INSPECTION PROCEDURE 43004

INSPECTION OF COMMERCIAL-GRADE DEDICATION PROGRAMS

PROGRAM APPLICABILITY: 2504, 2507, 2515C

43004-01 INSPECTION OBJECTIVES

01.01 To verify that the dedicating entity's commercial-grade dedication program satisfies the requirements of Appendix B to Title 10 of the *Code of Federal Regulations* (10 CFR) Part 50 (Appendix B) with regard to the procurement and acceptance of commercial-grade items (CGIs) for use as basic components in accordance with 10 CFR Part 21.

01.02 To verify that the dedicating entity's process for dedicating CGIs, as implemented, meets the applicable portions of Appendix B and provides reasonable assurance that CGIs will perform their intended safety function.

43004-02 INSPECTION REQUIREMENTS

02.01 Verify that the dedicating entity has established adequate controls for performing technical evaluations of items or services to be dedicated. This includes the review of materials, parts, equipment, and processes for suitability of application as established in Criterion III of Appendix B.

02.02 Verify that the dedicating entity has established adequate controls for the acceptance of a CGI using the criteria established in Criterion VII of Appendix B.

02.03 Verify that the dedicating entity has properly developed and implemented a plan for commercial-grade dedications.

02.04 Verify that there are adequate controls for the acceptance of items procured that were dedicated by a third party.

02.05 Evaluate and assess failed dedicated CGI.

43004-03 INSPECTION GUIDANCE

The inspector should verify that the entity inspected has a dedication program that meets the applicable portions of Appendix B and 10 CFR Part 21.

03.01 Verify that the dedicating entity has established adequate controls for the technical evaluation of the items or services to be dedicated.

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

1. Determination of the item's safety function, performance requirements, component/part functional classification, and application requirements (e.g., service conditions).

2. Review of the vendor's 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.

3. Performance of a Failure Modes and Effects Analyses (FMEA), if necessary to identify the credible failure mechanisms of the item in the specific application under consideration.

4. The identification of the item's critical characteristics based on the information developed above that will assure the suitability of all parts, materials, and services for their intended safety-related applications. Factors that should be considered include:

    (a) The important design, material, and performance characteristics that have a direct effect on the item's ability to accomplish its intended safety function.

    (b) Active/passive safety-related functions, system safety/non-safety interfaces, and system compatibility under all design basis conditions.

    (c) Any changes in design, material, or manufacturing process that could impact the functional characteristics of the item.

    (d) Appropriate interface with the vendor to identify and characterize the design and functional parameters of specific parts.

    (e) 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.

    (f) Those critical characteristics that cannot be effectively verified during post-receipt inspection and testing should be identified in order to apply an appropriate verification method during the manufacturing process.

    The identified critical characteristics that are important for the item to perform its safety function, as determined in the technical evaluation, are to be verified. Not all design requirements need to be considered critical characteristics; however, dedicating entities must assure the suitability of all parts, materials, and services for their intended safety-related applications. This may involve the performance of surveys, special tests and/or inspections, or source verification on commercial-grade vendors as part of the vendor selection process to verify the adequacy of the vendor controls (see Acceptance Methods section below).

- Determination of the appropriate verification methods for each critical characteristic.

- Identification of the acceptance criteria for the verification method used consistent with the plant-specific application.

- Additional considerations for dedication of CGI for applications requiring environmental or seismic qualification:

  (a) Utilization of non-destructive methods to verify the critical characteristics of the item to provide reasonable assurance that each individual commercial-grade item 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). Like-for-like replacements should demonstrate performance equal to or better than the qualified prototype.

  (b) The commercial-grade item's safety function(s), functional performance requirements, and acceptance criteria determinations should include design service conditions (harsh environment, seismic).

  (c) Seismic and environmental qualification should be treated as critical characteristics to be verified, as necessary.

b. 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:

   - The replacement item was purchased from the same vendor (successor companies may be accepted), provided all design, materials, or manufacturing processes are kept the same, or

   - The replacement item was purchased at the same time and from the same vendor as the item it is replacing. For example, the item has the same manufacturing time frame as determined by the date purchased or date shipped from factory, date code, same batch or lot number.

   A like-for-like determination should not be based solely on the selection of a commercial-grade vendor 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, then the item is not identical, but similar to the item being replaced, and an equivalency evaluation is necessary to determine if any changes in design, material, manufacturing process, safety, form, fit, function or interchangeability could impact the alternate 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 in its equivalency evaluation, then the safety function, design requirements and critical characteristics need not be re-determined. However, item acceptance, qualification of vendors and examination of products is still required.

03.02 Verify that the dedicating entity inspected has established adequate controls for the acceptance of a CGI. The following are the four acceptance methods:

a. Method 1: Special Test and Inspections. Special test and inspections should be used after the CGI is received for verification of critical characteristics to assure 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 should 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 should include verification of objective evidence and performance of visual, dimensional, electrical, and mechanical inspections, or tests (as necessary) to assure product and material quality.

