



Department of Energy

Washington, DC 20585

October 21, 2011

MEMORANDUM FOR DISTRIBUTION

FROM: TRACY P. MUSTIN
PRINCIPAL DEPUTY ASSISTANT SECRETARY
FOR ENVIRONMENTAL MANAGEMENT

SUBJECT: Office of Environmental Management Guidance Documents for
Commercial Grade Dedication and Integrating Quality Assurance
During the Design and Construction Life Cycle

This memorandum serves to provide two Office of Environmental Management (EM) guidance documents that were developed as part of the EM Quality Assurance (QA) Corporate Board. Both Commercial Grade Dedication (CGD) and Integration of QA during Design have been high priority topics that have presented challenges recently for EM. The attached documents will help EM overcome those challenges and succeed in completion of our cleanup efforts.

Many suppliers that previously supported the construction of commercial nuclear power plants have discontinued maintenance of their nuclear grade quality programs. As a result, EM construction and operational projects have had to rely more on the procurement of components by purchasing commercial grade items and dedicating them for safety-related use. As part of this realization, the Office of Standards and Quality Assurance, developed, organized, and delivered a series of CGD training courses across the EM complex for Federal and contractor personnel. This effort significantly enhanced EM's ability to perform proper dedications, but the need for a guidance document to provide specific information was identified as part of the effort.

Similarly, integration of QA during design has been identified as a potential challenge within EM projects. In response, EM issued an Interim Policy establishing the Code of Record concept for EM nuclear facilities. A Code of Record serves as a management tool and source for the set of requirements that are used to design, construct, operate, and decommission a nuclear facility over its lifespan. Early establishment and lifecycle maintenance of applicable facility requirements are essential to provide for the protection of our workers, the public, and the environment. Again, the need for a guidance document to provide specific information was identified as part of the effort.

The EM QA Corporate Board accepted the challenge to develop the two referenced EM guidance documents and has provided a final product that has been approved by the Corporate Board. This development included input from both Federal (Headquarters and field elements) and Energy Facilities Contractor Group (EFCOG) QA staff members. While these documents do not constitute technical direction or contractual requirements, the information provided was developed in cooperation with both Federal and contractor organizations and represents an agreement on the expectations and best practices for successful completion of our EM work. The guidance documents are intended to be used internally by EM at this time, but please feel free to



share them with your colleagues and counterparts from other Agencies who may find some benefit from their use. The documents can also be found on our EM QA Corporate Board website at (<http://www.em.doe.gov/Pages/QACorporateBoard.aspx>).

If you have any further questions, please contact me or Mr. Robert Murray, Director, Office of Standards and Quality Assurance at (202) 586-7267 or robert.murray@em.doe.gov.

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U.S. DEPARTMENT OF ENERGY
OFFICE OF ENVIRONMENTAL SAFETY AND
QUALITY

GUIDANCE FOR COMMERCIAL GRADE DEDICATION
September 2011

FOREWORD

This Guide provides an acceptable process (Commercial Grade Dedication [CGD]) for EM facilities and projects to dedicate an item¹ or service that performs a nuclear safety function that was not manufactured, developed, or performed under a qualified American Society of Mechanical Engineers (ASME) NQA-1 Quality Assurance program. This Guide also provides guidance for the development of the associated documentation supporting the dedication activity.

CGD is an acceptance process performed in accordance with ASME NQA-1a-2009, Subpart 2.14 (ASME NQA-1) or ASME NQA-1-2004 with addenda through 2007, to provide reasonable assurance that an item or service will successfully perform its intended safety function and, in this respect, is deemed equivalent to an item or service provided under the requirements of ASME NQA-1.

The need for this Guide was recognized by EM-23, Office of Standards and Quality Assurance, following events at various EM facilities. Contractors across the EM complex have procedures or guidance documents on CGD based on ASME NQA-1 requirements and Electrical Power Research Institute guidelines. However, these documents vary widely from site to site. While the existing procedures and guidance documents are appropriate in some cases, individual prime contractors' or sub-tier supplier/fabricator/developers' implementing procedures may not have all the attributes that EM management considers important, including a reasonable degree of consistency or standardization. This Guide is a consolidation of the best existing practices from both the EM Complex and from the commercial nuclear industry and should be used as a companion document to the EM-approved CGD training.

This Guide has been developed with a technical content and level of detail intended to be applicable to safety Structures, Systems, and Components (SSCs), computer program(s) credited with safety functions, or safety computer program(s) at EM nuclear facilities and is approved for use by all DOE EM organizational units and contractors performing work for EM. This Guide should be applied in a manner that fits the specific procurement activity. This Guide can be applied either to new or existing facilities, systems, and activities.

It is the expectation of senior EM management that this Guide should be implemented for CGD. In the event that it is not, the burden of showing equivalency with the content of ASME NQA-1 requirements thus ensuring proper dedication of procured services and items falls entirely on the procuring organization. This Guide discusses the preferred way to meet EM expectations and requirements. This Guide does not modify or create any new requirements; instead, it explains how to satisfy existing requirements.

¹ DOE O 414.1D, 7.g, defines item to include software

Note: NQA-1a-2009 is used throughout this document. Reference to this version of NQA-1 does not constitute a change to any contractual requirements that specify earlier versions of NQA-1. Contractors will continue to implement the existing contractual requirements.

Definitions

These definitions are intended to provide a common set of terms for use in this Guide while retaining consistency of these terms with other standards and guidance currently used in nuclear applications. Where a definition is derived from an applicable consensus standard or other guidance document, the reference for the definition is provided in brackets.

Acceptance - The employment of methods to produce objective evidence that provides reasonable assurance that the Commercial Grade Item/Commercial Grade Services (as modified from source) received is the item specified. [EPRI NP-5652, “Guideline for the Utilization of Commercial Grade Items in Nuclear Safety Related Applications (NCIG-07)”]

Acceptance Criteria - Specified limits placed on the performance, results, or other characteristics of an item, process, or service defined in codes, standards, or other requirement documents. [American Society of Mechanical Engineers NQA-1a-2009, “Quality Assurance Requirements for Nuclear Facility Applications”]

Approved Supplier - A supplier whose quality assurance system has been evaluated and found to meet the owner’s quality assurance requirements for the item or service to be purchased. [IEEE STD-934]

Bounding Conditions - Parameters that envelop the normal, abnormal, and accidental environmental conditions an item is expected to meet during its lifetime in the plant (e.g., temperature, humidity, radiation, seismic response spectra). [EPRI Report NP-6046S, “Guidelines for Technical Evaluation of Replacement of Items in Nuclear Power Plants”]

Certificate of Conformance (C of C) - A document signed or otherwise authenticated by an authorized individual certifying the degree to which items or services meet specified requirements. [ASME NQA-1a-2009, “Quality Assurance Requirements for Nuclear Facility Applications”]

Certified Material Test Report (CMTR) - A document attesting that the materials are in accordance with specified requirements, including the actual results of all required chemical analyses, tests, and examinations. [EPRI Report TR-102260, “Supplemental Guidance for the Application of EPRI Report NP-5652 on the Utilization of Commercial Grade Items”]

Commercial Grade Item (CGI) - A structures, systems, and components, or part thereof that affects its safety function that was not designed and manufactured in accordance with the requirements of ASME NQA-1-2004. [ASME NQA-1-2004, “Quality Assurance Requirements for Nuclear Facility Applications”]

A structure, system, or component, or part thereof, that affects its safety function(s) that was not designed and manufactured in accordance with the requirements of this standard. [ASME NQA-1a-2009, Subpart 2.14]

Commercial Grade Services (CGS) - A service that is not provided in accordance with the requirements of ASME NQA-1-2004. [ASME NQA-1-2004, “Quality Assurance Requirements for Nuclear Facility Applications”]

A service that was not provided in accordance with the requirements of this Standard that affects the safety function(s) of a basic component. [ASME NQA-1a-2009, Subpart 2.14]

Commercial Grade Survey –Activities conducted by the purchaser or its agent to verify that a supplier of commercial grade items controls, through quality activities, the critical characteristics of specifically designated commercial grade items, as a method to accept those items for safety-related use. [EPRI NP-5652, “Guideline for the Utilization of Commercial Grade Items in Nuclear Safety Related Applications (NCIG-07)”]

Note: This is not an ASME NQA-1 Supplier Qualification Audit

Commodity Item² - An item having a generic application that lends itself to bulk procurement (e.g., nuts, bolts, materials, o-rings, gaskets, indicator lights, fuses, relays, resistors). [EPRI Report TR-102260, “Supplemental Guidance for the Application of EPRI Report NP-5652 on the Utilization of Commercial Grade Items”]

Computer Program^{3,4,5} - A combination of computer instructions and data definitions that enables computer hardware to perform computational or control functions. [ASME NQA-1a-2009]

Credible Failure Mechanism: - The manner by which an item may fail, degrading the item’s ability to perform the component/system safety function under evaluation. [IEEE std. 500-1984,] [EPRI Report TR-102260, “Supplemental Guidance for the Application of EPRI Report NP-5652 on the Utilization of Commercial Grade Items”]

Critical Characteristics – Important design, material, and performance characteristics of a commercial grade item or service that, once verified, will provide reasonable assurance that the item or service will perform its intended safety function. [ASME NQA-1a-2009, Subpart 2.14]

² DOE O 414.1D includes software in its definition of item. That definition is used as a basis for this guide.

³ Computer programs covered by this definition are those used for:

- Design analysis
- Operations or process control, or
- Data base or document control registers when used as the controlled source of quality information for a) or b) above.

⁴ This definition has been copied from ANSI/IEEE 610.12-1990, *Glossary of Software Engineering Terminology*, with the permission of IEEE.

⁵ To the extent that computer programs are a physical part of plant systems (e.g., digital reactor protection system, digital instrumentation) they are included in the term item.

Critical Characteristics for Acceptance (CCFA) - Identifiable and measurable attributes of an item or service that, when verified, will provide reasonable assurance that the item/service received is the item specified. [EPRI Report NP-5652]

Critical Characteristics for Design (CCFD) - 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 an item which provides assurance that the item will perform its design function. [EPRI Report NP-6406]

Dedication - An acceptance process performed in accordance with ASME NQA-1-2004 to provide reasonable assurance that an item or service will successfully perform its intended safety function and, in this respect, is deemed equivalent to an item or service provided by an ASME NQA-1 qualified vendor. This process includes the identification of Critical Characteristics for Acceptance and their verification by one or more of the dedication methods. [ASME NQA-1-2004, "Quality Assurance Requirements for Nuclear Facility Applications"]

An acceptance process performed in accordance with ASME NQA-1a-2009, Subpart 2.14 to provide reasonable assurance that a commercial grade item or service will perform its intended safety function and, in this respect, is deemed equivalent to an item or service designed and manufactured or provided under the requirements of ASME NQA-1a-2009, Subpart 2.14. This assurance is achieved by identifying the appropriate critical characteristics (Critical Characteristics for Acceptance) of the item or service and verifying their acceptability by inspections, tests, or analyses performed by the purchaser or third-party dedicating entity after delivery, supplemented as necessary by one or more of the following: commercial grade surveys; production inspections or witness at hold-points at the manufacturer's facility, and analysis of historical records for acceptable performance. In all cases, the dedication process must be conducted in accordance the applicable provisions of NQA-1a-2009, Part 1. [ASME NQA-1a-2009, Subpart 2.14]

Dedicating Entity - The organization performing the dedication process. [ASME NQA-1-2004, "Quality Assurance Requirements for Nuclear Facility Applications"]

The organization performing the dedication process. Dedication may be performed by the manufacturer of the item, a third-party dedicating entity, or by the facility. [ASME NQA-1a-2009, Subpart 2.14]

Equivalency evaluation – A technical evaluation performed to confirm that a replacement item (not identical to the original) can satisfactorily perform its intended functions, including its safety functions. [ASME NQA-1a-2009, Subpart 2.14]

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. [ASME NQA-1a-2009, Subpart 2.14]

Identical item – An item that exhibits the same technical and physical characteristics (physically identical). [ASME NQA-1a-2009, Subpart 2.14]

Item – An all-inclusive term used in place of appurtenance, assembly, component, equipment, material, module, part, structure, product, computer program(s) (computer program; added by author), subassembly, subsystem, system, unit, or support systems. [DOE O 414.1D, “Quality Assurance”]

Like-for-Like Replacement – The replacement of an item with an item that is identical. [ASME NQA-1a-2009, Subpart 2.14]

Parts - Items from which a component is assembled, such as resistors, capacitors, wires, connectors, transistors, tubes, lubricants, O-rings, and springs. [EPRI Report TR-102260, “Supplemental Guidance for the Application of EPRI Report NP-5652 on the Utilization of Commercial Grade Items”]

Post-Installation Tests - Activities conducted after installation of a Commercial Grade Item to verify required Critical Characteristics for Acceptance prior to placement in operation. An element of the “Special Tests and Inspection” method to accept an item for use in safety functions. [EPRI Report TR-102260, “Supplemental Guidance for the Application of EPRI Report NP-5652 on the Utilization of Commercial Grade Items”]

Reasonable Assurance: - A justifiable level of confidence based on objective and measurable facts, actions, or observations which infer adequacy. [EPRI Report TR-102260, “Supplemental Guidance for the Application of EPRI Report NP-5652 on the Utilization of Commercial Grade Items”]

Safety and Hazard Analysis Software and Design Software - Software that is used to classify, design, or analyze nuclear facilities. This computer program(s) is not part of a structure, system, or component but helps to ensure the proper accident or hazards analysis of nuclear facilities or a structure, system, or component that performs a safety function. [DOE O 414.1D, “Quality Assurance”]

Safety-class structures, systems, and components (SC SSC). Structures, systems, or components, including portions of process systems, whose preventive and mitigative function is necessary to limit radioactive hazardous material exposure to the public, as determined from the safety analyses. [10 CFR 830]

Safety Function – The performance of an item or service necessary to achieve safe, reliable, and effective utilization of nuclear material processing. [ASME NQA-1a-2009, “Quality Assurance Requirements for Nuclear Facility Applications,” (Modified for DOE EM use)]

Note: A function that is necessary to prevent or mitigate a release of radioactive material in an accident scenario as discussed in DOE-STD-3009-94, Revision 3.

Safety Management and Administrative Controls Software - Software that performs a hazard control function in support of nuclear facility or radiological safety management programs or technical safety requirements or other computer program(s) that performs a control function necessary to provide adequate protection from nuclear facility or radiological hazards. This computer program(s) supports eliminating, limiting, or mitigating nuclear hazards to workers, the public, or the environment as addressed in 10 CFR 830, 10 CFR 835, and the DEAR ISMS clause. [DOE O 414.1D, “Quality Assurance”]

Safety-significant structures, systems, and components (SS SSC). Structures, systems, and components which are not designated as safety-class SSCs but whose preventive or mitigative function is a major contributor to defense in depth and/or worker safety as determined from safety analyses. [10 CFR 830]

Safety Software – Safety system software, safety and hazard analysis software and design software, and safety management and administrative controls software. [DOE O 414.1D, “Quality Assurance”]

Safety Structure, System, or Component – Both safety class SSCs and safety significant SSCs. [10 CFR 830.3, “Nuclear Safety Rule, Sub-part A, Quality Assurance Requirements”]

Safety System Software – Software for a nuclear facility² that performs a safety function as part of a structure, system, or component and is cited in either (a) a DOE approved documented safety analysis or (b) an approved hazard analysis per DOE P 450.4, “Safety Management System Policy,” dated October 15, 1996, and the DEAR clause. [DOE O 414.1D, “Quality Assurance”]

Sample - A sample consists of one or more units of product drawn from a lot with the units of the sample being selected at random without regard to their quality. The number of units of product in the sample is the sample size. [EPRI TR-017218-R1, “Guideline for Sampling in the Commercial-Grade Item Acceptance Process, January 1999”]

Sample Plan - A plan developed to determine the definition of appropriate lot and sample size(s) in order to achieve reasonable assurance that the sample size chosen provides an adequate representation of the item(s) quality. [EPRI TR-017218-R1, “Guideline for Sampling in the Commercial-Grade Item Acceptance Process, January 1999,” Established from General Discussion]

Service - The performance of activities such as design, fabrication, inspection, nondestructive examination, repair, or installation. [ASME NQA-1-2004, “Quality Assurance Requirements for Nuclear Facility Applications”]

Source Verification - Activities are witnessed at the supplier's facilities by the Buyer, or its agent, to verify that a supplier of a Commercial Grade Item/Commercial Grade Service controls the critical characteristics. (Method 3) [EPRI NP-5652]

Special Tests and Inspections - Activities conducted during or after receipt of a Commercial Grade Item to verify one or more critical characteristics. (Method 1) [EPRI NP-5652]

Standard Receipt Inspection - Activities conducted upon receipt of items, including Commercial Grade Items, in accordance with ASME NQA-1a-2009 to check such elements as the quantity received, part number, general condition of items, and damage. [EPRI NP-5652 (Modified for DOE EM use)]

Supplier - An individual or organization who furnishes items or services in accordance with a procurement document. An all-inclusive term used in place of any of the following: vendor, seller, contractor, fabricator, consultant, and their sub-tier levels. [ASME NQA-1a-2009, “Quality Assurance Requirements for Nuclear Facility Applications”]

Technical Evaluation - An evaluation performed to assure that the correct technical requirements for an item are specified in a procurement document. [EPRI NP-5652]

Traceability - The ability to trace the history, application, or location of an item and like items and activities by means of recorded identification. [ASME NQA-1-2004, “Quality Assurance Requirements for Nuclear Facility Applications”]

1. INTRODUCTION

Over the past 20 years, accompanying the cessation of commercial utilities' nuclear construction activities, the number of suppliers maintaining a Quality Assurance (QA) program that meets the requirements of the American Society of Mechanical Engineers (ASME) NQA-1 has contracted severely. In many cases, suppliers/developers concluded that continuing business orders were inadequate to justify the costs associated with maintaining a strict QA program that met ASME NQA-1 requirements. Additionally, the use of digital technology has raised concerns over the potential for common cause failure resulting from computer program errors, the effects of Electromagnetic Interference on digital computer-based systems (e.g., different frequency ranges), and the use and control of equipment for configuring computer-based systems.

The U.S. Department of Energy (DOE), Office of Environmental Management (EM) has been pursuing construction of non-reactor nuclear facilities in order to perform the safe clean up of the EM Complex. These new nuclear facilities contain a subset of safety Systems Structures and Components (SSC) that are required to demonstrate that they can, with reasonable assurance, perform their safety functions on demand to either prevent or mitigate an accident condition.

DOE O 414.1D, "Quality Assurance," specifies that consensus standards be used for implementation of QA program requirements. It is EM policy⁶ that ASME NQA-1-2004, "Quality Assurance for Nuclear Facility Applications" (including addenda through 2007) will be used to support EM nuclear facilities (allowing for variance requests to earlier versions of NQA-1). ASME NQA-1-2004, states that items or services that provide a safety function will be provided and/or performed under an ASME NQA-1 QA program or be commercial grade dedicated to ASME NQA-1 requirements.

On October 8, 2010, EM issued a memorandum⁷ on the use of ASME NQA-1-2008 with the 2009 Addenda for issuance and implementation of the EM QA program. The memorandum stated that those sites that choose to implement the ASME NQA-1-2008 with the 2009 addenda as the basis for implementation of the EM Corporate QA Program are not required to obtain a variance or exemption. The review of the ASME NQA-1-2008 with the 2009 addenda concluded that the enhancements in the standard do not result in any additional risks to the quality of EM work, products or services. Information from ASME NQA-1-2008 with the 2009 Addenda has been used as the basis for this Guide.

⁶ The Office of Environmental Management (EM) Corporate Quality Assurance (QA) Program (EM-QA-001), issued in November 2008

⁷ Dr. Steve Krahn, Deputy Assistant Secretary for Safety and Security Program, Environmental Management, to Distribution, *Use of NQA-1-2009 Addenda for Issuance and Implementation of the Office of Environmental Management Quality Assurance Program*, Dated October 8, 2010.

As EM's construction of new non-reactor nuclear facilities increases with limited numbers of suppliers who have approved ASME NQA-1 programs, additional reliance is placed on Commercial Grade Dedication (CGD) to ensure parts and services can be procured that will have a reasonable assurance of meeting their safety function. These new non-reactor nuclear facilities are being designed using commercial computer program(s) applications with many of their safety functions controlled by Instrumentation and Control systems. Purchasing Commercial Grade Items (CGI) and services and verifying they are capable of performing specified safety functions (i.e., dedicating them – hence CGD) is one way of obtaining the needed items and services. Many contractors to the EM Complex have some mechanism that allows CGD to take place. The various processes are lacking in uniformity with regard to both classes of items and services allowed to be dedicated and methods for dedication. This Guide will establish consistency in the methods employed and the outcome of the process.

2.0 PROCESS DESCRIPTION

A facility procuring an item or service that supports a nuclear safety function has two options to procure the item or service. The item or service must be either procured or performed subject to the requirements of ASME NQA-1 (appropriate addenda) Part I and II or be commercial grade dedicated in accordance with the requirements of ASME NQA-1 (appropriate addenda). A dedication plan shall be developed for the item or service that identifies the critical characteristics for acceptance and dedication methods, including acceptance criteria. The dedication plan should be developed by engineering with input from QA regarding how selected critical characteristics should be verified. ASME NQA-1 requires that the technical evaluation be performed by engineering. Dedication plans may be developed for a specific item, service, or for a generic group of items or services. Dedication requirements shall be included in applicable procurement and technical documents as necessary to support the dedication.

Suitability of an item or service must be established before CGD of that item or service can be considered. Suitability is determined through the detailed design process where the design inputs and conditions are established and the appropriate item or service is selected. The process may require calculations, analyses, cost benefit evaluations, and other design activities. The design must consider all applicable design requirements including operability, maintainability, fit, form, function, process, interfaces, seismic, environmental, etc. If seismic or environmental qualification is required, it must be established as part of the design process. Only after suitability of a design has been established can the CGD process be implemented. Design verification, as addressed in ASME NQA-1, Requirement 3, is not part of the CGD process.

