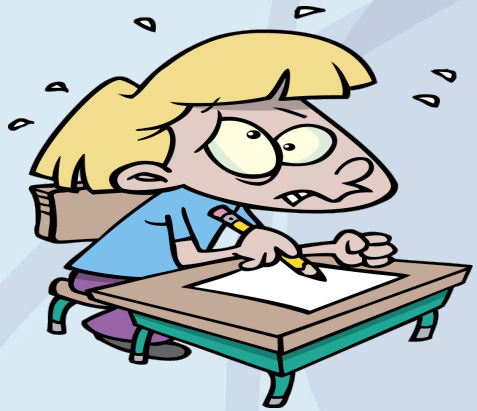
Commercial-Grade Dedication

Inspector Training

U.S.NRC
United States Nuclear Regulatory Commission
Protecting People and the Environment

Pop Quiz, Hotshot!

- What is commercial grade dedication?
- What is a commercial grade item?
- What are critical characteristics?
- Where are these definitions found?
- What are acceptable methods of dedication?



Engineering Inspection Guidelines

- Maintain risk-informed focus.
- Identify deficient conditions that would not normally be readily identifiable through routine plant activities or performance indicators (e.g., monitoring during normal operation or surveillance tests).
- Allow inspections that are focused on recent plant changes and operating experience.
- Maintain the NRC's role as an independent regulator.

Why inspect CGD Next?

- CGD of safety/risk significant components is important.
- More CGD conducted by licensees recently
  - Less 10 CFR Part 50 App B vendors
- Chance to review licensee procurement
- NRC haven’t recently inspected these areas at licensees

Objectives

- Understand the regulatory requirements and guidance regarding CGD
- Understand some CGD methods licensees/vendors may use
- Understand CGD inspection requirements, guidance and implementation
- Discuss CGD inspection planning, logistics, implementation guidance and support during inspections
- Review EQ and POV inspection lessons learned

Agenda

- Definitions
- Regulatory Requirements
- Commercial-Grade Item Dedication (CGD) Process
  - Examples
- CFSI
- Inspection Preparation and Key Points
- Inspection Procedure
- Inspection Implementation Support

Definition

**All definitions found in 10 CFR Part 21

Commercial-grade dedication is a **process** by which a commercial-grade item (CGI) is designated for use as a basic component. **This acceptance process** is undertaken to provide **reasonable assurance** that a CGI to be used as a basic component will perform its intended safety function and, in this respect, is deemed equivalent to an item designed and manufactured under a 10 CFR Part 50, Appendix B, quality assurance (QA) program.

Definition

A **basic component** is a structure, system, or component, or part thereof that affects its safety function necessary to assure:

- The integrity of the reactor coolant pressure boundary;
- The capability to shut down the reactor and maintain it in a safe shutdown condition; or
- The capability to prevent or mitigate the consequences of accidents which could result in potential offsite exposures comparable to those referred to in § 50.34(a)(1), § 50.67(b)(2), or § 100.11 of this chapter, as applicable.

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

Definition

Commercial grade item (CGI) is a structure, system, or component, or part thereof that affects its safety function, that was not designed and manufactured as a basic component. Commercial grade items do not include items where the design and manufacturing process require in-process inspections and verifications to ensure that defects or failures to comply are identified and corrected (i.e., one or more critical characteristics of the item cannot be verified).

Definition

Critical characteristics are those important design, material, and performance characteristics of a commercial grade item that, once verified, will provide reasonable assurance that the item will perform its intended safety function

Definition

A **dedicating entity** is the organization that performs the dedication process. Dedication may be performed by the manufacturer of the item, a third-party dedicating entity, or the licensee itself.

Regulatory Requirements

Three principal QA criteria that are significant to the CGD process:

- **Criterion III, "Design Control"**
- Criterion IV, "Procurement Document Control"
- **Criterion VII, "Control of Purchased Material, Equipment and Services"**

You may find issues under other 10 CFR Part 50 Appendix B criteria as well.

10 CFR 50 Appendix B

Criterion III, “Design Control”

- Measures shall also be established for the **selection and review for suitability of application of materials, parts, equipment, and processes that are essential to the safety-related functions** of the structures, systems and components.

10 CFR 50 Appendix B

Criterion IV, “Procurement Document Control”

- Measures shall be established to assure that **applicable regulatory requirements, design bases, and other requirements** which are necessary to assure adequate quality are suitably included or referenced in the documents for procurement of material, equipment, and services, **whether purchased by the applicant or by its contractors or subcontractors**. Procurement documents shall require contractors or subcontractors to provide a **quality assurance program**

10 CFR 50 Appendix B

Criterion VII, “Control of Purchased Material, Equipment and Services”

