages of the product realization process in accordance with the planned arrangements, and evidence of conformity with the acceptance criteria must be documented and maintained. The criterion also requires the organization to document evidence of the conformity (of purchased product and/or the subsequently manufactured product) are documented and maintained as records.

Result:

The requirements of ANSI/ISO/ASQ Q2001:9000 meet the fundamental requirements of this sub-criterion of 10CFR50, Appendix B, to the extent the quality requirements apply to an organization furnishing products and services to the nuclear power industry.

Table 3-7D
10CFR50, Appendix B, Criterion VII – Control of Purchased Material, Equipment, and Services

10CFR50, Appendix B, Criterion VII	ISO Q9001:2000 – 7.5.3 and 8.2.4 and 4.2.4
This documentary evidence shall be retained at the nuclear powerplant or fuel reprocessing plant site and shall be sufficient to identify the specific requirements, such as codes, standards, or specifications, met by the purchased material and equipment.	7.5.3 Identification and traceability Where appropriate, the organization shall identify the product by suitable means throughout product realization. The organization shall identify the product status with respect to monitoring and measurement requirements. Where traceability is a requirement, the organization shall control and record the unique identification of the product (see 4.2.4) Note In some industry sectors, configuration management is a means by which identification and traceability are maintained. 8.2.4 Monitoring and measurement of product The organization shall monitor and measure the characteristics of the product to verify that product requirements have been met. This shall be carried out at appropriate stages of the product realization process in accordance with the planned arrangements. (see 7.1). Evidence of conformity with the acceptance criteria shall be maintained. Records shall indicate the person(s) authorizing release of product (see 4.2.4). Product release and service delivery shall not proceed until the planned arrangements (see 7.1) have been satisfactorily completed, unless otherwise approved by a relevant authority and, where applicable, by the customer. 4.2.4 Control of records Records shall be established and maintained to provide evidence of conformity to requirements and of the effective operation of the quality management system. Records shall remain legible, readily identifiable and retrievable. A documented procedure shall be established to define the controls needed for the identification, storage, protection, retrieval, retention time and disposition of records.

Fundamental Objective of the Quality Element:

That documented conformity of material and equipment to procurement requirements be retained and sufficiently detailed to identify specified requirements.

ISO Q9001:2000 Provisions:

Criterion 8.2.4 requires the organization to monitor and measure the characteristics of the product to verify that product requirements have been met. This must be carried out at appropriate stages of the product realization process, in accordance with the planned arrangements, and evidence of conformity with the acceptance criteria must be documented and maintained.

Criterion 4.2.4 further requires the organization to provide evidence of conformity to requirements and of the effective operation of the QMS.

Result:

The requirements of ANSI/ISO/ASQ Q2001:9000 meet the fundamental requirements of this sub-criterion of 10CFR50, Appendix B, to the extent the quality requirements apply to an organization furnishing products and services to the nuclear power industry.

Table 3-7E
10CFR50, Appendix B, Criterion VII – Control of Purchased Material, Equipment, and Services

10CFR50, Appendix B, Criterion VII	ISO Q9001:2000 – 7.4.1
The effectiveness of the control of quality by contractors and subcontractors shall be assessed by the applicant or designee at intervals consistent with the importance, complexity, and quantity of the product or services.	7.4.1 Purchasing process The organization shall ensure that purchased product conforms to specified purchase requirements. The type and extent of control applied to the supplier and the purchased product shall be dependent upon the effect of the purchased product on subsequent product realization or the final product. The organization shall evaluate and select suppliers based on their ability to supply product in accordance with the organization's requirements. Criteria for selection, evaluation, and re-evaluation shall be established. Records of the results of evaluations and any necessary actions arising from then evaluation shall be maintained (see 4.2.4).

Fundamental Objective of the Quality Element:

That the effectiveness of sub-supplier quality controls should be assessed at intervals consistent with the importance, complexity, and quantity of products or services being procured.

ISO Q9001:2000 Provisions:

Criterion 7.4.1 requires the organization to ensure that purchased product conforms to specified purchase requirements. The type and extent of control applied to the supplier and the purchased product can be dependent upon the effect of the purchased product on subsequent product realization or the final product. The organization must also evaluate and select suppliers based on their ability to supply product in accordance with the organization's requirements. Criteria for selection, evaluation (that is, assessment, audit, and the like), and re-evaluation (that is, re-assessment) of suppliers must be established; and records of the results of evaluations and any necessary actions arising from the evaluation must be maintained by the organization.

Result:

The requirements of ANSI/ISO/ASQ Q2001:9000 meet the fundamental requirements of this sub-criterion of 10CFR50, Appendix B, to the extent the quality requirements apply to an organization furnishing products and services to the nuclear power industry.

Table 3-8
10CFR50, Appendix B, Criterion VIII – Identification and Control of Materials, Parts, and Components

10CFR50, Appendix B, Criterion VII	ISO Q9001:2000 – 7.5.3
Measures shall be established for the identification and control of materials, parts, and components, including partially fabricated assemblies. These measures shall assure that identification of the item is maintained by heat number, part number, serial number, or other appropriate means, either on the item or on records traceable to the item, as required throughout fabrication, erection, installation, and use of the item. These identification and control measures shall be designed to prevent the use of incorrect or defective material, parts, and components.	7.5.3 Identification and traceability Where appropriate, the organization shall identify the product by suitable means throughout product realization. The organization shall identify the product status with respect to monitoring and measurement requirements. Where traceability is a requirement, the organization shall control and record the unique identification of the product (see 4.2.4) Note In some industry sectors, configuration management is a means by which identification and traceability are maintained.

Fundamental Objective of the Quality Element:

To establish means to identify, maintain identification, and control items, as deemed necessary, throughout fabrication, erection, installation, and use of the item to a degree necessary to prevent the use of incorrect or defective items.

ISO Q9001:2000 Provisions:

With respect to the ISO 9000 certified organization, provisions for traceability during erection, installation, and use by the licensee are not applicable. However, Criterion 7.5.3 requires the organization to identify the product by suitable means throughout product realization, which would include product verification, validation, monitoring, inspection, and test activities. All of these activities would prevent, in part, the use of incorrect or defective material, parts, and components during manufacture or during the provision of services. When traceability is a requirement or deemed necessary, the organization must control and record the unique identification of the product.

Result:

The requirements of ANSI/ISO/ASQ Q2001:9000 meet the fundamental requirements of this sub-criterion of 10CFR50, Appendix B, to the extent the quality requirements apply to an organization furnishing products and services to the nuclear power industry.

Table 3-9
10CFR50, Appendix B, Criterion IX – Control of Special Processes

10CFR50, Appendix B, Criterion IX	ISO Q9001:2000 – 6.3 and 6.4 and 7.2.1 and 7.5.1 and 7.5.2
Measures shall be established to assure that special processes, including welding, heat treating, and nondestructive testing, are controlled and accomplished by qualified personnel using qualified procedures in accordance with applicable codes, standards, specifications, criteria, and other special requirements.	6.3 Infrastructure The organization shall determine, provide and maintain the infrastructure needed to achieve conformity to product requirements. Infrastructure includes, as applicable a) buildings, workspace and associated utilities, b) process equipment (both hardware and software), and c) supporting services (such as transport or communication) 6.4 Work environment The organization shall determine and manage the work environment needed to achieve conformity to product requirements. 7.2.1 Determination of requirements related to the product The organization shall determine a) requirements specified by the customer, including the requirements for delivery and post-delivery activities, b) requirements not stated by the customer but necessary for specified or intended use, where known, c) statutory and regulatory requirements related to the product, and d) any additional requirements determined by the organization. 7.5.1 Control of production and service provision The organization shall plan and carry out production and service provision under controlled conditions. Controlled conditions shall include, as applicable a) the availability of information that describes the characteristics of the product, b) the availability of work instructions, as necessary, c) the use of suitable equipment, d) the availability and use of monitoring and measuring devices, e) the implementation of monitoring and measurement, and f) the implementation of release, delivery and post-delivery activities.

