Dedicating Commercial-Grade Items Procured From ISO 9000 Suppliers

Technical Report

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Dedicating Commercial-Grade Items Procured From ISO 9000 Suppliers

1003105

Final Report, December 2001

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REPORT SUMMARY

This report provides guidance to assist utilities when dedicating commercial-grade items procured from ISO 9000 suppliers. This guidance was developed using the assessment results documented in EPRI Report 1003104, *Assessment of the ISO 9000 Quality Management System Registrar Accreditation and Supplier Certification Processes*.

Background

In response to a declining sales market, many U.S. nuclear suppliers have abandoned their Appendix B quality assurance (QA) programs in favor of quality management systems (QMSs) with a more global acceptance, such as the ISO 9000 family of standards. To remain competitive, licensees must adapt to this new market reality and learn to effectively cope with a dynamic and dwindling source of nuclear suppliers. They must find more cost-effective ways to procure and accept commercial-grade items for nuclear safety-related applications.

The original objective of this project was to evaluate the existing ISO 9000 QMS registrar accreditation and supplier certification processes as administered by the U.S. Registrar Accreditation Board (RAB) and determine if these processes could be relied upon to reasonably assure that the supplier's controls are adequately implemented, in lieu of a licensee conducting an independent commercial-grade survey at the supplier's facility. As the project evolved, so did the objective. Key in that evolution were the results of the project's regulatory analysis, which did not support the original objective of directly substituting the audit activities performed by ISO 9000 registrars for a licensee's commercial-grade survey activities. The evolution resulted in a revised objective.

Objective

- To determine to what extent licensees can credit the ISO 9000 QMS registrar accreditation and supplier certification processes as part of the commercial-grade dedication process within the existing regulatory framework

Approach

A Plant Support Engineering (PSE) task group composed of utility procurement and QA personnel performed an assessment of the ISO 9000 QMS registrar accreditation and supplier certification processes. The assessment included the following activities:

- On-site assessment of the RAB's implementation of the registrar accreditation process
- Detailed review of supplier certification processes at three registrars accredited by the RAB
- Detailed review of several ISO 9000 audit reports and supporting documentation, if available
- Observation of registrar auditing practices

These assessment activities were intended to address the technical issues—Is the audit process used by the registrars rigorous enough to provide an adequate level of assurance that the necessary controls are in place and properly implemented by the supplier? The task group also explored the regulatory issues—Is the use of such an approach allowed under current regulatory requirements and licensee commitments?

Results

The results of the evaluation are published in two reports. This report discusses the regulatory framework governing commercial-grade procurement activities and provides guidance on how to take credit for a supplier's ISO 9000 QMS in support of current dedication activities. The other report, EPRI Report 1003104, *Assessment of the ISO 9000 Quality Management System Registrar Accreditation and Supplier Certification Processes*, documents the task group's observations and conclusions regarding the ISO 9000 QMS registrar accreditation and supplier certification processes. It also provides some background information to familiarize the user with the ISO 9000 QMS.

EPRI Perspective

In 2002, PSE will begin phase two of this effort—to pursue a broader acceptance of supplier ISO 9000 quality programs when procuring items intended for safety-related applications. Two paths will be explored—ISO 9000 as an alternate method for dedication of commercial-grade items, and ISO 9000 as an alternate to 10CFR50, Appendix B for manufacturers and suppliers of safety-related materials.

Keywords

Acceptance
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EXECUTIVE SUMMARY

1.1 Purpose of the Report

The purpose of this report is to provide guidance to licensees on the application of ISO 9000 during the dedication of commercial-grade items, within the current regulatory framework to which utilities are committed. The report was developed in recognition of the ongoing increase in the number of suppliers certified to ISO 9000 and, by extension, of how that trend can be used by licensees to procure and dedicate items intended for nuclear safety-related applications.

This guidance was developed using the results described in EPRI Report 1003104, *Assessment of the ISO 9000 Quality Management System Registrar Accreditation and Supplier Certification Processes*, which documents the assessment of key processes associated with administration and implementation of the ISO 9000 family of standards.

1.2 Scope and Organization of the Report

The report comprises three major sections. Section 2 provides a regulatory analysis that explains the regulatory basis for the guidance offered in this report. Section 3 describes the various elements of the Technical Evaluation as it applies to items procured from ISO 9000 suppliers certified by accredited Registrars. Section 4 provides guidance on how the ISO 9000 Quality Management System (QMS) can be credited and integrated into a commercial-grade item dedication plan.

Appendix A provides an overview of the documents reviewed during the regulatory analysis. Some documents listed in this appendix were not applicable to the acceptance of commercial-grade items or the dedication of items procured from ISO 9000 suppliers, and therefore are not discussed in detail in Section 2 of this report.

Much of the guidance contained in this report amplifies existing guidance found in other EPRI reports and NRC documents. This report focuses particularly on the integration of the ISO 9000 QMS into the acceptance process. Use of the companion EPRI report 1003104 for input and technical justification is suggested.

1.3 Summary Guidance for Procuring Items From ISO 9000 Suppliers

Commercial-grade items procured from an ISO 9000 certified supplier that the licensee intends to use in a safety-related application must be dedicated. The guidance contained in the following guidance documents is applicable to these items:

- EPRI Report NP-5652, *Guideline for the Utilization of Commercial-Grade Items in Nuclear Safety-Related Applications (NCIG-07)*
- EPRI Report NP-6406, *Guidelines for the Technical Evaluation of Replacement Items in Nuclear Power Plants (NCIG-11)*
- EPRI Report TR-102260, *Supplemental Guidance for the Application of EPRI Report NP-5652 on the Utilization of Commercial-Grade Items*
- NRC Generic Letter 89-02, "Actions to Improve the Detection of Counterfeit and Fraudulently Marketed Products"
- NRC Generic Letter 91-05, "Licensing Commercial Grade Procurement and Dedication Programs"

From a regulatory perspective, the audit activities performed by accredited Registrars cannot substitute directly for a commercial-grade survey conducted by licensees under a 10CFR50, Appendix B Quality Assurance (QA) program. However, existing guidance does provide means by which the licensee can take credit for the ISO 9000 QMS in general, and the Registrar's certification audits in particular. This input can be integrated into the acceptance/dedication plan for items as means to gain additional assurance that the items procured from ISO 9000 suppliers will perform their safety-related function(s).

1.4 Highlighting of Key Points

Throughout this report, important information is summarized in "Pop Outs." Pop Outs are bold-lettered boxes that succinctly restate information covered in detail in the surrounding text, making the key point easier to locate.

The primary intent of a Pop Out is to emphasize information that will allow individuals to take action for the benefit of their plant. The Pop Outs in this report are organized according to three categories: Engineering, Quality Assurance, and Regulatory. Each category has an identifying icon, as shown in this section, to draw attention to it when a reader is quickly reviewing the report.

Key Engineering Point

Targets information that will lead to improved engineering processes and/or equipment performance.

Key Quality Assurance Point

Denotes information that results in an increased assurance of supplier quality.

Key Regulatory Point

Emphasizes regulatory information that will lead to enhanced performance of plant support engineering processes.

Appendix B contains a listing of all key points in each category. The listing restates each key point and provides reference to its location in the body of the report. By reviewing this listing, users of this report can determine if they have taken advantage of key information that the writers of the report believe would benefit their plants.

2
REGULATORY BASIS

Procuring an item or service as “commercial-grade” and then dedicating it for use in a safety-related application is one of two primary means of obtaining needed items and services to support operations and maintenance of nuclear power plants. The other primary means is procurement of the items or services as “basic components” from a supplier maintaining a 10CFR50, Appendix B QA program.

Two different regulatory frameworks have been put in place to govern these two procurement methods, as illustrated in Figure 2-1.

