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Plant Support Engineering: Information for Use in Conducting Audits of Supplier Commercial Grade Item Dedication Programs

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REPORT SUMMARY

Background

The Electric Power Research Institute (EPRI) has published a series of documents pertaining to commercial grade item dedication (CGID). Each of these documents was written from a licensee's perspective and was intended for use by member utilities. EPRI released six of these documents as copyrighted publications in 2007, making them available to suppliers in the nuclear generation industry. Suppliers can use these documents as guidance for implementing supplier CGID programs.

Recent experience conducting Nuclear Procurement Issues Committee (NUPIC) audits of suppliers has revealed challenges performing audits of nuclear suppliers' CGID programs, and it has identified an opportunity to enhance the consistency of licensees' audits of suppliers' commercial grade dedication programs.

Objective

- To promote consistency in licensee auditors' expectations when auditing nuclear suppliers' CGID programs (the information presented is intended to be compatible with current regulatory guidance)

Approach

This report summarizes key elements of utility and supplier CGID programs and points out potential differences between licensee and nuclear supplier implementation of CGID programs. In addition, this report contains a set of generic forms that could be used to document CGID evaluations. These forms could be used by suppliers as a starting point for documenting their CGID evaluations, and they might be useful to licensee technical specialists when evaluating the adequacy of supplier CGID evaluations.

Results

Different procurement scenarios can result in differences between how a supplier and a licensee implement CGID. An infinite variety of dedication/procurement scenarios exist. In some cases, the entity performing dedication has access to design and fabrication information for the item being dedicated. In other cases, the item being dedicated is essentially a "black box" for which information must be determined through research and reverse engineering. Sometimes, the entity performing dedication fabricates the item from raw materials. Other times, the entity performing dedication procures the item from a supplier. Each situation must be assessed and addressed accordingly.

Differences in how dedications are performed often stem from the fact that certain suppliers might have access to a complete set of original design and manufacturing information, whereas utilities typically do not have this information. The methodology for determining critical characteristics used to dedicate commercial grade items may vary based upon the information available to the dedicating entity.

Regardless of differences in methodology, the objective of CGID is to obtain reasonable assurance that the item being dedicated is capable of performing its safety function(s). Certain suppliers might not be familiar with licensees' specific safety functions or applications; therefore, the suppliers might perform dedication based upon the full range of known design functions. In these cases, the audit team evaluating a supplier's CGID program must ensure that the functions included in the suppliers' dedication package envelop the licensees' safety functions.

The guidance developed as a result of this collaborative effort between the EPRI Plant Support Engineering (PSE) Joint Utility Task Group (JUTG) and NUPIC is focused on implementation of joint audits. However, it may also be applied to the conduct of any performance-based supplier audit.

EPRI Perspective

This report draws upon the experience and knowledge of member utilities, and it addresses key areas of concern identified by a task group composed of representatives from the EPRI PSE JUTG and representatives from NUPIC.

Keywords

Audit
Commercial grade item
Dedication
Nuclear supplier
Performance-based supplier audit
Survey

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INTRODUCTION

1.1 Background

In 1990, the Electric Power Research Institute (EPRI) published NP-6630, *Guidelines for Performance-Based Supplier Audits (NCIG-16)* [1], which became part of an industrywide, comprehensive procurement initiative [2] led by the Nuclear Utility Management and Resources Council (NUMARC) the following year. EPRI NP-6630 complemented industry guidance previously implemented by licensees to meet the intent of American National Standards Institute (ANSI) N45.2.12-1977, "Requirements for Auditing of Quality Assurance Programs for Nuclear Power Plants" [3]. EPRI NP-6630 stressed the importance of conducting performance-based audits, the importance of engineering involvement in the audit process, and the need for auditors to understand the critical characteristics/attributes of the items being furnished by the audited organization. The process of preparing for performance-based audits of nuclear suppliers contained in EPRI NP-6630 paralleled the process described in the EPRI report NP-5652, *Guideline for the Utilization of Commercial Grade Items in Nuclear Safety Related Applications (NCIG-07)* [4] regarding the conduct of commercial grade surveys of non-nuclear suppliers.

The documents referenced in the preceding paragraph did not include detailed explanation of expectations regarding a nuclear supplier's commercial grade dedication program, nor did they contain guidance on how to conduct an audit of a supplier's commercial grade item dedication (CGID) program. Recent experience conducting Nuclear Procurement Issues Committee (NUPIC) audits of suppliers has revealed difficulties in applying clear and consistent requirements during audits of nuclear suppliers' CGID programs.

This report is the result of a collaborative project between the EPRI Plant Support Engineering (PSE) Joint Utility Task Group (JUTG) and Nuclear Procurement Issues Committee (NUPIC) to promote consistency during the conduct of audits of nuclear suppliers' CGID programs.

1.2 Purpose

The purpose of this report is to provide guidance to audit team members who evaluate suppliers' CGID programs during the course of performance-based supplier audits (PBSAs).

1.3 Scope of This Report

The scope of this report includes clarification of regulatory requirements with respect to supplier commercial grade dedication programs/practices. The following four key elements of a CGID program are addressed:

- Safety function or design function
- The dedication of assemblies/components versus dedication of parts
- The level of documentation required
- The dedication of seismically sensitive items

1.3.1 Report Structure and Organization

This report contains two key sections—one provides information for utility personnel performing audits, and the other provides guidance for auditing suppliers' CGID programs to ensure that they meet the intent of regulatory requirements. Use of the PBSA and critical characteristic worksheets is also discussed. Finally, a set of forms that could be used to document a supplier's CGID evaluation is included in Appendix A.

1.3.2 Basic Premises of This Report

This report is based upon several premises with regard to the conduct of an audit of a nuclear supplier's CGID program. Those premises are discussed in this section.

1.3.2.1 Organizations Capable of Dedicating Commercial Grade Items

Only organizations maintaining a quality assurance (QA) program meeting the intent of 10CFR50, Appendix B [5] are capable of dedicating commercial grade items. Suppliers maintaining commercial QA programs and controls (such as ANSI/International Organization for Standardization [ISO]/American Society for Quality [ASQ] Q9001:2000, statistical process controls, and so on) cannot dedicate commercial grade items or furnish basic components to a nuclear licensee.

1.3.2.2 Adoption of 10CFR50, Appendix B by a Supplier

A supplier voluntarily elects to adopt the requirements of 10CFR50, Appendix B. In contrast, a nuclear licensee commits to implementation of a QA program meeting the requirements of 10CFR50, Appendix B as part of its operating license and is subsequently regulated by the U.S. Nuclear Regulatory Commission (NRC) to ensure compliance.

The regulation was originally written for licensees (that is, the applicants) in 1971. The NRC intended for the requirement to be specified by licensees in purchase orders to suppliers willing and able to meet the intent of the requirements. The regulation was not originally written as a regulation with which manufacturers or suppliers of equipment were intended to comply.

However, many organizations have adapted applicable criteria from the regulation and have built QA programs around those requirements to meet the needs of their nuclear customers. A nuclear licensee is committed to maintaining compliance with the regulation throughout the lifetime of its licensed facilities. A supplier, however, is not committed to maintaining compliance. Therefore, a supplier can change the structure and content of its QA program at any time to best meet the needs of its current customers.

A supplier does have a legal obligation to the licensee to meet the regulatory requirements of 10CFR50, Appendix B when the supplier's quality program has been audited and approved by the licensee and when it is specified as a requirement by the licensee in a contract or purchase order.

1.3.2.3 Compliance with 10CFR, Part 21

Compliance with 10CFR, Part 21 [6] is required by any organization, including suppliers, that designs, manufactures, furnishes, or uses basic components. Therefore, a supplier furnishing an item designed and manufactured as a basic component (that is, under the supplier's approved QA program meeting the requirements of 10CFR50, Appendix B) is required to comply with 10CFR, Part 21 for those particular items. In contrast, a supplier furnishing an item that was not designed and manufactured as a basic component nor dedicated and furnished as a basic component (that is, a dedicated commercial grade item) is exempt from the regulation. Suppliers that maintain commercial QA programs (QA programs not meeting the requirements of 10CFR50, Appendix B) are not subject to compliance with the requirements of 10CFR, Part 21.

1.3.2.4 Scope of Dedicated Commercial Grade Items

Suppliers decide whether they will apply 10CFR50, Appendix B criteria to the manufacture of items or whether they will dedicate commercial grade items (that is, items not designed and manufactured under a nuclear QA program). Suppliers can apply 10CFR50, Appendix B criteria to items that they manufacture. Suppliers also can dedicate items under their 10CFR50, Appendix B QA program. Typically, suppliers dedicate items that are not designed or manufactured under their 10CFR50, Appendix B program (for example, subassembly or part-level items procured from commercial sub-tier suppliers, or parts that they design or manufacture as commercial grade items).

1.3.2.5 Use of Audit Reports to Determine a Procurement Scenario

Procurement engineers—who are typically responsible for determining whether a safety-related item will be procured as a basic component or as a commercial grade item (and subsequently dedicated by the licensee)—review audit reports. Therefore, it is important that the audit report clearly describe how the nuclear supplier applies its 10CFR50, Appendix B program to furnish basic components (that is, the methodologies used by the supplier to furnish various products as basic components). It is also essential for engineering to be involved in the audit process.

1.4 Definitions of Key Terms and Glossary

All definitions in this section (see Table 1-1) have been copied from the source documents noted.

Table 1-1
Definitions of Key Terms

Basic component	(1)(i) When applied to nuclear power plants licensed pursuant to 10 CFR Part 50 of this chapter, basic component means a structure, system, or component, or part thereof that affects its safety function necessary to assure: (A) The integrity of the reactor coolant pressure boundary; (B) The capability to shut down the reactor and maintain it in a safe shutdown condition; or (C) The capability to prevent or mitigate the consequences of accidents which could result in potential offsite exposures comparable to those referred to in §50.34(a)(1) or §100.11 of this chapter, as applicable. (ii) Basic components are items designed and manufactured under a quality assurance program complying with 10 CFR Part 50, appendix B, or commercial grade items which have successfully completed the dedication process. (2) When applied to other facilities and when applied to other activities licensed pursuant to 10 CFR Parts 30, 40, 50 (other than nuclear power plants), 60, 61, 70, 71, or 72 of this chapter, basic component means a structure, system, or component, or part thereof that affects their safety function, that is directly procured by the licensee of a facility or activity subject to the regulations in this part and in which a defect or failure to comply with any applicable regulation in this chapter, order, or license issued by the Commission could create a substantial safety hazard. (3) In all cases, basic component includes safety-related design, analysis, inspection, testing, fabrication, replacement of parts, or consulting services that are associated with the component hardware whether these services are performed by the component supplier or others. (Reference: 10CFR50.2) [11].
Commercial grade item	When applied to nuclear power plants licensed pursuant to 10 CFR Part 50, commercial grade item means a structure, system, or component, or part thereof that affects its safety function, that was not designed and manufactured as a basic component. Commercial grade items do not include items where the design and manufacturing process require in-process inspections and verifications to ensure that defects or failures to comply are identified and corrected (i.e., one or more critical characteristics of the item cannot be verified). (Reference 10CFR, Part 21) [6].
CGID package	An auditable collection of documents that is the result of the commercial grade dedication process for a specific item and specific safety function. These documents contain the technical and quality basis for satisfying the commercial grade item dedication process, and provide the objective evidence to reasonably assure that the dedicated commercial grade item will perform its required safety function. (Source: NRC IP 43004) [8].

