

# NRC INSPECTION MANUAL

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## INSPECTION PROCEDURE 88114

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### QUALITY AFFECTING ITEM PROCUREMENT (10 CFR PART 21) AND COMMERCIAL GRADE ITEM DEDICATION PROCESS (REACTIVE)

PROGRAM APPLICABILITY: 2630

#### 88114-01 INSPECTION OBJECTIVES

To determine whether the failure of an item relied on for safety (IROFS) was the result of a deficient quality-affecting item (QAI) procurement process (10 CFR Part 21) or a commercial-grade item (CGI) dedication process.

#### 88114-02 INSPECTION REQUIREMENTS

02.01 Reactive Inspection Requirements (to be performed after the failure of a QAI or CGI dedicated for safety-related applications during the pre-operational or operational phases).

- a. Initial Evaluation After reviewing the licensee's evaluation of the failed item, determine if the failed item was procured as a QAI or CGI and dedicated for safety-related applications. If the failed item was dedicated, review the complete procurement and dedication records to determine if the commercial-grade dedication process was sufficiently thorough.
- b. Further Assessments If it is determined that the dedicated item failed as the result of certain critical characteristics not being identified and/or properly verified, perform the following assessments:
  1. Determine if other QAIs or CGIs from the same accepted lot or batch as the failed QAI or dedicated CGI have been similarly dedicated and installed in other safety-related applications. If yes, determine if the licensee has evaluated the operability of the systems or components where these QAIs or CGIs are installed. The inspector also should review licensee-provided data, if available, for some CGIs (non-dedicated) that failed in applications that were not safety-related. Explore the possibility that the same CGIs also may have been used (following dedication) in a safety-related application and may have the potential to affect the safe operation of a structure, system or component (SSC).
  2. If possible select and evaluate, as in step 1 above, at least three other QAIs or dedicated CGIs having similar applications and critical characteristics as the QAI(s) or CGI(s) that resulted in the identified failures.

02.02 Programmatic Reactive Inspection Requirements (If, after performing the step above, it is determined that there were weaknesses in the CGI dedication process, the

inspector should perform a more comprehensive inspection of the licensee's dedication process, in accordance with the inspection requirements in Section 02.02 below.)

- a. Review of Program and Procedures Using the inspection guidance contained in Section 03.02 and Appendix A to this procedure, review the licensee's program and procedures for the procurement of QAs and procurement and dedication of CGIs, to understand the basic operation of the licensee's program.
- b. Selection of Dedication Packages Select several dedication packages for evaluation from a list of commercially dedicated items provided by the licensee. Request that the licensee provide (or make available for review) a complete package of the pertinent procurement and dedication records for each item.
- c. Evaluation of Dedication Packages Using the inspection guidance contained in Section 03.01 of this procedure, perform a detailed evaluation of the dedication packages selected in item b, above.
- d. Evaluation of Training Effectiveness If the inspector's evaluation of commercial-grade dedication activities indicates there are weaknesses in the way these activities are being performed, the inspector should investigate further to determine if weaknesses within the licensee's training program may have contributed to the cause. The inspector should determine if the licensee is implementing an effective training program.

#### 88114-03 INSPECTION GUIDANCE

Background. Licensees are required to ensure the quality of items purchased and installed in safety-related applications. In the past, licensees procured major assemblies from approved vendors who maintained quality assurance (QA) programs pursuant to the licensee's NRC-approved QA program requirements. Because of the decrease in the number of qualified vendors, licensees are increasing the number of commercial-grade replacement parts that they procure and dedicate for use in safety-related applications.

Since CGI dedications have increased in number, it is intended that this inspection procedure provide guidance to assist the inspector in assessing the effectiveness of the implementation of the licensee's commercial-grade procurement practices and provide for identification of any adverse trends or emerging problems.

Scheduling the Inspection. This inspection procedure should be considered for implementation when there is reason to believe that the failure of an IROFS, or a part thereof, to perform its intended safety function, was the result of weaknesses in QA procurement or CGI dedication. This inspection procedure may be implemented independently, or it may be used as a supplement to other major team inspections. Such inspections may include maintenance; modification; or system-specific inspections, where review of failed IROFS, or parts thereof, is appropriate; or an augmented inspection team investigating failures.

