ELECTRIC POWER RESEARCH INSTITUTE

Plant Engineering: Guideline for the Acceptance of Commercial-Grade Items in Nuclear Safety-Related Applications

Revision 1 to EPRI NP-5652 and TR-102260

2014 TECHNICAL REPORT

Plant Engineering: Guideline for the Acceptance of Commercial-Grade Items in Nuclear Safety-Related Applications

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3002002982

Final Report, September 2014

EPRI Project Manager
M. Tannenbaum

All or a portion of the requirements of the EPRI Nuclear Quality Assurance Program apply to this product.

YES NO

ELECTRIC POWER RESEARCH INSTITUTE
3420 Hillview Avenue, Palo Alto, California 94304-1338 ▪ PO Box 10412, Palo Alto, California 94303-0813 ▪ USA
800.313.3774 ▪ 650.855.2121 ▪ askepri@epri.com ▪ www.epri.com

THE FOLLOWING ORGANIZATION(S), UNDER CONTRACT TO EPRI, PREPARED THIS REPORT:

Electric Power Research Institute (EPRI)

Sequoia Consulting Group, Inc.

System Integration Services, Inc.

NOTE

For further information about EPRI, call the EPRI Customer Assistance Center at 800.313.3774 or e-mail askepri@epri.com.

ACKNOWLEDGMENTS

The following organizations prepared this report:

Electric Power Research Institute (EPRI)
1300 West W.T. Harris Blvd.
Charlotte, NC 28262

Principal Investigator
M. Tannenbaum

Sequoia Consulting Group, Inc.
163 Pleasant Street
Attleboro, MA 02703

Principal Investigator
M. Tulay

System Integration Services, Inc.
3940 Bentley Bridge Road
Raleigh, NC 27612

Principal Investigator
L. Jones

This report describes research sponsored by EPRI.

EPRI thanks the following individuals who participated in the Technical Advisory Group and made significant contributions to the development of this report. Their valuable insight and experience were essential to the successful completion of the project.

Craig Irish	AZZ Nuclear Logistics
Greg Keller	AZZ Nuclear Logistics
Dave Jantosik	CBI
Jim Grant	Duke Energy
Bhavesh Patel	Duke Energy
Steven Steele	Duke Energy
Frank Strehle	Duke Energy
Marc Tannenbaum	Electric Power Research Institute

Judy Patin	Entergy
Ed Wynne	Fluor
John Simmons	Luminant/Nuclear Procurement Issues Committee
Al Lafleur	NextEra Energy
Clyde McCullough	NextEra Energy
Michael Tulay	Sequoia Consulting Group, Inc.
William Ware	Southern Nuclear
Steve Martin	Tennessee Valley Authority
Jeffrey Black	Westinghouse
Juan Peralta	Westinghouse
Victor Hall	U.S. Nuclear Regulatory Commission
Rich McIntyre	U.S. Nuclear Regulatory Commission
Paul Prescott	U.S. Nuclear Regulatory Commission

Special appreciation goes to FirstEnergy’s BetaLabs for developing the testing matrices included in Appendices J and K of this report.

In addition, Harold Gretzky (AEP), Ujjal Mondal (COG), Bob Lane (ATC Nuclear), Daryl Prisby (Exelon), Eugene Wasson (Exelon), Barney Poole (Luminant), Jeff Duckett (ORNL), Joe Thompson (PSE&G), Alan Davidson (QualTech NP), Larry Davenport (TVA), are acknowledged for previewing the report.

The following individuals were ongoing members of the Nuclear Construction Issues Group’s Commercial-Grade Items Task Group, which made significant contributions to the development of the original NP-5652 and TR-102260 reports by attending meetings, reviewing and commenting on various drafts, and writing portions of the report.

		NP-5652	**TR-102260**
Theodore Bernard	ABB Combustion Engineering		X
Chuck Vincent	ABB Impell		X
Clyde McCullough	Arizona Public Service Co.		X
Kevin Cellars	Baltimore Gas & Electric Co.		X
Jim Spina	Baltimore Gas & Electric Co.		X
John Duffin	Bechtel Corp.	X	
Edward Martin	Commonwealth Edison Co.		X
Walter Shewski	Commonwealth Edison Co.	X	
William Razlaff	Cygna Energy Services	X	
William Barnhardt	Duke Power Co.		X

		NP-5652	TR-102260
Michael Mirchich	Duquesne Light Co.		X
Warren Bilanin	Electric Power Research Institute	X	
William Houston	Electric Power Research Institute		X
Tom Mulford	Electric Power Research Institute	X	X
Fran Rosch	Electric Power Research Institute		X
Charles Tyrone	Entergy Operations, Inc.		X
George Regal	Florida Power & Light Co.		X
Michael P. Tulay	Gilbert/Commonwealth, Inc.	X	X
Frank Yurich	Gilbert/Commonwealth, Inc.	X	X
Alan Soni	Gulf States Utilities		X
Robert Stafford	Gulf States Utilities	X	
Allan Miller	Impell Corp.	X	X
Kenneth Peveler	Iowa Electric Light & Power Co.	X	
Rory Segan	Limitorque		X
Robert Pettrey	Namco Controls		X
Dennis Weaver	Niagara Mohawk Power Corp.		X
Eugene McNatt	Northeast Utilities		X
Darlene Stimart	Northern States Power Co.		X
Larry Templeton	Northern States Power Co.	X	X
Lawrence Patterson	Nutherm International		X
K. D. Ramsey	On Site Engineering		X
Douglas Aaron	Pacific Gas & Electric Co.		X
Ed Kahler	Pacific Gas & Electric Co.		X
Steven Skidmore	Pacific Gas & Electric Co.	X	
Dennis O'Rourke	Philadelphia Electric Co.	X	
Mark Shaw	Rochester Gas & Electric Co.		X
Mansoor Sanwarwalla	Sargent & Lundy Engineers		X
Robert Tjernlund	Sargent & Lundy Engineers	X	
Marlin Hutson	S.E.A. Consultants		X
Joe Kiwak	Sequoia Consulting Group		X
Dan Maret	Sequoia Consulting Group		X

		NP-5652	TR-102260
Kenneth Baldwin	Southern California Edi son Co.	X	
Raymond Lahti	Tennessee Valley Authority	X	
Joseph Webb	Tennessee Valley Authority		X
Jack Martin	TU Electric Co.	X	
Ken Kuechenmeister	Union Electric Co.	X	
William Craig	United Energy Services Corp.	X	X
Robert Geier	Wisconsin Electric Power Corp.		X
William Eales	Wolf Creek Nuclear Operating Corp	X	

In addition, David Powell (Nuclear Data Services), Philip Holzman (Strategic Technology and Resources), and Howard Newton (Southern California Edison) are acknowledged for their valuable review and comments on the various drafts of the original NP-5652 guideline report.

This publication is a corporate document that should be cited in the literature in the following manner:

Plant Engineering: Guideline for the Acceptance of Commercial-Grade Items in Nuclear Safety-Related Applications: Revision 1 to EPRI NP-5652 and TR-102260. EPRI, Palo Alto, CA: 2014. 3002002982.

ABSTRACT

This report describes a methodology that can be used to dedicate commercial-grade items for use in safety-related applications. The scope of applications for which commercial-grade item dedication is used has evolved significantly since the Electric Power Research Institute (EPRI) published its reports *Guideline for the Utilization of Commercial Grade Items in Nuclear Safety Related Applications (NCIG-07)* (NP-5652) and *Supplemental Guidance for the Application of EPRI Report NP-5652 on the Utilization of Commercial Grade Items* (TR-102260) in 1988 and 1994, respectively. The guidance in this report reflects lessons learned and addresses challenges that have been identified through expanded use of the original guidance. This report supersedes both original reports in their entirety.

Keywords
Acceptance
Commercial-grade
Dedication
Survey
Technical evaluation

EXECUTIVE SUMMARY

Background

The use of commercial-grade dedication methodology to support operation and maintenance of nuclear power plants has evolved significantly since the current fleet of operating reactors in the United States was constructed. Originally developed as an alternative means for licensees to use when accepting items from suppliers who abandoned their nuclear quality assurance program, dedication methodology is used in an increasing number of applications that support operations and maintenance. In addition, requirements applicable to dedication methodology currently appear to varying degrees in quality standards, such as American Society of Mechanical Engineers (ASME) NQA-1 [1].

The guidance provided in the Electric Power Research Institute (EPRI) reports *Guideline for the Utilization of Commercial Grade Items in Nuclear Safety Related Applications (NCIG-07)* (NP-5652) [2] and *Supplemental Guidance for the Application of EPRI Report NP-5652 on the Utilization of Commercial Grade Items* (TR-102260) [3] was sound and provided a strong technical basis for application of the methodology. However, Code of Federal Regulations (CFR) 10CFR21 [4] (the regulation originally published in 1977 that introduced commercial-grade item dedication) was revised subsequent to the publications of EPRI NP-5652 [2] and TR-102260 [3]. Furthermore, in the years since these reports were issued, use of the methodology has expanded from domestic commercial licensees to a much broader community, including entities licensed to parts other than Part 50 of Title 10 of the CFR [5], international nuclear plant operators, manufacturers, third-party qualifiers, and engineering, construction, and procurement firms. In addition to replacement parts, the methodology now finds application in supplying new structures, systems, and components and in new plant construction.

Purpose

The purpose of this report is to provide guidance for dedicating entities (licensees and nuclear suppliers alike) regarding the acceptance of commercial-grade items for use in safety-related applications. Specifically, the objectives of this report are as follows:

- Incorporate lessons learned through application of the guidance since NP-5652 [2] and TR-102260 [3] were issued.
- Communicate guidance in a format that can be understood and applied by the current community of dedicating entities.
- Establish a baseline vocabulary for discussing the procurement and dedication of commercial-grade items.
- Emphasize the importance of basing each commercial-grade item dedication plan on the item's end-use applications.

- Emphasize the importance of documenting the commercial-grade item's technical evaluation, acceptance plan, and acceptance activities.
- Provide a generic process that can be used to dedicate commercial-grade items, and expand upon the process in a way that facilitates implementation of effective commercial-grade item dedication programs.
- Provide guidance about situations in which the commercial-grade item dedication methodology has proven to be problematic.
- Provide guidance relative to improper applications of the guidance.

Applicability of Guidance

The guidance included in this report is applicable to any dedicating entity, including licensees, suppliers, and other organizations that support plant design, analysis, construction, operations, and maintenance.

Approach

The process guidance included in this report expands on the basic methodology included in EPRI NP-5652 [2] and TR-102260 [3]. It is shown as process flow charts that present steps that can be used to develop or enhance commercial-grade item dedication processes and procedures.

In addition, the report includes a set of basic forms that can be used to document a commercial-grade item's technical evaluation and other tools that address indicated by experience to be problematic when implementing commercial-grade item dedication programs, such as commercial-grade surveys. This report also references other documents that provide guidance specific to certain elements of the dedication process and dedication of complex items, such as digital devices and computer programs.

Important Updates

This report includes important updates to dedication methodology that reflect key additions as well as differences between the original guidelines and this report. The updates include the following:

- Discussion related to the two paths a supplier can follow to provide a basic component.
- Clarification that a completed and accepted design is required prior to beginning the commercial-grade dedication process.
- A shift in focus from "identifiable and measurable characteristics" to characteristics necessary to perform a safety function.
- Clarification that a failure modes and effects analysis is an effective tool to determine critical characteristics when complete design information is not available.
- Clarification that product identification attributes are not necessarily *critical characteristics* as defined in 10CFR, Part 21 [4]. However, product identification attributes—such as the part and model numbers and nameplate data—are important and should always be verified during the receipt inspection process.

- Use of the terms *critical characteristics* in place of *critical characteristics for acceptance* and *design characteristics* in place of *critical characteristics for design*.
- References to the applicable content in ASME NQA-1 [1] (in addition to American National Standards Institute [ANSI] N42.2-1978 [6]).

Use of Forms and Checklists

Examples of forms and checklists are included in this report to illustrate the types of information that should be included in a commercial-grade dedication technical evaluation and acceptance plan. Although the forms are useful examples, the ways in which suppliers and licensees document commercial-grade dedication evaluations may differ. The amounts, types, and organization of a dedicating entity's documentation may vary, depending on 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 commercial-grade item dedication evaluations/packages.

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 commercial-grade item dedication might be contained in different documents, such as engineering evaluations, purchase orders, design documents, drawings, and procedures.

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1
BACKGROUND AND INTRODUCTION

The use of commercial-grade dedication methodology to support operation and maintenance of nuclear power plants has evolved significantly since the current fleet of operating reactors in the United States was constructed. Originally developed as an alternative means for accepting items from suppliers who abandoned their nuclear quality assurance (QA) program, dedication methodology is currently used in an increasing number of applications that support operations and maintenance as well as new nuclear construction. The methodology has also been incorporated into quality standards, such as American Society of Mechanical Engineers (ASME) NQA-1 [1].

Although the guidance provided in the Electric Power Research Institute (EPRI) reports *Guideline for the Utilization of Commercial Grade Items in Nuclear Safety Related Applications (NCIG-07)* (NP-5652) [2] and *Supplemental Guidance for the Application of EPRI Report NP-5652 on the Utilization of Commercial Grade Items* (TR-102260) [3] was sound and has provided a strong technical basis for the methodology, lessons learned and industry developments have accumulated subsequent to their releases. In addition, Code of Federal Regulations (CFR) 10CFR21 [4] (the regulation originally published in 1977 that introduced commercial-grade item dedication) has been revised several times subsequent to the publications of EPRI NP-5652 [2] and TR-102260 [3].

1.1 Objectives

The purpose of this report is to provide guidance for dedicating entities (licensees and nuclear suppliers alike) regarding the acceptance of commercial-grade items for use in safety-related applications. Specifically, the objectives of this report are as follows:

- Establish a baseline vocabulary for discussing the procurement and dedication of commercial-grade items.
- Emphasize the importance of basing each commercial-grade item dedication plan on the item's specific end-use application(s).
- Emphasize the importance of adequately documenting the commercial-grade item's technical evaluation, acceptance plan, and acceptance activities.
- Provide a generic process that can be used to dedicate commercial-grade items, and expand on the process in a way that facilitates implementation of effective commercial-grade item dedication programs.
- Provide guidance for situations in which commercial-grade item dedication methodology has proven to be problematic.
- Provide guidance relative to improper application of commercial-grade item dedication methodology.

1.2 Applicability of Guidance

The dedication methodology included in this report is applicable to any dedicating entity maintaining a QA program that meets the requirements of 10CFR50, Appendix B [7]. Dedicating entities include licensees, suppliers, and other organizations that support plant design, analysis, construction, operations, and maintenance.

1.3 Historical Perspectives

1.3.1 Before the Issue of Original EPRI Commercial-Grade Item Dedication Guidance

The nuclear industry commonly refers to the acceptance process for commercial-grade items in safety-related applications as *dedication* or *commercial-grade item dedication*. In the mid-1970s, more attention was given to commercial-grade item procurement practices in the nuclear industry due to the growing unavailability of equipment from suppliers with QA programs meeting the requirements of 10CFR50, Appendix B [7]. Some suppliers discontinued support of their nuclear QA programs as the industry transitioned from large equipment purchases supporting construction of many new nuclear power plants to smaller purchases of spare and replacement items to support operations and maintenance.

Appendix B of 10CFR50 [7] establishes baseline programmatic criteria that are required to ensure the quality of safety-related items. However, 10CFR50, Appendix B [7] does not specifically address the acceptance of commercial-grade items for use in safety-related applications. The introduction to 10CFR50, Appendix B, states: “As used in this appendix, ‘quality assurance’ comprises all those planned and systematic actions necessary to provide adequate confidence that a structure, system, or component will perform satisfactorily in service” [7].

Criterion III, Design Control, and Criterion VII, Control of Purchased Products and Services, of 10CFR50, Appendix B [7], require that controls be in place to ensure that the correct safety-related items are specified and accepted. These controls are applicable when furnishing basic components as well as commercial-grade items intended for safety-related use.

The first nuclear standard to specifically address commercial off-the-shelf items was American National Standards Institute (ANSI) N18.7-1976 [8], which states that spare and replacement parts found to be commercial “off-the-shelf” may be similarly procured as the original item or part, but care must be exercised to ensure at least equivalent performance. The care required is left to the purchaser’s discretion. ANSI N18.7 is endorsed by the U.S. Nuclear Regulatory Commission (NRC) in its Regulatory Guide 1.33 [9].

In June 1977, definitions pertaining to commercial-grade item dedication were included in the original issue of 10CFR21 [4], which focused primarily on reporting requirements for defects and noncompliance.

An October 1978 revision to 10CFR21 [4] required a commercial-grade item to be dedicated before it could be used as a basic component. The term *dedication* was defined as “the point in time when the commercial-grade item becomes subject to 10CFR21 reporting requirements” [4].

In 1988, the Nuclear Management and Resources Council (NUMARC) formed the Nuclear Plant Equipment Procurement (NPEP) working group to address the need for improvements in industry procurement practices.

1.3.2 After the Issue of Original EPRI Commercial-Grade Item Dedication Guidance

In June 1988, EPRI issued NP-5652, *Guideline for the Utilization of Commercial Grade Items in Nuclear Safety-Related Applications (NCIG-07)* [2]. The guidance was developed to address licensees' need for a documented methodology that would ensure that commercial-grade items used in nuclear safety-related applications were properly "dedicated" in accordance with the terminology included in the definitions section of 10CFR21 [4]. The following industry developments occurred after NP-5652 [2] was published:

- In March 1989, NUMARC's board of directors approved and introduced the first NPEP initiative, which directed utilities to meet the guidance provided in EPRI NP-5652 by January 1, 1990.
- Also in March 1989, the NRC issued Generic Letter 89-02, "Actions to Improve the Detection of Counterfeit and Fraudulently Marketed Products" [10]. This generic letter conditionally endorsed the guidance in EPRI NP-5652.
- In May 1989, the NRC issued SECY 89-010, Advanced Notice of Proposed Rulemaking Acceptance of Products Purchased for Use in Nuclear Power Plant Structures, Systems, and Components [11], which requested public comment on improvements needed for procurement, receipt inspection and testing, and dedication programs.
- In January 1990, EPRI issued NP-6406, *Guidelines for the Technical Evaluation of Replacement Items in Nuclear Power Plants (NCIG-11)* [12], which covered using design characteristics for the purpose of equivalency evaluations.
- In March 1990, the NRC issued SECY-90-076, *Inspection and Enforcement Initiatives for Commercial-Grade Procurement and Dedication Programs* [13]. In this SECY, the NRC officially informed the commission of the proposed NRC staff actions to address programmatic deficiencies in licensees' procurement and dedication programs. The NRC staff indicated its intent to work with NUMARC to ensure that the industry was informed of the NRC's expectations.
- In April 1990, the NRC provided NUMARC (now known as the *Nuclear Energy Institute* [NEI]) with draft Generic Letter (GL) 90-XX, *Licensee Commercial-Grade Procurement and Dedication Programs* [14]. NUMARC, in turn, provided GL 90-XX to utilities. In GL 90-XX, the NRC informs all licensees that programmatic inspections of procurement and dedication programs will be deferred until May 1991 to allow sufficient time for utilities to fully understand and implement guidance being developed by the industry. In addition, GL 90-XX addresses the NRC's views on NP-5652 and indicates that licensees must take corrective action if programmatic weaknesses exist or items are identified that have been installed in safety-related applications without adequate dedication.
- In May 1990, EPRI issued NP-6629, *Guidelines for the Procurement and Receipt of Items for Nuclear Power Plants (NCIG-15)* [15].

- In June 1990, NUMARC issued the *Comprehensive Procurement Initiative* [16], which required utilities to review, assess, and develop improvements to their procurement program by July 1, 1991, and implement the improvements by July 1, 1992. The initiative addressed vendor audits, tests and inspections, obsolescence, information exchange, and general procurement.
- In August 1990, the NRC issued SECY-90-304, *NUMARC Initiatives on Procurement* [17].
- In October 1990, NUMARC (now NEI) endorsed EPRI report NP-5652 [2] in NUMARC 90-13, *Nuclear Procurement Program Improvements* (which documented the *Comprehensive Procurement Initiative*) [18].
- From February 1991 through December 1991, the NRC conducted a series of procurement inspections at licensees' facilities.
- In April 1991, NRC issued GL 91-05, *Licensee Commercial-Grade Procurement and Dedication Programs* [19]. In GL 91-05, the NRC states that "resumed inspections will be conducted using l0CFR Part 50, Appendix B (not the NUMARC initiatives) as the applicable regulatory requirement." In addition, the NRC discusses past inspection findings, the NUMARC comprehensive procurement initiative, the term *critical characteristics*, and like-for-like replacements.
- In September 1991, the NRC issued SECY-91-291, *Status of NRC's Procurement Assessments and Resumption of Programmatic Inspection Activity* [20].
- In June 1992, EPRI issued report NP-7218, *Guideline for Sampling in the Commercial Grade Dedication Item Acceptance Process* [21].
- On April 21–22, 1993, the NRC held a commercial-grade procurement and dedication workshop in Dallas, Texas.

1.3.3 Subsequent to the Issue of Supplemental Guidance

Licensees worked to consistently implement the guidance included in NP-5652 [2] in the years following its release. As the guidance was institutionalized, areas in which supplemental guidance would be beneficial were identified.

In March 1994, the EPRI report TR-102260 (*Supplemental Guideline for the Application of EPRI Report NP-5652 on the Utilization of Commercial Grade Items* [3]) was issued to provide additional clarification in certain areas, capture lessons learned, and address industry and regulatory developments that occurred subsequent to the issue of NP-5652. Some of the key issues addressed in the supplemental guidance report are as follows:

- The definition and concept of the term *reasonable assurance*
- The intent of EPRI report NP-5652 to focus on verification of the characteristics necessary to perform safety functions, as opposed to verifying suitability of the original design
- Lessons learned regarding application of EPRI report NP-5652's generic dedication process, including the commercial-grade item acceptance methods

- The application of Method 4: Item/Supplier Performance Record
- The acceptance and dedication of commercial-grade items by suppliers, third-party qualifiers, and nuclear steam system suppliers (NSSSs) that maintain a QA program meeting the requirements of 10CFR50, Appendix B [7]

The use of commercial-grade item dedication methodology continued to expand after the supplemental guidance was issued, and industry developments included a revision to 10CFR21 and publishing of guidance documents associated with various aspects of the commercial-grade dedication process. The following bullets summarize some of the pertinent developments:

- In September 1995, the NRC issued a revision to 10CFR21 [4] that included changes relative to the terms *dedication, commercial-grade item,* and *critical characteristic*.
- In April 1996, the NRC issued Inspection Procedure 38703, "Commercial Grade Procurement Inspection" [22].
- In January 1999, EPRI issued TR-0-R1, a revision to the *Guideline for Sampling in the Commercial-Grade Item Acceptance Process* [23].
- In September 2000, EPRI issued TR-112579, *Critical Characteristics for Acceptance of Seismically Sensitive Items (CCASSI)* [24].
- In July 2006, EPRI issued technical report 1008256, *Plant Support Engineering: Guidelines for the Technical Evaluation of Replacement Items in Nuclear Power Plants (Revision 1)* [25].
- In October 2007, the NRC issued Inspection Procedure 43004, "Inspection of Commercial-Grade Dedication Programs" [26].
- In June 2008, EPRI issued 1016157, *Information for Use in Conducting Audits of Supplier Commercial Grade Item Dedication Programs* [27].
- In August 2009, NQA issued the 2009 Addenda to NQA-1 (NQA-1a-2009) [1] that included new requirements in Part I, Requirement 7, and Part II, Subpart 2.14, Quality Assurance Requirements for Commercial Grade Items and Services.
- In October 2009, EPRI issued 1019163, *Counterfeit, Fraudulent, and Substandard Items: Mitigating the Increasing Risk* [28].
- In June 2010, the NRC issued Regulatory Guide 1.28, Revision 4 [29], which endorsed ASME NQA-1-2008 (edition) and NQA-1a-2009 (addenda) [1] as a QA program that the NRC considers acceptable for complying with the provisions of Title 10 of the Code of Federal Regulations, Part 50, Domestic Licensing of Production and Utilization Facilities (10CFR50) [5], and Title 10 of the Code of Federal Regulations, Part 52, Licenses, Certifications, and Approvals for Nuclear Power Plants (10CFR52) [30]. This addendum included requirements applicable to commercial-grade items in Subsection 2.14.
- In October 2010, EPRI issued 1021493, *Plant Support Engineering: Counterfeit and Fraudulent Items: A Self-Assessment Checklist* [31].
- In February 2011, the NRC issued Information Notice 2011-01, "Commercial-Grade Dedication Issues Identified During NRC Inspections" [32].

- In September 2011, the NRC issued SECY-11-0135, "Staff Plans to Develop the Regulatory Basis for Clarifying the Requirements in Title 10 of the Code of Federal Regulations Part 21, Reporting of Defects and Noncompliance" [33].
- In June 2012, EPRI issued 1025243, *Guideline for the Acceptance of Commercial-Grade Design and Analysis Computer Programs Used in Nuclear Safety-Related Applications.*
- In December 2012, the NRC issued *Draft Regulatory Basis to Clarify Title 10 of The Code of Federal Regulations, Part 21, "Reporting of Defects and Noncompliance"* [35].
- In December 2013, EPRI issued 3002002289, *Plant Engineering: Guideline for the Acceptance of Commercial-Grade Design and Analysis Computer Programs Used in Nuclear Safety-Related Applications: Revision 1 of 1025243* [34].
- NRC inspection and Nuclear Procurement Issues Committee (NUPIC) audit findings concerning commercial-grade items and dedication increased significantly since 2007.

1.4 Basic Premises

1.4.1 Suitability of the Design

One of the basic premises derived from the definition of *dedication* in 10CFR21 [4] is that dedication is an acceptance process. The suitability of design must be established prior to initiating procurement of the item. In other words, the technical evaluation and acceptance activities involved in dedication are not substitutes for design; they cannot be used to change the design of a given item, nor are they a means to verify the suitability of a given design.

The organization purchasing an item should communicate design requirements in purchasing documents or specifications and select a product that meets the applicable design requirements. In some cases, the design of the item must be qualified through testing or analysis as meeting the applicable design requirements. Once design qualification and selection of the item to be procured are completed, procurement can begin. Design requirements are translated into appropriate technical procurement specification requirements, including an acceptance plan that will provide reasonable assurance that the design requirements are met. Together, these processes should provide reasonable assurance that the item being procured will perform its safety-related functions.

When procuring replacement items, equivalent performance is confirmed by conducting the technical evaluation to ensure that the item specified meets design requirements and remains suitable for its intended application(s). Acceptance ensures that the item received is the item that was specified in the procurement document. The combination of the two activities, therefore, ensures that the item received and accepted will perform in an equivalent fashion to the item being replaced. Neither activity need be conducted with the intention of improving the expected performance of a replacement commercial-grade item.

1.4.2 Application of the Guidance in This Report

This report has been prepared for use by any dedicating entity, including but not limited to commercial licensees, manufacturers, suppliers, and third-party qualifiers.

1.4.3 Consistency with Previously Published Guidance

This report is consistent and compatible with the guidance included in EPRI reports NP-5652 [2] and TR-102260 [3]. However, this report includes more detailed information about the dedication process itself and how it applies to various types of dedicating entities. In addition, it reflects current regulatory expectations.

The suggested methods for performing the technical evaluation and acceptance process are identical to those described in the EPRI reports developed in response to the Nuclear Management and Resources Council (NUMARC, now the Nuclear Energy Institute) industry procurement initiative of the early 1990s [16, 18], which have been effectively implemented by licensees and nuclear suppliers since then. Guidance provided in this report builds on current industry practice, lessons learned, and existing regulatory requirements.

1.4.4 *The Term* Commercial-Grade Item

When used in this report, the term *commercial-grade item* refers to both commercial-grade items and commercial-grade services.

1.4.5 *The Term* Basic Component

When used in this report, the term *basic component* can refer to structures, systems, and components (SSCs) as well as safety-related design, analysis, inspection, testing, fabrication, replacement of parts, or consulting services that are associated with the component hardware, design certification, design approval, and so forth. This is consistent with the definition of *basic component* in 10CFR21 [4].

1.4.6 Material Control and Maintenance Processes

Dedication cannot compensate for improper material control or maintenance practices (that is, improper shelf life control, lack of foreign material exclusion controls, improper installation, missing parts, use beyond qualified life, inappropriate application, and so forth).

Items that have been dedicated and accepted for use are basic components. Therefore, they are subject to the same requirements as other basic components.

1.4.7 Use of Qualified Personnel

Many of the decisions required in the performance of the technical evaluation and acceptance processes will be based on the knowledge and expertise of the personnel performing the evaluation. In order to make these technical decisions, individuals performing these evaluations must have appropriate qualifications, experience, and/or training in relevant areas, such as the following:

- Design
- Engineering
- Manufacturing
- Equipment functionality

- QA requirements
- Regulatory requirements

This report provides guidance for the accomplishment of relevant tasks, but it is not intended to eliminate the need for sound technical decisions and engineering judgment.

1.4.8 Repetitive or Ongoing Item Procurement

When adequate technical and quality requirements (including the commercial-grade acceptance plan) for an item in a specific application have been established, the requirements may be applied for ongoing procurement (subsequent purchases), unless a change has occurred in the item or its application or there is reason to believe that the requirements should be changed. All of the requirements must be met for each subsequent purchase.

1.4.9 Relationship to Regulatory Documents

When using the guidance in this report, dedicating entities should ensure that they are in compliance with current regulatory guidance and definitions.

1.4.9.1 10CFR50, Appendix B

The guidance provided in EPRI report NP-5652 [2] and this report is consistent with the requirements of 10CFR50, Appendix B [7]. The design/design basis of the SSC is developed under Criterion III, Design Control, at the inception of plant design and maintained through the modification process. Subsequently, the technical and quality requirements from the design/design basis are translated in the specifications, drawings, and other procurement documents to procure these SSCs under Criterion IV, Procurement Document Control. Criterion VII, Control of Purchased Material, Equipment, and Services, then controls the process by which purchasers verify (or provide reasonable assurance) that the technical and quality requirements have been met. Therefore, for commercial-grade items, Criterion VII is implemented by using this guidance through application of the four methods.

1.4.9.2 Relationship to NRC Regulatory Guide 1.33 (Endorsement of ANSI N18.7)

The guidance provided in this report and EPRI report NP-5652 [2] is consistent with NRC Regulatory Guide 1.33 [9] and the requirements contained in paragraph 5.2.13, Procurement and Materials Control, of ANSI N18.7 [8], which refers to ANSI N45.2.13-1976 [36] and states in part:

> Measures shall be provided for procurement, documentation and control of those materials and components including spare and replacement parts necessary for plant operation, refueling, maintenance and modification. These measures shall utilize American National Standards Institute's Quality Assurance Requirements for the Control of Procurement of Items and Services for Nuclear Power Plants, N45.2.13-1976. The Appendix to ANSI N45.2.13 is particularly useful in determining the quality assurance requirements depending on the complexity or safety of the item. Procedures shall be established and implemented to ensure that purchased materials and components associated with safety-related structures or systems are:

(1) Purchased to specifications and codes equivalent to those specified for the original equipment, or those specified by a properly reviewed and approved revision. (In those cases where the original item or part is found to be commercially “off the shelf,” or without specifically identified quality assurance requirements, spare and replacement parts may be similarly procured but care shall be exercised to assure at least equivalent performance;

(2) Produced or fabricated under requirements at least equivalent to that of the original equipment, or those specified by a properly reviewed and approved revision;

(3) Packaged and transported in a manner that will ensure that the quality is not degraded during transit;

(4) Properly documented to show compliance with applicable specifications, codes and standards;

(5) Properly inspected, identified and stored to protect against damage, deterioration or misuse;

(6) Properly controlled to ensure the identification, segregation and disposition of non-conforming material.

In those cases where the QA requirements of the original item cannot be determined, an engineering evaluation shall be conducted by qualified individuals to establish the requirements and controls. This evaluation shall assure that interfaces, interchangeability, safety, fit and function are not adversely affected or contrary to applicable regulatory or code requirements.

The results of this evaluation shall be documented. [8]

1.4.9.3 Relationship to NRC Regulatory Guide 1.28 (Endorsement of ASME NQA-1)

The guidance in this report is intended to be consistent with the requirements of the 2008 Edition, 2009 Addenda of NQA-1 (NQA-1a), as endorsed by Regulatory Guide 1.28 [29].

1.5 Key Updates in This Report

1.5.1 Evolution of the Methodology’s Application

Commercial-grade item dedication was originally developed as an alternative means for licensees to procure spare and replacement items for equipment originally procured but no longer available as a basic component. This situation became increasingly common as original suppliers of basic components discontinued their nuclear QA programs. This report includes guidance on use of dedication methodology by all types of dedicating entities (licensees, suppliers, and so forth).

1.5.2 Terminology

When NP-5652 was issued, 10CFR21 did not include much detail on commercial-grade dedication, nor did it include definitions for key terms such as *dedication* or *critical characteristic*. The regulation focused on the facts that commercial-grade items were items furnished in accordance with manufacturers’ published product literature [37] and that dedication of a commercial-grade item occurred "after receipt when that item is designated for use as a basic component" [37]. NP-5652 [2] pioneered a methodology that could be used to designate a commercial-grade item for use as a basic component. To accomplish this, NP-5652 defined terms, including *critical characteristic* and *dedication*, to form a basis for the methodology.

Lessons learned through implementation of the guidance have identified the need to update the terminology to ensure that the methodology is applied consistently and with a sound technical basis. The need to clarify different aspects of the methodology became evident as dedicating entities expanded beyond licensees and the methodology was applied to include increasingly complex items and services.

1.5.2.1 Definition of *Critical Characteristics*

NP-5652 defined critical characteristics as "identifiable and measurable attributes or variables of a commercial-grade item, which once selected to be verified, provide reasonable assurance that the item received is the item specified" [2]. Although this definition was functional, the focus on "identifiable" was misinterpreted by dedicating entities that, in some cases, based acceptance solely on identification attributes, such as part number.

NRC GL 89-02 [10], GL 91-05 [19], and Inspection Procedure 38703 [22] cover the term *critical characteristic*. In 1995 the NRC issued a revision of 10CFR21 to codify a definition for *critical characteristics* by defining them as "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" [4].

1.5.2.2 Identification Attributes vs. Critical Characteristics

NP-5652 specifically included an item's part number as a critical characteristic. However, the regulatory definition of *critical characteristic* in 10CFR21 [4] clearly points out that a critical characteristic must be directly related to the item's ability to perform its safety function(s). Therefore, identification attributes such as part number should be verified when applicable during the standard receipt inspection and are often included in the critical characteristics section of commercial-grade dedication acceptance plans to ensure that product identification is verified. This important distinction prevents acceptance based solely on identification attributes that are not directly related to the safety function(s) of the item being dedicated.

1.5.2.3 Critical Characteristics for Design and Critical Characteristics for Acceptance

The primary purpose of identifying critical characteristics during commercial-grade dedication is to identify those characteristics necessary to provide reasonable assurance that the item being dedicated is capable of performing its intended safety function(s). When used in this report (and regulatory documents), the term *critical characteristics* refers to the characteristics necessary to provide reasonable assurance that the item being dedicated is capable of performing its intended safety function(s).

EPRI guidance developed subsequent to NP-5652 recognized the value of using critical characteristics in other engineering processes, such as equivalency evaluations. Accordingly, the guidance adopted the term *critical characteristics for acceptance* to identify characteristics verified during the dedication process and *critical characteristics for design* to identify the entire set of design characteristics that might be considered when performing equivalency evaluations.

Regulatory documents in the United States have not adopted use of the terms *critical characteristics for design* and *critical characteristics for acceptance*. In recognition of this fact, this report uses the term *critical characteristics* in place of *critical characteristics for acceptance* and the term *design characteristics* in place of *critical characteristics for design*. This reflects a change in terminology, not methodology.

1.5.3 Failure Modes and Effects Analysis

NP-5652 [2] and TR-102260 [3] did not address the use of failure modes and effects analysis as a means to determine critical characteristics. However, the use of failure modes and effects analysis to identify critical characteristics is important and covered in this revision. In-depth discussion on failure modes and effects analysis to assist in determination of safety classification and to develop critical characteristics for design (for use in equivalency evaluation) first appeared in EPRI NP-6406, *Guidelines for the Technical Evaluation of Replacement Items (NCIG-11)* [12]. NRC IP 38703 included the following statement:

> An evaluation of credible failure modes of an item in its operating environment and the effects of these failure modes on the item's safety function may be used in the safety classification of an item and as a basis for the selection of critical characteristics. [22]

Subsequently, NRC IP 43004 states that technical evaluations should include "performance of a failure modes and effects analysis (FMEA) to identify the credible failure mechanisms of the item in the specific application under consideration" [26].

1.5.4 References to Standards

The QA standards that provided the foundation for development of the original commercial-grade dedication methodology were 10CFR50, Appendix B [7]; ANSI N45.2-1977 [6]; and the ANSI N45.2 daughter standards (N45.2.1–N45.2.20). The ANSI standards have since been incorporated into ASME NQA-1 [1]. Dedicating entities may be committed to QA program requirements included in 10CFR50, Appendix B [7]; ANSI N45.2; the ANSI daughter standards; or ASME NQA-1. For this reason, this report includes references to both ANSI and ASME NQA-1 when appropriate.

Table 1-1 provides a summary that links ANSI N45-series standards with the location of corresponding language in ASME NQA-1 standards that are endorsed by the NRC.

Table 1-1
ANSI N45 series standards and locations of the corresponding language in NQA-1

Topic/Standard Title	NRC: Endorsed Location(s)*	NRC Regulatory Guide	Regulatory Guide Title
Quality Assurance Requirements for the Installation, Inspection, and Testing of Instrumentation and Electric Equipment	ANSI N45.2.4 [37] NQA-1, Part II, Subpart 2.4 [39] IEEE 336 [40]	1.30 [38]	Quality Assurance Requirements for the Installation, Inspection, and Testing of Instrumentation and Electric Equipment
Quality Assurance Program Requirements (Operation)	ANSI/American Nuclear Society 3.2 [41] Not in NQA-1	1.33 [9]	Quality Assurance Program Requirements (Operation)
Quality Assurance Requirements for Cleaning of Fluid Systems and Associated Components of Water-Cooled Nuclear Power Plants	ANSI N45.2.1 [42] NQA-1, Part II, Subpart 2.2 [43]	1.37 [44]	Quality Assurance Requirements for Cleaning of Fluid Systems and Associated Components of Water-Cooled Nuclear Power Plants
Quality Assurance Requirements for Packaging, Shipping, Receiving, Storage, and Handling of Items for Water-Cooled Nuclear Power Plants	ANSI N45.2.2 [46] NQA-1, Part II, Subpart 2.2 [43]	1.38 [45]	Quality Assurance Requirements for Packaging, Shipping, Receiving, Storage, and Handling of Items for Water-Cooled Nuclear Power Plants
Housekeeping Requirements for Water-Cooled Nuclear Power Plants	ANSI N45.2.3 [47] NQA-1, Part II, Subpart 2.3 [48]	1.39 [49]	Housekeeping Requirements for Water-Cooled Nuclear Power Plants
Qualification of Nuclear Power Plant Inspection, Examination, and Testing Personnel (Withdrawn)	ANSI N45.2.6 [50] NQA-1, Part I [51]	1.58 [52]	Qualification of Nuclear Power Plant Inspection, Examination, and Testing Personnel (Withdrawn)
Quality Assurance Requirements for the Design of Nuclear Power Plants (Withdrawn)	ANSI N45.2.11 [53] NQA-1, Part I [51]	1.64 [54]	Quality Assurance Requirements for the Design of Nuclear Power Plants (Withdrawn)
Collection, Storage, and Maintenance of Nuclear Power Plant Quality Assurance Records (Withdrawn)	ANSI N45.2.9 [55] NQA-1, Part I [51]	1.88 [56]	Collection, Storage, and Maintenance of Nuclear Power Plant Quality Assurance Records (Withdrawn)
Quality Assurance Requirements for Installation, Inspection, and Testing of Structural Concrete and Structural Steel during the Construction Phase of Nuclear Power Plants	ANSI N45.2.5 [57] NQA-1, Part II, Subpart 2.5	1.94 [58]	Quality Assurance Requirements for Installation, Inspection, and Testing of Structural Concrete and Structural Steel during the Construction Phase of Nuclear Power Plants

Table 1-1 (Continued)
ANSI N45 series standards and locations of the corresponding language in NQA-1

Topic/Standard Title	NRC: Endorsed Location(s)*	NRC Regulatory Guide	Regulatory Guide Title
Quality Assurance Requirements for Installation, Inspection, and Testing of Mechanical Equipment and Systems	ANSI N45.2.8 [59] NQA-1, Part II, Subpart 2.8 [60]	1.116 [61]	Quality Assurance Requirements for Installation, Inspection, and Testing of Mechanical Equipment and Systems
Quality Assurance Requirements for Control of Procurement of Items and Services for Nuclear Power Plants (Withdrawn)	ANSI N45.2.13 [36] NQA-1 Part I [51]	1.123 [62]	Quality Assurance Requirements for Control of Procurement of Items and Services for Nuclear Power Plants (Withdrawn)
Requirements for Auditing of Quality Assurance Program for Nuclear Power Plants	ANSI N45.2.12 [63] NQA-1, Part I [51]	1.144 [64]	Auditing of Quality Assurance Programs for Nuclear Power Plants (Withdrawn)
Qualification of Quality Assurance Program Audit Personnel for Nuclear Power Plants	ANSI N45.2.23 [65] NQA-1, Part I [51]	1.146 [66]	Qualification of Quality Assurance Program Audit Personnel for Nuclear Power Plants (Withdrawn)
Application Criteria for Programmable Digital Computer System in Safety Systems of Nuclear Power Plants	NQA-1, Part II, Subpart 2.7 [67]	1.152 [68]	Criteria for Programmable Digital Computer Software in Safety-Related Systems of Nuclear Power Plants
Supplementary Quality Assurance Requirements for Subsurface Investigation for Nuclear Power Plants	ANSI N45.2.20 [69] NQA-1, Part II, Subpart 2.20 [70]	None	None
Quality Assurance Requirements for Maintenance of Nuclear Facilities	None NQA-1 Part II, Subpart 2.18 [71]	None	None
Supplementary Requirements for the Calibration and Control of Measuring and Test Equipment Used in the Construction and Maintenance of Nuclear Facilities	ANSI N45.2.16 [72] NQA-1, Part II, Subpart 2.16 [73]	None	None

*Reference is to 2008 Edition, 2009 Addenda of ASME NQA-1.

1.6 Availability of EPRI Guidance on Commercial-Grade Dedication

Prior to 2008, EPRI reports on commercial-grade dedication were not readily available to suppliers because they were written from a licensee's perspective for use by licensees. Today, however, EPRI reports on commercial-grade dedication are available to the public.

1.7 Scope and Content of This Report

Figures 1-1 and 1-2 provide an outline of the sections and appendices in this report.

Figure 1-1
Report sections

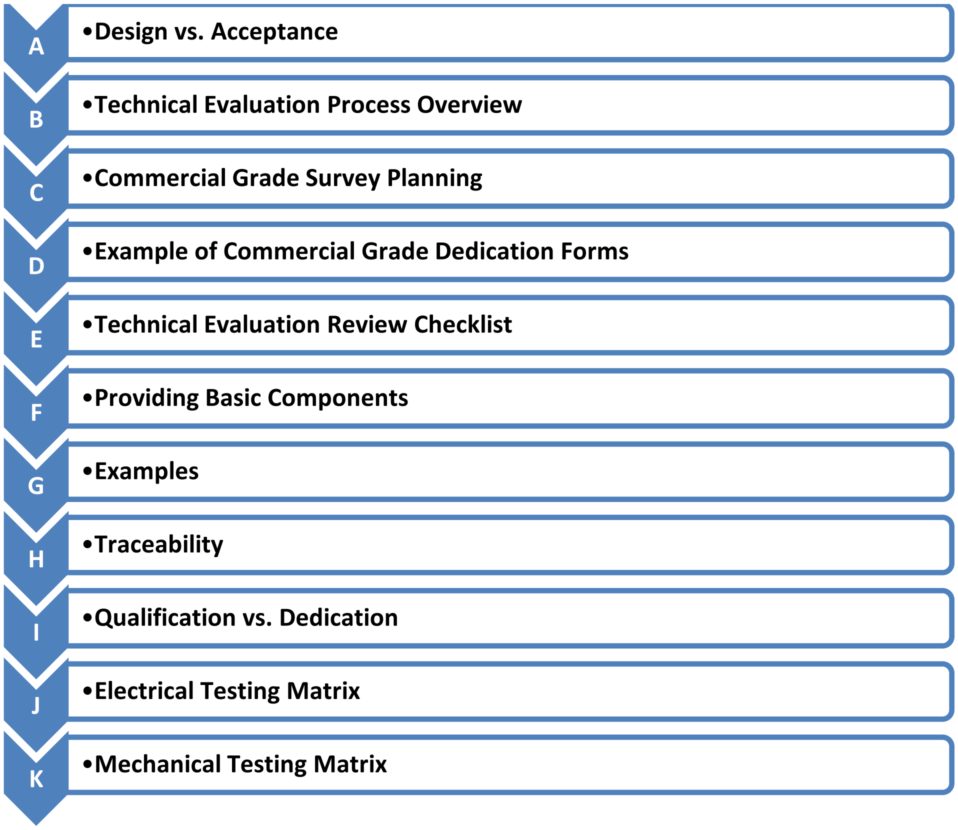


Figure 1-2
Report appendices

2
BASELINE TERMINOLOGY: DEFINITIONS AND ACRONYMS

2.1 Introduction

The terms presented in Section 2.2 are referenced throughout this report and used in the context of the definitions given. The source of each definition is referenced. Some definitions are taken directly from the definitions in 10CFR50 and 10CFR21 that were current at the time this report was published. In some instances, the definitions of terms that are defined in the regulations are rephrased here for simplicity or to provide additional clarity. In these cases, the definitions are consistent with those in regulations; however, if differences are found to exist, then the definition in the regulation takes precedence.

Some definitions have been edited to correct grammatical errors that were included in their source documents. The intended meaning of these definitions has not changed.

Some definitions are provided for terms that are used in the regulations but are not explicitly defined therein. Consistent with the role of guidance, these definitions are used to provide clarity in order to specify an approach to comply with the regulations.

2.2 Definitions of Key Terms

acceptance	The employment of one or more dedication methods to produce objective evidence which provides reasonable assurance that a commercial-grade item received will perform its intended safety function(s) [2, 4].
active component	A component in which mechanical or electrical change of state is required to occur for the component to perform its safety-related function [108, 25].
alternative replacement	A replacement item that is not physically identical to the original. These replacement items require an equivalency evaluation to ensure that the design function will be maintained [25].
assembly	A combination of subassemblies, components, or both which forms a workable unit (for example, control room panels, motor control centers, instrument and pining racks, skid-mounted equipment, etc.) [25].

audit A planned and documented activity performed to determine by investigation, examination, or evaluation of objective evidence the adequacy of and compliance with established procedures, instructions, drawings, and other applicable documents and the effectiveness of implementation. An audit should not be confused with surveillance or inspection activities performed for the sole purpose of process control or product acceptance [1].

augmented quality As used in this report, augmented quality is an optional subset of the classification category non-safety-related. It may be applied to any item that is subject to non-safety-related regulatory requirements or special requirements imposed by the customer. The scope of the classification category is station-specific. See EPRI NP-6895 [74].

basic component (safety-related) According to 10 CFR 21.3:

> (1)(i) When applied to nuclear power plants licensed under 10 CFR part 50 or part 52 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), § 50.67(b)(2), or § 100.11 of this chapter, as applicable.

(ii) Basic components are items designed and manufactured under a quality assurance program complying with appendix B to part 50 of this chapter, or commercial grade items which have successfully completed the dedication process.

> (2) When applied to standard design certifications under subpart C of part 52 of this chapter and standard design approvals under part 52 of this chapter, basic component means the design or procurement information approved or to be approved within the scope of the design certification or approval for a structure, system, or component, or part thereof, that affects its safety function necessary to assure:
>
> > (i) The integrity of the reactor coolant pressure boundary;
> >
> > (ii) The capability to shut down the reactor and maintain it in a safe shutdown condition; or
> >
> > (iii) 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), 50.67(b)(2), or 100.11 of this chapter, as applicable.

(3) When applied to other facilities and other activities licensed under 10 CFR parts 30, 40, 50 (other than nuclear power plants), 60, 61, 63, 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.

(4) 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, design certification, design approval, or information in support of an early site permit application under part 52 of this chapter, whether these services are performed by the component supplier or others. [4]

bounded technical requirements A subset of technical requirements that is established through engineering activities that translate the values chosen as reference bounds for design of controlling parameters (for example, the design bases as defined in 10CFR50.2) into specific requirements included in specifications, drawings, and other design-output documents [25].

bounding conditions Parameters that envelop the normal, abnormal, and accident environmental conditions an item is expected to meet during its lifetime in the plant (for example, temperature, humidity, radiation, seismic response spectra, etc.) [25].

certificate of compliance A document signed or otherwise authenticated by an authorized individual certifying the degree to which items or services are in accordance with specified requirements and accompanied by additional information to substantiate the statement [3].

certificate of conformance A document signed or otherwise authenticated by an authorized individual certifying the degree to which items or services meet specified requirements [1].

certification The act of determining, verifying, and attesting in writing to the qualifications of personnel, processes, procedures, or items in accordance with specified requirements [1].

certified material test report A document attesting that the material is in accordance with specified requirements, including the actual results of all required chemical analyses, treatments, tests, and examinations [26].

characteristic Any property or attribute of an item, process, or service that is distinct, describable, and measurable as conforming or nonconforming to specified quality requirements. Quality characteristics are generally identified in specifications and drawings that describe the item, process, or service [3].

classification A documented technical evaluation process that results in the determination of an item's safety classification design requirements (including environmental and seismic qualification) and QA requirements [3]).

code An industry standard as required by or committed to federal, state, or local jurisdictional authorities that specifies specific certification requirements (such as product stamps or labels) for an item from which mandatory compliance is provided as specified in the standard. Examples include ASME Boiler & Pressure Vessel Code stamps, UL labels, National Board of Boiler and Pressure Vessel inspectors' stamps, and National Board Certifications.

commercial-grade dedication package An auditable collection of documents that is the result of the commercial-grade dedication process for a specific item and its documented safety function(s). These documents contain the technical and quality basis for satisfying the commercial-grade item dedication process, and they provide the objective evidence to reasonably ensure that the dedicated commercial-grade item will perform its required safety function(s) [26].

commercial-grade item

1. When applied to nuclear power plants licensed pursuant to10CFR50, *commercial grade item* means a structure, system, component, or part thereof that affects its safety function and 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 (that is, one or more critical characteristics of the item cannot be verified).

2. When applied to facilities and activities licensed pursuant to 10CFR 30, 40, 50 (other than nuclear power plants), 60, 61, 63, 70, 71, or 72, an item that is:

(1) Not subject to design or specification requirements that are unique to those facilities or activities

(2) Used in applications other than those facilities or activities; and

(3) To be ordered from the manufacturer/supplier on the basis of specifications set forth in the manufacturer's published product description (for example, a catalog). [4]

commercial-grade survey

Activities conducted by the dedicating entity or its agent to verify that a supplier of commercial-grade items controls, through quality activities, some or all of the critical characteristics of the designated commercial-grade items to be purchased. The verification can be used as a method to accept those characteristics. The commercial grade survey should include verification of the supplementary documentation and the effective implementation of the commercial-grade quality program [26].

commercial supplier

An organization in the supply chain that does not provide items in accordance with a quality assurance program that meets the requirements of 10CFR50, Appendix B [7].

commodity item

An item having a generic application throughout a nuclear unit that lends itself to bulk procurement (such as nuts, bolts, materials, O-rings, gaskets, indicator lights, fuses, relays, and resistors).

component

A piece of equipment—such as a vessel, pump, valve, core support structure, relay, or circuit breaker—that is combined with other components to form an assembly. Typically, components are identified with a number (for example, a tag number) [25].

credible failure mechanism
The manner by which an item may fail, degrading the item's ability to perform the component or system function under evaluation [75].

critical characteristics
The 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. (10CFR21 [4].)

critical characteristics for acceptance
The important design, material, and performance characteristics of a commercial-grade item that, once selected to be verified, provide reasonable assurance that a commercial-grade item to be used as a basic component will perform its intended safety function(s). **Note**: Critical characteristics for acceptance are a subset of critical characteristics for design [25].

Note: This report uses the term *critical characteristics* in place of *critical characteristics for acceptance*.

critical characteristics for design
Those properties or attributes that 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 that provide assurance that the replacement item will perform its design function. Critical characteristics for design are referred to as *design characteristics* in this report [25].

Note: This report uses the term *design characteristics* in place of *critical characteristics for design*. This reflects a change in terminology, not methodology.

dedicating entity
The organization that performs the dedication process. Dedication may be performed by the manufacturer of the item, a third-party dedicating entity, and/or the licensee itself. The dedicating entity is responsible for identifying and evaluating deviations, reporting defects and failures to comply for the dedicated item, and maintaining auditable records of the dedication process [4].

dedication — An acceptance process that is 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 10CFR50, Appendix B QA program. (10CFR21 [4].)

design characteristics — Sometimes referred to as *critical characteristics for design*, those properties or attributes that 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 that provide assurance that the replacement item will perform its design function [25].

design function — The operation that an item is required to perform to meet the component or system design basis [25].

designed and manufactured — When applied to basic components the term *designed and manufactured* means *controlled* under a quality assurance program complying with appendix B to 10 CFR Part 50. [see Appendix F]

engineering judgment — A process of logical reasoning performed by a qualified individual that leads from stated premises to a conclusion. This process should be supported by sufficient documentation to permit verification by a qualified individual [26].

equivalency evaluation — A technical evaluation performed to confirm that an alternative item not identical to the original item will satisfactorily perform the design function(s) of the original item.

equivalent replacement — A replacement item not physically identical to the original. These replacement items require an equivalency evaluation to ensure that the intended functions, including its safety function, will be maintained [1].

failure — A mechanism that prevents an item from accomplishing its function [74].

failure mode — The effects or conditions that result from an item's credible failure mechanisms [25].

failure modes and effects analysis — An evaluation of an item's credible failure mechanisms and their effect on system and/or component function [25].

fit	The mounting configuration, interfaces, connections, and similar characteristics of an item.
form	The size, weight, shape, materials of construction, and similar characteristics of an item.
function	The operation(s) that a part/component is required to perform to meet the component or system design requirements. Functions may be expressed in terms of performance characteristics, range(s), accuracy, methods of adjustment, service environment qualification, service, life, and so forth.
harsh environment	An environment resulting from a design basis event that is not a mild environment.
hold point	A specified place in work processes, procedures, or instructions that requires a witness or verification action beyond which work is not to continue without approval indicating that the specified criteria for the hold were satisfactorily fulfilled.
identical item	An item that exhibits the same technical and physical characteristics (physically identical) [25].
item	An all-inclusive term used in place of any of the following: *appurtenance*, *assembly*, *component*, *equipment*, *material*, *module*, *part*, *structure*, *subassembly*, *subsystem*, *system*, or *unit*. (See ASME NQA-1-2008, NQA-1a-2009 Addenda [1].) For the purposes of this report, *item* includes services.
like-for-like replacement	The replacement of an item with an item that is identical.
material	A substance or combination of substances used to form parts, as a structure or component item. (Intended to include steel plate, welding rods, gaskets, lubricants, chemicals, grouting, and concrete constituents.) [3]
mild environment	An environment that would at no time be significantly more severe than the environment that would occur during normal plant operation, including anticipated operational occurrences. 10 CFR 50.49(c) [104] [76].
non-safety-related item	An item that does not perform a safety-related function.

part	Items from which a component is assembled (for example, resistors, capacitors, wires, connectors, transistors, lubricants, O-rings, springs, bearings, gaskets, bolting, and seals) [25].
part number	A product identifier; the supplier's assigned identifier for an item. *Part number* as used herein can also include identifiers such as the model number, material type, grade, and catalog reference number.
passive component	A component in which mechanical or electrical change of state is not required to occur for the component to perform its safety-related function 10 CFR 54.21(a)(1)(i) [104][25].
post-fabrication tests	Activities conducted after fabrication of a commercial-grade item to verify required critical characteristics prior to designation as a basic component. Tests that occur before installation (not performed by the licensee) are not considered to be post-installation tests.
post-installation tests	Activities conducted after installation of a commercial-grade item to verify required critical characteristics prior to placement in operation. An element of the Special Tests and Inspection method to accept an item for safety-related use [2].
procurement document	Contractually binding documents that identify and define the requirements that items or services must meet in order to be considered acceptable by the purchaser [3].
Q-list	A document identifying those structures, systems, or components for a nuclear power plant that are safety-related [25].
reasonable assurance	In the context of commercial grade item acceptance, reasonable assurance is an engineering determination premised upon a justifiable level of confidence based on objective and measurable facts, actions, or observations from which adequacy of the item for its intended purpose can be inferred [3]. (More information on reasonable assurance is included in Section 13 of this report and Appendix A, 4 of IP 43004 [26].)
receipt inspection	Activities conducted upon receipt of items, including commercial-grade items, in accordance with ANSI N45.2.2-1978 [47] (NQA-1, Part II, Subpart 2.2 [44]) or other applicable QA standard, to check such elements as the quantity received, part number, general condition of items, and damage [2].

replacement item	An item that replaces an original or installed item, either identical or alternative [25].
safety classification	An item's safety classification is safety-related, non-safety-related, or non-safety-related, augmented quality.
safety-related	Refer to the definition in 10 CFR 50.2.
service	The performance of activities such as design, fabrication, inspection, nondestructive examination, repair, or installation [1].
source verification	Activities witnessed at the supplier's facilities by the dedicating entity or its agent before releasing the CGI from the vendor or test laboratory facility to confirm by direct observation that the selected critical characteristics are verified by the vendor as a method to accept those characteristics without further dedication for safety-related use [22, 26].
special tests and inspection	Activities conducted after the receipt of a commercial-grade item to verify one or more critical characteristics as a method to accept the item for safety-related use [2].
supplier	The organization that furnishes a commercial grade item or basic component. Any individual or organization who furnishes items or services in accordance with a procurement document. This could include an original equipment manufacturer, part manufacturer, or distributor. An all-inclusive term used in place of any of the following: *vendor*, *seller*, *contractor*, *subcontractor*, *fabricator*, *consultant*, and their subtier levels [2].
technical evaluation	An evaluation performed to ensure that the correct technical requirements for an item are specified in a procurement document [2].
traceability	The ability to verify the history, location, or application of an item by means of recorded identification. Traceability to the manufacturer is required when the manufacturer is relied upon to verify one or more critical characteristics [26].
verification	An act of confirming, substantiating, and ensuring that the critical characteristics of the item meet the specified requirements [3].

2.3 Acronyms

A2LA	American Association of Laboratory Accreditation
ACLASS	Assured Calibration and Laboratory Accreditation Select Services
ANSI	American National Standards Institute
APS	Arizona Public Services
ASME	American Society of Mechanical Engineers
CFR	Code of Federal Regulations
CSSC	critical system, structure, and component
EPDM	ethylene propylene diene monomer
EPRI	Electric Power Research Institute
EQDB	Equipment Qualification Data Bank
FTIR	Fourier transform infrared
GL	Generic Letter (NRC)
G-STERI	generic seismic technical evaluation of replacement items
IEC	International Electrotechnical Commission
IEEE	Institute of Electrical and Electronics Engineers
ILAC	International Laboratory Accreditation Cooperation
ISO	International Standards Organization
M&TE	measurement and test equipment
NCIG	Nuclear Construction Issues Group
NEI	Nuclear Energy Institute
NPEP	Nuclear Plant Equipment Procurement
NQA	nuclear quality assurance
NRC	U.S. Nuclear Regulatory Commission
NSSS	nuclear steam system supplier
NUMARC	Nuclear Utility Management and Resource Council (now the Nuclear Energy Institute)
NUPIC	Nuclear Procurement Issues Committee
NVLAP	National Voluntary Laboratory Accreditation Program
OEM	original equipment manufacturer
OES	original equipment supplier

ppm	parts per million
Q-list	a list of components and their safety classifications
QA	quality assurance
QSC	quality system certificate
SER	Safety Evaluation Report (NRC)
SQURTS	Seismic Qualification Reporting and Testing Standardization
SSC	system, structure, and component
STERI	seismic technical evaluation of replacement items
TR	technical report

3
OVERVIEW OF COMMERCIAL-GRADE DEDICATION

This section provides a high-level overview of what a commercial-grade item is and the key elements involved in the commercial-grade item dedication process.

3.1 Commercial-Grade Items

Nuclear power plants include SSCs designated as safety-related or non-safety-related. A safety-related item meets the regulatory definition of *basic component*. The QA program requirements of 10CFR50, Appendix B [7], mandate planned and systematic actions to control the quality of safety-related items. Ideally, these controls are achieved by designing and manufacturing items in accordance with QA programs that meet the requirements of 10CFR50, Appendix B [7].

Situations occur where obtaining a safety-related item that was controlled under the auspices of a QA program meeting the requirements of 10CFR50, Appendix B, is not available or practical. These situations may call for use of a commercial-grade item, that is, an item that was not designed and manufactured in accordance with a QA program meeting the requirements of 10CFR50, Appendix B [7]. Commercial-grade dedication is a method of accepting commercial-grade items for use as basic components in safety-related applications.

In earlier revisions of 10CFR21, eligibility for dedication was established by criteria included in the regulatory definitions of *commercial-grade item*. These criteria were intended to limit the scope of items eligible for dedication. The criteria included in the first definition of *commercial-grade item* in the 1979 edition of 10CFR, Part 21 [4], were as follows:

- Criterion 1: The item is not be subject to design or specification requirements that are unique to facilities or activities licensed pursuant to Parts 30, 40, 50, 70, or 71 of Chapter 10 of the Code of Federal Regulations.
- Criterion 2: The item is used in applications other than facilities or activities licensed pursuant to Parts 30, 40, 50, 70, or 71 of Chapter 10 of the Code of Federal Regulations.
- Criterion 3: The item is ordered from the manufacturer or supplier on the basis of specifications set forth in the manufacturer’s published product description (for example, a catalog).

The definition has been revised several times to expand the scope of items eligible for dedication in certain types of facilities. The guidance in this report is based on the following definition which was updated in the NRC's 1995 revision to 10CFR, Part 21:

> A 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). [4]

For the purposes of interpreting the definition in day-to-day work, the definition may be read as follows: "*Commercial-grade item* means an item that is not a basic component." However, it is important to recognize that a commercial-grade item cannot be dedicated if any critical characteristic of the item cannot be verified. The realization that a commercial-grade item cannot be dedicated should be self-evident if the dedication process is correctly performed.

3.2 Overview of Commercial-Grade Dedication

Commercial-grade dedication is an acceptance process that is typically applied at the level of supply to the purchaser. For example, if a commercial-grade part of a valve that is classified as a basic component (such as a packing gland) is supplied as a spare part, the part must first be dedicated. If a commercial-grade valve is supplied as a basic component, the valve (not necessarily all of the parts) must first be dedicated. It may not be necessary to dedicate the individual commercial-grade parts and materials used to fabricate the valve if the dedication for the valve establishes reasonable assurance that it is capable of performing its safety-related function.

As illustrated in Figure 3-1, successful commercial-grade dedication involves two key elements. The first element is the technical evaluation, which ensures that the item is classified and specified correctly. Technical evaluations are typically performed to determine the quality and technical procurement requirements for purchased items. Technical evaluations are not limited to commercial-grade items; they are also performed for non-safety-related items and safety-related items procured as basic components.

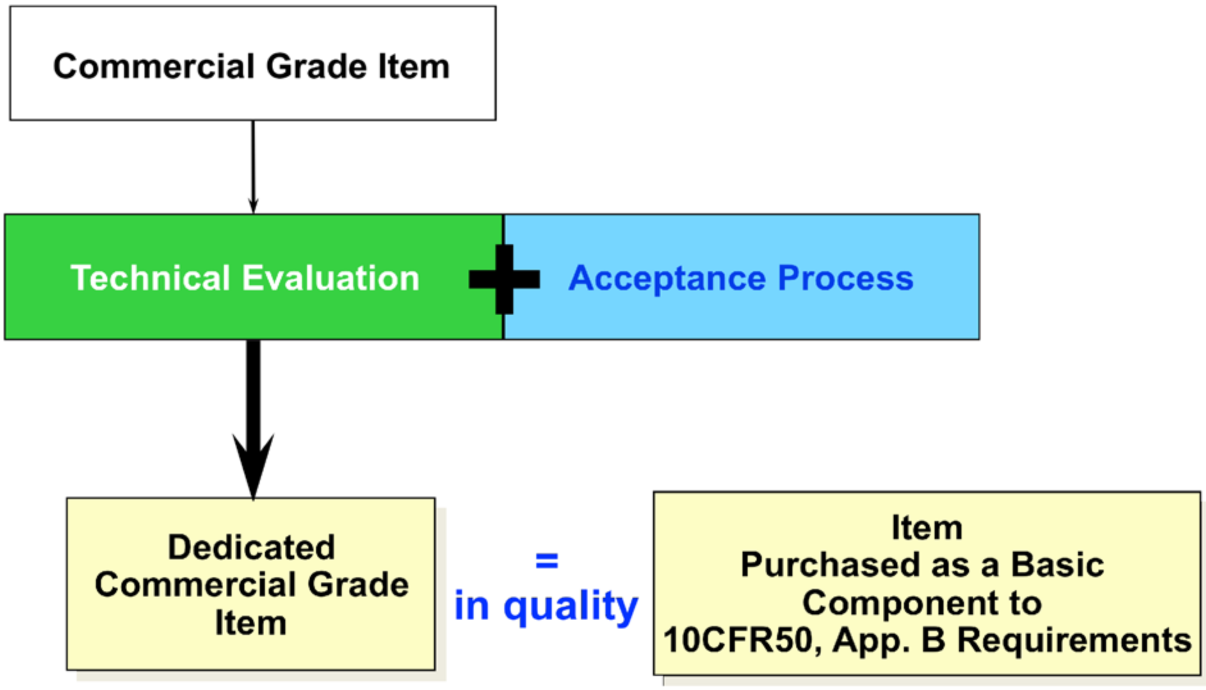


Figure 3-1
Key elements of commercial-grade dedication

The technical evaluation typically consists of the following:

- Safety classification (when the classification of the item being procured has not already been determined)
- An equivalency evaluation (when needed to ensure the suitability of a proposed alternative item)
- Development of appropriate technical and quality requirements
- Identification of critical characteristics, acceptance criteria, and acceptance methods as well as development of an acceptance plan (for commercial-grade items intended for use in safety-related applications)

The second element of commercial-grade dedication is the acceptance process, which provides reasonable assurance that the item procured meets the specified requirements and is therefore capable of performing its intended safety-related function(s). Acceptance of each critical characteristic is verified using one or more of the following acceptance methods:

- Method 1: Special Tests and Inspections
- Method 2: Commercial-Grade Survey
- Method 3: Source Verification (that is, inspections or witness hold points)
- Method 4: Item/Supplier Performance Record (that is, historical records of acceptable performance)

Together, the technical evaluation and acceptance processes constitute dedication, which, in accordance with the definition in 10CFR21, should

> 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 10CFR50, App. B QA program. [4]

3.3 Purpose and Limitations of Commercial-Grade Dedication

Commercial-grade item dedication is an acceptance method used to obtain reasonable assurance that an item will be capable of performing its intended safety-related function(s). Commercial-grade item dedication occurs after the design and qualification activities are complete.

Commercial-grade dedication is not intended for use in establishing design, verifying the acceptability of design, or qualifying design. The technical evaluation and acceptance processes are two of the five elements depicted in Figure 3-2 that ensure the overall quality of plant equipment.

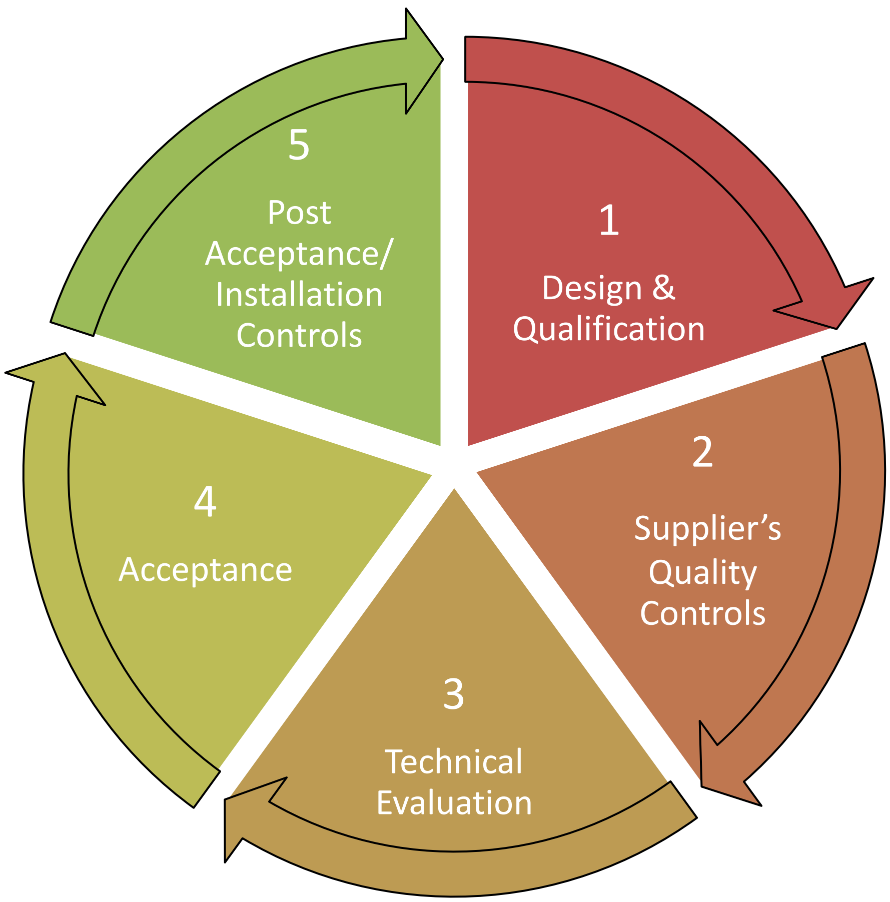


Figure 3-2
Elements ensuring the overall quality of plant equipment

The first element depicted in Figure 3-2 is design and equipment qualification. These processes establish the original design and its suitability and qualify the equipment selected for the original design. Specifications and procurement documents are used to communicate applicable design and qualification requirements to the supplier.

The second element depicted in Figure 3-2 is the supplier's quality control. The supplier uses their quality controls to ensure that the requirements communicated in the procurement document and the included specifications are met.

The third element depicted in Figure 3-2 is the technical evaluation, which is the start of the dedication process. The technical evaluation is based on approved design and qualification. The technical evaluation process is used to generate the information necessary to develop an acceptance plan.

The acceptance plan is the fourth element depicted in Figure 3-2. The acceptance plan is based on critical characteristics identified during the technical evaluation. In some cases, the acceptance plan can consider the supplier's commercial quality controls, particularly when using Method 2: Commercial-Grade Survey or Method 3: Source Verification. When successfully executed, the acceptance plan provides reasonable assurance that the item being dedicated will perform its intended safety-related function(s).

The fifth element depicted in Figure 3-2 includes post-acceptance controls, such as maintaining traceability, installation, and performance monitoring.

3.4 Commercial-Grade Dedication Versus Design and Manufacture Under a QA Program Meeting the Requirements of 10CFR50, Appendix B

Prior to a 1978 change to 10CFR21 [4], the term *dedication* was not part of the industry's vernacular. The only way a supplier could bring basic components to the nuclear marketplace was to "design and manufacture" them in accordance with a QA program meeting the requirements of 10CFR50, Appendix B [7].

As construction of new nuclear facilities declined in the 1970s and the demand for nuclear components decreased, many suppliers opted to leave the nuclear marketplace and discontinued their nuclear QA programs. Licensees were no longer able to purchase the safety-related spare and replacement items required to support operation and maintenance of installed equipment as basic components. Certain spare and replacement items previously available as basic components were available only as "commercial-grade" items. A method was needed to accept commercial-grade items for use as basic components.

3.4.1 Design and Manufacture Under a QA Program Meeting the Requirements of 10CFR50, Appendix B

The traditional (pre-1979) method of bringing a basic component to the marketplace was to design and manufacture it under a nuclear QA program.

It is not a regulatory requirement to use commercial-grade dedication when an item is designed and manufactured under a QA program that meets the requirements of 10CFR50, Appendix B [7]. In fact, the definition of a *basic component* states that basic components are items designed and manufactured under a QA program complying with 10CFR50, Appendix B [7]. However, Appendix B of 10CFR50 requires objective evidence demonstrating that the design requirements for the item were satisfied. This information is obtained through implementation of the QA program through procedures and processes that ensure that design requirements are satisfied through design controls, control of purchased items, manufacturing quality controls, final testing, and so on. In these cases, the entity "owns" or controls the design of the item.

Under a traditional approach, acceptance of the item is based on QA activities conducted to support the 18 criteria in 10CFR50, Appendix B [7]. Under the umbrella of their QA program, the supplier establishes an approved design. The design is proven to meet specified requirements using methods such as design reviews and prototype testing. If necessary, the design may be qualified to meet specific seismic or environmental requirements. The supplier implements QA activities to control the approved design and to ensure that the item being manufactured meets the design requirements. Documented controls (such as procedures and work instructions) detail the verifications, inspections, personnel qualifications, and other activities necessary throughout the production to ensure that the item is manufactured to meet the design requirements.

Implementation of these controls provides the supplier with objective evidence that the item meets all of the design requirements. Although sufficient objective evidence must exist to establish that the basic component conforms to the design, the objective evidence is not necessarily documented in the form of a commercial-grade item dedication technical evaluation and acceptance plan.

