UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D. C. 20555

April 9, 1991

TO: ALL HOLDERS OF OPERATING LICENSES AND CONSTRUCTION PERMITS FOR NUCLEAR POWER REACTORS

SUBJECT: LICENSEE COMMERCIAL-GRADE PROCUREMENT AND DEDICATION PROGRAMS (GENERIC LETTER 91-05)

This generic letter notifies the industry of the staff's pause in conducting certain procurement inspection and enforcement activities and identifies a number of failures in licensees' commercial-grade dedication programs identified during recent team inspections performed by the U.S. Nuclear Regulatory Commission (NRC). The pause, which began in March of 1990, will end in late summer of 1991. The purpose of the pause is to allow licensees sufficient time to fully understand and implement guidance developed by industry to improve procurement and commercial-grade dedication programs. This generic letter expresses staff positions regarding certain aspects of licensee commercial-grade procurement and dedication programs which would provide acceptable methods to meet regulatory requirements.

During the period from 1986 to 1989, the NRC conducted 13 team inspections of the licensees' procurement and commercial-grade dedication programs. During these inspections, the NRC staff identified a common, programmatic deficiency in the licensees' control of the procurement and dedication process of commercial-grade items for safety-related applications. In a number of cases, the staff found that licensees had failed to adequately maintain programs as required by 10 CFR Part 50, Appendix B, to assure the suitability of commercially procured and dedicated equipment for its intended safety-related applications. In addition, the staff identified equipment of indeterminate quality installed in the licensees' facilities.

Because of a decrease in the number of qualified nuclear-grade vendors, the NRC staff is aware that there has been a change in the industry's procurement practices. Ten years ago, licensees procured major assemblies from approved vendors who maintained quality assurance programs pursuant to Appendix B of Part 50 of Title 10 of the Code of Federal Regulations (10 CFR). Currently, due to the reduction in the number of qualified nuclear-grade vendors, licensees are increasing the numbers of commercial-grade replacement parts that they procure and dedicate for use in safety-related applications. This is a substantial change from the environment in which 10 CFR Part 50, Appendix B was promulgated. This has necessitated an increased emphasis by licensees and the NRC staff to maintain procurement and dedication programs that adhere to the requirements of 10 CFR Part 50, Appendix B, and thus assure the quality of items purchased and installed in safety-related applications. Therefore, dedication processes for commercial-grade parts have increased in importance and NRC inspections have determined that a number of licensees have not satisfactorily performed this procurement and dedication process.

The industry has been made fully aware of the NRC's concerns in this program area. In the past, escalated enforcement cases have provided notice to the affected licensees and to the industry of NRC's findings, concerns, and expectations in the implementation of procurement and dedication programs.

Further, the NRC staff continues to participate in numerous industry meetings and conferences at which the NRC's positions in this area have been presented. The Nuclear Utility Management and Resources Council (NUMARC) Board of Directors recently approved a comprehensive procurement initiative as described in NUMARC 90-13, "Nuclear Procurement Program Improvements," which commits licensees to assess their procurement programs and take specific action to enhance or upgrade the program if they are determined to be inadequate. The initiative on the dedication of commercial-grade items, which is part of NUMARC 90-13, was to be implemented by January 1, 1990. The staff is monitoring implementation of licensee program improvements by conducting assessments of their procurement and commercial-grade dedication programs and maintaining close interaction with the nuclear industry through participation in conferences, panels, and meetings.

The staff will continue to perform reactive inspections relating to plant specific operational events or to defective equipment and, as required, will continue to initiate resultant enforcement actions. In addition, the staff will continue to perform inspections of vendors. The staff expects to resume procurement and dedication inspection activities in the late summer of 1991. These resumed inspections will be conducted using 10 CFR Part 50, Appendix B (not the NUMARC initiatives) as the applicable regulatory requirement. Licensee programs must assure the suitability of commercially procured and dedicated equipment for its intended safety-related application.