Before the beginning of the onsite inspection, advise the licensee of information that will be needed, such as a list of items that the licensee purchased as commercial grade and subsequently dedicated for use in safety-related applications. In addition, the inspector should request and review the licensee's program and procedures to become familiar with the licensee's procurement and dedication process. Also explore with the licensee the possibility of obtaining a list of recent component failures. The list of component failures can be used by the inspector, during the selection of dedication packages for review, as described in this inspection procedure.

## SPECIFIC GUIDANCE

### 03.01 Reactive Inspection

- a. Initial Evaluation. A failure resulting from general weaknesses in the QAI procurement or commercial-grade dedication program may occur when the important design, material, and performance characteristics that are necessary to provide reasonable assurance that the QAI or dedicated CGI will perform its intended safety function are not addressed during procurement or dedication. For example, failures of safety-related bolting have occurred when the dedication process did not verify that the material composition and/or mechanical properties met the specified requirements, and nonconforming material was supplied.

Review and discuss, with licensee personnel, the failure/root-cause analysis when required or applicable for the failed QAI or CGI. The inspector should attempt to determine if the failure was caused by a design deficiency, failure unrelated to the item's safety function, or normal wear, and eliminate these from further review. The inspector should focus on the inspection of failures that appear to be caused by weaknesses in the commercial-grade dedication process. If none of the failures are caused by weaknesses in the commercial grade dedication process, then the inspector should not continue using this inspection procedure. If the inspector decides to change the focus of the inspection to examine other issues related to the failures, such as the adequacy of corrective actions, other procedures should be used. Once the failure mode and cause of failure have been postulated or determined, review the dedication package to determine if the licensee had identified critical characteristics. Appendix A to this inspection procedure should not be interpreted as inspection requirements, but only as a discussion of dedication issues, including guidance on selection and verification of critical characteristics. Appendix A, if properly implemented, represents an acceptable means of complying with regulatory requirements. The licensee may develop alternate methods of achieving compliance with 10 CFR Part 70, the Construction Authorization Request, the QA Plan; and the implementing procedures. Appendix B to this inspection procedure, provides definitions of terms used for commercial-grade dedication activities, and Appendix C provides the typical contents of a dedication package.

The goal of the review of the procurement or dedication packages is to provide reasonable assurance that the CGIs dedicated for safety-related applications will perform their intended safety functions. Inspection effort should be directed toward the identification of weaknesses, in the dedication process, that could potentially render IROFS, or parts thereof, inoperable.

(1) Review of Dedication Packages. After becoming familiar with the licensee's procurement and dedication program and procedures, perform a detailed review of dedication packages as described below.

- Determine if the safety function of the item for its intended use has been identified by reviewing the documents associated with the technical evaluation including, as applicable:
  - Classification of the item,
  - Consideration of credible failure modes, and
  - Item equivalency/substitution evaluations.

- Determine if the important design, material, and performance characteristics, necessary to provide reasonable assurance that the item will perform its intended safety function (critical characteristics), have been identified.
- Determine whether the licensee verified the critical characteristics, using appropriate acceptance methods. If appropriate, take into account post-installation testing and periodic surveillance testing and inspection. Review the engineering judgment when it is used as the basis for selection or verification of critical characteristics.
- Determine whether the item is an equivalent replacement or a new-item replacement of an obsolete item.
- Determine if the item is or may be used in a different safety-related application, than previously evaluated, in which different design, material, and performance characteristics may be applicable. This is especially applicable for generic dedications of bulk items and stock material. Determine if the dedication ensures the acceptability of those design, material, and performance characteristics relevant to the safety function.
- Determine why the item is being replaced. Have there been repeated failures? Is the degraded performance a result of adverse environment? Did it fail because it was a refurbished or fraudulent item?
- Determine how the identity of the item is controlled from the time it is receipt inspected, until the time it is installed.
- Determine if information learned during the dedication process is fed back to the appropriate persons to evaluate existing stock items, or installed items, and for future use in surveys and source verifications. This information could include positive and adverse findings obtained during surveys and source verifications.

Refer to the discussion of significant dedication issues in Appendix A for guidance during the review of dedication packages. Also refer to the specific guidance for each of the four dedication methods provided below.