An example of controlling an item under a 10CFR50, Appendix B–compliant [7] QA program would be the method used by ASME quality system certificate (QSC) or N certificate holders to upgrade unqualified source material in accordance with their Code-compliant QA programs and applicable Code requirements (for example, NCA-3855.5). In this case, the certificate holder satisfies the requirements of 10CFR50, Appendix B, through compliance with the requirements of the ASME Code and accepts responsibility for reporting of defects and noncompliance in accordance with the requirements of 10CFR21 when providing the material as a basic component.

3.4.2 Commercial-Grade Item Dedication

In the absence of original design requirements and information, commercial-grade item dedication may be used to accept an item based on its end use(s) and safety function(s). This process uses a technical evaluation that employs a failure modes and effects analysis or another effective means to identify critical characteristics that are necessary for the item to perform its intended safety function(s), and it uses an acceptance plan to verify that the item possesses the critical characteristics.

The implementation of the activities specified in the technical evaluation and acceptance plan provides the dedicating entity with objective evidence that the item is capable of performing its intended safety functions. When an item is accepted using commercial-grade item dedication, the objective evidence should be documented in the form of a commercial-grade item dedication technical evaluation and acceptance plan.

Figure 3-3 is a simplified illustration that contrasts the key differences between bringing an item to market using dedication and bringing an item to market by controlling it under a QA program meeting the requirements of 10CFR50, Appendix B [7]. Table 3-1 identifies some of the basic differences between the two approaches used to bring an item to market.

Table 3-1
Basic differences in approach between designing and manufacturing in accordance with a QA program meeting the intent of 10CFR50, Appendix B, and accepting an item using commercial-grade dedication

Topic	Design and Manufacture in Accordance with a QA Program That Meets the Intent of 10CFR50, Appendix B	Accept an Item Using Commercial-Grade Item Dedication
Regulatory position	Acceptable method (The only method of producing a basic component prior to 1979)	Acceptable method (An option for delivering a basic component since 1979)
QA program	Manufacturer's 10CFR50, Appendix B, QA program	Dedicating entity's 10CFR50, Appendix B, QA program
Prerequisites	Approved design (controlled under Criterion III) Suitability of design verified Design established as adequate/ suitable for intended application	Recovered/available item information Known use applications
Methodology	Acceptance of items used in manufacture (controlled under Criterion VII)	Acceptance of items based on critical characteristics necessary for the item to perform its safety function(s)
	Source evaluation and selection	Method 2: Commercial-Grade Survey
	Objective evidence of quality	Method 4: Item/Supplier Performance Record
	Inspection at contractor or subcontractor	Method 3: Source Verification
	Examination of products on delivery	Method 1: Special Tests and Inspections
	All design information is available, including design verification and qualification	Limited design information is available for the item Known item safety function(s) End-user specification(s) for item
Method of establishing and documenting objective evidence	Instructions, procedures, drawings, and documented results	Commercial-grade item dedication technical evaluation and acceptance plan
Basis for selection of verification/acceptance criteria	Must be able to provide a link between design requirement and the acceptance criteria being used	Must be able to provide a basis for the acceptance criteria (original design, value required for safety function, and so on)

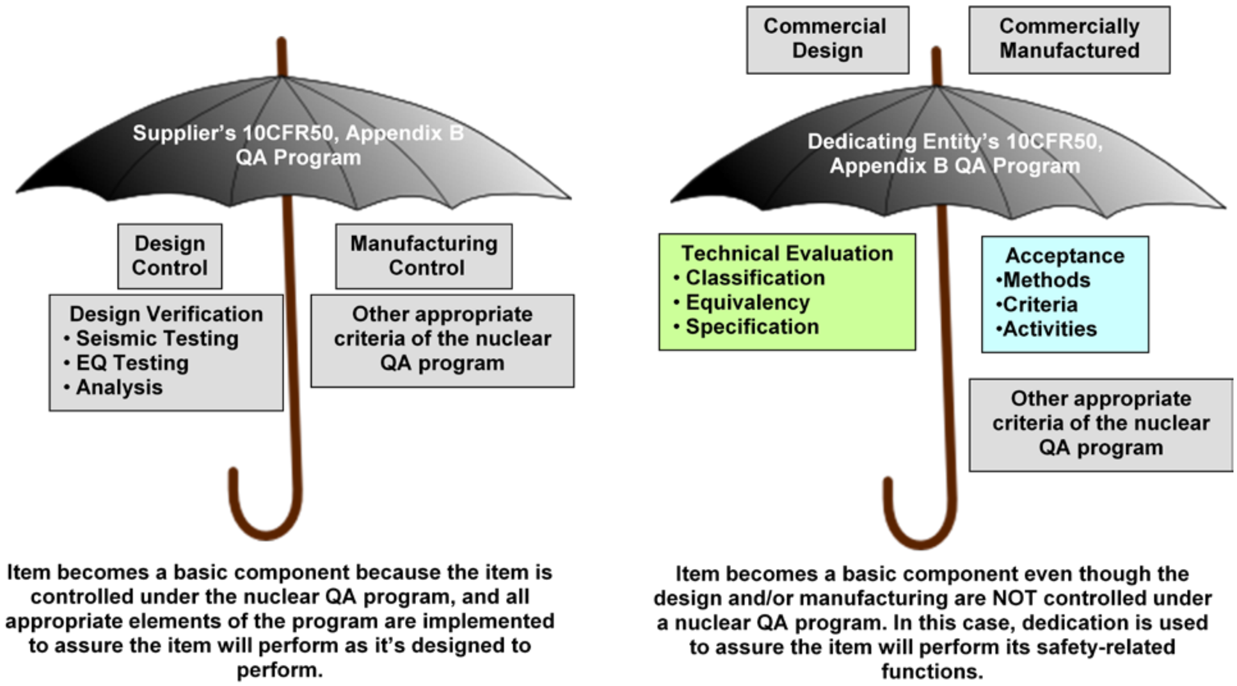


Figure 3-3
Controlling a basic component under 10CFR50, Appendix B (left), versus commercial-grade item dedication (right)

3.4.3 Use of a Technical Evaluation and Acceptance Plan to Document Conformance with Design

As covered in Sections 5.6.4 and 6.4 of this report, a commercial-grade item technical evaluation and acceptance plan may be developed using design information in lieu of a failure modes and effects analysis. This approach provides an effective way to document the basis for acceptance of commercial-grade items.

When design requirements are available to the dedicating entity (including cases where the dedicating entity "owns" or controls the design of the item being dedicated), commercial-grade dedication may be used to accept an item based on demonstrating conformance with applicable design requirements. This process uses a technical evaluation that identifies critical characteristics based on design information and follows an acceptance plan to verify that the item possesses the critical characteristics.

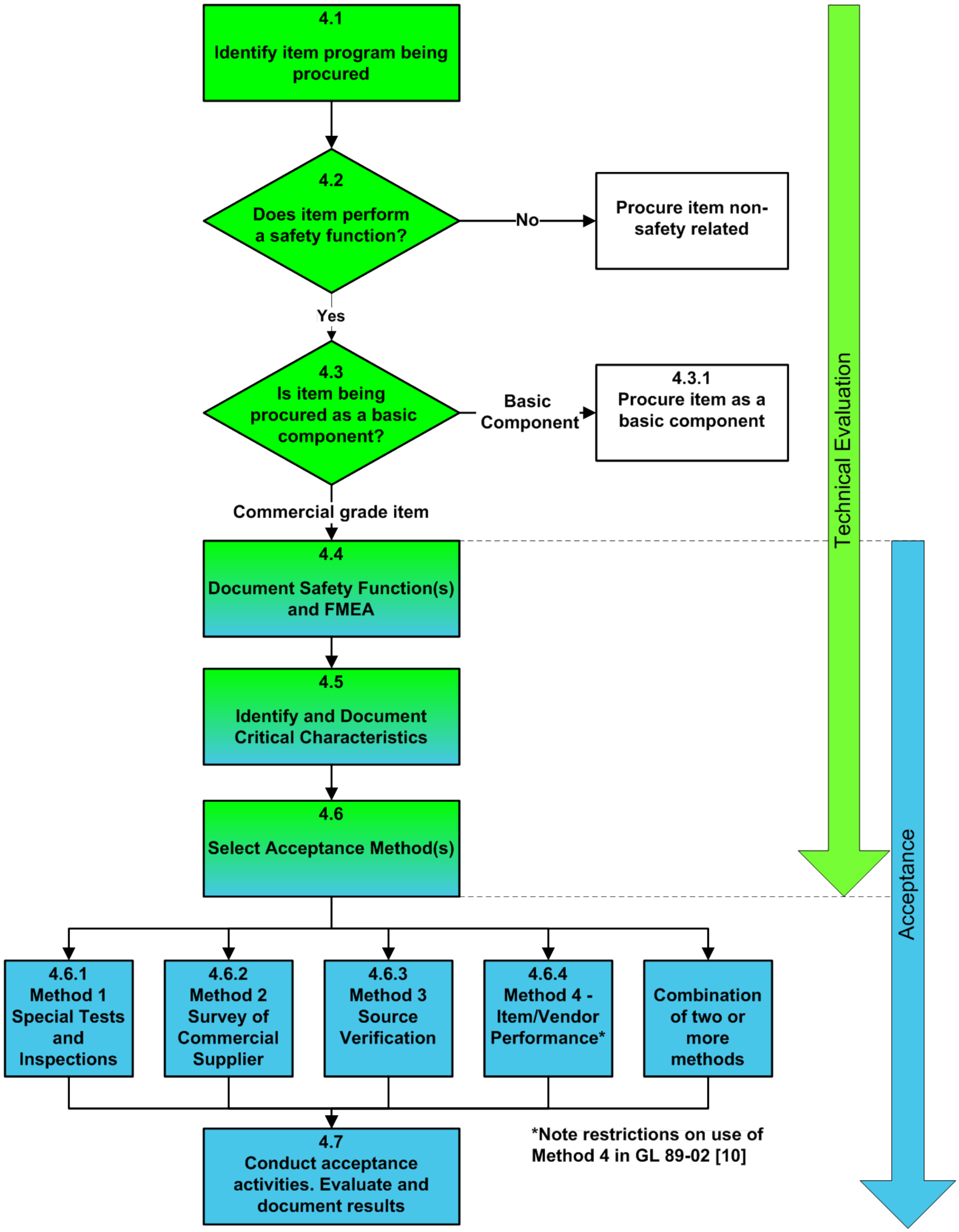
Due to the wide variety of supplier and licensee procurement scenarios, there is no standard format for dedication technical evaluations and acceptance plans.

4
GENERIC TECHNICAL EVALUATION AND ACCEPTANCE PROCESSES

This section reviews the basic process for commercial-grade item dedication that was originally presented in EPRI-5652 [2]. The processes included in Section 5 of this report find basis in and are consistent with the original generic process.

The generic process for acceptance of commercial-grade items is depicted in Figure 4-1. The process in Figure 4-1 includes the following three steps that are typically performed as part of the technical evaluation completed for procurement of any item, including those that are purchased as basic components (safety-related), those purchased as non-safety-related, and those purchased as commercial-grade items and dedicated:

- Step 4.1: identify the item being procured
- Step 4.2: determine if the item performs a safety function
- Step 4.3: determine if the item will be procured as a commercial-grade item



Note: FMEA = failure modes and effects analysis

Figure 4-1
A generic process for commercial-grade dedication

If Steps 4.1–4.3 have been completed prior to starting the commercial-grade item dedication process, they do not need to be repeated during the dedication process. However, it is necessary to document the results of them before proceeding with the steps in the process that are centered on commercial-grade dedication, which include the following:

- Step 4.4: identify and document safety functions and a failure modes and effects analysis
- Step 4.5: identify and document critical characteristics
- Step 4.6: select acceptance methods; develop and document acceptance criteria
- Step 4.7: conduct acceptance activities, and document the results

The flow charts in Section 5 illustrate a basic process that is more process-oriented.

4.1 Identify the Item Being Procured

The item being procured should be clearly identified in the request that prompts the technical evaluation. Identification attributes—such as part number, model number, original shop order number, and drawing number—should be documented as part of the item identification.

4.2 Does the Item Perform a Safety Function?

If the functional safety classification of the item is safety-related, the item performs a safety function and should be procured as a basic component or a commercial-grade item and dedicated for use as a basic component in a safety-related application. However, if the functional safety classification resulted in the item being classified as non-safety-related (including non-safety-related, augmented quality), the item should be procured as a non-safety-related item.

4.3 Is the Item Being Procured as a Basic Component?

An item that has been classified by the licensee or nuclear supplier as safety-related may be procured from a supplier with an audited and approved nuclear QA program as a basic component. Otherwise, the item must be procured commercial-grade and dedicated for use as a basic component in a safety-related application.

4.3.1 Procure Item as a Basic Component

An item that is controlled under a nuclear QA program should be procured as a basic component. Procurement documents would as a minimum require the item to be furnished in accordance with the supplier's QA program that meets the requirements of 10CFR50, Appendix B [7], and would require reporting of defects and noncompliance in accordance with 10CFR21 [4].

4.4 Identify and Document Safety Function(s) and the Failure Modes and Effects Analysis

It is important to clearly and completely document the technical evaluation process. Documenting safety function(s) and the results of the failure modes and effects analysis is necessary to provide a basis that explains the following:

- The logic behind why critical characteristics are selected
- How critical characteristics are related to safety function(s)
- How critical characteristics are related to postulated failure modes and mechanisms that could prevent the item from performing its intended safety-related function(s)

4.5 Identify and Document Critical Characteristics

Identifying critical characteristics is an essential step in the dedication process. Critical characteristics identified during the technical evaluation are verified during the acceptance process to provide reasonable assurance that the item being accepted is capable of performing its intended safety-related function.

Critical characteristics are defined in Revision 2 of 10CFR21 as "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" [4].

When detailed design information is available, critical characteristics for the item can be derived from the design information and specified in the procurement documents. The characteristics are subsequently verified during conduct of acceptance activities. If design information is not available, credible failure modes and mechanisms can be identified through a failure modes and effects analysis or other suitable engineering evaluation based on the safety-related function(s) of the item. The credible failure modes and mechanisms can be used to derive critical characteristics.

Consideration of failure modes can be helpful in identifying the characteristics of an item that are necessary for it to perform its safety function(s). Table 5-4 includes a list of some common failure mechanisms and the critical characteristics that may be selected for verification. The number and nature of the critical characteristics are to be based on the intended safety function(s), application requirements, complexity, credible failure modes and effects, and performance requirements.

Critical characteristics that cannot be effectively verified by inspection and testing after receiving should be verified prior to the item's delivery using Method 2 (described in Section 4.6.2) or Method 3 (described in Section 4.6.3).

4.6 Select Acceptance Methods and Develop and Document Acceptance Criteria

As Figure 4-1 illustrates, the acceptance methods associated with commercial-grade dedication are the following:

- Special tests and inspection (Method 1)
- Commercial-grade surveys (Method 2)
- Source verification (Method 3)
- An acceptable item and supplier performance record (Method 4)

Organizations performing commercial dedication have the latitude to use one or more of these methods (that is, two or more in combination), as appropriate. NRC Generic Letter (GL) 89-02 [10] and Information Notice 2011-01 [32] provide conditions applicable to the use of Methods 2 (commercial-grade surveys) and 4 (acceptable item/supplier performance record).

Any of the EPRI dedication methods can be considered as the primary method, provided that the conditions set forth in GL 89-02 are met. The dedication methods should provide a means to ensure that the commercial-grade item meets the acceptance criteria specified for the selected critical characteristics. The selection of acceptance methods should be based on the type of critical characteristics to be verified. Acceptance of the item will occur upon completion of the selected method(s).

4.6.1 Method 1: Special Tests and Inspections

Special tests and inspections, often referred to as *Method 1*, are performed by the dedicating entity after the item is received to verify selected critical characteristics. The testing and inspections performed should ensure that the selected critical characteristics of the item are verified. Acceptance criteria, including tolerances (when applicable), must be documented to facilitate conduct of acceptance activities when a special test or inspection is specified. Section 7 of this report covers special tests and inspections in more detail.

4.6.2 Method 2: Commercial-Grade Survey

Conducting a commercial-grade survey of a supplier is often referred to as *Method 2*. Supplier audits to verify compliance with a nuclear QA program (such as auditing to the requirements of 10CFR50, Appendix B [7]) do not meet the intent of a commercial-grade survey. A commercial-grade survey is a performance-based assessment of a supplier conducted to determine the adequacy of supplier quality controls that are directly related to ensuring that the critical characteristics of the product being dedicated are acceptable.

A survey plan is developed that identifies the critical characteristics as well as the types of programmatic and process controls that should be assessed during the survey. The controls must be captured in writing by the supplier (for example, in procedures or work instructions) so that they may be referred to in the buyer’s procurement documents. Although no specific format is required, controls are often documented in QA program requirements, procedures, work instructions, testing plans, and so forth. During conduct of the survey, the controls that the supplier has in place are evaluated to determine if they effectively ensure that the item is imparted with the identified critical characteristics. The survey should be performance-based, meaning that in addition to reviewing the documented controls, the supplier's effectiveness in implementing the controls is evaluated.

Controls determined to be effective during the survey are documented in a survey report. The controls are subsequently specified as quality requirements in procurement documents issued to the supplier. The procurement document also requires the supplier to provide certification attesting to the fact that the item was manufactured and tested (as applicable) and is being provided in accordance with the controls specified in the procurement documents. The certification is verified during receipt inspection and maintained as objective evidence that the critical characteristics associated with the specified controls are acceptable.

Section 8 of this report covers commercial-grade surveys in more detail.

4.6.3 Method 3: Source Verification

Source verification, often referred to as *Method 3*, entails verification of critical characteristics during manufacture and testing of the item being procured. Source verifications are typically performed in conjunction with key milestones in the production process or final testing so that important activities can be witnessed by the dedicating entity. Section 9 of this report explores source verification in more detail.

4.6.4 Method 4: Item/Supplier Performance Record

The performance history (good or bad) of the item and supplier is a consideration when determining the use of the other acceptance methods and the rigor with which they are used on a case-by-case basis. Specific regulatory expectations for the use of a supplier's or item's performance record are included in NRC GL 89-02 [10]. The item/supplier performance record is typically used as a factor in the selection of sampling plans when verifying physical and performance characteristics associated with hardware. Section 10 of this report covers item/supplier performance in more detail.

4.7 Conduct Acceptance Activities

Acceptance activities are conducted after the commercial-grade item dedication technical evaluation is complete. Acceptance activities are means by which critical characteristics can be verified. The results of acceptance activities are documented, and a determination is made that the acceptance activities have been successfully or unsuccessfully completed.

4.7.1 Identification and Maintaining Traceability

Once commercial-grade items are accepted for use in safety-related applications, they should be identified and controlled in accordance with the dedicating entity's procedures and processes for maintaining traceability. Traceability provides the means to locate and review associated documentation in the future as well as comply with regulatory requirements, such as reporting of defects and noncompliance. Appendix H provides additional guidance on the topic of traceability.

4.7.2 Indication That an Equivalency Evaluation Is Necessary

If it is indicated during conduct of acceptance activities that the item being dedicated is not the same as the item it is intended to replace (that is, the procurement is an alternative item procurement, not a like-for-like procurement as described in EPRI 1008256 [25]), processes to address control of design, such as equivalency evaluation, modification, or design changes, must be completed prior to completion of acceptance activities. This ensures that the alternative item's design remains suitable for the intended application.

4.7.3 Delegation of Acceptance

In certain situations, all or some acceptance activities may be delegated. This may be necessary when the dedicating entity does not have the necessary test equipment, expertise, or skills necessary to perform the acceptance. When dedication activities are delegated, they must be conducted under the auspices of a QA program that meets the requirements of 10CFR50, Appendix B [7].

4.8 Supplier Dedication Perspectives

The basic process depicted in Figure 4-1 was originally developed from a licensee's perspective. The detailed processes set forth in Section 5 are intended to include discussion from both licensee and supplier perspectives. In addition, Appendix F includes content that is specific to challenges faced by suppliers implementing the commercial-grade item dedication process.

5
COMMERCIAL-GRADE DEDICATION PROCESS

This section expands on the generic technical evaluation process and provides more detailed information for each step of the commercial-grade item dedication process. Activities and steps that are not included in the commercial-grade dedication technical evaluation and acceptance processes are not included in the flow charts. For example, purchasing activities are not included.

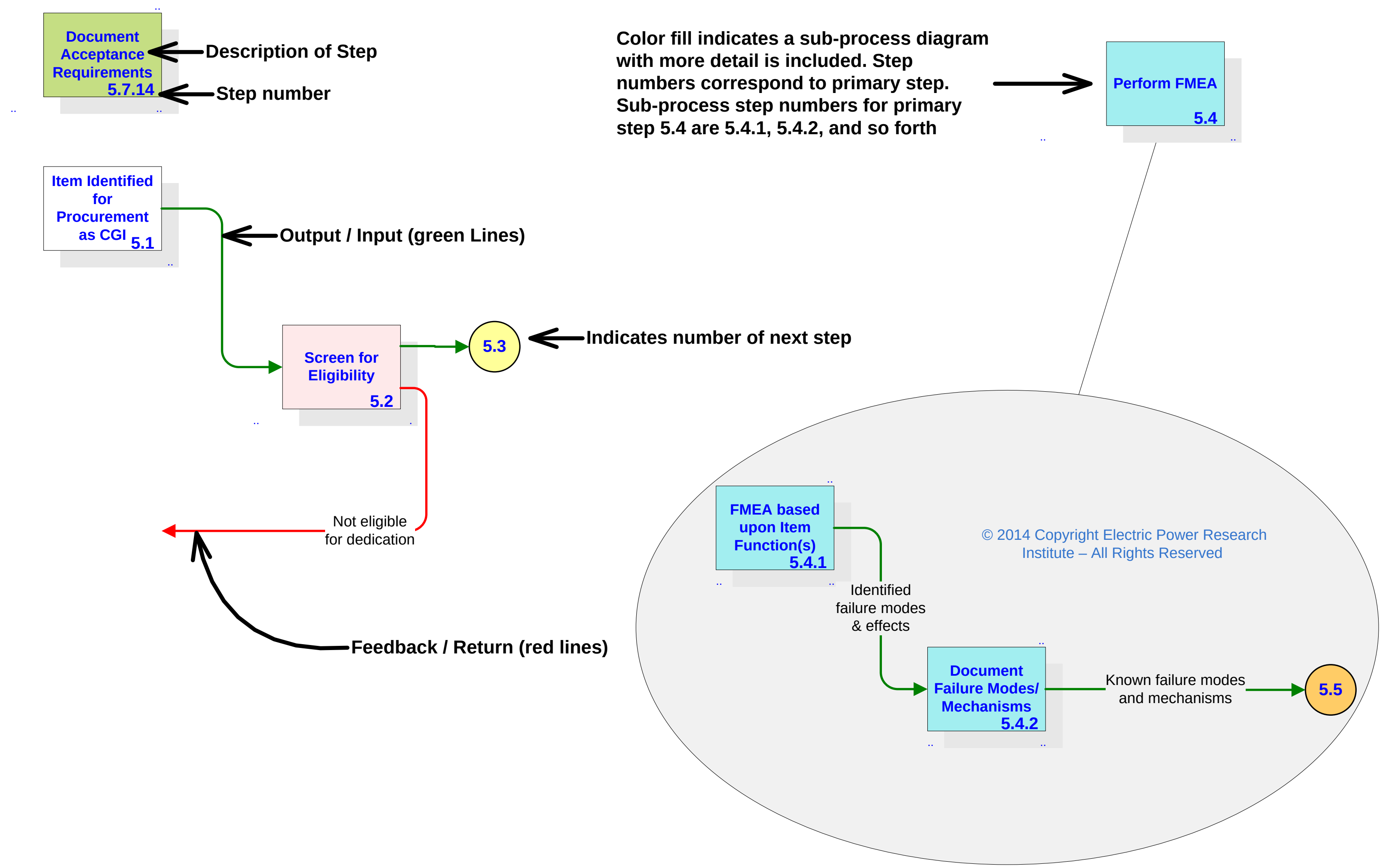
The name of the organization and title of individuals responsible for performing each step may vary for different types of dedicating entities. Steps included in the technical evaluation and acceptance processes should be performed by individuals with appropriate qualifications, experience, and/or training in relevant areas. Responsibilities for performing each step in the dedication process should be defined in appropriate documents.

Figure 5-1 is a key that explains the functions of the various graphic elements used in the subsequent figures in this section. For example, the major steps in the commercial-grade dedication process are depicted as numbered boxes in Figures 5-2 and 5-3. More detailed process maps are included for steps depicted by colored boxes (boxes that are not white or gray). For example, Step 5.2 on Figure 5-2, Screen for Eligibility, is depicted in a pink box. A more detailed (expanded) view of how to screen for eligibility is shown in Figure 5-4 by pink boxes representing Steps 5.2.1–5.2.6. The narrative text following each process map provides information on how to accomplish the map's steps.

Table 5-1 summarizes the process maps included in this report.

Table 5-1
Commercial-grade dedication process maps

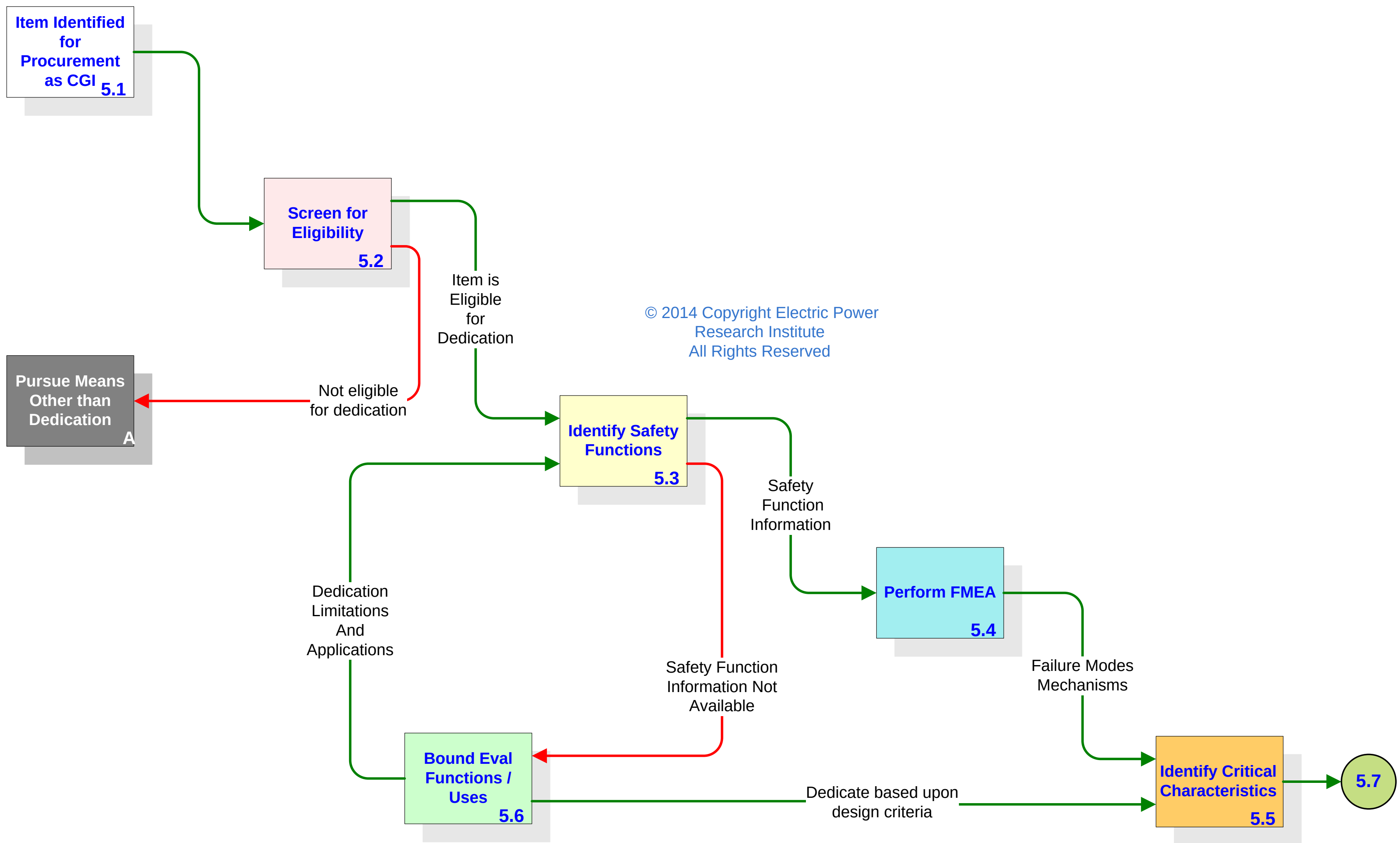
Figure	Page	Content	Major Step(s)	Expanded Steps
5-2	5-5	Overview of commercial-grade item dedication process	5.1–5.6	n/a
5-3	5-6	Overview of commercial-grade item dedication process	5.7-5.13	n/a
5-4	5-15	Screen for eligibility	5.2	5.2.1–5.2.6
5-5	5-21	Identification of safety function	5.3	5.3.1–5.3.3
5-6	5-27	Failure modes and effects analysis	5.4	5.4.1, 5.4.2
5-7	5-30	Identification of critical characteristics	5.5	5.5.1–5.5.4
5-8	5-37	Establishing dedication boundaries when the safety function is unknown	5.6	5.6.1–5.6.5
5-9	5-43	Identification of acceptance methods—Method 1: Special Tests and Inspections	5.7	5.7.1–5.7.7
5-10	5-50	Method 2: Commercial-Grade Survey	5.7	5.7.8–5.7.14
5-11	5-58	Method 3: Source Verification	5.7	5.7.15–5.7.19
5-12	5-64	Method 4: Item/Supplier Performance Record	5.7	5.7.20–5.7.22



Note: FMEA = failure modes and effects analysis; CGI = commercial-grade item

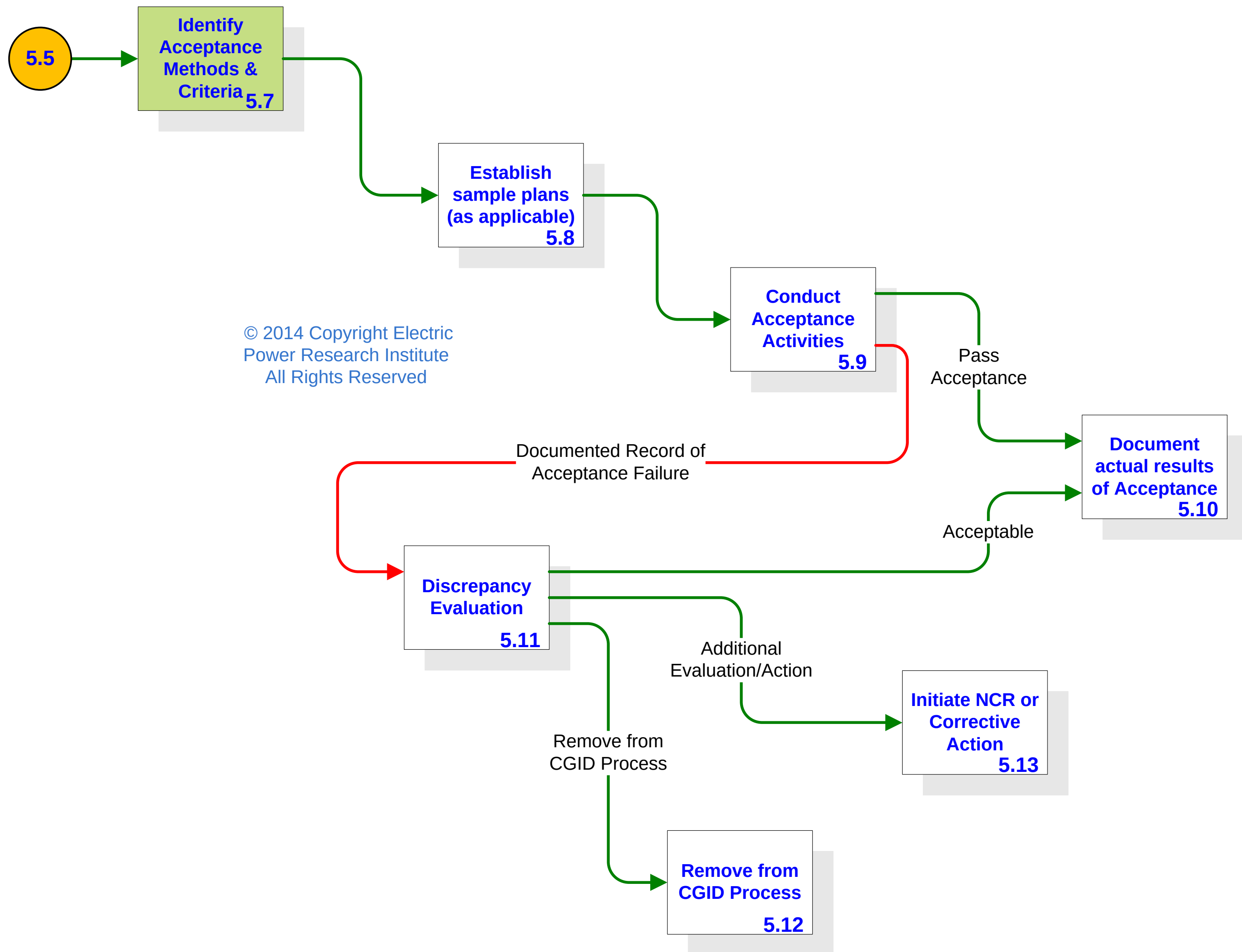
Figure 5-1
Process map key

Green lines represent output and forward movement in the process, whereas red lines represent feedback loops or a return to a previous step. Boxes with colored backgrounds are primary steps for which a more detailed subprocess is included in the report. Subprocess step numbers correspond to the primary step. For example, the step numbers for the subprocesses corresponding with primary Step 5.4 are 5.4.1, 5.4.2, and so forth.



Note: FMEA = failure modes and effects analysis; CGI = commercial-grade item

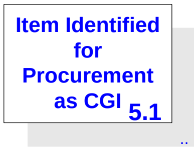
Figure 5-2
Commercial-grade dedication evaluation process (Page 1 of 2)



Note: CGID = commercial-grade item dedication; NCR = nonconformance

Figure 5-3
Commercial-grade dedication evaluation process (Page 2 of 2)

5.1 Step 5.1: Item Identified for Procurement as a Commercial-Grade Item



Description

This step involves identifying what is being considered as a candidate for procurement as a commercial-grade item or service. The candidate will have a functional safety classification of “safety- related” and is intended for use as a basic component. This step may occur during review of new purchase requests or reorder requests.

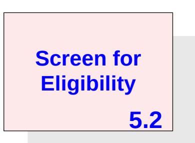
Methodology

Identification of candidates for procurement as commercial-grade items typically involves a search to determine if the item or service can be provided as a basic component by a supplier with an approved QA program that meets the requirements of 10CFR50, Appendix B. When an item intended for use as a basic component is not readily available as a basic component, it becomes a candidate for procurement as a commercial-grade item.

Precautions/Lessons Learned

It may be worthwhile to include third-party qualifiers and suppliers of similar product lines in the search for qualified suppliers in cases where the dedicating entity is not very familiar with the type of item or service being considered. Suppliers who are more familiar with the item or service in question may be aware of other qualified suppliers or procurement options.

5.2 Step 5.2: Determine If the Item or Service Is Eligible for Commercial-Grade Item Dedication



Description

Regulations and other applicable requirements exclude certain types of items from being accepted using the commercial-grade dedication process. This step screens candidates for dedication to determine if they are eligible to be dedicated. If the item is not eligible for dedication, it must be procured as a basic component or otherwise controlled in accordance with a 10CFR50, Appendix B-compliant QA program.

Additional guidance is included in the detailed process for screening for eligibility in Section 5.14, Figure 5-4, and associated Steps 5.2.1–5.2.6.

Methodology

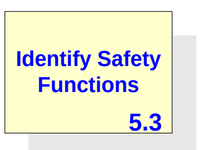
Determine if the item or service falls into a category that cannot be dedicated in accordance with applicable requirements. Additional guidance is included in the text for Steps 5.2.1 and 5.2.2. If the item is not eligible for dedication, other means of procuring the item should be pursued.

Precautions/Lessons Learned

Personnel specifying or approving purchase requirements must be familiar with the definition of a commercial-grade item that is applicable to their facility or activity.

Judicial use of dedication must be imposed when an industry code or standard is the basis for one or more critical characteristics. Dedication is not a substitute for establishing compliance with a code or standard. However, dedication can be used to establish reasonable assurance that an item will perform its intended safety-related function. Therefore, a dedicating entity cannot certify to compliance with a code or standard based on dedication unless all applicable requirements of the specification are verified. A dedicating entity can verify acceptability of certain critical characteristics based on a code or standard as part of the dedication process used to obtain reasonable assurance that the item will be capable of performing its intended safety-related functions.

5.3 Step 5.3: Identify the Safety Functions



Description

Identification of the safety function(s) of the item provides the foundation on which the selection of critical characteristics is based. Identification of safety functions involves identification of end-use applications, determining the safety function of the item in the end-use applications, and clearly documenting the safety functions in the technical evaluation. Additional guidance for identification of safety functions is provided in the detailed process for identifying safety functions in Section 5.15, Figure 5-5, and associated Steps 5.3.1–5.3.3.

Methodology

An evaluation is performed to determine an item’s end-use application(s) and the corresponding safety function(s) that form the basis for the item’s classification as safety-related. Information on safety function is typically included in documents such as the system description and design information, safety analysis reports, procurement technical evaluations, plant compilations (such as Q-lists and critical structures, systems, and components [CSSCs] lists), equipment lists, and enterprise asset management systems (such as Ventyx Asset Suite, Maximo, and SAP).

Dedicating entities without access to application-specific safety function information may need to establish boundaries for the dedication based on a range of intended safety functions as described in Steps 5.6.1–5.6.5.

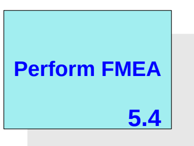
The technical evaluation should include a description of the item's safety-related function(s) as it relates to the boundaries for the dedication or the parent component's safety-related function(s) and functional mode (that is, active and/or passive). A part may have, for example, a safety-related passive functional mode and a non-safety active functional mode. Section 3.2 of EPRI 1008256 [25] provides further guidance on the functional classification of components and parts, and it lists typical component functions in Appendix A. These functions are included in an automated Microsoft Word[1] version of the example forms included in Appendix D of this report.

Precautions/Lessons Learned

The following lessons relate to safety function classification:

- An item may have more than one safety function.
- An item may have safety functions during normal operating conditions and additional safety functions during design basis events for which it is qualified (for example, functions during seismic events and in extreme environmental conditions).
- Documented technical evaluations typically include a summary of the item's intended safety-related functions and end-use applications and should be performed by knowledgeable qualified technical personnel.

5.4 Step 5.4: Perform a Failure Modes and Effects Analysis



Description

Information about the item's safety function(s) is used to postulate credible failure modes of an item in its operating environment. The effects of these failure modes on the safety function(s) are considered in the technical evaluation for the selection of the critical characteristics.

Additional detail on the failure modes and effects analysis is provided in the detailed failure modes and effects analysis process in Section 5.16, Figure 5-7, and associated Steps 5.4.1 and 5.4.2.

Methodology

Descriptions of the item's credible failure modes in its operating environment and the effects of these failure modes as they relate to the parent component's safety-related function(s) are documented in the technical evaluation.

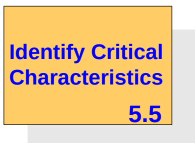
[1] Word is a registered trademark of Microsoft Corp.

Precautions/Lessons Learned

Failure modes and effects analyses should be performed by individuals with appropriate technical qualifications, experience, and/or training.

Use of failure modes and effects analysis should be documented in the technical evaluation with sufficient detail to ensure that the analysis and connection between safety functions and critical characteristics are clearly described.

5.5 Step 5.5: Identify Critical Characteristics



Description

Design information and/or knowledge ascertained during the failure modes and effects analysis of how the item could fail to perform its safety functions are used to identify appropriate critical characteristics that, once verified, will provide reasonable assurance that the item being dedicated is capable of performing its intended safety function(s). The critical characteristics selected for verification are documented, along with an explanation of how the critical characteristics relate to their associated safety functions.

Additional detail on identification of critical characteristics is provided in the detailed process for identification of critical characteristics in Section 5.17, Figure 5-8, and associated Steps 5.5.1–5.5.4.

Methodology

The characteristics necessary to provide reasonable assurance that the item being dedicated will be capable of performing its intended safety function are selected.

Identification of critical characteristics involves four basic steps. First, the characteristics necessary to preclude failure of the item to perform its safety functions are determined. Second, a set of critical characteristics to be verified is identified. Third, the set of critical characteristics identified is reviewed to ensure that they are adequate to provide reasonable assurance that the item being dedicated will be able to perform each intended safety function. If it is not, additional critical characteristics are identified. Finally, the critical characteristics selected are clearly documented in the technical evaluation along with the basis for their selection.

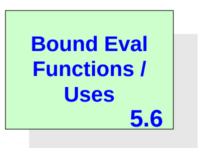
As an alternative to identification of critical characteristics based on known safety functions and a failure modes and effects analysis, critical characteristics can be identified using the design criteria, if they are available. For example, when the dedicating entity does not know the end-use applications for the item and does not establish specific boundaries for the dedication, **all** of the original design requirements and allowable tolerances are critical characteristics that must be verified. For this reason, it is advantageous to first establish a scope of use and perform a failure modes and effects analysis based on the scope of use so that the bounding conditions are justified. The basic premises in this case are as follows: if the suitability of the item's design was previously established through design and qualification activities and the items are verified as meeting all of the original design requirements, the item will be capable of performing the design functions (including safety functions) for which the suitability of its design was originally established.

Section 6 of this report provides additional guidance concerning critical characteristics. Section 13 presents the concept of reasonable assurance in more detail. Table C-1 in Appendix C provides potential sources of information that may be used to identify critical characteristics.

Precautions/Lessons Learned

Identification of critical characteristics should be performed by individuals with appropriate technical qualifications, experience, and/or training. Identification attributes are an important part of the acceptance process and may be part of the critical characteristic verification process. However, care should be taken to ensure that the dedication is never based solely on verification of identification attributes.

5.6 Step 5.6: Bound Evaluation Functions/End Uses



Description

In cases where the dedicating entity does not have information about the item's end use(s) or safety function(s), the dedicating entity must define the boundaries of the dedication technical evaluation and acceptance plan. The purpose of bounding the dedication evaluation is for the dedicating entity to clearly establish the scope of the technical evaluation by identifying the suitable end uses of the item along with applicable safety functions and any limiting conditions. This approach can be applied to dedication technical evaluations for both generic and specific applications.

Specific application items are generally engineered items that may be installed only in specific applications (that is, specific SSCs). Generic application items are typically commodity items that have a wide range of end-use applications in the plant.

Successful implementation of the technical evaluation and acceptance plan will provide reasonable assurance that the item being dedicated is capable of performing the safety functions identified (bounded by the technical evaluation and acceptance plan).

Additional detail on bounding evaluation functions and end uses is provided in the detailed process for bounding evaluation functions and end uses in Section 5.18, Figure 5-9, and associated Steps 5.6.1–5.6.5.

Methodology

The end uses and functions on which the technical evaluation and acceptance plan are based are clearly documented.

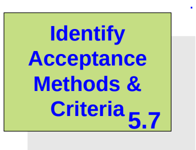
The dedicating entity may bound the dedication based on information provided by the customer, the item's intended design functions and design requirements, or by identifying the specific uses and safety function(s) on which the technical evaluation and acceptance plan are based.

Precautions/Lessons Learned

IN 2011-01 suggests that "the purchaser or licensee should review and approve the commercial-grade dedication technical evaluation and acceptance plan before the dedication of the item" [32]. Review may be requested by either the purchaser or the dedicating entity.

When the dedicating entity is not provided with end-use application and safety function information, the scope of the dedication technical evaluation and acceptance plan must include end uses and safety functions that can be postulated for the item or service being dedicated. Clear identification of end-use applications and safety functions by the licensee or organizations responsible for design can reduce the scope, lead time, and cost of a dedication and acceptance plan.

5.7 Step 5.7: Identify Acceptance Methods and Criteria



Description

This step involves identification of acceptance methods that will be used to verify the critical characteristics identified in the technical evaluation. The four acceptance methods used in commercial-grade item dedication find their basis in 10CFR50, Appendix B, Criterion VII, which states:

> Measures shall be established to assure that purchased material, equipment, and services, whether purchased directly or through contractors and subcontractors, conform to the procurement documents. These measures shall include provisions, as appropriate, for source evaluation and selection, objective evidence of quality furnished by the contractor or subcontractor, inspection at the contractor or subcontractor source, and examination of products upon delivery. [7]

Additional detail on identification of acceptance methods and criteria is provided in the detailed process Section 5.19, Figure 5-10, and associated Steps 5.7.1–5.7.7 (Method 1); Figure 5-11 and associated Steps 5.7.8–5.7.14 (Method 2); Figure 5-12 and associated steps 5.7.15–5.7.19 (Method 3); and Figure 5-13 and associated steps 5.7.2–5.7.22 (Method 4).

Table 5-2 identifies the four acceptance methods and the corresponding regulatory basis.

Table 5-2
Commercial-grade item dedication acceptance methods

Corresponding Dedication Acceptance Method	Measure Cited in Criterion VII of 10CFR50, Appendix B [7]
Method 1: Special Tests and Inspections	Examination of products on delivery
Method 2: Commercial-Grade Survey	Source evaluation and selection
Method 3: Source Verification	Inspection at the contractor or subcontractor source
Method 4: Item/Supplier Performance Record	Objective evidence of the quality furnished by the contractor or subcontractor

Methodology

An effective method of verification is selected for each critical characteristic. Factors to consider when selecting verification methods include the extent of verification necessary and the preferred time to verify the characteristic (during manufacture, during receiving, and so forth). The degree of verification should be commensurate with the relative importance of the critical characteristic. It may be necessary to review the basis for selection of a critical characteristic in order to determine an appropriate acceptance method.

Relationships between characteristics may be considered. In certain situations, verification of one characteristic may provide some assurance of another characteristic. For example, verification of hardness may provide some assurance of a related property, such as tensile strength.

Method 1: Special Tests and Inspections

Special tests and inspections include activities conducted after receipt of the items at the dedicating entity's facility. These tests can take place as part of the receiving process and include post-installation tests that occur after the item has been installed in its intended end-use application. Special tests and inspections are typically appropriate in the following situations:

- Items being dedicated are previously manufactured, off-the-shelf items.
- It is possible to purchase additional quantity if necessary to allow for destructive testing sampling plans.
- Equipment (including specialized jigs or fixtures) necessary to perform the tests and inspections are available at the dedicating entity's facility.
- Personnel qualified to conduct the tests and inspections are available to the dedicating entity.
- Items may be purchased from different suppliers (as is the case with commodity-type items, such as piping, tubing, gaskets, lubricants, sealants, coatings, strut, and structural steel).
- The dedicating entity is not able to obtain rights of access to the supplier's facilities.

Method 2: Commercial-Grade Survey

A commercial-grade survey is a performance-based assessment of a supplier conducted to determine the adequacy of supplier quality controls that are directly related to ensuring that the critical characteristics of the product being dedicated are acceptable.

The survey examines the supplier's documented controls as well as the supplier's ability to implement those controls for the specified critical characteristics. In the event that the survey determines that the controls are effectively implemented, the dedicating entity can impose the specific documented controls examined as requirements in future purchase orders and requires a supplier certification to the controls. A commercial-grade survey is typically appropriate in the following situations:

- The supplier is known to have an effective commercial QA program (for example, ISO 9001 [77]).
- Repeat purchases of similar items will be made from the supplier.
- Large quantities of items are being procured on a continuing basis (as may be the case when the supplier is supporting new construction).

Method 3: Source Verification

Source verification is an examination of the items at the supplier's facility by the dedicating entity that occurs prior to shipment. Source verification can be used to provide oversight at various points in the manufacturing process, witness inspections, witness testing, examine technical work, and so forth. Source verification is typically appropriate in the following situations:

- The supplier is providing a new item or an item fabricated to unique or custom specifications, as opposed to an off-the-shelf item.
- It is important to minimize the risk that items will be rejected after delivery or a later point that could have a severe impact on schedule.
- Operating experience, performance, or quality problems in the past indicate that exposure to manufacturing processes may help better understand and resolve issues and prevent them in the future.
- Fabrication, testing, or adjustment of the item is complex and/or requires specialized equipment and skills.
- The only opportunity for the dedicating entity to verify certain characteristics is during the manufacturing process.
- Time constraints do not permit verification of the supplier's capabilities via a commercial-grade survey.
- The equipment or qualified staff required to perform necessary verifications is available at the supplier's facility.

- The dedicating entity is in the process of establishing a documented record of the supplier's performance and ability to meet specification requirements.
- Future procurement of similar items is not anticipated.

Method 4: Item/Supplier Performance Record

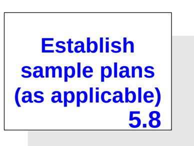
The use of an item/supplier performance record involves a documented record of historical evidence indicating acceptable results as a basis for accepting an item or supplier. Method 4 is typically used in combination with another acceptance method to reduce the sample size or frequency of oversight activities. Using an item/supplier performance record is typically appropriate in the following situations:

- Documented indication of the supplier's past performance can be used as a basis for selecting an appropriate sampling plan.
- Documented indication of an item's past performance can be used as a basis for selecting an appropriate sampling plan.
- Broad industry or other industry feedback is available to develop a documented basis for accepting certain characteristics based on successful performance in the past.
- The dedicating entity is not able to obtain rights of access to the supplier's facilities.

Combination of Two or More Methods

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

5.8 Step 5.8: Establish Sampling Plans (as Applicable)



Description

Sampling is particularly useful when performing Method 1 tests and inspections. It may be possible to implement a sampling plan that may be used in lieu of testing or inspecting 100% of the items received.

Methodology

Sampling for a particular critical characteristic involves defining the lot to be sampled, evaluating applicable factors to determine the homogeneity of the lot, and selecting a sampling plan that is consistent with the homogeneity of the lot formation.

Justification for use of sampling should be clearly documented in the technical evaluation. Additional guidance on sampling plans is included in EPRI TR-017218-R1, *Guideline for Sampling in the Commercial-Grade Item Dedication Process* [23].

Precautions/Lessons Learned

The basis for selection and use of a sampling plan specified should be clearly documented and available for independent review, and it must be based on established sampling methods.

5.9 Step 5.9: Conduct Acceptance Activities

Description

This consists of conducting the verification activities specified in the acceptance plan.

Methodology

Acceptance activities are performed in accordance with the acceptance plan and the dedicating entity's applicable procedures and processes. Guidance concerning each acceptance method is included in the following sections:

- Section 7, "Method 1: Special Tests and Inspections"
- Section 8, "Method 2: Commercial-Grade Survey"
- Section 9, "Method 3: Source Verification"
- Section 10, "Method 4: Item/Supplier Performance Record"

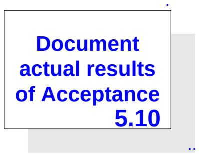
When an item fails to meet acceptance criteria, the discrepancy is documented and evaluated, as discussed in Step 5.11.

Precautions/Lessons Learned

Any required changes or revisions to the specified acceptance method or criteria shall be subject to the same level of review and approval as the original acceptance plan prior to implementation.

NRC IN 2011-01 [32] describes situations in which the dedicating entity changed acceptance methods and criteria during conduct of the acceptance activities without prior revision of the technical evaluation and acceptance plan.

5.10 Step 5.10: Document the Actual Results of Acceptance Activities



Description

The results of the acceptance process are documented to provide objective evidence of acceptance activities. Documentation should be complete enough for an individual who was not involved in the acceptance activities to gain a thorough understanding of the actual results and the acceptability of the results.

Responsibility

Individuals responsible for conducting acceptance activities are responsible for documenting the results.

Methodology

Acceptance activities should be performed in accordance with documented guidance that includes an acceptance plan. Results should be documented in the appropriate format (such as hard copy or an approved information system). Inspection and test results should be recorded against specified acceptance criteria. Actual values should be recorded when calibrated measuring and test equipment (M&TE) is required instead of an accept-versus-reject determination. For example, if the required range is 2.5–2.7 in. (63.5–68.6 mm), a measured value, such as 2.6 in. (66.0 mm), is expected to be recorded rather than “pass.” The identification and expiry date of the calibrated M&TE used should also be recorded.

All of the acceptance activities specified in the technical evaluation must be successfully completed prior to accepting an item for use. The results of acceptance activities should be documented and clearly identified as acceptable or not acceptable. Documentation should be clear and understandable enough to ensure that another person with similar training and qualification can easily arrive at the same conclusions included in the evaluation and acceptance package.

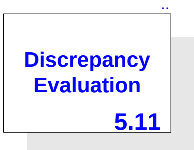
Some acceptance activities, such as commercial-grade surveys of the supplier or source verification, may be conducted well in advance of receiving the item. In these cases, it is important to ensure that documentation attesting to the successful completion of these activities is complete, traceable to the dedication technical evaluation, and retrievable.

Precautions/Lessons Learned

Lessons learned relating to the documentation of actual results of acceptance activities include the following:

- Records must be identifiable, retrievable, and traceable to the equipment being dedicated.
- Prior to concluding that an item is acceptable to perform its safety function, the dedicating entity should (as applicable) determine the following:
  - That damage was not sustained during shipment and handling
  - That the item has satisfied the specified acceptance criteria for the identified critical characteristics
  - That specified documentation was received and is acceptable
- Documented records of the acceptance should be easily retrievable and linked to other elements of the procurement (such as the request for proposal, purchase order, technical evaluation, associated nonconformances, deviations, and corrective actions). Although it is not required that all elements of a completed dedication be stored in the same location, they should be easily retrievable for review on demand.
- In the case of commercial-grade surveys, it is important to verify that there is documented evidence that indicates that the survey is current (has not expired) at the time of its use as a basis for acceptance.

5.11 Step 5.11: Discrepancy Evaluation



Description

When a commercial-grade item fails to meet its acceptance criteria during the acceptance process, the item is rejected. The cause of the failure should be documented and evaluated to determine if other like commercial-grade items will exhibit the same nonconformance. This generally is not a problem because all of the previously accepted items have been tested for the same characteristics. The reporting requirements of 10CFR Part 21 do not apply if the failed item was never accepted as a basic component. EPRI report TR-017218-R1 [23] includes guidance on dealing with a procured lot when a nonconformance is discovered.

Failures of commercial-grade items during the acceptance process should be tracked and trended to determine if other controls are necessary in the acceptance process or to performance history for vendors. The methods for controlling, tracking, and evaluating failed items should be documented in the user's quality procedures because commercial-grade acceptance is a safety-related activity controlled under the user's 10CFR50, Appendix B [7] program.

Responsibility

Receipt inspection and test personnel are responsible for identifying, segregating, and controlling items not meeting specified acceptance criteria. Receipt inspection and test personnel are responsible for clearly documenting the discrepant results to responsible engineering personnel for disposition. Engineering personnel are responsible for evaluating and dispositioning the discrepancy.

Evaluation typically results in the following:

- A determination that the item is acceptable and a continuation of the dedication process in accordance with Step 5.10.
- The need for additional evaluation or action, such as reporting for operating experience, in accordance with Step 5.13.
- Confirmation that the item is unacceptable and removal of the item from the dedication process in accordance with Step 5.12.

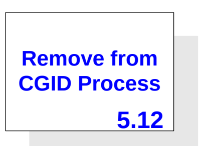
Methodology

The responsible organization should perform a documented evaluation of the discrepant condition based on the safety function of the item and other specified requirements. Disposition should be provided to appropriate personnel for implementation.

Precautions/Lessons Learned

The results and basis of the decisions for discrepant items must be clearly documented and available for independent review.

5.12 Step 5.12: Remove from Commercial-Grade Dedication Process



Description

Items determined to be unacceptable are removed from the dedication process.

Methodology

Unacceptable items are removed from the dedication process. Examples of removal would include returning the items in exchange for a replacement and disposing of the items.

5.13 Step 5.13: Initiate Nonconformance or Corrective Action

Initiate NCR or Corrective Action 5.13

Description

An appropriate reporting mechanism is used to document identification and evaluation of discrepant (potentially unacceptable) items. These reports are typically known as *receiving discrepancies*, *nonconformances*, or *corrective action reports*.

Methodology

Discrepant items are documented and evaluated in accordance with the dedicating entity's applicable procedures and processes. In certain cases, it is required or recommended that discrepant items be reported as operating experience to prevent similar incidents from impacting safety. Screening is typically an integral part of procedures for addressing nonconforming items or corrective action.

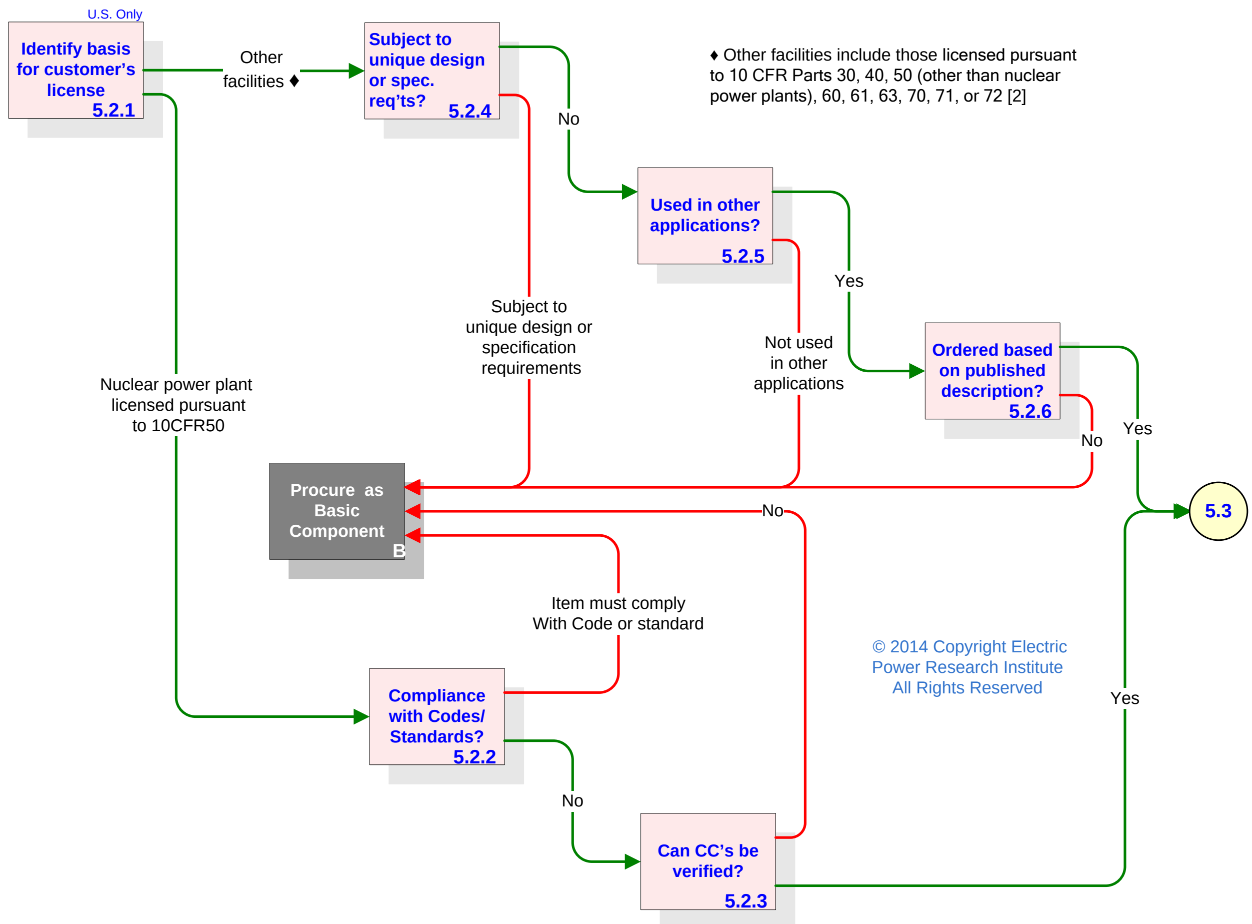
Precautions/Lessons Learned

The following lessons learned relate to initiating nonconformances or corrective actions:

- Nonconformance report disposition should be clearly documented, including the basis for the disposition of any engineering evaluations performed. Dispositions of "use-as-is" should clearly show that the item meets the required critical characteristics. The nonconformance report and resulting disposition should be traceable to the items involved and retrievable for third-party review.
- Although an item identified as discrepant prior to acceptance as a basic component may not be reportable under 10CFR21 [4], an evaluation should be performed to determine if it is reportable in accordance with other requirements or good practices.
- Items suspected to be fraudulent should be evaluated for reporting to applicable industry databases, such as operating experience and commercial databases.

5.14 Screen for Eligibility Process: Steps 5.2.1–5.2.6

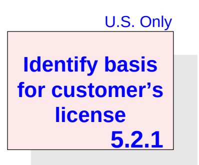
The process depicted in Figure 5-4 is used to determine if the item or service is eligible for commercial-grade dedication (subprocess).



Note: CC = critical characteristic

Figure 5-4
Determine if the item or service is eligible for commercial-grade dedication

Step 5.2.1: Identify Basis for Customer's License



Description

In the United States, the basis for the end user's license to operate a facility must be identified to determine eligibility for dedication. This process may not apply in jurisdictions outside of the United States.

Methodology

Eligibility for dedication in the United States is based on the definition of *commercial-grade item* in 10CFR21 [4], which specifies different criteria for nuclear power plants licensed pursuant to 10CFR, Part 50, than it does for other facilities and activities licensed pursuant to 10CFR30, 40, 50 (other than nuclear power plants), 60, 61, 63, 70, 71, or 72.

In cases where the dedicating entity is not the end user, the purchaser is responsible for providing the dedicating entity with the criteria applicable to the licensed facility. If the facility that will be using the item is a nuclear plant licensed pursuant to 10CFR, Part 50 (or has applied for and received an exemption to the requirement that commercial-grade items must meet definition [2] of a commercial-grade item included in 10CFR21 [4]), proceed to Step 5.2.2. If the facility is not licensed pursuant to 10CFR, Part 50 (and has not applied for and received an exemption to the requirement that commercial-grade items must meet definition [1] of a commercial-grade item included in 10CFR21 [4]), proceed to Step 5.2.4.

Step 5.2.2: Is the Item Required to Comply with Codes and/or Standards?

Description

The purpose of this step is to determine if the item proposed for dedication must be certified as being in full compliance with a Code or standard.

Dedication is a process used to accept an item by establishing reasonable assurance that it will perform its safety function. Dedication is not intended for use as a basis for providing certification to a Code or standard. Absolute assurance of compliance with all applicable requirements is necessary to certify an item’s compliance to a Code, such as ASME Section III [78]. Dedication is not appropriate in such cases because reasonable assurance that an item will perform its safety function (obtained through the dedication process) does not adequately establish compliance with the Code requirements. When certification to the appropriate Code is not required, dedication can provide reasonable assurance that an item possesses certain characteristics, such as tensile or yield strength, that are sufficient to satisfy its safety function. In such cases, the specified code or standard may be used to determine acceptance criteria.

Simple items that have limited characteristics regardless of their end use may be dedicated for generic applications.

Methodology

Sources of information pertaining to the item or service being screened for eligibility are identified and reviewed to determine if compliance with a specification is required. Possible sources of information include the following:

- Original purchase orders and purchase specifications
- Operating plant/system design information relative to end-use application
- Drawings and bills of materials provided with original equipment
- Original manufacturing information, such as drawings and tolerances
- Original equipment design information
- For replacement items, other applicable information obtained from entities that were involved in the original procurement, such as the original equipment manufacturer (OEM), original equipment supplier (OES), NSSS, or licensee

If absolute assurance of compliance with all applicable requirements of a code or standard is required, the item should be procured as a basic component. If not, and it is possible to dedicate the item based on intended end-use applications, proceed to Step 5.2.3.

If adequate information is not readily available, the following other options exist to obtain information that will help determine if an item can be dedicated:

- Facility visit. Suppliers may be able to make information available if the requesting party visits their facility.
- Purchase the information. Suppliers may agree to supply the information if the requester agrees to purchase it.
- Nondisclosure/release agreement. Suppliers may release information if the requester signs an agreement specifying the terms of use.
- Reverse engineering. An evaluation using reverse engineering techniques, such as testing, research of codes and standards, and inspection, may be performed to obtain the information requested.

Precautions/Lessons Learned

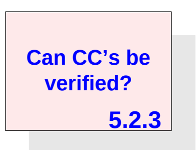
The following lessons learned apply to the determination of whether an item is required to comply with codes or standards:

- Dedication is not intended to be used as an alternative means of providing certification to a code or standard. Establishing that all applicable requirements of the specification are met is a prerequisite to providing certification to the specification.
- Dedication is an acceptance process based on reasonable assurance that an item can perform its intended safety-related functions. In contrast, certifying an item to a code or standard requires absolute assurance that the item meets all requirements of the specification.

Therefore, an item cannot be dedicated to meet a code or standard. Meeting a code, such as ASME Section III, or standard, such as an ASTM material specification, is a go/no go proposition. Assurance must be 100% to certify to a code or standard; reasonable assurance is not appropriate in such cases.

- It is not permissible to use sampling plans intended for use in commercial-grade dedication in lieu of more stringent sampling requirements delineated in codes and standards during the process of establishing compliance with a code or standard.
- As discussed in Section 3.4.1, controlling an item under a 10CFR50, Appendix B–compliant [7] QA program would be the method used by ASME QSC or certificate of authorization (N certificate) holders to upgrade unqualified source material in accordance with their Code-compliant QA programs and applicable Code requirements (for example NCA-3855.5). In this case, dedication is not required because the certificate holder satisfies the requirements of 10CFR50, Appendix B, through compliance with the requirements of the ASME Code and accepts responsibility for reporting of defects and noncompliance in accordance with the requirements of 10CFR21 when providing the material as a basic component.

Step 5.2.3: Can Critical Characteristics Be Verified?



Description

Verification of all critical characteristics is necessary to successfully complete dedication. For some items, verification of critical characteristics involves activities such as tests, inspections, and checks conducted during the manufacturing process. In some cases, these tests, inspections, and verifications can be accomplished during the dedication process through commercial-grade surveys or source verification. However, it may not always be possible to verify these types of critical characteristics during the dedication process or through testing or inspection performed on a finished product (that is, after manufacturing is complete). If the verifications cannot be performed, commercial-grade dedication should not be used, and the item must be purchased as a basic component or otherwise controlled in accordance with a 10CFR50, Appendix B–compliant QA program.

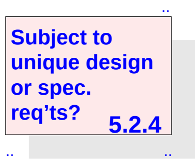
Methodology

The objective of this decision is to determine if one or more critical characteristics cannot be verified during the dedication process. It is important to consider that in addition to special tests and inspections after receipt, a commercial-grade survey or source verification can be used to verify critical characteristics during the manufacturing process.

Precautions/Lessons Learned

A fair amount of advance planning and inquiry (such as determining if a manufacturer will permit a survey or source verification) may be necessary to answer this question in certain cases.

Step 5.2.4: Is the Item Subject to Unique Design or Specification Requirements?



Description

This step involves determining if the item is subject to design or specification requirements that are unique to the facility for which the item is being dedicated. One example would be a component that must be constructed and certified in accordance with ASME Section III, Rules for Construction of Nuclear Facility Components [78].

Methodology

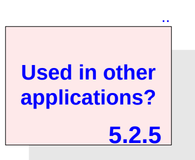
When applied to facilities and activities licensed pursuant to 10CFR Parts 30, 40, 50 (other than nuclear power plants), 60, 61, 63, 70, 71, or 72, one of the three criteria for consideration as a commercial-grade item is that the item not be subject to design or specification requirements that are unique to those facilities or activities [4].

Review applicable design requirements and specifications to determine if a unique specification is applicable. If a unique specification is applicable, the item must be procured as a basic component. If unique specifications are not applicable, proceed to Step 5.2.5.

Precautions/Lessons Learned

Certain facilities and activities licensed pursuant to 10CFR30, 40, 50 (other than nuclear power plants), 60, 61, 63, 70, 71, or 72 may have applied for an exemption to the requirement that items must meet definition (2) of a commercial-grade item included in 10CFR21 [4].

Step 5.2.5: Is the Item Used in Other Applications?



Description

This step involves determining if the item is used in applications other than nuclear power facilities or activities. An example of an item not used in other applications would be a system, component, or part thereof designed specifically for use in a nuclear facility, for example, a nuclear fuel assembly or control rod drive unit.

Methodology

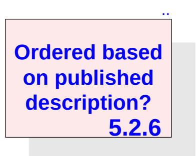
When applied to facilities and activities licensed pursuant to 10CFR Parts 30, 40, 50 (other than nuclear power plants), 60, 61, 63, 70, 71, or 72, one of the three criteria for consideration as a commercial-grade item is that the item be used in applications other than those facilities or activities [4].

Review available information about the item/service to determine if it is used in applications other than nuclear power facilities and activities. In some cases, it may be necessary to request additional information from the supplier. If the item is used in applications other than nuclear power, proceed to Step 5.2.6. If the item is not used in other applications, the item must be procured as a basic component.

Precautions/Lessons Learned

Certain facilities and activities licensed pursuant to 10CFR30, 40, 50 (other than nuclear power plants), 60, 61, 63, 70, 71, or 72 may have applied for an exemption to the requirement that items meet the second definition of a commercial-grade item included in 10CFR21 [4].

Step 5.2.6: Is the Item Ordered Based on the Published Description?



Description

This step involves determining if the item can be ordered from the manufacturer or supplier on the basis of specifications set forth in the manufacturer's published product description (for example, a catalog).

Methodology

When applied to facilities and activities licensed pursuant to 10CFR Parts 30, 40, 50 (other than nuclear power plants), 60, 61, 63, 70, 71, or 72, one of the three criteria for consideration as a commercial-grade item is that the item be ordered from the manufacturer/supplier on the basis of specifications set forth in the manufacturer's published product description (for example, a catalog) [4].

Review the manufacturer's published product information to determine if the item can be ordered based on it. If the item is ordered based upon the manufacturer's published product description, proceed to Step 5.3.1. If the item cannot be ordered based on the manufacturer's published product description, the item must be procured as a basic component.

5.15 Identify Safety Functions Process: Steps 5.3.1–5.3.3

The process depicted in Figure 5-5 is used to identify the safety functions of the item being dedicated.

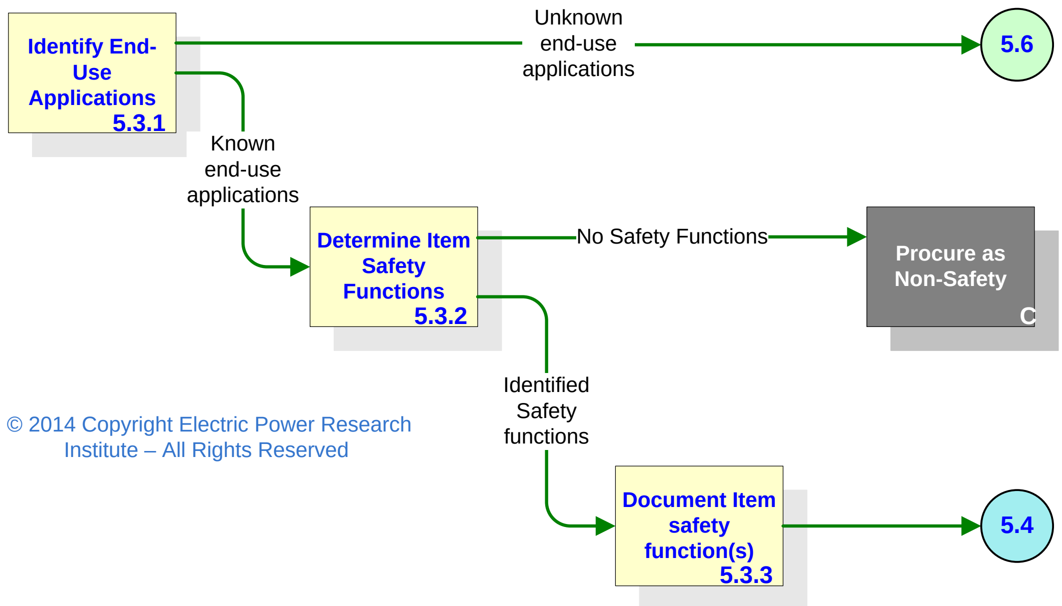
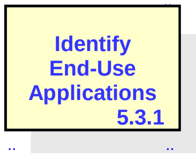


Figure 5-5
Identification of safety functions

Step 5.3.1: Identify End-Use Applications



Description

Identification of the end-use applications for an item is a prerequisite to determining the safety function(s) that the item will be required to perform during normal and design basis event conditions.

In some cases, technical evaluations are based on a known end use or set of end uses. Examples are technical evaluations specific to one or more applications (equipment tag numbers) documented in the evaluation as well as technical evaluations based on a known set of end uses. Although specific tag numbers may not be known, the scope of end uses can be identified based on knowledge of the facilities and equipment types for which they are intended, existing design documents and specifications, and so forth. In other cases, technical evaluations are performed without knowledge of specific end-use applications or even a range of end-use applications. In these cases, the technical evaluation is based on a set of bounded conditions defined by the dedicating entity.

Typically, technical evaluations based on bounded conditions involve identification of a larger set of design characteristics and verification of a larger set of critical characteristics to provide reasonable assurance that the item will perform as designed within the set of bounded conditions established.

If the technical evaluation is specific to one or more end uses documented in the evaluation, proceed to Step 5.3.2 to determine the safety function(s). If specific end-use applications are not known, proceed to Step 5.6.1 to establish a set of bounded conditions on which the dedication will be based.