The staff position is that the staff will not initiate enforcement action in cases of past programmatic violations that have been adequately corrected. In addition, the staff does not expect licensees to review all past procurements. However, if during current procurement activities, licensees identify shortcomings in the form, fit, or function of specific vendor products, or if failure experience or current information on supplier adequacy indicates that a component may not be suitable for service, corrective actions are required for all such installed and stored items in accordance with Criterion XVI of 10 CFR Part 50, Appendix B. Also in accordance with Criterion XVI, licensees must determine programmatic causes when actual deficiencies in several products from different vendors are identified during current procurement activities and these deficiencies lead to the replacement of installed items as part of the corrective action. In such cases, a further sampling of previously procured commercial-grade items may be warranted.

In NRC Generic Letter (GL) 89-02, "Actions to Improve the Detection of Counterfeit and Fraudulently Marketed Products," the staff described its perspective on good practices in procurement and dedication and provided the NRC's conditional

endorsement of an industry standard (EPRI NP-5652) on methods of commercial-grade procurement and dedication. A number of recent inspection findings, as discussed in Enclosure 1, indicate that licensees have failed to include certain key activities, as appropriate, in the implementation of the dedication process. The NRC staff's positions on the successful implementation of licensees' programs for commercial-grade dedication with respect to critical characteristics and like-for-like replacements are as follows. (These are also included in Enclosure 1.)

The term "critical characteristics" is not contained in Appendix B and has no special regulatory significance beyond its use and definition in various industry guides and standards. The NRC first used the term critical characteristics in GL 89-02 as constituting those characteristics which need to be identified and verified during product acceptance as part of the procurement process. The NRC has not taken the position that all design requirements must be considered to be critical characteristics as defined and used in EPRI NP-5652. Rather, as stated in Appendix B, Criterion III, licensees must assure the suitability of all parts, materials, and services for their intended safety-related applications (i.e., there needs to be assurance that the item will perform its intended safety function when required). The licensee is responsible for identifying the important design, material, and performance characteristics for each part, material, and service intended for safety-related applications, establishing acceptance criteria, and providing reasonable assurance of the conformance of items to these criteria.

A like-for-like replacement is defined as the replacement of an item with an item that is identical. For example, the replacement item would be identical if it was purchased at the same time from the same vendor as the item it is replacing, or if the user can verify that there have been no changes in the design, materials, or manufacturing process since procurement of the item being replaced. 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 evaluation is necessary to determine if any changes in design, material, or the manufacturing process could impact the functional characteristics and ultimately the component's ability to perform its required safety function. If the licensee can demonstrate that the replacement item is identical, then the licensee need not identify the safety function or review and verify the design requirements and critical characteristics. Engineering involvement is necessary in the above activities. Reliance on part number verification and certification documentation is insufficient to ensure the quality of commercially procured products.

The other matters discussed in Enclosure 1 do not constitute NRC staff positions, but provide information on inspection findings and clarify the characterization of effective procurement and dedication programs previously described in GL 89-02.

BACKFIT DISCUSSION:

Based on past inspection findings and the resulting enforcement actions, the NRC staff has determined that licensee commercial-grade procurement and

dedication programs needed to be improved to comply with the existing NRC requirements as described in 10 CFR Part 50, Appendix B, Criterion III (Design Control), IV (Procurement Document Control), VII (Control of Purchased Material, Equipment and Services), and XVIII (Audits). Specifically, licensees have failed to adequately maintain programs to assure the suitability of commercially procured and dedicated equipment for its intended safety-related application. Since the generic letter presents staff positions regarding implementation of existing regulatory requirements, as contained in Appendix B to 10 CFR Part 50, the staff has concluded, that this is a compliance backfit and has prepared the generic letter in accordance with 10 CFR 50.109 (a)(4)(i). In light of the inadequacies identified in the procurement and dedication programs of a large number of licensees, the issuance of this generic letter is necessary to express the staff's position on the key element that licensees must include as part of the dedication process, specifically that commercial-grade procurement and dedication programs must assure the suitability of equipment for its intended safety-related application. This generic letter is also intended to clarify the elements of effective procurement and commercial-grade dedication programs that were previously provided to licensees in GL 89-02. Since licensees' procurement and dedication programs may contain programmatic deficiencies, the staff has included in the generic letter the necessary licensee corrective action to address shortcomings identified in specific vendor products or components that directly lead to the component not being suitable for safety-related service.