Focus should be on those activities that are likely to affect the performance of the items being dedicated. Although the acceptance process for dedication is subject to the licensee's U.S. Nuclear Regulatory Commission approved QA program requirements, it is not necessary to review the licensee's programmatic compliance to the QA requirements, since they may not apply to the activities reviewed. The licensee's NRC-approved QA program requirements do not apply to commercial-grade activities, that occur before dedication for use in a safety-related system. It also should be recognized that Appendix B provides for the application of QA to safety-related systems and components consistent with their importance to safety (graded-quality approach).

Although guidance concerning the application of graded QA is discussed in the first paragraph of Appendix A to this inspection procedure, it is expected that the inspector will need to exercise considerable judgment in determining the adequacy of controls applied to a specific activity.

## (2) Review of Acceptance Methods

The following are the four acceptance methods that can be used to accept CGIs. These methods provide, either individually or in combination, a means to

reasonably ensure that a CGI that is received meets the requirements of the item specified. The results of employing each method should be documented.

### Method 1 - Special Tests and Inspections

General information on similar activities is provided in American National Standards Institute (ANSI N45.2.13-1976), Section 10, "Acceptance of Item or Service." Use the following approach to review packages that were dedicated using this method:

- To the extent practicable, attempt to witness receipt inspections and tests of in-process dedication of CGIs similar to that of the failed item, to verify the identified critical characteristics.
- Review receiving records and associated tests and inspections.
- Review post-installation test records.
- Verify that the tests and inspections specified for acceptance adequately verify the identified critical characteristics.
- Verify that sampling plans are controlled and have adequate technical basis, considering lot traceability and homogeneity, complexity of the item, and adequacy of supplier controls.
- Verify that CGI receiving inspection activities are adequately controlled, under a quality program, regardless of whether they are being performed in conjunction with other plant receipt inspection activities.
- Verify that receipt inspection activities establish and maintain traceability of CGIs by capturing and appropriately relating traceability documents through identification and monitoring of CGIs.
- Verify that measuring and test equipment were properly calibrated, that approved vendors were used to perform tests, and that personnel were qualified to perform the tests.

### Method 2 - Commercial-Grade Survey

Use the following guidance to review packages that were dedicated using this method:

- Confirm that: (1) the documented commercial-quality program was effectively implemented; and (2) the surveys were conducted at the location necessary to verify that adequate controls were exercised on distributors as well as manufacturers.
- Through interview, determine if the persons who perform vendor surveys are knowledgeable in the following:
  - The use of performance-based surveys
  - Screening third-party surveys; and
  - Processing and evaluating adverse findings resulting from the review of third-party surveys, to ascertain if those findings affect CGIs already installed, or stored in the warehouse, awaiting future installation.

- Verify that the supplier's commercial quality controls are imposed in the procurement documents.
- Determine if the critical characteristics that are to be verified by the survey team are accurately and completely incorporated in the survey plans.
- Determine if the validity of supplier documentation, relied on in the dedication of the item, is verified during the survey.
- Determine if surveys of commercial-grade suppliers are performance based, as opposed to programmatic. Specifically, verify that the critical characteristics for the CGIs being surveyed are controlled by the supplier's quality activities.
- Determine if survey teams include technical and quality personnel, as appropriate, who are knowledgeable in the operation of the item(s) and the associated critical characteristics to be verified, including any special processes such as welding and heat treatment that are specific to the critical characteristics.
- Determine if surveys are conducted at appropriate times relative to the procurement. Are surveys required to be updated on a regular basis to support dedication?
- Determine if the control of subvendors is adequately addressed by the surveys so that the supplier has an adequate basis to accept test results and certifications from the subvendor.
- Determine if pertinent information about a supplier or its products is used to plan, conduct, and report results of surveys and source verifications. Such information could have been available from source verifications, receiving inspections, the dedication process, supplier/product performance history, or outside sources, such as NRC information notices and bulletins.