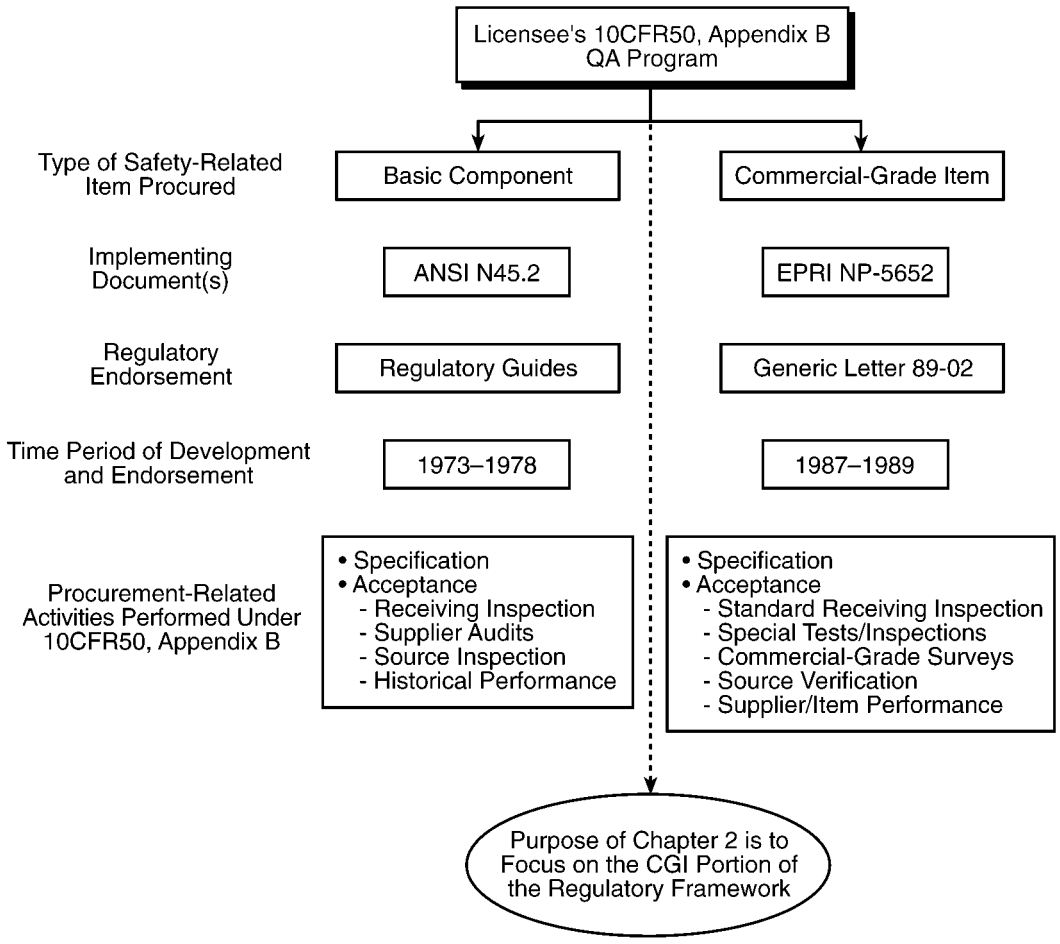

Figure 2-1
Regulatory Framework From a Procurement Perspective

Regulatory Basis

The purpose of this review is to summarize the regulatory framework governing commercial-grade procurement and dedication. Therefore, a detailed description of the framework for safety-related procurement is not provided. However, some of the aspects of that framework are discussed in order to contrast the framework for safety-related procurement with that for commercial-grade procurement and dedication.

It should be noted that this review focuses on the generic framework in place governing commercial-grade dedication throughout the nuclear industry. This review does not address plant-specific licensing commitments that may modify or augment the generic regulatory framework. Readers are cautioned to properly incorporate plant-specific licensing commitments related to commercial-grade procurement and dedication before taking any action to modify existing plant programs.

The reader is also reminded that after a commercial-grade item has been accepted for safety-related use and is dedicated, it is a basic component. From that point forward, the item is subject to the full scope of regulatory documents and implementation standards to which the licensee has committed. These will typically include 10CFR50, Appendix B and the ANSI N45.2 series of implementing standards.

2.1 Regulatory Framework Governing the Procurement and Receipt of Items Intended for Safety-Related Applications

2.1.1 10CFR50, Appendix B

10CFR50.34(b)(6)(ii) states that information must be provided in the Final Safety Analysis Report to describe managerial and administrative controls to be used to assure safe operation, and that 10CFR50, Appendix B sets forth the requirements for such controls for nuclear power plants and fuel reprocessing plants. The information on the controls is to include a discussion of how the requirements of 10CFR50, Appendix B are satisfied.

In its introduction, 10CFR50, Appendix B describes quality assurance as “all of those planned and systematic activities necessary to provide adequate confidence that SSCs (structures, systems, and components) will perform satisfactorily in service.” Criteria III, IV, and VII are the primary criteria associated with the procurement function. All procurement activities related to acquisition of safety-related items and services are subject to the provisions of 10CFR50, Appendix B and 10CFR21.

10CFR50, Appendix B Criteria VII states in part:

> 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.
>
> 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.

The measures for assuring that purchased items conform to procurement documents (that is, items meet specified requirements) are the basis for the acceptance methods described in ANSI N45.2.13. Both of these documents became the bases for the four commercial-grade item (CGI) acceptance methods described in EPRI Report NP-5652, which provides a means for licensees to perform acceptance of items purchased directly from commercial suppliers, under each licensee's own 10CFR50, Appendix B QA program.

2.1.2 Regulatory Frameworks for Basic Components and CGIs

The regulatory framework then splits, with different regulatory guidance in place dependent on whether the procurement activity is being performed for a basic component or for a commercial-grade item.

2.1.2.1 Basic Components

For safety-related procurement activities, the NRC has over the years issued a series of regulatory guides, which usually endorse (or endorse with comment) selected national standards or codes. In particular, various revisions of the ANSI N45.2 series of standards have been endorsed by the NRC over the years as providing guidance which meets the requirements of certain portions of 10CFR50, Appendix B when properly implemented. On an individual plant basis, utilities have typically committed to certain revisions of these regulatory guides and associated standards as part of the plant licensing process.

2.1.2.2 Commercial-Grade Items

For commercial-grade procurement and dedication activities, the NRC has used a different approach to establishing regulatory expectations and obtaining licensee commitments. In the early to mid-1980s the NRC's Vendor Inspection Branch performed a series of inspection activities reviewing the process used by licensees to dedicate items purchased as commercial grade for use in safety-related applications. As a result of those inspections, a series of Information Notices and Information Bulletins was issued, providing insight into the NRC's expectations. In response, the industry undertook efforts to develop generic guidance describing acceptable methods that could be used to dedicate commercial-grade items and services for safety-related applications. This guidance was provided in EPRI Report NP-5652.

Key Regulatory Point

ASNI N45.2 and the "daughter" standards do not directly apply to the procurement of commercial-grade items intended for safety-related applications, although many utilities have adopted some of these processes to apply to the procurement of both basic components and commercial-grade items.

2.1.3 10CFR21

10CFR21 provides licensees with requirements for reporting defects of items or processes that have been designated as basic components. 10CFR21.3(a)3 states:

> In all cases, basic component includes safety-related design, analysis, inspection, testing, fabrication, **replacement parts**, or consulting services that are associated with the component hardware whether these services are performed by the component supplier or others.

Though not providing quality assurance criteria as those described in 10CFR50, Appendix B, 10CFR21, Revision 2 (1995) does provide some key definitions and interpretations that affect licensees' commercial-grade dedication activities. These clarifications provided in the most recent revision to 10CFR21 do not directly apply to this regulatory analysis, however, and will not be discussed here in any further detail.

2.2 Regulatory Documents and Licensee Commitments Regarding Commercial-Grade Items

Regulatory guidance typically provides information regarding the NRC's position on acceptable methods for meeting regulatory requirements. Regulatory guidance may present an NRC staff position, endorse an industry standard, or endorse an industry initiative. Regulatory guidance is not regulation, but may take on additional significance if a commitment is made to that guidance by an individual licensee or by the industry as a whole. Regulatory guidance takes several forms, including Regulatory Guides, NUREGs, Generic Letters, NRC Bulletins, and NRC Information Notices. Generic Letters may require a response based on a backfit analysis and review as well as an impact review.

The NRC used many forms of regulatory guidance documents in presenting its position on commercial-grade dedication. Bulletins and Information Notices were used to present the results of licensee and vendor inspections. Two key Generic Letters, 89-02 and 91-05, provided integrated and detailed views of the NRC staff on the dedication process, and issues with existing programs at licensees.

2.2.1 NRC Generic Letter 89-02

Generic Letter 89-02 provides a conditional endorsement for licensees to utilize the methods in EPRI Report NP-5652 for dedicating commercial-grade items for safety-related applications. The NRC found that NP-5652, as conditionally endorsed, is an effective means of meeting 10CFR50, Appendix B requirements and provides reasonable assurance of the suitability of parts for their intended application. It is important to note that the NRC considers the dedication process in NP-5652 as a method of meeting 10CFR50, Appendix B requirements and not as an alternative to Appendix B requirements.

2.2.2 NRC Generic Letter 91-05

Generic Letter 91-05 was issued primarily to announce a pause in the NRC's inspection activities and to establish a date after which the implementation of EPRI Report NP-5652 would be required from a regulatory perspective. The generic letter also provided additional details on the NRC's position on commercial-grade dedication, with detailed information on the topics of selection and verification of "critical characteristics" and "like for like" replacements.

2.2.3 NUMARC 90-13—Comprehensive Procurement Initiative

The industry, through the Nuclear Management and Resources Council (NUMARC) Initiative on Commercial Grade Items approved in March of 1989, generically committed to review and, if necessary, develop or upgrade programs to meet the intent of the guidance provided in EPRI Report NP-5652. This commitment was restated in NUMARC 90-13, the Comprehensive Procurement Initiative. Through their implementation of these generic commitments, licensees transformed the guidance contained in NP-5652 (with some flexibility for interpretation on a licensee-by-licensee basis) into a commitment to the NRC (through NUMARC) regarding acceptable methods for performing commercial-grade dedication.

2.2.4 NRC Technical Inspection TI-38703

The primary purpose of NRC Technical Inspection TI-38703 is to assist NRC inspectors of nuclear procurement practices so the inspections are conducted in a consistent manner using a sound technical approach. This document does not provide implementation guidance for licensees and should not be considered as industry regulation.

