

NRC INSPECTION MANUAL

IRIB

INSPECTION PROCEDURE 71111 ATTACHMENT 21N.03

COMMERCIAL GRADE DEDICATION

Effective Date: 02/16/23

PROGRAM APPLICABILITY: IMC 2515 App A

CORNERSTONE: Initiating Events
Mitigating Systems
Barrier Integrity

INSPECTION BASES: IMC 0308 Attachment 2

SAMPLE REQUIREMENTS:

| Sample Requirements | | Minimum Baseline Sample Completion Requirements | | Budgeted Range | |
|---|---------|---|------------------------|--------------------|----------------|
| Sample Type | Section | Frequency | Sample Size (per site) | Samples (per site) | Hours per Site |
| Commercial Grade Dedication and Procurement | 03.01 | Quadrennial | 9 | 9-15 | 210 +/- 32 |

71111.21N.03-01 INSPECTION OBJECTIVE

01.01 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.

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

71111.21N.03-02 GENERAL GUIDANCE

Commercial-grade dedication is a process by which a CGI is an acceptance process 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 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

The purpose of this inspection activity is to evaluate the CGI sample to determine if the licensee's activities provide reasonable assurance the CGI will perform its safety function as if it were manufactured under an Appendix B program. In performing this inspection, the inspectors should select a sample of CGIs and/or aspects of the procurement process for safety-related components for a detailed review of the applicable licensee activities. Additional guidance for the performance of this inspection is provided in Appendix A, "Dedication Issues Considerations for the Selection and Verification of Critical Characteristics," and Appendix B, "Dedication Documents," of this inspection procedure. Definitions of CGD related terms are provided in Appendix C, "Definitions." Documents which contain additional background information on CGIs are found in the References section of this Inspection Procedure.

In preparation for this inspection, regional inspectors should consider consulting with subject matter experts from the NRC headquarters Division of Reactor Oversight, Quality Assurance and Vendor Inspection Branch, 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 consult with the Regional Senior Reactor Analysts (SRA)s and use risk insights to identify CGIs with increased risk significance for more detailed inspection. The inspectors should then 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 walk down 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.

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 **from the following list:**

- 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 **procured from suppliers with a 10 CFR Part 50 Appendix B-compliant QA program,**
- **or procured under a 10 CFR Part 50.69 alternative procurement treatment.**

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:

- a. discuss with the licensee the scope of the planned inspection;

- b. 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;
- c. ensure that the information to be reviewed is available at the beginning of the inspection; and
- d. 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.

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.

71111.21N.03-03 INSPECTION REQUIREMENTS

03.01 Commercial Grade Dedication

- a. **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.**

Specific Guidance:

1. Technical Evaluations.

Technical evaluations are conducted and documented by the responsible organization. Technical evaluations identify the necessary technical requirements that ensure the item will meet the intended design conditions. Technical requirements should include:

- (a) Determination of the item's safety function, performance requirements, component/part functional classification, and application requirements (e.g., service conditions).
- (b) Review of **available** vendor technical data as well as industry operating experience, including feedback from previous dedication activities, NRC bulletins and information notices, supplier information letters, available industry data, and customer feedback to identify relevant technical information that may affect the suitability of the item.
- (c) Performance of a Failure Modes and Effects Analyses (FMEA), if available, to identify the credible failure mechanisms of the item in the specific application under consideration.

- (d) The identification of the item's critical characteristics based on the information developed above that will ensure the suitability of all parts, materials, and services for their intended safety-related applications. Factors may include, but not limited to:
- (1) The important design, material, and performance characteristics that have a direct effect on the item's ability to accomplish its intended safety function.
 - (2) Active/passive safety-related functions, system safety/non-safety interfaces, and system compatibility under all design basis conditions.
 - (3) Any **known** changes in design, material, or manufacturing process that could impact the functional characteristics of the item.
 - (4) Appropriate interface with the vendor to identify and characterize the design and functional parameters of specific parts.
 - (5) 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.
 - (6) Any critical characteristics that cannot be effectively verified **after manufacturing** should be identified in order to apply an appropriate verification method (**Method 2, Commercial Grade Survey or Method 3, Source Verification**) during the manufacturing process. **If any critical characteristics cannot be verified acceptable, that item cannot be dedicated.**

The identified critical characteristics that are needed for the item to perform its safety function, as determined in the technical evaluation, should be verified **using one or more of the following acceptance methods:**

- **Method 1: Special tests and inspections**
 - **Method 2: Survey of a commercial grade supplier**
 - **Method 3: Source verifications (e.g., Product inspections or witness holdpoints)**
 - **Method 4: Supplier/Item history (e.g., Historical records for acceptable performance)**
- (e) Determination of the appropriate verification methods for each critical characteristic.
- (f) Identification of the acceptance criteria for the verification method used consistent with the plant-specific application.
- (g) Additional considerations for dedication of CGI for applications requiring environmental or seismic qualification:
- (1) Utilization of non-destructive methods to verify the critical characteristics of the item to provide reasonable assurance that each individual CGI will

perform in the design-basis accident/event harsh environment (e.g., loss of coolant accident, high-energy line break, operating basis earthquake or safe-shutdown earthquake).

