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Quality Assurance
Improvement Project Plan

Project Focus Area	Task # and Description	Deliverable
Project Area 3-Commercial Grade Item and Services Dedication	**3.1-Complete a survey of selected EM contractors to identify the process and basis for their CGI dedication program including safety classification of items being dedicated for nuclear applications within their facilities**	**Completed Survey**

Approvals:	Yes/No/NA
Project Managers: S. Waisley, D. Tuttel	**Yes**
Executive Committee: D. Chung, J. Yanek, N. Barker, D. Amerine	**No**
EM QA Corporate Board:	**No**

ISM

EM/EFCOG Quality Assurance Improvement Project Plan
Project Focus Area #3 -Commercial Grade Item and Services Dedication Implementation and Nuclear Services
Task #3.1: Commercial Grade Item (CGI) Dedication Survey Summary

1. Purpose:

   This survey was conducted to obtain input from EM contractors on processes used to perform Commercial Grade Item (CGI) dedication. The intended use of this information is to form the basis for providing a recommendation to EM for a standard process for CGI dedication.

2. Survey Approach and Response:

   A formatted survey request (Attachment 1) was sent to contractor points-of-contact across the DOE complex. Nine responses were received.

3. Survey Results (results align with question numbers in Attachment 1):

   1) Seven of 9 contractors providing a response use a CGI dedication process. Two contractors providing a response do not have Safety Class/Safety Significant Structures, Systems or Components; therefore, do not use a CGI dedication process.

   2) Seven of 7 responders using a CGI dedication process follow the process described in a DOE-approved Quality Assurance Program.

   3) Five of 7 responders control the CGI dedication process using a cross-cutting functional organization procedure. Two responders use project/organization specific procedures.
   Five of 7 responders cite Engineering as the principal organization responsible for the CGI dedication process. One organization cites Quality Assurance and one organization cites the organization originating the CGI dedication.

   4) Industry standards used as the basis for the CGI dedication process vary:

      a. Four of 7 responders cite NQA-1-2000.
      b. Three responders cite NQA-1-2004.
      c. Three responders cite EPRI NP-5652 in addition to NQA-1-2000 or 2004.

   5) Seven of 7 responders use CGI dedication for Safety Class and Safety Significant Structures, Systems and Components. One responder allows CGI dedication for items not classified as Important to Safety as determined by the responsible functional organization.

   6) Acceptance methods for CGI dedication vary:

      a. Five of 7 responders use Special Tests and Inspections, Commercial Grade Survey of Supplier, Source Verification and Acceptable Supplier/Item Performance.
      b. Two of 7 responders use only Special Tests and Inspections and Commercial Grade Survey of the Supplier.

   7) Six of 7 responders use a design output document to specify a commercial grade item for use in a nuclear safety application. One responder uses a special form for this approval.

   8) Seven of 7 responders indicate written guidance is provided for selection of critical characteristics. However, the level of detail in this guidance varies significantly.

9) Seven of 7 responders indicate testing/verification of critical attributes is self performed. One responder indicated self-performed testing/verification is minimal.

10) Seven of 7 responders indicated critical characteristics for CGI acceptance are documented. Four of 7 indicated special forms are used for this documentation.

11) Organizational responsibility for accepting a CGI for use varies:

    a. Three responders indicated that Engineering and Quality Assurance are responsible for item acceptance.
    b. Three responders indicated Quality Assurance/Quality Inspection is responsible for item acceptance.
    c. One responder indicated Quality Assurance and the Functional Department Manager are responsible for item acceptance.

4. Summary:

Commercial Grade Item dedication is widely used at EM sites. Engineering, Procurement and Construction (EPC) projects use CGI dedication much more extensively than EM contractors performing more standardized retrieval and waste treatment work. With few exceptions, processes used for CGI dedication are controlled by cross-cutting functional organization procedures, and requirements are relatively consistent. Standards used as the basis for the CGI dedication program and organizational responsibility for acceptance of CGI for use are not standardized and vary from contractor to contractor. However, no specific problems were identified related to CGI dedication other than those reported by EPC projects.

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COMMERCIAL GRADE ITEM DEDICATION SURVEY

1. Is a Commercial Grade Item (CGI) dedication process used by your organization?	☐ Yes	☐ No
2. Is the CGI dedication process described in a DOE-approved Quality Assurance Program (QAP)?	☐ Yes	☐ No
3. Is the CGI dedication process controlled by a cross-cutting functional organization procedure?	☐ Yes Identify Functional Org.:	☐ No
4. What industry standard is used as the basis for the CGI dedication process?	☐ NQA-1 (version) ☐ EPRI (version)	☐ Other (specify)
5. What nuclear safety item classifications are included in the CGI dedication process?	☐ Safety Class ☐ Safety Significant ☐ Safety Related ☐ Important to Safety	☐ Other (Specify)
6. What acceptance methods are used for CGI dedication? (Check all that apply.)	☐ Special Tests and Inspections ☐ Commercial Grade Survey of Supplier ☐ Source Verification ☐ Acceptable Supplier/Item Performance Record	☐ Other (Specify)
7. What design output documents are used to specify a commercial grade item for use in a nuclear safety application?	☐ System Drawings ☐ Component Drawings ☐ Equipment Specs/Data Sheets ☐ Equipment/Component Lists ☐ System Design Descriptions	☐ Other (Specify)
8. Is written guidance provided for selection of critical characteristics?	☐ Yes	☐ No
	"When selecting critical characteristics for CGI acceptance, how is "reasonable assurance" defined or utilized to assure the item will	

	perform its intended function?"	
	**COMMERCIAL GRADE ITEM DEDICATION SURVEY**	
9. Do you perform your own testing or verification of Critical Attributes?	☐ Yes	☐ No
	Do you perform tests for ☐ Hardness ☐ Alloy ID ☐ Meggar ☐ Dimensions Other:	
10. Where are critical characteristics for acceptance documented?	☐ System Drawings ☐ Component Drawings ☐ Equipment Specs/Data Sheets ☐ Equipment/Component Lists ☐ Acceptance Tests/Plans	☐ Other (Specify)
11. Briefly describe how acceptance of an item for its intended service is documented.	What organizations are responsible for accepting an item for use?	
	Is a receipt inspection performed on an item slated for CGI dedication?	
	How is CGI dedication documentation prepared and retained?	
	Other	
Comments (Include Lessons Learned):		

Name/Title:	Company:

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Project Focus Area	Task # and Description	Deliverable
Project Area 3-Commercial Grade Item and Services Dedication	**3.2-Complete a survey of selected EM contractors requesting them to identify the process and basis for the process used to accept nuclear services.**	**Completed Survey**

Approvals:	Yes/No/NA
Project Managers: S. Waisley, D. Tuttel	**Yes**
Executive Committee: D. Chung, J. Yanek, N. Barker, D. Amerine	**No**
EM QA Corporate Board:	**No**

ISM

EM/EFCOG Quality Assurance Improvement Project Plan
Project Focus Area #3 -Commercial Grade Item and Services Dedication Implementation and Nuclear Services
Task #3.2: Commercial Grade Services Dedication Survey Summary

1. Purpose:

   This survey was conducted to obtain input from EM contractors on processes used for Commercial Grade Services dedication. The intended use of this information is to form the basis for providing a recommendation to EM for a standard process for Commercial Grade Services dedication.

2. Survey Approach and Response:

   A formatted survey request (Attachment 1) was sent to contractor points-of-contact across the DOE complex. Seven responses were received.

3. Survey Results (results align with question numbers in Attachment 1):

   - Four of 7 contractors providing a response use a Commercial Grade Services dedication process. Two contractors providing a response do not have Safety Class/Safety Significant Structures, Systems or Components; therefore, do not use a Commercial Grade Services dedication process. One responder uses only evaluated suppliers for nuclear services.
   - Four of 4 responders using a Commercial Grade Services dedication process have the process described in a DOE-approved Quality Assurance Program.
   - Two of 4 responders using a Commercial Grade Services dedication process utilize a cross-cutting functional organization procedure. Two responders control the process on a case-by-case basis using work process documents such as a statement of work or a work package.
   - One responder cites Engineering as the organization with responsibility for the Commercial Grade Services dedication process. One responder cites Quality Assurance and two responders cite the organization procuring the service with Quality Assurance support.
   - Industry standards used as the basis for the CGI dedication process vary:
     - One of four responders cites NQA-1-2000.
     - Three responders cite NQA-1-2004.
     - Two responders cite EPRI NP-5652 in addition to NQA-1-2004
   - Four of 4 responders use one or a combination of methods for Commercial Grade Services acceptance such as:
     - Technical verification of data produced,
     - Surveillance/audit of the activity,
     - Review of objective evidence for conformance to procurement document requirements. Two of 4 responders provide written guidance for selection of critical characteristics for Commercial Grade Services dedication.
   - Documentation of services acceptance varies significantly:
     - Two responders use a Critical Characteristics acceptance form.
     - One responder uses a Quality Assurance assessment report.
     - One responder uses a Statement of Work deliverable.

4. Summary:

Commercial Grade Services dedication is not as widely used at EM sites as CGI dedication. Engineering, Procurement and Construction (EPC) projects use Commercial Grade Services dedication more extensively than EM contractors performing more standardized retrieval and waste treatment work. Processes used for Commercial Grade Services dedication are controlled by cross-cutting functional organization procedures by the one responding EPC contractor and one M&O Contractor. However, other contractors establish the acceptance process on a case-by-case basis. Standards used as the basis for the Commercial Grades Services dedication process vary from contractor to contractor and the organization assigned responsibility for acceptance of the service varies significantly. No specific problems related to Commercial Grade Services dedication were identified by the survey.

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COMMERCIAL GRADE SERVICES ACCEPTANCE SURVEY

1. Is a commercial grade services acceptance process used by your organization?	☐ Yes	☐ No
2. Is the commercial grade services acceptance process described in a DOE-approved Quality Assurance Program (QAP)?	☐ Yes	☐ No
3. Is the commercial grade services process controlled by a cross-cutting functional organization procedure?	☐ Yes Identify Functional Org.:	☐ No
4. What industry standard is used as the basis for the commercial grade services acceptance process?	☐ NQA-1 (version) ☐ EPRI (version)	☐ Other (specify)
5. What methods are used for acceptance of services? (Check all that apply.)	☐ Technical verification of data produced ☐ Surveillance/audit of the activity ☐ Review of objective evidence for conformance to procurement document requirements	☐ Other (Specify)
6. Are critical characteristics documented for acceptance of services?	☐ Yes	☐ No
7. Is written guidance provided for selection of critical characteristics?	☐ Yes	☐ No
FCOG	COMMERCIAL GRADE SERVICES ACCEPTANCE SURVEY	

8. Briefly describe how acceptance of a service for its intended service is documented? For example:	If critical characteristics are defined, how are they documented?
	What organizations are responsible for acceptance of services?
	Other
9. Comments (Include Lessons Learned):	
Name/Title:	Company:

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Project Focus Area	Task # and Description	Deliverable
Project Area 3- Commercial Grade Item and Services Dedication	Task #3.4: Provide EM for review and concurrence recommended baseline requirements/guidance actions considered necessary for implementation of an effective CGI/Services dedication process within EM nuclear facilities.	Recommendation to EM

Approvals:	Yes/No/NA
Project Managers: S. Waisley, D. Tuttel	**Yes**
Executive Committee: D. Chung, J. Yanek, N. Barker, D. Amerine	**Yes**
EM QA Corporate Board:	**Yes**

ATTACHMENT XXX-COMMERCIAL GRADE ITEM/SERVICES DEDICATION

Requirements:
Section 7.7 of the Environmental Management Quality Assurance Plan illustrates the relationship between Performance/Criterion 7-Procurement requirements and the ASME NQA-1 requirements used to implement them. To support standardized implementation of a commercial grade item/services dedication process by EM sites, the following additional requirements apply:

a. The Commercial Grade Item/Services dedication process shall be described in the DOE-approved QIP.
b. The Commercial Grade Item/Services dedication process shall be based on ASME NQA-1-2004, Requirement 7, Section 700 and Nonmandatory Appendix 7A-2.

Note: A more recent version of NQA-1 supplemented by an alternate guideline (i.e., EPRI NP 5652) may be used if approved by DOE in the QIP and determined consistent with the DOE EM Corporate QAP issued by the Deputy Assistant Secretary, Safety Management and Operations.

c. Technical evaluations for CGI/Services dedication shall be performed and documented by the appropriate technical authority for the item/service being dedicated.
d. Critical characteristics (i.e., dimension, configuration, material and operability) for CGI/Services dedication shall be determined and documented by the appropriate technical authority for the item/service being dedicated.
e. Acceptance method/criteria for critical characteristics shall be determined and documented by the appropriate technical authority for the item/service being dedicated.
f. Personnel responsible for performance and implementation of the CGI/Services dedication process shall be trained to develop the necessary skills to effectively execute the process.

GENERAL INFORMATION

Management Expectation:

The contractor's Commercial Grade Item/Services Dedication process shall be consistent with requirements established in this attachment, shall be described in the approved QIP, and effectively implemented for commercial items/services supporting nuclear safety applications.

DOE TRAINING

Commercial Grade Dedication Training

MODULE 1

Overview of CGD Process

Course Objectives

- Define the terms “commercial grade item” and “commercial grade services”
- Understand the process for commercial grade dedication
- Describe the bases for implementing each element of the generic process and how they relate to NQA-1 requirements and EPRI Guidelines
- Describe each element of the process and its purpose
- Understand the acceptance process for items and services

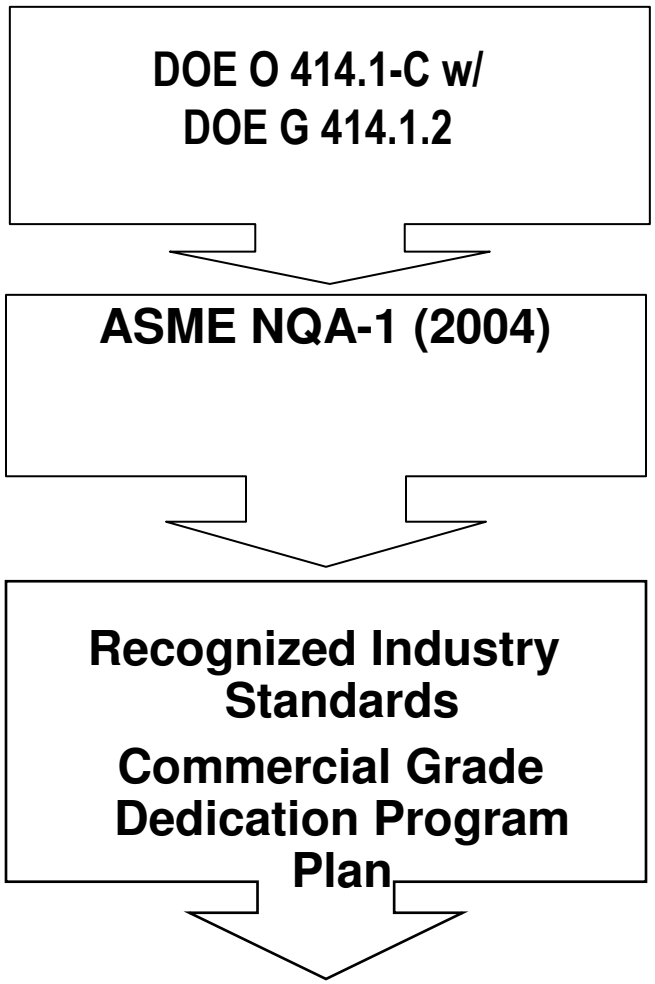
Course Content and Structure

- Module 1 – Overview of CGD Process
- Module 2 – Technical Evaluation
- Module 3 – Acceptance Planning
- Module 4 – Dedication Package
- Module 5 – Sample Selection Methodology
- Module 6 – Supplier Dedication Oversight
- Module 7 – CGD Implementation and Lessons Learned

Introduction

- **What is the purpose of dedication?**
  - Dedication is performed to establish the acceptability of an item to perform its safety function.
- **How is dedication performed?**
  - Dedication consists of a technical evaluation of an item followed by establishment of acceptance methods.
- **What is needed to start the dedication process?**
  - The design must be completed to the point that the suitability of the item for its intended application has been established?
- **When is Dedication of an Item Planned?**
  - Dedication planning should be part of the procurement strategy.
- **How much is enough?**
  - The selection of critical characteristics is commensurate with the complexity, application, function, and performance of the item or service for its intended safety function. This decision is based on engineering judgment. It is important to document this basis.

How does the CGD process meet the requirements of DOE O 414.1C?



DOE Order 414.1C states that a national/consensus standard(s) must be chosen for implementation. NQA-1 2004 Part 1 and Part 3 provide requirements and supporting guidance respectively implementing EPRI guidance for CGD. DOE G 414.1.2 Quality Management System Guide (for use with 10 CFR 830.120 and DOE O 414.1) – Commercial Grade Items intended for use in nuclear safety applications should be procured in accordance with documented processes using recognized consensus standards.