1. Functional tests before installation and/or operational tests after installation may be performed to verify critical characteristics of the CGI.

   Measuring and test equipment should be properly calibrated. Qualified personnel should be used to perform the tests.

2. Sampling plans for testing should be used in accordance with nationally recognized industry standards, and should have an adequate documented technical basis. This technical basis includes 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. The CGI sampling process should be documented to develop the necessary objective evidence of the vendor's ability to consistently provide acceptable items.

3. 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.

4. Reliance on part number verification and certification documentation alone on receipt is insufficient to ensure the quality and suitability of commercially procured products.

b. 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 quality 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 quality control programs or with programs that do not effectively implement their own necessary controls.

The entity should have a documented and effectively implemented program and/or procedures to control the critical characteristics of the item(s) being procured.

1. 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 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.

2. Critical characteristics that are not adequately controlled should be addressed by the contract requiring the vendor to institute additional controls or by utilizing other verification methods.

3. 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. Specific controls reviewed and accepted during the survey should be implemented during the manufacturing process.

   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.

4. For survey reports prepared by third parties (e.g., a Nuclear Procurement Issues Committee (NUPIC) joint or member survey), the following factors should be considered:

   (a) Review and acceptance of the surveyors' procedure(s), checklists, and personnel (e.g., the NUPIC commercial-grade survey procedure and checklist)

   (b) Ensure that the survey is critical characteristic-specific and plant application-specific.

   (c) 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.

5. 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:

   (a) The need for documented, verifiable traceability to the original equipment manufacturer.

   (b) Presence and integrity of original equipment manufacturer packaging/markings, etc.

   (c) The susceptibility of the item to undetectable damage or tampering.

   (d) History or experience with the particular vendor and distributor(s).

   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, and where the distributor has rigorous controls on items during possession.

   Acceptance Method 2 should not be employed as the basis for accepting items from distributors unless the survey includes the part manufacturer(s) and the survey confirms adequate controls by both the distributor and the part manufacturer(s).

6. The dedicating entity is responsible for the control of subsuppliers of parts, materials, or services. The dedicating entity is required to impose the necessary controls on subsuppliers consistent with the importance of the subcontracted item or service. Control of subsuppliers should also be adequately addressed by survey so that the supplier has an adequate basis to accept test results and certifications.

7. A certificate of conformance or certified material test report by the original equipment manufacturer/vendor or material supplier may be acceptable, provided:

   (a) Documented, verified traceability to the original equipment manufacturer has been established, and

   (b) The purchaser has verified that the original equipment manufacturer or material supplier has implemented adequate quality controls for the activity being certified.

8. 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:

   (a) 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 licensees and supplier's quality assurance (QA) program.

   (b) The method the licensees and suppliers need to follow and document in their QA program consists of:

      1) A documented review of the supplier's accreditation is performed and includes a verification of the following:

         a. 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 17025:2005, "General Requirements for Competence of Testing and Calibration Laboratories."

         b. For procurement of calibration services, the published scope of accreditation laboratory covers the needed measurement parameters, ranges, and uncertainties.

         c. 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.

2) The purchase documents require that:

a. The service must be provided in accordance with their accredited ISO/IEC 17025:2005 program and scope of accreditation.

b. 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).

c. The equipment/standards used to perform the calibration must be identified in the certificate of calibration (for calibration services only).

d. The customer must be notified of any condition that adversely impacts the laboratory's ability to maintain the scope of accreditation.

e. 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 17025:2005 program, and has been performed within their scope of accreditation; and

b. The purchase order's requirements are met.

For vendors implementing the Arizona Public Service (APS) Safety Evaluation Report (SER) (ADAMS Accession No. ML052710224), the following conditions must be met:

(a) The alternative method is documented in the vendor's QA program.

(b) Accreditation is to ANSI/ISO/IEC 17025:2005, "General Requirements for the Competence of Testing and Calibration Laboratories."

(c) The published scope of accreditation for the calibration laboratory covers the needed measurement parameters, ranges, and uncertainties.

(d) The purchase documents impose additional technical and administrative requirements, as necessary, to satisfy the vendor's QA program and technical requirements.

(e) The calibration certificate/report shall include identification of the laboratory equipment/standard used.

(f) The purchase documents require reporting as-found calibration data when calibrated items are found out to be out-of-tolerance.

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 inspections are required to verify selected critical characteristics and the equipment to perform these tests is available only at the vendor's facilities.

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

   (a) The identification of a specific process of interest that may be correlated with a manufacturing or testing phase.

   (b) The verification method utilized to verify the critical characteristics for acceptance.

   (c) 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.

   (d) 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.

   (e) 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.