### Method 3 - Source Verification

Use the following approach to review packages that were dedicated using this method:

- Determine if source verifications involve witnessing the supplier performing quality activities on the actual items being procured and adequately verify the item's critical characteristics.
- Determine if personnel who participated in the source verification surveys were qualified for their specific assignment.
- Determine if appropriate hold points are imposed in the purchase orders. This would include a hold point to verify design, material, and performance characteristics, relevant to the safety function, that cannot be verified after the item has been completely manufactured.
- Determine if the results of the source verifications were adequately documented.

## Method 4 - Acceptable Supplier/Item-Performance Record

Use the following guidance to review packages that were dedicated using this method:

- Determine if (1) the established historical record is based on industry-wide performance data that are directly applicable to the item's critical characteristics and the intended safety-related application; and (2) the manufacturer's measures for the control of design, process, and material changes have been adequately implemented, as verified by survey (multi-licensee team surveys are acceptable).
- Determine if information pertinent to the CGI's quality of performance, obtained from outside sources (e.g., operational event reports, NRC, vendor equipment, and technical information program) and from commercial-grade surveys, source verifications, receipt inspections, previous dedication, or qualification and operational history, is factored into the dedication process.
- Determine if the item or manufacturer is included in the licensee's performance-trending program.

### b. Further Assessments

1. No inspection guidance.
2. From the list of dedicated items provided by the licensee, the inspector should select for review approximately three other dedication packages having similar applications and critical characteristics as the CGI(s) that resulted in the identified failures. After the selections have been made, the inspector should request that the licensee 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. The inspector should review the dedication packages.
3. No inspection guidance.

### 03.02 Programmatic Inspection

- a. Review of Program and Procedures. The review of the program and procedures should be performed to familiarize the inspector with the licensee's QAI procurement and CGI dedication process. For cases in which problems are identified with the licensee's CGI dedication process, the inspector may decide to perform a more extensive review of the program and procedures, to determine if these problems are the result of inadequate procedures.

The inspector's review should include procedures for: (1) procurement activities; (2) material control; (3) the dedication of CGIs, including receipt inspection and acceptance testing; (4) surveys of commercial-grade suppliers; (5) classification of components; (6) training of personnel; (7) trending of supplier performance; and (8) equipment failures. Attempt to identify any apparent weak areas to concentrate on during the evaluation of the program implementation.

After arriving onsite, the inspector should request that the licensee explain its commercial-grade dedication process and conduct a walk-through of areas associated with it. Areas in the walk-through could include the engineering, receipt inspection, component testing, and warehouse. The inspector should become familiar with key licensee personnel involved in the commercial-grade dedication

process. These key personnel should include the responsible engineer(s) who developed the dedication package(s), and systems engineers, procurement engineers, receipt inspectors, QA engineers and inspectors, and warehouse personnel. The inspector should discuss the commercial-grade dedication process with these key personnel, to gain a better understanding of the process, including:

- How processing of QAI and CGI procurement documents is controlled under the QA program and how quality control will receive, review, and approve items.
- How technical personnel participate in the preparation, review, and approval process of procurement documents.
- How consistency and coordination is maintained between corporate level, engineering/support level, and site-level programs and implementing procedures.

b. Selection of Dedication Packages.

The selection process should be performance-oriented (e.g., weighted toward the review of dedication packages for equipment, components, or parts that have experienced failures). To accomplish this, the inspector should request, from the licensee, several packages for review, using the two-step approach described below. The licensee should be given sufficient lead time to prepare the packages and make them available for the first day of onsite inspection.

Step 1: Review the licensee's records available at the plant site, to identify recent failures (approximately the last 2 years) of equipment, components, or parts. Review these failures to determine if any were QAIs or CGIs dedicated for use in safety-related applications. If available, select approximately 75 percent of the total sample from QAI or CGI failures.

Step 2: From the list of dedication packages supplied by the licensee, under the "Inspection Guidance" section of this procedure, select the remainder of packages for review. The total sample size will vary, depending on the complexity of the packages and the time available. The inspector should select these packages on the basis of the following considerations:

- The inspector should select packages for items whose failure would have the most effect on the ability of the facility to safely operate, safely shutdown from an adverse condition, or maintain a safe shut down condition. If time permits, review the plant-specific integrated safety analysis and the safety evaluation report that provides information on the risk significance of safety-related plant equipment.
- The inspector should take a performance-oriented approach, to the selection process, by including, in the sample packages, those items that have been problems in the past. Review available sources of information to identify any known failures of QAIs or CGIs that were used in safety-related applications. These sources of information could include:
  - Component failure lists or lists of items requiring frequent maintenance or replacement, as provided by the licensee.
  - Misrepresented or fraudulent items reported in NRC information notices.
  - Licensee trending of equipment and supplier performance.
  - Previous history of component failures or malfunctions, as reported in licensee event reports or plant nonconformance reports.