ASME NQA-1a-2009 states that to utilize a CGI or service, controls shall be implemented to provide reasonable assurance that the item or service will perform its intended safety function. CGD requires:

- A determination that the item or service performs a safety function;

- Confirmation that the item or service meets the applicable CGI definitions;
- A technical evaluation identifying the Critical Characteristics for Design (CCFD), selecting the Critical Characteristics for Acceptance (CCFA);
- Selecting one or more acceptance methods, including development of acceptance criteria, for each CCFA; and
- After acceptance criteria and acceptance methods have been established, the dedicator uses this information to evaluate the item or service to be dedicated.

The goal is to provide reasonable assurance that the CGI or service can perform its intended safety function and is the part or service specified in the procurement documents. Reasonable assurance is established by engineering judgment. That is, a process of reasoning that leads from a stated premise to a logical conclusion. This process should be supported by sufficient documentation to permit verification by a qualified individual.

The word “reasonable” connotes a level of confidence which 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). While these bases are objective and measureable, 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.⁸

Each element of CGD, including responsibilities for implementation, is addressed below in greater detail. Items or services that successfully complete the dedication process are subsequently subject to the controls of Part 1 and Part II of ASME NQA-1a-2009.

The performance of the CGD process shall be on a case-by-case basis. Prior to initiating the CGD process, an estimate of the cost to perform the CGD process should be completed. Then the cost-effectiveness of pursuing CGD as opposed to buying the device from a vendor with an ASME NQA-1 program can be determined. There are also tradeoffs involved in choosing between available commercial devices. It may be more cost effective to select a somewhat higher priced item if the vendor of that device has a better process and will require less costly and/or time consuming supplemental activities by the dedicating entity to dedicate the item.

⁸ EPRI Report TR-102260, *Supplemental Guidance for the Application of EPRI Report NP-5652 on the Utilization of Commercial Grade Items*, Section 2.1.2.2.3.

Applying expertise in the subject matter associated with the item is critical. Procurement personnel may not have this expertise for all items being dedicated. Procurement personnel may need to rely on personnel in the design organization or outside sources for the requisite expertise. Many facilities have found that the procurement and design staffs must work hand-in-hand to reach sound decisions on applying the CGD process for safety applications.

Figure 1 and Appendix C provide an overview of the generic CGD process. These overviews demonstrate how the technical evaluation and acceptance process are applied to perform CGD. It should also be noted that the use of a supplier with an approved ASME NQA-1 program can still result in the need to perform CGD if items or services in support of the ASME NQA-1 procurement are provided by a commercial vendor/supplier. Documentation of the completion of the elements of CGD provides the quality record of the logic for selection of CC to be verified, verification of those CCs, and documentation of acceptance of the item or service.

Overview of the Generic Process

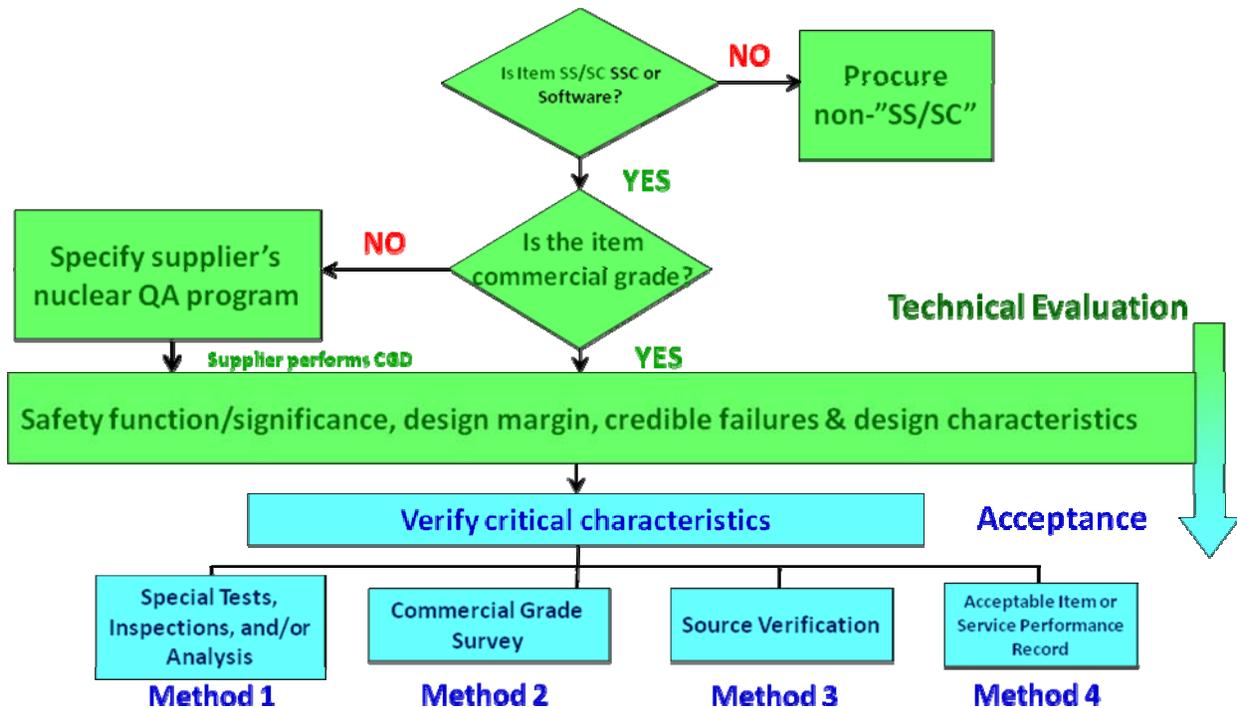


Figure 1: Overview of Generic Commercial Grade Dedication Process

2.1 Commercial Grade Dedication Plan

A CGD plan shall be established early in the CGD process to document the critical characteristics for acceptance, the methods for acceptance of the critical characteristics, and the acceptance criteria. Dedication plans may be developed for a specific item, service, or generic group of items or services. The CGD plan is based on the technical

evaluation. The dedication plan should be developed and approved by the engineering organization responsible for the CGD with input from the QA organization that will be performing the acceptance activity. Actual implementation of this process should be included in the organization's CGD implementing procedures. Dedication requirements shall be included in applicable procurement and technical documents as necessary to support the dedication. Appendix C provides a process flow diagram of the CGD process from the technical evaluation through the development of a CGD plan. The following discussions are provided to assist the dedicator in the performance of the technical evaluation, the development of the CGD plan, and documentation of acceptance of a CGD item or service.

2.1.1 Technical Evaluation

The technical evaluation is the key to effective dedication. The technical evaluation shall be performed by engineering and used to identify and document the safety function of each item/service based on review of the approved safety analysis and supporting data.

Analysis of system and component level safety functions may be required to determine item level safety functions if not discussed in the safety basis. Components that perform a safety function can contain items that do not perform a safety function. Replacement items shall be evaluated to determine their individual safety function in relation to the component or equipment. The dedicator's technical evaluation should also result in an understanding of the overall safety function. Based on this evaluation, the engineer should be able to determine which items/services of the procurement must be procured to ASME NQA-1 requirements or dedicated and which items/services can be procured from a commercial vendor/supplier. EPRI 5652, Appendix B provides additional guidance on part classification that can result in a sub-part within a Safety Class (SC)/Safety Significant (SS) item not providing a safety function and as a result being procured commercially.

The technical evaluation for a CGD item/service should also evaluate the scope and boundary for the item/service's use and whether or not the item is passive or active in performing the safety function. When an item has multiple functions in a facility, the dedicator's technical evaluation should be based on the most severe use of the item. If the technical evaluation does not evaluate the most severe function then controls must be established to ensure that the dedicated item is only used for the evaluated scope.

CGD is performed only on those items that provide a safety function. Design output documents, supplier technical information, and other relevant industry technical and operating experience information, as appropriate, shall be utilized to prepare the technical evaluation. It should be noted that there may be instances in which implementation of a state's (e.g., State of Washington) requirement to implement ASME NQA-1 on a non-safety related item such as an air permit, or the implementation of the Quality Assurance Requirements Document for high level waste, could also require performance of CGD. As such, the Critical Characteristics (CC)

would be those that support the performance of the item to meet program requirements and not the SC/SS safety function.

It is critical to understand that the technical evaluation is based on approved design documents. In order to perform the technical evaluation, suitability activities discussed in Section 2.0 must be complete. For example, for new construction or modifications to facilities, seismic and environmental qualification must be complete in order to have an approved configuration on which to base selection of critical characteristics. A methodical approach to technical evaluations provides thorough, accurate and consistent results. The technical evaluation(s) shall be performed by the responsible engineering organization to:

- Determine the safety function(s) of the item or service;
- Identify performance requirements, the item functional classification, and applicable service/state conditions (seismic and/or environmental) including failure modes analysis;
- Confirm that the item or service meets the commercial grade definition criteria;
- Identify the critical characteristics, including acceptance criteria;
- Identify the dedication method(s) for verification of the acceptance criteria; and
- Determine if a replacement item is a like-for like or equivalent item.

The credible failure modes of an item in its operating environment and the effects of these failure modes on the safety function shall be considered in the technical evaluation for the selection of the critical characteristics. Services shall be evaluated to determine if the failure or improper performance of the service could have an adverse impact on the safety function of equipment, materials, or the facility operations.

If the design criteria for the CGI are known by the dedicating entity, then the item may be dedicated to these criteria in lieu of defining a specific safety function (the design criteria envelope the safety function). In this case, consideration of failure modes is not required and the item's design parameters become the critical characteristics and acceptance criteria. This would be most appropriate when applied to a large number of simple commodity items.

ASME NQA-1 states that when evaluating a replacement item, if the design criteria or safety function of the original item have changed, the replacement item must meet the new design criteria and safety function. Like-for-like and equivalent items are not a design change subject to Part I, Requirement 3, Section 600, "Change Control."

1. **Like-for-Like evaluation**

The term like-for-like was used in Electrical Power Research Institute (EPRI) Report NP-5652 and EPRI Report NP-6406 to describe a procurement scenario in which a minimal technical evaluation is required for a replacement item. ASME NQA-1 defines like-for-like replacement as the replacement of an item with an item that is identical. It further defines “identical item” as an item that exhibits the same technical and physical characteristics (physically identical). If the design, materials, manufacturing processes, and end use of an item are identical to an item or service that has already been accepted and CGD performance issues have not been identified for that item, then ASME NQA-1 states that no further technical evaluation is required. The item must still meet CCFA acceptance criteria established by the initial CGD plan. The like-for-like evaluation is to determine if there is an existing technical evaluation for the item, not an evaluation to determine if an alternate item is acceptable for use in the design. The equivalency evaluation is discussed in Section 2.1.1.2. When considering a like-for-like procurement, the process of achieving a high confidence that the replacement is identical to the original or the process of establishing the degree of engineering evaluation deemed necessary should consider the following:

- Same Manufacturer;
- Complexity of the item;
- Same published product description of the item;
- Supplier performance;
- Adequate supplier design change process to ensure no changes have been made to the design;
- Adequate supplier controls of the manufacturing and procurement process; and
- Supplier reaffirms no changes in material, design, physical characteristics (fit, form), function or inter-changeability.

Items may be considered identical or like-for-like if one of the following applies:

- The item is provided from the original equipment manufacturer (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.

A like-for-like determination shall not be based solely on the selection of a commercial-grade vendor with items manufactured to meet the same industry standards of the original item. Meeting the same industry standards may be a necessary condition, but is not sufficient condition for a like-for-like determination.

If the dedicating entity can demonstrate that the replacement item is identical, then the safety function, design requirements, and critical characteristics need not be re-determined. However, verification of the identified critical characteristics by an appropriate dedication method (s) is required to verify the acceptability of the replacement item.

Computer program(s), including programs embedded in digital equipment, do not wear-out. Generally they are only replaced if the computer program fails to perform as expected or is upgraded to include new functionality. Therefore, a computer program typically is not subject to like-for-like replacement.

2. Equivalent Items

When difference(s) exist from the original item, an equivalency evaluation is required to determine if any changes in design, material, manufacturing process, form, fit, or function could prevent the replacement item from being interchangeable under the design condition of the original items and performing its required safety function.

The equivalency evaluation shall be documented and include the following:

- Identification of the change(s) in design, material, manufacturing process, computer program(s) development process, configuration, form, fit, or function of the replacement item that is different from the original item;
- Evaluation of the change(s); and
- Confirmation that the changes do not adversely affect the current design or safety function of the item.

If the change(s) adversely affects or is not bounded by the current approved design bases, the replacement item is not equivalent and must be rejected or processed as a design change in accordance with Part 1, Requirement 3, section 600, "Change Control." Equivalency can be used for computer program(s) when the computer instructions associated with the safety function and any of the safety functions' interfaces are not changed. This allows for independent non-safety functions to change or computer program(s) tools that assist in the creation of the computer program(s) item (e.g., compilers) to be changed.

Equivalency evaluations can determine the acceptability of the difference in the item to perform its safety function and identify critical characteristics for acceptance for the

replacement item. Equivalency evaluations are not to be used as the sole basis to accept a commercial grade item. Selection and verification of the identified critical characteristics by an appropriate dedication method(s) is required to verify the acceptability of the replacement item.

3. Item/Service Safety Functions

The CGI's specific safety function to be assured must be clearly identified. The safety function includes on-demand performance to prevent or mitigate a nuclear hazardous condition through correct design of safety SSC, proper analysis of credible accident scenarios, and automated management and administrative decisions impacting safety. The safety functions performed by the item or a host component in support of the overall safety function are described in the Documented Safety Analysis for an existing facility, the Preliminary Documented Safety Analysis for a facility under construction, or other safety basis documentation. For systems or complex components it may be that not all subcomponents would impact the safety function. If this is the case, the logic used by engineering for selecting the specific subcomponents to dedicate should be documented.

The safety function is often a subset of the item function. For instance, the function of an instrument may be to maintain the pressure boundary of a pipe system and provide a flow signal, but the safety function may only be to maintain the pressure boundary. For computer program(s) that tracks surveillances of safety SSCs to meet the technical safety requirements, the portion of the computer program(s) that calculates dates based upon past surveillances completed and automatically notifies an engineer to schedule the surveillance would be the safety function, where as the portion of that same computer program(s) that stores the surveillance report may not be part of the safety function. If there is any question as to the safety function, the question should be raised to the responsible engineer to ensure the proper determination of safety function.

4. Environmental and Natural Phenomena Evaluation

The environmental conditions under which a safety function may need to perform over the life of the item, system, or complex component are established during design work and need to be evaluated during the technical evaluation. ASME NQA-1 states that CGI's designated for installation or installed in seismically or environmentally qualified equipment or in locations which require such qualification shall include the selection of appropriate critical characteristics required to maintain the qualification of the component or equipment. For example, environmental conditions such as the presence of high pH, and/or high radiation levels that would result in a negative impact on an item's material characteristics needs to be identified and verified. The expectation for long term performance of a valve seat in a high pH could require a specific material selection and subsequent CCFA. The need to preserve seismic qualifications could also impact material selection and CCFA to ensure that the item will perform as expected relative to the seismic event. Typically, computer programs, including program(s) embedded in digital equipment, do not require an environmental

or natural phenomena evaluation. The computer hardware and other equipment where the computer program(s) resides shall be evaluated for impacts from any environmental or natural phenomena condition.

EPRI TR-102260, Section 2.2.3.2, states that the CGD process as described in EPRI Report NP-5652 is the same when used to accept an item where the application has equipment qualification requirements as it is for applications which do not have equipment qualification requirements. The purpose of CGD acceptance is to provide reasonable assurance that an item meets specified requirements. Therefore, for applications which have equipment qualification requirements, these equipment qualification requirements simply become an input to the commercial grade acceptance process when the selection of critical characteristics for acceptance is performed. The critical characteristics for design which relate to the equipment qualification requirements should be weighted heavily when critical characteristics for acceptance are selected.

2.1.1.5 Item Characteristics

Item characteristics include product identification characteristics and other characteristics that are inherent to the item's design but are not required or used in the purchaser's application to support the safety function. Item characteristics may include characteristics such as;

- Item part number including revision number;
- Software/firmware revision number;
- Dimensions;
- Location of mounting holes or brackets; and
- Color.

2.1.1.6 Critical Characteristics for Design (CCFD)

The CCFD are those design characteristics that are important to the performance of the item which allows the item to perform its safety function and are a subset of item characteristics.

Critical Characteristics for Design

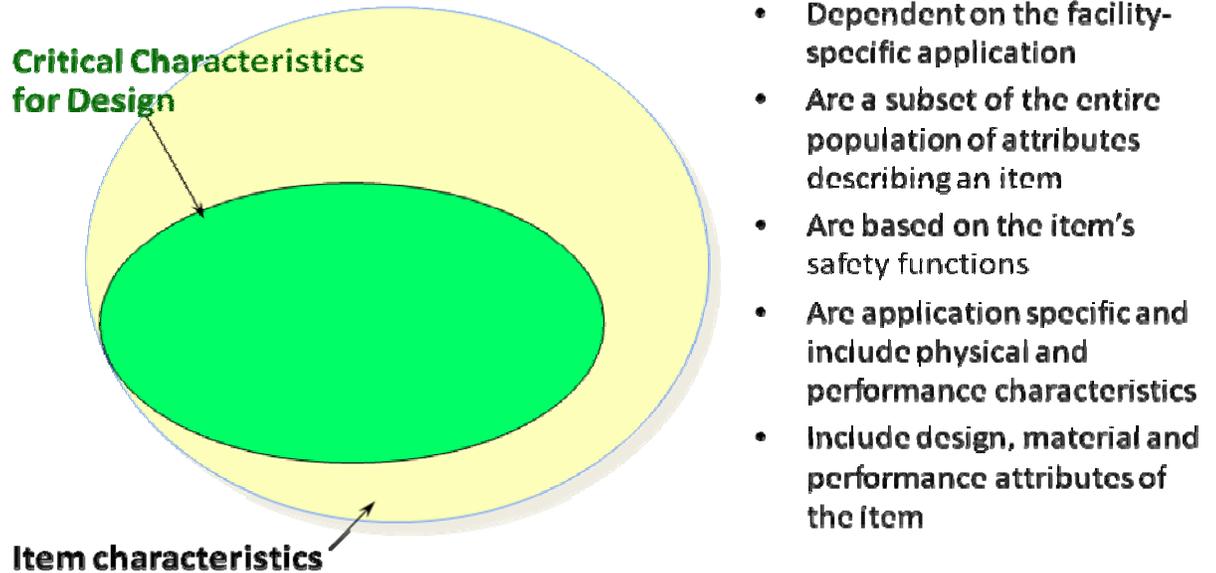


Figure 2: Critical Characteristics for Design

The CCFD normally ties back to the performance of the safety function. 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. Important performance characteristics that do not impact the safety function are also valid CCFD⁹. See Appendix A. In addition to specific design criteria, CCFD is also made up of critical characteristics dealing with performance, material, and reliability where applicable. Not all CCFD that support the safety function must be verified during the dedication process. The selection of CCFD supporting CCFA is discussed in more detail in Section 2.1.1.7 below. Examples of CCFD that could be selected as CCFA for hardware are listed in Appendix A and examples for CCFD that could be selected as CCFA for digital equipment and computer program(s) are listed in Appendix D, Table D-1.

A complete understanding of the item or service specifications is important prerequisite to ensuring the item or service is properly dedicated. Examples of specification include

⁹ EPRI NP 6406, *Guidelines for the Technical Evaluation of Replacement Items in Nuclear Power Plants*, December 1989.

instrumentation, equipment, computer hardware, computer program(s), human-machine interface, quality and reliability requirements. Experience has shown that many of the problems that occur in dedication are due to inadequate understanding/description of the item specification. This is especially true with computer program(s). The design requirements for the intended safety functions and anticipated failure modes factor heavily into ensuring the correct critical characteristics for acceptance are identified. For computer program(s), it is particularly important to identify specifications and design features that are related to unused, and unintended or prohibited functions.

Critical characteristics fall into the three categories: physical, performance, and dependability. Dependability is significant when dedicating digital equipment and computer program(s). The three categories are used to help the reader understand what types of attributes may represent critical characteristics. The names of the categories (physical, performance, and dependability) were selected from an EPRI Guide and chosen simply to be descriptive of the characteristics. The names have no formal significance in themselves.

Physical Characteristics

Physical characteristics include characteristics of the item such as mounting attributes, dimensions, computer file size, manufacturer's part number, and computer program(s)/firmware revision number. Most of these characteristics are verified using inspection and measurement, which fall under Method 1 (Tests and Inspections).

Performance Characteristics

The engineer should, as part of the technical evaluation, determine if there are specific performance expectations that must be met by the item or service to perform the safety function. Examples could include start up and loading time for an emergency diesel generator, closing time for an automatic closing damper, blow-down percent for a relief valve, or operation during normal service conditions. For computer program(s), performance could also include the functionality required of the device (the "must-do" functions) and performance related to this functionality (e.g., response time). Performance CCFD could also include environmental requirements related to the needed performance (e.g., meeting accuracy requirements over a specified range of ambient temperatures).

Performance characteristics also include characteristics related to failure management and "must-not-do" functions. Although applicable to mechanical and electrical systems, failure management is especially applicable to computer program(s). For example, based on a failure analysis, a required behavior of the item under certain abnormal or faulted conditions may be identified in the specifications. This behavior most likely is a critical characteristic that will require verification. Acceptance criteria might include items such as detection of failures, and "preferred" or fail-safe failure modes to be entered under prescribed circumstances. Verification methods may include testing and design reviews, supported by failure analysis and reviews of

operating history. These activities can involve Methods 1 (Tests and Inspections), 2 (Commercial Grade Survey), 3 (Source Verification), and 4 (Supplier/Item Performance Record).

Dependability¹⁰ Characteristics

Dependability characteristics are the category in which dedication of computer program(s) differs from that of other types of items. Dependability addresses attributes that typically cannot be verified through inspection and testing alone and are generally affected by the process used to produce the item. A key issue is that mechanical and electrical item failures are typically associated with fabrication defects, aging and wear-out, but computer program(s) do not wear out. If there is a problem in the computer program(s) that degrades its dependability, this reflects a computer program(s) design defect that was built into the item, or a mismatch between the item specifications and its design.

In traditional dedications of mechanical and electrical equipment, dependability issues have been treated within the supplier's QA program and have been delineated in the commercial grade survey or source inspection plan. Due to the increased importance of the "built-in" attributes to computer program(s), this Guide has defined these attributes as critical characteristics to ensure that they are adequately addressed and documented during the dedication process.

