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NUCLEAR REGULATORY COMMISSION
OFFICE OF NUCLEAR REACTOR REGULATION
OFFICE OF NEW REACTORS
OFFICE OF NUCLEAR MATERIALS SAFETY AND SAFEGUARDS
WASHINGTON, DC 20555-0001

February 15, 2011

NRC INFORMATION NOTICE 2011-01: COMMERCIAL-GRADE DEDICATION ISSUES IDENTIFIED DURING NRC INSPECTIONS

ADDRESSEES

All holders of an operating license or construction permit for a nuclear power reactor issued under Title 10 of the *Code of Federal Regulations* (10 CFR) Part 50, "Domestic Licensing of Production and Utilization Facilities," except those who have permanently ceased operations and have certified that fuel has been permanently removed from the reactor vessel.

All holders of or applicants for an early site permit, standard design certification, standard design approval, manufacturing license, or combined license issued under 10 CFR Part 52, "Licenses, Certifications, and Approvals for Nuclear Power Plants."

All holders of or applicants for a license for a fuel cycle facility issued pursuant to 10 CFR Part 70, "Domestic Licensing of Special Nuclear Material," or 10 CFR Part 40, "Domestic Licensing of Source Material."

All vendors that supply basic components to NRC-licensed facilities.

PURPOSE

The U.S. Nuclear Regulatory Commission (NRC) is issuing this information notice (IN) to summarize the NRC staff's observations and findings in the area of commercial-grade dedication (CGD), as it applies to operating reactors, over the previous 2 years. The NRC expects recipients to review the information and to consider actions, as appropriate, to review lessons learned and avoid similar problems. Suggestions contained in this IN are not NRC requirements; therefore, no specific action or written response is required.

DESCRIPTION OF CIRCUMSTANCES

This IN summarizes NRC staff findings from vendor inspections related to CGD performed over the last 2 years. The NRC Office of Nuclear Reactor Regulation and Office of New Reactors perform vendor inspections; one of the areas covered in these inspections is CGD. CGD is the 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 a quality assurance (QA) program under Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," to 10 CFR Part 50, "Domestic Licensing of Production and Utilization

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Facilities." The following summary of NRC staff findings from vendor inspections done in the last 2 years is divided into four main areas of concern: (1) lack of engineering justification during the CGD process, (2) documentation, (3) vendor audits versus commercial-grade surveys, and (4) sampling plans.

Lack of Engineering Justification during the CGD Process

NRC inspectors found several instances in which the vendor made design or engineering changes during the dedication process without an engineering justification to validate these changes.

During the review of a dedication package for a stainless steel ball bearing, the NRC inspectors noted that an ElectroSpot test was performed instead of the required Rockwell hardness test for critical metallic parts identified in a technical memo that was part of the dedication package. The NRC inspectors determined that the ElectroSpot test provided reasonable assurance of the material composition. However, the vendor performing the dedication did not have an engineering justification for the acceptability of the ElectroSpot method instead of hardness testing.

NRC inspectors also identified a lack of engineering justification while reviewing the dedication package for a battery cell cover. This dedication package contained a table that defined the critical characteristics (CCs) and dedication requirements for battery components. A previous version of this table identified the battery cell cover as having a safety-related function, but the current version identified the cover as nonsafety related. In this instance, the vendor failed to provide engineering justification for downgrading the function of the battery cell cover from safety related to nonsafety related.

