

MAY 17 2001

Docket Nos. 50-245  
50-336  
50-423  
B18407

RE: 10 CFR 50.54(a)

U.S. Nuclear Regulatory Commission  
Attention: Document Control Desk  
Washington, DC 20555

Millstone Nuclear Power Station, Unit Nos. 1, 2, and 3  
Response to Request for Additional Information  
Proposed Change to the Quality Assurance Program Topical Report  
Utilization of Other Documented Oversight Processes to Supplement Audits

On January 26, 2001,<sup>(1)</sup> the Millstone Nuclear Power Station licensee, Northeast Nuclear Energy Company (NNECO), now Dominion Nuclear Connecticut, Inc. (DNC), submitted proposed changes to Revision 22 of the Northeast Utilities Quality Assurance Program (QAP) Topical Report for the Nuclear Regulatory Commission (NRC) review and approval pursuant to 10 CFR 50.54(a)(4). The proposed change to Section 18.2.1 and Appendix E of the QAP would allow taking credit for audits or 'other documented oversight processes' to supplement regularly scheduled audits. This is an alternative to the current method which for certain conditions only allows crediting audits to assess performance. This change represents a reduction in commitment to ANSI N45.2.12-1977,<sup>(2)</sup> but is consistent with current industry practice.

On March 19, 2001,<sup>(3)</sup> the NRC issued a request for additional information (RAI) involving this proposed change to the QAP Topical Report. Attachment 1, provides a response to each of the questions.

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- (1) R. G. Lizotte, Northeast Nuclear Energy Company to the U.S. Nuclear Regulatory Commission, "Millstone Nuclear Power Station, Unit Nos. 2 and 3, Proposed Change to Revision 22 of the Northeast Utilities Quality Assurance Program Topical Report To Allow Other Documented Oversight Processes to be Utilized in Lieu of Audits," dated January 26, 2001, (B18319).
- (2) ANSI N45.2.12-1977, "Requirements for Auditing of Quality Assurance Programs for Nuclear Power Plants."
- (3) Daniel S. Collins, U.S. Nuclear Regulatory Commission to Mr. R. G. Lizotte, Northeast Nuclear Energy Company, "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. MBI 105B and MB1 106B), dated March 19, 2001.

Q004

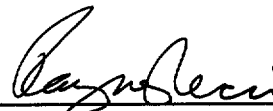
Note, that the Millstone Unit 1 Northeast Utilities Quality Assurance Program Topical Report was recently reintegrated into the formerly Millstone Unit Nos. 2 and 3 QAP Topical Report. This reintegration was performed in accordance with 10 CFR 50.54(a). The Dominion Nuclear Connecticut, Inc. Quality Assurance Program Topical Report applies to all the Millstone units, i.e., Units Nos. 1, 2, and 3. Therefore, the proposed change to allow taking credit for audits or 'other documented oversight processes' to supplement regularly scheduled audits now also applies to Millstone Unit No. 1.

There are no regulatory commitments contained within this letter.

If you have any questions regarding this submittal, please contact Mr. Paul Willoughby at (860) 447-1791, extension 3655.

Very truly yours,

DOMINION NUCLEAR CONNECTICUT, INC.



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Raymond P. Necci - Vice President  
Nuclear Technical Services/Millstone

Attachment 1: Response to Request for Additional Information, Utilization of Other Documented Oversight Processes to Supplement Audits

cc: H. J. Miller, Region I Administrator  
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Attachment 1

Millstone Nuclear Power Station, Unit Nos. 1, 2, and 3

Response to Request for Additional Information  
Utilization of Other Documented Oversight Processes to Supplement Audits

**Response to Request for Additional Information  
Utilization of Other Documented Oversight Processes  
to Supplement Audits**

**Introduction**

On January 26, 2001,<sup>(1)</sup> the Millstone Nuclear Power Station licensee, Northeast Nuclear Energy Company (NNECO), now Dominion Nuclear Connecticut, Inc. (DNC), submitted proposed changes to Revision 22 of the Northeast Utilities Quality Assurance Program (QAP) Topical Report for the Nuclear Regulatory Commission (NRC) review and approval pursuant to 10 CFR 50.54(a)(4). The proposed change to QAP Section 18.2.1, "Implementation – Program" and to QAP Appendix E, "Program Exceptions" would allow taking credit for audits or 'other documented oversight processes' to supplement regularly scheduled audits. On March 19, 2001,<sup>(2)</sup> the NRC issued a request for additional information (RAI). The proposed change involves an alternative to the current method which for certain conditions only allows crediting the performance of audits to assess quality performance.