2. The dedicating entity inspector authorizes shipping and establishes initial traceability.

d. 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.

   1. 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.

2. 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.

03.03 Review a representative sample of dedication packages to assess whether procedures for dedication activities have been adequately planned and implemented.

a. Verify that the dedication process identifies those design, material, and performance characteristics relevant to the safety function as described in Section 03.01 of this procedure.

b. Verify that the dedicating entity demonstrated that the critical characteristics are met using appropriate acceptance methods as described in Section 03.02 of this procedure.

03.04 Review a representative sample of procurement documents for items dedicated by a third party.

a. Verify that the procurement documents have adequate controls for the dedicating entity and the proper critical characteristics and acceptance methods were used for the dedication.

b. Verify that receipt inspections performed adequately check for the acceptance of the dedicated item.

c. Verify 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.

03.05 Inspection of failed dedicated CGI

a. 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.

1. Review and discuss with dedicating entity personnel the failure/root-cause analysis when required or applicable for the failed CGI. Look for failures due to weaknesses in the commercial-grade dedication process.

2. Review 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.

b. Further Assessments

1. From the list of dedicated items provided by the dedicating entity, the inspector should select for review other dedication packages having similar applications and critical characteristics as the CGI(s) that resulted in the identified failures.

2. Request that the dedicating entity compile a complete package of all the procurement and dedication records for each item. Typical contents of a dedication package are described in Appendix C of this inspection procedure. Review the dedication packages as described in Appendix B of this inspection procedure.

03.06 Definitions.

a. Basic component: A structure, system, 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 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: A structure, system, or component, or part thereof that affects its safety function that was not designed and manufactured as a basic component.

e. Commercial-grade survey: Activities conducted by the purchaser 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 designated commercial-grade items to be purchased. 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.

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. 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.

h. 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)

i. 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. This assurance is achieved by identifying the critical characteristics of the item (not required in like-for-like replacements) and verifying its acceptability by inspections, tests, or analyses performed by the purchaser or third-party dedicating entity after delivery (Method 1), supplemented as necessary by one or more of the following: commercial-grade surveys (Method 2), product inspections or witness at holdpoints at the manufacturer's facility (Method 3), and analysis of historical records for acceptable performance (Method 4). In all cases, the dedication process must be conducted in accordance with the applicable provisions of Appendix B. (10 CFR Part 21).

j. 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.

k. Like-for-like Replacement: Replacement of an item with one that is identical.

l. Procurement Document: A contract that defines the technical and quality requirements that must be met in order to be considered acceptable by the purchaser.

m. 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.

n. 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.

43004-04 RESOURCE ESTIMATE

Inspection resources necessary to complete this inspection procedure are estimated to be 160 hours of direct inspection per facility.

43004-05 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."

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. (ADAMS Accession No. ML031140060)

U.S. Nuclear Regulatory Commission, Generic Letter 91-05, “Licensee Commercial-Grade Procurement and Dedication Programs.” NRC: Washington, DC. April 9, 1991. (ADAMS Accession No. ML031140508)

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

EPRI NP-5652, "Guideline for the Utilization of Commercial - Grade Items in Nuclear Safety-Related Applications (NCIG-07)."

EPRI TR-102260, “Supplemental Guidance for the Application of EPRI Report 5652 on the Utilization of Commercial-Grade Items.”

EPRI NP-6406, "Guidelines for the Technical Evaluation of Replacement Items in Nuclear Power Plants (NCIG-11)."

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 NP-7218, "Guideline for the Utilization of Sampling Plans for Commercial - Grade Item Acceptance (NCIG-19)."

EPRI TR-1019163, “Plant Support Engineering: Counterfeit, Fraudulent and Substandard Items – Mitigating the Increasing Risk.”

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

Final Safety Evaluation for Technical Report NEI 14-05, “Guidelines for the Use of Accreditation in Lie of Commercial-Grade Surveys for Procurement of Laboratory Calibration and Test Services,” Revision 1, dated on February 9, 2015, (ADAMS Accession No. ML14322A535)

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.” (ADAMS Accession No. ML103220180)

Information Notice 2014-11, “Recent Issues Related to the Qualification and Commercial-Grade Dedication of Safety-Related Components.” (ADAMS Accession No. ML14149A520)

Information Notice 2016-01, “Recent Issues Related to the Commercial-Grade Dedication of Allen Bradley 700-RTC Relays.” (ADAMS Accession No. ML1529A173)

Manual Chapter 2504, “Construction Inspection Program Inspection of Construction and Operational Programs.”
Manual Chapter 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, (ADAMS Accession No. ML15075A434)

Regulatory Issue Summary 2016-01, “Nuclear Energy Institute Guidance for the Use of Accreditation in Lieu of Commercial-Grade Surveys for Procurement of Laboratory Calibration and Test Services,” dated on March 16, 2016, (ADAMS Accession No. ML15323A346)

Safety Evaluation by the Office of Nuclear Reactor Regulation Proposed Change to the Quality Assurance Program Commercial-Grade Calibration Services Arizona Public Service Company, ET AL. Palo Verde Nuclear Generating Station, Units 1, 2, and 3, dated September 28, 2005, (ADAMS Accession No. ML052710224)

END

Appendices:
A. Dedication Issues
B. Contents of Dedication Packages

Attachment:
Revision History for IP 43004

APPENDIX A
DEDICATION ISSUES BASIS FOR THE SELECTION AND VERIFICATION OF CRITICAL CHARACTERISTICS

1. 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.