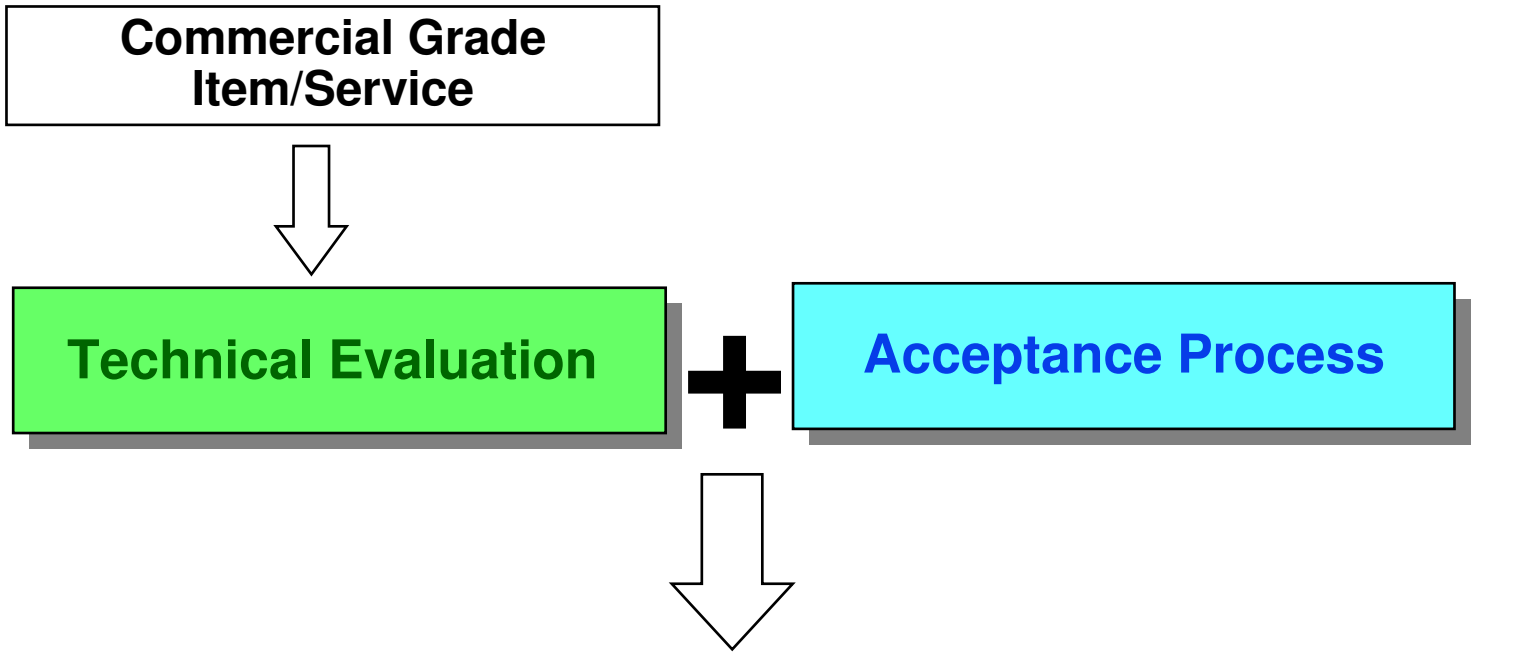
NQA-1 Quality Assurance Requirements for Nuclear Facilities Applications – Establishes Quality Assurance requirements for items and services that provide a safety function. CGD process is used when items or services that provide a safety function are not provided by NQA-1 qualified suppliers.

For Example: EPRI NP-5652, EPRI TR-106439 and EPRI TR-102260 – EPRI NP-5652, Guideline for the Utilization of Commercial Grade Items in Nuclear Safety Related Applications; EPRI TR-106439, Guideline on Evaluation and Acceptance of Commercial Grade Digital Equipment for Nuclear Safety Application; and EPRI TR-102260, Supplemental Guidance for the Application of EPRI Report NP-5652 on the Utilization of Commercial Grade Items are recognized in the nuclear industry as the standard documents regarding the purchase of commercial grade items for use in nuclear related applications.

Major Steps In The Dedication Process

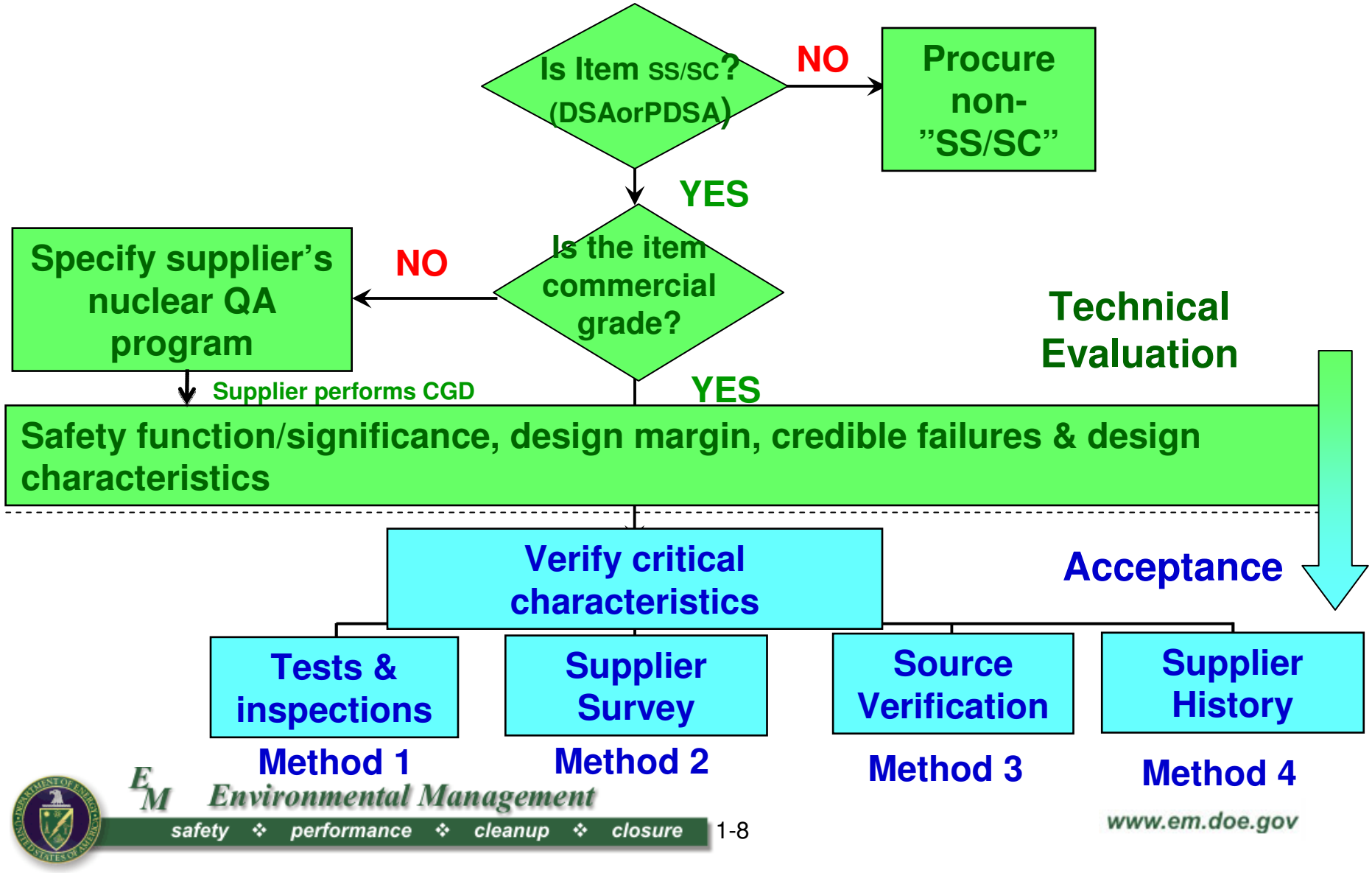
- Clearly identify the item
- Bound the application
- Research the design to identify the safety functions, the service conditions and the design margin
- Determine the safety significance of the item considering the consequences and likelihood of failure
- Determine the characteristics of the item that 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
- Document the basis

Commercial Grade Procurement Fundamentals



The combination of theses two processes contribute to assuring that the procured item or service will perform its safety function(s)

Overview of the Generic Process



Quality Level Determination

- Determination of item safety function is part of the design process
- Safety functions are reflected in specifications, drawings, data sheets, procurement packages, Preliminary Hazards Analysis, Hazards Analysis, safety basis documents (e.g. Preliminary Documented Safety Analysis (PDSA), Documented Safety Analysis (DSA)), and in DOE Safety Evaluation Reports.
- Technical justification should be documented for items classified differently than their host system/component
- Quality level of a service is equivalent to the quality level of the items associated with the service

Determine if the Item or Service Meets the "Commercial Grade" Definition

- NQA-1-2004 provides two definitions for a commercial grade item depending on the application of the item.
  - Definitions were modified from NQA-1-2000 to recognize that the availability of NQA-1 qualified suppliers who were fabricating one-of-a-kind and/or new technology to support construction activities was less than in previous years.
- Definition 1, a commercial grade item meets all of the following:
  - Not subject to design or specification requirements that are unique to nuclear facilities;
  - Used in applications other than nuclear facilities;
  - To be ordered from the manufacturer/supplier on the basis of specifications set forth in the manufacturer's published product description (for example, a catalog)

Determine if the Item or Service Meets the "Commercial Grade" Definition – cont.

- Definition 2:
  - Commercial Grade Item (CGI) is a structure, system or component (safety-class/safety-significant), or part thereof, that affects its safety function, that was not designed and manufactured by an NQA-1 qualified supplier
    - The NQA-1a-2009 clarifies in Note 4 that this definition is applicable to Department of Energy nuclear facilities and activities regulated under 10 CFR 830, Nuclear Safety Management
  - Commercial Grade Service (CGS) is a service that is not provided by an NQA-1 qualified supplier

Utilization of the CGD Process

- Utilization of the CGD process for procuring items or services include the following:
  - Technical evaluation to determine that the item or service performs a safety function
  - Confirmation that the item or service meets the commercial grade definition criteria
  - Identification of the critical characteristics, acceptance criteria, and methods of acceptance
  - Documentation of the basis for the acceptance requirements
- When one or more critical characteristics for acceptance cannot be verified, then the CGD procedure is not used to procure or accept the CGI/CGS

Identify Critical Characteristics

Safety functions of the item

+

Postulated credible failures of the item

What physical or performance attributes of the item enable it to perform design functions related to the safety function or prevent it from failing as postulated?

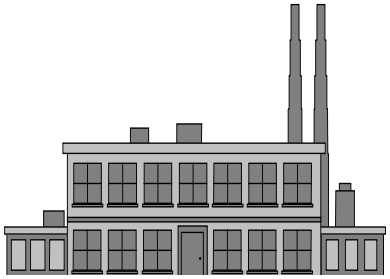
Critical characteristics

When Critical Characteristics Are Verified

During Manufacturing at Supplier/Sub-Supplier

During or After Receiving

After Installation



In-process and final product testing

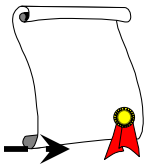
(Method 1)

Source Survey

(Method 2)

Source Verification

(Method 3)



Review of supplier documentation

(Method 2)

Inspection of the item

(Method 1)

Post installation testing of the item

(Method 1)

Testing of the item

(Method 1)

Commercial Grade Dedication

- Commercial grade dedication (CGD) is an acceptance process performed in accordance with procedures to provide reasonable assurance that a CGI or CGS will successfully perform its intended safety function and is deemed equivalent to an item or service provided from a qualified NQA-1 supplier
- Commercial grade dedication consists of two processes: (1) technical evaluation – assures that the requirements for an item/service are specified in procurement documents, and (2) acceptance process – provides methods to reasonably assure that the item/service received is what was specified

Commercial Grade Dedication

- Dedication can be performed by the Prime Contractor, a qualified NQA-1 supplier, or a NQA-1 qualified third-party dedicating entity in accordance with their approved NQA-1 Program
- Dedication performed by a qualified NQA-1 Supplier or a third-party dedicator must be performed in accordance with a Buyer accepted CGD program.
- Dedication plans and records from suppliers/dedicators should be obtained as part of the record set when the supplier/dedicator is the Dedicating Entity.
- Dedication is complete when the organization verifying the critical characteristics completes the acceptance activities

DOE TRAINING

Commercial Grade Dedication Training

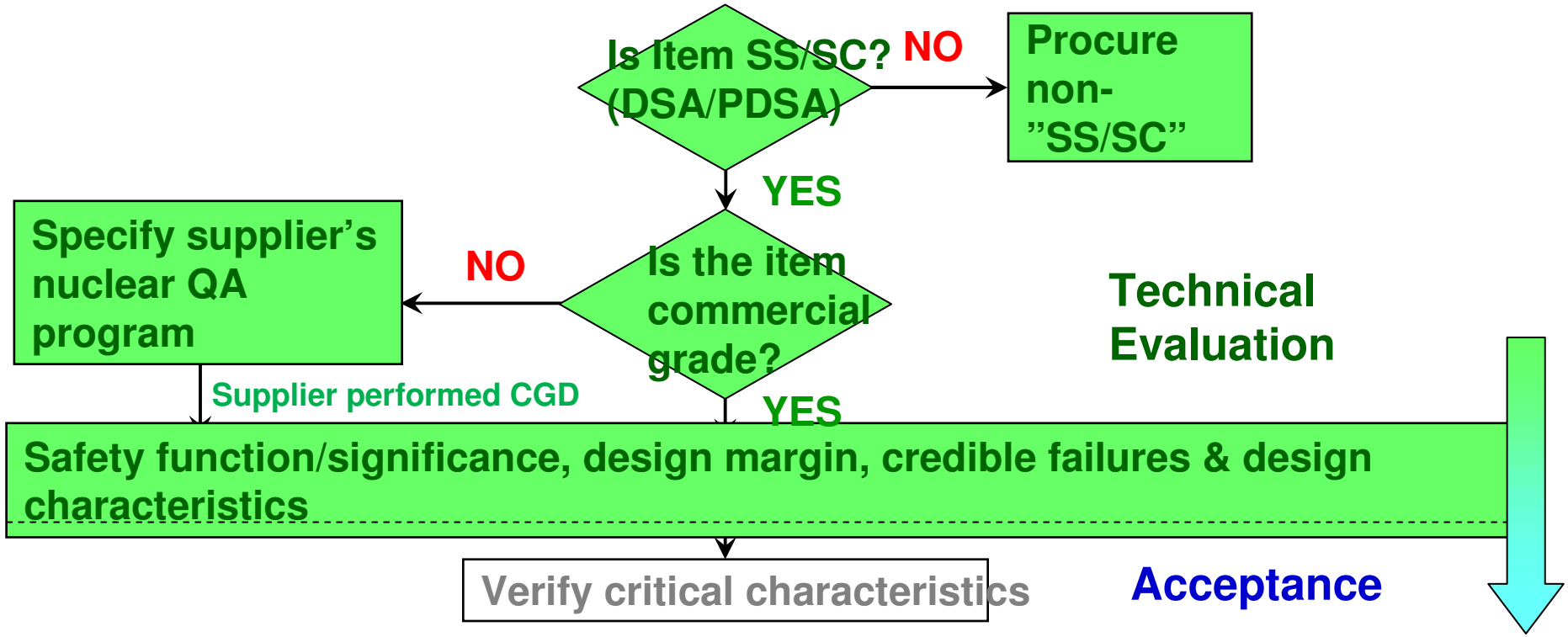
MODULE 2

Technical Evaluation

Enabling Objectives

- Describe the purpose of the technical evaluation
- Describe the steps in performing the technical evaluation
- Describe the thought process for determining critical characteristics of design for items and services

Overview of the Technical Evaluation



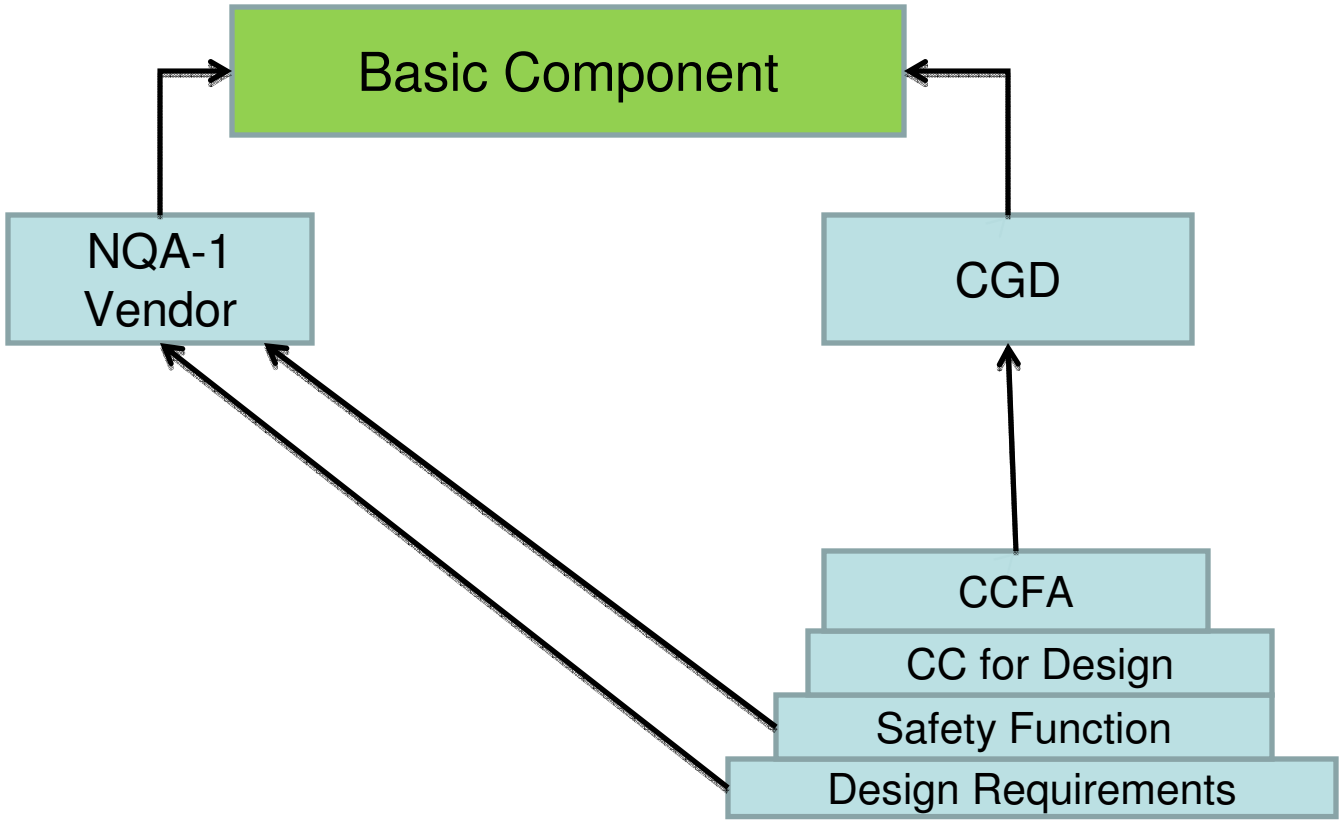
Purpose of the Technical Evaluation

- Enable the item to be *specified correctly in a procurement document*
- For this to happen, the following is required:
  - Identification of the item being procured
  - Identify Performance Requirements
  - Identify Design Requirements
  - Identify Quality Level or Quality Class
  - Confirm Item meets Commercial Grade Definition
  - Understanding of end-use application(s) including the most severe location of the item or the item impacted by the service
  - Identify Safety function of the item as listed in Safety Basis
  - Identify Critical Characteristics

Basic Components

- Basic Components are those that have been shown to have adequate assurance that they will perform their intended safety functions on demand.
- Historically basic components were procured from nuclear vendors meeting the requirements of ASME NQA-1.
- Alternative means needed to meet needs.