Methodology

This step may involve gathering original specifications, design information, and design requirements pertaining to the item or service being dedicated. The following information is useful:

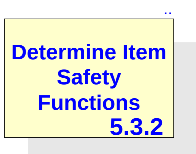
- Original purchase orders and purchase specifications
- Operating plant/system design information relative to end-use applications, such as equipment databases
- Drawings and bills of materials provided with the original equipment
- Original manufacturing information and tolerances
- Original equipment design information
- For replacement items, other applicable information obtained from entities that were involved in the original procurement, such as the OEM, OES, NSSS, or licensee

Precautions/Lessons Learned

The following lessons learned apply when considering end-use applications:

- It is important to identify the end-use application(s) of the item so that the plant can determine all applicable safety functions and, in turn, determine the critical characteristics to be verified and accepted that will provide reasonable assurance that the item is capable of performing the safety functions.
- Ensure that documents/databases reviewed are relevant to the item under consideration (such as applicable to the model/part number/revision of the item under consideration). Determination of end-use applications will help narrow critical characteristics to be verified (specific to those applications) versus having to dedicate to the larger set of design characteristics (because the end-use application is unknown or not properly defined).
- If a generic item is intended to be used in a more severe application than that for which it was originally accepted, additional critical characteristics may have to be verified.

Step 5.3.2: Determine the Item's Safety Function(s)



Description

Identification of the safety function(s) of the item provides the foundation on which the selection of critical characteristics is based. Therefore, it is important to identify all safety functions of the item being dedicated. It is possible for an item to have more than one safety function. Furthermore, it is possible for an item that has certain safety functions during normal operations to have additional safety functions during design basis events.

Methodology

Safety functions of component-level items (such as valves, pumps, and motors) are typically described in documents, such as the final safety analysis report/updated final safety analysis report, system descriptions, system design criteria CSSC lists, Q-lists, and equipment databases. In some cases, documents or databases that include component safety classifications also include a description of the component safety function or reference to a document that describes the safety function.

Analysis is usually required to determine the safety functions of part-level items (for example, a valve stem or a bushing that is part of a mechanical seal in a pump). The function or purpose of the part-level item is identified, and analysis is performed to determine the function(s) that the part must provide to enable its host component to perform the component safety function(s). Information about the parent component that is useful in determining safety functions for parts includes assembly drawings, bills of material, and vendor technical manuals that include discussion related to theory of operation. The safety functions of part-level items are typically described in the safety classification section of technical evaluations performed to determine how the item should be procured.

If the item being procured is a commodity-type item (such as a fastener, lubricant, or capacitor) intended for use in a variety of applications, all possible safety functions for the item should be identified.

Whereas licensees and design organizations typically have access to the information needed to identify an item's safety function, other dedicating entities may not. In fact, suppliers of basic components are often not provided with information relating to specific applications in which their product will be used. A dedicating entity that does not have access to information about the item's safety function has the following options:

- The dedicating entity can work with the customer to obtain end-use application and functional requirements information necessary to identify specific safety functions.
- The dedicating entity can request that the customer's engineering organization review and approve the safety functions identified.
- The dedicating entity can identify all possible functions of the item as safety functions.
- If the dedicating entity has access to all of the design information for the item, the dedication can be based on establishing assurance that all of the design requirements are met. In this case, consideration of failure modes is not required because all of the item's design parameters and allowable tolerances are used as the critical characteristics and acceptance criteria.

Additional information on safety classification is included in EPRI report NP-6895 [74].

If it is determined that the item does not perform any safety functions, it may be procured as a non-safety-related item. Non-safety-related items do not require commercial-grade dedication. Therefore, they are procured as non-safety-related items.

However, if safety functions are identified, they are documented in accordance with Step 5.3.3.

Precautions/Lessons Learned

The following lessons learned relate to determining an item's safety function:

- Dedications based on specific safety functions can be more cost-effective than dedications based on the entire range of possible uses and functions for an item.
- Dedicating entities can request the purchaser to review identified safety functions in cases where the dedicating entity is not familiar with end-use applications.
- Parts and materials used in a safety-related component may be non-safety-related if failure of the part or materials does not impact the safety functions of the component.

Step 5.3.3: Document the Item's Safety Function(s)

Document Item safety function(s) 5.3.3

Description

Document the item's safety-related function(s) as it relates to the host equipment/parent component's safety-related function(s).

Methodology

Describe the item's safety-related function(s) as it relates to the parent component's safety-related function(s). It may be helpful to identify a basic function, such as those included in Table 5-3, and expand upon it with a description that relates the function to its impact on the parent or host equipment or system.

Table 5-3
Typical component functions

Component Function	Description
Maintain pressure integrity	Mechanical function. Pressure integrity is required to prevent the escape or entry of an unacceptable leakage rate or quantity of fluid past the pressure boundary. It applies to both active and passive equipment, inclusive of the item that contains a fluid.
Open	Mechanical function. Active components are normally closed and required to perform a mechanical movement to achieve and maintain an open position, thereby allowing the minimum design flow.
Remain open	Mechanical function. Passive components are normally open and required to maintain an open position, allowing the minimum design flow.
Close and isolate	Mechanical function. Active components are normally open and required to perform a mechanical movement to achieve and maintain a closed position, thereby stopping process flow. (Absolute sealing is not considered part of this function.)
Remain closed and isolate	Mechanical function. Passive components are normally closed and required to maintain a closed position, thereby stopping process flow. (Absolute sealing is not considered part of this function.)
Provide directional control	Mechanical function. Active and passive components are required to govern the direction of process fluid or gas movement, which is determined by the operating parameters of the system.
Activate or modulate	Mechanical function. Active components are required to perform continuing mechanical movement (for example, a component that modulates the position in order to regulate flow).

Table 5-3 (Continued)
Typical component functions

Component Function	Description
Maintain structural integrity	Mechanical function. Active and passive components are required to maintain their structural form. The component does not collapse, disassemble, or disintegrate. Failure of a part confined internally to the component does not constitute a violation of structural integrity.
Provide pressure and flow	Mechanical function. Active components are required to provide minimum design pressure/flow of process fluid or gas through component movement.
Provide containment isolation	Mechanical function. Active or passive components are required to be closed for containment isolation (not to be used as a replacement of component function to close and isolate).
Provide combustible gas control	Mechanical function. Combustible gas control is required in order to prevent the buildup of volatile fluids within containment.
Blend	Mechanical function. This applies to blenders or mixers that combine ingredients or chemicals by mixing.
Provide support and secure	Mechanical function. This is required in order to restrict movement or provide damping to ensure dynamic stability.
Maintain circuit integrity	Electrical function. Maintain intact electrical state such that the design current flow is accomplished through the component and excess current flow caused by shorting does not occur. Components that must distribute or allow rated current flow include buses, distribution panels, fuses, and circuit breakers. This function applies to all electrical components to prevent excess current flow and shorts.
Maintain electrical isolation	Electrical function. Applies to components that prevent excess current flow, usually caused by short circuit, from propagating through the circuit and impeding the operation of other components. Components with this function are typically used to isolate non-Class 1E circuit failures from Class 1E circuits.
Change state	Electrical function. Changes state to perform a control function. State changes include normally energized to de-energized and normally de-energized to energized state. Modulate between these states. Examples of devices that change state in order to function are relays, circuit breakers, and solenoid-operated valves.
Transform or supply energy	Electrical function. This applies to components required to provide voltage/current to appropriate power levels for use by other components.
Provide signal	Electrical function. This applies to components that generate or transmit a process signal used for control or indication purposes. It applies to transmitters, elements, and signal conditioners.
Provide control	Electrical function. This applies to components whose primary function is to control other components. This function is typically accomplished through a change in contact position(s) and applies to switches.

Table 5-3 (Continued)
Typical component functions

Component Function	Description
Provide filtering	Mechanical or electrical function. Passive components are required to remove particles or debris from process fluid or gas.
Provide motive force	Mechanical or electrical function. Active components are required to provide motive force, start and commence a performance or operation, and continue such operation as required.
Provide heat control	Mechanical or electrical function. This relates to the process of heating or cooling a fluid, gas, or other component. Mechanically, this function is typically accomplished by a heat exchanger or cooling coil. Electrically, this function is accomplished by an electrical heater.
Provide indication	Mechanical or electrical function. This is required to provide indication, either local or remote, to operations or maintenance personnel.

Items may have more than one safety function as well as active and passive safety functions. For example, a circuit breaker may have a passive function of maintaining circuit integrity and an active function of changing state to open the circuit.

Section 3.2 of EPRI 1008256 [25] provides further guidance on the functional classification of components and parts and a listing of typical component functions in Appendix A.

5.16 Failure Modes and Effects Analysis Process: Steps 5.4.1 and 5.4.2

The process depicted in Figure 5-6 is used to perform a commercial-grade dedication technical evaluation failure modes and effects analysis.

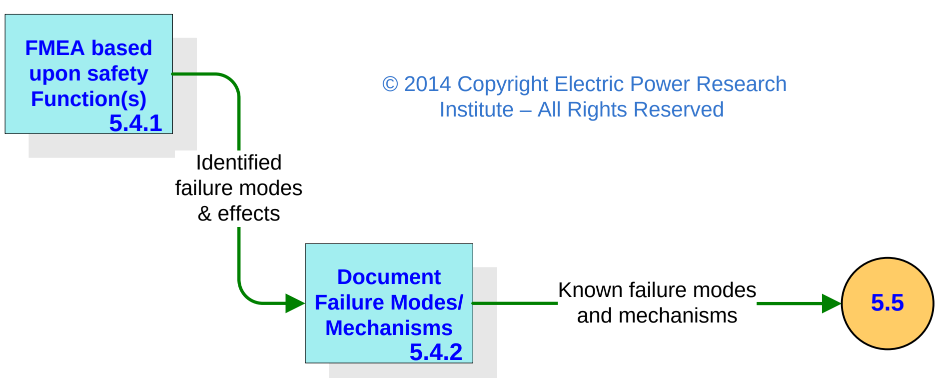


Figure 5-6
Failure modes and effects analysis

Step 5.4.1: Perform a Failure Modes and Effects Analysis Based on the Item's Intended Safety Function(s)

Description

Failure modes and effects analysis can be used to identify critical characteristics when design information is not available. It involves postulating failures for the item being evaluated that would prevent it from performing its intended safety-related functions.

Understanding how an item might fail in its application helps determine the characteristics of the item that are necessary to avoid failure. The failure modes and effects analysis is particularly useful when access to the decision-making process that led to the design and production of an item is not available to the dedicating entity.

Methodology

Intended safety functions for the item are identified. Taking the design and theory of operation of the item being dedicated into consideration, failure modes and mechanisms are postulated to determine the types of failures that could prevent the item from performing each intended safety function. These include the following:

- Safety functions during normal operating conditions
- Safety functions during design basis events
- Active safety functions
- Passive safety functions

After determining the types of failures, the characteristics necessary to prevent each failure mode or mechanism from occurring are determined.

When performing a failure modes and effects analysis for services, the adverse impact that improper performance or failure of the service could have on the safety function of the structure, system, or component on which the service is performed is considered.

Section 3.3 of EPRI 1008256 [25] provides further guidance on the failure modes and effects analysis of components and a listing of typical failure mechanisms/modes.

Step 5.4.2: Document the Failure Modes/Mechanisms

Document Failure Modes/ Mechanisms 5.4.2

Description

The failure modes and mechanisms and how they relate to the item's ability to perform its safety-related function(s) are documented in the technical evaluation.

Methodology

Failure modes and mechanisms are typically documented in a specified format or form, such as Section F of the example forms included in Appendix D.

It may be helpful to consider typical failure modes and mechanisms, such as the ones identified in Table 5-4. Once a typical failure mode is identified, a more detailed description of the failure mode/mechanism and how it could result in failure of the item to perform the intended safety function can be developed. A basis statement should be provided in the evaluation to document the engineering judgment for the selection of the credible failure mechanisms. For example, failure mechanisms for an electrical connector that has a safety function of "maintain a low resistance connection for signal applications and carry rated current without excessive heating in power applications" might be documented as follows:

> Fracture; fracture due to cyclic loading (caused by vibration, etc.) could result in open circuit during normal operation or design basis events.
>
> Short circuit; insulation breakdown could result in short to ground or adjacent channel that could prompt incorrect signal or loss of power to devices in the circuit.
>
> Overheating; overheating could result in loss or degradation of signal causing inaccurate instrument readings, response and control functions.

Table 5-4
Examples of typical failure modes/mechanisms

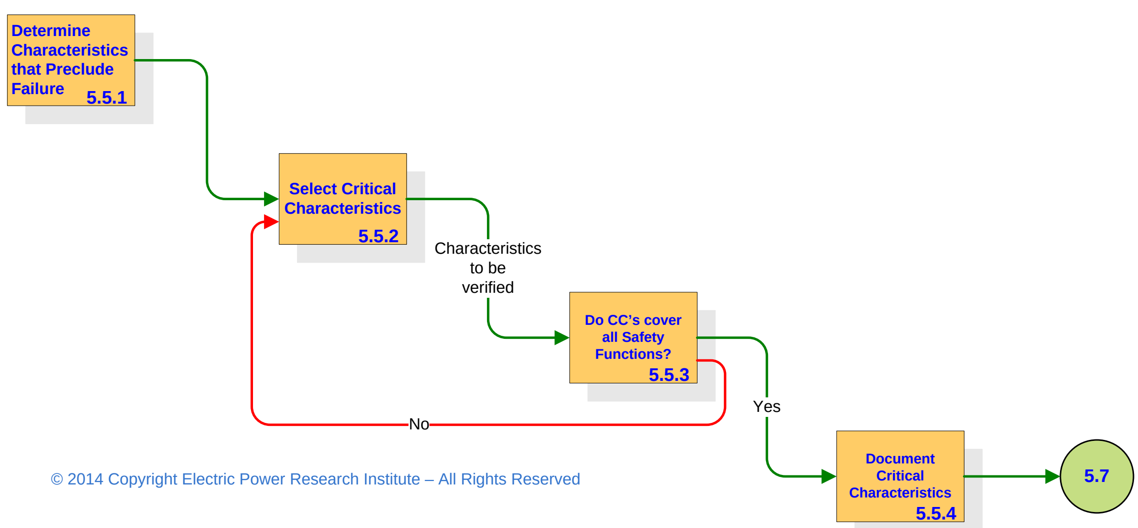
Failure Mode/Mechanism	Description
Blockage	Clogging of a filtering medium, resulting in the inability to perform the item's purification function or blockage of flow.
Corrosion	The gradual deterioration of a material due to chemical or electromechanical reaction, such as oxidation, between the material and its environment.
Ductile fracture	Fracture characterized by tearing of metal accomplished by appreciable gross plastic deformation.
Erosion	Destruction of materials by the abrasive action of moving fluids, usually accelerated by the presence of solid particles carried with the fluid.
Excess strain	Under the action of excessive external forces, the material of the part becomes deformed or distorted.

Table 5-4 (Continued)
Examples of typical failure modes/mechanisms

Failure Mode/Mechanism	Description
Fracture	Separation of a solid accompanied by little or no macroscopic plastic deformation.
Loss of properties	A loss of mechanical and physical properties of a material due to exposure to high temperature or radiation.
Mechanical creep	From prolonged exposure to high temperature and stress, the object shows a slow change in its physical (shape and dimension) and mechanical characteristics.
Open circuit	An electrical circuit that is unintentionally broken so that there is no complete path for current flow.
Seizure	Binding of a normally moving item through excessive pressure, temperature, friction, or jamming.
Short circuit	An abnormal connection by which an electric current is connected to the earth or some conducting body, usually resulting in excessive current flow.
Unacceptable vibration	Mechanical oscillations produced that are beyond the defined permissible limits due to unbalancing, poor support, or rotating at critical speeds.

5.17 Identification of Critical Characteristics Process: Steps 5.5.1–5.5.4

The process depicted in Figure 5-7 is used to identify the critical characteristics of the item being dedicated.



Note: CC = critical characteristic

Figure 5-7
Identification of critical characteristics

The meaning of the term *critical characteristics* has evolved since commercial-grade item dedication methodology was originally developed. The definitions of *critical characteristics* included in EPRI NP-5652 (1988) [2] and EPRI TR-106220 (1994) [3] are the same: "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" [2, 3].

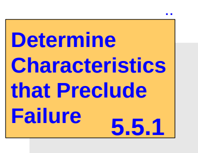
As the industry gained more experience with commercial-grade dedication, the focus of critical characteristics shifted away from "verification that the item received is the item specified" toward "providing reasonable assurance that the item could perform its intended safety-related function(s)." Accordingly, when 10CFR21 was revised in 1995 [4], the NRC added the following definition of *critical characteristics*:

> 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. [4]

Therefore, critical characteristics must be directly related to safety function(s). Although critical characteristics are tied to safety function, verifying that the item received is the item specified is an important part of the acceptance process that typically occurs prior to verification of critical characteristics.

This report refers to identifiers such as the manufacturer, part, and model number as *identification attributes*. In many cases, these identification attributes are listed under the critical characteristics section in implementing forms to ensure that they are verified. Care should be taken to ensure that dedication is never based solely on verification of identification attributes.

Step 5.5.1: Determine the Characteristics Necessary to Preclude Failure



Description

Design characteristics that are necessary to preclude failure of the item are identified by taking various types of information into account, such as the following:

- Original design basis information
- Known or bounded end uses
- Known or bounded safety functions
- Credible failure mechanisms and modes (the results of failure modes and effects analysis or other engineering evaluation)
- Review of available technical data provided by the supplier, including supplier information letters

- Review of operating experience
- Service conditions (such as seismic and environmental qualification)

Methodology

The methodology used to identify design characteristics necessary to preclude failure may vary based on the types of information available to the dedicating entity. Two basic methods can be used to identify design characteristics necessary to preclude failure. The method on which the dedication methodology was originally based considers end-use applications, safety functions, and evaluations (such as failure modes and effects analyses) to identify design characteristics in the absence of original design information. The other method can be used when original design information is available in sufficient detail to identify and use original design requirements as the basis for characteristics.

The extent to which each method is used in an evaluation is dependent on the dedicating entity's access to original design documentation and knowledge of end use(s) and safety function(s). Dedicating entities that are OEMs for the equipment being dedicated or that have access to the OEM's design and manufacturing information are more apt to identify design characteristics using original design information. Dedicating entities without design and manufacturing information are more likely to identify design characteristics based on knowledge of the item's applications and safety functions.

More information on these approaches is included in Section 6 of this report.

When Design Information and Acceptance Criteria Are Unavailable

Dedication methodology was originally developed for use by licensees to accept spare and replacement items when the acceptance criteria used by the original supplier in accordance with the supplier's 10CFR50, Appendix B–compliant QA program was not available. In cases where the design characteristics cannot be determined through available design information, the dedicating entity may employ any or a combination of the following methods of identifying characteristics necessary to preclude failure:

- Examination
- Testing
- Engineering evaluation (failure modes and effects analysis or other suitable means)
- Consideration of safety function(s)
- Interface with the supplier

When Design Information and Acceptance Criteria Are Available

The second, more recent approach to dedication involves identification of critical characteristics based on the original design requirements and acceptance criteria used by the original manufacturer or supplier. This approach might be used in cases where the original design basis information is available and includes applicable acceptance requirements and criteria. Under this approach, all applicable design requirements become critical characteristics.

When an item's original specifications (or current approved revisions) are available or can reasonably be obtained, they can be used as a source for determining critical characteristics.

Specifications used to identify critical characteristics must be at the appropriate level of detail for the item being procured. For example, a valve specification may be an appropriate source for determining design characteristics when an entire replacement valve is being procured. However, a valve specification may not include the level of detail necessary to identify design characteristics for a valve part, such as a disk or stem. In some cases, additional design information may be available from the valve supplier.

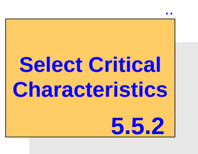
When design information is obtained from the supplier, the dedicating entity is responsible for evaluating the input and identifying the design characteristics that support the safety function and are necessary to preclude failure of the item.

Precautions/Lessons Learned

When selecting design characteristics necessary to preclude failure, ensure that all safety functions and failure modes of the item identified in Steps 5.3 and 5.4 are addressed.

Note that although most classification evaluations are application-specific, many commodity-type items can be evaluated and dedicated on a generic basis using a set of bounding conditions (Step 5.6). When commodity-type items are dedicated for use in safety-related applications, the dedication should be based on the most restrictive application in which the item can be used.

Step 5.5.2: Select Critical Characteristics



Description

Critical characteristics are selected from the design characteristics necessary to preclude failure of the item that were identified in Step 5.5.1. Not all design requirements need to be considered critical characteristics. However, the critical characteristics selected must provide reasonable assurance that the item being dedicated is capable of performing its intended safety-related functions.

Methodology

The selection of critical characteristics should be based on the information reviewed and characteristics identified in Step 5.1.1. The number and nature of the critical characteristics are to be based on the intended safety function(s), application requirements, complexity, credible failure modes and effects, and service conditions (such as seismic and environmental qualification).

The critical characteristics of an item should include physical, performance, and dependability characteristics, as appropriate. In-depth discussion on the selection of critical characteristics is included in Section 6, along with lists of typical physical, performance, and dependability characteristics in Tables 6-2 through 6-4.

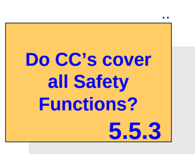
Not all design requirements need to be considered critical characteristics. When selecting critical characteristics, it is important to recognize that every critical characteristic must be verified. Critical characteristics and the justification for their selection must be documented.

Precautions/Lessons Learned

The following lessons learned relate to the selection of critical characteristics:

- Once a design characteristic is selected as a critical characteristic, it must be verified. If a critical characteristic cannot be verified after the item is received, an appropriate verification method (such as source verification or commercial-grade survey) must be applied during the manufacturing process.
- The dedication process should not rely on identification attributes—such as part number—as the only characteristics to be verified. Sole reliance on verification of the product identification attributes is inadequate to reasonably ensure that the commercial-grade item will be capable of performing its intended safety function(s).
- Engineering judgment may be required when selecting critical characteristics. Engineering judgment is covered in more detail in Section 6.5.2.4. When engineering judgment is used, it should be documented, along with a basis for the conclusion.
- It is not the intent of commercial-grade dedication to require verification of all design characteristics.
- Obtaining objective evidence of the acceptability of every design characteristic related to safety function through the acceptance process would be inconsistent with the existing guidance of ANSI N18.7 [8].
- Ensure that the hold points for in-process inspections to verify critical characteristics are adequately communicated and documented (such as in purchase orders and source verification plans).

Step 5.5.3: Do the Critical Characteristics Address All Safety Functions?



Description

The selected critical characteristics are reviewed to determine if they will provide reasonable assurance that the item being dedicated is capable of performing all of its intended safety functions. If not, Step 5.5.2 is revisited to identify additional critical characteristics. If the critical characteristics do address all safety functions, proceed to Step 5.5.4.

The methodology for establishing boundaries of the dedication when the specific safety function is unknown to the dedicating entity is included in Section 5.7.

Methodology

Determine if the selected critical characteristics are adequate to provide reasonable assurance that the item will be able to perform each intended safety function. Additional critical characteristics should be added if necessary.

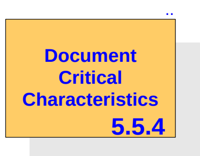
Care should be taken when selecting critical characteristics for items that are seismically and environmentally qualified to ensure that they are capable of performing intended safety functions during seismic events or in harsh environments. Dimensions and physical material properties are typically critical in seismic applications. Additional information is included in TR-112579, *Critical Characteristics for Acceptance of Seismically Sensitive Items (CCASSI)* [24]. Physical and chemical material properties are typically critical for environmentally qualified applications.

If the critical characteristics do not address all safety functions, Step 5.5.2 is revisited to select additional critical characteristics.

Precautions/Lessons Learned

The documentation should clearly indicate when one characteristic is relied on to provide assurance for multiple safety functions.

Step 5.5.4: Document Critical Characteristics



Description

The technical evaluation shall clearly document critical characteristics and their basis for selection.

Methodology

The documentation should identify each critical characteristic and contain sufficient detail to clearly identify the relationship between the critical characteristics and the associated safety function(s).

When engineering judgment is used, it should be clearly documented. Documentation should be thorough and clear enough to enable a reviewer to come to the same conclusion reached by the preparer during the evaluation.

Precautions/Lessons Learned

Inadequate documentation of critical characteristics is noted in NRC Information Notice 2011-01 [32] as one of four main areas of concern noted during NRC inspections of dedication programs.

Critical characteristics should be documented in enough detail to clearly establish how they relate to the ability of the item to perform its safety-related function(s) and not succumb to failure modes.

5.18 Establishing Dedication Boundaries When the Safety Function Is Unknown to the Dedicating Entity Process: Steps 5.6.1–5.6.5

The process depicted in Figure 5-8 is used to establish boundaries of the commercial-grade item dedication when the safety functions are unknown to the dedicating entity.

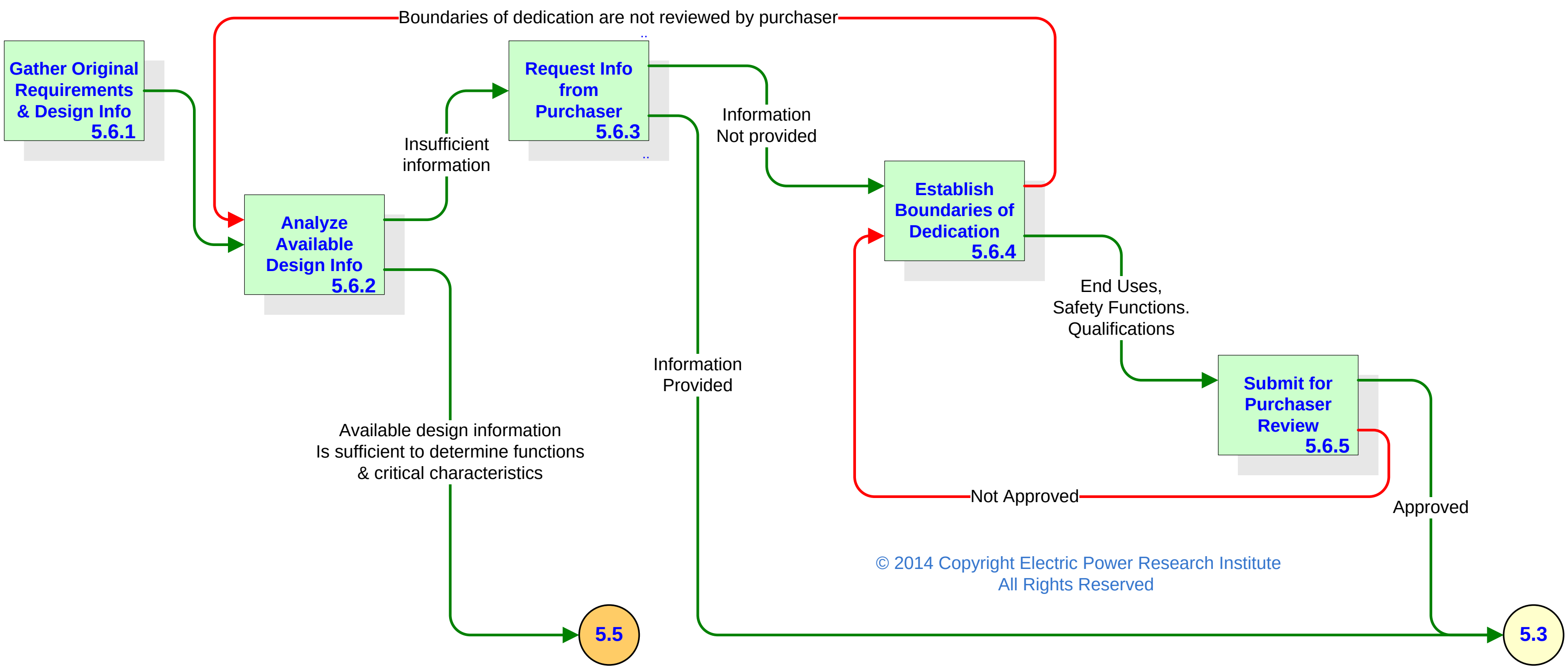
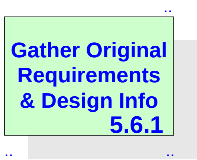


Figure 5-8
Establishing dedication boundaries when the safety function is unknown to the dedicating entity

Step 5.6.1: Gather Original Requirements and Design Information



Description

In cases where the dedicating entity is not aware of the specific safety function(s) and end-use application(s) for the item or service being dedicated, the first step in developing a commercial-grade dedication plan is to gather the original requirements and/or design information.

Methodology

This step involves assembling original specifications, design information, and design requirements pertaining to the item or service being dedicated. Useful information includes the following:

- Original purchase orders and purchase specifications
- Operating plant/system design information relative to end-use applications
- Drawings and bills of materials provided with the original equipment
- Original manufacturing information and tolerances
- Original equipment design information
- For replacement items, other applicable information obtained from entities involved in the original procurement, such as the OEM, OES, NSSS, or licensee

Precautions/Lessons Learned

The best practice for organizations that are responsible for the original design of the item or service being procured is to accept the items based on verification of all applicable design requirements using QA activities conducted under a QA program meeting the requirements of 10CFR50, Appendix B [7]. However, it is possible to use original design information to develop critical characteristics for accepting a commercial-grade item using the dedication process.

Step 5.6.2: Analyze the Available Design Information

Description

Available information is analyzed to determine if it is sufficient to clearly articulate all of the item's intended end-use application(s), function(s), and design characteristics with confidence.

Methodology

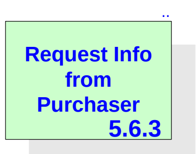
If analysis of available design information leads to the conclusion that insufficient information exists to identify the intended end uses, functions, and design characteristics with confidence, proceed to Step 5.6.3 to request the necessary additional information from the purchaser.

If analysis of available design information permits the dedicating entity to identify end-use applications and safety functions, proceed to Step 5.5.1 to begin the process of identifying critical characteristics based on the original design basis and allowable tolerances. It is prudent practice to capture the list of design documents reviewed.

Precautions/Lessons Learned

Identification of end-use applications does not necessarily refer to identification of equipment tag numbers or locations. In cases where specific applications are not available, it refers to identification of the functional application. For example, the tag number of a valve is not required to perform a failure modes and effects analysis or identify critical characteristics, but the fact that the valve is used in vent lines that are normally closed is necessary information to perform the evaluation activities.

Step 5.6.3: Request Information from the Purchaser



Description

Additional information regarding function and application is requested from the purchaser in cases where analysis of available information (Step 5.6.2) leads to the conclusion that insufficient information exists to identify end uses and safety functions with confidence.

Methodology

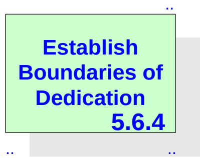
Develop a list of required information and questions and submit it to the purchaser. If the required information is provided, proceed to Step 5.3.1.

Precautions/Lessons Learned

Many devices may be used in more than a single application. When requesting information, be sure to establish if the item is used in more than one application. If an item is used in multiple applications, it may be necessary to clearly identify the applications included in the boundaries of the dedication technical evaluation and acceptance process.

Including an explanation in the request that communicates why the information is required and being as specific as possible may enhance the quality of information received.

Step 5.6.4: Establish the Boundaries of the Dedication Evaluation



Description

In cases where attempts to establish the specific or generic end use(s) and safety function(s) for an item are unsuccessful, the dedicating entity must clearly establish the boundaries of the dedication. Establishing the boundaries of the dedication involves clearly defining the postulated safety function or set of safety functions on which the dedication technical evaluation and acceptance plan are based.

In cases where the dedicating entity owns the design of the item or has expertise working with the item's design, the full range of applications, and associated safety functions, the dedicating entity may decide to dedicate the item based on all applicable design criteria. In these cases, the dedication should establish that the item meets all design requirements.

Methodology

Available design information and knowledge of typical applications and functions are used to develop and document a bounding scope of applications and functions that will be used as the basis for the dedication technical evaluation and acceptance plan. Functions during normal conditions as well as functions in design basis accidents (such as seismic events and harsh environmental conditions) should be included as applicable. The bounding applications and functions are documented and submitted to the licensee or purchaser for concurrence in Step 5.6.5.

As an alternative to dedicating based on a bounding scope of applications and functions submitted to the purchaser for concurrence, it may be possible to dedicate the item based on all applicable design criteria for use in the full range of functions and applications. In these cases, the design parameters and allowable tolerances are considered critical characteristics. This approach is discussed in Steps 5.6.2 and 5.5.1.

Precautions/Lessons Learned

The following lessons learned relate to establishing the boundaries of a dedication evaluation:

- When postulating functions, be careful to consider requirements associated with the item's ability to function in both normal and design basis event conditions.
- IN 2011-01 suggests that "the purchaser or licensee should review and approve the commercial grade dedication package before the dedication of the item" [32]. A review may be requested by either the purchaser or the dedicating entity.
- Review by the licensee or purchaser is particularly important in cases where the dedicating entity may not be familiar with the end-use applications and safety functions of the items being dedicated. Also, review by the licensee or purchaser is important when problems have been identified with the dedicating entity's commercial-grade dedication program.
- Review by the licensee or purchaser may not be appropriate in situations involving the following:
  - Dedications performed by entities with access to design information (with 10CFR50, Appendix B [7] QA programs) on materials and part-level items that may have been purchased to support manufacturing prior to identification of a purchaser.
  - Dedications performed by suppliers that are familiar with the end-use applications and safety functions of the items being dedicated.

When developing lists of applications and functions, the intent is not to develop a comprehensive list of all the unique identification numbers or locations associated with the item. Rather, the intent is to establish the ways in which the item will be used. For example, if the item being dedicated is a pipe elbow, it is not necessary to identify all of the piping systems or specifications that use the elbow. Instead, the application can be described in generic terms as "maintains pressure boundary integrity."

Step 5.6.5: Submit for Licensee/Purchaser Concurrence

Description

The boundaries established for the dedication are submitted to the purchaser for concurrence.

Methodology

The dedicating entity submits the boundaries established for the dedication to the licensee or purchaser in writing for concurrence. The purchaser reviews the applications and safety functions included in the boundaries of the dedication plan to ensure that the applications and safety functions for which the item is intended are addressed. If necessary, the licensee or purchaser and dedicating entity can work together to establish boundaries that are acceptable and appropriate for the intended end-use application(s).

If the boundaries are found to be acceptable by the licensee or purchaser, they are used as the basis to start identification of safety functions in Step 5.3.1. If the boundaries are not found to be satisfactory, new boundaries are established according to Step 5.6.4.

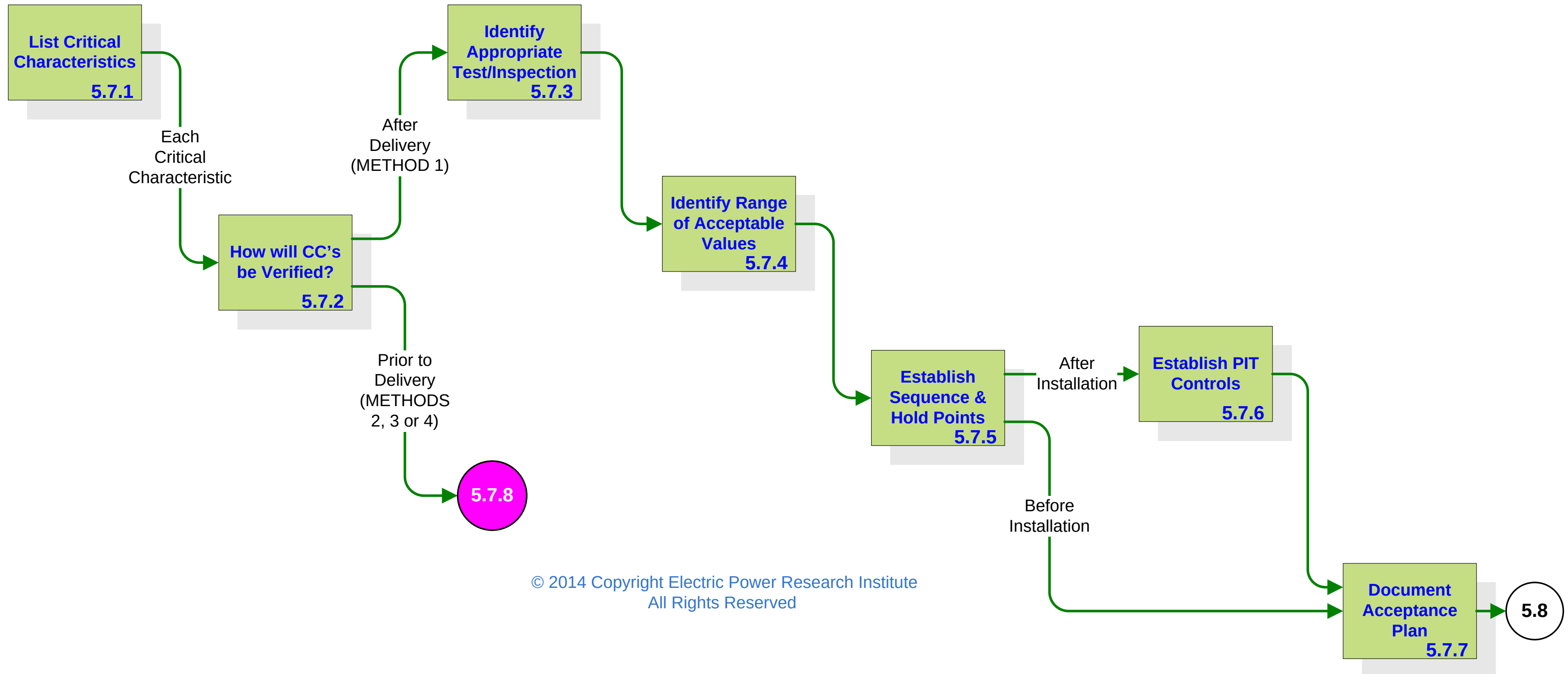
Precautions/Lessons Learned

The purchaser should be careful to consider requirements that may not be obvious to the dedicating entity. For example, relays or starters used in certain applications may be required to function in degraded voltage conditions. When bounding the evaluation for such relays or starters, the ability to function during both normal and degraded voltage conditions should be included in the dedication technical evaluation.

Concurrence from the purchaser as well as cases in which the purchaser declines the opportunity to review for concurrence should be documented and maintained for future reference.

5.19 Identification of Acceptance Methods—Method 1: Special Tests and Inspections Process (Steps 5.7.1–5.7.7)

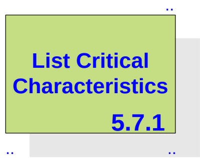
The process depicted in Figure 5-9 is used to implement Method 1: Special Tests and Inspections.



Notes: CC = critical characteristic, PIT = post-installation testing

Figure 5-9
Identification of acceptance methods, Method 1: Special Tests and Inspections

Step 5.7.1: List Critical Characteristics



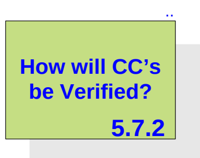
Description

Document the critical characteristics in a list to facilitate identification of appropriate acceptance methods and criteria.

Methodology

Critical characteristics are typically listed in a standard format or form. Appendix D of this report includes examples of commercial-grade dedication technical evaluation forms that can be used to document critical characteristics.

Step 5.7.2: How Will Critical Characteristics Be Verified?



Description

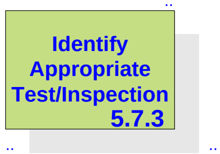
Determine when each critical characteristic will be verified—after receipt (Method 1) or prior to receipt (Methods 2, 3, or 4).

Methodology

Once a characteristic is identified as a critical characteristic, it must be verified. Verification can take place before or after delivery. For verification of critical characteristics that will be performed after delivery using Method 1: Special Tests and Inspections, proceed to Step 5.7.3.

For verification of critical characteristics that will be performed prior to delivery using Methods 2, 3, or 4, proceed to Step 5.7.8.

Step 5.7.3: Identify Appropriate Tests/Inspections



Description

Method 1: Special Tests and Inspections is applied to critical characteristics verified after receipt. Identify tests or inspections that are appropriate for each critical characteristic.

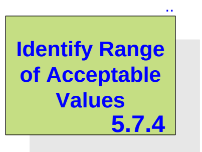
Methodology

Section 7 provides detail on the use of Method 1, and Appendices J and K include matrices that provide examples of the types of tests and inspections that might correlate with different critical characteristics.

Precautions/Lessons Learned

When using post-installation testing to verify a critical characteristic, verify that the testing being performed truly verifies the specific acceptance criteria identified in the dedication/testing plan.

Step 5.7.4: Identify the Range of Acceptable Values (Tolerances)



Description

Identify the acceptance criteria (including tolerances as applicable) for each critical characteristic that is to be verified using Method 1.

Methodology

The basis for tolerances can be found in original design requirements or may be developed through engineering techniques, such as those used for reverse engineering.

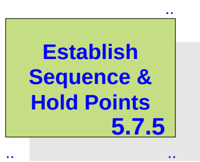
Identify the acceptance criteria (including tolerances) for each critical characteristic that is to be verified using Method 1. A review of the original design requirements, design documents, vendor catalogs, industry standards, material specifications, and/or other technical documents considered as part of the dedication technical evaluation may be helpful. Acceptance criteria may or may not be identical to the design criteria. Acceptance criteria of an item should be application-specific or, in the case of a commodity item, used in multiple applications. Acceptance criteria should be established based on the most restrictive application. Acceptance criteria must be objective (not subjective) and quantitative. Provide a documented technical basis for the value specified and the tolerances provided.

Precautions/Lessons Learned

The following lessons learned relate to identification of the range of acceptable values:

- The intent of the word *nominal* must be clearly identified in procedures when tolerances are expressed in terms of nominal dimensions or values.
- Avoid *similar to*, *consistent with*, and other terms that are subjective.
- When the acceptance criteria includes a tolerance, expressing the acceptance criteria as a range may be helpful to the inspector performing the inspection and may prevent human error when the inspector has to perform his or her own calculations. For example, 1 in. ± 0.05 in. (25.4 mm ± 12.7 mm) might be expressed as 0.95–1.05 in. (24.1–26.7 mm) in the acceptance plan.
- Items that are stored in the warehouse prior to completion of post-installation testing should be identified with a tag or other effective means to indicate that their acceptance is conditional and based on successful post-installation testing.

Step 5.7.5: Establish Sequence and Hold Points



Description

For each test or inspection specified within a given acceptance plan, sequence and/or hold points should be used to identify critical steps in the acceptance process. The purpose of this is to ensure that a specific sequence of inspections/examinations and tests is followed and that appropriate personnel are notified to witness a test, validate the test process, or review test data.

Methodology

When preparing an acceptance plan, care should be taken to ensure that the plan is well organized and structured. It should also be logically sequenced. This will give the testing organization clear steps to follow and ensure that inspections, examinations, and test activities are completed in a logical order. This sequencing may be captured in a shop traveler, work order, inspection plan, or a computer process that identifies the necessary steps to be followed in the acceptance process.

Proper sequencing of the acceptance plan may help identify significant issues early in the acceptance process of those critical or high-risk characteristics, such as material identification or physical properties. Early identification of quality concerns will allow for adequate engineering involvement and timely resolution. A carefully designed acceptance plan may prevent inadvertently missing an inspection, examination, or test.

A hold point is a mandatory verification point beyond which a work process cannot proceed without authorization. A hold point may be used to ensure that quality personnel evaluate compliance to the test procedure. It may also be used to ensure that engineering evaluates test data and test processes if necessary prior to proceeding to the next step. At each hold point, a decision can be made to go forward or hold for further instructions. All hold points should be carefully planned and clearly stated in the acceptance plan.

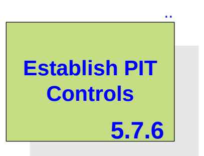
For verification of critical characteristics that will be performed after the item is installed, proceed to Step 5.7.6. For verification of critical characteristics that will be performed before the item is installed, proceed to Step 5.7.7.

Precautions/Lessons Learned

The following lessons learned relate to establishing sequence and hold points:

- Hold points should be used only when it is necessary to prevent continuation of the work process and/or inspection/test activities until verification of the activity with the hold point assigned has been satisfactorily accomplished.
- Inadequate communication between the purchaser and dedicating entity could result in key hold points being missed.
- Ensure that hold points for in-process inspections are adequately communicated and documented (such as in purchase orders and source verification plans).
- Consideration for waiving the verification of a hold point after notification may be addressed in the acceptance plan with concurrence from the organization assigned to verify and/or waive the hold point.

Step 5.7.6: Establish Post-Installation Testing Controls



Description

The intent of using post-installation testing is to provide utilities (licensees) with a method for verifying critical characteristics through tests performed after the item is installed in the plant.

Methodology

To use post-installation testing most effectively during the acceptance process, the dedicating entity must ensure that a formal process is in place and that procedures are adequate to ensure that specific acceptance criteria are found to be satisfactory and documented prior to acceptance. Section 7 provides details on post-installation testing for verification of critical characteristics.

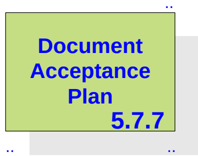
Precautions/Lessons Learned

The following lessons learned relate to establishing post-installation testing controls:

- Documented controls must be in place to ensure that post-installation testing is completed.
- When selecting post-installation testing as a means to verify a critical characteristic, engineering should be careful to ensure that the post-installation test used does in fact provide verification of the critical characteristics and their associated acceptance criteria.
- Instances have occurred where operations or maintenance personnel have waived a post-installation test that was to be included in the commercial-grade acceptance. Administrative mechanisms, such as witness/hold/notification points or database flags, should be implemented to preclude these types of occurrences.
- The dedicating entity should also be aware that the acceptance process is not complete until the test results are available prior to return to operability to demonstrate that the item meets its acceptance criteria. When engineering evaluations of test results are required to verify that acceptance criteria have been met, they must be accomplished prior to putting the item in service.
- Dedicating entities should be aware of the requirements of ANSI N45.2.13, QA Requirements for Control of Procurement of Items and Services [36], Section 10.3.4, which states:

> Acceptance by Post-Installation Test at the Nuclear Power Plant Site. Acceptance by this method is satisfactory when performed following the accomplishment of at least one of the preceding methods [i.e., Receipt Inspection, Certificate of Conformance, Source Verification] and when
>
> (a) it is difficult to verify the quality characteristics of the item without it being installed and in use; or
>
> (b) the item requires an integrated system checkout or test with other items to verify its quality characteristics; or
>
> (c) the item cannot demonstrate its ability to perform its intended function except when in use. [36]

Step 5.7.7: Document the Acceptance Plan



Description

The acceptance plan is clearly documented in the technical evaluation.

Methodology

The following information is included in the documented acceptance plan:

- Identification of critical characteristics
- Verification methods for those critical characteristics
- Identification of special tests and inspections, acceptance ranges (tolerances), test sequences, and special test requirements, such as those associated with post-installation testing
- Source verification and survey plans or references

Appendix D of this report includes examples of forms that can be used to document the technical evaluation and acceptance plan.

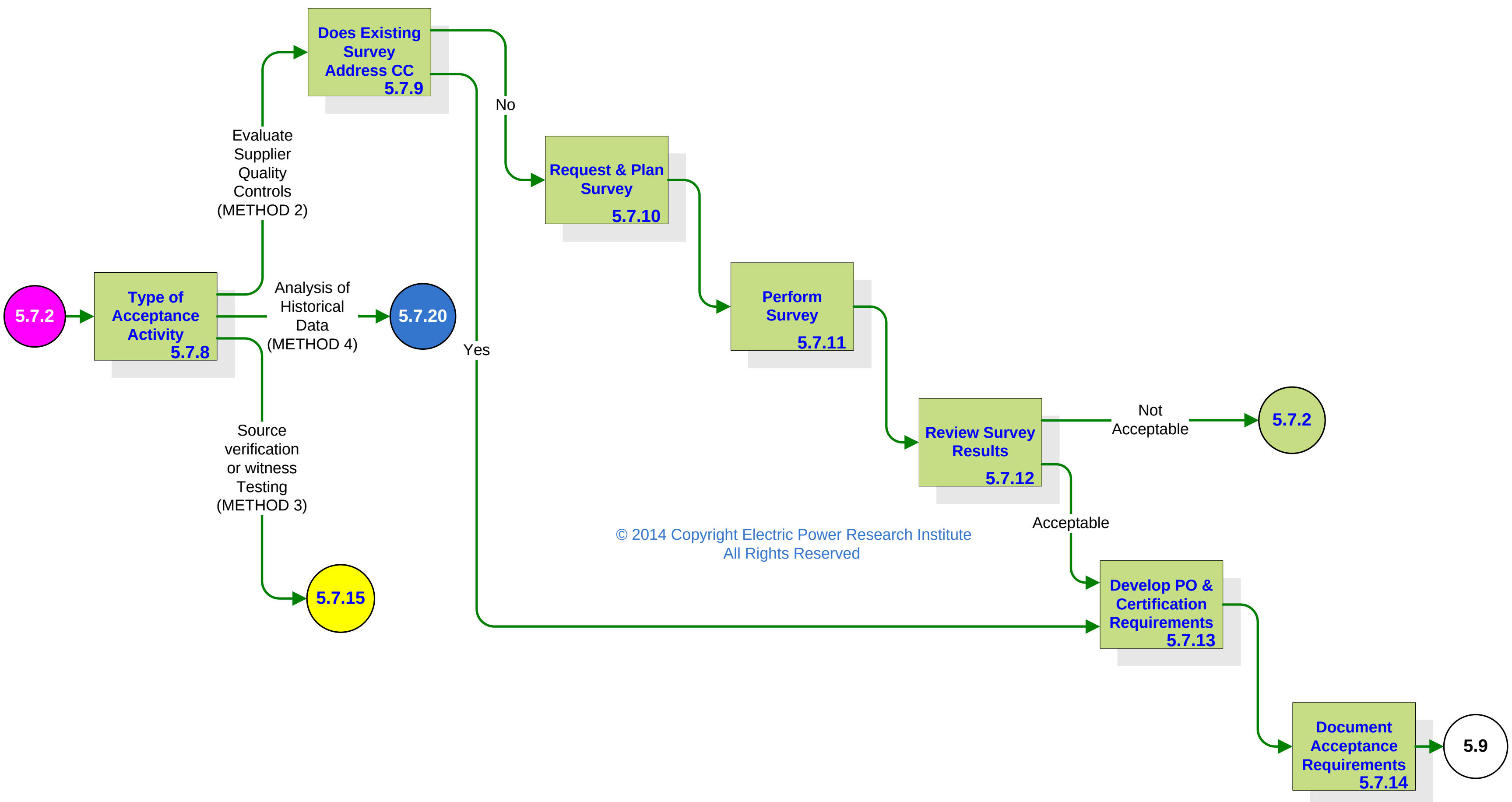
Precautions/Lessons Learned

The following lessons learned relate to documenting the acceptance plan:

- The acceptance plan should be documented in enough detail to ensure that it can be successfully implemented.
- Failure to properly document the acceptance plan and inspection, examination, and test results may result in inadequate objective evidence to support a commercial-grade dedication.
- Ensure that the acceptance plan addresses each critical characteristic.

5.20 Method 2: Commercial-Grade Survey Process (Steps 5.7.8–5.7.14)

The process depicted in Figure 5-10 is used to implement Method 2: Commercial-Grade Survey.



Note: CC = critical characteristic; PO = purchase order

Figure 5-10
Method 2: Commercial-Grade Survey

Step 5.7.8: Determine the Type of Acceptance Activity

Type of Acceptance Activity 5.7.8

Description

When critical characteristics are to be verified prior to delivery, Methods 2, 3, and 4 are considered for use as acceptance methods, either individually or in combination with one or more other methods. When using Method 4, the restrictions in GL 89-02 [10] apply.

Methodology

Factors such as the type and complexity of the item, point in the procurement process, quantity of items, and anticipated frequency of purchase are considered when determining the appropriate type of acceptance activity.

For verification of critical characteristics that will be performed prior to delivery using Method 2: Commercial-Grade Survey, proceed to Step 5.7.9. For verification of critical characteristics that will be performed prior to delivery using Method 3: Source Verification, proceed to Step 5.7.15. For verification of critical characteristics that will be performed prior to delivery using Method 4: Item/Supplier Historical Performance, proceed to Step 5.7.20.

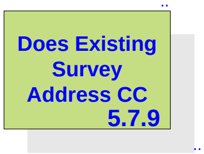
Precautions/Lessons Learned

If present, the following conditions should be considered when selecting an appropriate acceptance method or combination of methods:

- The acceptance history of the commercial-grade item exists but is not documented.
- The item is complex.
- The item is being procured from the surplus market (unable to determine if the item is used).
- The item is a first-of-a-kind product or has undergone extensive design modification.
- The item is procured from a distributor or multiple suppliers, and there is no traceability to the manufacturer of the item.
- The dedicating entity is aware of negative performance of the item or its supplier.

A commercial-grade survey should be performed prior to procurement of the item to ensure that the supplier's quality controls evaluated and accepted during the survey are specified in the procurement documents.

Step 5.7.9: Does the Existing Survey Address the Applicable Critical Characteristics?



Description

If Method 2 is to be employed, the first step is to determine if the item is already covered by an existing survey.

Methodology

First, the date of the survey should be reviewed to determine if the survey is still acceptable for use. Surveys are typically valid no longer than three years. Surveys may also be invalidated if operating experience or other input gives reason to believe that the suppler is no longer effectively controlling applicable critical characteristics.

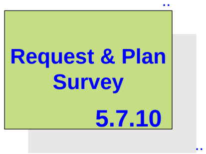
The survey report should be reviewed as necessary to ensure that it covers the critical characteristics to be verified by Method 2. If an existing survey addresses the required critical characteristics, proceed to Steps 5.7.13 and 5.7.14. If no existing survey covers the required critical characteristics, proceed to Steps 5.7.10–5.7.12.

Precautions/Lessons Learned

The following lessons learned relate to determining whether the existing survey addresses the applicable critical characteristics:

- An existing survey for an item may not have covered the specific critical characteristics for the application(s) being considered, or the survey may be outdated.
- The survey may not have been performed at the location of manufacture of the item or where the controls of the critical characteristic are being implemented.
- The evaluation should consider any distributors in the supply chain. If the distributor's activities could impact the traceability of the item, the dedicating entity may need to assess whether additional actions need to be taken to ensure the item's quality.

Step 5.7.10: Request and Plan the Survey



Description

If a survey is required, a request to the organization responsible for performance of surveys should be initiated, and a plan for the survey should be developed.

Methodology

The survey request should be in sufficient detail to allow the surveying organization to properly prepare a plan that verifies supplier controls for the specific critical characteristics requiring verification.

Two basic criteria must be met when conducting a commercial-grade survey. First, the dedicating entity must confirm that the selected commercial-grade item's critical characteristics are controlled under the scope of commercial-quality system activities. Second, the dedicating entity must be reasonably assured that the commercial supplier's activities adequately control the commercial-grade items supplied.

The survey plan is prepared using as input the information from the engineering technical evaluation. Engineering/technical involvement is essential when identifying the critical characteristics. Item identification and the critical characteristics to be verified by the survey will be included.

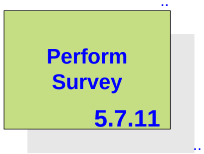
Appendix C of this report includes information on planning a commercial-grade survey.

Precautions/Lessons Learned

The following lessons learned relate to requesting and planning a survey:

- Engineering involvement is necessary to determine if the appropriate critical characteristics are identified and included in the survey plan.
- The technical resources needed to assist during the survey should be identified during the planning phase.
- A review of the item manufacturer's performance history should be included in the planning phase (for example, review of nonconformances and industry operating experience).

Step 5.7.11: Perform the Survey and Document the Results



Description

The survey is performed in accordance with the approved plan for the survey.

Methodology

Engineering involvement is essential to an effective commercial-grade survey. Trained or qualified survey personnel (see Section 8.4.2) along with technical experts, as needed, should perform the survey.

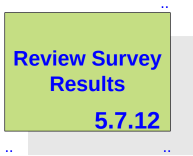
Survey personnel should follow approved procedures and the survey plan when performing the survey. It is important that the survey cover the processes that control conformance to the applicable critical characteristics. The verification should be accomplished by reviewing the vendor’s program/procedures controlling these characteristics and observing the actual implementation of these controls in the manufacture of items identical or similar to the items being purchased. The results of commercial-grade surveys should be documented in an approved survey plan/checklist.

Precautions/Lessons Learned

The following lessons learned relate to performing surveys:

- Procedures are required to be developed and followed for the performance of commercial-grade item surveys.
- The survey should include a check of the supplier’s purchase controls. Also, the check of purchase controls should include how the supplier accepts certification documentation, such as certificates of compliance, certified test reports, and certificates of conformance.
- Method 2 must be performed under control of an approved 10CFR50, Appendix B–compliant QA program.
- Personnel knowledgeable about the function and critical characteristics of the items being supplied can provide needed insight to adequately evaluate supplier controls.

Step 5.7.12: Review the Survey Results



Description

The documented results of the survey should be reviewed to ensure that the supplier's controls of the critical characteristics were adequately evaluated and traceable to the items to be supplied.

Methodology

The review of the survey will determine if the controls of the critical characteristics are adequate. If the survey identifies inadequate controls of the critical characteristics, the dedicating entity must take steps to address the weaknesses. These weaknesses may be addressed by invoking in the procurement document the additional controls to be instituted by the supplier or using other acceptance methods described in this report to verify adequacy.

Acceptance of the item will be completed by the dedicating entity performing a receipt inspection that includes verifying the adequacy of the supplier's certificate of conformance. If the survey results are acceptable, purchase order and certification requirements are developed according to Step 5.7.13. If the results are unacceptable, a different acceptance option is considered in accordance with Step 5.7.2.

Use of Third-Party or External Survey Reports

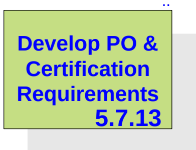
The dedicating entity attempting to use Method 2 may use survey reports performed by other organizations. In those cases, the dedicating entity should evaluate the survey methodology and personnel qualification of the external organization and ensure that they are acceptable. In addition, the dedicating entity should evaluate the survey report to ensure that the specific critical characteristics for the item to be purchased are included in the survey documentation.

Precautions/Lessons Learned

The survey report should provide a clear connection between the identified critical characteristics of the items and the vendor's controls of them. The conclusions of the report should definitively evaluate the adequacy of those controls.

Surveys used as a basis for acceptance must be performed under a 10CFR50 Appendix B–compliant QA program. Acceptance of the surveying entity's 10CFR50, Appendix B QA program is required prior to using the survey report as a basis for dedication. In general, licensees accept the results of each other's audit/survey report without a review of the audit program or personnel because all licensees are regulated to the requirements of 10CFR50, Appendix B, and the supplier evaluation process used by licensees has been evaluated by the NRC for adequacy and consistent implementation. Acceptance based on membership in recognized industry organizations—for example, NUPIC or the Nuclear Industry Assessment Committee—is typically sufficient when allowed by the dedicating entity's QA program. However, the survey must still be reviewed to ensure that the results indicate that controls are in place to address critical characteristics being verified by Method 2 for the item being dedicated.

Step 5.7.13: Develop the Purchase Order and Certification Requirements



Description

Once a supplier's controls have been deemed adequate, the dedicating entity should invoke or reference the observed commercial or quality controls as a part of the procurement document requirements for the commercial-grade item.

Methodology

Applicable program/procedure(s), including revisions, should be specified. If multiple working-level procedures are applicable to the vendor's activities; affect the item's critical characteristics; and, in turn, are controlled by a higher-level document, it may be appropriate to reference that document in the purchase order. Certification from the supplier indicating that purchase order requirements have been met should be requested.

For example, the purchaser could include requirements such as the following:

- Reference to a survey report provided to the supplier by the dedicating entity:

  > This order shall be processed in accordance with the design, procurement, manufacturing, calibration, inspection, and testing controls observed during the survey dated dd/mm/yyyy as documented in Survey Report Number of Company X. Any significant change in the observed controls shall be identified to the Purchaser. Certification that the order was processed accordingly is required.

- Reference to the supplier's commercial QA manual:

  > This order shall be processed in accordance with Company X's Commercial QA Manual, Revision X, dated dd/mm/yyyy. Any revisions to this manual shall be forwarded to the Purchaser for review. Certification that the order was processed accordingly is required.

- Reference to specific documented controls verified during survey of the supplier:

  This order shall be processed in accordance with the following Company Y procedures:

  – Heat Treat Procedure XYZ, Rev. X

  – Calibration Procedure XYZ, Rev. X

  – Product Testing Procedure XYX, Rev. X

- Inspection Procedure XYZ, Rev. X
- Any significant changes in these procedures shall be forwarded to the purchaser for review Certification that the order was processed accordingly is required.

Precautions/Lessons Learned

Any revisions to the quality programs, procedures, quality manuals, or the control processes evaluated by the survey should be identified to the purchaser for evaluation. In cases where revised documents are used, they should be reviewed by the dedicating entity to ensure that the supplier still adequately controls the critical characteristics. Changes to manufacturing locations must also be evaluated.

Step 5.7.14: Document Acceptance Requirements

Description

Method 2 acceptance requirements are appropriately documented.

Methodology

The acceptance plan should be clearly documented in the technical evaluation and reflect the results of the commercial-grade survey. Appropriate acceptance instructions should be provided to personnel responsible for acceptance of the item.

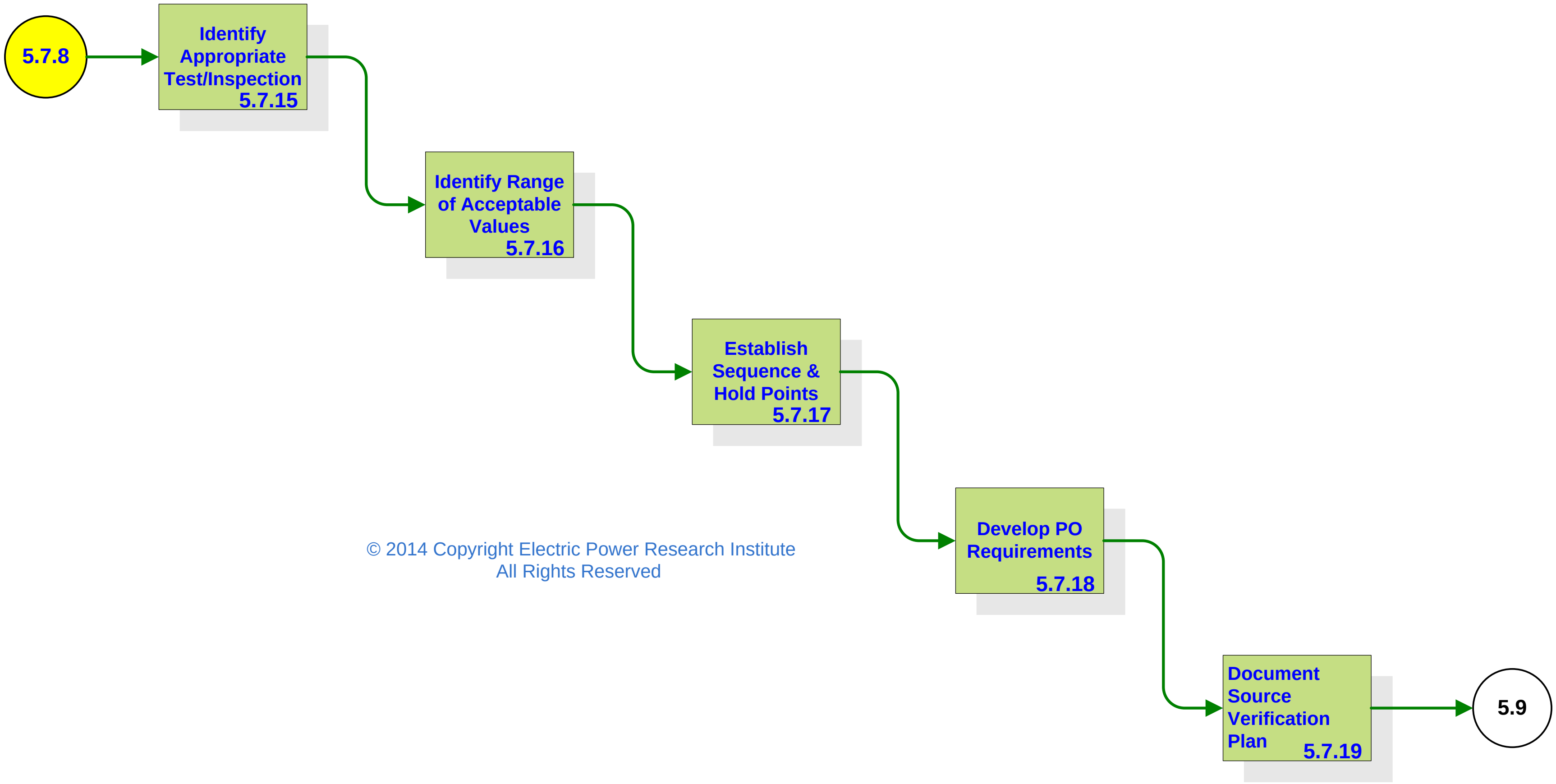
Precautions/Lessons Learned

The acceptance plan should be documented in enough detail to ensure that it can be successfully implemented. For each critical characteristic, the acceptance plan should include identification of the corresponding specific documented activity (the work instruction, procedure, program instruction, and so forth) required in the procurement document as well as the method of verification (for example, verify that the certification provided by the supplier clearly states that the specific documented activities were applied to the order).

The dedicating entity's receiving personnel should review the purchase order documentation to ensure that the required certification is received and meets the acceptance requirements.

5.21 Method 3: Source Verification Process (Steps 5.7.15–5.7.19)

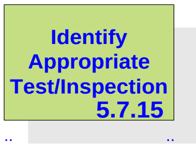
The process depicted in Figure 5-11 is used to implement Method 3: Source Verification.



Note: PO = purchase order

Figure 5-11
Method 3: Source Verification

Step 5.7.15: Identify the Appropriate Test/Inspection



Description

The purpose of conducting source verification is to confirm that the selected commercial-grade item's critical characteristics are satisfactorily controlled by the supplier. This is accomplished through observation/witnessing activities important for the control and verification of the critical characteristics by the supplier. These verification activities are typically associated with witnessing inspection/test of the commercial-grade item being supplied. Source verification is conducted at the facility where the tests/inspections are taking place.

Methodology

As with all acceptance methods, the critical characteristics must be clearly identified and selected, and the acceptance criteria must be provided. The critical characteristics and the supplier's controls/activity to be observed should be clearly identified in a documented plan/checklist, as described in Section 9.

Because this method may be implemented using contracted inspection agencies and/or in locations away from the dedicating entity's engineering personnel, a carefully considered and documented verification plan should be developed by the dedicating entity with sufficient technical input to ensure that the plan can be executed by the verification personnel.

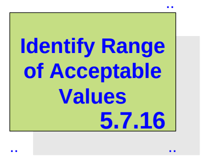
This process is required to be controlled under the dedicating entity's 10CFR50, Appendix B–compliant QA program and procedures.

Precautions/Lessons Learned

The following lessons learned relate to identification of appropriate tests/inspections:

- Caution should be used to ensure that adequate guidance is provided to the source verifier regarding the critical characteristics, the acceptance criteria, and the method of verification.
- Care should be exercised to avoid generic source verification plans that do not specifically address the selected critical characteristics and acceptance criteria of the item.
- Source verification is applicable only as a verification method for the actual items being supplied.

Step 5.7.16: Identify the Range of Acceptable Values (Tolerances)



Description

The source verification plan should provide clear instructions to personnel performing source verification, including the range of acceptable values.

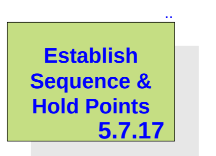
Methodology

Acceptance criteria should be identified on the source verification plan for each critical characteristic in a precise manner so that the acceptance value is clearly understood. Acceptance values may be obtained from design information, supplier's published product data, and/or information maintained by the dedicating entity based on previous inspection/test/performance history. Acceptance values should be specified with ranges, minimum/maximum allowances, or tolerances in order to allow an objective evaluation of the results of the supplier's control/activity for verification of the critical characteristic. Acceptance criteria specified in "approximate" terms should be avoided whenever possible because this may result in subjective determination as to the acceptability of the supplier's control/activity used to verify the critical characteristic.

Precautions/Lessons Learned

The acceptance values should be based on the critical characteristics. Use of vague/general acceptance criteria can result in inadequate verification of critical characteristics.

Step 5.7.17: Establish Sequence and Hold Points



Description

Appropriate hold points for source verification should be provided in procurement documents.

Methodology

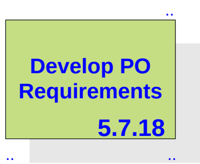
Hold points are specified in procurement documents to prevent the supplier from performing an activity that requires observation in order to verify adequate performance/control of the critical characteristic. These hold points could be activities requiring witnessing during and/or after fabrication of the item. The specific hold point is specified in the procurement document, with notification provided by the supplier when the hold point has been reached, requiring verification by the dedicating entity. In some instances, the supplier may revise their fabrication document (for example, traveler) to include a customer witness point for the specific activity to ensure notification to the customer.

Precautions/Lessons Learned

The following lessons learned relate to the establishment of sequence and hold points:

- Appropriate understanding with the supplier must be achieved to ensure compliance with the hold point.
- Hold points should be clearly identified and described in the procurement document when activities require witnessing by the dedicating entity.
- For items being verified by Method 3, the purchase order should specify a right of access to examine the supplier's product controls in the areas of design, procurement, manufacture, calibration, testing, inspection, and others as applicable to the critical characteristics being verified.

Step 5.7.18: Develop Purchase Order Requirements



Description

Once hold points and an appropriate sequence are determined, the dedicating entity should include hold point requirements and provisions for rights of access to the supplier's facilities procurement document requirements for the commercial-grade item.

Methodology

Applicable language is included in the procurement document to request notification in advance of hold points. Advance notification is necessary so that the dedicating entity can arrange to be present at the supplier's facility at the correct time. The procurement document should reference all working-level instructions and procedures that are applicable to the supplier's activities and affect the item's critical characteristics. It may also be appropriate to reference higher-level documents (such as a commercial QA program manual or design document) that affect the item's critical characteristics. Certification from the supplier indicating that the purchase order requirements have been met should be requested.

For example, the purchaser could include requirements such as the following:

- Rights of access requirements, as follows:

  Purchaser or their Agent may perform surveillance, source verification, or inspection at any time(s) for compliance with the quality program and examine the work wherever situated for conformance to product quality requirements. The Inspector(s) shall have free access, at all reasonable times, to the premises of both the Company and its subcontractors.

- Reference to the specific activities that are to be included in the scope of source verification(s), as follows:

  The following activities require source verification/witnessing:

  – Heat treating

  – Final testing

- Requirements to provide a schedule and notify the purchaser in advance of activities that require source verification, as follows:

  Verification of supplier manufacturing/process controls is required for this item. The supplier shall submit a manufacturing schedule to the contact indicated below prior to fabrication for review/approval and for establishment of witness and/or hold points. This will normally consist of a flowchart, traveler, diagram, or narrative description of the major manufacturing, inspection and test activities, including a listing of procedures to be used and a schedule when major activities will be performed.

  Name and Title
  Company
  Address
  Phone Number

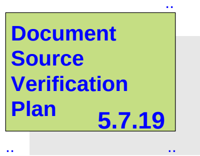
  After submittal of the manufacturing schedule, purchaser will provide a list of notification points. Upon receipt of notification points the supplier shall give the purchaser five working days prior notice before reaching any notification point.

  If the requirements or the procurement documents have not been fulfilled, the Vendor Quality Department of purchaser or its agents have the authority to refuse release of the item(s) for shipment.

Precautions/Lessons Learned

Coordination is required to ensure that source verification can be performed with minimal impact on the supplier’s and purchaser’s schedules.

Step 5.7.19: Document the Source Verification Plan



Description

The source verification plan should be clearly documented to enable adequate verification of the selected critical characteristics.

Methodology

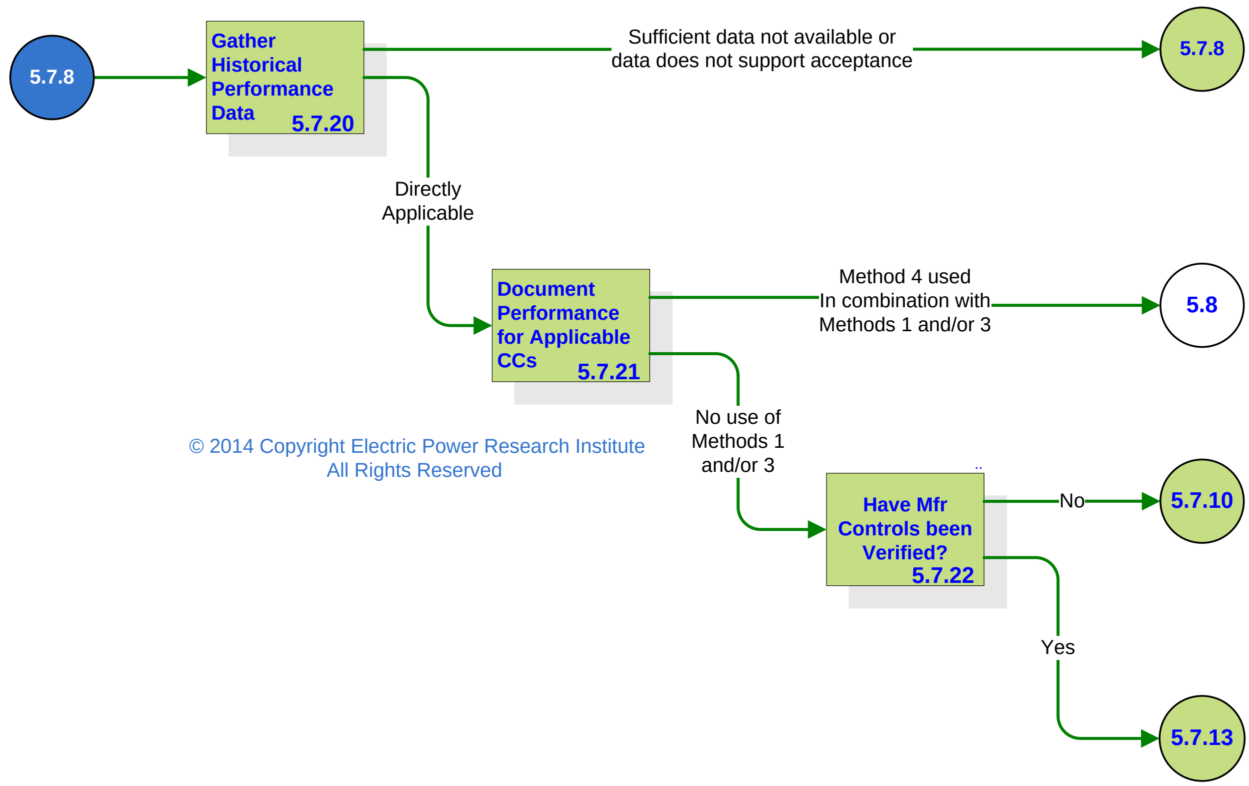
The critical characteristics and the supplier's controls/activity to be observed should be clearly identified in a documented plan/checklist, as described in Section 9.