Table 1-1 (continued)
Definitions of Key Terms

Critical characteristic	When applied to nuclear power plants licensed pursuant to 10 CFR Part 50, critical characteristics are those important design, material, and performance characteristics of a commercial grade item that, once verified, will provide reasonable assurance that the item will perform its intended safety function. (Source: 10CFR, Part 21) [6].
Critical characteristic for acceptance	Identifiable and measurable attributes/variables of a commercial grade item, which once selected to be verified, provide reasonable assurance that the item received is the item specified (Source: EPRI Report NP-6406) [8]. Critical characteristics for acceptance are typically a subset of critical characteristics for design.
Critical characteristic for design	Those properties or attributes which are essential for the item's form, fit and functional performance. Critical characteristics for design are the identifiable and/or measurable attributes of a replacement item which provides assurance that the replacement item will perform its design function. (Source: EPRI Report NP-6406) [8].
Critical characteristics worksheet	A worksheet used during planning, performing and reporting of performance based commercial grade surveys that is included in the final issued survey report package. A unique worksheet is prepared in advance of each survey by the Technical Specialist/Lead Auditor and survey team members. The worksheet describes the scope of items, services or processes to be surveyed, as well as critical characteristics and acceptance criteria. The Critical Characteristics Worksheet identifies characteristics that must be controlled to ensure the items will perform their intended safety functions. The survey team determines if the vendor being surveyed adequately controls the identified critical characteristics.
Dedication	When applied to nuclear power plants licensed pursuant to 10 CFR Part 50, dedication is an acceptance process undertaken to provide reasonable assurance that a commercial grade item to be used as a basic component will perform its intended safety function and, in this respect, is deemed equivalent to an item designed and manufactured under a 10 CFR Part 50, appendix B, quality assurance program. This assurance is achieved by identifying the critical characteristics of the item and verifying their acceptability by inspections, tests, or analyses performed by the purchaser or third-party dedicating entity after delivery, supplemented as necessary by one or more of the following: commercial grade surveys; product inspections or witness at hold points at the manufacturer's facility, and analysis of historical records for acceptable performance. In all cases, the dedication process must be conducted in accordance with the applicable provisions of 10 CFR Part 50, appendix B. The process is considered complete when the item is designated for use as a basic component. (Source: 10CFR, Part 21) [6].

Table 1-1 (continued)
Definitions of Key Terms

Design function	The operation an item is required to perform to meet the component or system design basis. (Reference: EPRI Report TP-6406) [8]. Design functions are UFSAR-described design bases functions and other SSC functions described in the UFSAR that support or impact design bases functions. Implicitly included within the meaning of design function are the conditions under which intended functions are required to be performed, such as equipment response times, process conditions, equipment qualification and single failure. (NEI 96-07 Revision 1) [9].
Design bases function	Design bases functions are functions performed by systems, structures and components (SSCs) that are (1) required by, or otherwise necessary to comply with, regulations, license conditions, orders or technical specifications, or (2) credited in licensee safety analyses to meet NRC requirements. (Source: NEI 96-07 Revision 1) [9].
PBSA worksheet	A worksheet used during planning, performing and reporting of performance based supplier audits that is included in the final issued audit report package. A unique worksheet is prepared in advance of each audit by the Technical Specialist/Lead Auditor and audit team members. The worksheet describes the scope of items, services or processes provided by the supplier as well as technical characteristics and/or other items of interest, and corresponding acceptance criteria for items provided by the supplier. The PBSA worksheet identifies characteristics that are assessed during the audit to ensure items provided by the supplier will perform their intended functions.
Reasonable assurance	A justifiable level of confidence based on objective and measurable facts, actions, or observations which infer adequacy. (Source: EPRI TR 102260) [10].
Safety function	A function that a system, structure or component must perform to assure: ● The integrity of the reactor coolant pressure boundary ● The capability to shut down the reactor and maintain it in a safe shutdown condition, or ● The capability to prevent or mitigate the consequences of accidents that could result in potential offsite exposures comparable to the guideline exposures of 10CFR50.34(a)(1) or 10CFR100.11 (10CFR50.2) [21, 22] At the sub-component level, safety function is a function an item must perform to support the safety function of its parent component. Systems, structures, components and sub-component level items may have more than one safety function.

Table 1-1 (continued)
Definitions of Key Terms

Safety-related	Any structure, system, component, or part used in a nuclear power plant that is relied upon during or following design basis events to assure: ● The integrity of the reactor coolant pressure boundary ● The capability to shut down the reactor and maintain it in a safe shutdown condition, or ● The capability to prevent or mitigate the consequences of accidents that could result in potential offsite exposures comparable to the guideline exposures of 10CFR50.34(a)(1) or 10CFR100.11 [21, 22] (Reference: 10CFR50.2 / EPRI NP-6895) [11, 12]

1.5 Acronyms

A2LA American Association for Laboratory Accreditation

ANSI American National Standards Institute

ASME American Society of Mechanical Engineers

ASQ American Society for Quality

ASTM ASTM International (formerly the American Society for Testing and Materials)

CFR Code of Federal Regulations

CGID commercial grade item dedication

EPDM ethylene propylene diene monomer

EPIX Equipment Performance Information Exchange

EPRI Electric Power Research Institute

FMEA failure modes and effects analysis

INPO Institute for Nuclear Power Operations

ISO International Organization for Standardization

JUTG Joint Utility Task Group (EPRI PSE)

NCIG Nuclear Construction Issues Group

NEI	Nuclear Energy Institute
NIST	National Institute of Standards and Technology
NRC	U.S. Nuclear Regulatory Commission
NSSS	nuclear steam system supplier
NUMARC	Nuclear Utility Management and Resources Council
NUPIC	Nuclear Procurement Issues Committee
NVLAP	National Voluntary Laboratory Accreditation Program (administered by NIST)
OEM	original equipment manufacturer
OPEX	operational experience
PBSA	performance-based supplier audit
PSE	Plant Support Engineering
QA	quality assurance
QMS	quality management system
RFQ	request for quote
SME	subject matter expert
TR	technical report

2
INTENT AND USE OF EPRI GUIDANCE DOCUMENTS

2.1 Intent of EPRI Reports

The EPRI reports referred to in this report were originally written for use by licensees. Therefore, they were written in the context of providing guidance for a licensee implementing an internal CGID program. The guidance provided in these reports is sound, but interpretation is required when applying the guidance to implementation or evaluation of suppliers' CGID programs for the following reasons:

- Suppliers often have access to original design documents and information not available to utilities.
- Dedications prepared by utilities typically consist of a single engineering evaluation and easily linked documents, such as inspection plans and results.
- The various elements of a supplier's dedication evaluation might not be captured in a single evaluation or document. The information required to support a supplier's CGID might be contained in a number of different documents, such as engineering evaluations, purchase orders, design documents, drawings, procedures, and so forth.
- EPRI reports are generally not available to suppliers. The following procurement-related EPRI reports were only recently made available to suppliers:
  - *Guideline for the Utilization of Commercial Grade Items in Nuclear Safety Related Applications (NCIG-07)* (NP-5652) [4]
  - *Supplemental Guidance for the Application of EPRI Report NP-5652 on the Utilization of Commercial Grade Items* (TR-102260) [10]
  - *Guideline for Sampling in the Commercial-Grade Item Acceptance Process* (TR-017218-R1) [13]
  - *Critical Characteristics for Acceptance of Seismically Sensitive Items (CCASSI)* (TR-112579) [14]
  - *Guideline for the Seismic Technical Evaluation of Replacement Items for Nuclear Power Plants* (NP-7484) [15]
  - *Guidelines for the Technical Evaluation of Replacement Items in Nuclear Power Plants (Revision 1)* (1008256) [16]

Therefore, an auditor or technical specialist should not expect to find that the supplier's CGID procedures, processes, or technical evaluations always closely resemble those of a utility.

The EPRI reports referenced herein were prepared in order to provide guidance to licensees on how to accept items purchased as commercial grade items (not as basic components) for use in safety-related applications. It is important to recognize that these reports were written from a utility perspective and were not originally intended to be invoked as standards for suppliers or as requirements in procurement documents.

2.2 Intent of EPRI Commercial Grade Item Technical Evaluations

In the early 1990s, the EPRI JUTG utility representatives collaborated to develop approximately 140 commercial grade item technical evaluations [17] that address dedication of items commonly used to support plant operations and maintenance activities.

These evaluations were developed from a utility perspective, meaning that much of the manufacturers' original design and fabrication parameters for items being dedicated by the licensee were not known, so critical characteristics were identified by the licensee using the failure modes and effects analysis (FMEA) process.

These evaluations were intended to serve as references for utilities developing technical evaluations for the same types of items. In many cases, the technical evaluation covered a range of several functions and corresponding critical characteristics for an item. Using the evaluations in combination with the item-specific information (such as safety function[s]), licensees can select those functions and critical characteristics appropriate for a specific application/CGID package. The evaluations represent a snapshot of applicable requirements at the time they were written. Therefore, the codes and standards cited in the evaluations should be verified as current when using the evaluations for guidance.

Suppliers generally do not have access to these evaluations. These evaluations may be used as reference material when developing PBSA worksheets and preparing for an audit. However, for reasons previously cited, these technical evaluations should not be used by licensee personnel as the sole basis for determining the adequacy of a supplier's commercial grade dedication evaluation. Likewise, these technical evaluations should **not** be used by suppliers as the sole basis for the contents of a supplier's commercial grade dedication evaluation.

If deviations from requirements included in EPRI technical evaluations are noted during the course of an audit or preparation for an audit, the technical specialist should be enlisted to provide guidance on the acceptability of the supplier's commercial grade dedication package and plan. Deviations are not necessarily indicative of errors in either the EPRI or supplier's technical evaluation.

3
CGID BACKGROUND INFORMATION

3.1 Purpose

This section explains the reasons that a licensee uses CGID, as well as the way in which a licensee (utility) approaches CGID.

A basic understanding of how and why a licensee approaches dedication is presented prior to discussing supplier dedication so that attention can be drawn to the differences between a licensee's approach to performing CGID and the approaches that different types of suppliers might take.

3.1.1 Existing EPRI Guidance on CGID

As a minimum, personnel evaluating a supplier's CGID program should be familiar with the following EPRI reports and regulatory guidance:

- The EPRI report *Guideline for the Utilization of Commercial Grade Items in Nuclear Safety Related Applications (NCIG-07)* (NP-5652) [4]
- The EPRI report *Supplemental Guidance for the Application of EPRI Report NP-5652 on the Utilization of Commercial Grade Items* (TR-102260) [10]
- The EPRI report *Critical Characteristics for Acceptance of Seismically Sensitive Items (CCASSI)* (TR-112579) [14]
- 10CFR, Part 21 (current revision) [6]
- US NRC Inspection Procedure 38703, "Commercial Grade Dedication" [18]
- US NRC Inspection Procedure 43004, "Inspection of Commercial Grade Dedication Programs" [7]

3.1.2 The Role of CGID in Ensuring Performance of Plant Components

In the context of procurement, consideration is given to the five key elements involved in achieving overall assurance of plant component performance (see Figure 3-1, adapted from *Supplemental Guidance for the Application of EPRI Report NP-5652 on the Utilization of Commercial Grade Items* [10]) (TR-102260). The purpose of reviewing these elements in this report is to point out that CGID is part of the acceptance process and does not include re-qualification or re-determination of an item's suitability for design.

