D509 6687 G. Potapovs 58FR15167

USNRC
OFFICE OF ADMINISTRATION

'93 MAY 34 A10:17

3/19/93

(18)

Florida Power
CORPORATION

May 27, 1993
DNSP93-0004

Mr. David L. Meyer, Chief
Rules Review and Directives Branch
Office of Administration
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555

Subject: Solicitation of Public Comments on Draft NRC Inspection Procedure 38703, "Commercial Grade Procurement Inspection"

Reference: NUMARC Letter Dated May 17, 1993, William H. Rasin to David L. Meyer

Dear Mr. Meyer:

The referenced NUMARC letter contains general comments relative to the subject draft inspection procedure. Florida Power Corporation takes this opportunity to endorse NUMARC's comments and to provide more specific comments as requested in Federal Register, Volume 58, Number 52, dated March 19, 1993. To facilitate your review of our document, we have italicized those comments we consider to be duplicate comments contained within the referenced NUMARC letter.

We appreciate the opportunity to comment on the draft inspection procedure and agree with NUMARC's assessment that the inspection approach described in the draft procedure represents a significant improvement.

Sincerely,

Rolf C. Widell, Director
Nuclear Operations Site Support

TWC:pkt

Enclosure

xc Mr. P. M. Beard, Jr.

COMMENTS ON NRC INSPECTION PROCEDURE 38703
(PROCUREMENT INSPECTION MODULE)

FPC has specific comments with respect to the subject inspection procedure beginning on page 2 of this attachment. However, there are several general concerns as follows with respect to Commercial Grade Item (CGI) dedication activities that must be acknowledged by the NRC to avoid the possibility for conflict between licensees and NRC Region inspectors after the Regional offices have inspection responsibility for this module.

PERFORMANCE BASED ASPECTS OF REACTIVE INSPECTIONS

FPC has no objections to a reactive inspection and welcomes the benefits that can be derived from oversight of its procurement process to determine if it can be enhanced to prevent the failure of components and parts used in our facility. However, the guidance contained in the subject procedure does not take into account the fact that 1993 criteria applicable to the dedication of commercial grade items is much more prescriptive than it was in previous years. FPC's commitments in this area are described in NUMARC's Comprehensive Procurement Initiative (NUMARC 90-13) which was required to be fully implemented in June, 1992. This initiative was a forward-looking effort that assumed no inadequacies of dedications performed prior to implementation of improvements to the dedication process, but recognized that improvements were warranted to address performance-based verifications of technical and quality requirements. As such, ***dedication packages associated with parts used in items that may fail in 1993 and beyond are most likely to be of a vintage prior to the implementation of the Comprehensive Procurement Initiative*** and should be evaluated in accordance with requirements in effect when the dedication took place. Therefore, additional guidance should be provided to incorporate reasoning to allow the inspector to evaluate other aspects of the licensee's pre-existing program regarding dedication.

PARTS PROCURED UNDER APPENDIX B PROGRAMS VS. COMMERCIALLY AVAILABLE

It is important for the Regional Inspector to understand that items procured commercially and dedicated for nuclear use by the utility have no inherent deficiencies. ***There should be no bias towards one program that purchases a majority of safety related items from vendors having nuclear QA programs as opposed to another that uses a commercial grade dedication process*** to achieve the same acceptable item.

PROCUREMENT QA AS A SUBSET OF OVERALL QA

No one element of a licensee's QA program can provide 100 percent assurance that a failure will not occur. The concept expressed in the reactive inspection guidance that a failure can result from an inadequate dedication (missed inspection) is a reasonable one only when placed in the proper context. There are several examples provided with the inspection module that suggest the inspector take into consideration such things as post-installation testing, surveillance programs, functional performance history, etc. Unless it can be shown that commercial grade items have a higher failure rate than items procured under Appendix B programs, ***the emphasis on failure with respect to dedication in a different manner than other items does not appear to be warranted.***

Additionally, the procurement process should not be expected to solve failure-related problems. A procurement engineer who may be asked to procure a replacement item because of a failure should not, as part of the procurement process, be expected to analyze the need to specify a different item to compensate for the failure. This responsibility is covered by other aspects of the licensee's QA Program.

