



57-302

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

February 16, 1993

MEMORANDUM FOR: Charles E. Rossi, Director  
Division of Reactor Inspection  
and Licensee Performance

FROM: Leif J. Norrholm, Chief  
Vendor Inspection Branch  
Division of Reactor Inspection  
and Licensee Performance

SUBJECT: MINUTES OF PUBLIC MEETING WITH FLORIDA POWER CORPORATION ON  
COMMERCIAL GRADE DEDICATION AT CRYSTAL RIVER UNIT 3

Background

Between December 1991 and June 1992, the NRC completed five pilot inspections that were conducted to evaluate the implementation of licensee programs for the procurement and dedication of commercial grade items (CGIs) and to finalize an inspection procedure for future inspections of this type. These inspections identified weaknesses in licensee CGI dedication programs and their implementation. During this same period, the NRC received significant feedback from several utilities and the Nuclear Management and Resources Council (NUMARC) questioning the regulatory basis for the CGI dedication guidance contained in NRC Generic Letter (GL) 91-05, as well as specific interpretations of that guidance by the NRC inspection teams. Because of the need for additional discussion of the requirements and implementing guidance for dedication of CGIs, no enforcement action was taken based on any of the five pilot inspections. Rather, it was decided that a series of meetings with licensees and industry representatives would be beneficial to identify, and attempt to resolve, specific areas of difference. This meeting with Florida Power Corporation (FPC) representatives was the first of several such meetings with licensees inspected during the pilot inspections. The purpose of the meeting was to discuss specific dedication examples which were identified as findings during the NRC's March 1992 inspection at Crystal River Unit 3 (CR3).

Meeting Summary

On December 4, 1992, Division of Reactor Inspection and Licensee Performance management and members of the Vendor Inspection Branch met with representatives of FPC to discuss key procurement and commercial grade dedication issues on which the NRC and FPC have differing views. During the opening remarks, FPC stated that the NRC's inspection has helped to enhance FPC's program, however, professional differences of opinion still exist. The NRC stated that the objective of the meeting was to obtain input for the NRC to aid in its effort to identify the proper level of dedication necessary to assure safety and compliance with 10 CFR 50, Appendix B (Appendix B).

In order to facilitate the discussion, the NRC provided FPC a list of generic dedication issues (Enclosure 1) which was previously provided to NUMARC in a public meeting held with the NRC on November 13, 1992. These dedication issues were used as discussion points for the meeting and included: the basis for the selection and verification of critical characteristics, sampling, traceability, commercial grade surveys, like-for-like replacements, and acceptance of vendor/supplier documentation. These issues were derived from previous meetings with NUMARC and represent the major points for discussion.

The following is a summary of views expressed by FPC with respect to these generic dedication issues.

1. BASIS FOR THE SELECTION AND VERIFICATION OF CRITICAL CHARACTERISTICS

Consideration of the Item's Safety Function.

FPC indicated that not all critical characteristics derived from the item's safety functions need to be identified and verified, but only a subset is necessary to provide "reasonable assurance." The NRC stated that there must be a sound rationale established to justify the subset for all CGIs (classified by the licensee as safety-related) since the item must ultimately comply with Appendix B requirements.

FPC does not believe that Appendix B is particularly effective in assuring a high degree of performance reliability. They feel that Appendix B is too focused on the paper trail and may not necessarily assure product quality. FPC stated that the industry believes that CGIs purchased from reputable suppliers are just as good as similar items purchased from Appendix B suppliers and that the NRC appears to be focusing on the documented certification process (possibly due to the issue of fraud and substandard parts).

Failure Modes and Effects Analysis.

The NRC inspection at CR3 identified that FPC does not evaluate failure modes in identifying critical characteristics. Also FPC's dedication program does not consider effects of CGI failures on surrounding safety-related items. FPC believes that it is not necessary or required to use failure modes and effects analysis to perform dedication.

2. SAMPLING

Establishment of Lot/Batch Control.

With respect to determining sample size, FPC recommended that the term "standard statistical methods" be broadened to account for factors such as supplier history, complexity of the item and manufacturing process as discussed in Electric Power Research Institute (EPRI) Final Report NP-7218, "Guideline for the Utilization of Sampling Plans for

Commercial Grade Item Acceptance (NCIG-19)," May 1991. FPC also indicated its acceptance of the statement, "manufactured under essentially the same conditions" (emphasis added), since this affords the industry more added flexibility than the language contained in GL 91-05.

3. TRACEABILITY

Material/Items Purchased from Distributors.

FPC stated that in instances where the distributor does not affect the item (e.g., distributor purchases a sealed package direct from the original equipment manufacturer), only an audit of the distributor's program to warehouse and control the item would be necessary to assure quality. FPC's example is consistent with the NRC position in this area.

4. COMMERCIAL GRADE SURVEYS

Documentation of Survey Results.

FPC stated that the CGI's application should be commensurate with the type of survey performed (e.g., broad-based or narrow), but, in general, FPC agreed with the NRC position as stated.