Technical Evaluation Supporting a Basic Component



Safety Function and Safety Classification

- The need for CGI dedication is not solely a result of safety designation, but may also be a result of OCRWM waste affecting items designation and Air Permit functions that are part of an emission unit that meets the requirements of Stated Codes.
- The safety function or functions of item are determined during hazard and accident analysis during the development of the safety basis.
- Safety functions are assigned by the approved safety basis based on DOE-mandated requirements and guidelines to prevent/mitigate release of radiological/chemical materials.

Safety Function and Safety Classification (cont.)

- Output of the development of the safety basis is a set of Safety Class (SC) and Safety Significant (SS) structures, systems, and components (SSC) designed to protect the facility workers and public from excess radiation and chemical hazard doses.
- Engineering evaluates CGI dedication services to determine if the service could adversely affect the safety function of an item

Critical Characteristics

- ASME NQA-1-2004, Part 1, Introduction, Section 400, defines a critical characteristic as,
  - "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"

Reasonable Assurance

EPRI TR-102260, *Supplemental Guidance for the Application of EPRI Report NP-5652 on the Utilization of Commercial Grade Items, defines reasonable assurance as;*

> A justifiable level of confidence based on objective and measurable facts, actions, or observations which infer adequacy.

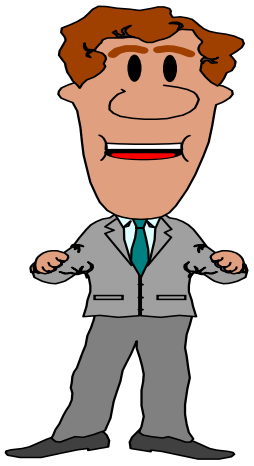
NQA-1-2004 states,

> The dedication activities are intended to provide reasonable assurance that the item or service will perform its intended safety function.

Recommended Process for Identifying Safety Function and Determining Critical Characteristics

Thought Process

Research design documents and databases to determine system and component level safety functions. Part level safety functions must be deduced from this information



Perform a search of the Design Documents and Design Criteria Databases

Typical Mechanical Safety Functions

- Maintain pressure integrity
- To open
- To remain open
- To close/isolate
- To actuate/modulate flow

Typical Electrical Safety Functions

- Electrical isolation
- Provide signal or power

Recommended Process for Identifying Safety Functions and Determining Critical Characteristics

Thought Process

What are the safety function(s) of the item/service?

↓

What are the facility design function(s) (including known safety functions and seismic/environmental conditions) of the item/service?

This information should be obtained from the appropriate design documents!

Recommended Process for Identifying Safety Functions and Determining Critical Characteristics

Thought Process

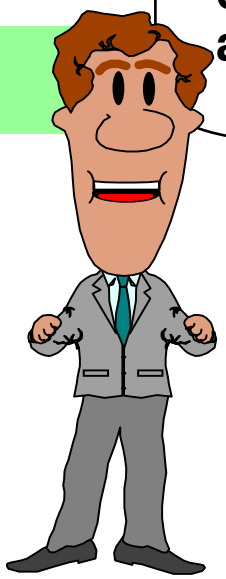
What are the safety function(s) of the item/service?

↓

What are the facility design function(s) (including known safety functions and seismic/environmental conditions) of the item/service?

↓

What are the postulated, credible failure mechanisms of the item/service?



Hypothetically, how could this item/service fail during normal *and* accident conditions?

Credible Failure Mechanisms

- Once the safety functions are determined, the selection of critical characteristics begins with the understanding that failure of some important design features of an item may not be credible, and therefore do not need to be verified. The below listed features should be considered in mechanical and electrical applications.
  - Fracture
  - Corrosion
  - Erosion
  - Loss of properties
  - Excess strain
  - Mechanical creep
  - Ductile fracture
- The basis for determining that specific failure mechanisms are not credible should be documented

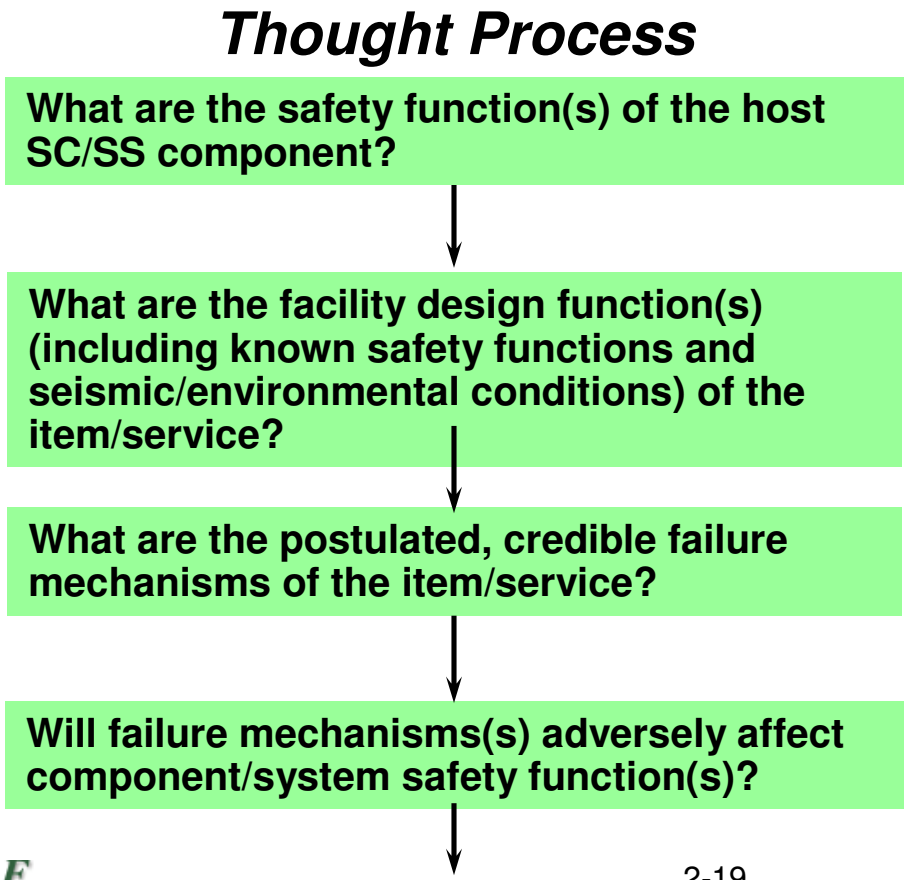
Potential Failures in the Performance of Services

- Repair Services – use of unacceptable parts, improper welding or soldering, improper assembly, component requirements not met after repair
- Testing – use of uncalibrated equipment, technical inadequacies in performing the test, improper specimen preparation, improper calculation of test results
- Fabrication/Machining/Cleaning/Unique Manufacturing Processes – failure to meet dimensional requirements, material contamination, special process controls
- Training – errors in instructional materials used
- Engineering/Technical Services – calculation errors, unconfirmed assumptions, unconfirmed/unverified computer codes to perform analyses/calculations
- Calibration – equipment out of calibration causing failure to accurately measure or actuate at the proper time, incorrect equipment calibration

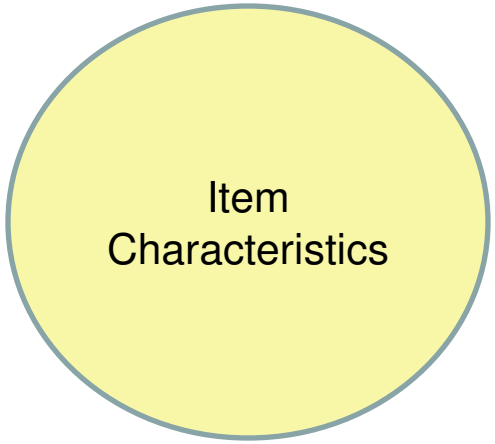
Postulating Failures

- Consider single-failure analysis
  - Redundancy in design should not be considered as a means to mitigate a failure
- Postulate failures based upon the safety functions of the host component, considering normal and accident design bases.
- Do ***not*** consider the following as credible failures of an item:
  - Normal wear-out (over a long period of time)
  - Failure due to improper maintenance
  - Failure due to improper installation
  - Failure caused by failure of adjacent items

Recommended Process for Identifying Safety Function and Determining Critical Characteristics



Item Characteristics



- Characteristics Including Product Identification Characteristics
- Other characteristics that are inherent to the item's design but are not required/used in the purchaser's application.

Recommended Process for Determining Design Characteristics

What are the safety function(s) of the item system/component?

↓

What are the facility design function(s) (including known safety functions and seismic/environmental conditions) of the item?

↓

What are the postulated, credible failure mechanisms of the item?

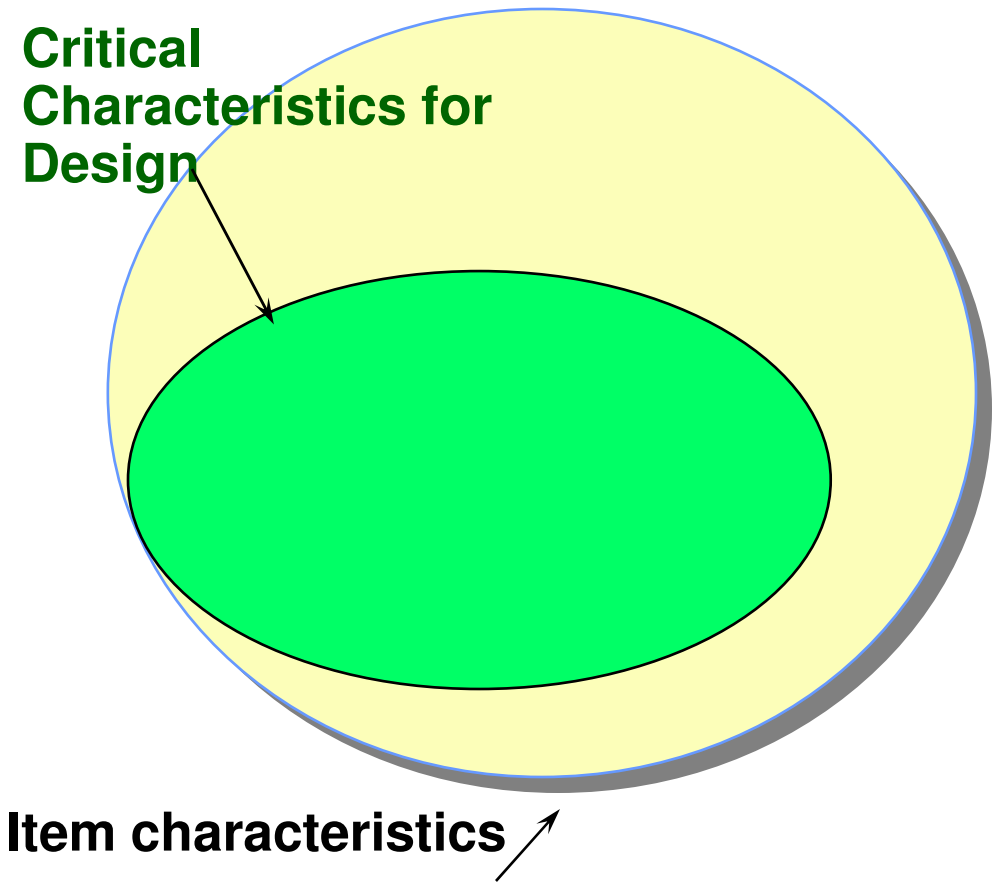
↓

What identifiable and measurable attributes are essential for the item's form, fit, and functional performance?

↓

Design Characteristics

Critical Characteristics for Design



- Dependent on the facility-specific application
- Are a subset of the entire population of attributes describing an item
- Are based on the item's safety functions
- Are application specific and include physical and performance characteristics
- Include design, material and performance attributes of the item

DOE TRAINING

Commercial Grade Dedication Training

MODULE 3

Acceptance Planning

Enabling Objectives

- Describe the thought process for determining critical characteristics for items and services
- Understand the concept of “reasonable assurance” commensurate with the significance of the safety function
- Describe the different types of critical characteristics
- Describe the critical processes for acceptance of services
- Describe how to achieve reasonable assurance in the context of commercial grade item dedication

Critical Characteristics of an Item or Service

- Critical Characteristics (CC) defined in NQA-1-2004
  - 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.
- Critical Characteristics for Design – EPRI NP-6406
  - Critical characteristics include physical and performance characteristics of the item but not product identification characteristics
- Critical Characteristics for Acceptance – EPRI 102260
  - Critical characteristics for acceptance are generally a subset of the critical characteristics for design but can include physical characteristics of an item, identification marking, or performance characteristics of the item (refer to slide 3-5)

Recommended Process for Determining Critical Characteristics

What are the safety function(s) of the host component?

↓

What are the facility-specific safety function(s) of the item?

↓

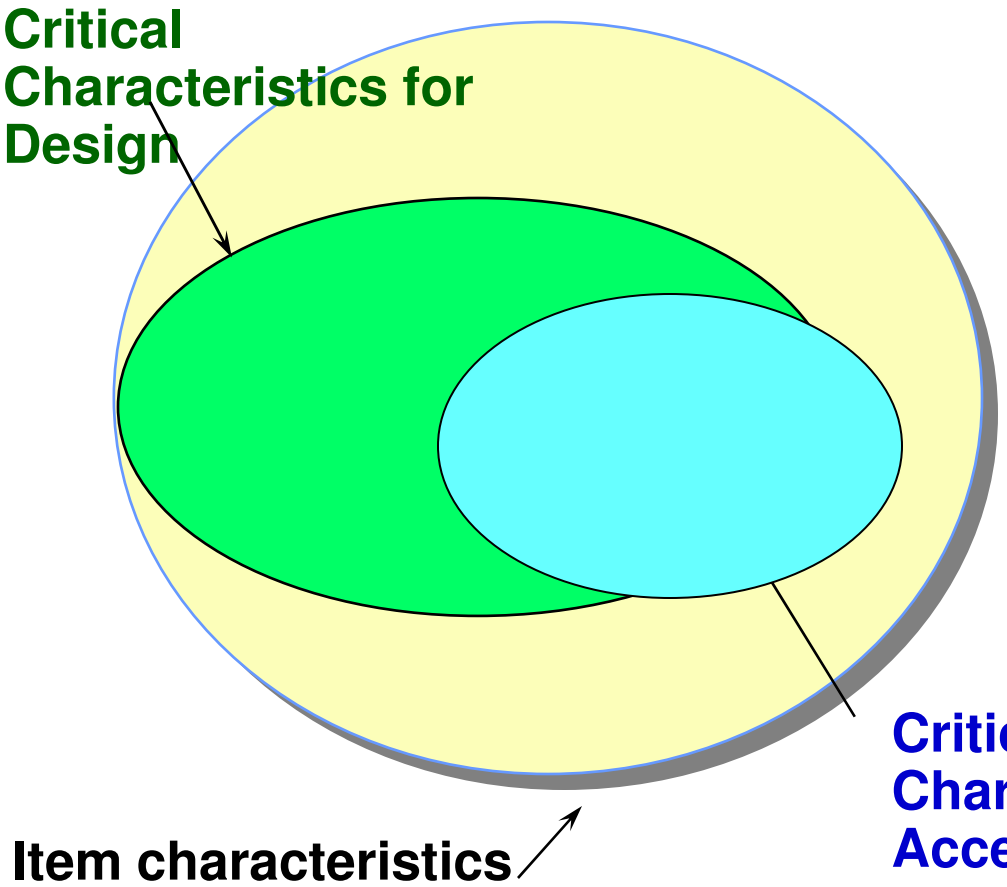
What are the postulated, credible failure mechanisms of the item that potentially affect the safety function?