Dependability attributes, such as reliability and built-in quality, are generally influenced by the process and personnel used by the supplier in the design, development, verification, and validation of the item. For computer program-based systems, high quality is best achieved by; building it in, following a systematic life cycle approach from requirements through implementation, with verification and validation steps, and appropriate documentation for each phase of the life cycle. Hence, understanding the vendor's development process can be very useful in developing confidence in the dependability of a product.

The dependability of an item can be heavily influenced by designed-in elements, including robustness of the computer hardware and computer program(s) architectures, self-checking features such as watchdog timers, and failure management schemes such as use of redundant processors with automatic fail-over capabilities. Evaluation of these attributes requires that the dedicator focus on more than just the development and QA processes. It may require gaining an understanding of the specific computer program(s) and computer hardware features embodied in the design, and ensuring that they are correct and appropriate in light of the requirements of the intended application. Accordingly, a survey team may need to include specialists who understand the

¹⁰ The term "dependability" is used in various ways within the software and safety communities. In this document it is used broadly to include a number of characteristics of computer programs such as reliability, availability, built-in quality, and other related characteristics.

computer program(s) and the system in which it will be applied in addition to QA and programmatic issues.

The dependability category captures those critical characteristics that must be evaluated to establish reasonable assurance regarding built-in quality of the item. It also includes characteristics related to problem reporting and configuration control. Verification of these characteristics typically involves a survey of the vendor's processes (Method 2), and review of the vendor performance record and product operating history (Method 4). Source inspections (Method 3) may be used to verify certain computer hardware quality characteristics during manufacture, or to ensure quality of changes made to computer program(s) as part of a particular procurement. Source inspections would not be used in verifying built-in quality of pre-existing computer program(s), because the computer program(s) development has already occurred.

The critical characteristics in the dependability category, including the "built-in quality" characteristic discussed in Appendix D, Table D-1, are somewhat different from those in the other categories because they are less tangible and quantifiable than a part number or a physical dimension. A commercial item may be judged to have sufficient quality, even if its development process lacked some of the rigorous steps of modern computer program(s) engineering and/or some formal documentation. Reaching a reasonable level of assurance of quality of a CGI typically involves making a judgment based on a combination of the item development process and its documentation, operating history, testing, review of design features such as failure management, and other factors noted in the critical characteristics.

The dedicator must determine what activities are appropriate to verify the built-in critical characteristics. In general, the choice and extent of activities undertaken to verify adequate quality, and the specific criteria applied in making the assessment, depend on the safety significance and complexity of the item.

Failure Modes and Effect Analysis

Failure analysis provides information that assists in evaluating and verifying critical characteristics. It is important to understand the failure modes of the commercial device and their impact on the system failure modes. Failure analysis supports CGD as well as design. Consideration of potential failure modes and mechanisms helps to identify critical characteristics. Without an understanding of the item/service failure modes and the effects of failure in its operating environment it can be difficult to discern the impact of a failure on the safety function. ASME NQA-1 states in the technical evaluation general discussion that the credible failure modes of an item in its operating environment and the effects of these failure modes on the safety function shall be considered in the technical evaluation for the selection of the critical characteristics. Services shall be evaluated to determine if the failure or improper performance of the service could have an adverse impact on the safety function of equipment, materials, or the facility operations.

It is incumbent on the engineer to ensure that failure modes are properly developed and evaluated through a suitability review of the item's characteristics for design. Suitability reviews are discussed in Section 2.0. Some common failure modes are listed in Appendix B, Potential Failure Modes, "Examples of Creditable Failure Mechanisms."

2.1.1.8 Critical Characteristics for Acceptance

ASME NQA-1 states that the CCFA shall be identifiable and measurable attributes based on the complexity, application, function, and performance of the item or service for its intended safety function. The CCFA criteria shall include tolerances and computer data input ranges when appropriate. CCFA shall include the part number, computer program(s) version identifier, physical characteristics, identification markings, and performance characteristics, as appropriate. ASME NQA-1 also states that an item's part or catalog number shall be considered a critical characteristic if it provides a method to link the item with the manufacturer's product description and published data.

Critical Characteristics for Acceptance

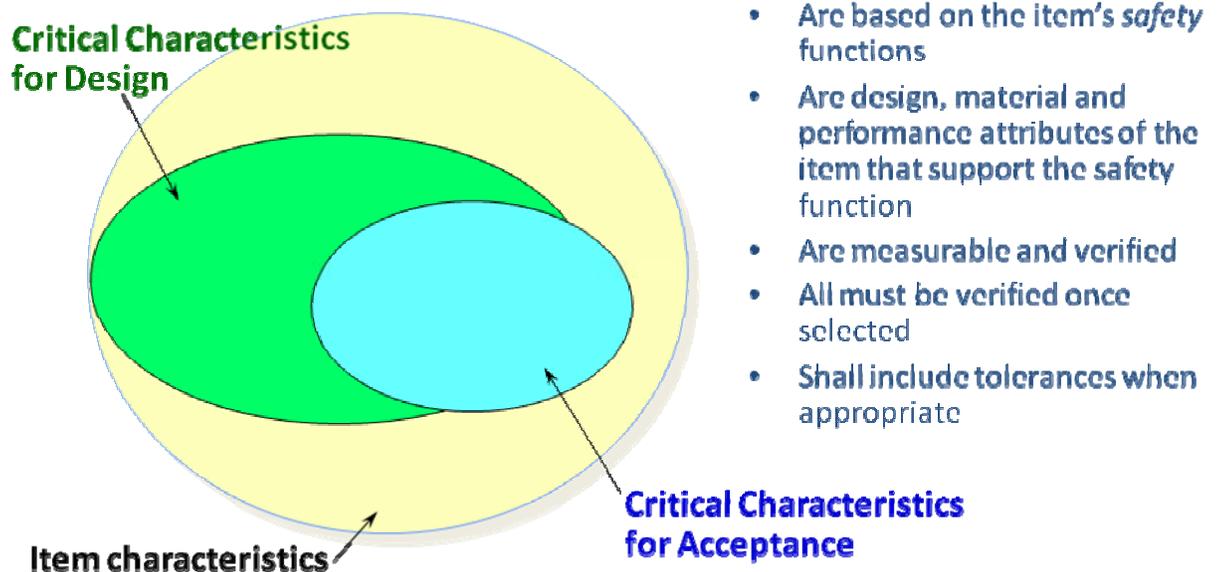


Figure 3: Critical Characteristics for Acceptance

The dedication process shall not rely on the part number or computer program(s) version identifier alone as the only critical characteristic to be verified. CGIs or services can have numerous characteristics that are related to composition, identification, or performance of the item or service. However, it is not normally prudent or fiscally sound to verify all item characteristics and/or CCFD to provide

reasonable assurance that the item or service will perform its intended safety function. The CCFA are those characteristics that one or more of the four acceptance methods discussed in Section 2.2 will be applied to in order to verify acceptability. Both the specific acceptance method and the acceptance criteria will be specified for each CCFA in the dedication package.

Reasonable assurance is considered to have been provided when, in the opinion of the responsible engineer, a sufficient number of CCFD and item characteristics have been verified and documented as CCFA to cause one to believe that the item will be capable of performing its safety function. The level of verification is expected to be graded. Items with less impact to safety or with large design margins may not need as many characteristics verified with as much rigor as items with critical safety importance and/or lower design margin. The following factors should be considered in determining the extent and type of verification to be applied:

- The consequences of malfunction, defect, or failure of the item;
- The complexity or uniqueness of the item;
- The need for special controls over process parameters and surveillance of equipment resulting from use of the item; and
- The degree of standardization of the item.

EPRI 102260 also states that when establishing reasonable assurance the engineer should consider; a) what is the degree of verification of any critical characteristic for acceptance; b) was an adequate sample of items chosen for verification; and c) were the proper critical characteristics for acceptance selected for verification?

Critical characteristics selected for acceptance shall be identifiable and measurable attributes based upon functional complexity and the application and performance of the item or service. Unless controls are in place to prevent usage in undesignated locations, include criteria related to the location/design basis conditions (or manufacturing design limits) of the item in the facility. For computer program(s) the location of the computer hardware and its computer configuration where the computer program(s) is installed may be a CCFA. For acceptance, not all CCFD need to be verified to provide reasonable assurance that the item or service will perform its intended safety function(s). This Guide does not require justification for failure to select a CCFD as a CCFA, however a clear understanding of why the set of CCFA's selected for verification was sufficient to provide reasonable assurance should be documented.

The vendor/supplier's published product description or additional technical information typically identifies technical criteria or performance characteristics inherent in the design and manufacturing or development of the item. The vendor/supplier can employ standard tests or inspections as part of the manufacturing or developing process and utilize a quality program to assure that appropriate controls are applied. This type of

information is an example to be considered in the selection of critical characteristics and the related acceptance criteria.

In cases where the CCFA criteria cannot be determined from the manufacturer's documentation or other documentation, the dedicating entity may perform an engineering evaluation, examination, or test (or any combination thereof) of the original item to develop the CCFA criteria.

Dedication

Engineering performs the selection of acceptance methods as part of the Technical Evaluation and documents the selection in the CGD Plan.

The selection of an acceptance method or combination of acceptance methods for the CCFA of a given CGI or Commercial Grade Services (CGS) should be based on factors such as the selected CCFA, available supplier information, supplier quality history, and degree of standardization.

The dedicating entity shall provide reasonable assurance that the item meets the acceptance criteria for the identified CCFA. The four methods that can be used are:

Method 1 - Special Tests, Inspections, and/or Analyses;

Method 2 - Commercial Grade Survey of Supplier;

Method 3 - Source Verification; and

Method 4 - Acceptable Supplier/Item Performance Record.

The four acceptance methods provide, either individually or in combination, a means to reasonably assure that the CGI/CGS meets the requirements that were specified. The justification for the method(s) selected and the results of employing each method must be documented in the CGD plan.

Prior to classifying the item or service as acceptable to perform its safety function, the dedicating entity shall determine if the following have been successfully performed:

Damage was not sustained to the item during shipment;

The item or service has satisfied the specified acceptance criteria for the identified critical characteristics; and

Specified documentation was received and is acceptable.

The selection of acceptance method(s) shall be planned and based on the type of critical characteristics to be verified, available supplier information, quality history of the item

and the supplier, and degree of standardization. If a critical characteristic cannot be verified by the selected dedication method, the dedication entity may select another or combination of dedication methods to verify the critical characteristics. The selection of another or combination of other dedication methods should be documented in a revision to the CGD Plan including justification for the revision.

The organization that performs or directs the dedication activity and determines the item or service has satisfactorily met the acceptance criteria for the selected critical characteristics is the dedicating entity. The dedicating entity can be the manufacturer/vendor/supplier, a third-party organization, the purchaser, or the nuclear facility organization. In some instances the responsibilities for the technical evaluation and performing the acceptance methods in accordance with the CGD Plan are performed by different organizations. For example, when the supplier does not have design responsibilities, the CCFA are provided by the purchaser/design authority. In this case the purchaser is directing the CGD activity and as such, is the dedicating entity. The ultimate responsibility for CGD is the owner who initiated the procurement.

Third Party Dedication

A third party dedicator is any company other than the original equipment manufacturer or buyer that procures and accepts commercial grade items and supplies the dedicated items as safety-related under their approved QA program¹¹. The purchase order to a third party organization (TPO) from the buyer is a safety-related purchase order. As such, the TPO's ASME NQA-1 program should be evaluated and approved prior to performance of the dedication activity.

The TPO may establish a working or teaming relationship with the original equipment or part manufacturer. This allows the TPO to obtain information on design, technical requirements, and CC for design.

The Buyer can provide the TPO with the technical information needed to accept the commercial grade item. Where design information is not known, the TPO may perform the dedication activities typically by the design organization. When the TPO is an authorized representative for a supplier and has access to the supplier's design information, the TPO may also be responsible for assuring the CGI is like-for-like. If the CGI is equivalent, the TPO can be assigned to assure the item will not degrade the seismic and/or environmental qualification of the host equipment. The TPO's responsibility for like-for-like or equivalent evaluations needs to be clearly specified in the contract.

2.2.2 Method 1 – Special Tests, Inspections, or Analyses

Special test(s), inspection(s), or analyses either individually or in combination shall be conducted upon or after receipt of an item to verify conformance with the acceptance

¹¹ ERPR TR-102260, *Supplemental guidance for the Application of EPRI Report NP-5652*

criteria for the identified critical characteristics. Use of Method 1 solely may be appropriate for the following:

- When the item is simple in design;
- When the computer program(s) does not include functionality beyond the safety functions;
- Commodity items;
- When critical characteristics are able to be verified with tests/inspections;
- Data to verify critical characteristics is available in existing documents such as specifications, drawings, computer program(s) life cycle documents, instruction manuals, bills of material and catalogs;
- Where multiple suppliers of the item exist;
- Items are purchased in small quantities or larger homogeneous lots where sampling can be applied; and
- Items on which post-installation tests can be conducted.

If Method 1 is not appropriate as the only method of acceptance, than it can be used in conjunction with Methods 2, 3, or 4.

Special tests, inspections, and/or analysis may be carried out by third parties (e.g., test labs or third party dedicator) provided they have been approved by the buyer as acceptable for use. Acceptance is either provided by an ASME NQA-1 evaluation and subsequent placement on an approved suppliers list or by survey if not part of an ASME NQA-1 program. In general, the services of an outside testing laboratory should be treated as any other service the user is procuring. Testing laboratories, as other types of suppliers, have a wide range of quality programs which may include 10 CFR 50, Appendix B. When outside services are utilized, the purchaser must have verified that the test laboratory has in place programs and procedures which ensure as a minimum:¹²

Tests are conducted properly and to industry standards (American Society for Testing and Materials [ASTM], etc.);

Test equipment is calibrated and maintained in accordance with manufacturer recommendations;

¹² EPRI TR-102260, *Supplemental Guidance for the Application of EPRI Report NP-5652 on the Utilization of Commercial Grade Items*, Section 2.4.1.2

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; and

Calibration standards are traceable to nationally recognized standards.

Some tests and inspections cannot be performed until after an item is installed. When post-installation test(s) are used to verify acceptance criteria for the critical characteristics, the CGI or CGS shall be identified and controlled to preclude inadvertent use prior to satisfactory completion of the dedication activities.

It is important to the process of implementing Method 1 to understand the difference between standard receipt inspections and/or simple computer program(s) installation checkouts and special tests and inspections performed after receipt. Even though receipt inspection and/or simple computer program(s) installation checkouts are important to the CGD process, they are not adequate on their own for CGD. With that said, it is recognized that while the part number or computer program(s) version identifier are attributes of a receipt inspection, they should also be part of the dedication process for the item. They can be verified during receipt inspection but should be listed as a CCFA.

ASME NQA-1 describes the standard receiving inspection as checking the quantity received, damage, general conditions of items, and part number. For computer program(s) receipt inspections are as simple as checking that the computer program(s) media has not been damaged and that the version identifier(s) are correct. Special tests and inspections go beyond the standard receiving inspection activities to verify that the CCFD selected as a CCFA are met. Example CCFD's that could be verified as CCFA include:

- Material type (chemical make-up);
- Material physical characteristics (e.g., Hardness, yield strength);
- Length;
- Open or closing time;
- Leak rate;
- Computer program(s) version identifier; and
- Computer program(s) application size (e.g., number of KB).

Acceptance Criteria are generally contained in engineering documents held by the organization responsible for the design of the item. This may be the prime contractor's engineering organization, computer program(s) development organization, or a supplier engineering organization, depending on the item. Specific acceptance criteria from the item specifications, design documents, technical codes, or industry standards must be listed in the CGD plan for each CCFA when applicable. Experience has shown that Engineering and QA organizations should be working together during the development of acceptance criteria.

When evaluating the results of the test or inspection, all values tested or inspected must fall within the tolerance or data input range specified in the acceptance criteria. If one or more of the acceptance criteria is not met, the item is documented as nonconforming resulting in an engineering evaluation of the results of the test and/or inspection relative to the item being able to meet the safety function. Other like items should be evaluated to determine if they would exhibit the same nonconformance (i.e., extent of condition)

In addition to performance of a test or inspection by the dedicating entity or third party, the results of tests and inspections performed by the vendor/supplier may be reviewed to establish acceptability if sufficient confidence of the vendor/supplier's performance of the test or inspection is established. This is normally accomplished by performance of a Commercial Grade Survey discussed in Section 2.2.3. The following approach may be used to prepare or review packages for items that are dedicated using Method 1:

- Perform receipt inspections to verify that the associated CCFA have been properly verified;
- Review receiving records and associated supplier tests and inspection results;
- Verify that the tests and inspections specified for acceptance using Method 1 will adequately verify the identified CCFA;
- Verify that sampling plans are controlled and have adequate technical basis, considering lot traceability and homogeneity, complexity of the item, and adequacy of supplied controls;
- Verify that the CGI receiving inspection activities are adequately controlled under a quality program regardless of whether the inspections are being performed in conjunction with other receipt inspection activities;
- Verify that receipt inspection activities establish and maintain traceability of CGIs by capturing and appropriately relating traceability documents through identification and monitoring of CGIs;

- Verify that measuring and test equipment were properly calibrated, that approved third party vendors were used to perform tests, and that personnel were qualified to perform the tests; and
- Ensure results of test performed are documented in test reports.

Where a number of identical items are being dedicated using Method 1, sampling¹³ may be used for the performance of non-destructive and destructive testing to establish reasonable assurance that items received are the items ordered and that they perform their intended safety functions.

Sampling plans used to select items for special tests, inspections, and/or analysis shall have an adequate technical basis based on established standards that consider lot traceability, homogeneity, and complexity of the item. The approved sampling plan is part of an item's CGD package. EPRI Final Report TR-017218-R1, "Guideline for Sampling in the Commercial-Grade Item Acceptance Process," provides an enhanced methodology for the use of sampling in accepting and dedicating CGIs. Use of this EPRI guide provides useful information in establishing the basis for the sampling plan. Sampling plans are discussed in more detail in Section 4.

Services can result in a deliverable product that can be evaluated upon receipt or result in an activity that can be evaluated during or at the conclusion of its performance.

2.2.3 Method 2 – Commercial Grade Survey

The purpose of using a commercial grade survey of a supplier (Method 2) is to dedicate a CGI or CGS based on approval of a suppliers' implementing process and commercial controls as related to the items CCs when ASME NQA-1 is not invoked in the purchase order. The survey of the supplier must be performed and deemed acceptable prior to issuing the purchase order for the item or service. A survey of a supplier may be appropriate:

- When the supplier/manufacture has implemented appropriate, documented commercial controls over the critical characteristics (as verified by the commercial grade survey);
- When multiple items are being procured from the same supplier/manufacturing facility;
- When those items are procured relatively frequently; and
- When critical characteristics are not easily verified after receipt¹⁴.

¹³ Sampling of software is only applicable for software embedded in digital equipment

¹⁴ For CGD of computer programs, frequently, only Commercial Grade Survey can verify some of the critical characteristics. As such, this method will be used in most CGD of computer programs.

The basis of the commercial grade survey is to specifically identify the process controls and their controlling documents used or planned for use during the manufacture or development of the specific CGI. A commercial grade survey is a method to verify critical characteristics by evaluating the adequacy and effectiveness of the supplier/manufacture's commercial quality controls. A commercial grade survey is performed at the supplier/manufacture's facility using a checklist or survey plan developed by the dedicating entity. The survey shall address the following:

- Identification of the item(s), product line, or service included within the scope of the survey;
- Identification of the critical characteristics to be controlled by the supplier;
- Verification that the supplier's processes and quality program controls are effectively implemented for control of the critical characteristics;
- Identification of the survey methods or verification activities performed with results obtained; and
- Documentation of the adequacy of the supplier's processes and controls.

A commercial grade survey shall not be employed as a method for accepting CGIs or CGSs from suppliers with undocumented quality programs or with programs lacking effective implementation of the supplier's own specified processes and controls. After a supplier's specified processes and controls have been determined to be adequate, the dedicating entity shall invoke or reference the verified processes and controls, including revision level, as a part of the purchase order or control requirements for the CGI or CGS and then require the supplier to provide a Certificate of Conformance (C of C) attesting to the implementation of the identified processes and controls. Reliance is placed on the supplier/manufacture to verify critical characteristics during the fabrication process. Commercial grade surveys do not qualify a commercial vendor to ASME NQA-1 requirements.

The following approach shall be used to prepare or review packages for items that are dedicated using Method 2:

- When a CCFA is based on Certified Material Test Reports or C of C, the criteria of ASME NQA-1a-2009, Part I, Requirement 7, Section 503 shall be met. Specifically,
 - The certificate shall identify the purchased material or equipment.
 - The certificate shall identify the specific procurement requirements met by the purchased material or equipment, such as codes, standards, and other specifications. This may be accomplished by including a list of the specific requirements or by providing, onsite, a copy of the purchase order and the

- procurement specifications or drawings, together with a suitable certificate. The procurement requirements identified shall include any approved changes, waivers, or deviations applicable to the subject material or equipment.
- The certificate shall identify any procurement requirements that have not been met, together with an explanation and the means for resolving the nonconformance.
 - The certificate shall be signed or authenticated by a person who is responsible for this QA function and whose function and position are described in the Purchaser's or Supplier's QA program.
 - The certification system including the procedures to be followed in filling out a certificate and the administrative procedures for review and approval of the certificate shall be described in the Purchaser's or Supplier's QA program.
 - Means shall be provided to verify the validity of Supplier certificates and the effectiveness of the certification system such as during the performance of audits of the Supplier or independent inspection or test of the items. Such verification shall be conducted by the Purchaser at intervals commensurate with the Supplier's past quality performance.
- Surveys shall not be employed as a method for accepting items from distributors unless the survey includes the manufacturer/developer of the item and the survey confirms adequate processes and controls by both the distributor and the manufacturer/developer. A survey of the distributor may not be necessary if:
 - The distributor acts only as a broker and does not store or repackage the items.
 - In cases where traceability of the item(s) can be established by other means such as verification of the manufacturer's markings or shipping records.
 - Surveys performed by organizations other than the dedicating entity may be used as a basis for acceptance if the survey results of the critical characteristics, survey scope, supplier's processes and controls, and acceptance criteria are evaluated by the dedicating entity to be acceptable and consistent with the dedicating entity's dedication requirements. The dedicating entity should also establish a basis on which to accept performance of a survey from another organization. One method to accomplish this would be for dedicating entities to consider partnering with other prime contractors to perform surveys together on the same supplier resulting in more efficient vendor oversight. The scope of the survey should be similar with each dedicating entity responsible to ensure that their CCFA are appropriately evaluated.
 - The scope of the survey shall be determined by the dedicating entity based upon the item or service and critical characteristics to be verified. The survey shall be specific to the scope of the CGI or CGS being procured. When several items or services are purchased from a supplier, a survey of representative groups of CGIs or CGSs can be sufficient to demonstrate that adequate processes and controls exist. The survey report shall provide objective evidence that the critical characteristics are verified and controlled by the supplier.