REASONABLE ASSURANCE

Any attempts to define the term "reasonable assurance" only within the context of commercial item dedication should be avoided. The NRC has not applied this term to other areas subject to inspection and by doing so may find itself in the position of having to create additional definitions. ***Reasonable assurance is inherent in the process for dedication of commercial grade items*** for nuclear use as described in EPRI NP-5652.

SPECIFIC INSPECTION PROCEDURE COMMENTS BY REFERENCED SECTION

[38703-01] INSPECTION OBJECTIVE

Replace the word "ensures" in the fifth line with the words ". . . ***provides reasonable assurance*** . . . that CGI's will perform their intended safety function."

[38703A-01] REACTIVE INSPECTION OBJECTIVES

Replace the word "ensure" in the fifth line with the words ". . . ***provide reasonable assurance*** . . . that the dedicated CGI will perform its intended safety function."

[38703A-02] REACTIVE INSPECTION REQUIREMENTS

02.04 Determine if the Failure was the Result of an Inadequate Dedication

The guidance in the first paragraph of this item should expand the use of the term "failure analysis" to "failure/root cause analysis when required or applicable". This would address the fact that complex Failure Modes and Effects Analyses (FMEA) should not be expected by the inspector. It would also address the fact that a failed item will have been replaced well before completion of a root cause analysis. The inspector should request the results of such an analysis only if completed.

The term "adequately addressed" in the second line of the second paragraph of this item should be modified to delete the word "adequately". Critical characteristics associated with the failure of an item should either be addressed or not addressed. The scope of Item 02.04 focuses on whether or not the verification of identified critical characteristics is satisfactory with respect to the failure, whereas Item 02.04 addresses those instances in which associated critical characteristics may not have been identified.

The introduction of adequacy with respect to identification of critical characteristics in Item 02.04 confuses the issue and has the potential for conflict.

[38703B-01] PROGRAM INSPECTION OBJECTIVES

Replace the word "ensures" in the second line of this paragraph with the words ". . . ***provides reasonable assurance*** . . . that CGI's will perform their intended safety function."

[38703B-02] PROGRAM INSPECTION REQUIREMENTS

02.01 Scheduling the Inspection and Contacting Licensee

This item suggests the inspector request a list of recent component failures. Such a list identifies parent component numbers and is readily available at CR3. The list does not differentiate whether or not the component contains dedicated commercial grade items. There is an interface between the configuration management, Work Request system, and the inventory control computer bases that would allow for a reasonable determination of the parts used in the parent component and whether or not those parts are currently purchased commercially and dedicated. This information does not provide any assurance, however, that the part installed in the failed component was subject to dedication prior to use. To obtain assurance of the actual parts installed would require a review of the Work Request history of the parent component and a search of associated microfilm records to obtain reference to part issue documentation and, ultimately, the applicable Purchase Order. The above explanation is provided in an attempt to explain the comment relative to Item 02.02 below.

02.02 Selection and Content of Dedication Packages

The flow chart provided during the NRC Public Workshop on April 21-22, 1993, along with guidance contained in Section 38703B-03, Item 03.02, indicates the inspector should select 15 packages associated with items derived from the list of recent failures provided by the licensee and another 5 from the list of items dedicated by the licensee over the past 2 years. First, it should be understood that ***failures caused by normal wear, end-of-life, or other similar causes will not provide meaningful examples for the subject type of inspection.*** This then will most probably result in a smaller "lot size" of available failures to use as input to the programmatic inspection. In view of this and in recognition of the resources that will be required to retrieve the necessary information, it is recommended that a total sample size of 10, evenly divided between those associated with known failures and those from the list of dedicated items, would be more appropriate.

02.04 Review of Dedication Packages

The first bulleted paragraph of this item indicates the inspector should "review the technical evaluation portion of the (dedication) package." This should refer to "associated documents" which contain technical evaluations. FPC uses Modification Approval Records (MARs), Plant Equipment Equivalency Evaluation Reviews (PEERE), calculations, and Safety Classifications of Items to implement the intent of the technical evaluations associated with commercial grade items used in safety related applications. These documents are not maintained with the dedication "package" and may or may not be directly referenced as the basis of purchase for the items selected for review by the inspector.

