



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

NOV 28 1990

MEMORANDUM FOR: Edward L. Jordan, Chairman
Committee to Review Generic Requirements

FROM: Frank J. Miraglia, Deputy Director
Office of Nuclear Reactor Regulation

SUBJECT: PROPOSED GENERIC LETTER ON LICENSEE COMMERCIAL-GRADE
PROCUREMENT AND DEDICATION PROGRAMS

The Office of Nuclear Reactor Regulation requests that the Committee to Review Generic Requirements (CRGR) consider the enclosed proposed generic letter. The staff is proposing the enclosed generic letter to notify the industry of the staff's intent to pause in conducting programmatic procurement inspection and enforcement activities and to identify a number of failures in the licensees' commercial-grade dedication programs identified during past NRC inspections. This generic letter also provides information from the NRC's inspections of the licensees' commercial-grade procurement and dedication programs which, if included in licensees' implementation of these programs, could have avoided violations of regulatory requirements.

The commercial-grade dedication inspection findings discussed in Enclosure 1 to the generic letter are based upon 10 CFR Part 50, Appendix B requirements and do not involve changes in the staff's positions. Further, the proposed generic letter does not require any specific licensee action or response to the NRC based on the issuance of this generic letter. Because no new regulations or regulatory practices are involved, the relation to the Commission's safety goals has not been explicitly addressed. However, this action appears to relate to how well a plant is operated. The matters addressed in this generic letter contribute to reducing or avoiding a substantial increase in uncertainty in the assumptions on which safety goal calculations are based.

Enclosure 2 to this memorandum is the proposed generic letter and Enclosure 1 contains the CRGR review package. Brian K. Grimes, Director, Division of Reactor Inspection and Safeguards, is the sponsoring division director. OGC concurrence is currently being sought.

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Frank J. Miraglia
Frank J. Miraglia, Deputy Director
Office of Nuclear Reactor Regulation

Enclosure:

1. CRGR Review Package
2. Draft Generic Letter on Licensee
Commercial-Grade Procurement
and Dedication Programs

CONTACT: Richard P. McIntyre, NRR
492-3215

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CRGR REVIEW PACKAGE

RESPONSE TO REQUIREMENTS FOR CONTENT OF PACKAGE SUBMITTED FOR CRGR REVIEW

- (i) The proposed generic requirement as it is proposed to be sent out to all holders of operating licenses and construction permits for nuclear power plants.

The staff position is:

The proposed position is stated in the proposed generic letter. In summary, all holders of operating licenses and construction permits for nuclear power reactors would be notified of the staff's intent to pause in conducting programmatic procurement inspection and enforcement activities. However, the NRC will conduct selected assessments to determine the progress of the industry in improving procurement and dedication programs. (Utilities are now implementing the Nuclear Management Resources Council (NUMARC) Initiative on the Dedication of Commercial-Grade Items and the Comprehensive Procurement Initiative). This generic letter identifies a number of failures in the licensees' commercial-grade dedication programs that were identified during recent NRC inspections. In addition, this generic letter provides the staff's views on key activities, which, if included in licensee implementation of these programs, could have avoided such failures.

- (ii) Draft staff papers or other underlying staff documents supporting the requirements or staff (regulatory) positions. (A copy of all materials referenced in the document shall be made available upon request to the CRGR staff. Any committee member may request that the CRGR staff obtain a copy of any referenced material for his or her use.)

The following documents support the staff's position:

- (a) Proposed NRC Generic Letter 90-XX: "Licensee Commercial-Grade Procurement and Dedication Programs" (See generic letter in Enclosure 2).
- (b) Enclosure 1 of the proposed generic letter lists 13 NRC Inspection Reports regarding licensees' procurement and dedication programs.
- (c) NRC Generic Letter 89-02: "Actions to Improve the Detection of Counterfeit and Fraudulently Marketed Products." Enclosure 1 to Generic Letter 89-02 lists NPC bulletins and information notices regarding nonconforming materials and equipment.