- If the scope of the survey cannot verify a designated critical characteristic due to controls by the supplier's sub-supplier(s), the dedicating entity shall extend the survey to the sub-supplier(s) or select another dedication method(s) to verify the critical characteristic.
- Organizations performing surveys shall develop criteria for the personnel qualifications and processes used to perform surveys.
- The survey documentation shall provide objective evidence that the processes and controls for the identified critical characteristics were observed and evaluated for acceptance. Deficiencies identified in the supplier's process or controls shall be corrected, if the survey is used for acceptance of the identified critical characteristic(s).
- If items are to be procured over time or the manufacture and/or development of the item occurs over a period of time, the dedicating entity shall establish a survey frequency to ensure that 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:
 1. The complexity of the item or service, frequency of procurement, receipt inspection, performance history, and knowledge of changes in the supplier's process and controls.
 2. The survey frequency interval may be the same used for supplier audits, but shall not exceed the frequency interval for supplier audits.

The following additional items may be used to prepare or review packages for items that are dedicated using Method 2:

- Determine if supplier documentation (e.g., production and quality records) relied on in the dedication of the item, is verified during the survey;
- Determine if surveys of a CGI vendor are performance-based as opposed to compliance-based or programmatic. Specifically, verify that the critical characteristics for the CGIs being surveyed are controlled by the vendor's quality control activities;
- If a potential supplier has multiple fabrication facilities, verify that the facility surveyed is the one providing the CGI or CGS;
- Determine if survey teams include technical and quality personnel, as appropriate, that are knowledgeable in the operation and safety function of the item(s) and the associated CCFA to be verified, including any special processes such as welding, computer program(s) development, and heat treatment that are specific to the critical characteristics;

- Determine if the control of sub-vendors is adequately addressed by the surveys so that the vendor has an adequate basis to accept test results and certifications (e.g. Certified Material Test Reports) from their sub-vendor;
- Determine if pertinent information about a vendor or its products is used to plan, conduct, and report results of surveys and source verifications. (Such information could have been available from source verifications, receiving inspections, the dedication process, supplier/product performance history, or other sources [e.g., from DOE, or other government agencies (e.g., Nuclear Regulatory Commission {NRC}, Environmental Protection Agency, National Institute of Standards and Technology), information notices and bulletins, nuclear plant reliability data system reports, or Nuclear Utility Procurement Issues Committee commercial grade survey reports];
- Confirm that: a) the documented commercial quality program was effectively implemented; and b) the surveys were conducted at the location necessary to verify that adequate controls were exercised on distributors as well as manufacturers;
- Ensure the persons who perform vendor surveys are knowledgeable in: a) the use of performance-based surveys; and b) screening third-party surveys. The allowance for use of third-part surveys including guidance is discussed in Section 2.2.1 above.
- Determine if a previously performed survey is being used to establish the acceptability of a vendor or supplier's commercial quality program. If so, verify that for each procurement, the program requirements necessary to ensure that a CGI or CGS will perform its safety function are the same. Determine if the surveys have been updated on a regular basis to support dedication;
- Evaluate adverse findings resulting from the review of third party surveys to ascertain if those findings affect CGIs already received.

The dedicating agency shall complete the commercial grade survey, review the survey report and determine the extent to which the vendor's controls were found adequate. Then the dedicating agency will make a final determination of which critical characteristics are to be accepted using Method 2 alone and document the basis in the technical evaluation.

The dedicating agency should also ensure that the procurement documents specify that the vendor/fabricator/supplier or sub-tier supplier will provide a certificate of conformance attesting to the fact that the item was fabricated or the service was performed to the requirements of the procurement contract. The procurement contract should invoke or reference the verified processes and controls including revision level for the CGI or CGS.

2.2.4 Method 3 – Source Verification

Source verification is a method of acceptance conducted at the supplier's facility or other applicable location to verify conformance with the identified critical characteristics and acceptance criteria during the fabrication/development process. The scope of the source verifications shall include activities such as witnessing the fabrication and assembly processes, computer program(s) development, non-destructive examinations, performance tests, computer program(s) performance tests, or final inspections, as applicable. It shall also include verification of the supplier's design, procurement, calibration, and material process and control methods employed for the particular commercial grade item or service being purchased, as applicable to the identified critical characteristics. For example a requirement to perform an inspection of a welding activity would also expect that an evaluation of welder qualification, rod control, and the weld procedure would be performed.

Organizations performing source verification shall develop criteria for the personnel qualifications and processes used to perform source verification. Source verification documentation shall provide objective evidence that the supplier's activities for the identified characteristics were observed and evaluated for acceptance.

Source verification is only applicable to the actual item(s) or services(s) that are verified at the supplier's facility or other applicable location. Source verification shall be performed in accordance with a checklist or plan with the documented evidence of the source verification furnished to the dedicating entity for approval and shall include or address the following:

- Identification of the items(s) or service(s) included within the scope of the source verification.
- Identification of the critical characteristics, including acceptance criteria being controlled by the supplier.
- Verification that the supplier's processes and controls are effectively implemented for the identified critical characteristics.
- Identification of the activities witnessed during the source verification and the results obtained.
- Identification of mandatory hold points to verify critical characteristics during manufacture, development, and/or testing for those characteristics that cannot be verified by evaluation of the completed item.
- Documentation of the adequacy of the supplier's processes and controls associated with the critical characteristics and acceptance criteria.

When using source verification, critical characteristics are verified by witnessing the quality activities of the supplier specific to the item being dedicated before an item is released for shipment to the Purchaser.

It may be appropriate to use Method 3 if the following conditions exist:

When in-process verification of one or more critical characteristics is needed;

When non-conformances have been detected during prior receipt inspections;

When problems/deficiencies exist with the supplier's QA program/procedures;

Buyer schedule demands;

Single supplier of the item;

Item purchased infrequently;

Manufacture, computer program(s) development or fabrication requires a significant amount of time; and

Item being procured is the first of its kind being manufactured, developed or fabricated.

The requirements for CGIs are defined in the purchase order which includes supporting technical documents. The documents include the identification of witness and hold points during the development of or fabrication of a CGI for performance of a CGS. The source verifier may be an auditor, inspector, engineer, Subject Matter Expert consultant or combination thereof.

Source verification activities may include witnessing a test such as:

Material hardness;

Nondestructive examinations;

Tensile test;

Hydrostatic test;

Leak rate test;

Material type (chemical analysis);

Calibration;

Operability;

Electrical continuity;

Insulation resistance;

Pressurization; and

Computer program(s) module functionality.

Witnessing an inspection:

Dimensional;

Configuration;

Coating thickness;

Weld;

Non-destructive examination; and

Computer code.

Observing a process:

Welding;

Assembly;

Insulating;

Coating;

Heat treatment;

Machining;

Testing;

Reviewing of computer program(s) specifications; and

Reviewing of computer program(s) design.

The following approach may be used to prepare or review packages for items that are dedicated using Method 3:

- Determine what critical characteristics can be best verified during the manufacturing, development, or fabrication activities at the vendor's location;
- Determine and define the necessary witness or hold points to allow proper verification activities of CCFA during the fabrication process. Include the required

inspection/verification points in the order to the sub-supplier to ensure notification of the dedicating entity; and

- Verify and document the acceptance of the critical characteristics selected for source verification in the CGD package.

In the application of this method proper care should be exercised to ensure that the data used is directly applicable to the verification of critical characteristics specific to the intended application of the item being dedicated.

2.2.5 Method 4 – Acceptable Supplier Item or Service Performance Record

Before using Method 4 as a means to justify that an item or service can demonstrate an acceptable CGD process, the dedicating entity needs to understand that EM considers this method very difficult to implement as a stand-a-lone method of acceptance. Method 4 should not be used unless it is in conjunction with Methods 1, 2, and/or 3.

This method of acceptance is based upon the documented, demonstrated past performance of the supplied item over a period of time for identical or similar items and/or services. The method can be applied best when the historical performance results can be compiled using: a) industry product tests; b) national codes and standards (ASME, ASTM, International Electrical and Electronics Engineers, etc.); c) monitored performance of the item installed and operated in a similar environment as the intended facility; d) industry data bases (Institute of Nuclear Power Operations [INPO], EPRI, Aerospace, Military etc.) or performance data resulting from use of Methods 1, 2, or 3.

Method 4 is a valuable means to assist in accepting CGI/CGS since it relies on documented historical performance and may not require costly and time-consuming inspection and auditing activities. However, Method 4 should only be used when a large dataset of successful historical performance for the item is available. The supplier item or service performance record or data shall be from the condition of service, environmental condition, failure mode, maintenance program, testing, or other conditions equivalent to the intended application of the CGI or CGS. Method 4 cannot be used if the only history available is with the purchaser.

Use of Method 4 allows the purchaser to accept CGIs based upon a confidence in the supplied item achieved through proven performance of identical or similar items or services. The method allows the purchaser to take credit for item performance based upon the historical performance and the records of the successful utilization of Methods 1, 2, or 3. In the application of this method proper care should be exercised to ensure that the performance data used is directly applicable to the verification of critical characteristics specific to the intended application.

The basis of this acceptance should include the following as applicable:

- User Historical Performance;
 - Results of Monitored Performance
 - Conducting Periodic Maintenance and Surveillance Tests
- User Historical verification (Methods 1, 2, and 3);
- Industry Wide Performance – Must be specific and applicable to the item being accepted if it is to be used to establish an acceptable supplier/item performance record;
- Product/Performance Test Results;
- INPO Nuclear Parts Reliability Data System;
- Seismic Experience/Test Data Bases and Equipment Qualification Data Bank;
- Commercial Program Audits/Surveys Conducted by Industry Groups;
- Supplier Response(s) to Commercial Grade Program Controls questionnaire;
- Utilization of National Codes and Standards;
- Shall not be a single source of information; and
- Should not be used as the sole method of acceptance.

An acceptable supplier item or service performance record shall include the following:

- Identification of the supplier item or service being evaluated;
- Identification of previously established critical characteristics specific to the item or supplier;
- Identification of utility/industry data examined to evaluate the supplier/item;
- Basis for determining that industry data substantiates acceptability of the supplier/item;
- Documentation of the adequacy and acceptance of the supplier/item/service performance record; and
- Statement of the purchaser attesting to the acceptability of the supplier/item.

An acceptable item or service performance record shall not be employed alone as a method of acceptance unless:

- The established historical record is based on industry-wide performance data that is directly applicable to the critical characteristics and the intended facility application. Single sources of information are not adequate to demonstrate satisfactory performance.
- The manufacturer's measures for the control of applicable design, process, and material change have been accepted by the dedicating entity, as verified by survey.

Continued application of an acceptable supplier/item/service performance record as a method of acceptance shall include a documented periodic update and review to assure the supplier/item/service maintains an acceptable performance record.

3. SAMPLING PLANS AND LOT FORMATION¹⁵

When sampling is required as a part of the acceptance process, the selection of the appropriate sampling plan complements the critical characteristic selection. Because of numerous procurement qualitative factors, it is normally not necessary to perform 100 percent tests or inspections to obtain reasonable assurance. Nuclear Facility procurements usually involve quantities that are small relative to large production lots unless new facility construction or modification is involved. Just as in the selection of critical characteristics, sound engineering judgment in the selection of sampling size is a key factor. The basis of the acceptability of random sample selection is that each item in the lot has an equal opportunity of being selected as part of the sample. Acceptance of the lot is then based on the sample results. If the sample results are acceptable then there is reasonable assurance that the remainder of the lot is acceptable.

Sampling plans used to select the number of items for special tests, inspections, and/or analysis should have an adequate technical basis using established standards that consider lot traceability, homogeneity, and complexity of the item. EPRI Final Report TR-07218-R1, "Guideline for Sampling in the Commercial-Grade Item Acceptance Process," provides an enhanced methodology for the use of sampling in accepting and dedicating CGIs.

Verify lot homogeneity when it is relied upon to apply a sample plan. The extent to which lot homogeneity must be verified is a factor of the safety significance of the item, the method of testing selected, whether verification technique is destructive or non-destructive, the number of critical characteristics being verified, the cost effectiveness of the test or inspection and the correlation between the destructive and non-destructive testing. Objective evidence of the supplier's ability to provide acceptable items through its manufacturing product controls is a key factor. It is important to recognize that heat number, manufacturer lot number or other manufacturing identification intended to demonstrate traceability to common production cannot be used unless the traceability can be verified back to the source of manufacture. Groups of

¹⁵ Sampling of computer programs is only applicable for computer programs embedded in digital equipment. It should be noted that in most instances the quantity of the same digital equipment item is small, requiring 100% sampling because of the small lot size.

components or commodities obtained through a distribution chain without traceability control established through QA audit or commercial survey cannot be considered homogenous.

After the lot has been established, the EPRI report listed above can be used as a guide in determining the sample size. The results of the above evaluation should be used to develop the sampling plan. Selection of the appropriate sampling plan should also consider the additional level of confidence considered necessary. For a given CGI dedication, different CCFA can have different sampling plans. Sampling plans for non-destructive testing can be normal sampling plans, tightened sampling plans, or reduced sampling plans depending on lot formation. Development of sampling size for destructive and non-destructive testing based on lot homogeneity is discussed in detail in EPRI Final Report TR-07218-R1 and should be used by the dedicating entity when developing the specific sampling plan for a CGI. Guidance for determining an acceptable sample size may also be found in ANSI/ASQ Z1.4, "Sampling Procedures and Tables for Inspection by Attributes," and ANSI/ASQ Z1.9, "Sampling Procedures and Tables for Inspection by Variables for Percent Nonconforming." There may be cases where more or less than the recommended sample size should be tested based on specific details of the procurement. The basis for definition of the lot and sample size should be documented.

Lot Formation

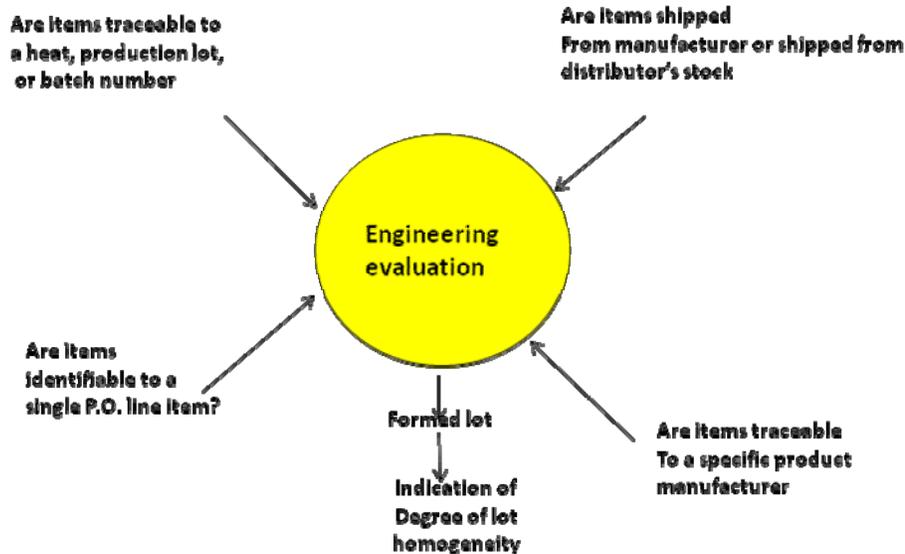


Figure 4: Lot Formation

4. OVERSIGHT AND FLOW-DOWN EXPECTATIONS

Each ASME NQA-1 supplier must be qualified by audit under the DOE contractor's QA program and placed on their approved supplier list. Periodic re-audits must be

conducted as required by the DOE contractor's QA program for the vendor to remain a ASME NQA-1 qualified supplier and hence, remain on the Approved Supplier List.

Each sub-vendor to an ASME NQA-1 qualified supplier (vendor) that provides safety items or services under their own QA program must be audited and qualified in accordance with the vendor's QA program for the scope of supply and placed on the vendor's approved supplier list. If an approved vendor will have design responsibility, the DOE contractor or the vendor must specify the safety function based on the DOE approved safety analysis. If the sub-tier supplier with design responsibility is expected to perform CGD of items and/or services, then the CGD aspect of their ASME NQA-1 program must be evaluated and accepted as part of their approved program. If the vendor will not have design responsibility, then it is the DOE Contractor's/buyer's responsibility to perform a technical evaluation of the safety function, design, environmental conditions, failure modes analysis and significance of the item/services' safety function. Based on the technical evaluation, the DOE Contractor will provide the CCFA and acceptance criteria to the sub-supplier. The same logic applies to an approved sub-tier supplier with design and CGD responsibility that is receiving material from supplier/fabricator that is not on their approved supplier list (based on an approved ASME NQA-1 program).

The above expectation should be included in procurement contract language to a company's ASME NQA-1 qualified vendors along with instructions for them to further promulgate the guidance to any of their ASME NQA-1 qualified vendors. However, even after having flowed down this guidance, the responsibility for the competent performance of CGD activities remains with the DOE contractor placing the procurement. Therefore, it is important that the DOE contractor maintain oversight of the entire supply chain where dedication activities could be performed.

4.1 Supplier Deficiency Correction

Deficiencies with the supplier's processes and controls identified by the acceptance method(s) shall be corrected by the supplier if it affects the acceptance criteria for critical characteristic(s) utilized for CGD. Corrective actions shall be evaluated for acceptability by the dedicating entity. Uncorrected deficiencies in processes or controls may result in the selection of another dedication method for determining acceptance or rejection of the item.

5. DOCUMENTATION

Documentation of the CGD process of an item or service shall be traceable to the item, group of items, or services and shall contain the following types of documents, depending on the applicable dedication method:

- a) Dedication plans or procedures including the essential elements of the dedication process;

- b) CGI or CGS procurement documents;
- c) Facility commercial grade definition criteria;
- d) Technical evaluations;
- e) Critical characteristic identification and acceptance criteria, including or referencing design documents and failure mode analysis;
- f) Test reports or results, inspection reports, analysis reports;
- g) Commercial grade survey reports;
- h) Source verification reports;
- i) Historical performance information; and
- j) Dedication report containing sufficient data to accept the item or service.

6. REFERENCES AND READING LIST

6.1 Codes and Standards

ANSI/ASQ Z1.4	“Sampling Procedures and Tables for Inspection by Attributes”
ANSI/ASQ Z1.9	“Sampling Procedures and Tables for Inspection by Variables for Percent Nonconforming”
ANSI N45.2.13	“Quality Assurance Requirements for Control of Procurement of Items and Services for a Nuclear Power Plant”
ASME B&PV Code, Section III	“Rules for Construction of Nuclear Facility Components”
ASME NQA-1-2004, and Addenda through 2007	“Quality Assurance Requirements for Nuclear Facility Application”
ASME NQA-1a-2009, Sub-Part 2.14	“Quality Assurance Requirements for Nuclear Facility Application”
DOE G 414.1-2	“Quality Assurance Management System Guide for use with 10 CFR 830.120, and DOE O 414.1 C, Quality Assurance”

DOE/RW-0333P “Quality Assurance Requirements and Description”

6.2 Industry References

EPRI NP-5652 (1988) “Guideline for the Utilization of Commercial Grade Items in Nuclear Safety Related Applications (NCIG-07)”

EPRI NP-6406 (1989) “Guidelines for Technical Evaluation of Replacement of Items in Nuclear Power Plants (NCIG – 11)”

EPRI Report TR-017218 (Rev 1) “Guideline for Sampling in the Commercial-Grade Item Acceptance Process”

EPRI Report TR-102260 (1994) “Supplemental Guidance for the Application of EPRI Report NP-5652 on the Utilization of Commercial Grade Items”

EPRI Report TR-106439 (1996) “Guideline on Evaluation and Acceptance of Commercial Grade Digital Equipment for Nuclear Safety Applications”

NRC Generic Letter 89-02 “Actions to Improve the Detection of Counterfeit and Fraudulently Marketed Products”

NRC Generic Letter 91-05 “Licensee Commercial-Grade Procurement and Dedication Programs”

NRC IP 38703 (1996) “Commercial Grade Dedication”

NRC IP 43004 (2007) “Inspection of Commercial Grade Dedication Programs”

NRC IN 2011-01 “Commercial Grade Dedication Issues Identified During NRC Inspections”

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APPENDIX A
Examples of Critical Characteristics for Design

Table 1 - Examples of Critical Characteristics for Design

Identification	
Color coding Display type (scale, graduations) Enclosure type	Industry Standard Markings Part Number / Unique Identifier Nameplate Data
Physical Characteristics	
Balance Capacitance Cloud point Coating Color Composite material hardness Concentration Conductivity Continuity Density/Specific Gravity Dielectric strength Dimensions (to within manufacturer's tolerance) Drop point Ductility Durometer Hardness Elasticity Fatigue resistance Flammability Flashpoint General Configuration of Shape Homogeneity Inductance	Leachable Halogen Luminescence Material hardness Material chemistry Oil/water separation Permeability Plating Polarity Pour-point Purity Resilience Resistance Rockwell Hardness Surface Finish Solubility Spring constant Surface finish Surface hardness Tensile Strength Torque Total chloride content Viscosity Weight Yield Strength
Performance Characteristics	
Accuracy Burn-in endurance Chatter Current Rating Cycle Time Dead-band width Flow rate Gain Horsepower Input/output voltage Interrupt rating Interrupting current Leakage	Operating range Performance during under voltage conditions Pickup & Drop-out voltage Power rating Pressure Drop Pressure Rating Pressure Test Repeatability Rotational Direction Set point stability (no drift) Speed Time/current response Voltage rating

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Examples of Critical Characteristics for Design

Load rating Open/closure time Operability (fail, open/close, stroke)	
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Table 2 – Examples of Item Critical Characteristics for Design

Commercial Grade Item (Example) ⁽¹⁾	Critical Characteristics ⁽²⁾
Anchor Bolt (Seismically Qualified Concrete Anchors)	Configuration, dimensions, material, wedge hardness, pitch
Control Switch (Reactor Building Sump Reset)	General configuration, contact configuration, voltage rating, current rating, materials, dimensions, operability
Crane Wheel Axle (Spent Fuel Bridge Crane)	Configuration, dimension, 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
Globe Valve, Seismically and Environmentally Qualified	Ductility, finish, markings, hardness, material, dimensions
Impeller Key (Auxiliary Feed Water Pump)	Configuration, dimensions, material, hardness
Integrated Circuit (Reactor Protection System)	Configuration, gain, input/output impedance, frequency responses, operability
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
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, reinforced material
Pinion Gear (Spent Fuel Bridge Crane Hoist)	Configuration, dimensions, material, hardness, pitch
Pressure Transmitter (Main Steam Isolation Valve Air Accumulator)	Configuration, voltage rating, current output, pressure rating, materials, accuracy
Pump Impeller (Make-up Water Transfer Pump)	Configuration, dimensions, material, hardness, balance, flow rate
Pump Mechanical Seal Assembly (Service Water Booster Pump)	Configuration (completeness of assembly), materials, finish, leakage, leachable halogen content, dimensions
Shaft Coupling (Diesel Generator)	Configuration, dimensions, materials, hardness

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APPENDIX A
Examples of Critical Characteristics for Design

Table 2 – Examples of Item Critical Characteristics for Design (continued)

Commercial Grade Item (Example) ⁽¹⁾	Critical Characteristics ⁽²⁾
Solenoid Valve (Torus vacuum breaker)	Configuration, size, pressure rating, materials, voltage rating, current rating, coil class, open/closure time
Spring (Pressure relief valve, seismically qualified)	Configuration, dimensions, (free length, coil diameter), spring rate, finish
Torque Switch (Operator for globe valve, seismically and environmentally qualified)	Configuration, dimensions, materials (metallic and nonmetallic), operability
Transistor (Uninterrupted Power Supply)	Markings, gain, input/output impedance, current rating, voltage rating, operability
Valve Packing Gland (Active control valve, seismically qualified)	Configuration, dimensions, material, tensile strength, hardness, finish
Valve Seal Ring (Emergency Closed Cooling System Globe Valve)	Configuration, material, dimensions, finish leakage
Valve Body	Configuration, material,
(1) Seismic and environmental qualification pertains to the parent component.	
(2) Part Number is a critical characteristic for each item.	