- (2) The CGI's safety function(s), functional performance requirements, and acceptance criteria determinations should include design service conditions (harsh environment, seismic).
- (3) When applicable, seismic and environmental qualification is maintained by verifying critical characteristics related to seismic and environmental qualification (critical characteristics that provide reasonable assurance the dedicated item will be able to perform its safety functions during and after design basis events for which the item was qualified.)

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

A like-for-like replacement is a replacement of an item with one that is identical. Characteristics of like-for-like items are described below. A like-for-like replacement may be considered identical if:

- (a) The item is provided by the original equipment manufacturer (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
- (b) The item was purchased at the same time and from the same supplier, as determined by the purchase date, shipping date, date code, or same batch/lot identification.
- (c) Evaluation of the item confirms that no changes in the design, materials, or manufacturing process have occurred since the procurement of the original item.

A like-for-like determination should not be based solely on the selection of a commercial-grade supplier with items manufactured to meet the same industry standards of the item that was originally supplied. Meeting the same industry standards may be a necessary condition, but is not a sufficient condition for a like-for-like determination.

An equivalency evaluation is needed if differences from the original item are identified in the replacement item to determine if any changes, such as in design, material, manufacturing process, safety, form, fit, function or interchangeability could impact the replacement item's ability to function under all design conditions (including design-basis event conditions) and ultimately the component's ability to perform its required safety function. Equivalency evaluations should not be used as the sole basis to accept a CGI for safety-related use. 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.

- 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.**

Specific Guidance:

The following are the four acceptance methods:

1. Method 1: Special Tests and Inspections

Special tests and inspections verify critical characteristics to ensure that the purchased material, equipment, or service, whether purchased directly or through contractors and subcontractors, meet the technical and quality requirements.

Tests and inspections specified for acceptance are to be documented in a plan or checklist that may include:

- The tests and inspections to be performed.
- The test methods and inspection techniques to be utilized.
- Verification of the identified critical characteristics consistent with the acceptance criteria determined in the technical evaluation.
- Documentation of the inspection and test results.

Receipt inspection activities should be used to establish and maintain traceability of CGIs. Inspections may include verification of objective evidence and performance of visual, dimensional, electrical, and mechanical inspections, or tests (as necessary) to assure product and material quality. Consider the following:

- Functional tests before installation and/or operational tests after installation may be performed to verify critical characteristics of the CGI.
- Calibration methods of measuring and test equipment should be traceable to nationally recognized standards
- Qualification of personnel or vendors used to perform the tests.
- Sampling plans for dimensional/visual inspection and/or testing should be used in accordance with nationally recognized industry standards and should have an adequate documented technical basis. This technical basis may include homogeneity, complexity of the item, lot/batch control for items, heat traceability for materials, and adequacy of the vendor's controls as confirmed by a survey. Other means of demonstrating adequate lot/batch control may include satisfactory performance history and the results of receipt inspections/testing. When such methods are used as a basis for developing product sampling strategy, they should be supported by documented objective evidence.
- When the verification of one or more critical characteristics is based on vendor-certified material test reports or certificates of conformance/compliance, the validity of these documents should be verified (see Method 2 below). The purchaser should verify that the vendor has established adequate traceability

controls and that these controls are effectively implemented. When distributors are included in the supply chain, the activities of these distributors may need to be surveyed to ensure that traceability and proper storage conditions are maintained. Acceptance of an item using this method will be completed by performing a receipt inspection that includes the accompanying vendor's certificate of conformance/compliance or certified material test report.

- Reliance on part number verification and certification documentation alone on receipt does not ensure the quality and suitability of commercially procured products.

2. Method 2: Commercial-Grade Survey of Supplier.

Commercial-grade surveys should be used when the purchaser desires to verify one or more critical characteristics based on the merits of a vendor's commercial programmatic controls.

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

Acceptance Method 2 should not be employed as the sole basis for accepting items from vendors with undocumented commercial programmatic controls.

