# Waste Treatment Plant Project

## 2016 Supply Chain Collaboration Event

## WTP Project Supplier Commercial Grade Dedication

## Part 1

OFFICE OF RIVER PROTECTION
United States Department of Energy

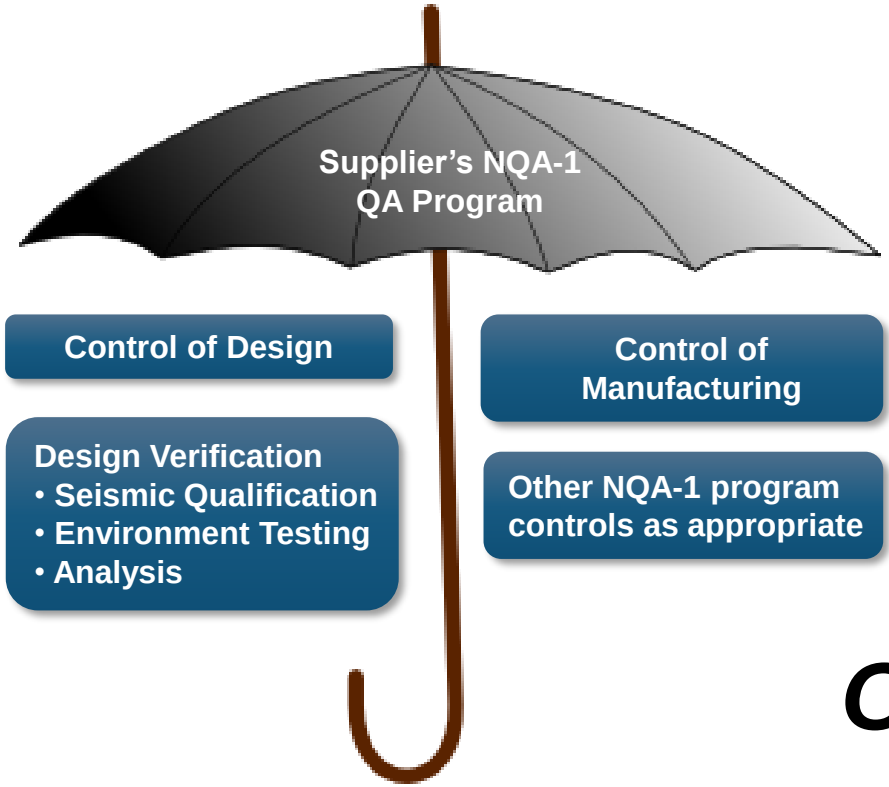
Bechtel National, Inc.

URS

# Topics

- Providing Commercial Items For Use In Q Applications At The WTP
- T0019 CGD Process Overview
- CGD Roles & Responsibilities
- Technical Evaluation and Acceptance Plan
- Critical Characteristics vs. Design Characteristics
- Requirements Flow Down & Oversight
- Importance of CGD Result Traceability
- CGD Package Contents
- Submittal Requirements

# Providing Commercial Items for Use In Q Applications at the WTP

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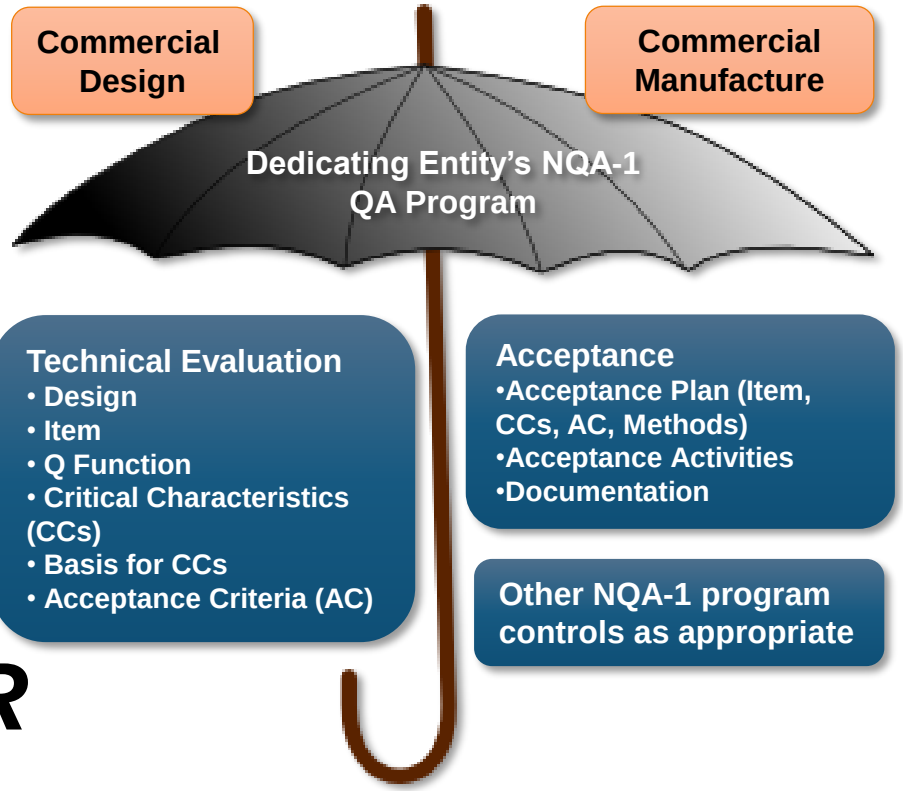