Table 3 – Examples of Bulk Item Critical Characteristics for Design

Commercial Grade Item	Critical Characteristics¹⁶
Bearing	Configuration, dimensions, load rating, material, model number
Bolting (Nuts, Bolts, Studs, etc.)	Configuration, dimensions, pitch, material, tensile strength, hardness, plating
Cotter Pin	Configuration (point type), dimensions, material, finish, hardness
Crimped Terminal	Configuration, material, dimensions (wire size, ring tongue size),
Connector	voltage rating, continuity, tensile pullout strength, color
Drive Belt	Dimensions, cross-sectional shape, fatigue resistance, load rating, material, tensile strength
Fitting	Marking, material, dimensions
Flange	Marking, material, dimensions, sealing surface flatness and finish, bolting arrangement
Framing Device	Configuration, shape, dimensions, material, tensile strength, coating
Fuel Oil	Density, flash point, cloud point, pour point, kinematic viscosity, chemical composition, BTU rating, viscosity

¹⁶ Part number is a critical characteristic for each item.

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APPENDIX A**

Examples of Critical Characteristics for Design

Fuse	Configuration, current rating, interrupt rating, time/current response, dimensions
Lubricating Grease/Oil	Color, specific gravity, viscosity, drop point, cone penetration, pour point, chemical composition, cloud point
Structural Material (e.g., Plate, Bar, Rod, etc)	Dimensions, shape, material, tensile strength, hardness, ductility, markings, coating
O-ring	Dimensions, material, durometer hardness, elongation, leachable halogens
Pipe	Marking, material, dimensions
Relay	Configuration, pick-up/drop out voltage, voltage rating, current rating, chatter, response time
Resistor	Configuration, markings, resistance, power rating
Spiral Wound Gasket	Configuration, dimensions, markings, style number, materials (filler and windings), pressure rating, leachable chlorides, spiral density
Temperature Switch	Configuration, dimensions, material, voltage rating, response time, accuracy, nameplate data, temperature range, wire rating, enclosure type dielectric strength (insulation), dead band width
Terminal Block	Configuration, voltage rating, current rating, materials, dielectric strength
Digital Valve	Product/Part Identifier, Computer program Version Identifier, Size of executable code, Receipt Media (embedded), Software Life Cycle Documentation (software specification, tests performed and results, user/configuration manual, maintenance manual), input signal, power, EMI, loss of signal, loss of power, operating history, response to abnormal conditions and events, configuration control, problem reporting, reliability
Seismic Design Standalone Application	Computer program version identifier, identification of all associated databases and data input files, size of executable code, size of all associated data input files, receipt media type, output file format, User interface functionality, cyber security functions, response to abnormal conditions and events, accuracy of results, isolation of safety functions, maintainability, quality of design, software life cycle documentation, problem reporting, requirements completeness and correction, design completeness and traceability, implementation completeness and traceability, configuration control, change control process, internal reviews and verifications, thoroughness of computer program testing.

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APPENDIX B
Examples of Credible Failure Mechanisms

B.1 Typical Credible Failure Mechanisms (CFM)

- Blockage
- Corrosion
- Ductile fracture
- Erosion
- Excess strain
- Fracture
- Loss of properties
- Mechanical creep
- Open circuit
- Seizure
- Short circuit
- Unacceptable vibration
- Unresponsive computer program
- Computer program exception encountered
- Computer program crash

B.2 Potential Failures in the Performance of Services

Repair Services

- Use of unacceptable replacement part
- Improper welding or soldering
- Improper assembly
- Component functional requirement not being met after repair

Testing

- Use of un-calibrated testing equipment
- Technical inadequacies in performing the test
- Improper test specimen preparation
- Improper calculation of test results

Fabrication/Machining/Cleaning/Unique Manufacturing Processes

- Failure to meet dimensional requirements
- Material contamination

Training

- Errors in instructional materials used by trainees to perform a safety-related activity

Engineering / Technical Services

- Incorrect voltage drop calculations
- Failure to confirm initial assumptions

Calibration

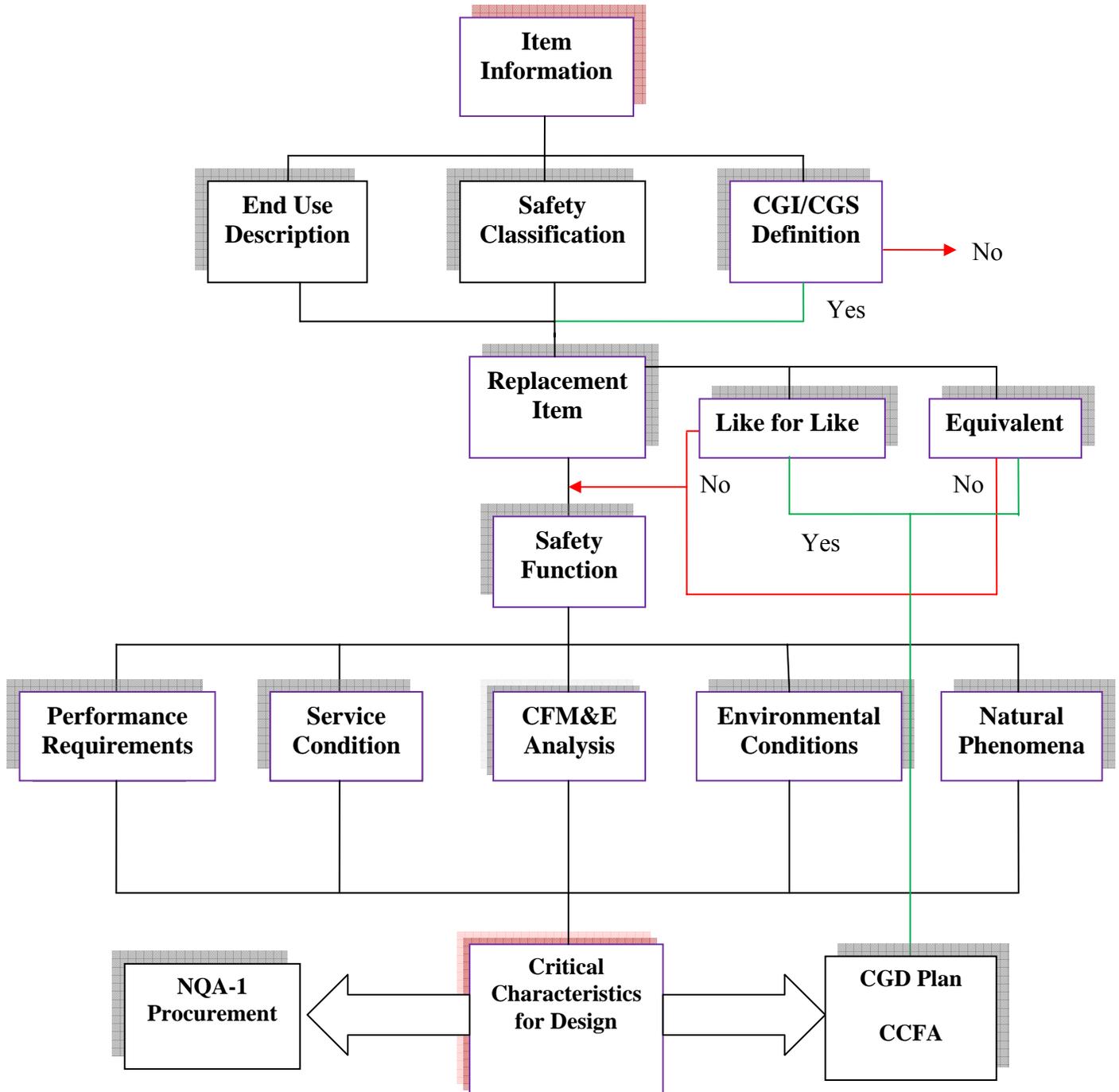
- Equipment is out of calibration causing failure to accurately measure or actuate at the proper time
- Plant equipment is calibrated incorrectly by maintenance because the measuring and testing equipment has not been properly calibrated

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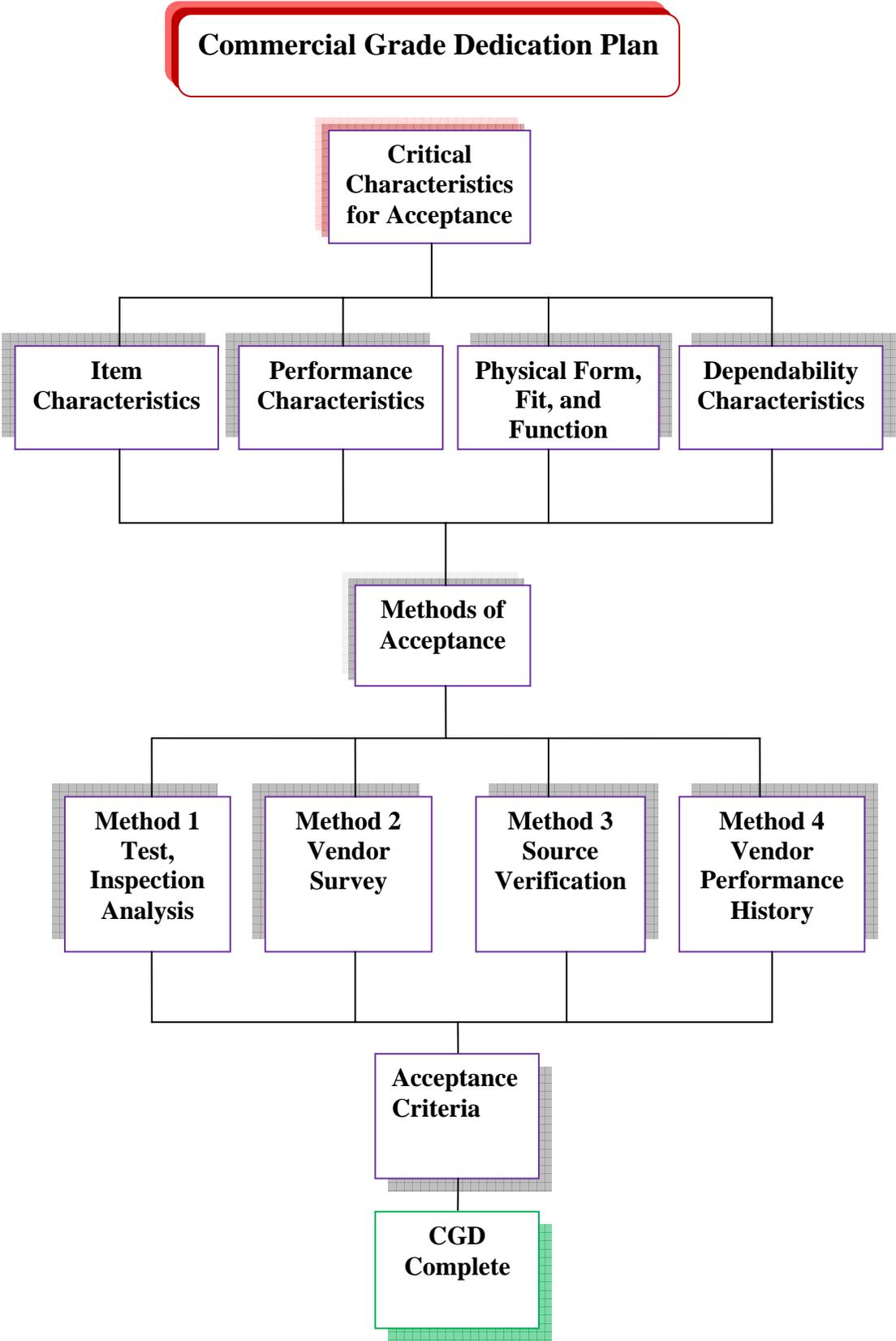
Example Commercial Grade Dedication Activity Flow Chart

COMMERCIAL GRADE DEDICATION ACTIVITY
PROCESS FLOW CHART

Technical Evaluation



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Example Commercial Grade Dedication Activity Flow Chart



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Critical Characteristic Development for Digital Equipment and Software

Table D
Critical Characteristics for Digital Equipment,
Embedded Computer program(s), Off-The-Shelf Computer program(s) and Stand Alone Computer program(s)

Item Characteristics

<i>CC</i>	<i>Description</i>	<i>Acceptance Criteria</i>	<i>Method of Verification</i>
Host computer operating environment	The manufacture and model number of the host assembly or computer hardware computer program is intended to reside. This critical characteristic is applicable to all computer programs.	Host computer operating environment criteria must match the purchase specification. This should include the manufacturer name and model from a supplier's catalog. (e.g., Dell PowerEdge T110 Tower Server, IBM AIX & System, and Dell Precision T3500 Workstation, Siemens Simatic S7-400)	Verified through one or more of the following: <ul style="list-style-type: none"> ○ Inspection of receipt inspection documentation (Method 1) ○ Inspection of test system operating system identifiers. (Method 1)
Host computer operating system identifier	Vendor name, operating system version, service packs or patch identifiers that are needed for the computer program to be executed. This critical characteristic is applicable to all computer programs.	Host computer operating system identifier must match the identifier in the vendor product list (e.g., Microsoft Windows 7, UNIX Operating System Version 5.1, B-5, and Yokogawa Pro-Safe-RS R2.01.00)	Verified through one or more of the following: <ul style="list-style-type: none"> ○ Inspection of receipt inspection documentation (Method 1) ○ Inspection of test system operating system identifiers. (Method 1)
Computer program(s) Name	The full name of the computer program(s). It should be the same identifier as used for during the procurement/acquisition process. This critical characteristic is applicable to all computer programs.	Computer program(s) name must match the product name from vendor catalog. (e.g., CFAST, Wolfram Mathematica 8, Monte Carlo N-Particle Transport Code System (MCNP5), Emerson valve Link, and Organic Concatenater)	Verified through one or more of the following: <ul style="list-style-type: none"> ○ Inspection of receipt inspection documentation (Method 1) ○ Inspection of test system operating system identifiers. (Method 1)
Computer program(s) Version Identifier	The complete version identifier including any patches. This critical characteristic is applicable to all computer programs.	Computer program(s) version identifier must match the product identifier from the vendor catalog the includes computer program(s) name-major functional version.minor functional version.	Verified through one or more of the following: <ul style="list-style-type: none"> ○ Inspection of receipt inspection documentation (Method 1) ○ Inspection of test system

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		corrective revision (e.g., CFAST-05.00.01, Hotspot-02.07.01, Emerson valve Link-02.04-13, and Organic Concatenater-3.1b)	operating system identifiers. (Method 1)
Support Tools Name(s) and Identifier(s)	The complete name, including version identifier of all support tools that are used during the CGD process to assist in performing special tests or other support tools used in the operations environment. These tools, such as PLC test simulator tools and database management systems, could impact the correct operation of the safety functions performed by the computer program during special tests or operations.	Support tool name and identifier must match the product identifier from the vendor catalog or specification.	Verified through one or more of the following: <ul style="list-style-type: none"> ○ Inspection of receipt inspection documentation (Method 1) ○ Inspection of test system operating system identifiers. (Method 1)

Physical CC:

<i>CC</i>	<i>Description</i>	<i>Acceptance Criteria</i>	<i>Method of Verification</i>
Interfaces: User Interface	The computer program user interface design that provides consistency in design, including the use of symbols, notations, terminology, conventions, and layout that are important to the safety function. Although applicable to all computer programs, this critical characteristic may be more important for computer programs that have multiple users, used in control rooms or used by safety component maintenance staff.	User interface can be expressed by how well the user interface that is related to the safety function meets company HMI designs (e.g., 100% of UI meets Americans with Disability Act requirements)	Verified through: Review of computer program inspection reports against industry interface standards. (Method 1)
Receipt Media	The physical object or distribution media received from the supplier that contains the computer program. This critical characteristic is applicable to all computer programs.	Receipt media criteria is expressed as the method in which the computer program is distributed to the dedicating entity (e.g., CD, embedded, and downloadable.)	Verified through: Inspection of media (Method 1)
Size (lines of code, function points)	The size of the computer program. This can be the quantity of folders received, the size in Kb of the executable(s), number of function points, or other physical means of measuring the size of the	Size criteria can be expressed in terms several different methods of measurement (e.g., 500K source lines of code (SLOC), number of data functions,	Verified through one or more of the following: Review of design documentation (Method

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	computer program. This critical characteristic can be important for embedded computer programs that must operate in processors with limited memory or storage or standalone computer programs that must execute with limited memory or storage.	and number of transactional functions)	2) Execution of support tools that measure size (e.g., function points, SLOC) (Method 1)
Life Cycle Documentation	The documentation that is produced during all phases of the software life cycle. Documentation is evidence of the activities being performed. Documentation from multiple life cycle phases may be combined into one or more physical documents.	Life cycle document include separate or combined documents that include: Software Requirements Specification, Requirements traceability matrix, Design documentation, Architecture views, Design description document, Interface Documentation, Test Plans, Test Reports, and User Documentation.	Verified through: Inspection of life cycle documents (Method 1)

Performance CC

CC	Description	Acceptance Criteria	Method of Verification
Abnormal Behavior: Response to Abnormal Conditions and Events	Action(s) or behavior which the computer program detects and responds to invalid inputs, erroneous states, and abnormal conditions. This critical characteristic is important to identify risks of the computer program failing to execute its safety functions.	As described in computer program requirements or procurement specification documentation. The criteria can be expressed as actions to the operations console when a warning event occurs (e.g., alarm on low power signal, entry of erroneous data input, entry of erroneous data sets, or initiation of data backups).	Verified through a combination of one or more: Inspection and Testing (Method 1) Review of design (Method 2) Observation of development (Method 3) Review the installed base to determine performance history (Method 4)
Accuracy/Precision/Tolerance Outputs	For accuracy the degree in which there is a close correlation with the expected or desired outcome. For precision the degree of repeatability or degree of measure. For Tolerance the allowable possible error in measurement.	As described in computer program requirements or vendor specification documentation. Criteria may be: accuracy- +- 1%; precision +- 0.0001; tolerance +- 0.00001.	Verified through a combination of one or more: <ul style="list-style-type: none"> ○ Observation and review of design (Method 3) ○ Inspection and Testing (Method 1) ○ Review the installed base to determine

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<i>CC</i>	<i>Description</i>	<i>Acceptance Criteria</i>	<i>Method of Verification</i>
			performance history (Method 4)
Environmental Compatibility: Portability	The measure of the effort required to migrate the computer program to a different hardware platform, component or environment. This critical characteristic may only be important for computer programs that are expected to be executed in a different environment.	As described in computer program requirements or vendor specification documentation. Portability criteria can be expressed as a unit of time (e.g., 16 hours or 15 days).	Verified through: Performing migration to one or more environments equivalent to the dedicating entities. (Method 1)
Functionality: Completeness	The measure of the extent the computer program design and implementation has satisfied the allocated safety requirements. This critical characteristic is important to identify risks of the computer program failing to execute its safety functions.	Functionality completeness is based upon how many of the computer program's requirements have been verified to be successfully implemented. Functional completeness can be expressed as a percentage of requirements implemented (e.g., 100% of allocated safety requirements are met.)	Verified through a one of the following: Performing a review of the functional requirements traceability to test cases and verification that those test cases were successfully executed. (Method 2) If requirements traceability is unavailable, the dedicating entity can develop the traceability matrix from the computer program's requirements or procurement specifications and test cases performed. (Method 2)
Functionality: Consistency with appropriate engineering/scientific research and professional technical approaches	The degree in which the computer program's sample or complete data sets of results correlate with experimental data, expected data results or professional analyses and any erroneous data sets do not correlate with the experimental data or professional analyses. This critical characteristic most likely is important to computer programs used to perform analysis of accident and structural integrity analyses for determining proper design of safety components.	Consistency with appropriate engineering/scientific research and professional technical approaches is based upon peer reviewed published technical papers or industry accepted computer programs performing a similar function. The output of the computer program can be viewed as how closely the computer program's output matches the technical report or baseline computer	Verified through a combination of one or more; A comparison of peer reviewed technical publication detail results against the computer program's output for a similar problem being solved. (Method 1) A comparison of the