**Discussion**

It is proposed to modify QAP Section 18.2.1, "Implementation – Program," to allow 'other documented oversight processes,' e.g., surveillances and results from inspections (as appropriate), to be utilized to supplement regularly scheduled audits for any of the four conditions listed in QAP Section 18.2.1 (see below). The conditions listed were taken from Section 3.5.3 of ANSI Standard N45.2.12-1977<sup>(3)</sup> (section numbers in brackets). This change is a reduction in commitment to ANSI N45.2.12-1977, but is consistent with current industry practice. Currently, Section 18.2.1 of the QAP states:

"Regularly scheduled audits are supplemented by audits for one or more of the following conditions:" [Section 3.5.3]

It is proposed to revise QAP Section 18.2.1 to state (change hi-lited in bold):

"Regularly scheduled audits are supplemented by audits **or other documented oversight processes** for one or more of the following conditions: [Section 3.5.3]

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<sup>(1)</sup> R. G. Lizotte, Northeast Nuclear Energy Company to the U.S. Nuclear Regulatory Commission, "Millstone Nuclear Power Station, Unit Nos. 2 and 3, Proposed Change to Revision 22 of the Northeast Utilities Quality Assurance Program Topical Report To Allow Other Documented Oversight Processes to be Utilized in Lieu of Audits," dated January 26, 2001, (B18319).

<sup>(2)</sup> Daniel S. Collins, U.S. Nuclear Regulatory Commission to Mr. R. G. Lizotte, Northeast Nuclear Energy Company, "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. MBI 105B & MB1 106B)," dated March 19, 2001.

<sup>(3)</sup> ANSI N45.2.12-1977, "Requirements for Auditing of Quality Assurance Programs for Nuclear Power Plants."

1. When significant changes are made in functional areas of the quality assurance program, such as significant reorganization or procedure revisions; [Section 3.5.3.3]
2. When it is suspected that the quality of the item is in jeopardy due to deficiencies in the quality assurance program; [Section 3.5.3.4]
3. When a systematic, independent assessment of program effectiveness is considered necessary; [Section 3.5.3.5] (or)
4. When necessary to verify implementation of required corrective action. [Section 3.5.3.6]

Millstone Nuclear Power Station Unit Nos. 1, 2, and 3 are committed to NRC Regulatory Guide (RG) 1.144, "Auditing of Quality Assurance Programs for Nuclear Power Plants,"<sup>(4)</sup> which conditionally endorses ANSI/ASME N45.2.12-1977 as partially stated below. Within RG 1.144 the NRC imposed a condition in Section C., "Regulatory Position," Item 6, stating that:

"The guideline in Section 3.5.3.6 of ANSI/ASME N45.2.12-1977 recommending an audit "when necessary to verify implementation of required corrective action" does not meet the provisions of Criterion XVIII of Appendix B to 10 CFR Part 50. **Audits as well as other methods of surveillance can be used to verify implementation of required corrective action** [emphasis added]."

Therefore, for Item 4 above, performance of surveillances is an NRC approved method of verifying the implementation of corrective action. Because DNC is committed to RG 1.144, "audits as well as other methods of surveillance can be used to verify implementation of required corrective action."

The last paragraph under QAP Section 18.2.1, "Implementation – Program," states:

"In addition to the audits, other methods, such as surveillances and inspections are used to assure that quality activities are in compliance with this QAP."

Similar statements are found throughout the QAP. Various 'other documented oversight processes,' e.g., audits, surveillances and inspections, can currently only be utilized to verify quality if the situation does not fit the circumstances specified in Items 1 through 3. Therefore, while for the vast majority of situations the entire repertoire of verification methods is available for the quality organization to apply, for the situations specified in Items 1 through 3, they are forced to conduct additional audits when there may be more effective means of assessment available. For this reason it is proposed to modify QAP Section 18.2.1 to allow 'other documented oversight processes,' to be utilized to supplement regularly scheduled audits.