Table 3-9 (cont.)
10CFR50, Appendix B, Criterion IX – Control of Special Processes

	7.5.2 Validation of processes for production and service provision The organization shall validate any processes for production and service provision where the resulting output cannot be verified by subsequent monitoring or measurement. This includes any processes where deficiencies become apparent only after the product is in use of the service has been delivered. Validation shall demonstrate the ability of these processes to achieve planned results. The organization shall establish arrangements for these processes including, as applicable a) defined criteria for review and approval of the processes, b) approval of equipment and qualification of personnel, c) use of specific methods and procedures, d) requirements for records, (see 4.2.4) e) revalidation.

Fundamental Objective of the Quality Element:

To control special processes and to ensure they are performed by qualified personnel using qualified procedures and in accordance with the applicable requirements.

ISO Q9001:2000 Provisions:

Criteria 6.3 and 6.4 require the organization to establish the appropriate infrastructure and work environment necessary to achieve conformity to product requirements.

Criterion 7.2.1 requires the organization to determine requirements related to the product that could include statutory and regulatory requirements related to the product (that is, codes and standards), and any additional requirements determined by the organization. This requirement enables the organization to identify, as necessary, any special processes needed to manufacture the product in accordance with design requirements.

Criterion 7.5.1 requires the organization to plan and carry out production and service provisions under controlled conditions that include, as applicable, the availability of work instructions (that is, procedures), as well as the availability of information that describes the characteristics of the product, the use of suitable equipment, the availability and use of monitoring and measuring devices, and the implementation of release, delivery, and post-delivery activities.

Criterion 7.5.2 requires the organization to validate any processes for production and service provisions where the resulting output cannot be verified by subsequent monitoring or measurement. This includes any (special) processes where deficiencies become apparent only after the product is in use or the service has been delivered. Validation must demonstrate the ability of these processes to achieve planned results. The organization must also establish arrangements for these processes, including the approval of equipment and qualification of personnel, as well as other requirements.

Result:

The requirements of ANSI/ISO/ASQ Q2001:9000 meet the fundamental requirements of this sub-criterion of 10CFR50, Appendix B, to the extent the quality requirements apply to an organization furnishing products and services to the nuclear power industry.

Table 3-10A
10CFR50, Appendix B, Criterion X – Inspection

10CFR50, Appendix B, Criterion X	ISO Q9001:2000 – 7.1 and 8.1 and 8.2.2
A program for inspection of activities affecting quality shall be established and executed by or for the organization performing the activity to verify conformance with the documented instructions, procedures, and drawings for accomplishing the activity.	7.1 Planning of product realization The organization shall plan and develop the processes needed for product realization. Planning of product realization shall be consistent with the requirements of the other processes of the quality management system (see 4.1) In planning product realization, the organization shall determine the following, as appropriate. a) quality objectives and requirements for the product; b) the need to establish processes, documents, and provide resources specific to the product; c) required verification, validation, monitoring, inspection and test activities specific to the product and the criteria for product acceptance; d) records needed to provide evidence that the realization processes and resulting product meet requirements (see 4.2.4) 8.1 Measurement, analysis and improvement – General The organization shall plan and implement the monitoring , measurement, analysis and improvement processes needed a) to demonstrate conformity of the product, b) to ensure conformity of the quality management system, and c) to continually improve the effectiveness of the quality management system. This shall include determination of applicable methods, including statistical techniques, and the extent of their use.

Table 3-10A (cont.)
10CFR50, Appendix B, Criterion X – Inspection

	8.2.2 The organization shall conduct internal audits of planned intervals to determine whether the quality management system a) conforms to the planned arrangements (see 7.1), to the requirements of this International Standard and to the quality management system requirements established by the organization, and b) is effectively implemented and maintained. An audit programme shall be planned, taking into consideration the status and importance of the processes and areas to be audited, as well as the results of previous audits. The audit criteria, scope, frequency and methods shall be defined. Selection of auditors and conduct of audits shall ensure objectivity and impartiality of the audit process. Auditors shall not audit their own work. The responsibilities and requirements for planning and conducting audits, and for reporting results and maintaining records (see 4.2.4) shall be defined in a documented procedure. The management responsible for the area being audited shall ensure that actions are taken without undue delay to eliminate detected nonconformities and their causes. Follow-up activities shall include the verification of the actions taken and the reporting of verification results (see 8.5.2).

Fundamental Objective of the Quality Element:

To establish a program for inspection of activities that verifies conformity of those activities to documented instructions, procedures, or drawings.

ISO Q9001:2000 Provisions:

Criterion 7.1 requires the organization, in part, to verify, validate, monitor, inspect, and test the product (all of which contribute to and are inherent to the planning of product realization).

Criterion 8.1 requires the organization to implement the monitoring, measurement, analysis, and improvement processes needed to demonstrate conformity of the product, to ensure conformity of the QMS, and to continually improve the effectiveness of the QMS.

The Criterion also requires the organization to determine the most applicable/appropriate method(s) for monitoring, measurement, analysis, and improvement, which could include statistical techniques. ANSI/ISO/ASQ Q9000:2000 include measurement, testing, or gauging in the definition of inspection which states that inspection is "conformity evaluation by observation and judgment accompanied as appropriate by measurement, testing, or gauging."

Criterion 8.2.2 requires the organization to conduct internal audits of planned intervals to determine whether the QMS conforms to the planned arrangements described in the planning or product realization (Criterion 7.1). ANSI/ISO/ASQ Q9000:2000 describe an audit as the "systematic, independent and documented process for obtaining audit evidence and evaluating it objectively to determine the extent to which audit criteria are fulfilled." Audit criteria are defined as the "set of policies, procedures or requirements used as a reference." As such, the auditing activities described in ANSI/ISO/ASQ Q9001:2000 provide an adequate level of independent review when ensuring that processes (including inspections) are performed in accordance with applicable procedures.

The criteria noted above all require the organization to inspect in some form (that is, audit, measure, or monitor) activities that verify either conformity of those activities to the QMS (that is, documented instructions, procedures, and the like), or conformity of the product itself.

Result:

The requirements of ANSI/ISO/ASQ Q2001:9000 meet the fundamental requirements of this sub-criterion of 10CFR50, Appendix B, to the extent the quality requirements apply to an organization furnishing products and services to the nuclear power industry.

Table 3-10B
10CFR50, Appendix B, Criterion X – Inspection

10CFR50, Appendix B, Criterion X	ISO Q9001:2000 – 5.5.1 and 7.5.2 and 8.2.3 and 8.2.4 and 8.2.2
Such inspection shall be performed by individuals other than those who performed the activity being inspected.	5.5.1 Responsibility and authority Top management shall ensure that responsibilities and authorities are defined and communicated within the organization. 7.5.2 Validation of processes for production and service provision The organization shall validate any processes for production and service provision where the resulting output cannot be verified by subsequent monitoring or measurement. This includes any processes where deficiencies become apparent only after the product is in use of the service has been delivered. Validation shall demonstrate the ability of these processes to achieve planned results. The organization shall establish arrangements for these processes including, as applicable a) defined criteria for review and approval of the processes, b) approval of equipment and qualification of personnel, c) use of specific methods and procedures, d) requirements for records, (see 4.2.4) e) revalidation. 8.2.3 Monitoring and measurement of processes The organization shall apply suitable methods for monitoring and, where applicable, measurement of the quality management system processes. These methods shall demonstrate the ability of the processes to achieve planned results. When planned results are not achieved, correction and corrective action shall be taken, as appropriate, to ensure conformity of the product.

Table 3-10B (cont.)
10CFR50, Appendix B, Criterion X – Inspection

	8.2.4 Monitoring and measurement of product The organization shall monitor and measure the characteristics of the product to verify that product requirements have been met. This shall be carried out at appropriate stages of the product realization process in accordance with the planned arrangements. (see 7.1). Evidence of conformity with the acceptance criteria shall be maintained. Records shall indicate the person(s) authorizing release of product (see 4.2.4). Product release and service delivery shall not proceed until the planned arrangements (see 7.1) have been satisfactorily completed, unless otherwise approved by a relevant authority and, where applicable, by the customer. 8.2.2 The organization shall conduct internal audits of planned intervals to determine whether the quality management system a) conforms to the planned arrangements (see 7.1), to the requirements of this International Standard and to the quality management system requirements established by the organization, and b) is effectively implemented and maintained. An audit programme shall be planned, taking into consideration the status and importance of the processes and areas to be audited, as well as the results of previous audits. The audit criteria, scope, frequency and methods shall be defined. Selection of auditors and conduct of audits shall ensure objectivity and impartiality of the audit process. Auditors shall not audit their own work. The responsibilities and requirements for planning and conducting audits, and for reporting results and maintaining records (see 4.2.4) shall be defined in a documented procedure. The management responsible for the area being audited shall ensure that actions are taken without undue delay to eliminate detected nonconformities and their causes. Follow-up activities shall include the verification of the actions taken and the reporting of verification results (see 8.5.2).