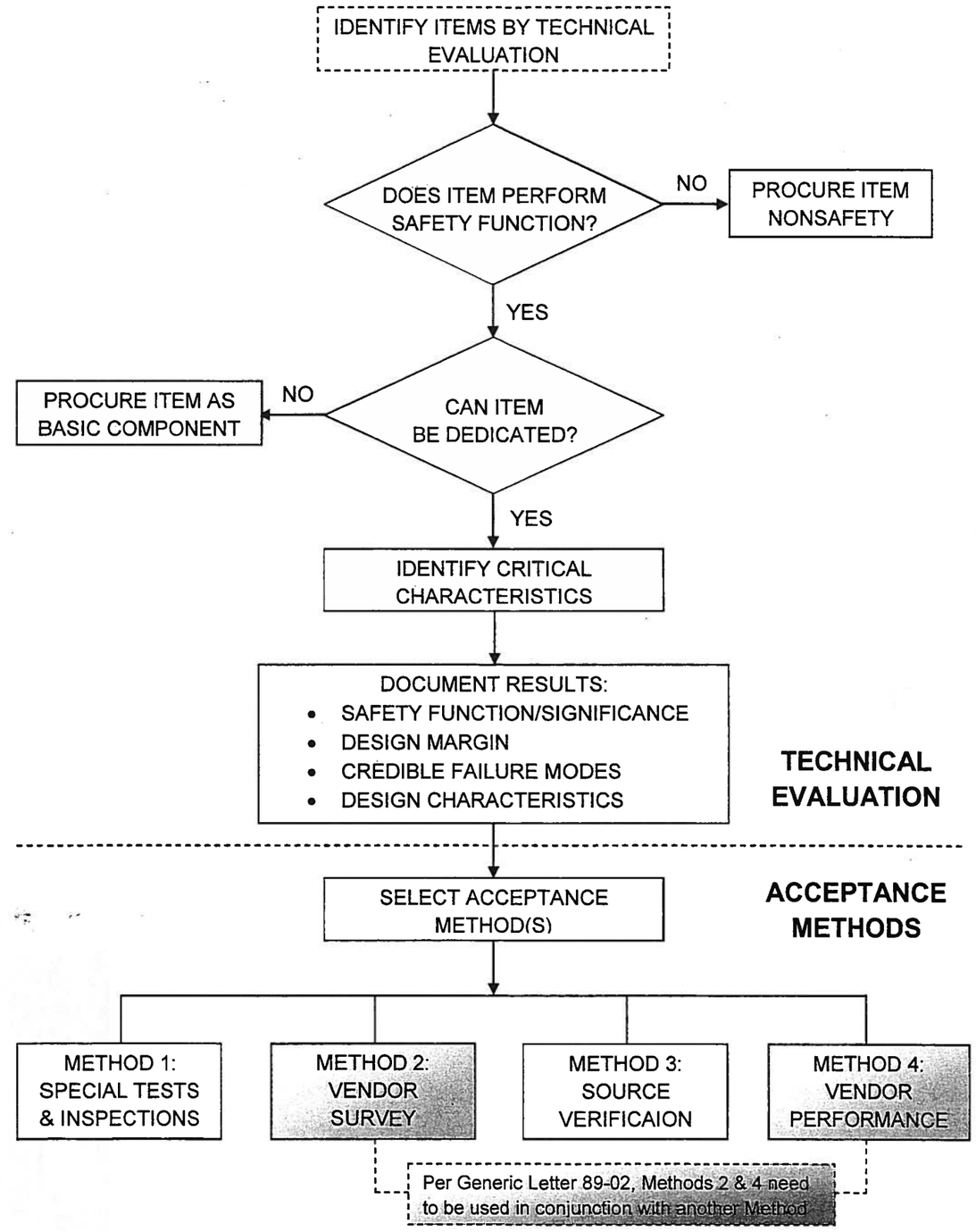
Documentation of the CGD Process

In order to have an acceptable CGD program, the vendor must document the dedication process, from the selection of the CCs to the acceptance criteria and acceptance methods used to verify these CCs. Additionally, the purchaser or licensee should review and approve the CGD package before the dedication of the item. CGD is an engineering process that concludes with the reasonable assurance that a commercial-grade item to be used as a basic component will perform its intended safety function. Each step taken during the dedication process should be documented and auditable.

During review of a dedication package, the NRC inspectors noted that a locked rotor current test could not be completed to the motor's rated voltage because of testing equipment limitations. The motor was tested by application of single-phase power to two of the motor's terminals. Institute of Electrical and Electronics Engineers (IEEE) Standard 112-2004, "IEEE Standard Test Procedure for Polyphase Induction Motors and Generators," permits this test to be performed in lieu of mechanically locking the rotor to check the quality of squirrel-cage machines. The motor successfully completed the test; however, the vendor's dedication plan failed to document the IEEE standard or list the single-phase test as an acceptance criterion.