2.2.5 Other Licensee Commitments

It should also be noted that certain utilities made additional specific dedication-program-related commitments in response to NRC inspection report findings. However, identifying these commitments is beyond the scope of this review.

2.3 Industry Guidance Documents

Several industry guidance documents were reviewed to identify the extent to which they contained guidance that might be applicable to the issue of crediting the ISO 9000 Quality Management System during the commercial-grade item dedication process. It should be noted that other than EPRI Report NP-5652, the documents discussed in this section have no formal place in the current regulatory framework other than the extent to which they have been committed to by individual licensees. Because they have been used by licensees in establishing dedication programs, they do provide some information on current industry practices.

2.3.1 Guideline for the Utilization of Commercial-Grade Items in Nuclear Safety-Related Applications (NCIG-07), EPRI Report NP-5652

EPRI Report NP-5652 provides the general framework for implementing CGI programs in the industry. Discussion here is limited to portions of that guideline that address crediting non-10CFR50, Appendix B quality controls within the dedication process.

CGI Acceptance Method 2 allows acceptance of a commercial-grade item based on certification from the commercial-grade supplier, provided the certification has been validated by evaluation of the supplier's commercial quality controls over the critical characteristics of the item. This evaluation is typically performed prior to the item being procured and is known as the *commercial-grade survey*.

CGI Acceptance Method 4 describes a method for dedicating commercial-grade items through establishing an acceptable supplier/item performance record. Use of national codes and standards is one among many means of verifying adequate supplier/item performance using Acceptance Method 4.

Appendix E of NP-5652 provides additional guidance on the specific issue of using national codes and standards. Appendix E discusses crediting national codes and standards in relation to both Method 1 and Method 4 of NP-5652. In the discussion of Method 1, the following statement is made:

> If the national code or standard includes some independent product endorsements based on qualification testing or periodic testing of selected critical characteristics, then credit can be taken for those critical characteristics being verified. When a national code or standard only establishes certain process controls and end product acceptance requirements, the accepting party must still verify the selected critical characteristics.

This statement suggests that critical characteristics may be considered adequately verified, if such verification activities are appropriate and completed under the requirements of a national code and standard.

Crediting inspection and testing activities (performed inherent to national codes and standards) is not specifically described in Section 3.1 of NP-5652, which contains the actual guidance for using Method 1, Special Tests and Inspections, in the dedication process.

Appendix E of NP-5652 provides some additional guidance on crediting quality checks performed to the requirements of national codes and standards when establishing an acceptable item performance record. In order to facilitate use of this guidance, EPRI undertook a more detailed effort to review and document the extent to which national codes and standards could be credited under Method 4. This effort led to the development of EPRI Report TR-101752, discussed in Section 2.3.3 of this report.

2.3.2 Supplemental Guidance for the Application of EPRI Report NP-5652 on the Utilization of Commercial-Grade Items, EPRI Report TR-102260

EPRI Report TR-102260 provides clarification on many issues related to the dedication process that arose subsequent to the issuance of EPRI Report NP-5652. Sections 2.4.2.3 and 2.4.2.4 of TR-102260 address use of third-party or external survey reports as part of the commercial-grade acceptance process. The guidance provided indicates that users of NP-5652 may utilize survey reports performed by other entities, subject to several conditions. The conditions are that the user should evaluate the survey methodology and the personnel certification of the external entity and ensure that they are acceptable. Also, the user should evaluate the survey report to ensure that the specific critical characteristics selected for the item are included in the survey documentation. Further, a statement is made that licensees generally accept each other's survey reports with a review of the audit program or personnel because all licensees must meet the same requirements of 10CFR50, Appendix B.

Section 2.4.2.6 of TR-102260 suggests as a benchmark that commercial-grade surveys be performed on a three-year cycle. It also suggests that extensions beyond three years should be justified on a case-by-case basis.

2.3.3 Guideline for Using Items Manufactured to Other Industry Standards in Nuclear Safety-Related Applications, EPRI Report TR-101752

The stated objective of EPRI Report TR-101752 was to provide guidance on how non-nuclear-industry standards and specifications can be used to facilitate commercial-grade procurement and acceptance activities in the nuclear power industry. TR-101752 expands upon and provides information to assist with implementation of guidance provided in Appendix E of EPRI Report NP-5652.

The guidance suggests that quality control activities performed by third parties can be credited as part of the commercial-grade item acceptance process (under each licensee's 10CFR50, Appendix B QA program). Many product-specific codes and standards were evaluated and ranked in categories based on the extent to which they control critical characteristics and verify quality.

TR-101752 provides information about other standards, summarizing the extent to which each specifies and requires verification of item critical characteristics. For those standards providing the highest level of specification and verification of critical characteristics, acceptance of the item is based almost entirely on crediting quality verification activities performed under a given supplier's commercial quality controls. TR-101752 provides guidance that is subject to review, interpretation, and use by individual licensees under their own 10CFR50, Appendix B QA programs.

TR-101752 may provide licensees a basis for crediting quality control activities performed under commercial quality controls as part of the dedication process. However, several points to consider regarding the guidance in TR-101752 and crediting elements of the ISO 9000 QMS are as follows:

- The guidance in TR-101752 is very focused on evaluation of the specific critical characteristics for each type of item defined in each product-specific code or standard. Determination of the extent to which credit can be taken is dependent on the extent to which those critical characteristics are in fact verified by quality activities mandated by the standard.
- Use of other industry standards, such as those described in TR-101752, is mentioned in Section 3.4.3 and Appendix E of NP-5652 as an acceptable means for procurement and acceptance of commercial-grade items.
- The final evaluation of whether or not any given licensee will credit industry standards as part of the acceptance process on any given item procurement is made under a 10CFR 50 Appendix B program by each licensee.

2.4 Summary of Discussion

Appendix A provides an overview of the documents reviewed during the regulatory analysis.

2.4.1 Regulatory Framework Governing the Procurement and Receipt of Items Intended for Safety-Related Applications

For the current purpose, the key aspects of the regulatory framework governing commercial-grade dedication can be summarized as follows:

- First, the NRC has established repeatedly and consistently that 10CFR50, Appendix B is the source of their authority to regulate commercial-grade dedication. Proper performance of dedication activities is necessary to meet Appendix B requirements. Further, the activities performed by licensees to dedicate commercial-grade items are safety-related activities and must be performed under a 10CFR50, Appendix B QA program.
- Second, ANSI N45.2 and the “daughter” standards do not apply directly to commercial-grade dedication.

2.4.2 Regulatory Documents and Licensee Commitments

The guidance in EPRI Report NP-5652 regarding commercial-grade dedication (as conditionally endorsed by Generic Letter 89-02) became implementing requirements through commitment to the industry NUMARC initiatives. On a licensee-by-licensee basis, decisions were made regarding how to comply with the NUMARC initiatives, including the specific program elements to be implemented from NP-5652.

The NRC TI-38703 is valuable to licensees because it provides insight into NRC expectations regarding licensee commercial-grade dedication practices.

Other specific commitments related to commercial-grade dedication may have been made by licensees on a case-by-case basis in response to NRC inspection findings.

2.4.3 Industry Guidance Documents

The guidance in EPRI Report TR-102260 suggests that the third-party or external reports being evaluated are commercial-grade surveys (as defined in EPRI Report NP-5652) and does not take a position on the acceptability or use of other supplier evaluation reports (such as a Registrar's certification audit report).

Taken as a whole, it is clear that the industry guidance related to crediting other quality systems as part of dedication activities has been limited to discussing use of controls applied on a well-defined scope of commercial-grade items. Credit has been allowed through EPRI Report TR-101752 only to the extent that the controls clearly verify (through testing) the appropriate critical characteristics for those items.

The ISO 9000 QMS is a substantially different type of standard when compared to those product-specific codes and standards discussed in TR-101752. Rather than focusing on means to verify specific critical characteristics of specific items, ISO 9000 defines a overall system for managing quality on an organization-wide basis.

3
IMPLEMENTATION GUIDANCE—TECHNICAL EVALUATION OF REPLACEMENT ITEMS PROCURED FROM ISO 9000 SUPPLIERS

Figure 3-1 presents a simplified flowchart for the Technical Evaluation of Replacement Items, summarizing the steps described in EPRI Report NP-6406.