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<i>CC</i>	<i>Description</i>	<i>Acceptance Criteria</i>	<i>Method of Verification</i>
		program output (e.g., computer program output correlates with experimental data to +/- 3σ.)	<p>baseline computer output against the computer program's output that is being dedicated. The baseline computer program must solve the same or closely similar physical problem as the dedicating computer program. (Method 1)</p> <p>A review of the computer program's current user base and its applicability to the intended use by the dedicating entity. (Method 4)</p>
Functionality: Correctness (correctness, proof of correctness)	The degree to which the computer program is free from errors, meets the specified requirements, and meets the user's needs. Correctness differs from completeness in that the number of requirements implemented is not considered. Formal techniques may be used to mathematically prove that the computer program satisfies its specified requirements. This critical characteristic is important to identify risks of the computer program failing to execute its safety functions.	Correctness may be expressed as the how well the computer program satisfies its requirements. The number of errors identified for each requirement can be an indicator as to the correctness. The severity or impact on performing the safety function correctly should be a factor in determining correctness. (e.g., 0 major errors reported, 5 minor errors reported, and 3 minor errors repaired and being tested	Verified through the following: A review of the test results error categorization. (Method 2)
Functionality: Security functions	The protections included in the computer program and operating environment which provide access to authorized users or which eliminate or mitigate unwanted access or unintended modification or the computer program. This critical characteristic may be important for computer programs that are executed on computer networks that are used by multiple individuals or are susceptible to intrusions.	As described in computer program requirements, procurement specification documentation and/or compliance standards. The criteria can be expressed as the presence of strong passwords, or biometric access, and network design including firewalls.	Verified through a combination of one or more: Observation and review of design (Method 3) Inspection and Testing (Method 1) Review the installed base to determine performance history

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<i>CC</i>	<i>Description</i>	<i>Acceptance Criteria</i>	<i>Method of Verification</i>
Functionality: Interface Communications (usability, interoperability, communicativeness)	The measure to which the computer program operates properly and shares resources with other computer program or hardware operating in the same environment, the ease in which the various components of the system communicate with each other and external entities, to which the complexity of the interfaces is minimized. This critical characteristic may be important to standalone computer programs that are part of a complex analysis or component design and for many operator controlled devices such as digital cranes.	Interface communication may be expressed as how the computer program uses standardized or industry approaches in its design and implementation. These interfaces identify how well the computer program accepts input from or can send output to other systems (e.g., number of manual process steps to transfer the computer program output to be used as input to another computer program), uses industry and accepted port assignments (e.g., controller output port 3 is used to communicate with operator console) and ease in which operator controls are received by the computer program (e.g., all operator controls are via haptic devices such as joysticks).	Verified through one or more of; <ul style="list-style-type: none"> Observation of computer program execution to assure interface standards are met. Review of computer network design drawings. Execution or observation of tests that exercise the external interfaces. (Method 1) Inspect the user manual content that describes the process to receive or send electronic information to or from the computer program. (Method 1).
Functionality: Specific safety functions and algorithms	The critical functions or calculations that are performed. This includes time dependent functions. This critical characteristic is important to verify for all computer programs being dedicated.	As described in computer program requirements or procurement specification documentation. Functionality criteria may be similar to: given detector signal, close valve or given source input data, calculate dose exposure at 10 meters and 0 receptor height.	Verified through a combination of one or more: 6.0 Observation and review of design (Method 3) 7.0 Inspection and Testing (Method 1) Review the installed base to determine performance history (Method 4)
Interfaces: Critical input parameters and valid ranges	The set of input parameters that are used in the critical functions of the computer program and the range of their valid values. This critical characteristic is important to all computer program types to ensure that the computer program will function properly for all possible operational inputs.	As described in computer program requirements or procurement specification documentation. This criteria may be input voltage (e.g., 1.5 to 2.8 ohms), deposition receptor height (e.g. 0 to 1 ft), time: (dd/mm/yyyy hh:mm:ss); and length (1.00 to 5.00 meters).	Verified through a combination of one or more: <ul style="list-style-type: none"> ○ Observation and review of design and or implementation (Method 3) ○ Inspection and Testing (Method 1) ○ Inspection of user's

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<i>CC</i>	<i>Description</i>	<i>Acceptance Criteria</i>	<i>Method of Verification</i>
			<p style="text-align: center;">manual (Method 1)</p> Review the installed base to determine performance history (Method 4)
Interfaces: Outputs parameters	The characteristics of the critical output parameters. The characteristics of the critical output parameters include file formats, signal specification, mathematical notations type, signal strength, signal type. This critical characteristic is important to all computer program types to ensure the computer program output is in the expected format or units of measure.	As described in computer program requirements or procurement specification documentation. This criteria can be specification of output filename (e.g., 28 characters, case insensitive with a file extension of pdf), output format specification (e.g., comma delimited) and units of measure (e.g., ohms, 1.0E-24, barns)	Verified through a combination of one or more: <ul style="list-style-type: none"> ○ Observation and review of design (Method 3) ○ Inspection and Testing (Method 1) ○ Inspection of user's manual (Method 1) Review the installed base to determine performance history (Method 4)
Response Time	The time in which it takes the computer program to execute a specific action. This critical characteristic may be important to digital equipment that must perform an action within a specific period of time. Rarely is response time important to stand alone computer program applications.	Response time can be expressed in terms of time in days, minutes, seconds or milliseconds (e.g., the alarm is reported to the console 3 seconds after detection and calculation results are completed within 20 minutes.)	Verified through: Observation or execution of functional test that is timed. (Method 1)
Throughput	The measure of the amount of work performed by a computer program system over a period of time. This critical characteristic would rarely be important for digital equipment that performs on demand safety functions. This critical characteristic may be of best use for large analytical computer programs that require several hours to perform calculations.	Throughput can be expressed in terms of completing a specified quantity of an object over a period of time (e.g., number of millions of instructions per second, and number of bits per second)	Verified through: Observation or execution of functional test that is timed. (Method 1)
Reliability	The extent to which the computer program can perform its critical functions without failure for a specified period of time under specified conditions. This critical characteristic more likely to be important for dedication of digital equipment. However, it can be used to for	Reliability is typically expressed in terms of number of failures over a period of time (e.g., 1 failure per year in high radiation environment.) or number of failures for any given of executions of the computer program (e.g., 3 failures	Verified through: Observation or execution of functional test that is timed or otherwise uses a counting attribute. (Method 1)

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<i>CC</i>	<i>Description</i>	<i>Acceptance Criteria</i>	<i>Method of Verification</i>
	standalone computer programs used in design or analyses.	for every 100 computer runs).	

Dependability CC

<i>CC</i>	<i>Description</i>	<i>Acceptance Criteria</i>	<i>Method of Verification</i>
Built-in Quality: Existence of QA Program	A QA program that includes documented procedures or process controls. QA Program generally complies with a recognized standard (e.g. ISO 9000, ASME NQA-1). This critical characteristic can be used to determine if the foundation of a QA Program exists.	QA Program criteria are based upon the vendor's procedural compliance to a recognized standard that addresses development and quality assurance for computer programs. This criteria can be expressed in terms of the number of significant findings from a compliance audit against the chosen recognized standard, or achievement of certification for the chosen recognized standard.	Verified through one or more of the following: <ul style="list-style-type: none"> Inspection of evidence of any 3rd party certification. (Method 1) Review internal or external audit reports. (Method 2) Performance of a survey against the chosen recognized standard. (Method 2)
Built-in Quality: Training, knowledge and proficiency of personnel performing the work	Staff training, knowledge and proficiency associated with the design, development, testing, oversight of the computer program, experience in similar projects, and familiarity with specific tools, languages used in design and implementation. This critical characteristic can be used to provide an indicator of the errors remaining in the computer program.	Staff training, knowledge and proficiency criteria may include how well the specific staff member satisfies the vendor's qualification requirements for the position held. The criteria can be the percentage of qualification requirements met.	Verified through: Review of objective evidence of attendance at courses, staff resumes, and on the job training against the vendor qualification requirements to determine how well the staff member satisfies the requirements. (Method 2)
Built-in Quality: Adherence to coding practices	The degree to which the computer program complies with the approved coding standards, use of code libraries, or automated configuration management tool. This critical characteristic can be used to provide an indicator of the errors remaining in the computer program.	Coding practice criteria can be a percentage (e.g., 90%) of the vendor coding standards met, and where appropriate 100% of possible code library modules are used instead of recoding.	Verified through: Review of code inspection reports or other vendor evidence that included reviews of coding practice for the subject code modules. The dedicating entity during a survey may also review the code module(s) compliance with the vendor's documented coding practices. (Method 2)

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Built-in Quality: Code Structure (complexity, conciseness)	The measure in which the computer program is legible, complexity is minimized, code length is minimized. This critical characteristic can be used to provide an indicator as to the difficulty to verify through reviews and testing that the code will perform as expected.	Code structure criteria can be quantitative through the use of static analysis tools or qualitative through reviews of the documented design or inspection of the code. Code structure criteria may take the form of number of internal subroutine interfaces, number of do-loops, numbers of exits from a module, straightforward flow of logic in code module, and code module depth and breath.	Verified through: Review of vendor documented evidence from the use of a static analysis tool or the dedicating entity performing an inspection and manual analysis of the documented design or computer program code. (Method 2)
Built-in Quality: Error Minimization (defect density, defect containment effectiveness, defect severity)	The degree in which errors are minimized. Indicators include defect density, effectiveness of error detection techniques to keep errors from entering the next software life cycle phase, and severity of the errors detected. This critical characteristic can be used to provide an indicator of the errors remaining in the computer program.	Error minimization criteria can include quantitative and qualitative measures. The acceptance criteria selected should be appropriate for the computer language or code generation tool used to create the computer code. Error minimization criteria may be the number of errors detected per lines of code (e.g. 5 errors per 100 lines of code), number of errors per pre- and post release (5 major and 10 minor errors), and number of errors per software lifecycle phase (7 errors in requirements phase).	Verified through: The review of vendor tracked errors detected during reviews and inspections during the development and testing of the computer program. The dedicating entity may through the inspection of the vendor's documented reviews develop the values associated with the acceptance criteria. (Method 2)
Built-in Quality: Internal reviews and verifications	The degree in which static analysis methods (e.g. peer reviews) are performed during the computer program's development to identify errors and non-compliance to vendor procedures and standards.	Criteria for internal reviews and verifications effectiveness is based upon the ratio of errors identified during the review/verification and the number of errors that are discovered in the next life cycle phase. (e.g., ratio of the number of requirements errors identified during requirements review and the number of error detected during the design phase).	Verified through: Inspection and analysis of results from reviews or verification activities performed in two or more adjacent life cycle phases. (Method 2 and/or Method 3).
Built-in Quality: Maintainability	The computer program design that provides for ease in performing modifications to the computer program. This critical characteristic may be more	Maintainability criteria are based upon the time required to change the computer program. This criterion can be expressed	Verification through: Review of vendor metrics associated with the length of time

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	appropriate for computer programs whose failure could result in few or no alternatives should the computer program be unusable.	as mean time to change or mean time to fix.	to evaluate the change/error correction, made the code change/correction, test the change/correction, update all computer program documentation, and release the change. (Method 2).
Built-in Quality: Process Effectiveness	A measure of how well the Vendor's QA process meets its purpose and objectives. This critical characteristic can be used to provide an indicator of the errors remaining in the computer program.	Process effectiveness criteria are based upon the degree in which 3 rd party certification/recertification programs are achieved (e.g., 90% of achievement of compliance to CMMI SEI maturity level 4 or achieved ISO 9000) or by qualitative measures of conformance to the vendor procedures (e.g., 75% of vendor computer program procedures are met).	Verified through one or more of the following: Inspection of the proof of 3 rd party certification (Method 1) Review of vendor procedures and objective evidence that processes performed to produce the computer program is complaint with those procedures. (Method 2)
Built-in Quality: Testability	The measure of the effort required to perform computer program verification, validation, and installation testing. This critical characteristic may be appropriate to use when assurance is needed that reviews and tests were adequately performed.	Testability criteria are based on the ease or difficulty in conducting verification and validation activities. Testability criteria may include: number of hours to perform peer reviews, number of hours to pretest a module, and number of hours to develop test cases.	Verified through: Inspection of documented review reports and test records that include the time spent to prepare, conduct, and perform post review or test activities. (Method 1)
Built-in Quality: Thoroughness of computer program testing	A measure of the completeness of the computer program testing to ensure that the computer program correct and complete. This critical characteristic may be appropriate to use for ensuring that tests were adequate to provide the reasonable assurance that the safety functions can be performed satisfactorily.	Thoroughness of computer program testing criteria can be measures that identify the quantity of errors discovered during the various testing activities (e.g., trend analysis of errors per module, comparison of pre- and post release errors) and traceability of tests performed to the safety requirements for the computer program (e.g., 95% of the requirements were tested).	Verified through: Review of the objective evidence of the errors identified during the testing processes or traceability of safety requirements to tests completed. If objective evidence is not available, the dedicating entity may be able to create the traceability of the safety requirements to tests performed from the computer program's

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<i>CC</i>	<i>Description</i>	<i>Acceptance Criteria</i>	<i>Method of Verification</i>
			documented requirements and test reports. (Method 2)
Configuration Control: Control of enhancements	The computer program improvements are controlled, approved, and necessary. Requirements churn is minimized but not zero. Control of enhancements minimizes unintended or prohibited functions. This critical characteristic may be appropriate to use when the stability of the computer program is important. This critical characteristic can provide an indicator as to the number of errors inserted into the computer program during the change process.	Control of enhancements criteria can be obtained from configuration control board statistics. These statistics may include number of enhancements (e.g., 15 changes/last year), and number of approved enhancements (e.g., 7 changes/last year), and number of completed enhancements (e.g., 3 changes/last year).	Verified through: Review of meeting minutes of a configuration control board, data from change logs and release notes. (Method 2)
Failure Management: Isolation of safety functions	The computer program design implements methods of cohesion, reduces coupling, and promotes modularity. Cohesion is a module or routine that performs a single task or function. Modularity or decoupling is a module or routine that performs an independent task or function. Nominally, this is a qualitative measure. This critical characteristic provides an indicator to determine how much of the non-safety portions of the computer program must be included in the CGD process to provide the reasonable assurance that the failure of non-safety functions will not impact the proper execution of the safety functions.	Isolation of safety functions criteria can be the total number of computer program modules that perform safety and non-safety functions, there is no sharing of logic between safety and non-safety modules, and non-safety modules or routines may only read output of safety modules or routines.	Verified through: Review of the computer program design or source code. (Method 2)
Failure Management: Redundancy	The computer program design to implement duplication of critical components with the intention of increasing reliability. This critical characteristic may be important when the failure of the safety function can lead to severe consequences that harm the individuals or the environment. This critical characteristic may be more applicable to computer program that controls instrumentation.	Redundancy criteria may include the existence of back-up critical hardware computing systems, multiple computer program development teams, information redundancy, multiple controllers, and dual processors.	Verified through: Review of the computer program design, computer processor specifications, and computer system drawings. (Method 2)

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Problem Reporting: Notification to Customers	Notification by the vendor to customers of potential computer program errors or weaknesses.	Notification to Customers criteria may be the presence and use of a problem reporting system, use of problem reporting metrics, and number of notifications to the users over time.	Verified through: Notification to Customers criteria verification is performed by reviewing communications of errors with users, review of any web site or other form of communicating with the vendor, and review of a log of communications. (Method 2)
Supportability	The ability for the vendor to continue support for the computer program over the life of its use. This critical characteristic is important for because of the difficulty to ensure the computer program is free of all errors. This critical characteristic should be considered when alternative computer programs are not easily obtained or where financially not feasible.	Supportability criteria can be the stability of the vendor based upon longevity of business (e.g. 20 years in business), size of customer base (e.g. 1000 customers world-wide), planned future product releases (e.g. vendor R&D has updates scheduled for next 3 years), and vendor history of discontinuing products (e.g., cancelled 3 product lines over past 2 years).	Verified through: Review of the vendor history for the specific computer program as well as their history in supporting similar computer programs or products. (Method 4)
Build In Quality: Conformance to national codes and standards	The computer program's compliance to applicable national codes and standards.	Conformance criteria can be a measure of well the computer program meets industry accepted practices that provide a qualitative pedigree of the computer program.	Verified through: Inspection of vendor performed assessments of the computer program against the national code or standard (Method 1) Review of computer program documentation and artifacts against the selected national code or standard (Method 2)

U.S. DEPARTMENT OF ENERGY
OFFICE OF ENVIRONMENTAL MANAGEMENT

Guidance Document for Integrating Quality Assurance
During the
Design and Construction Life Cycle

September 2011

FOREWORD

This Department of Energy (DOE) Environmental Management (EM) guidance document is approved for use by all DOE EM organizational units and contractors performing work for EM.

A project's Quality Assurance Program assigns responsibilities and authorities, defines policies and requirements, and provides for the performance and assessment of work that provides confidence that required level of quality is achieved, commensurate with the various project requirements.

This guidance document offers for evaluation, by project personnel from EM and contractor organizations, activities and approaches to be considered as projects establish QA requirements to be used throughout the lifecycle of the project.

The need for this was recognized by the EM Quality Assurance Corporate Board as the membership was questioned regarding gaps in existing program support literature to be used on EM projects.

This guidance document should be considered throughout the lifecycle of project related activity and applied in a manner that fits the specific conditions applicable to the project and is intended to complement other guidance such as that found in DOE G 413.3-2, Quality Assurance Guide for Project Management.

Existence of a guidance document does not mandate its use. However, it is the expectation of senior EM management that this guide should be considered for implementation locally as conditions warrant. This guide details considerations that should be evaluated in establishing Quality Assurance Programs on EM Projects in fulfilling the requirements of 10 CFR 830 and DOE Order 414.1D, Quality Assurance. This guidance does not modify or create any new requirements; instead, it explains how to satisfy existing requirements. As such, no contract requirements are altered by use of the guide.

Within this guidance document, any use of the term "shall" designates requirements contained in 10 CFR 830 or DOE Order 414.1D, Quality Assurance, DOE Order 413.3B, Program and Project Management for the Acquisition of Capital Assets, and "should" designates recommendations to meet EM expectations. Compliance with the standard is achieved by adherence to its requirements and consideration of its recommendations.

ACRONYMS

A/E	Architect/Engineering firm, external entity providing of professional design service support
ACI	American Concrete Institute
AISC	American Institute of Steel Construction
ASL	Approved Supplier List
ASME	American Society of Mechanical Engineers
ASNT	American Society for Nondestructive Testing
ASTM	American Society of Testing Materials
CD	Critical Decision
CFR	Code of Federal Regulations
CGD	Commercial Grade Dedication
CMTR	Certified Material Test Report
CoC	Certificate of Conformance
CRA	Contractor Readiness Assessment
DOE	US Department of Energy
DSA	Documented Safety Analysis
EFCOG	Energy Facility Contractors Group
EM	Environmental Management
EPC	Engineering, Procuring and Constructing Contractor
FPD	Federal Project Director
HVAC	Heating, Ventilation and Air Conditioning
M&O/I	Managing and Operating/Integrating Contractor
M&TE	Material and Test Equipment
MSA	Management Self-Assessment
NCA-xxxx	Series of ASME Requirements, a subsection to Section III of the Boiler and Pressure Vessel Code
NDE	Nondestructive Examination
NQA-1	Nuclear Quality Assurance-1, ASME's Quality Assurance national consensus code for nuclear activities
O&M	Operating and Maintaining
ORR	Operational Readiness Review
QA	Quality Assurance
QC	Quality Control
QSL	Qualified Supplier List
RT	Radiographic (volumetric) Examination
S/CI	Suspect/Counterfeit Items
SC	Safety Class
SS	Safety Significant
SSC	Systems, Structures and Components
TSR	Technical Safety Requirements
UT	Ultrasonic (volumetric) Examination

1. INTRODUCTION

This document will examine the roles and responsibilities of the Quality Assurance (QA) organization during the life cycle of projects. As a result, this paper will draw closely upon DOE Order 413.3B, *PROGRAM AND PROJECT MANAGEMENT FOR THE ACQUISITION OF CAPITAL ASSETS* and associated guides, since those documents define how DOE manages projects. The capital project “critical decision” defined phases will provide the framework for this guide’s discussions regarding the involvement of the QA program and will address considerations that local project teams (DOE and contractors) will use in devising/tailoring their project’s Quality Assurance Program throughout the project’s life.

It is the intent of this paper to provide guidance to two audiences; DOE project personnel who are planning and overseeing projects within Environmental Management (EM), and contractor personnel who will be responsible for executing project QA activities. Also, the paper will examine the evolution of the QA program as different acquisition strategies (including Engineering, Procuring, Constructing (EPC), Architect/Engineer (A/E), and Management and Operating/Integrating (M&O/I) options) are considered.

This paper will also discuss the concept of an assurance system where quality is expressed as a project value that is shared in by all personnel assigned to the project throughout its life. Noteworthy practices that have been identified during audits and assessments of EM activities will be highlighted where appropriate.

In accordance with the project stages defined in DOE Order 413.3B, the discussions in this paper will generally align as follows:

- CD-0, Approve Mission Need
- CD-1, Approve Alternative Selection and Cost Range
- CD-2, Approve Performance Baseline
- CD-3, Approve Start of Execution; and
- CD-4, Approve Start of Operations or Project Completion

Projects often evolve from ongoing program funded activities where mission needs are understood and possible approaches to meeting those newly identified needs begin their evolutionary development process.

2. ACTIVITIES UNDERWAY SUPPORTING CD-0, APPROVE MISSION NEED

- Conceptual design activities
- Request PED funding
- Justification of mission need document

- Acquisition Strategy
- Pre-conceptual planning
- Mission Need Independent Project Review

General Discussion:

During the CD-0 time frame, EM needs to focus on developing a project quality system that assures early activities are performed in a manner that provides information of sufficient quality to support subsequent tasks. Putting the project QA framework in place at the outset will also institute the type of quality environment necessary for delivering a project that meets all the performance requirements needed to fulfill the mission.