Fundamental Objective of the Quality Element:

To ensure personnel performing the inspection are not the same individuals who performed the activity being inspected.

ISO Q9001:2000 Provisions:

Criterion 5.5.1 requires the organization's top management ensure that responsibilities and authorities are defined and communicated within the organization.

Criterion 7.5.2 requires the organization to plan and implement an independent process defined as validation of processes for production and service provisions. Validation, as defined in ANSI/ISO/ASQ 9000:2000, is the confirmation through the provision of objective evidence, that the requirements for a specific intended use or application have been fulfilled. Criterion 7.5.2 also requires that during validation of processes for production (which could include inspection or testing), the organization approves the use of equipment and qualify personnel appropriately.

Criterion 8.2.3 requires the organization to monitor and, where applicable, measure the QMS processes. Processes included in this requirement are design, production, and service provision. Inherent to these activities are tests and inspections employed to ensure the product conforms to design requirements. The organization must establish methods to demonstrate the ability of these processes to achieve planned results. When planned results are not achieved, the organization must take corrective action to ensure conformity of the product.

Criterion 8.2.4 requires that the organization monitor and measure the characteristics of the product (which could include inspection or testing) to verify that product requirements have been met. It also requires that evidence of conformity with the acceptance criteria is maintained, and that records indicate the person(s) authorizing release of the product.

Criterion 8.2.2 requires the organization to ensure that individuals do not audit their own work, thereby providing a level of independence between the individual performing the activity/process and the individual ensuring that the activity/process is under control.

Result:

The requirements of ANSI/ISO/ASQ Q2001:9000 do not meet the stated requirements of this sub-criterion of 10CFR50, Appendix B.

Table 3-10C
10CFR50, Appendix B, Criterion X – Inspection

10CFR50, Appendix B, Criterion X	ISO Q9001:2000 –7.1 and 8.2.4 and 8.1
Examinations, measurements, or tests of material or products processed shall be performed for each work operation where necessary to assure quality.	7.1 Planning of product realization The organization shall plan and develop the processes needed for product realization. Planning of product realization shall be consistent with the requirements of the other processes of the quality management system (see 4.1) In planning product realization, the organization shall determine the following, as appropriate. a) quality objectives and requirements for the product; b) the need to establish processes, documents, and provide resources specific to the product; c) required verification, validation, monitoring, inspection and test activities specific to the product and the criteria for product acceptance; d) records needed to provide evidence that the realization processes and resulting product meet requirements (see 4.2.4) 8.2.4 Monitoring and measurement of product The organization shall monitor and measure the characteristics of the product to verify that product requirements have been met. This shall be carried out at appropriate stages of the product realization process in accordance with the planned arrangements. (see 7.1). Evidence of conformity with the acceptance criteria shall be maintained. Records shall indicate the person(s) authorizing release of product (see 4.2.4). Product release and service delivery shall not proceed until the planned arrangements (see 7.1) have been satisfactorily completed, unless otherwise approved by a relevant authority and, where applicable, by the customer. 8.1 Measurement, analysis and improvement – General The organization shall plan and implement the monitoring , measurement, analysis and improvement processes needed a) to demonstrate conformity of the product, b) to ensure conformity of the quality management system, and c) to continually improve the effectiveness of the quality management system. This shall include determination of applicable methods, including statistical techniques, and the extent of their use.

Fundamental Objective of the Quality Element:

To perform examinations, measurements, or tests of items for each work operation when necessary to assure quality.

ISO Q9001:2000 Provisions:

Criterion 8.1 requires, in general, that the organization plan and implement the monitoring, measurement, and analysis of processes needed to demonstrate conformity of the product.

Criterion 8.2.4 requires the organization to monitor and measure the characteristics of the product to verify that product requirements have been met. This must be carried out at appropriate stages of the product realization process, which are described in Criterion 7.1.

Result:

The requirements of ANSI/ISO/ASQ Q2001:9000 meet the fundamental requirements of this sub-criterion of 10CFR50, Appendix B, to the extent the quality requirements apply to an organization furnishing products and services to the nuclear power industry.

Table 3-10D
10CFR50, Appendix B, Criterion X – Inspection

10CFR50, Appendix B, Criterion X	ISO Q9001:2000 – 6.3 and 6.4 and 7.5.1 and 7.5.2 and 8.2.3 and 8.2.4
If inspection of processed material or products is impossible or disadvantageous, indirect control by monitoring processing methods, equipment, and personnel shall be provided. Both inspection and process monitoring shall be provided when control is inadequate without both.	6.3 Infrastructure The organization shall determine, provide and maintain the infrastructure needed to achieve conformity to product requirements. Infrastructure includes, as applicable a) buildings, workspace and associated utilities, b) process equipment (both hardware and software), and c) supporting services (such as transport or communication) 6.4 Work environment The organization shall determine and manage the work environment needed to achieve conformity to product requirements. 7.5.1 Control of production and service provision The organization shall plan and carry out production and service provision under controlled conditions. Controlled conditions shall include, as applicable a) the availability of information that describes the characteristics of the product, b) the availability of work instructions, as necessary, c) the use of suitable equipment, d) the availability and use of monitoring and measuring devices, e) the implementation of monitoring and measurement, and f) the implementation of release, delivery and post-delivery activities. 7.5.2 Validation of processes for production and service provision The organization shall validate any processes for production and service provision where the resulting output cannot be verified by subsequent monitoring or measurement. This includes any processes where deficiencies become apparent only after the product is in use of the service has been delivered. Validation shall demonstrate the ability of these processes to achieve planned results.

Table 3-10D (cont.)
10CFR50, Appendix B, Criterion X – Inspection

	The organization shall establish arrangements for these processes including, as applicable a) defined criteria for review and approval of the processes, b) approval of equipment and qualification of personnel, c) use of specific methods and procedures, d) requirements for records, (see 4.2.4) e) revalidation. 8.2.3 Monitoring and measurement of processes The organization shall apply suitable methods for monitoring and, where applicable, measurement of the quality management system processes. These methods shall demonstrate the ability of the processes to achieve planned results. When planned results are not achieved, correction and corrective action shall be taken, as appropriate, to ensure conformity of the product. 8.2.4 Monitoring and measurement of product The organization shall monitor and measure the characteristics of the product to verify that product requirements have been met. This shall be carried out at appropriate stages of the product realization process in accordance with the planned arrangements. (see 7.1). Evidence of conformity with the acceptance criteria shall be maintained. Records shall indicate the person(s) authorizing release of product (see 4.2.4). Product release and service delivery shall not proceed until the planned arrangements (see 7.1) have been satisfactorily completed, unless otherwise approved by a relevant authority and, where applicable, by the customer.

Fundamental Objective of the Quality Element:

To perform monitoring of processing methods, equipment, and personnel when inspection is not possible or disadvantageous.

ISO Q9001:2000 Provisions:

Criteria 6.3 and 6.4 require the organization to establish the appropriate infrastructure and work environment necessary to achieve conformity to product requirements.

Criterion 7.5.1 requires the organization to plan and carry out production and service provisions under controlled conditions that include, as applicable, the availability of work instructions (that is, procedures), as well as the availability of information that describes the characteristics of the product, the use of suitable equipment, the availability and use of monitoring and measuring devices, and the implementation of release, delivery and post-delivery activities.

Criterion 7.5.2 requires the organization to validate any processes for production and service provision where the resulting output cannot be verified by subsequent monitoring or measurement. This includes any (special) processes where deficiencies become apparent only after the product is in use or the service has been delivered. Validation must demonstrate the ability of these processes to achieve planned results. The organization must also establish arrangements for these processes, including the approval of equipment and qualification of personnel, as well as other requirements.

Criterion 8.2.3 requires the organization to apply suitable methods for monitoring and, where applicable, measurement of QMS processes. These methods must demonstrate the ability of the processes to achieve planned results.