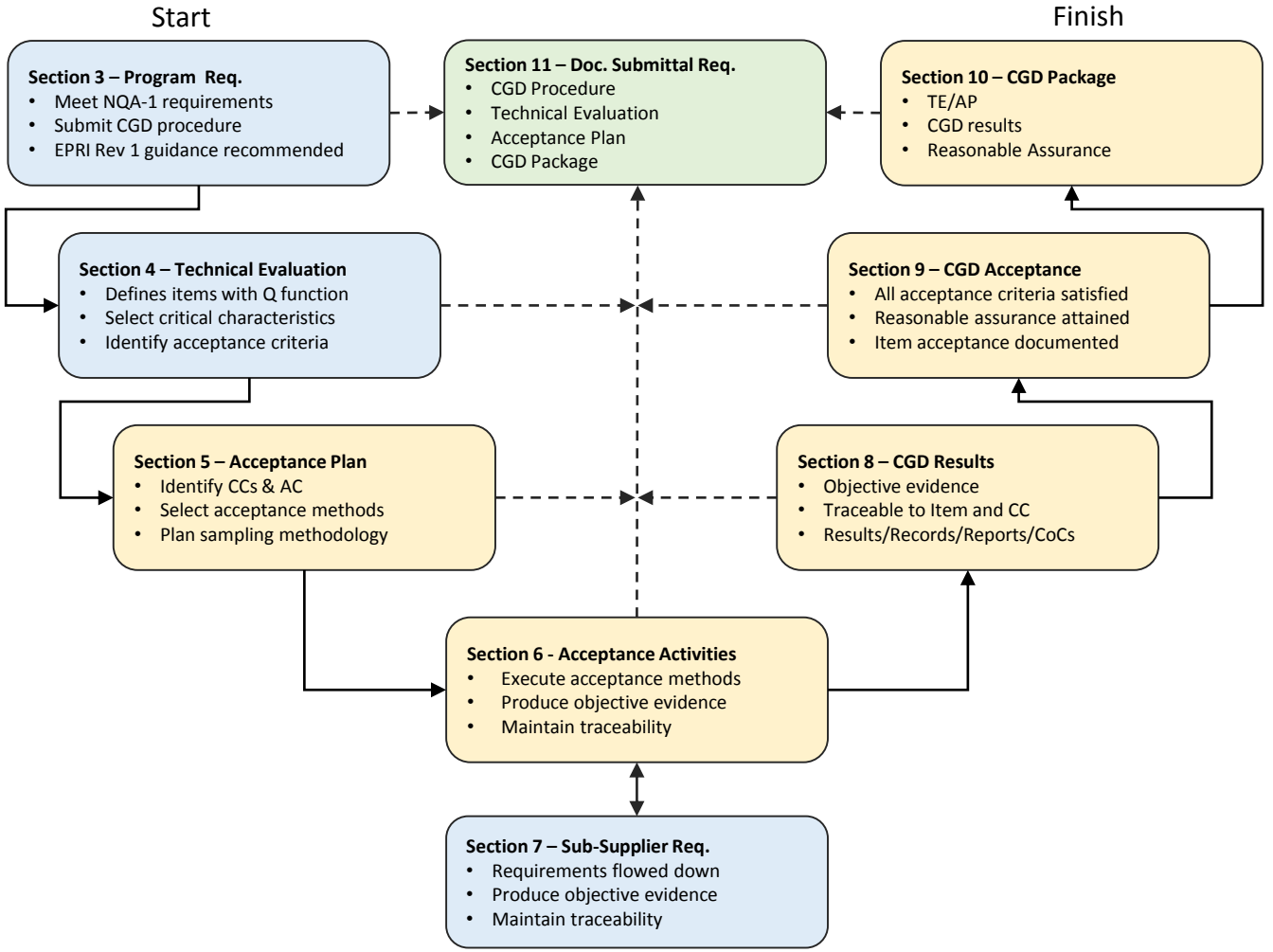

**Item becomes Q as it is controlled under a nuclear QA program, and all appropriate elements of the program are implemented to provide *adequate confidence* the item will perform as its designed to perform.**

**Item becomes Q through CGD. The design and/or manufacturing are NOT controlled under a nuclear QA program. Dedication is needed to provide *reasonable assurance* the item will perform its safety (or Q) functions.**

# Providing Commercial Items for Use In Q Applications at the WTP

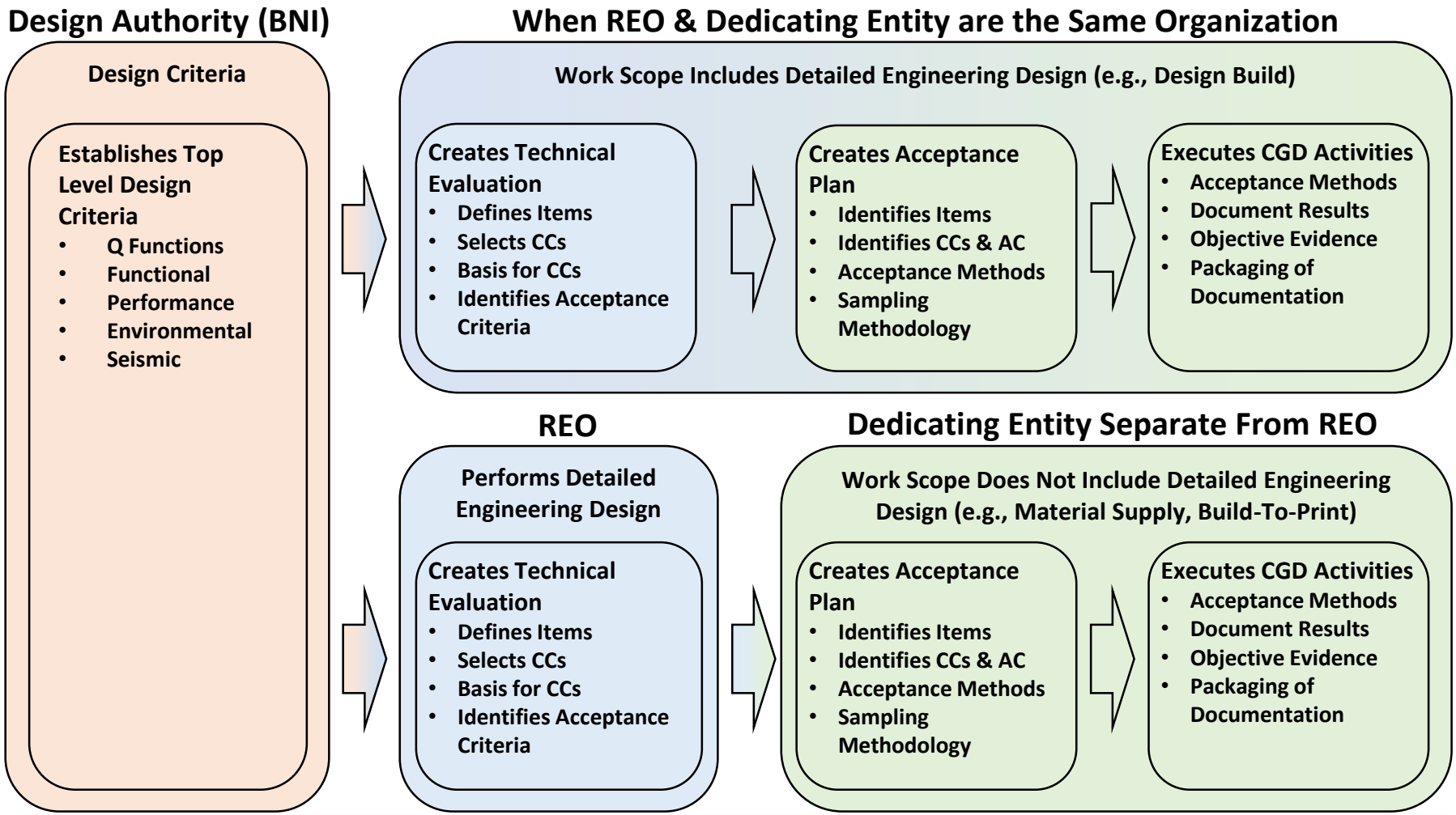
| Topic | Control an item through an NQA-1 QA Program | Implement the Commercial Grade Dedication Process |
|---|---|---|
| QA Program | Supplier's qualified NQA-1 QA program. | Dedicating entity's qualified NQA-1 QA program & dedication procedure. |
| Prerequisites | Design has been verified to be suitable for the application.<br><br>Design changes have been controlled. | Suitability of the item's design has been established for one or more Q functions.<br><br>Critical Characteristic selection supports Q function. |
| Methodology | Procurement controls in NQA-1, Requirement 7, Sections 200-600.<br><br>Conformance to design is controlled through the QA program. | Acceptance methods in NQA-1, Requirement 7, Section 700.<br><br>Acceptance of items by verifying Critical Characteristics necessary for the item to perform its Q function |
| Availability of item's design information | Design information is available, including design verification and qualification. | Limited design information available.<br>Q functions known.<br>End-user specifications for item known. |
| Method of establishing objective evidence of item acceptability | Instructions, procedures, drawings, and documented results. | Commercial grade item technical evaluation and acceptance plan, and the results of CGD acceptance methods used. |

# T0019 CGD Process Map




**Specification T0019, revision 2, is organized around this CGD process map. Each step of the map provides reference to corresponding sections of the specification.**