Precautions/Lessons Learned

The verification plan should be documented in enough detail to ensure that it can be successfully implemented. For each critical characteristic, the verification plan should include identification of the specific activity to be witnessed and the acceptance criteria. The source verification plan must include the critical characteristics, the acceptance criteria, and the method of verification.

5.22 Method 4: Item/Supplier Performance Record Process (Steps 5.7.20–5.7.22)

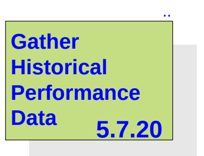
The process depicted in Figure 5-12 is used to implement Method 4: Item/Supplier Performance Record.



Note: CC = critical characteristic; Mfr = manufacturer

Figure 5-12
Method 4: Item/Supplier Performance Record

Step 5.7.20: Gather Industrywide Performance Data



Description

In order to establish a performance record for a supplier or item, it is necessary to gather industrywide performance data.

Methodology

For the particular critical characteristic for which Method 4 is being considered, sufficient performance data over a sufficient length of time must be collected to facilitate an evaluation of the acceptability of the item, service, or supplier's performance history. Based on the critical characteristic and/or manufacturer in question, perform the necessary research to identify and acquire the historical data necessary to be able to evaluate the historical performance record. The three typical categories of historical performance are as follows:

- Historical performance of an item while in service
- Historical dedication results from the use of Methods 1, 2, and/or 3 for the item, service, or supplier/manufacturer
- Industrywide performance of the item, service, or supplier/manufacturer

Depending on the category of performance history to be used, applicable data must be collected to support an evaluation and determination of whether the performance history is sufficient to justify the use of Method 4 to accept the critical characteristic in question. See Section 10 for more details.

Unless the item is a widely used commodity, collection of industrywide performance data may be the most challenging, particularly when other organizations in the industry have not had reason or occasion to mine or produce data or records pertaining to the item, service, or supplier in question. For a widely used commodity, there may be extensive performance data; however, the information may not be public, and acquiring the data may present a challenge.

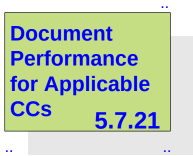
In any event, sufficient data must be collected in order to evaluate the performance history to potentially take advantage of a proven favorable performance record. If sufficient data cannot be acquired to support historical performance, Method 4 cannot be used, and another acceptance method must be selected (return to Step 5.7.8 in the flow chart in Figure 5-10).

Precautions/Lessons Learned

Performance data must be specific and applicable to the item, service, or supplier/manufacturer and critical characteristic(s) being accepted.

The dedicating entity's historical experience from applying Method 1, 2, or 3 for acceptance of a particular critical characteristic often yields the most readily available and directly applicable historical performance data.

Step 5.7.21: Document Performance for the Applicable Critical Characteristics



Description

The performance record for each applicable critical characteristic to be accepted by Method 4 must be clearly documented and justified.

Methodology

The item's/supplier's performance record, supporting data, and applicable justification must be documented to support use of Method 4. An acceptable item, service, or supplier performance record shall include the item and critical characteristic being evaluated, the supporting data, the basis for determining the acceptable performance history, the adequacy of the performance record, limits or stipulations, and the applicable procurement document requirements. See Section 10 for more details. Additionally, a continued application of Method 4 shall include a documented periodic update and review to ensure that the item, service, or supplier maintains an acceptable performance record.

For Method 4 to be employed alone as the sole method of acceptance for all of the critical characteristics of a particular item or service, two conditions must be satisfied. First, the established historical record must be based on industrywide performance data that are directly applicable to the critical characteristics and the intended safety-related application. Second, the item manufacturer's measures (or the service supplier's measures) for the control of applicable design, process, and material changes have been adequately implemented, as verified by a commercial-grade survey and the survey results accepted by the dedicating entity.

If the intent is to base acceptance solely on the documented item, service, or supplier history, proceed to Step 5.7.22 to determine if the supplier's controls have been adequately verified. If the intent is to use Method 4 in combination with Method 1 and/or Method 3, the historical performance data can be considered as input when establishing sampling plans in Step 5.8.

Precautions/Lessons Learned

The performance record for each critical characteristic should be documented in enough detail to ensure that it can be successfully understood and that a reviewer would concur with the conclusions.

If the supplier or manufacturer's controls require verification and they are not going to be verified though a survey (Method 2) or source verification (Method 3)—or if the performance does not warrant acceptance based solely on the item, service, or supplier/manufacturer historical experience—consider using the performance record to help determine the sample size (Step 5.8).

Step 5.7.22: Determine If Manufacturer Controls Have Been Verified

Description

For Method 4 to be employed alone as the sole method of acceptance for all of the critical characteristics of a particular item or service, the item manufacturer's measures (or the service supplier's measures) for the control of applicable design, process, and material changes must have been adequately implemented as verified by a commercial-grade survey (or source verification) and the results accepted by the dedicating entity.

Methodology

If Method 4 is to be employed alone as the sole method of acceptance for all of the critical characteristics of a particular item or service, obtain the survey or source verification report of the item manufacturer or service supplier. Review the report, and verify that a recent commercial-grade survey or source verification concluded that the item manufacturer's measures (or the service supplier's measures) for the control of applicable design, process, and material changes were adequately implemented.

If a commercial-grade survey or source verification is necessary to verify these controls, initiate these activities in Steps 5.7.10 or 5.7.15, respectively. If the manufacturer's controls have been verified by a commercial-grade survey, the purchase order and certification requirements are developed according to Step 5.7.13.

Precautions/Lessons Learned

The commercial-grade survey or source verification evaluating the manufacturer or supplier's controls must have been performed recently (that is, within the last three years) to be valid.

If Method 4 is being evaluated for application to only a subset of the total critical characteristics of the item or service, verification of the manufacturer's or supplier's controls is not necessarily required. See Section 10 for more information.

6
CRITICAL CHARACTERISTICS

Identification of meaningful critical characteristics is perhaps the most important aspect of a commercial-grade dedication technical evaluation. The primary purpose of identifying critical characteristics during commercial-grade dedication is to determine which characteristics are necessary to provide reasonable assurance that the item being dedicated is capable of performing its intended safety function(s).

Because critical characteristics play a central role in dedication, it is important to clearly understand the terminology associated with critical characteristics. The regulatory definition of *critical characteristics* is provided in the context of a commercial-grade item dedication. In other words, the regulatory definition of *critical characteristics* describes characteristics used to accept an item for safety-related use.

Critical characteristics are also used in a different process known as *equivalency evaluation*, which may evaluate the suitability of an alternative item's design for both safety-related and non-safety-related items. The equivalency evaluation process is used to assess a proposed replacement (alternative) item for use in lieu of the originally designed item. In the equivalency evaluation process, design characteristics are used to compare the original item with the proposed alternative.

6.1 Critical Characteristic Terminology

The definition of *critical characteristics* has evolved since dedication methodology was first developed. Changes in the regulatory definition have increased the emphasis on the relationship to safety function, prompted inclusion of an updated definition in this report, and impacted the types of attributes that can be considered critical characteristics.

6.1.1 Definition of Critical Characteristics

A regulatory definition for *critical characteristics* did not exist at the time NP-5652 was developed. NP-5652 originally defined *critical characteristics* as "identifiable and measurable attributes or variables of a commercial grade item, which, once selected to be verified, provide reasonable assurance that the item received is the item specified" [2].

A regulatory definition of *critical characteristics* first appeared in the 1991 revision of 10CFR21 [79]. That original regulatory definition was the same as the definition in NP-5652. Although the definition was functional, the focus on "identifiable" was misinterpreted by dedicating entities that acceptance could sometimes be based solely on identification attributes, such as part number.

In 1995 the NRC issued a revision of 10CFR21 to address the potential to accept items based solely on verification of identification attributes by redefining critical characteristics as “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” [4].

The definition’s shift in focus from “identifiable and measurable” characteristics to “important design, material, and performance” characteristics clearly focuses on characteristics directly related to the item’s intended safety function. The guidance in this report is based on this definition, which remains the current regulatory definition in 10CFR21 [4].

6.1.2 Identification Attributes

Deliberate use of the term *identification attribute* (instead of *identification characteristic*) is intended to emphasize the difference between critical characteristics related to an item’s safety function and product identifiers that are not directly related to an item’s safety function. This distinction is helpful because it prevents acceptance based solely on identification attributes that are not directly related to the safety function(s) of the item being dedicated.

In 1988, EPRI NP-5652 [2] specifically included an item’s part number as a critical characteristic. However, the current regulatory definition of *critical characteristic* in 10CFR21 [4] clearly points out that a critical characteristic must be directly related to the item’s ability to perform its safety function(s).

Nevertheless, identification attributes, such as part number, are recognized as important. Verification of identification provides preliminary assurance that the item is correct. In addition, changes in identifiers, such as part and model numbers, often indicate that the design of the item has changed. This is an important indicator because it prompts further evaluation to determine if the item has changed and if the changes impact the item’s ability to perform its intended functions.

Therefore, identification attributes, such as those identified in Table 6-1, should be verified when applicable during the standard receipt inspection and are often included in the critical characteristics section of commercial-grade dedication acceptance plans as a convenient means to prompt verification of product identification.

Table 6-1
Typical product identification attributes

Typical Product Identification Attributes	
Part number/unique identifier	Industry standard markings
Display type (scale, graduations)	Nameplate data
Markings	Color
Enclosure type	Color coding

6.1.3 Critical Characteristics for Design and Critical Characteristics for Acceptance

The term *critical characteristic* in the context of dedication was initially defined in EPRI NP-5652 [2]. Work on other procurement guidance documents immediately followed the publication of NP-5652. While developing NP-6406 [12], it was recognized that in addition to using critical characteristics to accept commercial-grade items for use in safety-related applications, they could be used to perform equivalency evaluations for all procured items (including items procured as basic components and non-safety-related items). Further, the realization was made that critical characteristics used to accept an item could be a subset of all of the design critical characteristics.

To clarify the distinction in use, the terms *critical characteristics for design* and *critical characteristics for acceptance* were introduced in NP-6406 [12], reiterated in TR-102260 [3], and remain in EPRI 1008256 [25] (the current revision of NP-6406).

6.1.3.1 Critical Characteristics for Acceptance

Critical characteristics for acceptance (referred to in this report as *critical characteristics*) are defined in NP-6406 [12] and TR-102260 [3] as

> Identifiable and measurable attributes and variables of a commercial grade item that, once verified, provide reasonable assurance that the item received is the item specified. Note: Critical characteristics for acceptance are a subset of critical characteristics of design. [3, 12, 25]

This is the same definition used for critical characteristics in NP-5652, with a note added to indicate that the critical characteristics for acceptance are a subset of critical characteristics for design.

The definition of *critical characteristics* in this report has been updated to be consistent with the regulatory definition in 10CFR, Part21, as follows:

> 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(s). [4]

6.1.3.2 Critical Characteristics for Design

Critical characteristics for design (referred to in this report as *design characteristics*) are defined in NP-6406 [12], TR-102260 [3], and 1008256 [25] as

> …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 provide assurance that the replacement item will perform its design function.

Guidance on the technical evaluation process also differentiates those critical characteristics selected for verification during the acceptance process from those that more fully describe the design of the item relating to its plant-specific design function(s).

Two separate definitions are maintained in this report to facilitate discussion of the equivalency evaluation process (based on critical design characteristics) and the commercial-grade item acceptance process (based on critical characteristics for design).

6.1.3.3 Compatibility

The two definitions are consistent and compatible because of the following:

- The equivalency evaluation process used by licensees (described in EPRI reports 6406 and 1008256) is not limited to commercial-grade items, but can be applied to all replacement items.
- The intent of selecting critical characteristics for acceptance is to identify the characteristics relative to safety function(s) from a larger population of critical characteristics for designs. Verification of all critical characteristics for designs is not required in order to achieve the reasonable assurance necessary to accept a commercial-grade item.
- The item's particular safety-related function(s) are key considerations in determining both groups of critical characteristics because both groups are application-specific.
- The selection of critical characteristics for acceptance is based on the complexity, intended safety-related function, and performance of the commercial-grade item using engineering judgment.

6.1.4 Design Characteristics and Critical Characteristics

As mentioned in Section 1.5.2, U.S. regulatory documents have not adopted use of the terms *critical characteristics for design* and *critical characteristics for acceptance*. In recognition of this fact, this report uses the term *critical characteristics* in place of *critical characteristics for acceptance* and the term *design characteristics* in place of *critical characteristics for design*. This reflects a change in terminology, not methodology.

6.2 Relationship Between Design Characteristics and Critical Characteristics

The typical relationship between design characteristics and critical characteristics is conveyed in Figure 6-1. The sizes of the ellipses in Figure 6-1 are not intended to represent mathematical values.

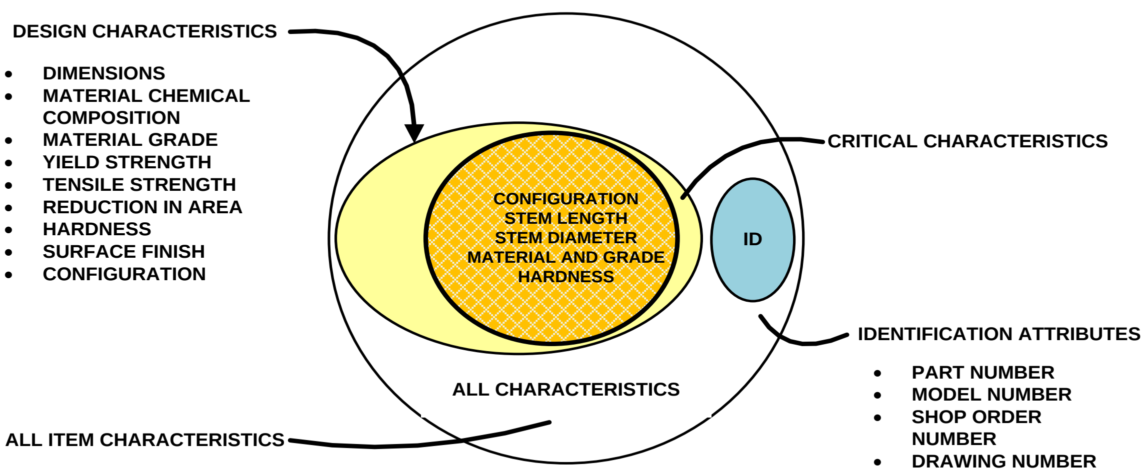


Figure 6-1
Typical relationship between design characteristics and critical characteristics

Critical characteristics (selected for acceptance) are typically a subset of the design characteristics and are based on the item's safety function(s) and complexity. However, when the safety function(s) or end use(s) are unknown, critical characteristics selected for acceptance may include all design characteristics.

Critical characteristics are depicted by the orange ellipse in Figure 6-1 as a subset of the larger population of design characteristics represented by the yellow ellipse. Selected design characteristics that are essential for the item's safety-related functional performance would be included in the critical characteristics. The acceptance process would also include verification of applicable identification attributes represented by the blue ellipse.

The dedication process is intended to achieve reasonable assurance that the item is capable of performing its intended safety function by verifying the selected critical characteristics. It is not required that all design characteristics be included as critical characteristics, as depicted in Figure 6-2. In the context of achieving reasonable assurance, verification of properly selected critical characteristics provides assurance that the item will perform its intended safety function(s) and that the remaining design characteristics are acceptable.

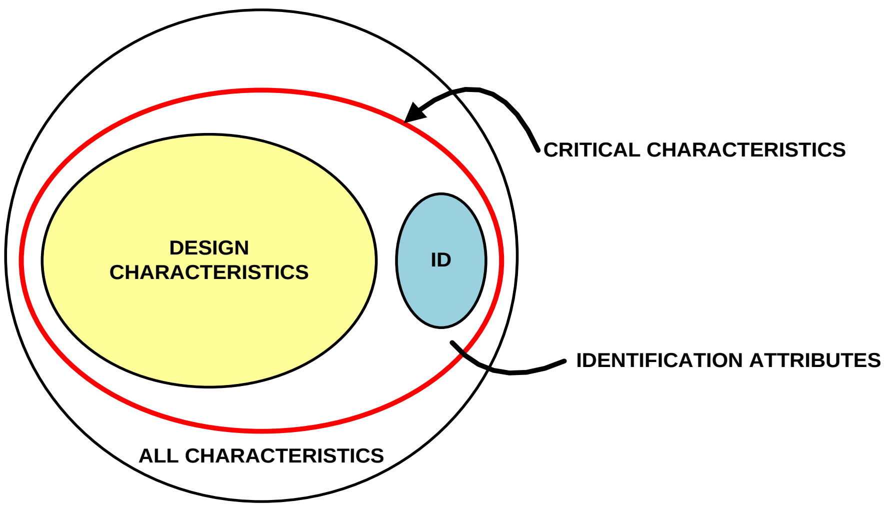


Figure 6-2
Critical characteristics when safety functions and applications are unknown

Therefore, the scenario depicted in Figure 6-2 may be inappropriate in cases where safety function is known by the dedicating entity and reasonable assurance can be achieved through verification of a subset of properly selected critical characteristics.

Conversely, sole reliance on verification of identification attributes (as depicted in Figure 6-3) is clearly inadequate to reasonably ensure that the commercial-grade item is capable of performing its intended safety-related function(s).

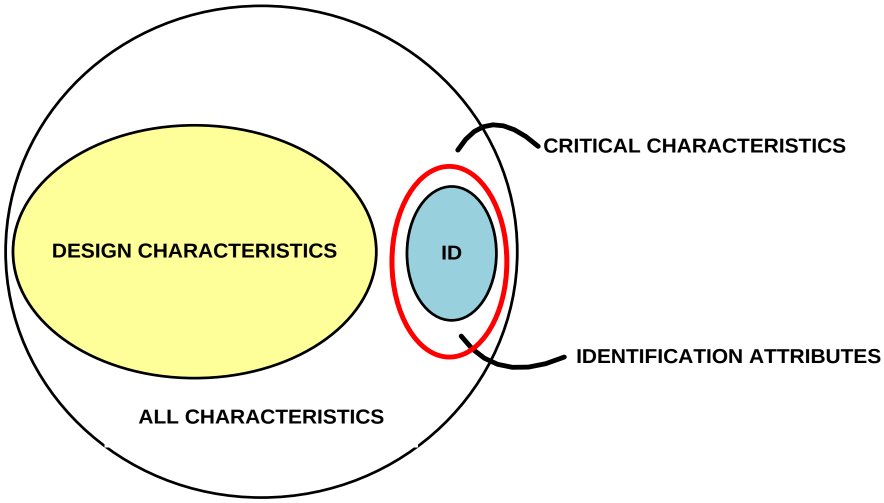


Figure 6-3
Inadequate critical characteristics

Figure 6-3 depicts a scenario in which the dedicating entity is incorrectly selecting critical characteristics (represented by the area within the red ellipse) that do not include design characteristics, but instead include only identification attributes and other item attributes that do not impact the item's ability to function as designed.

6.3 Categories of Characteristics

Categories of characteristics were developed to facilitate consistent consideration and selection of appropriate critical characteristics. The categories typically include physical characteristics, performance characteristics, and dependability characteristics.

When selecting critical characteristics, the dedicating entity can use questions such as the following as prompts:

- Are any physical characteristics appropriate?
- Are any performance characteristics appropriate?
- Are any dependability characteristics appropriate?

6.3.1 Physical Characteristics

Physical characteristics include dimensions, materials of construction, and configuration. Examples of physical characteristics are included in Table 6-2.

Table 6-2
Typical physical characteristics

amperage	elasticity	plating
balance	fatigue resistance	polarity
capacitance	flammability	pour point
chemical content	flash point	purity
cloud point	general configuration or shape	resilience
coating	impedance	resistance
color	inductance	shear strength
composite material hardness	leachable halogen content	solubility
concentration	load rating	spring constant
conductivity	luminescence	surface finish
continuity	material of construction	surface hardness
density/specific gravity	melting point	tensile strength
dielectric strength	mounting	thermal conductivity
dimensions	nil-ductility temperature	torque
drop point	oil/water separation	viscosity
ductility	permeability	weight/mass
durometer hardness		

6.3.2 Performance Characteristics

Performance characteristics include opening time, closing time, spring constant, resistance, and pick-up and drop-out voltage. Examples of physical and performance characteristics are included in Table 6-3.

Table 6-3
Typical performance characteristics

Accuracy	Input/output voltage	Radiation rating
Bias current	Interrupt rating	Relief range
Burn-in endurance	Interrupting current	Repeatability
Calibration	Leakage	Ride out
Chatter	Load rating	Rotational direction
Current rating	Open/closure time	Set point stability (no drift)
Cycle time	Operability (fail open/close, stroke)	Speed
Deadband width	Operating range	Temperature rating
Flow rate	Performance during under voltage conditions	Time/current response
Gain	Pick-up/drop-out voltage	Voltage rating
Horsepower	Pressure rating	

6.3.3 Dependability Characteristics

Whereas hardware failures can typically be attributed to fabrication defects and failure mechanisms associated with aging, digital equipment and computer program failures are typically attributed to errors in computer program design or coding, that is, the ability of the computer program to provide dependable results.

EPRI TR-106439, *Guideline on Evaluation and Acceptance of Commercial-Grade Digital Equipment for Nuclear Safety Applications* [80], identified *dependability characteristics* (see Table 6-4) as a category of characteristics that should be considered when determining critical characteristics for digital devices installed in plant SSCs.

Table 6-4
Typical dependability characteristics

built-in quality (quality of design and manufacture)	failure modes and failure management	problem reporting
reliability		

The concept of dependability characteristics extends to computer programs used in safety-related design and analysis applications. Dependability characteristics are typically associated with the reliability of the device under the entire range of operating conditions and event sequences. Therefore, dependability characteristics are directly related to the design or built-in capabilities of the device or computer program to correctly perform all safety-related functions and handle anticipated as well as unexpected inputs, fault conditions, and so on.

Dependability characteristics, which may include attributes such as reliability and built-in quality, are heavily dependent on the computer program development process and the individuals who develop, verify, and validate the software integral to the computer program. Examples of dependability critical characteristics are included in Table 6-4.

6.4 Methods for Identification of Critical Characteristics

Tables 6-5 and 6-6 provide examples of potential critical characteristics for commodity and specific application items. Although the characteristics in Tables 6-5 and 6-6 may be appropriate for some applications, they are included only as examples. Critical characteristics should always be selected based on the end-use applications and safety functions of the item. There are two basic sources of information that can be used to identify critical characteristics. First, critical characteristics may be based on actual design information. Second, critical characteristics may be identified using a failure modes and effects analysis or other suitable engineering evaluation process. The extent to which each method is used in an evaluation is dependent on the dedicating entity's access to original design basis documentation and knowledge of end use(s) and safety function(s). Dedicating entities that are OEMs for the equipment being dedicated or that have access to the OEM's design and manufacturing information are more apt to base critical characteristics on design information.

Table 6-5
Potential critical characteristics for commodity-type items[1, 2]

Commercial-Grade Item	Critical Characteristics and Identification Attributes
Bearing	Configuration, dimensions, load rating, material, model number
Bolting	Configuration, dimensions, pitch, material, tensile strength, hardness, plating
O-ring	Dimensions, material, durometer hardness, elongation, leachable halogens
Terminal block	Configuration, voltage rating, current rating, materials, dielectric strength
Crimped terminal connector (lug)	Configuration, voltage rating, current rating, materials, dielectric strength continuity, tensile pullout strength, color
Relay	Configuration, pick-up/drop-out voltage, voltage rating, current rating, chatter, response time
Fuse	Configuration, current rating, interrupt rating, time/current response, dimensions
Resistor	Configuration, markings, resistance, power rating
Drive belt	Dimensions, cross-sectional shape, ride-out, fatigue resistance, load rating, material, tensile strength
Spiral-wound gasket	Configuration, dimensions, markings, style number, materials (filler and windings), pressure rating, leachable halogens, spiral density
Cotter pin	Configuration (point type), dimensions, material, finish, hardness

Table 6-5 (Continued)
Potential critical characteristics for commodity-type items[1, 2]

Commercial-Grade Item	Critical Characteristics and Identification Attributes
Pressure switch	Configuration, dimensions, material (pressure retaining parts), voltage rating, response time, accuracy, nameplate data, pressure range, wire rating, enclosure type, dielectric strength (insulation), deadband width
Temperature switch	Configuration, dimensions, material, voltage rating, response time, accuracy, nameplate data, temperature range, wire rating, enclosure type, dielectric strength (insulation), deadband width
Lubricating grease/oil	Color, specific gravity, viscosity, drop point, cone penetration, pour point, chemical composition, cloud point
Fuel oil	Density, flash point, cloud point, pour point, kinematic viscosity, chemical composition, Btu rating
Framing device	Configuration, shape, dimensions, material, tensile strength, coating
Structural steel	Dimensions, shape, material, tensile strength, hardness, ductility, markings, coating

Notes:

1. These potential critical characteristics are provided for illustration only.
2. The lists are not intended to be all-inclusive or exclusive of critical characteristics that may be deemed important by the purchaser or appropriate for the intended applications and safety functions.

Table 6-6
Potential critical characteristics for specific application items[1, 2]

Commercial-Grade Item (Application)[3]	Critical Characteristics and Identification Attributes[4]
Valve stem (active, low-pressure cooling system globe valve, seismically and environmentally qualified)	Configuration, dimensions, material, tensile strength, ductility, finish, markings, hardness
Pump impeller (makeup water transfer pump)	Configuration, dimensions, material, hardness, balance, flow rate
Motor (cooling room fan)	Nameplate data (horsepower, speed), insulation class, frame size, materials, weight, shaft type, coupling type, bearing types
Nonmetallic diaphragm (air operator for a globe valve, seismically and environmentally qualified)	Configuration, dimensions, material, durometer hardness, reinforcement material
Solenoid valve (Torus vacuum breaker)	Configuration, size, pressure rating, materials, voltage rating, current rating, coil class, open/closure time
Limit switch (electric motor operator for a gate valve, seismically and environmentally qualified)	Configuration, dimensions, materials (metallic and nonmetallic), markings, operability, voltage rating, current rating
Impeller key (auxiliary feedwater pump)	Configuration dimensions, material, hardness

Table 6-6 (Continued)
Potential critical characteristics for specific application items[1, 2]

Commercial-Grade Item (Application)[3]	Critical Characteristics and Identification Attributes[4]
Spring (pressure relief valve, seismically qualified)	Configuration, dimensions (free length, coil diameter), spring rate, finish
Valve packing gland (active control valve, seismically qualified)	Configuration, dimensions, material, tensile strength, hardness, finish
Filter regulator assembly (high-pressure control valve, seismically qualified)	Configuration, dimensions, materials, flow rate, pressure range, pressure rating, temperature rating, filter micron size
Pinion gear (spent fuel bridge crane hoist)	Configuration, dimensions, material, hardness, pitch
Crane wheel axle (spent fuel bridge crane)	Configuration, dimensions, material, tensile strength, hardness, finish
Shaft coupling (diesel generator)	Configuration. dimensions, materials, hardness
Anchor bolt (seismically qualified concrete anchor)	Configuration, dimensions, material, wedge hardness, pitch
Torque switch (operator for globe valve, seismically and environmentally qualified)	Configuration, dimensions, materials (metallic and nonmetallic), operability
Pump mechanical seal assembly (service water booster pump)	Configuration (completeness of assembly), materials, finish, leakage, leachable halogen content, dimensions
Valve seal ring (emergency closed cooling system globe valve)	Configuration, material, dimensions, finish, leakage
Integrated circuit (reactor protection system)	Configuration, gain, input, output impedance, frequency responses, operability
Pressure transmitter (main steam isolation valve air accumulator)	Configuration, voltage rating, current output, pressure rating, materials, accuracy
Control switch (reactor building sump reset)	General configuration, contact configuration, voltage rating, current rating, materials, dimensions, operability
Transistor (uninterrupted power supply)	Markings, gain, input, output impedance, current rating, voltage rating, operability

Notes:

1. The potential critical characteristics are provided for illustration only.
2. The lists are not intended to be all-inclusive or exclusive of critical characteristics appropriate for the various functions associated with the types of items included in the list.
3. Seismic and environmental qualifications pertain to the parent component.
4. The part number is identified as an identification attribute for each item.

Figure 6-4 illustrates the basic steps followed when identifying critical characteristics using either existing design basis information or a safety function and failure modes and effects analysis as a starting point.

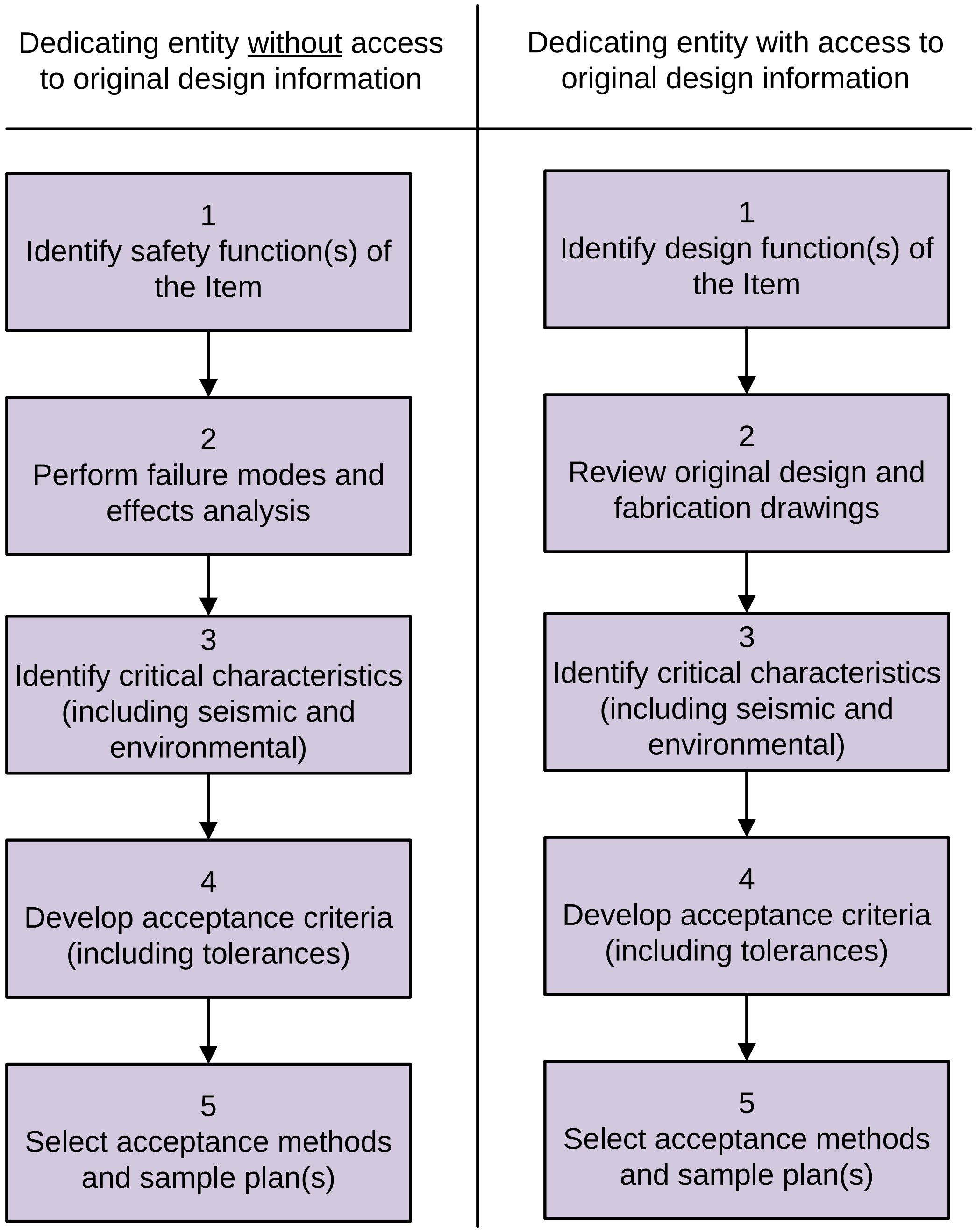


Figure 6-4
Original design information and/or failure modes and effects can be used to identify critical characteristics

6.4.1 Use of Existing Design Basis Information to Determine Critical Characteristics

Existing or actual design information can be used to determine critical characteristics. If adequate technical and quality requirements for the item are available from existing design basis information, they may be used to establish critical characteristics without performing a new determination of design characteristics.

ANSI N18.7 [8] requires that replacement parts be purchased to specifications and codes equivalent to those specified for the original. Technical and quality requirements that applied to procurement of the original item must be met when procuring a replacement item or revised through a properly reviewed and approved revision.

The original item's specifications (or current approved revisions) are the preferred source for determination of design characteristics where such specifications are available or can reasonably be obtained. The technical evaluation should identify the original design information used to identify critical characteristics.

The specifications used to identify design characteristics must be at the appropriate level of detail for the item being procured. For example, if an entire replacement valve is being procured, the valve specification may be the appropriate specification for the determination of design characteristics. Specifications at this level of detail are most often available in utility records. However, if a replacement valve stem is being procured, the valve specification alone may not completely define the stem's technical and quality requirements. Additional design information may be available from the valve supplier. If the information can be reasonably obtained, it is the preferred source of information from which to determine design characteristics.

6.4.2 Use of Failure Modes and Effects Analysis 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 the safety functions and failure modes and effects. This is the method used when the dedicating entity is not in possession of the complete set of design information used to manufacture the items. In this situation, the dedicating entity would ensure that the replacement item will be able to perform its intended safety function(s).

Briefly summarized, development of a utility's commercial-grade item dedication evaluation or plan involves the following elements, as depicted on the left side of Figure 6-4:

- Identifying the item's safety function(s)
- Using failure modes and effects analysis 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 sampling plan (when applicable) for use when executing the acceptance method

6.4.3 Original Design and Procurement Specifications

Requirements and characteristics of the item included in original design and procurement specifications and procurement documents that affect the item's safety-related functional performance should be considered for selection as critical characteristics.

6.4.4 Original Equipment Specifications

The physical or performance characteristics of the item that may have been specified in the original equipment specification and affect the item's safety-related functional performance should be considered as those selected for verification. If the original equipment specification did not specify technical and quality requirements at the item level or if the original specification is not available, the critical characteristics selected for verification during the acceptance process should be based on the complexity, intended safety-related function, and performance of the item.

If adequate technical and quality requirements for the item are available from existing design basis information, they may be used to establish critical characteristics without performing a new determination of design characteristics. If adequate design information cannot be obtained at the level of detail necessary, determination of design characteristics based on an analysis of safety functions and failure modes and effects may be performed.

Sole reliance on the original item's specification as a way to establish critical characteristics may not be sufficient to provide reasonable assurance that the replacement item received will perform its intended safety function.

6.4.5 Critical Characteristics and Acceptance Methods

An acceptance method must be selected to verify each critical characteristic. The most effective acceptance method or combination of methods should be used to verify selected critical characteristics. Application of more than one acceptance method may be necessary to effectively verify the set of critical characteristics.

6.5 Technical Information Provided by Suppliers

In order to implement the commercial-grade acceptance process, technical information related to the commercial-grade item must often be obtained. This information may be solicited from the OES, OEM, a distributor, or the part manufacturer. Guidance is needed on how to obtain and document the different types of information provided by these suppliers. How to attain confidence that the information provided is correct also needs additional guidance.

6.5.1 Published or Supplier Controlled Documents

Where possible, supplier technical information should be obtained from the appropriate edition of published or controlled documents. These sources can include the following:

- Part drawings
- Assembly drawings
- Supplier catalogs

- Supplier technical manuals
- Supplier product specifications
- National codes and standards

These are reliable sources of information issued by the supplier or national standards organizations.

6.5.2 Supplier Technical Information Obtained from Other Than Controlled or Published Documents

In many cases, technical information must be obtained from suppliers' representatives by telephone or in supplier meetings. Confidence that the information provided is correct is achieved by ensuring that the information is obtained from a knowledgeable supplier representative and by requiring formalized documentation, where appropriate. For certain types of technical information, further confidence is attained through the implementation of the commercial-grade item dedication process.

When determining how to attain confidence in the correctness of supplier-provided technical information, the following four factors should be considered:

- Types of technical information
- Who provides the data
- Method of documentation
- Engineering judgment

6.5.2.1 Types of Technical Information

The six major types of supplier technical information are as follows:

- **Safety classification input.** Purchasers often solicit information from the 10CFR50, Appendix B, OEM on the design function of parts within the safety-related host component. In many cases, the OEM has made its own safety classification determination at the part or subcomponent level. This information is used strictly as input by the dedicating entity's engineering organization to make its own safety classification decision. (This information might also be obtained from a responsible third-party organization that represents the OEM or has purchased the product rights.)
- **Determining eligibility for dedication (if the item meets the commercial-grade item definition applicable to facilities licensed pursuant to other than 10CFR50).** The primary input that the supplier would provide is whether the item is used in industries other than the nuclear industry. If the same item is used in other industries but additional technical requirements are imposed (such as specific materials, hardness ranges, liquid penetrant testing, or tighter tolerances), this should not preclude the item from being considered commercial-grade. The purchaser's imposition of special requirements on a commercial item to meet its specific needs is a common commercial practice.

- **Critical characteristics of an item.** The OEM or part manufacturer should have the best understanding of how the item is designed and intended to function in the host component. Information on an item's critical characteristics and how they can be verified may be requested by the purchaser. The purchaser's engineering organization would consider the supplier's input during its engineering evaluation and factor in plant-specific considerations before finally selecting the appropriate critical characteristics.
- **Acceptance criteria.** The purchaser needs to identify the acceptance criteria for each critical characteristic to implement Acceptance Method 1. When the acceptance criteria information is obtained from the supplier, the purchaser is responsible for evaluating the input and deciding on the actual acceptance criteria to be used for commercial-grade item acceptance. When using Acceptance Methods 2 and 3, acceptance information can be obtained or examined during the plant visit. The lot formation practices of an OEM, part manufacturer, and/or distributor are important when the purchaser verifies critical characteristics through special tests and inspections using sampling plans. EPRI report TR-017218-R1 [23] provides information on different types of lot formations.
- **Information used in specifying an item.** The purchaser should provide a detailed description of the item in the purchase order to assist in ensuring that the correct item will be supplied.

6.5.2.2 Who Provides the Data?

The source of information is the most significant factor in attaining confidence that the technical information provided by the supplier is correct. The contact to obtain needed technical information will vary from supplier to supplier based on organizational responsibilities. When possible, the information should be obtained from the technical source responsible for the information or activity. For example, information related to drawing acceptance criteria or the function of a part should normally be obtained from the supplier's engineering organization. Many suppliers, however, designate sales, sales service, or contracts personnel as the principal interface with the purchaser. These individuals take purchaser questions to the appropriate technical organizations for answers. The purchaser must decide whether information obtained in this manner can be relied upon. The past history of the correctness of the information provided is the best indicator of the validity of information obtained from these nontechnical sources.

Table 6-7 lists recommended supplier sources for different types of technical information.

Table 6-7
Typical sources of information

Types of Technical Information	Recommended Supplier Source Information
Safety classification input	Supplier's engineering organization
Eligibility for dedication	Supplier's engineering, QA, or production organizations
Critical characteristics	Supplier's engineering organization
Acceptance criteria	Supplier's engineering, QA, or production organizations
Lot formation practices	Supplier's engineering, QA, or production organizations
Information used in specifying an item	Supplier's engineering, QA, or production organizations

6.5.2.3 Method of Documentation

When the technical information is provided by the supplier, formal documentation of how the information was obtained is a good practice, but not required. The purchaser should document its final technical decision in accordance with its procedures. For example, a utility may document a part's safety classification decision on a safety classification worksheet. Information that a supplier might have provided on the part's function or potential failure modes would be documented on the safety classification worksheet. Formal documentation of supplier-furnished technical information, however, has some benefits. Such a practice clearly documents the source of the information, what information was obtained, and who received the information from the supplier. One way of formally documenting the information is to have it confirmed in writing by the supplier's representative. Alternatively, the purchaser's technical representative could document the following in a telephone conference memorandum:

- The supplier's name and location
- The name and title of the representative providing the information
- The technical information provided
- The date

A practice followed by some purchasers is to send the telephone conference memorandum to the supplier representative so that any miscommunication can be identified.

6.5.2.4 Engineering Judgment

The efforts and documentation needed to attain confidence in the correctness of supplier-provided technical information is a matter of engineering judgment. Obtaining the technical information from a credible supplier source normally provides reasonable assurance to the purchaser's technical representative that the information is correct. Discrepancies in information received are almost always due to miscommunication. This problem can be minimized by ensuring that documentation of the information provided is sent to both parties. Specific visits to the supplier to verify that the information obtained is correct are considered unwarranted. If experience, however, reveals that the supplier's information has been incorrect, actions should be taken to determine the source of the errors. These actions might include a visit to the supplier.

6.6 Maintaining Seismic and Environmental Qualification

Seismic and environmental qualification are activities undertaken to verify that a component's design is suitable for the intended nuclear power plant application. The suitability of design must be established prior to initiating procurement of the item. In other words, the technical evaluation and acceptance activities involved in dedication are not substitutes for design; they cannot be used to change the design of a given item, nor are they a means to establish seismic or environmental qualification.

If a commercial-grade item is intended for installation in a seismically or environmentally qualified application or component, the dedicating entity shall be reasonably assured that, once installed, the item will not adversely affect the original qualification of the component. This assurance can be obtained by performing a technical evaluation and accepting the item using any of the four acceptance methods described in this report. In addition to the critical characteristics selected based on the safety function of the item, commercial-grade items intended for installation in seismically or environmentally qualified equipment or in locations that require such qualification shall include the selection of appropriate critical characteristics required to maintain the qualification of the component or equipment.

Technical staff who specialize in environmental or seismic equipment qualification should be consulted when considering dedication of environmentally qualified component-level items. All critical non-metallic materials that affect the component's safety functions and environmental qualification need to be verified as being the same material that successfully completed environmental qualification testing. Therefore, it may not be possible to dedicate certain complex, environmentally qualified, component-level items.

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 qualifications 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 testing on a sample of replacement items to the original qualification requirements—for example, the ability to withstand a harsh environment in terms of temperature, radiation, or chemical spray or the ability to withstand a seismic event
- 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 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. Depending on the criticality of the item (such as the O-ring), if it is the limiting material for qualification, a more detailed material verification up to ensuring that the material is a specific grade of EPDM may be necessary. This should be determined with assistance from technical staff who specialize in environmental or seismic equipment qualification.

Material characteristics (such as chemical composition and material strength) are often verified to ensure that environmental qualification is maintained. Verification that seismic qualification is maintained is typically complex. EPRI report TR-112579, *Critical Characteristics for Acceptance of Seismically Sensitive Items (CCASSI)* [24], provides additional guidance.

Appendix I contains additional information on equipment qualification and the difference between equipment qualification and commercial-grade dedication.

6.6.1 Seismically Sensitive Items

In applying the commercial-grade dedication process to seismically sensitive items, nuclear plant licensees have developed a guideline for selection and verification of critical characteristics related to seismic performance (see EPRI TR-112579, *Critical Characteristics for Acceptance of Seismically Sensitive Items [CCASSI]*) [24]. This report provides a consistent industry approach for licensees to maintain seismic qualification through the commercial-grade dedication process. CCASSI provides a basis for establishing similarity between the commercial-grade items purchased today and the items previously qualified. Application of this methodology allows the user to maintain seismic qualification of replacement items without incurring the costs of performing seismic qualification testing on each batch of items procured.

6.6.2 Identification of Seismic and Environmental Critical Characteristics at the Part Level

EPRI TR-112579, *Critical Characteristics for Acceptance of Seismically Sensitive Items (CCASSI)* [24], includes detailed guidance on selecting critical characteristics for seismically sensitive items.

Equipment qualification requirements are usually established at the component or system level. However, replacement items are frequently parts within a qualified component or system. Therefore, it is difficult to determine critical characteristics both for design and acceptance at the part level as they relate to the component's or system's equipment qualification requirements.

Replacement of parts within a qualified component or system is usually based on a replacement-in-kind philosophy, where the replacement part is identical to that in service. Many qualification reports provide bills of materials or parts lists of the items on which the qualification was based. Where design characteristics of the originally qualified part cannot be determined, an engineering analysis up to and including completely new environmental and/or seismic qualification may be required. In most cases, however, the engineering analysis can determine the impact on the component by evaluating the specific qualification parameters against the purpose of the qualification. For example, replacing metallic parts within a component environmentally qualified to meet radiation, temperature, and humidity-related degradation parameters on the component's polymer-based parts will have no effect on the environmental qualification report. However, when the chemical composition of a polymer-based item cannot be determined, an engineering analysis or test can evaluate the ability of the chemical composition of the replacement item to perform in the application's environmental parameters. EPRI report NP-7484, *Guideline for the Seismic Technical Evaluation of Replacement Items for Nuclear Power Plants* [81], provides detailed guidance on the evaluation of replacement items with seismic considerations.

The selection of critical characteristics for these parts then becomes a matter of focusing on the results of the technical evaluation. Where the replacement part is identical and minimal technical evaluation is performed, the user should focus on critical characteristics that ensure that the part meets its specified requirements.

7

METHOD 1: SPECIAL TESTS AND INSPECTIONS

Special tests and inspections are activities performed during or after an item is received to verify the critical characteristics. Post-installation testing is a type of special test or inspection performed at the owner's (licensee's) nuclear facility after the item has been installed. Final product testing performed at a supplier's facility is not considered post-installation testing. Therefore, post-installation tests are available only to dedicating entities that are responsible for installing the item in the owner's (licensee's) nuclear facility. Figure 7-1 is a standard flow chart depicting the special tests and inspection process.

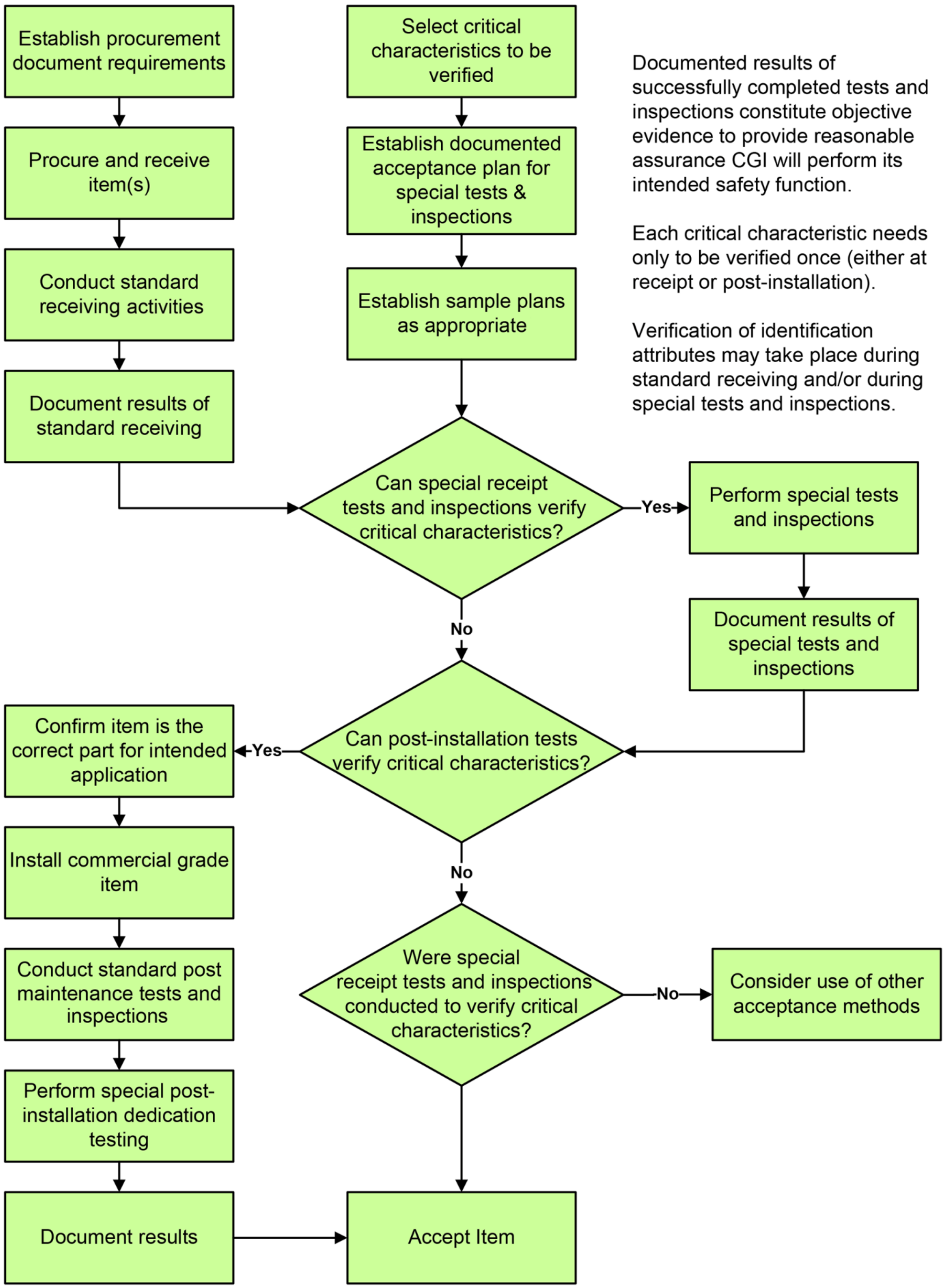


Figure 7-1
Use of special tests and inspections

7.1 Difference Between Special Tests and Inspections and Receipt Inspection

Receipt inspection activities are typically performed before the verification of critical characteristics and include verification of attributes such as the following:

- Quantity received
- Evidence of damage incurred during shipment
- General condition of the item
- Part number
- Model number
- Appropriate packaging
- Supplier documentation

Method 1: Special Tests and Inspections are additional activities performed to verify that critical characteristics conform to the acceptance criteria.

7.2 Applications for Method 1

Method 1 should be used when the purchaser desires to verify critical characteristics after the item is received. The purchaser can apply this method to all commercial-grade items when sufficient data exist to perform appropriate inspections and tests. Method 1 is most appropriate for the following:

- Items furnished by multiple suppliers
- Items that are relatively simple in nature
- Items on which post-installation tests can be conducted to verify critical characteristics

Method 1 may also be used in the following situations:

- There is no evidence that a commercial-grade survey was conducted, or there is a reluctance to rely on the supplier’s commercial quality controls.
- Concerns were identified during a prior commercial-grade survey.
- Items are procured frequently and in large quantities (such as commodity items).

Information needed to identify critical characteristics is generally available in existing documents, such as specifications, drawings, instruction manuals, bills of material, and catalogs. Interface with the supplier may be necessary to obtain additional information.

Where sufficient information to use Method 1 cannot be obtained from suppliers because of proprietary considerations, other methods of acceptance must be considered.

Acceptance criteria should be objective (not subjective) and quantitative when appropriate.

Method 1 can be used if the technical data are known, test facilities are available, and critical characteristics of the items can be verified by inspection and tests. Method 1 may be used in combination with other acceptance methods. Combining acceptance methods is discussed in Appendix F.

7.3 Use of Method 1

Critical characteristics must be verified through special inspections and/or tests (including post-installation tests). These inspections and tests should be performed in addition to, or in conjunction with, receipt inspection.

To employ Method 1, critical characteristics should be verified in accordance with a documented plan or checklist. This plan/checklist should include the following:

- Tests and inspections to be performed
- Test methods and inspection techniques to be used (documented test and inspection procedures may be required as appropriate)
- Acceptance criteria previously derived from the technical evaluation
- Documentation requirements for inspection and test results

The tests and inspections may be performed using a sampling plan when appropriate. Justification for selection and use of the sampling plan must be documented.

It should be noted that the purchaser may subcontract the special inspections and tests by using the services of a purchaser-approved test facility.

In the following example, special tests and inspections are used to verify selected critical characteristics for a valve stem. The critical characteristics to be verified for the valve stem include the material of construction, dimensions, material hardness, and configuration. These critical characteristics could be verified with the special tests and inspections shown in Table 7-1.

Table 7-1
Example of critical characteristics and associated special tests and inspections for a valve stem

Critical Characteristic/ Identification Attribute	Acceptance Method	Description of Inspection or Test and Test Equipment	Acceptance Criteria
Material (chemistry)	Method 1, Special Tests and Inspections	Material test using spectrographic analysis	The material of construction meets the product analysis criteria of the material specification.
Material (hardness)	Method 1, Special Tests and Inspections	Hardness test using Rockwell B	Material hardness is within the allowable criteria, including tolerances.

Table 7-1 (Continued)
Example of critical characteristics and associated special tests and inspections for a valve stem

Critical Characteristic/ Identification Attribute	Acceptance Method	Description of Inspection or Test and Test Equipment	Acceptance Criteria
Dimensions	Method 1, Special Tests and Inspections	Physical measurement using calibrated instruments	Dimensions are within the allowable criteria, including tolerances.
Configuration	Method 1, Special Tests and Inspections	Visual comparison	Configuration is consistent with the drawing.

Note that the manufacturer and part number would be verified as identification attributes during receipt inspection.

7.4 Use of Sampling

7.4.1 Sampling Guidance

EPRI TR-017218-R1, *Guideline for Sampling in the Commercial-Grade Item Acceptance Process* [23], includes detailed guidance on the use of sampling plans to accept commercial-grade items. The normal, reduced, and tightened sampling plans in the report are based on the premise that the entire lot is rejected when a single defective item is identified. When using the sampling plans in TR-017218-R1 [23], it is imperative that the report be read in its entirety and the basis for selection of sampling plans be clearly documented.

Caution: sampling should not be used with post-installation testing.

7.4.2 Basis for Use of Sampling

When used with a well-documented basis, sampling is useful in conducting receipt inspection and verification activities, as indicated in the following standards and regulatory documents:

- ANSI N45.2.13: "Sampling may be utilized during receipt inspection when conducted in accordance with established procedures or recognized standards" [36].
- IP43004: Sampling plans for testing should be used in accordance with nationally recognized industry standards, and should have an adequate documented technical basis. This technical basis includes homogeneity, complexity of the item, lot/batch control for items, heat traceability for materials, and adequacy of the vendor's controls as confirmed by a survey. Other means of demonstrating adequate lot/batch control may include satisfactory performance history and the results of receipt inspections/testing. When such methods are used as a basis for developing product sampling strategy, they should be supported by documented objective evidence. [26]
- ASME NQA-1 2008 Edition, 2009 Addenda, Requirement 10, 402: "Sampling procedures, when used, shall be based upon standard statistical methods with engineering approval" [1].

- ASME NQA-1 2008 Edition, 2009 Addenda, Part II, Subpart 2.2, Section 502.2a: "Where specific inspection requirements can be achieved, statistical sampling methods may be used for groups of similar items" [1].
- ASME NQA-1 2008 Edition, 2009 Addenda, Part II, Subpart 2.14, Section 602:

  > Special test(s), inspection(s), and / or analysis may . . . be performed utilizing a sampling plan, when appropriate. . . .Sampling plans utilized to select items for special test(s), inspection(s), and / or analysis shall be based upon standard statistical methods with supporting engineering justification and shall consider lot/batch traceability, homogeneity, and the complexity of the item. [1]

- Revision 1 of NRC NUREG-1475, Applying Statistics, provides guidance on the application of statistical sampling from a regulatory perspective [83].

Caution: It is not appropriate to employ the sampling plans included in EPRI TR-017218-R1 [22] without first carefully evaluating and documented the basis for selection of a particular sampling plan for the specific critical characteristic being verified.

When providing items with certification stating that they comply with a code or standard (such as an ASME or ASTM material specification), it is not appropriate to use the EPRI sampling plans in lieu of specific sample sizes required by the applicable standard.

7.4.3 Application of Sampling

Consideration of whether to employ sampling is made during the technical evaluation process after critical characteristics are selected. Establishing the lot to be sampled is an important consideration when selecting the appropriate sampling plan. Confidence in the homogeneity of the lot is directly related to how the lot is formed. There are three types of lot formations, as follows:

- If production traceability exists, a high degree of lot homogeneity would be expected, and a relatively small sample size would be needed to detect a nonconforming characteristic. These items are traceable to raw material(s), time of production, manufacturing process, manufacturer, and purchase order.
- If line item/single product manufacturer traceability exists, a smaller degree of lot homogeneity would be expected, and a larger sample size may be needed to detect a nonconforming characteristic. These items are traceable to manufacturing process, the manufacturer, and the purchase order.
- If only line item/multiple product manufacturer traceability exists, a larger sample size would be selected to have greater confidence that the sample results are representative of the lot. These items are only traceable to a distributor and a purchase order.

Factors to consider in addition to the anticipated lot formation are the ability to control homogeneity of the lot through procurement requirements and activities, the number of critical characteristics selected for verification, and the relationship between the characteristics.

Some of the factors typically considered when selecting a sampling plan include the following:

- Complexity of the item
- Applicability of industry standards to the item
- The item's performance history
- Supplier controls and performance history
- Cost- effectiveness of the test or inspection
- Safety significance of the critical characteristic
- Quantity of other critical characteristics being verified
- Correlation between destructive and nondestructive tests

Sampling plans are selected during the technical evaluation. It is important to document the basis for selection of a sampling plan during the technical evaluation and to recognize that sampling may impact other aspects of the procurement and dedication process, such as the following:

- It may be necessary to increase the quantity of items procured to ensure that enough are available for sampling.
- It may be necessary to perform a survey or source verification to provide assurance of lot homogeneity upon which the selected sampling plan is based.
- It may be necessary to adjust the sequence in which various critical characteristics are verified to ensure that enough are available for sampling.

Sampling plans are implemented during the acceptance process. It is not acceptable to change a sampling plan during the acceptance process without first revising the technical evaluation to ensure that the basis for revision is justifiable and documented accordingly.

7.5 Internal Testing Capability

Special tests and inspections can be conducted internal to the dedicating entity's organization or by external organizations when the dedicating entity does not have the appropriate equipment or resources necessary to perform the testing.

7.5.1 Guidance

The decision to perform special tests and inspections internally or externally lies with the dedicating entity based on personnel availability, access to testing equipment and individuals qualified in its use, and so on. A list of some typical tests and inspections is provided in Table 7-2. The list is not intended to be all-inclusive; it simply includes some common internal testing capabilities.

Table 7-2
Typical tests and inspections

Typical Tests and Inspections	
Continuity test	Silicon-controlled rectifier testing
Hardness testing or twist testing	RPM measurement
Viscosity testing	Balance checking
Spring constant testing	Vibration testing
Insulation resistance testing	Nondestructive evaluation—penetrant, ultrasonic, magnetic particle
Voltage and ampere rating	Pressure testing at design pressure
Specific gravity testing	Temperature range verification
Durometer hardness testing	Pressure range verification
Dimensional verification	Contact rating—voltage, continuous current, interrupting capacity
Resistance testing	Material verification
Motor load testing	Pull-in voltage, drop-out voltage, die-electric strength, insulation resistance, repeatability (%), contact resistance for relays
Dielectric testing	Ductility
Capacitance testing	Material composition—ash, fluorine, chlorine, sulfur content

The question of economics for in-house test capability cannot be ignored. To determine whether capability should be in-house, the user should determine the frequency of tests, cost of outside testing, criticality of item to be tested, average number of tested items on hand, labor cost and skill required to perform the test, and costs of test equipment, including depreciation and obsolescence. By comparing these values, the user can make the determination. In general, the simpler the test and the higher the frequency (hardness, alloy verification, durometer, continuity, insulation resistance, electrical resistance, and so on), the more likely it should be performed in-house. The test equipment required to implement these tests should be selected based on accuracy requirements, ease of operation, reliability, calibration requirements, and so forth. It is imperative that the test equipment used to perform acceptance testing be controlled under a calibration program and maintained in an environment that is not detrimental to the M&TE's operation. The supplier of the M&TE will provide guidance on the use and care of their respective equipment.

Selection of critical characteristics should be based on safety function(s), not internal availability of testing equipment. Selection of critical characteristics is part of an engineering evaluation process based on achieving reasonable assurance that an item will be capable of performing its intended safety function(s). The availability of test equipment will affect only the method of verification for a particular critical characteristic and not whether the characteristic is valid.

7.6 Use of External Testing Laboratories

Dedicating entities may elect to use outside testing laboratories in lieu of maintaining testing capability in-house or to perform unique, infrequent, or complicated testing.

Testing and inspections conducted pursuant to commercial-grade dedication should be either performed under the auspices of a QA program meeting the requirements of 10CFR50, Appendix B, or procured and dedicated as commercial-grade services by the dedicating entity.

7.6.1 Control of Inspection and Testing

In general, testing laboratories, like other types of suppliers, may implement quality programs ranging from 10CFR50, Appendix B, and ASME NQA-1 to unique internal programs, ISO programs, and programs accredited by organizations such as International Laboratory Accreditation Cooperation (ILAC), Assured Calibration and Laboratory Accreditation Select Services (ACLASS), and the American Association of Laboratory Accreditation (A2LA).

When outside services are used, the purchaser must have verified that the test laboratory has in place programs and procedures that, at a minimum, ensure that the following:

- Tests are conducted properly and to industry standards (ASTM and so on) where necessary.
- Test equipment is calibrated and maintained in accordance with manufacturer recommendations.
- The accuracy of test equipment used is appropriate to the acceptance criteria and tolerances specified.
- Testing personnel are trained and qualified in the use of the test equipment and test methodologies.
- Calibration standards are traceable to nationally recognized standards.

7.7 Post-Installation Testing

During the acceptance process, the dedicating entity must ensure that a formalized process for using post-installation testing to verify critical characteristics is in place and that procedures are adequate to ensure that the specified acceptance criteria have been found satisfactory, documented, and accepted. Examples of effective controls include confirmation that the post-installation testing is included as a mandatory step in the associated work order prior to issuance of the item, a conditional release process to ensure that post-installation tested items are not considered operable until testing is completed, and clear identification of items requiring post-installation testing with tags or other appropriate labels.

The post-installation test requirements and acceptance criteria should be delineated clearly in the work/job order package as defined by the dedicating entity's process control. Additionally, measures should be established to ensure that processes have adequate controls in place to prevent any organizations involved in the post-installation testing process from waiving a post-installation test that was to be included in the commercial-grade acceptance plan. Care should be exercised to ensure that the post-installation test used does in fact provide verification that the selected critical characteristics meet their associated acceptance criteria. For example, the operability run of a pump/motor will not verify acceptable vibration or shaft alignment unless those measurements are specifically recorded. Post-installation testing may also put the utility at risk of having to scramble to find a replacement when failure of the item is found during post-installation testing rather than receipt. Items that prove to have high failure rates or high probability for failure should not continue to be accepted through post-installation testing.

Good material control practices are critical throughout the post-installation testing process. To ensure that tests or surveillance activities are not missed, material control processes should include items such as component tagging indicating that post-installation testing is required. Simple measures, such as component tagging combined with administrative mechanisms and process controls for witness/hold/notification points or database flags, are other effective means of controlling an item through the post-installation testing process.

Post-installation testing should not be used to verify every critical characteristic associated with a specific item unless this method is the only practical approach. Post-installation testing should also not be confused with final product testing performed at a supplier's facility.

Because post-installation testing would occur after receipt and prior to or after installation of the item by the purchaser, suppliers providing such items as basic components based on commercial-grade dedication should not use post-installation testing to verify the critical characteristics. In most cases, the supplier could not certify the item as being safety-related because all critical characteristics selected by the supplier have not been verified and would prevent the purchaser from accepting the item as a basic component. Regardless, the necessary controls that would need to be established between the supplier and the purchaser to ensure that critical characteristics are adequately verified by the purchaser's post-installation testing process would be cumbersome, with a potential for inadequate verification of the critical characteristic. Post-installation testing is not a viable method for supplier verification of critical characteristics.

Once the post-installation testing has been completed, the test documentation associated with the specific test or surveillance should be retained as a record of the test activities conducted and proof of satisfactory completion of the post-installation test. There is no requirement or intent to require any specific storage location of documentation associated with post-installation testing. Documentation may stay with the work/job order package or any other place as defined by the dedicating entity's process controls. The work/job order package can be considered acceptable documentation as long as it is traceable to the installed items. However, a feedback loop should exist to ensure that engineering and QA personnel are aware of the acceptance or failure of items during post-installation testing.

Upon completion of the post-installation test with satisfactory acceptance results, the item can be considered accepted for safety-related use.

Refer to Section 5.7.6 for precautions/lessons learned associated with post-installation testing for verification of critical characteristics.

8
METHOD 2: COMMERCIAL-GRADE SURVEY

8.1 Commercial-Grade Surveys Versus Audits

8.1.1 Background

During the development of EPRI NP-5652 [2], there was a concerted effort among utility members to establish a new methodology for evaluating supplier commercial QA programs that was a departure from the compliance and programmatic-based approaches that had been prevalent in the industry until then. This is why Acceptance Method 2 was not called a commercial-grade *audit* but rather something different—a *commercial-grade survey*. Members of the group that developed the guidance recognized that a performance-based approach would be more effective for verifying the extent to which a commercial supplier adequately controlled the critical characteristics of a given item than the programmatic-type reviews that had been used for qualifying suppliers with nuclear QA programs and who primarily provided original plant equipment/components.

Also during the development of EPRI NP-5652 [2], the NRC challenged the industry to extend the performance-based approach when evaluating nuclear supplier QA programs. NRC conditional endorsement of Acceptance Method 2 and EPRI NP-5652 led to the publication of EPRI NP-6630, *Guidelines for Performance-Based Supplier Audits (NCIG-16)* [84], in June 1990.

The main objective of evaluating a commercial supplier should be verification that the critical characteristics of the items being procured are adequately controlled.

8.1.2 Purpose of Commercial-Grade Surveys vs. Audits

The distinction between the terms *commercial-grade survey* and *audit* can be confusing, particularly when the terms are applied to supplier audits of their subtier supplier's programs. In many cases, subtier suppliers maintain commercial QA programs that use the term *audit* and, as a result, use *audit* to describe any assessment. Audits conducted in accordance with commercial QA programs are not always performance-based. In many cases, "audits" of subsuppliers are not focused on the verification of critical characteristics and therefore do not fulfill the requirements of a commercial-grade survey.

Commercial-grade surveys should not be confused with audits. Inadequate implementation of Method 2 for verification of critical characteristics has resulted from dedicating entities using the terms *commercial-grade survey* and *audit* interchangeably.

Although both types of assessments have similar general requirements for planning, performance, and reporting results, their purpose and focus are not the same. The purpose of an audit is to determine the adequacy of a QA program and its compliance with a regulation or standard. The purpose of a commercial-grade survey is to determine if the supplier of the commercial-grade item or service has documented controls in place that adequately control the critical characteristics that have been determined to be applicable by the dedicating entity; it should also determine whether those controls are being implemented effectively.

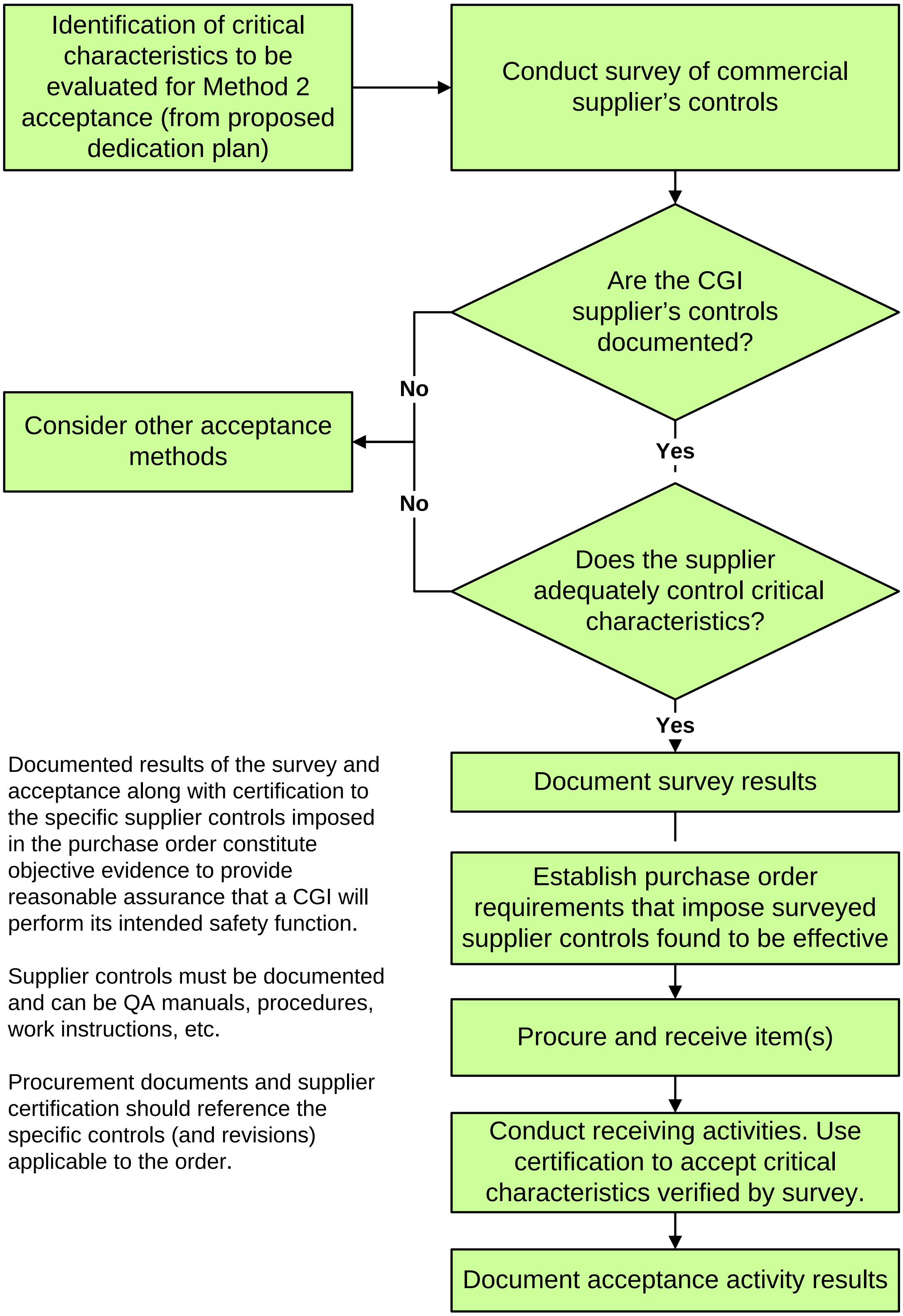
Both the audit and commercial-grade survey will evaluate the supplier’s controls/processes; however, unlike a commercial-grade survey, a programmatic-based audit may not require identification of critical characteristics, resulting in a potentially inadequate assessment of the supplier’s ability to sufficiently control the specified critical characteristics necessary for dedication of the item or service.

8.1.3 Conclusion

Assessments of commercial-grade suppliers where the supplier’s controls will be used as the basis for verification of one or more critical characteristics for the dedication of items and services should be performance-based. Additionally, documentation (that is, certificates of conformance and so on) received from a commercial-grade supplier or subtier supplier can be used only by the dedicating entity to support the dedication process if a commercial-grade survey had been conducted that verified the adequacy of controls over the critical characteristics of the item(s).

8.2 Method 2: Commercial-Grade Survey of Supplier

Figure 8-1 is a basic process flow chart for the use of a commercial-grade survey to accept a supplier’s programmatic controls of selected critical characteristic for a commercial-grade item.



Note: CGI = commercial-grade item

Figure 8-1
The commercial-grade survey process

8.3 Appropriate Applications for Method 2

Method 2 is used when the dedicating entity desires to verify applicable critical characteristics of commercial-grade items based on the merits of a supplier’s commercial quality controls. These controls may constitute qua1ity programs, procedures, or practices.

The types of suppliers that can be surveyed include approved nuclear suppliers maintaining both a commercial program and a 10CFR50, Appendix B, QA program [7] as well as commercial-grade suppliers with no 10CFR50, Appendix B, QA program. These suppliers include the following:

- NSSS suppliers
- OEMs
- Original part manufacturers
- Distributors (NRC Generic Letter 89-02 [10] includes cautions associated with the use of distributors.)

A commercial-grade survey can be used to accept simple or complex items. The method is most appropriate in the following situations:

- A single supplier of the commercial-grade item is being used.
- The technical information required for a successful technical evaluation and acceptance plan cannot be obtained from the supplier.
- A large group of items is repeatedly procured from a supplier for an entire line of components.
- The commercial-grade item is an assembly of many parts.
- The dedicating entity cannot easily verify critical characteristics by inspections or tests.

Significant technical and quality information about a supplier’s line of replacement items can be obtained during the survey. This information can subsequently be used in other acceptance scenarios as necessary.

Where a supplier demonstrates adequate controls for all applicable critical characteristics, verification of the product identification and the supplier’s certificate of conformance is required during the receipt inspection to complete item acceptance. If only certain critical characteristics are controlled by the supplier’s Method 2 controls, other acceptance method(s) must be used to complete acceptance of the remaining critical characteristics. Maximizing reliance on the supplier’s Method 2 controls will minimize the need to supplement acceptance verifications with other methods, such as Method 3: Source Verifications, at specified hold points during manufacturing or fabrication.