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

CGD Process

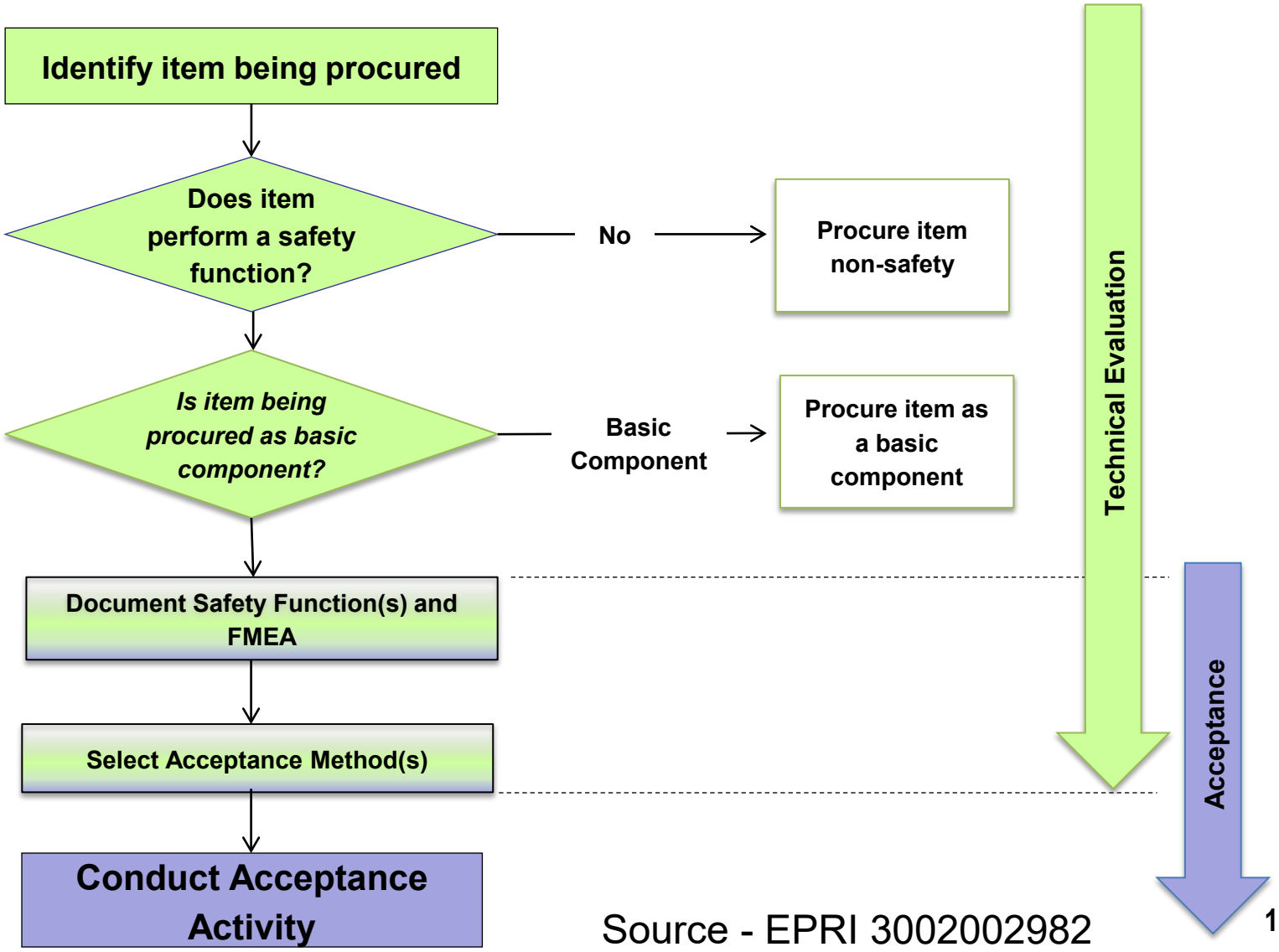
- Necessary Elements
  - **Engineering Involvement**
    - Specialized knowledge
  - **Documentation**
    - Technical Evaluation
      - Failure Modes and Effects Analysis (FMEA)(optional)
    - Clear identification of CC's
  - **Acceptance Criteria, and methods**
  - **Established Process**
    - Controlled under a 10CFR Part 50 Appendix B program
    - Formalized approach, repeatable, reliable
    - Governed by policies, procedures, instructions
    - Auditable and scrutable via objective evidence

CGD Process Guidance

– General

- RG 1.164, “Dedication of Commercial-grade Items for Use in Nuclear Power Plants”
- EPRI NP-5652, Revision 1, “Guideline for the Utilization of CGI in Nuclear Safety Related Applications”
- GL 89-02, “Actions to Improve the Detection of Counterfeit and Fraudulently Marketed Products”
  – Conditionally endorsed EPRI NP-5652
- GL 91-05, “Licensee Commercial-Grade Procurement and Dedication Programs”
  – Identified weaknesses in licensee dedication programs found during inspections

Dedication Flow Chart



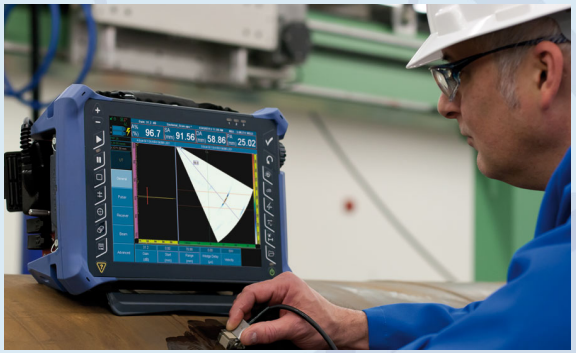
Source - EPRI 3002002982

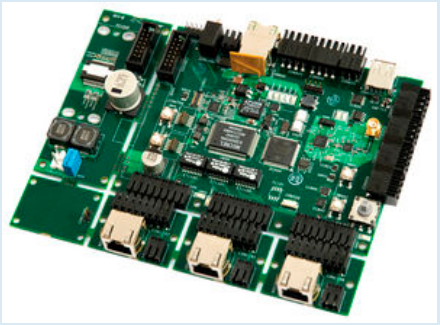
CGD Process (cont'd)

- What are the main steps in the CGD process?
- Technical Evaluation – Pre-requisite to performing CGD
  - Identifies technical (physical, performance) and quality requirements (dependability)
- Develop technical evaluation from:
  - Licensee documents
  - Vendor design documents
  - FMEA
  - Engineering judgment

CGD Process (cont'd)

- What is the purpose of the technical evaluation?
  - Determine safety function:
  - Special considerations:
    - EQ & Environmental Factors (EMI/RFI)
    - Seismic qualification
  - Identify critical characteristics
  - Determine acceptance criteria
  - Determine acceptance methods





CGD Process (cont'd)

- What is the product of the technical evaluation?
  - Identification of critical characteristics, acceptance criteria, and acceptance methods
    - safety function(s) and classification (active and passive)
    - material specification (form)
    - configuration (fit)
    - response time, communication (function)
    - operation (function)

CGD Process (cont'd)

- Critical Characteristics are defined in 10 CFR 21.3:
  - 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.
- Number and nature of critical characteristics are based on safety function, application requirements, FMEA, and performance requirements.

CGD Process (cont'd)

- Example of acceptance criteria

Critical Characteristic	Value	Verification Method
Materials	Design & Manufacturing Specs	Test (Allow Analyzer, Chemical, Hardness)
Configuration	Design & Manufacturing Specs	Visual, Weight
Size/Dimensions	Manufacturing Specs	Measurement
Pressure & Temperature Rating	Design, System & Manufacturing Specs	Test (Hydro, PMT)
Seat Leakage & Operation	Function	Test Operation

CGD Process (cont'd)

How are critical characteristic verified?