- (d) SECY-90-057, Advance Notice of Proposed Rulemaking, "Acceptance of Products Purchased for Use in Nuclear Power Plant Structures, Systems, and Components."
- (e) SECY-90-304, "NUMARC Initiatives on Procurement."
- (f) SECY-90-261, "Inspection and Enforcement Initiatives for Commercial-Grade Procurement and Dedication Programs."

- (iii) Each proposed requirement or staff (regulatory) position shall contain the sponsoring office's position as to whether the proposal would increase requirements or staff (regulatory) positions, implement existing requirements or staff (regulatory) positions, or would relax or reduce existing requirements or staff (regulatory) positions.

The commercial-grade dedication approaches discussed in Enclosure 1 of the proposed generic letter do not constitute new NRC requirements or positions, but provide specific clarifications to implementation guidance to meet 10 CFR Part 50, Appendix B. However, if current or improved procurement activities 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 should include a look-back for all such installed and stored items. The licensees' actions in this regard for both warehouse and installed items should follow the existing requirements for corrective action and follow-up contained in Criterion XVI of 10 CFR Part 50, Appendix B.

- (iv) The proposed method of implementation along with the concurrence (and any comments) of OGC on the method proposed.

The staff proposes to promulgate the clarification by means of a generic letter. This method has been effective in the past. The Office of the General Counsel (OGC) has provided comments and has concurred in the proposed generic letter.

- (v) Regulatory analyses generally conforming to the directives and guidance of NUREG/BR-0058 and NUREG/CR-3568. (Make sufficient to address the Paperwork Reduction Act, the Regulatory Flexibility Act, and Executive Order 12291).

- (a) This request for information was approved by the Office of Management and Budget under blanket clearance number 3150-0011 as meeting the requirements of the Paper Reduction Act and Executive Order 12291.
- (b) Because this request is not a rulemaking action, the Regulatory Flexibility Act does not apply.

- (vi) Identification of the category of reactor plants to which the generic requirement or staff position is to apply (that is, whether it is to apply to new plants only, new OLs only, OLs after a certain date, OLs before a certain date, all OLs, all plants under construction, all plants, all water reactors, all PWRs only, some vendor types, some vintage types such as BWR 6 and 4, jet pump and nonjet pump plants, etc.)

As described in Item (i) above, the proposed requirements apply to all holders of operating licenses and construction permits for nuclear power reactors.

- (vii) For each such category of reactor plants, an evaluation which demonstrates how the action should be prioritized and scheduled in light of other ongoing regulatory activities. The evaluation shall document for consideration information available concerning any of the proposed backfit factors as may be appropriate and any other information relevant and material to the proposed action:

Response to this item is not required pursuant to Revision 4 of the CRGR Charter, Section III.D., because the proposed generic letter announces an NRC inspection pause and conforming to the staff views on key dedication activities would bring licensees into compliance with existing regulatory requirements. This action should not affect the industry's schedule for improvements because the initiative on commercial-grade dedication was implemented in early 1990 and the comprehensive procurement initiative is already underway.

- (viii) For each evaluation conducted pursuant to 10 CFR 50.109, the proposing office director's determination, together with the rationale for the determination based on the considerations of paragraphs (i) through (vii) above, that:

- (a) There is a substantial increase in the overall protection of public health and safety or the common defense and security to be derived from the proposal; and

This item is not applicable since no changes in staff positions are involved. However, the following discussion provides the safety significance of this action:

The NRC has identified numerous instances in which the nuclear industry received, accepted, and installed products that were not of the quality identified by the manufacturer or supplier. The NRC has also identified examples of significant deficiencies in the procurement and dedication of commercial-grade items with errors traceable to both suppliers and purchasers who dedicate the items for safety-related application.

The inadequate dedication of commercial-grade items by suppliers and purchasers (including licensees), increases the probability that hardware installed in safety-related applications may not perform as desired. Therefore, the guidance in the proposed generic letter provides for overall protection of public health and safety.