↓

What identifiable and measurable attributes enable the item to perform its safety function(s)?

Critical Characteristics

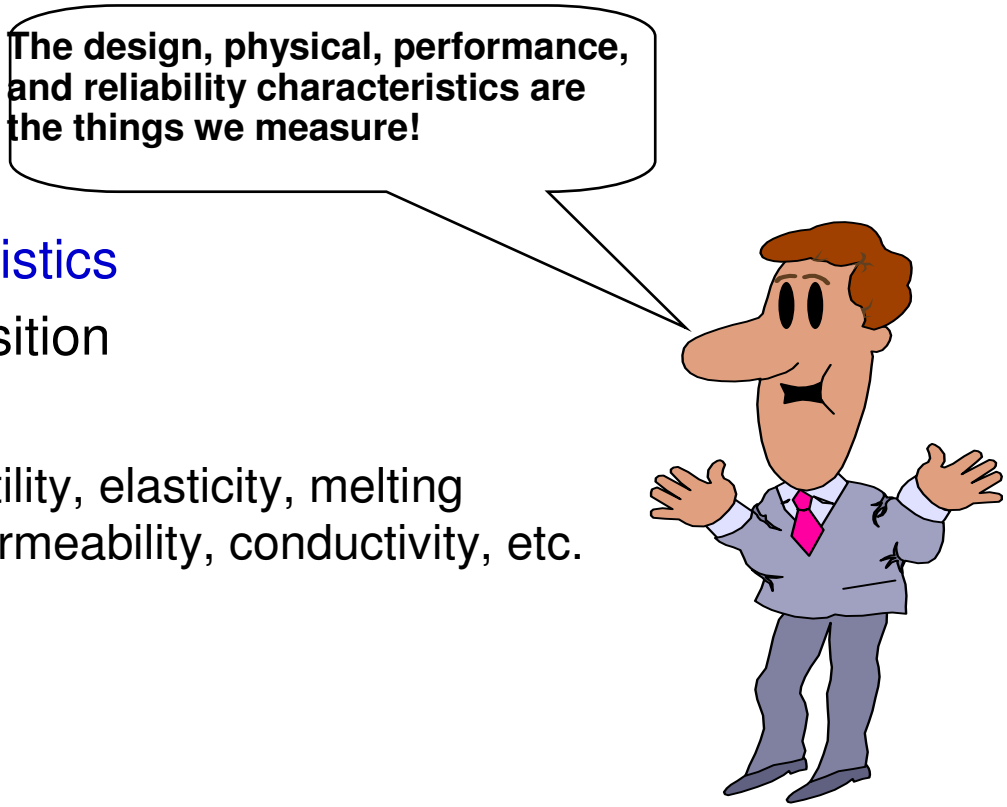
Critical Characteristics for Acceptance



- Are based on the item's *safety* functions
- Are design, material and performance attributes of the item that support the safety function
- Are measurable and verified
- All must be verified once selected

Representative Types of Critical Characteristics

- *Design (Configuration)* Characteristics
  - Dimensions
  - Electrical resistance
  - Durometer hardness
  - Part number if assigned
- *Material (Physical)* Characteristics
  - Material chemical composition
  - Material properties
    - Strength, hardness, ductility, elasticity, melting temperature, density, permeability, conductivity, etc.
- *Performance* Characteristics
  - Pick-up/drop-out voltage
  - Open/close time
  - Input/output voltage

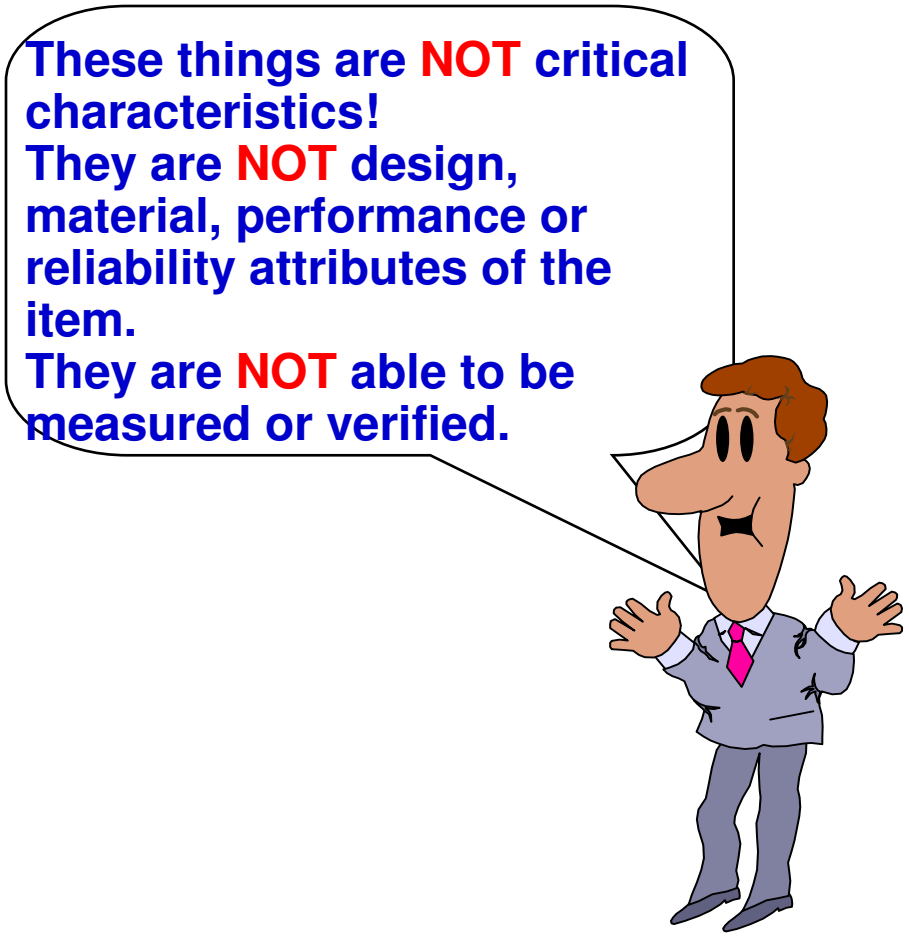


Representative Types of Critical Characteristics, Cont.

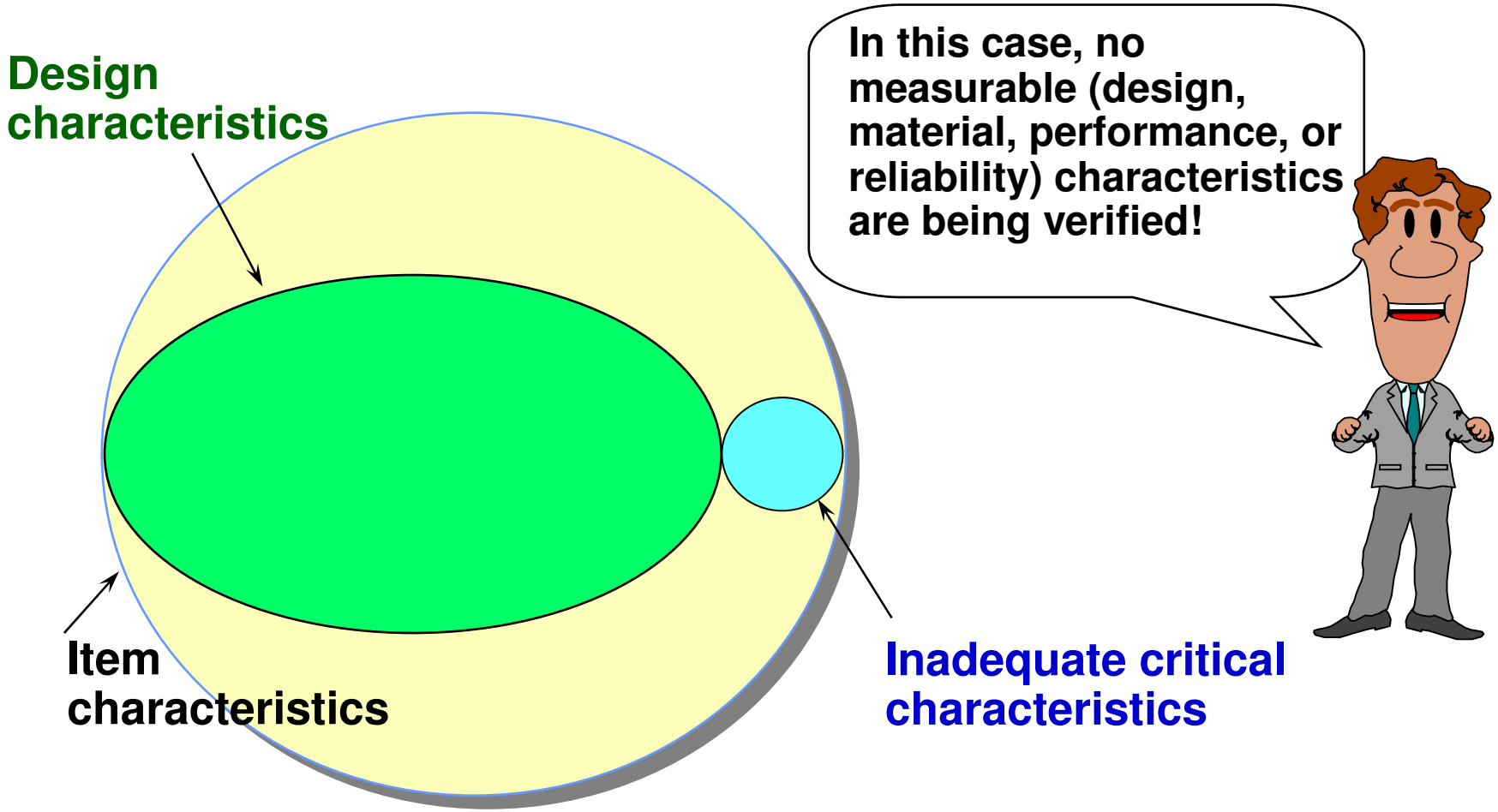
- *Dependability Characteristics – Digital Equipment and Software*
  - Typically cannot be verified by inspection and testing alone
  - Are generally affected by the process used to produce the device.
  - Includes reliability, safety, availability, maintainability, and built-in quality

Understanding What Does Not Constitute a Critical Characteristic

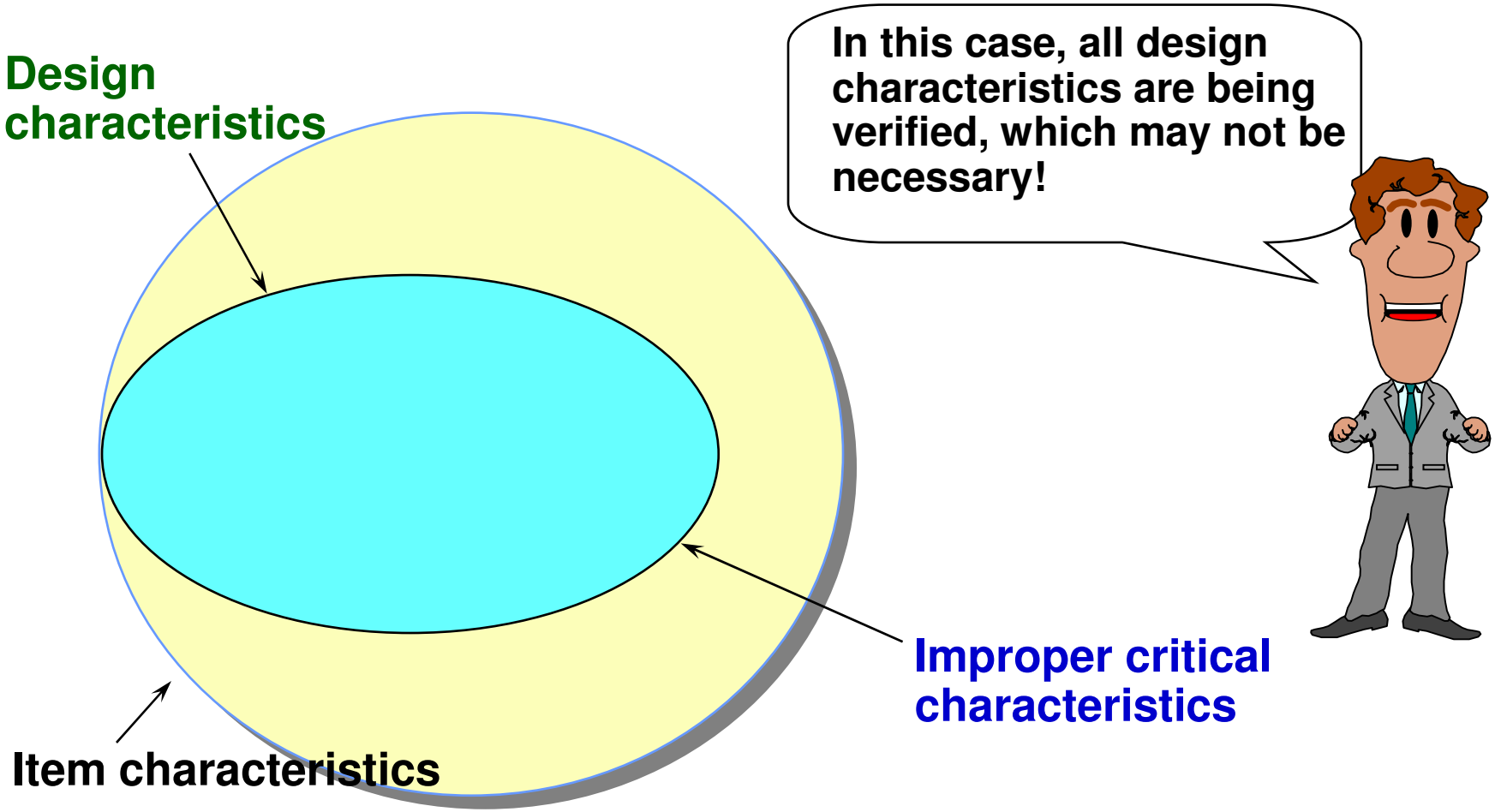
- Form, fit and function
- Seismic
- Environmental Qualification
- Certificate of conformance
- Hydrostatic test
- Receipt inspection
- Lot homogeneity
- Commercial grade survey
- Maintenance instruction
- Environmental test report
- Vendor manual



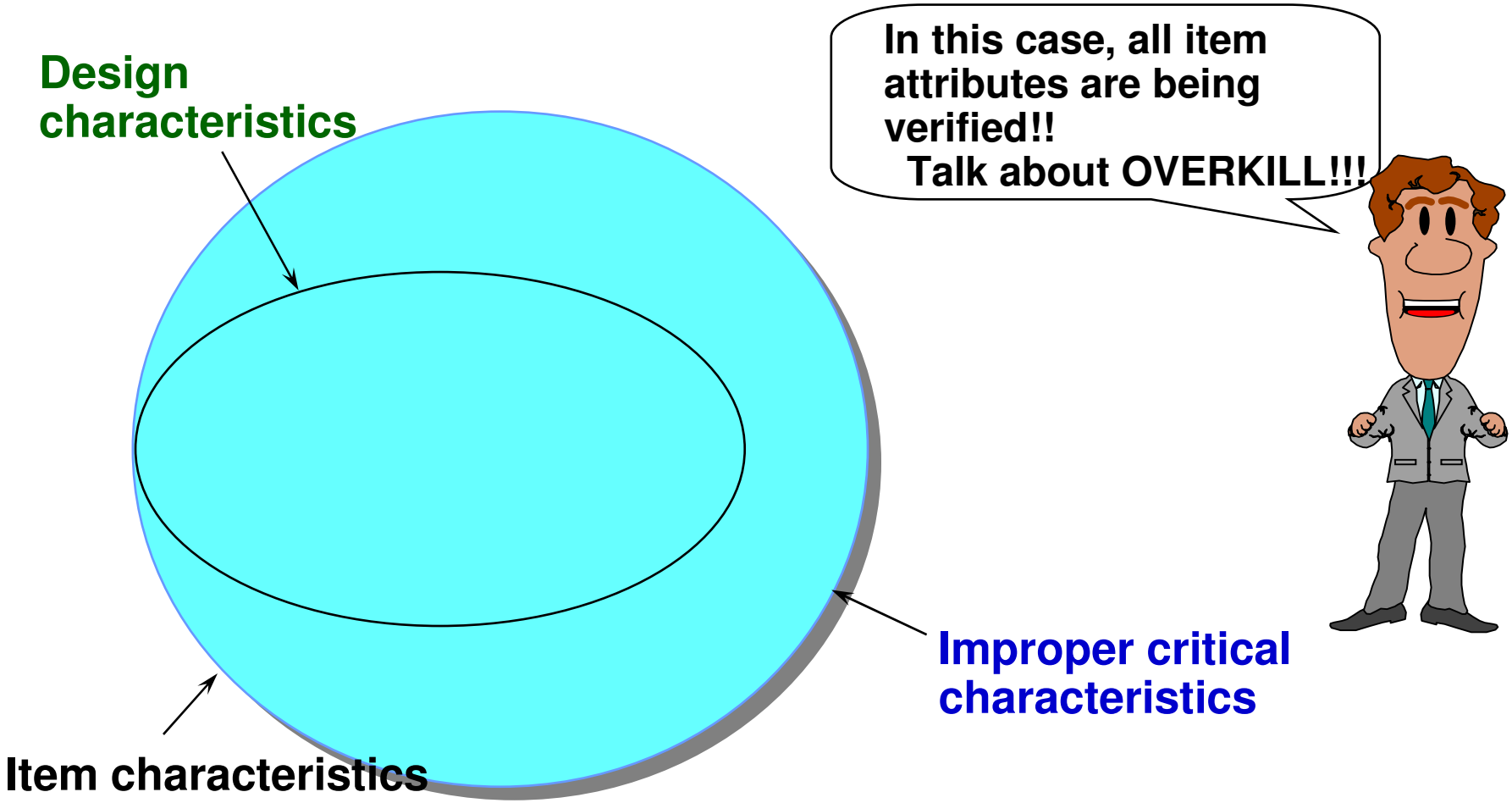
Inadequate Selection of Critical Characteristics