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<sup>(4)</sup> NRC Regulatory Guide 1.144, "Auditing of Quality Assurance Programs for Nuclear Power Plants," Revision 1, September 1980.

Since RG 1.144 was issued in 1980, the nuclear industry has evolved and developed alternative means to verify implementation of quality activities. The idea of source surveillance has been brought over from the procurement side of quality assurance (see ANSI N45.2.13)<sup>(5)</sup> and has been utilized to permit the conduct of multiple, ongoing, real time, observations of plant activities. In particular this methodology lends itself to operational and maintenance activities involving the physical performance of a task. An audit takes a "snapshot" of activities occurring during its performance. The NRC has recognized these developments, and while they have not codified them within a regulatory guide, have endorsed and even encouraged their adoption. For example, NRC Inspection Manual (IM) 35702, "Inspection of Quality Verification Function," Subsection 03, "Inspection Guidance, General Guidance" <sup>(6)</sup> states:

"... Licensee management has a number of organizations that perform quality verification functions. The organizations include Quality Assurance (QA), Quality Control (QC), Quality Engineering (QE), and independent review groups, such as the Independent Safety Engineering Group (ISEG). **Quality verification organizations perform various types of verifications, such as audits, surveillances, and third-party observations** [emphasis added]. ...

**An effective quality verification organization is technically and performance oriented; its primary focus tends to be toward the end product** [emphasis added] with a secondary effort toward processes and procedures. "

IM Section 35702-03, "Inspection Guidance, Specific Guidance," Subsection 03.02, 'Assess Licensee Quality Verification,' Item c.,<sup>(6)</sup> states, "Organizations perform various types of quality verifications. Audits are one of the most obvious. The inspector should be aware of the various types of verifications and their relation to other parts of the quality verification program." IM Section 40500-03, "Inspection Guidance, Specific Guidance," Subsection 03.05, 'Self-Assessment Activities,'<sup>(7)</sup> requires the NRC Inspector to "**Verify that quality activity [surveillance] reports, assessments, and audits accurately reflect the findings and observations of the auditors,** [emphasis added] to ensure that management is receiving a complete and unbiased perspective of the plant's quality achievement and deficiencies."

IM Section 40801-02, "Inspection Requirements," Subsection 02.01, 'Preparation,' Item b.,<sup>(8)</sup> requires that the NRC Inspector "Review licensee procedures, Quality Assurance (QA) Plan, or other **controlled document for the conduct of self-assessment, audits, and QA audits and surveillances.**" [emphasis added].

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<sup>(5)</sup> ANSI N45.2.13-1976, "Quality Assurance Requirements for Control of Procurement of Items and Services for Nuclear Power Plants."

<sup>(6)</sup> NRC Inspection Manual, Inspection Procedure 35702, "Inspection of Quality Verification Function," Issue Date: September 9, 1998.

<sup>(7)</sup> NRC Inspection Manual, Inspection Procedure 40500, "Effectiveness of Licensee Process to Identify, Resolve, and Prevent Problems," Issue Date: May 3, 1999.

<sup>(8)</sup> NRC Inspection Manual, Inspection Procedure 40801, "Self-Assessment, Auditing, And Corrective Action At Permanently Shutdown Reactors."

Therefore, the NRC is aware of the various means available today to a licensee to verify the quality of activities. Implementation of a surveillance or assessment program permits ongoing real time observation of plant activities. IM Section 35702-03, "Inspection Guidance, Specific Guidance," Subsection 03.02, 'Assess Licensee Quality Verification,' Item a.,<sup>(6)</sup> states, **"Successful verification programs use a "living" schedule that permits important plant activities and events to be verified and documented as they are occurring.** [emphasis added] This process provides for the greatest impact and most effective follow-up."

Surveillances and inspections are already recognized in the QAP Topical Report in various sections, and are currently used for oversight of contracted vendor services and certain line activities. ANSI N45.2.13<sup>(5)</sup> defines the expectations and requirements for planning and performing surveillances in Sections 7.1, 7.2, 7.6, and 9.3. These requirements specify the measures which must be defined and implemented in the oversight of vendors/contractors.