During an inspection of a vendor's CGD process, the NRC inspectors noted that all components for an item were procured as commercial grade. The components that had CCs were identified.

Attachment 1: General Steps to Perform Commercial-Grade Dedication*



* This is a graphical representation of the commercial-grade dedication process used for illustrative purposes only and based on the guidance in Electric Power Research Institute NP-5652, "Guideline for the Utilization of Commercial Grade Items in Nuclear Safety-Related Applications (NCIG-07)," dated June 1, 1988.

CONTACT

This IN requires no specific action or written response. Please direct any questions about this matter to the technical contact listed below or to the appropriate Office of Nuclear Reactor Regulation project manager.

Timothy J. McGinty, Director
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Note: NRC generic communications may be found on the NRC public Web site, http://www.nrc.gov, under Electronic Reading Room/Document Collections.

Attachment 1: "General Steps to Perform Commercial-Grade Dedication"

However, none of the CCs had any documented technical evaluation or acceptance method bases.

The NRC inspectors identified one instance in which a vendor's QA manual did not define or document its dedication process as a controlled activity under Appendix B to 10 CFR Part 50. The vendor also did not have procedures for implementing dedication activities. The vendor performed dedication primarily by using Method 1 of Electric Power Research Institute (EPRI) NP-5652, "Guideline for the Utilization of Commercial Grade Items in Nuclear Safety-Related Applications (NCIG-07)," dated June 1, 1988. During the inspection, the NRC staff noted that some of the dedication packages did not contain signoffs or records that indicated the units were inspected by the in-process inspection department before being certified by the QA department, as required by the vendor's dedication process.

Vendor Audit versus Commercial-Grade Survey

A commercial-grade survey provides the purchaser with a method to take credit for the documented programmatic controls that the supplier applies to a CC for a given item. Guidance in EPRI NP-5652 states that the purchaser must confirm, as part of the survey, that the selected commercial-grade item's CCs are controlled under a documented quality program for the scope of the activity. The NRC inspectors found various instances in which the vendor performed limited-scope audits of the commercial subsupplier's QA program rather than a commercial-grade survey specific to certain CCs of an item. If Method 2 (see Attachment 1 diagram) will be used as an acceptance method as part of the dedication of an item, the guidance in EPRI NP-5652 states that a commercial-grade survey of the commercial supplier should be performed.

During one vendor inspection, the NRC inspectors found that a vendor's commercial-grade survey failed to verify that the subvendor's quality controls included specific processes, such as material traceability and lot or batch controls, relevant to the CCs to support the sampling plan during the dedication process.

The NRC inspectors also noted that one vendor performed a limited-scope audit of a subsupplier that had an International Organization for Standardization (ISO) 9000 QA program. The inspectors determined that the subsupplier should have been surveyed as part of the dedication process because only organizations maintaining a QA program meeting the intent of Appendix B to 10 CFR Part 50 are subject to audits. Suppliers maintaining commercial QA programs are surveyed as part of the dedication process for a specific item. In this instance, the vendor did not maintain a quality program that meets Appendix B to 10 CFR Part 50 and therefore an audit was not acceptable.

Sampling Plans for Commercial-Grade Item Dedication

Sampling of commercial-grade items during dedication should provide reasonable assurance that items inspected and tested conform to specification requirements. Sampling of items for dedication can be controlled by establishing heat traceability of metallic material or establishing lot/batch controls on the components. When neither can be established, documented sampling plans can be established on an individual, item-specific basis for providing assurance of the items suitability. Guidance on how sampling is used during commercial-grade item dedication

and the selection of sampling plans is described in NRC Inspection Procedures (IP) 38703, "Commercial Grade Dedication," and IP 43004, "Inspection of Commercial-Grade Dedication Programs."

NRC inspectors found cases during vendor inspections where vendor procedures did not provide adequate guidance for the development of sampling plans. In two inspections, vendor procedures did not provide adequate guidance for the development of sampling criteria to include qualitative factors, such as safety significance of the item, adequacy of supplier controls, complexity of the item, and performance history to ensure adequate selection, documentation and implementation of sampling plans.