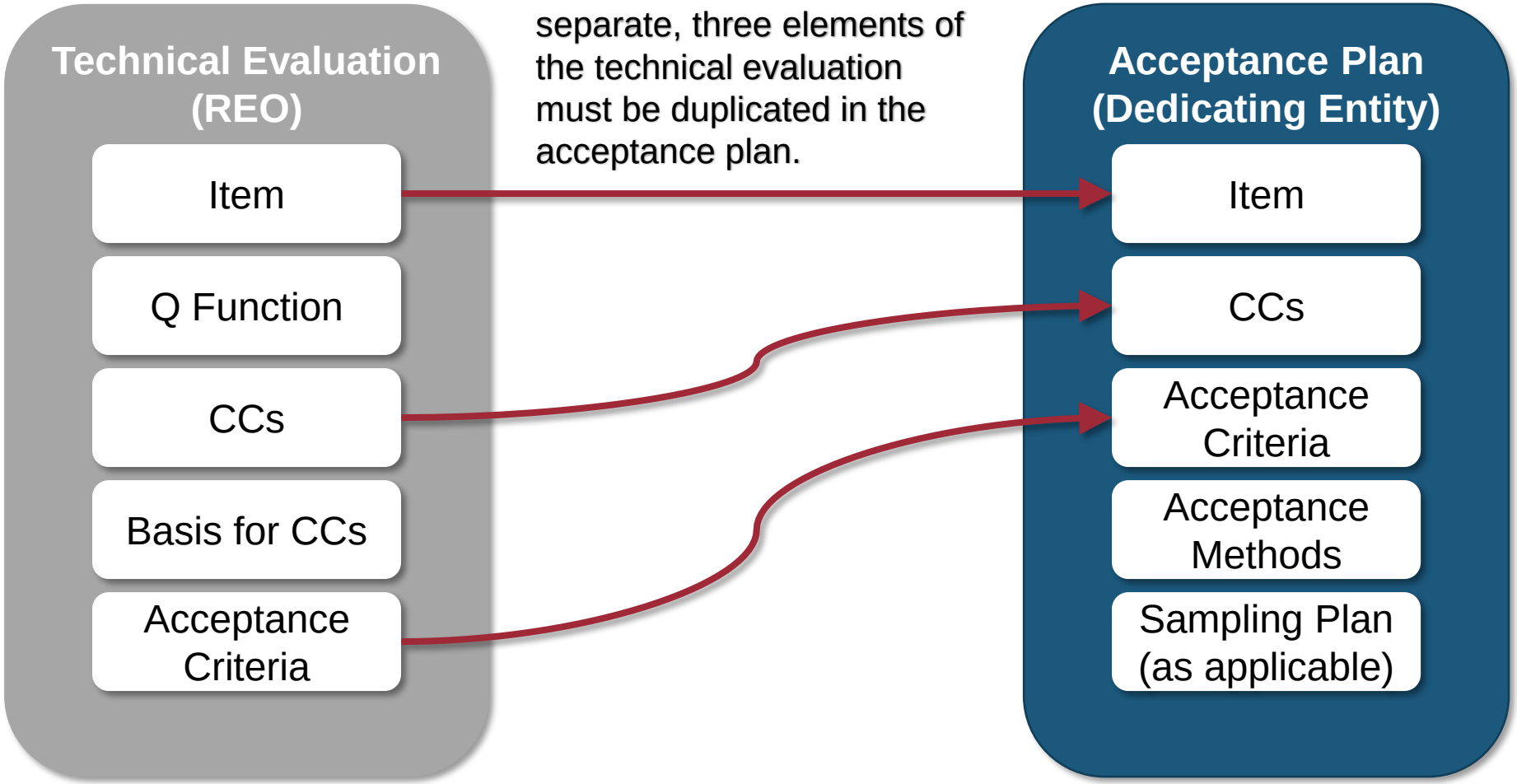
# CGD Roles & Responsibilities




**The Responsible Engineering Organization (REO) is typically responsible for the technical evaluation. Dedicating Entity is typically responsible for the acceptance plan and CGD activities.**

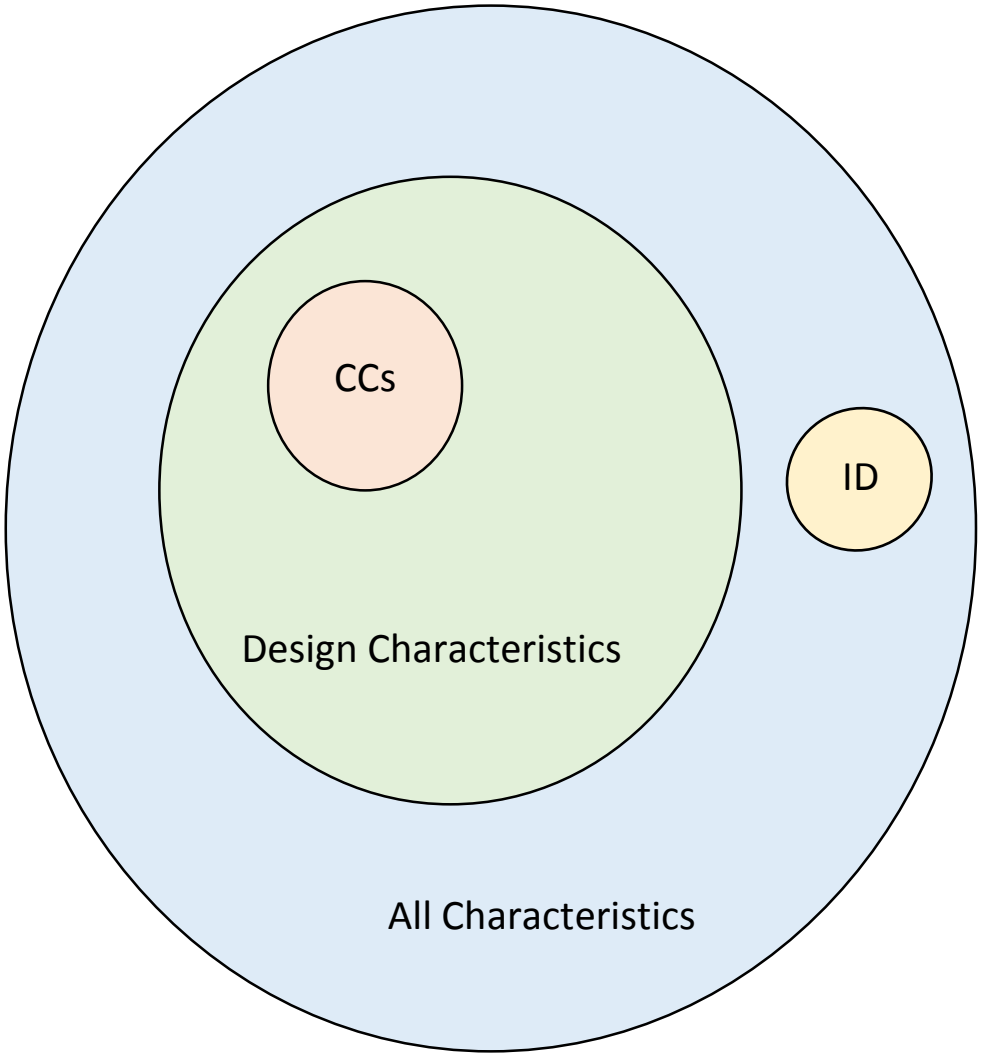
# Technical Evaluation vs. Acceptance Plan

When these documents are separate, three elements of the technical evaluation must be duplicated in the acceptance plan.




**Specification T0019, revision 2, delineates the technical evaluation separately from the acceptance plan to account for a variety of contractual arrangements.**

# Critical Characteristics vs. Design Characteristics




**Critical Characteristics (CCs)**

- Dimensions
- Yield Strength
- Material Grade
- Hardness

**Design Characteristics**

- Dimensions
- Material Chemical Composition
- Material Grade
- Yield Strength
- Tensile Strength
- Reduction in Area
- Hardness
- Surface Finish Configuration