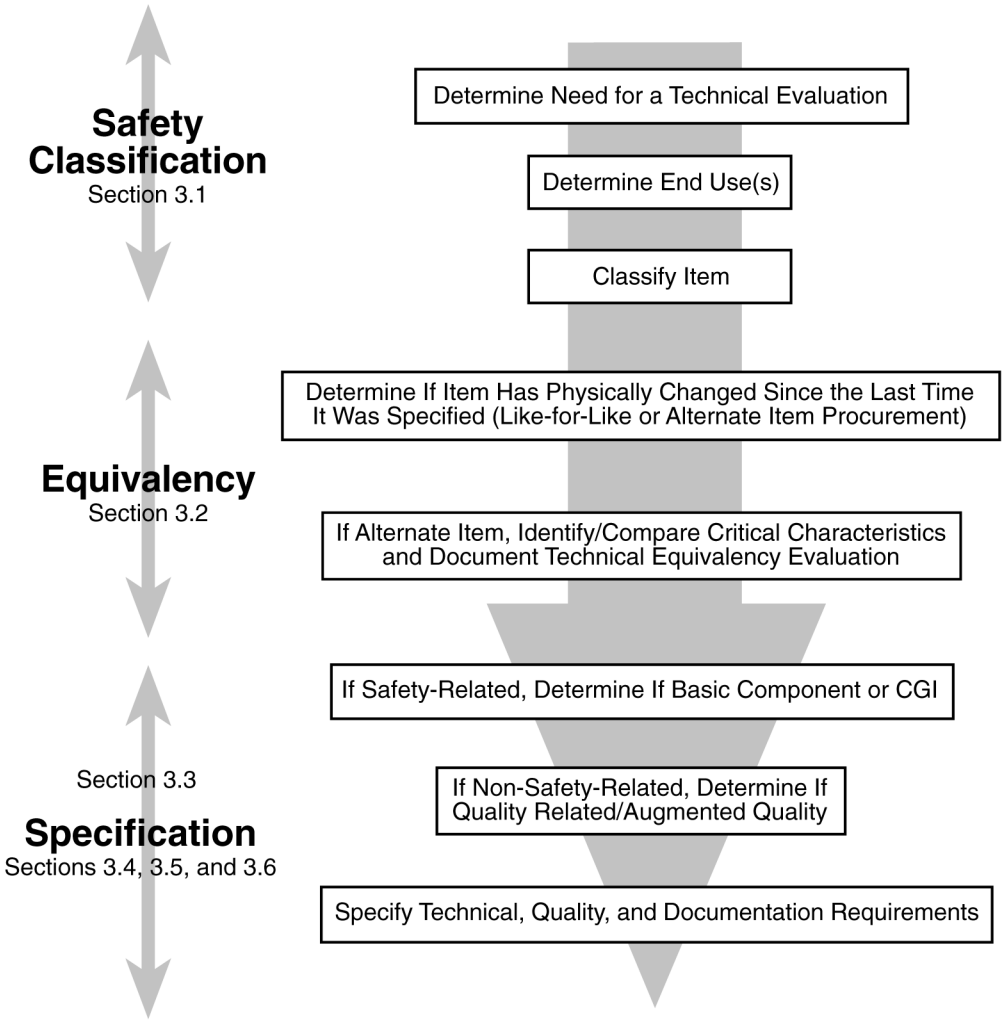

Figure 3-1
Generic Process for the Technical Evaluation of Replacement Items

3.1 Safety Classification of Items

The safety classification of items procured from ISO 9000 suppliers should not differ in any way from the process used to classify items procured from other suppliers. The safety classification of an item is not dependent upon the type of supplier QA program, but rather is based upon the item's functions and the effects of postulated failures on the safety-related functions of its host structure/system/component (SSC).

Therefore, the type of QA program implemented by the supplier does not relate to the safety (functional) classification of the item being procured. After an item has been classified for use in a safety-related application, it may either be procured as a basic component from a supplier maintaining a 10CFR50, Appendix B QA program, or as a commercial-grade item and dedicated. Commercial-grade items procured from ISO 9000 suppliers must be dedicated if they are intended for use in a safety-related application (that is, classified as safety-related).

Guidance found in EPRI Reports NP-5652, NP-6406, NP-6895, and TR-102260 and NRC Generic Letters 89-02 and 91-05 is applicable for classifying items procured from ISO 9000 suppliers.

3.2 Evaluation of Alternate Items Procured From ISO 9000 Suppliers

The evaluation of alternate items procured from ISO 9000 suppliers should not differ in any way from the process used to evaluate alternate items procured from other suppliers. The key element of the technical equivalency evaluation (that is, identifying and comparing critical characteristics for design between the original item and the alternate item) is not dependent upon the type of supplier QA program, but rather is based upon the item's design functions and its application(s) in the plant.

Guidance found in EPRI Reports NP-6406 and TR-102260 and NRC Generic Letters 89-02 and 91-05 is applicable for evaluating alternate items procured from ISO 9000 suppliers.

3.3 Selecting the Procurement Category for Items Furnished From ISO 9000 Suppliers

Most utilities have designated four primary procurement categories or "quality levels" in their procurement processes. These are summarized as follows:

- **Safety-Related** – A basic component procured from an approved supplier maintaining a QA program meeting the requirements of 10CFR50, Appendix B
- **Commercial-Grade** – An item, intended for a safety-related application, that is not manufactured or supplied under a 10CFR50, Appendix B QA program

- **Augmented Quality** – An item not intended for a safety-related application, but to which some plant-specific quality requirements may apply
- **Non-Safety** – An item not intended for a safety-related application; plant-specific quality requirements typically do not apply

Commercial-grade items that are procured from an ISO 9000 certified supplier and that the licensee intends to use in a safety-related application must be dedicated. An item procured from an ISO 9000 certified supplier that was intended for a non-safety-related application could be procured in a similar manner as other non-safety items.

3.4 Technical Procurement Requirements for ISO 9000 Suppliers

The specification of technical procurement requirements represents the translation of design requirements for an item into procurement requirements. The proper specification of technical requirements is critical because it ensures clear communication of expectations to the supplier. The ISO 9000 supplier ensures, through the implementation of the necessary quality controls, that customer requirements are consistently met and that the technical/design requirements specified are imparted to their products. As customer requirements change, the supplier modifies its products, quality controls, or both to ensure continuous improvement and ongoing customer satisfaction. This concept is illustrated in Figure 3-2.

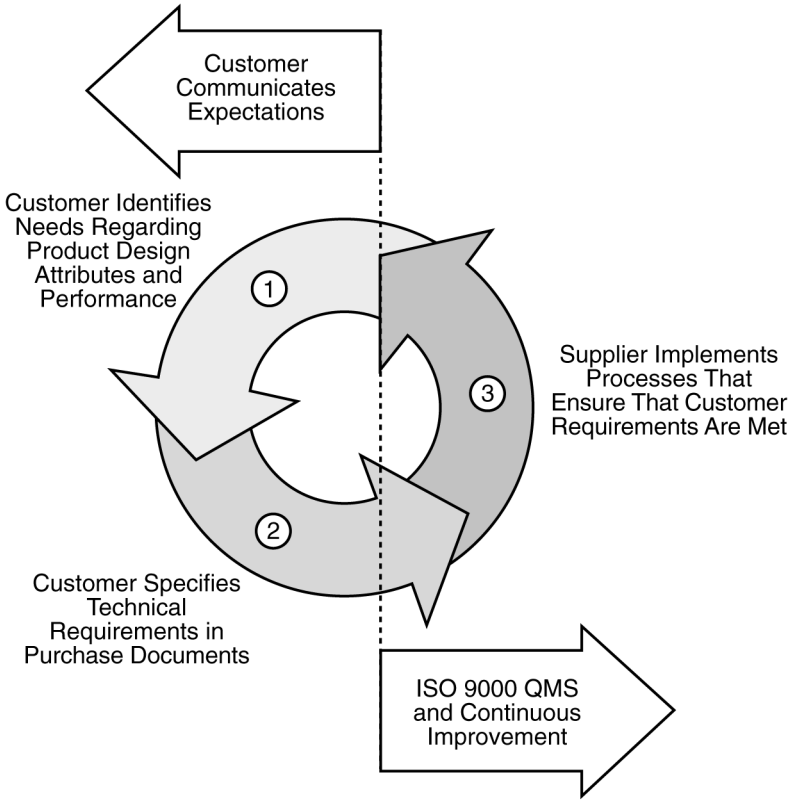

Figure 3-2
How Customers Communicate Requirements to ISO 9000 Suppliers

QA

Key Quality Assurance Point

The ISO 9000 QMS, as administered by an accrediting body (such as RAB) and as certified by accredited Registrars, provides a measure of assurance that suppliers are implementing quality controls to effectively impart the customer's specified technical requirements to the purchased items.

The ISO 9000 Quality Management System is structured to assure quality based upon customer requirements. Therefore it requires the customer to clearly communicate these requirements to the necessary level of specificity, and this level of specificity typically constitutes more than just the name and part number of the item.

Technical requirements represent the translation of design requirements into procurement requirements. Although the level of specificity may vary depending on the complexity of the item, the following should be considered for specification in the procurement document:

- Part number. This should be the same as the number documented in the supplier literature/product specification.
- Expanded description of the item being procured. This may include more than what appears in the published product description.
- Known physical characteristics. For example, "material shall be ASTM A276, keyway length shall be 3.25" ±0.05", resistance shall be 10 ohms."
- Known performance characteristics. For example, "the actuator shall provide a torque of 75 ±1 foot-pounds."
- National codes or standards to which the item is designed or manufactured.

In cases where the actual design criteria are not available, the critical characteristic may still be communicated by reference to the appropriate supplier procedure/quality control measure. The user may consider planned coordination with the supplier as the procurement document is being developed to ascertain the appropriate quality controls that should be specified.