The EM staff managing the early phases of major projects must ensure that the overall quality requirements for the project are communicated to and understood by all organizations and personnel involved with the project. Understanding and communicating expectations that define the quality requirements and goals of the project are a key consideration. Although the final project contractual structure may be nebulous at this early point in the project, the approach to be used for including EM quality expectations into the project should be part of the project execution planning activities. This early planning should include items such as:

- What will be the overall quality program requirements?
- How will EM ensure that these requirements (and any other quality expectations) are communicated to prospective project organizations?
- Is preliminary work to support the project being performed, and is this work subject to EM's quality expectations? (one example might be early phase R&D and pilot/prototype activities needed to support project design activities).
- Are persons familiar with the EM quality systems part of the early phase project planning teams?
- When will certain quality oversight activities be implemented for the project?

In summary, at this early stage of the project when the executing organization may be somewhat unclear in terms of the level of involvement the M&O/I organizations will have (leading or supporting), whether or not A&E specialty contractors will be relied upon for design services, or if the project will be acquired thru the services of an EPC contractor, QA needs should be understood and accounted for either in existing M&O/I contracts or through independently developed A&E/EPC contracts and other related documents that will be defining EM's expectations for the execution of the project. Building an effective quality environment early in the project is essential. As has been noted, projects are evolutionary in nature and the establishment of clear QA requirements and expectations early will ensure reliable data is developed. Establishing appropriate and clearly communicated Quality Assurance requirements

and expectation will ensure the reliability of early efforts later in the project lifecycle, minimizing the need for the project to regress.

The goal of early phase project quality activities is to build an organization that understands EM's quality expectations and communicates to all project personnel that *Quality is bigger than QA*. Regardless of the acquisition strategy selected, the Federal Project Director (FPD) should be focused on instituting a "project assurance" mentality within the executing organization(s) whereby all project personnel understand that the responsibility for achieving quality resides at the level where work is being performed. Individuals and organizations must be focused on delivering quality products that contribute directly towards mission success (e.g., programs, procedures, calculations, designs, drawings, specifications, plans, etc.).

When acquisition strategies identify the use of A&E/EPC contractors, the FPD will need to assure those contracts fully describe the expectations for Quality Assurance activities under the contract. Assurance requirements will need to fully describe, not only lifecycle QA expectations, but also how EM expects the oversight of early research, development, and design related activities to be performed.

It is not unusual that during this time, process flow sheets are leading to preliminary calculations and design products used to describe early concepts associated with the project (pre-conceptual design documents). The project quality system must ensure that the quality status of such early work is identified to personnel who will subsequently be using this information as sources of design inputs or safety analyses. Concurrently, the FPD needs to understand where his project is headed in terms of new construction or modification of existing facilities, purchase of services, and what safety significant/safety class systems the FPD anticipates being needed. These and other considerations will play heavily on the project's QA requirements as well as the structure of the FPD's assurance team.

The contractor's assurance system must provide for clear definition of interfaces between the varying disciplines involved in design and provide for a process of cross-checking of deliverables at those interface points by the involved organizations. The system needs a strong and independently functioning Quality Assurance organization performing oversight of critical activities such as long lead-time procurements and the design activities producing the specifications for these items. The contractor's assurance system also needs a strong management review process wherein senior leadership of the organization evaluates the performance of their organization and takes effective corrective actions where their oversight identifies deficiencies. The FPD may also decide it is important to establish expectations within the contract requiring the parent corporation to periodically review the work of the local entity and identify weaknesses and initiate improvement.

The efforts included within the CD-0 time frame are largely engineering and design support functions, and the need for a significant QA organization independently overseeing these

activities is to be determined by the FPD. This is a prime example where an assurance system that places responsibility for quality at the point where work is performed adds tremendous value. Introducing quality assurance concepts, even at this early stage of the project, creates a project culture that allows the continued evolution of assurance to proceed and develop as project conditions warrant.

As the project progresses, the activities being performed will transition to those necessary for executing the CD-1 project phase.

3. ACTIVITIES SUPPORTING CD-1, APPROVE ALTERNATIVE SELECTION AND COST RANGE

- Allow expenditure of PED funds for design
- Acquisition Plan
- Conceptual Design Report
- Code of Record
- Preliminary Project Execution Plan and baseline range
- Project Data Sheet for design
- Verification of mission need
- Preliminary Hazard Analysis Report
- Process Related Studies such as Material Balance and Process Flowsheets associated with facility mission

General Discussion

Generally, M&O/I contractors will be supporting EM as directed in developing the pre-conceptual design information as well as other documents that support the decision related processes.

In cases where the acquisition decision defines the M&O/I contractor organization as the executing organization, understanding how that contractor's quality processes will be engaged early needs to be considered. Contractors should examine the applicability of their quality system to any project tasks assigned to their organization.

EM and any project contractors will also need to begin defining the project Code of Record. The Code of Record work should identify those upper-tier design basis documents that will apply to the project. Also, the method for configuration management of the Code of Record as well as products extending from their use, from a project perspective, must be developed.

Specific Considerations:

- Ensure that contract procurement documents include the requirements communicated within the EM Quality Assurance Program (EM-QA-001).
- Where appropriate, incorporate the standard Quality Assurance Clause as communicated via Memorandum of August 21, 2009 into the prime contract responsible for executing the project. (available online at www.em.doe.gov/Pages/QABoardMeetings.aspx#feb2010)
- Cross reference existing M&O/I Quality Programs to the requirements in EM-QA-001 to assure existing program scopes adequately address the projects anticipated needs.
- Begin defining the Code of Record and institute configuration management.
- Verify that project-related research and development work is proceeding under acceptable quality assurance requirements.

4. ACTIVITIES SUPPORTING CD-2, APPROVE PERFORMANCE BASELINE

- Establish baseline budget for construction
- Continue design development
- Request construction funding
- Preliminary design
- Process Related Studies: Material Balance and Process Flowsheet associated with facility mission
- Review of contractor project management system
- Final Project Execution Plan and performance baseline
- Independent cost estimate
- NEPA documentation
- Project Execution Planning (PEP)
- Project Control System Descriptions
- Project Data Sheet for construction
- Draft Preliminary Safety Analysis Report
- Performance Baseline External Independent Design Review reports and other Technical Baseline Documents
- Geotechnical/seismic investigations, studies, and reports
- Optimization/Value Engineering Studies
- Design Reviews
- Modeling/prototyping
- Testing programs (demonstrating technologies or material sufficiency)
- Analytical Laboratory Design Requirements
- Technology Readiness Reviews
- Process Flow Diagrams

Project Related Quality Activities:

The following are activities projects will be engaging as they marshal project documentation in preparation for CD-2.

- Supporting Design processes and review of design deliverables:
 - Develop and implement procedures for reviewing:
 - Specifications
 - Drawings
 - Calculations
 - Design reviews
 - Design interfaces
 - Design changes
 - Provide oversight of configuration management program for control of upper tier design requirements such as design inputs and design criteria
 - Provide oversight of design change control process
 - Assist engineering in developing commercial grade dedication process
- Supporting Procurement Processes:
 - Develop comprehensive quality related procurement subcontract clauses to be flowed to applicable subcontractors, suppliers and vendors addressing:
 - NQA-1 related expectations and requirements
 - Suspect/Counterfeit Item (S/CI) program requirements
 - Commercial Grade/Item Dedication (CGD) requirements
 - Software QA requirements
 - Flow-down of requirements to lower level suppliers
 - Institute grading process for requirements identification and flow-down in subcontracts
 - Define and implement a comprehensive process for qualifying subcontractors, suppliers and other vendors
 - Identify long-lead procurements and ensure the capability to provide required QA/QC oversight is available
 - Develop receiving processes in conjunction with the engineering organization addressing normal receipt inspection activities as well as CGD capabilities and S/CI evaluation processes
- Implement Software Quality Assurance program for applicable design and analysis activities including modeling codes and calculations.
- Develop Quality Control (QC) program plans and procedures
- Develop training and indoctrination plans and procedures for project participants
- Early Procurements: Ensure QA/QC capabilities to oversee those early activities are available (CD-3x requests: project specific as the project employs the approach)

General Discussion

Progress on the project will begin to pick up momentum during the period leading to CD-2. Testing and/or modeling programs are normally nearing completion during the phase which allows process definition to mature. As that maturation process continues, material selections based on process parameters will be made. Drawings and specifications, as well as the calculations supporting those designs, will be underway. Geotechnical investigations will likely be in the field gathering fundamental data to support resolution of soil/structure interactions as well as seismic conditions that will play into the civil/structural design of the building(s) that will house the process. As process definition matures, the ancillary supporting processes and perhaps the facilities where they will be housed will be defined. As stated initially, a tremendous amount of activity will be performed by the technical organizations.

The contractor QA organization will be busy confirming the bases for engineering decisions are well executed as data and calculations are translated into plans, designs, specifications, etc. Particular care needs to be paid to ensure adequate and appropriate QA requirements are defined within those specifications. NQA-1, Part II contains insight within the amplified requirements that the project should consider.

The QA organization must also ensure the contractor QC programs and procedures are appropriate to measure those characteristics that will define the quality of an item being installed. The codes and standards defined by the code of record and referenced in the various design documents will define attributes that must be achieved to assure that Structures, Systems, and Components (SSCs) will perform as expected. Procedure authors must consider all these requirements and devise a set of procedures that ensures data is collected and retained that demonstrates reasonable assurance the SSC will perform as required.

For example, QC inspection procedures must confirm that fit-up requirements defined within Weld Process Specifications (WPS) are accurately used by crafts performing welding of pipe, accurately referenced and used by the QC personnel at all organizations including fabrication related suppliers or field personnel, etc. Another example is drawn from structural steel erection. The American Institute of Steel Construction (AISC) provides a Specification of Structural Joints Using ASTM A325 and A490 Bolts. Therein it discusses acceptable fastening processes for the various kinds of joining operations associated with bolted connections. QC procedures should address specific fastening processes selected by the designer and collect information as necessary to substantiate fastening of the structural components to achieve the design expectations.

Also during this phase, the QA organization must verify that all appropriate organizational interfaces have been defined and understood. In particular, lines of communication and organizational responsibilities for activities specified in project execution plans must be clearly defined in interface documents and understood by the appropriate project personnel. For example, close coordination of procurement and fabrication organizations with design personnel

is required so that QC and QA procedures accurately plan for the collection of the right information that verifies the design intent is actually achieved. The specific responsibilities for design and fabrication activities by all involved organizations, including contractors and EM organizations, should be defined in interface control documents or other project plans, procedures and subcontracts, where applicable. The design authority and design agency functions should be included in these interface definitions.

Specific Considerations:

Early Procurements:

As projects develop, the need for specialty services, such as geotechnical/seismic engineering services and/or soil sampling/testing capabilities to support in-house engineering activities may be identified. Also, it is often appropriate for early CD3x authorities to be granted to address long lead procurements or site development needs. These are business decisions and will be tailored to the particular project based on their needs to move in an orderly fashion to executing the full CD-3 scope.

The FPD and contractor will be working closely to identify those strategies that are appropriate for their particular project. When such authority is granted, special care must be taken to ensure the QA/QC requirements and programs/procedures supporting those scopes are well developed and adequate to assess those early activities. That may require expediting development of these kinds of documents, particularly in the case of EPC managed projects, to ensure the early work is performed in a competent manner. Procedures controlling Supplier Qualification Audits as well as those needed to provide oversight of suppliers/subcontractors must be available when executing early work.

FPDs should have resources associated with the oversight of the contractor's early services subcontracts, as well as any subcontracts related to early CD3x activities, identified, available, and deployable as the authority is conveyed and work moves to execution. Further, the FPD should carefully examine how the contractor is overseeing both in-house and subcontracted work to help identify weaknesses and correct them before full CD-3 construction authorities are granted.

Supplier Qualification:

Experience suggests supplier evaluation/qualification is a very important process and weak processes may allow problem suppliers onto project approved supplier lists (ASLs/QSLs). Both EM and EFCOG have concluded that diverse audit teams, representing QA and technical organizations are best to effectively evaluate supplier capabilities.

EM's experience has shown there are suppliers with effective QA programs predicated on NQA-1, which appear competent based upon initial reviews. However, some suppliers have been ineffective in operating those programs as the work is performed. This forces EM's prime contractor to dedicate additional resources to assure the adequacy of supplier performed work. This experience is primarily in heavy industries engaged in ASME related activities (vessels/piping) and needs to be evaluated based on the scope of the project and market surveys completed by the contractor in ascertaining potential participants in subcontracts.

EM has a collective wealth of experience with numerous suppliers and regularly observes that suppliers are contracted to multiple projects. Contractors should engage other EM/DOE contractors within the complex as these kinds of decisions are being made. The FPD may need to facilitate those discussions.

The project may experience poorly implemented QA programs within some supplier shops. Projects will have to be ready to focus additional resources to assure the quality of the items being fabricated in that supplier's shop meet the project's design expectations. A best practice observed in the EM complex is to assemble teams of QA and select technical personnel that bring the requisite skills to the problem and deploy them to the problem shop to supplement supplier resources and perform additional assurance functions as required. These are often diverse teams involving QC, NDE, welding and QA expertise. Depending on the nature of the engineered equipment being fabricated and observed performance issues, these teams may be deployed for extended periods. EM has observed skills possessed by the NDE and welding engineering personnel are not needed on a daily basis in the supplier shops. They normally rotate thru the supplier's shops as suppliers perform radiographic/ultrasonic examinations (RTs/UTs) or qualify welders.

Welding engineers may need to pay additional attention as suppliers introduce new welding processes into the work or begin welding under different WPS to ensure the supplier's qualified welders possess the appropriate skills for the work. The welding engineers should review the supplier's welder qualification processes to ensure they are adequate.

There have been instances where skill of supplier's NDE interpreters has been less effective than necessary. In these instances, prime contractors have bolstered their Level III interpretation resources and periodically deploy them to perform oversight of this crucial process. The NDE skills, particularly of RT examiners may also rotate thru shops as the work necessitates.

These decisions will be considered in the context of the problems being encountered and the need for compensatory oversight plans to address the unique weaknesses discovered within the supplier's organization.

Software Quality Assurance:

The EM contractor requirements for software quality assurance are defined in Attachment 2 Section 5 and Attachment 5 of DOE Order 414.1D. Guidance on implementing a software quality assurance program that meets EM expectations is provided in DOE Guide 414.1-4. Early establishment of a software quality program is essential to providing confidence in the quality of design results because many design activities are now performed using computer codes and models. Additionally, the proficiency of today's engineers in writing software and developing spreadsheet models virtually ensures that such personally-developed calculation routines will be part of the design process. The quality assurance program must include persons with knowledge of software quality assurance early on and must develop procedures for identifying and controlling software used in design activities, research, or development work that develops design inputs.

Many of EM facilities are reliant on distributive control systems to operate facilities. Computer software used to automate Safety Instrument Systems and Balance of Plant DCS systems require special care. EM observations are that it is crucial to develop clear and concise technical requirements to all procurements, but perhaps the best example is with DCS related equipment and software.

QA Organization and Budgeting:

Special care must be taken when building budgets in support of project oversight by the QA organization. There are times contractors present these costs as Level of Effort (LOE) activities and this approach is routinely viewed as suspicious by those tasked with assuring budgetary requests are reasonable. Contractors should consider directly linking QA/QC activities to specific work activities within resource loaded project schedules. This approach represents a clearly correlating link between the work being overseen and the resource(s) needed to perform its oversight. It is recognized that all oversight, particularly that of other LOE activities in project budgets, isn't practical. In those instances, contractors need to pay careful attention to documenting the scopes included in the LOE and making the clearest possible link to those LOE activities being performed by other organizations. It may best serve the QA Organizations' interests to use the WBS dictionary descriptors as it develops these narratives and expand on the nature of the oversight attributable to discrete WBS entries rather than attempting to generate overarching discussions to justify resource requirements grouped together. The former should result in a clearer case for the resource allocations being requested within the CD-3 budget request.

When allocating risks within the project baseline, the contractor and FPD should work closely together to understand the nature of the work, the nature of the supplier pool likely assisting the project, and evaluate risk appropriately. FPDs observing contractors planning minimal oversight of suppliers should enter discussions with the contractor to understand their basis for this

decision and determine if their approach for identifying project risks is reasonable. FPDs should ensure their contractor is adequately examining the risks associated with subcontractor/supplier performance and, when appropriate, addressing those risks within the project's risk management/mitigation planning.

Commercial Item Dedication:

The project will likely be engaged in the dedication of commercially available items. Requirement 7 of NQA-1 should provide the basis for project programs and procedures involving the dedication process. The project personnel responsible for establishing Commercial Item Dedication requirements/programs should consult a document entitled Guidance for Commercial Grade Dedication, published July 2011 and may be found at: <http://www.em.doe.gov/Pages/QACorporateBoard.aspx>.

QA will have a role in the dedication activities; however, their responsibilities should be generally limited to performing the tasks associated with item acceptance, as identified by engineering. Therefore, engineering must have the lead in identifying the required dedication activities. QA's participation can, however, be invaluable as assure Critical Characteristics for Acceptance (CCFAs) adequately relate to safety function(s) associated with a SSC, and CGD documents, be they supplier or project originated documents, adequately address the dedication data being communicated.

Commercial Item/Service Dedication must:

- Clearly identify the item/service
- Bound the application
- Research the design to identify the safety functions, the service conditions and the design margin
- Determine the safety significance of the item considering the consequences and likelihood of failure
- Determine the characteristics of the item that are critical to performance of the safety function
- Select acceptance methods, acceptance values and sample plans commensurate with the items significance
- Document approval that the item/service will, with reasonable assurance, perform its safety function
- Fully document the basis for all decisions associated with the dedication of an item or service

QA and Engineering will also have important duties for suppliers performing dedication activities. Validating the effectiveness of dedication actions down in the supplier's supply chain

is essential to understanding how dedicated components get assembled into larger assemblies and eventually accepted for use in the project/facility. Lessons learned by EM projects suggest the lower tier suppliers often don't understand the dedication process or how to implement it with the level of rigor required to adequately demonstrate the item/material/service will perform its intended function. Contractor specifications need to thoroughly address the expectations associated with commercial item/service dedication and establish requirements within prime-subcontracts that the requirement be passed down to subordinate subcontractors.

The contractor must review each dedication plan developed by prime-subcontractors and their subordinates to ensure the lower level dedications are performed effectively and do not introduce unresolved quality issues as the eventual item or service is delivered to the facility. Although the engineering organization will have the lead, QA has a role in supporting the validation of subsupplier dedication activities.

In order that these reviews are performed correctly and consistently, project QA programs must address oversight of supplier dedication activities. Particular care needs to be paid, in plan approval, to supplier's technical evaluations to assure the item or service will perform as intended. Close communication may be required to adequately convey the functional requirements associated with the item or service so those responsible for identifying critical characteristics associated for the item or service are effective. The project may see the need to have review/approval of this process so engineering organizations are assured the communications leading to the identification of those critical characteristics, and eventually the selection of those key characteristics for acceptance by suppliers, will be effective.

Material Verifications:

The project needs to identify, within its procedures, the methods to be employed for verifying materials by both self-performed activities as well as those activities performed by suppliers. The project should identify sources of specialized laboratory support in performing chemical and physical properties testing. QA will need to qualify laboratories in terms of adequate procedures, appropriately qualified personnel, and the adequacy of equipment to perform against the various consensus standards controlling the properties of the material. Similar considerations will be needed by suppliers, depending on the approach to material verification they will use.

EM contractors are widely using Positive Material Identification (PMI) techniques in validating material. Project engineering personnel need to consider the convenience and limitations of the available equipment. Particular care needs to be taken in describing, in project procedures, the expectations regarding verifying certified material test reports (CMTRs) for all materials. Depending on the materials identified within the design, engineering may need to identify additional controls that are needed when examining exotic metals, particularly those low-carbon alloys with chemical makeup beyond the limits of PMI equipment or other alloying materials not measured by PMI equipment. Recognizing its limitations, PMI should NOT be viewed as an

independent analysis of alloying ingredient content. Rather, PMI provides a degree of confidence that the material is accurately represented by the accompanying CMTR; that no mix-up has occurred during procurement and storage. If the chemical and physical properties of the material must be independently tested, or the content of light elements such as carbon and nitrogen must be verified, then a sample should be sent to a qualified laboratory for the appropriate analyses.

The project needs to address, if it selects to utilize PMI in material validation, how it relies on PMI-obtained chemical properties in accepting physical properties (tensile and yield strength, hardness, ductility, etc.) data found on CMTRs and CoCs. ASME Code Case N-483 entitled *Alternative Rules to the Provisions of NCA-3800, Requirements for Purchase of Material Section III, Divisions 1 and 3*, is an instance where that code body has devised a methodical approach to using alternative data to validate vessel material. Engineering must identify the bounds within which PMI can be used and define where it may not.

Inspection and Testing Support:

In general, NQA-1, Part I, Requirement 10 states within 100 Basic “Inspections required to verify conformance of an item or activity to specified requirements or continued acceptability of items in service shall be planned and executed.” Identifying those attributes of an item or activity that are essential and are to be documented will require close coordination and identification/agreement of the engineer designing the item or specifying the activity.

The requirements continue by emphasizing “Characteristics subject to inspection and inspection methods shall be specified. Inspection results shall be documented.” This is where QA/QC procedures will clearly layout the expectations and preferably the actual requirements associated with the work being executed. At a minimum, the QA/QC procedures must define where inspection requirements or acceptance criteria is found, such as concrete specifications (compressive strength, slump/air content, temperatures, truck revolutions, etc.), Weld Process Specifications [fit-up requirements (gap, land, bevel, preheat, post-weld heat treatment, etc.)], etc. are to be found.

Project QA personnel need to plan for specialized testing services that may be needed to support QA and QC activities. These services may be obtained via staff augmentation or may take the form of specialty subcontracts where services are needed to perform supporting activities like concrete testing, radiographic examinations, material testing, etc.

These services will either be obtained from organizations with existing and effective NQA-1 QA programs or from service suppliers with QA programs finding their basis in some other standard, and dedicated (CGD) by the project. The decision regarding the method the project will use will likely be driven by commercial conditions that will only be known as the procurement is

processed. As a result, it is recommended these services be procured at the appropriate time, such that the services are available when needed to support the work.

