

January 10, 1991

MEMORANDUM FOR: James M. Taylor  
Executive Director for Operations  
  
FROM: Edward L. Jordan, Chairman  
Committee to Review Generic Requirements  
  
SUBJECT: MINUTES OF CRGR MEETING 197

The Committee to Review Generic Requirements (CRGR) met on Tuesday, December 18, 1990 from 2:00 - 5:00 p.m. A list of attendees at the meeting is enclosed (Enclosure 1). The following items were discussed at the meeting.

1. B. Grimes of NRR presented for CRGR review a proposed generic letter on licensee commercial-grade dedication and procurement programs. Although the package stated that it involved no new positions or backfitting, the CRGR expressed the opinion that the package, as presented, seemed to be a backfit. The staff agreed to provide another package, modified so it would not constitute backfitting in the near future. This matter is discussed in Enclosure 2.

In accordance with the EDO's July 18, 1983 directive concerning "Feedback and Closure of CRGR Review," a written response is required from the cognizant office to report agreement or disagreement with CRGR recommendations in these minutes. The response, which is required within five working days after receipt of these minutes, is to be forwarded to the CRGR Chairman and if there is disagreement with CRGR recommendations, to the EDO for decision making.

Questions concerning these meeting minutes should be referred to Dennis Allison (492-4148).

Original Signed by:  
Denwood F. Ross

*for*

Edward L. Jordan, Chairman  
Committee to Review Generic  
Requirements

Enclosures:  
As stated

cc w/enclosures:  
Commission (5)  
SECY  
J. Lieberman  
P. Norry  
D. Williams  
Regional Administrators  
CRGR Members

Distribution: See next page

<i>DA</i> CRGR:AEOD	DU:AEOD	C:CRGR:AEOD
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P. Kadambi

CRGR C/F

CRGR S/F

J. Sniezek

M. Taylor

W. Russell

B. Grimes

G. Cwalina

G. Mizuno

D. Ross

D. Allison

E. Jordan

J. Conran

ATTENDENCE LIST

CRGR Meeting No. 197

December 18, 1990

CRGR Members

E. Jordan  
G. Arlotto  
F. Miraglia  
B. Sheron  
L. Reyes  
L. J. Callan

CRGR Staff

J. Conran  
D. Allison  
D. Ross

NRC Staff

W. Russell  
B. Grimes  
W. Brach  
G. Cwalina  
E. McKenna  
E. Baker  
A. Herdt  
U. Potapovs  
R. McIntyre  
C. Vandenburg

Enclosure 2 to the Minutes of CRGR Meeting No. 197  
Proposed Generic Letter on Licensee  
Commercial-Grade Dedication and Procurement Programs

December 18, 1990

TOPIC

B. Grimes of NRR presented for CRGR review a proposed generic letter on licensee commercial-grade dedication and procurement programs. The staff had recently instituted a pause in inspection in this area in order to allow time for licensees to improve their programs in accordance with an industry initiative. When inspection activities were resumed, they would initially consist of assessments to determine that a substantive improvement effort was underway. The purposes of the proposed generic letter were to: (1) announce (or confirm) the staff's recent pause in inspections; (2) describe the staff's enforcement practices; and, (3) discuss misunderstandings or weaknesses found in NRC inspections. The package stated that it involved no new positions or backfitting.

BACKGROUND

The review package was transmitted by a memorandum for E. Jordan from F. Miraglia dated November 28, 1990. The package included:

- (1) CRGR review package (answers to standard questions)
- (2) Draft generic letter

A revised draft generic letter was provided for discussion at the meeting. A copy is provided as Attachment 1 to this enclosure.

The CRGR also received comments from the Nuclear Management and Resources Council (NUMARC) which were distributed at the meeting. A copy is provided in Attachment 2 to this enclosure.

## CONCLUSIONS/RECOMMENDATIONS

The CRGR expressed the opinion that the package, as presented, seemed to be a backfit and, unless modified, it should be justified as a backfit.