- (a) The survey should be conducted by an individual(s) that is also trained in auditing and knowledgeable in the operation of the item(s) and the associated critical characteristics to be verified. The verification is accomplished by the licensee reviewing the vendor's program/procedures controlling these critical characteristics and observing the actual implementation of these controls in the manufacture of items identical or similar to the items being purchased.
- (b) If the vendor's controls are determined to be satisfactory, purchase orders for these items should invoke these controls as contract requirements by referencing the applicable program/procedure(s) and revision.
- (c) Commercial-grade survey plans should include the identification of the item or items for which the vendor is being surveyed, identification of the critical characteristics of these items that the vendor is expected to control, identification of the controls to be applied (program/procedure and revision), and a description of the verification activities performed.
- (d) For survey reports prepared by third parties (e.g., a Nuclear Procurement Issues **Corporation** (NUPIC) joint or member survey), the following factors should be considered:
 - (1) Review and acceptance of the surveyors' procedure(s), checklists, and personnel (e.g., the NUPIC commercial-grade survey procedure and checklist)

- (2) Ensure that the survey is critical characteristic-specific and plant application-specific.
- (3) The survey report should demonstrate that the critical characteristics required for the purchaser's own application are in fact verified to be controlled by the vendor.
- (e) Actual handling of the item by a distributor should be addressed in terms of the distributor's controls (e.g., segregation of customer returns). However, other factors may be taken into account that may warrant the need for a distributor survey, such as:

- (1) The need for documented, verifiable traceability to the OEM.
- (2) Presence and integrity of OEM packaging/markings, etc.
- (3) The susceptibility of the item to undetectable damage or tampering.
- (4) History or experience with the particular vendor and distributor(s).
- (5) Environmental controls and time limited products (shelf-life).

A survey of the distributor may not be necessary if there is a low probability of a distributor being able to have any effect on the condition of an item merely by having it in its physical possession.

- (f) The dedicating entity is responsible for assessing the supplier's control of subsuppliers of parts, materials, or services when the supplier relies upon subsupplier's controls and does not otherwise verify that parts, materials, or services provided by subsuppliers meet applicable requirements. In such cases, control of subsuppliers should be adequately addressed by survey and requirements imposed in subsupplier procurement documents to establish an adequate basis for accepting test results and certifications.
- (g) A certificate of conformance or certified material test report by the OEM/vendor or material supplier provides the evidence that the critical characteristics have been met.
- (h) A dedicating entity may dedicate commercial-grade calibration and testing services purchased from domestic and international calibration and testing laboratories accredited by an International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement (MRA) signatory. The dedicating entity may take credit for ILAC accreditation in lieu of performing a commercial-grade survey provided the following conditions are met:
 - (1) The method to use accreditation by an ILAC MRA signatory in lieu of performing a commercial-grade survey (i.e., the alternative method) is documented in the licensee's and supplier's quality assurance (QA) program.
 - (2) The method the licensees and suppliers need to follow and document in their QA program consists of:

- [a] A documented review of the supplier's accreditation is performed and includes a verification of the following:
 - [1] The calibration or test laboratory hold accreditation by an accrediting body recognized by the ILAC MRA signatory or full member. The accreditation encompasses ISO/IEC 17025:2017, "General Requirements for Competence of Testing and Calibration Laboratories."
 - [2] For procurement of calibration services, the published scope of accreditation laboratory covers the needed measurement parameters, ranges, and uncertainties.
 - [3] For procurement of testing services, the published scope of accreditation for the test laboratory covers the needed testing services including test methodology and tolerances/uncertainty.
 - [4] The laboratory has achieved accreditation based on an onsite accreditation assessment by the selected accrediting body within the past 48 months. The laboratory's accreditation cannot be based on two consecutive remote accreditation assessments.

- [b] The purchase documents require that:
 - [1] The service must be provided in accordance with their accredited ISO/IEC 17025:2017 program and scope of accreditation.
 - [2] As-found calibration data must be reported in the certificate of calibration when calibrated items are found to be out-of-tolerance (for calibration services only).
 - [3] The equipment/standards used to perform the calibration must be identified in the certificate of calibration (for calibration services only).
 - [4] The customer must be notified of any condition that adversely impacts the laboratory's ability to maintain the scope of accreditation.
 - [5] Performance of services listed on this order is contingent on the laboratory's accreditation having been achieved through an onsite accreditation assessment by the accrediting body within the past 48 months.
 - [6] Subcontracting of these accredited services is prohibited.
 - [7] Any additional technical and quality requirements, as necessary, based upon review of the procured scope of services, which may include, but are not necessarily limited to, tolerances, accuracies, ranges, and industry standards.

(3) It is validated, at receipt, that the laboratory's documentation certifies that:

[a] The contracted calibration or test services has been performed in accordance with their ISO/IEC 17025:2017 program, and has been performed within their scope of accreditation; and

[b] The purchase order's requirements are met.