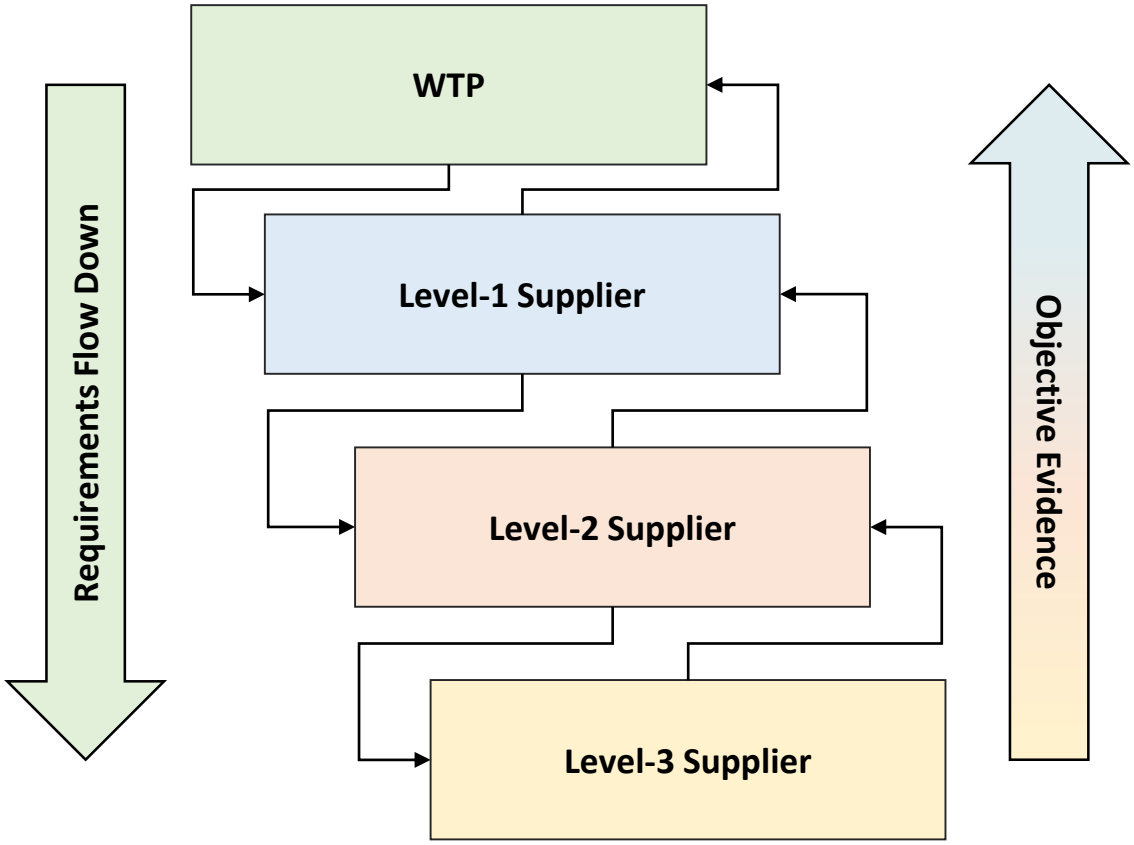
**Identification Attributes (ID)**

- Part / Model Number
- Shop Order Number
- Heat Number
- Drawing Number

**All Characteristics**

**Critical Characteristics are generally a subset of design characteristics specifically related to a Q function.**

# Requirements Flow Down & Oversight




**The Level-1 Supplier shall flow down all requirements and perform oversight when the Level-2 Supplier is the dedicating entity. Additional sub-suppliers shall likewise have requirements and responsibilities flowed down.**

# Importance of CGD Result Traceability

**Acceptance Plan**

- Item
- CCs
- Acceptance Criteria
- Acceptance Methods
- Sampling Plan (as applicable)

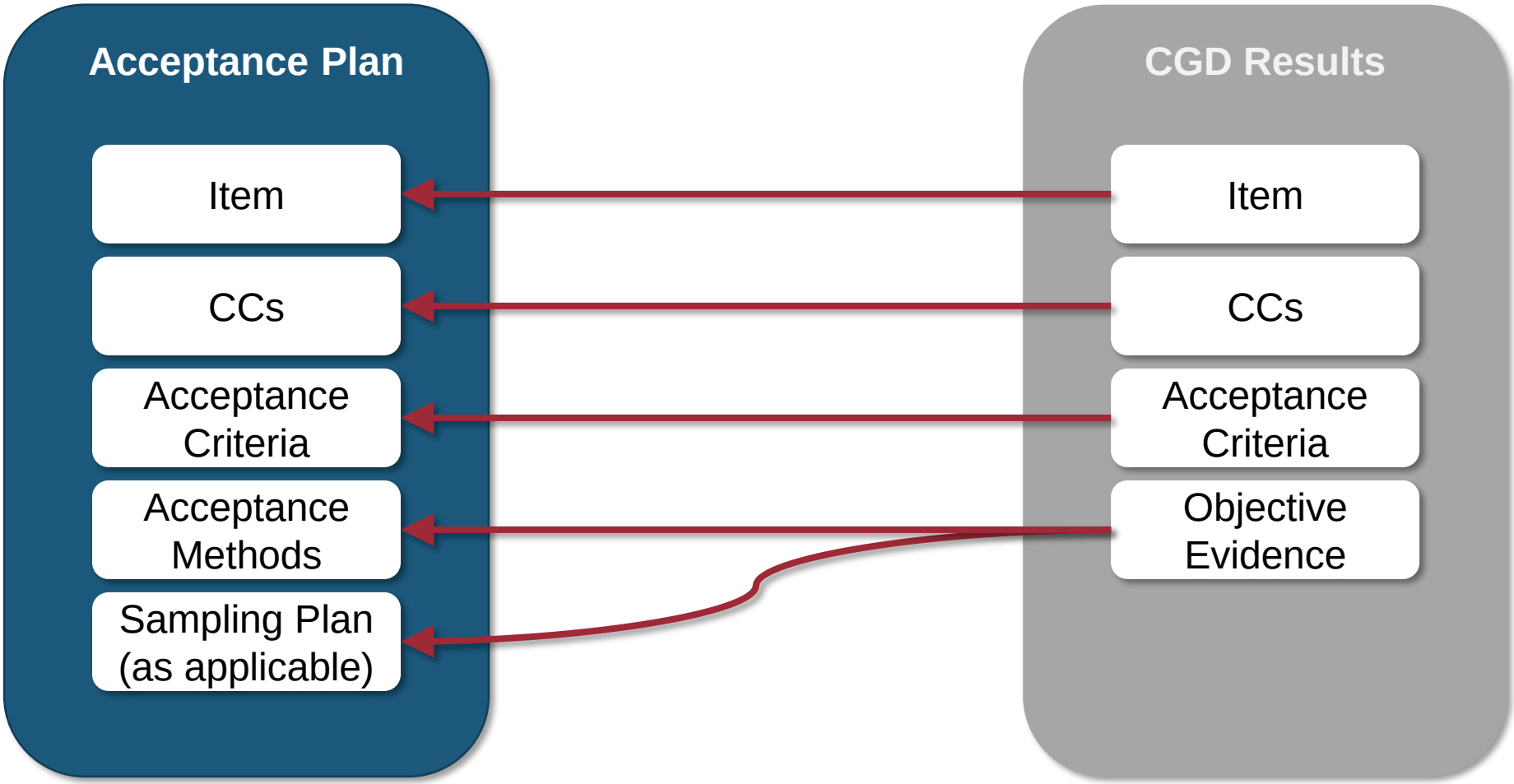
CGD Results must Traceable to the Acceptance Plan.