Criterion 8.2.4 requires the organization to monitor and measure the characteristics of the product to verify that product requirements have been met. This must be carried out at appropriate stages of the product realization process, which are described in Criterion 7.1.

Result:

The requirements of ANSI/ISO/ASQ Q2001:9000 meet the fundamental requirements of this sub-criterion of 10CFR50, Appendix B, to the extent the quality requirements apply to an organization furnishing products and services to the nuclear power industry.

Table 3-10E
10CFR50, Appendix B, Criterion X – Inspection

10CFR50, Appendix B, Criterion X	ISO Q9001:2000 – 7.4.3 and 8.2.4
If mandatory inspection hold points, which require witnessing or inspecting by the applicant's designated representative and beyond which work shall not proceed without the consent of its designated representative are required, the specific hold points shall be indicated in appropriate documents.	7.4.3 Verification of purchased product The organization shall establish and implement the inspection or other activities necessary for ensuring that purchased product meets specified purchase requirements. Where the organization or its customer intends to perform verification at the supplier's premises, the organization shall state the intended verification arrangements and method of product release in the purchasing information. 8.2.4 Monitoring and measurement of product The organization shall monitor and measure the characteristics of the product to verify that product requirements have been met. This shall be carried out at appropriate stages of the product realization process in accordance with the planned arrangements. (see 7.1). Evidence of conformity with the acceptance criteria shall be maintained. Records shall indicate the person(s) authorizing release of product (see 4.2.4). Product release and service delivery shall not proceed until the planned arrangements (see 7.1) have been satisfactorily completed, unless otherwise approved by a relevant authority and, where applicable, by the customer.

Fundamental Objective of the Quality Element:

To define and require indication of hold points that require witnessing or inspection by the licensee (that is, the customer).

ISO Q9001:2000 Provisions:

Criterion 7.4.3 requires, in general, that the organization establish and implement inspection or other activities necessary for ensuring that purchased product meets specified purchase requirements. Where the organization or its customer intends to perform verification at the supplier's premises, the organization must state the intended verification arrangements and method of product release in the purchasing information.

Criterion 8.2.4 further requires the organization to monitor and measure the characteristics of the product to verify that product requirements have been met. This must be carried out at appropriate stages (which may be noted by the organization as hold-points in

order to facilitate a particular test, inspection, or measurement) of the product realization process and evidence of conformity with the acceptance criteria must be maintained. Records must indicate the person(s) authorizing release of product, and product release and service delivery cannot proceed until the planned arrangements have been satisfactorily completed, unless otherwise approved by a relevant authority and, where applicable, by the customer.

Result:

The requirements of ANSI/ISO/ASQ Q2001:9000 meet the fundamental requirements of this sub-criterion of 10CFR50, Appendix B, to the extent the quality requirements apply to an organization furnishing products and services to the nuclear power industry.

Table 3-11A
10CFR50, Appendix B, Criterion XI – Test Control

10CFR50, Appendix B, Criterion XI	ISO Q9001:2000 – 7.1 and 8.1 and 5.4.2
A test program shall be established to assure that all testing required to demonstrate that structures, systems, and components will perform satisfactorily in service is identified and performed in accordance with written test procedures which incorporate the requirements and acceptance limits contained in applicable design documents. The test program shall include, as appropriate, proof tests prior to installation, preoperational tests, and operational tests during nuclear power plant or fuel reprocessing plant operation, of structures, systems, and components.	7.1 Planning of product realization The organization shall plan and develop the processes needed for product realization. Planning of product realization shall be consistent with the requirements of the other processes of the quality management system (see 4.1) In planning product realization, the organization shall determine the following, as appropriate. a) quality objectives and requirements for the product; b) the need to establish processes, documents, and provide resources specific to the product; c) required verification, validation, monitoring, inspection and test activities specific to the product and the criteria for product acceptance; d) records needed to provide evidence that the realization processes and resulting product meet requirements (see 4.2.4) 8.1 Measurement, analysis and improvement – General The organization shall plan and implement the monitoring , measurement, analysis and improvement processes needed a) to demonstrate conformity of the product, b) to ensure conformity of the quality management system, and c) to continually improve the effectiveness of the quality management system. This shall include determination of applicable methods, including statistical techniques, and the extent of their use. 5.4.2 Quality management system planning Top management shall ensure that a) the planning of the quality management system is carried out in order to meet the requirements given in 4.1, as well as the quality objectives, and b) the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented.

Fundamental Objective of the Quality Element:

To establish a test program that includes pre-installation proof tests, pre-operational tests, and operational tests, that identifies the test requirements and that employs written procedures containing design information/acceptance criteria.

ISO Q9001:2000 Provisions:

Establishing a test program that includes pre-installation proof tests, pre-operational tests, and operational tests of SSCs installed at a nuclear power plant would not be applicable to a supplier/manufacturer/organization certified to ISO 9000:2000. However, establishing a test program to ensure that manufactured products conform to design requirements is an appropriate and applicable element of the QMS.

Criterion 7.1 requires the organization to plan and develop the processes needed for product realization, which includes, as appropriate, verification, validation, monitoring, inspection, and test activities specific to the product and the criteria for product acceptance.

Criterion 8.1 requires the organization to plan and implement the monitoring, measurement, analysis, and improvement processes needed to demonstrate conformity of the product.

Result:

The requirements of ANSI/ISO/ASQ Q2001:9000 meet the fundamental requirements of this sub-criterion of 10CFR50, Appendix B, to the extent the quality requirements apply to an organization furnishing products and services to the nuclear power industry.

Table 3-11B
10CFR50, Appendix B, Criterion XI – Test Control

10CFR50, Appendix B, Criterion XI	ISO Q9001:2000 – 8.2.4 and 5.4.2 and 7.1 and 6.3 and 6.4 and 7.5.1 and 7.5.2
Test procedures shall include provisions for assuring that all prerequisites for the given test have been met, that adequate test instrumentation is available and used, and that the test is performed under suitable environmental conditions.	8.2.4 Monitoring and measurement of product The organization shall monitor and measure the characteristics of the product to verify that product requirements have been met. This shall be carried out at appropriate stages of the product realization process in accordance with the planned arrangements. (see 7.1). Evidence of conformity with the acceptance criteria shall be maintained. Records shall indicate the person(s) authorizing release of product (see 4.2.4). Product release and service delivery shall not proceed until the planned arrangements (see 7.1) have been satisfactorily completed, unless otherwise approved by a relevant authority and, where applicable, by the customer. 5.4.2 Quality management system planning Top management shall ensure that a) the planning of the quality management system is carried out in order to meet the requirements given in 4.1, as well as the quality objectives, and b) the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented. 7.1 Planning of product realization The organization shall plan and develop the processes needed for product realization. Planning of product realization shall be consistent with the requirements of the other processes of the quality management system (see 4.1) In planning product realization, the organization shall determine the following, as appropriate. a) quality objectives and requirements for the product; b) the need to establish processes, documents, and provide resources specific to the product; c) required verification, validation, monitoring, inspection and test activities specific to the product and the criteria for product acceptance; d) records needed to provide evidence that the realization processes and resulting product meet requirements (see 4.2.4)

Table 3-11B (cont.)
10CFR50, Appendix B, Criterion XI – Test Control

	6.3 Infrastructure The organization shall determine, provide and maintain the infrastructure needed to achieve conformity to product requirements. Infrastructure includes, as applicable a) buildings, workspace and associated utilities, b) process equipment (both hardware and software), and c) supporting services (such as transport or communication) 6.4 Work environment The organization shall determine and manage the work environment needed to achieve conformity to product requirements. 7.5.1 Control of production and service provision The organization shall plan and carry out production and service provision under controlled conditions. Controlled conditions shall include, as applicable a) the availability of information that describes the characteristics of the product, b) the availability of work instructions, as necessary, c) the use of suitable equipment, d) the availability and use of monitoring and measuring devices, e) the implementation of monitoring and measurement, and f) the implementation of release, delivery and post-delivery activities. 7.5.2 Validation of processes for production and service provision The organization shall validate any processes for production and service provision where the resulting output cannot be verified by subsequent monitoring or measurement. This includes any processes where deficiencies become apparent only after the product is in use of the service has been delivered. Validation shall demonstrate the ability of these processes to achieve planned results. The organization shall establish arrangements for these processes including, as applicable a) defined criteria for review and approval of the processes, b) approval of equipment and qualification of personnel, c) use of specific methods and procedures, d) requirements for records, (see 4.2.4) e) revalidation.