A primary contributor to this opinion was the enclosure to the generic letter which described weaknesses and misunderstanding found in previous inspections. This appeared to be conveying new staff positions. Further, it appeared to go beyond the industry initiative which had been endorsed by the staff, with some conditions, as an acceptable approach. Finally, the package could appear contradictory - implying that licensees should meet all the recommendations of the industry initiative (and the enclosure) but at the same time maintaining that there were no new positions and the staff's only enforcement standard was Appendix B to 10 CFR 50.

The CRGR expressed the opinion that the package could be modified so it would not constitute backfitting. The primary modification would be deleting or substantially modifying the enclosure which discussed weaknesses and misunderstandings found in the previous inspections. In this case, the CRGR would support issuance of the generic letter, subject to CRGR staff check of the revised letter (and possibly circulating the revised letter to the members). The staff agreed to provide a revised package along these lines in the near future.

It was noted that the CRGR wanted to see the procedures for the forthcoming assessments to determine that a substantive improvement effort was underway. The staff agreed to provide the procedures when they were written.



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

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**DRAFT**

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

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

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

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 to assure the suitability of commercially procured and dedication equipment for its intended safety-related applications. In addition, the staff identified equipment of indeterminate quality installed in the licensee's facilities.

The NRC staff believes from these inspection findings that, there has been a change in the industry's procurement practices and a decrease in the number of qualified nuclear-grade vendors. 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 has resulted in an increased emphasis by the staff that licensees maintain dedication programs that assure the quality of items purchased. 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 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.

ATTACHMENT 1 TO  
ENCLOSURE 2

**DRAFT**

The Nuclear Utility Management and Resources Council (NUMARC) Board of Directors recently approved a comprehensive procurement initiative. While monitoring industry implementation of licensee program improvements, the NRC staff is deferring inspections of licensees' procurement and commercial-grade dedication processes for about a year to allow utilities sufficient time to fully understand and implement the guidance being developed by the industry and to evaluate the effectiveness of the programs.

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. The staff expects to resume procurement inspection activities in the late summer of 1991.

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 B. 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.

In NRC Generic Letter 89-02, "Actions to Improve the Detection of Counterfeit and Fraudulently Marketed Products," the staff described its perspective 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 recent 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, but rather are intended to ensure a common understanding of implementation issues in this area.

**DRAFT**

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

Uldis Potapovs, NRR  
(301) 492-0959



# DRAFT

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 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 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 process of procurement and dedication of commercial-grade items. In a number of cases, licensees have not maintained

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programs to ensure 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 dedications 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

<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

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 related to special processes and tests, 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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REMARKS

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*MATERIAL RELATED TO CR6R MEETING NO. 197*

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MATERIAL RELATED TO CRGR MEETING NO. 197  
TO BE MADE PUBLICLY AVAILABLE

1. MEMO FOR J. TAYLOR FROM E. JORDAN DATED  
SUBJECT: MINUTES OF CRGR MEETING NUMBER  
INCLUDING THE FOLLOWING ENCLOSURES WHICH WERE NOT  
PREVIOUSLY RELEASED:

- a. ENCLOSURE 2  
A SUMMARY OF DISCUSSIONS OF A PROPOSED *Generic Letter*  
*on License Commercial - Trade Dedication and*  
*Procurement Programs*
- b. ENCLOSURE \_\_\_\_\_  
A SUMMARY OF DISCUSSIONS OF A PROPOSED
- c. ENCLOSURE \_\_\_\_\_  
A SUMMARY OF DISCUSSIONS OF A PROPOSED

2. MEMO FOR E. JORDAN FROM F. Muroglio DATED 11-28-90  
FORWARDING REVIEW MATERIALS ON A PROPOSED *Generic Letter*  
*on License Commercial - Trade Dedication and*  
*Procurement Programs*

3. MEMO FOR E. JORDAN FROM \_\_\_\_\_ DATED \_\_\_\_\_  
FORWARDING REVIEW MATERIALS ON A PROPOSED

4. MEMO FOR E. JORDAN FROM \_\_\_\_\_ DATED \_\_\_\_\_  
FORWARDING REVIEW MATERIALS ON A PROPOSED