5. LIKE-FOR-LIKE REPLACEMENTS

Replacement with an Identical Item.

FPC stated that the like-for-like definition used by many licensees may not be consistent with the NRC's definition and that the term "identical" may be too absolute. FPC recommended that the NRC consider adding some flexibility into the last sentence (e.g., ....purchased from the same vendor at essentially the same time).

Like-for-like Verification.

In addition to the above, FPC also stated that other industries rely on performance history more than documentation and encouraged the NRC to become familiar with ISO 9000 (an international quality standard) as other licensees are doing.

DISCUSSION OF CR3 DEDICATION EXAMPLES

The following specific dedication examples, identified during the CR3 inspection, were also discussed during the meeting.

- Adapter Nozzle.

FPC stated they purchased the nozzle directly from the original equipment manufacturer (OEM) and had it installed by the OEM service representatives during the recent outage at CR3. Therefore, it is FPC's opinion that not all safety functions and critical characteristics need to be identified and verified to provide reasonable assurance that the item received is the item specified.

- Thrust Bearing Sets.

FPC stated that material identification and verification was not considered necessary and that this position was supported by the sample technical evaluations prepared by EPRI's Joint Utilities Task Group. In the area of sampling, FPC stated that their use of MIL-STD-105D is adequate to determine sample size when lot homogeneity has been established.

- Stainless Steel Plate Material.

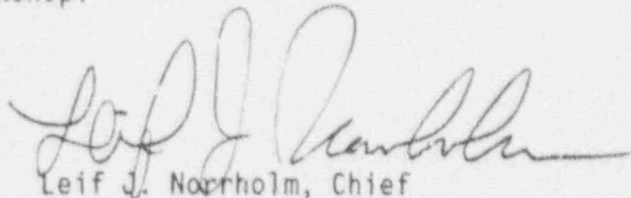
FPC performed a hardness test to verify receipt of the proper material but did not compare the results to a manufacturer's certified material test report (CMTR). FPC's reason, consistent with NRC's position, was that the CMTR would not have been useful since the material supplier was never audited. FPC also stated that the material had limited (restricted) applications.

- Swing Check Valve Disc Seat.

FPC agreed, in general, with the NRC position and stated that it will improve the level of documentation and objective evidence contained in source inspection reports in the future.

In summary, progress was made in identifying areas which warrant further review, including what constitutes reasonable assurance and the level of dedication necessary to achieve such assurance. FPC also stated that some disagreements were inevitable since the inspection team inspected to the guidance contained in GL 91-05 while FPC dedicated CGIs to EPRI NP-5652.

Finally, it was stated that the NRC would be conducting a public workshop which will address issues concerning the existing dedication guidance and specific interpretations of that guidance. Prior to the public workshop, the proposed inspection procedure for future inspections will be issued for public comment and discussion at the workshop.

A handwritten signature in dark ink, appearing to read 'Leif J. Norrholm', is written over the typed name.

Leif J. Norrholm, Chief  
Vendor Inspection Branch  
Division of Reactor Inspection  
and Licensee Performance  
Office of Nuclear Reactor Regulation

Enclosures:

1. Dedication Issues
2. Meeting Attendees

cc w/o enclosures:  
W. Russell



ENCLOSURE 1

## DEDICATION ISSUES

### 1. BASIS FOR THE SELECTION AND VERIFICATION OF CRITICAL CHARACTERISTICS

#### a. Consideration of Item's Safety Function

Critical characteristics should be based on the item's safety function. The licensee is responsible for identifying the important design, material, and performance characteristics for each item, establishing acceptance criteria for these characteristics, and providing reasonable assurance of conformance to these criteria. Upon the completion of the dedication process, the quality assurance or compensatory measures applied to those aspects of the item which directly affect its safety function should result in the same level performance reliability as for a like item manufactured under an Appendix B program.

#### b. Failure Modes and Effects Analysis

Failure modes and effects analysis can be a valuable tool which can be used for both, classification of an item as safety-related or nonsafety-related and for identifying the critical characteristics of an item. An evaluation of credible failure modes of an item in its operating environment and the effect of these failure modes on the item's safety function should be used as the basis for selection of critical attributes to be verified during the dedication process.

#### c. Reasonable Assurance

The dedication process is not substitute for Appendix B. Rather, it represents a method of achieving compliance with Appendix B, with the purchaser assuming many of the responsibilities for assuring quality and functionality of an item which had previously been the responsibility of the vendor. In this context, reasonable assurance consists of the purchaser providing control over the activities affecting the item's quality to an extent consistent with the item's importance to safety. For more complex items, dialogue with the original equipment manufacturer may be necessary to identify the design and functional parameters of specific piece parts.

#### d. Engineering Judgement

The use of engineering judgement in the dedication process is acceptable providing that the bases for such judgements are documented.