Although no response to this letter is required, if you have any questions regarding this matter, please contact the persons listed below.

Sincerely,

J.G. Partlow

James G. Partlow
Associate Director for Projects
Office of Nuclear Reactor Regulation

Enclosures:
1. Characteristics of Effective Commercial-Grade Procurement and Dedication Programs
2. List of Recently Issued Generic Letters

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CHARACTERISTICS OF EFFECTIVE COMMERCIAL-GRADE PROCUREMENT AND DEDICATION PROGRAMS

Background

Appendix B to 10 CFR Part 50 contains the NRC's regulations for procurement quality assurance (QA) and quality control (QC) for products to be used in safety-related applications. In addition, the NRC has provided further guidance in Regulatory Guides 1.28, 1.33, and 1.123. These requirements and guides, if properly implemented, provide a measure of assurance for the suitability of equipment, including commercial-grade items for use in safety-related systems. Criterion III of Appendix B requires licensees to select and review for suitability of application materials, parts, equipment, and processes that are essential to the safety-related functions of the structures, systems, and components. Criterion IV requires that procurement documents specify the applicable requirements necessary to ensure functional performance. Criterion VII requires licensees to assure that the following are sufficient to identify whether specification requirements for the purchased material and equipment have been met: source evaluation and selection, objective evidence of quality, inspection of the source, and examination of products upon delivery. The process used to satisfy these requirements when upgrading commercial-grade items for safety-related applications is commonly called "dedication." The process of ensuring compliance with 10 CFR Part 50, Appendix B, must include all those activities necessary to establish and confirm the quality and suitability of commercially procured and dedicated equipment for its intended safety-related application. Some of the dedication activities may occur early in the procurement cycle, before the item is accepted from the manufacturer. Generic Letter (GL) 89-02, "Actions to Improve the Detection of Counterfeit and Fraudulently Marketed Products," discussed commercial-grade dedication in terms of engineering involvement in the procurement process, product acceptance, and the dedication process as identified in the EPRI NP-5652 guidelines. This enclosure further discusses the characteristics of effective procurement and dedication programs previously discussed in GL 89-02 and provides examples of specific failures by licensees to effectively implement these characteristics for dedicating and ensuring the suitability of commercial-grade products for safety-related applications. Appropriate implementation of these characteristics would have avoided many of the failures to meet 10 CFR Part 50, Appendix B requirements in licensee procurement and commercial-grade dedication programs which were identified during past NRC inspections.

Inspection Observations and Findings

From 1986 to 1989, headquarters and regional personnel conducted 13 team inspections of licensees' procurement and dedication programs. These inspections have identified a common, broad programmatic deficiency in licensees' control over the process of procurement and dedication of commercial-grade

items. In a number of cases, licensees have not maintained programs to ensure the suitability of equipment for use in safety-related applications as required by 10 CFR Part 50, Appendix B, Criterion III. These 13 inspections resulted in findings with significant safety implications. The staff identified eight findings that were considered to be Severity Level III violations and three findings that were Severity Level IV violations. At one plant, the staff did not assign a severity level to individual violations. Instead, the staff considered the entire group to be a Severity Level III problem and used enforcement discretion, as provided under the enforcement policy, based on the licensee's corrective actions (see 10 CFR Part 2, Appendix C, Section V.G.2). Only one of the plants that were inspected did not receive violations in this program area.