2. 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.

3. 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.

4. Reasonable Assurance

   The dedication process represents an acceptable method of achieving compliance with Appendix B to 10 CFR Part 50 with the purchaser assuming many of the responsibilities for ensuring quality and functionality of an item that had previously been the responsibility of the vendor. In this context, reasonable assurance consists of the purchaser 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, 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.

5. 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 in the supply chain and can question the purchaser on their assurances and best practices to avoid acceptance of those items.

SAMPLING

1. 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.

2. 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.

3. 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

1. 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.

2. 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.

3. 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.

4. 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 10 CFR Part 50, Appendix B, 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) NP-5652, "Guideline for the Utilization of Commercial-Grade Items in Nuclear Safety Related Applications (NCIG-07)," defines critical characteristics as "identifiable and measurable attributes/variables of a CGI, which once selected to be verified, provide reasonable assurance that the item received is the item specified." NRC's conditional endorsement of EPRI NP-5652 by Generic Letter 89-02 was based on interpreting that in the EPRI definition of critical characteristics the "item specified" encompassed those attributes that are essential for the performance of the item's safety function. This interpretation is consistent with the definition of "critical characteristics for acceptance" found in EPRI NP-6406, "Guidelines for the Technical Evaluation of Replacement Items in Nuclear Power Plants," which notes that critical characteristics for acceptance are a subset of "critical characteristics for design."

The EPRI NP-6406 definition of "critical characteristics for design" includes those attributes that ensure the performance of the item's design function.

EPRI TR-1019163, “Plant Support Engineering: Counterfeit, Fraudulent and Substandard Items- Mitigating the Increasing Risk” describes 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.

Published NRC guidance does not differentiate between design and acceptance critical characteristics and the CGI dedication guidance provided 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."

END

APPENDIX B
DEDICATION DOCUMENTS

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

- Purchase requisitions and purchase orders.
- Other pertinent vendor/licensee correspondence.
- 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.
- Catalog specifications.
- Procurement basis evaluation - like-for-like, equivalency, plant design change packages, drawing and specification updates.
- 10 CFR 50.59 safety evaluation, if required.
- Material receiving reports, packing lists/invoices, and other shipping documents.
- Receipt inspection reports and any related test reports.
- Other documents to trace the item from the time it was dedicated to the time it was installed, tested, and accepted.
- Certificates of conformance/compliance/quality.
- Vendor test and inspection reports.
- Third-party or subvendor test and inspection reports.
- Shelf life information.
- Vendor dedication/partial dedication information.
- Design/material/process change history information.
- Completed commercial-grade dedication document including:
  - safety classification
  - identification of safety functions/application requirements
  - identification of critical characteristics
  - identification of verification methods and acceptance criteria for the critical characteristicsevaluation of credible failure modes (if applicable)

- identification of the suppliers quality assurance program that meets 10 CFR Part 50, Appendix B

- Any deviation from design, material, and performance characteristics relevant to the safety function (nonconformance dispositions).

- Documents showing objective evidence:
  - special test and inspection procedures and results
  - commercial-grade survey reports -item, design, material, and specific performance characteristic (relevant to safety function)
  - source inspection reports

- Completed post-installation test procedure and results.

- Completed stock or material issue forms and installation work orders or reports.

- Historical performance information.

END

Attachment 1 - Revision History For 43004

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
N/A	10/03/07 CN 07 030	Researched commitments for 4 years and found none. Initial issuance	N/A	N/A
N/A	ML110871957 04/25/11 CN 11-007	Revised Inspection Procedure to refer to the applicable Manual Chapter. Added the applicable Manual Chapters to the references. This revision is in response to OIG audit (OIG-10-A-02 (ML103020267)).	N/A	N/A
N/A	ML13280A478 11/29/13 CN 13-027	This revision is a complete re-write. IP 38703 has been integrated into this procedure to have one CGD inspection procedure for the agency.	N/A	ML13280A479
N/A	ML16344A092 01/27/17 CN 17-002	Revised Inspection Procedure to incorporate the QA aspects involved in the use of ILAC accreditation process in lieu of commercial-grade surveys for laboratory calibration and testing services	N/A	ML16344A090