- The acceptance methods include:
  - Method 1: Special tests and inspections
  - Method 2: Commercial-grade survey*
  - Method 3: Source verification
  - Method 4: Acceptable supplier/item performance record*

❖***Per GL 89-02 these Methods need to be used in conjunction with another Method**

CGD Process (cont'd)

Method 1

- Inspections *
  - Receipt
  - Installation
  - Post Installation
  - Documents Review
- Test*
  - Pre-Installation
    - Bench
    - Aging
    - Destructive
    - Non-Destructive
  - Post Installation
    - Post Maintenance Test
    - Surveillance/Test Procedure

*Critical Characteristics (CCs)

CGD Process (cont'd)

Method 1

- Sampling may be acceptable provided:
  - Documented technical basis
    - Considers lot traceability, homogeneity and complexity of the item
  - If items are to be accepted by a Certificate of Conformance or Certified Material Test Report, the validity of the document should be verified by the dedicating entity (Method 2)

CGD Process (cont'd)

Method 2

- Dedicating entity verified commercial supplier's **documented** quality controls.
- Typical areas of consideration include:
  - Procurement
  - Material Control
  - SW Quality Control
  - Fabrication
  - Assembly
  - Calibration
  - Test
  - Inspection

❖ **Verified quality controls should be invoked as requirements in the purchase order (PO) issued to the suppliers. Verify compliance of PO requirements with certificate of conformance provided by the supplier.**

CGD Process (cont'd)

Method 3

- Dedicating entities may use source verification
- Source verification is direct observation of a CC.
  - The CCs may be verified by witnessing:
    - Coding process
    - Fabrication process
    - Assembly process
    - Nondestructive examination test
    - Performance test

CGD Process (cont'd)

Method 4

- Acceptance of one or more CCs based upon confidence in the supplied item's performance
  - Item performance could be based on historical verification, acceptable quality control of CCs (as confirmed periodically by survey) or other acceptance methods
  - Not an acceptable method when used by itself (GL 89-02)

Example
CGD Instrument Valve

• 1-in. instrument valve
• Safety function: pressure retention and maintain structural integrity during and after design basis events.
• Supplier information: The supplier is a manufacturer of rugged, reliable, high-quality commercial instrument valves machined from stainless steel.

- Approach: a component-level replacement item.
- The dedicating entity is a licensee who operates commercial nuclear units. The valve will be dedicated using special tests and inspections (Method 1). The preparer completed Section B to identify the end-use applications because the dedication is based on the safety functions of the specific equipment.

Example from EPRI NP-5652, Revision 1

Example

CGD Instrument Valve

- Technical Evaluation
- Failure Modes and Effects Analysis

CREDIBLE FAILURE MODE/MECHANISM	EFFECTS ON SYSTEM/COMPONENT FUNCTION
Fracture	Fracture of valve pressure boundary parts will lead to loss of the system pressure boundary and structural integrity. Loss of the pressure boundary can lead to failure of the associated component to perform its safety function
Corrosion	Corrosion of valve pressure boundary parts will lead to fracture or rupture and loss of the system pressure boundary and structural integrity. The primary pressure retaining components of the this particular valve are 316 stainless steel, which is known to not promote corrosion
Wear	Wear of the valve internals can lead to excessive leakage of the valve and result in the valve no longer being capable of isolating flow and controlling flow rate
Binding	Corrosion or ill-fitting parts can cause binding and result in the inability to open and close the valve. This can result in fracture as mentioned above
BASIS FOR SELECTION OF CREDIBLE FAILURE MODE(S)/MECHANISM(S)	
Failure modes of the valves would be stripping of the end connections, splitting of the pressure boundary material, and excessive leakage. Fracturing can result from excess stress due to binding or improper material. Corrosion will be caused by incompatible mating material or localized environmental conditions causing galvanic corrosion resulting in material destruction.	

Example from EPRI NP-5652, Revision 1

Example

CGD Instrument Valve

- Method 1 Special Tests and Inspection

Critical C's	Method	Description of Activity	Acceptance Criteria
Pressure integrity	Test	Pressure test	Visual monitor pressure, observed leakage
Disc integrity	Test	Leak test	Measure leakage
End Connection	Inspection	Visual inspection	Measurement of threads
Valve Dimensions	Inspection	measurement	Tolerances to design drawings

Example from EPRI NP-5652, Revision 1

CGD Process Guidance

(Digital I&C and Computer Programs)

