DS09 6687 M. Potapous 58FR15167 3/19/93 (15)

Stephen B. Bram
Vice President

Consolidated Edison Company of New York, Inc.
Indian Point Station
Broadway & Bleakley Avenue
Buchanan, NY 10511
Telephone (914) 737-8116

May 20, 1993

Re: Indian Point Unit No. 2
Docket No. 50-247

Chief, Rules Review and Directives Branch
Office of Administration
US Nuclear Regulatory Commission
Washington, DC 20555

Subject: NRC Draft Commercial Grade Dedication Inspection Procedure

Consolidated Edison is pleased to provide comments in response to the request for comments included in the notice of the Commercial Grade Procurement and Dedication Workshop which appeared in the Federal Register dated March 19, 1993 (58 FR 15167). In that request, comments were invited on the draft inspection procedure 38703, entitled "Commercial Grade Procurement Inspection". Comments were requested by May 21, 1993.

The Nuclear Management and Resources Council (NUMARC) has submitted comments by their letter dated May 17, 1993. We have reviewed their letter and endorse their comments. In addition, we also offer general comments on the draft procedure, as well as comments directed to specific statements in the draft procedure, provided in Enclosure 1.

Overall, we are concerned that the NRC's expectations for licensee documentation and testing in order to dedicate commercial grade items apparently exceeds requirements imposed in the past on 10 CFR 50 Appendix B vendors who have supplied equivalent items. We believe that this additional effort, while adding substantially to our procurement costs and schedules, would not provide commensurate improvements in the level of assurance that commercial grade items would perform as expected. Under the draft inspection approach, we may order testing which would not meaningfully enhance our knowledge about component performance, and expend effort to create volumes of unnecessarily detailed documentation.

The solution to this problem would appear to be performance-based inspections, initiated in response to an industry or licensee event, focused more on results than on procedures. We believe that the subject draft procedure is heavily weighted toward evaluating process and procedural details, and incorrectly emphasizes documentation over performance. Indeed, the subtle but pervasive philosophy of the draft inspection procedure could elicit an excessive commitment of NRC staff inspection resources to commercial grade procurement issues.

We recognize that this procedure, and the NRC positions communicated at the Dallas workshop April 21 and 22, represent a movement toward reasonable procurement quality assurance and performance-based inspection. However, we believe that significant further efforts in the same direction are necessary before the NRC's commercial grade procurement guidance can become sufficiently workable in practical applications. Because of the breadth of our comments, and what we presume will be other similar comments from the industry, we urge the NRC to circulate another version of the procedure in draft prior to finalization.

Should there be any questions regarding these comments, please contact Mr. Charles W. Jackson, Manager, Nuclear Safety & Licensing, at (914) 526-5127.

Very truly yours,

cc: Document Control Desk
US Nuclear Regulatory Commission
Mail Station P1-137
Washington, DC 20555

Mr. Thomas T. Martin
Regional Administrator - Region I
US Nuclear Regulatory Commission
475 Allendale Road
King of Prussia, PA 19406

Mr. Francis J. Williams, Jr., Project Manager
Project Directorate I-1
Division of Reactor Projects I/II
US Nuclear Regulatory Commission
Mail Stop 14B-2
Washington, DC 20555

Senior Resident Inspector
US Nuclear Regulatory Commission
PO Box 38
Buchanan, NY 10511

ENCLOSURE 1

COMMENTS ON DRAFT NRC INSPECTION PROCEDURE 38703

General

It appears that this procedure requires more detailed documentation and testing than would be provided under a Quality Assurance program which meets the requirements of 10 CFR 50 Appendix B. This represents a backfit, for which there has been no demonstration of necessity. To the extent the NRC's premise is that dedicated commercial grade items contribute to more and graver safety significant problems than items procured from vendors who meet Appendix B requirements, a full explanation should be afforded.

General

The draft inspection procedure is highly detailed and prescriptive. It anticipates detailed documentation of every decision and action during the procurement and acceptance process for dedicated commercial grade items. The motivation appears to be that licensees take over responsibility for certain functions normally performed by the vendor when the vendor has an Appendix B program. However, such detailed documentation has not normally been required under Appendix B programs. Appendix B requires only that certain activities be controlled, not that every consideration be documented in detail. It appears that the proposed inspection procedure would look for licensee documents that are more specific and detailed than would generally be found in Appendix B vendor records, and go far beyond demonstrating that applicable activities are adequately controlled. This requirement would therefore represent a backfit, for which no supporting justification has been put forth.

General

Consideration should be give to amending the draft inspection procedure to include items purchased from vendors with Appendix B QA programs. The imposition of any requirements for the licensee (when the item is procured commercial grade and dedicated) that would not also have applied to a vendor who met Appendix B requirements at the time of the original purchase should be deleted.