3. Method 3: Source Verification.

Method 3 involves witnessing quality-related activities before releasing the CGI from the vendor or test laboratory facility to confirm by direct observation that the selected critical characteristics of the item being procured are satisfactorily controlled by the vendor. Source verification could also be used when specialized tests and/or licensee inspections are required to verify selected critical characteristics and the equipment to perform these tests is available only at the vendor's facilities.

(a) Source verifications should be controlled by a documented plan. Factors to be considered in the plan include:

- (1) The identification of a specific process of interest that may be correlated with a manufacturing or testing phase.
- (2) The verification method utilized to verify the critical characteristics for acceptance.
- (3) Appropriate hold points to verify design, material, and performance characteristics during manufacture and/or testing relevant to the safety function of the item when those characteristics cannot be verified after the item has been completely manufactured.
- (4) A dedicating entity inspector(s) who performs direct observations of the verification of a commercial-grade item's critical characteristics and manufacture at the supplier facility. The inspector(s) should be a technical specialist skilled in audit practice and knowledgeable in operation of the item(s) and the associated critical characteristics to be verified.
- (5) Documentation of the source verification results. This includes the critical characteristics for acceptance and the actual results obtained during verification. Deficiencies observed should be corrected by the supplier before shipping.

(b) The dedicating entity inspector authorizes shipping and establishes initial traceability.

4. Method 4: Acceptable Supplier/Item Performance Record.

This method could be used to demonstrate one or more critical characteristics based upon documented acceptable item performance.

(a) Examples of such documented performance records include acceptable quality control of critical characteristics or acceptable industry-wide performance. The use of industry-wide performance should not be employed alone unless the established documented performance record is based on industry-wide

performance data that is directly applicable to the item's critical characteristics and the intended safety-related application.

Information pertinent to the commercial-grade item's quality of performance obtained from outside sources (e.g., operational event reports, NRC, vendor equipment technical information program, and Institute of Nuclear Power Operations data associated with operating experience) and from commercial-grade surveys, source verifications, receipt inspections, previous dedication or qualification, and operational history is factored into the dedication process.

- (b) This method should be used in combination with one or more of the methods explained above to collect the objective evidence necessary to ensure acceptable historical performance of the supplier.

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

Specific Guidance:

1. 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.

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

Specific Guidance:

1. 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.
2. Consider if receipt inspections performed adequately check for the acceptance of the dedicated item.
3. 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.

e. Evaluate and assess any failed dedicated CGI.

Specific Guidance:

1. 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.
- (b) 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.

2. Further Assessments

- (a) From the list of dedicated items provided by the licensee, the inspector should select for review other dedication packages having similar applications.
- (b) 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.

f. **Verify adequate controls for procurement of Appendix B components.**

Specific Guidance:

1. Consider assessing implementation of design controls and design configuration controls by performing the following:
 - (a) 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.
 - (b) 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.
 - (c) 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.
2. Consider the implementation of procurement document controls:
 - (a) Consider if the procedures are established and implemented for the control and release of procurement documents and subsequent changes.
 - (b) 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.

- (c) 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.

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

- (a) Consider if procedures have been established and implemented to select and qualify vendors **with Appendix B-compliant QA programs** 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.
- (b) 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.
- (c) Consider if storage requirements are met for the components including preventive maintenance, surveillances, shelf life, environmental conditions, and environmental qualifications.
- (d) Consider if applicable Part 21, operating experience, and corrective action program items are used to evaluate the acceptability of basic components.
- (e) 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.
- (f) 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).
- (g) 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.
- (h) 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).
- 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.
- 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).

71111.21N.03-04 REFERENCES

10 CFR Part 21, "Reporting of Defects and Noncompliance."

10 CFR Part 50, Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants."

Final Regulatory Basis to Clarify 10 CFR Part 21, "Reporting of Defects and Noncompliance" (ML15152A457)

U.S. Nuclear Regulatory Commission, Generic Letter 89-02, "Actions to Improve the Detection of Counterfeit and Fraudulently Marketed Products." NRC: Washington, DC. March 21, 1989. (ML031140060)

U.S. Nuclear Regulatory Commission, Generic Letter 91-05, "Licensee Commercial-Grade Procurement and Dedication Programs." NRC: Washington, DC. April 9, 1991. (ML031140508)

ANSI/ASME NQA-1, "Quality Assurance Program Requirements for Nuclear Facility Applications."

EPRI 3002002982 "Plant Engineering Guidelines for the Acceptance of Commercial - Grade Items in Nuclear Safety-Related Applications: Revision 1 to EPRI NP-5652 and TR-102260."