**CGD Results**

- Item
- CCs
- Acceptance Criteria
- Objective Evidence

**CGD Results must be auditable to the Acceptance Plan and identifiable to the attributes shown herein.**

# Importance of CGD Result Traceability

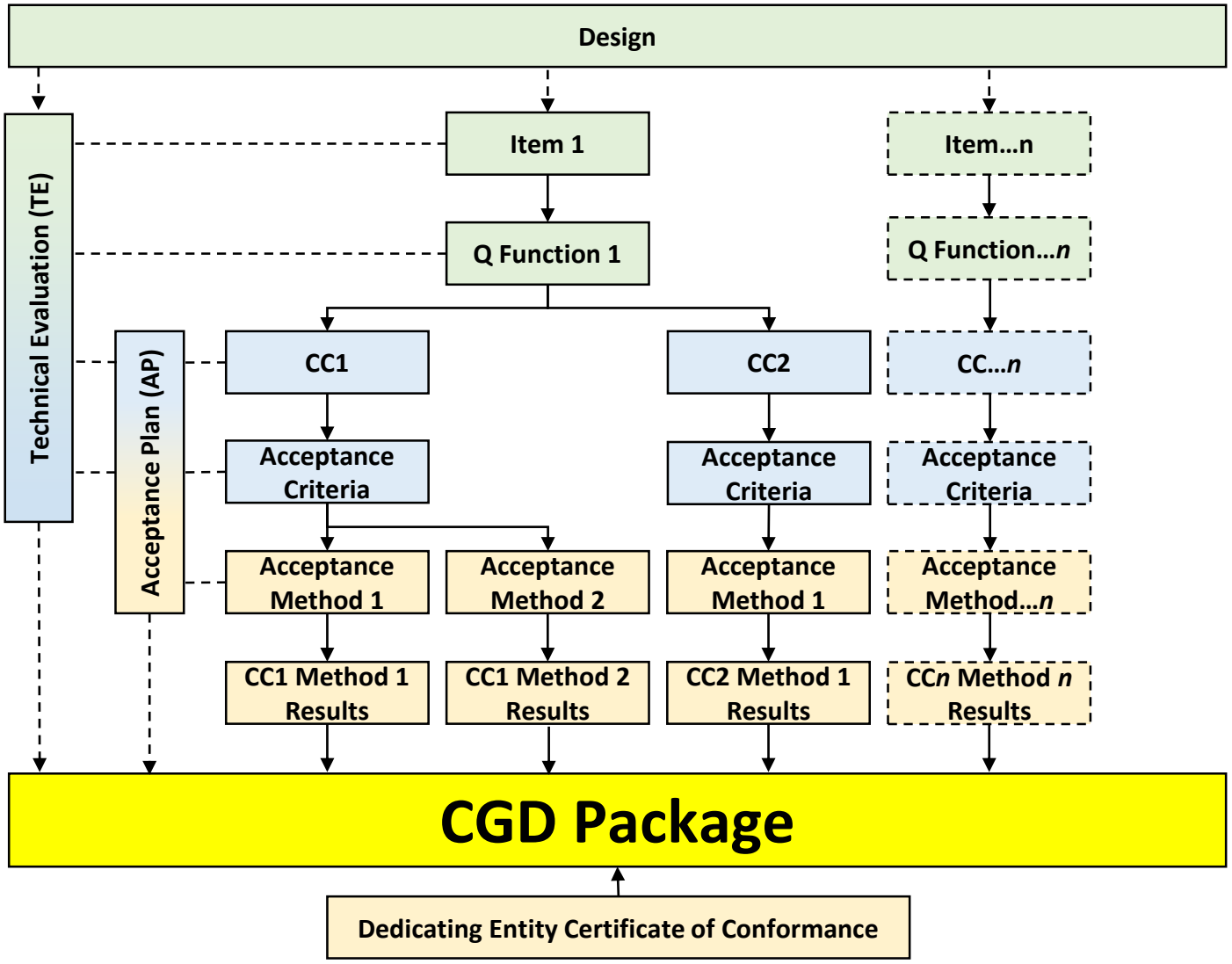



**Traceability from the CGD Results to the Acceptance Plan is through the CGD Package**

# Dedicating Entity Certificate of Conformance

- Specific Certificate of Conformance for Commercial Grade Dedicated Items
- Certification by the Dedicating Entity
- Certificate to be included in CGD Package
- Identifies
  - Dedicated Items
  - Buyer's Purchase Document Nos.
  - Acceptance Plans (CGD Plan)
  - CGD Packages
- Certifies
  - Commercial Grade Dedication performed in accordance with identified Acceptance Plans
  - CGD Packages provide the objective evidence that demonstrate the item has satisfied the specified acceptance criteria for the identified critical characteristics, and as such, reasonable assurance the item will perform its intended Q function has been attained.

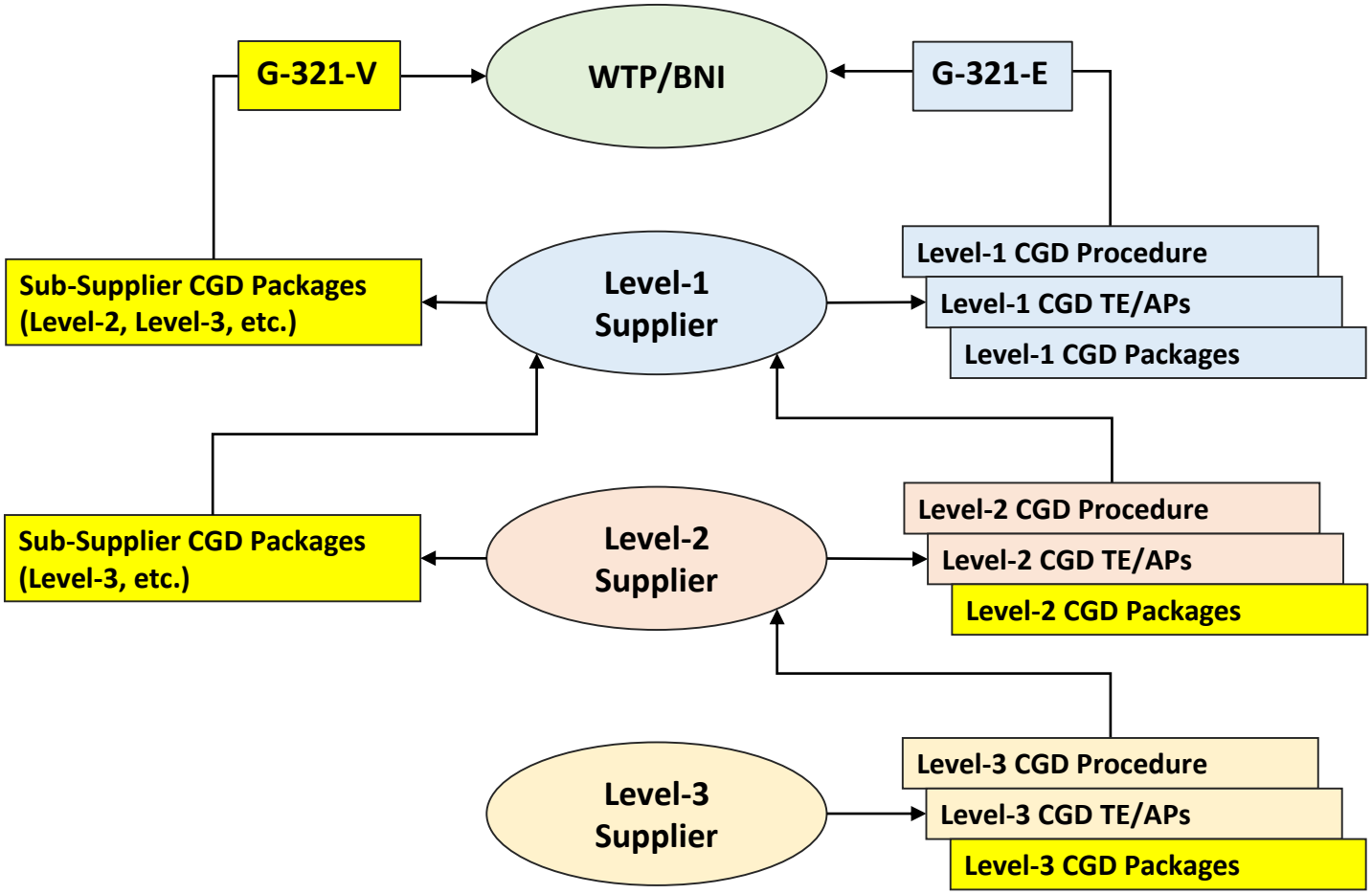
# CGD Package Contents



# CGD Package Contents

| CGD Package | | | |
|---|---|---|---|
| Package Document No.: | | | Rev: |
| Package Title: | | | |
| Buyers PO Number: | | | |
| **Items** | | | |
| **Buyer PO Line Items** | **Description of Item/Service** | | |
| | | | |
| | | | |
| **Supporting CGD Documentation** | | | |
| Title: | | | Ref ID: |
| Document #: | | Rev: | Release Date: |
| Document Details/Notes: | | | |
| Title: | | | Ref ID: |
| Document #: | | Rev: | Release Date: |
| Document Details/Notes: | | | |
| Title: | | | Ref ID: |
| Document #: | | Rev: | Release Date: |
| Document Details/Notes: | | | |
| Title: | | | Ref ID: |
| Document #: | | Rev: | Release Date: |
| Document Details/Notes: | | | |
| **Results** | | | |
| Dedicated Item/Service: | | | |
| **Critical Characteristic** | **Acceptance Criteria** | **Results of Acceptance Activities** | |
| | | | |
| | | | |
| | | | |
| Dedicated Item/Service: | | | |
| **Critical Characteristic** | **Acceptance Criteria** | **Results of Acceptance Activities** | |
| | | | |
| | | | |
| | | | |
| **Notes** | | | |
| | | | |