In GL 89-02, the NRC has conditionally endorsed the dedication methods described in EPRI NP-5652 guidelines. The staff believes that licensees who implement these dedication methods, in accordance with the NRC's endorsement, can establish a basis for satisfying the existing requirements of Appendix B to 10 CFR Part 50 as these requirements apply to the dedication process for commercial-grade items. An effective commercial-grade dedication program must include provisions to demonstrate that a dedicated item is suitable for safety-related applications. For a licensee to adequately establish suitability, certain key activities must be performed, as appropriate, as part of the dedication process. This generic letter is intended to clarify the dedication approaches described in GL 89-02.

During each of the 13 inspections, the staff identified a common element in each of the inspection findings. This element was the failure of the licensee to assure that a commercially procured and dedicated item was suitable for the intended safety-related application. A dedicated commercial-grade item must be equivalent in its ability to perform its intended safety function to the same item procured under a 10 CFR Part 50, Appendix B QA program. The following is a list of the 13 licensees inspected and the inspection report numbers. A summary of the general inspection findings and NRC observations on these findings follows the list of licensee inspections.

	LICENSEE and PLANT	INSPECTION REPORT NO.
1.	Tennessee Valley Authority (Sequoyah)	50-327/86-61 50-328/86-61
2.	Southern California Edison (San Onofre)	50-206/87-02 50-361/87-03 50-362/87-04
3.	Alabama Power (Farley)	50-348/87-11 50-364/87-11
4.	Louisiana Power and Light (Waterford)	50-382/87-19

LICENSEE and PLANT	INSPECTION REPORT NO.
5. Sacramento Municipal Utility District (Rancho Seco)	50-312/88-02
6. Maine Yankee Atomic Power (Maine Yankee)	50-309/88-200
7. Northern States Power (Prairie Island)	50-282/88-201 50-306/88-201
8. Portland General Electric (Trojan)	50-344/88-39 50-344/88-46
9. Connecticut Yankee Atomic Power (Haddam Neck)	50-213/89-200
10. Washington Public Power Supply System (WNP-2)	50-397/89-21 50-397/89-28
11. Florida Power (Crystal River)	50-302/89-200
12. Gulf States Utilities (River Bend)	50-458/89-200
13. Commonwealth Edison (Zion)	50-295/89-200 50-304/89-200

1. Inspection Findings

   a. Failure to identify the methods and acceptance criteria for verifying the critical characteristics, such as during receipt inspection, dedication process, or post-installation testing.

   b. Failure to establish verifiable, documented traceability of complex commercial-grade items to their original equipment manufacturers in those cases where the dedication program cannot verify the critical characteristics.

   c. Failure to recognize that some commercial-grade items cannot be fully dedicated once received on site. Certain items are manufactured using special processes, such as welding and heat treating. Dedication testing of these items as finished products would destroy them. For these items, licensees may need to conduct vendor surveillances or to witness certain activities during the manufacturing process.

   Discussion

   The NRC staff has met on several occasions with NUMARC and licensee representatives to discuss "critical characteristics" as used in the context of commercial-grade procurement and dedication. The term "critical characteristics" is not contained in Appendix B and has no special regulatory significance beyond its use and definition in various industry

guides and standards. The NRC first used the term critical characteristics in GL 89-02 as constituting those characteristics which need to be identified and verified during product acceptance as part of the procurement process. The NRC has not taken the position that all design requirements must be considered to be critical characteristics as defined and used in EPRI NP-5652. Rather, as stated in Appendix B, Criterion III, licensees must assure the suitability of all parts, materials, and services for their intended safety-related applications (i.e., there needs to be assurance that the item will perform its intended safety function when required). The licensee is responsible for identifying the important design, material, and performance characteristics for each part, material, and service intended for safety-related applications, establishing acceptance criteria, and providing reasonable assurance of the conformance of items to these criteria. There is no minimum or maximum number of critical characteristics that need to be verified. Further, the critical characteristics for an item may vary from application to application depending on the design and performance requirements unique to each application.