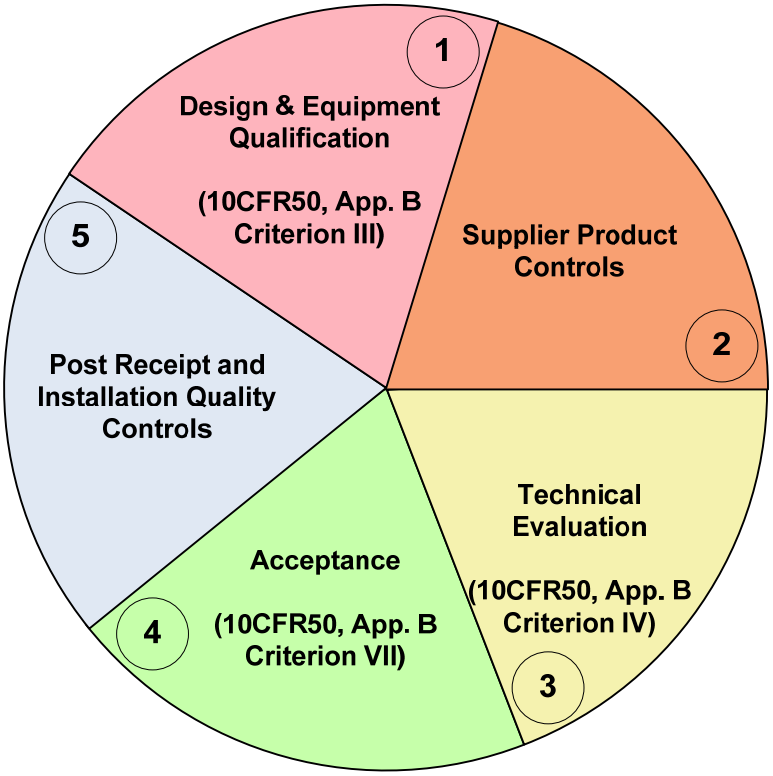

Figure 3-1
Key Elements Employed to Achieve Assurance of Plant Component Performance

3.1.2.1 Key Elements Employed to Achieve Assurance of Plant Component Performance

Figure 3-1 was adapted from a similar figure included in *Supplemental Guidance for the Application of EPRI Report NP-5652 on the Utilization of Commercial Grade Items* (TR-102260) [10])

3.1.2.1.1 Design and Equipment Qualification

The first elements in ensuring the performance of plant components are design and qualification of plant equipment. These activities are conducted pursuant to the requirements of 10CFR50, Appendix B, Criterion III (“Design Control”).

During construction or modification activities, engineering specifications and requirements are developed, and a component capable of meeting the requirements is selected.

In some cases, qualification of the selected component is necessary to ensure that it is capable of performing its intended functions. When qualification is necessary, a prototype of the selected item is subjected to testing, such as environmental and seismic qualification testing.

Once the design is established, licensees typically prepare original equipment specifications that are used to procure the original plant equipment. These specifications are used to capture the requirements that procured equipment must meet and to communicate these design and performance parameters to suppliers. Often, these specifications address whole components and do not specifically address part-level items.

Suppliers sometimes develop new or improved products in order to meet the design requirements. New products must be tested to establish that they meet design and qualification requirements. Often, this involves fabrication and testing of prototypes to prove that design and qualification parameters are met.

3.1.2.1.2 Supplier Product Control

The second element is supplier product control. Suppliers implement controls to ensure that the products they manufacture meet applicable design requirements.

During the course of designing and manufacturing the equipment, suppliers develop a complete set of design information for their equipment and the parts from which the equipment is constructed. This design information typically includes fabrication drawings and instructions for assemblies, subassemblies and parts, design calculations, materials selected for each part, processes employed to fabricate the part, and so on.

Using methods such as prototype testing, functional testing, and design analysis, suppliers ensure that the design of the equipment that they will provide meets the utility specification. Once a design is proven to meet the requirements of the utility specification (that is, the design is proven suitable for its intended application), it is approved, and the supplier manufactures the equipment in accordance with the qualified design information. The supplier also implements controls to ensure that the equipment meets applicable design requirements.

3.1.2.1.3 Licensee Technical Evaluation

The third element is the technical evaluation (or *engineering evaluation* as it is referred to in ANSI N18.7 [19]). When a licensee procures an item, a technical evaluation is performed to ensure that the technical and QA requirements indicated in design documents are correctly translated into procurement specifications and documents. Licensees often document part or all of a CGID in a technical evaluation.

The technical evaluation is conducted pursuant to the requirements of 10CFR50, Appendix B, Criterion IV (“Procurement Document Control”).

3.1.2.1.4 Acceptance Process

The fourth element is the acceptance process. The acceptance process is used by the licensee to ensure that the item received meets the specified requirements. CGID is part of the acceptance process.

3.1.2.1.5 Post-Receipt and Installation Quality Controls

The fifth element in ensuring performance of plant components is implementation of quality controls after the received item has been accepted and installed. These controls include activities such as ongoing equipment monitoring, surveillance, and testing.

3.1.2.1.6 CGID's Role in Assurance of Item Performance

Generally, the performance of any item in the plant is ensured through various controls implemented by licensees and suppliers. These controls include design controls (10CFR50, Appendix B, Criterion III); procurement controls (10CFR50, Appendix B, Criterion IV); and acceptance tests and inspections (10CFR50, Appendix B, Criterion VII).

CGID activities are conducted pursuant to 10CFR50, Appendix B, Criterion VII ("Acceptance Tests and Inspections"). However, a technical evaluation is often used to capture information necessary to perform CGID. When used in combination, the technical evaluation and acceptance process provide reasonable assurance that a commercial grade item is equal to an item purchased as a basic component to the requirements of 10CFR50, Appendix B [5].

3.2.1 Basic CGID Methodology

The CGID methodologies presented in the EPRI reports referenced in Section 3.1.1 **were originally developed for use by utility personnel** (licensees) specifically to address the problem of obtaining safety-related spare and replacement items that are no longer furnished by suppliers as basic components.

Most of the original equipment in the current U.S. fleet was furnished by suppliers with a QA program that met 10CFR50.

The need for CGID typically occurs when a licensee needs to procure replacement equipment or spare parts and the original supplier (or an alternative supplier) is no longer able to furnish the equipment or item as a basic component.

In this scenario, the licensee would prepare a CGID evaluation. The evaluation would include critical characteristics that must be verified in order to provide reasonable assurance that the item is capable of performing its safety function(s).

There are two basic sources of critical characteristic information. First, critical characteristics may be based upon actual design information. Second, critical characteristics may be developed using methodology discussed in the EPRI report NP-5652, *Guideline for the Utilization of Commercial Grade Items in Nuclear Safety Related Applications (NCIG-07)* [4], such as FMEA.

3.2.1.1 Use of Existing Design Basis Information to Determine Critical Characteristics

Existing or actual design information can be used to determine critical characteristics, as discussed in Section 2.3.2.5 of *Supplemental Guidance for the Application of EPRI Report NP-5652 on the Utilization of Commercial Grade Items* (TR-102260) and excerpted as follows:

> If adequate technical and quality requirements for the item are available from existing design basis information, then they may be used to establish critical characteristics for acceptance without performing a new determination of critical characteristics for design.
>
> ANSI N18.7 requires that replacement parts be purchased to specifications and codes equivalent to those specified for the original. Technical and quality requirements which applied to procurement of the original item must either be met when procuring a replacement item, or revised through a properly reviewed and approved revision.
>
> Original item specifications (or current approved revisions) are the preferred source for determination of critical characteristics for design, where such specification are available or can reasonably be obtained [10].

3.2.1.2 Use of FMEA to Determine Critical Characteristics

If adequate design information cannot be obtained at the level of detail necessary to determine critical characteristics, determination of critical characteristics may be based on an analysis of safety functions and failure modes and effects. This is often the case when the utility that needs to replace the item is not in possession of the complete set of design information used by the supplier to manufacture the items.

In this situation, the utility would use CGID methodology to ensure that the replacement item will be able to perform its intended safety function(s).

Briefly summarized, development of a utility CGID evaluation or plan involves the following elements, as depicted on the left side ("Licensee Without Access to Original Design Information") of Figure 3-2:

- Identifying the item's safety function(s)
- Using FMEA to develop a set of critical characteristics—that is, characteristics that the item must possess in order to be able to perform its safety function
- Developing acceptance criteria (that is, values, tolerances, and so on) for the selected critical characteristics
- Selecting an appropriate acceptance method for verifying each of the critical characteristics
- Specifying an appropriate sample plan (when applicable) for use when executing the acceptance method

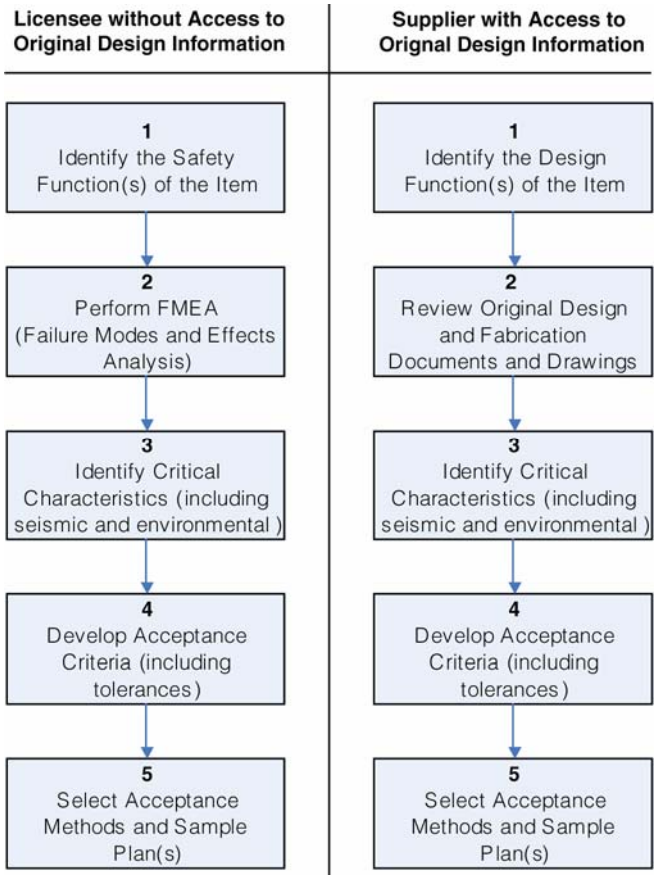

Figure 3-2
The Basic Elements of the CGI Dedication Process

3.2.1.3 Determination of Critical Characteristics

The methodology used to determine critical characteristics may differ based upon the amount and level of detail available to the dedicating entity. This is particularly true when the dedicating entity has access to some or all of the design information used in the original manufacture of the items. When this information is available, the supplier may rely on analysis of design functions and information in lieu of FMEA to develop critical characteristics. In some cases, the methods may be used in combination.

3.3 Communication with Suppliers

Longstanding utility experience in resolving supplier CGID program issues has demonstrated that the incidence and severity of supplier CGID program concerns can be reduced when a utility clearly communicates expectations and requirements to the supplier in procurement documents.

Communication is particularly important when the supplier is not the original manufacturer of the item, or when the supplier might not be familiar with the item as the result of mergers and acquisitions, loss of personnel, and so forth. In these cases, several types of communication should be considered.

3.3.1 Licensee Provides Technical Information to the Dedicating Entity

One communication tool for ensuring the adequacy of dedication plans is for the utility to include certain technical information—such as the item's safety function, failure mode(s), critical characteristics, and equipment qualification requirements (such as harsh environmental conditions and seismic response spectra)—in procurement documents. This approach is particularly useful when the dedicating entity is a third-party qualifier.

3.3.2 Licensee Approves the Dedication Plan Prior to Implementation

Another effective means of communication is for the utility to require the supplier to submit the supplier's dedication plan to the utility for review and approval before the utility authorizes the start of work. Similarly, it might be beneficial for the supplier (dedicating entity) to require the utility to review and approve the supplier's dedication plan and obtain approval before they commence work on specific utility purchase orders.

The communication tools previously noted are only examples of how communication can be used to preclude CGID concerns. Other means of communication can be employed as necessary. In cases where a utility has confidence in the supplier's activities and program, the utility might not find it necessary to communicate additional information to the supplier (in other words, they might not use either of the two methods described).

3.4 Items Dedicated by Suppliers with Nuclear QA Programs

Several types of items may be dedicated by suppliers maintaining a 10CFR50, Appendix B QA program. As noted in the basic premises of this report, at its discretion, a supplier can decide to either (a) apply its nuclear QA program to dedicate items that the supplier provides or (b) apply its nuclear QA program to control all design and manufacturing associated with the item. Some suppliers apply their nuclear QA program when a licensee is procuring a whole component. Others, however, use the nuclear QA program to dedicate spare and replacement items that were not designed and manufactured as basic components (that is, commercial grade items). In some cases, suppliers might control the manufacture of some part-level items under their QA program and dedicate other part-level items.