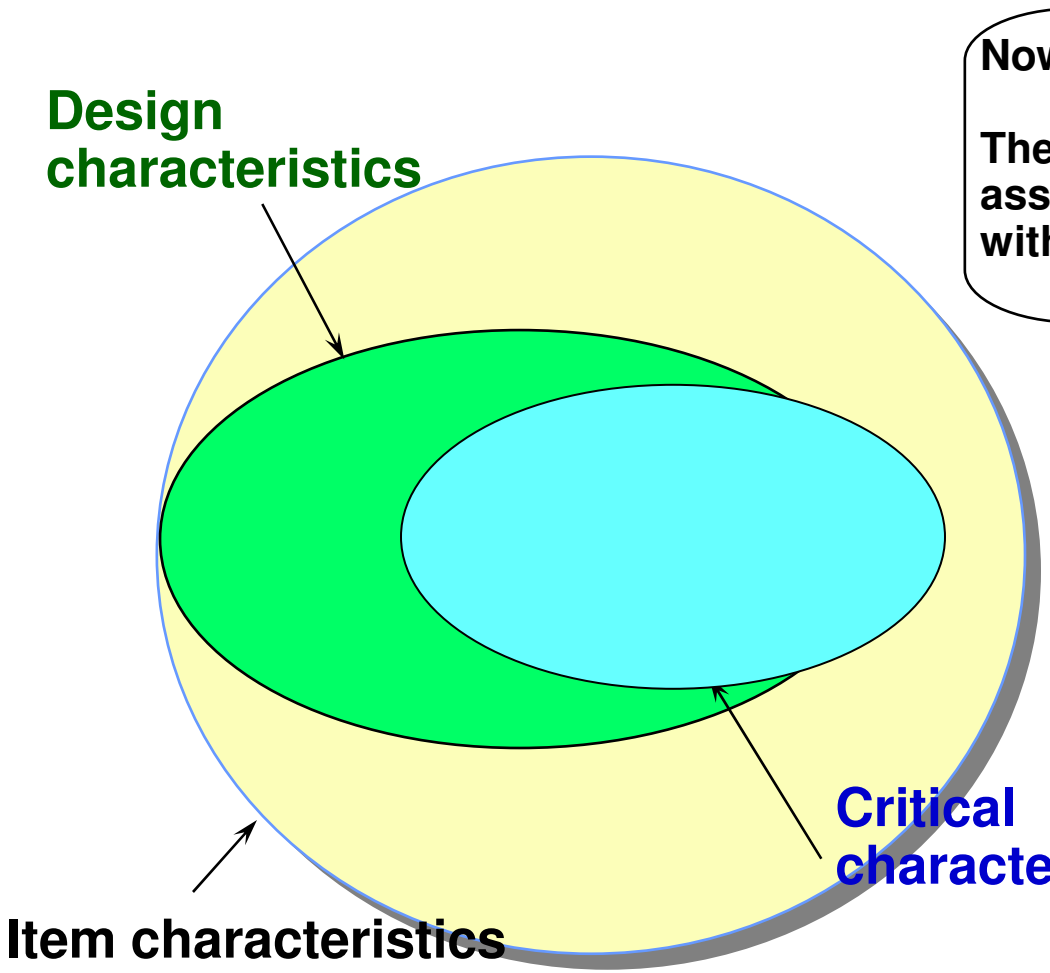
Inadequate Selection of Critical Characteristics



Inadequate Selection of Critical Characteristics



Critical Characteristics



Critical Characteristics for Services

- Process for CGD evaluation for services similar to that for items
- Selection considerations for CC for services are:
  - Identify measurable attributes of the impacted item that affects the usability of the service AND are critical to the item performing its safety function
  - Identify in-process controls that are critical for the item impacted by the service to perform its safety function
  - Select a set of CC, that once verified, provide reasonable assurance that the service was performed properly, and the items impacted by the service perform their intended safety functions

Note: Another option is the performance of the service under the dedicating entity's quality program that meets the requirements of an approved NQA-1 program and as specified in procurement documents

Critical Characteristics for Design Services

- Those process controls that must be applied to ensure that the design of the item, once translated into the delivered items through manufacturing processes, will meet the requirements of the safety application in which it is to be used
- Items to be verified include:
  - Control of design inputs
  - Control of methods of analysis and design
  - Control of development, review and approval of design outputs
  - Design verification and integrated system design review

Critical Characteristics for Digital Equipment and Software

- Detailed information in EPRI TR-106439, *Guideline on Evaluation and Acceptance of Commercial Grade Digital Equipment for Nuclear Safety Applications. (Oct 1996)*
- Documented operating history of the equipment can be an important factor in providing confidence in the product
- Experience may be gained through applications in industries other than nuclear power
- Experience must be shown to be relevant to the planned nuclear applications
- Additional activities such as testing will be required by the dedicator to reach an adequate level of assurance
- Additional reviews, analysis, and documentation may also be required

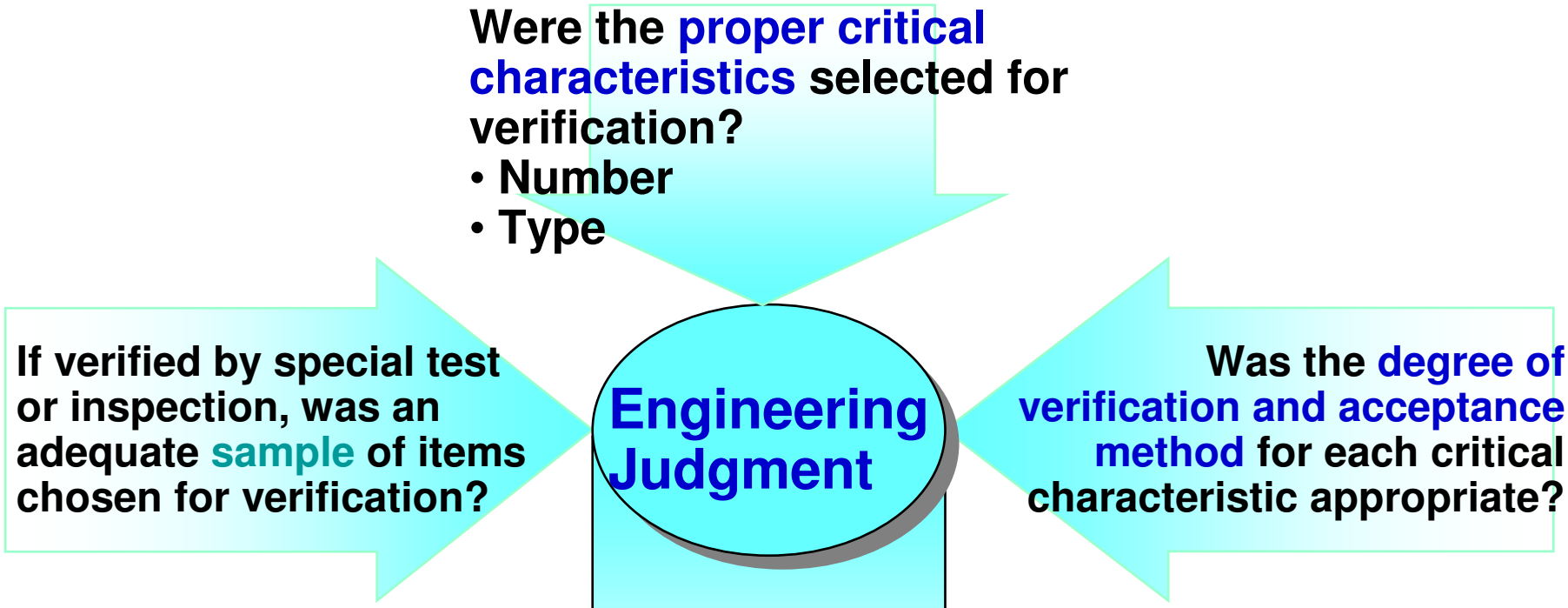
Selection of Critical Characteristics

- CGI's intended for installation in seismically or environmentally qualified applications, require CCs necessary to assure that the original qualification of the parent component is maintained.
- Environmental Qualification may deal with harsh environments or mild environments
- CGI's intended for generic safety-related applications instead of specific applications should be selected based on the most severe conditions encountered unless controls for item use are in place.

Methods for Acceptance

- Engineering selects the acceptance method
- Four methods used to accept commercial grade items/services are:
  - Method 1 – Special Tests, Inspections, or Analysis
  - Method 2 – Commercial Grade Survey of Supplier
  - Method 3 – Source Verification
  - Method 4 – History of Performance
- Methods provide individually or in combination a means to reasonably assure:
  - Commercial grade item received meets specified requirements
  - Services provided are services ordered and the safety items affected by the service will perform their safety functions

Achieving Reasonable Assurance in the Context of CGI Dedication



"Reasonably assured"
the item received conforms to the procurement document
and
the item will perform its safety functions!

Key Elements of Critical Characteristics For Acceptance

1) A listing of the selected critical characteristics

2) Which method will be used to verify each critical characteristic

- The method(s) chosen:
  - Should be based on the type of critical characteristics to be verified for acceptance, available Supplier information, quality history, and degree of standardization
  - Determine when and how the critical characteristics will be verified
  - Determine what organizations will be involved in the dedication

Acceptance Methods

- Think of the acceptance methods as four different ways to establish CCFA for the selected critical characteristics
- The acceptance methods can be used individually or in combination
- They can vary from one item to another based on a number of factors:
  - Purchase price of the item
  - Lead times and plant schedule demands
  - Supplier capabilities and quality controls
  - Accessibility to item design information
  - Testing/inspection costs
  - Lot size

DOE TRAINING

Commercial Grade Dedication Training

MODULE 4

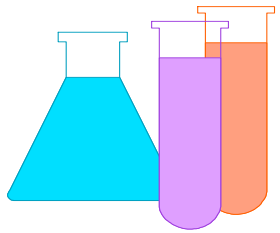
Dedication Methods and Support Documentation

Enabling Objectives

- Describe the purpose of acceptance methods 1-4
- Describe the process for implementing acceptance methods 1-4
- Describe documentation associated with implementing acceptance methods 1-4
- Describe how performance history of the item and the supplier can affect the selection and implementation of the acceptance methods

Purpose and Implementation of Acceptance Method 1 (Special Tests & Inspections)

- Purpose
  - To dedicate a CGI for safety-related use by verifying one or more critical characteristics using testing or inspections during and/or after receipt
- Special tests and Inspections shall be conducted upon or after receipt of an item to verify conformance with the acceptance criteria for the identified critical characteristics.



Method 1, cont.

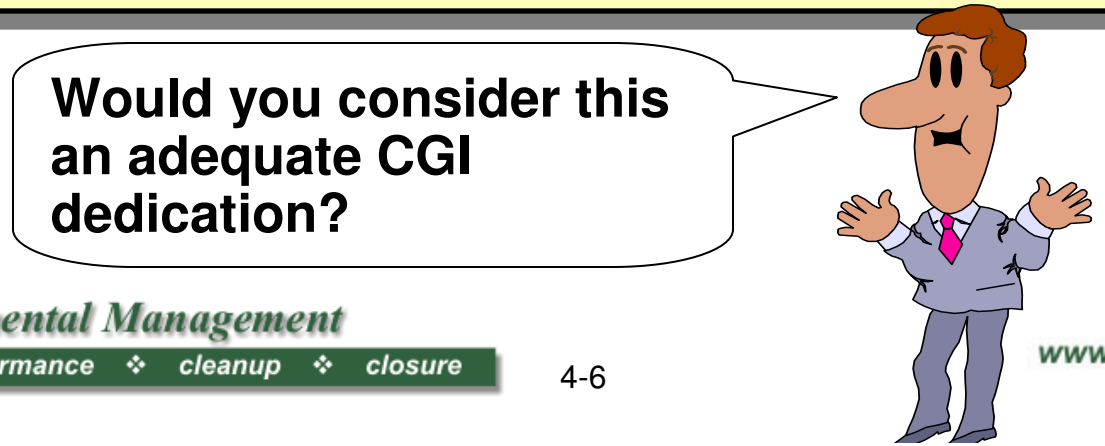
- Special tests/inspections can occur:
  - During receipt of raw material or a manufactured item
  - During and after fabrication of individual piece-parts
  - During and after assembly of the final product
  - Post installation testing (PIT)
- Sampling is permitted when testing/inspecting a batch/lot of items

Acceptance Method 1 (Special Tests & Inspections) Guidance on Utilization

- When the item is simple in design
- Commodity items
- When critical characteristics are able to be verified with tests/inspections
- Data may be available in existing documents such as specifications, drawings, instruction manuals, bills of material and catalogs.
- Multiple suppliers of the item
- Items purchased in small quantities or larger homogeneous lots where sampling can be applied
- Items on which post-installation tests can be conducted

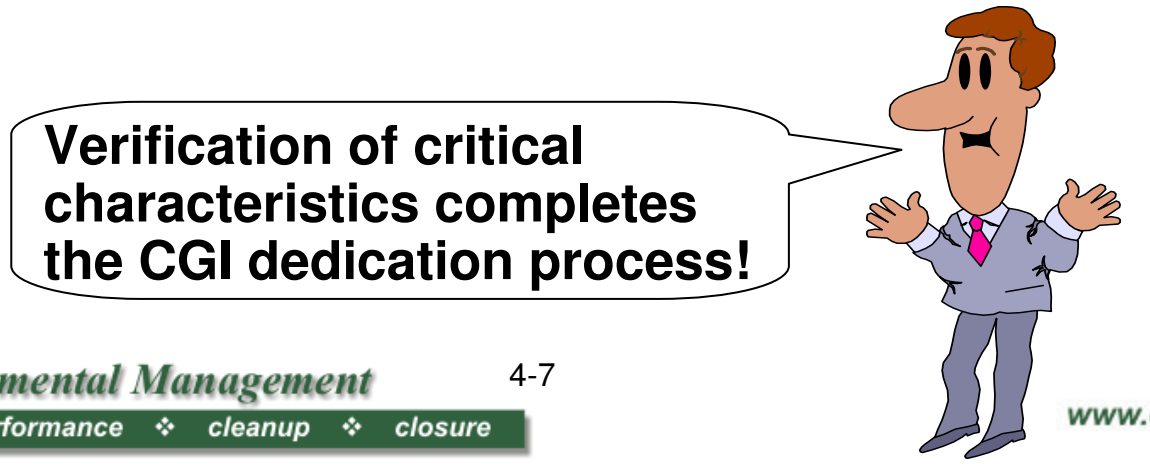
Standard Receipt Inspection vs. Special Tests & Inspections

- ANSI/ASME NQA-1 describes the standard receiving inspection as checking the following:
  - Quantity received
  - Damage
  - General condition of items
  - Part number
- Often referred to as a “kick-and-count” inspection

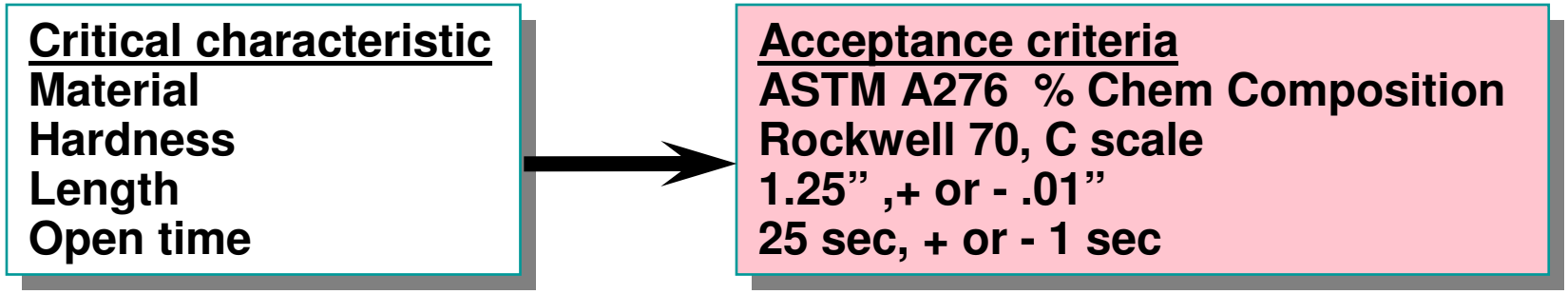


Standard Receipt Inspection vs. Special Tests & Inspections

- Special Tests and Inspections are one method for verifying selected critical characteristics
- These go beyond the standard receiving inspection activities
- The tests/inspections verify that the critical characteristics conform to Design



Critical Characteristics and Acceptance Criteria



- 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, or a supplier engineering organization, dependent on the item

Items Not Meeting Acceptance Criteria

- All values tested or inspected must fall within the tolerance range specified in the acceptance criteria
- If the acceptance criteria is NOT met, the item is documented as nonconforming
- Other like items should be evaluated to determine if they would exhibit the same nonconformance (i.e., extent of condition)

Sample Size Considerations

- When sampling is required as part of the acceptance process, a key consideration is how much sampling is appropriate
- Sampling size is dependent on lot homogeneity.
  - High confidence the lot is homogeneous should result in small sample size to provide additional assurance
  - Low confidence the lot is homogeneous should result in a larger sample size to provide the additional assurance.
- Sample selection should be in accordance with a dedicating entity's implementing procedure or recognized standard. EPRI TR-017218-R1, *Guideline for Sampling in the Commercial-Grade Item Acceptance Process*
- The logic on how the sampling size was determined needs to be documented since sampling decisions can vary from procurement to procurement.