# Submittal Requirements




**The organization performing the oversight is responsible for submittal review and acceptance of the dedicating entity's work products and CGD package.**

# Waste Treatment Plant Project

## 2016 Supply Chain Collaboration Event

## CGD Supplier Quality Programs and Procurement Practices

## Part 2

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# Back in the Day (Prior to 1979)

- Many players in the nuclear marketplace, buyers and sellers
- Manufacturers and distributors had 10CFR50, Appendix B QA programs
- Focus on whole components and new builds
- Manufacturers bought commercial items and produced Basic Components (the utility term for nuclear safety related items)
- Implicit and not of concern:

***<u>Everything</u> starts as commercial grade items and materials***

# 1980 and later

- Marketplace changed: Less whole components, more aftermarket support demanded by Customers
- Manufacturers less interested in supplying parts and subcomponents as Basic Components, aggravated by high level of customer support required (changing regulatory climate)
- Decline in number of suppliers with Quality Programs and manufacturers willing to sell items as Basic Components (or Q items)

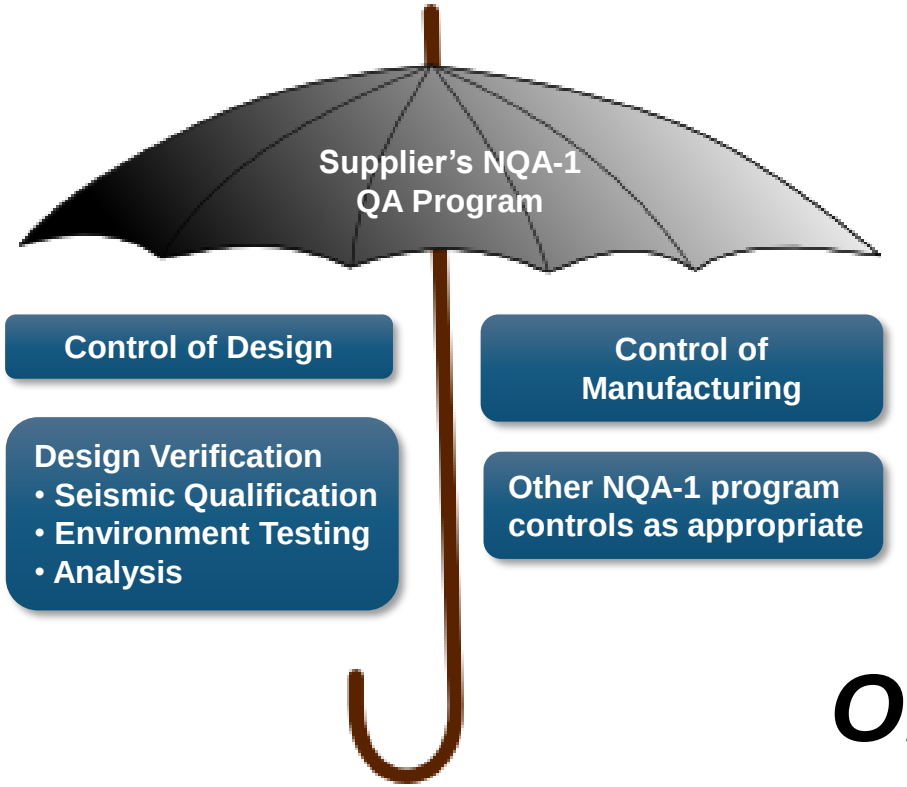
# “Its not available as a safety-related part…”

- Suppliers willing to sell replacement parts, but not always as Basic Components
- Most buyers had no formal acceptance process for using a commercial grade item in a safety-related application
- Utilities, facing scrutiny from internal QA and from USNRC, struggled with how this was done
- USNRC expected some type of “engineering process” to address this, saw a wide range of solutions, but few appropriate to items required to perform a safety function

# Industry Actions – Late 1980's

- Utility executives raised this issue as a critical problem, industry groups tried to provide solutions
- Electric Power Research Institute (EPRI) and sponsored user groups proposed the Commercial Grade Dedication process in 1988, with the issuance of NP-5652 "Guideline for the Utilization of Commercial Grade Items"
- NRC reviewed and conditionally endorsed EPRI Report NP-5652 in Generic Letter 89-02 (1989)
- ***Concept of Commercial Grade Dedication was established as an industry "acceptance process" for using commercial grade items as Basic Components***

# Providing Commercial Items for Use In Q Applications at the WTP

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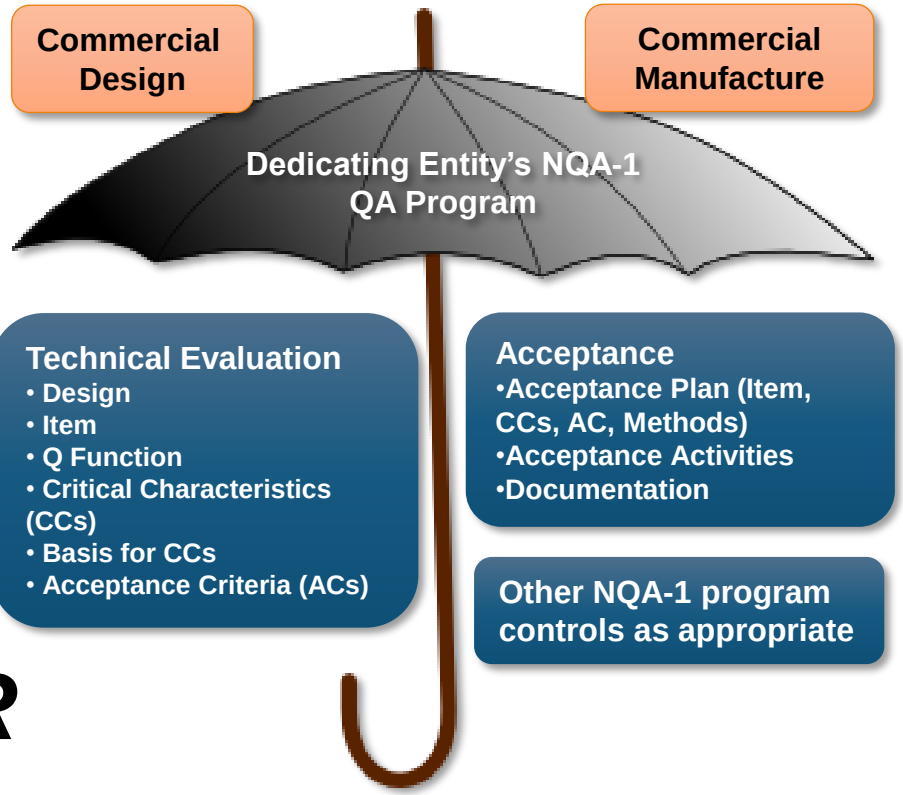


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| Method of establishing objective evidence of item acceptability | Instructions, procedures, drawings, and documented results. | Commercial grade item technical evaluation and acceptance plan, and the results of CGD acceptance methods used. |

# Supplier Providing a Q Item…

- Q items are designed and manufactured under an NQA-1 Quality Program that addresses:
  - Design control, verification, and maintenance (drawings and documents); application suitability; performance specifications; seismic/environmental qualification
  - Specification, acceptance, control and storage, handling of purchased materials and subcomponents
  - In-process manufacturing special processes, fit-up and assembly, in-process testing and final acceptance
- In addition to the above, the Supplier (e.g. the employees) have extensive experience with and understanding of the design, procurement practices, manufacturing processes, and testing/acceptance methods, together with feedback from customers and experience with how product lines are used throughout the industrial marketplace they serve