EPRI 1008256, "Guidelines for the Technical Evaluation of Replacement Items in Nuclear Power Plants."

EPRI NP-6629, "Guidelines for the Procurement and Receipt of Items for Nuclear Power Plants (NCIG-15)."

EPRI NP-6630, "Guidelines for Performance - Based Supplier Audits (NCIG-16)."

EPRI NP-6895, "Guidelines for the Safety Classification of Systems, Components, and Parts Used in Nuclear Power Plant Applications (NCIG-17)."

EPRI TR-017218-R1, "Guideline for Sampling in the Commercial - Grade Item Acceptance Process."

EPRI 3002002276, "Plant Support Engineering: Counterfeit, Fraudulent and Items – Mitigating the Increasing Risk, Revision 1 of TR-1019163."

EPRI TR-017218-R1, "Guideline for Sampling in the Commercial-Grade Item Acceptance Process."

Final Safety Evaluation for Technical Report 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, dated on November 23, 2020, (ML20322A019)

Information Notice 1989-14, "Inadequate Dedication Process for Commercial-Grade Components Which Could Lead to Common Mode Failure of a Safety System."

Information Notice 1996-40, "Deficiencies in Material Dedication and Procurement Practices and in Audits of Vendors," issued July 25, 1996. Supplement 1 issued October 7, 1996.

Information Notice 2011-01, "Commercial-Grade Dedication Issues Identified During NRC Inspections." (ML103220180)

Information Notice 2014-11, "Recent Issues Related to the Qualification and Commercial-Grade Dedication of Safety-Related Components." (ML14149A520)

Information Notice 2016-01, "Recent Issues Related to the Commercial-Grade Dedication of Allen Bradley 700-RTC Relays." (ML1529A173)

IMC 2504, "Construction Inspection Program: Inspections of Construction and Operational Programs"

IMC 2507, "Vendor Inspections"

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, (ML15075A434)

Regulatory Guide 1.164, "Dedication of Commercial-Grade Items for Use in Nuclear Power Plants," Revision 0, (ML17041A206)

Regulatory Guide 1.234, "Evaluating Deviations and Reporting Defects and Noncompliance Under 10 CFR Part 21," Revision 0, (ML17338A072)

Regulatory Guide 1.250, "Dedication of Commercial-Grade Digital Instrumentation and Control Items for Use in Nuclear Power Plants," Revision 0, (ML22153A408)

END

Appendix A: Dedication Issues Considerations for the Selection and Verification of Critical Characteristics

a. Consideration of Item's Safety Function

Critical characteristics of a commercial-grade item (CGI) should be based on the item's safety function. The licensee is responsible for (a) identifying the important design, material, and performance characteristics that have a direct effect on the item's ability to accomplish its intended safety function and (b) selecting from these characteristics a set of critical (or acceptance) characteristics that, once verified, will provide reasonable assurance that the item will perform its intended safety function. The selection of critical characteristics for verification can be based on a graded approach consistent with the item's importance to safety. When an existing equipment specification is available that contains adequate technical requirements for the item being purchased, that specification can be used to select the critical characteristics for this item.

b. Graded Quality Assurance

Criterion II of Appendix B to 10 CFR Part 50 provides for the application of quality assurance over activities affecting the quality of structures, systems, and components to an extent consistent with their importance to safety. The application of graded quality assurance to the CGI dedication process should include consideration of the item's importance to safety and other factors specific to the item being procured. Certain items and services may require extensive controls throughout all stages of development while others may require only a limited quality assurance involvement in selected phases of development. The following factors should be considered in determining the extent of quality assurance to be applied: (a) The importance of malfunction or failure of the item to plant safety, (b) the complexity or uniqueness of the item, (c) the need for special controls and surveillance over process and equipment, (d) the degree to which functional compliance can be demonstrated by inspection and test, and (e) the quality history and degree of standardization of the item. Additional guidance on the use of graded quality assurance can be found in the non-mandatory appendix to ANSI N45.2.13-1976 and ASME NQA-1.

c. Consideration of Failure Modes

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

d. Reasonable Assurance

The dedication process represents an acceptable method of achieving compliance with Appendix B to 10 CFR Part 50. In this context, reasonable assurance consists of the licensee controlling or verifying the activities affecting the item's quality to an extent consistent with the item's importance to safety or ensuring that these activities are adequately controlled by the supplier.