Purpose and Implementation of Commercial Grade Survey of Supplier (Method 2)

- Purpose
  - To dedicate a CGI or CGS based on approval of a suppliers' implementing process and commercial controls as related to the items CCs
- Use:
  - MUST be validated through prior implementation of a commercial grade survey
  - MUST verify that the supplier adequately controlled the CC necessary for the dedication
  - Certificates of Conformance
    - Documents surveyed controls applied
    - Specific requirements in Procurement Documents

Acceptance Method 2 (Supplier Documentation) Guidance on Utilization

- When the sub-supplier/manufacturer 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
- When critical characteristics are not easily verified after receipt

Practical Methodology

- Determine if a commercial grade survey has been conducted for the supplier, sub-supplier, or manufacturer
- If YES, consider the following:
  - Is the survey information current?
  - Was it conducted at the location where the CGI being procured was manufactured?
  - Does it confirm adequate supplier controls over the critical characteristics for acceptance?
  - Are the sub-supplier controls documented so they can be specified in the purchase order?

Practical Methodology

- Determine if a commercial grade survey has been conducted for the supplier, sub-supplier, or manufacturer
- If NO, consider the following:
  - Is it cost effective to conduct a survey at this time?
  - Would other acceptance methods be more cost effective?
    - Source verification
    - Special tests/inspections

Conducting the Commercial Grade Survey

- Should be “performance-based” (not compliance-based)
- Organizations performing surveys should develop criteria for the personnel and processes used to perform surveys
- The survey should be specific to the scope of the particular commercial grade item or service being procured
- The survey criteria and the Supplier’s documented processes and commercial controls, which should be determined by the dedicating entity, may vary for the item or service depending on the number and type of critical characteristics to be verified. These may be quality programs, procedures, or practices.

Performance-based vs.. Compliance-based

Performance-based approach

What equipment is furnished?

What are equipment safety functions?

What are the CC?

-

How are CC controlled?

Are controls adequate and documented?

Are they doing what they committed to do *and* are they doing the right things?

Vendor qualification is "based on performance" and can be graded.

Compliance-based approach

-

-

-

What QA program is the supplier committed to?

How is it implemented?

Do they comply?

Are they doing what they committed to do?

Go or no-go

Preparing for the Commercial Grade Survey

- Determine the scope of the survey based on the commercial grade items to be purchased
- Engineering to provide critical characteristics and/or critical processes (e.g., test control) from the Technical Evaluation for each item within the scope of the survey
- Select the survey team (including an engineer technically competent for subject matter of the survey)
- Coordinate with the supplier and review quality assurance program documents and procedures including supplier controls for preparation, approval and issuance of Certificate of Conformance

Examining Appropriate Implementation of Quality Controls

Design Control
Do the supplier's controls assure an identical or equivalent item will be provided?

Material Controls
Is the item controlled from receipt through shipment to assure the correct item is being shipped?

Procurement Control
How are items specified to sub-suppliers?
How are procured items verified as being conforming to design?

Inspection/Test Control Are the inspections and tests controlled and conducted by capable people?

Nonconformance
Are non-conforming materials controlled and properly dispositioned?

Calibration
Is measuring and test equipment controlled in accordance with some program?

Special Processes
How effectively are critical characteristics controlled/imparted during manufacturing?

Certificate of Conformance
Is preparation, approval, and issuance of C of C's properly controlled by procedure?

Addressing Inadequate Supplier Controls

- Determine nature of the inadequacy
  - The supplier does not adequately implement the QA program
  - The supplier is not conforming to current procedures
  - The supplier does not feel the critical characteristic needs to be verified
  - The supplier verifies the critical characteristic, but does not document the verification adequately
- Determine if the supplier is willing/able to enhance the controls to meet customer expectations

Commercial Grade Survey Procurement Clause Examples

- "This order shall be processed in accordance with Superior Pumps Inc. Quality Assurance Manual dated 10/17/05. Any revisions to this manual shall be forwarded to the purchaser for review."
- "This order shall be processed in accordance with the following company procedures:
  - Heat treat procedure 101-63B, Rev. 2
  - Product testing procedure101-77C, Rev 0."
- "Dimensions of valve stem, Part No. XYZ123, shall be controlled in accordance with Erie Valve Inc. Machining & In-process Testing Procedure A754, Rev. 1."

Documentation Associated with Survey

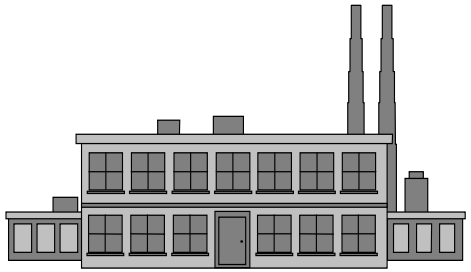
- CGI Technical evaluation and dedication plan
  - Identifies the acceptance method
  - Identifies the CCFAs to be verified
- Commercial Grade Survey results/reports
- Standard receipt inspection
  - Supplier Certificates of Conformance

Summary of Acceptance Method 2

- Reliance is placed on the sub-supplier/manufacturer to verify critical characteristics
- The commercial grade survey validates that the supplier has the appropriate quality controls and they are being implemented satisfactorily
- The commercial grade survey results must be documented for use by engineering
- Engineering must specify the appropriate quality controls on each subsequent order
- Evidence that the controls were implemented each time is via supplier documentation (i.e., certificates of conformance)
- Subject to recertification

Purpose and Implementation of Source Verification (Method 3)

- Purpose
  - To accept a CGI by witnessing at the manufacturer's facility that the supplier controls the critical characteristics. Source verification is applicable only to the items being purchased
- The purchaser may witness tests or inspections, or may evaluate quality processes as they apply to the critical characteristics of the items being procured



Acceptance Method 3 (Source Verification) Guidance on Utilization

- 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 manufacturer's quality assurance program/procedures
- Owner schedule demands
- Single supplier of the item
- Item purchased infrequently

Commercial Grade Design Services – Method 3, Source Verification

- Used where CC's cannot be easily verified following completion of the design or manufacturing processes
- Used where supplier controls are insufficient for use of Method 2
- Personnel would observe key activities in the design process such as:
  - Verification of design inputs
  - Use of appropriate calculation methods
  - Performance of independent verification and design review activities

Preparing for the Source Verification

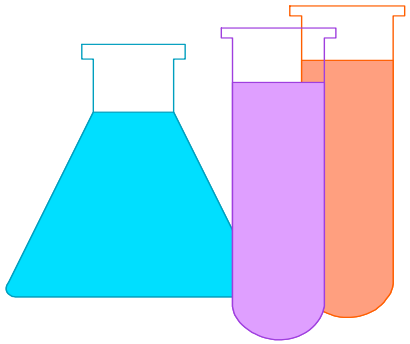
- The requirements for commercial grade items are defined in the purchase order which includes supporting technical documents
- Provide critical characteristics for each item being procured
- Select the source verifier(s)
- Coordinate with the manufacturer and review quality assurance program documents and procedures, if applicable
- Ensure right(s) of access are specified in the purchase document prior to issue
- Conduct an entrance meeting (If required by verification activities)

Conducting the Source Verification

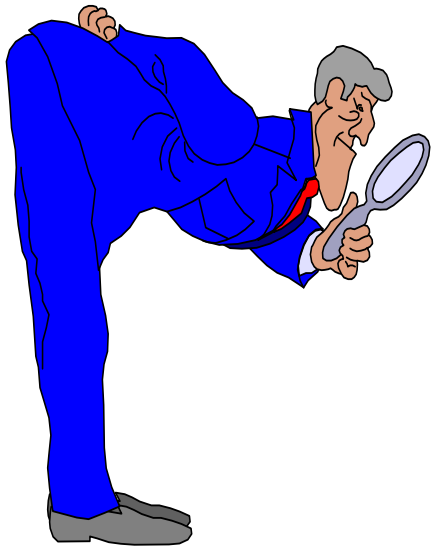
- Source verification personnel are provided the critical characteristics. The source verifier may be an auditor, inspector, engineer, or SME consultant or combination thereof.
- The purchaser may witness tests or inspections or may evaluate processes as they apply to the critical characteristics of the items being procured
- The items are released for shipment if the item's critical characteristics are conforming.

Source Verification Activities – Witnessing a Test (Typical)

- Material hardness
- Nondestructive examinations
- Tensile test
- Hydrostatic test
- Leak rate test
- Material type (chemical analysis)
- Calibration
- Operability
- Electrical continuity
- Insulation resistance
- Pressurization



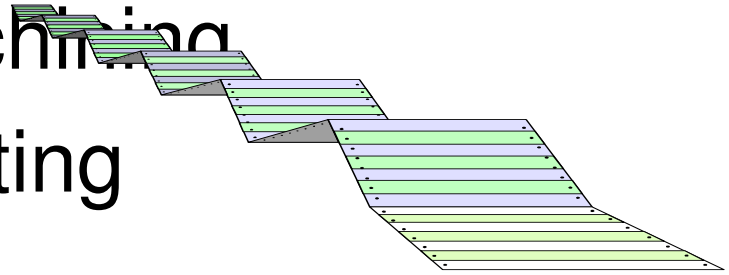
Source Verification Activities – Witnessing an Inspection (Typical)



- Dimensional
- Configuration
- Coating thickness
- Weld
- Non-destructive examination

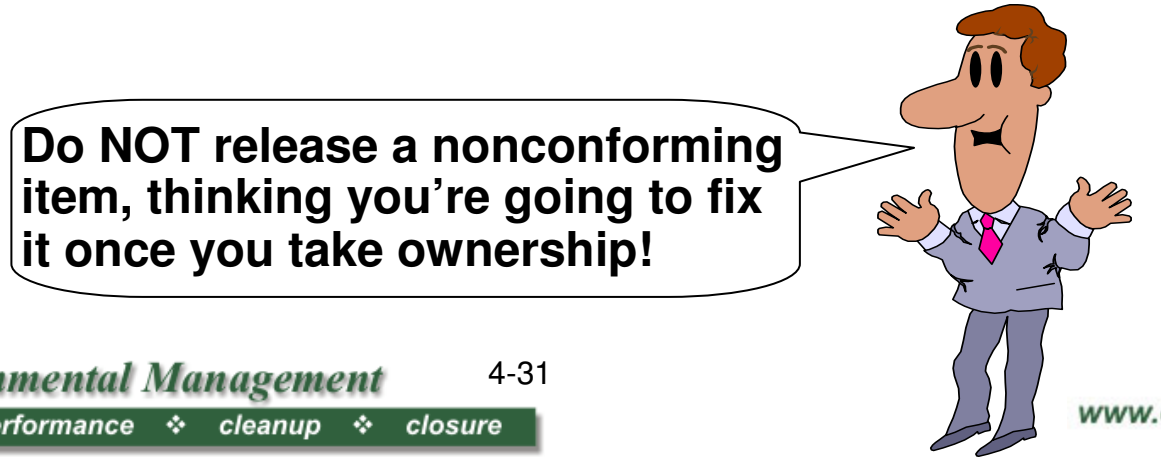
Source Verification Activities – Observing a Process

- Welding
- Assembly
- Insulating
- Coating
- Heat treatment
- Machining
- Testing



Addressing Inadequate Supplier Controls

- Determine nature of the inadequacy
  - The manufacturer is not conforming to current procedures
  - The manufacturer does not feel the critical characteristic needs to be verified
  - The manufacturer verifies the critical characteristic, but does not document the verification adequately
- Determine means by which the manufacturer can correct the non-conformance



Activities Following the Source Verification

- Conduct an exit meeting (if required by scope of verification activities)
- Prepare and issue the quantified results of the source verification
- Review technical adequacy of the source verification results to ensure all critical characteristics have been properly verified

Documentation Associated with Source Inspection (Method 3)

- CGI technical evaluation and dedication plan
  - Identifies the acceptance method
  - Identifies the CC to be verified
- Source verification plan provided to the personnel conducting the source verification
- Source verification plan completed with actual results documented
- Release for shipment documentation
- Standard receipt inspection

Summary of Acceptance Method 3

- Reliance is placed on the supplier/manufacturer to verify critical characteristics
- The source verification determines that the manufacturer implements appropriate quality controls as the items being procured are manufactured
- Source verification is applicable only to the actual items being procured

Purpose and Implementation of Acceptable Supplier/Item Performance Record (Method 4)

- Allows the purchaser to accept commercial grade items based upon a confidence in the supplied item achieved through proven performance of the item.
- Allows purchaser to take credit for item performance based upon historical verification gained from the successful utilization of Methods 1, 2, and 3.
- Based on:
  - 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.

Purpose and Implementation of Acceptable Supplier/Item Performance Record, cont.

- 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
- Should not be a single source of information

- To utilize Method 4, the purchaser should perform an evaluation of the supplier/item performance record which includes the following:
  - Supplier/item being evaluated.

Purpose and Implementation of Acceptable Supplier/Item Performance Record, cont.

  - 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
  - Statement of the purchaser attesting to the acceptability of the supplier/item.
- If the performance record provides reasonable assurance that the critical characteristics have been met, Method 4 can be used.
- The supporting information should be periodically updated and reviewed to assure the supplier/item maintains an acceptable performance record.

Dedication of Commercial Grade Services

- CGD process can be applied to services such as:
  - Design services
  - Repair and testing services
  - Fabrication/Machining/Cleaning
  - Training
  - Calibration services
- CC for services:
  - Measurable attributes of the impacted item(s) affected by the service and critical for the item to perform its safety function
  - In-process controls of the service critical for the item(s) impacted by the service to perform its safety function

Commercial Grade Item/Services Dedication Documentation

- Documentation of the commercial grade item or service dedication process should be traceable to the item, group of items, or services
- Documentation should include the following information depending on the applicable dedication method
  - Dedication plans or procedures including the essential elements of the dedication process
  - Commercial grade item or service procurement documents
  - Facility commercial grade dedication criteria
  - Technical evaluation of the safety function
  - Critical characteristic identification and acceptance criteria, including or referencing design documents and failure mode analysis

Commercial Grade Item/Services Dedication Documentation, cont.

- Test reports or results, inspection reports, analysis reports
- Commercial grade survey reports
- Source verification reports
- Historical performance information
- Dedication report containing sufficient data to accept the item or service

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Commercial Grade Dedication Training

MODULE 5

Sample Selection Methodology

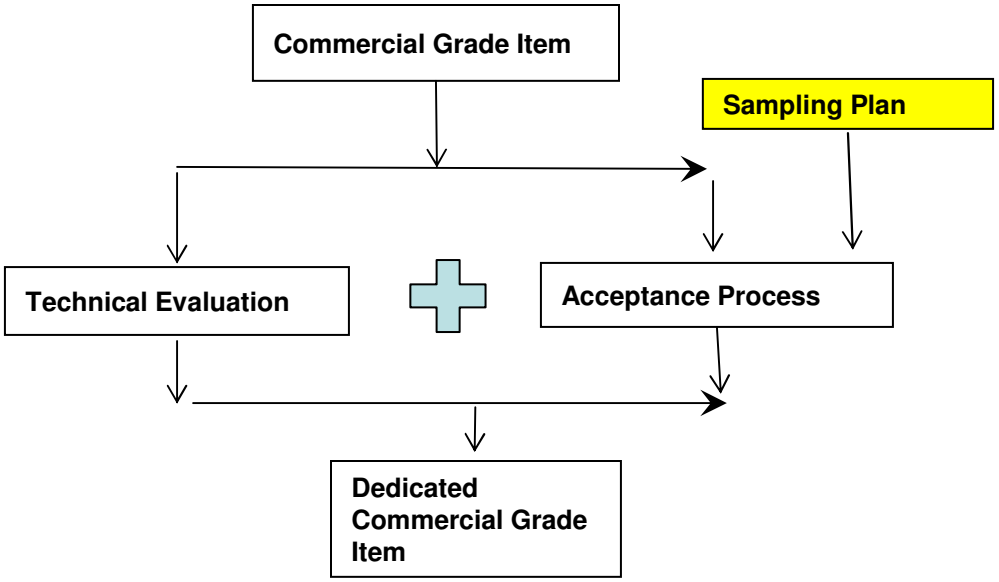
Applicability of Sampling to CGI Acceptance

- EPRI Report NP-5652 is based on the premise that the combination of the technical evaluation and the acceptance process provides reasonable assurance that the CGI will meet its safety function.
- 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.