8.4 Use of Method 2

Two basic criteria must be met when conducting a commercial-grade survey. The dedicating entity must confirm that the supplier’s controls are documented. Second, it must be confirmed that the selected commercial-grade item’s critical characteristics are adequately controlled.

The survey criteria and the supplier controls will vary from item to item. The survey criteria and necessary supplier controls should be determined by the dedicating entity.

The survey should be specific to the scope of the particular commercial-grade item(s) being purchased. When many items are purchased from a supplier, a survey of representative groups of commercial-grade items can be sufficient to demonstrate that adequate controls exist. For each item, appropriate quality controls should be confirmed as being exercised and properly documented.

Table 8-1 provides general guidance on the types of supplier controls that should be surveyed to ensure that critical characteristics are being controlled.

Table 8-1
Supplier controls typically surveyed

Supplier Control	Description
Design	Controls that ensure that an identical or equivalent item will be provided.
Procurement	Controls the supplier is exercising over subtier suppliers to ensure that items provided by subtier suppliers conform to specified requirements.
Material identification and control	Controls that ensure that only correct and accepted items are used, identification is established, and traceability is maintained.
Fabrication	Controls that ensure that fabricated items meet design requirements, such as statistical process control and in-process inspections. Fabrication controls might include controls over special manufacturing processes, such as welding.
Assembly	Controls that ensure that assembly is correctly performed and the assembly meets design requirements.
Calibration	Controls that ensure that M&TE are periodically calibrated and adjusted to maintain accuracy within necessary limits.
Testing	Controls that ensure that testing that verifies conformance to specified requirements or demonstrates satisfactory performance for service is successfully planned and executed.
Inspection	Controls that ensure that inspection that verifies conformance to specified requirements is successfully planned, executed, and documented.
Other controls may be necessary as they relate to the critical characteristics being verified.	

8.4.1 Documentation Associated with a Survey

The results of commercial-grade surveys should be documented and include the following:

- Any items included in the scope of the survey
- Critical characteristics controlled by the supplier
- Supplier controls verified specific to the critical characteristics

- Survey methods or verification activities performed with results obtained
- Conclusions attesting to the adequacy of the supplier controls

Inadequate supplier controls identified during the commercial-grade survey may be corrected by the supplier at the time they are made aware of the inadequacy. If the controls are not corrected by the supplier, the dedicating entity may use other acceptance methods presented in this report to verify those critical characteristics that were found to be inadequately controlled.

Once a supplier's controls have been deemed adequate, the dedicating entity shall invoke or reference the observed commercial or quality controls as a part of the purchase order requirements for the commercial-grade item. The supplier's compliance to the purchase order requirements should be documented by a certificate of conformance. Acceptance of the item will be completed by performing a receipt inspection with the accompanying supplier's certificate of conformance and additional acceptance methods, when applicable.

8.4.2 Qualification of Personnel Performing a Survey

Use of technically competent personnel is key in the successful application of Method 2. Personnel performing surveys should be subject matter experts in the type of items or services being furnished by the supplier being surveyed. In order to effectively evaluate the effectiveness of the supplier controls being witnessed and verified, survey personnel should be knowledgeable in the operation of the item(s) and the associated critical characteristics to be verified, including any special processes (such as welding and heat treatment) that are specific to the critical characteristics.

In addition, the survey team should include personnel familiar with performance-based evaluations (see EPRI NP-6630 [85]). Technically qualified or trained personnel often can provide valuable input by participating in survey plan development and/or participating as part of the survey team. Personnel qualifications should be delineated in procedures and documented.

8.4.3 Distributors

For situations in which intermediaries (distributors) are included in the supply chain, the activities of these organizations may need to be surveyed to ensure that the dedicating entity's purchase order requirements are communicated to the manufacturer and that traceability and proper storage conditions are maintained. A survey of the distributor may not be necessary if the distributor acts only as a broker and does not warehouse or repackage the items or in cases where traceability can be established by other means, such as verification of the manufacturer's markings or shipping records. In many cases, the dedicating entity may be reasonably assured that the distributor performs no actions that could have an effect on the quality of the item (that is, the item is never removed from its original packaging). In these cases, a survey of the manufacturer is necessary, but a survey of the distributor may not be necessary. If the distributor's activities could impact the traceability or quality of the item, the dedicating entity may need to assess the distributor's actions to determine whether additional actions need to be taken to ensure the quality of the item.

Actual handling of the item by a distributor should be addressed in terms of the distributor's controls (for example, segregation of customer returns). However, other factors may be taken into account that may warrant the need for a survey of the distributor, such as the following:

- The need for documented, verifiable traceability to the OEM
- The presence and integrity of OEM packaging/markings and so forth
- The susceptibility of the item to undetectable damage or tampering
- History or experience with the particular vendor and distributor(s)
- Procurements considered at risk of counterfeiting and fraud

As stated in Generic Letter 89-02:

> Method 2 should not be employed as the basis for accepting items from distributors unless the survey includes the item manufacturer(s) and the survey confirms adequate controls by both the distributor and the item manufacturer(s). [10]

For the purposes of this report, an authorized distributor is an organization approved by an original manufacturer to distribute, promote, and sell their products. Care should be taken when purchasing commercial-grade items from an unauthorized distributor (that is, brokers) because there may be an increased risk of receiving counterfeit or fraudulent items. Additionally, unauthorized distributors may not be aware of the proper protocols for storage, shipment, and handling of the items, and items handled by unauthorized distributors may be sourced from multiple suppliers/manufacturers.

8.4.4 Survey Frequency

Commercial-grade surveys should be conducted at sufficient frequency to ensure that the process controls applicable to the critical characteristics of the item or service procured continue to be effectively implemented. Factors to be considered in determining the frequency of commercial-grade surveys include the complexity of the item, frequency of procurement, receipt inspection, item performance history, and knowledge of changes in the vendor's controls.

NRC Regulatory Guides 1.28, Revision 4 [29], and 1.144 [64] state that a supplier maintaining a 10CFR50, Appendix B, program be audited at least every three years. This timeframe should serve as a benchmark for determining the frequency for commercial-grade supplier surveys. Annual evaluations of the supplier's performance should be incorporated into the dedicating entity's program. Indication of supplier deficiencies or significant changes in product design and quality should be followed with a new survey to verify that critical characteristics are being maintained. Interface with the commercial-grade supplier through the purchase order requirements and the supplier's certification of conformance is a key factor in identifying the need for additional surveys.

8.5 Survey Examples

8.5.1 Survey for a Volume Booster

An example of a replacement of a complex item that lends itself to acceptance by a survey is a commercial-grade volume booster assembly for a diaphragm control valve. A volume booster consists of approximately 20 parts, ranging from brass and aluminum items to elastomers. The critical characteristics to be controlled are the materials of construction, dimensions, operability, leakage, and pressure rating. Table 8-2 includes an example of survey activities that might be included in a survey for a volume booster.

Table 8-2
Example of supplier controls surveyed for a volume booster

Supplier Control	Typical Survey Activities
Design	Review the design documents to determine if the manufacturer has modified the design of the item that was originally qualified and supplied. Design changes should be addressed. Documentation should be available to demonstrate that the supplier performed an equivalency evaluation. If there were modifications, a review should verify the adequacy of the changes for the purchaser’s specific application.
Procurement	Review the procurement controls the supplier exercises, both on raw materials to be used in-house and on procured finished parts. Receipt inspection practices or procedures should be reviewed to verify that the supplier is ensuring that the correct material and items are being received.
Material	Examine the supplier’s material controls in the receiving, storage, and production areas to ensure that the proper parts are available for assembly and installation.
Fabrication	Review manufacturing controls for any items fabricated at the supplier’s facility.
Assembly	Review assembly practices to determine if changes have been made. Review inspections, torque, dimensions, and controls to ensure that the assembly is correct.
Calibration	Ensure that the supplier calibrates applicable measuring and testing equipment.
Inspection and testing	Investigate the types and frequency of inspections and bench tests that are performed. A bench test would confirm that the assembly was complete and the piece-parts were of the correct dimensions.

8.5.2 Survey for an Impeller Key

An impeller key is an example of a simple replacement item for which a commercial-grade survey could be used to accept it. The critical characteristics to be controlled for this item would be dimensions and material properties. Table 8-3 includes an example of survey activities that might be included in a survey for an impeller key.

Table 8-3
Example of supplier controls surveyed for an impeller key

Supplier Control	Typical Survey Activities
Design	Review the detailed design/fabrication drawing to determine if the manufacturer has modified the item's dimensions or material of construction.
Procurement	Review the procurement controls that the supplier exercises on the raw materials to be used in-house. Receipt inspection practices or procedures should be reviewed to verify that the supplier is ensuring that the correct materials are being received.
Material	Examine the supplier's material controls in the receipt and machining areas.
Fabrication	Review manufacturing controls for any machining or other fabrication activities conducted at the supplier's facility.
Calibration	Verify that the supplier calibrates applicable measuring and testing equipment.
Inspection	Confirm the types and frequency of inspections and tests that are performed.

In summary, by reviewing the commercial controls in several areas, reasonable assurance can be gained that the supplier's commercial-grade items are subject to adequate quality activities and that the supplier controls those features or characteristics deemed critical by the purchaser.

8.5.3 Example of a Survey Identifying Inadequate Design Control

Design control is being evaluated during a commercial-grade survey of a chiller manufacturer. The chiller manufacturer uses its own internal part numbers to identify valves and other subcomponents used to fabricate the chiller and has drawings for each internal part number that identifies the OEM and OEM part number. The drawings typically include more than one OEM and OEM part number that can be used for the same internal part number. Upon questioning, it is learned that the manufacturer stocks products from any of the OEMs listed in the drawing in the same bin. As a result, chillers with the same model number may contain different internal parts.

The survey team determines that the controls are not adequate to maintain the design of the chillers being procured. Although using two different OEM parts interchangeably may be acceptable to a commercial customer, this practice might challenge the dedicating entity's ability to control design, manage configuration, maintain seismic or environmental qualification, and so forth.

To compensate, the dedicating entity works with the supplier to agree on a bill of material that identifies a specific OEM/OCM and part number for each part used in fabrication of the chiller. Use of the agreed-on bill of material is specified in the purchase order, and the dedicating entity decides to use Method 3: Source Verification and Method 1: Special Tests and Inspections to ensure that each chiller they purchase consists of parts identified in the bill of material.

8.5.4 Example of a Survey Identifying Inadequate Calibration Controls

During a commercial-grade survey, the dedicating entity learned that a manufacturer of small valves relied on verification of dimensions and material properties associated with piece-parts used to manufacture and assemble their products. Although the tests and inspections were found to be appropriate, the survey team learned that the supplier’s calibration program was inadequate to ensure that the measurements being taken were accurate.

Therefore, the dedicating entity could not take credit for the commercial supplier’s control over identified critical characteristics. The dedicating entity could select one of the following options to remedy this supplier inadequacy:

- The dedicating entity procures the services of a qualified calibration service provider to calibrate the manufacturer’s equipment.
- The dedicating entity conducts Method 3: Source Verification using their own M&TE during the manufacture of the valves to ensure that the measurements of the critical characteristics are accurate and conform to design requirements.
- The dedicating entity procures the services of a testing facility with an adequate calibration program to test/inspect the piece-parts at their facility prior to the valves being assembled. This option is feasible only if there are adequate material controls and traceability to ensure that the tested/inspected parts are returned to the manufacturer for use. The test results are reviewed by the dedicating entity for accuracy prior to returning the tested items to the manufacturer.

8.6 Commercial-Grade Survey Precautions and Lessons Learned

8.6.1 Use of a Survey as the Sole Basis for Acceptance

Dedicating entities and suppliers have questioned the ability to use a survey as the sole basis for accepting an item in light of precautions provided NRC Generic Letters 89-02 [10] and 91-05 [19].

Receipt inspection should be used to complete the acceptance of items being dedicated using Method 2.

In Generic Letter 89-02, the NRC established two caveats in the use of commercial-grade survey as a basis of acceptance. They are as follows:

> (1) Acceptance Method 2, “Commercial-Grade Survey of Supplier,” should not be employed as the basis for accepting items from suppliers with undocumented commercial quality control programs or with programs that do not effectively implement their own necessary controls.
>
> (2) Method 2 should not be employed as the basis for accepting items from distributors unless the survey includes the part manufacturer(s) and the survey confirms adequate controls by both the distributor and the part manufacturer(s). [10]

Therefore, when the use of Method 2 clearly demonstrates that critical characteristics are controlled as documented in the survey report, Method 2 can be a sole basis of acceptance coupled with receipt inspection by the dedicating entity. However, it must be noted that suppliers may manufacture several product lines and may not apply the same controls to all of their products. In addition, different products may not have the same critical characteristics. Care should be taken to ensure that survey reports are specific to all product lines being accepted. It is also prudent for the user to obtain a certificate of conformance when using this method as a sole basis of acceptance to reconfirm, as a minimum, that the supplier used the controls that were surveyed on the item being supplied.

8.6.2 Use of Surveys Prepared by Others

Survey reports prepared by other entities may be used as described in the text corresponding to Step 5.7.12.

9
METHOD 3: SOURCE VERIFICATION

9.1 Source Verification

Source verification includes activities where the dedicating entity verifies the applicable critical characteristics at the supplier's facility. The source verification process is controlled under the dedicating entity's QA program and procedures that meet the requirements of 10CFR50, Appendix B [7].

Source verification can involve a wide range of activities, including oversight of supplier processes and quality controls, witnessing or performing tests and inspections, review of supplier documentation, and so forth. Figure 9-1 is a standard flow chart depicting the source verification process.

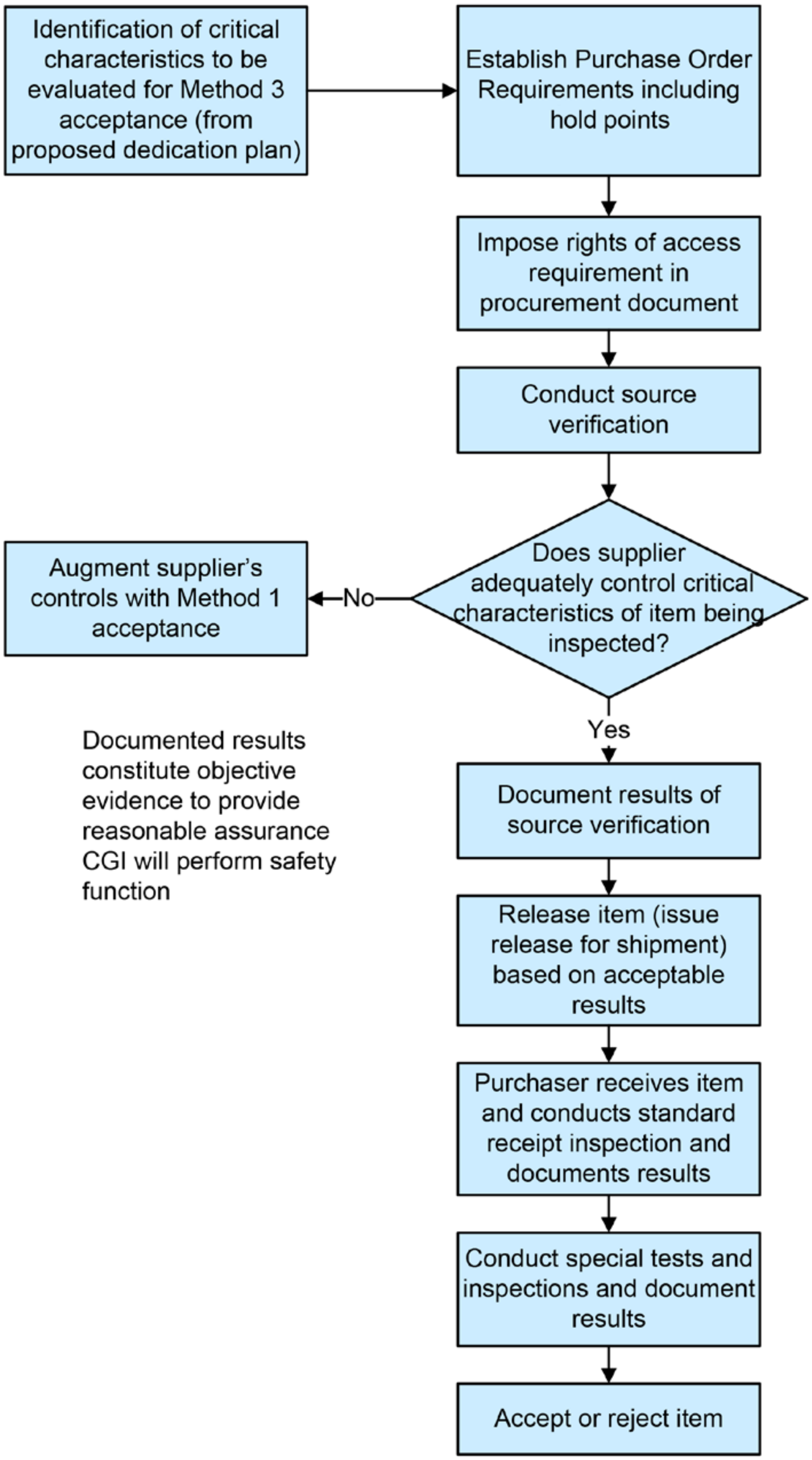


Figure 9-1
Method 3: Source Verification Process

9.2 Typical Applications for Method 3

Source verification (Method 3) is applied to accept a single item or shipment of items. This is different from a commercial-grade survey (Method 2), which is intended to qualify a supplier for multiple shipments of items within the scope of the survey. Source verification may be useful in the following situations:

- A vendor does not have a documented QA program for controlling critical characteristics.
- A single item or batch of items purchased infrequently requires dedication.
- Complicated or critical processes used during the manufacture of an item prevent after-the-fact verification from providing adequate assurance.

9.3 Use of Method 3

9.3.1 Critical Characteristics to Verify

The basic purpose of conducting source verification is to confirm that the selected commercial-grade item's critical characteristics are satisfactorily controlled by the supplier.

The activities witnessed by the dedicating entity will vary from item to item and should be dependent on the number and type of critical characteristics. The scope of the source verification may include witnessing fabrication and assembly processes, nondestructive examinations, performance tests, or final inspections. It may also include confirmation of the supplier's design, procurement, calibration, and material control methods employed for the particular commercial-grade item being purchased.

9.3.2 Planning for Source Verification

An effective plan that clearly identifies critical characteristics and acceptance criteria is essential to successful source verification.

The plan is developed during the technical evaluation process (refer to Sections 5.7.15–5.7.18) and as a minimum includes the following:

- Scope of the source verification that clearly identifies the item(s) and activities to be witnessed that will verify each critical characteristic
- Identification of any M&TE, personnel, and so on required to perform the verification
- Acceptance criteria for the activities to be witnessed
- Identification of hold points in the supplier's processes
- Identification of the sequence in which verification activities should be conducted

Verification activities should be discussed with the supplier during planning of the verification to confirm the schedule and availability of personnel, equipment, and so forth.

9.3.3 Qualification of Personnel Performing Source Verification

Use of technically competent personnel is a key in the successful use of Method 3. The personnel performing source verification should be subject matter experts in the type of items or services being furnished. In order to effectively evaluate the effectiveness of the supplier controls being witnessed and verified, source verification personnel should be knowledgeable in the operation of the item(s) and the associated critical characteristics to be verified, including any special processes—such as welding and heat treatment—that are specific to the critical characteristics.

Technically qualified or trained personnel often can provide valuable input by participating in the development of the source verification plan and/or participating as part of the source verification team. Personnel qualifications should be delineated in procedures and documented.

9.3.4 Use of External Resources

Dedicating entities may enlist contracted agencies to perform source verification activities on their behalf. When external resources are used, it is important that the verification plan include sufficient technical input to ensure that the plan can be executed by the verification personnel. It is not appropriate to use generic verification plans designed for a wide variety of items that do not specifically address the selected critical characteristics and acceptance criteria of the item(s) being verified.

When using contracted agencies, the dedicating entity should ensure that personnel performing verification activities have appropriate experience and are qualified in the methods and processes included in the plan.

9.3.5 Documenting the Results of Source Verification

Documented results of the source verification should include the following:

- Identification and qualifications of personnel conducting (not witnessing) tests or inspections
- The identity and revision of procedures, processes, tests, or inspections being performed
- The identity and calibration status of the M&TE used
- Photographs (when permitted)
- The results of the activities witnessed that establish verification of critical characteristics

Documentation of the source verification can be by hard-copy records or electronic records under control of a 10CFR50, Appendix B–compliant QA program.

9.3.6 Identification of Deficiencies

Deficiencies identified during the source verification should be dispositioned by the supplier before shipping. Source verification personnel typically authorize shipment and establish initial traceability. These individuals also provide initial traceability so that on subsequent receipt of the item, the dedicating entity can establish appropriate correlation between the items received and the source verification documentation.

9.3.7 Example: Pump Impeller

As an example, consider a pump impeller with the following parameters:

- **Item:** A safety-related replacement pump impeller (non-ASME Section III).
- **Safety function:** To produce flow and pressure during and after design basis accidents.
- **Supplier information:** The supplier of the impeller is the original pump manufacturer, who no longer maintains a nuclear QA program. Therefore, the pump impeller cannot be furnished as a basic component and is eligible for commercial-grade dedication.
- **Approach:** Procure the impeller as commercial-grade and accept it using Method 3: Source Verification.

Method 3 was chosen as the optimal means for dedicating the pump impeller. A commercial-grade survey (Method 2) was not selected. The plant does not anticipate purchasing any other items from the supplier in the next four years. Special tests and inspections (Method 1) is not a viable option because the plant is not in possession of the detailed design information required to identify appropriate acceptance criteria. In addition, some of the characteristics must be verified during the manufacturing process. Table 9-1 lists the critical characteristics and the verification activities that were witnessed and examined during the source verification. Note that numerous visits to the facility were required in order to verify these six critical characteristics.

Table 9-1
Example of using Acceptance Method 3

Selected Critical Characteristics	Source Verification Activities
Material of construction	Examine supplier's design, procurement, and material controls. Also, determine how the supplier verified material characteristics.
Surface hardness	Witness heat treatment process prior to milling.
Homogeneity of the blanks	Witness NDE (ultrasonic testing).
Dimensions/configuration	Witness dimensional inspection using supplier drawing for dimensions and tolerances.
Integrity of the welds and milled segments	Witness NDE (penetrant testing and magnetic particle testing).
Balance at design speed	Witness supplier's balancing test for impellers.

9.4 Special Acceptance Practices When Using Method 3

A release for shipment is signed by personnel conducting a source verification to provide objective evidence that the supplier did (or did not) adequately control the critical characteristics and/or complete the scope of activities required by the source verification plan. The release for shipment typically includes serial numbers or other identifying information, such as lot or batch numbers or container numbers. This identifying information can be used during receipt inspection at the customer site to ensure that the items shipped are the actual items for which the verification was performed. A copy of the release for shipment is typically included with the item(s) being shipped.

When source verification is successful, the acceptance activities at the customer's site typically include receipt inspection, verification of the release for shipment, and verification of identifying information.

10

METHOD 4: ITEM/SUPPLIER PERFORMANCE RECORD

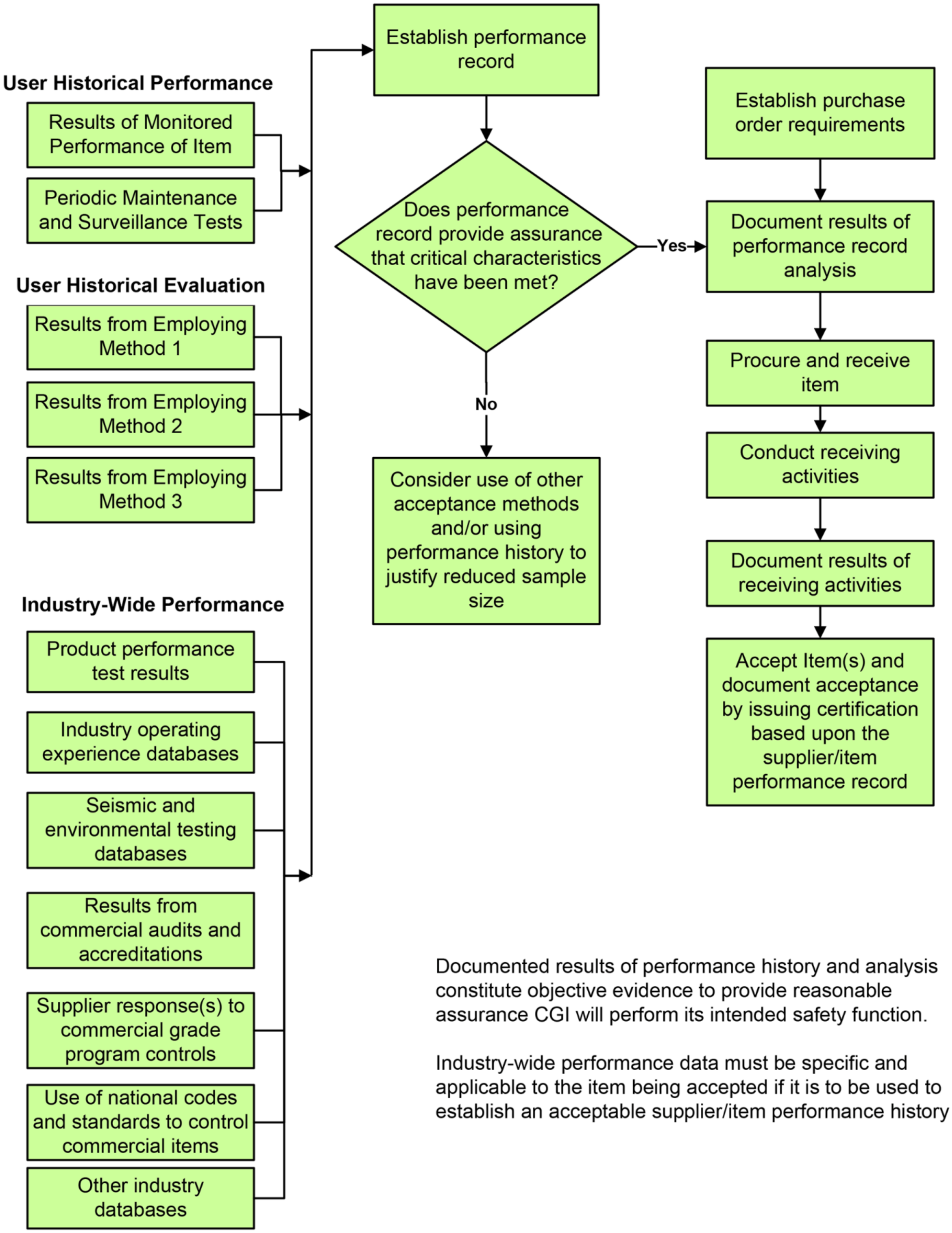
10.1 Description of Method 4

A documented item or supplier performance record is a method of acceptance that may be used under certain stipulations to verify acceptability of one or more of the identified critical characteristics of a commercial-grade item or service. This may require evaluation of the supplier's performance record for identical or similar items or services. Use of Method 4 to confirm the acceptability of one or more critical characteristics can provide the dedicating entity with the capability to establish reasonable assurance of the item's or supplier's performance based on historical performance gained from the successful utilization of other acceptance methods and/or pertinent industrywide performance data. Acceptable data for historical performance may be compiled using monitored performance of the item, industry product tests, compliance with national codes and standards (non-nuclear-specific), and other industry records or databases. The item or supplier performance record (or data) shall be from service conditions, environmental conditions, failure modes, maintenance program, testing, or other applicable conditions equivalent to the intended safety-related application of the commercial-grade item or service being dedicated.

If the documented performance record provides reasonable assurance that the critical characteristic satisfactorily meets applicable acceptance criteria, Method 4 can be used for acceptance of that critical characteristic. After the establishment of an acceptable performance record, acceptance of the item using Method 4 is completed by performing a receipt inspection. The supporting information is periodically updated and reviewed to ensure that the item/supplier maintains an acceptable performance record.

10.2 Application of Method 4

Figure 10-1 is a standard flow chart for accepting a commercial-grade item by relying on a documented acceptable item/supplier performance record.



Note: CGI = commercial-grade item

Figure 10-1
Method 4: Item/Supplier Performance Record process

Although it was originally envisioned that Method 4 could be used as the sole basis for accepting some commercial-grade items, experience has proven that Method 4 is best suited for use in the following two situations: as a basis for reducing the sample size for one or more critical characteristics associated with the use of another acceptance method and as a basis for accepting a particular critical characteristic while the other critical characteristics are verified by the use of another acceptance method.

The objective in considering Method 4 is to use a sufficiently broad spectrum and volume of data over a period long enough to provide the objective evidence necessary to establish a sound technical basis for determining acceptable performance. As stated in NRC Generic Letter 89-02:

> Method 4 should not be employed alone unless:
>
> The established historical record is based on industry-wide performance data that is directly applicable to the item's critical characteristics and the intended safety-related application and
>
> The manufacturer's measures for the control of design, process, and material changes have been adequately implemented as verified by audit (multi-licensee team audits are acceptable). [10]

Care should be taken in application of this method to ensure that the performance data are directly applicable to the verification of the critical characteristic specific to the intended safety-related application. Method 4 should not be used as the sole method of acceptance for all of the critical characteristics of an item or service, unless specific measures are implemented to ensure the validity of this method of acceptance.

10.3 Use of Method 4

Method 4 allows the dedicating entity to accept commercial-grade items based on a confidence in the supplied item achieved through proven performance of the item. It also allows the dedicating entity to take credit for demonstrated item performance based on historical verification gained from the successful utilization of Methods 1, 2, or 3 or pertinent industrywide performance data.

When properly used, Method 4 can be a valuable means to accept certain critical characteristics of a commercial-grade item because it relies on proven historical performance and thereby negates the need for costly time-consuming or repetitive activities, which, because of the proven history, do not add value to the verification of quality or performance of the item. Similarly, Method 4 could be used to reduce the sample size for a particular critical characteristic of an item.

In using Method 4, the results of historical performance can be objectively compiled and documented using sources such as the following:

- The monitored performance of or certain critical characteristics of the item
- Industry standard product tests
- National codes and standards (not specific to the nuclear industry) governing the manufacture or performance of the item
- Industry or government databases (military, aerospace, and so on)

The dedicating entity could establish a documented item/supplier performance record using the following sources of information. Although individual sources of information may be adequate to adjust sample sizes or to support acceptance of a particular characteristic, they are not intended to stand alone and may not be adequate as the sole means of verifying critical characteristics of the item or service.

With regard to supplier performance, for dedication of commercial-grade items, the historical performance record should be focused on the actual manufacturer (or production source) of the item. However, for dedication of commercial-grade services, the historical performance record should be focused on the supplier actually performing the service activities.

For Method 4 to be employed as the sole method of acceptance for all of the critical characteristics of a particular item or service, two conditions must be satisfied. First, the established historical record must be based on industrywide performance data that are directly applicable to the critical characteristics and the intended safety-related application (that is, single sources of information are not adequate to demonstrate satisfactory performance without the use of other methods of acceptance). Second, the item manufacturer's measures (or the service supplier's measures) for the control of applicable design, process, and material changes have been adequately implemented as verified by a commercial-grade survey and the survey results accepted by the dedicating entity.

10.3.1 Historical Performance

10.3.1.1 Results of Monitored Performance

An item's performance record can be determined by monitoring the performance of the item's manufacturer. Depending on the nature of the item, this could also include monitoring the performance of the parent component in which the item was installed. Component performance data are normally available from maintenance records, failure history, or ongoing product proof tests. Once documented, performance and failure history data provide an acceptable source for establishing a record for a given commercial-grade item. The objective basis to support the satisfactory performance of the commercia1-grade item in service will vary with the application, but it could simply be the lack of failures during a suitably long in-service period under applicable operating conditions.

In this sense, *failure* refers to a malfunction caused by some deficiency in a critical characteristic of the item that prevents it from performing its intended safety function. *Failure* in this context is not intended to mean failure of a part or parent component because of misuse or normal wear/deterioration or failure induced from the failures or malfunctions of other items.

10.3.1.2 Results of Maintenance, Production, or Periodic Surveillance Tests

The dedicating entity could have (or acquire) documented records of the results of routine maintenance tests, production tests, and/or periodic operational surveillance test results over a sufficient length of time. Acceptable and repeatable test results could be used to demonstrate that a particular critical characteristic of the item (or the item itself) satisfactorily performed (or was capable of performing) its intended safety function for a sufficient period.

10.3.2 Historical Dedication Results

The successful acceptance of a critical characteristic of an item or service using Methods 1, 2, or 3 or a combination thereof over a sufficient period could be used to establish reasonable assurance of acceptability of that critical characteristic based on its proven history. An update and review of the supporting performance information is required to ensure that an acceptable performance record is maintained. Periodic confirmatory testing, a limited-scope commercial-grade survey, or an occasional source verification should be considered to maintain ongoing confidence in the established performance history.

10.3.3 Industrywide Performance

Industrywide performance data must be specific and applicable to the item and critical characteristics being accepted if they are to be used to establish an acceptable item or manufacturer/supplier performance record. In this case, *industrywide* refers to a cross-section of users of the item or service.

Depending on the nature of the item and its applications, *industrywide* may or may not include data sources outside the field of nuclear facilities. For the manufacturer of an item or a supplier with direct access to manufacturer data, *industrywide* could include the manufacturer's customer base, both foreign and domestic.

10.3.3.1 Product Performance Test Results

The manufacturer of an item may routinely test production samples or periodically send product samples to an independent test laboratory. The results of these tests could be used as a basis to establish acceptable performance history to accept certain critical characteristics. Other information that supports the item's performance history (such as reliability data from operating nuclear plants, suppliers, or industrial users) may also be considered.

10.3.3.2 Equipment Performance Data

Operating experience and customer feedback databases can be used to obtain information on component failures that can be used to compile data on component failure history.

10.3.3.3 Seismic and Environmental Equipment Qualification Databases

The nuclear industry, as a result of empirical studies of earthquake-induced failures, has developed a seismic experience database for EPRI members called "Seismic Qualification Reporting and Testing Standardization" (SQURTS) that could be used to acquire historical data. Similarity by item, category, or general type should be established to demonstrate an item's inherent seismic sensitivity or ruggedness. EPRI members or members of programs such as SQURTS also have access to qualification data and reports developed by those organizations.

Another useful source of information is the Equipment Qualification Data Bank (EQDB). Originally established by EPRI, the EQDB was commercialized and is currently a product maintained by the Scientech Division of Curtiss-Wright. The database includes several libraries of information related to equipment qualification. One library lists summarized equipment qualification parameters for Class 1E equipment in operating nuclear plants. Other libraries contain seismic qualification data as well as thermal and radiation properties of nonmetallic materials that commonly appear in electrical and mechanical equipment of nuclear power plants.

Care should be exercised to ensure that the use of these databases is acceptable under plant-specific conditions relative to the particular critical characteristic under evaluation.

10.3.3.4 Audits or Surveys Conducted by Industry Groups

An audit or survey conducted by an industry group on the manufacturer of an item or the supplier of a service could be used to support justification of an acceptable supplier performance history. To take credit for this type of information, the dedicating entity should ensure that the audit or survey addressed the supplier quality controls applicable to the specific commercial-grade item and critical characteristic(s) in question and that those quality controls were employed by the manufacturer or supplier when the supplied item was produced or the service performed.

10.3.3.5 Supplier Responses to the Commercial-Grade Program Controls Questionnaire

The dedicating entity may determine by questionnaire those controls established, previously verified, and currently maintained by the manufacturer that reasonably ensure that the critical characteristic in question for the commercial-grade item to be furnished is the same as the commercial-grade item provided with the original equipment. The most important information to be obtained is as follows:

- Identification of changes that would result in a part number or design change to the item
- Material, configuration, interface, or mounting changes
- Changes to the manufacturing processes that could impact the acceptability of a critical characteristic

10.3.3.6 Utilization of National Codes and Standards

The credit a dedicating entity can take for a product manufactured to a national code or standard must be investigated on a case-by-case basis for the critical characteristic in question. To take credit for an item being manufactured to a recognized code or standard, the dedicating entity shall ensure that the item was actually manufactured in accordance with the specified code or standard. This assurance can be obtained as follows:

- Invoking the applicable code or standard in the purchase order
- Requiring and receiving certification from the supplier as delineated in the applicable code or standard
- Researching and documenting that it is standard industry practice to manufacture the product to this code or standard

- Verifying manufacturer testing or independent agency testing with certification or documentation as delineated in the code or standard (including the product listing in an agency certification registry similar to the U.S. Defense Logistics Agency's Qualified Product List and Qualified Manufacturer List)
- Verifying by inspection at receipt that the item is marked or tagged as conforming to the specified code or standard

The manufacture of a product to a recognized code or standard provides some degree of confidence in the uniformity and quality of the item. This is particularly true if an independent endorsement is given based on testing. Production to a recognized code or standard helps to justify continual acceptance of a commercial-grade item by Method 4.

For example, certain electrical items are manufactured to a UL product specification. The UL product specifications require tests or controls of certain attributes, some of which could also be a critical characteristic of the item. If the commercial-grade item is listed by UL, UL will periodically test a product specimen to ensure continued product conformance, that the manufacturer is authorized by UL to label the product with the applicable UL mark, and that the item is listed in the applicable UL product directory. The UL labeling and directory listing should be verified at receipt.

10.3.4 Ongoing Assurance of Performance

The historical performance of an item or a supplier does not guarantee future results. Therefore, when employing Method 4, measures must be established and implemented to verify continued satisfactory performance for recurring use of Method 4 for acceptance of a particular critical characteristic of a particular item or service. For example, if Method 4 is used based on the historically successful acceptance of a critical characteristic of an item by a Methods 1 test, the Method 1 test should be performed at an appropriate periodicity, either time-based or event-based (such as annually or every X purchases), to verify that the performance history of the critical characteristic in question is still valid.

10.4 Documentation to Support Method 4

The item/supplier performance record, supporting data, and applicable justification must be documented to support use of Method 4. An acceptable item, service, or supplier performance record shall include the following:

- Identification of the item, service, or supplier being evaluated
- Identification of the critical characteristic(s) being evaluated specific to the item, service, or supplier
- Identification of the data examined to evaluate the item, service, or supplier performance
- Identification of the basis for determining that the performance data substantiate the acceptability of the applicable critical characteristic(s) for the item, service, or supplier
- Documentation of the adequacy and acceptance of the item, supplier, or service performance record

- Any limits or stipulations on the application of Method 4 for acceptance of the applicable critical characteristic
- Procurement document requirements and any supplier submittals necessary to support the Method 4 acceptance

Continued application of Method 4 shall include a documented periodic update and review to ensure that the item, service, or supplier maintains an acceptable performance record. Alternatively, measures can be implemented to verify continued performance with each receipt (see the UL example in Section 10.3.3.6).

10.5 Use of Item's/Supplier's Performance Record to Support Sample Size

The processes and methodologies described for use of Method 4 as a means to accept a particular critical characteristic of a commercial-grade item can also be used as input to determine the sample size for a Method 1 test or inspection.

11
COMMERCIAL-GRADE SERVICES

11.1 Procurement Options for Safety-Related Services

Several procurement options exist for procuring a safety-related service. The option chosen will be based primarily on the type and extent of the supplier's QA program. Figure 11-1 illustrates the three procurement options.

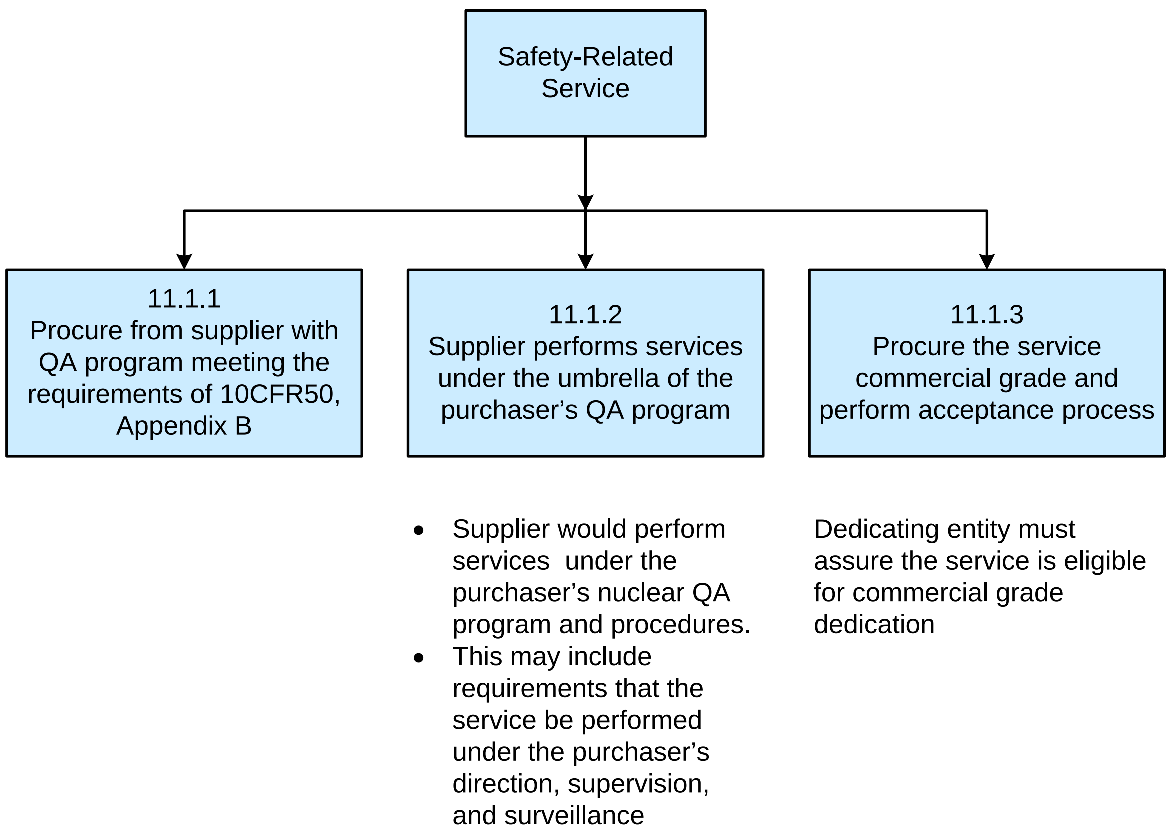


Figure 11-1
Options for procuring safety-related services

11.1.1 Procure from Supplier with 10CFR50, Appendix B–Compliant QA Program

In this option, the service would be provided by a service supplier with a QA program meeting the requirements of 10CFR50, Appendix B. The QA program should cover the safety-related service being procured. For many services, certain 10CFR50, Appendix B, criteria would not be applicable because of the limited scope of the service.

11.1.2 Supplier Services Are Controlled Under the Purchaser's Nuclear QA Program

In this second option, the supplier may not have a 10CFR50, Appendix B program, or the supplier's quality program may be deemed inadequate by the purchaser. However, the purchaser may opt to have the service supplier's personnel perform the service as part of the purchaser's organization following the purchaser's program and procedures. In this scenario, the purchaser would control the service under their nuclear QA program. The requirements of 10CFR50, Appendix B, would be met by having the service performed under the purchaser's nuclear quality program and procedures. This may include requiring the service to be performed under the purchaser's direction, direct supervision and surveillance, and approval.

11.1.3 Dedicate the Commercial-Grade Service for Safety-Related Application

If the service were eligible for commercial-grade dedication, it could be accepted by verifying the critical characteristics/controls described in Sections 11.3.5 and 11.3.6. One or more of the acceptance methods could be used to verify the critical characteristics/controls.

11.2 Commercial-Grade Services

Although the commercial-grade item dedication process was originally developed to address the acceptance of items, it can also be applied to the acceptance of services. The requirements of 10CFR21 apply to items and services as indicated by the following statement that appears in the definition of *basic component* in 10CFR21:

> 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, design certification, approval, or information in support of an early site permit application under part 52 of this chapter whether these services are performed by the component supplier or others. [4]

11.2.1 Services That May Require Dedication

The following are examples of services that could meet the definition of *basic component*:

- Repair services
- Testing services
- Fabrication/machining/cleaning/manufacturing services
- Consulting services
- Engineering/technical services
- Calibration services
- Computer software services (note that additional information on the dedication of computer programs is included in EPRI 3002002289 [34])

The user should note that not all of these services may be classified safety-related in all applications and need to be dedicated.

11.3 Basic Process for Accepting Commercial-Grade Services

Figure 11-2 illustrates the basic process for accepting commercial-grade services. This process is similar to the generic acceptance process for items described in Section 4 of this report.

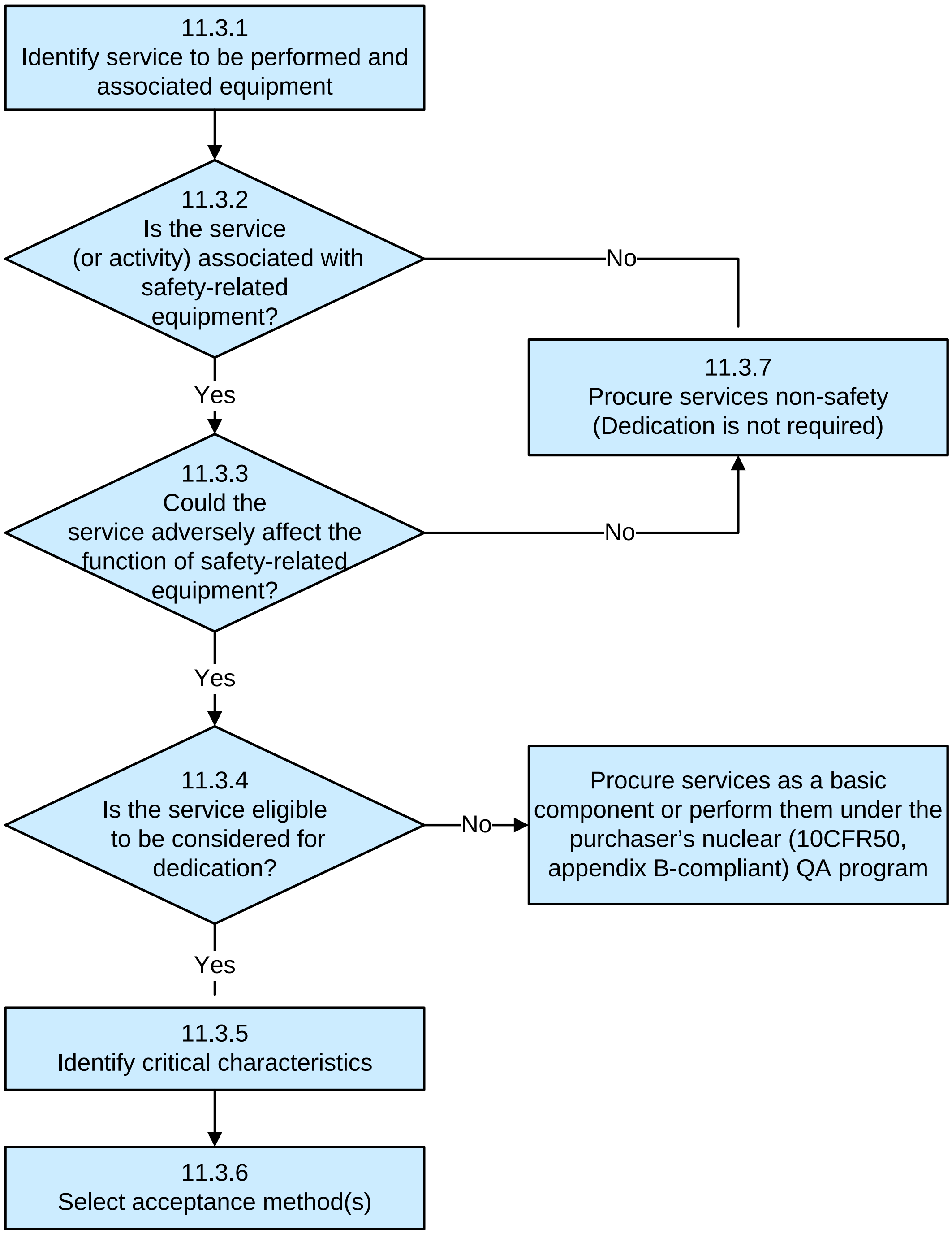


Figure 11-2
Process for acceptance of commercial-grade services

11.3.1 Identify Service to Be Performed and Associated Equipment

Identification of the service to be performed involves examining the scope of the service, determining which plant equipment the service is associated with, and developing the appropriate requirements to specify the service correctly.

11.3.2 Is the Service (or Activity) Associated with Safety-Related Plant Equipment?

The first step in classifying the service is to determine if the service is associated with safety-related plant equipment (for example, repair of a safety-related chiller or stress analysis for safety-related structural steel). If the service is *not* associated with any safety-related equipment, it may be classified non-safety and procured as a non-safety-related service. An example would be sending out a non-safety-related motor for repair.

If the service *is* associated with safety-related plant equipment, the next step is to determine if the service could adversely affect the function of safety-related equipment.

11.3.3 Could the Service Adversely Affect the Function of Safety-Related Plant Equipment?

In the second step, an evaluation is required to determine whether the service could have an adverse effect on the safety-related function of equipment. The evaluation requires a full understanding of the purpose of the service and any potential adverse effects on the safety-related function of the equipment. When performing this evaluation, an examination of credible failures of the service is useful. Table 11-1 provides examples of potential failures in the performance of different types of services that can affect the safety-related function of equipment. The potential failures of the service are also useful in selecting the appropriate critical characteristics.

Table 11-1
Typical services and the associated potential failures

Type of Service	Potential Failures
Repair/refurbishment	• Use of unacceptable replacement items • Improper welding or soldering • Improper assembly • Functional requirements not met after repair
Testing	• Use of improperly calibrated M&TE • Technician inadequacies in performing the test • Improper test specimen preparation • Improper calculation of test results
Fabrication Machining Cleaning Manufacturing	• Failure to meet dimensional requirements • Material contamination • Foreign material—failure or lack of foreign material exclusion controls
Engineering or technical services	• Incorrect calculations • Failure to confirm initial assumptions • Errors conveyed during training
Calibration	• Improperly calibrated M&TE • Improper standards

If the evaluation determines that the service could have a credible adverse effect on the safety-related function of plant equipment, the service should be classified as safety-related. For example, the refurbishment of a safety-related motor could adversely affect its ability to perform its safety function. Therefore, the refurbishment service would be classified as safety-related (that is, a basic component).

Another example is the procurement of NDE services performed on safety-related equipment. NDE not being performed properly could result in placing a basic component into service without verification that it will be capable of performing its safety-related function. Therefore, NDE service would be considered a basic component and would require dedication or procurement as a basic component or controlled under the purchaser's 10CFR50, Appendix B–compliant program.

If the evaluation determines that the service will have no credible adverse effect on the safety-related function of plant equipment, the service could be classified non-safety-related. An example would be a safety-related, motor-operated valve with a passive function that requires repair of the motor. The valve has no active safety-related function requiring opening or closing. Although the valve is classified safety-related, the operator may be classified as non-safety. The repair of the motor could be considered non-safety-related because the service would have no effect on the safety-related function of the valve (that is, maintaining a pressure boundary).

11.3.4 Is the Service Eligible for Dedication?

11.3.4.1 Services for Nuclear Power Plants Licensed Pursuant to 10CFR, Part 50

When determining whether a service being performed for a nuclear power plant licensed pursuant to 10CFR50 is eligible for dedication, the critical characteristics of the service must be adequately verified. In other words, a service can be dedicated if the critical characteristics identified in the technical evaluation can be verified during the acceptance process.

11.3.4.2 Services for Facilities and Activities Licensed Pursuant to 10CFR, Parts 30, 40, 50, 60, 61, 63, 70, 71, or 72

When determining whether a service being performed for facilities and activities licensed pursuant to 10CFR Parts 30, 40, 50 (other than nuclear power plants), 60, 61, 63, 70, 71, or 72 is eligible for dedication, the following three criteria defined in 10CFR21 must be met:

(1) Not subject to design or specification requirements that are unique to nuclear facilities the commercial nuclear industry.

(2) Used in applications other than commercial nuclear facilities.

(3) To be ordered from the manufacturer/supplier on the basis of specifications set forth in the manufacturer's published product description This criterion can be met if the service is offered, for example, in supplier catalogs, supplier service descriptions, or commercial quality manuals. [4]

If the service meets all three criteria, the dedicating entity has the option of procuring the service commercial-grade, implementing the acceptance process, and dedicating the service. If the service is not eligible for commercial-grade dedication, the purchaser may procure the service as a basic component if the service provider has a QA program meeting the requirements of 10CFR50, Appendix B. If the supplier does not maintain such a program, the purchaser can perform/control the services under their nuclear QA program.

11.3.5 Identify Critical Characteristics

If the service is eligible for dedication and the plant elects to purchase the service commercial-grade, the next step is to identify the critical characteristics to be verified. However, 10CFR21 defines *critical characteristics* in the context of dedicating an item; the definition states that critical characteristics are

> The 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. [4]

For services, the definition of *critical characteristics* is expanded to also address quality controls, in addition to any design, material, or performance characteristics of the safety-related equipment being serviced. Thus, the definition in the context of services is expanded to be

> The controls over a commercial grade service, which once selected to be verified, provide reasonable assurance that the service provided meets specified requirements. Verification of these controls will provide reasonable assurance that the safety function of plant equipment impacted by the service will not be adversely affected. [4]

The types of controls to be identified will vary depending on the type of commercial-grade service provided and the controls necessary to provide reasonable assurance that an acceptable service has been provided. In selecting critical controls, the impact of the different activities associated with the service on the safety function of plant equipment should be a key consideration.

It may be possible to verify some services by measuring/inspecting/verifying the characteristics of the device (when it is hardware) resulting from the service. This would be the best way to verify characteristics that provide assurance that the hardware will perform its intended safety-related function. However, there may be some types of services—such as software development, training, and perhaps calibration—where the dedicating entity has no way to verify the results by examining the hardware.

In these cases, you may need to identify critical characteristics as well as the critical controls that correspond to each critical characteristic.

11.3.6 Select the Acceptance Method

When a commercial-grade service is to be accepted, the four acceptance methods described in industry guidance and this report are applicable. The four methods are as follows:

- Method 1: Special Tests and Inspections
- Method 2: Commercial-Grade Survey
- Method 3: Source Verification
- Method 4: Acceptable Supplier/Item (Service) Performance Record

For services, the types of critical characteristics selected should be related to the safety function of the equipment being serviced. Sections 11.3.6.1 and 11.3.6.2 cover the acceptance of the service by verifying critical characteristics or critical controls.

A discussion of how to use accreditation to accept calibration services is provided in Section 12 of this report.

11.3.6.1 Determine Acceptability Through Verification of Critical Characteristics

Acceptability of the service can be determined by identifying and verifying the critical characteristics associated with safety-related equipment being serviced. An example would be the repair of an instrument by a commercial supplier.

Important material, design, and/or performance characteristics could be selected and verified using an appropriate acceptance method. This acceptance could occur as follows:

1. Verify that the critical characteristics are conforming through special tests and inspections after receipt of the repaired instrument.
2. Perform a commercial-grade survey to verify that the supplier has adequate controls over the instrument's critical characteristics affected by the service, and ensure that a written quality program is in place to control similar services in the future.
3. Conduct a source verification while the service is being performed to ensure that the repaired instrument's critical characteristics remain conforming.

11.3.6.2 Establishing Acceptability Through Verification of Critical Controls

In some cases, the acceptability of a service cannot be established by verification of equipment critical characteristics after the service is performed. In these situations, the critical characteristics selected for verification may include the supplier's controls. As noted in the preceding section, the critical controls selected for verification should provide reasonable assurance that the service provided meets the specified requirements.

Adequacy of the supplier's controls could be assessed by conducting a commercial-grade survey or source verification. As an example, Table 11-2 illustrates the methodology for accepting a service with a commercial-grade survey that verifies the service provider's quality controls.

Table 11-2
Example of calibration services for a flow meter installed in a safety-related system

Item/service	Calibration of a flow meter installed in a safety-related system in a plant licensed pursuant to 10CFR50.
Safety function	The flow meter's safety functions include pressure boundary integrity and accurate measurement and transmission of flow data. If the measurements are inaccurate due to the flow meter being out of calibration, safety-related equipment functions cannot be ensured. The service is therefore classified as safety-related. The associated safety function of the calibration service is establishing accuracy of the flow meter.
Supplier information	Accurate Calibration Services (ACS) a regional calibration service provider with experience in calibrating flow meters. They do not have a QA program meeting the requirements of 10CFR50, Appendix B, but they do have a documented commercial quality program.
Approach	A decision is made to procure the service commercial-grade and dedicate the service.

Table 11-3
Example of critical controls and acceptance criteria for calibration services

Critical Control	Acceptance Criteria
Adequacy of measurement standards	Standards have the accuracy, stability, range, and resolution required for the item being calibrated.
Calibration procedures	Adequate documented instructions exist for performance of accurate calibration.
Qualification of personnel	Personnel have the adequate skills, training, and experience to ensure accurate and repeatable calibration.
Environmental controls	The calibration environment is controlled to the extent necessary to ensure continued measurement with required accuracy on standards and measuring equipment.
Calibration status	M&TE and standards are uniquely identified and labeled to indicate the calibration status.
Calibration traceability	Calibration standards and reference materials are traceable to national, international, or intrinsic standards where available.
Storage and handling	M&TE and standards are handled, stored, and transported to avoid deterioration or damage, which could affect the calibration of the equipment.
Out-of-tolerance notification	The notification process when the supplier's M&TE/standards are found to be out of tolerance to an extent that customer's calibration results may be invalid.

To select the acceptance method, the critical characteristics are selected and verified by a performance-based commercial-grade survey of the calibration facility. The results were documented as shown in Table 11-3.

Table 11-4
Example of critical controls and commercial-grade survey results for calibration services

Critical Control	Commercial-Grade Survey Results[1]
Adequacy of measurement standards	ACS's Quality Program Manual QAM1 is based on ISO-17025. Accuracy and measurement uncertainty requirements are established in ACS procedure CAL-1. These requirements specify that the standards used to calibrate M&TE shall have the proper range and accuracy for the characteristics being calibrated. In addition, the collective uncertainty of the measurement standards should not exceed 25% of the acceptable tolerance for each characteristic being calibrated. The actual uncertainty is required to be indicated on the calibration certificate.
Calibration procedures	ACS's Quality Program Manual QAM1 requires each calibration activity to be performed using approved procedures/instructions specifying the range and accuracy of the instrument being calibrated, any special environmental conditions, standards to be used, detailed steps for performing the calibration, and documentation of calibration data. ACS may use the original equipment manufacturers manual in lieu of ACS-developed calibration procedures.

Table 11-4 (Continued)
Example of critical controls and commercial-grade survey results for calibration services

Critical Control	Commercial-Grade Survey Results[1]
Qualification of personnel	ACS's Quality Program Manual QAM1 requires calibration activities to be performed by personnel that have been trained as evidenced by personnel qualification and certification records.
Environmental controls	ACS maintains environment conditions, including temperature and humidity, as specified in ACS procedure CAL-1. Temperature and humidity are continuously monitored by calibrated equipment. Temperature and humidity charts are reviewed on a weekly basis to determine if these controls are outside the specified range. In addition, the technician is required is to verify that temperature and humidity conditions are within the required range prior to start of the calibration.
Calibration status	M&TE and standards are labeled to indicate the unique identification number, calibration date/due date, and person who performed the calibration as required by ACS procedure CAL-1. Calibration records are maintained for each M&TE/standard indicating the current calibration status as well as the history of calibration.
Calibration traceability	ACS Quality Program Manual QAM-1 requires all calibration standards to be identified, controlled, and traceable to NIST or other recognized national standards as evidenced by the standard's record of certification and traceability.
Storage and handling	ACS procedure CAL-1 specifies requirements to ensure that M&TE and standards are handled, stored, and transported to avoid deterioration or damage, which could affect the calibration of the equipment. These requirements include adequate shelving, padded transport carts, and static discharge prevention equipment. ACS primarily uses the customer's containers for return shipment of M&TE/standards or constructs containers that provide adequate protection during shipment.
Out-of-tolerance notification	ACS procedure CAL-1 provides the controls for out-of-tolerance evaluations and reporting. All out-of-tolerance conditions are documented using the nonconformance reporting process and are evaluated. If any M&TE or measurement standard is found to be significantly out of tolerance (that is, could impact the acceptability of the data/measurements obtained from the device calibrated with the out-of-tolerance M&TE/standard) during the calibration process, the user/customer is required to be notified of the out of-tolerance condition with associated measurement data so that appropriate action can be taken.

Note:
[1]Actual survey results should include objective evidence with specific references supporting the results.

Successful completion of the preceding verification activities and a supplier certificate of conformance attesting that the quality program surveyed was in fact implemented for this service provide reasonable assurance that the service meets specified requirements and is acceptable.

11.3.7 Procure Services as Non-Safety

Services that are not associated with safety-related plant equipment are not basic components and therefore do not require dedication. Services that are associated with safety-related plant equipment but do not affect the safety-related function of a basic component are not basic components and therefore do not require dedication. An example might be services procured for records retention, when a licensee elects to outsource records retention to a commercial supplier. The records are associated with safety-related plant equipment, but the records themselves cannot affect how that equipment performs its safety-related functions. Thus, the records retention service would not be basic component and would not require dedication.

However, in the case of records, the licensee is required to maintain them in accordance with 10CFR50, Appendix B, Criterion XVII. This makes records retention a quality activity, and the licensee may control the services performed by the supplier by imposing quality controls on how the services are provided. These quality controls might include an assessment of the supplier's capabilities, contractual requirements, and oversight necessary to ensure that the supplier meets applicable requirements. In this case, the licensee applies some quality controls to a service that is not a basic component, although this would not constitute a commercial-grade dedication. The application of limited quality controls will vary depending on the importance of the service.

12
USE OF DEDICATION TO ACCEPT ACCREDITED CALIBRATION SERVICES

12.1 Use of Accreditation to Dedicate Calibration Services

As explained in Section 11, the same requirements that apply to dedication of commercial-grade items apply to dedication of commercial-grade services, such as calibration. Therefore, a documented technical evaluation that identifies safety function, critical characteristics, and acceptance methods is required when dedicating calibration services. The acceptance method typically used for verification of critical characteristics associated with calibration services is a commercial-grade survey (Method 2) of the supplier’s applicable commercial quality controls.

Accreditation is not an acceptable alternative to commercial-grade dedication of calibration services. However, accreditation can be used in lieu of a commercial-grade survey in cases where a technical evaluation has been completed and the accreditation body is recognized by the NRC. Use of accreditation in lieu of a commercial-grade survey should be documented in the technical evaluation.

This review should be performed by appropriate individuals. When calibration service suppliers may have multiple locations (each with a separate accreditation), a review of accreditation should be performed for each supplier location that will be conducting calibration services for the dedicating entity.

12.2 Background

In 2004, Arizona Public Service (APS) requested the NRC to provide acceptance of the National Voluntary Laboratory Accreditation Program (NVLAP) accreditation of suppliers of commercial-grade calibration services in lieu of a commercial-grade survey, audit, or surveillance. In a letter dated September 28, 2005 [85], the NRC approved APS’s request in a Safety Evaluation Report (SER) [86] based on the review of the NVLAP and A2LA programs recognized through the mutual recognition arrangement of International Laboratory Accreditation. The SER accepted the use of the NVLAP and A2LA accreditation as an alternative acceptance method for the dedication of commercial-grade calibration services, provided that the following conditions are met:

- Use of the alternative method is documented in the licensee’s or supplier’s QA program.
- Use of the alternative method is applied only to commercial-grade calibration services as defined by 10CFR21 [4].
- Use of the alternative method is applied only to domestic commercial calibration laboratories that have been accredited by NRC- recognized domestic accrediting bodies.

- Prior to use of the alternative method, a documented review of accreditation is performed. The review should verify the following:
  - Accreditation is to ANSI/ISO/IEC 17025, General Requirements for the Competence of Testing and Calibration Laboratories [87]
  - Accrediting body is either NVLAP or A2LA
  - The published scope of accreditation for the calibration service supplier covers the needed measurement parameters, ranges, and uncertainties

Purchase documents impose the supplier’s use of their ANSI/ISO IEC 17025 [87] accreditation and additional technical and administrative requirements, as necessary, to satisfy the purchaser’s QA program and technical requirements. These requirements include reporting as-found calibration data when calibrated items are found to be out of tolerance and ensuring that the calibration certificate/report includes identification of the laboratory equipment/standards used.

12.3 Accrediting Bodies Recognized by the NRC Subsequent to the APS SER

The requirements included in the SER for NVLAP or A2LA [86] also apply to other accrediting bodies recognized by NRC. Subsequent to the issuance of the Arizona Public Service SER, the NRC recognized the accreditation provided by the following U.S. accrediting bodies (by letters):

- ACLASS [88]
- Laboratory Accreditation Bureau [89]
- International Accreditation Services, Inc. [90]
- Perry Johnson Laboratory Accreditation [91]

The NRC may elect to recognize additional accrediting bodies in the future.

12.4 Implementation Guidance

12.4.1 Documented Review of Accreditation

The documented review of the accreditation should be performed prior to issue of the purchase order. Consideration should be given to establishing a process for identifying when a calibration service supplier’s accreditation will expire in order to prevent issuance of a purchase document for calibration services that may no longer be within the scope of the supplier’s accreditation and/or meet the purchaser’s technical requirements. The documented review of the accreditation discussed earlier in this section must be performed each time the accreditation is renewed.

12.4.2 Technical and Quality Requirements

The technical and quality requirements to be imposed in purchase documents should be specific to the M&TE/standard being calibrated, such as the following:

- Tolerances
- Accuracies

- Ranges over which the item is to be calibrated
- Specific industry standards to be used
- Requirement for an accredited, endorsed calibration certificate

12.4.3 Receipt Inspection

Receipt inspection of the calibrated M&TE/standard should include a review of the calibration certificate/record to verify that the preceding purchase document requirements have been met as well as the following requirements:

- Calibration is within the scope of the accreditation.
- Calibration was performed by a commercial calibration supplier accredited by one of the NRC-recognized domestic accrediting bodies.
- Accreditation was current (not expired) at the time of calibration.
- The calibration certificate contains the certificate number and accrediting body's logo.

12.5 NEI 14-05

In April 2014, NEI published NEI 14-05, Guidelines for the Use of Accreditation in Lieu of Commercial Grade Surveys for Procurement of Laboratory Calibration and Test Services, Revision 0 [92]. The guidance in NEI 14-05 is consistent with the guidance in this report for use of accreditation to dedicate services provided by domestic commercial calibration suppliers.

In addition, the NEI guidance expands on the approach taken by APS and others following the NRC's endorsement in the SER. The NEI guidance includes laboratory testing services in addition to calibration services. In addition, the NEI guidance includes both domestic and international ILAC mutual recognition arrangement signatories. The NEI guidance also includes continued oversight of the ILAC process by the U.S. nuclear industry to ensure that the ILAC process continues to be an acceptable alternative to performing surveys for commercial-grade dedication [93]. At the time this report was published, NEI had submitted the document to the NRC for endorsement.

13
REASONABLE ASSURANCE

13.1 Reasonable Assurance

The word *reasonable* connotes a level of confidence that is justifiable but not absolute. In the context of product or service quality, *reasonable assurance* of performance must be based on facts, actions, or observations (objective evidence). Although these bases are objective and measurable, the inference of adequacy drawn from them—the decision that reasonable assurance has been attained—is inherently subjective, and the judgment of reasonability may vary between different observers. These judgments are commonly referred to as *engineering judgment* and should be documented. Reasonable assurance of the item's ability to perform its intended safety function results from the combination of the technical evaluation and acceptance processes.

In this report, reasonable assurance consists of the dedicating entity controlling or verifying the item's quality to an extent consistent with the item's importance to safety and/or ensuring that quality is adequately controlled by the supplier. Once the dedication process is completed, the quality assurance and/or other measures applied to those aspects of the item that directly affect its safety function should result in the same level of performance as an item manufactured by or purchased from an entity implementing a QA program meeting the requirements of 10CFR50, Appendix B [7].

13.2 Factors Required to Achieve Reasonable Assurance in the Context of Commercial-Grade Item Acceptance

Several factors should be considered in achieving reasonable assurance, as depicted in Figure 13-1. The primary factor is the set of critical characteristics to be verified. Considerations include the number as well as the type of critical characteristics. Section 6 covers critical characteristics in detail.

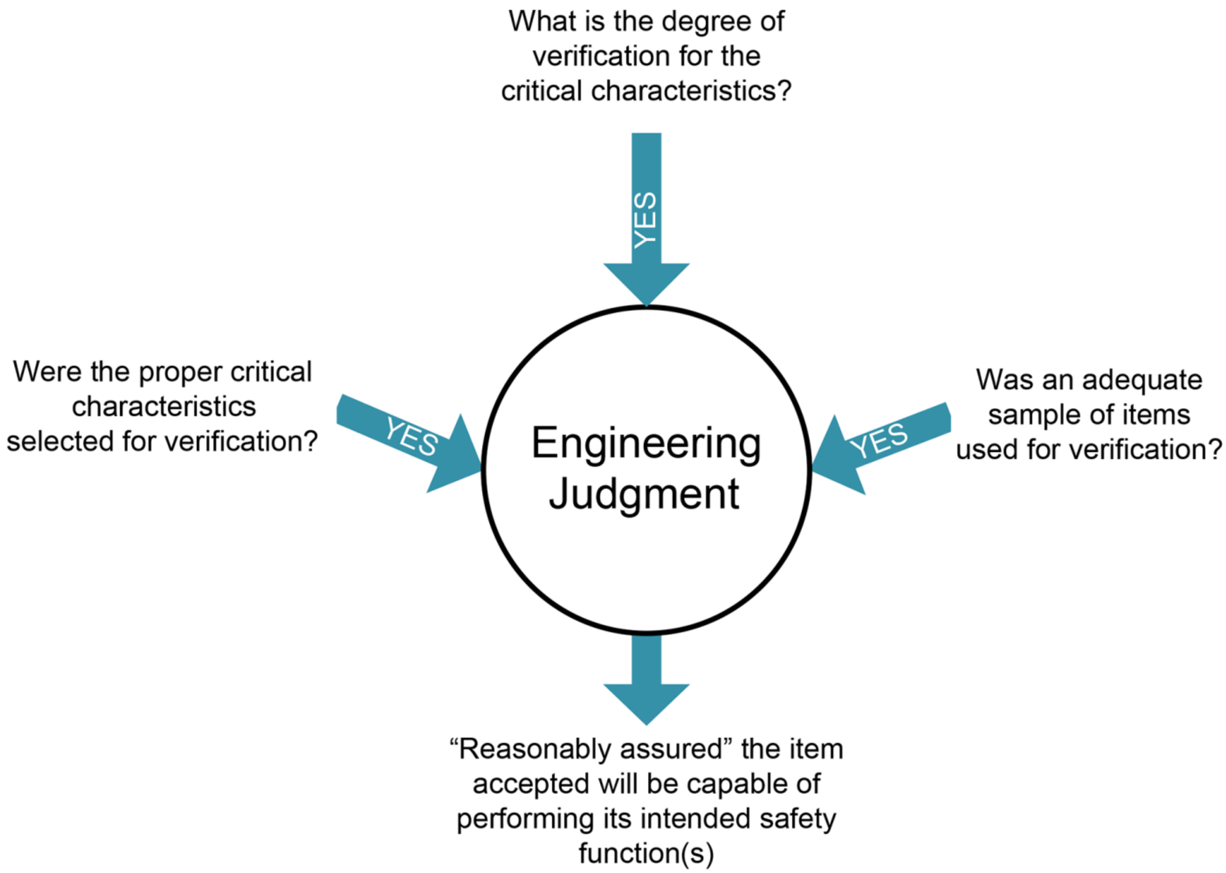


Figure 13-1
Achieving reasonable assurance in the context of commercial-grade item acceptance

A second factor to consider in achieving reasonable assurance is the adequacy of the sample size of items chosen for verifying selected critical characteristics. EPRI report TR-017218-R1, *Guideline for Sampling in the Commercial-Grade Item Acceptance Process* [23], provides detailed guidance on sampling for the acceptance of commercial-grade items.

The third factor to be considered in achieving reasonable assurance is the degree of verification of each selected critical characteristic. For accepting commercial-grade items, the degree of verification for a given critical characteristic corresponds to the acceptance criteria to be met and may vary from item to item based on each end-use application.

14
DIGITAL EQUIPMENT AND COMPUTER PROGRAMS

14.1 Digital Equipment and Computer Programs Integral to Plant SSCs

Examples of digital equipment and devices that are SSCs or devices of SSCs that rely on embedded computer programs include the following:

- Programmable logic controllers
- Plant computers
- Digital control systems
- Smart transmitters
- Embedded microprocessors and programmable read-only memory devices
- Erasable programmable read-only memory devices

Digital devices and embedded computer programs are complex in design. In many cases, the ability of a digital device to function properly depends on an embedded computer program. For these reasons, special methodology must be applied to accept digital devices and computer programs that are integral to plant SSCs. Consideration of dependability characteristics is a key concept when dedicating digital devices and computer programs.

Guidance for accepting digital devices may be found in the following documents:

- *Commercial-Grade Digital Equipment for High-Integrity Applications: Oversight and Review of Evaluation and Acceptance Activities*, 1025283 [94]
- *Evaluating Commercial Digital Equipment for High-Integrity Applications: A Supplement to EPRI Report TR-106439*, TR-107339 [80, 95]
- *Guideline on Evaluation and Acceptance of Commercial-Grade Digital Equipment for Nuclear Safety Applications*, TR-106439 [80], and the NRC's SER "Review of EPRI Topical Report TR-106439, *Guideline on Evaluation and Acceptance of Commercial Grade Digital Equipment for Nuclear Safety Applications*" [96]
- *Generic Requirements Specification for Qualifying a Commercially Available PLC for Safety-Related Applications in Nuclear Power Plants*, TR-107330 [97]
- *Handbook for Evaluating Critical Digital Equipment and Systems*, 1011710 [98]
- *Handbook for Verification and Validation of Digital Systems*, TR-103291 [99]

14.2 Computer Programs Not Integral to Plant SSCs

It is possible for computer programs that are not integral to plant SSCs to be classified as safety-related. An example would be a computer program used to perform design analysis for safety-related SSCs.