General

The flow charts shown at the workshop did not match the draft procedure. Because these flow charts would be a helpful training tool, they should be reviewed in detail against the procedure as issued. Consideration should be given to including flow charts in the procedure.

General

A great deal of information and experience has been gained by the industry and the NRC on procurement issues in recent years. In recognition of this progress and for ease of reference, a new Generic Letter is warranted to supersede Generic Letters 89-02 and 91-05, to consolidate the NRC position into one document.

General

Due to the many variables in the procurement process, and the need for application of judgement, it is important that inspectors receive training in this procedure. For the same reasons, there should be central oversight of inspection results to assure consistency among Regions. The goal of training and central oversight should be to keep the focus on the safety significance of results and to avoid overemphasis on programmatic rigidity and detailed documentation.

38703A-02.04

Guidance is needed for the NRC inspectors when the commercial grade item of interest was dedicated prior to the industry's commitment to the procurement initiative.

38703A-02.04e

"Any documentation...should be validated by a commercial grade survey, source verification, or methods discussed in Section 6 of Appendix A to Inspection Procedure 38703."

Should be changed to "...should have an established basis for its validity. Methods for establishing a basis for validity may include a commercial grade vendor survey, source verification, history of spot check results during receipt inspections, history of installed performance, or other suitable means commensurate with the safety significance and complexity of the item."

38703B-01

"Verify that the licensee's process for dedicating CGIs...ensures that CGIs will perform their intended safety function."

Recommend changing "ensures" to "appropriately contributes to assurance".

The original wording is too broad, and "ensure" is too absolute as a concept. Dedication is a procurement and acceptance process. The Appendix B requirements clearly do not intend procurement and initial acceptance to bear the full burden of assuring performance of the intended safety function. The other elements of the Quality Assurance program also contribute to this assurance.

38703B-02.02

"...select approximately twenty dedication packages for review."

Instead of a definite number of packages, alternative approaches such as selecting a percentage or a statistical sampling, not to exceed 20, should be acknowledged as appropriate. The sample should be balanced to assess the program results and not be biased to focus on failures.

38703B-02.02

"...the inspector should request that the licensee compile a complete package of all the procurement and dedication records for each item."

The inspector's list should be provided to the licensee at least 2-4 weeks before the site visits, to allow retrieval and reproduction of the material outlined in Section 03.02(b). This material is typically maintained in various files and locations, and would have to be located, accessed, copied and brought to the site of the inspection.

38703B-02.04; 38703B-03.02, 03.03, 03.04 and 03.05; and 38703B-05

Replace bullets with alphanumeric characters so that these items can be more easily referenced.

38703B-02.04, 02.05, 03.03 and 03.04

When referencing ANSI standards, add a note to indicate that these standards are applicable only to the extent of the licensee's commitment to them.

38703B-02.04

1st bullet: "...safety-related function"

Change to "safety function," for clarity.

38703B-02.04

1st bullet: "..consideration of credible failure modes"

Delete because Appendix R does not require an explicit listing of credible failure modes.

38703B-02.04

1st and 3rd bullets: "- item equivalency/substitution evaluations" and "Determine whether the item is a like-for-like replacement, or a new item replacement of an obsolete item."

Delete these statements. They pertain to the plant modification control process, and not to procurement or dedication.

38703B-02.04

5th bullet: "Determine why the item is being replaced..."Corrective Action.""

This guidance should be deleted. Failure analysis is not a routine part of the procurement process. There are other licensee programs which address failure analysis and which have their own NRC inspection guidance, which could be referenced by this procedure.

How is this level known? How is this level measured? Where is such data available? This standard should not be imposed without identifying how the comparison can be objectively made. Since commercial grade dedication is based on verifying adequacy of critical characteristics, and Appendix B quality assurance is based on documented control of activities, the results may not be directly comparable.

Appendix A, 1d

"The bases for engineering judgement for this application should be documented."

Deleted or change to "Any references used should be documented".

This sentence should be deleted or changed. If bases can be provided, then selection is based on analysis, not judgement.

Appendix A, 2a

Expand to make clear that single sample testing may also be adequate for nonmetallic material, if the material is known to be uniform for the particular application intended.

Appendix A, 5

Delete the section on "Like-For-Like Replacements". The same procurement and, if necessary, dedication process applies regardless of whether the item is an identical replacement, an equivalent replacement, or part of a design modification.

Appendix A, 6

This section should be generalized to address all types of certification by vendors.

Appendix B

Add a definition of "failure" in terms of triggering entry to Inspection Procedure 37803. The definition should explicitly exclude normal wear-out, end-of-life and random occurrence.

Appendix B

Delete the terms "Equivalency Evaluation" and "Like-For-Like Replacement", and their definitions. The same procurement and, if necessary, dedication process applies regardless of whether the item is an identical replacement, an equivalent replacement, or part of a design modification.

