INSPECTION OF COMMERCIAL-GRADE DEDICATION PROGRAMS

PROGRAM APPLICABILITY: 2504, 2507, 2700

43004-01 INSPECTION OBJECTIVES

01.01 To verify that the facility's commercial-grade dedication program satisfies the requirements of Appendix B to 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 facility'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 dedication plan.

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.

Specific Guidance

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, and available industry data, to identify relevant technical information that may affect the suitability of the item.

3. Performance of a Failure Modes and Effects Analyses (FMEA) 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, long-term reliability/durability, 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.

All critical characteristics (i.e., those 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, licensees or applicants 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).

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

6. 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:

1. 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, safe-shutdown earthquake). Like-for-like replacements should demonstrate performance comparable to the qualified prototype.

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

3. Seismic and environmental qualification should be treated as critical characteristics to be verified.

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.

1. A replacement may be considered identical if:

   - The item was purchased from the same manufacturer (successor companies may be accepted provided all product changes can be identified, analyzed, and verified acceptable for the specific application), and

- The item has the same model or part number (number changes where no product change is verified may be accepted, considering drawing revision and/or date as drawings may change without an associated change in part number), and

- The item has the same manufacturing time frame as determined by, for example, date purchased or date shipped from factory, date code, same batch or lot number.

2. An equivalency evaluation should demonstrate that an alternate replacement is identical in form, fit, function process and material to the item it is replacing, and that it will function under all design conditions (including design-basis event conditions).

3. 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.

4. 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 redetermined. However, item acceptance, qualification of vendors and examination of products is still required.

5. 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, or interchangeability could impact the functional characteristics and ultimately the component's ability to perform its required safety function.

6. Equivalency evaluations should not be used as the sole basis to accept a CGI for safety-related use. All critical characteristics should still be verified as part of the acceptance process.

03.02 Verify that the entity inspected has established adequate controls for the acceptance of a CGI.

The following are the four acceptance methods that should be included in the dedication program and used to accept CGIs. The most appropriate acceptance method should be selected for each critical characteristic.

Method 1: Special Test and Inspections

1. Special test and inspections should be used after the CGI is received or during manufacture to assure that the purchased material, equipment, or service, whether purchased directly or through contractors and subcontractors, meet the technical and quality requirements.

2. 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

3. Receipt inspection activities should be used to establish and maintain traceability of CGIs.

4. Post-installation testing, functional tests before installation, and/or operational tests after installation may be performed to verify critical characteristics of the CGI.

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

6. 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. The CGI sampling process should be documented to develop the necessary objective evidence of the vendor's ability to consistently provide acceptable items.

7. 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.

8. 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 ensured (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.

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

Method 2: Commercial-Grade Survey of Supplier

1. 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.

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

3. 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.

4. 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.

5. 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.

6. 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.

7. 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.

8. 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.

9. 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.

10. 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 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.

11. 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.

12. 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.

13. 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. Likewise, 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).

Method 3: Source Verification

1. 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.

2. 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.

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

Method 4: Acceptable Supplier/Item Performance Record

1. This method could be used to accept one or more critical characteristics based upon a confidence in the supplied item achieved through proven performance of the item. The purchaser can also take credit for item performance based upon historical verification, acceptable quality control of critical characteristics, or acceptable industry-wide performance. 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) and from commercial-grade surveys, source verifications, receipt inspections, previous dedication or qualification, and operational history is factored into the dedication process. The established historical record is based on acceptable industry-wide performance data that is directly applicable to the item's critical characteristics and the intended safety-related application.

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.

3. This method is more suited to providing a basis for sampling plans.

4. This method should not be employed alone unless the established historical record is based on industry-wide performance data.

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 Definitions

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.

Certificate of Compliance: A document attesting that the materials are in accordance with specified requirements.

Certified Material Test Report: 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.

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.

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 specifically designated commercial-grade items to be purchased, 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.

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.

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.

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.

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 and verifying their acceptability by inspections, tests, or analyses performed by the purchaser or third-party dedicating entity after delivery, supplemented as necessary by one or more of the following: commercial-grade surveys; product inspections or witness at holdpoints at the manufacturer's facility, and analysis of historical records for acceptable performance. In all cases, the dedication process must be conducted in accordance with the applicable provisions of Appendix B. The process is considered complete when the item is designated for use as a basic component.

Engineering Judgment: A process of logical reasoning that leads from stated premises

to a conclusion. This process should be supported by sufficient documentation to permit verification by a qualified individual.

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

Procurement document: A contract that defines the technical and quality requirements which facilities or basic components must meet in order to be considered acceptable by the purchaser.

Source Verification: Activities witnessed at the supplier's facilities by the purchaser or its agent for specific items to verify that a supplier of a commercial-grade item controls some or all the critical characteristics of that item, as a method to accept those characteristics only.

Traceability: Is 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.)

NRC Inspection Procedure (IP) 38703, "Commercial-Grade Dedication."

ANSI/ASME NQA-1, "Quality Assurance Program Requirements for Nuclear Facility Applications," 1994 Edition

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

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)"

END