## 2. SAMPLING

### a. Established Heat Traceability (materials)

When heat traceability of material is established through a commercial grade survey, the party performing dedication of this material may accept the certified material test report (CMTR) that certifies activities which must be performed during (1) the melting, and (2) the heat analysis; provided that the party dedicating the material performs or subcontracts the performance of all other requirements of the material specification and/or those requirements identified as critical characteristics, on a representative sample of that material.

### b. Established Lot/Batch Control

When Lot/Batch (defined as units of product of a single type, grade, class, size and composition, manufactured under essentially the same conditions, and at essentially the same time) control is established through a commercial grade survey, the party performing dedication can develop sampling plans based on standard statistical methods. Such sample plans should be documented and provide for the verification of the critical characteristics with confidence level consistent with the item's importance to safety.

### c. Bulk Commodity Items

When Lot/Batch traceability can not be established, each item may need to be tested. Any sampling plans for such items would need to be considered on individual, item-specific basis and assure that they are capable of providing a high level of assurance of the item's suitability for service.

## 3. TRACEABILITY

### a. Material/Items Purchased from Distributors

Traceability can be defined as the ability to verify the history, location, or application of an item by means of recorded identification (NQA-1). Traceability is necessary to prevent the use of incorrect or defective material and should be maintained throughout the dedication process. Where the item's acceptance is based entirely or partially on a certification by the manufacturer, the traceability must extend to the manufacturer. If intermediaries (distributors) are included in the supply chain, their capability of maintaining traceability should be assured by audit.



#### 4. COMMERCIAL GRADE SURVEYS

##### a. Verification of Vendor's Control of Specific Characteristics

A commercial grade survey should be specific to the scope of the commercial grade item or items being purchased. The vendor's controls of specific critical characteristics to be verified during the survey should be identified in the survey plan. The verification should be accomplished by reviewing the vendor's program/procedures controlling these characteristics and observing the actual implementation of these controls in the manufacture of items identical or similar to the items being purchased.

##### b. Identification of Applicable Program/Procedures

The vendor must have a documented program and/or procedures to control the critical characteristics of the item or items being procured which are to be verified during the survey. When many items are being purchased, a survey of a representative group of similar items may be sufficient to demonstrate that adequate controls exists. If the vendor's controls are determined to be satisfactory, purchase orders for these items should invoke these controls as contract requirements by referencing the applicable program/procedure and revision. Upon completion of the work, the vendor should certify compliance with the purchase requirements.

##### c. Documentation of Survey results

Commercial grade survey documentation should include the identification of item or items for which the vendor is being surveyed, identification of the critical characteristics of these items which the vendor is expected to control, identification of the controls to be applied (program/procedure and revision) and a description of the verification activities performed and results obtained. Deficiencies identified during the survey which may affect control of the identified critical characteristics should be addressed by requiring the vendor to institute additional controls or by utilizing other verification and acceptance methods.

#### 5. LIKE FOR LIKE REPLACEMENTS

##### a. Replacement with Identical Item

If it can be demonstrated that the replacement item is identical to the item that it replaces, review of the replacement item's safety functions and identification of the critical characteristics are not necessary. An example of such replacement would be the replacement of an installed commercial grade item with an item from warehouse which has the same model/part number and which was purchased from the same vendor at the same time.

b. Like-for-Like Verification

If it can not be demonstrated that the replacement item is identical or if differences between the items are identified, an evaluation is necessary to determine if any changes in design, material, or manufacturing process could impact the item's critical characteristics and its ability to perform the intended safety function.

6. ACCEPTANCE OF CERTIFIED MATERIAL TEST REPORTS (CMTRs) AND CERTIFICATES OF COMPLIANCE (COCs)

a. Validity Verified Through Vendor/Supplier Audit or Testing

The validity of vendor CMTRs and COCs should be verified. This can be accomplished through a commercial grade survey or, for simple items, periodic testing of the product upon receipt. Such verifications should be conducted at intervals commensurate with the vendor's past performance. If the item's supply chain includes a distributor, the verification survey should include warehousing and/or traceability controls at the distributor's facility.

ENCLOSURE 2

FPC - NRR MEETING  
COMMERCIAL GRADE DEDICATION  
December 4, 1992

NAME	ORGANIZATION
Robert Peltis	NRR/VIB
Leif J. Norrholm	NRR/VIB
Charles E. Rossi	NRR/DRIL
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Joseph J. Petrosino	NRR/VIB
Art Gallow	OI/NRR
Harley Silver	NRR/PDII2
McKenzie Thomas	Reactor Inspector, NRC/Region II
Biff Bradley	NUMARC
Steve Alexander	NRR/VIB
Gary Zech	NRR/RPEB
Tim Catchpole	FPC

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OFFICE	VIB/DRIL	VIB/DRIL	VIB/DRIL	DRIL/NRR	DRIL/NRR	
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NAME	RPETTIS	UPOTAPOVS	LNORRHOUM	RZIMMERMAN	CECH	
DATE	12/30/92	12/30/92	12/27/92	12/13/92	2/16/93	
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