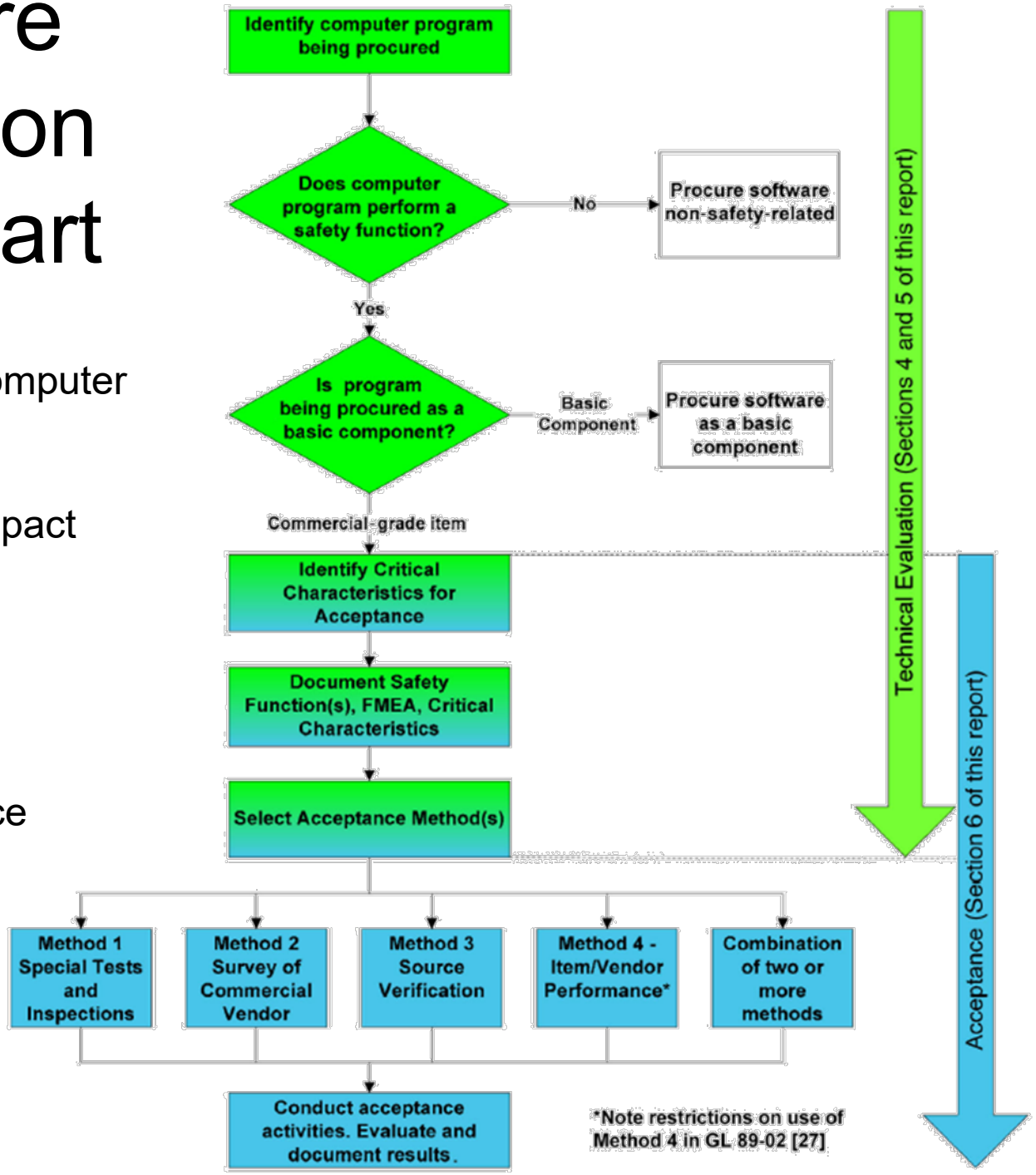
– Digital I&C Specific

- EPRI-TR-106439, "Guideline On Evaluation And Acceptance Of Commercial Grade Digital Equipment For Nuclear Safety Applications" (ML103360462)
- EPRI Technical Report 1025243, "Plant Engineering: Guideline for the Acceptance of Commercial-Grade Design and Analysis Computer Programs Used in Nuclear Safety-Related Applications," Revision 1, dated December 2013 (ML14085A084)
- REGULATORY GUIDE 1.231, "Acceptance Of Commercial-grade Design And Analysis Computer Programs Used In Safety-related Applications For Nuclear Power Plants," Revision 0, dated January 2017 (ML16126A183)
- IP 43004, "INSPECTION OF COMMERCIAL-GRADE DEDICATION PROGRAMS," dated 1/27/17 (ML16344A092)
- IP 35710, "QUALITY ASSURANCE INSPECTION OF SOFTWARE USED IN NUCLEAR APPLICATIONS," Effective Date: 01/30/2018 (ML17278A510)

Software Dedication Flow Chart

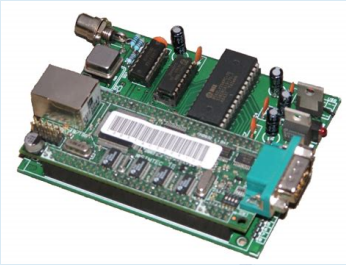
- Dedication based upon computer program's
  - Safety Functions(s)
  - Failures that could impact Safety Function(s)
- Identification of Critical Characteristics
- Identification of Acceptance Methods
- Acceptance Activities

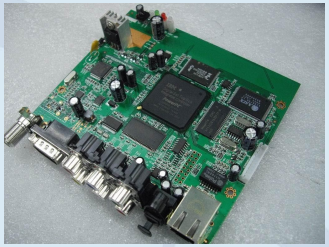
Source - EPRI 3002002289



Example

CGD DI&C Component (CIM Module)





Component Interface Module (CIM)– used to control plant components based on evaluation of various plant parametric inputs from a variety of safety and non-safety sources

- Is manufactured by a commercial supplier with a documented quality assurance program (surveyed by purchaser)
- Manufacturing is performed from build to print specifications supplied by purchaser
- Component is a sub-component of larger a safety-related system
- System software designed and installed by purchaser using FPGA Technology

Example
CGD DI&C Component (CIM Module)

– **Typical SW Failure modes**

- Functionality – software does not behave like requirements
- Timing – events happen too late or too early
- Sequence – event happen out of order
- Faulty data – data corrupt
- Faulty data tracking – error detection not working
- Web based – HTML or other coding issues
- Database related – storing or retrieving data
- Security – security issues
- Faulty I/O – incorrect or incomplete
- Faulty logic - incorrect
- Incorrect algorithm – formula implemented incorrectly or arithmetic error
- User instructions – poor instructions

Example

What are the CIM's Hardware Critical Characteristics?

Critical Characteristics	Measurable Attributes	Description of Critical Characteristics	Acceptance Criteria
Materials	Material	Housing material (chemical & mechanical properties) Board materials (lead or non-lead solder) Coated or non-coated	HDWR Design Specs HDWR Design Requirements Mfr. Specs
Configuration	Physical	Type/style selected on basis of function, PIN and socket types and placement	HDWR Design Specs HDWR Design Requirements Mfr. Specs
Size/Dimensions	Dimensions	Dimensions, tolerances between sub-components, circuit boards, PIN and socket dimensions	HDWR Design Specs HDWR Design Requirements Mfr. Specs
Current/voltage	Function	Selected based on specified end use (e.g., integration into system and equipment to be controlled)	HDWR Design Specs HDWR Design Requirements Mfr. Specs

Example

What are the CIM's Software Critical Characteristics?