Appendix B

Add "technical and quality" before "requirements" in the definition of "Technical Evaluation".

38703B-03.04a

4th bullet: "Verify that the tests and inspections specified for acceptance adequately verify performance and suitability for all intended applications."

Change to "Verify the identified critical characteristics."

The original wording is too broad, and puts the entire burden of assuring performance of the intended safety function on receipt and pre-service tests and inspections. This is not the intent of Appendix B, which outlines other required elements of a quality assurance program. These elements are intended to work together to provide such assurance. Compare the fourth bullet under Section 03.04b and the first bullet under Section 03.04c for more suitably focused wording.

38703B-03.04a

6th bullet: Delete second "QA", so that the cited activities will not be misunderstood to be necessarily a QA Department function.

38703B-03.04a

7th bullet: Delete this item for several reasons. First, traceability does not depend solely on receipt inspection activities. Second, traceability considerations are not limited to Method 1. Third, traceability applies to items purchased from Appendix B vendors the same as to dedicated commercial grade items.

38703B-03.04b

1st bullet: Delete "the guidance... Specifically, that." This will delete the reference to Generic Letter 89-02 and make the inspection procedure more self-contained. Also, a previous comment recommends a new Generic Letter to supersede Generic Letters 89-02 and 91-05.

38703B-03.04b

2nd bullet: "- Processing and evaluating adverse findings..." This statement should be deleted because it implies a documented feedback program which would be redundant to the existing corrective action programs. Also, this type of approach is not required for items purchased from Appendix B vendors and commercial grade items should not be treated any differently after dedication.

38703B-03.04b

Last bullet: Delete last sentence. The list of information sources could be misconstrued as a check list.

38703B-03.04b

6th bullet: Delete first two lines.

38703B-02.04

6th and 7th bullets

Delete both these bullets. Control of items after receipt inspection and feedback of information are not unique to the dedication process, and therefore do not belong in this procedure.

38703B-02.01 and 03.02a

Since most plant documents do not identify whether items were purchased from Appendix B vendors or dedicated, it will generally be difficult to identify which failures involved equipment or parts that had been dedicated. Therefore, include in the inspection procedure the alternative of selecting dedication packages to be traced through to installation and performance in the installed application.

38703B-03.02a, Step 1

Reduce selection of dedication packages from among CGI failures from 75% to a maximum of 50%. This will allow the inspection to determine more accurately whether there are programmatic problems. Focusing too much on failures could give a distorted view of the nature and pervasiveness of any problems found.

38703B-03.02a, Step 2

At the end of the second bullet, explain what the "NRC morning reports" are.

38703B-03.02b

Divide the list of documents into two sets, those which pertain specifically to dedications and those which may pertain to any items with safety related applications. Most of the information listed will fall into the latter category. This will help the inspector differentiate between dedication specific activities and activities related to more general plant programs.

38703B-03.02b

Under sixteenth bullet, last item: "- evaluation of credible failure modes"

Delete this item. It is not a required part of the commercial grade dedication document, or of any procurement or acceptance document. Such an evaluation may serve as a useful aid at times, but should not be understood to be a requirement of the procurement or acceptance process.

38703B-03.03

1st bullet: Delete second "QA", so that the cited review and approval will not be misunderstood to be necessarily a QA Department function.

38703B-03.03

2nd bullet: Change "purchase requisitions and purchase orders" to "procurement documents", for consistency with Appendix B.

38703B-03.04b

7th bullet: Delete "teams include technical and quality". Surveys may be performed by a single individual with support, as needed, from others who do not actually visit the vendor. Also, there need be no distinction between technical and quality personnel.

38703B-03.04d

1st bullet: Delete "the guidance...Specifically". This will delete the reference to Generic Letter 89-02 and make the inspection procedure more self-contained. Also, a previous comment recommends a new Generic Letter to supersede Generic Letters 89-02 and 91-05.

38703B-03.04d

1st bullet: "...the manufacturer's measures for the control of design, process, and material changes".

Change to "measures for the control of the design, material, and performance characteristics relevant to the safety function."

This change would make Method 4 compatible with the other methods, by focusing on the critical characteristics. Otherwise, the manufacturer could very carefully control the design, process and materials, yet not recognize effects on characteristics which are significant to the nuclear safety application.

38703B-03.05

4th bullet: Changes "purchase orders" to "procurement documents" for consistency with Appendix B.

38703B-05

Add dates to the references. This will identify the documents more completely, and give a better sense of historical development.

Appendix A

Add a section on distributors, to gather guidance in one place. In other sections (e.g., 3a and 6a), reference the new section instead of giving specific guidance. Distinguish between those distributors who merely process orders and those who handle, repackage, or otherwise could affect the delivered items.

Appendix A, 1c

"...same level performance as for a like item manufactured or purchased under an Appendix B program."