The NUMARC Initiative on the Dedication of Commercial-Grade Items requested that utilities review and, if necessary, develop or upgrade current programs to meet the intent of Electric Power Research Institute (EPRI) NP-5652. Generic Letter 89-02 conditionally endorses EPRI NP-5652 as a guideline for commercial-grade dedication. The EPRI guideline presents several approaches to implement existing requirements as they apply to commercial-grade items.

- (b) The direct and indirect costs of implementation, for the facilities affected, are justified in view of this increased protection.
 - (1) Direct and indirect costs associated with the required actions by the generic letter result primarily from the evaluation by licensees of their existing procurement programs, and, for deficient programs, the necessary corrective actions. The licensees are performing this review as a result of the NUMARC initiative and should not require substantial additional resources in order to consider the staff views expressed in the generic letter.

The amount of effort needed to correct deficient programs will be a function of the current adequacy of licensee's programs and may range from no changes to changes that require several FTEs each year. The staff believes that the costs of implementation are justified in view of the need to ensure the suitability of materials and equipment procured for use in nuclear safety-related applications.
 - (2) Occupational radiation exposure should not increase because of the actions requested by this generic letter.
 - (3) NRC resources will be required to conduct selected assessments to determine the progress of the industry in implementation of the initiative on the dedication of commercial-grade items.

- (ix) For each evaluation conducted for proposed relaxations or decreases in current requirements of staff positions, the action is justified because of the proposing office director's determination, together with the rationale for the determination based on the considerations of the above, that:
 - (a) the public health and safety and the common defense and security would be adequately protected if the proposed reduction in requirements or (regulatory) positions were implemented; and

(b) the cost savings attributed to the action would be substantial enough to justify taking the action.

This item is not applicable to the proposed generic letter because the staff is not proposing a relaxation or decrease in current requirements.



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ENCLOSURE 2

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

SUBJECT: LICENSEE COMMERCIAL-GRADE PROCUREMENT AND DEDICATION PROGRAMS
(GL 90-XX)

This generic letter notifies the industry of the staff's intent to pause in conducting certain procurement inspection and enforcement activities and to identify a number of failures in the licensees' commercial-grade dedication programs identified during recent inspections performed by the U.S. Nuclear Regulatory Commission (NRC). This generic letter also provides further discussion of the staff's views on key activities which, if included in licensee implementation of these programs, could have avoided such failures.

During 1986 to 1989, the NRC has conducted 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 of commercial-grade items for safety-related applications. In a number of cases, the staff found that licensees had not maintained programs to ensure the suitability of equipment for safety-related applications. In addition, the staff identified equipment of indeterminate quality installed in the licensee's facilities.

The NRC staff believes that these inspection findings, in part, indicate a change in the industry's procurement practices and the decrease in the number of qualified nuclear-grade vendors. Ten years ago, licensees made most procurements for major assemblies from approved vendors with programs pursuant to Appendix B of Part 50 of Title 10 of the Code of Federal Regulations (10 CFR). Currently, licensees are increasing the numbers of commercial-grade replacement parts that they procure for use in safety-related applications. This has resulted in a shift of responsibility for ensuring the quality of the item purchased from the suppliers to the licensees. 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 dedication process.

The industry should be 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 to discuss the NRC's positions in this area.

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The Nuclear Utility Management and Resources Council (NUMARC) Board of Directors recently approved a comprehensive procurement initiative which if effectively implemented should markedly improve the assurance that quality components are installed in nuclear power plants. While monitoring industry implementation of these programs, the NRC staff is deferring inspections of licensees' procurement and commercial-grade dedication processes for about a year to allow utilities to have sufficient time to fully understand and implement the guidance being developed by the industry.