Fundamental Objective of the Quality Element:

To ensure test procedures include test prerequisites and employ adequate test equipment, and that testing is performed under suitable environmental conditions.

ISO Q9001:2000 Provisions:

In general, Criterion 8.2.4 requires the organization to monitor and measure the characteristics of the product to verify that product requirements have been met.

Criteria 6.3 and 6.4 require the organization to establish the appropriate infrastructure and work environment necessary to achieve conformity to product requirements.

Criterion 7.1 requires the organization to plan and develop the processes needed for product realization, which includes, as appropriate, verification, validation, monitoring, inspection, and test activities specific to the product and the criteria for product acceptance.

Criterion 7.5.1 requires the organization to plan and carry out production and service provisions under controlled conditions that include, as applicable, the availability of work instructions (that is, procedures), as well as the availability of information that describes the characteristics of the product, the use of suitable equipment, the availability and use of monitoring and measuring devices, and the implementation of release, delivery, and post-delivery activities.

Both Criteria 7.1 and 7.5.1 require some degree of planning prior to performing any inspection/test activities or the use of monitoring and measuring devices. The planning inherent to these requirements addresses the need to establish any prerequisites necessary to properly perform the inspection/test activities.

Criterion 7.5.2 requires the organization to validate any processes for production and service provisions where the resulting output cannot be verified by subsequent monitoring or measurement.

Result:

The requirements of ANSI/ISO/ASQ Q2001:9000 meet the fundamental requirements of this sub-criterion of 10CFR50, Appendix B, to the extent the quality requirements apply to an organization furnishing products and services to the nuclear power industry.

Table 3-11C
10CFR50, Appendix B, Criterion XI – Test Control

10CFR50, Appendix B, Criterion XI	ISO Q9001:2000 – 7.5.3 and 8.2.4
Test results shall be documented and evaluated to assure that test requirements have been satisfied.	7.5.3 Identification and traceability Where appropriate, the organization shall identify the product by suitable means throughout product realization. The organization shall identify the product status with respect to monitoring and measurement requirements. Where traceability is a requirement, the organization shall control and record the unique identification of the product (see 4.2.4). Note In some industry sectors, configuration management is a means by which identification and traceability are maintained. 8.2.4 Monitoring and measurement of product The organization shall monitor and measure the characteristics of the product to verify that product requirements have been met. This shall be carried out at appropriate stages of the product realization process in accordance with the planned arrangements. (see 7.1). Evidence of conformity with the acceptance criteria shall be maintained. Records shall indicate the person(s) authorizing release of product (see 4.2.4). Product release and service delivery shall not proceed until the planned arrangements (see 7.1) have been satisfactorily completed, unless otherwise approved by a relevant authority and, where applicable, by the customer.

Fundamental Objective of the Quality Element:

To ensure test results are documented and evaluated to ensure test requirements are met.

ISO Q9001:2000 Provisions:

In general, Criterion 8.2.4 requires the organization to monitor and measure the characteristics of the product to verify that product requirements have been met. Criterion 8.2.4 also requires that evidence of conformity with the acceptance criteria shall be maintained and that these records must indicate the person(s) authorizing release (that is, verifying conformity) of the product.

Criterion 7.5.3 further requires the organization to identify (that is, evaluate) the product status with respect to monitoring and measurement requirements, and where traceability is a requirement to control and record (that is, document) the unique identification of the product.

The above Criteria require the organization to ensure documents associated with product conformity with acceptance criteria are defined as records and are controlled in accordance with Criterion 4.2.4.

Result:

The requirements of ANSI/ISO/ASQ Q2001:9000 meet the fundamental requirements of this sub-criterion of 10CFR50, Appendix B, to the extent the quality requirements apply to an organization furnishing products and services to the nuclear power industry.

Table 3-12
10CFR50, Appendix B, Criterion XII – Control of Measuring and Test Equipment

10CFR50, Appendix B, Criterion XII	ISO Q9001:2000 – 7.6
Measures shall be established to assure that tools, gages, instruments, and other measuring and testing devices used in activities affecting quality are properly controlled, calibrated, and adjusted at specified periods to maintain accuracy within necessary limits.	7.6 Control of monitoring and measuring devices The organization shall determine the monitoring and measurement to be undertaken and the monitoring and measuring devices needed to provide evidence of conformity of product to determined requirements (see7.2.1). The organization shall establish processes to ensure that monitoring and measurement can be carried out and are carried out in a manner that is consistent with the monitoring and measurement requirements. Where necessary to ensure valid results, measuring equipment shall a) be calibrated or verified at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards; where no such standards exist, the basis used for calibration or verification shall be recorded; b) be adjusted or re-adjusted as necessary; c) be identified to enable the calibration status to be determined; d) be safeguarded from adjustments that would invalidate the measurement result; e) be protected from damage and deterioration during handling, maintenance and storage. In addition, the organization shall assess and record the validity of the previous measuring results when the equipment is found not to conform to requirements. The organization shall take appropriate action on the equipment and any product affected. Records of the results of calibration and verification shall be maintained. When used in the monitoring and measurement of specified requirements, the ability of computer software to satisfy the intended application shall be confirmed. This shall be undertaken prior to initial use and reconfirmed as necessary. Note See ISO 10012-1 and ISO 10012-2 for guidance.

Fundamental Objective of the Quality Element:

To ensure measurement and test equipment is controlled, calibrated, and adjusted periodically, and maintained to accuracy within specified limits.

ISO Q9001:2000 Provisions:

Criterion 7.6 requires the organization to determine the monitoring and measurement to be undertaken and the monitoring and measuring devices needed to provide evidence of conformity of product to determined requirements. The organization must establish processes to ensure that monitoring and measurement can be carried out and are carried out in a manner that is consistent with the monitoring and measurement requirements.

The criterion also requires that, when necessary to ensure valid results, measuring equipment must:

a) Be calibrated or verified at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards; where no such standards exist, the basis used for calibration or verification shall be recorded
b) Be adjusted or re-adjusted as necessary
c) Be identified to enable the calibration status to be determined
d) Be safeguarded from adjustments that would invalidate the measurement result
e) Be protected from damage and deterioration during handling, maintenance, and storage

In addition, Criterion 7.6 requires the organization to assess and record the validity of the previous measuring results when the equipment is found not to conform to requirements. Finally, the organization must take appropriate action on the equipment and any product affected. Records of the results of calibration and verification must be maintained by the organization.

Result:

The requirements of ANSI/ISO/ASQ Q2001:9000 meet the fundamental requirements of this sub-criterion of 10CFR50, Appendix B, to the extent the quality requirements apply to an organization furnishing products and services to the nuclear power industry.

Table 3-13A
10CFR50, Appendix B, Criterion XIII – Handling, Storage, and Shipping

10CFR50, Appendix B, Criterion XIII	ISO Q9001:2000 – 6.3 and 6.4 and 7.5.5
Measures shall be established to control the handling, storage, shipping, cleaning and preservation of material and equipment in accordance with work and inspection instructions to prevent damage or deterioration.	6.3 Infrastructure The organization shall determine, provide and maintain the infrastructure needed to achieve conformity to product requirements. Infrastructure includes, as applicable a) buildings, workspace and associated utilities, b) process equipment (both hardware and software), and c) supporting services (such as transport or communication) 6.4 Work environment The organization shall determine and manage the work environment needed to achieve conformity to product requirements. 7.5.5 Preservation of product The organization shall preserve the conformity of product during internal processing and delivery to the intended destination. The preservation shall include identification, handling, packaging, storage and protection. Preservation shall also apply to the constituent parts of the product.

Fundamental Objective of the Quality Element:

To ensure products are not damaged or deteriorate during handling, storage, shipping, preservation, and cleaning.

ISO Q9001:2000 Provisions:

Criteria 6.3 and 6.4 require the organization to establish the appropriate infrastructure and work environment necessary to achieve conformity to product requirements.

Criterion 7.5.5 requires the organization to preserve the conformity of the product while it is being manufactured (that is, during internal processing) through its delivery to the customer. This would include preservation of the product during any special processes that might include cleaning. Specifically, the criterion defines the scope of preservation to include maintaining product identification, as well as during its handling, packaging, and storage. The criterion also provides a general need to protect the product from damage, which might also be incurred during a number of activities such as handling, packaging, and storage.