Critical Characteristics	Measurable Attributes	Description of Critical Characteristics	Acceptance Criteria
Accuracy/Precision/ Tolerance	Input/Output Data values	Data values calculated in program modules correct based on known inputs	SW Design Specs SW Design Requirements Mfr. Specs
Functions and algorithms correct and complete	Input/Output Data values	Functions and algorithms produce expected results based on known problem results	SW Design Specs SW Design Requirements
Logic correct	System response	Logic is verified through testing to confirm end-state results are consistent with software design and functional requirements	SW Design Specs SW Design Requirements
Error Tolerance	System response Self check diagnostics	System error tolerance is verified through testing over range of potential values System diagnostic routines respond correctly to system conditions	SW Design Specs SW Design Requirements Mfr. Specs
Timing /Sequence	System response	Completion of functions within required cycle times are evaluated. System response consistent with design and functional requirements	SW Design Specs SW Design Requirements

Additional References

- RG 1.28 ANSI NQA-1-2015 Quality Assurance Program
- RG 1.152 IEEE Std 7-4.3.2-2003 Criteria for use of Computers
- RG 1.168 IEEE Std 1012-1998 Software Verification and Validation
- RG 1.169 IEEE Std 828-1900 and 1042-1987 Configuration Management Plans for Digital Computer Software
- RG 1.170 IEEE Std 829-1983 Software Test Documentation for Digital Computer Software
- RG 1.171 IEEE Std 1008-1987 Software Unit Testing for Digital Computer Software
- RG 1.172 IEEE Std 830-1993 Software Requirements Specifications for Digital Computer Software
- RG 1.173 IEEE Std 1074-1995 Development of Software Life Cycle Processes for Digital Computer Software
- RG 1.231 Acceptance of Commercial-grade Design and Analysis Computer Programs Used in Safety Related Applications for Nuclear Power Plants

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CFSI – Counterfeit, Fraudulent and Suspect Items

Why is CFSI important?

- Public Perception:
- CBS Boston ***"I-Team: Report Shows Counterfeit, Untested Parts In Nuclear Power Plants"[video]*** March 8, 2022, YouTube.com

https://www.youtube.com/watch?v=5m9IBtSqI6Q

Inspector General Interest:

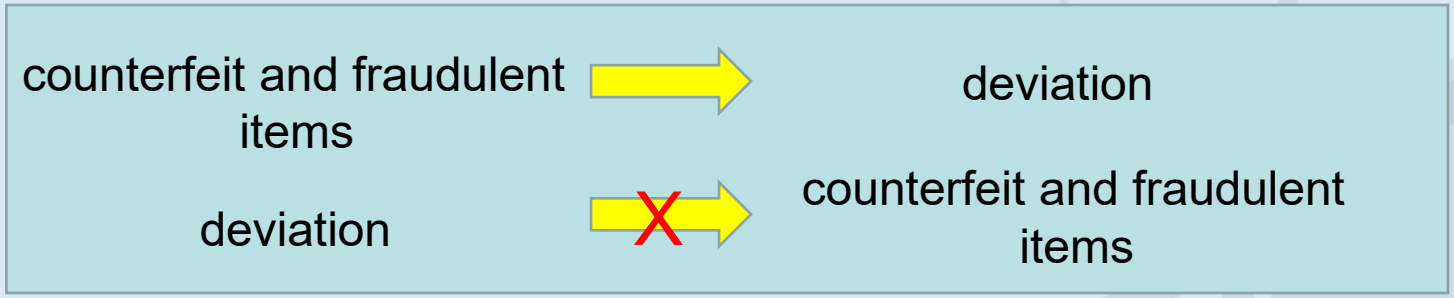
NRC OIG Releases Two Reports on Findings Regarding Counterfeit, Fraudulent, and Suspect Items in U.S. Nuclear Power Plants | Nuclear Regulatory Commission Defense Nuclear Facilities Safety Board OIG (oversight.gov)

Definition

CFSI are items that are intentionally manufactured or altered to imitate a legitimate product without the legal right to do so **(counterfeit)**; intentionally misrepresented with the intent to deceive **(fraudulent)**; or reasonably suspected of being counterfeit or Fraudulent **(suspect)**.

CFSI and Deviations

- RG 1.234, “Evaluating Deviations and Reporting Defects and Noncompliance Under 10 CFR Part 21,” Revision 0, endorses NEI 14-09, “Guidelines for Implementation of 10 CFR Part 21 Reporting of Defects and Noncompliance” Revision 1, with conditions.
- Section 2.7 of NEI 14-09, Revision 1 clarified that counterfeit and fraudulent items are considered to be “deviations” that must be evaluated in accordance with the requirements of 10 CFR Part 21.



- Not all deviations or nonconformances may be caused by counterfeit, fraudulent, or suspect items.
- Design deficiencies, poor testing strategies, and substandard parts are quality issues but do not involve CFSIs.

DELIBERATE MISCONDUCT

Deliberate misconduct by a person means an intentional act or omission that the person knows:

(1) Would cause a licensee or applicant to be in violation of any rule, regulation, or order; or any term, condition, or limitation, of any license issued by the Commission; or

(2) Constitutes a violation of a requirement, procedure, instruction, contract, purchase order, or policy of a licensee, applicant, contractor, or subcontractor.

- 10 CFR 50.5 (c)

Falsified and fraudulent information provided by an Appendix B supplier to the licensee are within the scope of deliberate misconduct.

COMPLETENESS AND ACCURACY OF INFORMATION

(a) Information provided to the Commission by an applicant for a license or by a licensee or information required by statute or by the Commission's regulations, orders, or license conditions to be maintained by the applicant or the licensee shall be complete and accurate in all material respects.

(b) Each applicant or licensee shall notify the Commission of information identified by the applicant or licensee as having for the regulated activity a significant implication for public health and safety or common defense and security.

- 10CFR 50.9

What is your role as an inspector?

- As part of the inspection using IP 71111.21N.03, review the licensee's procurement documentation to verify whether the licensee has included measures to prevent, identify, and segregate potential CFSI parts for further evaluation.
- Consider sampling condition reports to determine whether the issue involved significant conditions adverse to quality and there is reason to suspect involvement of CFSI.
- In the above case, verify that the licensee performed an adequate root cause analysis to determine whether the event involved CFSI.