For more complex items, additional analysis and when possible, dialogue with the original equipment manufacturer may be necessary to identify the design and functional parameters of specific piece parts. Once the dedication process is completed, the quality assurance and/or other measures applied to those aspects of the item that directly affect

its safety function should result in the same level of performance as for a like item manufactured or purchased under a quality assurance program of Appendix B to 10 CFR Part 50.

e. Engineering Judgment

Engineering judgment can be used in selecting those important design, material, and performance characteristics that are identified as the item's critical characteristics. The bases for engineering judgment utilized in the selection process should be documented.

TRACEABILITY

Material/Items Purchased From Distributors

Traceability can be defined as the ability to verify the history, location, or application of an item by means of recorded identification. Where the item's acceptance is based entirely or partially on a certification by the manufacturer, the traceability must extend to the manufacturer. The purchaser should ensure by survey or by other means that the manufacturer has established adequate traceability controls and that these controls are effectively implemented. For situations in which intermediaries (distributors) are included in the supply chain, the activities of these organizations may need to be surveyed to ensure that traceability and proper storage conditions are maintained. A survey of the distributor may not be necessary if the distributor acts only as a broker and does not warehouse or repackage the items or in cases where traceability can be established by other means such as verification of the manufacturer's markings or shipping records. Inspectors should be mindful of potential Counterfeit, Fraudulent or Suspect Items (CFSI) in the supply chain and can question the purchaser on their assurances and best practices to avoid acceptance of those items.

SAMPLING

a. Established Heat Traceability (Materials)

When heat traceability of metallic material has been established and each piece of the material is identified with the material heat number, chemical analysis and destructive testing required for the acceptance of this material may be performed on one piece of the material. The same rationale may be used for the acceptance of containers of nonmetallic materials such as lubricants providing that traceability has been established and each container is identified with a unique mix or batch number.

b. Established Lot/Batch Control (Items)

When lot / batch (defined as units of product of a single type, grade, class, size, and composition, manufactured under essentially the same conditions and at essentially the same time) control is established through a commercial-grade survey, the party performing dedication of such items can use sampling prescribed by standard statistical methods that are based on homogeneous product lots. Such sample plans should be identified and should provide for the verification of the critical characteristics with a confidence level consistent with the item's importance to safety.

Other means of demonstrating adequate lot/batch control may include satisfactory performance history and the results of receipt inspection/testing. When such methods are used as a basis for developing product sampling strategy, they should be supported by documented objective evidence.

c. Material and Items with No Lot/Batch Control

When lot / batch control cannot be established, sampling plans need to be considered on individual, item-specific basis and ensure that they are capable of providing a high level of assurance of the item's suitability for service. There may be situations where each item needs to be tested.

COMMERCIAL-GRADE SURVEYS

a. Verification of Vendor's Control of Specific Characteristics

A commercial-grade survey should be specific to the scope of the CGI(s) being purchased. The vendor's controls of specific critical characteristics to be verified during the survey should be identified in the survey plan. The verification should be accomplished by reviewing the vendor's program / procedures controlling these characteristics and observing the actual implementation of these controls in the manufacture of items identical or similar to the items being purchased.

b. Identification of Applicable Program/Procedures

The vendor must have a documented program and / or procedures to control the critical characteristics of the item or items being procured that are to be verified during the survey. When many items are being purchased, a survey of a representative group of similar items may be sufficient to demonstrate that adequate controls exist. If the vendor's controls are determined to be satisfactory, purchase orders for these items should invoke these controls as contract requirements by referencing the applicable program/procedure(s) and revision. If multiple working level procedures are applicable to the vendor's activities, which affect the item's critical characteristics and these procedures, in turn, are controlled by a higher level document, it may be appropriate to reference that document in the purchase order. It is important to ensure that the specific controls reviewed and accepted during the survey be applied during the manufacturing process. Upon completion of the work, the vendor should certify compliance with the purchase order requirements.

c. Documentation of Survey Results

Commercial-grade survey documentation should include the identification of the item or items for which the vendor is being surveyed, identification of the critical characteristics of these items that the vendor is expected to control, identification of the controls to be applied (program/procedure and revision), and a description of the verification activities performed, and results obtained. Critical characteristics that are not adequately controlled should be addressed by contractually requiring the vendor to institute additional controls or by utilizing other verification and acceptance methods.

d. Survey Frequency

Commercial-grade surveys should be conducted at sufficient frequency to ensure that the process controls applicable to the critical characteristics of the item procured continue to be effectively implemented. Factors to be considered in determining the frequency of commercial-grade surveys include the complexity of the item, frequency of procurement, receipt inspection, item performance history, and knowledge of changes in the vendor's controls. The survey frequency should not exceed the audit frequency established for Appendix B to 10 CFR Part 50 suppliers.