Finally the criterion requires the organization to apply these preservation activities to constituent parts of the product.

Result:

The requirements of ANSI/ISO/ASQ Q2001:9000 meet the fundamental requirements of this sub-criterion of 10CFR50, Appendix B, to the extent the quality requirements apply to an organization furnishing products and services to the nuclear power industry.

Table 3-13B
10CFR50, Appendix B, Criterion XIII – Handling, Storage, and Shipping

10CFR50, Appendix B, Criterion XIII	ISO Q9001:2000 – 6.3 and 6.4 and 7.5.5 and 7.5.1
When necessary for particular products, special protective environments, such as inert gas atmosphere, specific moisture content levels, and temperature levels, shall be specified and provided.	6.3 Infrastructure The organization shall determine, provide and maintain the infrastructure needed to achieve conformity to product requirements. Infrastructure includes, as applicable a) buildings, workspace and associated utilities, b) process equipment (both hardware and software), and c) supporting services (such as transport or communication) 6.4 Work environment The organization shall determine and manage the work environment needed to achieve conformity to product requirements. 7.5.5 Preservation of product The organization shall preserve the conformity of product during internal processing and delivery to the intended destination. The preservation shall include identification, handling, packaging, storage and protection. Preservation shall also apply to the constituent parts of the product. 7.5.1 Control of production and service provision The organization shall plan and carry out production and service provision under controlled conditions. Controlled conditions shall include, as applicable a) the availability of information that describes the characteristics of the product, b) the availability of work instructions, as necessary, c) the use of suitable equipment, d) the availability and use of monitoring and measuring devices, e) the implementation of monitoring and measurement, and f) the implementation of release, delivery and post-delivery activities.

Fundamental Objective of the Quality Element:

When necessary for particular products, to provide special protective environments.

ISO Q9001:2000 Provisions:

Criteria 6.3 and 6.4 require the organization to establish the appropriate infrastructure and work environment necessary to achieve conformity to product requirements.

The requirement in 10CFR50, Appendix B, makes the licensee responsible for determining which products require special environmental conditions such as inert gas atmosphere, and specific moisture content and temperature levels. This is typically performed with input from the supplier/manufacturer of the product. Criterion 7.5.5 requires the organization to preserve the conformity of the (any) product while it is being manufactured (that is, during internal processing) through its delivery to the customer. Therefore, what could be considered a special protective environment from a nuclear plant operator's perspective might not be considered special from the manufacturer's perspective given the fundamental requirement to preserve the conformity of product during internal processing and delivery.

Result:

The requirements of ANSI/ISO/ASQ Q2001:9000 meet the fundamental requirements of this sub-criterion of 10CFR50, Appendix B, to the extent the quality requirements apply to an organization furnishing products and services to the nuclear power industry.

Table 3-14
10CFR50, Appendix B, Criterion XIV – Inspection, Test, and Operating Status

10CFR50, Appendix B, Criterion XIV	ISO Q9001:2000 – 7.5.3
Measures shall be established to indicate, by the use of markings such as stamps, tags, labels, routing cards, or other suitable means, the status of inspections and tests performed upon individual items of the nuclear power plant or fuel reprocessing plant. These measures shall provide for the identification of items which have satisfactorily passed required inspections and tests, where necessary to preclude inadvertent bypassing of such inspections and tests. Measures shall also be established for indicating the operating status of structures, systems, and components of the nuclear power plant or fuel reprocessing plant, such as by tagging valves and switches, to prevent inadvertent operation.	7.5.3 Identification and traceability Where appropriate, the organization shall identify the product by suitable means throughout product realization. The organization shall identify the product status with respect to monitoring and measurement requirements. Where traceability is a requirement, the organization shall control and record the unique identification of the product (see 4.2.4) Note In some industry sectors, configuration management is a means by which identification and traceability are maintained.

Fundamental Objective of the Quality Element:

To establish measures that indicate both the operating status and the status of tests/inspections performed on SSCs of the nuclear power plant.

ISO Q9001:2000 Provisions:

The requirement to indicate both the operating status and the status of tests/inspections performed on SSCs of the nuclear power plant would not be applicable to an organization (that is, supplier/manufacturer) certified to ISO 9000:2000.

However, Criterion 7.5.3 correlates these requirements to the organization as the product is being manufactured, tested, or inspected. Criterion 7.5.3 requires the organization to identify the product by suitable means throughout product realization and to identify the product status with respect to monitoring and measurement requirements. It also requires that when traceability is a requirement, the

organization must control and record the unique identification of the product. ISO Q9001:2000 requirements for maintaining the status of product during/after testing or inspection is discussed in the correlating to Criteria X and XI of 10CFR50, Appendix B.

Result:

The requirements of ANSI/ISO/ASQ Q2001:9000 meet the fundamental requirements of this sub-criterion of 10CFR50, Appendix B, to the extent the quality requirements apply to an organization furnishing products and services to the nuclear power industry.

Table 3-15
10CFR50, Appendix B, Criterion XV – Nonconforming Materials, Parts, or Components

10CFR50, Appendix B, Criterion XV	ISO Q9001:2000 – 8.3
Measures shall be established to control materials, parts, or components which do not conform to requirements in order to prevent their inadvertent use or installation. These measures shall include, as appropriate, procedures for identification, documentation, segregation, disposition, and notification to affected organizations. Nonconforming items shall be reviewed and accepted, rejected, repaired or reworked in accordance with documented procedures.	8.3 Control of nonconforming product The organization shall ensure that product which does not conform to product requirements is identified and controlled to prevent its unintended use or delivery. The controls and related responsibilities and authorities for dealing with nonconforming product shall be defined in a documented procedure. The organization shall deal with nonconforming product by one or more of the following ways: a) by taking action to eliminate the detected nonconformity; b) by authorizing its use, release or acceptance under concession by a relevant authority and, where applicable, by the customer; c) by taking action to preclude its original intended use or application. Records of the nature of nonconformities and any subsequent actions taken, including concessions obtained, shall be maintained (see 4.2.4). When nonconforming product is corrected it shall be subjected to re-verification to demonstrate conformity to the requirements. When nonconforming product is detected after delivery or use has started, the organization shall take action appropriate to the effects, or potential effects, of the nonconformity.

Fundamental Objective of the Quality Element:

To establish measures to control nonconforming items that could include procedures for identification, documentation, segregation, disposition, and notification.

ISO Q9001:2000 Provisions:

Criterion 8.3 requires the organization to ensure that product, which does not conform to product requirements, is identified and controlled to prevent its unintended use or delivery. The controls and related responsibilities and authorities for dealing with nonconforming product must be defined in a documented procedure.

The criterion requires the organization to deal with nonconforming product by one or more of the following ways:

a) By taking action to eliminate the detected nonconformity
b) By authorizing its use, release, or acceptance under concession by a relevant authority and, where applicable, by the customer
c) By taking action to preclude its original intended use or application

Records of the nature of nonconformities and any subsequent actions taken, including concessions obtained, must be maintained by the organization. When nonconforming product is corrected, it must be subjected to re-verification to demonstrate conformity to the requirements, and when nonconforming product is detected after delivery or use has started, the organization must take action appropriate to the effects, or potential effects, of the nonconformity. These actions inherently include appropriate notification of effected customers.

Result:

The requirements of ANSI/ISO/ASQ Q2001:9000 meet the fundamental requirements of this sub-criterion of 10CFR50, Appendix B, to the extent the quality requirements apply to an organization furnishing products and services to the nuclear power industry.