What is your role as an inspector? Part Deux

- Consider sampling Part 21 evaluations to identify whether there were potential CFSI that met the criteria of a defect and confirm that the licensee have reported the defect in accordance with 10 Part 21 reporting requirements.
- If the CFSI event does not rise to the criteria of being reportable, consider forwarding the condition report/Part 21 evaluation to the OpE Clearinghouse for the CFSI technical review group to evaluate.
- If you see evidence through your normal inspection that it is likely Counterfeit or Fraudulent---- Use the Allegations Process!!

Inspection Key Points

- We are looking at how licensees handle CGD through performance-based inspection:
  - Select risk-informed samples
  - How were critical characteristics determined and verified?
    - Understand the licensee's process
      - How they performed CGD OR
      - How they verified CGI through procurement
    - Understand the licensee engineering change

Inspection Key Points

- Clear delineation between licensee responsibilities and vendors.
  - We're not inspecting vendors.
    - If you have feedback during the inspection on potential vendor issues, contact IQVB/DRO/NRR. IQVB tracks potential vendor issues and use this information to help prioritize vendor inspections.

Inspection Preparation

- Review plant-specific information for CGIs.
- Review and understand site licensing basis regarding CGIs (if applicable).
- Review licensees CGD training material.
- Discuss planned inspection and technical assistance with QA/vendor staff at headquarters, and resident inspectors for past and current issues.
- Discuss planned inspection with licensee CGD/procurement engineers and necessary information.
- Review OpE for potential issues that may affect CGI at the site you are inspecting.

Inspection Team

- 3 NRC inspectors
  - 2-week onsite inspection with an in-between week.
- Inspection team make-up
  - Primarily engineering inspectors
    - Resident and other ROP inspectors can be considered
    - Inspection samples may call for regional cross-branch expertise. (i.e. electrical inspector)

Are You and Your Team Ready to Inspect?

- Have you received the required training? (this!)
- Do you have enough knowledge and information to select samples and plan the inspection?(applicable OpE, and known issues/weaknesses with CGD)
- If the answer to the above questions is “No,” stop and contact your supervisor for guidance.

CGD Inspection Procedure

IP 71111.21N.03 Objectives

- To review the implementation of the licensee's process for dedicating commercial-grade items (CGIs), as required in applicable portions of Appendix B to Title 10 of the Code of Federal Regulations (10 CFR) Part 50 (Appendix B) to ensure reasonable assurance is provided that CGIs will perform their intended safety function.

- To review implementation of the licensee's procurement process for safety-related components as required in Appendix B or 10 CFR 50.69.

Content

- IP 71111 Attachment 21.N.03 specifies CGD inspection requirements.
- Appendix A provides background on dedication issues that should be considered for selection and verification of critical characteristics.
- Appendix B provides guidance on licensee documentation that may be part of the dedication process.
- Appendix C contains useful definitions.

General Guidance

- Commercial-grade dedication is a process by which a (CGI) is designated for use as a basic component. This acceptance process is undertaken to provide reasonable assurance that a CGI to be used as a basic component will perform its intended safety function and, in this respect, is deemed equivalent to an item designed and manufactured under an Appendix B quality assurance program. This assurance is achieved by identifying the critical characteristics of the item and verifying their acceptability by inspections, tests, or analyses by the purchaser or third-party dedicating entity.

02.01 Sample Selection

- Inspectors should select approximately 9-15 samples from the list of CGIs or procured safety-related components at the site for detailed review and assessment. The samples may be CGIs dedicated by the licensee, a CGI dedicated by vendor (or other licensee) and procured by the licensee, or a CGI that failed after completing the dedication process, or reviewing the procurement of a safety-related component.

- Consider consulting with SMEs from the vendor inspection branch in DRO/NRR, the site resident inspectors, and the NRR licensing project manager for any operating experience regarding CGD issues that may affect their inspection samples. Inspectors should also consider consult with the Regional Senior Reactor Analysts (SRA)s and use risk insights to identify CGIs with increased risk significance for more detailed inspection.

02.01 Sample Selection (continued)

- Review licensee provided information on dedicated components in their facility. Specific design-basis capability information for those CGIs to be reviewed may include their function, safety significance, procurement information, dedication package, and any other information used to provide assurance the component was adequately dedicated.
- The request for information from the licensee should occur at least 3 months ahead of the inspection preparation week. See Appendix B to this inspection procedure for guidance on appropriate information to request from the licensee.

- **To the extent possible, inspectors should walkdown components to ensure they were installed in environments/conditions for which they were dedicated and observe that the correct critical characteristics/acceptance were criteria identified by the licensee for each component's application**.

02.02 Site Visit

- If necessary, the team leader (TL) may make a site visit/information gathering trip to the nuclear power plant to be inspected. Purposes of the site visit are to:
  - discuss with the licensee the scope of the planned inspection;
  - obtain advance information (e.g., a list of items that the licensee purchased as CGI and subsequently dedicated, licensee's program and procedures and recent component failures) to review in preparation for the inspection;
  - ensure that the information to be reviewed is available at the beginning of the inspection; and
  - verify that logistical issues (such as obtaining both site and computer system access and arranging the location of the inspection team working area) will be resolved prior to inspector arrival.

02.02 Site Visit (continued)

- It is recommended that the TL perform this trip at least one month prior to the onsite portions of the inspection. The TL shall make arrangements to transfer inspection-related information to other NRC staff assigned to the inspection.

- Some licensees have consolidated their CGD program and/or procurement process under a corporate organization or location, if this is the case, the TL should consider conducting a visit/information gathering trip to that organization or location.
  - This may be the preferred method for any licensee that has a shared corporate CGD program. Some licensees only use a shared CGD laboratory for all of their dedication activities.
  - There may be inspection preparation efficiencies gained. Shared documents and insights from other inspectors could make for shorter preparation time.

03.03 Inspection Requirements

- **Verify the established controls for performing technical evaluations of items or services to be dedicated. Verify materials, parts, equipment, and processes for suitability of application regarding each CGI as established in Criterion III of Appendix B.**
- **Verify that the licensee has established adequate controls for the acceptance of each CGI using the criteria established in Criterion IV and VII of Appendix B.**
- **Verify that the licensee had properly developed and implemented a plan for each CGI.**
- **Verify that there were adequate controls for the acceptance of CGI procured that were dedicated by a supplier or sub-supplier.**
- **Evaluate and assess any failed dedicated CGI.**
- **Verify adequate controls for procurement of Appendix B components.**

Inspection Guidance

Verify the established controls for performing technical evaluations of items or services to be dedicated. Verify materials, parts, equipment, and processes for suitability of application regarding each CGI as established in Criterion III of Appendix B.