The following types of items are examples of the types of items that can be dedicated by a supplier maintaining a nuclear QA program:

- Raw materials, chemical compounds, and chemicals procured from a sub-tier supplier (as examples, gases, bar stock, weld rod, and iodine)
- Fabricated parts procured from a sub-tier supplier (such as fasteners, O-rings, gaskets, simple metallic items, resistors, diodes, diaphragms, wear rings, and so on)
- Fabricated assemblies procured from a sub-tier supplier (as examples, circuit boards, relays, breakers, disc assemblies, and kits)
- Consumables procured from a sub-tier supplier (as examples, grease, oil, and coatings)

Entire parts and assemblies manufactured by the nuclear supplier (when the design and/or manufacture of the item is not controlled under the supplier's nuclear QA program).

4
TECHNICAL SPECIALISTS AND PBSA WORKSHEETS

4.1 Technical Audit Team Personnel

4.1.1 Technical Specialists

Technical specialists should be involved in preparation of PBSA worksheets as well as the conduct of the audit itself. Technical specialists are individuals who possess technical knowledge about the items or services being dedicated and supplied by the supplier being audited.

It is common practice for the same technical specialists who prepare PBSA worksheets to participate in the audit. When additional technical experience is required to prepare for the audit, the technical specialist and audit team leader preparing the PBSA worksheet should enlist the aid and assistance of other technical resources (such as subject matter experts [SMEs], system/component engineers, and so forth) who have knowledge and insight pertaining to the equipment that the supplier being audited provides.

Typically, resources preparing PBSA worksheets for evaluating a supplier's CGID program will have expertise in one or more of the following areas:

- Procurement engineering experience in preparing CGID evaluations or functional safety classifications
- Knowledge of equipment qualification requirements (such as seismic and environmental)
- Applicable plant/system engineering experience, if specific performance issues are identified for the equipment that the supplier provides
- Familiarity with equipment performance and/or operating experience issues related to the equipment provided by the supplier being audited

It is recommended that the lead auditor work together with the technical specialist before the audit to identify personnel who are SMEs in the types of equipment, items, or services provided by the supplier. These SMEs might be system engineers, component engineers, and so on. A list of SMEs along with their contact information should be available during the audit so that any questions that emerge can be quickly addressed.

4.2 PBSA Worksheets

PBSA worksheets are an important part of audit preparation. The PBSA worksheet captures engineering's input for the audit process, and engineering participation in the audit process is an essential component of performance-based audits.

New PBSA worksheets should be prepared for each audit and should be based upon the scope of items currently provided by the supplier and, if applicable, issues (such as performance and quality) related to items that the supplier provides. PBSA worksheets from previous audits should be reviewed when completing new PBSA worksheets.

Operational experience (OPEX) should also be considered when preparing PBSA worksheets. Both plant and industry sources of OPEX, such as the Institute for Nuclear Power Operations' (INPO's) Equipment Performance Information Exchange (EPIX), should be queried.

Technical characteristics and/or items of interest included on the PBSA worksheet should not include generic programmatic attributes or other characteristics or concerns that are specifically addressed in the audit checklist.

The PBSA worksheet(s) should provide the technically oriented information needed to conduct the audit. It might be necessary to prepare multiple PBSA worksheets to address the entire scope of supply. In the case of suppliers that furnish a broad range of items (such as a nuclear steam system supplier [NSSS] or a third-party qualifier), it might not be feasible to include a separate PBSA for each type of item furnished. However, the PBSA worksheets included should include technical characteristics and/or items of interest that are representative of the types of items typically provided by the supplier.

Sections 4.2.1–4.2.3 discuss the types of information that PBSA worksheets should include.

4.2.1 Safety Function(s)

It is important that information included in the PBSA worksheet be based upon the safety functions of the items being procured from the supplier. The supplier is not always aware of the utility's application(s) for the items that the supplier provides. Including information related to the safety function(s) on the PBSA worksheet will assist auditors and technical specialists in determining if a supplier's CGID plan will provide assurance that the item dedicated will perform its intended safety-related function.

In the case of suppliers that furnish a broad range of items (such as NSSSs or third-party qualifiers), it might not be feasible to include information related to the safety functions of each type of item furnished. Instead, information related to the safety function(s) for key groups or a representative cross-section of the types of items furnished can be included.

4.2.2 Scope of Supply

The scope of supply should reflect information provided by the licensees who submit input in preparation for the audit.

It is important that PBSA worksheets address a complete listing of items and/or item types that are included in the supplier facility's scope of supply. If the supplier provides a wide variety of items, it might be necessary to group the items into logical categories and prepare individual PBSA worksheets for each category. For example, if a supplier provides valves and actuators, it might be necessary to prepare one PBSA worksheet for valves and valve parts and another for actuators and actuator parts.

4.2.3 Technical Characteristics and Acceptance Criteria

Technical characteristics are key to the PBSA worksheet. Even in cases where a supplier has access to a complete set of design and fabrication data for an item that it provides, the supplier might not be aware of the utility's application (or all applications) for the item(s) provided.

The supplier might also not be aware of critical characteristics that are related to equipment qualification. Therefore, characteristics related to both seismic and environmental qualification should be included in the PBSA worksheet.

For example, if the utility's equipment qualification for items provided by a supplier is based upon a specific characteristic, such as the chemical composition of a particular material or a spring constant that prevents the device from chattering during a seismic event, the PBSA worksheet should clearly indicate that verification of the specific material or spring constant is an item of importance (a critical characteristic) in order to ensure that qualification is maintained.

The EPRI report *Critical Characteristics for Acceptance of Seismically Sensitive Items (CCASSI)* (TR-112579) [14] contains detailed guidance on selection of critical characteristics related to seismic qualification.

Auditors and technical specialists should ensure that the technical characteristics of importance to the utility included on the PBSA worksheet are adequately verified by the supplier's dedication plan, and that the supplier's plan envelops the characteristics that the utility believes are essential to the item(s)' ability to perform their intended safety-related function(s).

Noting acceptance criteria for each technical characteristic is also an important part of the PBSA worksheet. In some cases, the acceptance criteria required by the utility might vary from the supplier's acceptance criteria. This is particularly true when the supplier's acceptance criteria are based upon the original design requirements and the utility's criteria are based upon actual OPEX or engineering analysis. Auditors and technical specialists should use the acceptance criteria in the PBSA worksheet to verify that the supplier's acceptance criteria meet the licensee's expectations.

5
CONDUCTING AUDITS OF CGID PROGRAMS

This section provides an overview of how CGID programs should be examined during a PBSA and a summary of expectations regarding those programs as a reference point for utility auditors.

5.1 Sequence of Examining CGID Activities During the Audit

As mentioned in Section 4.1.1 of this report, the audit team leader should work with the technical specialist in advance of the audit to identify SMEs who can be contacted during the audit to address questions that emerge relative to the supplier's scope(s) of supply.

The audit team leader assigns duties to audit team members at his or her discretion. However, it is recommended that a sample of the supplier's CGID plans be reviewed early in the week so that any questions requiring resolution can be addressed by the technical specialist or other SMEs as the audit progresses.

5.2 Audit Team Expectations Regarding the CGID Program

5.2.1 CGID Program Description

The supplier should maintain a documented program (procedure and so forth) that defines how CGID is accomplished and outlines the process, methodology, and requirements for performing dedication. The methods for verifying selected critical characteristics should be consistent with those described in Criterion VII of 10CFR50, Appendix B [5] and ANSI N45.2.13 [20], which include the following:

- **Inspection of products**. Note that in the case of a nuclear supplier/manufacturer, these inspections could occur during manufacture of the item or during receipt of the item when manufactured by a sub-supplier or during receipt of raw materials used to manufacture the item.
- **Sub-tier supplier documentation**. Documentation/certification is acceptable only from a sub-tier supplier that has been surveyed or audited by the dedicating entity and when the basis for acceptability and validity of the supplier's documentation has been established and documented.
- **Source verification** (inspections performed by the dedicating entity at the location[s] of the sub-tier supplier manufacturing the commercial grade item).

Auditors should recognize that a nuclear supplier should have the same flexibility in selecting a cost-effective combination of methods as that permitted by the regulation for licensees.

Suppliers' dedication processes may be somewhat different from the process employed by utilities. Suppliers might consider design functions or functional performance requirements in lieu of application-specific safety functions. Instead of using the FMEA process to derive critical characteristics, suppliers may employ a different method that involves screening the original set of design information (design characteristics) to identify and select appropriate critical characteristics for acceptance.

Over the course of the audit, audit team members should validate that the CGID process provides reasonable assurance that items being dedicated will perform their intended safety-related function(s). When doubt exists as to the effectiveness of the process, the technical specialist and/or SMEs in CGID and the items in the supplier's scope of supply should be consulted.

5.2.2 Nuclear Supplier Documentation

Audit team members should not always expect to find suppliers who document their commercial grade dedication program in the same ways a licensee would. Documentation maintained by a supplier to support its CGID program can sometimes differ markedly from documentation maintained by a licensee. The amounts, types, and organization of a supplier's documentation vary depending upon the supplier's relationship to the item being supplied and the amount of design information available. Typically, when more design information is available in supplier design documents, less information will be documented separately by the supplier in CGID evaluations/packages.

5.3 Suppliers' Relationships with the Items That They Provide

When evaluating a supplier's CGID program, it is helpful to consider the relationship between the supplier and the item(s) that they provide. The amount of information documented in the supplier's dedication package about safety function(s) or design function(s) will vary based upon the type of supplier being evaluated.

NSSSs such as Westinghouse, General Electric, AREVA, and Atomic Energy of Canada, Limited are typically familiar with functional design requirements at the system and component level. Typically, the NSSS developed the original design requirements at the system and component levels and included them in the original system requirements, equipment specifications, and requests for quotes (RFQs) that were submitted to their sub-tier suppliers. An NSSS might not be as familiar with design requirements at the part level. The NSSS's sub-tier suppliers were ordinarily responsible for ensuring that equipment design at the part level was sufficient to ensure that their components would perform their design functions. However, NSSSs should be able to use their knowledge of system and component safety functions to determine the safety function of replacement parts.

Original equipment manufacturers (OEMs) are typically familiar with functional design requirements at the component level because they furnished components to meet the functional requirements specified in a licensee or NSSS specification. However, OEMs might not be familiar with design requirements at the system level (unless they provided the entire system or *skid*). OEMs typically are familiar with the design function of each part, but they might not be aware of the part's safety function. In some cases, the OEM may not be aware of all of the component's safety functions (for example, a valve that has to modulate versus a valve that has to provide isolation).

It is important to keep in mind that some OEMs are not familiar with functional design requirements at the component level because that information is no longer available as the result of mergers, acquisitions, and personnel changes. These suppliers often do not know specific applications or safety functions; instead, they are better aware of the item's typical design function(s). A control valve manufacturer might know that the valves that it supplies are used in applications that require the valves to open, close, and modulate. However, the supplier might not know that the safety functions in a specific plant are to close on demand and maintain pressure boundary integrity.

Sub-tier suppliers, including manufacturers and distributors who provide component OEMs with materials, commodity items, or individual parts used in the assembly of components are typically not familiar with the part's intended design function in the component. A spring manufacturer might know the basic design requirements for a spring but not what function the spring will perform in its intended host component. Table 5-1 summarizes these relationships.

Table 5-1
Design Information Typically Familiar to Various Supplier Organizations

Type of Information with Which Each Organization Is Typically Familiar	NSSS	OEM	Sub-Tier (Part) Supplier	Licensee
System Functions	Yes	No	No	Yes
Component Functions	Yes	Yes	No	Yes
Part Functions	No	Yes	No	Yes (via evaluation process)
Item Design Characteristics	No	Yes	Yes (part only)	No

A supplier's use of design and safety functions in its CGID program typically aligns with one of the following three scenarios:

- In the first scenario, the supplier knows the safety function(s) of the item because the supplier is an NSSS supplier or played a key role in design and/or seismic and environmental qualification of the host equipment.
- In the second scenario, the licensee provides the safety function to the supplier, as might be the case with third-party qualifiers or OEMs of equipment that was originally provided by the NSSS original equipment suppliers (OES) that were not involved in the qualification of the items.
- The third scenario is when the supplier does not know the safety function(s) but is familiar with the item's design functions. Typically, the safety function(s) are a subset of the design functions required in original design specifications prepared by the licensee, NSSS, or architect/engineering organization.