Table 3-16
10CFR50, Appendix B, Criterion XVI – Corrective Action

10CFR50, Appendix B, Criterion XVI	ISO Q9001:2000 – 8.3, 8.5.2 and 8.5.3
Measures shall be established to assure that conditions adverse to quality, such as failures, malfunctions, deficiencies, deviations, defective material and equipment, and nonconformances are promptly identified and corrected. In the case of significant conditions adverse to quality, the measures shall assure that the cause of the condition is determined and corrective action taken to preclude repetition. The identification of the significant condition adverse to quality, the cause of the condition, and the corrective action taken shall be documented and reported to appropriate levels of management.	8.3 Control of nonconforming product The organization shall ensure that product which does not conform to product requirements is identified and controlled to prevent its unintended use or delivery. The controls and related responsibilities and authorities for dealing with nonconforming product shall be defined in a documented procedure. The organization shall deal with nonconforming product by one or more of the following ways: a) by taking action to eliminate the detected nonconformity; by authorizing its use, release or acceptance under concession by a relevant b) authority and, where applicable, by the customer; c) by taking action to preclude its original intended use or application. Records of the nature of nonconformities and any subsequent actions taken, including concessions obtained, shall be maintained (see 4.2.4). When nonconforming product is corrected it shall be subjected to re-verification to demonstrate conformity to the requirements. When nonconforming product is detected after delivery or use has started, the organization shall take action appropriate to the effects, or potential effects, of the nonconformity. 8.5.2 Corrective action The organization shall take action to eliminate the cause of nonconformities in order to prevent recurrence. Corrective actions shall be appropriate to the effects of the nonconformities encountered. A documented procedure shall be established to define requirements for a) reviewing nonconformitities (including complaints), b) determining the causes of nonconformities, c) evaluating the need for action to ensure that nonconformities do no recur, d) determining and implementing action needed, e) records of the results of action taken (see 4.2.4), and f) reviewing corrective action taken.

Table 3-16A (cont.)
10CFR50, Appendix B, Criterion XVI – Corrective Action

	8.5.3 Preventive action The organization shall determine action to eliminate the causes of potential nonconformities in order to prevent their occurrence. Preventive actions shall be appropriate to the effects of the potential problems. A documented procedure shall be established to define requirements for a) reviewing nonconformitities (including complaints), b) determining the causes of nonconformities, c) evaluating the need for action to ensure that nonconformities do no recur, d) determining and implementing action needed, e) records of the results of action taken (see 4.2.4), and f) reviewing corrective action taken.

Fundamental Objective of the Quality Element:

To establish measures to correct nonconforming conditions, identify the cause, preclude its recurrence, and to document/report the results of corrective actions taken.

ISO Q9001:2000 Provisions:

Criterion 8.3 requires the organization to identify and control non-conforming items in order to prevent their unintended use or delivery.

Criteria 8.5.2 and 8.5.3 require the organization to address both corrective and preventive actions respectively. Specifically, Criterion 8.5.2 requires the organization to eliminate the cause of nonconformities in order to prevent recurrence, and that the corrective actions are appropriate to the effects of the nonconformities encountered. The Criterion also requires that the organization establish a documented procedure that defines requirements for the following:

a) Reviewing nonconformitities (including complaints)
b) Determining the causes of nonconformities
c) Evaluating the need for action to ensure that nonconformities do no recur

d) Determining and implementing action needed
e) Records of the results of action taken
f) Reviewing corrective action taken

Criterion 8.5.3 requires the organization to eliminate the causes of potential nonconformities in order to prevent their occurrence, and that preventive actions are appropriate to the effects of the potential problems. The Criterion also requires that the organization establish a documented procedure that defines the requirements for the following:

a) Determining potential nonconformities and their causes
b) Evaluating he need for action to prevent occurrence of nonconformities
c) Determining and implementing action needed
d) Records of results of action taken
e) Reviewing preventive action taken

Result:

The requirements of ANSI/ISO/ASQ Q2001:9000 meet the fundamental requirements of this sub-criterion of 10CFR50, Appendix B, to the extent the quality requirements apply to an organization furnishing products and services to the nuclear power industry.

Table 3-17A
10CFR50, Appendix B, Criterion XVII – Quality Assurance Records

10CFR50, Appendix B, Criterion XVII	ISO Q9001:2000 – 4.2.4
Sufficient records shall be maintained to furnish evidence of activities affecting quality.	4.2.4 Control of records Records shall be established and maintained to provide evidence of conformity to requirements and of the effective operation of the quality management system. Records shall remain legible, readily identifiable and retrievable. A documented procedure shall be established to define the controls needed for the identification, storage, protection, retrieval, retention time and disposition of records.

Fundamental Objective of the Quality Element:

To maintain records to furnish sufficient evidence of activities affecting quality.

ISO Q9001:2000 Provisions:

Criterion 4.2.4, which is cross-referenced in numerous other requirements of ISO Q9001:2000, requires the organization to establish and maintain records that provide evidence of conformity to requirements and of the effective operation of the quality management system. These records must remain legible, readily identifiable, and retrievable. The Criterion also requires the organization to establish documented procedure(s) that define the controls needed for the identification, storage, protection, retrieval, retention time, and disposition of records.

Result:

The requirements of ANSI/ISO/ASQ Q2001:9000 meet the fundamental requirements of this sub-criterion of 10CFR50, Appendix B, to the extent the quality requirements apply to an organization furnishing products and services to the nuclear power industry.

Table 3-17B
10CFR50, Appendix B, Criterion XVII – Quality Assurance Records

10CFR50, Appendix B, Criterion XVII	ISO Q9001:2000 – 4.2.4 and 5.6.1 and 8.5.1 and 5.4.2 and 7.1 and 7.3.4 and 7.3.5 and 6.3 and 6.4 and 7.5.1 and 7.5.2
The records shall include at least the following: Operating logs and the results of reviews, inspections, tests, audits, monitoring of work performance, and materials analyses. The records shall also include closely-related data such as qualifications of personnel, procedures, and equipment.	4.2.4 Control of records Records shall be established and maintained to provide evidence of conformity to requirements and of the effective operation of the quality management system. Records shall remain legible, readily identifiable and retrievable. A documented procedure shall be established to define the controls needed for the identification, storage, protection, retrieval, retention time and disposition of records. 7.5.3 Identification and traceability Where appropriate, the organization shall identify the product by suitable means throughout product realization. The organization shall identify the product status with respect to monitoring and measurement requirements. Where traceability is a requirement, the organization shall control and record the unique identification of the product (see 4.2.4). Note In some industry sectors, configuration management is a means by which identification and traceability are maintained. 8.2.4 Monitoring and measurement of product The organization shall monitor and measure the characteristics of the product to verify that product requirements have been met. This shall be carried out at appropriate stages of the product realization process in accordance with the planned arrangements. (see 7.1). Evidence of conformity with the acceptance criteria shall be maintained. Records shall indicate the person(s) authorizing release of product (see 4.2.4). Product release and service delivery shall not proceed until the planned arrangements (see 7.1) have been satisfactorily completed, unless otherwise approved by a relevant authority and, where applicable, by the customer.

Fundamental Objective of the Quality Element:

To ensure records are kept for operating logs and results of reviews, inspections, tests, audits, monitoring of work performance and materials analysis, qualification of personnel, procedures, and equipment.

ISO Q9001:2000 Provisions:

The requirement to maintain records of operating logs and results of reviews of plant equipment of the nuclear power plant would not be applicable to an organization (that is, supplier/manufacturer) certified to ISO 9000:2000. However, Criteria 8.2.4 and 7.5.3 require the organization to maintain records of evidence of product conformity and product status with respect to monitoring and measurement requirements.

As noted, Criterion 4.2.4 is cross-referenced in numerous other requirements of ISO Q9001:2000 to ensure records are maintained for specific quality activities. A summary of these cross-references is provided below:

- Criterion 4.2.3 requires the organization to define records as a special type of document requiring special controls.
- Criterion 5.6.1 requires the organization to maintain records of management reviews of the QMS.
- Criterion 6.2.2 of personnel requires the organization to maintain records of personnel qualifications (that is, education, training, skills and experience).
- Criterion 7.2.2 requires the organization to maintain records of the results of product reviews.
- Criteria 7.3.2, 7.3.4, 7.3.5, 7.3.6, and 7.3.7 requires the organization to maintain records of design inputs relating to product requirements, design and development reviews, verification, validation, and changes respectively.
- Criterion 7.4.1 requires the organization to maintain records of supplier evaluation (for example, audits) and selection.
- Criterion 7.5.2 requires the organization to maintain records for validation of processes for production and service provision.
- Criterion 7.5.4 requires the organization to maintain records of customer property while under the organization's control.
- Criterion 7.6 requires the organization to maintain records of calibration and verification activities.
- Criterion 8.2.2 requires the organization to maintain records of internal audits.
- Criterion 8.3 requires the organization to maintain records of nonconformities and any subsequent actions taken.
- Criterion 8.5.2 requires the organization to maintain records of corrective action.
- Criterion 8.5.3 requires the organization to maintain records of preventive action.