# EPC Purchaser (or Agent) Acting as a Dedicating Entity…

- Structures, systems and components (SSC) are properly classified during facility design
- SSC specified in the design are suitable for applications in all operating conditions
- Commercial Grade Dedication process conforming to NQA-1 and industry guideline requirements is implemented through approved procedures under an NQA-1 QA Program

# EPC Purchaser Acting as a Dedicating Entity…

- Facility design information is current and readily available to procurement organizations*
- Elements of Technical Evaluation are often not necessary in performing CGD, i.e. Classification, Like-for-Like evaluation, Equivalency Evaluation, Failure Modes & Effects Analysis (FMEA)
- For many items, design detail is sufficient to directly serve as basis for selection of Critical Characteristics*

***Not typical in utility industry application of CGD, particularly for replacement items.**

# What's the point of all this?

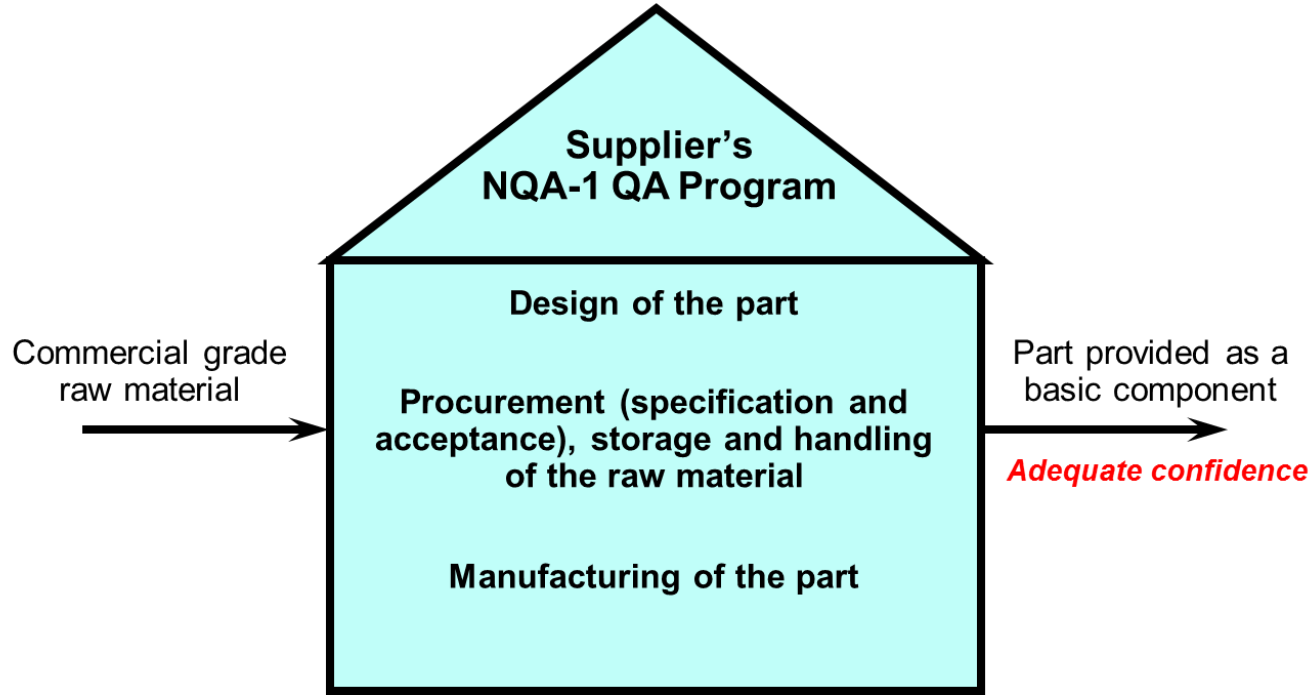
- Suppliers with NQA-1 (or 10CFR50 App. B) QA Programs have always had the ability to procure commercial grade materials under those programs for incorporation into Q items (or Basic Components in a utility environment).
- Those other than Suppliers, needing to use commercial items in Q applications (such as EPC contractors and nuclear utilities), were required to use Commercial Grade as the alternative method, as permitted by NQA-1 and 10CFR Parts 50 and 21.
- As so much interest and energy was focused on CGD as "the way commercial material could be used as Q or Safety items", the industry (meaning Purchaser's, some Regulatory staff, and sometimes even Suppliers) have attempted to push CGD down into the supplier world as something they had to do in procuring production materials. Those suppliers new to the nuclear marketplace usually tried to comply and those experienced in the ways of the world pushed back.

# What's the point of all this….

- The degree to which Supplier's might need to utilize CGD and situations where it was appropriate for them to do so in providing replacement items has been a significant issue in the nuclear industry in general and in utility industry user groups in recent years.
- EPRI, working together with the USNRC and utility Procurement Engineering and Supplier Qualification employees, has included information and guidance regarding Supplier quality programs and procurement practices in an appendix (F) to EPRI NP-5652 Revision 1.
- These questions and issues were also a topic for the DOE/BNI "CGD Working Group" that was organized late in 2015. Thus it was seen as beneficial to include a presentation and discussion of Appendix F to EPRI NP-5652-R1 in this training.

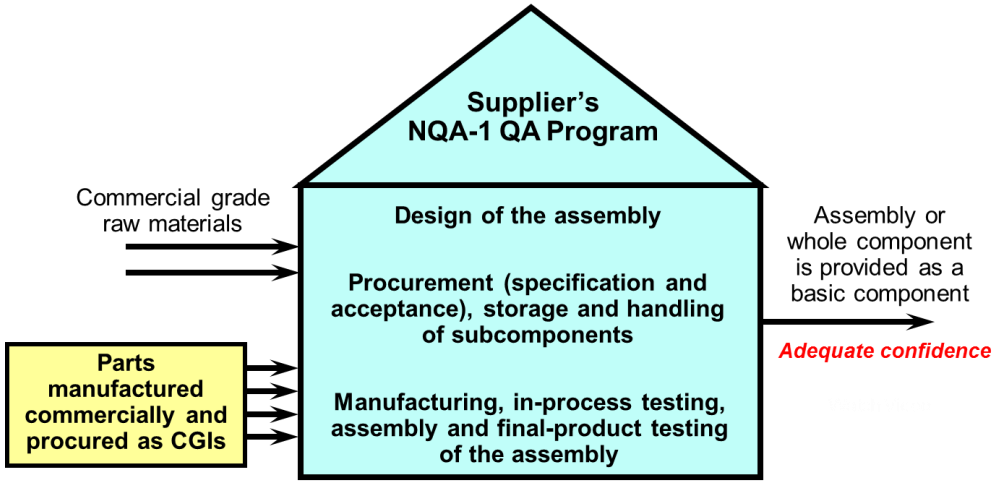
# Controlling a Part under a Nuclear QA Program

- Supplier controls design under its NQA-1 Program.
- Raw material is specified and procured from a commercial supplier.
- Specification, acceptance, storage, issuance, manufacturing and final acceptance is all done under the Supplier's QA Program.
- Thus, the item becomes a Q item based on the Suppliers controlling it under its QA Program.