QA

Key Quality Assurance Point

When procuring through a distributor, care must be taken to ensure that technical procurement requirements are communicated to the manufacturer or supplier maintaining the ISO 9000 QMS certification.

3.5 Quality Requirements for ISO 9000 Suppliers

Quality procurement requirements represent the capabilities of the supplier to assure that the specified technical requirements are met. Each licensee should decide the degree to which a supplier's documented quality controls will be credited and the most appropriate acceptance method(s). As a result, the specification of quality requirements may vary for each dedication.

3.5.1 Planning and Coordinating a Procurement With an ISO 9000 Supplier

Typically, the determination whether the supplier has documented quality controls is performed when developing the CGI acceptance plan and determining the optimum means for verifying the critical characteristics for acceptance. The planning and coordination phase is an integral step of the process, regardless of the degree to which the ISO 9000 quality controls will be credited. The first step is to ensure that the item being procured is in fact controlled under the supplier's ISO 9000 Quality Management System, and that the supplier's ISO 9000 certification is current. (See Section 4.2.2 for additional details and guidance.)

Key Engineering Point

The licensee must ensure that the item being procured is in fact controlled under the supplier's ISO 9000 Quality Management System.

The next step is typically to determine the extent of the supplier's quality controls. In order to credit supplier quality controls, 1) the supplier must have documented quality controls **and** 2) those controls must be effectively implemented. The user must determine first that the supplier maintains the necessary documented quality controls, and then that those controls have been assessed and are being adequately implemented. This guidance is reiterated in NRC Generic Letter 89-02.

Key Engineering Point

The user cannot assume that the supplier has the necessary quality controls over the critical characteristics solely because the supplier is ISO 9000 certified.

A common way of determining whether the supplier has documented quality controls is to review the results of a commercial-grade survey. Licensees have performed and continue to perform individual (or joint, such as NUPIC sponsored), commercial-grade surveys of ISO 9000 supplier quality systems. These surveys reach a determination, on a supplier-by-supplier basis, of whether or not adequate controls exist to properly control necessary critical characteristics of the item being procured. Then, by including contractual requirements on the supplier to apply the surveyed controls, the licensee can credit that survey activity on subsequent procurement documents.

Thus, the benefits of having performed a commercial-grade survey are as follows:

- Both the scope of the programmatic quality controls and their implementation are evaluated at the supplier's facility.
- Objective evidence of both the supplier's quality controls and their implementation practices are typically documented in the survey report.

Other ways for determining the extent of supplier quality controls over critical characteristics during the planning and coordination phase of the procurement include:

- Contacting the supplier directly
- Asking the supplier to submit a procedure describing the quality control and reviewing it to ensure that the critical characteristic(s) are adequately controlled/imparted/rendered to the product
- Asking the supplier to submit their QA program manual so appropriate quality controls (procedures and practices) can be reviewed
- Asking the supplier for actual test reports (certification that the process was implemented, quantified results of the process)
- Determining through discussions with the supplier whether there are other processes that could indicate acceptability of the critical characteristic(s) of interest
- Determining whether other customers have already established the extent of the supplier's quality controls
- Determining whether independent industry organizations (for example, oversight organizations associated with the concrete, bearings, or automotive industries) may have identified/monitored/audited the supplier's quality controls
- Determining whether any source verifications have been previously performed at the supplier's facility
- Evaluating the results of special tests/inspections that might have been previously conducted
- Determining whether the item was manufactured to National Codes and Standards
- Evaluating the actual item performance history in the plant

If the procurement is through a distributor, then consideration should be given to the potential impact the distributor may have on the item, and to whether additional controls are warranted.

3.5.2 Specifying Quality Requirements

When quality procurement requirements are specified, they should be specific enough to ensure that each applicable technical requirement is conforming to the supplier's own design for the item being procured. The primary quality requirement that should be considered for inclusion in the procurement document is invoking the ISO 9000 Quality Management System. This might be

supplemented by referencing a company QA manual or specific operating procedures that control the critical characteristics specified.

When procuring through a distributor, care must be taken to ensure that quality procurement requirements are communicated to the manufacturer or supplier maintaining the ISO 9000 QMS certification.

3.5.3 Examples of How to Specify the ISO 9000 QMS

Examples of how the ISO 9000 QMS could be invoked are as follows:

- "This item shall be controlled under the ISO 9000 Quality Management System."
- "The item as specified herein shall be furnished in accordance with the ISO 9000 Quality Management System as implemented by QA Manual, Revision 3, dated 12/12/2000."
- "The dimensions and tolerances of the item specified herein shall be controlled in accordance with the ISO 9000 Quality Management System and the following procedures:
  - Material Control Procedure OP-273, dated 12/12/2000
  - Material Machining and Inspection Procedure OP-555, dated 3/12/2000"
- "The item as specified herein shall be furnished in accordance with the ISO 9000 Quality Management System, as implemented by QA Manual, Revision 3, dated 12/12/2000, and the appropriate company procedures."
- "A copy of this purchase order in its entirety must be transmitted to the manufacturer/supplier maintaining the ISO 9000 QMS." (Note: This clause is relevant when purchasing through a distributor.)

QA

Key Quality Assurance Point

The level of specificity should correlate to the level of assurance needed to reasonably ensure that the procured items meet specified requirements and conform to the established design of the item.

3.6 Requesting Supplier Documentation From an ISO 9000 Supplier

3.6.1 General Guidance

Supplier documentation is the objective evidence that the quality controls invoked on the procurement document were implemented for the actual items being procured. This may include a certificate of conformance, certified material test report, and final product test report. Both the level of specificity contained in the documentation and the kind of documentation requested in the purchase document often vary depending on the degree to which the quality program is credited.

When procuring through a distributor, care must be taken to ensure that documentation requirements are communicated to the manufacturer or supplier maintaining the ISO 9000 QMS certification.

3.6.2 Examples of How to Specify Documentation Requirements

Examples of how the supplier documentation can be requested are as follows:

- "The supplier shall furnish a Certificate of Conformance stating that this item was controlled under the ISO 9000 Quality Management System and meets all of the requirements specified in this procurement document."
- "The supplier shall furnish a Certificate of Conformance stating that this item as specified herein was furnished in accordance with the ISO 9000 Quality Management System as implemented by QA Manual, Revision 3, dated 12/12/2000. The Certificate of Conformance shall also certify that the item meets all of the requirements specified in this procurement document."
- "The supplier shall furnish a Certificate of Conformance stating that the dimensions and tolerances of the item specified herein were controlled in accordance with the ISO 9000 Quality Management System and the following procedures:
  - Material Control Procedure OP-273, dated 12/12/2000
  - Material Machining and Inspection Procedure OP-555, dated 3/12/2000

  The Certificate of Conformance shall also certify that the item meets all of the requirements specified in this procurement document."
- "The supplier shall furnish a hydrostatic test report indicating that the test was performed in accordance with the appropriate company procedures. The Certificate of Conformance shall also certify that the item meets all of the requirements specified in this procurement document."

4
IMPLEMENTATION GUIDANCE—ACCEPTANCE OF ITEMS PROCURED FROM ISO 9000 SUPPLIERS

Figure 4-1 illustrates the generic process for commercial-grade item acceptance as it applies to items procured from ISO 9000 certified suppliers. The process has been appropriately modified from what is shown in EPRI Reports NP-5652 and TR-102260.