The second bulleted paragraph of this item suggests the inspector take into consideration such things as post-installation testing and periodic surveillance testing and inspection when reviewing the licensee's selection of critical characteristics. It should also suggest to the inspector that the ***licensee may use engineering judgment based upon a graded approach in the selection process in terms of the item's relative safety significance.***

The fourth bulleted paragraph of this item should delete reference to the term "like-for-like" since its definition is cumbersome and confuses the issue of the dedication of replacement items. It should be sufficient for the inspector to determine if the item is a replacement item or new.

The fifth bulleted paragraph of this item provides guidance on determining why a particular item has been replaced (repeated failures, degraded performance as a result of adverse environment, etc.). While this may be useful input to allow the inspector some perspective, it should be understood that the ***procurement process is typically not used on an item-by-item basis to evaluate the causes of failures or if a different item is more appropriate than an available replacement item.*** This is the function of a trending program or programs such as the feedback process suggested in the seventh bulleted paragraph of this item.

[38703B-03] PROGRAM INSPECTION GUIDANCE

03.02 Selection and Content of Dedication Packages

a. Selection of Dedication Packages

For the reasons stated above, in Section 38703B-02, Item 02.02, the sample size should be 10, not 20 packages.

b. Contents of Dedication Packages

For the inspector who may not be fully conversant in dedication activities, it would be helpful to suggest that dedication "packages" may consist also of the results of the licensee's evaluation of commercial grade survey reports. Often these

evaluations provide useful insight regarding how much of the commercial grade vendor's program is being taken credit for or how the reviewer determined the survey could apply to similar products even though they may not have been addressed in the survey report.

03.04 Review of Dedication Packages

The word "ensure" in the second line of the first paragraph of this item should be replaced with the words ". . . ***provide reasonable assurance*** . . . that the CGI's being dedicated . . . will perform their intended safety function."

b. Method 2 - Survey

In the first bulleted paragraph of this item, ***reference to Generic Letter (GL) 89-02 should be deleted. FPC never committed to this guidance and has docketed correspondence indicating the guidance depicted in GL 89-02 amounts to a backfit.*** FPC procedures for conducting surveys of commercial grade suppliers follow the guidance of EPRI NP-5652 as referenced in the Comprehensive Procurement Initiative which constitutes the latest commitments in this area.

The fifth bulleted paragraph of this item implies that a commercial grade survey should verify the validity of supplier documentation. FPC views this activity as inherent in the survey process. There should be no expectation that the survey report contains a separate discussion of how the supplier's certification may be considered valid.

The sixth bulleted paragraph of this item should not infer that technical specialists are always included on survey teams, in addition to Quality personnel. The use of technical specialists on survey teams is desirable but discretionary depending on the scope and complexity of the item being surveyed. FPC's commitments as a member of NUPIC involve the use of technical specialists on all NUPIC Joint Commercial Surveys led by FPC. In addition, the majority of the other surveys led by FPC include engineering or other subject matter specialists. However, FPC has made no commitment to augment survey teams on a 100 percent basis.

The seventh bulleted paragraph of this item contains the possibility for subjectiveness. It suggests that the inspector question whether or not the licensee regularly updates a survey. During the NRC Public Workshop conducted April 21-22, 1993, one member of the Vendor Inspection Branch suggested that a survey should not be valid beyond the triennial approval period applied to audits of suppliers which have 10 CFR 50 Appendix B programs. While FPC currently uses this approval period as a basis for its CGI Survey Program, we are investigating the use of Method 4 performance information as a means of extending the period during which a survey may represent the acceptable implementation of supplier controls relative to critical characteristics. Based on a combination of annual evaluations and good performance history (FPC and industry), FPC may choose to

continue to apply judgement to the decision regarding the need to update a particular survey.

d. Acceptable Supplier/Item Performance Record

For the reasons described above, ***reference to GL 89-02 in this item should be deleted.***

03.05 Review of Training Effectiveness

The word "enhanced" used in the third bulleted paragraph of this item should be removed. The term attempts to interpret post-receipt verification testing or inspection in a different manner than its normal context. It creates the possibility that an inspector may, in all cases, expect special plans to be developed for all post-maintenance tests associated with dedicated items.