Result:

The requirements of ANSI/ISO/ASQ Q2001:9000 meet the fundamental requirements of this sub-criterion of 10CFR50, Appendix B, to the extent the quality requirements apply to an organization furnishing products and services to the nuclear power industry.

Table 3-17C
10CFR50, Appendix B, Criterion XVII – Quality Assurance Records

10CFR50, Appendix B, Criterion XVII	ISO Q9001:2000 – 7.5.3 and 8.2.4
Inspection and test records shall, as a minimum, identify the inspector or data recorder, the type of observation, the results, the acceptability, and the action taken in connection with any deficiencies noted.	7.5.3 Identification and traceability Where appropriate, the organization shall identify the product by suitable means throughout product realization. The organization shall identify the product status with respect to monitoring and measurement requirements. Where traceability is a requirement, the organization shall control and record the unique identification of the product (see 4.2.4) Note In some industry sectors, configuration management is a means by which identification and traceability are maintained. 8.2.4 Monitoring and measurement of product The organization shall monitor and measure the characteristics of the product to verify that product requirements have been met. This shall be carried out at appropriate stages of the product realization process in accordance with the planned arrangements. (see 7.1). Evidence of conformity with the acceptance criteria shall be maintained. Records shall indicate the person(s) authorizing release of product (see 4.2.4). Product release and service delivery shall not proceed until the planned arrangements (see 7.1) have been satisfactorily completed, unless otherwise approved by a relevant authority and, where applicable, by the customer.

Fundamental Objective of the Quality Element:

To provide specific, minimum requirements for records of inspections and tests.

ISO Q9001:2000 Provisions:

Criterion 8.2.4 requires the organization to record the person(s) authorizing release of product following monitoring and measurement, evidence of conformity with the acceptance criteria, and the type of monitoring and measurement of product carried out at appropriate stages of the product realization process in accordance with planned arrangements.

Criterion 7.5.3 requires the organization, when traceability is required, to record the unique identification of the product.

Criterion 8.3 requires the organization to maintain records of nonconformities and any subsequent actions taken, which includes those noted during testing or inspection of product.

Criterion 8.5.2 requires the organization to maintain records of corrective action.

Criterion 8.5.3 requires the organization to maintain records of preventive action.

Result:

The requirements of ANSI/ISO/ASQ Q2001:9000 meet the fundamental requirements of this sub-criterion of 10CFR50, Appendix B, to the extent the quality requirements apply to an organization furnishing products and services to the nuclear power industry.

Table 3-17D
10CFR50, Appendix B, Criterion XVII – Quality Assurance Records

10CFR50, Appendix B, Criterion XVII	ISO Q9001:2000 – 4.2.4
Records shall be identifiable and retrievable. Consistent with applicable regulatory requirements, the applicant shall establish requirements concerning record retention, such as duration, location, and assigned responsibility.	4.2.4 Control of records Records shall be established and maintained to provide evidence of conformity to requirements and of the effective operation of the quality management system. Records shall remain legible, readily identifiable and retrievable. A documented procedure shall be established to define the controls needed for the identification, storage, protection, retrieval, retention time and disposition of records.

Fundamental Objective of the Quality Element:

To ensure records are identifiable, retrievable, and retained appropriately and consistent with applicable regulatory requirements.

ISO Q9001:2000 Provisions:

Criterion 4.2.4 requires the organization to maintain records that are legible, readily identifiable, and retrievable. The Criterion also requires that the organization establish a documented procedure defining the controls needed for the identification, storage, protection, retrieval, retention time, and disposition of records.

Result:

The requirements of ANSI/ISO/ASQ Q2001:9000 meet the fundamental requirements of this sub-criterion of 10CFR50, Appendix B, to the extent the quality requirements apply to an organization furnishing products and services to the nuclear power industry.

Table 3-17E
10CFR50, Appendix B, Criterion XVII – Quality Assurance Records

10CFR50, Appendix B, Criterion XVII	ISO Q9001:2000 – 8.2.2 and 8.2.3
A comprehensive system of planned and periodic audits shall be carried out to verify compliance with all aspects of the quality assurance program and to determine the effectiveness of the program. The audits shall be performed in accordance with the written procedures or check lists by appropriately trained personnel not having direct responsibilities in the areas being audited. Audit results shall be documented and reviewed by management having responsibility in the area audited. Followup action, including reaudit of deficient areas, shall be taken where indicated.	8.2.2 The organization shall conduct internal audits of planned intervals to determine whether the quality management system a) conforms to the planned arrangements (see 7.1), to the requirements of this International Standard and to the quality management system requirements established by the organization, and b) is effectively implemented and maintained. An audit programme shall be planned, taking into consideration the status and importance of the processes and areas to be audited, as well as the results of previous audits. The audit criteria, scope, frequency and methods shall be defined. Selection of auditors and conduct of audits shall ensure objectivity and impartiality of the audit process. Auditors shall not audit their own work. The responsibilities and requirements for planning and conducting audits, and for reporting results and maintaining records (see 4.2.4) shall be defined in a documented procedure. The management responsible for the area being audited shall ensure that actions are taken without undue delay to eliminate detected nonconformities and their causes. Follow-up activities shall include the verification of the actions taken and the reporting of verification results (see 8.5.2). Note See ISO 10011-1, ISO 10011-2 and ISO 10011-3 for guidance. 8.2.3 Monitoring and measurement of processes The organization shall apply suitable methods for monitoring and, where applicable, measurement of the quality management system processes. These methods shall demonstrate the ability of the processes to achieve planned results. When planned results are not achieved, correction and corrective action shall be taken, as appropriate, to ensure conformity of the product.

Fundamental Objective of the Quality Element:

To ensure internal audits are planned, implemented at regular intervals, performed by qualified personnel, documented, and reviewed to verify compliance and effectiveness of the QA program

ISO Q9001:2000 Provisions:

Criterion 8.2.2 requires the organization to conduct internal audits of planned intervals to determine whether the QMS:

a) Conforms to the planned arrangements (see Criterion 7.1), to the requirements of this International Standard, and to the QMS requirements established by the organization
b) Is effectively implemented and maintained

The audit program must be planned, taking into consideration the status and importance of the processes and areas to be audited, as well as the results of previous audits. The audit criteria, scope, frequency, and methods must all be defined. Selection of auditors and conduct of audits must ensure objectivity and impartiality of the audit process, and auditors cannot audit their own work.

The management responsible for the area being audited must ensure that actions are taken without undue delay to eliminate detected nonconformities and their causes. ISO 10011-1, ISO 10011-2, and ISO 10011-3 provide implementation guidance.

Criterion 8.2.3 requires the organization to apply suitable methods for monitoring and, where applicable, measurement of the QMS processes. These methods must demonstrate the ability of the processes to achieve planned results. When planned results are not achieved, correction and corrective action must be taken, as appropriate, to ensure conformity of the product.

Result:

The requirements of ANSI/ISO/ASQ Q2001:9000 meet the fundamental requirements of this sub-criterion of 10CFR50, Appendix B, to the extent the quality requirements apply to an organization furnishing products and services to the nuclear power industry.

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CONCLUSIONS

Upon completion of the report and discussion of the results among interested licensees, the following consensus conclusions were drawn from the analysis:

- The analysis was performed adequately and provided technically sound results consistent with the level at which the comparison was performed.
- With the exception of the two gaps identified, the actual quality requirements were consistent between ANSI/ISO/ASQ Q9001:2000 and 10CFR50, Appendix B, for the level at which the comparison was performed.

5
REFERENCES

1. 10CFR50, Appendix B, Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Facilities, Code of Federal Regulations.

2. ANSI/ISO/ASQ Q9000:2000, American National Standard, Quality Management Systems – Fundamentals and Vocabulary, American National Standards Institute/International Organization for Standardization/American Society for Quality, 2000.

3. ANSI/ISO/ASQ Q9001:2000, American National Standard, Quality Management Systems – Requirements, American National Standards Institute/International Organization for Standardization/American Society for Quality, 2000.

4. NUPIC Audit Checklist, Nuclear Utility Procurement Issues Committee, 2002.

Program:
Nuclear Power

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