1. Technical requirements should include:

- Determination of the item's safety function, performance requirements, component/part functional classification, and application requirements (e.g., service conditions).
- Review of the vendor's technical data, operating experience, supplier information letters, and available industry data.
- Performance of a Failure Modes and Effects Analyses (FMEA), if available.
- The identification of the item's critical characteristics. Factors may include, but not limited to:
  - The important design, material, and performance characteristics that have a direct effect on the item's ability to accomplish its intended safety function.
  - Active/passive safety-related functions, system interfaces, and system compatibility under all design basis conditions.
  - Any changes in design, material, or manufacturing process that could impact the functional characteristics of the item.
  - Appropriate interface with the vendor to identify and characterize the design and functional parameters of specific parts.
  - The number and nature of the critical characteristics are to be based on the intended safety function, application requirements, complexity, credible failure modes and effects, and performance requirements of the item.
  - Any critical characteristics that cannot be effectively verified during the dedication process should be identified in order to apply an appropriate verification method during the manufacturing process.

Inspection Guidance

Verify the established controls for performing technical evaluations of items or services to be dedicated. Verify materials, parts, equipment, and processes for suitability of application regarding each CGI as established in Criterion III of Appendix B.

2. Like-for-Like Commercial-Grade Item Replacements.

- A like-for-like replacement is a replacement of an item with one that is identical. A like-for-like replacement may be considered identical if:
  - The item is provided by the OEM (successor companies that maintain equivalent quality controls are acceptable) and has not been subject to design (form, fit, or function), materials, manufacturing, or nomenclature changes
  - The item was purchased at the same time and from the same supplier, as determined by the purchase date, shipping date, date code, or batch/lot identification.
  - Evaluation of the item confirms that no changes in the design, materials, or manufacturing process have occurred since the procurement of the original item.
- An equivalency evaluation is needed if differences from the original item are identified in the replacement item to determine if any changes in design, material, manufacturing process, safety, form, fit, function or interchangeability could impact the replacement item's ability to perform its required safety function under all design conditions (including design-basis event conditions). Equivalency evaluations should not be used as the sole basis to accept a CGI. The identified critical characteristics should still be verified for acceptance of the item.
- If the dedicating entity can demonstrate that the replacement item is identical, then the safety function, design requirements and critical characteristics need not be re-determined. However, the identified critical characteristics should still be verified.

Inspection Guidance

Verify that the licensee has established adequate controls for the acceptance of each CGI using the criteria established in Criterion IV and VII of Appendix B.

- Method 1: Special Tests and Inspections
- Method 2: Commercial-Grade Survey of Supplier.
- Method 3: Source Verification.
- Method 4: Acceptable Supplier/Item Performance Record.

Inspection Guidance

Verify that the licensee had properly developed and implemented a plan for each CGI.

- Consider if the dedication process identifies those design, material, and performance characteristics relevant to the safety function as described in Section 3.01.a of this procedure.
- 2. Consider if the dedicating entity demonstrated that the critical characteristics are met using appropriate acceptance methods described in Section 3.01.b of this procedure.

Inspection Guidance

Verify that there were adequate controls for the acceptance of CGI procured that were dedicated by a supplier or sub-supplier.

- Consider if the procurement documents have adequate controls for the dedicating entity and the proper critical characteristics and acceptance methods were used for the dedication.
- Consider if receipt inspections performed adequately check for the acceptance of the dedicated item.
- Consider if that upon receipt any restrictions to the use of the dedicated item are clearly documented so that the item is only used in an application that is prescribed in the procurement documents.

Inspection Guidance

Evaluate and assess any failed dedicated CGI.

Initial Evaluation. Weaknesses in the commercial-grade dedication program may cause a failure when the important design, material, and performance characteristics that are necessary to provide reasonable assurance that the dedicated CGI will perform its intended safety function are not addressed during dedication. (a) Consider reviewing and discussing with dedicating entity personnel, the failure/ root-cause analysis for the failed CGI. Consider looking for failures due to weaknesses in the commercial-grade dedication process.

- Consider reviewing the dedication package as described in Section 03.01 to determine if appropriate critical characteristics had been identified by the dedicating entity. Appendix A to this inspection procedure should not be interpreted as inspection requirements but only as a discussion of important dedication issues, including guidance related to these specific dedication issues.

Inspection Guidance

Evaluate and assess any failed dedicated CGI.

(Continued)

Further Assessments: From the list of dedicated items provided by the licensee, the inspector should select for review other dedication packages having similar applications.

- Consider requesting that the licensee compile a complete package of all the procurement and dedication records for each item. Consider reviewing the dedication packages as described in Appendix B of this inspection procedure.

Inspection Guidance

Verify adequate controls for procurement of Appendix B components.

1. Consider assessing implementation of design controls and design configuration controls by performing the following:

- Consider if the provisions in the design process permit the selection and review for suitability of application of materials, parts, equipment, and processes that are essential to the safety-related function of the product.
- Consider if the applicable design inputs are correctly translated into specifications, drawings, procedures, or instructions. Consider if the design translation is supported by engineering data (i.e., calculations, performance tests), including verification that design inputs are satisfied. Consider if the final design (approved design output documents and approved changes) is relatable to the design input and identifies assemblies and/or components that are part of the item being designed.
- Consider if the design changes were controlled by the supplier. Consider if the design changes are subject to design control measures commensurate with those applied to the original design. Consider if the design verification is performed by individuals or groups other than those who performed the original design, but who may be from the same organization.

Inspection Guidance

Verify adequate controls for procurement of Appendix B components.