When the supplier performs dedication based upon the item's design function(s), it is important for the audit team members to ensure that the critical characteristics being verified by the supplier envelop the characteristics included on the PBSA worksheet. This will provide reasonable assurance that the item will perform its intended safety function(s).

The methods used and the extent to which suppliers document their selection of critical characteristics may vary. The dedicating entity should be able to justify the basis for critical characteristics included in the dedication package. This justification may include documentation of plant-specific safety functions, and it may or may not be based to some extent on original design documentation. The level of documentation should be commensurate with the complexity of the item being provided and the supplier's relationship to the item.

5.4 Supplier Commercial Grade Dedication Expectations

5.4.1 Review of Differences in Licensee and Supplier CGID Methodology

This section presents a brief discussion of licensees' and suppliers' approaches to developing CGID criteria. The intent of the discussion is to point out several reasons why the functions included in a supplier's CGID might vary from that of a utility, based upon the supplier's familiarity with the item and the amount of original design information available for the item.

5.4.1.1 Licensees

A licensee's engineering organization determines if the item originally procured from a supplier (for example, during construction) is acceptable for use in its application; therefore, the design aspects of the item are evaluated by engineering (as discussed in Section 3.1.2.1.1 of this report). Once an item is accepted for use, future procurements of the item must include provisions to

ensure that the item will perform as intended. These provisions can be verification of the vendor's processes and might require review and approval of the vendor's dedication package (as appropriate).

When a licensee procures a replacement item as a basic component, the licensee relies (in part) upon the supplier's design control processes to ensure that the item will be capable of performing its intended safety function. The supplier is responsible for detailed design and fabrication activities, and, in most cases, the supplier does not provide the licensee with all of the information required to fabricate the item (as discussed in Section 3.1.2.1.2 of this report).

When the licensee procures a commercial grade replacement for an item originally procured as a basic component and dedicates it, the licensee typically does not have access to a complete set of design and manufacturing information for the item. Using the methodology established for use by utilities in dedicating commercial grade items, a licensee identifies the item's safety functions and performs an FMEA to develop characteristics and acceptance criteria that can be used to reasonably verify that the item will be capable of performing its intended safety-related function.

5.4.1.2 Suppliers

When a supplier (such as a third-party qualifier) that does not have detailed design information at its disposal dedicates an item, its CGID should be very similar to that developed by a utility. The supplier must be aware of the item's safety functions so that the supplier can perform an FMEA to develop characteristics and acceptance criteria that can be used to reasonably verify that the item will be capable of performing its intended safety-related function. In these cases, the safety functions upon which the dedication is based should be included in the supplier's CGID. The licensee might provide safety function information to the supplier, or the supplier might glean functional information from published technical data.

In contrast to licensees and third-party organizations, some suppliers do have access to original design information and know all the design functions of the items that they manufacture. This is particularly true when the supplier of the commercial grade item is the OEM that established the original design requirements for the components and items that they provided to the licensee during construction or in prior procurements.

While these suppliers might not be aware of utility/plant design basis information, they do have access to design and manufacturing information. This information can be used to determine the characteristics originally specified by the manufacturer to support fabrication of the item. This information includes raw material specifications, purchased part specifications, manufacturing methods and tolerances, and so forth. In other words, the manufacturer has access to the original set of design characteristics for the item, and it therefore does not need to derive them using the same type of analysis used by licensees. In such cases, the approach used by a supplier to identify (and document) critical characteristics may be different from the method used by licensees.

Intimate knowledge of their equipment can enable suppliers who have access to detailed design information to translate design information into critical characteristics and acceptance criteria that, when verified, will reasonably assure the supplier that the item is capable of performing its design function(s).

In this type of scenario, a supplier can perform and document an acceptable dedication without identification of the licensee's specific safety functions for each installed application.

In fact, the first step taken by a supplier might be to examine the entire set of design characteristics, and then identify a subset of characteristics that are critical to that item's ability to perform its manufacturer-intended design functions. In the context of a supplier's program, these design functions are the functions that the device was originally designed and manufactured to perform.

As discussed in previous EPRI reports [4, 10], critical characteristics for acceptance are a subset of critical characteristics for design. Therefore, in many cases, a supplier may not need to understand an item's application-specific safety function in a licensee's plant in order to effectively identify critical characteristics for use in CGID.

In these cases, suppliers might not include identification of the licensee's safety function(s) in their commercial grade dedication package—they may instead select critical characteristics based upon original design characteristics or typical item functions without knowing and documenting their customers' specific safety functions. However, in such cases, the audit team is responsible for ensuring that the functions and/or critical characteristics identified by the supplier envelop the licensees' safety functions and/or critical characteristics for the item being dedicated.

5.4.2 Identification of Safety Function

Briefly described, safety functions are functions that the item must perform (and that the plant's design basis credits the item for performing) in order to ensure one or more of the following:

- The integrity of the reactor coolant pressure boundary
- The capability to shut down the reactor and maintain it in a safe shutdown condition
- The capability to prevent or mitigate the consequences of accidents that could result in potential offsite exposures comparable to those referred to in §50.34(a)(1) or §100.11 of the Code of Federal Regulations [21, 22]

As shown in Figure 5-1, safety functions in the context of this report are a subset of the entire set of design functions that an item is capable of performing.

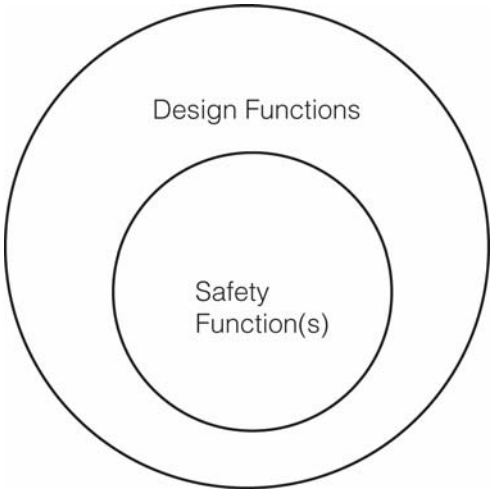

Figure 5-1
Relationship Between Safety Functions and Design Functions

As an example, a control valve's design functions might include modulating flow, opening on demand, closing on demand, and maintaining pressure integrity. However, the control valve's only safety function might be maintaining pressure integrity if the modulation, open, and close functions are not required in order for the valve to meet the three criteria previously described.

It is good practice for a supplier to identify an item's safety function(s). However, it is not always a requirement. When a supplier does not identify the safety functions of the items being dedicated, the audit team is responsible for ensuring that the functions and/or critical characteristics identified by the supplier envelop the safety functions and/or critical characteristics identified by the licensee in the PBSA worksheet and audit checklist.

Examination of the supplier's CGID program should be focused on ensuring that the supplier is verifying the same types of critical characteristics that are important to the licensees (that is, the supplier's critical characteristics envelop those deemed critical by the licensee[s]). A representative sample of these types of characteristics should be identified by licensees prior to the audit in the PBSA worksheet as technical characteristics.

5.4.3 Identification of Critical Characteristics

Critical characteristics are one of the most important building blocks of any CGID. During initial development of the EPRI reports describing the technical evaluation and CGID process, critical characteristics were often separated into critical characteristics for design and critical characteristics for acceptance.

Critical characteristics for design were defined in the EPRI report NP-6406, *Guidelines for the Technical Evaluation of Replacement Items in Nuclear Power Plants (NCIG-11)* as follows:

> Those properties or attributes which are essential for the item's form, fit and functional performance. Critical characteristics for design are the identifiable and/or measurable attributes of a replacement item which provides assurance that the replacement item will perform its design function [8].

Critical characteristics for acceptance were defined in the EPRI report NP-6406, *Guidelines for the Technical Evaluation of Replacement Items in Nuclear Power Plants (NCIG-11)* as follows:

> Identifiable and measurable attributes/variables of a commercial grade item, which once selected to be verified, provide reasonable assurance that the item received is the item specified [8].

As indicated in Figure 5-2, critical characteristics for acceptance are recognized as a subset of critical characteristics for design.

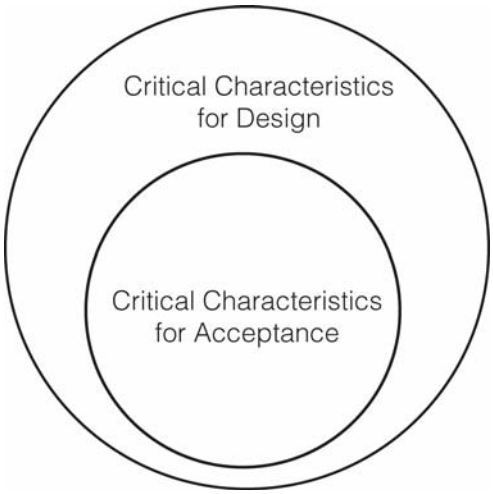

Figure 5-2
Relationship Between Critical Characteristics for Design and Critical Characteristics for Acceptance

From a licensee perspective, the distinction between critical characteristics for design and acceptance provided a way to differentiate between the entire set of characteristics required to capture the design of the item (design characteristics) and the subset of these characteristics that could be verified to provide reasonable assurance that item being dedicated would be capable of performing its safety function(s) (acceptance characteristics).

The distinction was also made in order to clarify the terminology used when licensees perform technical equivalency evaluations for alternate items intended for use in non-safety-related components. Because these components inherently have no safety functions, a distinction was made so that critical characteristics for design could still be identified and compared during the implementation of the technical equivalency evaluation.

The current regulatory definition of *critical characteristics* given in 10CFR21 is as follows:

> When applied to nuclear power plants licensed pursuant to 10 CFR Part 50, critical characteristics are those important design, material, and performance characteristics of a commercial grade item that, once verified, will provide reasonable assurance that the item will perform its intended safety function [6].

Because critical characteristics are a cornerstone of any CGID, suppliers should identify the critical characteristics used to dedicate the items that they provide.

The critical characteristics selected by the supplier for verification must be documented. However, it is important to recognize that the supplier's documentation might not be contained in a single document or set of documents that resembles a licensee's CGID evaluation.

Critical characteristics might be identified by the supplier in various types of supplier documentation, including the following:

- Original design specifications and documents (for example, fabrication drawings and specifications)
- Test or inspection results
- Procedures
- Work instructions

The basis or reasons for critical characteristic selection should also be evident in the supplier's documentation. Again, a supplier's documentation may take many forms and can sometimes be as simple as original product specifications captured in design documents, catalog cut sheets, specific evaluations, purchase orders, and so forth.

Unlike licensee evaluations, there might not be a specific place (such as a "basis" field on a form) where the basis is captured as a succinct explanation. Therefore, audit team members might have to work with the supplier to connect the dots, close gaps, or establish the link between the characteristics selected to be verified and the basis for their selection. Note that Appendix A of this report contains a sample format that suppliers could use to capture their dedication information. These forms might also be of use to audit team members in determining if enough information is provided in the supplier's commercial grade dedication packages.

The basis for selection of critical characteristics should be based upon the functions and characteristics of the specific item being dedicated, and it should be consistent with the complexity of the item being dedicated. Items that are subject to equipment qualification requirements often have more complex critical characteristics.

5.4.4 Maintaining Qualification of Equipment

PBSA worksheets should clearly indicate whether the scope of supply includes items that are subject to seismic and/or environmental qualification requirements. When seismic qualification requirements apply, the supplier's commercial grade dedication package should include seismic critical characteristics (that is, those characteristics of the item that support the ability of the host equipment to perform safety functions during and after a design basis accident). When environmental qualification requirements apply, the supplier's commercial grade dedication package should include environmental critical characteristics (that is, those characteristics of the item that support the ability of the host equipment to perform safety functions during and after a design basis accident).