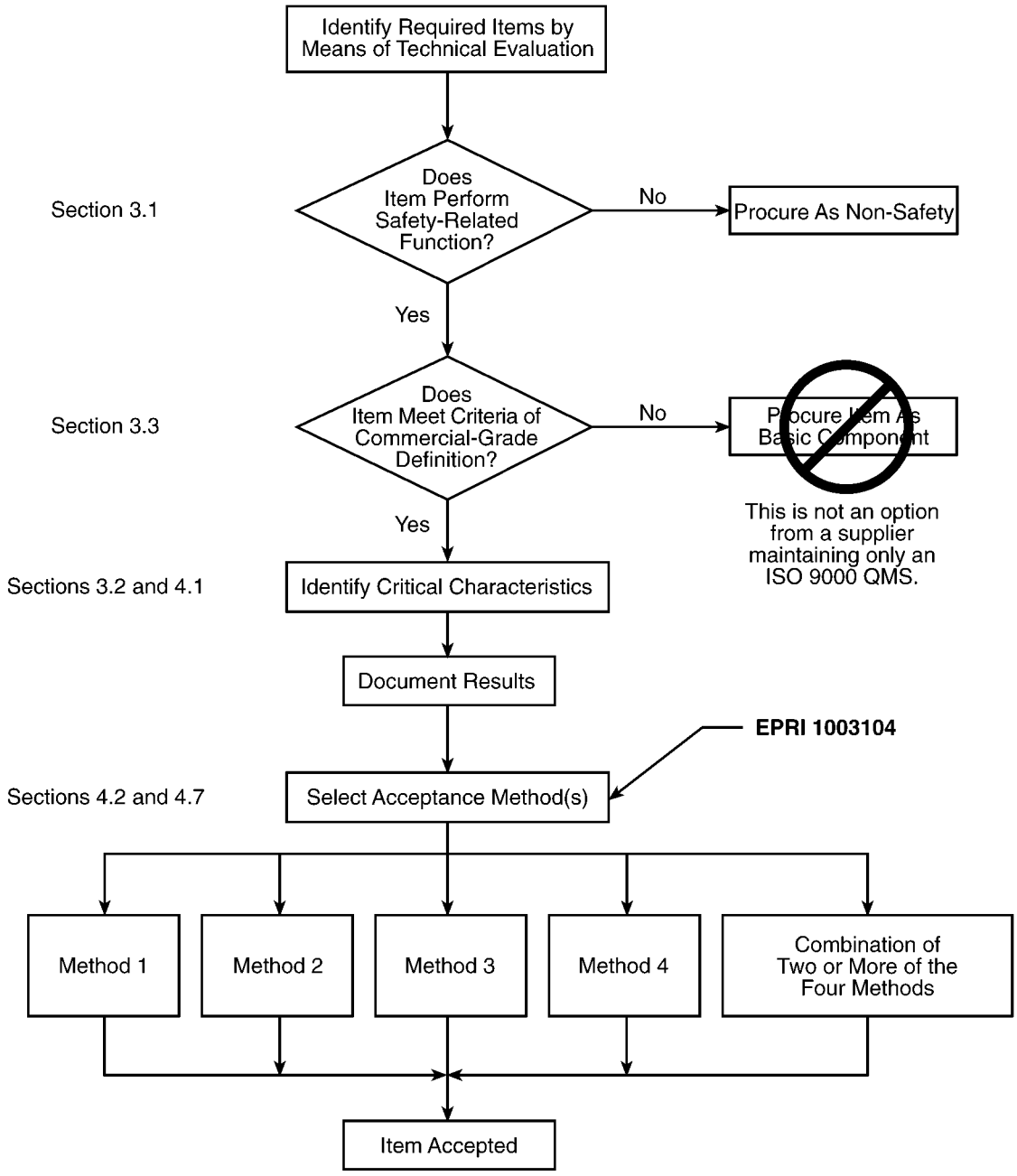

Figure 4-1
Generic Process for Acceptance of Items Procured From ISO 9000 Certified Suppliers

4.1 Selecting Critical Characteristics for Acceptance for Items Procured From ISO 9000 Suppliers

The selection of critical characteristics for acceptance (CCAs) for items procured from ISO 9000 suppliers should not differ in any way from the process used to determine critical characteristics for items procured from other suppliers. The selection of critical characteristics is primarily based on the item's safety function and is not dependent upon the type of supplier QA program.

However, the selection of critical characteristics for acceptance to achieve reasonable assurance may be influenced by the credibility of the supplier's quality controls.

Guidance found in EPRI Reports NP-5652 and TR-102260 and NRC Generic Letters 89-02 and 91-05 is applicable for selecting critical characteristics for items procured from ISO 9000 suppliers.

4.2 Selecting Commercial-Grade Item Acceptance Methods

4.2.1 General Guidance

Figure 4-2 illustrates a number of factors that might affect the selection of acceptance methods for the dedication of a commercial-grade item.

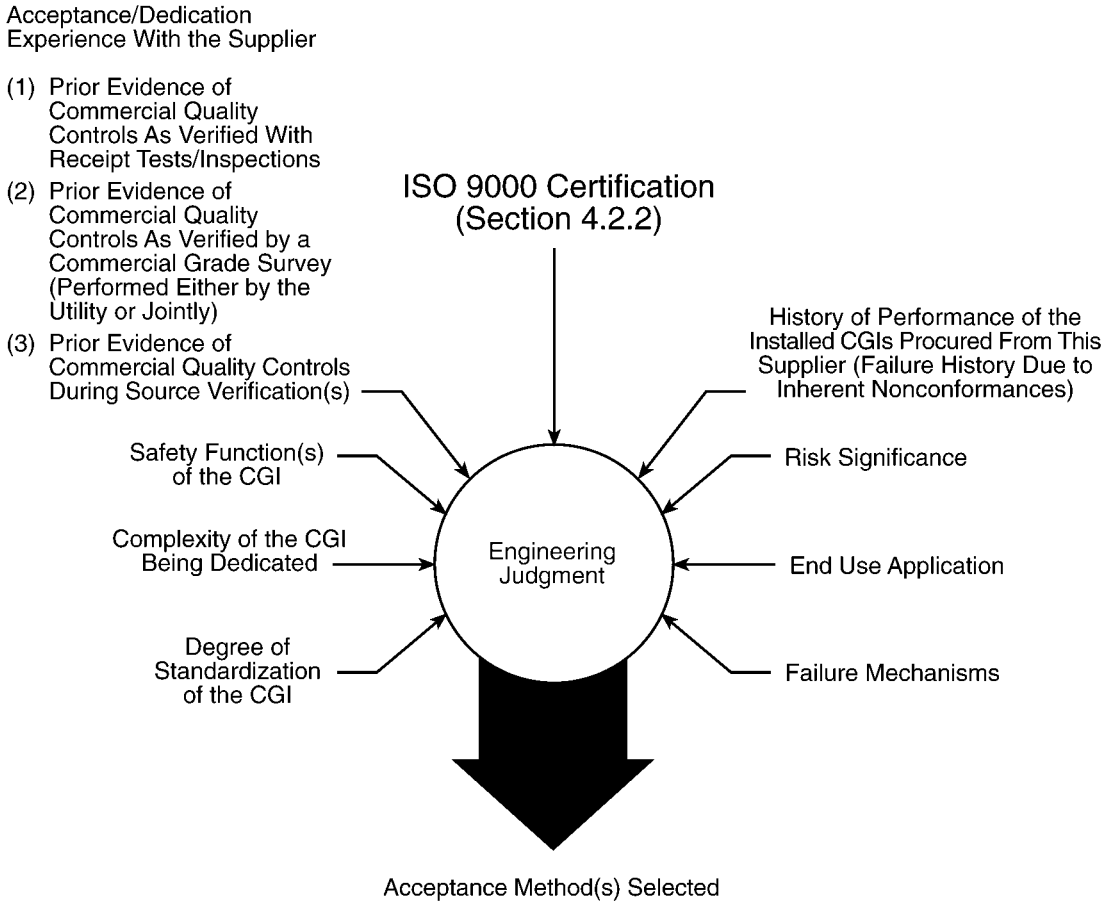

Figure 4-2
Considerations for Selecting CGI Acceptance Methods

4.2.2 Considerations Regarding the ISO 9000 QMS

As illustrated in Figure 4-2, one of the key factors to consider when selecting the appropriate Acceptance Methods is the supplier's ISO 9000 QMS. Specifically, the following issues may be considered:

- **Accrediting Body** – Although EPRI Report 1003104 focuses primarily on the credibility of Registrars accredited by the RAB, sufficient confidence was gained during the RAB visit that other accrediting bodies function in a manner similar to the RAB. The primary reason for the consistency among international accrediting bodies is the International Accreditation Forum (IAF) which presently has 27 signatory members and 35 accrediting bodies overall. The IAF monitors the performance of each accrediting body's performance through joint audits. Therefore, the user may consider other accrediting bodies when evaluating the combined performance of the ISO 9000 supplier and its accredited Registrar.
- **Supplier's Certification Status** – Supplier ISO certification status is maintained by the Registrar Accreditation Board as well as several industry organizations. A convenient way to determine a supplier's current ISO 9000 certification status is via the Internet. Searches can be made by using the RAB's web site, www.rabnet.com, which has links to Registrars. Information can also be obtained from World Preferred, www.worldpreferred.com. The licensee may consider performing periodic verification of the supplier's certification status.

4.3 Employing Method 1—Special Tests and Inspections

EPRI Report NP-5652 Method 1 discusses the use of special tests and inspections as a means of verifying critical characteristics of a commercial-grade item. Generally, these special tests and inspections are performed after receipt of the item from the supplier, either by the licensee or by a contracted third party. Items procured from ISO 9000 suppliers have been and continue to be dedicated using this acceptance method.

Section 4.7 of this report discusses how credit may be taken for the ISO 9000 QMS to support the use of Method 1.

4.4 Employing Method 2—Commercial-Grade Survey

EPRI Report NP-5652 Method 2 addresses means by which a licensee may take credit for a commercial supplier's quality controls. The means of evaluating the quality controls is defined as a commercial-grade survey and includes the following activities:

- Identifying the scope of commercial-grade items
- Identifying the safety-related function(s) of each commercial-grade item being dedicated
- Identifying critical characteristics for acceptance
- Developing a commercial-grade survey plan that includes the results of the above activities and the supplier controls that will be evaluated

- Conducting the evaluation of the supplier controls
- Documenting the results of the survey in a report that would be made available to personnel developing CGI dedication plans

NP-5652 then provides guidance on how to specify the surveyed quality controls and the need to also request supplier documentation (certification) that those controls were in fact implemented for the items being procured.