Due to the complex nature of computer programs, special methodology must be applied to accept safety-related computer programs that are not integral to plant SSCs. Guidance for accepting commercial-grade design and analysis computer programs may be found in the EPRI report *Plant Engineering: Guideline for the Acceptance of Commercial-Grade Design and Analysis Computer Programs Used in Nuclear Safety-Related Applications: Revision 1 of 1025243* [34] and NRC Draft Guide 1305, *Commercial-Grade Dedication of Software* [100].

14.3 Other Requirements That May Apply

When dedicating digital equipment, it is important to determine the applicability of other requirements associated with digital devices, such as NRC Regulatory Guide 5.71, Cyber Security Programs for Nuclear Facilities [101], and 10CFR 73.54, Protection of Digital Computer and Communication Systems and Networks [102].

15
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A
DESIGN VERSUS ACCEPTANCE

As defined in 10CFR, Part 21,

> 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 an Appendix B, quality assurance program. [4]

Acceptance of a commercial-grade item is the process of verifying critical characteristics identified for the item using one or more of the acceptance methods to reasonably ensure that the item will perform its safety-related function(s). Verification methods may include inspections, tests, or analyses performed by the purchaser or third-party dedicating entity after delivery (Method 1), commercial-grade surveys (Method 2), product inspections or witness at hold points at the manufacturer's facility (Method 3), or evaluation of historical performance of both the supplier and the item (Method 4).

Commercial-grade dedication as an acceptance process is not intended to validate or establish the suitability of design. The item is selected and its design's suitability is established prior to initiating the commercial-grade dedication acceptance process. Engineering personnel working under the controls of 10CFR50, Appendix B, Criterion III are responsible for selection and specification of items for use and establishing the suitability of design.

The amount and level of detail of design and qualification information available can impact the types of dedication acceptance methods used as well as the direction in which the inspections and tests are targeted. The design criteria established by the dedicating entity for safety-related items (whether purchased commercially and dedicated or purchased as a basic component) are provided in design documents as required by 10CFR50, Appendix B, Criterion III [7].

Technical evaluation(s) performed to support the commercial-grade dedication process are acceptance review documents controlled under 10CFR50, Appendix B, Criteria IV and VII [7] and are not required to be processed the same as design documents. This report assumes that the design requirements of the item have been satisfactorily translated into specification requirements reflected in the procurement document. A technical evaluation may be performed as part of the purchase order/requisition process to ensure that the specification requirements are correctly translated into the purchase document.

EPRI report 1008256, Section 1.4.1, states:

> This document assumes that a plant initiated design change is not required if the equivalency of the form, fit, function, and interchangeability (including seismic and environmental qualification requirements) of a replacement item has been established. The basis for this premise is that the plant's, system's, or component's design has not been altered. [25]

It should be concluded that the technical evaluation and the commercial-grade acceptance process described in EPRI report NP-1008256 and the present report are not substitutes for a design change/modification process. The process for technical evaluation of replacement items outlined in EPRI 1008256 [25] ensures that the design basis of a plant, system, structure, or component is maintained. ANSI N45.2.11, Quality Assurance Requirements for the Design of Nuclear Power Plants, Paragraph 6.2, states:

> Where the design of a particular structure, system or component has been subjected to the verification process in accordance with this standard, the verification process need not be duplicated for identical designs. [53]

Similarly, ASME NQA-1, Part 1, Requirement 3 states: "Where the design has been subjected to a verification process in accordance with this Part (Part I), the verification process need not be duplicated for identical designs" [51]. This guidance applies to technical evaluations performed for parts within a component as well as evaluations performed at the component level. Caution should be taken to ensure that the component's ability to perform the plant-specific design functions is not degraded. Therefore, the process of performing the technical evaluation and the commercial-grade acceptance is not intended to be a design change mechanism and does not require design verification. However, commercial-grade technical evaluations should be subjected to an independent peer or supervisory technical review.

Once a technical evaluation has been performed, it is not necessary to repeat the review for repetitive purchases as long as the bounding conditions of the applications remain the same. For plant configuration purposes, plant records should be updated to reflect the installed equivalent components and parts.

This premise is reinforced in NRC-DCS-000654 [103], which includes the following paraphrased question and answer:

> Question:
>
> Is the specification of critical characteristics of basic components and the development of criteria to be used for verification of these critical characteristics during the commercial-grade dedication process a: (1) design control process as implemented as part of QA program design control provisions, or (2) an acceptance and verification process as implemented by QA program control of purchased material, equipment, and services provisions?
>
> Answer:
>
> In general, the specification of critical characteristics of basic components and the development of criteria to be used for verification of these critical characteristics during the commercial-grade dedication process is an acceptance and verification process as implemented by QA program activities that provide control of purchased material, equipment, and services. Furthermore, the activities of identifying critical characteristics for commercial-grade items and developing criteria to be used for verification of these critical characteristics are, in part, measures that should be established to assure that purchased material equipment and services, whether purchased directly or through contractors and subcontractors, conform to the procurement documents that satisfy Criterion VII. Also, these activities are required to ensure that the commercial-grade item will perform its intended safety function, resulting in an acceptable dedication of a commercial-grade item into a basic component. Critical characteristics for commercial-

grade items must be determined and approved by the manager responsible for the procurement based on the performance requirements for the item's safety function. Specific characteristics used for acceptance or dedication of the item are selected based on providing reasonable assurance that the item will meet their catalog or manufacturer specifications and perform the specified functions as intended.

The specification of critical characteristics basic components and the development of criteria to be used for verification of these critical characteristics during the commercial-grade dedication process is not a design control process, but the decision should be based on design output documents. Process controls must be established to ensure the item's safety design function is verified. The dedicating entity staff (e.g. procurement and design engineers) must ensure design configuration is maintained. Also, the answer might be heavily dependent on the extent of engineering involvement and specific activities required for the particular dedication being conducted by the dedicating entity.

As discussed in GL 89-02, "Actions to Improve the Detection of Counterfeit and Fraudulently Marked Products," appropriate engineering involvement is warranted during the procurement and product acceptance processes, including testing, for products used in nuclear power plants.

Involvement of a licensee's engineering staff in an effective procurement process would normally include (1) development of specifications to be used for the procurement of products to be used in the plant, (2) determination of the critical characteristics of the selected products that are to be verified during product acceptance, (3) determination of specific testing requirements applicable to the selected products, and (4) evaluation of test results. The extent of necessary engineering involvement is dependent on the complexity of the nature and use of the products involved.

It is important to note that the specific regulatory basis for dedication is found in Regulatory Guide 1.33, Revision 2, "Quality Assurance Program Requirements (Operations)," which endorses American National Standards Institute N18.7/ANS3.2-1976, "Administrative Controls and Quality Assurance for the Operational Phase of Nuclear Power Plants," Section 5.2.13, which states:

> "…procedures shall be established and implemented to assure that purchased materials and components associated with safety-related structures or systems are purchased to specifications and codes equivalent to those specified for the original equipment, or those specified by a properly reviewed and approved revision. In those cases where the original item or part is found to be commercially 'off the shelf,' or without specifically identified quality assurance requirements, spare or replacement parts may be similarly procured but care shall be exercised to assure at least equivalent performance. In those cases where the quality assurance requirements of the original item cannot be determined, an engineering evaluation shall be conducted by qualified individuals to establish the requirements and controls. This evaluation shall assure that interface, interchangeability, safety, fit and function requirements are not adversely affected or contrary to applicable regulatory or code requirements. The results of these evaluations shall be documented."

In other words, dedication shall be conducted in accordance with the requirements contained in Appendix B to Title 10 of the Code of Federal Regulations (10 CFR) Part 50 and shall have engineering involvement and controls as necessary, to assure the component will perform its safety function.

Question:

Is the process of identifying and modifying specified critical characteristics for basic components and the criteria for verifying the critical characteristics subject to the requirements of Design Control or subject to the requirements of Control of Purchased Material, Equipment, and Services?

Answer:

The answer is dependent on the extent to which engineering involvement was required to identify the critical characteristics. For instance, in a like-for-like dedication scenario, there may be little engineering involvement other than to verify that the item is indeed identical.

Critical characteristics for CGIs must be determined and approved by the (engineering organization) manager responsible for the procurement based on the performance requirements for the item including the intended safety function. Specific characteristics used for acceptance or dedication of the item are selected based on providing reasonable assurance that the item will meet their catalog or manufacturer specifications and perform the specified functions as intended.

The process of identifying critical characteristics for commercial-grade items and the criteria for verifying the critical characteristics should be subject to the requirements Criterion VII of Appendix B to 10 CFR Part 50.

Provided that the change to critical characteristics is not representative of a change to the form, fit, or function of the item, the process of modifying specified critical characteristics for commercial-grade items, should be subject to the requirements in place to assure Control of Purchased Material, Equipment, and Services. In the case that the commercial-grade item has been dedicated to a basic component, any modification (to) the form, fit, or function of the item must be subject to the requirements in place to assure Design Control. In addition, in the case of modifying specified critical characteristics, the expectation would be that engineering was heavily involved to ensure design configuration is maintained. Modification of critical characteristics in a manner that would eliminate or reduce verification of characteristics that are necessary for adequate commercial-grade dedication would not be acceptable. The criteria for verifying the critical characteristics should be subject to the requirements in place to assure Control of Purchased Material, Equipment, and Services.

B
TECHNICAL EVALUATION PROCESS OVERVIEW

B.1 Background

The commercial-grade dedication process relies heavily on detailed and well-prepared technical evaluations and acceptance plans that carefully document the engineering thought process associated with a commercial-grade dedication. However, commercial-grade item dedication is just one aspect of a complete technical evaluation for procurement.

The term *technical evaluation* as it relates to procurement was first used to describe the evaluation performed to correctly specify and procure spare and replacement items. Currently, technical evaluations are also performed for new items (to support construction, modification, and so forth). The technical evaluation process was introduced in EPRI report NP-5652 [2] as the process by which the required technical input necessary (the safety classification, functional analysis, and technical and quality requirements) to perform the acceptance of commercial-grade items could be obtained. The technical evaluation process was generically described in Appendix A of EPRI report NP-5652 and developed in detail in EPRI report NP-6406 [12] (currently EPRI 1008256, *Guidelines for the Technical Evaluation of Replacement Items in Nuclear Power Plants* [25]).

Technical evaluations are prepared by individuals with appropriate technical qualifications, experience, and training who have an excellent understanding of the item's design, safety function, and end use. Input may also be required from others with appropriate experience and/or training in design, manufacturing, equipment operation, maintenance, quality assurance, and regulatory requirements as needed to make these engineering judgments.

B.2 Relationship to the Design Process

Although the technical evaluation process for safety-related items is considered to be engineering in nature, it is not a design engineering process. As discussed in Section A.1 of Appendix A, engineering personnel working under the controls of 10CFR50, Appendix B, Criterion III, are responsible for the selection and specification of items for use and establishing the suitability of design. The design criteria established by the dedicating entity for safety-related items (whether purchased commercially and dedicated or purchased as basic components) are provided in design documents as required by 10CFR50, Appendix B, Criterion III [7], and ANSI N45.2.11 [53].

Technical evaluation(s) performed to support procurement, including the commercial-grade dedication process, are controlled under 10CFR50, Appendix B, Criteria IV and VII [7], and are not required to be processed using the same controls applied to design documents.

Commercial-grade dedication is an acceptance process and is not intended to validate the suitability of design. Selection of the item and suitability of its design are established prior to initiating the commercial-grade dedication acceptance process. Therefore, the design must be completed and its suitability established prior to the start of dedication.

EPRI report 1008256, Section 1.4.1, states:

> This document assumes that a plant-initiated design change is **not** required if the equivalency of the form, fit, function, and interchangeability (including seismic and environmental qualification requirements) of a replacement item has been established. The basis for this premise is that the plant, system, or component's design has not been altered. [25]

The technical evaluation and the commercial-grade acceptance process described in EPRI report 1008256 [25] and the present report are not substitutes for a design change/modification process. The relationship between the overall technical evaluation process and the commercial-grade item acceptance process is summarized in Table B-1.

Table B-1
Relationship between technical evaluation and commercial-grade item acceptance process

	Technical Evaluation	Commercial-Grade Item Acceptance
Regulatory Basis	10CFR50, Appendix B, Criterion IV [7]; ANSI N45.2.13 [36]; ANSI N18.7 [8]	10CFR50, Appendix B, Criterion VII [7]
Guidance	EPRI 1008256 [25]	This report
Reasonably assures	That the correct requirements are specified in procurement documents (requirements that reflect the current design)	That the item received is capable of performing its intended safety-related function
Method	Evaluation/specification of technical and quality requirements	Verification of selected critical characteristics
Results	Technical and quality procurement requirements documented in a procurement document	Documented commercial-grade item acceptance plan

The process of performing the technical evaluation and the commercial-grade acceptance is not intended to be a design change mechanism and therefore does not require design verification. It is prudent, however, that the user of this report institute a peer or supervisor review of commercial-grade dedication documentation for accuracy and consistency of these evaluations. Once a technical evaluation has been performed, it is not necessary to repeat the review for repetitive purchases as long as the bounding conditions of the applications remain the same. For plant configuration purposes, plant records should be updated to reflect the installed equivalent components and parts.

B.3 Overview of Technical Evaluation Contents

A technical evaluation is usually completed by a dedicating entity for any item or service that is being purchased to support plant equipment.

The contents of a technical evaluation may vary depending on the needs of the organization that prepares it. Although technical evaluations are not limited to those described in Sections B.3.1–B.3.9, some of the elements typically included in the overall technical evaluation are as follow.

B.3.1 Identification of the Item to Be Procured and Its End-Use Application(s)

Licensees and organizations that design and build plants typically identify intended applications by equipment tag number or describe a range of generic or bounded intended usage. OEMs typically describe the item's capabilities in product specifications that indicate the range of intended uses or applications or design requirements. Other dedicating entities may describe bounded end-use applications for the item.

B.3.2 Purchasing Description

A purchasing description entails the development of a complete description that includes enough detail for a supplier to recognize the desired product. The purchasing description references applicable specifications, standards, drawings, shop order numbers, and so forth.

B.3.3 Like-for-Like/Alternative Item Determination

For replacement items, this item involves a determination as to whether the replacement item is like-for-like or a proposed alternative item. If the item is a proposed alternative item (different from the original), an equivalency evaluation is included in the technical evaluation to determine if the item is equivalent (see EPRI 1008256 [25]). If the item is not equivalent, a modification or design change is typically initiated to address the change.

Figure B-1 depicts some of the types of factors that may contribute to developing confidence that procurement is like-for-like. The item is specified with the same technical requirements (design criteria) as the original, and the item will not require an equivalency evaluation.

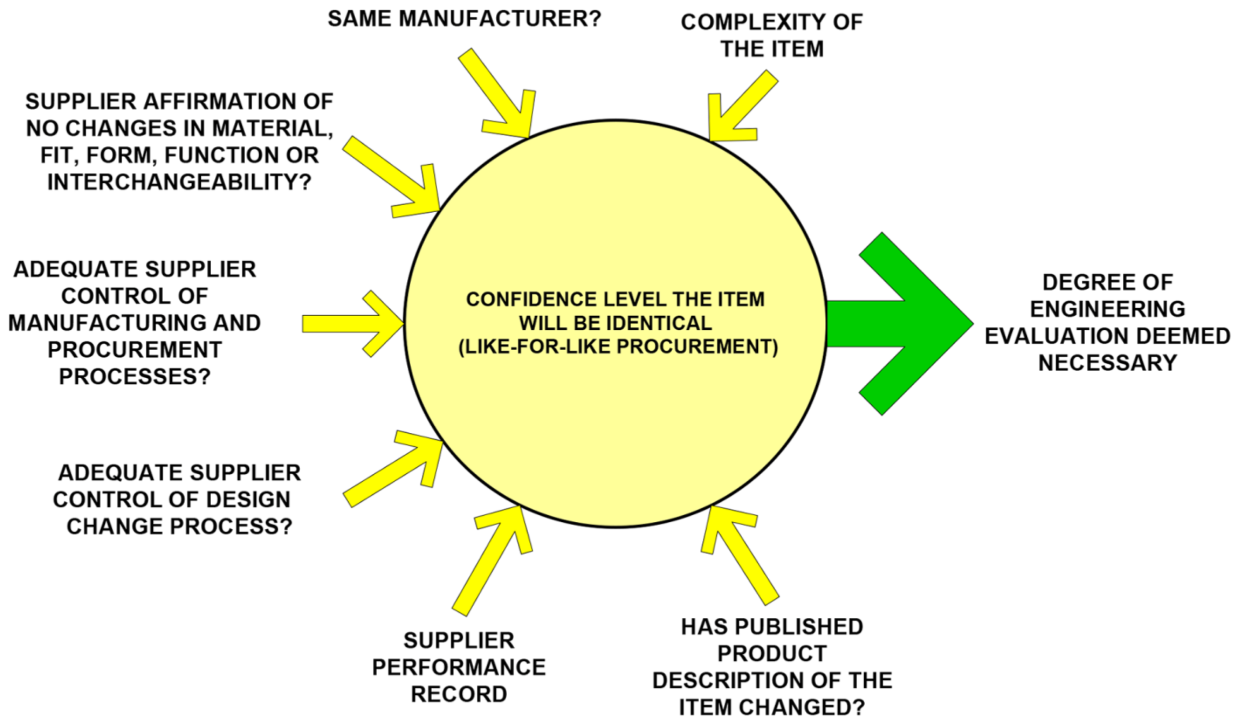

Figure B-1
Considerations for determining if the procurement is like-for-like

The determination involves engineering judgment, but, as a general rule, items may be considered identical or like-for-like if one of the following applies:

- The item is provided by the OEM (successor companies that maintain equivalent quality controls are acceptable) and has not been subject to design, materials, manufacturing, or nomenclature changes.
- The item was purchased at the same time and from the same supplier, as determined by the purchase date, shipping date, date code, or batch/lot identification.
- Evaluation of the item confirms that no changes in the design, materials, or manufacturing process have occurred since the procurement of the original item.

B.3.3.1 Like-for-Like Item

The term *like-for-like* is associated with the technical evaluation process and not the acceptance process. Like-for-like procurement is based on the premise that the original item was designed correctly, satisfied its intended design basis, was suitable for its intended end-use application, and was specified correctly with the proper technical and quality requirements.

If confidence is high that an item will be like-for-like (no changes have occurred with the item's material, design, fit, form, function, manufacturing process or interchangeability), the item is considered like-for-like, and additional evaluation is not required. The technical evaluation is based on the original design requirements, and an equivalency evaluation is not required.

B.3.3.2 Alternative Replacement

If confidence is low and there is reason to believe that the item may have changed, the item is considered to be an alternative item. Additional evaluation may be necessary to make the determination, and an equivalency evaluation may be required to determine if the proposed alternative is equivalent or a design change is necessary.

An equivalency evaluation is typically conducted for alternative replacements caused by the following situations:

- The original item cannot be purchased like-for-like.
- The technical/quality requirements of the original item cannot be determined.
- There is reason to believe that changes have occurred to the item's material, design, fit, form, function, manufacturing process, or interchangeability characteristics.

The equivalency evaluation in itself is not a means to accept a commercial-grade item for safety-related use as defined herein. Rather, it is a sound engineering method to ensure that an alternative item specified is an acceptable substitute for the originally designed item. For a commercial-grade item requiring dedication, verification of the identified critical characteristics by an appropriate dedication method(s) would still be required to verify the acceptability of the replacement item.

B.3.4 Identification of Safety Classification

The safety classification and procurement scenario for the item (see EPRI report NP-6895 [74] and 1008256 [25]) may be included in the technical evaluation.

Licensees typically include a functional safety classification of safety-related or non-safety-related based on the item's specific function(s) in the plant. Dedicating entities without access to end-use application information necessary to perform a safety classification include the designed safety classification or the safety classification specified by the purchaser.

When the procurement classification is safety-related, the evaluation indicates under which of the following three scenarios the items will be procured:

- Procured as a basic component
- Procured as a commercial-grade item and dedicated for use as a basic component using a commercial-grade item technical evaluation and acceptance plan
- Procured as a commercial item and controlled under the purchaser's 10CFR50, Appendix B–compliant QA program, as discussed in Section 3.4.1.

B.3.5 Commercial-Grade Dedication Information

When the item is being dedicated, the following information is included in the technical evaluation as described in this report:

- Eligibility for dedication
- Safety function, performance requirements, and service conditions (seismic, environmental, and so forth)

- A failure modes and effects analysis (if required)
- Critical characteristics
- Acceptance methods and criteria

B.3.6 Applicable Risk Assessments

Risk assessments associated with the procurement—such as determining if the item could be counterfeit or fraud, an obsolete item, a single-point vulnerability item, or a critical component item—may be included in the technical evaluation. When necessary, appropriate precautions/stipulations are included in technical and quality requirements.

B.3.7 Technical Requirements

Technical requirements (description, applicable specifications and requirements, required documentation, and so forth) may be established in the technical evaluation.

B.3.8 Quality Requirements

Quality requirements (QA program applicability, defect reporting requirements, required certification, rights of access, hold points, witness points, acceptance activities, and so forth) may be established in the technical evaluation.

B.3.9 Results of Operating Experience Review

When applicable, the results of a review of the vendor’s technical data, industry operating experience, NRC bulletins and information notices, supplier information letters, and so forth may be included in the technical evaluation.

B.3.10 Basis for Conclusions

Many of the decisions and engineering judgments made during the course of a technical evaluation are based in part on the knowledge and expertise of the personnel performing the evaluation. As stated throughout this report, it is important to include adequate explanation for conclusions made in the technical evaluation.

C
COMMERCIAL-GRADE SURVEY PLANNING

A commercial-grade survey is an effective way to gain confidence in a supplier's ability to control an item's critical characteristics. In order for a survey to be effective, the following are important:

- Technical specialists with the correct experience and expertise participate.
- Critical characteristics are identified well in advance for the entire scope of items being furnished commercial-grade.
- Processes and activities that should be surveyed are identified well in advance.
- Processes and activities that should be surveyed occur during the period during which the survey is conducted.

C.1 Identification of Technical Specialists

Technical specialists selected to participate in a commercial-grade survey should be individuals with knowledge of how the equipment works, including its applications and safety-related functions. It is also desirable to have individuals participating who are familiar with the technical aspects of the manufacturing and testing processes associated with the types of items that the supplier provides.

The type and extent of expertise and available sources of information for use in planning the survey may vary depending on which type of organization is serving as the dedicating entity. Table C-1 provides some potential sources of technical information during the survey planning process.

Table C-1
Potential sources of information used for planning commercial-grade surveys

Dedicating Entity	End-Use Applications and Safety Functions	Critical Characteristics	Processes Used to Impart Critical Characteristics	QA Activities Used to Control Processes
Licensee	Final Safety Analysis Report Bills of Material Safety Classifications	Available design and qualification information Failure modes and effects analysis Technical evaluation Operating experience Product manuals and theory-of-operation documents	Communication with operations and maintenance (craft labor) personnel Communication with supplier Communication with equipment subject matter experts Codes and standards	Communication with experienced supplier quality assessors, source verification personnel, inspectors
OEM Third-party dedicator with access to design information	Applications noted in design documents and published literature Customer specifications	Design requirements Design drawings Design specifications Qualification reports Failure modes and effects analysis Technical evaluations Operating experience Product manuals and theory-of-operation documents	Communication with manufacturing process subject matter experts Communication with technical manufacturing personnel Codes and standards	Manufacturing QA personnel Technical manufacturing personnel Communication with experienced supplier quality assessors, source verification personnel, inspectors
Primary Supplier (non-OEM) Third-party dedicator with no access to design information	Applications noted in published literature Customer specifications Customer safety classifications and technical evaluations	Available design information Failure modes and effects analysis Technical evaluation Operating experience Customer technical evaluation Product manuals and theory of operation documents	Communication with the licensee Communication with manufacturing personnel Communication with supplier Communication with equipment subject matter experts Codes and standards	Communication with experienced supplier quality assessors, source verification personnel, inspectors

Figure C-1 provides an example of how a dedicating entity can document a plan for a commercial-grade survey.

Supplier Name	**Description of Item(s)/Service(s) in Scope of Survey**
Item/Service Safety Function(s)	
Operating Experience	

Critical Characteristic	**Process(es) That Influence/Impart Critical Characteristic**	**Supplier Controls to Be Evaluated During the Commercial-Grade Survey (See Table 8-1 for supplier controls that are typically surveyed.)**

Note: a copy of the NUPIC survey checklist can be obtained at www.nupic.com as an example of a format used to perform and document commercial-grade surveys.

Figure C-1
Commercial-grade survey planning worksheet

In cases where it is not possible for all of the individuals with pertinent experience to participate as technical specialists during the survey, it is recommended that the individuals participate in survey planning meetings or, as a minimum, provide input to the technical specialist for use in planning and conducting the survey.

Technical specialists should be active participants in the survey planning process. In addition to assembling technical information, technical specialists should work with the survey team leader and supplier as appropriate to identify manufacturing processes and quality activities that are important to ensuring that the items possess the identified critical characteristics. These are the processes and activities that will be observed during conduct of the survey.

C.2 Identification of Critical Characteristics

Critical characteristics form the baseline for a commercial-grade survey and can typically be found in technical evaluations or design requirement documents. The survey evaluates the supplier's control of these critical characteristics. Effective control of critical characteristics provides reasonable assurance that the item/service will perform its intended safety function. The technical specialist is typically responsible for determining the critical characteristics that require evaluation during preparation and planning for the commercial-grade survey.

C.3 Identification of Processes and Activities

A survey that is truly performance-based involves observation of the processes and activities used by the supplier to ensure that items possess the desired critical characteristics. It is often necessary to contact the supplier and other individuals with manufacturing and maintenance experience to determine what manufacturing processes are associated with achieving the desired critical characteristics. A review of operating experience for the items in question can also be helpful in identifying processes that may have been problematic in the past.

The identified processes will be observed during the survey to determine if they are adequately controlled. Activities and processes important for ensuring that the critical characteristics of the item/service are being adequately controlled by the supplier must be documented in the suppliers' instructions and procedures. Therefore, during the survey, requests are made for the supplier to identify the documented controls for each process or activity observed. If the survey is successful, the documented controls will form the basis for the purchase order requirements and the supplier's certification.

To facilitate conduct of the survey, it is helpful to consider the types of quality activities that might be used to control each process. Individuals with experience conducting supplier audits can identify the types of quality activities typically associated with various manufacturing and testing processes.

C.4 Survey Performance and Documentation

Commercial-grade surveys should be performed by qualified individuals. Commercial-grade surveys are typically planned and scheduled by an individual responsible for the approval/ qualification of suppliers working with the technical specialist. It is important to work with the supplier to ensure that the processes and activities in the scope of the survey can actually be observed during the course of the survey.

Documentation of survey results should include the following:

- Item or items included within the scope of the survey
- Critical characteristics to be controlled by the supplier
- Supplier controls to be verified specific to the critical characteristics
- Verification activities performed with results obtained
- Conclusions attesting to the adequacy of the supplier controls

D
TYPICAL COMMERCIAL-GRADE ITEM DEDICATION FORMS

There is no single or standard format for documenting a commercial-grade dedication technical evaluation. It is acceptable for different organizations to document technical evaluations in different ways, and the format may vary depending on the type of organization. In some cases, the various elements of a commercial-grade item technical evaluation may not be included in the same document.

However, the forms in this section are intended to provide one example of a basic format for documenting commercial-grade item technical evaluations that can be customized by dedicating entities. These forms do not include provisions for other aspects of a complete technical evaluation—a safety classification, equivalency evaluation, and so forth. More information on the technical evaluation of replacement items can be found in EPRI 1008256 [25].

Where applicable, the form references sections of this report that include additional information.

Section D.2 includes a set of basic instructions for completing the forms included in Section D.1.

D.1 Commercial-Grade Dedication Forms

A set of standard forms is included in Figures D-1 through D-5.

Commercial Grade Item Dedication Technical Evaluation

EPRI Joint Utility Task Group
Form CGI1, Rev. 0

Evaluation Number ______________________ **Revision** ____________

SECTION A ITEM DESCRIPTION

INVENTORY CONTROL NO:	
NOUN IDENTIFIER:	
MANUFACTURER NAME:	**MANUFACTURER MODEL / PART / CATALOG NUMBER(S)**

SECTION B END USE / PARENT / HOST EQUIPMENT INFORMATION

Note: If the specific end-use(s) / plant applications are not known, complete Section C of this form in lieu of Section B prior to proceeding.

☐ Not Applicable (Section C Completed Below)

EQUIPMENT ID (TAG) NUMBERS OR DESCRIPTION OF ITEM USAGE:		
PARENT COMPONENT/HOST DESCRIPTION:		
FUNCTIONAL SAFETY CLASS OF COMPONENT / HOST:		**BASIS / SOURCE:**
☒ Safety-Related ☐ Non-Safety Related (If non-safety, item is not a candidate for dedication)		
IDENTIFICATION OF PARENT COMPONENT/HOST EQUIPMENT FUNCTION(S)		
FUNCTIONAL MODE	**BASIC SAFETY FUNCTION(S)**	**DESCRIBE (AS REQUIRED)**
☐ Active ☐ Passive		
☐ Active ☐ Passive		
☐ Active ☐ Passive		
☐ Active ☐ Passive		
PARENT COMPONENT/HOST EQUIPMENT IS (CHECK ALL THAT APPLY):		
☐ EQ ☐ CLASS 1E ☒ SEISMIC CLASS 1 ☐ OTHER: (see below)	☐ ASME SECTION III ☐ CONTAINMENT PRESSURE BOUNDARY ☐ SERVICE LEVEL 1 COATING	

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Figure D-1
Standard forms, Sections A and B

Commercial Grade Item Dedication Technical Evaluation

EPRI Joint Utility Task Group
Form CGI1, Rev. 0

Evaluation Number ______________________ **Revision** ____________

SECTION C BOUNDED SCOPE OF USE

Only complete Section C when specific end-use of the item being dedicated unknown.

☐ Not Applicable (Section B Completed Above)

Is the item being dedicated a commodity or standard item designed and constructed in accordance with an industry standard?	☐ Yes ☐ No
IF "YES", LIST THE STANDARD(S) BELOW	
LIST FUNCTIONS AND/OR APPLICATIONS CONSIDERED WHEN COMPLETING THIS EVALUATION	
EQUIPMENT QUALIFICATION CONSIDERATIONS / LIMITATIONS (CHECK ALL THAT APPLY):	
CONSIDERATION ☐ ENVIRONMENTAL QUALIFICATION ☐ SEISMIC QUALIFICATION ☐ OTHER: (see below)	**QUALIFICATION BASIS / LIMITATIONS OF USE:**

SECTION D ITEM INFORMATION

ITEM DESCRIPTION:	
FUNCTIONAL SAFETY CLASS OF ITEM:	**BASIS / SOURCE:**
☐ Safety-Related ☐ Non-Safety Related (If non-safety, item is not a candidate for dedication)	

IDENTIFICATION OF ITEM FUNCTION(S)

FUNCTIONAL MODE	BASIC SAFETY FUNCTION(S)	DESCRIBE (AS REQUIRED)
☐ Active ☐ Passive		
☐ Active ☐ Passive		
☐ Active ☐ Passive		

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Figure D-2
Standard forms, Sections C and D

Commercial Grade Item Dedication Technical Evaluation | **EPRI Joint Utility Task Group** Form CGI1, Rev. 0

Evaluation Number ______________________ **Revision** _____________

ITEM IS (CHECK ALL THAT APPLY):	
☐ EQ	☐ ASME SECTION III
☐ CLASS 1E	☐ CONTAINMENT PRESSURE BOUNDARY
☐ SEISMIC CLASS 1	☐ SERVICE LEVEL 1 COATING
☐ OTHER: (see below)	
Click here to enter text.	

SECTION E ELIGIBLITY FOR DEDICATION

Is the item eligible for dedication in accordance with 10CFR, Part 21? **If the answer is no, this item cannot be dedicated.**	☒ Yes ☐ No

SECTION F FAILURE MODES / MECHANISMS AND EFFECTS ANALYSIS

CREDIBLE FAILURE MODE/MECHANISM	EFFECTS ON SYSTEM/COMPONENT FUNCTION

BASIS FOR SELECTION OF CREDIBLE FAILURE MODE(S)/MECHANISM(S)

SECTION G OPERATING EXPERIENCE / HISTORICAL PERFORMANCE INFORMATION

SOURCES REVIEWED AND RESULTS

Page 3 of 5

Figure D-3
Standard forms, Sections E–G

Commercial Grade Item Dedication
Technical Evaluation

EPRI Joint Utility Task Group
Revision 0

Evaluation Number ____________________ **Revision** ____________________

SECTION H IDENTIFICATION ATTRIBUTES

IDENTIFICATION ATTRIBUTES	DESCRIPTION OF INSPECTION	ACCEPTANCE CRITERIA
Manufacturer	Visual	
Identification Number	Visual	

SECTION I CRITICAL CHARACTERISTICS

CRITICAL CHARACTERISTICS	ACCEPTANCE METHOD	DESCRIPTION OF ACCEPTANCE ACTIVITY	SAMPLING PLAN	ACCEPTANCE CRITERIA (INCLUDING TOLERANCES)

DESCRIPTION OF SAMPLING PLANS (if "see below" is selected in the sampling plan column above)

SAFETY FUNCTION(S) SUPPORTED / BASIS FOR SELECTION OF CRITICAL CHARACTERISTICS / ACCEPTANCE CRITERIA INCLUDING MAINTAINING SEISMIC AND ENVIRONMENTAL QUALIFICATION

Page 4 of 5

Figure D-4
Sample forms, Sections H and I

Commercial Grade Item Dedication
Technical Evaluation

EPRI Joint Utility Task Group
Revision 0

Evaluation Number ____________________ **Revision** ____________________

BASIS FOR SELECTION OF SAMPLING PLANS (IF SAMPLING PLANS ARE USED)

SECTION J REFERENCES

DOCUMENT / SOURCE	REVISION / DATE	COMMENTS

SECTION K REVIEW AND APPROVAL

Prepared by: ______________________________ Date: ____________________

Reviewed by: ______________________________ Date: ____________________

Page 5 of 5

Figure D-5
Sample forms, Sections J and K

D.2 Instructions for Completing Commercial-Grade Item Dedication Technical Evaluation Forms

D.2.1 Section A, Item Description

The information to include in each of the data fields of Form A in Figure D-1 is as follows:

- **Evaluation number and revision:** the internal tracking number and revision level (as applicable) used to identify the evaluation.
- **Inventory control number:** the unique code used to identify the item in the inventory management system. (Examples include stock code, catalog identifier, material number, and stock keeping unit).
- **Noun identifier:** the name of the item, typically presented in a noun-adjective-additional information format. An example is “pipe, carbon steel, Schedule 80, 4-in. (100.8-mm) diameter, 20-ft (6.1-m) long.”
- **Manufacturer name:** the name of the entity that manufactures the item.
- **Manufacturer model/part/catalog number(s):** a product identifier, such as the manufacturer or supplier’s assigned identifier for an item. The part number (as referred to in this report) can also include identifiers such as model number, material type, grade, or catalog reference number.

D.2.2 Section B, End Use/Parent/Host Equipment Information

Either Section B or Section C should be completed for a commercial-grade item dedication technical evaluation. Section B is provided to capture information about the end use, parent, or host equipment. Section B would typically be used when the dedicating entity knows the parent/host equipment and end uses for the item being dedicated or when the dedicating entity has a design document or other information that clearly defines the intended scope of use. An example might be dedicating an item to meet the requirements of a plant design specification.

Recognizing that dedicating entities do not always have information about the specific end-use application of products they dedicate, the standard form also provides Section C to capture a bounded scope of use on which a dedication may be based. Section C would typically be used when the dedicating entity wants to have safety-related items available for use but does not have information about the specific end-use applications or does not have access to design documents or other information that clearly define all of the possible uses for the safety-related items. An example might be dedicating an item based on all applicable design requirements and uses for the item. Such items might include discrete electronic devices, such as capacitors or resistors. Section C might also be used when dedication is being used to establish and document that an item meets all of the requirements of an industry standard.

The information to include in each of the data fields of Section B (shown in Figure D-1) is as follows:

- **Equipment ID (tag) numbers or description of item usage**. Identify the host equipment (such as by tag numbers) for which the item is intended. When the item is used in numerous applications, such as a commodity item, describe the intended end-use applications. For example: "This cap screw is used in accordance with piping specifications ABC and XYZ as a pressure-retaining bolting component in safety-related piping system flanged connections."
- **Parent component/host description.** Briefly describe the parent/host components/systems.
- **Functional safety class of component/host**. Identify the component/host as safety-related or non-safety-related. If the component/host is non-safety-related, the item does not require dedication, and the dedication process does not apply. If the component/host is safety-related, continue with the commercial-grade item dedication technical evaluation.
- **Basis/source**. List the basis or source of the component/host safety classification. Typical sources might include previous safety classification evaluations, system descriptions, equipment lists, Q-lists, CSSC lists, and so forth.
- **Identification of parent component/host equipment function(s)**. Provide information on the actual function(s) of the component within the system in which it is installed. Information should include functional requirements during normal operations as well as during and following a design basis accident. For each basic safety function (basic safety functions are listed in Table 5-3), include the functional mode (active or passive) and a brief description as required. Example: a relay could have both a passive safety function (maintaining 1E circuit integrity) and an active safety function (close to prevent damage to the 1E circuit). Both safety functional classifications would be listed.
- **Parent component/host equipment is (check all that apply)**. This section further defines the technical requirements of the parent component.

D.2.3 Section C, Bounded Scope of Use

Note: This section is used only when the specific end use of the item is unknown.

Bounding the scope requires clearly defining the postulated safety functions on which the commercial-grade item dedication technical evaluation and acceptance plan are based.

The dedicating entity may decide to dedicate the item based on all applicable design criteria and establish in the dedication that the item meets all design requirements, thereby capable of performing any function in any application.

The information to include in each of the data fields of Section C (shown in Figure D-2) is as follows:

- **Is the parent/host a commodity or standard item designed and constructed in accordance with an industry standard?** If the answer is "yes," list all of the known industry standards that apply.
- **List functions and/or applications considered when completing this evaluation.** This information provides the basis for bounding the scope for which this evaluation can be used. The evaluation can be used only for those functions and applications considered, documented, and evaluated in this technical evaluation.
- **Equipment qualification considerations/limitations (check all that apply).** This section further defines the technical requirements of the parent component.

D.2.4 Section D, Item Information

The information to include in each of the data fields of Section D (shown in Figure D-2) is as follows:

- **Item description**. Describe the item being evaluated for purchase/acceptance. (It could be the parent component, a specific piece-part of the parent component, or a commodity item.)
- **Functional safety class of the item**. Identify the item as safety-related or non-safety-related. If the item is non-safety-related, the item does not require dedication; document the basis/source of the determination (see the following), and this process is exited. If the item is safety-related, document the basis/source of the determination (see the following), and continue with the technical evaluation.
- **Basis/source**. The basis or source of the item's safety classification is to be listed here. **Note**: If the functional classification of the item is non-safety-related, exit this process, and procure the item as non-safety-related.
- **Identification of item function(s)**. Provide information on the actual safety function(s) of the item within the component and the system in which it is installed. Information should include functional requirements during normal operations as well as during and following a design basis accident. For each basic safety function (basic safety functions are listed in Table 5-3), include functional mode (active or passive), and a brief description as required. Example: a relay could have both a passive safety function (maintaining 1E circuit integrity and an active safety function to close to prevent damage to the 1E circuit. Both safety functional modes would be listed in this section.
- **Item is (check all that apply)**. This section further defines the technical requirements of the item.

D.2.5 Section E, Eligibility for Dedication

Does the item meet the applicable regulatory definition of a commercial-grade item? Answer "yes" or "no." If the answer is no, this item cannot be dedicated.

D.2.6 Section F, Failure Modes/Mechanisms and Effects Analysis

The information to include in each of the data fields of Section F (shown in Figure D-3) is as follows:

- **Credible failure mode/mechanism**. The credible failure mode(s)/mechanism(s) associated with safety functions of the item in its operating environment are considered in the selection of critical characteristics. Note that there may be more than one failure mode/mechanism. Select all that apply from the list included in Table 5-4; also, consider the information contained in Section 3.3 of EPRI report 1008256 [25].
- **Effects on the system/component function**. The effects of each credible failure mode/mechanism of the item on its safety function(s) are considered in the selection of critical characteristics. For each credible failure mode/mechanism previously listed, document its effect on the safety function(s) of the item in its operating environment (normal and postulated accidents).
- **Basis for selection of credible failure mode(s)/mechanism(s)**. Document a basis statement for the selection of each credible failure mode/mechanism. If a failure modes and effects analysis is not performed, a basis should be provided.

D.2.7 Section G, Operating Experience/Historical Performance Information

Document the operating experience reviewed to identify information about the quality of the item. Examples of operating experience sources of information can be internal and external and may include corrective action programs, industry databases, customer feedback, generic regulatory communications, and so forth.

D.2.8 Section H, Identification Attributes

Verification of identification attributes (such as those identified in Table 6-1) provides preliminary assurance that the item received is correct. In addition, changes in identifiers, such as the part and model number, often provide indication of a design change and prompt further evaluation to determine if physical changes to the item impact its ability to perform its intended safety functions. Document appropriate identification attributes, a description of the inspection to be performed, and the acceptance criteria for each identification attribute listed.

D.2.9 Section I, Critical Characteristics

Document the appropriate physical (see Table 6-2) and performance (see Table 6-3) characteristics. For digital equipment, dependability (see Table 6-4) characteristics should also be considered. (See Section 6 for more information.)

Document the acceptance method (or group of acceptance methods) selected to verify each critical characteristic (the acceptance methods are listed in Table 5-2). Provide a description of the acceptance activity and the acceptance criteria that must be met.

Include a description of the inspection or test, the type of test equipment (as appropriate), and the sampling plan (as applicable). Typical sampling plan options are 100%, normal (nondestructive), normal (destructive), reduced (nondestructive), reduced (destructive), tightened (nondestructive), and tightened (destructive). See EPRI report TR-017218-R1 [23] for information on selection of sampling plans.

The information to include in each of the data fields of Section I (shown in Figure D-4) is as follows:

- **Description of sampling plan**. Provide additional information as necessary to describe the sampling plan.
- **Safety function(s) supported/basis for selection of critical characteristics/acceptance criteria**. Describe how verification of the critical characteristics selected will provide reasonable assurance that the item will be capable of performing its safety function(s). The basis should include considerations for maintaining seismic and environmental qualifications when applicable.
- **Basis for selection of sampling plans**. When sampling is used, document the sampling plan selected for each critical characteristic and the basis/factors considered when selecting the sampling plan.

D.2.10 Section J, References

List reference documents/sources used in the development of the commercial-grade item dedication technical evaluation.

D.2.11 Section K, Review and Approval

Review and approval should be performed and documented in accordance with the dedicating entity's procedures.

E
TECHNICAL EVALUATION REVIEW CHECKLIST

There are no standard criteria for reviewing a commercial-grade dedication technical evaluation. It is acceptable for different organizations develop different criteria based on how their technical evaluations are performed and the information they contain.

However, the checklist shown in Figure E-1 is intended to provide one example of criteria that may be used to improve the consistency and content of commercial-grade item dedication technical evaluations. Used as a starting point, the checklist can be customized by dedicating entities.

Commercial Grade Dedication Review Checklist

Dedication Evaluation Number: ____________________

Basic Technical Evaluation

No.	Criteria	Yes	No	N/A
1	End-use application or scope of application is identified	☐	☐	☐
2	Safety function(s) is identified and functional safety classification is complete and includes active and passive safety functions as applicable	☐	☐	☐
3	Service conditions/requirements such as seismic, environmental, ASME Section III, etc. are identified	☐	☐	☐
4	A review of pertinent technical information has been performed	☐	☐	☐
4a	Vendor technical information such as technical manuals, drawings, and so forth	☐	☐	☐
4b	Available operating experience	☐	☐	☐
5	A failure modes and effects analysis (FMEA) has been performed to identify critical characteristics (such as in cases where original design information / requirements are not available) The FMEA addresses failure modes/mechanisms in the applications for which the item is intended	☐	☐	☐
6	Critical characteristics are identified and address:	☐	☐	☐
6a	Important design, material and performance characteristics with a direct effect on the item's ability to perform it intended safety function(s)	☐	☐	☐
6b	Active and passive safety functions	☐	☐	☐
6c	Ability to perform in all design basis conditions (e.g. harsh environment, seismic event, etc.)	☐	☐	☐
6d	When verified, the critical characteristics selected will provide reasonable assurance that the item will perform it's intended safety function(s) Critical characteristics related to safety function are selected Critical characteristics that relate to failure modes/mechanisms are selected Critical characteristics address seismic and environmental requirements	☐	☐	☐
6e	The basis for selection of critical characteristics is documented	☐	☐	☐
7	An appropriate verification method is identified for each critical characteristic	☐	☐	☐
8	Acceptance criteria including appropriate tolerances are identified for each critical characteristic	☐	☐	☐

Figure E-1
Sample commercial-grade dedication review checklist

Commercial Grade Dedication Review Checklist

Dedication Evaluation Number: ____________________

Equivalency Evaluation

No.	Criteria	Yes	No	N/A
9	An equivalency evaluation is performed if there are indications the replacement item is different from the item being replaced, for example, there are changes in design, material or manufacturing processes that could impact the functional characteristics of the item	☐	☐	☐
10	If the item is determined not to be equivalent, appropriate engineering change evaluations are initiated or performed	☐	☐	☐
11	If the item is determined to be equivalent, the dedication technical evaluation is completed. That is, equivalency itself is not used as the sole basis for accepting the item	☐	☐	☐

Method 1 – Special Tests and Inspection

Not Applicable ☐

No.	Criteria	Yes	No	N/A
12	Special tests and inspections are conducted after the item(s) arrives on-site	☐	☐	☐
12a	Special tests and inspections are conclusive enough to verify the characteristics they are intended to verify	☐	☐	☐
13	Special tests and inspections are documented in a plan or checklist that includes:	☐	☐	☐
13a	Test methods and inspection techniques	☐	☐	☐
13b	Verification of the identified critical characteristics consistent with the acceptance criteria in the technical evaluation	☐	☐	☐
13c	Documentation of the inspections, tests, and results (actual values recorded)	☐	☐	☐
14	When sampling plans are employed:	☐	☐	☐
14a	An adequate technical basis for the sampling plan selected is documented (factors such as lot homogeneity, complexity of the item, extent of traceability, experience with the supplier/item, etc.)	☐	☐	☐
15	When post-installation testing is employed:	☐	☐	☐
15a	Measures are in place to assure post-installation testing is not waived	☐	☐	☐
15b	The host device or system is not declared functional or operational until the dedication is complete	☐	☐	☐

Figure E-1 (Continued)
Sample commercial-grade dedication review checklist

Commercial Grade Dedication Review Checklist

Dedication Evaluation Number: ____________________

Method 2 – Commercial Grade Survey — Not Applicable ☐

No.	Criteria	Yes	No	N/A
16	A commercial grade survey was conducted to verify the supplier implements adequate programmatic controls over the specific critical characteristics and items identified in the survey plan	☐	☐	☐
17	The results of the commercial grade survey are clearly documented in the survey plan/report	☐	☐	☐
18	The vendor's controls are documented in the instructions and procedures identified in the completed survey report	☐	☐	☐
19	Applicable vendor controls are invoked in the procurement documents for each order (for example, by vendor instruction number and revision)	☐	☐	☐
20	Certification to the vendor controls invoked is also a requirement in the procurement document	☐	☐	☐
20a	Documentation including certification is verified during the acceptance process	☐	☐	☐
21	Critical characteristics that were determined not to be adequately controlled during the survey are verified by other means in the dedication technical evaluation and acceptance plan	☐	☐	☐
22	Measures are in place to ensure dedication is based upon a valid, current survey	☐	☐	☐
23	If items are provided by a distributor, the distributor was surveyed or a requirement to drop-ship from the location surveyed is included in the procurement document	☐	☐	☐

Method 3 – Source Verification — Not Applicable ☐

No.	Criteria	Yes	No	N/A
24	Source verification activities are controlled by a documented plan that includes the critical characteristics to be verified	☐	☐	☐
25	Appropriate hold and verification points are included in the documented plan and are communicated to the supplier in procurement documents	☐	☐	☐
26	The source verification witnesses activities performed on the actual items that will be shipped	☐	☐	☐
27	The results of the source verification are clearly documented in the source verification plan/report	☐	☐	☐

Figure E-1 (Continued)
Sample commercial-grade dedication review checklist

Commercial Grade Dedication Review Checklist

Dedication Evaluation Number: ____________________

Method 4 – Acceptable Supplier/Item Performance Record — Not Applicable ☐

No.	Criteria	Yes	No	N/A
28	Is Method 4 being used as the acceptance method for all critical characteristics? (If the answer is Yes, the dedication violates the restrictions for the use of Method 4 discussed in NRC GL 89-02 and the dedication requires use of additional Methods.)	☐	☐	☐
29	Is the basis for use of Method 4 explained with adequate references to documented records of the item/supplier's performance history?	☐	☐	☐
30	Are the documented historical records directly related to verification of the critical characteristic(s) identified in the dedication technical evaluation?	☐	☐	☐

Figure E-1 (Continued)
Sample commercial-grade dedication review checklist

F
PROVIDING BASIC COMPONENTS

As construction of new nuclear facilities declined in the 1970s and the demand for nuclear components decreased, many suppliers opted to leave the nuclear marketplace and discontinued their nuclear QA programs. Licensees were no longer able to purchase the safety-related spare and replacement items required to support operation and maintenance of installed equipment as basic components. Certain spare and replacement items previously available as basic components were available only as “commercial-grade” items. A method was needed to accept commercial-grade items for use as basic components.

A commercial-grade item dedication methodology was originally developed to enable nuclear licensees to use commercial-grade items in safety-related applications. Use of the methodology expanded down the supply chain among organizations maintaining nuclear QA programs, however, because it was conditionally endorsed by the NRC. Over time, the methodology proved to be robust and effective.

Many of these organizations developed a commercial-grade item dedication program to better meet the needs of their utility customers. They recognized that by providing this service, it provided them another way to supply a basic component to their customers.

F.1 Regulatory Definition of *Commercial-Grade Item*

Prior to a 1978 change to 10CFR21 [4], the term *dedication* was not part of the industry’s vernacular. The only way a supplier could bring basic components to the nuclear marketplace was to control them in accordance with a QA program meeting the requirements of 10CFR50, Appendix B [7]. Application of the 18 criteria of 10CFR50, Appendix B [7], most often included controlling the design, specification, acceptance, handling, special manufacturing processes, in-process testing/inspection, and final product testing.

In 1995 the NRC issued a revision to 10CFR21.3 [4] to define *commercial-grade item* as “a structure, system, or component, or part thereof, that affects its safety function, that was not designed and manufactured as a basic component.” Also, 10CFR21.3 [4] provided a definition for basic component as follows, and added the condition specified in (1)(ii):

> (1)(i) When applied to nuclear power plants licensed under 10CFR part 50 or part 52 of this chapter, basic component means a structure, system, 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 10 CFR 50.34(a)(1), 10 CFR 50.67(b)(2), or 10 CFR 100.11, as applicable.

(ii) Basic components are items designed and manufactured under a QA program complying with Appendix B to 10 CFR Part 50, or commercial-grade items which have successfully completed the dedication process.

(2) When applied to standard design certifications under subpart C of part 52 of this chapter and standard design approvals under part 52 of this chapter, basic component means the design or procurement information approved or to be approved within the scope of the design certification or approval for a structure, system, or component, or part thereof, that affects its safety function necessary to assure:

(i) The integrity of the reactor coolant pressure boundary;

(ii) The capability to shut down the reactor and maintain it in a safe shutdown condition; or

(iii) 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), 50.67(b)(2), or 100.11 of this chapter, as applicable.

(3) When applied to other facilities and other activities licensed under 10 CFR parts 30, 40, 50 (other than nuclear power plants), 60, 61, 63, 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.

(4) 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, design certification, design approval, or information in support of an early site permit application under part 52 of this chapter, whether these services are performed by the component supplier or others.

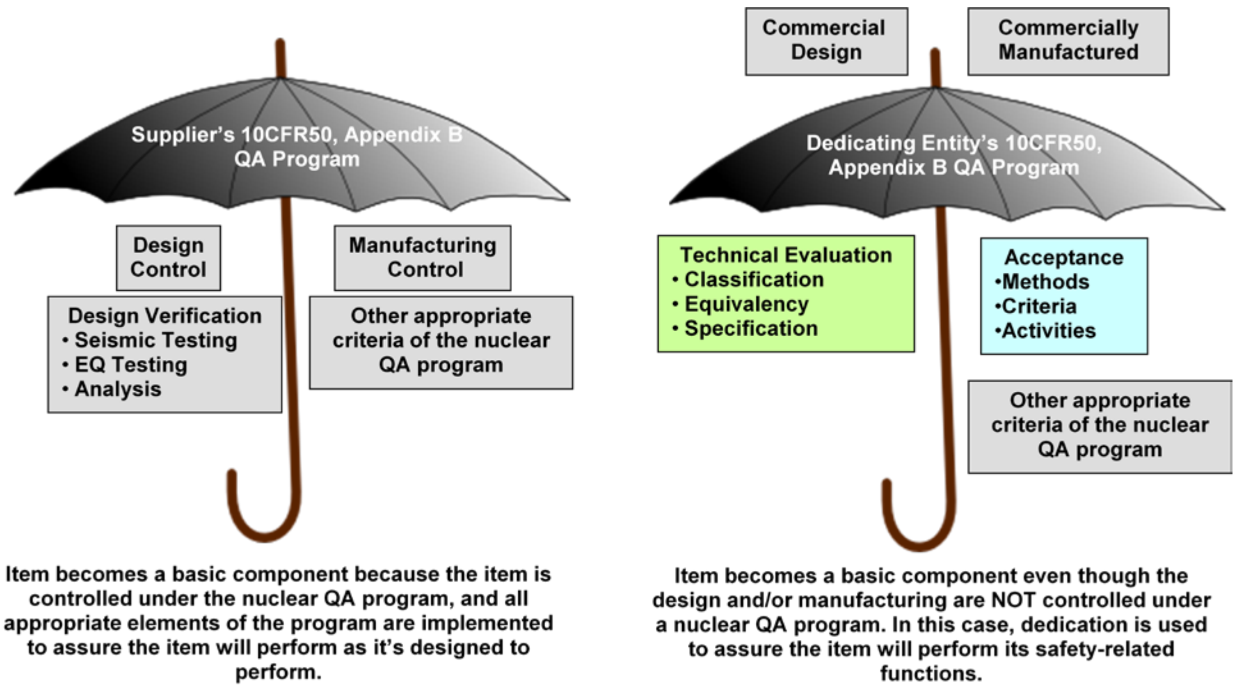
The second paragraph (1)(ii) of the definition clarifies that there are two methods by which a basic component is created —by controlling the item under a 10 CFR Part 50, Appendix B [7]-compliant QA program or by successfully completing the dedication process for the item (note that the dedication process is itself controlled under a 10 CFR Part 50, Appendix B [7] QA program). Since these are two distinct processes for creating a basic component, an item does not need to be subject to both processes to become a basic component.

In that light, paragraph (1)(ii) is appropriately considered to include items ‘controlled’ under a quality assurance program complying with 10 CFR Part 50, Appendix B [7].

An organization that controls a basic component typically maintains access to the design requirements and information (either developed by the organization or specified by the customer) for the basic component necessary for it to perform safety functions. It also typically implements processes that may include machining, assembly, in-process testing, in-process inspections, special manufacturing processes, and so on, to ensure that the basic component meets the design requirements necessary for it to perform safety functions.

F.2 Overview of How Items Become Basic Components

Figure F-1 is a simplified illustration that contrasts the key differences between bringing an item to market by controlling it under a QA program meeting the requirements of 10CFR50, Appendix B [7], and bringing an item to market using dedication.



Note: EQ = environment qualification

Figure F-1
Controlling a basic component under 10CFR50, Appendix B (left), versus commercial-grade item dedication (right)

Table F-1 identifies some of the differences between the approaches used to bring an item to market by controlling it under a QA program meeting the requirements of 10CFR50, Appendix B [7], and using commercial-grade item dedication. Table F-1 expounds on the simplified illustration provided in Figure F-1. Additional guidance is provided in Sections F.2.1 and F.2.2.

Table F-1
Comparing two ways of providing a basic component

Topic	Control an Item in Accordance with a QA Program Meeting the Intent of 10CFR50, Appendix B	Implement the Commercial-Grade Item Dedication Process
Regulatory position	Acceptable method (only method of providing a basic component prior to 1979).	Acceptable method (option for delivering a basic component since 1979).
QA program	Manufacturer’s nuclear QA program compliant with 10CFR50, Appendix B [7] (such as ANSI N45.2 [37] or ASME NQA-1 [1]).	Dedicating entity’s nuclear QA program.
Prerequisites	Per 10CFR50, Appendix B, Criterion III [7], the design has been verified to be suitable for the licensee’s application(s), and changes to the design have been controlled.	Suitability of the item’s design has been established for one or more safety-related applications. Safety-related applications/functions should support the selection of critical characteristics.
Methodology	Conformance to the item’s design is controlled during its manufacture using the measures in 10CFR50, Appendix B [7], including those in Criterion VII: • Source evaluation and selection • Objective evidence of quality • Inspection at source • Examination of products on delivery	Acceptance of items based on verifying critical characteristics necessary for the item to perform its safety function(s) by: • Method 2: Commercial-Grade Survey • Method 4: Item/Supplier Performance Record • Method 3: Source Verification • Method 1: Special Tests and Inspection
Availability of item’s design information	Design information is typically available, including design verification and qualification documentation (that is, seismic test reports and so forth).	Design information may be available for the item.
Method of establishing and documenting objective evidence of acceptability	Instructions, procedures, drawings, and documented results of acceptance measures used.	Commercial-grade item technical evaluation and acceptance plan.

F.2.1 Control a Basic Component Under a QA Program That Meets the Requirements of 10CFR50, Appendix B

The traditional (pre-1979) method of bringing a basic component to the marketplace was to control it under a nuclear QA program. It is not a regulatory requirement to use commercial-grade dedication when an item is adequately controlled under a QA program that meets the requirements of 10CFR50, Appendix B [7]. The definition of *basic component* states that basic components are items designed and manufactured under a QA program complying with

10CFR50, Appendix B [7]. However, 10CFR50, Appendix B, also requires objective evidence demonstrating that the design requirements for the item were met. This evidence is obtained through implementation of the QA program through procedures and processes that ensure that the design requirements are met through design controls, control of purchased items, manufacturing quality controls, final product testing, and so on. In these cases, the entity "owns" or controls the design of the item.

Under a traditional approach, acceptance of the item is based on QA activities conducted to support and implement the 18 criteria in 10CFR50, Appendix B [7]. Under the umbrella of their QA program, the original supplier established an approved design. The design is proven or verified to meet specified requirements using methods such as design reviews and testing a prototype. If necessary, the design may be qualified to meet specific seismic or environmental requirements. Once the design has been established as suitable for the intended application, the supplier implements QA activities to control the approved design and to ensure that the item being manufactured meets the design requirements. Documented controls (such as procedures and work instructions) detail the verifications, inspections, personnel qualifications, and other activities necessary throughout the manufacturing process to ensure that the item is manufactured to meet its design requirements.

Implementation of these controls provides the supplier with objective evidence that the item is manufactured in strict accordance with the design proven suitable for the licensee's applications. Although sufficient objective evidence must exist to establish that the basic component conforms to the design and is acceptable to use in a safety-related application, the objective evidence is typically not documented following a format used by a dedicating entity (that is, a commercial-grade item dedication technical evaluation and acceptance plan).

F.2.2 Commercial-Grade Item Dedication

In cases when the item is **not** adequately controlled under a nuclear QA program, commercial-grade item dedication may be used to provide the item as a basic component or, in the licensee's case, to use the item as a basic component. In order to implement the process, the entity performing the commercial-grade item dedication must know the licensee's end-use application/range of applications or the critical characteristics selected by the licensee.

If the licensee's end-use application(s) is (are) known, a technical evaluation that employs failure modes and effects analysis or other effective means should be used to identify critical characteristics that are necessary for the item to perform its intended safety function(s). The process then requires an acceptance plan to verify that the critical characteristics are appropriately verified.

Implementation of the activities specified in the technical evaluation and acceptance plan provide the dedicating entity with objective evidence that the item is capable of performing its intended safety functions. When an item is accepted using commercial-grade item dedication and subsequently furnished/used as a basic component, the objective evidence should be documented with the technical evaluation and acceptance plan.

F.3 Licensee Procurement Options for Items Intended for Safety-Related Applications

For items intended for a safety-related application, the licensee can either procure an item as a basic component or procure a commercial-grade item and dedicate it using the methodology described in this report. Therefore, short of procuring a basic component from a qualified nuclear supplier, the only option available when procuring commercial-grade items intended for safety-related applications to a licensee is successfully completing the dedication process.

The remainder of this appendix provides examples of how organizations in the supply chain can implement the two options described in the regulatory definitions of *basic component*, which are 1) items adequately controlled (without the use of dedication) under a QA program complying with Appendix B to 10CFR, Part 50 [7], or 2) commercial-grade items that have successfully completed the dedication process under a QA program complying with Appendix B to 10CFR50 [7].

F.4 Options and Examples When Providing a Basic Component

This section provides examples of how organizations maintaining a nuclear QA program can provide a basic component to the nuclear utility. Although this section includes many examples of how the two scenarios described in 10CFR21 [4] may be implemented by different types of organizations for both replacement items and whole components, other procurement scenarios may be encountered that are not described in this report.

F.4.1 Controlling a Part Under a Nuclear QA Program

F.4.1.1 General Guidance

Figure F-2 illustrates how a supplier (who is the manufacturer) can use their nuclear QA program to control the quality of a part that is subsequently provided as a basic component. In accordance with 10CFR21 [4], the basic component can be provided because it was adequately controlled under a QA program complying with 10CFR50, Appendix B.

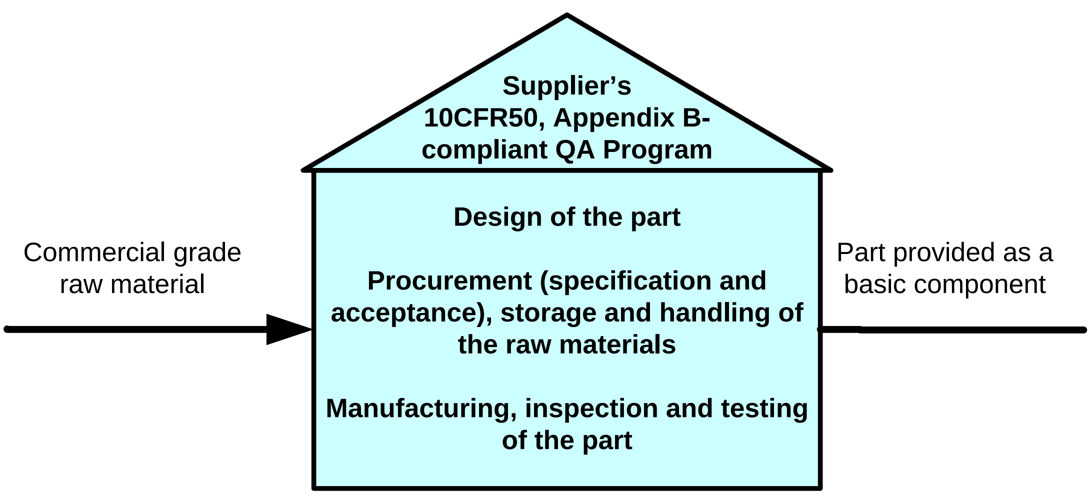


Figure F-2
Controlling a part under a nuclear QA program

In this scenario, the manufacturer controls the design of the part under Criterion III of their nuclear QA program. The raw material is specified and procured from a subtier supplier. However, the purchase order to the subtier supplier does not invoke 10CFR50, Appendix B [7], nor 10CFR21 [4]. The raw material is therefore purchased non-safety-related. Criterion IV is met through the translation of their design into technical procurement requirements for the raw material subsupplier. The acceptance of the raw material may be achieved by implementing one or more of the measures described in Criterion VII (that is, source evaluation and selection, objective evidence of quality, inspection at the subsupplier source, and/or examination of products on delivery).

Throughout the storage, issuance, and manufacturing, the supplier implements the applicable and relevant criteria of their nuclear QA program. Therefore, the manufacturer controls the part under their nuclear QA program, which provides adequate confidence that the item conforms to its design and will perform as designed once installed in the customer's safety-related application. In this scenario, the part becomes a basic component by controlling it under the manufacturer's nuclear QA program, not through the commercial-grade item dedication process.

F.4.1.2 Example of Controlling a Part Under a Nuclear QA Program

BHP3, Inc., is a major provider of ASME Section III valves to the nuclear power industry. Therefore, they continue to maintain a 10CFR50, Appendix B [7], QA program and accept 10CFR21 [4] whenever they provide a basic component to one of their nuclear customers.

One utility is planning to refurbish BHP3 valves during their next refueling outage, including valve stems. For those valves that have been classified safety-related and have an active function, the utility has classified the valve stems as safety-related and anticipates procuring them from BHP3 as basic components.

BHP3 controls the design of valve stems under Criterion III of their nuclear QA program. The raw material is specified and procured from a subtier supplier with a longstanding relationship with BHP3. However, the purchase order to the subtier supplier does not invoke 10CFR50, Appendix B [7] or 10CFR21 [4]. The raw material is therefore purchased non-safety-related. BHP3, however, ensures that their design of the stem is accurately translated into technical procurement requirements for the raw material. The acceptance of the raw material is achieved through reliance on one of the measures described in Criterion VII (that is, examination of products upon delivery). The manufacturer accepts the non-safety raw material by performing tests and inspections (in accordance with documented instructions in 10CFR50, Appendix B [7]) to ensure that it meets the specified design requirements.

Once the raw materials are accepted, the valve stems are manufactured by BHP3 to the non-ASME Code quality assurance manual that meets 10CFR50, Appendix B [7]. Throughout the storage, issuance, and manufacturing, the supplier implements the applicable, relevant criteria of their nuclear QA program that ensure that design requirements were met. Therefore, BHP3 controls the quality of the part under their nuclear QA program, which provides them adequate confidence both that the valve stem conforms to its design and that it will perform as designed once installed in the customer's safety-related application.

In this example, the valve stem becomes a basic component by BHP3 controlling the valve stem under their nuclear QA program, not through the commercial-grade item dedication process.

F.4.2 Controlling an Assembly or Whole Component Under a Nuclear QA Program

F.4.2.1 General Guidance

Figure F-3 illustrates how a supplier (who is the manufacturer) can use their nuclear QA program to control the quality of an assembly or whole component that is subsequently provided as a basic component. In accordance with 10CFR21 [4], the basic component can be provided because it was adequately controlled under a QA program complying with 10CFR50, Appendix B [7].

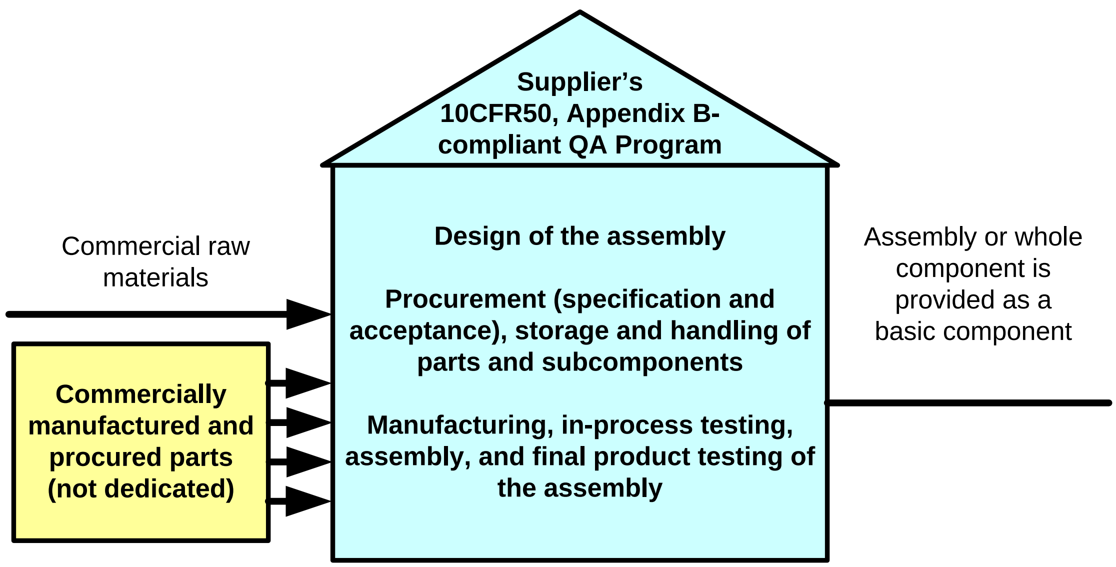


Figure F-3
Controlling an assembly or whole component under a nuclear QA program

In this scenario, the manufacturer controls the design of the assembly or whole component under Criterion III of their nuclear QA program. The supplier procures raw materials from which parts are manufactured and commercially manufactured parts (in other words, subcomponents of the assembly). These subcomponents are specified and procured from various subtier suppliers. However, the purchase orders to these subtier suppliers do not invoke 10CFR50, Appendix B [7], or 10CFR21 [4]. The subcomponents are therefore purchased non-safety-related. The supplier however ensures that their design for each subcomponent is accurately translated into technical procurement requirements. The acceptance of the subcomponents may be achieved by implementing one or more of the measures described in Criterion VII (that is, source evaluation and selection, objective evidence of quality, inspection at the subsupplier source, and examination of products on delivery).

Throughout the storage, issuance, manufacturing, in-process testing, assembly, and final product testing, the supplier implements the applicable and relevant criteria of their nuclear QA program, which occurs subsequent to procuring each individual part or material. Therefore, the manufacturer controls the quality of the assembly or whole component under their nuclear QA program, which provides adequate confidence that the assembly conforms to its design and will perform as designed once installed in the customer's safety-related application.

If the combination of the design controls, assembly, inspection, and final product testing of the assembly or whole component demonstrates the acceptability of the parts, the individual commercial-grade parts may be accepted (without the use of dedication). An example of this could be the assembly of discrete electronic components into a circuit board that is inspected to the circuit board drawing, visually examined for acceptable manufacturing, and then verified to perform correctly using automated testing equipment. Therefore, 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 supplier's overall 10CFR50, Appendix B [7], quality program should provide the controls necessary to achieve adequate confidence that the assembly or whole component meets its specified design requirements.

When a commercial-grade part or material is installed, assembled, and tested as part of the component manufacturing process (and supplied as part of the assembled component), assurance is gained through the manufacturing processes and design controls that the part or material can perform its intended design functions.

In addition, when parts are provided in an assembly or whole component manufactured under a 10CFR50, Appendix B [7] program, several verifications may be performed that ensure that acceptable parts are used during assembly and manufacture of the whole component. These activities can include verification of the following:

- Design characteristics
- Material characteristics
- Performance characteristics

As previously covered, activities performed during the implementation of the equipment supplier's 10CFR50, Appendix B [7], program can provide adequate confidence of the parts and materials used to manufacture the assembly or whole component. The supplier should be able to identify the acceptance basis for parts or subassemblies used. Where credit is being taken for the assembly process or in-process/final performance tests, this should be considered as part of the acceptance basis.

In this scenario, the scope of supply is limited to an assembly or whole component that becomes a basic component through implementation of the equipment manufacturer's nuclear QA program, not through the commercial-grade item dedication process.

F.4.2.5 Example of Controlling an Assembly or Whole Component Under a Nuclear QA Program

JPB Electronics, Inc., maintains a 10CFR50, Appendix B [7], nuclear QA program and manufactures printed circuit boards that are provided as basic components. The boards are an assembly consisting of the base (printed circuit board) and the discrete electronic parts mounted on the board. In this example, JPB Electronics controls the design of the printed circuit board under Criterion III of their nuclear QA program. Subcomponents are specified and procured from various subtier suppliers and local electronic distributors. Technical requirements are specified in JPB's purchase orders for the various types of discrete electronic parts, including resistors, diodes, capacitors, transistors, and silicon-controlled rectifiers. JPB Electronics also procures the insulator sheeting from a commercial-grade subsupplier. However, the purchase orders to the subtier suppliers do not invoke 10CFR50, Appendix B [7], nor 10CFR21 [4]. The subcomponents are therefore purchased as non-safety-related. JPB Electronics ensures that the design for each subcomponent is accurately translated into technical procurement requirements. Acceptance of the subcomponents begins by implementing one of the measures described in Criterion VII (that is, examination of products on delivery by performing a sample visual and identification inspection upon receipt).

Throughout the storage, issuance, manufacturing, in-process testing, assembly, final product testing, and acceptance, JPB Electronics implements applicable and relevant criteria of their nuclear QA program that ensures that design requirements are met. The printed circuit board acceptance activities consist of a visual inspection against the circuit board drawing to ensure that the proper parts have been assembled, a visual inspection to ensure sound connections, a burn-in of the boards to detect infant mortality, and a verification of proper electronic performance of the printed circuit boards using automatic testing equipment controlled under JPB Electronics' 10CFR50, Appendix B [7] program. The successful completion of the burn-in and performance testing provides adequate confidence that the individual electronic parts are acceptable for the safety-related utility application.

Therefore, the manufacturer controls the quality of the printed circuit boards under their nuclear QA program, which provides them adequate confidence that each board conforms to its design and will perform as designed once installed in the customer's safety-related application.

In this example, the combination of the assembly, inspection, and final product testing of the complete assembly demonstrates the acceptability of the parts, thus allowing JPB Electronics to accept the individual commercial parts by this process.