ACCEPTANCE OF CERTIFIED MATERIAL TEST REPORTS (CMTRs) AND CERTIFICATES OF COMPLIANCE (CoCs)

Validity Verified Through Vendor / Supplier Audit or Testing

When the verification of critical characteristics is based on vendor CMTRs or CoCs, the validity of these documents should be ensured. This can be accomplished through a commercial-grade survey or, for simple items, periodic testing of the product on receipt. Such verifications should be conducted at intervals commensurate with the vendor's past performance. If the item's supply chain includes a distributor, a survey of the distributor's activities may be necessary (see "Traceability").

USE OF INDUSTRY GUIDANCE

The Electric Power Research Institute (EPRI) 3002002982, "Plant Engineering: Guideline for the Acceptance of Commercial-Grade Items in Nuclear Safety Related Applications," Revision 1 to EPRI NP-5652 and TR-102260, defines critical characteristics as "The important design, material, and performance characteristics of a commercial grade item that--once verified--will provide reasonable assurance that the item will perform its intended safety function." Previously, EPRI referred to "critical characteristics" as critical characteristics for acceptance." EPRI 3002002982 also defines design characteristics as follows, "Sometimes referred to as critical characteristics for design, those properties or attributes that are essential for the item's form, fit, and functional performance. Critical characteristics for design are the identifiable and/or measurable attributes of a replacement item that provide assurance that the replacement item will perform its design function." NRC's conditional acceptance of EPRI 3002002983 by RG 1.164 recognizes the definition of an older term, "critical characteristics for acceptance" included in 3002002982, which notes that critical characteristics for acceptance are a subset of "critical characteristics for design" (or in using current terminology, critical characteristics are a subset of design characteristics.)

Published NRC guidance in Generic Letters 89-02 and 91-05 does not suggest that all design requirements of an item need to be verified during the dedication process. Rather, the licensee is expected to identify the item's design, material, and performance characteristics that have a direct effect on the item's ability to accomplish its intended safety function and select from these characteristics a set of critical (or acceptance) characteristics that, once verified, will provide reasonable assurance that the item will perform that function. Consistency in the definition of critical characteristics can be improved by equating the NRC's definition of critical characteristics to the EPRI definition of "critical characteristics for acceptance."

EPRI 3002002276, "Plant Support Engineering: Counterfeit and Fraudulent Items- Mitigating the Increasing Risk, Revision 1 of 1019163" referenced in NRC SECY 15-0003 describes the best practices for avoiding entrance of Counterfeit, Fraudulent or Suspect items into the commercial nuclear supply chain and can be helpful to increase awareness of the potential. EPRI 1021493, "Plant Support Engineering: Counterfeit and Fraudulent Items, A Self-Assessment Guideline" provides questions that can be used to identify opportunities to improve identification and prevention of counterfeit and fraudulent items.

END

Appendix B: Dedication Documents

A list of CGIs dedicated by the licensee in recent years (typically 5 years and could expand to 10 years). Within that list inspectors may ask for CGIs that specifically:

- Have been installed in the plant
- Have been in the Hold process or are currently in the hold process.
- CGIs that were dedicated to support emergent work.

A list of items procured from suppliers with a 10 CFR Part 50 Appendix B-compliant QA program that are known to be dedicated.

The dedication documentation compiled by the licensee may contain the following items, as applicable, depending on the item chosen and the dedication methods used:

- a. Completed commercial-grade dedication documents (e.g., dedication package or dedication plan) including:
 1. safety classification
 2. identification of safety functions/application requirements
 3. identification of critical characteristics
 4. identification of verification methods and acceptance criteria for the critical characteristics evaluation of credible failure modes (if applicable)
 5. identification of the supplier's commercial quality assurance program or other documented controls
- b. Documents showing objective evidence:
 1. special test and inspection procedures and results
 2. commercial-grade survey reports -item critical characteristics, for example design, material, and specific performance characteristic (relevant to safety function)
 3. source verification reports
- c. Purchase requisitions and purchase orders.
- d. Other pertinent vendor/licensee correspondence.
- e. Design specifications - original and updated to verify certain important parameters, such as original design pressure of a system or degraded pickup voltage of a solenoid or relay.
- f. Catalog specifications.
- g. Procurement basis evaluation - like-for-like, equivalency, plant design change packages, drawing and specification updates.
- h. 10 CFR 50.59 evaluation, if required.

- i. Material receiving reports, packing lists/invoices, and other shipping documents.
- j. Receipt inspection reports and any related test reports.
- k. Other documents to trace the item from the time it was dedicated to the time it was installed, tested, and accepted.
- l. Certificates of conformance/compliance/quality.
- m. Vendor test and inspection reports.
- n. Third-party or sub vendor test and inspection reports.
- o. Shelf life information.
- p. Vendor dedication/partial dedication information.
- q. Design/material/process change history information.
- r. Any deviation from design, material, and performance characteristics relevant to the safety function (nonconformance dispositions).
- s. Completed post-installation test procedure and results.
- t. Completed stock or material issue forms and installation work orders or reports.
- u. Historical performance information.