NRC Generic Letter 89-02 discusses two conditions for employing Method 2, which are still appropriate when procuring items from commercial suppliers maintaining an ISO 9000 QMS. Generic Letter 89-02 states:

> Acceptance Method 2, "Commercial Grade Survey of Supplier," should not be employed as the basis for accepting items from suppliers with undocumented commercial quality control programs or with programs that do not effectively implement their own necessary controls.
>
> Method 2 should not be employed as the basis for accepting items from distributors unless the survey includes the part manufacturer(s) and the survey confirms adequate controls by both the distributor and the part manufacturer(s).

Further discussion of these two conditions is provided in EPRI Report TR-102260. Section 4.7 of the present report discusses how credit may be taken for the ISO 9000 QMS to support the use of Method 2.

4.5 Employing Method 3—Source Verification

Source verification involves witnessing certain key activities in process at the supplier to verify proper control of critical characteristics. Items procured from ISO 9000 suppliers have been and continue to be dedicated using this Acceptance Method.

Section 4.7 of this report discusses how credit may be taken for the ISO 9000 QMS to support the use of Method 3.

4.6 Employing Method 4—Acceptable Item/ISO 9000 Supplier Performance Record

Method 4 has not been widely used in the industry as a sole means of dedicating commercial-grade items. Licensee feedback suggests that the primary reason is that the NRC applied significant caveats to using Method 4 alone, in its conditional endorsement of EPRI Report NP-5652 in Generic Letter 89-02. However, neither NP-5652 nor GL 89-02 precludes the use of Method 4, either alone or in combination with other acceptance methods. If Method 4 is to be used alone, the conditions in the NRC's GL 89-02 endorsement of NP-5652 apply.

EPRI Reports NP-5652 and TR-102260 describe different sources of information that can be used to document the satisfactory performance of a commercial-grade supplier, such as an ISO 9000 supplier. This documented history of satisfactory supplier performance can be used to support other acceptance methods, and is discussed in Section 4.7. One of the three sources of satisfactory performance is information learned on an industrywide level with regard to the performance of commercial-grade suppliers. The industrywide sources listed in NP-5652 and TR-102260 included two relevant documents/activities that may be credited/considered, as noted below:

- Commercial program evaluations performed by industry groups
- Product/performance test results

Section 4.7 of this report discusses how credit may be taken for the ISO 9000 QMS to support the use of Method 4.

4.7 Crediting the ISO 9000 QMS to Support CGI Acceptance

4.7.1 Employing Acceptance Method 1

In this approach, licensees might seek to lessen the amount of testing or inspections being performed by considering (using engineering judgment) the results of EPRI Report 1003104. The supplier's ISO 9000 program, as certified by an accredited Registrar, could be used in the dedication process to initially determine or to reduce the amount of testing/inspections of items dedicated under CGI Method 1. For example, if the supplier is performing the same tests/inspections under its ISO 9000 QMS as are required for Method 1 dedication, then the level of sampling at receipt could potentially be reduced.

Decisions as to the degree to which the supplier's ISO 9000 program would be credited should be made by each licensee on a supplier-by-supplier (or perhaps Registrar-by-Registrar) basis.

Example 1. The licensee determines that the ISO 9000 supplier has a procedure for verifying the dimensions of fasteners that are either machined by the supplier or procured from its subsuppliers. Thus, the licensee initially establishes a reduced sampling level when verifying the dimensions of commercial-grade fasteners from this ISO 9000 supplier.

Example 2. After procuring and successfully verifying the durometer hardness of O-rings from an ISO 9000 supplier for several years, the licensee determines that the supplier has a procedure for verifying the durometer of its organic products that is described in its ISO 9000 QMS. As a result, the licensee modifies its acceptance plan by reducing the sample size of O-rings that are subject to independent verification of durometer hardness during dedication.

4.7.2 Employing Acceptance Method 2

In this case, the licensee might first credit ISO 9000 quality activities as a means to reduce the programmatic review that may be performed during a commercial-grade survey. This would make the survey more efficient and reduce the scope of survey activities performed.

The licensee may establish or reduce the frequency of commercial-grade surveys of the supplier based on taking credit for the continued implementation of the supplier's certified ISO 9000 QMS. The licensee would continue to specify/invoke the same technical and quality procurement requirements, but could be relieved of performing the survey on the same frequency as before. In some cases additional surveys might be warranted only if there were actual performance problems/failures of the procured hardware from the particular ISO 9000 certified supplier.

The approach of taking generic credit for supplier audits performed by ISO 9000 Registrars, in lieu of performing commercial-grade surveys on a supplier-by-supplier basis, was evaluated. While a case might be made regarding the technical adequacy of the Registrar audits, significant issues exist from a regulatory perspective.

Once again, decisions as to the degree to which the supplier's ISO 9000 program would be credited should be made by each licensee on a supplier-by-supplier (or perhaps Registrar-by-Registrar) basis.

Example 1. A licensee plans to initially qualify a new supplier that is certified to ISO 9000. The supplier furnishes a line of commercial-grade coatings that the licensee intends to use in safety-related applications. The licensee determines that the supplier has procedures for controlling many of the critical characteristics of the coatings, and the procedures are integral to the supplier's ISO 9000 QMS. As a result, the commercial-grade survey plan is developed so as to reduce the programmatic review and scope of survey activities to be performed.

Example 2. A licensee performs a commercial-grade survey of a molded-case circuit breaker supplier that maintains an ISO 9000 QMS. The survey determines that the supplier has documented quality controls of the critical characteristics of breakers, and that those controls are being adequately implemented in accordance with the procedures comprising the ISO 9000 QMS. The licensee determines that unless there are either physical or performance nonconformances discovered with breakers procured in the future, additional surveys of this supplier on a regular frequency will not be needed. The licensee determines that further independent verification of the supplier's quality controls is unnecessary, and reliance is placed on the certification audits conducted by the ISO 9000 supplier's accredited Registrar on a six-month interval.

4.7.3 Employing Acceptance Method 3

In this case, the licensee may credit ISO 9000 quality activities as a means to reduce the programmatic reviews and/or product surveillance that may be performed during a source verification. This would make the source verification more efficient and may reduce the scope of activities witnessed.

As in the previous two acceptance scenarios, decisions as to the degree to which the supplier's ISO 9000 program would be credited should be made by each licensee on a supplier-by-supplier (or perhaps Registrar-by-Registrar) basis.

Example. A licensee determines that an ISO 9000 supplier has a procedure for performing heat treatments of valve stems and routinely tests surface hardness to verify that the correct surface hardness was rendered. The licensee takes credit for these programmatic controls over surface hardness (that is, the special process procedure and the testing) and reduces the level of surveillance associated with the special process when dedicating a shipment of valve stems needed on an expedited basis.

4.7.4 Employing Acceptance Method 4

The ISO 9000 QMS can lend further credibility to acceptability of the supplier/item performance history that the licensee has already established. Therefore, performance history solicited from the ISO 9000 supplier could be used to supplement existing performance history.

For Acceptance Method 4, the supply of a product to ISO 9000 in combination with an acceptable supplier/item performance record provides added confidence in the uniformity and quality of the item. Production under an ISO 9000 QMS helps to justify continual acceptance of a commercial-grade item by Method 4.

As noted in Section 4.6, the following two examples of performance history are relevant to ISO 9000 suppliers and may be considered when establishing satisfactory supplier performance.

4.7.4.1 Commercial Program Evaluations Performed by Industry Groups

EPRI Reports NP-5652 and TR-102260 clearly allow other commercial program audits, surveys, and product evaluations conducted by industry groups. These may be used as input for establishing a history of performance under Method 4. ISO 9000 certification audits conducted by accredited Registrars fit into this category. An assessment of various Registrars and observations of some audits performed by these Registrars are provided in EPRI Report 1003104.

4.7.4.2 Product/Performance Test Results

Some independent testing facilities (for example, Underwriters Laboratories or National Electrical Manufacturers Association) perform testing on products provided by ISO 9000 suppliers. This product testing may provide added assurance that a given ISO 9000 supplier's products are performing satisfactorily.

4.7.5 Employing a Combination of Acceptance Methods

The combination of acceptance methods is described in both EPRI Report NP-5652 and EPRI Report TR-102260, and the guidance provided in these two reports is applicable to commercial-grade items procured from ISO 9000 suppliers. NP-5652 states:

> The acceptance methods may be used in combinations to effectively verify critical characteristics and produce the objective evidence necessary to provide reasonable assurance of acceptability.

Procuring commercial-grade items from an ISO 9000 supplier would not affect how the methods could be combined and therefore is not described in any further detail in this report.

5
REFERENCES

10CFR21, Revision 2, "Reporting of Defects and Noncompliances."

10CFR50, Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants."

10CFR100.11, "Determination of Exclusion Area Low Population Zone and Population Center Distance."

ANSI N45.2.10-1973. *Quality Assurance Terms and Definitions.*

ANSI N45.2.12-1977. *Requirements for Auditing of Quality Assurance Programs for Nuclear Power Plants.*

ANSI N45.2.13-1976. *Quality Assurance Requirements for Control of Procurement of Items and Services for Nuclear Power Plants.*

ANSI N45.2.23-1976. *Qualification of Quality Assurance Program Audit Personnel for Nuclear Facilities.*

ANSI/ASME NQA-1-1986 and NQA-2-1986. *Quality Assurance Program Requirements for Nuclear Facilities.*

ANSI/EIA Standard RS-407-A-83 EIA/NARM. *Standard Testing Procedures for Relays for Electrical and Electronic Equipment*.

