

March 19, 2001

Mr. R. G. Lizotte  
Master Process Owner - Assessment  
c/o Mr. David A. Smith  
Northeast Nuclear Energy Company  
P. O. Box 128  
Waterford, CT 06385-0128

SUBJECT: REQUEST FOR ADDITIONAL INFORMATION (RAI) REGARDING REVIEW OF  
PROPOSED REVISION TO THE NORTHEAST NUCLEAR ENERGY  
COMPANY QUALITY ASSURANCE PROGRAM FOR MILLSTONE NUCLEAR  
POWER STATION, UNIT NOS. 2 & 3 (TAC NOS. MB1105B AND MB1106B)

Dear Mr. Lizotte:

By letter dated January 26, 2001, Northeast Nuclear Energy Company (NNECO) submitted proposed changes to Revision 22 of the Northeast Utilities Quality Assurance Program (NUQAP) Topical Report for U.S. Nuclear Regulatory Commission (NRC) review and approval in accordance with Title 10 of the *Code of Federal Regulations* (10 CFR) Section 50.54(a)(4). The proposed revisions to Section 18 and Appendix E of the NUQAP would allow NNECO to take credit for audits or other documented oversight processes in supplementing regularly scheduled audits.

The NRC staff has determined that additional information is required from NNECO in order to complete the review of the requested changes. Based on our need for the additional information, we do not regard the proposed changes to be acceptable pursuant to 10 CFR 50.54(a). Therefore, NNECO should refrain from implementing the proposed changes until you have been formally notified otherwise.

The NRC requests that you provide your response to the enclosed RAI within 60 days of receipt of this letter. This 60-day response time has been discussed with Mr. Ravi Joshi of your staff, and was established as a mutually agreeable timetable for your response. If circumstances result in the need to revise the target date, please call me at the earliest opportunity.

Should you have any questions regarding this request, please contact me at (301) 415-1427.

Sincerely,

/RA/

Daniel S. Collins, Project Manager, Section 2  
Project Directorate I  
Division of Licensing Project Management  
Office of Nuclear Reactor Regulation

Docket Nos. 50-336 and 50-423

Enclosure: Request for Additional Information

cc w/encl: See next page

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Project Directorate I  
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\*Input received 2/26/01; no major changes made.

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Official Record Copy

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REQUEST FOR ADDITIONAL INFORMATION  
PROPOSED REVISION TO THE NORTHEAST NUCLEAR ENERGY COMPANY  
QUALITY ASSURANCE PROGRAM TOPICAL REPORT  
MILLSTONE NUCLEAR POWER STATION, UNIT NOS. 2 AND 3  
DOCKET NOS. 50-336 AND 50-423

Millstone Nuclear Power Station (Millstone) is currently committed to U.S. Nuclear Regulatory Commission (NRC) Regulatory Guide 1.144, Revision 1, 1980 "Auditing Quality Assurance Program for Nuclear Power Plants," which conditionally endorses ANSI/ASME N45.2.12-1977, "Requirements for Auditing of QA Programs for Nuclear Power Plants." These commitments are described in the Section 18 "Audit" of the Northeast Utilities Quality Assurance Program (NUQAP) Topical Report. These commitments are used to meet requirements of Title 10 of the *Code of Federal Regulations* (10 CFR) Part 50, Appendix B, Criterion XVIII "Audits."

10 CFR Part 50, Appendix B, Criterion XVIII Audits states:

A comprehensive system of planned and periodic audits shall be carried out to verify compliance with all aspects of the quality assurance program and to determine the effectiveness of the program. The audits shall be performed in accordance with the written procedures or check lists by appropriately trained personnel not having direct responsibilities in the areas being audited. Audit results shall be documented and reviewed by management having responsibility in the area audited. Followup action, including reaudit of deficient areas, shall be taken where indicated.

Currently, Section 18.2 of the NUQAP states --

... Regularly scheduled audits are supplemented by audits for one or more of the following conditions:

- a. When significant changes are made in functional areas of the quality assurance program, such as significant reorganization or procedure revisions;
- b. When it is suspected that the quality of the item is in jeopardy due to deficiencies in the quality assurance program;
- c. When a systematic, independent assessment of program effectiveness is considered necessary;
- d. When necessary to verify implementation of required corrective action.

Enclosure

However, NNECO has proposed to revise Section 18.2 of the NUQAP to state:

... Regularly scheduled audits are supplemented by audits **or other documented oversight processes** for one or more of the following conditions:

This proposed revision does not provide adequate assurance that a comprehensive system of planned and periodic audits shall be carried out to verify compliance with all aspects of the quality assurance program and to determine the effectiveness of the program. The four supplemental conditions must be accomplished under an audit program that complies with 10 CFR Part 50, Appendix B, Criterion XVIII. If these four supplemental conditions are not handled under an audit process, then the NRC has no adequate assurance to verify compliance with all aspects of the quality assurance programs and the NRC has no adequate assurance of the effectiveness of the program. Also, the "other documented oversight processes" is not described or referenced in the NUQAP Topical Report. However, the audit process can credit other programs such as surveillances as stated in NRC Regulatory Guide 1.144, C6.

Therefore, the audit process (ANSI/ASME N45.2.12 or acceptable alternative):

1. must be performed in accordance with the written procedures or check lists by appropriately trained personnel not having direct responsibilities in the areas being audited;
2. results shall be documented and reviewed by management having responsibility in the area audited;
3. follow-up action, including re-audit of deficient areas, shall be taken where indicated; and
4. must be described in the NUQAP Topical Report

The licensee should provide sufficient description of the "other documented processes as an alternative to an audit program for the four supplemental conditions that meet the requirements listed above and listed within 10 CFR Part 50, Appendix B, Criterion XVIII and 10 CFR 50.34(b)(6)(ii). This would require Millstone to:

1. Define "appropriately trained personnel".
2. Describe what results would be documented.
3. Define the management responsibilities for reviews (i.e., which management reviews what area?)
4. Identify the people/organizations responsible for follow-up actions?
5. Identify who resolves conflicts?

Millstone should note that this is very similar to ANSI/ASME N45.2.12. Alternatively, “other documented process” that satisfies the definition of “audit” in ANSI/ASME N45.2.12 may be addressed in implementing procedures without modifying the existing licensee commitments in the NUQAP topical report.