- The inspector should include both simple and complex packages in the sample, as well as packages that include a variety of dedication methods (e.g., Methods 1 through 4) described above.
  - In addition to selecting packages based on the above considerations (safety significance, complexity, and failures), the inspector should attempt to select samples from each of the following areas: electrical, instrumentation and control, mechanical equipment, and materials.
- c. Evaluation of Dedication Packages. Perform a detailed review of the dedication packages, as described above.
- d. Evaluation of Training Effectiveness. Experience gained during the procurement assessments and pilot inspections suggested that training of personnel involved in CGI dedication activities was a very important factor in the development of a good CGI dedication program. The CGI dedication process generally requires more highly qualified/trained personnel than specified in the licensee's procurement program requirements. Personnel involved in this process need to be familiar with current industry and NRC guidance and have a strong interface with the licensee's design/engineering organizations. The training expectations, however, should not exceed what is required by the existing licensee's QA program.

As applicable to their job functions, select and review the training records for individuals involved in the following areas:

- Determining the safety classification of an item. Training in this area is appropriate when the job function includes reclassification of items or establishing safety classification of piece parts of safety-related components.
- Specifying design, material, and performance characteristics relevant to the safety function and establishing the acceptance criteria for these characteristics.
- Specifying or performing commercial-grade surveys, source verifications, and tests and inspections, including enhanced post-receipt verification testing or inspection.
- The preparation and review of procurement documents.

Through observation, interviews, and a review of records of work performed by the individuals:

- Determine if the individuals selected have adequate knowledge to perform the specific tasks assigned to them. Attend a training course, if available, or review the lesson plans for selected training courses.
- Determine if training inadequacies contributed to any of the deficiencies that may be identified during the inspection.
- Determine if the personnel are familiar with the program requirements and procedures and if they have been properly trained in the dedication process.

#### 88114-04 INSPECTION RESOURCES

This inspection procedure should be considered for implementation when there is reason to believe that the failure of an IROFS, or a part thereof, to perform its intended safety

function, was the result of weaknesses in QAI procurement or CGI dedication (reactive inspection). This inspection procedure may be implemented independently or it may be used as a supplement to other major team inspections. It is expected that this inspection should consist of one inspector on site for 16-24 hours.

## 88114-05 REFERENCES

The following documents are listed for the inspector's information only and are not considered regulatory requirements unless the licensee has formally committed to implementing any of these documents for application to safety-related activities. The inspector may wish to review these documents to become familiar with commercial grade dedication issues.

American National Standards Institute, ANSI N45.2-1977, "Quality Assurance Program Requirements for Nuclear Power Plants," as endorsed by NRC Regulatory Guide 1.28, Revision 2.

American National Standards Institute, ANSI N45.2.13-1976, "Quality Assurance Requirements for Control of Procurement of Items and Services for Nuclear Power Plants," as endorsed by NRC Regulatory Guide 1.123, Revision 1.

Duke, Cogema, Stone and Webster, "Mixed-Oxide Fuel Fabrication Facility, MOX Project Quality Assurance Plan (MPQAP)", Docket Number 070-03098, under US Department of Energy Contract DE-AC02-99-CH10888, latest revision accepted by NRC.

Duke, Cogema, Stone and Webster, "Mixed-Oxide Fuel Fabrication Facility Construction Authorization Request", latest revision accepted by NRC.

Electric Power Research Institute (EPRI) NP-5652, "Guidelines for the Utilization of Commercial-grade Items in Nuclear Safety-Related Applications (NCIG-07)," as conditionally endorsed in NRC Generic Letter 89-02.

U.S. Nuclear Regulatory Commission, Generic Letter 89-02, "Actions to Improve the Detection of Counterfeit and Fraudulently Marketed Products" (microfiche 48960-001).