Surveillances and inspections by their nature permit more direct and timely involvement in activities, and permit problems to be identified and corrected in real-time, as the activities occur, before the deficiencies are disclosed and propagated into actual equipment performance problems in the plant. This proposed QAP change will permit the use of real-time assessment processes, i.e., surveillances and inspection results, to be coordinated and utilized together with audits to more effectively monitor quality related activities.

Utilization of alternate quality verification techniques will provide additional flexibility in the manner by which the 'supplemental audits' can be performed. This will provide Oversight (quality assurance) the ability to address potential problems rapidly when they develop due to the utilization of more immediate assessment techniques.

### **Response To The Five Questions In The Request For Additional Information**

The Oversight (quality assurance) organization is currently divided into three major process assessment groups, Operate the Asset, Maintain the Asset and Manage the Asset, reflecting the makeup of the organizations onsite. Each process assessment group reports to a Team Leader (supervisor) who in turn report to the Process Owner - Oversight (manager). The Process Owner - Oversight reports directly to the Vice President and Senior Nuclear Executive - Millstone (the highest corporate official onsite).

#### **1. Define "appropriately trained personnel."**

Each of the process assessment groups is staffed with personnel who are experienced in their respective areas, and are knowledgeable of the processes which they review by audits or surveillances and inspections. Procedure MP-02-NO-FAP-2.1, "Performance, Reporting and Follow-up of Surveillances," requires that personnel in Oversight who lead surveillances be qualified prior to actual performance of the surveillance. Procedure MP-02-NO-FAP-4.1, "Quality

Control Inspection And Quality Verification Process,” requires that personnel in Oversight who conduct inspections be qualified and certified prior to performance. These procedures also cover the performance and reporting of surveillances and inspection results.

Training requirements are developed and approved by Oversight management and documented in accordance with the Nuclear Training Manual requirements.

**2. Describe what results would be documented.**

The Oversight organization documents the results of surveillance activities and inspections at the conclusion of the observations and reviews. Observations are evaluated against standards and criteria approved by Oversight management. Quality Control inspection results are documented in the applicable work documents. Surveillance reports are issued by the Team Leaders in Oversight. The results are first debriefed with line counterparts, and any identified adverse conditions are reported, as they are identified, in Condition Reports in accordance with the station’s Corrective Action Program.

**3. Define the management responsibilities for reviews (i.e., which management reviews what area?)**

As described previously, the Team Lead for a particular process area is responsible for and issues surveillance reports for their respective area. Quality Control inspection results are documented in the applicable work documents. The reviews of the completed reports and any Condition Reports which are issued are defined in the respective procedure. Team Leaders in Oversight review and comment on both products prior to the issuance. The Condition Reports are also discussed with line counterparts prior to being issued.

**4. Identify the people/organizations responsible for follow-up actions.**

Oversight’s procedures for surveillances and inspections specify that conditions adverse to quality, observed deficiencies and recommendations are reported through the station’s Corrective Action Program. QAP Section 18.2.3, “Review, Action, And Follow-Up Of Audit Findings,” states “Follow-up of audit findings involving conditions adverse to quality is performed by the auditing organization as necessary to verify appropriate actions have been taken to resolve audit findings.” The results of ensuing investigations and resulting corrective actions are documented allowing trending and follow-up actions to be readily performed. Procedure MP-16-CAP-FAP-1.3, “Responsibilities for ACR Owners and Personnel Implementing the Corrective Action Program,” describes the process for escalation of disagreements when Condition Reports are processed. Procedure/guideline MP-02-NO-GDL102, “Follow-up of Oversight Issues,” describes the process for follow-up on issues. Similar to what is defined in Section 7.6 and Section 9.3 of ANSI N45.2.13, the surveillance process provides



for decisions to follow-up the line's corrective actions to verify they are completed.

**5. Identify who resolves conflicts?**

As previously described, Station corrective action procedures define expectations for resolution of disagreements and provide for escalation of those disagreements where needed. In addition, Oversight has procedures for conflict escalation and resolution which involves Oversight and line management when needed. Ultimately, as indicated in QAP Section 18.2.3, "Review, Action, And Follow-Up Of Audit Findings," ... "Items which cannot be resolved by [the] affected management are submitted for resolution to the Vice President and Senior Nuclear Executive - Millstone."