A licensee may take different approaches for the verification of the critical characteristics, depending on the complexity of the item. In many cases, the licensee can verify the critical characteristics of each item during receipt inspection testing. However, for a complex item with internal parts which receive special processing during manufacturing, the licensee may need to conduct a source verification of the manufacturer during production to verify the critical characteristics identified as necessary for the item to perform its safety function. When these methods cannot verify the critical characteristics related to special processes and tests, certification by the original equipment manufacturer may be an acceptable alternative provided documented, verified traceability to the original equipment manufacturer has been established and the purchaser has verified by audit or survey that the original equipment manufacturer has implemented adequate quality controls for the activity being certified.

For items with critical characteristics that can be verified for the most severe or limiting plant application, the licensee might prefer to identify and verify the item's critical characteristics to qualify that item for all possible plant applications. For complex items that would be purchased for specific plant applications, it may be appropriate to address the acceptance criteria for each item individually. Engineering involvement is important in either method because the technical evaluation will identify the critical characteristics, acceptance criteria, and the methods to be used for verification.

2. Inspection Findings

   a. Failure to demonstrate that a like-for-like replacement item is identical in form, fit, and function to the item it is replacing. Part number verification is not sufficient because of the probability of undocumented changes in the design, material, or fabrication of commercial-grade items using the same part number.

b. Failure to evaluate changes in the design, material, or manufacturing process for the effect of these changes on safety function performance (particularly under design basis event conditions) of replacement items that are similar as opposed to identical to the items being replaced.

c. Failure to ensure that items will function under all design requirements. On some occasions, licensees only ensured that the commercial-grade item would function under normal operation conditions.

d. Failure to verify the validity of certificates of conformance received from vendors not on the licensee's list of approved vendors/suppliers. An unverified certificate of conformance from a commercial-grade vendor is not sufficient.

Discussion

A like-for-like replacement is defined as the replacement of an item with an item that is identical. For example, the replacement item would be identical if it was purchased at the same time from the same vendor as the item it is replacing, or if the user can verify that there have been no changes in the design, materials, or manufacturing process since procurement of the item being replaced. 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 evaluation is necessary to determine if any changes in design, material, or the manufacturing process could impact the functional characteristics and ultimately the component's ability to perform its required safety function. If the licensee can demonstrate that the replacement item is identical, then the licensee need not identify the safety function or review and verify the design requirements and critical characteristics.

Engineering involvement is necessary in the above activities. The extent of this involvement is dependent on the nature, complexity, and use of the items to be dedicated. Participation of engineering personnel is appropriate in the procurement process, and product acceptance, to develop purchase specifications, determine specific testing requirements applicable to the products, and evaluate the test results. When engineering personnel specify design requirements for inclusion on the purchase documents for replacement components, they need not reconstruct and reverify design adequacy for procurement purposes, but need only ensure that the existing design requirements (which may reference the original design basis) are properly translated into the purchase order.

Reliance on part number verification and certification documentation is insufficient to ensure the quality of commercially procured products. Effective product acceptance programs have as elements, receipt and source inspection, appropriate testing criteria, effective vendor audits and surveillances (including witness/hold points as appropriate), special tests and inspections, and post-installation tests. Procedures and adequate qualifications and training for implementing personnel are also necessary factors in successful implementation.