The original seismic and environmental qualification of the parent equipment must be maintained as items within those components are replaced. Several methods are typically employed to verify that qualification is maintained, including the following:

- Conducting the original testing on a sample of replacement items to the original qualification tests (for example, loss of coolant accident chamber, shake-table, and so on)
- Inspecting (sometimes requiring disassembly of) items to ensure that the item's design has not changed from that of the item originally tested
- Conducting tests that verify the item's seismic critical characteristics (that is, functional tests, measuring spring force, and so on)

It is important to remember that original qualification requirements apply at the part level as well as at the component level. If the original qualification report for a transmitter qualified ethylene propylene diene monomer (EPDM) as the suitable O-ring material, a critical characteristic of O-ring material should be identified in dedication packages for both replacement transmitters and replacement O-rings, and the dedication should verify that the O-ring material is EPDM.

Audit team members should pay particular attention to seismic and environmental qualification requirements when auditing third-party qualifiers who might not have been involved in the original qualification effort or be fully aware of the original equipment qualification requirements.

Material characteristics (such as chemical composition and material strength) are most often verified to ensure that environmental qualification is maintained. Verification that seismic qualification is maintained is typically more complex. The EPRI report *Critical Characteristics for Acceptance of Seismically Sensitive Items (CCASSI)* (TR-112579) [14] provides additional guidance.

5.4.5 Specifying Procured Items Correctly

Auditors should ensure that the nuclear supplier is correctly specifying items procured from sub-tier suppliers. Technical requirements should correctly translate the supplier's design requirements into procurement requirements. Quality requirements specified should reflect the audited and approved quality controls that each sub-tier supplier is capable of providing for each given item procured. Documentation requirements specified should ensure that the quality controls of the sub-tier supplier were implemented for the items being procured.

5.5 Audit Team Expectations Regarding Implementation of the Acceptance Process

Criterion VII of 10CFR50, Appendix B allows flexibility in determining the most appropriate method(s) for ensuring that the critical characteristics of product(s) are adequately controlled and that they conform to design requirements. Therefore, the supplier may opt to verify selected critical characteristics using any of the following methods:

- **Sub-supplier documentation**. (Note that in the case of a 10CFR50, Appendix B supplier, this documentation would be received from an audited sub-supplier). Documentation/ certification is acceptable only from a sub-tier supplier that has been surveyed/audited by the dedicating entity and when the basis for acceptability and validity of the supplier's documentation has been established and documented. The implementation of this acceptance method is described in Section 5.5.1 and is analogous to Method 2, Commercial Grade Survey, as described in the EPRI report *Guideline for the Utilization of Commercial Grade Items in Nuclear Safety Related Applications (NCIG-07)* (NP-5652) [4] and the NRC Generic Letter 89-02 [23].
- **Source verification**. (Inspections performed by the dedicating entity at the location(s) of the sub-tier supplier manufacturing the commercial grade item.) The implementation of this acceptance method is described in Section 5.5.2 and is analogous to Method 3, Source Verification, as described in the EPRI report *Guideline for the Utilization of Commercial Grade Items in Nuclear Safety Related Applications (NCIG-07)* (NP-5652) [4] and the NRC Generic Letter 89-02 [23].
- **Inspection of products**. (Note that in the case of a 10CFR50, Appendix B supplier/ manufacturer, these inspections could occur during receipt of raw materials used to manufacture the item, during manufacture of the item, or during receipt of the items manufactured by a sub-supplier.) The implementation of this acceptance method is described in Section 5.5.3 and is analogous to Method 1, Special Tests and Inspections, as described in the EPRI report *Guideline for the Utilization of Commercial Grade Items in Nuclear Safety Related Applications (NCIG-07)* (NP-5652) [4] and the NRC Generic Letter 89-02 [23].

5.5.1 Sub-Tier Supplier Audits and Using Documentation from Sub-Suppliers

5.5.1.1 Approval of Sub-Tier Suppliers

Dedication based upon activities of sub-tier suppliers must be based upon objective evidence. If a supplier (dedicating entity) bases acceptance of one or more critical characteristics on controls implemented by a sub-tier supplier, the supplier must have documented measures in place and implemented for the evaluation of the sub-tier supplier that are consistent with the importance, complexity, and quality of the item(s) or service(s) that the sub-tier supplier provides.

These measures must clearly verify or demonstrate capability of the sub-tier supplier's controls to effectively verify the critical characteristics that the dedicating entity is accepting (based upon those sub-tier supplier controls).

As applicable, the supplier's procurement document(s) to their sub-tier suppliers should clearly specify the sub-tier supplier's commercial quality controls. For example, the supplier's purchase order might require items to be manufactured in accordance with the sub-tier supplier's QA program that is regularly audited/surveyed and approved by the supplier.

Documentation received from a sub-tier supplier may not be considered as a valid basis for acceptance of items unless it is based upon one or more of the following types of quality activities:

- The documented results of an audit/survey. Whenever a dedicating entity bases acceptance of items on documentation received from a sub-tier supplier, the basis for the validity of the sub-tier supplier's certification should be documented in the dedicating entity's audit/survey report for the sub-tier supplier.
- Periodic inspection or test activities (over-checks) by the dedicating entity of selected characteristics after receipt of items from the sub-tier supplier. These activities can be performed during the dedicating entity's receiving, assembly, or final acceptance activities and must be sufficiently implemented and documented to ensure continuing validity of sub-tier supplier documentation.
- A review of documentation received from sub-tier suppliers to confirm that the reported results are in accordance with the supplier's purchase order requirements and, as applicable, with industry standards provided by the National Institute of Standards and Technology (NIST), National Voluntary Laboratory Accreditation Program (NVLAP)/American Association for Laboratory Accreditation (A2LA), or ACLASS Certified Lab, or an American Society of Mechanical Engineers (ASME) Code Certificate of Authorization or Quality System Certificate. Reviews must be sufficiently implemented and documented by the dedicating entity to ensure the validity of sub-tier supplier documentation in accordance with NRC Information Notice 86-21, Supplement 2 [24].

The frequency with which or the degree to which any of the preceding verification actions is performed by the dedicating entity should take into consideration the performance of the sub-tier supplier and the products that they are furnishing. Commercial products received from sub-tier

suppliers for which the supplier has evidence of failures or non-conformances (poor or indeterminate quality) warrant more stringent verification actions (such as inspections at the sub-tier supplier's facility, no sampling of items undergoing receipt tests/inspections, and so on).

5.5.1.2 Role of the Commercial Grade Survey for Suppliers

The commercial grade survey was initially established as a method for licensees to use, and it has a regulatory basis in 10CFR50, Appendix B, Criterion VII [5] and ANSI N45.2.13 [20]. A survey can be used by a licensee to incorporate the commercial QA and quality program controls employed by suppliers into the licensee's dedication process. The QA and quality program controls examined during a survey should be those that control an item's critical characteristics. Licensees use the term *commercial grade survey* to describe these types of activities when applied to commercial suppliers. Use of the word *survey* instead of *audit* distinguishes these activities from similar activities used to audit nuclear suppliers. Suppliers may employ the same terminology or may simply refer to these activities as *audits*.

Licensees perform commercial grade surveys to verify a supplier's control of certain selected critical characteristics, not simply to verify that the supplier has implemented a quality program or quality controls. To this end, licensees use a critical characteristics worksheet to identify technical characteristics of importance before conducting the survey. During the survey, the survey team should determine if the supplier has documented controls in place that ensure that the item's critical characteristics meet design requirements. A copy of the critical characteristics worksheet is included in Appendix B of this report.

These controls can be in many forms, but they must be documented. Examples include commercial QA programs (for example, ANSI/ISO/ASQ Q9001:2000), manufacturing process inspections and quality controls, work procedures for special processes, statistical process controls, and so forth. Finally, the survey should verify implementation of the controls.

5.5.1.3 Commercial Quality Controls Versus 10CFR50, Appendix B

As discussed in the EPRI report *Supplemental Guidance for the Application of EPRI Report NP-5652 on Commercial Grade Items* (TR-102260) [10], most commercial suppliers' quality programs are not based upon 10CFR50, Appendix B requirements. Nevertheless, most commercial suppliers' quality programs include programmatic quality controls and inspections that do effectively ensure that critical characteristics are imparted to the manufactured items. Although commercial suppliers might not be subject to regulatory requirements, they are subject to the demands of the marketplace and therefore are motivated to produce high-quality items.

It is not the intent of a survey to verify or determine if the sub-tier supplier's commercial quality controls meet the requirements of a 10CFR50, Appendix B QA program. Auditors performing surveys of commercial suppliers must be careful to realize that the methods used to implement, monitor, and document quality controls employed by commercial suppliers may differ from those used by suppliers operating under a 10CFR50, Appendix B QA program. This results from the fact that the commercial suppliers' QA and quality control measures were not developed

based upon the requirements of 10CFR50, Appendix B. In these cases, careful judgment must be applied to determine if the commercial quality controls successfully control critical characteristics. Survey team members should be flexible and remain open to quality methods used by commercial suppliers, such as statistical process control and final product testing and inspection.

In addition, audit team members should expect methods and documentation used by commercial suppliers to support calibration, material traceability, personnel qualification, and validation of sub-tier supplier capabilities to differ from methods and documentation employed by nuclear suppliers and utilities to support similar quality activities.

5.5.1.4 Supplier Commercial Grade Survey Plan

Surveys of sub-tier suppliers should be conducted in accordance with the nuclear supplier's procedures, which should address the conduct of sub-tier supplier audits/surveys and the qualifications of the personnel performing them. Surveys should be performance-based (in other words, the evaluation should demonstrate that the sub-tier supplier has adequate quality controls in place to assure the nuclear supplier that the products being furnished conform to the nuclear supplier's design and that they will perform their design function). Surveys should focus on the critical characteristic of the specific item(s) being supplied by the organization being surveyed to the organization performing the survey.

The degree to which a nuclear supplier documents the survey plan and the detail contained in the checklist that is used will vary from supplier to supplier. Ideally, the dedicating entity should prepare a survey plan for the sub-tier supplier prior to the survey (with input from technical personnel)—one that addresses the critical characteristics that require verification.

The results of the dedicating entity's survey should be documented in a survey report in accordance with their applicable procedures. The report should provide a basis for how the supplier validates or confirms acceptability of documentation (for example, certified material test reports, certificates of calibration, certificates of compliance, and so on) received from the sub-tier supplier. The basis should include confirmation that the sub-tier supplier adequately controls the applicable critical characteristics.

The report should also note the sub-tier supplier's documented controls or requirements that should be specified in future procurement documents to ensure that the sub-tier supplier implements the controls for future orders.

5.5.1.5 Supplier Procurement Documents

When appropriate, the supplier's procurement document(s) to their sub-tier suppliers should include provisions for specifying the sub-tier supplier's controls that were determined to be effective during the survey. Examples of such provisions are the following:

- A requirement in the supplier's purchase order to the sub-tier supplier that requires items to be manufactured in accordance with the sub-tier supplier's QA program (that is regularly audited and approved by the supplier)
- A requirement in the supplier's purchase order to the sub-tier supplier that imposes specific procedures or controls during the manufacture of the items furnished (such as "Items shall be inspected in accordance with procedure DIM CHECK-006, Revision 7 and MATL VER-002, Revision 1")
- As applicable, a requirement for certification that the requirements imposed on the purchase order have been met

5.5.1.6 Qualifications of Supplier Personnel

Qualifications of individuals should be consistent with the activities that they perform and should meet the requirements described in the supplier's procedures. This is particularly important for activities that require application of special engineering knowledge or judgment, such as determination of safety functions, FMEA, and identification of critical characteristics. Evidence of an individual's qualifications can vary among different suppliers. Although the format(s) used by suppliers might vary, individual qualifications should be commensurate with the tasks being performed.