Therefore, using an acceptance methodology for the commercial parts provided in the complete component similar to that used to accept commercial-grade replacement parts is unnecessary. JPB Electronics' overall 10CFR50, Appendix B [7], quality program provided the necessary controls to achieve adequate confidence the assembly (printed circuit board) meets its design requirements and will perform its safety-related function.

In this example, the printed circuit board becomes a basic component by controlling the item under JPB Electronics' nuclear QA program, not through the commercial-grade item dedication process.

F.4.3 Commercially Manufactured Part Dedicated Under a Nuclear QA Program

F.4.3.1 General Guidance

Figure F-4 illustrates how a supplier (who is not the manufacturer) can use their nuclear QA program to provide a part as a basic component that was not manufactured under their nuclear QA program. In accordance with 10CFR21 [4], a basic component can be provided because the commercial-grade item successfully completed the dedication process.

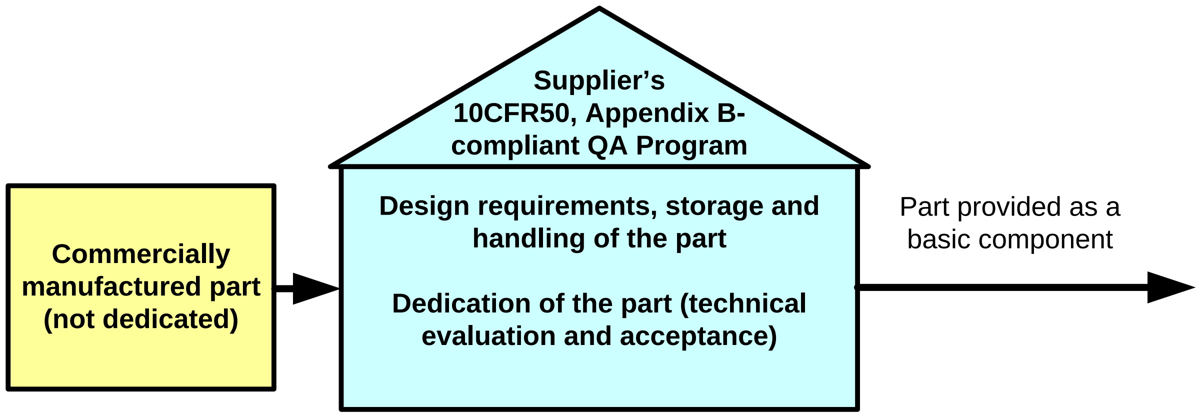


Figure F-4
Dedicating a commercially manufactured part

In this scenario, the supplier is purchasing a commercial-grade part that was manufactured commercially by a subtier manufacturer. This commercial-grade part needs to be dedicated as prescribed in the supplier's 10CFR50, Appendix B [7], program before it can be provided as a basic component to a utility.

The nuclear supplier translates the design of the commercially manufactured part into technical procurement requirements. In this scenario, the acceptance of the part is achieved by implementing one or more of the commercial-grade item acceptance methods (that is, Method 2: Commercial-Grade Survey, Method 4: Item/Supplier Performance Record, Method 3: Source Verification, and/or Method 1: Special Tests and Inspections), which verify critical characteristics.

In these scenarios, the critical characteristics of the part may be as follows:

- Derived by the supplier (if the end-use application is known or is provided by the licensee)
- Provided directly to the supplier by the licensee
- Enveloped by verifying all design characteristics of the part

In all cases, the critical characteristics should be verified using one or more of the commercial-grade item acceptance methods. Therefore, the supplier dedicates the part under their nuclear QA program, which provides them reasonable assurance that the commercially manufactured part conforms to its design and will perform as designed once installed in the customer's safety-related application.

In this scenario, the part becomes a basic component through commercial-grade item dedication.

F.4.3.2 Example of Commercially Manufactured Part Dedicated Under a Nuclear QA Program

RPV is a provider of diaphragm valves to the nuclear power industry. RPV maintains a 10CFR50, Appendix B–compliant [7] QA program and accepts 10CFR21 [4] when they provide basic components to nuclear customers.

A nuclear utility has identified the need to purchase a replacement diaphragm for use in a safety-related valve that was originally manufactured and furnished by RPV. The utility has classified the diaphragm as safety-related and is procuring the replacement part from RPV as a basic component.

RPV does not manufacture diaphragms for their valves. Instead, they purchase diaphragms that are manufactured commercially from one of two subtier manufacturers. This diaphragm needs to be dedicated as prescribed in RPV's commercial-grade dedication procedure, which is controlled under their 10CFR50, Appendix B-complaint [7] QA program.

RPV ensures that the appropriate design attributes of the diaphragm are specified as technical procurement requirements and provides design drawings of the diaphragm when a diaphragm is procured. RPV's dedication for diaphragms requires implementing a combination of commercial-grade item acceptance Method 2: Commercial-Grade Survey and Method 1: Special Tests and Inspections.

Because RPV is the OEM of the diaphragm valves, they are aware of the original design requirements for the diaphragm and derive critical characteristics based on knowledge of the original design. RPV is on the utility's approved supplier list, and the utility approved RPV's commercial-grade item dedication program and procedure during a recent performance-based audit of RPV's 10CFR50, Appendix B–compliant [7] QA program. Therefore, the utility has assurance that the critical characteristics verified by RPV are appropriate and will provide the necessary level of assurance.

During the utility's audit of RPV's commercial-grade item dedication program, objective evidence was reviewed that demonstrates that RPV regularly conducts commercial-grade surveys of their diaphragm manufacturers to ensure that the diaphragm chemical and physical material properties meet their specified requirements. Upon receipt, RPV inspects the critical dimensions of a sample of diaphragms from each batch or lot and has clearly documented the justification for use of sampling.

Therefore, RPV dedicates the diaphragm under their nuclear QA program, which provides them reasonable assurance that the commercially manufactured item conforms to its design and will perform as designed once installed in the customer's safety-related application. In this scenario, the part becomes a basic component through commercial-grade item dedication by RPV.

F.4.4 Commercially Manufactured Assembly Dedicated Under a Nuclear QA Program

F.4.4.1 General Guidance

Figure F-5 illustrates how a supplier (who is not the manufacturer) can use their nuclear QA program to provide an assembly as a basic component that was not manufactured under their nuclear QA program. In accordance with 10CFR21 [4], the basic component can be provided because the commercial-grade item successfully completed the dedication process.

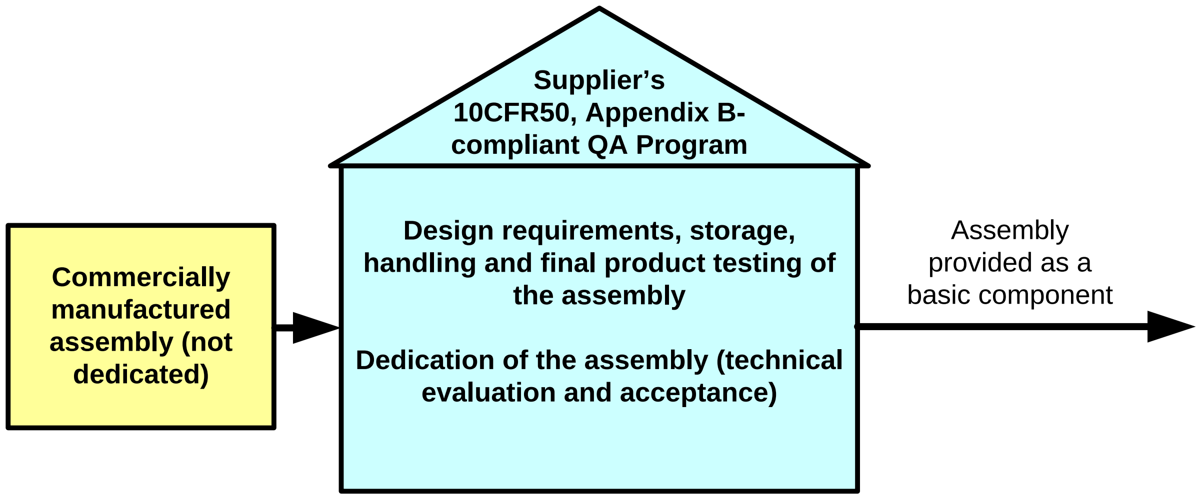


Figure F-5
Dedicating a commercially manufactured assembly or whole component

In this scenario, the supplier is purchasing a commercial-grade assembly that was manufactured commercially by a subtier manufacturer. This commercial-grade assembly needs to be accepted and dedicated as prescribed in the supplier's 10CFR50, Appendix B–compliant [7] QA program before it can be provided as a basic component to a utility.

The nuclear supplier controls the design basis requirements for the assembly for its use in a whole component in accordance with their nuclear QA program. The nuclear supplier also evaluates any changes to the item made by the manufacturer to ensure that the current design remains suitable for use in their equipment. The nuclear supplier translates the design of the commercially manufactured assembly into appropriate technical procurement requirements. In this scenario, the acceptance of the assembly is achieved by implementing one or more of the commercial-grade item acceptance methods.

In this scenario, the critical characteristics of the assembly may be as follows:

- Derived by the supplier (if the end-use application is known or provided by the licensee)
- Provided directly to the supplier by the licensee
- Enveloped by verifying appropriate design, material, and performance characteristics of the assembly based on its application and functions in the host equipment

In all cases, the critical characteristics should be verified using one or more of the acceptance methods. Therefore, the supplier dedicates the assembly under their nuclear QA program, which provides them reasonable assurance that the commercially manufactured assembly conforms to its design and will perform as designed once installed in the customer's safety-related application.

In cases where verification of critical characteristics cannot be demonstrated through inspection and testing of the assembly or whole component, additional acceptance actions may be required to verify acceptability of parts used to manufacture the assembly or whole component. This may require additional testing/inspection of the parts, verification of part acceptability during manufacturing, or performance-based evaluation of the assembly manufacturer's commercial-grade QA program. In this scenario, the assembly becomes a basic component through the commercial-grade item dedication process because the manufacturing of the assembly was not controlled under a nuclear QA program.

F.4.4.2 Example of a Commercially Manufactured Assembly Dedicated under a Nuclear QA Program

TPO, Inc., is a provider of chillers to the nuclear power industry. TPO maintains a 10CFR50, Appendix B [7], quality assurance program and accepts 10CFR21 [4] whenever they provide a basic component to one of their nuclear customers.

A utility needs to replace the expansion valve on a chiller originally furnished and manufactured by the original chiller manufacturer (OEM, Incorporated). The utility has classified the expansion valve as safety-related. OEM, Incorporated, no longer has a nuclear QA program. Therefore, the utility is procuring the replacement expansion valve from TPO as a basic component.

TPO does not manufacture expansion valves for chillers, but it has obtained rights to the original design information for the chillers from OEM, Incorporated. They purchase commercially manufactured expansion valves from the valve manufacturer identified in the original design, X-Valves, Inc. TPO dedicates the replacement expansion valve as prescribed in their commercial-grade dedication procedure, which is controlled under their 10CFR50, Appendix B–compliant [7] QA program.

TPO controls the design basis requirements for the expansion valve for its use in a whole component in accordance with their nuclear QA program. They also evaluate any changes to the expansion valve design made by the manufacturer to ensure that the current design remains suitable for use in their equipment. TPO translates the design of the commercially manufactured expansion valve into appropriate technical procurement requirements. TPO's dedication for expansion valves requires implementing a combination of commercial-grade item acceptance Method 2: Commercial-Grade Survey and Method 1: Special Tests and Inspections.

Because TPO is not the OEM of the chillers, they use original design information obtained from OEM, Incorporated, to identify critical characteristics.

TPO is on the utility's approved supplier list, and the utility has approved TPO's commercial-grade item dedication program and procedure during a performance-based audit of TPO's 10CFR50, Appendix B–compliant [7] QA program. Therefore, the utility has assurance that the critical characteristics verified by TPO are appropriate and will provide the necessary level of assurance.

During the audit of TPO's commercial-grade item dedication program, objective evidence was reviewed that demonstrates that TPO periodically conducts commercial-grade surveys of X-Valves, Inc. TPO verifies during the surveys that X-Valves adequately controls the raw materials used to fabricate their valves. In addition, X-Valves implements appropriate controls during commercial manufacturing and assembly of the expansion valves to ensure that appropriate design and material characteristics meet specified requirements.

TPO inspects critical dimensions against X-Valves' assembly drawing and performs a hydrostatic test on 100% of the expansion valves received. Finally, TPO performs a functional test on one expansion valve from each lot/batch of valves received. The functional test simulates the pressure differential conditions in the utility's chiller.

Therefore, TPO dedicates the commercial-grade expansion valve under their nuclear QA program, which provides reasonable assurance that the commercially manufactured expansion valve conforms to its design and will perform as intended once installed in the licensee's safety-related chiller application.

In this scenario, the expansion valve becomes a basic component through commercial-grade item dedication.

F.4.5 Commercially Manufactured Part Dedicated Under a Nuclear QA Program

F.4.5.1 General Guidance

Figure F-6 illustrates how a supplier (who is the manufacturer) can use the commercial-grade item dedication process to provide a part as a basic component that was manufactured under their own commercial QA program by using their nuclear QA program to dedicate it. In accordance with 10CFR21 [4], the basic component can be provided because the commercially manufactured item successfully completed the dedication process.

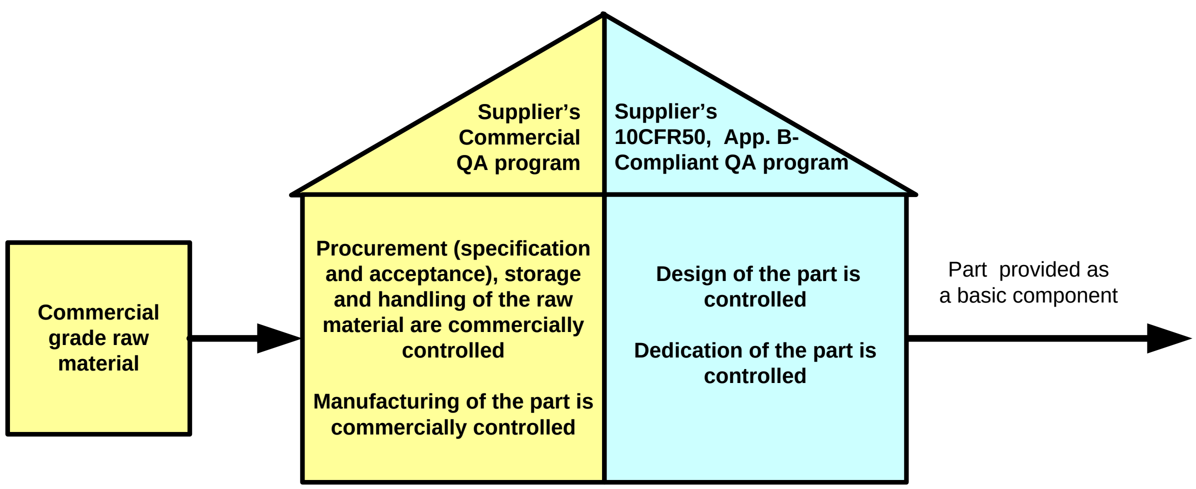


Figure F-6
Dedicating a commercially manufactured part

In this scenario, an OEM controls the design of a part under their nuclear QA program. The raw material is specified and procured from a subtier supplier. Appropriate technical requirements are included in procurement documents for the raw material. However, the purchase orders for the raw material do not invoke 10CFR50, Appendix B [7], nor 10CFR21 [4] because the raw material is purchased as a commercial-grade item.

The commercial raw material is received and used to manufacture a part under the OEM’s commercial quality program. There are several reasons that a supplier may choose to manufacture these items commercially, such as wanting to avoid the cost of implementing nuclear program controls for items that are typically not considered to be safety-related and to fulfill an expedited shipment of an item that can only be met by using commercial-grade parts previously manufactured and currently in stock. In this example, acceptance of the commercially manufactured part is achieved by using commercial-grade item Acceptance Method 1: Special Tests and Inspections to verify critical characteristics.

In these scenarios, the critical characteristics of the part may be as follows:

- Enveloped by verifying all applicable design characteristics of the part
- Derived by the supplier (if the end-use application is known or provided by the licensee)
- Provided directly to the supplier by the licensee

In all cases, the critical characteristics are verified using Acceptance Method 1. Therefore, the OEM dedicates the part under their nuclear QA program, which provides reasonable assurance that the commercially manufactured part conforms to its design and will perform as designed once installed in the customer’s safety-related application.

If a replacement part is manufactured by the OEM and used in both nuclear and commercial product lines, additional testing and inspection may be necessary to verify critical characteristics that were not verified through standard commercial quality controls.

In this scenario, the part becomes a basic component through commercial-grade item dedication.

F.4.5.2 Example Commercially Manufactured Part Dedicated Under a Nuclear QA Program

MK&F, Inc., is a provider of pneumatic actuators to the nuclear power industry. MK&F maintains a 10CFR50, Appendix B–compliant [7] QA program and accepts 10CFR21 [4] whenever they provide a basic component.

A nuclear plant needs to replace elastomeric diaphragms in some safety-related air-operated actuators during their upcoming refueling outage. The plant has classified the diaphragms as safety-related and is procuring replacement diaphragms from MK&F as basic components.

One of the materials MK&F, Inc., uses to manufacture diaphragms for their commercial and nuclear air actuators is a commercial-grade elastomeric sheet reinforced with nylon mesh. The commercial-grade diaphragm material is dedicated as prescribed in MK&F’s 10CFR50, Appendix B–compliant QA program [7] before it can be provided as a basic component to the utility.

The material specified in MK&F’s design documents is procured from a subtier supplier, Elastomeric Products, Inc. (EPI). MK&F translates their design requirements into technical procurement requirements for EPI. The purchase order to EPI does not invoke 10CFR50, Appendix B [7], nor 10CFR21 [4]; therefore, the raw material is purchased as a commercial-grade item. In this scenario, MK&F will dedicate the diaphragm using commercial-grade item dedication Acceptance Method 1: Special Tests and Inspections to verify critical characteristics, such as dimensions, materials, and tensile strength.

Because MK&F is the OEM of the air actuators, they are aware of the design parameters and select critical characteristics that provide reasonable assurance that all applicable design requirements are met. MK&F is on the utility's approved supplier list, and the utility approved MK&F's commercial-grade item dedication program and procedure during a recent performance-based audit of MK&F's 10CFR50, Appendix B–compliant [7] QA program. Therefore, the utility has confidence that the critical characteristics verified by MK&F are appropriate.

MK&F establishes traceability of each received sheet of material received from EPI and cuts a sample coupon from it. The coupons are sent to a test facility approved by MK&F to verify the critical characteristics related to material. If the test results for a sheet are acceptable, MK&F maintains traceability of the sheet material under their 10CFR50, Appendix B–compliant [7] QA program and manufactures the diaphragms in accordance with their standard commercial processes. When manufacturing is complete, MK&F verifies the remaining dimensional critical characteristics to ensure that they are within design tolerances. Once dedication is complete, the diaphragms can be provided to the utility as basic components.

F.5 Third-Party Organizations

A third-party organization is any company other than the OEM that procures and accepts commercial-grade items and supplies them as basic components under their approved 10CFR50, Appendix B–compliant [7] QA program. The third-party organization, being the organization performing the acceptance, must comply with 10CFR21 [4] for the basic components it provides. Therefore, the purchase order to a third-party organization should impose compliance with 10CFR50, Appendix B [7] and 10CFR21 [4] if they are furnishing a basic component.

The services that a third-party organization can provide are varied and typically customized to meet specific needs. The ranges of services that a third-party organization may provide include design control, equipment qualification, procurement, manufacturing, repair/refurbishment, and commercial-grade item dedication. Inherent to these processes, a third-party organization may be required to perform seismic or environmental testing, technical equivalency evaluations of alternative items, and implementation of all four commercial-grade item acceptance methods.

F.5.1 Design Controls

The third-party organization may establish a working or teaming relationship with the OEM (for example, a chiller manufacturer) or the original part manufacturer (for example, a fuse manufacturer). This relationship allows the third-party organization to obtain information regarding design, technical requirements, and critical characteristics. Equipment qualification is addressed by testing and/or analysis. Equipment qualification of the item is a separate issue from commercial-grade item acceptance, as discussed in the text for Step 5.2.23 in this report's Section 5. When the third-party organization is an authorized representative for a manufacturer and has access to the design information, the third-party organization may also ensure that the design of the replacement item being furnished remains suitable for its intended application.

F.5.2 Acceptance Processes When Providing Basic Components

This appendix explains the key differences between bringing an item to market by controlling it under a QA program meeting the requirements of 10CFR50, Appendix B [7], and bringing an item to market using the dedication process.

F.5.2.1 Controlling an Item Under a Nuclear QA Program

There may be cases where the third-party organization can provide a basic component without knowing a specific end use or its critical characteristics and subsequently without being able to dedicate the item. In lieu of dedication, the third-party organization may choose to verify all design requirements specified in industry specifications (ASTM/ASME/ANSI) used to manufacture the item (such as a fastener). Although the third-party organization did not manufacture the item, they can adequately verify that it was manufactured in accordance with its design by verifying all design characteristics using similar or equivalent tests/inspections that could be employed during or after manufacture. So the third-party organization can perform verification activities that replicate the quality controls that would be necessary to achieve adequate confidence that the item will perform its safety-related functions.

F.5.2.2 Dedicating a Commercial-Grade Item Under a Nuclear QA Program

There may be cases when a third-party organization is provided with the technical information needed to dedicate a commercial grade item (such as end-use application, host equipment/system safety functions, and/or critical characteristics). In this case, the third-party organization can dedicate the item by verifying those critical characteristics.

F.5.3 Examples of a Third-Party Organization Providing a Basic Component

A third-party organization is providing fasteners as basic components. They do not design the fastener, nor do they manufacture them. The design of the fastener is established by ASTM, which designates certain physical and chemical material requirements, dimensional requirements, and tests and inspections to verify material properties. A subsupplier to the third-party organization commercially manufactures the fasteners.

The third-party organization specifies the ASTM standard when procuring it from the subsupplier, but because the fasteners are procured as commercial-grade items (that is, non-safety-related), 10CFR50, Appendix B [7], and 10CFR21 [4] are not specified.

F.5.3.1 Controlling an Item under a Nuclear QA Program

The third-party organization controls the fastener under their 10CFR50, Appendix B [7], program by verifying all of the design requirements of the item specified in the ASTM specification. This is done by nondestructive and destructive testing and inspections on an appropriate sample from the batch furnished from the fastener manufacturer. Upon successful completion of the tests and inspections, the third-party organization certifies that the fasteners conform to the ASTM specification and meet all design requirements. They are furnished as basic components to be installed in safety-related applications. In this scenario, the third-party organization uses its nuclear QA program (without dedication) to control the fasteners, provide adequate confidence that they are acceptable, and establish that they meet all of the design requirements in the ASTM specification.

F.5.3.2 Dedicating a Commercial-Grade Item Under a Nuclear QA Program

The third-party organization dedicates the fastener by verifying critical characteristics. The number and type of critical characteristics may vary depending on the safety-related application. Therefore, the third-party organization can either obtain information about the end use (that is, the end-use application, safety function, critical characteristics, and so on) or conservatively verify all of the design characteristics of the fastener so as to be certain that a given customer's critical characteristics are enveloped. The critical characteristics are verified using Acceptance Method 1: Special Tests and Inspections on an appropriate sample of fasteners from each batch furnished from the fastener manufacturer. The dedicated fasteners are furnished as basic components to be installed in those safety-related applications bounded by the dedication. In this scenario, the third-party organization dedicates the fasteners and provides reasonable assurance that they will perform their intended safety function(s).

F.6 Precautions

The means by which a nuclear supplier provides a basic component should be understood by the customer. Typically, the performance-based supplier audit of the organization's 10CFR50, Appendix B, QA program reveals how the nuclear supplier opts to bring the basic component to market. To summarize, the nuclear supplier can do one of two things. The first is to control the SSC or part thereof under a QA program complying with 10CFR50, Appendix B [7], to ensure that its design, material, and performance characteristics meet those necessary to perform its safety functions. The second option is to successfully complete the dedication process for a commercial-grade item. The option used by the supplier should ultimately provide adequate confidence that the basic component will perform its safety functions once installed.

Care should be taken not to cause a nuclear supplier to unnecessarily dedicate an item when they are already controlling the item under their nuclear QA program and achieving an appropriate level of quality by implementing the applicable criteria of 10CFR50, Appendix B [7]. Conversely, care should be taken not to cause a nuclear supplier to implement unnecessary criteria of their nuclear QA program when they are already successfully completing the dedication process and achieving an appropriate level of quality by doing so.

G
EXAMPLES OF COMMERCIAL-GRADE DEDICATION

G.1 Use of Examples Included in This Section

The examples in this section are provided only to illustrate how the guidance in this report can be used. The dedication evaluations and activities included in the examples may not be appropriate for all applications of the commercial-grade item described because applications exist for which different critical characteristics should be verified.

Dedicating entities shall ensure that each dedication’s technical evaluation is completed based on the specific end use or bounded conditions applicable to the items being dedicated.

G.2 Grout

The parameters of the grout example are as follows:

- Item/service: grout, non-shrink, nonmetallic.
- Safety function: The grout must maintain structural integrity and is used in a variety of applications permitted by the dedicating entity’s design specifications.
- Supplier information: The grout is being purchased from a local construction materials company that supplies commercial items to the dedicating entity. The grout is manufactured by PRVs Corporation, known for high-quality commercial cement products. PRV sells several different grades of grout, including a non-shrink grout that meets the specified design requirements.
- Approach: The dedicating entity typically purchases the grout in relatively small quantities on an infrequent basis. The grout will be dedicated using special tests and inspections (Method 1). The preparer completed Section B to identify the end-use information the dedication is based on applications and safety functions for the grout included in the plant engineering design specification upon which use of the grout is based.

Figure G-1 is an example of a completed commercial-grade item dedication technical evaluation for grout.

Commercial Grade Item Dedication Technical Evaluation

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Form CGI1, Rev. 0

Evaluation Number Grout Example **Revision** 0

SECTION A ITEM DESCRIPTION

INVENTORY CONTROL NO:	PRVs-001
NOUN IDENTIFIER:	Grout, Non-shrink, Non-metallic
MANUFACTURER NAME:	**MANUFACTURER MODEL / PART / CATALOG NUMBER(S)**
PRVs, Incorporated	G-FES

SECTION B END USE / PARENT / HOST EQUIPMENT INFORMATION

Note: If the specific end-use(s) / plant applications are not known, complete Section C of this form in lieu of Section B prior to proceeding.

☐ Not Applicable (Section C Completed Below)

EQUIPMENT ID (TAG) NUMBERS OR DESCRIPTION OF ITEM USAGE:

No specific tag numbers associated with use / application of grout. The grout is a generic material that is used in various applications. The material is a non-metallic, non-shrink, cement grout intended for interior and exterior use in confined (e.g. under support plates) and unconfined areas (e.g. structure surface repairs). Use of the subject grout is limited to applications where specifically approved by design documents (specifications, procedures, and Plant Change Requests)

PARENT COMPONENT/HOST DESCRIPTION:

Grout is a generic material used in various applications involving systems, components, and structures

FUNCTIONAL SAFETY CLASS OF COMPONENT / HOST:	**BASIS / SOURCE:**
☒ Safety-Related ☐ Non-Safety Related (If non-safety, item is not a candidate for dedication)	Engineering Data Base Quality Class for application referenced by various work orders. Grout is a generic material that may be used in many applications including "worst-case" Quality Class "Safety Related" components or structures.

IDENTIFICATION OF PARENT COMPONENT/HOST EQUIPMENT FUNCTION(S)

FUNCTIONAL MODE	**BASIC SAFETY FUNCTION(S)**	**DESCRIBE (AS REQUIRED)**
☒ Active ☒ Passive	Maintain Structural Integrity	Grout is a generic material used in various structural support applications for systems, components and structures that perform Passive and Active safety related functions.

PARENT COMPONENT/HOST EQUIPMENT IS (CHECK ALL THAT APPLY):

☒ EQ	☒ ASME SECTION III
☒ CLASS 1E	☒ CONTAINMENT PRESSURE BOUNDARY
☒ SEISMIC CLASS 1	☐ SERVICE LEVEL 1 COATING
☐ OTHER: (see below)	

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Figure G-1
Example of a completed commercial-grade item dedication technical evaluation for grout

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SECTION C BOUNDED SCOPE OF USE

Only complete Section C when specific end-use of the item being dedicated is unknown.

☒ Not Applicable (Section B Completed Above)

Is the item being dedicated a commodity or standard item designed and constructed in accordance with an industry standard?	☐ Yes ☐ No
IF "YES", LIST THE STANDARD(S) BELOW	
LIST FUNCTIONS AND/OR APPLICATIONS CONSIDERED WHEN COMPLETING THIS EVALUATION	
EQUIPMENT QUALIFICATION CONSIDERATIONS / LIMITATIONS (CHECK ALL THAT APPLY):	
CONSIDERATION ☐ ENVIRONMENTAL QUALIFICATION ☐ SEISMIC QUALIFICATION ☐ OTHER: (see below)	**QUALIFICATION BASIS / LIMITATIONS OF USE:**

SECTION D ITEM INFORMATION

ITEM DESCRIPTION:		
Non-metallic, non-shrink, cement grout		
FUNCTIONAL SAFETY CLASS OF ITEM:		**BASIS / SOURCE:**
☒ Safety-Related ☐ Non-Safety Related (If non-safety, item is not a candidate for dedication)		Design Specification NP-1-C-001, DVD-02
IDENTIFICATION OF ITEM FUNCTION(S)		
FUNCTIONAL MODE	**BASIC SAFETY FUNCTION(S)**	**DESCRIBE (AS REQUIRED)**
☐ Active ☒ Passive	Provide Support	The subject item is used for repairing concrete surfaces and grouting equipment base plates, columns, anchors, etc. Upon hardening (cure), the grout functions as an extension of a structure or equipment support.
☐ Active ☒ Passive	Maintain Structural Integrity	
ITEM IS (CHECK ALL THAT APPLY):		
☐ EQ ☐ CLASS 1E ☒ SEISMIC CLASS 1 ☐ OTHER: (see below)	☐ ASME SECTION III ☐ CONTAINMENT PRESSURE BOUNDARY ☐ SERVICE LEVEL 1 COATING	

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Figure G-1 (Continued)
Example of a completed commercial-grade item dedication technical evaluation for grout

Commercial Grade Item Dedication Technical Evaluation | **EPRI Joint Utility Task Group** Form CGI1, Rev. 0

Evaluation Number Grout Example **Revision** 0

SECTION E ELIGIBLITY FOR DEDICATION

Is the item eligible for dedication in accordance with 10CFR, Part 21? **If the answer is no, this item cannot be dedicated.**	☒ Yes ☐ No

SECTION F FAILURE MODES / MECHANISMS AND EFFECTS ANALYSIS

CREDIBLE FAILURE MODE/MECHANISM	EFFECTS ON SYSTEM/COMPONENT FUNCTION
Fracture	Excessive compressive loads may cause fracture and loss of structural integrity affecting building surfaces, component supports, anchor integrity, etc.
Deformation	Excessive expansion or shrinkage of the cured grout may cause fracture and loss of structural integrity affecting component supports, anchor integrity, etc.
BASIS FOR SELECTION OF CREDIBLE FAILURE MODE(S)/MECHANISM(S)	
Grout supports compressive loads only and due to the brittle nature fails by fracture. Excessive expansion or shrinkage of the cured grout could cause deformation of component supports and base plates.	

SECTION G OPERATING EXPERIENCE / HISTORICAL PERFORMANCE INFORMATION

SOURCES REVIEWED AND RESULTS
Industry Operating Experience Report FTSDPC dated 1/1/95 - After placement of grout under a structural support plate at Zulu Unit 1, the support plate cracked due to excessive expansion force on the plate. Volume change (shrinkage) is cited as a contributor to cracking of the support plate.

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Figure G-1 (Continued)
Example of a completed commercial-grade item dedication technical evaluation for grout

Commercial Grade Item Dedication
Technical Evaluation

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SECTION H IDENTIFICATION ATTRIBUTES

IDENTIFICATION ATTRIBUTES	DESCRIPTION OF INSPECTION	ACCEPTANCE CRITERIA
Manufacturer	Visual	PRVs Inc.
Identification Number	Visual	G-FES
Lot / Batch Identification	Visual	Each bag is identified with a lot or batch number

SECTION I CRITICAL CHARACTERISTICS

CRITICAL CHARACTERISTICS	ACCEPTANCE METHOD	DESCRIPTION OF ACCEPTANCE ACTIVITY	SAMPLING PLAN	ACCEPTANCE CRITERIA (INCLUDING TOLERANCES)
Compressive Strength	Method 1	Test. May be performed by approved outside Vendor on the qualified supplier list. Test Parameters: Mix as directed for Plastic Consistency as shown on product label instructions. [4 quarts per 50 lb bag)]	See below	Following the methodology of ASTM C 1107, verify that the compressive strength of the subject item is ≥ 9500 psi after 7 days
Volume Change	Method 1	Test. May be performed by approved outside QSL vendor. Test Parameters: Mix as directed for Plastic Consistency as shown on product label instructions. [4 quarts per 50 lb bag)]	See below	Following the methodology of ASTM C 1107, verify that the observed shrinkage / expansion of set is between -0.00% and +0.2% after 7 days.
DESCRIPTION OF SAMPLING PLAN (if "see below" is selected in the sampling plan column above)				
Sampling size for "Compressive Strength Test" and "Volume Change Test" shall be one (1) bag per each vendor lot.				

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Figure G-1 (Continued)
Example of a completed commercial-grade item dedication technical evaluation for grout

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SAFETY FUNCTION(S) SUPPORTED / BASIS FOR SELECTION OF CRITICAL CHARACTERISTICS / ACCEPTANCE CRITERIA INCLUDING MAINTAINING SEISMIC AND ENVIRONMENTAL QUALIFICATION
Compressive strength is the single most important characteristic of grout. The achievement of full bearing and complete load transfer is directly related to the compressive strength and shrinkage characteristics of the grout. The specific subject grout achieves an early high compressive value which is well above the original 5000 psi concrete. In addition to the early high compression capability, the grout exhibits minimal expansion with no shrinkage which is required particularly for use beneath equipment base plates. The required design minimum compressive strength at 28 days is 5000 psi. Using 7 day results versus 28 day results provides sufficient conservatism for acceptance. End use installations may use fluid consistency even though the grout was tested at plastic consistency. Per manufacturer's data sheet, the subject grout with fluid consistency has a 7 day value of 7500 psi. This is 79% of the 7 day plastic value. 79% of the plastic acceptance value must be greater than 5000 psi. ASTM C 109 Table 2 has a multi-lab acceptable range of results of 18.1%. By calculation: [9500 psi – 18.1 % (9500 psi) = 9500 psi – 1720 psi = 7780 psi], where 9500 psi is the 7 day plastic value. Verification: 79% of 7780 psi = 6146 psi and is greater than the minimum required 5000 psi. The '7-day' test results, as compared to the '28-day' results, are considered sufficient. The grout has design requirement to attain 5000 psi compressive strength after 28 days. Per manufacturer's data sheet, the grout attains 86.36% (9500 psi) of its '28-day' compressive strength (11,000 psi) after 7 days Applying a range of -0.00% to +0.2% after 7 days for the Volume Change is based on past recommendation by the manufacturer and past testing. Additionally, 0.2% is considerably below the ASTM C 1107 limit of 0.3% for such a product and will provide reasonable assurance that the material will perform as intended. Attachment 1 of NP1-C-001 identifies grout as seismically insensitive, which is defined as an "item (or class of items) with no specific seismic attributes whose performance is unaffected by earthquake loads."

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Figure G-1 (Continued)
Example of a completed commercial-grade item dedication technical evaluation for grout

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BASIS FOR SELECTION OF SAMPLING PLANS (IF SAMPLING PLANS ARE USED)
Each bag shall be visually inspected for manufacturer name, part number, and lot/batch number. Destructive Tests - Sample size for 'Compressive Test' and 'Volume Change' of one (1) bag per each vendor lot is acceptable as similar items from the same vendor (PRVs, Inc.) have been successfully procured and dedicated in the past by the Dedicating Entity, is manufactured to industry standards (ASTM C 1107), and is simple in form.

SECTION J REFERENCES

DOCUMENT / SOURCE	REVISION / DATE	COMMENTS
NP1-C-001	Rev. 55, 3/19/14	
DBD-02	Rev. 4, 3/29/76	
ASTM C 1107-08, Standard Specification for Packaged Dry, Hydraulic-Cement Grout (Nonshrink)	2008	
ASTM C 1090-01 (Reapproved 2005), Standard Test Method for Measuring Changes in Height of Cylindrical Specimens from Hydraulic-Cement Grout	2001 (re-approved 2005)	
ASTM C 109-08, Standard Test Method for Compressive Strength of Hydraulic Cement Mortars	2008	

SECTION K REVIEW AND APPROVAL

Prepared by: Mr. Preparer Date: 03/17/2014

Reviewed by: Mr. Reviewer Date: 03/18/2014

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Figure G-1 (Continued)
Example of a completed commercial-grade item dedication technical evaluation for grout

G.3 Instrument Valve

The parameters of the instrument valve example are as follows:

- Item/service: valve, instrument, 1-in. (25.4-mm) NPS.
- Safety function: The valve must retain pressure, remain in its configuration (open or closed), and maintain structural integrity during and after design basis events.
- Supplier information: The supplier is an authorized regional representative for FTS Instrument Valves, a manufacturer of rugged, reliable, high-quality commercial instrument valves machined from stainless steel.
- Approach: The instrument valve is a component-level replacement item. The valve is being dedicated as a replacement in ASME Section III, Class 2 and 3 piping systems. This special application of the valve is permissible in accordance with IWA 4121.1 of ASME Section XI and the dedicating entity's ASME Section XI repair and replacement program. The dedicating entity is a licensee who operates commercial nuclear units. The valve will be dedicated using special tests and inspections (Method 1). The preparer completed Section B to identify the end-use applications because the dedication is based on the safety functions of the specific equipment whose tag numbers are identified in the evaluation.

Figure G-2 is an example of a completed commercial-grade item dedication technical evaluation for an instrument valve.

Commercial Grade Item Dedication Technical Evaluation | **EPRI Joint Utility Task Group**
Form CGI1, Rev. 0

Evaluation Number CGID 0002 **Revision** 0

SECTION A ITEM DESCRIPTION

INVENTORY CONTROL NO:	Cat ID 22222
NOUN IDENTIFIER:	Valve, Needle, 0.5 IN, Socket Weld, 316 Stainless Steel
MANUFACTURER NAME:	**MANUFACTURER MODEL / PART / CATALOG NUMBER(S)**
FTS Instrument Valves	NV-12-SS

SECTION B END USE / PARENT / HOST EQUIPMENT INFORMATION

Note: If the specific end-use(s) / plant applications are not known, complete Section C of this form in lieu of Section B prior to proceeding.

☐ Not Applicable (Section C Completed Below)

EQUIPMENT ID (TAG) NUMBERS OR DESCRIPTION OF ITEM USAGE:

Foxtrot plant tag numbers 1&2 CVSS-V100 through V120; 1&2 RHR-V100 through V120, 1&2 CS V20 through V28. Instrument valves are used in small fluid lines to provide isolation, flow-rate control, or flow direction control. The valves are manually adjusted to open and close. Valves included in this evaluation are manually operated, 2-way instrument valves intended for use as replacements in ASME Section III, Class 2 & 3 piping systems in accordance with IWA 4121.1 of ASME Section XI.

PARENT COMPONENT/HOST DESCRIPTION:

Manual, 2-way instrument valve

FUNCTIONAL SAFETY CLASS OF COMPONENT / HOST:	**BASIS / SOURCE:**
☒ Safety-Related ☐ Non-Safety Related (If non-safety, item is not a candidate for dedication)	Most restrictive use in Foxtrot plant's Engineering-approved equipment database

IDENTIFICATION OF PARENT COMPONENT/HOST EQUIPMENT FUNCTION(S)

FUNCTIONAL MODE	**BASIC SAFETY FUNCTION(S)**	**DESCRIBE (AS REQUIRED)**
☐ Active ☒ Passive	Maintain Pressure Integrity	
☐ Active ☒ Passive	Remain Closed	
☐ Active ☒ Passive	Remain Open	
☐ Active ☒ Passive	Maintain Structural Integrity	

PARENT COMPONENT/HOST EQUIPMENT IS (CHECK ALL THAT APPLY):

☐ EQ	☒ ASME SECTION III
☐ CLASS 1E	☐ CONTAINMENT PRESSURE BOUNDARY
☒ SEISMIC CLASS 1	☐ SERVICE LEVEL 1 COATING
☐ OTHER: (see below)	

Use of a dedicated valve in an ASME Section III application is allowable in accordance with ASME Section XI, IWA-4131.1 in conjunction with Foxtrot's plants licensing basis and repair and replacement program. Foxtrot Unit 1 is governed by ASME Section XI 2001 Edition, 2003 Addenda and Unit 2 by ASME Section XI 2007 Edition, 2008 Addenda. (Note that dedication of a valve for use in an ASME Section III application by a non-licensee is not allowed)

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Figure G-2
Example of a completed commercial-grade item dedication technical evaluation for an instrument valve

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SECTION C BOUNDED SCOPE OF USE

Only complete Section C when specific end-use of the item being dedicated unknown.

☒ Not Applicable (Section B Completed Above)

Is the item being dedicated a commodity or standard item designed and constructed in accordance with an industry standard?	☐ Yes ☐ No
IF "YES", LIST THE STANDARD(S) BELOW	
LIST FUNCTIONS AND/OR APPLICATIONS CONSIDERED WHEN COMPLETING THIS EVALUATION	
EQUIPMENT QUALIFICATION CONSIDERATIONS / LIMITATIONS (CHECK ALL THAT APPLY):	
CONSIDERATION ☐ ENVIRONMENTAL QUALIFICATION ☐ SEISMIC QUALIFICATION ☐ OTHER: (see below)	**QUALIFICATION BASIS / LIMITATIONS OF USE:**

SECTION D ITEM INFORMATION

ITEM DESCRIPTION:	
Valve, Needle, 0.5 IN, Socket Weld, 316 Stainless Steel	
FUNCTIONAL SAFETY CLASS OF ITEM:	**BASIS / SOURCE:**
☒ Safety-Related ☐ Non-Safety Related (If non-safety, item is not a candidate for dedication)	Foxtrot plant's Engineering-approved equipment database, Equipment Specification M-001 Rev. 4

IDENTIFICATION OF ITEM FUNCTION(S)

FUNCTIONAL MODE	BASIC SAFETY FUNCTION(S)	DESCRIBE (AS REQUIRED)
☐ Active ☒ Passive	Maintain Structural Integrity	
☐ Active ☒ Passive	Maintain Pressure Integrity	
☐ Active ☒ Passive	Remain Open	
☐ Active ☒ Passive	Remain Closed	

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Figure G-2 (Continued)
Example of a completed commercial-grade item dedication technical evaluation for an instrument valve

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ITEM IS (CHECK ALL THAT APPLY):	
☐ EQ	☒ ASME SECTION III
☐ CLASS 1E	☐ CONTAINMENT PRESSURE BOUNDARY
☒ SEISMIC CLASS 1	☐ SERVICE LEVEL 1 COATING
☐ OTHER: (see below)	

SECTION E ELIGIBLITY FOR DEDICATION

Is the item eligible for dedication in accordance with 10CFR, Part 21? **If the answer is no, this item cannot be dedicated.**	☒ Yes ☐ No

SECTION F FAILURE MODES / MECHANISMS AND EFFECTS ANALYSIS

CREDIBLE FAILURE MODE/MECHANISM	EFFECTS ON SYSTEM/COMPONENT FUNCTION
Fracture	Fracture of valve pressure boundary parts will lead to loss of the system pressure boundary and structural integrity. Loss of the pressure boundary can lead to failure of the associated component to perform its safety function
Corrosion	Corrosion of valve pressure boundary parts will lead to fracture or rupture and loss of the system pressure boundary and structural integrity. The primary pressure retaining components of the this particular valve are 316 stainless steel, which is known to not promote corrosion
Wear	Wear of the valve internals can lead to excessive leakage of the valve and result in the valve no longer being capable of isolating flow and controlling flow rate
Binding	Corrosion or ill-fitting parts can cause binding and result in the inability to open and close the valve. This can result in fracture as mentioned above

BASIS FOR SELECTION OF CREDIBLE FAILURE MODE(S)/MECHANISM(S)
Failure modes of the valves would be stripping of the end connections, splitting of the pressure boundary material, and excessive leakage. Fracturing can result from excess stress due to binding or improper material. Corrosion will be caused by incompatible mating material or localized environmental conditions causing galvanic corrosion resulting in material destruction.

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Figure G-2 (Continued)
Example of a completed commercial-grade item dedication technical evaluation for an instrument valve

Commercial Grade Item Dedication Technical Evaluation			EPRI Joint Utility Task Group Form CGI1, Rev. 0
Evaluation Number	CGID 0002	Revision	0

SECTION G OPERATING EXPERIENCE / HISTORICAL PERFORMANCE INFORMATION

SOURCES REVIEWED AND RESULTS
External – A search of the INPO database was performed for failure attributed to Instrument Valve Inc. valves. The following OE was located: OE 98765: Failure of RHR/LPSI System (PWR) Globe Valve Event Summary: While the unit was at power plant personnel discovered that the solenoid operated leak detection drain valve, between the two(2)check valves on the outlet line from the 'D' safety injection tank to the reactor vessel was leaking past its closed seat. This leak did not significantly degrade the safety injection train. The unit operations were not affected. Cause Summary: The leak apparently resulted from normal wear of the valve internals, dirt on seating surfaces, and engineering/design. However, no one of these things could be identified as the root cause of the leakage. Thus, the root cause is unknown. Corrective Action Summary: The valve was disassembled, inspected, and cleaned. Internal parts were replaced and lapped to insure full contact and a leak free seal in the closed position. Internal – A search of work order history of cat ID 22222 showed several valve replacements in non-safety applications due to valve leakage past the seat. No work order history of leakage in the safety related applications was located. For the safety related valves, one work order was discovered to fix a valve that was binding and unable to operated. This valve was replaced with no safety repercussions.

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Figure G-2 (Continued)
Example of a completed commercial-grade item dedication technical evaluation for an instrument valve

Commercial Grade Item Dedication
Technical Evaluation

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SECTION H IDENTIFICATION ATTRIBUTES

IDENTIFICATION ATTRIBUTES	DESCRIPTION OF INSPECTION	ACCEPTANCE CRITERIA
Manufacturer	Visual	FTS Instrument Valves
Identification Number	Visual	NV-12-SS

SECTION I CRITICAL CHARACTERISTICS

CRITICAL CHARACTERISTICS	ACCEPTANCE METHOD	DESCRIPTION OF ACCEPTANCE ACTIVITY	SAMPLING PLAN	ACCEPTANCE CRITERIA (INCLUDING TOLERANCES)
Configuration	Method 1	Visual	100%	Consistent with attached drawing XYZ, Revision 5
Materials: Body (item #10) Bonnet (item #9 Stem (item #12) Packing Nut (item #7) See attached drawing for component part identification	Method 1	Alloy analyzer or similar	Reduced	316SS

Figure G-2 (Continued)
Example of a completed commercial-grade item dedication technical evaluation for an instrument valve

Commercial Grade Item Dedication
Technical Evaluation

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CRITICAL CHARACTERISTICS	ACCEPTANCE METHOD	DESCRIPTION OF ACCEPTANCE ACTIVITY	SAMPLING PLAN	ACCEPTANCE CRITERIA (INCLUDING TOLERANCES)
Dimensions:	Method 1		100%	Tolerances per dimensional measurement instruction 5129, Revision 1, unless otherwise noted.
1. End connection		1. Visual and Direct Measure		1. 0.855 +/- 0.050" (0.5 inch NPS) socket weld both inlet and outlet. See Note 1.
2. Max Height (inlet centerline to top of hand wheel with valve fully open)		2. Direct Measure		2. 3.59375 (3-19/32) inches
3. Bottom of valve to inlet centerline		3. Direct Measure		3. 0.625(5/8) inches
4. Hand wheel Diameter		4. Direct Measure		4. 2.375 (2-3/8) inches
5. Valve Length		5. Direct Measure		5. 2.5 (2-1/2) inches
(See Attached drawing for dimensions and location				Note 1: Dimensions of valve socket welded end ports is per ASME B16.11-2009.

Figure G-2 (Continued)
Example of a completed commercial-grade item dedication technical evaluation for an instrument valve

Commercial Grade Item Dedication
Technical Evaluation

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CRITICAL CHARACTERISTICS	ACCEPTANCE METHOD	DESCRIPTION OF ACCEPTANCE ACTIVITY	SAMPLING PLAN	ACCEPTANCE CRITERIA (INCLUDING TOLERANCES)
Pressure Integrity	Method 1	Shell Test Using water or gas, pressure test valve in the partially open position to at least 9000 psig for at least 10 minutes	100%	Visually detectable leakage through the pressure boundary walls (body, bonnet, body/bonnet bolting) is not acceptable
Disc Integrity	Method 1	Seat Leak Test Using water, pressure test the valve in the closed position to at least 6600 psig for 1 minute OR Pressure test the valve with nitrogen to a minimum of 80 psi for at least 1 minute	100%	Maximum allowable leakage is 5 ml/hr of liquid or 1.5 liter/hr of gas.

DESCRIPTION OF SAMPLING PLAN (if "see below" is selected in the sampling plan column above)

SAFETY FUNCTION(S) SUPPORTED / BASIS FOR SELECTION OF CRITICAL CHARACTERISTICS / ACCEPTANCE CRITERIA INCLUDING MAINTAINING SEISMIC AND ENVIRONMENTAL QUALIFICATION

Verification of the Manufacturer Name and Part Number provides reasonable assurance that the item received is the item ordered. The manufacturer part number corresponds to the configuration, materials, and dimensions of the received part.

Verification of dimensions and configuration provide reasonable assurance that the valve will fit into its designated location within the system.

Verification of metallic materials by alloy analyzer provides reasonable assurance that the valves are manufactured of materials that are compatible with system fluids and the environment.

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Figure G-2 (Continued)
Example of a completed commercial-grade item dedication technical evaluation for an instrument valve

Commercial Grade Item Dedication
Technical Evaluation

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CRITICAL CHARACTERISTICS	ACCEPTANCE METHOD	DESCRIPTION OF ACCEPTANCE ACTIVITY	SAMPLING PLAN	ACCEPTANCE CRITERIA (INCLUDING TOLERANCES)

Verification of the pressure test provides reasonable assurance that the valve ordered has adequate strength to perform its safety related function of providing a pressure boundary within the system it is used. Pressure testing requirements are based on the requirements of MSS SP-61 and ASME B16.34. A duration of 10 minutes for the shell test and 1 minute for the seat test was selected to allow for valve installation into ASME Section III applications.

Verification of the specified Critical Characteristics (CCs) provides reasonable assurance that the instrument valves "dedicated" are "like-for-like" to the original; thus, no new seismic considerations have been introduced in accordance with Foxtrot Plant Procedure ABC, Revision 2, Instructions for Application of the EPRI CCASSI document, Latest Revision.

BASIS FOR SELECTION OF SAMPLING PLANS (IF SAMPLING PLANS ARE USED)

Verification of valve materials requires disassembly of the valve; therefore, reduced sampling in accordance with procedure PE-Sampling Plans Rev. 12, Attachment 2 is acceptable for instrument valves as other similar items from Instrument Valves Inc. have been successfully procured

SECTION J REFERENCES

DOCUMENT / SOURCE	REVISION / DATE	COMMENTS
Equipment Specification M-001	R-6 5/5/96	
ASME Section XI	Foxtrot Unit 1 - 2001 edition, 2003 addenda. Foxtrot Unit 2 - 2007 edition, 2008 addenda.	
MSS SP-61, Pressure Testing of Valves	1961 Edition, 1964 Edition, and 1977 Edition	
ASME B16.34, Valve Standard	2009 Edition	
ASME B16.11, Forged Fittings, Socket Welding and Threaded	2009 Edition	
ASME Section III	1971 Edition through Winter 1976 addenda	
PE Sampling Plan	R-12, 1/1/14	
Dimensional Measurement Instruction 5129	R-1, 2/2/96	
Seismic Criteria Instruction 5278	R-6, 2/2/96	

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Figure G-2 (Continued)
Example of a completed commercial-grade item dedication technical evaluation for an instrument valve

Commercial Grade Item Dedication Technical Evaluation	**EPRI Joint Utility Task Group Revision 0**

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SECTION K REVIEW AND APPROVAL

Prepared by:	Mr. Preparer	Date:	04/15/14
Reviewed by:	Ms. Reviewer	Date:	04/15/14

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Figure G-2 (Continued)
Example of a completed commercial-grade item dedication technical evaluation for an instrument valve

G.4 Pressure Switch

The parameters of the pressure switch example are as follows:

- Item/service: switch, differential pressure.
- Safety function: The switch provides a control function and must change state (open/close) to provide an electrical actuation signal. The switch must also maintain circuit integrity, and the wetted (connected to plant process system) portions of the switch must maintain pressure integrity.
- Supplier information: The switch is purchased directly from the manufacturer. The manufacturer produces high-quality pressure-sensing devices for use in commercial and industrial applications.
- Approach: The switch will be procured commercially and dedicated using special tests and inspections (Method 1). The preparer completed Section B to identify the end-use applications because the dedication is based on the safety functions of the specific equipment whose tag numbers are identified in the evaluation.

Figure G-3 is an example of a completed commercial-grade item dedication technical evaluation for a pressure switch.

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SECTION A ITEM DESCRIPTION

INVENTORY CONTROL NO:	33333
NOUN IDENTIFIER:	Switch, Differential Pressure

MANUFACTURER NAME:	MANUFACTURER MODEL / PART / CATALOG NUMBER(S)
WGW Controls	KW-456-7891-SCS

SECTION B END USE / PARENT / HOST EQUIPMENT INFORMATION

Note: If the specific end-use(s) / plant applications are not known, complete Section C of this form in lieu of Section B prior to proceeding.

☐ Not Applicable (Section C Completed Below)

EQUIPMENT ID (TAG) NUMBERS OR DESCRIPTION OF ITEM USAGE:
Q1/2P16PDS565, Q1/2P16PDS566, Q1/2P16PDS568, Q1/2P16PDS569; Service Water Flow Switch
PARENT COMPONENT/HOST DESCRIPTION:
Turbine Building Service Water Supply Isolation Valves (Motor Operated Valve)

FUNCTIONAL SAFETY CLASS OF COMPONENT / HOST:	BASIS / SOURCE:
☒ Safety-Related ☐ Non-Safety Related (If non-safety, item is not a candidate for dedication)	Service Water System Functional System Description, Document # A-1234567; FSAR Section 9.2

IDENTIFICATION OF PARENT COMPONENT/HOST EQUIPMENT FUNCTION(S)

FUNCTIONAL MODE	BASIC SAFETY FUNCTION(S)	DESCRIBE (AS REQUIRED)
☒ Active ☐ Passive	Close/Isolate on Demand	The motor operated turbine building service water supply isolation valves automatically close on high fluid flow based on the differential pressure across the monitored flow element in the fluid stream to isolate the nonessential service water loads in the event of excessive flow to ensure adequate cooling water flow to safety related equipment.
☐ Active ☐ Passive		

PARENT COMPONENT/HOST EQUIPMENT IS (CHECK ALL THAT APPLY):

☐ EQ	☐ ASME SECTION III
☒ CLASS 1E	☐ CONTAINMENT PRESSURE BOUNDARY
☒ SEISMIC CLASS 1	☐ SERVICE LEVEL 1 COATING
☐ OTHER: (see below)	

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Figure G-3
Example of a completed commercial-grade item dedication technical evaluation for a pressure switch

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SECTION C BOUNDED SCOPE OF USE

Only complete Section C when specific end-use of the item being dedicated unknown.

☒ Not Applicable (Section B Completed Above)

Is the item being dedicated a commodity or standard item designed and constructed in accordance with an industry standard?	☐ Yes ☐ No
IF "YES", LIST THE STANDARD(S) BELOW	
Click here to enter text.	
LIST FUNCTIONS AND/OR APPLICATIONS CONSIDERED WHEN COMPLETING THIS EVALUATION	
Click here to enter text.	
EQUIPMENT QUALIFICATION CONSIDERATIONS / LIMITATIONS (CHECK ALL THAT APPLY):	
CONSIDERATION ☐ ENVIRONMENTAL QUALIFICATION ☐ SEISMIC QUALIFICATION ☐ OTHER: (see below) Click here to enter text.	**QUALIFICATION BASIS / LIMITATIONS OF USE:**

SECTION D ITEM INFORMATION

ITEM DESCRIPTION:	
Switch, Differential Pressure With Vapor Seal; Manufacturer: WGW Controls P/N: KW-456-7891-SCS (with the vapor seal) K - Dual Switch Output with Internal Hex Screw Adjustment W - Differential Pressure Model 456 - Buna-N Diaphragm And O-Ring With Aluminum 1/4 Inch NPT Female Pressure Connections Adjustable Setpoint. 2-20 PSID, Deadband 0.1-0.3 PSI, Working Pressure 30 Inch Hg - 225 PSI, Proof Pressure 225 PSI 7891 - Switch Option, Vapor Sealed 15A 125/250 VAC Resistive SCS - Switch No. 1 Factory Set To 9 PSID Rising; Switch No. 2 Factory Set To 11 PSID Rising	
FUNCTIONAL SAFETY CLASS OF ITEM:	**BASIS / SOURCE:**
☒ Safety-Related ☐ Non-Safety Related (If non-safety, item is not a candidate for dedication)	Service Water System Functional System Description, Document # A-1234567, FSAR Section 9.2

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Figure G-3 (Continued)
Example of a completed commercial-grade item dedication technical evaluation for a pressure switch

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IDENTIFICATION OF ITEM FUNCTION(S)		
FUNCTIONAL MODE	**BASIC SAFETY FUNCTION(S)**	**DESCRIBE (AS REQUIRED)**
☒ Active ☐ Passive	Provide Control	Respond to differential pressure across the monitored flow element in the fluid stream to operate switch contacts that provide a valve actuation signal on high fluid flow.
☒ Active ☐ Passive	Change State	Pressure switch contacts must change state to provide the electrical actuation signal.
☐ Active ☒ Passive	Maintain Pressure Integrity	The fluid side of the device is connected through safety related tubing directly to the fluid system piping and thereby forms part of the system pressure boundary.
☐ Active ☒ Passive	Maintain Circuit Integrity	Circuit integrity must be maintained to ensure that spurious signals / actuations do not occur and that valid signals / actuations are generated.

ITEM IS (CHECK ALL THAT APPLY):

☐ EQ	☐ ASME SECTION III
☐ CLASS 1E	☐ CONTAINMENT PRESSURE BOUNDARY
☒ SEISMIC CLASS 1	☐ SERVICE LEVEL 1 COATING
☐ OTHER: (see below)	

Click here to enter text.

SECTION E ELIGIBLITY FOR DEDICATION

Is the item eligible for dedication in accordance with 10CFR, Part 21? **If the answer is no, this item cannot be dedicated.**	☒ Yes ☐ No

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Figure G-3 (Continued)
Example of a completed commercial-grade item dedication technical evaluation for a pressure switch

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SECTION F FAILURE MODES / MECHANISMS AND EFFECTS ANALYSIS

CREDIBLE FAILURE MODE/MECHANISM	EFFECTS ON SYSTEM/COMPONENT FUNCTION
Short Circuit	Short circuit or ground fault results in an electrical fault that generates a spurious signal and causes invalid valve actuation or prevents generation of a valid control signal
Seizure	Mechanical failure of the bellows or pressure sensing portion of the device (rupture or seizure) precludes operation of the switch mechanism

BASIS FOR SELECTION OF CREDIBLE FAILURE MODE(S)/MECHANISM(S)
Failure Modes, Effects and Diagnostic Analysis reports for various manufacturers and models of pressure switches performed by MHT, LLC. U.S. Navy, NAVSEA Systems Command guide for selection of switches

SECTION G OPERATING EXPERIENCE / HISTORICAL PERFORMANCE INFORMATION

SOURCES REVIEWED AND RESULTS
Industry Operating Experience database showed no relevant failures with similar components NRC letter to TVA dated October 3, 2003: Sequoyah Nuclear Power Plant - NRC Special Inspection Report 05000327/2003010 and 05000328/2003010 discusses out of tolerance behavior for United Electric Series 400 pressure switches. 10CFR21 Report 84120 concerning fuel oil filter differential pressure switches does not apply.

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Figure G-3 (Continued)
Example of a completed commercial-grade item dedication technical evaluation for a pressure switch

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SECTION H IDENTIFICATION ATTRIBUTES

IDENTIFICATION ATTRIBUTES	DESCRIPTION OF INSPECTION	ACCEPTANCE CRITERIA
Manufacturer	Visual	WGW Controls
Identification Number	Visual	KW-456-7891-SCS
Nameplate	Visual	Similar to the photo below: 

Figure G-3 (Continued)
Example of a completed commercial-grade item dedication technical evaluation for a pressure switch

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SECTION I CRITICAL CHARACTERISTICS

CRITICAL CHARACTERISTICS	ACCEPTANCE METHOD	DESCRIPTION OF ACCEPTANCE ACTIVITY	SAMPLING PLAN	ACCEPTANCE CRITERIA (INCLUDING TOLERANCES)
Configuration	Method 1	Visual comparison to drawing A-12345 Rev. ZZ	100%	Configuration corresponds to drawing; sensor connections and conduit entry are as shown.
Dimensions: Height Width Depth Mounting	Method 1	Measure with a ruler or caliper; see drawing A-12345 Rev. ZZ for dimensional references	100%	Height – 7 in ± 1/8 in Width – 5-3/32 in ± 1/16 in Depth – 5-1/2 in ± 1/8 in Mounting – 2 holes 2-1/2 in apart, 4 in from top of housing, diameter sufficient for ¼ in size screw
Dimensions: Sensor Connections	Method 1	Measure with pipe size gauge	100%	2 connections, ¼ inch Female NPT each
Mechanical Function: Differential Pressure Response	Method 1	Differential Pressure Test – Switch #1 (Switch #1 is on the left-hand side of the device)	100%	Switch #1: closes at 9 psid ± 0.5 psi increasing pressure Switch opens at 1 psi or less below the close actuation point on decreasing pressure
Mechanical Function: Differential Pressure Response	Method 1	Differential Pressure Test – Switch #2 (Switch #2 is on the right-hand side of the device)	100%	Switch #2: closes at 11 psid ± 0.5 psi increasing pressure Switch opens at 1 psi or less below the close actuation point on decreasing pressure

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Figure G-3 (Continued)
Example of a completed commercial-grade item dedication technical evaluation for a pressure switch

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CRITICAL CHARACTERISTICS	ACCEPTANCE METHOD	DESCRIPTION OF ACCEPTANCE ACTIVITY	SAMPLING PLAN	ACCEPTANCE CRITERIA (INCLUDING TOLERANCES)
Mechanical Function: Pressure Integrity	Method 1	Pressure Test **Cautions**: Test both legs simultaneously, do not exceed 20 psid between the low and the high inputs, and do not allow the inputs to be reversed.	100%	225 psi +0, -2 psi
Electrical Property: Contact Resistance	Method 1	With an Ohmmeter, measure the closed switch contact resistance on both switches **before** the current and voltage testing.	100%	Less than 0.1 ohm on each switch
Electrical Property: Current Interrupt Capability	Method 1	Verify that each switch operates at 125 VAC (+ /- 3.75 volts), 15 Amps (+0 /- 0.5 amps).	100%	Verify each contact opens and closes under the specified load without visible damage (no signs of smoke, melting parts, or burning smell).
Electrical Property: Current Carrying Capability	Method 1	Verify that each switch carries 15 Amps (+0 /- 0.5 amps) for at least 10 minutes after the applied current stabilizes		Verify each contact opens and closes under the specified load without visible damage (no signs of smoke, melting parts, or burning smell).
Electrical Property: Contact Resistance	Method 1	With an Ohmmeter, measure the closed switch contact resistance on both switches **after** the current and voltage testing.	100%	Less than 0.1 ohm on each switch. Verify the ohmmeter over-ranges with each switch contact open.
Electrical Property: Insulation Integrity	Method 1	With an insulation resistance tester verify the insulation resistance between each switch terminal and the metal housing of the device. Test at approximately 1000 Volts RMS for at least one minute.	100%	Insulation between each terminal and the case is 1.1 megohm or greater.

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Figure G-3 (Continued)
Example of a completed commercial-grade item dedication technical evaluation for a pressure switch

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DESCRIPTION OF SAMPLING PLAN (if "see below" is selected in the sampling plan column above)
Not applicable

SAFETY FUNCTION(S) SUPPORTED / BASIS FOR SELECTION OF CRITICAL CHARACTERISTICS / ACCEPTANCE CRITERIA INCLUDING MAINTAINING SEISMIC AND ENVIRONMENTAL QUALIFICATION
The basic safety function of the differential pressure switch is to close the electrical circuit at a specified differential pressure, which is proportional to fluid flow, for the purpose of initiating a control signal to initiate the operation of a motor operated valve that isolates cooling water flow to non-essential components and thereby accomplishes the safety function of retaining cooling water to essential components. To accomplish this function, the critical characteristics were determined as follows: Marking / Identification: The pressure switch must have the proper description, markings, and part number to ensure that the correct component has been obtained. Manufacturer's name, part number, and installed options are checked by visual inspection of the nameplate. 2. Configuration: The pressure switch must have the proper configuration to ensure its ability to interface properly with existing equipment. Configuration is verified by visual inspection. 3. Dimensions: The pressure switch must have the proper dimensions to ensure its ability to fit into its intended application. Dimensions are verified by direct measurement. 4. Material: The pressure switch is manufactured of various materials. These materials have a direct impact on the ability of the switch to perform its safety related function; however, the device is not located in a harsh environment and the exact materials of construction are not critical to the fulfillment of the item's safety function. The critical electrical and mechanical characteristics of the device will be verified by this dedication plan and if the device meets the acceptance criteria for these characteristics, then there will be reasonable assurance that the device is manufactured of materials suitable for performance of its safety function. Therefore, no specific testing of material is required. 5. Mechanical Characteristics: The pressure switch must change states at the proper differential pressure in order to perform its safety function to send a control signal to the parent component. The switches will be verified to actuate at the required settings and then reset (the reset point is not critical to the safety function but the switch must reset near the device's dead-band for repeatability of the actuation point). Pressure differential actuation is verified by testing. 6. Electrical Characteristics:

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Figure G-3 (Continued)
Example of a completed commercial-grade item dedication technical evaluation for a pressure switch

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SAFETY FUNCTION(S) SUPPORTED / BASIS FOR SELECTION OF CRITICAL CHARACTERISTICS / ACCEPTANCE CRITERIA INCLUDING MAINTAINING SEISMIC AND ENVIRONMENTAL QUALIFICATION

The switches in the device must function to provide an actuation control signal to the parent component when the set-point pressure is reached in order for the switch to perform its primary safety function. For the switches to make and break the electrical control circuit, they must function properly under design electrical conditions in response to the pressure signal in the device.

6.1 Contact Resistance – To deliver a proper control signal, the contact resistance of the switches must be at an acceptable level and remain at an acceptable level. The contact resistance will be confirmed to be less than 0.1 ohm prior to electrical testing and must remain this condition after the Contact Interrupt Capability and Current Carrying Capacity testing to ensure that the control signal passes unimpeded through the closed switch contacts.

6.2 Contact Interrupt Capability – The switches must be capable of making and breaking at their rated current and voltage to apply or remove the control signal to the parent component. This characteristic ensures the switches' ability to perform their safety function when the system current and voltage are applied. This item is used in control circuitry that does not exceed 125 volts in the plant application. Contact Interrupt Capability is verified by testing of each switch.

6.3 Current Carrying Capacity – The switches must be capable of carrying their highest rated current. This ensures their ability to perform their safety function when the maximum system current is applied. Current Carrying Capacity is verified by testing of each switch.

6.4 Insulation Integrity – The switches must be capable on maintaining the circuit integrity while preventing a short circuit condition with the adjacent circuits or a grounding condition with the surrounding housing and structure. Insulation integrity is verified by Insulation Resistance testing.

<u>Seismic Qualification:</u>

As described in EPRI Plant Support Engineering: Generic Seismic Technical Evaluations of Replacement Items for Nuclear Power Plants—Item-Specific Evaluations: TR-105849 Rev. 1. EPRI, Palo Alto, CA: 2008. 1016694 (Generic Seismic Technical Evaluation for Replacement Items for Pressure / Differential Pressure Switch, G-STERI Number: I-95003, Revision 1), the device is seismically rugged and meets the stipulations in this G-STERI evaluation. Also, since the G-STERI evaluation did not specifically include United Electric pressure switched, a specimen of this same United Electric J402 switch was seismically tested by the dedicating entity to validate the seismic ruggedness determination. Therefore, no additional action are needed during the procurement and dedication process to address seismic considerations for this device.

<u>Environmental Qualification:</u>

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Figure G-3 (Continued)
Example of a completed commercial-grade item dedication technical evaluation for a pressure switch

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SAFETY FUNCTION(S) SUPPORTED / BASIS FOR SELECTION OF CRITICAL CHARACTERISTICS / ACCEPTANCE CRITERIA INCLUDING MAINTAINING SEISMIC AND ENVIRONMENTAL QUALIFICATION
The device is not located in a harsh environment location and environmental qualification requirements are not applicable.
BASIS FOR SELECTION OF SAMPLING PLANS (IF SAMPLING PLANS ARE USED)
Sampling Considerations: Although the device could be considered a "Line Item / Single Manufacturer" product in accordance with EPRI TR-01721, Guideline for Sampling in the Commercial-Grade Item Acceptance Process, because of the potential randomness of the critical subcomponents in the device and because the item is typically purchased in small quantities (less than 5) through a distributor, it was determined that all the tests and inspections should be performed on each device being dedicated. The device is labeled with a manufacturing date code that could be used for similarity / batch considerations but no sampling plan is being used for dedication of these pressure switches; the small purchase quantities neither provide a benefit nor a justification for sampling.

SECTION J REFERENCES

DOCUMENT / SOURCE	REVISION / DATE	COMMENTS
EPRI TR-105849, Generic Seismic Technical Evaluations of Replacement Items for Nuclear Power Plants—Item-Specific Evaluations	Revision 1, dated September 2008	
EPRI TR-017218-R1, Guideline for Sampling in the Commercial-Grade Item Acceptance Process	Revision 1, dated January 1999	
MIL-STD 202G, Department of Defense Standard for Test Methods for Electronic & Electrical Parts	Click here to enter text.	
NEMA ICS 1, Industrial and Control Systems General Requirements	Click here to enter text.	
WGW Controls drawing A-12345	Revision ZZ, dated June 28, 2004	

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Figure G-3 (Continued)
Example of a completed commercial-grade item dedication technical evaluation for a pressure switch

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DOCUMENT / SOURCE	REVISION / DATE	COMMENTS
U.S. Navy NAVSEA Systems Command, public document entitled "Switches"		The document was produced as a guide to aid a designer in the selection of an appropriate switch for the intended application. The document has a section discussing failure mechanisms of switches.
MHT LLC, various studies and documents on failure modes, effects, and diagnostic analysis of electronic switches		These studies were commissioned by the respective switch manufacturer (mostly for "smart" electronic devices) and are available through the switch manufacturer's web site. The reports provide insights into failure modes and effects to consider.

SECTION K REVIEW AND APPROVAL

Prepared by: Ms. Preparer Date: 04/16/14

Reviewed by: Mr. Reviewer Date: 04/17/14

Figure G-3 (Continued)
Example of a completed commercial-grade item dedication technical evaluation for a pressure switch

G.5 Capacitor

The parameters of the capacitor example are as follows:

- Item/service: capacitor, aluminum electrolytic.
- Safety function: The capacitor stores energy (electrical charge) and inherently resists or dampens changes in voltage across the capacitor.
- Supplier information: The supplier is an authorized distributor for an electronics manufacturer that produces a line of high-quality, industrial-grade capacitors.
- Approach: The capacitor will be dedicated using special tests and inspection (Method 1). The preparer completed Section C to identify the bounded scope of use upon which the dedication is based because the capacitor is going to be stocked for a variety of applications. In Section C, the preparer explains that there is a limited set of critical characteristics for the capacitor and that the dedication will address all but equivalent series resistance because applications requiring that attribute would not use the type of capacitor being dedicated.

Figure G-4 is an example of a completed commercial-grade item dedication technical evaluation for a capacitor.

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SECTION A ITEM DESCRIPTION

INVENTORY CONTROL NO:	444444-02
NOUN IDENTIFIER:	Capacitor, Aluminum Electrolytic
MANUFACTURER NAME:	**MANUFACTURER MODEL / PART / CATALOG NUMBER(S)**
JLD Electronics	12AB345C678DC9B

SECTION B END USE / PARENT / HOST EQUIPMENT INFORMATION

Note: If the specific end-use(s) / plant applications are not known, complete Section C of this form in lieu of Section B prior to proceeding.

☒ Not Applicable (Section C Completed Below)

EQUIPMENT ID (TAG) NUMBERS OR DESCRIPTION OF ITEM USAGE:

Click here to enter text.

PARENT COMPONENT/HOST DESCRIPTION:

Click here to enter text.

FUNCTIONAL SAFETY CLASS OF COMPONENT / HOST:	**BASIS / SOURCE:**
☒ Safety-Related ☐ Non-Safety Related (If non-safety, item is not a candidate for dedication)	Click here to enter text.

IDENTIFICATION OF PARENT COMPONENT/HOST EQUIPMENT FUNCTION(S)

FUNCTIONAL MODE	BASIC SAFETY FUNCTION(S)	DESCRIBE (AS REQUIRED)
☐ Active ☐ Passive	Choose an item.	Click here to enter text.
☐ Active ☐ Passive	Choose an item.	Click here to enter text.
☐ Active ☐ Passive	Choose an item.	Click here to enter text.
☐ Active ☐ Passive	Choose an item.	Click here to enter text.