Enclosure 2

LIST OF RECENTLY ISSUED GENERIC LETTERS

Generic Letter No.	Subject	Date of Issuance	Issued To
91-04	CHANGES IN TECHNICAL SPECIFICATION SURVEILLANCE INTERVALS TO ACCOMMODATE A 24-MONTH FUEL CYCLE (GENERIC LETTER 91-04)		ALL HOLDERS OF OL OR CONSTRUCTION PERMITS FOR NUCLEAR POWER REACTORS
91-03	REPORTING OF SAFEGUARDS EVENTS	03/06/91	ALL HOLDERS OF OLs OR CPs FOR NUCLEAR POWER REACTORS AND ALL OTHER LICENSED ACTIVITIES INVOLVING A FORMULA QUANTITY OF SPECIAL NUCLEAR MATERIAL (SNM)
91-02	REPORTING MISHAPS INVOLVING LLW FORMS PREPARED FOR DISPOSAL	12/28/90	ALL OPERATORS OF LOW-LEVEL RADIOACTIVE WASTE (LLW) DISPOSAL SITES, WASTE PROCESSORS, & ALL HOLDERS OF LICENSES FOR NUCLEAR FUELS, NUCLEAR MATERIALS & NUCLEAR POWER REACTORS
91-01	REMOVAL OF THE SCHEDULE FOR THE WITHDRAWAL OF REACTOR VESSEL MATERIAL SPECIMENS FROM TECHNICAL SPECIFICATIONS	01/04/91	ALL HOLDERS OF OLs OR CPs FOR NUCLEAR POWER PLANTS
90-09	ALTERNATIVE REQUIREMENTS FOR SNUBBER VISUAL INSPECTION INTERVALS AND CORRECTIVE ACTIONS	12/11/90	ALL LIGHT-WATER REACTOR LICENSEES AND APPLICANTS
89-10 SUPP. 3	CONSIDERATION OF THE RESULTS OF NRC-SPONSORED TESTS OF MOTOR-OPERATED VALVES	10/25/90	ALL LICENSEES OF OPERATING NUCLEAR POWER PLANTS AND HOLDERS OF CONSTRUCTION PERMITS FOR NUCLEAR POWER PLANTS
90-08	SIMULATION FACILITY EXEMPTIONS	08/10/90	ALL HOLDERS OF OPERATING LICENSES OR CONSTRUCTION PERMITS FOR NUCLEAR POWER REACTORS
90-07	OPERATOR LICENSING NATIONAL EXAMINATION SCHEDULE	08/10/90	ALL POWER REACTOR LICENSEES AND APPLICANTS FOR AN OPERATING LICENSE
89-10 SUPP. 2	AVAILABILITY OF PROGRAM DESCRIPTIONS	08/03/90	ALL LICENSEES OF OPERATING NPPs AND HOLDERS OF CPs FOR NPPs

dedication programs needed to be improved to comply with the existing NRC requirements as described in 10 CFR Part 50, Appendix B, Criterion III (Design Control), IV (Procurement Document Control), VII (Control of Purchased Material, Equipment and Services), and XVIII (Audits). Specifically, licensees have failed to adequately maintain programs to assure the suitability of commercially procured and dedicated equipment for its intended safety-related application. Since the generic letter presents staff positions regarding implementation of existing regulatory requirements, as contained in Appendix B to 10 CFR Part 50, the staff has concluded, that this is a compliance backfit and has prepared the generic letter in accordance with 10 CFR 50.109 (a)(4)(i). In light of the inadequacies identified in the procurement and dedication programs of a large number of licensees, the issuance of this generic letter is necessary to express the staff's position on the key element that licensees must include as part of the dedication process, specifically that commercial-grade procurement and dedication programs must assure the suitability of equipment for its intended safety-related application. This generic letter is also intended to clarify the elements of effective procurement and commercial-grade dedication programs that were previously provided to licensees in GL 89-02. Since licensees' procurement and dedication programs may contain programmatic deficiencies, the staff has included in the generic letter the necessary licensee corrective action to address shortcomings identified in specific vendor products or components that directly lead to the component not being suitable for safety-related service.

Although no response to this letter is required, if you have any questions regarding this matter, please contact the persons listed below.

Sincerely,

ORIGINAL SIGNED BY:

James G. Partlow
Associate Director for Projects
Office of Nuclear Reactor Regulation

Enclosures:
1. Characteristics of Effective Commercial-Grade Procurement and Dedication Programs
2. List of Recently Issued Generic Letters

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*SEE PREVIOUS CONCURRENCES

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