5.5.1.7 Supplier Implementation of Commercial Grade Surveys

When a survey of a sub-tier supplier reveals that certain critical characteristics are not adequately controlled, or when documented controls or requirements are not included in purchase orders to sub-tier suppliers, the supplier should employ alternative methods to verify those critical characteristics. One acceptable alternative method is verification of critical characteristics by the dedicating entity at receipt or during the dedicating entity's receiving, assembly, or final acceptance activities. Another example of an acceptable alternative method is verification of critical characteristics by the dedicating entity through witnessing or performing special tests or inspections at the sub-tier supplier's facility during the assembly or manufacturing process (source verification).

When a supplier determines that a sub-tier supplier's controls effectively ensure that the item being supplied is imparted with the correct critical characteristics, the supplier should follow the same general practices that a licensee would under similar circumstances. The supplier documents the specific controls required to address each critical characteristic in the survey report and should identify the documented controls and/or critical characteristics that were found to be adequately controlled in their qualified supplier list entry for the sub-tier supplier surveyed

or another appropriate location. In addition, the supplier should specify these controls in procurement documents released to the sub-tier supplier that has been surveyed. Furthermore, supplier procurement documents should include provisions for the sub-tier supplier to furnish certification that the items supplied were manufactured in accordance with the controls specified in the procurement document.

Suppliers can use commercial grade surveys to verify a sub-tier supplier's control of certain selected critical characteristics. However, the same basic methodology applies. When a supplier bases acceptance of critical characteristics on a commercial grade survey of a sub-tier supplier, the supplier (as the dedicating entity) should have documented objective evidence that the sub-tier supplier adequately controls the critical characteristics.

5.5.2 Verification at Sub-Supplier/Manufacturer Facility (Source Verification)

As noted previously in this report, 10CFR50, Appendix B, Criterion VII allows the supplier flexibility in determining the most appropriate method for ensuring that the critical characteristics of its product are adequately controlled and conform to their design. As such, the supplier might opt to witness or perform special tests or inspections at the sub-tier supplier's facility during the assembly, manufacture, or fabrication of the commercial grade item. This method of acceptance is analogous to Method 3, Source Verification, as described in the EPRI report *Guideline for the Utilization of Commercial Grade Items in Nuclear Safety Related Applications (NCIG-07)* (NP-5652) [4] and the NRC Generic Letter 89-02 [23].

The supplier should retain documentation of the source verification activities that include the following information:

- The commercial grade item (name, part number, and so on)
- The date(s) of the source verification visit(s) to the sub-tier facility
- The facility where the inspections/tests were performed/witnessed
- The design attributes (that is, critical characteristics) of the commercial grade item that were verified during the source verification
- The tests/inspections performed/witnessed
- The quantified results of the tests/inspections that demonstrate that the critical characteristics were adequately controlled and conforming to the supplier's design

5.5.3 Special Testing and Inspection of Commercial Grade Products

As noted in the previous sections, 10CFR50, Appendix B, Criterion VII allows the supplier flexibility in determining the most appropriate method for ensuring that the critical characteristics of its products are adequately controlled and are conforming to their design. This method of acceptance is analogous to Method 1, Special Tests and Inspections, as described in

the EPRI report *Guideline for the Utilization of Commercial Grade Items in Nuclear Safety Related Applications (NCIG-07)* (NP-5652) [4] and the NRC Generic Letter 89-02 [23]. Suppliers can opt to perform the following special tests or inspections:

- During receipt of raw materials used during the manufacture or fabrication of the commercial grade item
- During receipt of a commercial grade item manufactured or fabricated by a commercial sub-supplier
- During the assembly, manufacture, or fabrication of the commercial grade item or its host equipment
- After the completion of assembly, manufacture, or fabrication of the commercial grade item or its host equipment

In the context of CGID, *post-installation testing* refers to testing an item after it is installed in its operating location in the plant. Unlike a licensee, a supplier is not afforded the opportunity to conduct special tests and inspections after the item is installed (post-installation tests).

The supplier should retain documentation of test/inspection activities that include the following information:

- The commercial grade item (name, part number, and other identifying information)
- The date(s) on which the special tests/inspections were conducted
- The design attributes (the critical characteristics) of the commercial grade item that was verified by the special tests/inspections
- The tests/inspections performed
- The quantified results of the tests/inspections that demonstrate that the critical characteristics were adequately controlled and conforming to the supplier's design

5.6 Dedication of the Parts of a Basic Component

As a general practice, suppliers should dedicate items at the level of supply (the level at which they are supplied to the licensee). If replacement parts are supplied, the supplier may dedicate each part in much the same way that a licensee would dedicate the item, given that the part is furnished by itself and not as part of a larger assembly or component.

If assemblies or components are provided, it might not be necessary for the supplier to dedicate each part before it is used in manufacture of the assembly or component.

Section 3.3.2 of the EPRI report *Supplemental Guidance for the Application of EPRI Report NP-5652 on Commercial Grade Items* states the following:

> The utilization of an acceptance methodology for commercial grade parts provided in a complete component similar to that used to accept commercial grade replacement parts is typically unnecessary. The original equipment manufacturer's overall 10CFR50, Appendix B quality program should provide the necessary controls to reasonably assure the component meets its specified requirements [10].

This is because the manufacturer's design, procurement, material, inspection, and testing controls govern the manufacture of components. These programmatic controls typically apply to the purchase of commercial grade parts. In addition, these controls include in-process inspections and tests and final functional testing to ensure that the component can perform its design functions.

CGID at the supplier's facility might not be required for items purchased from sub-tier suppliers if the supplier has verified (through audit, source verification, or other programmatic QA activities) that the sub-tier supplier has quality controls in place to ensure that the items conform to their design and the items meet specified requirements.

In many cases, acceptability of the parts in an assembled component is inherent in correct specification of purchased items, and through the in-process and final inspections/testing performed on the complete component.

For example, dimensional and material nonconformance can be detected several ways. It can be detected during machining and assembly by virtue of the fact that parts do not properly fit together. It could also be detected after completion of assembly by functional testing designed to identify binding, leakage, a failure to activate, or other failure to perform to the requirements of design specifications.

It is important to note that final testing does not always verify all of the critical characteristics that are important to the licensee. To illustrate this point, consider a utility undergoing a cobalt reduction effort. The utility places a purchase order for a valve and specifies that the disc must not be hard-faced with Stellite. The purchase order is awarded to a valve supplier that functionally (for example, hydrostatically) tests every completed valve. The hydrostatic test does verify that the valve will perform at indicated temperatures and pressures. Depending upon the valve's application, the hydrostatic test might also contribute to verification of dimensional and material characteristics of valve parts, including the valve disc. A successful hydrostatic test provides an indication that the individual parts fit properly, do not leak, and can move relative to one another in accordance with the design of the valve. However, the hydrostatic test alone cannot verify that the valve disc was Stellite hard-faced. Therefore, if Stellite hard-facing was a design requirement, the supplier would be expected to implement other controls (such as material specification, traceability, and nondestructive material verification) that ensure that the valve disc meets the design requirements specified by the licensee.

5.7 Supplier Options for Furnishing a Basic Component

Another important consideration is that some suppliers categorize the items that they use and sell, and they may apply their nuclear QA programs in different ways in order to furnish basic components to their nuclear customers. In some cases, the supplier uses different assembly areas, manufacturers, and procurement methods for different categories of items, or for the same item when it falls into a different category. As an example, consider a control valve manufacturer who categorizes items as shown in Table 5-2.

Table 5-2
Examples of Nuclear Supplier Procurement Categories

Category	Description	Method for Furnishing a Basic Component
A	Item controlled by the ASME Code	Manufacture to requirements of ASME Code in accordance with the supplier's NCA-4000 QA program
B	Item designed and manufactured under 10CFR50, Appendix B	Non-ASME, safety-related items manufactured in accordance with controls included in the nuclear supplier's 10CFR50, Appendix B QA program.
C	Commercial grade item (that is, an item not designed and manufactured under 10CFR50, Appendix B)	Items are not provided as basic components.
D	CGID (that is, an item that is not designed and manufactured under 10CFR50, Appendix B but that is dedicated)	Items are considered safety-related by the licensee but must be dedicated using a process similar to the licensee's CGID program before they are furnished as basic components. These items might include commercial grade items that licensees classify as safety-related.

In one example, the supplier procures commercial diaphragms as non-safety-related items from a sub-tier supplier. When used as a part during manufacture of a complete control valve/actuator assembly, the supplier categorizes the diaphragms as *C* and procures them commercially. Because the diaphragm is provided as one piece of a complete assembly supplied as a basic component, the in-process assembly, manufacturing controls, tests, and inspections implemented under the supplier's 10CFR50, Appendix B program sufficiently verify that diaphragms installed in manufactured valves will perform their intended design functions.

When furnished to a utility as a replacement part that is specified as safety-related (a basic component) in the licensee's purchase order, the supplier might opt to categorize the diaphragms as *D* and subsequently dedicate the commercial grade diaphragm. Dedication could include special tests and inspections to verify the diaphragm's critical characteristics and that it will perform its intended function(s). These additional verification activities are necessary because diaphragms furnished as replacement parts do not benefit from the same manufacturing controls, tests, and inspections applied to the manufacture of a complete valve actuator assembly (that is, an assembly manufactured and furnished as a basic component). Table 5-3 illustrates the difference in how the supplier approaches the B and D scenarios.

Table 5-3
Furnishing an Item as Part of a Basic Component Versus as a Dedicated Replacement Item

Design (Critical) Characteristic	Scenario B Item is Provided as Part of an Assembly Supplied as a Basic Component	Scenario D Item is Provided as a Dedicated Replacement Item
Dimensions	Successful completion of assembly and fit-up processes included in the 10CFR50, Appendix B QA Program	Dimensional inspection to verify conformance with design drawing for the diaphragm
Configuration	Successful completion of assembly and fit-up processes included in the 10CFR50, Appendix B QA Program	Visual inspection to count and confirm the correct location of bolt holes
Materials of Construction	Certificate of conformance from surveyed sub-supplier indicating filler is EPDM and reinforcement is Nylon.	Certificate of conformance from surveyed sub-supplier indicating filler is EPDM and reinforcement is Nylon.
Tensile Strength	Successful final functional test of complete assembly (basic component). Successful pressure test to failure of diaphragm assembly performed on a skip-lot basis in accordance with manufacturing procedures (not performed on each diaphragm supplied).	Control of purchased lot of diaphragms Successful laboratory tensile test on a diaphragm procured in the same purchased lot.

In summary, audit team members should identify and record the supplier's approach to dedication. When suppliers provide a partial or complete assembly sold as a basic component, it is not required that each part of the assembly undergo a discrete CGID prior to manufacture.

If dedication of the basic component or assembly is heavily based upon post-manufacturing testing, such as functional tests, the tests should provide reasonable assurance that the critical characteristics for acceptance identified in the supplier's commercial grade dedication package are adequately verified. Final tests might not adequately verify all material characteristics (for example, chemical composition of the material, physical strength, corrosion resistance, and so forth). As such, additional verification activities might be required to verify certain material characteristics.

5.8 Supplier Dedication of Commercial Grade Services

The same CGID process used for items can be adapted and applied to services. When a supplier dedicates services provided by a sub-tier supplier, the critical characteristics of the service should be considered.

Dedication of services should also consider any materials used during the course of performing services, such as filler metal, spare parts, and so on.

Additional guidance on the dedication of services can be found in Section 4 of the EPRI report *Supplemental Guidance for the Application of NP-5652 on the Utilization of Commercial Grade Items* (TR-102260) [10].

5.9 Identification of Deficiencies

When CGID deficiencies are identified in audit reports, each problem(s) should be clearly identified with specific examples and details illustrating the deficiency. Identification of the deficiency should be clear and complete enough so that a person reading the deficiency can easily understand the problem and the corresponding requirement(s) that is (or are) not being met.