Basic Premises of the Guideline

- Engineering Judgment – Just as in the selection of critical characteristics, sound engineering judgment in the selection of sampling size is a key factor
- Manufacturers' Product Controls – Objective evidence of the supplier's ability to provide acceptable items is a key factor
- Random Sample selection – Each item in the lot has an equal opportunity of being selected as part of the sample
- Acceptance of the Lot – If the sample results are acceptable than there is reasonable assurance that the remainder of the lot is acceptable
- Documentation – The CGI acceptance sampling process and the bases for sampling plan selection and application should be adequately documented

Sampling Methodology



Lot Formation

- Lot homogeneity is typically a matter of degree and not an absolute
- The reason sampling plans can be used when the ideal of production traceability does not exist stem from the statistical structure of sampling plans.
- When a purchase order line item is presented for acceptance, there is reason to assume a certain level of homogeneity.
- The line item is made up of like type items, specified with the same technical and quality requirements, expected to meet the same acceptance criteria
- Additional confidence in lot homogeneity is directly related to how the lot was formed

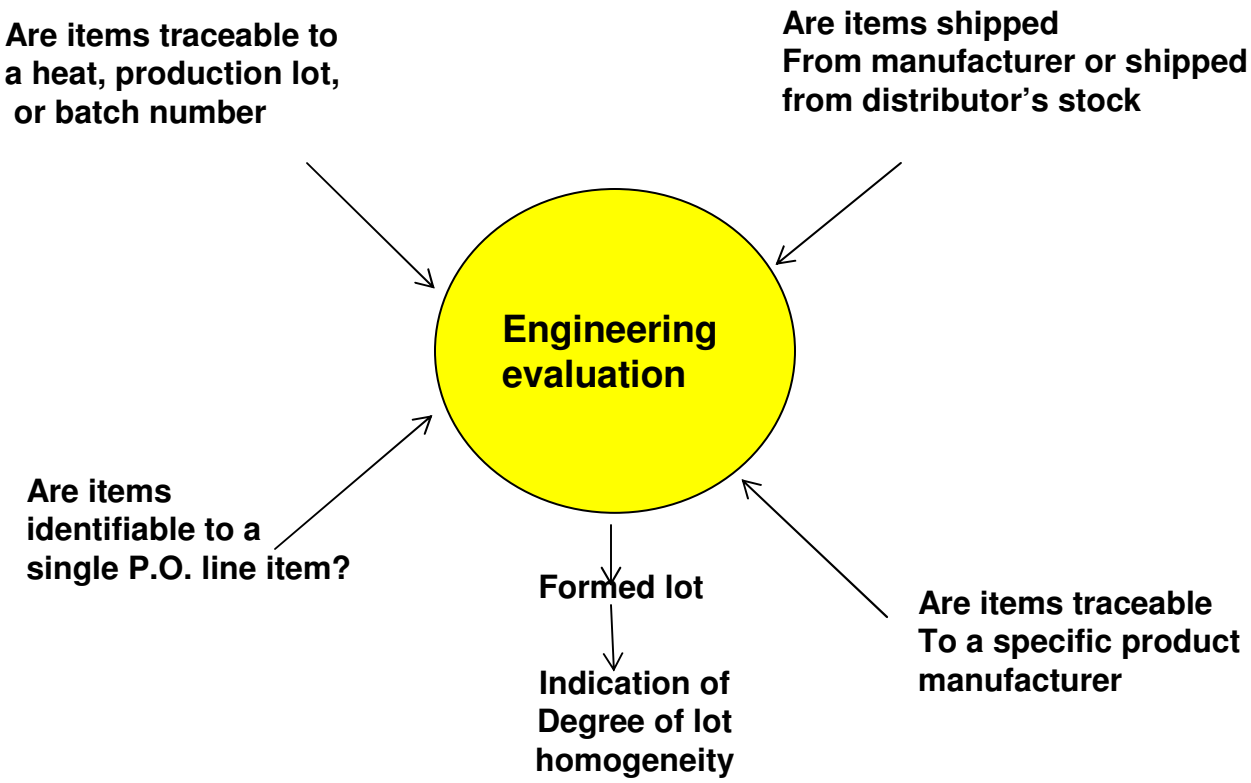
Lot Formation, cont.

- Lot formation is typically established in one of the following ways:
  - Production Traceability – heat number, production lot number, or batch number
  - Line Item/Single Manufacture – traceable to a specific purchase order line item and the products are from a single product manufacturer.
  - Line Item/Multiple Product Manufacturers – specific purchase order line item but either different product manufacturers may have produced the item or a product manufacturer does not exist.

Relationship Between Lot Homogeneity and Sample size

- High confidence the lot is homogeneous, then only a small sample size is needed to provide additional assurance
- Low confidence the lot is homogeneous, than a larger sample size is needed to provide additional assurance

Lot Formation



Sampling Plan Selection Factors

- Sampling plan selecting factors for a given critical characteristic include the following:
  - Product /Supplier Factors
    - Acceptance history of supplier's products
    - Formed lot
    - Item performance history
    - Complexity of the item
    - Applicability of industry standards to the item
    - Supplier controls
    - **Safety Significance of the item**

Sampling Plan Selection Factors, cont.

- Testing or Inspection Factors
  - Acceptance method chosen
  - Whether verification technique is nondestructive or destructive
  - Number of other critical characteristics being verified
  - Cost-effectiveness of the test or inspection
  - Correlation between nondestructive and destructive tests

Sampling Plans for Nondestructive Tests and Inspections

- The selection factors listed in the previous slides should be considered when selecting the appropriate sampling plan
- Selection of the appropriate sampling plan should be based on the additional level of confidence considered necessary
- For a given CGI requiring acceptance, different sampling plans can be selected for different critical characteristics
- Sampling plans are:
  - Normal Sampling Plan
  - Reduced Sampling Plan
  - Tightened Sampling Plan

Normal Sampling Plan

- Normal Sampling Plan should be initially considered when selecting a sampling plan for nondestructive tests and inspections
- Factors to consider:
  - The lot will be acceptable based upon available knowledge of the product manufacturer or supplier
  - The lot is expected to have a sufficient homogeneity that a randomly selected sample will represent the whole

Reduced Sampling Plan

- The Reduced Sampling plan should be considered when less discrimination is considered necessary to assure critical characteristic conformance
- Factors to consider include:
  - Acceptance trending provides objective evidence that the product manufacturer or distributor has consistently had a satisfactory product acceptance history
  - The lot formation is based on a product manufacturer's heat number, production lot number, or batch number
  - Multiple CC are being verified on items in the formed lot from a single product manufacturer. Once these multiple critical characteristics are found conforming, the Reduced Sampling Plan can be considered for the remaining CC because it is reasonable to assume that the manufacturer has exercised similar controls over other CC

Reduced Sampling Plan, cont.

- A satisfactory item performance history exists
- The item is a standardized product manufactured to a national standard
- The cost-effectiveness of the test/inspection is low
- The item is simple
- The critical characteristic has a low safety significance

Tightened Sampling Plan

- The Tightened Sampling Plan should be considered when more discrimination is considered warranted to assure critical characteristic conformance.
- Factors to consider include:
  - Based upon available information on the manufactured, distributor, or item, there is concern that the lot is nonconforming
  - The lot consists of like-items from multiple or unknown product manufactures
  - The homogeneity of the lot needs to be assessed to justify small sample sizes for other critical characteristics
  - The item is not produced to a national standard
  - The cost-effectiveness of the inspection/test is high
  - The item is a complex assembly
  - The item has a high safety significance

Sampling Plan Tables for Nondestructive Tests and Inspections

- EPRI TR-017218-R1, Table 2-1 provides the recommended set of nondestructive test and inspections sampling plan tables.
- For all three sampling plans, if a CC of a sampled item does not meet the established acceptance criteria, the sampled item is classified as defective
- The lot acceptance basis is to accept the lot if the sample does not have a defect and reject the lot if the sample has one or more defects

- **Examples from Table 2-1**

	NP	RP	TP
Lot Size	7-11	6-13	12-13
Sample Size	4	2	8

Sample Size Selection for Destructive Tests and Inspections

- When destructive testing or inspection is required to verify a critical characteristic, using the sampling tables 2-1 of EPRI- TR-017218-R1 is not practical.
- The need for smaller sample sizes when destructive testing is involved has been recognized for material testing and equipment qualification testing.
- For CGI, prudent up-front planning to obtain the optimum lot formation available and consideration of the interrelationship between CC can justify smaller sample sizes.

Sample size selection criteria

- If the lot to be sampled is all from the same heat number, production lot number, or batch number, then there is a high level of confidence that the items within the lot will have similar properties.
  - When production traceability exists, a sample size of one is normally sufficient
- If you cannot obtain production traceability, then determine if the item can be obtained with a Line Item/Single Product Manufacturer lot formation.
  - If so, then use EPRI- TR-017218-R1, Table 2-2. For example, for lot size 1-10, sample 1. For 71-150, sample 4, for 1271-2550, sample 8 and greater than 2550, sample 9.

Sample size selection criteria, cont.

- Lot formation with Line Item/Multiple Production Manufactures should be avoided whenever destructive testing is required.
- If this must be used, then table 2-1 should be used to select sample size.

Sample Plan Implementation

- When destructive testing is required, special consideration should be given to the number and types of test samples needed. May need to adjust order number to accommodate.
- The type of test specimen should be verified prior to issuing the purchase order.
- Once the CC have been selected to be tested and the sample size for each CC has been chosen, there are different approaches for selecting samples.
- Approach A

CC	Sample Size	ID Number
A	8	1, 5,10, 12, 16, 23, 27, 30
B	8	1, 5,10, 12, 16, 23, 27, 30
C	8	1, 5, 10, 12,16, 23, 27, 30

Sample Plan Implementation, cont.

- Approach B

CC	Sample Size	ID Number
A	8	15, 25, 28, 18, 10, 3, 30, 5
B	8	16, 26, 29, 19, 11, 4, 13, 30
C	8	14, 24, 27, 17, 9, 2, 1, 6

- For Approach A, three critical characteristics would be verified on 27% of the items in the lot. In Approach B, one CC would be verified on 80% of the items in the lot.
- The types of verifications and where they will be accomplished will often dictate whether Approach A, Approach B, or a combination of both approaches is used.

Evaluation of Results

- The lot shall be accepted if the sample has no defects.
- The lot shall be rejected if the sample has one or more defects.
- Possible actions when one or more defects are found include:
  - An additional sample from the remainder of the lot could be selected to determine if the nonconformance is an isolated case or a systemic problem. The additional sample size should be larger than the original sample size.
  - A 100% sorting of the lot could be conducted and would consist of test and inspection of each item in the lot. It could be limited to the nonconforming characteristic or all characteristics. Each item would than be classified as conforming or nonconforming

Evaluation of Results, cont.

- An engineering evaluation can be performed to disposition the defect(s)
- The lot can be rejected and returned to the supplier in lieu of an engineering evaluation
- If the item is repaired by the supplier or the supplier provides a replacement that is resubmitted for inspection, then an increased or 100% sampling of the previous nonconforming critical characteristic might be prudent.

Documentation

- The CGI acceptance sampling process and the bases for sampling plan selection and application should be adequately documented.
- Documentation should address lot formation, complexity of the item, adequacy of supplier control as appropriate, safety function, test methodology, product performance, acceptance history of a supplier, item performance history, and so on.
- The following details for CGI acceptance should be considered:
  - Technical basis for sampling
  - Lot size
  - For each CC, that sample size or a reference to the sampling plan
  - Sample results
  - Lot disposition

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MODULE 6

Supplier Dedication Oversight

Enabling Objectives

- Describe basic elements under which an NQA-1 supplier performs CGD for a Commercial Sub-Supplier
- Describe how an NQA-1 supplier should implement a CGI/CGS dedication program
- Describe appropriate activities to perform to review suppliers' dedication activities

Commercial Grade Dedication – Supplier Submittals

- Suppliers may be requested to submit procedures or dedication plans when the dedication program requires supplemental assistance or when the significance or complexity of the item warrants oversight
- Supplier submittals related to CGD to consider:
  - Commercial Grade Dedication (CGD) procedure
  - CGD test/inspection plan for items requiring dedication
  - Review supplier's dedication procedure to determine whether it addresses the technical evaluation and acceptance planning processes effectively
  - Verify that technical evaluation process includes either determining safety function or safety function information from the purchase order

Commercial Grade Dedication – Supplier Submittals (cont.)

- Verify that the technical evaluation associated with the safety function results in a logical selection of critical characteristics and acceptance activities commensurate with the significance of the item
- Verify that the supplier inspection, test, sub-supplier audit and source verification activities are prescribed in a concise manner and conducted and documented in a manner that captures the intended results
- Tests results for CGD related tests and inspections as identified by the CGD plan

Review and Acceptance of Supplier Submitted CGD Procedures

- Submittal review must include an understanding of the scope of the CGID activity
- Scope of Supply Cases:
  - Case 1. Supplier performing CGD as Fabricator
  - Case 2. Supplier performing CGD as both Design and Fabrication and procuring and dedicating items from commercial suppliers

Case 1. NQA-1 Supplier Performing CGD as Fabricator – Scope and Submittals

- Responsible for fabrication and delivery of an item designed by a higher tier supplier
- Responsible for ensuring design requirements are met by the delivered item
- CC defined in drawings, specifications, and other design documents provided by designer
- The Fabricator should be provided with the CCFA or provided with sufficient safety function, design characteristics, and mode failure analysis information to develop the CGD package

Case 1. NQA-1 Supplier Performing CGD as Fabricator – Scope and Submittals

- The Fabricator's CGD program needs to be evaluated as part of the Fabricator's NQA-1 program acceptance and placement on the evaluated supplier's list
- The CGD package needs to be approved by the buyer through the procurement submittal process
- Scope items: obtaining base metals, simple items (flanges, fittings, piping, weld materials, gaskets, seals)
- Focus on material properties, dimensions

Case 2. NQA-1 Supplier Performing CGD as Both Design and Fabrication Scope

- Procuring and dedicating items of greater complexity from commercial suppliers such as pumps, valves, or electrical and instrumentation equipment
- CGD process must include the development and documentation of design documents from the analysis of safety functions; and then selection of appropriate CC as the basis for item acceptance

Case 2. NQA-1 Supplier Performing CGD as both Design and Fabrication (cont.)

- Purchaser reviews scope of supplier dedication activities required to be met and evaluates supplier CGD procedures, work instructions, and forms considering the following:
  - Has supplier been approved to perform CGD Technical Evaluations by Supplier Quality through supplier survey activities?
  - Does the supplier's CGD process contain the correct level of detail for their sub-supplier's scope of supply?
  - The CGD package needs to be approved by the buyer through the procurement submittal process

Supplier CGD Plans and Test Results – Review Considerations

- Supplier CGD Plans
  - Basis for selection of CC, acceptance methods, acceptance criteria
  - Reasonable assurance that plan implementation will result in items ordered are received and they perform required functions
- Supplier Test Results
  - Tests properly document completion of acceptance activities and dedicated items meet acceptance criteria
  - Do tests results include post-receipt or post-installation test, inspection or analysis requirements that must be tracked to completion?

Expectations Regarding CGI Dedications by Suppliers

- Supplier must have an appreciation for:
  - The most severe end use application
  - Accident conditions under which the item must function
    - Seismic events
    - Other design basis events
  - The safety functions of the host equipment and the item
- Supplier must select and verify a set of critical characteristics that provides reasonable assurance that the item will perform its intended safety function

Expectations Regarding CGI Dedications by NQA-1 Suppliers

- Supplier has the same flexibility the purchaser has in selecting the optimum means of critical characteristic verification
  - Source inspections of sub-suppliers/manufacturers
  - Audits/surveys of sub-suppliers/manufacturers
  - Tests/inspections of the CGI
    - During receipt of raw material or a manufactured item
    - During and after fabrication of individual piece-parts
    - During and after assembly of the final product
  - History of Performance
  - “Trust But Verify”

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Commercial Grade Dedication Training

MODULE 7

Implementation and Lessons Learned

Enabling Objectives

- Describe basic elements under which a supplier performs CGD for a Commercial Sub-Supplier
- Describe how a supplier should implement a CGI/CGS dedication program including supplier submittals and their review
- Understand prime contractor expectations regarding:
  - Determination of plant applications
  - Critical characteristics selection
  - Optimization of acceptance methods

CGD Example: FASTENERS

Item – .5” X 1.0” UNC-2A heavy hex screw per ASTM A193 Grade B8M, Class 1

Application – items are stocked for use in plant wide applications

Safety function, service conditions and design margin - service loading that would rely upon the screw having the full mechanical properties for high temperature or high pressure service or other special purpose applications with corrosion resistance as stated in ASTM A193.

Safety significance – the bounding condition for the screw is being relied upon for severe service conditions including maintenance of pressure boundary and seismic qualification, therefore a high level of confidence in the item’s quality is necessary

Example: FASTENERS (cont)

Critical characteristics:

Dimensions:	diameter
	length
	threads
Chemical content:	Carbon
	Manganese
	Phosphorus
	Sulfur
	Silicon
	Chromium
	Nickel
	Molybdenum
Mechanical Properties:	Tensile strength
	Yield strength
	Elongation
	Reduction of Area
	Hardness

Example: FASTENERS (cont)

Acceptance Methods:

Dimensional testing in accordance with ASME B18.18.2M is performed

Chemical analysis and mechanical properties are verified per ASTM F593.

Basis:

- This material is manufactured to ASTM A193.
- This standard has acceptance criteria established for the physical, chemical, configuration and dimensional characteristics required for the fasteners.
- The application of the standard such that confidence is established that the acceptance criteria in the standards are met.