U.S. Nuclear Regulatory Commission, Generic Letter 91-05, "Licensee Commercial Grade Procurement and Dedication Programs" (microfiche 57468-264).

END

Appendices:

- A. "Dedication Issues"
- B. "Definitions"
- C. "Contents of Dedication Packages"

## 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

The application of graded QA 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, whereas others may require only a limited QA involvement in selected phases of development. The following factors should be considered in determining the extent of QA 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 QA can be found in the non-mandatory appendix to American National Standards Institute 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 the licensee's U.S. Nuclear Regulatory Commission-approved quality assurance program, with the purchaser assuming many of the responsibilities for ensuring quality and functionality of an item that had previously been the vendors responsibility. 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 QA 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 an NRC approved QA program.

#### 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 used 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 nor 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.

### 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 to 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. On 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: (1) The identification of the item or items for which the vendor is being surveyed; (2) identification of the critical characteristics of these items that the vendor is expected to control; (3) identification of the controls to be applied (program/procedure and revision); and (4) 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 using 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.

## 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.

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 NRC's definition of critical characteristics to the EPRI definition of "critical characteristics for acceptance."

END

## APPENDIX B

### DEFINITIONS

The following terms are listed to provide the inspectors with working definitions of important terms used during the procurement and dedication of commercial-grade items (CGIs). These terms are defined only in the context of the CGI dedication process and are solely to aid the inspector in the inspection process.

Basic Component - A plant structure, system, component, or part thereof necessary to ensure one of the following:

- The integrity of the reactor coolant pressure boundary
- Capability to shut down the reactor and maintain it in a safe shutdown condition; and
- The capability to prevent or mitigate the consequences of accidents that could result in offsite radiation exposures comparable to those referred to in 10 CFR 100.11.

Basic components are items designed and manufactured under a U.S. Nuclear Regulatory Commission-approved quality assurance program, or CGIs that have successfully completed the dedication process. (See definition in 10 CFR 21.3.)

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, tests, and examinations.

Commercial Grade Item (CGI) - A CGI means a structure, system, or component, or part thereof, that affects its safety function, which was not designed nor manufactured as a basic component. CGIs do not include items that have one or more critical characteristics that cannot be verified by one or more acceptance methods (see definition in 10 CFR 21.3).

Commercial-Grade Survey - Activities conducted, by the purchaser or its agent, to verify, that a supplier of CGI controls, through quality activities, the critical characteristics of specifically designated CGIs, as a method to accept those characteristics, only without further dedication for safety-related use.

Critical Characteristics - Those important design, material, and performance characteristics that, once verified, will provide reasonable assurance that the item will perform its intended safety function.

Dedication - An acceptance process undertaken to provide reasonable assurance that a CGI to be used as a basic component will perform its intended safety function. This process includes the identification of critical characteristics and their verifications by one or more of the dedication methods. (See definition in 10 CFR 21.3.)

Dedicating Entity - The organization that performs the dedication activity. Dedication may be performed by the manufacturer, a third-party dedicating entity, or the licensee itself. (See definition in 10 CFR 21.3)

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.

Source Verification - Activities witnessed at the supplier's facilities, by the purchaser or its agent, for specific items, to verify that a supplier of CGIs controls the critical characteristics of that item as a method to accept those characteristics, only without further dedication for safety-related use.

Traceability - Is the ability to verify the history, location, or application of an item, by means of recorded identification.

END



## APPENDIX C

### CONTENTS OF DEDICATION PACKAGES

The dedication packages 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 70.72 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 sub-vendor 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 characteristics,
  - Evaluation of credible failure modes (if applicable), and
  - Identification of the supplier's quality assurance program that meets the licensee's U.S. Nuclear Regulatory Commission-approved quality assurance program.

- 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), and
  - 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 IP 88114

Commitment Tracking Number	Issue Date	Description of Change	Training Needed	Training Completion Date	Comment Resolution Accession Number
	10/25/06 CN 06-031 06-NMSS	IP 88114 is a newly issued procedure. Issued for MOX inspection program to improve effectiveness and efficiency by incorporating and consolidating inspection requirements involving commercial grade dedication and 10 CFR Part 21 inspection.	None	N/A	