Reporting in accordance with the requirements of 10CFR, Part 21 [6] is not required for commercial grade items until after they have been accepted for use.

6
REFERENCES

1. *Guideline for Performance-Based Supplier Audits (NCIG-16)*. EPRI, Palo Alto, CA: 1990. NP-6630.
2. "Nuclear Procurement Program Improvements." Nuclear Utility Management and Resources Council, Washington, D.C.: 1990. NUMARC 90-13.
3. "Requirements for Auditing of Quality Assurance Programs for Nuclear Power Plants." American National Standards Institute/American Society of Mechanical Engineers: 1977. ANSI N45.2.12.
4. *Guideline for the Utilization of Commercial Grade Items in Nuclear Safety Related Applications (NCIG-07)*. EPRI, Palo Alto, CA: 1988. NP-5652.
5. Code of Federal Regulations, Title 10 (Energy), Chapter 1, Part 50, Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Facilities." Office of the Federal Register, National Archives and Records Administration, U.S. Government Printing Office, Washington, D.C.
6. Code of Federal Regulations, Title 10 (Energy), Chapter 1, Part 21, "Reporting of Defects and Noncompliances." Office of the Federal Register, National Archives and Records Administration, U.S. Government Printing Office, Washington, D.C.
7. Inspection Procedure 43004, "Inspection of Commercial Grade Dedication Programs." U.S. Nuclear Regulatory Commission, Washington, D.C.: 2007.
8. *Guidelines for the Technical Evaluation of Replacement Items in Nuclear Power Plants (NCIG-11)*. EPRI, Palo Alto, CA: 1990. NP-6406.
9. "Guidelines for 10 CFR 72.48." Nuclear Energy Institute, Washington, D.C.: 2001. NEI 96-07, Revision 1.
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11. Code of Federal Regulations, Title 10 (Energy), Chapter 1, Part 50.2, "Definitions." Office of the Federal Register, National Archives and Records Administration, U.S. Government Printing Office, Washington, D.C.
12. *Guidelines for the Safety Classification of Systems, Components, and Parts Used in Nuclear Power Plant Applications (NCIG-17)*. EPRI, Palo Alto, CA: 1991. NP-6895.
13. *Guideline for Sampling in the Commercial-Grade Item Acceptance Process.* EPRI, Palo Alto, CA: 1999. TR-017218-R1.
14. *Critical Characteristics for Acceptance of Seismically Sensitive Items (CCASSI)*. EPRI, Palo Alto, CA: 2000. TR-112579.

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

16. *Guidelines for the Technical Evaluation of Replacement Items in Nuclear Power Plants (Revision 1).* EPRI, Palo Alto, CA: 2006. 1008256.

17. *JUTG Commercial Grade Item Technical Evaluations.* EPRI, Palo Alto, CA: 2003. 1008034.

18. Inspection Procedure 38703, "Commercial Grade Dedication," *USNRC Inspection Manual*. U.S. Nuclear Regulatory Commission, Washington, D.C.: 1996.

19. "Administrative Controls and Quality Assurance for the Operational Phase of Nuclear Power Plants." American National Standards Institute/American Nuclear Society: 1976. ANSI N18.7/ANS 3.2.

20. "Quality Assurance Requirements for Control of Procurement of Items and Services for Nuclear Power Plants." American National Standards Institute/American Society of Mechanical Engineers: 1977. ANSI N45.2.13-1976.

21. Code of Federal Regulations, Title 10 (Energy), Chapter 1, Part 50, §50.34(a)(1).34,"Domestic Licensing of Production and Utilization Facilities." Office of the Federal Register, National Archives and Records Administration, U.S. Government Printing Office, Washington, D.C.

22. Code of Federal Regulations, Title 10 (Energy), Chapter 1, Part 100, "Reactor Site Criteria." Office of the Federal Register, National Archives and Records Administration, U.S. Government Printing Office, Washington, D.C. or §100.11 of the Code of Federal Regulations.

23. Generic Letter 89-02, "Actions To Improve the Detection of Counterfeit and Fraudulently Marketed Products." U.S. Nuclear Regulatory Commission, Washington, D.C.: March 1989.

24. Information Notice 86-21, Supplement 2, "Recognition of American Society of Mechanical Engineers Accreditation Program for N Stamp Holders." U.S. Nuclear Regulatory Commission, Washington, D.C.: April 1991.

7
ADDITIONAL REFERENCES AND RECOMMENDED READING

7.1 Additional Regulations and Regulatory Guidance

Generic Letter 91-05, Licensee Commercial Grade Procurement and Dedication Programs. U.S. Nuclear Regulatory Commission, Washington, D.C.: April 1991.

Regulatory Guide 1.123, Revision 1, Quality Assurance Requirements for Control of Procurement of Items and Services for Nuclear Power Plants. U.S. Nuclear Regulatory Commission, Washington, D.C.: 1977.

Regulatory Guide 1.33, Revision 2, Quality Assurance Program Requirements (Operational). U.S. Nuclear Regulatory Commission, Washington, D.C.: 1978.

U.S. Nuclear Regulatory Commission letter to ACLASS Accreditation Services dated December 19, 2007.

7.2 Additional Implementing Standards

Quality Assurance Program Requirements for Nuclear Power Plants. American National Standards Institute/American Society of Mechanical Engineers: 1977. ANSI N45.2-1977.

Quality Assurance Program Requirements for Nuclear Facility Applications, 1994 Edition. American National Standards Institute/American Society of Mechanical Engineers: 1994. ASME/ANSI NQA-1 (1994). (Note that some utilities are committed to an NQA-1 program in lieu of a 10CFR50, Appendix B program.)

7.3 EPRI Reports

Guidelines for the Procurement and Receipt of Items for Nuclear Power Plants (NCIG-15). EPRI, Palo Alto, CA: 1990. NP-6629.

Guideline on Evaluation and Acceptance of Commercial-Grade Digital Equipment for Nuclear Safety Applications. EPRI, Palo Alto, CA: 1996. TR-106439.

Packaging, Shipping, Storage, and Handling Guidelines for Nuclear Power Plants. EPRI, Palo Alto, CA: 1997. TR-107101.

Guidelines for Reverse Engineering at Nuclear Power Plants. EPRI, Palo Alto, CA: 1998. TR-107372.

Evaluating Commercial Digital Equipment for High-Integrity Applications: A Supplement to EPRI Report TR-106439. EPRI, Palo Alto, CA: 1997. TR-107339.

A
EXAMPLE OF FORMS FOR USE IN DOCUMENTING A CGID

Commercial Grade Item Evaluation

1.0 GENERAL INFORMATION

STOCK CODE:	
MANUFACTURER(S):	**MANUFACTURER MODEL / PART / CATALOG NUMBER(S):**
METHOD USED TO DETERMINE CGID REQUIREMENTS: ☐ Dedication based upon known design functions ☐ Dedication based upon customer's safety function(s) Note: Functions are listed in Section 5 of this form **DOCUMENTED SOURCE(S) OF DESIGN / SAFETY FUNCTIONS**	

2.0 PARENT COMPONENT / HOST EQUIPMENT SUMMARY INFORMATION

DESCRIPTION OF ITEM USEAGE:	
REFERENCE DOCUMENT(S) (INCLUDE ALL APPLICABLE DESIGN DOCUMENTS):	
SAFETY CLASSIFICATION OF ITEM ☐ Safety-Related - Basic Component ☐ Safety – Dedicated Commercial Grade Item) ☐ Non-safety, Augmented QA)	**BASIS/SOURCE:**
SUMMARY INFORMATION AND REQUIREMENTS: ☐ **ENVIRONMENTAL QUAL** ☐ **ASME SECTION III** ☐ **SEISMIC QUALIFICATION** ☐ **IEEE CLASS 1E** ☐ **CONTAINMENT PRESSURE BOUNDRY** ☐ **OTHER (EXPLAINED BELOW)** **SPECIAL REQUIREMENTS:**	
CGID ELIGABILITY: Does the part meet the definition of a Commercial Grade Item? ☒ Yes ☐ No (Reference applicable definition in current revision of 10CFR, Part 21)	

3.0 IDENTIFICATION OF ITEM FUNCTIONS

Note: Requirements identified for the host component in Section 2 should be addressed in Section 3

ITEM FUNCTION(S):		
Classification:	**Basic Function:**	**Expanded Description of Item Function (as required):**
Select One	Select One	
(Active/Passive)	(see Section 9)	

4.0 FMEA

CREDIBLE FAILURE MECHANISMS/MODES: Select One (see Section 9)	**EFFECTS ON SYSTEM/COMPONENT FUNCTION:**
BASIS:	

5.0 CRITICAL CHARACTERISTICS AND ACCEPTANCE METHODS SUMMARY

IDENTIFICATION OF CRITICAL CHARACTERISTICS & ACCEPTANCE METHODS:

FUNCTION	CHARACTERISTIC	INSPECTION / TEST METHOD	ACCEPTANCE CRITERIA AND SOURCE DOCUMENT REFERENCE	ACCEPT (Y/N)	Rec't Insp Initial/Date

INSPECTOR NAME:	**INSPECTOR COMMENTS/OBSERVATIONS:**

6.0 DEDICATION BASIS AND SAMPLING PLAN JUSTIFICATION

BASIS FOR SELECTION (JUSTIFICATION THAT THE SELECTED CC'S WHEN VERIFIED WILL PROVIDE REASONALBE ASSURANCE THAT THE ITEM WILL PERFORM ALL IDENTIFIED DESIGN FUNCTIONS)
SAMPLING PLAN SPECIFICATION AND BASIS:

7.0 SPECIAL REQUIREMENTS/INSTRUCTIONS

SPECIAL STORAGE / RECEIVING:
IN STORAGE MAINTENANCE:
TRACEABILITY / IDENTIFICATION OF LOT / BATCH:

8.0 REFERENCES / ATTACHMENTS

REFERENCES:	
ATTACHMENTS:	
DOCUMENTS / DATABASES REQUIRING REVISION:	
DOCUMENT/DATABASE	**METHOD OF REQUEST**

9.0 INFORMATION FOR USE IN COMPLETING THIS FORM:

Typical Basic Item Functions	Typical Failure Mechanisms / Modes
Actuate Modulate Blend Change State Close Combustible Gas Control Containment Isolation Electrical Isolation Isolate Maintain Circuit Integrity Maintain Pressure Integrity Maintain Structural Integrity Open Provide Control Provide Directional Control Provide Filtering Provide Heat Control Provide Indication Provide Motive Force Provide Pressure / Flow Provide Signal Provide Support / Secure Remain Open Transform / Supply Energy	Blockage Corrosion Ductile Fracture Erosion Excess Strain Fracture Loss of Properties Mechanical Creep Open Circuit Seizure Short Circuit Unacceptable Vibration

B
PBSA WORKSHEET AND CRITICAL CHARACTERISTICS WORKSHEET FORMS

Form 4.1
Revision 28

Supplier: _____
Audit No: _____
Page: _____ of _____

PBSA WORKSHEET

Items Description: _____

(Part #, Process, Service) _____

1) Technical Characteristics (Essential for Form, Fit, or Function) and/or Items of Interest	2) Acceptance Criteria	3) Supplier's Method of Control	Results	References (Checklist Section)

_____ _____ _____ _____
Technical Specialist **Date** **Audit Team Leader** **Date**

SUMMARY SHEET
CRITICAL CHARACTERISTICS WORKSHEET

PRODUCT/ITEM/SERVICE (specify): _____

JUTG TECHNICAL EVALUATION # (include revision and date): _____

(Ref. EPRI TR-102260, Section 4.0 for Commercial Grade Services)

CC#	*CRITICAL CHARACTERISTICS (CC) TO BE VERIFIED*	*ACCEPTANCE CRITERIA*	*SAT/ UNSAT/ N/A* or N/V**	*REFERENCE CHECKLIST SECTION*

PREPARED BY: _____ *DATE:* _____

NUPIC REPRESENTATIVE: _____ *DATE:* _____

* Explanation required

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