The project, if it involves concrete, needs to be mindful of the storage requirements for test specimen that will be generated as construction proceeds. ASTM C31 will normally be the standard that establishes the storage requirements for freshly molded concrete test specimen. It establishes the physical requirements as well as temperature limitations associated with temporary storage of the specimen. Potential difficulties associated with temperature extremes need to be understood and planning effective in assuring cylinders do not exceed the limits established within the standard. Other controlling codes or standards to a project need to be understood and similar considerations recognized and planned to avoid disruptions.

Nondestructive Examination (NDE):

Engineering needs to define the requirements associated with NDE as it pertains to the various materials to be used within the project. In the case of weld examination for process piping systems, ASME B31.3 establishes visual examination as well as other examinations required under the code. In the case of Normal Fluid Service piping, Section 341.4 requires at least 5% of circumferential butt and miter groove welds be examined fully by random radiography. The code goes on to provide some cautionary statements associated with the RT examination frequency. The code body advises:

Random or spot examination will not ensure a fabrication product of a prescribed quality level throughout. Items not examined in a lot of piping represented by such examination may contain defects which further examination could disclose. Specifically, if all radiographically disclosable weld defects must be eliminated from a lot of piping, 100% radiographic examination must be specified.

This advice needs to be considered by engineering as they are determining the NDE requirements for the systems they are designing. If the service of the piping, or other welded components, mandates the potential presence of a weld defect could compromise the integrity of the system and that compromise would result in an unacceptable consequence, then the NDE requirements associated with that work needs to be commensurate.

EM has observed piping that underwent 5% random sampling within the initial inspections, actually contained ~30% defects. Engineering needs to be mindful of this potential as it establishes NDE requirements for piping, vessels and similar components.

EM's experience has shown instances where 100% radiographic examination of piping or vessel components is appropriate. In instances where components are destined for areas of the facility that, due to design considerations, repairs are impossible or otherwise inconceivable, (e.g., embedded within concrete structures) an increased radiographic examination is warranted. These

considerations will not only affect QA inspection plans but also will affect specifications of procured engineered equipment destined for these areas. Fabricated components (i.e., spool pieces) performed via subcontract agreements will also be included.

Another consideration engineering needs to define as it prepares its specifications is how piping “lots” will be managed within the context of the NDE examination processes. ASME B31.3 states:

A designated lot is that quantity of piping to be considered in applying the requirements for examination in this Code. The quantity or extent of a designated lot should be established by agreement between the contracting parties before the start of work. More than one kind of designated lot may be established for different kinds of piping work.

It may be in the project’s interest to manage piping lots around those components shipped concurrently. This allows for a simplistic approach to the transfer of QA supporting document that may benefit the project. By defining shipped quantities as lots where possible, all QA records, including radiographic or other NDE examination records, may accompany the shipment, making records management more simple. This approach may be particularly helpful when subcontracting for large quantities of spool pieces or other similar fabricated items with NDE associated with the item’s production. Similarly, defining lots for internally produced spool pieces will make NDE, particularly when predicated on sampling approaches, more manageable and defensible as reviews of QA documents take place.

Although it is recommended specifications establish lot designations, it is not imperative. As advised by ASME, there needs to be agreement between the parties before the start of work. Since the lot designation process has the potential to effect the amount of NDE performed as the items are fabricated, it is recommended that subcontract documents clearly establish the expectations so that suppliers may appropriately plan and bid the work.

Lastly, Engineering needs to define those processes, acceptable under the various codes that are deemed acceptable processes to be used on the project. For example, ASME allows volumetric examination using ultrasonic (UT) as well as radiographic (RT) processes. Engineering needs to evaluate the pros and cons as they define the project NDE requirements. There are instances where geometry limitations restrict RT. There are other instances where interferences restrict UT. When Phased Array UT is contemplated, the limitations and difficulties associated with the approach need to be understood and planned. Digital RT also involves considerations that need to be understood and planned by the project. These processes need to be considered and any project specific expectations addressed within specifications for engineered equipment or other items fabricated by suppliers.

Measuring and Test Equipment:

The project will need material and test equipment (M&TE) in validating the work performed. Planning must also address the calibration capabilities that will support the confirmatory process associated with M&TE. Understanding the design associated with the various SSCs found within the project will aid in understanding the nature of the M&TE inventory needed to support the project. Ensuring these items are available when needed is essential to ensure work is not delayed.

Qualifying QC personnel:

ASME NQA-1 Requirement 10 establishes “Inspection for acceptance shall be performed by qualified persons other than those who performed or directly supervised the work being inspected.” Accordingly, testing procedures must require that QA/QC personnel divorce themselves from the performance of work in order to maintain their independence and objectivity when performing their duties. QA/QC programs and procedures must establish minimum qualifications for personnel performing tests and inspections and should likely reference the recommended practices found within the ASNT SNT-TC-1A. SNT-TC-1A provides guidance concerning the qualification of personnel performing the various NDE testing methods typically relied on by EM projects and operating facilities. Contractor qualification processes are to conform to the contract requirements concerning QA, but at a minimum should be relying on processes described in SNT-TC-1A.

Note to FPDs:

NQA-1, Requirement 2 identifies an expectation that NDE, Inspection and Testing personnel will be qualified. In communicating this expectation and while preparing prime contract QA requirements, it is suggested that consideration be given to elevating the “recommended practices” found within American Society for Nondestructive Testing, Inc.’s (ASNT) SNT-TC-1A and convey the qualification process as the minimum requirement for qualifying QA/QC personnel. The SNT-TC-1A requirements associated with Written Practices (Ref. Chapter 2) should also be required within the contract. The FPD should convey the expectation that these requirements be flowed into appropriate subcontracts where applicable work is to be performed, including, but not limited to, any procurement for engineered equipment or other items where fabrication activities requiring NDE to validate the acceptable nature of the work is to be performed. Although other qualification and training processes are potentially acceptable and capable of ensuring testing personnel are appropriately capable, ASNT processes are widely recognized as a competent method for qualifying NDE personnel.

EM personnel:

The FPD will continue assembling his integrated project team (IPT) adding different talents as the project moves from design to construction. During CD-2, the IPT will be reviewing contractor originated programs, plans and procedures that will define the QA program and activities used throughout the duration of the project. These reviews will be focused on adequacy to provide the required oversight of the project. Planning for the availability of personnel with the skill sets required within the scope is necessary as the FPD puts together the oversight team. In scopes where considerable welding of piping systems and vessels are included, it is recommended the FPD obtain the services of personnel with experience in the appropriate ASME codes. It is also recommended, since many EM projects have considerable civil/structural features, that personnel experienced in the American Concrete Institute (ACI) and American Institute of Steel Construction (AISC) be integrated into the staff. Electrical, HVAC, instrument and controls, and radiological controls are skills that will be needed to support final design and installation.

The FPD will need to understand how to obtain these resources and plan accordingly. Often time, these skills may not exist within DOE employees and will have to be obtained thru contract support instruments. As the FPD develops the budget for the DOE related costs associated with the project, the planning needs to not only provide for the employment related costs associated with these resources, but for the travel and perhaps equipment and other supplies required to support oversight of contractor and supplier quality processes.

The Quality Assurance program developed during the CD-2 phase will then be implemented across a wide range of activities during the CD-3 project phase.

5. ACTIVITIES SUPPORTING CD-3, APPROVE START OF EXECUTION:

- Approve expenditure of funds for Construction
- Update Project Execution Plan and performance baseline
- Final design and procurement packages
- Verification of mission need
- Budget and congressional authorization and appropriation enacted
- PDSA is updated
- Execution Readiness Independent Review
- Operations Assessment (HAZOPS Review)
- Operations Requirements Document
- Site Layout Drawings
- Construction, Procurement, and Acceptance Testing Planning
- Procurement System
 - Qualifying suppliers of SS/SC SSCs and other critical procurements

- Supplier oversight
- NDE/QC presence when appropriate
- Acceptance of supplier delivered items
- CGD oversight of supplier and subsupplier organizations
- Receipt Inspection Plans
- Construction Work Packages
- QA/QC programs
 - Audits and assessments
 - Acceptance Testing Program of Constructed SSCs
 - NDE/Destructive testing
 - Inspection in the field/supplier shops
 - Accepting work
 - Record generation and retention
 - Inspection Guides/Plans
- S/CI
- CGD
- SQA
- Start-Up/Commissioning Plans
- System Operational Tests/Integrated System Operational Tests

General Discussion

The Quality Assurance organization is entering the project period during which it will be processing numerous quality related activities concurrently. The organization will have to be staffed and organized in order to meet the challenges. The work will not only be at the project site, but will likely begin to accelerate in supplier shops as engineered equipment and other items are being fabricated for the project.

At this point in the project, the QA organization's procedures must be mature and ready to support construction. An important part of supporting the project involves remaining cognizant of those activities being performed as well as those upcoming. The schedule is an important tool in remaining aware, but involvement in the construction organization's internal meetings is also needed. Plan of the Day meetings and the like should be attended so emerging events are understood and planning for effective and timely oversight may be accomplished.

Generally, Civil/Structural activities will be the early focus although other discipline activities may be underway depending on the project's use of early construction authorities. Receipt inspection activities, as raw commodities are delivered, will be numerous. Inspection plans that cover installation, as well as the receipt of materials, need to be available as these activities occur. If the execution strategy is to utilize M&O/I contractors to deliver the project, the QA/QC procedures, Receipt Inspection Plans, etc. will likely be already developed. If the execution

strategy is to use an EPC contractor, these plans may not exist immediately prior to the inspection activity. Regardless, inspection procedures need to thoroughly document the quality requirements identified by design that are essential to the performance of the item and capture the details to be documented as the item is inspected.

Specific Considerations

Appropriately qualified personnel must perform inspections.

The QA staffing level will be influenced by several decisions by the Contractor. One model in use today places responsibility for the achievement of quality with the work crews and assigned Field Engineers. The FEs provide crucial guidance to the crafts in understanding the design, and FEs also help communications (interface) with Engineering, QA and other organizations. If the contractor elects to not assign sufficient FE resources, then QA and QC personnel, may fill the vacuum. As management seeks to maintain adequate resources on the project needs to be mindful that QA/QC must maintain its independence from the execution of work and take action when the interactions between QA/QC and other personnel begins to encroach on that independence. The same point may be made for Field Welding Engineers.

ASNT SNT-TC-1A provides guidance concerning the qualification of personnel performing the various NDE testing methods typically relied on by EM projects. SNT-TC-1A conveys methodological approach that is widely recognized to meet the qualification expectations NQA-1 expresses within Requirement 2. This document should provide the basis for prime contractor, subordinate subcontractor, and supplier qualification programs. QA personnel assigned to oversee supplier operations will be reviewing the qualifications of personnel performing various inspections within those shops. It is imperative that the suppliers' qualification processes effectively demonstrate the abilities of the NDE personnel and other inspectors, as well as the welders when necessary, within the scope of work assigned. Equally important are the inspection procedures, written practices, etc. these personnel will be using as they perform inspections. Weld Process Specifications (WPS) will communicate both the fit-up requirements to the welder and the same information becomes acceptance criteria for the QC personnel as they inspect that work. The inspector will utilize written practices in defining the steps to be used while performing those inspections. Written practices are particularly important to nondestructive examiners (NDE) personnel. Whether the examination uses dye penetrant testing, ultrasonic tests, radiographic tests, etc., those practices are of critical importance. The written practice must faithfully implement the applicable standard controlling the work and be followed closely by the NDE personnel. Prime contractor surveillance of supplier performed inspections should regularly focus on the adherence of the inspection to the written practice covering it.

Quality Assurance and Quality Control (QA/QC) personnel must be thoroughly familiar with all the provisions of the documents that describe the work, including submittals and other documents pertinent to the work (design changes, requests for information, etc.). The inspections

are to be directly relatable to plans and specifications, including all revisions, changes, and amendments.

Records:

The Quality Assurance organization of the prime contractor and suppliers' organizations will generate numerous records that provide documentary evidence that items or activities meet specified quality requirements. These records will fall into two broad categories:

- Lifetime records: Those records that meet one or more of the following criteria:
 - Would be of significant value in demonstrating capability for safe operations,
 - Would be of significant value in maintaining, reworking, repairing, replacing or modifying an item,
 - Would be of significant value in determining the cause of an accident or malfunction of an item.
 - Provides baseline data for in-service inspections

Lifetime records are required to be maintained for the life of the particular item while it is installed in the plant or stored for future use.

- Nonpermanent Records:
 - Those records required to show evidence that an activity was performed in accordance with the applicable requirements but need not be retained for the life of the item because they do not meet the criteria for lifetime records.

Nonpermanent records shall be maintained for the retention period identified by project procedures or as identified in applicable national code or standard.

Part II of NQA-1 contains additional guidance on the records normally required. NQA-1 integrates national consensus code requirements associated with record retention into the record retention requirements. Part II subparts typically end with a Records Section that requires:

Record copies of procedures, reports, required qualification records, test equipment calibration records, test deviation or exception records, and inspection, examination, and check records shall be prepared. These records shall be retained with other project records as required by code, standard, specification, or project procedures.

Additional records requirements may be defined in design codes or standards specified in the project Code of Record. ASME B31.3, *Process Piping*, for example, is a code typically used in EM projects. Chapter VI entitled Inspection, Examination, and Testing establishes the requirements associated with the QA/QC activities for Process Piping. Section 346 specifically discusses the minimum records required under the code and should provide the basis for the

project's determinations associated with lifetime and nonpermanent records. As the design work proceeds, the project may decide other tests are required to confirm the acceptability of the component to perform the design intent. Records associated with those additional tests will be generated and retained as indicated by project procedures. These additional records will be additive to those identified by the national code or consensus standard upon which the design is predicated since the code or standard identifies those minimum tests required.

Other codes will similarly be used as the record determinations are made, acceptance criteria are identified, testing and inspection activities are developed and performed, and QA documents are prepared and accepted into the project's document control system. Procured items require special care when reviewing deliverables that accompany the item. Quality documentation will be retained by the project, some are lifetime while others are not. Radiographic film requires extraordinary care. Project design and QA personnel will need to ensure procurement requirements associated with vessel weld radiographs are addressed in a manner consistent with project's QA and records-retention needs. Many projects identify vessel RTs as Life-Time Records under one or more of the criteria associated with its definition. The code is requiring the fabricator retain RT films. The project may decide to require vessel fabricators (and perhaps others) to prepare double cassettes when radiographing welds. This will allow the fabricator to remain compliant with the code requirements and the project to possess a lifetime record of the vessel installed in the facility.

As preparation for operation begins, the quality assurance organization must transition its activities and staff to support an operating facility.

6. ACTIVITIES SUPPORTING CD-4, APPROVE START OF OPERATIONS OR PROJECT COMPLETION

The tasks that involve quality assurance include:

- DSA
- TSRs
- Cold Commissioning Process Verification Report
- Design Capacity Performance Tests
- Off-standard Operational Testing
- Cold Commissioning Results
- Certification of Completion of Cold Commissioning
- Final Documented Safety Analyses
- Readiness for Hot Operations
- Hot Commissioning Start
- Environment Performance Test
- Hot Commissioning Results

- Documents Attesting to Completion of Hot Commissioning
- Project Closure Package
- Facility Turnover
- As-built drawings
- Document close-out
- Start-up Plan

General Discussion

There are several tasks within CD-4 (Approval of Start of Operations and Project Completion) that the Contractor quality assurance organization completes or supports to assist the project. These activities generally verify that processes for preparation, review, approval, issuance, use and revision of documents that prescribe processes, requirements, and design are implemented (including change control for revision) to ensure that actions are planned and carried out by qualified personnel using approved procedures, instructions, and equipment under administrative, technical, and environmental controls.

Also, the quality organization must verify that design processes are implemented which provide appropriate control of design inputs, outputs, verification, configuration and design changes, and technical and administrative interfaces. These processes include configuration management activities pertaining to operations and maintenance and transition of the design authority role to cognizant individuals within the operating facility organization.

Specific Considerations

The following discussion provides insight into specific items needed within the general tasks mentioned above.

Checkout, Testing, and Commissioning Plan

QA should review all associated documents and records to assure that processes for preparation, review, approval, issuance, use, and revision of the plan are implemented and that the plan addresses the QA requirements of the operating organization. This should include inspection and acceptance testing to assure that performance expectations, acceptance criteria, inspections and tests, and calibration of M&TE are adequately addressed. Some of the documents that QA should be monitoring may include: Test instructions (TI), Grooming Packages (or other packages that may be used locally to establish prerequisites for system testing), Test procedures, Test Deficiency reports, Test Directives and Procedure Change Requests. QA/QC personnel should remain engaged as other organizations conclude testing to assure tested systems are restored appropriately as the testing program concludes.

Allow start of operations or project close-out including document closeout

As construction work is completed, the work control documents are reviewed for closeout. If the construction was performed by a subcontractor with responsibility for the cold/hot testing, then the work control document closeout may be a subcontractor responsibility with final acceptance by the Contractor as vendor data. Alternately, if the construction was performed by the Contractor, then the Contractor would be responsible to review and close the work control documents. In either case, QA should review the documents ensuring the necessary signatures, dates and inspection reports were completed. In addition, QA should review any nonconformances or deficiency reports related to the work control document ensuring those reports were closed. If there is a transition between construction work control and operations work control processes, the QA organization should be engaged in this transition and turnover process to assure QA requirements for documentation and work control are effective. This includes verification that processes for preparation, review, approval, issuance, use and revision of documents that prescribe processes, requirements, and design are implemented (including change control for revision) to assure that actions are planned and carried out by qualified personnel, using approved procedures, instructions, and equipment under administrative, technical, and environmental controls. QA will verify that design processes, which provide appropriate control of design inputs and outputs, verification, configuration and design changes, and technical and administrative interfaces, are implemented.

Operational Readiness Review and acceptance report

QA is an integral part of testing and commissioning. The QA tasks include test plans and procedure reviews ensuring adequate acceptance criteria are cited, verifications during the testing phase that acceptance criteria are met, and review of the test reports for completeness. Testing would include the design capacity tests, hot and cold commissioning tests, environmental performance test, component tests, and integration tests. As part of the testing process, QA would complete surveillances of testing operations ensuring procedure compliance. QA also is responsible for the quality control and inspection activities that support the testing and commissioning activities. This includes completing and validating inspection reports, pressure tests, and other hold points as called out in design and work control documents.

There is also a need for QA to assure that processes are in place to identify, control, and correct items, services, and processes. If the processes do not meet established requirements, then corrective actions are developed and implemented to preclude recurrence.

It is also critical for QA to review work control and work documentation to assure that the planned scope of work demonstrates that work prerequisites have been satisfied, personnel have been suitably trained and qualified, and detailed implementing documents and management controls are available and approved.

Project transition to operations plan/report

QA is responsible to assist operations and construction organizations in preparation and implementation of processes that assure quality management approaches are established and implemented for preparation, review, approval, issuance, use, and revision of the transition plans.

Final Documented Safety Analyses

During the final Documented Safety Analysis preparation, QA reviews the QA chapter to ensure the information is up-to-date. During subsequent operating procedure reviews, QA determines if the appropriate QA requirements are included in the procedures and helps assure that processes for preparation, review, approval, issuance, use, and revision of the DSA and TSR documents are implemented to assure that applicable design inputs are controlled and configuration management requirements are met.

As-Built Drawings

QA may provide several services during the as-built drawing phase including, some field verification of the drawings, review and approval of the final drawings, and confirmation that the drawings have been properly reviewed, approved, and placed in document control. Another QA activity is the verification that a key or essential drawing list has been established for operations and that those drawings have been as-built and released for use. The as-built process is part of the overall facility turnover activity.

Facility Turnover

When the facility is ready for turnover or partial turnover, a punch list of items is normally generated between the constructor and the facility owner. Those punch list items are remaining work that either must be done before the constructor leaves or items the owner agrees to finish. Many times the QA organization helps develop and verify the punch list items. As a minimum, QA ensures there is a defined process for the turnover process including the use of punch lists. The facility owner may decide to use a corrective action system to track the punch list items. In which case, QA will have to factor those action items from the corrective action system into the close out verification before operations start.

O&M Manuals

The facility owner will have to ensure that all the needed O&M Manuals are obtained from the constructor. Those manuals should have been transmitted via a vendor data system during construction turnover. However, a review of the vendor data system by the appropriate system engineers is necessary to ensure all needed vendor data, including the O&M Manuals are present.

Management Self-Assessment

During management self-assessments (MSA) the project determines their readiness for an independent review, usually an ORR. QA evaluates the existing QA program at the project level to determine adequacy for operations. QA also reviews QA training records to ensure required QA pre-operational training is completed. If the QA staff supporting operations must complete some operations-related training (i.e., DSA training) this verification would include evaluating completion of that training. In addition, a review of open nonconformance and deficiency reports is completed and a list provided to project management. Project management then determines the priority of open issues as either pre-start or post-start issues. QA provides support to the project during MSA, ORR, CRA, etc. preparation and performance. The QA support during MSA, ORR, and other internal or external reviews is to assist with the preparation of objective evidence files, providing status on nonconformance and/or deficiency reports, verification that the as-built drawings and other operational documents are approved and released, and close-out of construction work control documents.

Oversight Plan

Another QA task during CD-4 is preparation of an oversight plan or strategy for the upcoming operations phase of the project. QA may periodically complete surveillance on various operations to verify procedure compliance and identify opportunities for improvement. The schedule or strategy is coordinated with the operations staff to ensure the surveillances focus on important operational activities.

Final Project Closeout Report

QA is also tasked with helping assure that project has established, implemented, and documented processes to detect and prevent quality problems and that problems have been corrected and documented.

7. CLOSING THOUGHTS

As communicated within the body of this guide, establishing a comprehensive QA program appropriate for the project scope requires considerable investment in understanding the work to be performed by all parties involved. There is no “model” that may be applied to individual projects that shortens this process.

This guide would be remiss if it weren't to reference the vast number of tools for EM projects to consider as projects are managed, and particularly as those projects' QA Programs are developed. These tools include the Standard Review Plan Modules, which are available on the EM Website (<http://www.em.doe.gov/Pages/qualityassurance.aspx>). DOE personnel should consider the content of these modules when considering what particular requirements and

expectations are being developed. The lines of inquiry should point out to contractors what elements need to be addressed within quality programs and procedures.