PARENT COMPONENT/HOST EQUIPMENT IS (CHECK ALL THAT APPLY):

☐ EQ	☐ ASME SECTION III
☐ CLASS 1E	☐ CONTAINMENT PRESSURE BOUNDARY
☒ SEISMIC CLASS 1	☐ SERVICE LEVEL 1 COATING
☐ OTHER: (see below)	

Click here to enter text.

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Figure G-4
Example of a completed commercial-grade item dedication technical evaluation for a capacitor

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SECTION C BOUNDED SCOPE OF USE

Only complete Section C when specific end-use of the item being dedicated unknown.

☐ Not Applicable (Section B Competed Above)

Is the item being dedicated a commodity or standard item designed and constructed in accordance with an industry standard?	☐ Yes ☒ No
IF "YES", LIST THE STANDARD(S) BELOW	
Not Applicable	
LIST FUNCTIONS AND/OR APPLICATIONS CONSIDERED WHEN COMPLETING THIS EVALUATION	
For this type capacitor, the parent component is an electrical device such as inverter, rectifier, or power supply. In general, a capacitor is a device that can store electrical charge. Because it can store a charge and then quickly release that charge, it resists any change of voltage across it. Therefore, a capacitor can be used to "damp" changes in voltage, and it can also be used to block DC while permitting AC to "pass through" it (which is a filtering or coupling type function, depending on the circuit). Regardless of the electrical circuit application, there are limited electrical and physical characteristics critical to the use of the capacitor. This dedication plan addresses those critical characteristics except for Equivalent Series Resistance (ESR) because ESR is not critical for most applications. ESR could be critical if the capacitor is used in certain resonant circuit applications; however, the particular capacitor addressed by this dedication plan is not the type that would typically be used in resonant circuit applications. Therefore, ESR is not included in this dedication plan and should be addressed separately if critical for the specific application. Mounting brackets and terminal screws are also not included in this dedication and must be addressed by a separate dedication plan if required.	

EQUIPMENT QUALIFICATION CONSIDERATIONS / LIMITATIONS (CHECK ALL THAT APPLY):

CONSIDERATION	QUALIFICATION BASIS / LIMITATIONS OF USE:
☒ ENVIRONMENTAL QUALIFICATION	Device was not evaluated for use in Harsh Environment applications.
☒ SEISMIC QUALIFICATION	This item is a subcomponent part of a parent component that is a seismically qualified unit.
☐ OTHER: (see below)	

Click here to enter text.

SECTION D ITEM INFORMATION

ITEM DESCRIPTION:

Capacitor Aluminum Electrolytic 41000 Microfarad 50 VDC -10%, +75% Tolerance
Polar With Maximum Surge of 65 VDC, Blue PVC Insulating Jacket
High Post With 10 X 32 Internal Threads (Terminal Screws not Included)
Dimensions: Diameter = 3 Inch
Canister Length = 4-1/8 Inch
Terminal Spacing = 1-1/4 Inch

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Figure G-4 (Continued)
Example of a completed commercial-grade item dedication technical evaluation for a capacitor

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FUNCTIONAL SAFETY CLASS OF ITEM:	BASIS / SOURCE:
☒ Safety-Related ☐ Non-Safety Related (If non-safety, item is not a candidate for dedication)	Item is to be dedicated for generic safety related use in any application where the design includes this particular capacitor within the bounds described in Section C above

IDENTIFICATION OF ITEM FUNCTION(S)

FUNCTIONAL MODE	BASIC SAFETY FUNCTION(S)	DESCRIBE (AS REQUIRED)
☐ Active ☒ Passive	Store Energy	A capacitor is an electrical energy storage device that is passive in all modes of operation

ITEM IS (CHECK ALL THAT APPLY):

☐ EQ	☐ ASME SECTION III
☐ CLASS 1E	☐ CONTAINMENT PRESSURE BOUNDARY
☒ SEISMIC CLASS 1	☐ SERVICE LEVEL 1 COATING
☐ OTHER: (see below)	

Click here to enter text.

SECTION E ELIGIBLITY FOR DEDICATION

Is the item eligible for dedication in accordance with 10CFR, Part 21? **If the answer is no, this item cannot be dedicated.**	☒ Yes ☐ No

SECTION F FAILURE MODES / MECHANISMS AND EFFECTS ANALYSIS

CREDIBLE FAILURE MODE/MECHANISM	EFFECTS ON SYSTEM/COMPONENT FUNCTION
Open Circuit	Mechanical damage, internal corrosion, electrolyte deterioration, dielectric failure, or film failure can result in an open electrical circuit within the device such that it no longer conducts when required.
Air Tightness Failure or Gas Generation	Results in deformation of internal parts of the device causing electrical failure or degradation of the capacitor.
Short Circuit	Mechanical damage, internal corrosion, electrolyte deterioration, dielectric / separator paper failure, or film failure can result in an electrical short circuit within the device such that it does not store the required electrical charge.
Degradation Failure	The internal components can deteriorate over time causing the device to longer function within its rated parameters.

BASIS FOR SELECTION OF CREDIBLE FAILURE MODE(S)/MECHANISM(S)

- Panasonic Corporation, “Reliability of Aluminum Electrolytic Capacitors”
- Nichicon Corporation, “Application Guidelines for Aluminum Electrolytic Capacitors”

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Figure G-4 (Continued)
Example of a completed commercial-grade item dedication technical evaluation for a capacitor

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SECTION G OPERATING EXPERIENCE / HISTORICAL PERFORMANCE INFORMATION

SOURCES REVIEWED AND RESULTS
• NRC Part 21 Report Log No. 2001-21-0 concerning electrolytic capacitors in diesel generator governor control devices • NRC Information Notice 94-033 concerning capacitor failures in plant protection systems

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Figure G-4 (Continued)
Example of a completed commercial-grade item dedication technical evaluation for a capacitor

Commercial Grade Item Dedication
Technical Evaluation

EPRI Joint Utility Task Group
Revision 0

Evaluation Number CGI 0004 **Revision** 0

SECTION H IDENTIFICATION ATTRIBUTES

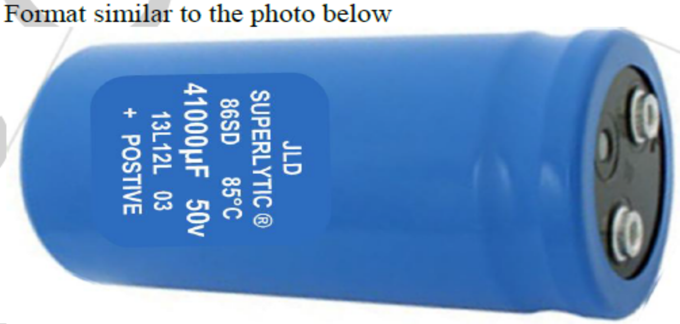
IDENTIFICATION ATTRIBUTES	DESCRIPTION OF INSPECTION	ACCEPTANCE CRITERIA
Manufacturer	Visual	"JLD" and "SUPERLYTIC®" brand names printed on device
Identification Number	Visual	Electrical rating matching the item description marked on device (see below example picture). Based on the manufacturing date code, verify that the item was manufactured within the last 5 years.
Marking	Visual	Format similar to the photo below 

Figure G-4 (Continued)
Example of a completed commercial-grade item dedication technical evaluation for a capacitor

Commercial Grade Item Dedication
Technical Evaluation

EPRI Joint Utility Task Group
Revision 0

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SECTION I CRITICAL CHARACTERISTICS

CRITICAL CHARACTERISTICS	ACCEPTANCE METHOD	DESCRIPTION OF ACCEPTANCE ACTIVITY	SAMPLE PLAN	ACCEPTANCE CRITERIA (INCLUDING TOLERANCES)
Configuration	Method 1	Visual comparison to photo in Section H (above) and the dimension drawing shown below	Reduced	Configuration corresponds to picture and drawing; vent-hole screen is intact
Dimensions: Diameter (D max.) Length (L max) Terminal Spacing (M)	Method 1	Measure with a ruler or caliper; see below drawing for dimensional references (with blue PVC insulating sleeve) Nominal dimensions per Inspection Instruction 924 Revision 4.	Reduced per EPRI TR-017218-R1, Table 2-1	Diameter – 3 in nominal (3.078 in maximum Length – 4-1/8 in nominal (4.250 in maximum) Terminal Spacing – 1.250 ± 0.016 in
Dimensions: Terminal Screw Hole	Method 1	Measure with thread gauge or go/no-go screw tester.	Reduced per EPRI TR-017218-R1, Table 2-1	2 - # 10 x 32 female
Electrical Property: Capacitance	Method 1	Test with Capacitance Meter	100%	41000 Micro Farad – 10%, +75% tolerance.
Electrical Property: DC Working Voltage	Method 1	Applied during leakage current testing	See below	50 VDC
Electrical Property: DC Leakage Current	Method 1	Test with Capacitor Tester	Reduced per EPRI TR-017218-R1, Table 2-1	Maximum Leakage of 5727 Micro-Amps at 50 VDC

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Figure G-4 (Continued)
Example of a completed commercial-grade item dedication technical evaluation for a capacitor

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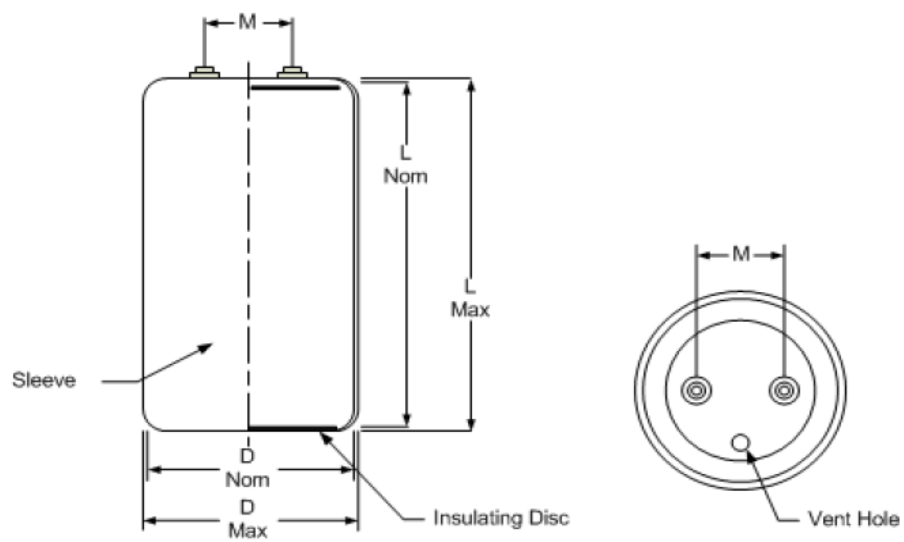
DESCRIPTION OF SAMPLING PLAN (if "see below" is selected in the sample plan column above)
DC Working Voltage of 50 VDC is to be applied during Leakage Current Testing

Outline and Dimension Drawing



SAFETY FUNCTION(S) SUPPORTED / BASIS FOR SELECTION OF CRITICAL CHARACTERISTICS / ACCEPTANCE CRITERIA INCLUDING MAINTAINING SEISMIC AND ENVIRONMENTAL QUALIFICATION
The basic safety function of this aluminum electrolytic capacitor is to store electrical charge. For generic uses, the critical characteristics of this device are as follows: 1. Marking / Identification: The capacitor must be properly marked with the manufacturer, capacitance, and working voltage to ensure it is the correct part. This information is marked on the item. Manufacturer's trade name and pertinent information are checked by visual inspection of the item.

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Figure G-4 (Continued)
Example of a completed commercial-grade item dedication technical evaluation for a capacitor

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SAFETY FUNCTION(S) SUPPORTED / BASIS FOR SELECTION OF CRITICAL CHARACTERISTICS / ACCEPTANCE CRITERIA INCLUDING MAINTAINING SEISMIC AND ENVIRONMENTAL QUALIFICATION
The manufacturing date code is verified to establish sampling lot and to verify that the item is recently manufactured. Electrolytic capacitors are susceptible to age degradation; therefore, recent manufacture is a consideration. 2. Configuration: The capacitor must have the proper configuration to ensure its ability to interface properly with existing equipment. Configuration is verified by visual inspection. 3. Dimensions: The capacitor must have the proper dimensions to ensure its ability to fit into its intended application. The critical dimensions (diameter, length, terminal spacing, and terminal screw hole size) are verified by direct measurement. 4. Electrical Characteristics: 4.1 Capacitance – Capacitance is the measurement of the capacitor's ability to store energy and is the primary electrical characteristic of the device. Capacitance is measured in units of farads and is verified by direct measurement. 4.2 Voltage (Working Voltage) – The voltage rating defines the maximum DC voltage that the capacitor is designed to operate under. If the maximum voltage, commonly called the working voltage, is exceeded for an extended time the capacitor may be damaged and fail. Working voltage cannot be measured directly but it can be verified in conjunction with leakage current. Leakage current measured to be below the maximum indirectly verifies acceptable capacitor performance at the applied working voltage. 4.3 Leakage Current – Leakage current is the direct current that flows through the dielectric of a capacitor when voltage is impressed across its terminal and is a function of the applied voltage. Leakage current is an indication of how well the capacitor is storing the electrical charge by not allowing current flow between the poles. Leakage current is verified by direct measurement. 4.4 Insulation Integrity – The switches must be capable on maintaining the circuit integrity while preventing a short circuit condition with the adjacent circuits or a grounding condition with the surrounding housing and structure. Insulation integrity is verified by Insulation Resistance testing. 4.5 Equivalent Series Resistance (ESR) – ESR is defined as a single resistance representing all the ohmic losses in the capacitor and, as stated above, is not critical for most applications. ESR could be critical if the capacitor is being used in certain resonant circuit applications which are not a typical use for this particular capacitor. The leakage current is an indication of the dielectric conductance and thus ESR. Since capacitance, working voltage and leakage current are being verified; ESR is not to be measured <u>Seismic Qualification:</u> Various EPRI and general industry references indicate that a fixed electrolytic can capacitor is considered to be seismically rugged for use in

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Figure G-4 (Continued)
Example of a completed commercial-grade item dedication technical evaluation for a capacitor

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SAFETY FUNCTION(S) SUPPORTED / BASIS FOR SELECTION OF CRITICAL CHARACTERISTICS / ACCEPTANCE CRITERIA INCLUDING MAINTAINING SEISMIC AND ENVIRONMENTAL QUALIFICATION
nuclear power plants provided it is properly installed and mounted in the host component. Therefore, there are no additional actions are required as part of the dedication activities to address seismic qualification. Environmental Qualification: The device was not evaluated for use in a harsh environment location and environmental qualification requirements are not applicable.

BASIS FOR SELECTION OF SAMPLING PLANS (IF SAMPLING PLANS ARE USED)
Sampling Considerations: All items will be inspected for markings and identification, configuration, and capacitance. Verifying the capacitance on each item ensures that the item is functional. Each capacitor should be marked with the manufacturer's date code for aging considerations and a degree of traceability. Since these items are supplied by the same manufacturer and have a reliable manufacturer's date code, EPRI TR-017218, Table 2-1, Reduced Plan, will be used for dimensions and working voltage / leakage current for each date code group provided. Also, if the electrical verification results are consistent across the specimens in the sample, this reinforces the homogeneity of the date coded lot; however, if the electrical tests or visual inspections yield significantly inconsistent results among the specimens, the homogeneity of the lot should be questioned and reevaluated even if the parameters are within the specified tolerances particularly since this product has some relatively wide tolerance values

SECTION J REFERENCES

DOCUMENT / SOURCE	REVISION / DATE	COMMENTS
JLD Document Number: 45678	November 7, 2013	Capacitor specifications available from JLD's website as are approved distributors
Capacitor Application and Maintenance Guide. EPRI TR-112175	1999	
Guidelines for Establishing, Maintaining, and	Revision 1, dated November 2011	

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Figure G-4 (Continued)
Example of a completed commercial-grade item dedication technical evaluation for a capacitor

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DOCUMENT / SOURCE	REVISION / DATE	COMMENTS
Extending the Shelf Life Capability of Limited Life Items, Revision 1 of NP-6408 (NCIG-13). EPRI 1022959		

SECTION K REVIEW AND APPROVAL

Prepared by: T. Preparer Date: 04/18/14

Reviewed by: L. Reviewer Date: 04/20/14

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Figure G-4 (Continued)
Example of a completed commercial-grade item dedication technical evaluation for a capacitor

G.6 Terminal Lug

The parameters of the terminal lug example are as follows:

- Item/service: connector, copper, terminal, ring tongue 16-14 AWG, #6 stud, PISG, blue stripe, PVF2 insulated.
- Safety function: The terminal lug must maintain circuit integrity in both power and signal applications.
- Supplier information: The supplier is an OEM of high-quality, industrial-grade terminals used in a variety of commercial, military, and industrial applications.
- Approach: The terminal lugs comply with one of the dedicating entity's electrical specifications, and the terminal lugs are purchased repetitively for use in various applications for which the specification applies. The preparer completed Section B to identify the end-use applications, and safety functions are those covered by the specification. The terminal lugs will be dedicated using a combination of Methods 1 and 2.

Figure G-5 is an example of a completed commercial-grade item dedication technical evaluation for a terminal lug.

Commercial Grade Item Dedication Technical Evaluation — **EPRI Joint Utility Task Group**
Form CGI1, Rev. 0

Evaluation Number CGI 0005 **Revision** 0

SECTION A ITEM DESCRIPTION

INVENTORY CONTROL NO:	EMW-JS2
NOUN IDENTIFIER:	Connector, Copper, Terminal, Ring Tongue 16-14 AWG, #6 Stud, PISG, Blue Stripe, PVF2 Insulated

MANUFACTURER NAME:	MANUFACTURER MODEL / PART / CATALOG NUMBER(S)
BCP Industries	630319

SECTION B END USE / PARENT / HOST EQUIPMENT INFORMATION

Note: If the specific end-use(s) / plant applications are not known, complete Section C of this form in lieu of Section B prior to proceeding.

☐ Not Applicable (Section C Completed Below)

EQUIPMENT ID (TAG) NUMBERS OR DESCRIPTION OF ITEM USAGE:

Various applications in accordance with Juliet Plant Electrical Specification 2323-EWJS-100

PARENT COMPONENT/HOST DESCRIPTION:

Various terminations made in accordance with Juliet Plant Electrical Specification 2323-EWJS-100

FUNCTIONAL SAFETY CLASS OF COMPONENT / HOST:	BASIS / SOURCE:
☒ Safety-Related ☐ Non-Safety Related (If non-safety, item is not a candidate for dedication)	Juliet Plant Electrical Specification 2323-EWJS-100

IDENTIFICATION OF PARENT COMPONENT/HOST EQUIPMENT FUNCTION(S)

FUNCTIONAL MODE	BASIC SAFETY FUNCTION(S)	DESCRIBE (AS REQUIRED)
☐ Active ☒ Passive	Maintain Circuit Integrity	Maintain electrical continuity for power, control and instrumentation circuits of various safety related equipment
☐ Active ☒ Passive	Maintain Structural Integrity	Maintain structural integrity during normal operating and design basis event conditions
☐ Active ☐ Passive		
☐ Active ☐ Passive		

PARENT COMPONENT/HOST EQUIPMENT IS (CHECK ALL THAT APPLY):

☒ EQ
☒ CLASS 1E
☒ SEISMIC CLASS 1
☐ OTHER: (see below)
☐ ASME SECTION III
☐ CONTAINMENT PRESSURE BOUNDARY
☐ SERVICE LEVEL 1 COATING

Use includes applications qualified via IEEE Test Report RST, Rev. 4 and Dudek Laboratory Environmental Qualification Report EEQ-THOM-12, Rev. 8.

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Figure G-5
Example of a completed commercial-grade item dedication technical evaluation for a terminal lug

Commercial Grade Item Dedication Technical Evaluation — **EPRI Joint Utility Task Group**
Form CGI1, Rev. 0

Evaluation Number CGI 0005 **Revision** 0

SECTION C BOUNDED SCOPE OF USE

Only complete Section C when specific end-use of the item being dedicated unknown.

☒ Not Applicable (Section B Completed Above)

Is the item being dedicated a commodity or standard item designed and constructed in accordance with an industry standard?	☐ Yes ☐ No
IF "YES", LIST THE STANDARD(S) BELOW	
Click here to enter text.	
LIST FUNCTIONS AND/OR APPLICATIONS CONSIDERED WHEN COMPLETING THIS EVALUATION	
Click here to enter text.	
EQUIPMENT QUALIFICATION CONSIDERATIONS / LIMITATIONS (CHECK ALL THAT APPLY):	
CONSIDERATION ☐ ENVIRONMENTAL QUALIFICATION ☐ SEISMIC QUALIFICATION ☐ OTHER: (see below) Click here to enter text.	**QUALIFICATION BASIS / LIMITATIONS OF USE:**

SECTION D ITEM INFORMATION

ITEM DESCRIPTION:	
Connector, Copper, Terminal, Ring Tongue 16-14 AWG, #6 Stud, PISG, Blue Stripe, PVF2 Insulated	
FUNCTIONAL SAFETY CLASS OF ITEM:	**BASIS / SOURCE:**
☒ Safety-Related ☐ Non-Safety Related (If non-safety, item is not a candidate for dedication)	Juliet Plant Electrical Specification 2323-EWJS-100

IDENTIFICATION OF ITEM FUNCTION(S)

FUNCTIONAL MODE	BASIC SAFETY FUNCTION(S)	DESCRIBE (AS REQUIRED)
☐ Active ☒ Passive	Maintain Circuit Integrity	The lug must maintain a low resistance connection for signal applications. In addition, the lug must carry rated current without excessive heating in power applications.
☐ Active ☒ Passive	Maintain Structural Integrity	Maintain structural integrity during normal operating and design basis event conditions
☐ Active ☐ Passive		

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Figure G-5 (Continued)
Example of a completed commercial-grade item dedication technical evaluation for a terminal lug

Commercial Grade Item Dedication Technical Evaluation | **EPRI Joint Utility Task Group** Form CGI1, Rev. 0

Evaluation Number CGI 0005 **Revision** 0

ITEM IS (CHECK ALL THAT APPLY):	
☒ EQ	☐ ASME SECTION III
☒ CLASS 1E	☐ CONTAINMENT PRESSURE BOUNDARY
☒ SEISMIC CLASS 1	☐ SERVICE LEVEL 1 COATING
☐ OTHER: (see below)	
Click here to enter text.	

SECTION E ELIGIBLITY FOR DEDICATION

Is the item eligible for dedication in accordance with 10CFR, Part 21? **If the answer is no, this item cannot be dedicated.**	☒ Yes ☐ No

SECTION F FAILURE MODES / MECHANISMS AND EFFECTS ANALYSIS

CREDIBLE FAILURE MODE/MECHANISM	EFFECTS ON SYSTEM/COMPONENT FUNCTION
Fracture	Fracture due to cyclic loading (caused by vibration, etc.) could result in open circuit during normal operation or design basis events.
Short Circuit	Insulation breakdown could result in short to ground or adjacent channel that could prompt incorrect signal or loss of power to devices in the circuit.
Overheating	Overheating could result in loss or degradation of signal causing inaccurate instrument readings, response and control functions.
Click here to enter text.	Click here to enter text.

BASIS FOR SELECTION OF CREDIBLE FAILURE MODE(S)/MECHANISM(S)
Open circuit would interrupt circuit continuity removing power/control to safety equipment. Excessive resistance could cause circuit malfunction or failure. Insulation breakdown due to incorrect material could occur in EQ applications. Terminals are considered seismically insensitive per Design Calculation KMK 710319, Rev. 1.

SECTION G OPERATING EXPERIENCE / HISTORICAL PERFORMANCE INFORMATION

SOURCES REVIEWED AND RESULTS
A review of external and internal operating experience did not identify any recent failures or concerns with this product. Previous receipt inspection history of this product and performance history for plant installations have not identified any failures or performance issues with terminal lugs.

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Figure G-5 (Continued)
Example of a completed commercial-grade item dedication technical evaluation for a terminal lug

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SECTION H IDENTIFICATION ATTRIBUTES

IDENTIFICATION ATTRIBUTES	DESCRIPTION OF INSPECTION	ACCEPTANCE CRITERIA
Manufacturer	Visual	BCP Industries
Identification Number	Visual	630319
Insulation Color	Visual	Blue

SECTION I CRITICAL CHARACTERISTICS

CRITICAL CHARACTERISTICS	ACCEPTANCE METHOD	DESCRIPTION OF ACCEPTANCE ACTIVITY	SAMPLING PLAN	ACCEPTANCE CRITERIA (INCLUDING TOLERANCES)
Dimensions	Method 2	Current commercial grade survey verifies critical controls are in place to assure dimensions of the lug are controlled in accordance with design requirements.	Not Applicable	Certification from BCP for the PO indicates dimensions were controlled in accordance with BCP statistical process control instructions 101338 Rev. S and 092825 Rev D.
Base Material	Method 2	Current commercial grade survey verifies critical controls are in place to assure base copper material is controlled in accordance with design requirements.	Not Applicable	Certification received from BCP for the PO indicates base material was verified in accordance with BCP Material Inspection Instruction MI-CU-0519 Rev. 2 and controlled per BCP QA Procedure 2009-0412 Rev. 1

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Figure G-5 (Continued)
Example of a completed commercial-grade item dedication technical evaluation for a terminal lug

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CRITICAL CHARACTERISTICS	ACCEPTANCE METHOD	DESCRIPTION OF ACCEPTANCE ACTIVITY	SAMPLING PLAN	ACCEPTANCE CRITERIA (INCLUDING TOLERANCES)
Plating Material	Method 2	Current commercial grade survey verifies critical controls are in place to assure plating materials are controlled in accordance with design requirements.	Not Applicable	Certification received from BCP for the PO indicates plating material was verified in accordance with BCP Material Inspection Instruction MI-TIN-0519 Rev. 2 and controlled per BCP QA Procedure 2009-0412 Rev. 1.
Plating thickness and consistency	Method 2	Current commercial grade survey verifies critical controls are in place to assure plating in performed in accordance with design requirements.	Not Applicable	Certification received from BCP for the PO indicates application of plating is controlled in accordance with BCP Plating Instruction 610822 Rev. 5
Insulation Material	Method 1	Material verification using Infrared Spectroscopy	Normal	Spectral match with library Spectra for PVF 2.
Insulation Dielectric Strength (in lieu of Method 2)	Method 1	Dielectric withstand test at twice rating + 1000V	Normal	>1600 Vdc no breakdown indicated

DESCRIPTION OF SAMPLING PLAN (if "see below" is selected in the sampling plan column above)
Use Juliet Plant Normal Destructive Test Sample Procedure 345 for testing base material

SAFETY FUNCTION(S) SUPPORTED / BASIS FOR SELECTION OF CRITICAL CHARACTERISTICS / ACCEPTANCE CRITERIA INCLUDING MAINTAINING SEISMIC AND ENVIRONMENTAL QUALIFICATION

If the dimensions and materials of the terminal are correct, it should be able to conduct the rated current without unacceptable temperature rise.

Configuration/Dimensions – Verification of configuration and dimensions provides assurance that the lug is the one specified in the PO and is the proper size/configuration (per the manufacturer's catalog) for the intended applications.

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Figure G-5 (Continued)
Example of a completed commercial-grade item dedication technical evaluation for a terminal lug

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SAFETY FUNCTION(S) SUPPORTED / BASIS FOR SELECTION OF CRITICAL CHARACTERISTICS / ACCEPTANCE CRITERIA INCLUDING MAINTAINING SEISMIC AND ENVIRONMENTAL QUALIFICATION

Base Material - Verification of material ensures the item will carry rated current with the design voltage drop. Also, material verification provides an indirect indication of the terminal's ability to resist fracture and thus endangering the continuity of various Class 1E circuits.

Plating Material - Proper plating material ensures the proper resistance to corrosion and low resistance connection. Uniform plating without bare spots will assure the satisfactory application of coating material.

Insulation Material - Verification of the material ensures that the insulation is the same as the qualified material addressed in the Dudek Laboratories qualification test report for BCP connectors, splices and terminals.

Insulation Dielectric Strength – Dielectric strength testing demonstrates the integrity of the insulation and provides indication that voltage breakdown of the insulation will not occur. (Rated at 300V) Tested at twice rated plus 1000Vdc.

Note - Based on a review of EEQ-THOM-12, Rev. 8, the insulation of connectors is not considered to have a safety function. The insulation material and dielectric strength are listed as critical characteristics to obtain reasonable assurance that the insulation will not experience failure resulting in short to ground or adjacent conductors. Specification 2323-EJWS-100 specifically requires that safety related terminals from BCP be Pre-Insulated Sure Grip (PISG). Design of the PISG terminals calls for a specific insulating material. EEQ-THOM-12, Rev. 8 qualified the terminals for use in the environments outlined in 2323-EJWS-100. Verification of insulating material and dielectric strength provides maximum flexibility in use of the dedicated terminals.

Because there is no information in the current commercial grade survey that specifically confirms the chemical composition of the insulation, this critical characteristic will be verified at receipt for all pre-insulated terminals purchased from BCP.

BASIS FOR SELECTION OF SAMPLING PLANS (IF SAMPLING PLANS ARE USED)

Part number and identification verification is performed as part of QC receiving inspection using a sampling plan based on EPRI TR-017218-R1, Normal Sampling Plan. The normal sampling plan was selected based on these products being procured directly from the manufacturer with satisfactory verification of material and traceability controls accomplished via commercial grade survey.

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Figure G-5 (Continued)
Example of a completed commercial-grade item dedication technical evaluation for a terminal lug

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BASIS FOR SELECTION OF SAMPLING PLANS (IF SAMPLING PLANS ARE USED)
Chemical composition testing for insulation material is performed on a smaller sample based on this testing being classified as destructive. The sample size is selected using a Destructive Sampling Plan that is based on the EPRI TR-017218-R1, Destructive Sampling Plan. As noted above, the products are procured directly from the manufacturer with satisfactory verification of material and traceability controls accomplished via commercial grade survey.

SECTION J REFERENCES

DOCUMENT / SOURCE	REVISION / DATE	COMMENTS
Survey Planning Worksheet 2261, Rev. 8	03/19/2014	
Juliet Plant Commercial Grade Survey Report 2013-MHT-CGS-0001	Rev. 5, 08/22/2014	Report references documented BCP controls that are to be specified on the PO including BCP Plating Instruction 610822, Rev. 5, SPC Instructions 101338 Rev. S and 092825 Rev. D, Inspection Instructions MI-TIN-0519, Rev. 2 and Material Inspection Instruction MI-CU-0519 Rev. 2, and QA Procedure 2009-0412, Rev. 1
Juliet Plant Electrical Specification 2323-EJWS-100	1982	
IEEE Test Report RST, Rev. 4	6/1988	
Dudek Laboratory EQ Report EEQ-THOM-12, Rev. 8	4/1985	
Design Calc KMK 710319, Rev. 1		
BCP Catalog 63, Page 319	2013	
BCP Drawings 610822, 0519	2011	
ASTM B-188, Cu Bus Pipe and Tube	2010	
ASTM B-152, Copper Sheet, Strip, Plate, & Rolled Bar	2013	
ASTM D149, Dielectric Test Method	2009	
SAE AS-7928 (formerly MIL-T-7928) Lugs and Splices	3/2011	

Figure G-5 (Continued)
Example of a completed commercial-grade item dedication technical evaluation for a terminal lug

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SECTION K REVIEW AND APPROVAL

Prepared by: L. Preparer Date: 04/20/14

Reviewed by: T. Reviewer Date: 04/24/14

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Figure G-5 (Continued)
Example of a completed commercial-grade item dedication technical evaluation for a terminal lug

Figures G-6 and G-7 show excerpts from the commercial-grade survey planning worksheet that the Joliet Plant used to prepare for the survey of BCP Industries (see Attachment 1) as well as excerpts from the completed survey report that describe conclusions regarding the ability of BCP Industries to control critical characteristics of the terminal lugs.

Attachment 1

Joliet Plant Survey Planning Worksheet CGSP-2013-089

Supplier Name	Description of Item(s)/Service(s) in scope of survey
BCP Industries	Pre-Insulated Sure Grip (PISG) Terminal connectors included in BCP Industries Catalog 63. Ring, slotted ring, spade, flanged spade, splices, and barrel connectors are include in the scope of the survey as these product are specified in Juliet Plant Electrical Specification 2323-EWJS-100 and have been qualified per EEQ-THOM-12, Rev. 8

Item / Service Safety Function(s)

The safety functions of these connectors is to maintain circuit integrity for power and instrumentation (signal) circuits. The connectors must maintain a low resistance connection for signal applications and must carry rated current without excessive temperature rise.

Operating Experience

A review of internal and external operating experience did not identify recent failures or concerns with products of this type

Critical Characteristic	Process(es) that influence / impart Critical Characteristic	Supplier Controls to be Evaluated during the Commercial Grade Survey
Base Material	Design Control of materials Procurement of materials Inspection/verification materials meet design requirements Control of materials during manufacturing	Controls that assure base Copper materials (for lug and sleeve) conform to design and are not changed without engineering evaluation and approval. Control of sub-tier suppliers and verification of incoming Copper materials to assure they conform to design requirements. Controls to assure traceability of base Copper material during manufacturing activities

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Figure G-6
Joliet Plant survey planning worksheet

Attachment 1

Joliet Plant Survey Planning Worksheet CGSP-2013-089

Critical Characteristic	Process(es) that influence / impart Critical Characteristic	Supplier Controls to be Evaluated during the Commercial Grade Survey
Plating Material	Design Control of materials Procurement of materials Inspection/verification materials meet design requirements Control of materials during manufacturing	Controls that assure Tin plating material conforms to design and is not changed without engineering evaluation and approval. Control of sub-tier suppliers and verification of incoming Tin plating material to assure it conforms to design requirements. Controls to assure traceability of Tin plating material during manufacturing activities
Dimensions	Manufacturing processes such as forming, stamping, cutting, punching, plating	Controls that assure fabricated terminals meet design requirements such as statistical process control, in-process inspections, and post production tests and inspections
Plating configuration	Manufacturing controls over plating process Inspections to assure quality of plating process	Controls to assure consistency of plating process such as statistical process control, in-process inspections, and post production tests and inspections

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Figure G-6 (Continued)
Joliet Plant survey planning worksheet

Attachment 1

Joliet Plant Survey Planning Worksheet CGSP-2013-089

Critical Characteristic	Process(es) that influence / impart Critical Characteristic	Supplier Controls to be Evaluated during the Commercial Grade Survey
Insulating Material	Design Control of materials Procurement of materials Inspection/verification materials meet design requirements Control of materials during manufacturing	Controls that assure insulating sleeve material conforms to design and is not changed without engineering evaluation and approval. Control of sub-tier suppliers and verification of incoming insulating sleeve material to assure it conforms to design requirements. Controls to assure traceability of insulating sleeve material during manufacturing activities
Dielectric Strength of Insulation Material	Design Control of materials Procurement of materials Inspection/verification materials meet design requirements Control of materials during manufacturing	Dielectric strength testing performed on insulation material Controls that assure insulating sleeve material conforms to design and is not changed without engineering evaluation and approval. Control of sub-tier suppliers and verification of incoming insulating sleeve material to assure it conforms to design requirements. Controls to assure traceability of insulating sleeve material during manufacturing activities

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Figure G-6 (Continued)
Joliet Plant survey planning worksheet

Attachment 2

Excerpts from Juliet Plant Survey Report CGS-2013-003

"Supplier quality performed a commercial grade survey of BCP Industries terminal manufacturing facility in city, ST the week of March 19, 2013. The survey was conducted in accordance with a survey planning worksheet provided by Juliet Plant Procurement Engineering (CGSP-2013-089, Rev. 0 dated February 27, 2013."

"The scope of the survey included manufacture of Pre-Insulated Sure Grip (PISG) Terminal connectors included in BCP Industries Catalog 63. Ring, slotted ring, spade, flanged spade, splices, and barrel connectors."

"The following conclusions were noted with respect to control of the critical characteristics included in the scope of the survey."

Critical Characteristic	Conclusion
Base Material	Base Copper material for PISG terminals (lug and sleeve) is effectively verified in accordance with BCP Material Inspection Instruction MI-CU-0519 Rev. 2 prior to use and controlled per BCP QA Procedure 2009-0412 Rev. 1. No changes to material are permitted without engineering evaluation and Engineering Directive BCP-PE-DIR-319, Rev. 8 requires a part number change if design is altered.
Plating Material	Plating (Tin) material is verified in accordance with BCP Material Inspection Instruction MI-TIN-0519 Rev. 2 prior to use and the material is controlled per BCP QA Procedure 2009-0412 Rev. 1
Dimensions	Dimensions of PISG terminals are effectively controlled in accordance with BCP statistical process control instructions 101338 Rev. S and 092825 Rev D.
Plating thickness and consistency	Application of plating is controlled in accordance with BCP Plating Instruction 610822 Rev. 5 that includes provisions for statistical process control during the plating process as well as inspection of finished product.
Insulating Material	Although insulating material is procured from a single supplier, no additional routine testing or inspection is performed to verify the material composition.
Dielectric Strength of Insulation Material	Although dielectric strength testing was performed to establish product specifications, no additional routine dielectric strength testing is performed.

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Figure G-7
Excerpts from the Joliet Plant survey report

H
TRACEABILITY

H.1 Traceability

Traceability focuses on an item’s genealogy and the compilation of product data generated throughout the procurement and dedication process. The NRC defines *traceability* in IP 43004 as:

> The ability to verify the history, location, or application of an item by means of recorded identification. Traceability to the manufacturer is required when the manufacturer is relied upon to verify one or more critical characteristics [26].

Traceability provides the means to locate and review items and associated documentation in the future as well as a means to comply with regulatory requirements, such as reporting defects and noncompliance and pressure vessel registration.

Traceability must be maintained for a commercial-grade item once it has been accepted for use as a basic component. Suppliers performing commercial-grade dedication, therefore, must have traceability to every nuclear facility or customer to whom they have supplied items that could create a substantial safety hazard. When a utility performs the commercial-grade item dedication and the item has a defect or failure to comply that could create a substantial safety hazard in accordance with 10CFR, Part 21 [4], the utility must be able to trace the location of all of the dedicated items in the plant.

H.2 Traceability Prior to Acceptance

Maintaining traceability prior to acceptance of a commercial-grade item is not a regulatory requirement. However, maintaining some form of traceability from receipt of items until commercial-grade dedication is complete is a good practice. Implementing item traceability early in the dedication process is essential to maintaining an effective material control program.

Varying types of traceability exist. For example, when a commercial-grade item is ordered, a form of traceability is established simply by issuance of a purchase order that identifies the item’s part number and a product description. In cases where the procurement documents do not include traceability requirements, traceability to the purchase order and line item number is the initial type of traceability for items undergoing the dedication process. When a commercial-grade item or a lot of items is received at the dedicating entity’s facility, additional layers of traceability are added by association with numbered receipt inspection reports and production/shop travelers to control work throughout the dedication process. These activities are typically identified and controlled for each purchased lot of items. In cases involving large equipment, they may be identified and controlled for each item. As the dedication process continues, traceability to additional dedication data collected by means of test and inspection reports, nonconformances, and so forth is maintained.

To ensure compliance to 10CFR21 [4], a very specific traceability number must be assigned to an individual item. This unique identifier may be assigned at any time in the dedication process. Some programs assign this unique code, number, or serial number at receipt, or it may be assigned at the completion of the dedication process. The degree and type of traceability prior to an commercial-grade item becoming a basic component are essentially a cost/benefit decision for both suppliers and licensees and may take on many forms as defined by the dedicating entity's 10CFR50, Appendix B [7] QA program.

H.3 Types of Traceability

The term *traceability* is used in many different contexts. The following are types of item traceability:

- Identification to the original part manufacturer (that is, the actual manufacturer of the piece-part)
- Identification to the original part manufacturer and a specific heat number, batch number, or production lot
- Identification of an item to a purchase order and line item
- Identification to the authorized distributor that supplied the part
- Identification to the component manufacturer that supplied the part
- The ability to identify where a dedicated item has been installed in the plant
- Identification using a paper trail of all of the suppliers involved in the procurement process (such as the original part manufacturer, distributor, OEM, third parties, and other utilities)

H.4 Imposing Traceability Requirements on Suppliers

The decision about the type of traceability required is ultimately the responsibility of the dedicating entity. In determining the type of traceability to be imposed on a supplier for a given item, the following factors should be considered:

- Method of acceptance
- Need for traceability should a problem investigation be required
- Ability to obtain traceability
- Quantity of procured items
- Criticality of the procured items
- Cost

The type of traceability desired should be clearly specified in procurement documents.

I
QUALIFICATION VERSUS DEDICATION

I.1 Qualification

Criterion III of 10CFR50, Appendix B, requires that measures be established for the selection and review for suitability of application of materials, parts, equipment, and processes that are essential to the safety-related functions of the SSCs [7].

Appendix A of 10CFR50 [5] requires that SSCs important to safety be designed to withstand the effects of natural phenomena (earthquakes, tornadoes, and so forth) and accommodate the effects of environmental conditions. Additional information on qualification requirements can be found in documents such as 10CFR50.49 [104] and RG 1.100 [105].

In this context, the word *qualification* is used to describe the process that establishes suitability of an item’s design to function during applicable design basis events and postulated service conditions (for example, loss-of-coolant accidents, high-energy line breaks, and seismic or other vibration conditions) that might subject it to seismic forces and harsh environmental conditions, such as humidity, radiation, chemical spray, extreme temperatures, and so forth.

I.2 Dedication Is Not Qualification

Qualification is an activity undertaken to verify that a component’s design is suitable for the intended nuclear power plant application. The suitability of design must be established prior to initiating procurement of the item. In other words, the technical evaluation and acceptance activities involved in dedication are not substitutes for design; they cannot be used to change the design of a given item, nor are they a means to verify the suitability of a given design.

One of the basic premises derived from the definition of *dedication* in 10CFR21 [4] is that dedication is an acceptance process. The dedication acceptance process is used to provide reasonable assurance that the component/part supplied can perform the same safety function as the design that was qualified. This is accomplished by verification of the critical characteristics, including environmental and seismic-related ones, associated with those safety functions. Dedication of commercial equipment, parts, or materials includes verification of characteristics necessary to maintain the previously qualified design.

I.3 Maintaining Seismic and Environmental Qualification

As discussed in Section 6.6, if a commercial-grade item is intended for installation in a seismically or environmentally qualified application or component, the dedicating entity shall be reasonably assured that, once installed, the item will not adversely affect the original qualification of the component.

I.3.1 Harsh Environment Qualification

For devices requiring environmental qualification, the identification and verification of appropriate material properties should be considered for nonmetallic items, such as lubricants, O-rings, gaskets, seals, and packing. The use of improper nonmetallic material could result in material decomposition, degradation, and failure after exposure to harsh environments. Material properties typically include chemical composition (verification of material type), physical properties, and so forth.

I.3.2 Mild Environment Qualification

The threshold of radiation, temperature, and humidity deterioration for nonmetallic materials is normally above the level encountered in a mild environment. Thus, material verification based solely on environmental considerations may not be necessary for nonmetallic commercial-grade items installed in components located in a mild environment. However, material of construction may still be a critical characteristic based on the item's safety function. In addition, the need for material verification should be evaluated if the material is critical from a functional standpoint (for example, potential degradation of an incorrect material by lubricants) or when the parent component is subject to environmental qualification requirements.

I.3.3 Seismic Qualification

The dedicating entity should reasonably ensure that the commercial-grade items will not adversely affect the original seismic qualification of the parent component in which they are intended for installation. Reasonable assurance for a simple metallic item can typically be achieved by verifying appropriate material properties (chemical and/or physical) and dimensions. Verification of these characteristics will generally ensure that the mass, distribution of mass, and the strength of the item are conforming to the item's design requirements.

For more complex items, modifications made to internal piece-parts may result in a redistribution of mass. Changes in assembly or types of materials should also be considered for complex items. These modifications could all adversely affect the way in which the item reacts during a seismic event. Therefore, the verification of design controls, modifications to internal part characteristics, and assembly procedures should be considered if maintaining seismic qualification is an issue. Additional information on maintaining the seismic qualification of complex items is included in EPRI Report TR-1112579, *Critical Characteristics for Acceptance of Seismically Sensitive Items (CCASSI)* [24].

Although the scope of nuclear facility components subject to environmental qualification requirements is relatively narrow, the scope of components subject to seismic qualification requirements is relatively broad. Consequently, EPRI developed guidance in the report *Guidelines for the Seismic Technical Evaluation of Replacement Items for Nuclear Power Plants (STERI)* (NP-7874) [81] to ensure that replacement activities will not degrade the seismic adequacy of an item or its host. The STERI process is not limited to a specific plant design, but it explicitly excludes design changes and modifications.

EPRI also developed standalone generic seismic evaluations for commonly replaced items, most of which could be considered commercial grade items, through selected implementation of the STERI guidance. This generic STERI (G-STERI) methodology is an ongoing effort and evaluates items on more of a class basis using data from qualification tests, other seismic tests, earthquake experience, and engineering analyses. G-STERI addresses only equivalent replacement items and not new seismic qualification needed for design changes. The G-STERI guidance is contained in EPRI 1016694, *Plant Support Engineering: Generic Seismic Technical Evaluations of Replacement Items for Nuclear Power Plants, Item Specific Evaluations – TR-105849, Rev.* 1 [82].

I.4 Qualification Conducted Independently from Commercial-Grade Item Acceptance

Similarity between the commercial-grade item dedication acceptance process and the process used to perform qualification of equipment has resulted in dedicating entities attempting to use one process to accomplish the objectives of both. This practice is inappropriate because it could result in inadequately qualified equipment or specification of unnecessary acceptance requirements.

Equipment qualification is a part of the design process covered under 10CFR50, Appendix B, Criterion III [7], which demonstrates that an item exhibits design characteristics that allow it to function or survive a set of environmental conditions and/or seismic spectra. This can be demonstrated through testing of a prototype, engineering analysis of a prototype, or by historical performance demonstrated by an item of the same design under corresponding parameters.

The technical evaluation process translates the design criteria established under Criteria III into procurement specifications as delineated in Criterion IV of 10CFR50, Appendix B [7]. When the design criterion for the plant application contains equipment qualification requirements, these requirements are translated in the procurement specification along with any other technical and performance criteria. When the specified item meets the commercial-grade item definition, performance of commercial-grade acceptance is the transition point from Criteria IV to “Control of Purchased Items” described in 10CFR50, Appendix B, Criterion VII [7].

The commercial-grade acceptance process as described in this report is the same when used to accept an item where the application has equipment qualification requirements as it is for applications that do not. The purpose of commercial-grade item acceptance is to provide reasonable assurance that an item meets specified requirements. Therefore, equipment qualification requirements simply become an input to the commercial-grade acceptance process when the selection of critical characteristics is performed. The design characteristics that relate to the equipment qualification requirements must be considered when critical characteristics are selected. Testing or other acceptance methods used in achieving reasonable assurance that an item meets specified requirements do not necessarily demonstrate that an alternative item (not identical to the original or current design) is adequate with respect to its equipment qualification. The adequacy of design of an alternative item can be determined only through the design modification/control requirements contained in 10CFR50, Appendix B, Criteria III [7] and/or as described in EPRI reports 1008256 [25], *Guidelines for the Technical Evaluation of Replacement Items in Nuclear Power Plants*, and NP-7484, *Guideline for the Seismic Technical Evaluation of Replacement Items for Nuclear Power Plants* [81].

Table I-1 illustrates the distinct difference between these two processes.

Table I-1
Equipment qualification versus commercial-grade item dedication for equipment subject to environmental and/or seismic qualification requirements

	Equipment Qualification	Commercial Grade Item Dedication
Regulatory basis	10CFR50, Appendix B, Criterion III [7]; 10CFR50.49 [104]; U.S. NRC RG 1.100 [105]; 10CFR100 [106]	10CFR50, Appendix B, Criterion VII [7], 10CFR21 [4]
Guidance	IEEE 344 [107] IEEE 323 [76]	EPRI 3002002982 (this report), U.S. NRC GL 91-05 [19]
Provides	Assurance that the equipment is adequate for applications involving harsh environmental and seismic conditions	Reasonable assurance that the item received is capable of performing its intended safety-related function
Basic method	Testing, analysis, or historical demonstration that an equipment design is suitable for its intended application	Verification of selected critical characteristics
Results	Qualification report resulting from testing, analysis, or historical demonstration	Documented commercial-grade item technical evaluation and acceptance plan

J
ELECTRICAL TEST METHODS AND APPLICATIONS

J.1 Precautions

Table J-1 provides general information intended to provide basic insights into test methods and typical applications. The information provided can be used as an aid in selecting tests that are appropriate for certain critical characteristics. However, Table J-1 is not intended to be used as a "cookbook" and is certainly not a substitute for consulting with subject matter experts in testing and materials. The information provided is not a full academic description of each test, nor does it capture all of the variables affecting the test. Test standards referenced in the table are typical. It is important that test standards selected for use are appropriate for the facility and the item being tested. Applicability of typical testing standards referenced in the tables should be confirmed prior to specifying their use. When unsure, appropriate subject matter experts should be consulted to determine what test to perform and how to evaluate the test results.

Table J-1
Electrical test methods

Type of Item	Test Equipment Used	Typical Indication of Characteristics	Destructive to the Sample?	Notes
Fuse	Digital low-resistance ohmmeter Circuit breaker or relay test set (or any capable current source) Timing device	Fuse resistance (document lot homogeneity) Hold in Clearing per specifications	Yes, but only fuses selected for clearing	Circuit breaker or relay test set if available allows streamlined testing.
Capacitor	LCR meter Digital multimeter AC or dc power source Timing device	Capacitance and leakage current at rated working voltage per specifications.	No	Sometimes date codes are overlooked. Ensure that shelf life has not expired. May elect to reform based on age.
Resistor	Digital multimeter Power supply capable of supplying required voltage and current Digital low-resistance ohmmeter	Resistance value, power capacity	No	Post power capacity test is typically resistance verification and visual for heat damage.
Semiconductors	Curve tracer or Calibrated data acquisition equipment	Transistor: breakdown voltage, saturation voltage, cutoff current, current gain Diode: forward voltage at rated current, reverse leakage current, reverse breakdown voltage	No	Look for counterfeit items, especially if surplus suppliers are used for purchases. See the EPRI report *Counterfeit, Fraudulent, and Substandard Items* [28].

Table J-1 (Continued)
Electrical test methods

Type of Item	Test Equipment Used	Typical Indication of Characteristics	Destructive to the Sample?	Notes
Fuse	Digital low-resistance ohmmeter Circuit breaker or relay test set (or any capable current source) Timing device	Fuse resistance (document lot homogeneity) Hold in Clearing per specifications	Yes, but only fuses selected for clearing	Circuit breaker or relay test set if available allows streamlined testing.
Switch contact block	Digital low-resistance ohmmeter Current source Insulation resistance tester Timer	Contact resistance Contact configuration (NO/NC) in all switch positions Contact operation (make before break, break before make, and so on) if applicable Insulation resistance (contact-to-contact, contact-to-ground)	No	n/a
Switch assembly (including sensor/actuating devices, that is, temperature, pressure, vacuum)	Pressure source, digital low-resistance ohmmeter, insulation resistance tester, digital multimeter	Switch characteristics plus pressure boundary integrity, switch set point actuation	No	n/a
Cable	Insulation resistance tester Digital multimeter	Continuity and insulation resistance	No	Test at degrade, nominal, and overvoltage. Immerse sample in saline solution and insulation resistance test when wet.
Lamp	Power supply Digital multimeter	Illumination and current draw	No	n/a

Table J-1 (Continued)
Electrical test methods

Type of Item	Test Equipment Used	Typical Indication of Characteristics	Destructive to the Sample?	Notes
Relay	Digital low-resistance ohmmeter, current source Voltage source, capable of supplying the relay coils rated voltage and current Insulation resistance tester Timer Digital multimeter Relay test set	Coil resistance Coil (current draw) Contact resistance/configuration (check all NO and NC contacts in de-energized and energized condition) Insulation resistance (contact-to-contact, coil-to-contact, contact-to-ground, coil-to-ground) Pickup at nominal voltage Pickup at undervoltage (application specific criteria) Pickup at overvoltage (application specific criteria) Dropout (for electromechanical relay in particular)	No	n/a

It is important to recognize that multiple characteristics and verifications beyond material composition may be required depending on the safety function. Therefore, it is of utmost importance that the critical characteristics and verification methods be based on the intended safety function and that selection tools, such as Table J-1, not be used as a “cookbook” for developing technical evaluations.

Note that seismic and harsh environment critical characteristics are not included in Table J-1.

K
MECHANICAL TEST METHODS AND APPLICATIONS

K.1 Precautions

Tables K-1 through K-4 provide general information intended to provide basic insights into test methods and typical applications. The information provided can be used as an aid in selecting tests that are appropriate for certain critical characteristics. However, the tables are not intended to be used as “cookbooks” and are certainly not substitutes for consulting with subject matter experts in testing and materials. The information provided is not a full academic description of each test, nor does it capture all of the variables affecting the test. Test standards referenced in the tables are typical. It is important that test standards selected for use are appropriate for the facility and the item being tested. Applicability of typical testing standards referenced in the tables should be confirmed prior to specifying their use. When unsure, appropriate subject matter experts should be consulted to determine what test to perform and how to evaluate the test results.

It is important to recognize that multiple characteristics and verifications beyond material composition may be required based on the safety function. For example, in addition to material of construction, strength (imparted by processes such as heat treatment) may be critical for shafts or rods used to transmit motive force. In this case, a test such as hardness or tensile may be required in addition to verification of material. The surface finish of the shaft may also be a critical characteristic if the shaft needs to hold lubricant. Therefore, it is of utmost importance that critical characteristics and verification methods be based on the intended safety function and that selection tools such as Tables K-1 through K-4 not be used as “cookbooks” for developing technical evaluations.

K.2 Terminology

The following are the intended meanings for terms used in Tables K-1 through K-4:

- **qualitative**. The identification of the constituents of a substance/alloy without regard to the quantity of each element.
- **quantitative**. The identification of not only the constituents but also the quantity of each element that makes up the substance/alloy.
- **semiquantitative**. The identification of the constituents of a substance/alloy with some quantification but not at the accuracy of a full chemical analysis technique.

Table K-1
Material verification: ferrous and nonferrous metal

Type of Test/Exam	Primary Use	Types of Uses	Destructive to the Sample?	Notes or Limitations
Magnet test	Sorting of some alloys. Provides some indication of the material type, but must be used in conjunction with other tests or inspections to make a valid determination.	A magnet test in conjunction with visual inspection and density or weight may provide an indication that a nonmagnetic material is a non-cold-worked 300 series, aluminum, copper alloy, or titanium. Most ferrous alloys, 400 series stainless steels, cold-worked 300 series stainless steel, nickel, and cobalt alloys are magnetic. A magnet test in conjunction with portable X-ray fluorescence could help identify if the material is a non-cold-worked 300 series, aluminum, copper alloy, or titanium.	No	Used alone, a magnet test will not provide conclusive evidence of material composition. When used in combination with another test or inspection, a magnet test may be useful to sort two known materials where one is magnetic and the other is nonmagnetic. A sorting tool that does not produce any quantitative chemical analysis results. This test can be performed in the field or laboratory.

Table K-1 (Continued)
Material verification: ferrous and nonferrous metal

Type of Test/Exam	Primary Use	Types of Uses	Destructive to the Sample?	Notes or Limitations
Spark testing (use grinding wheels of various compositions to metallic materials to identify materials by color and morphology of sparks)	Sorting of some alloys. Provides some indication of the material type, but must be used in conjunction with other tests or inspections to make a determination.	Can identify alloy groups but does not provide confirmation of chemical composition.	Yes, because the surface is ground. This may not be critical on a vessel or frame but would probably be unacceptable to highly machined or moving parts.	Although proven accurate, spark testing must be performed by a highly qualified individual with significant training and experience in holding grinding wheels against a sample of metal and differentiating the color of sparks, length of spark lines, and characteristics of the ends of the spark lines. When used in combination with another test or inspection, a spark test may be useful to sort known materials. A sorting tool that does not produce any quantitative chemical analysis results. This test can be performed in the field or laboratory.

Table K-1 (Continued)
Material verification: ferrous and nonferrous metal

Type of Test/Exam	Primary Use	Types of Uses	Destructive to the Sample?	Notes or Limitations
Chemical spot tests	Sorting of some alloys. Provides some indication of the material type, but must be used in conjunction with other tests or inspections to make a determination.	Can identify alloy groups but does not provide confirmation of chemical composition. If extensive testing is used, you may be able to distinguish material types (304, 316, 310) but will not confirm that the material complies with the specification requirements.	Yes, because the surface is chemically attacked. This may not be critical on a vessel or frame but would probably be unacceptable to highly machined or moving parts.	Use of a prepared kit with battery and dilute acids is safer than raw chemicals, but care still must be taken with these hazardous chemicals. This test can be performed in the field or laboratory.
Positive material verification: X-ray fluorescence	Sorting of some alloys. Semiquantitative chemical analysis of some elements and a search of its available internal alloy library will produce alloy identification.	Can identify some alloy type and produce semiquantitative chemical analysis for certain elements.	No.	Most units do not detect elements lower than atomic number 16 (Si, Al, C). The detection is of the surface and should not be used for the bulk alloy determination if a coating or surface modification has been performed. Inversely, because it is a surface analysis technique, it can be used to identify some coatings or plating. This test can be performed in the field or laboratory. This apparatus usually requires a calibration and then standardization before use.

Table K-1 (Continued)
Material verification: ferrous and nonferrous metal

Type of Test/Exam	Primary Use	Types of Uses	Destructive to the Sample?	Notes or Limitations
Optical emission spectrographic analysis	Quantitative chemical analysis of metals, which can be used to identify the specific type and grade of material and determine if they met the specification.	Produces fully quantitative chemical analysis for comparison to specification requirements. Capabilities depend on the number of standards available (curves for each element) in the test equipment's library.	Yes. The surface is melted. This may not be critical on a vessel or frame but would probably be unacceptable to highly machined or moving parts.	Usually a laboratory instrument, but there are also portable systems that require considerable hardware and, usually, protective gas shielding. The curves for this instrument must be constructed with known standards and then a standardization before use is required. A type standard of the same alloy group is advisable to improve accuracy and reliability.

Table K-1 (Continued)
Material verification: ferrous and nonferrous metal

Type of Test/Exam	Primary Use	Types of Uses	Destructive to the Sample?	Notes or Limitations
Scanning electron microscope	Imaging or microchemical analysis, which, with standards and proper surface preparation, can be fully quantitative. Usual operation is standardless and therefore semiquantitative. The usual identification is for elemental analysis of inorganic materials because all of the organics are seen as carbon.	Imaging of surface features for fractography and the determination of the failure mode, quantitatively measure features percentages and size. Also used for semiquantitative determination of corrosion contaminants in pits or cracks for failure mode and particulate or contamination microchemical analysis.	No. Nondestructive if small enough to fit in the chamber. Destructive if sample is larger than the chamber.	Laboratory device for metallic or nonmetallic materials. If the sample is nonconductive, some high-vacuum scanning electron microscopes require sputtering of the surface with a conductive material. Some variable-pressure scanning electron microscopes do not require the conductive sputter coating. Usual chemical analysis is for elemental composition and does not determine the compounds present. This apparatus is only for laboratory use and requires calibration of both chemical lines and pixel dimension.

Table K-1 (Continued)
Material verification: ferrous and nonferrous metal

Type of Test/Exam	Primary Use	Types of Uses	Destructive to the Sample?	Notes or Limitations
Mechanical testing	Determines mechanical properties for comparison with specification requirements.	Determines whether fabrication methods or heat treatments were performed properly to get required strength and whether material can be fabricated as expected. Determine if service exposure has changed mechanical properties.	Yes for most tests except hardness.	Mechanical properties can vary with orientation and through the thickness; therefore, consult the test specifications before removing samples. A portable hardness testing apparatus is available, but most hardness testers have specific surface and mass requirements. All other tests are only for laboratory use.
Tensile		Determines the ultimate strength of a material under relatively slow straining.	Yes.	A flat or round sample is machined out of the component with specific requirements on the dimensions and is pulled to failure. The load at failure is recorded, and the pounds per square inch of section size are calculated.

Table K-1 (Continued)
Material verification: ferrous and nonferrous metal

Type of Test/Exam	Primary Use	Types of Uses	Destructive to the Sample?	Notes or Limitations
Yield		Determines when a material starts to yield or change in length and cross-section. The yield point is the point at which if the load is taken off it will not return to its original condition but some plastic deformation has occurred.	Yes.	A flat or round sample is machined out of the component with specific requirements on the dimensions and is pulled with an instrumentation (extensometer) attached to record the load versus strain. This graph is analyzed for specific criteria—usually, 0.2% offset strain from the elastic modulus line.
Elongation and reduction in area		Determines the material's ability to deform and stretch before failure.	Yes.	A flat or round sample is machined out of the component with specific requirements on the dimensions and is pulled to failure. The amount of linear stretch and the reduction in cross-sectional area are measured.
Bend		Determines the material's ability to be deformed without visible cracking.	Yes.	A roughly machined sample is bent around specified anvils to 180°, and the bend is visually evaluated to see if cracking occurred. This is also a standard test for evaluating weld procedures and welder qualifications.

Table K-1 (Continued)
Material verification: ferrous and nonferrous metal

Type of Test/Exam	Primary Use	Types of Uses	Destructive to the Sample?	Notes or Limitations
Impact		Determines how a material responds to dynamic loading.	Yes.	A specified sample is machined, and a notch or other specified stress riser is machined in the sample. A dynamic load is imposed, and instrumentation evaluates the material's response to the load and how the fracture occurs.
Fracture or toughness		Determines how a material responds to a notch or pre-crack under strained loading.	Yes.	A specified sample is machined, and a notch or other specified stress riser is machined in the sample. A dynamic load is imposed, and instrumentation evaluates the material's response to the load and how the fracture occurs.
Hardness/microhardness		Determines the material's resistance to a loaded indenter. The hardness also relates to the material's tensile strength. Can also be used to measure the hardness of surface treatments and to evaluate coatings.	Yes, if the macrohardness of the bulk or cross-section is wanted. Minimally if a microhardness of the surface is measured. This may not be critical on a vessel or frame but would probably be unacceptable to highly machined or moving parts.	The surface of the sample is important and must be considered. It is especially important, and there are critical surface roughness requirements for microhardness measurements. This testing can be performed in the laboratory or in the field.

Table K-1 (Continued)
Material verification: ferrous and nonferrous metal

Type of Test/Exam	Primary Use	Types of Uses	Destructive to the Sample?	Notes or Limitations
Spring constant		Determines the elastic behavior of a spring.	No.	The spring is loaded, and the linear deflection is measured.
Creep and stress rupture		Determines the mechanical behavior to a time-dependent straining, usually at elevated temperatures.	Yes.	A machined sample is instrumented and strained, usually for long times and at elevated temperature. The creep rate or straining with time is measured and used in engineering calculations. Additionally, if the test is taken to failure, the stress rupture strength and elongation can be measured.
Fatigue		Determines the material's response to cyclic loading as a function of load.	Yes.	A machined sample is loaded, and the load is cycled on and off to determine the cycles to failure at different loads. This is typically termed *high-cycle low stress* or *low-cycle high stress*.

Table K-1 (Continued)
Material verification: ferrous and nonferrous metal

Type of Test/Exam	Primary Use	Types of Uses	Destructive to the Sample?	Notes or Limitations
Chemical analysis: wet chemistry or wet instrumental analysis, including inductive coupled plasma, mass spectrometer.	Quantitative chemical analysis of metals, which can be used to identify the specific type and grade of material and determine if they met the specification.	Produces fully quantitative chemical analysis for comparison to specification requirements.	Yes.	The sample must be put into solution, then chemical or instrumental analysis is performed. These techniques are very accurate for trace levels. In the case of instrumental analysis for major concentrations, elemental interferences may result; therefore, only reliable, experienced laboratories with the alloys in question should be used.

Table K-2
Material verification: nonmetallic

Type of Test/Exam	Primary Use	Types of Uses	Destructive to the Sample?	Notes or Limitations
Infrared spectrometer (Fourier transform infrared [FTIR])	Identification of specific type and grade of organic material.	Determine the type of polymer, elastomeric, or oil. Usually for qualitative confirmation versus compositional analysis.	Yes	Usually compound identification and not quantitative, except where standards are used. Laboratory test.
Wet chemistry: selective ion electrode, ion chromatography	Quantitative chemical analysis of material, which can be used to identify the specific type and elements and determine if they meet the specification.	Produces fully quantitative chemical analysis for comparison to specification requirements. Evaluate trace elements in materials.	Yes	Sample must be put into solution, and elemental interferences can result; therefore, only reliable experienced laboratories should be used.

Table K-2 (Continued)
Material verification: nonmetallic

Type of Test/Exam	Primary Use	Types of Uses	Destructive to the Sample?	Notes or Limitations
Mechanical testing	Determine mechanical properties for comparison to specification.	Determines if the manufacturing methods were performed properly to get required properties.	Yes	Usually requires destructive testing to obtain specimens for testing. Mechanical properties can vary with orientation and through the thickness. Therefore, consult test specifications before removing samples. All of these tests are performed in the laboratory.
Tensile	—	Determines the ultimate strength of a material under relatively slow straining.	Yes	A sample (machined in some cases) is pulled to failure, and the load at failure is recorded.
Compression strength	—	The ability of the material to resist the force that tends to crush or buckle. The maximum compressive load sustained by the specimen divided by the original cross-sectional area of the specimen.	Yes	n/a
Flexural strength	—	The property of a material when the sample is subject to transverse bending force perpendicular to its longitudinal axis producing shear and tensile stresses.	Yes	n/a

Table K-2 (Continued)
Material verification: nonmetallic

Type of Test/Exam	Primary Use	Types of Uses	Destructive to the Sample?	Notes or Limitations
Hardness/durometer	—	Determines the material's resistance to a loaded indenter.	Yes	The surface of the sample is important and must be considered. It is especially important, and there are critical surface roughness requirements for microhardness measurements.
Shear	—	Shear strength measures a material's response to a force that tends to produce a sliding failure on a material along a plane that is parallel to the direction of the force.	Yes	n/a
Torque	—	Torque testing is the tendency of a force to rotate an object about an axis.	Yes	n/a

Table K-3
Material verification: oils and lubricants

Type of Test/Exam	Primary Use	Indication of Characteristics	Destructive to the Sample?	Notes or Limitations
Optical emission spectroscopy	Metal analysis identification of the specific type and grade of material. This compositional analysis is for the elements soluble in the oil but does not tell the composition of the particulate in the oil.	Produces fully quantitative chemical analysis for comparison to specification requirements. Can determine if materials are wearing or inhibitors are being lost.	Yes	ASTM D6595
Viscosity	A measure of the internal resistance of flow for a sample.	Viscosity measurement at 40°C, 100°C. Viscosity Index calculation.	No	ASTM D445
Neutralization number	Determines the oxidation level of the sample.	Determines acid or base content of sample.	Yes	ASTM D664/D4739
Karl Fisher moisture analysis	Determines the amount of water contamination.	Determines amount of moisture present in ppm.	Yes	ASTM D6304
Flash point	Temperatures at which a heated sample causes a flash and then combustion.	Necessary to know for safe use of lubricant.	Yes	ASTM D92
Cone penetration	Used to determine NLGI grade of grease.	Useful for identifying grease type.	Yes	ASTM D217
Dropping point	Temperatures where grease passes from a semisolid to liquid state.	Useful for identifying grease type.	Yes	ASTM D566
Particle count	Determines cleanliness level of sample.	Comparison against specifications or to trend for preventive maintenance or problem solving.	Yes	ISO 4406

Table K-3 (Continued)
Material verification: oils and lubricants

Type of Test/Exam	Primary Use	Indication of Characteristics	Destructive to the Sample?	Notes or Limitations
FTIR: grades from spectral analysis perspective	Determines if the compounds in the oil or grease for an unknown match a known.	Useful to compare against specifications or to compare knowns vs. unknowns.	Yes	ASTM E-1252
Scanning electron microscope: analyze particulate in oils	By filtering the oil, the scanning electron microscope/EDS can determine the elemental analysis and morphology for the filtered particulate.	Determines if wear or contamination is occurring in the component using the oil.	No	—

Table K-4
Material verification: fuels

Type of Test/Exam	Primary Use	Indication of Characteristics	Destructive to the Sample?	Notes or Limitations
Biodiesel	Determines the amount of biodiesel in diesel oil. Test method that covers the determination of the content of fatty acid methyl esters biodiesel in diesel fuel oils.	The oil sample is examined by FTIR, and the percent bioconstituents is determined and reported for comparison to site requirements.	Yes	ASTM D7371 and EN 14078
Specification for diesel fuel	Outlines the specifications for seven grades of diesel fuel oils used in various types of diesel engines.	Comparison against specifications or to trend for preventive maintenance or problem solving.	Yes	ASTM D975

Table K-4 (Continued)
Material verification: fuels

Type of Test/Exam	Primary Use	Indication of Characteristics	Destructive to the Sample?	Notes or Limitations
Flash point	Determination of the flash point of petroleum products in the temperature range of 40–360°C by a manual Pensky-Martens closed-cup apparatus.	Comparison against specifications or to trend for preventive maintenance or problem solving.	Yes	ASTM D93
Water and sediment	This test method describes the laboratory determination of water and sediment in fuel oils in the range of 0–30% volume by means of the centrifuge.	Comparison against specifications or to trend for preventive maintenance or problem solving.	Yes	ASTM D1796
Distillation	Test method that covers the atmospheric distillation of petroleum products by distillation to determine quantitatively the boiling range characteristics of such products as light and middle distillates in diesel fuels and biodiesel blends.	Comparison against specifications or to trend for preventive maintenance or problem solving.	Yes	ASTM D86
Kinematic viscosity	Measures a fluid's resistance to flow.	Comparison against specifications or to trend for preventive maintenance or problem solving.	No	ASTM D445
Ash content	Measures the amount of ash-forming material present in a petroleum product.	Comparison against specifications or to trend for preventive maintenance or problem solving.	Yes	ASTM D482

Table K-4 (Continued)
Material verification: fuels

Type of Test/Exam	Primary Use	Indication of Characteristics	Destructive to the Sample?	Notes or Limitations
Sulfur content	Determines the total sulfur content in petroleum products by energy-dispersive X-ray spectroscopy.	Comparison against specifications or to trend for preventive maintenance or problem solving.	No	ASTM D4294
Copper strip corrosion	The copper strip corrosion test is designed to assess the relative degree of corrosivity of a petroleum product.	Comparison against specifications or to trend for preventive maintenance or problem solving.	Yes	ASTM D130
Cloud point	The temperature at which dissolved solids are no longer completely soluble in diesel or biodiesels and form a cloudy appearance.	Comparison against specifications or to trend for preventive maintenance or problem solving.	Yes	ASTM D2500
Cetane Index	This test method covers the Calculated Cetane Index formula, which represents a means for directly estimating the ASTM cetane number of distillate fuels from API gravity and mid-boiling point. It is a substitute for the cetane number of diesel fuel.	Comparison against specifications or to trend for preventive maintenance or problem solving.	Yes	ASTM D976

Table K-4 (Continued)
Material verification: fuels

Type of Test/Exam	Primary Use	Indication of Characteristics	Destructive to the Sample?	Notes or Limitations
API gravity at 15°C	Determines the density, relative density (specific gravity), or API gravity of petroleum products. An important quality indicator for fuels, where it affects storage, handling, and combustion.	Comparison against specifications or to trend for preventive maintenance or problem solving.	No	ASTM D1298
Carbon residue	Method that determines the amount of carbon residue left after evaporation and pyrolisis of an oil. Intended to provide some indication of relative coke-forming propensity.	Comparison against specifications or to trend for preventive maintenance or problem solving.	Yes	ASTM D524
Particulate contamination	A gravimetric measurement of the particulate matter present in a sample of fuel oil. Minimizing contaminants helps avoid filter plugging and other operational problems.	Comparison against specifications or to trend for preventive maintenance or problem solving.	Yes	ASTM D5452
Acid number	This test method covers procedures for the determination of acidic constituents in petroleum products, lubricants, biodiesel, and blends of biodiesel.	Comparison against specifications or to trend for preventive maintenance or problem solving.	Yes	ASTM D664/D974

Table K-4 (Continued)
Material verification: fuels

Type of Test/Exam	Primary Use	Indication of Characteristics	Destructive to the Sample?	Notes or Limitations
Heat content (Btu)	This test method covers the determination of the heat of combustion of liquid hydrocarbon fuels.	Comparison against specifications or to trend for preventive maintenance or problem solving.	Yes	ASTM D240
Lubricity	This test method covers the evaluation of the lubricity of diesel fuels using a high-frequency reciprocating rig. The lubricity of a fluid is evaluated by the wear scar, in microns, produced on an oscillating ball from contact with a stationary disk immersed in the fluid operating under defined and controlled conditions.	Comparison against specifications or to trend for preventive maintenance or problem solving.	Yes	ASTM D6079
Existent gum	Test method for determining the gum content in fuels. It has been proved that high gum can cause induction-system deposits and sticking of intake valves.	Comparison against specifications or to trend for preventive maintenance or problem solving.	Yes	ASTM D381 (Steam Jet)
Oxidation Stability	This test method is used to describe the ageing behavior of fuels during transport and storage.	Comparison against specifications or to trend for preventive maintenance or problem solving.	Yes	EN 15751

Table K-4 (Continued)
Material verification: fuels

Type of Test/Exam	Primary Use	Indication of Characteristics	Destructive to the Sample?	Notes or Limitations
Karl Fisher Water	This test method covers the direct determination of water in the range of 10 to 25,000 ppm entrained water in petroleum products and hydrocarbons using automated instrumentation.	Comparison against specifications or to trend for preventative maintenance or problem solving.	Yes	ASTM D6304
Heat of Combustion	This test method determines the heating value (BTU) value and can be expressed as a higher and lower heating value.	Comparison against specifications or to trend for preventative maintenance or problem solving.	Yes	ASTM D-1405, D4862

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Electric Power Research Institute
3420 Hillview Avenue, Palo Alto, California 94304-1338 • PO Box 10412, Palo Alto, California 94303-0813 USA
800.313.3774 • 650.855.2121 • askepri@epri.com • www.epri.com