However, the NRC will continue to perform certain types of inspection activities. For example, the staff will conduct selected assessments to determine the progress of the industry in improving the procurement and dedication processes. The staff will continue to perform reactive inspections relating to operational events or to defective equipment and, as required, will continue to initiate resultant enforcement actions which will not be affected by the decision to defer programmatic inspections. In addition, the staff will continue to perform inspections of vendors. To further encourage timely and effective implementation of the NUMARC initiatives, 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 should include a look-back for all such installed and stored items. In performing these actions for both stored and installed items, licensees should follow the existing requirements for corrective and follow-up actions contained in Criterion XVI of 10 CFR Part 50, Appendix I. A licensee should determine programmatic root causes when actual deficiencies in several different vendor products are identified during current procurement activities and when these deficiencies lead to the replacement of installed or warehouse items as part of corrective action. In such cases, a further sampling of previously procured commercial-grade items may be warranted.

NRC Generic Letter 89-02, "Actions to Improve the Detection of Counterfeit and Fraudulently Marketed Products," described the NRC's observations on good practices in procurement 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 inspection findings indicate that licensees have failed to include certain key activities as appropriate in the implementation of the dedication process. Enclosure 1 includes further discussion of the NRC staff's views on the successful implementation of licensees' programs for commercial-grade dedication. The commercial-grade dedication approaches discussed in Enclosure 1 do not constitute new NRC requirements or positions. We will continue to meet with the industry to ensure a common understanding of implementation issues in this area.

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

Sincerely,

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

Technical Contact: Richard P. McIntyre, NRR
(301) 492-3215

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Enclosure 1

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 assure 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 function 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 those items to be installed in safety-related applications. Some of the dedication activities may occur early in the procurement cycle, before the item is accepted from the manufacturer. (10 CFR Part 21 has a more restricted definition of commercial-grade item dedication related to responsibility for evaluation and reporting of defects.) 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 provides examples of specific failures by licensees to fully implement certain key activities for dedicating and ensuring the suitability of commercial-grade products for safety-related applications. Appropriate implementation of these key activities would have avoided the failures in procurement and commercial-grade dedication observed 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 procurement and dedication of commercial-grade items. In a number of cases, licensees have not maintained programs to ensure

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the suitability of equipment for use in safety-related applications as required by 10 CFR Part 50, Appendix B, Criterion III. From these 13 inspections, the staff identified 8 findings that were considered to be Severity Level III violations and 3 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 shutdown 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 should 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.

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. In its ability to perform its intended safety function, a dedicated commercial-grade item should be equivalent 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.

<u>LICENSEE and PLANT</u>	<u>INSPECTION REPORT NO.</u>
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

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<u>LICENSEE and PLANT</u>	<u>INSPECTION REPORT NO.</u>
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

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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 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 a simple item during the receipt inspection. However, for a complex item with internal parts which receive special processing during manufacturing, the licensee would probably need to audit or survey the vendor to verify the critical characteristics necessary for the item to perform its safety function. When the dedication program cannot verify the critical characteristics, the licensee should establish documented, verifiable traceability to the original equipment manufacturer. For simple items with critical characteristics that can be verified for the most severe or limiting plant application, the licensee might prefer a broad dedication program 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, the licensee should address the acceptance criteria for each item individually. Engineering involvement is essential 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.

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- 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. A like-for-like replacement does not change the engineering analysis or as-built configuration of the component or system in which it is installed, and the replacement item meets the same design specifications, technical and quality requirements, and functional characteristics as the item it replaces. 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 must be performed 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. 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.

Engineering involvement is essential in the above activities. The extent of this involvement is dependent on the nature, complexity, and use of the items to be dedicated. Engineering personnel should participate 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 the design adequacy, but only ensure that these 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. To conduct effective product acceptance programs, licensees should ensure that these programs include receipt and source inspection, appropriate testing criteria, effective vendor audits (including witness/hold points), special tests and inspections, and post-installation tests. The licensees should establish procedures to implement their programs and should ensure that the implementing personnel have adequate qualifications and training.

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Original signed by

Frank J. Miraglia

Frank J. Miraglia, Deputy Director
Office of Nuclear Reactor Regulation

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Enclosure: see next page

1. CRGR Review Package
2. Draft generic letter on Licensee
Commercial-Grade Procurement
and Dedication Programs

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* see previous concurrence

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