Example Fasteners, Cont.

- The supplier program will maintain material heat traceability and manufacturing lot traceability.
  - Every lot of material will be independently tested using approved sample size, giving a high level of confidence in the material properties.
  - A commercial grade survey will be performed on the fastener manufacturer to evaluate the quality program for controlling forming and machining activities.
  - An inspection will be performed at the supplier's facility on the first lot of items ready for shipment.
- Taken together, these activities provide a high level of confidence in the items supplied.

CGD Example: MANUAL GATE VALVE

Item – 1" gate valve per ASME B16.34, hand wheel, Class 600, socket weld ends, ASTM A105 material, Valvco model 0829.

Application – Service water system intertie line drain valve

Safety function, service conditions and design margin - The valve serves as service water system pressure boundary with disc closed during operation. The service water system provides cooling for plant safety components that perform critical functions. The service water system has 150% capacity with one of six pumps in reserve.

The valve will be closed when the system is in service and only opened during maintenance.

Service conditions are 85 psi at 88F for fresh lake water. The valve is rated at 1350 psi at 100F.

Safety significance – Maintenance of service water system boundary is important to plant equipment function. The safety significance of this valve is low considering:

available design margin of over 1000 psi

large system flow capacity margin

a failure mechanism considering the design margin of seat or stem leakage that would result in a small amount of service water loss

Example: MANUAL GATE VALVE (cont)

Critical characteristics:

Dimensions: socket weld end diameter and depth
body and bonnet wall thickness
body - bonnet fastener diameter, threads, length
disc thickness, diameter
seat diameter, width

Material: Body, disc and bonnet compliance with SA105
Fastener compliance with SA193/SA194

Assembly and Test Related Process Controls

- Work control
- Nondestructive examination control
- Test control
- Nondestructive examination control
- Document Control

Example: MANUAL GATE VALVE (cont)

Acceptance Methods:

- A survey was performed to evaluate the suppliers quality program for the following:
  - Procurement control for acceptance of purchased forgings and fasteners
  - Work control for fabrication of valve parts from purchased material and assembly
  - Inspection and test control for dimensional verification activities and hydrostatic and seat leakage tests per ASTM B16.34
  - Nondestructive examination control for qualification of personnel and compliance with ASTM standards for performance
  - Nonconformance control for segregation of defective items
  - Document control to assure use of the appropriate drawings and procedures
  - The supplier is required to provide certification with shipment of the valve that the valve was processed under their approved QA program.

Example: MANUAL GATE VALVE (cont)

Basis:

•This is a standard commodity valve manufactured to meet ASME B16.34.

•It was selected by the system design engineer for this application considering the ratings in ASTM B16.34 in relation to the service conditions.

•The commercial grade survey determined that the valve manufacturer placed appropriate controls on their supplier to assure that appropriate assurance of material quality was achieved for the pressure retaining items.

•ASTM B16.34 requires hydrostatic testing and seat leakage that are incorporated in the supplier's procedures that were evaluated during the program survey.

CGD Example: SERVICE

Service – Qualification testing for building exterior wall siding system

Application – Emergency diesel generator building

Safety function, service conditions and design margin – The safety function of the wall is to protect the diesel generator from the effects of wind and associated high speed debris impingement. The building must remain intact and protect the diesel generator from an 111 mph wind and a 15 pound piece of 2 x 4 lumber traveling at 50 MPH.

Safety significance – The building function is to protect the integrity of the diesel generator who's function is to provide backup power to plant cooling and off gas filtration systems, thus the building wall importance is high. The qualification test is critical to establishing the suitability of the design and will serve the basis upon which the following material and installation acceptance activities will be performed.

Example: SERVICE (cont)

Critical characteristics:

The supplier will be required to perform the qualification test in accordance with the methodology stated in industry standard FM 7882 in line with the application.

Acceptance Methods:

A source surveillance will be performed by the Design Engineer at the supplier's facility to:

- review the supplier's test procedure for compliance with FM 7882
- witness each step of the test to verify performance in accordance with the approved procedure
- verify that the equipment used for the test is calibrated
- verify that results are accurately captured

Basis:

Considering the criticality of the test, a high level of oversight of the supplier's activities was warranted. Each step was observed by the Design Engineer for compliance with his expectations in the contract.

CGD Example: SUPPLIER OVERSIGHT

Item – 5000 cfm centrifugal fan assembly (without motor)

Application – Main fabrication facility exhaust system

Safety function, service conditions and design margin – The fan is required to maintain the main fabrication facility at .25 psi negative pressure after a design basis seismic event for 1000 hours at a maximum temperature of 97F and a minimum temperature of 69F. The fan housing is constructed from stainless steel for ease of decontamination. The seismic analysis of the fan determined that the fan has a design margin of over 50%. The supplier was provided with the system performance expectations and selected a fan model with a 30% capacity margin.

Safety significance – The function of the fan provides the motive energy for maintaining a negative pressure for prevention of radioactive gas release from the confined area. Failure of the fan may result in small leakage around seals but not widespread large contamination. Backup provisions exist to prevent significant personnel exposure in this event.

Critical characteristics:

Material: housing, blade, shaft, bearing and sleeve material

Example: SUPPLIER OVERSIGHT (cont)

- ***Acceptance Methods:***
  Each piece of stock material for the housing, blade, shaft, bearing and sleeve was tested to verify chemical and physical/mechanical properties
- ***Basis:***
  The manufacturer purchases raw material for the fan commercial grade and dedicates it prior to machining, forming and assembling. Each piece is tested to verify specification compliance, thus providing a high level of confidence in the product quality.

Example: SUPPLIER OVERSIGHT (cont)

Dedication Program Oversight:

The customer performed a pre-award audit of the suppliers QA program including dedication activities. The technical specialist on the audit team reviewed the manufacturer's dedication procedure for technical evaluation and acceptance planning activities. It was verified that on other similar nuclear orders the supplier had performed suitability activities effectively, understand safety function development and critical characteristic selection, and had accurately performed the prescribed tests. Sample plans were based on technical understanding of the items performance as related to the characteristics selected. Nonconformance evaluation included consideration of other potentially affected items.

The supplier submitted the dedication plan for the stock material for review prior to purchase. It was verified that:

- The manufacturer stated the fan safety function and significance
- The supplier had completed the suitability activities and stated the seismic and capacity design margin
- The supplier selected the raw material chemical and mechanical properties for test
- Heat traceability to the mill for the raw material was established by audit of the intermediate supplier's material control program

The manufacturer provided a purchase order certification stating that all requirements of the order had been met, including the dedication activities.

Lessons Learned

- "Safety" classification MUST precede the determination of procurement category
- "Safety" classification is NOT determined by the supplier
- "Safety" classification is NOT based on whether the item is supplied as ASME NQA-1 or CGI
- Even though original component specifications did not identify a particular sub-item or its critical design characteristics, it doesn't mean there are no CC's of the item that are important requiring verification.
- Once selected, each CC must be adequately verified
- Not every technical requirement specified in a procurement document may need to be verified as a CC

Lessons Learned (cont)

- Failures of commercial grade items shall be documented and trended
- Methods for controlling, tracking and evaluating failed items shall be procedurally defined and controlled
- Information can be used to adjust the sample size (from one item up to 100%)
- DEDICATION PLANNING INCLUDES SPECIFIC INSPECTION/TEST/SURVEY CRITERIA.

  The output of the dedication planning should include specific information that is directly useable by the organization performing the acceptance activity.

  DON'T – State "Test valve to ASME B16.34"

  DO – State "Perform a hydrostatic test of the valve body at 300 psi. Hold the pressure for 10 minutes then inspect for leakage. No leakage is allowed."

Lessons Learned (cont)

- UNDERSTAND THE DIFFERENCE BETWEEN SUITABILITY AND DEDICATION

  Part of the design process is to establish the suitability of an item for it's intended service. When the Design Engineer selects a candidate item for an application, suitability includes establishing the technical basis for the item being able to perform it's functions in the system. This can be done by testing or analysis, and for safety related applications may include environmental and seismic qualification, etc. When suitability is complete, the technical evaluation for dedication and acceptance planning can be performed based on the approved design documents.

  Lesson learned – Do not incorporate suitability/qualification testing in dedication activities. For example, the dedication activities should not include "Perform environmental qualification to IEEE - 323-1974."

Lessons Learned (cont)

- DEDICATION PLANNING PACKAGES DO NOT NEED TO INCLUDE A COMPILATION OF ALL THE PRESCRIBED INSPECTION AND TEST ACTIVITY RESULTS
  - The activities prescribed in the dedication planning package are performed by the groups stated in accordance with their normal work performance procedures and the associated records are captured as specified by those procedures. It is not necessary to also have those records included with the dedication planning package for the items.
  - NQA-1-2004, Part III, Section 800 states that test reports or results, inspection reports, and analysis reports are part of the CGD documentation.

    Lesson learned - An effective dedication process integrates planning activities into existing procedures without causing unnecessary duplication.

    DON'T – Have additional copies of inspection test reports also sent to Procurement Engineering to be placed in the dedication planning package.

    DO – Have inspection test reports documented as directed by the governing procedure and referenced in the CGD package.

Lessons Learned (cont)

- <u>INDUSTRY GUIDANCE DOCUMENTS ARE JUST THAT - GUIDANCE</u>

  There are several industry guidance documents and standards that are tools to be used to develop a program and to be used by a Procurement Engineer to do individual evaluations. However, each dedication activity is based on plant application and the technical evaluation of the critical characteristics. The rigor of the acceptance activities are commensurate with the safety significance.

  DON'T – Adapt EPRI JUTG Commercial Grade Item Evaluations as prescriptive consensus methods for dedicating the items addressed.

  DO – Use the evaluations as a compilation of information related to an item to assist in the performance of the technical evaluation, and therefore select characteristics relevant to the plant application.

Examples of CGID Issues

- Failure to recognize the need for a CGID activity to support the procurement process
- Implementing procedures were expert based instead of being developed at the level of detail to support the knowledge and experience level of the organization performing the activity.
- Lack of understanding of the relationship between the safety function, design criteria, critical characteristics, acceptance criteria, and methods for acceptance.

CGID Benchmarking Lessons Learned

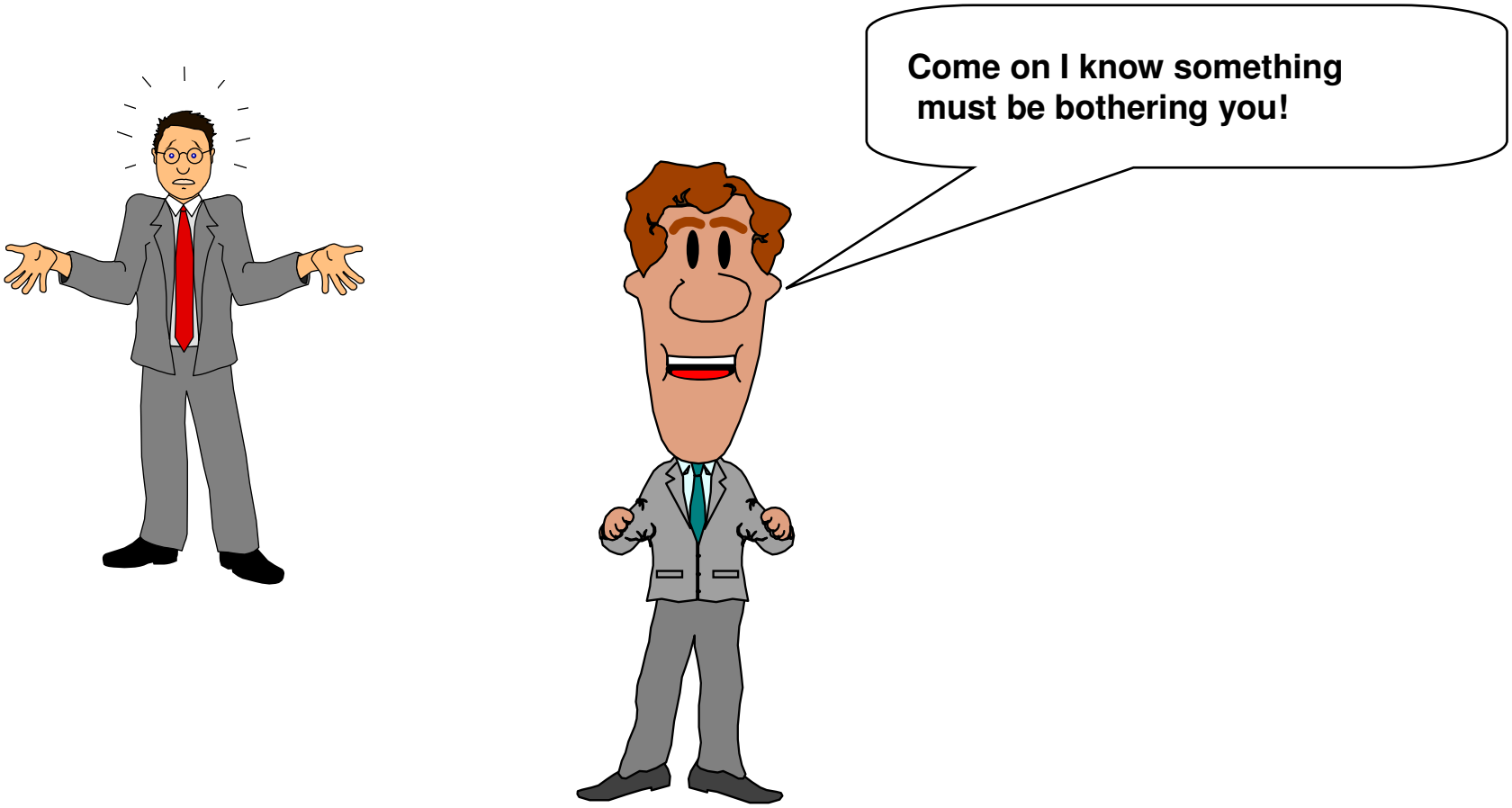
- Several positive lessons learned were identified during the review of three commercial power organizations.
  - Utilities have adopted the Electric Power Research Institute (EPRI) NP-5652, Guideline for Utilization of Commercial Grade Items in Nuclear Safety Related Applications (NCIG-07), as the basis for conducting CGD activities.
  - Utility engineering organizations develop the CGD critical characteristics and acceptance requirements based on a detailed technical evaluation.
  - Utility quality organizations are responsible for assuring implementation of the CGD requirements.
  - Utilities use the EPRI Sponsored JUTG database to identify critical characteristics of items/ components.

CGID Benchmarking Lessons Learned, cont.

- Utilities stressed early communication and integration of CGD team (Engineering and QA).
- Utilities have implemented Engineering Organization CGD training programs
- Utility QA organizations rely on nuclear power industry QA/quality control training programs
- Utility use of CGD surveys to identify/correct supplier commercial quality program concerns prior to procurement

Questions & Answers

- Questions or Comments



References:

- DOE Order 414.1C, *Quality Assurance*
- DOE Guide 414.1-2A, *Quality Assurance Management System Guide*.
  - Discusses using a recognized international consensus standard for conducting Commercial Grade Dedication
- ASME-NQA-1-2004
  - Part I, Introduction (defines commercial grade item (two definitions), commercial grade service, critical characteristics, dedication, and dedicating entity
  - Part I, Requirement 7, *Control of Purchased Items and Services*
  - Part III, NonMandatory Appendix 7A-2, *Guidance on Commercial Grade Items and Services*

References, Cont.

- **EPRI Documents requiring purchase**:
  - JUTG Commercial Grade Item Technical Evaluations
  - Information for Use in Conducting Audits of Supplier Commercial Grade Item Dedication Programs
  - Generic Qualification and Dedication of Digital Components: Project Status and Lessons Learned
  - Generic Qualification/Dedication of Digital Components: Summary of 2004 Generic Qualification Activities
- **Documents free of charge**:
  - Generic Topic of Commercial Grade Dedication:
    - Guideline for the Utilization of Commercial Grade Items in Nuclear Safety Related Applications (NCIG-07)
    - Supplemental Guidance for the Application of EPRI Report NP-5652 on the Utilization of Commercial Grade Items

References, cont.

- Critical Characteristics
  - Guideline for the Technical Evaluation of Replacement Items in Nuclear Power Plants (NCIG-11), NP-6404
  - Critical Characteristics for Acceptance of Seismically Sensitive Items (CCASSI)
- Digital Equipment
  - EPRI TR-106439, *Guideline on Evaluation and Acceptance of commercial Grade Digital Equipment for Nuclear Safety Applications.*
- Sampling Plan Development
  - EPRI TR-017218-R1, *Guideline for Sampling in the Commercial-Grade Item Acceptance Process*

References, cont.

- NRC Generic Letter 89-02: Conditionally endorses EPRI NP-5652, *Guideline for the Utilization of Commercial-Grade Items in Nuclear Safety-Related Applications (NCIG-07)*. Promotes the use of method one, test and inspection, and if method two or four are used they must be used in conjunction with additional methods.
- NRC Generic Letter 91-05: Defined critical characteristics. The Enclosure provided characteristics of effective commercial-grade procurement and dedication programs.

References, cont.

- NRC Inspection procedure 38703, *Commercial Grade Dedication*
- NRC Inspection Procedure 43004, *Inspection of Commercial-Grade Dedication Programs*
- NRC Inspection Procedure 38703 and 43004, *Assessing Sampling Techniques*