BACKGROUND

The following NRC and industry documents address the CGD process:

- Generic Letter (GL) 89-02, "Actions to Improve the Detection of Counterfeit and Fraudulently Marketed Products," dated March 21, 1989 (Agencywide Documents Access and Management System (ADAMS) Accession No. ML031140060)
- GL 91-05, "Licensee Commercial-Grade Procurement and Dedication Programs," dated April 9, 1991 (ADAMS Accession No. ML031140508)
- Inspection Procedure 38703, "Commercial Grade Dedication," dated April 8, 1996 (http://www.nrc.gov/reading-rm/doc-collections/insp-manual)
- Inspection Procedure 43004, "Inspection of Commercial-Grade Dedication Programs," dated October 3, 2007 (ADAMS Accession No. ML071860546)
- EPRI Report NP-5652, "Guideline for the Utilization of Commercial Grade Items in Nuclear Safety-Related Applications (NCIG-07)," dated June 1, 1988
- CGD material from the NRC's "Workshops on Vendor Oversight 2008 Conference" (http://www.nrc.gov/reactors/new-reactors/oversight/quality-assurance/vendor-oversight/past/2008/index.html)
- NRC vendor QA inspection reports (http://www.nrc.gov/reactors/new-reactors/oversight/quality-assurance/vendor-insp/insp-reports.html)

DISCUSSION

Licensees rely on CGD as a means of satisfying the requirements of Appendix B to 10 CFR Part 50 for procurement and acceptance of commercial-grade items and services for use as basic components. An acceptable dedication program consists of the technical evaluation that identifies the CCs and acceptance criteria for the item to be dedicated, the acceptance methods that verify that the CCs have been met, and the documentation of the steps taken during the dedication process. Complete documentation and auditable records of

the rationale, justifications, and engineering analyses must be available as part of the dedication package for the item or service being dedicated. In addition, purchaser or licensee review and approval before the dedication of the item should be part of the process.

The references mentioned in the "Background" section of this IN contain specific guidance on how to perform CGD. This IN does not endorse specific guidance or methods to perform dedication. However, some stakeholders have expressed a concern that the NRC's expectations on how dedication should be performed are not clear to the industry. As previous NRC documents have stated, the following is a method acceptable to the staff for meeting the regulations when performing dedication: implement the guidance of EPRI NP-5652, as modified by the provisions contained in GL 89-02 and the requirements of 10 CFR Part 21, "Reporting of Defects and Noncompliance." In GL 89-02, the NRC conditionally endorsed the dedication methods described in EPRI NP-5652. Guidance on the application of Appendix B to 10 CFR Part 50 appears in Regulatory Guide 1.28, "Quality Assurance Program Criteria (Design and Construction)," and Regulatory Guide 1.33, "Quality Assurance Program Requirements (Operation)." When properly implemented, these NRC and industry guidance documents together provide reasonable assurance for the suitability of dedicated items to be used in safety-related applications.

The attached diagram, based on the guidance contained in EPRI NP-5652 and GL 89-02, can be used to identify the general steps necessary to perform CGD. As the diagram indicates, during the technical evaluation the dedicating entity identifies the safety function, performance requirements, part functional classification, and service conditions of the item; the CCs, including acceptance criteria; and dedication methods for verification of the acceptance criteria. Some of the bases to identify CCs are design, material and performance characteristics; active or passive safety-related functions; safety or nonsafety interfaces; and changes in design, material, or manufacturing process.

Guidance in EPRI NP-5652 encourages the dedicating entity to provide the most suitable or appropriate acceptance method for each CC rather than attempting to use one method for an entire dedication. For example, it may be appropriate to use Method 1 (see attached diagram) to verify certain CCs during receipt inspection or post installation testing of an item, but to use Methods 2 or 4 for other CCs that the supplier or manufacturer is being relied upon to verify for that item. It should be noted that GL 89-02 restricts the use of Methods 2 and 4 as standalone acceptance methods.