[APPENDIX A] DEDICATION ISSUES

1. Basis for selection and verification of critical characteristics

a. Consideration of an Item's Safety Function

The concept that critical characteristics for acceptance should be all those that have a direct impact on the item's safety function promotes the idea that the individual item's safety function must be identified. Since most safety functions are determined on a component level and CGI dedications are typically performed on the piece-part level, the need for re-engineering is introduced. CR3 was generally "designed" at a component level and then only for important component functions. Usually, materials of construction and detailed design (including piece parts) were the vendor's responsibility. Using the NRC's concept of how critical characteristics relate to safety function would obviate the need for licensees to assume responsibility for piece-part design. This is not the most efficient process as relates to procurement and places the procurement engineer in a position of having to become expert in the design of the piece part in order to satisfy the scrutiny of the NRC inspector. It is ***more appropriate to be able to select, using a graded approach, critical characteristics that relate to important technical and quality requirements (including operational performance parameters) specified or referenced in the procurement document(s).*** This is adequately described in EPRI NP-5652 which is endorsed by the NUMARC Comprehensive Procurement Initiative and forms the basis of FPC's commitment in this area.

c. Reasonable Assurance

The only comment regarding the discussion in this item is that ***"reasonable assurance" should be applied to the process of selecting critical characteristics as well as to verification of the same.*** Instead of the phrase "must have a direct impact of the item's ability to accomplish its intended safety function", Item 1.a should use the term ". . . must ***provide reasonable assurance*** of the item's ability. . . ."

d. Engineering Judgment

The wording in this item is acceptable. However, its interpretation by some members of the Vendor Inspection Branch results in a concern regarding unnecessary documentation. It should be clear that FPC does intend to document the bases of engineering judgments used in the dedication process relative to decisions made. It is not our intention, nor should it be expected, that documentation will be provided for why certain decisions were not made. If a decision is made to verify only a portion of a list of critical characteristics (identified by FPC), the basis for the decision should be documented. Conversely, if a procurement engineer determines that a listing of important functions and typical failures are related to an item, a description of these should be identified. An explanation as to why others were not chosen should not be required.

2. Sampling

a. Established Heat Traceability (materials)

This item should be expanded to cover greases, plastics, polymers, etc. that also have lot controls analogous to metals.

The use of "reasonable assurance" should be applied to the selection of analyses and tests to verify critical characteristics. It should be clarified that not all analyses or tests depicted in the material specification or product literature need be repeated to determine that a lot with established heat controls is acceptable.

b. Established Lot/Batch Control

It should be understood that, in addition to commercial grade, "other means" of establishing lot/batch control may include, but not be limited to, receipt inspection, source inspection, and other industry standards such as SAE, ISO 9000 Certification, etc.

3. Traceability

a. Material/Items Purchased From Distributors

A more practical criteria for determining if a distributor needs to be surveyed would be to identify whether or not the distributor affects (converts, modifies, or otherwise corrupts) the item in some way.

Terminology such as "physical possession of the item" leads to interpretation and potential conflict regarding whether or not a survey of a particular distributor should have been performed.

4. Commercial Grade Surveys

b. Identification of Applicable Program/Procedures

FPC agrees that a commercial vendor should have a formal program to be a candidate for a survey. However, it is ***not always practical to invoke the vendor's applicable program/procedure and revision in procurement documents***. Flexibility is needed similar to that suggested by EPRI NP 5652 Table 3-1 which indicates the "observed controls" should be referenced in the purchase document. This would allow certification to the controls observed during a particular reference survey in lieu of a QA Manual that may be considered proprietary and not available in a controlled format.

5. Like-for-Like Replacements

a. Like-for-Like Verification

The term ***"like-for-like" should be deleted from this discussion.*** It is terminology more suited for discussion of design issues and is confusing to discussion of controls associated with replacement items.

[APPENDIX B] DEFINITIONS

1. ***Remove the definition of "like-for-like".***

2. Review all definitions for agreement with accepted EPRI definitions. Note, the recently issued Supplemental Guidance to NP-5652 should also be reviewed to determine if changes to previously accepted EPRI definitions incorporate the latest industry consensus. Those differing from EPRI definitions include "acceptance", "critical characteristic" (should differentiate between critical characteristics for design and critical characteristics for acceptance), "equivalency evaluation", and "reasonable assurance".

3. Add a definition for distributor to ensure the term is meant to apply to "agents", manufacturer's sales offices, authorized representatives, stocking distributors, etc.