END

Appendix C: Definitions

- a. Basic component: A structure, system, component, or part thereof that affects its safety function necessary to assure:
1. The integrity of the reactor coolant pressure boundary;
 2. The capability to shut down the reactor and maintain it in a safe shutdown condition; or
 3. The capability to prevent or mitigate the consequences of accidents which could result in potential offsite exposures comparable to those referred to in 10 CFR 50.34(a)(1), 10 CFR 50.67(b)(2), or 10 CFR 100.11, as applicable.

Basic components are items designed and manufactured under a QA program complying with Appendix B to 10 CFR Part 50, or commercial-grade items which have successfully completed the dedication process.

In all cases, a basic component includes safety-related design, analysis, inspection, testing, fabrication, replacement of parts, or consulting services that are associated with the component hardware whether these services are performed by the component supplier or others.

- b. Certificate of Compliance: A document attesting that the materials are in accordance with specified requirements.
- c. Certified Material Test Report (CMTR): A document attesting that the material is in accordance with specified requirements, including the actual results of all required chemical analyses, treatments, tests, and examinations.
- d. Commercial-grade item: **An item that is not a basic component. (Source draft reg basis ML15152A457)**
- e. Commercial-grade survey: Activities conducted by the **dedicating entity** or its agent to verify that a supplier of commercial-grade items controls, through quality activities, some or all of the critical characteristics of the commercial-grade items to be purchased **and accepted**. The verification can be used as a method to accept those characteristics. The commercial-grade survey should include verification of the supplementary documentation and the effective implementation of the commercial-grade quality program **or otherwise documented quality activities**.
- f. Commercial-grade dedication package: An auditable collection of documents that is the result of the commercial-grade dedication process for a specific item and specific safety function. These documents contain the technical and quality basis for satisfying the commercial-grade item dedication process and provide the objective evidence to reasonably assure that the dedicated commercial-grade item will perform its required safety function.
- g. Counterfeit, Fraudulent, or Suspect Items (CFSI): 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).

- h. Critical characteristics: 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.
- i. Dedicating entity: The organization that performs the dedication process. Dedication may be performed by the manufacturer of the item, a third-party dedicating entity, and/or the licensee itself. The dedicating entity is responsible for identifying and evaluating deviations, reporting defects and failures to comply for the dedicated item, and maintaining auditable records of the dedication process. (10 CFR Part 21)
- j. Dedication: An acceptance process undertaken to provide reasonable assurance that a commercial-grade item to be used as a basic component will perform its intended safety function and, in this respect, is deemed equivalent to an item designed and manufactured under an Appendix B, quality assurance program. (Source: 10 CFR Part 21) When applied to basic components the term “designed and manufactured” means controlled under a quality assurance program complying with Appendix B to 10 CFR Part 50.
- k. Engineering Judgment: A process of logical reasoning performed by a qualified individual that leads from stated premises to a conclusion. This process should be supported by sufficient documentation to permit verification by a qualified individual.
- l. Like-for-like Replacement: Replacement of an item with one that is identical.
- m. Procurement Document: A contract that defines the technical and quality requirements that must be met in order to be considered acceptable by the purchaser.
- n. Source Verification: Activities witnessed at the supplier's facilities by the purchaser or its agent before releasing the CGI from the vendor or test laboratory facility to confirm by direct observation that the selected critical characteristics are verified by the vendor.
- o. Traceability: The ability to verify the history, location, or application of an item by means of recorded identification. Traceability to the manufacturer is required when the manufacturer is relied upon to verify one or more critical characteristics.

END

Attachment 1: Revision History for IP 71111.21N.02

| Commitment Tracking Number | Accession Number Issue Date Change Notice | Description of Change | Description of Training Required and Completion Date | Comment Resolution and Closed Feedback Form Accession Number (Pre-Decisional, Non-Public Information) |
|----------------------------|---|--|--|---|
| | ML22075A251 06/28/22 CN 22-014 | First issuance. Completed 4-year search for commitments and found none. This IP is one of the Focused Engineering Inspections recommended by staff in SECY 18-0113. | 2-day Instructor-led training on CGD concepts and procedure implementation | ML22090A282 |
| | ML23005A288 02/16/23 CN 23-004 | Updated references and edited guidance in accordance with the updated references. Added additional guidance on International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement (MRA) signatory reviews. | None | ML23005A287 |