Assessment of the ISO 9000 Quality Management System Registrar Accreditation and Supplier Certification Processes. EPRI, Palo Alto, CA: 2001. 1003104.

"Frequently Asked Questions." Registrar Accreditation Board, Milwaukee, WI. March 2000. www.rabnet.com.

Guideline for the Utilization of Commercial-Grade Items in Nuclear Safety-Related Applications (NCIG-07). EPRI, Palo Alto, CA: 1988. NP-5652.

Guidelines for the Seismic Technical Evaluation of Replacement Items in Nuclear Power Plants. EPRI, Palo Alto, CA: 1993. NP-7484.

Guidelines for the Technical Evaluation of Replacement Items in Nuclear Power Plants (NCIG-11). EPRI, Palo Alto, CA: 1989. NP-6406.

Items Manufactured to Other Industry Standards. EPRI, Palo Alto, CA: 1993. TR-101752.

Supplemental Guidance for the Application of EPRI Report NP-5652 on the Utilization of Commercial-Grade Items. EPRI, Palo Alto, CA: 1994. TR-102260.

NRC Generic Letter 89-02, "Actions to Improve the Detection of Counterfeit and Fraudulently Marketed Products." U.S. Nuclear Regulatory Commission.

NRC Generic Letter 91-05, "Licensing Commercial Grade Procurement and Dedication Programs." U.S. Nuclear Regulatory Commission.

A
OVERVIEW OF DOCUMENTS REVIEWED DURING REGULATORY ANALYSIS

This appendix provides an overview of the documents reviewed during the regulatory analysis portion of this project. Some documents listed in the table were not applicable to the acceptance of commercial-grade items or to dedicating items procured from ISO 9000 suppliers and, as a result, are not discussed in detail in the body of this report. They are included here to assist the reader in understanding the scope of documents that were originally thought to be relevant to the regulatory analysis.

Table A-1
Overview of Documents Reviewed to Support Regulatory Analysis

Document	Title	Comments
10CFR21 Revision 2	Reporting of Defects and Noncompliances	Provides requirements for reporting defects of items or processes that have been designated as basic components. Provides some key definitions and interpretations that affect licensees' commercial-grade dedication activities.
10CFR50, Appendix B	Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants	Establishes the regulatory basis for quality assurance criteria for licensees. May also be the basis for some supplier QA programs.
ANS 3.2/ANSI N18.7-1976	Administrative Controls and Quality Assurance for the Operational Phase of Nuclear Power Plants (Revision of N18.7-1972)	Not applicable to acceptance of commercial-grade items. Includes by reference N45.2 and various "daughter" standards.
ANSI N45.2.6-1973	Qualification of Inspection, Examination, and Testing Personnel for Nuclear Power Plants	Not applicable to acceptance of commercial-grade items. Some inspection practices described in this implementing standard have been adapted for performing source verifications as part of the commercial-grade acceptance process.
ANSI N45.2.10-1973	Quality Assurance Terms and Definitions	Not applicable to acceptance of commercial-grade items.
ANSI N45.2.12-1977	Requirements for Auditing of Quality Assurance Programs for Nuclear Power Plants	Not applicable to acceptance of commercial-grade items. Some auditing practices described in this implementing standard have been adapted for commercial-grade supplier evaluations.
ANSI N45.2.13-1976	Quality Assurance Requirements for Control of Procurement of Items and Services for Nuclear Power Plants	Not applicable to acceptance of commercial-grade items. Provides implementation guidance for the acceptance of basic components. Acceptance methods became the basis for the four methods described in EPRI Report NP-5652.
ANSI N45.2.23-1976	Qualification of Quality Assurance Program Audit Personnel for Nuclear Facilities	Not applicable to acceptance of commercial-grade items. Some auditor certification practices described in this implementing standard have been adapted for personnel performing commercial-grade supplier surveys.

Table A-1 (cont.)
Overview of Documents Reviewed to Support Regulatory Analysis

Document	Title	Comments
ANSI/ASME N45.2	Quality Assurance Program Requirements for Nuclear Facilities	Not applicable to acceptance of commercial-grade items. Some processes described in these implementing standards have been adapted for the procurement and receipt of commercial-grade items intended for safety-related use.
ANSI/ASME NQA-1-1986 and NQA-2-1986	Quality Assurance Program Requirements for Nuclear Facilities	Establishes the regulatory basis for quality assurance criteria for licensees. May also be the basis for some supplier QA programs.
EPRI Report NP-5652	Guideline for the Utilization of Commercial-Grade Items in Nuclear Safety Related Applications (NCIG-07)	Provides licensees a process for procuring commercial-grade items and accepting them for safety-related use under each licensee's 10CFR50, Appendix B QA program. Through its endorsement with NRC Generic Letter 89-02, the report attained recognition as a regulatory document.
EPRI Report NP-6406	Guidelines for the Technical Evaluation of Replacement Items in Nuclear Power Plants (NCIG-11)	Provides licensees a process for specifying replacement items. The technical evaluation process includes functional classification of items, evaluation of alternate items, and development of appropriate technical and quality procurement requirements. The technical evaluation process compliments the acceptance process for commercial-grade items.
EPRI Report TR-101752	Items Manufactured to Other Industry Standards	Provides information about the quality controls inherent to certain industry standards used to design, manufacture, and/or test products.
EPRI Report TR-102260	Supplemental Guidance for the Application of EPRI Report NP-5652 on the Utilization of Commercial-Grade Items	Provides supplemental guidance and lessons learned regarding the specification and acceptance of commercial-grade items. Provides responses to caveats and interpretive guidance provided by NRC Generic Letters 89-02 and 91-05 respectively.
NRC Generic Letter 89-02	Actions to Improve the Detection of Counterfeit and Fraudulently Marketed Products	Conditionally endorsed EPRI NP-5652.

Table A-1 (cont.)
Overview of Documents Reviewed to Support Regulatory Analysis

Document	Title	Comments
NRC Generic Letter 91-05	Licensee Commercial-Grade Procurement and Dedication Programs	Announced a pause in NRC inspection activity. Provided some interpretive guidance regarding the dedication of commercial-grade items. Established a date prior to which utility procurement practices would not be subject to further review.
Regulatory Guide 1.123, Rev. 1 July 1977	Quality Assurance Requirements for Control of Procurement of Items and Services for Nuclear Power Plants	Not applicable to acceptance of commercial-grade items. Endorses ANSI N45.2.13-1976, with some caveats. Is not currently an active RG as it was withdrawn when NQA 1 was approved (per 56 FR 36175, 7/31/1991). However, it is still applicable to most plants.
Regulatory Guide 1.144	Auditing of Quality Assurance Programs for Nuclear Power Plants	Not applicable to acceptance of commercial-grade items. Some auditing practices described in this implementing standard have been adapted for commercial-grade supplier evaluations.
Regulatory Guide 1.33, Rev. 2, February 1978	Quality Assurance Program Requirements (Operation)	Not applicable to acceptance of commercial-grade items. Describes a method acceptable for complying with regulations with regard to overall QA program requirements. Endorses ANS 3.2/N18.7-1976 with some caveats.
SECY-98-279	Partial Granting of Petition for Rulemaking Submitted by the Nuclear Energy Institute (PRM-50-62)	NRC response to NEI petition to change 10CFR 50.54(a)(3) so it would not require prior NRC approval of QA program changes.

B
LISTING OF KEY INFORMATION

The following list provides the location of key Pop Out information in this report.

Key Engineering Point

Targets information that will lead to improved engineering processes and/or equipment performance.

Section	Page	Key Point
3.5.1	3-5	The licensee must ensure that the item being procured is in fact controlled under the supplier's ISO 9000 Quality Management System.
3.5.1	3-5	The user cannot assume that the supplier has the necessary quality controls over the critical characteristics solely because the supplier is ISO 9000 certified.

QA

Key Quality Assurance Point

Denotes information that results in an increased assurance of supplier quality.

Section	Page	Key Point
3.4	3-4	The ISO 9000 QMS, as administered by an accrediting body (such as RAB) and as certified by accredited Registrars, provides a measure of assurance that suppliers are implementing quality controls to effectively impart the customer's specified technical requirements to the purchased items.
3.4	3-4	When procuring through a distributor, care must be taken to ensure that technical procurement requirements are communicated to the manufacturer or supplier maintaining the ISO 9000 QMS certification.
3.5.3	3-7	The level of specificity should correlate to the level of assurance needed to reasonably ensure that the procured items meet specified requirements and conform to the established design of the item.

Key Regulatory Point

Emphasizes regulatory information that will lead to enhanced performance of plant support engineering processes.

Section	Page	Key Point
2.1.2.2	2-3	ANSI N45.2 and the “daughter” standards do not directly apply to the procurement of commercial-grade items intended for safety-related applications, although many utilities have adopted some of these processes to apply to the procurement of both basic components and commercial-grade items.

Target:
Nuclear Power

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