(Continued)

2. Consider the implementation of procurement document controls:

- Consider if the procedures are established and implemented for the control and release of procurement documents and subsequent changes.
- Consider if quality requirements, including technical, administrative, regulatory, and reporting requirements are specified in procurement documents. This includes drawings, specifications, codes, standards, tests, inspections, special processes, witness and hold points, cyber security requirements (if applicable), and applicability of 10 CFR Part 21) Consider if these requirements are extended to lower tier suppliers, where necessary.
- Consider if deviations from previously established requirements, including design changes, are adequately controlled and reviewed. These deviations are documented to provide objective evidence of the review. Consider if procurement document changes are subject to the same degree of control as used in the preparation of the original documents.

Inspection Guidance

Verify adequate controls for procurement of Appendix B components.

(Continued)

3. Consider assessing the controls implemented on purchased items and services:

- Consider if procedures have been established and implemented to select and qualify vendors supplying basic components and procured services. Procured services can include calibration, non-destructive examination (NDE), testing laboratories, software codes/programs, heat treatment, third-party inspections, engineering and consulting services, installation, repair, or maintenance work.
- Consider if appropriate methods are used to accept a basic component from a supplier, such as certificates of conformance, source verifications, audits, surveillances, receiving inspections, or a combination thereof.
- Consider if storage requirements are met for the components including preventive maintenance, surveillances, shelf life, environmental conditions, and environmental qualifications.
- Consider if applicable Part 21, operating experience, and corrective action program items are used to evaluate the acceptability of basic components.

Inspection Guidance

Verify adequate controls for procurement of Appendix B components.

(Continued)

3.

- Consider if licensees conduct audits and surveys of commercial-grade suppliers. These activities should be based upon the suppliers' capability to supply the commodity desired in accordance with applicable codes/regulations.
- Consider if the effectiveness of the control of quality is assessed at intervals consistent with the importance, complexity, and quantity of the product or service (i.e., approved suppliers list).
- Consider if there are provisions in the procedures to verify the validity of certificates and determine the effectiveness of the certification system when desired, such as during the performance of audits. Consider if certificates of conformance/compliance identify the material, equipment, or service supplied; identify specific procurement requirements (codes, standards, certificates, or other specifications such as cyber security requirements) that have been met as well as those that have not been met, together with an explanation and the means for resolving the nonconformance; and identify the supplier's QA individual responsible for authenticating such certificates. If any criteria have not been met, consider if a nonconformance report was initiated and follow up on its resolution.

Inspection Guidance

Verify adequate controls for procurement of Appendix B components.

(Continued)

3.

- Consider if licensee receiving inspections examine objective evidence of purchased items by verifying attributes specified in procurement documents. Licensee receiving inspections should verify, as a minimum, item configuration, critical dimensions, physical characteristics, and identification and traceability of material and equipment, including status of licensee inspection or tests performed, as required.
- (i) Consider if the licensee has a documented method for the identification and control of nonconforming material and components, to preclude inadvertent use. This includes Counterfeit, Fraudulent, or Suspect Items (CFSI).

Inspection Guidance

Verify adequate controls for procurement of Appendix B components.

(Continued)

4. When deficiencies are identified for components, consider if the licensee has established and implemented a hold process to ensure components are not released until properly evaluated.

5. When possible, observe and assess actual techniques being used and their acceptability relative to contract/procedural requirements. (This includes implementation of cyber security requirements passed down from the licensee or applicant). A licensee may dedicate commercial-grade calibration and testing services purchased from domestic and international calibration and testing laboratories accredited by a signatory to the International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement (MRA). A licensee may take credit for ILAC accreditation in lieu of performing a commercial-grade survey as part of the commercial-grade dedication process.

Inspection Guidance

Verify adequate controls for procurement of Appendix B components.

(Continued)

6. Consider if the licensee is adequately implementing the conditions listed in the Safety Evaluation Report (SER) of NEI 14-05A, “Guidelines for the Use of Accreditation in Lieu of Commercial Grade Surveys for Procurement of Laboratory Calibration and Test Services,” Revision 1 (ADAMS Accession No. ML20322A019).

Additional Considerations
50.69

50.69 components- sampling RISC 1-4

- **RISC 1 – It's CGD, follows App B- good to go!**
  - **Focus sample selections on RISC 1 components**
- **RISC 2 & 3* - NOT CGD. Only in scope of Objective 2 in this inspection. Must inspect against the licensee's 50.69 program specific procurement requirements. (App B Does NOT apply.)**
- **RISC 4- Not CGD. Low risk, not recommended to be considered for samples.**

***App A still applies to RISC 3**

During/After the inspection

- All findings are processed through normal ROP/enforcement processes.
  - Just like all previous engineering inspections.
- Following the exit, will hold cross-regional panels to ensure consistency and allow for information sharing between regions. (First 6 months, then as needed)
- Follow all normal guidance for inspection exit, inspection report timing, etc.

EQ/POV Inspection Lessons Learned

FEI Inspection Enhancements

- Training for inspectors developed and provided (technical and process focused).
- Identification of singular technical and programmatic points-of-contact.
- Tabletop Dry Run scenarios included as part of training including Minor/more-than-minor examples .
- Technical and Programmatic leads provide support for inspections as needed.
- Findings Review Panel established for first 6 months of implementation.

Points of Contact

- Technical POCs:
  - Greg Galletti – Senior Reactor Operations Engineer (QA Inspector)- NRR/DRO/IQVB
  - Aaron Armstrong- Reactor Operations Engineer (QA Inspector)- NRR/DRO/IQVB
- Programmatic POC:
  - Doug Bollock – Senior Reactor Operations Engineer - NRR/DRO/IRIB

Inspection Support

Technical POCs

- Communicate with as much as needed
  - Before the inspection: for OpE, potential issues, sample selection assistance.
  - During the inspection: for any technical questions regarding dedication.
  - After the inspection: in helping develop any findings or violations

Inspection Support

Programmatic POCs

- Communicate with as much as needed
  - Before the inspection: any questions on inspection preparation
  - During the inspection: for any inspection implementation questions
  - After the inspection: in helping develop any findings or violations

Inspection Support

POCs will observe the first inspection in each region:

- Provide immediate feedback to inspectors on any implementation issues or questions.
- Answer any programmatic questions the licensees may have.
- Field industry observer questions so the inspection team can focus on implementation
- Note feedback from the inspections to make timely changes to the IP if needed.

Q&A Session

Future questions

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