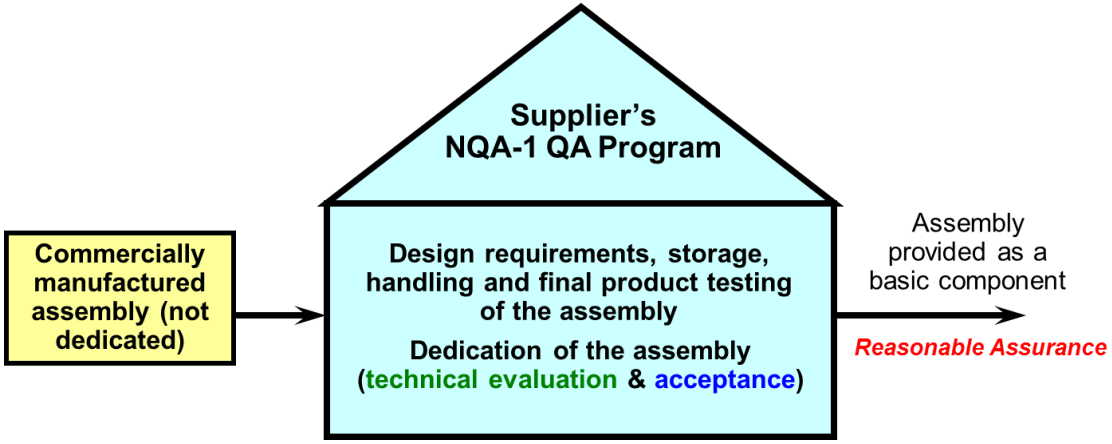
# Controlling an Assembly/Whole Component

- Supplier controls design under its NQA-1 Program.
- Commercial raw material and commercially manufactured parts are purchased, with Supplier design requirements translated into technical procurement requirements to the subsupplier(s).
- Supplier's acceptance process for commercial materials and items must comply with NQA-1 Requirement 7, Sections 200 through 600.
- Specification, acceptance, storage, issuance, manufacturing and final acceptance is all done under the Supplier's QA Program.
- Thus, the item becomes a Q item based on the Suppliers controlling it under its QA Program.



# Commercial Assembly Dedicated by a Supplier

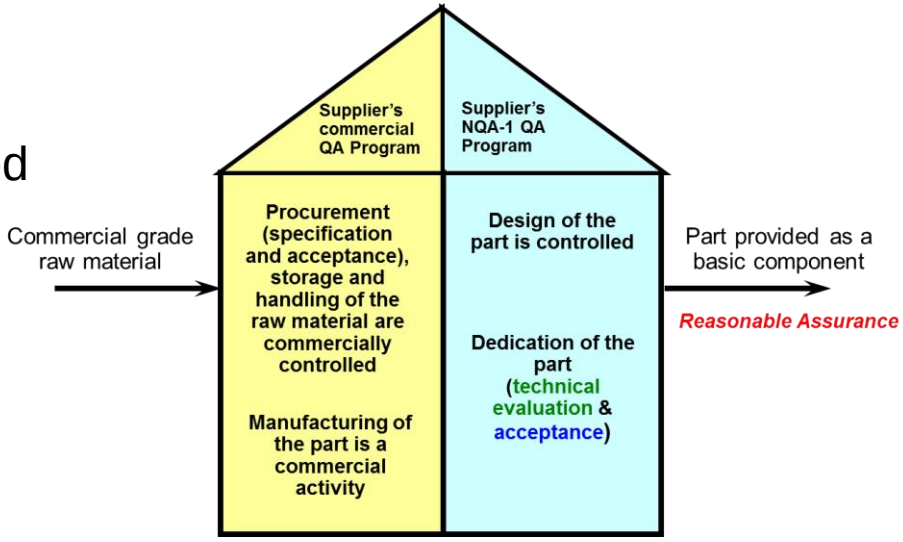
- Supplier is purchasing a commercial assembly from a commercial manufacturer, for sale as a Q item to a customer – The Supplier will use an approved CGD procedure to accomplish a Dedication.
- Supplier design requirements are translated into technical procurement requirements to the subtier manufacturer.
- Supplier controls the design basis requirements for the assembly as used in its whole component, and evaluates any design changes made by the subtier manufacturer.
- The Critical Characteristics used by the Supplier may be obtained as follows:
  - Derived by the Supplier if end-use is known or provided by the Purchaser
  - Derived by the Supplier based on the assemblies function in the host equipment
  - Provided by the Purchaser



# Commercial Part Dedicated by the Manufacturer

A supplier, who is the manufacturer of the item, uses its approved CGD procedure to provide a commercial part as a Q item to a customer.

- The OEM Supplier controls the design of a part under its NQA-1 Program
- Raw material is specified and procured from a commercial subsupplier, and used to manufacture the item under the OEM's commercial quality program
- The Critical Characteristics of the part might be derived as follows:
  - Enveloped by verifying all applicable design characteristics of the part
  - Derived by the Supplier (if end-use if know or provided by the Purchaser)
  - Provided by the Purchaser
- NOTE: Only Method 1 would be appropriate for the scenario described



# Third Party Organizations (TPO)

- These are any company other than the Original Equipment Manufacturer (OEM) that purchases commercial items and supplies them as Q items under an approved NQA-1 QA Program. TPOs are often referred to as “Third Party Dedicators,” although their capability often goes well beyond just performing CGD for customers.
- TPOs play a significant role in supplying procurement and CGD services to the nuclear industry, providing a source of Q items for use as replacement items or new construction/modifications that is:
  - Not otherwise available in the marketplace as a Q item, and
  - Where original OEM design basis information is not available, and establishing a basis for CGD or other procurement actions requires special analysis and expertise
- TPOs can provide a wide range of services including design control, equivalency evaluation, equipment qualification, procurement, manufacturing, and repair/refurbishment, as well as CGD.

# Third Party Organizations (TPO)

- TPOs may have special relationships with OEMs that are no longer active in the nuclear marketplace, giving them access to design information not otherwise available.
- Most TPOs typically have amassed design and manufacturing information that can be used, together with Customer application information, to apply CGD as a means of providing Q items to customers.  Most also have special capabilities in defining and accomplishing equipment qualification testing.
- Information, together with experienced and capable employees, allows TPOs to fill a unique niche for customers in the re-engineering of replacement components and the custom manufacturing of replacement components.  This is particularly valuable in limiting the cost of design changes forced by equipment obsolescence.

# Other Considerations – Supplier QA Programs

- Suppliers and manufacturers with NQA-1 Programs can benefit from the efficiency of a clear and well implemented process for design control, and specification, evaluation and acceptance of commercial items to be used in Q components.
- While the Supplier's procedures may not exactly duplicate the steps and actions of a Purchaser's CGD process, the key is compliance with the requirements and intent of NQA-1 Requirement 7 and any other procurement requirements imposed by Customers.
- Customers have a primary responsibility in performing Supplier Qualification Audits to be attentive to those elements in a Supplier's QA Program that are directly tied to design, procurement and material control actions.

# Supplier CGD Procedure?

Suppliers might elect to implement a CGD procedure in order to:

- Provide customers with Q items or material that are procured directly from subtier suppliers as commercial items and not otherwise processed through the Supplier's NQA-1 QA Program – This is a significant motivator for a supplier to implement a CGD procedure for selective use.
- Comply with requirements in the Supplier's QA Program requiring use of CGD as an acceptance process for selected commercial items.
- Meet Customer requirements imposed via Purchase Order for application of CGD for selected or all commercial items.

# Potential Issues with Supplier QA Programs

- New or infrequently used QA Programs.
- Poor understanding of how and at what point commercial grade items can become Q items, whether through Dedication or processing through an NQA-1 Program.
- QA Programs with weak processes for Design Control (NQA-1 Requirement 3) or Control of Purchased Items (NQA-1 Requirement 7) need to be identified during the Supplier Qualification Audit process – discovering problems after delivery and install of hardware is too late.
- Where CGD procedures exist, poorly documented CGD Plans and over-emphasis on item identification characteristics as a basis for acceptance vs. chemical or physical tests.

# The Old and New Ways of Procurement

- Suppliers can apply their customer-approved NQA-1 QA Programs to procure materials and items and provide Q items to the nuclear marketplace based on:
  - Effective implementation of QA procedures
  - Knowledge of design information and the control and definition of design and technical requirements
  - Controls over procurement, handling of items, manufacturing processes, assembly and in-process and final acceptance testing
  - Feedback from its nuclear and non-nuclear customer base and experience with long-time suppliers of items and materials
- Commercial Grade Dedication can be used by Suppliers as an alternative means of supplying commercial items as Q items to Customers, particularly where items are not subject to any processes or conditioning by the Supplier (other than CGD).
- Care should be taken not to cause a qualified NQA-1 Supplier to unnecessarily Dedicate an item when they are already adequately controlling the item under their QA Program.