

Licensing and Performance-  
Based Regulation  
Nuclear Energy Institute  
1776 I Street, NW.  
Suite 400  
Washington, DC 20006-3708

Central Files/PDR  
T503

SUBJECT: REVIEW OF NUCLEAR ENERGY INSTITUTE (NEI) PROPOSED  
IMPROVEMENTS TO QUALITY ASSURANCE PROGRAMS (REFERENCE  
NEI LETTER, DATED JANUARY 30, 1996)

Dear Mr. Floyd:

We have reviewed the improvements proposed by NEI to quality assurance (QA) programs regarding the processes for qualifying lead auditors and conducting annual evaluations of suppliers as described in your letter of January 30, 1996. In general, we consider some of the proposals acceptable alternatives to existing QA program commitments. However, because these acceptable alternatives may represent reductions in QA program commitments (as compared to typical licensee commitments to NRC regulatory guides), they may need to be processed by licensees in accordance with the requirements of Section 50.54(a) of Title 10 of the Code of Federal Regulations (10 CFR). The enclosure to this letter comments specifically on the alternatives you propose to existing NRC regulatory guide positions and NRC-endorsed American National Standards Institute (ANSI) provisions for lead auditor qualification and annual supplier evaluations. We have also elaborated on the staff's opinion about what types of QA program changes constitute a reduction in commitment.

Your January 30, 1996, letter also stated that the selection and scheduling of audits based on performance is still the subject of discussion among industry, specific utilities, and the NRC. We are presently evaluating several acceptable alternatives to existing NRC regulatory guides and ANSI standard QA program commitments for the scheduling of audits and will provide you the results of our evaluations when they are completed.

Should you have any comments or questions regarding this letter or its enclosure, please contact Mr. Robert Gramm at (301) 415-1010 or Mr. Larry Campbell at (301) 415-2976.

Sincerely,  
/s/

Suzanne C. Black, Chief  
Quality Assurance and Maintenance Branch  
Division of Reactor Controls  
and Human Factors  
Office of Nuclear Reactor Regulation

**NRC FILE CENTER COPY**

PROJECT NO. 689  
DISTRIBUTION:  
CCasto, R2  
Ron Langstaff, R3  
OGormley, RES  
VWagner, R4  
DMatthews

Enclosure: As stated  
Central Files/PDR  
AThadani  
HQMB QA Section Staff  
SMagruder  
JShannon, RI  
GHallstrom, R2

WRuland, RI  
JJacobson, R3  
CVanDenburgh, R4  
WAng, R4  
RWeisman

DOCUMENT NAME: NEI96A.LTR

To receive a copy of this document, indicate in the box: "C" = Copy without enclosures "E" = Copy with enclosures "N" = No copy

OFFICE	HQMB/DRCH	C	HQMB/DRCH	E	HQMB/DRCH	E	DRCH/NRR		DRCH/NRR
NAME	LCampbell	YXC	RGramm	R6	SBlack	SB	LSpessard		EGoggin
DATE	10/18/96		10/18/96		10/24/96		10/24/96		10/24/96

9610280140 961024  
PDR PROJ  
689 PDR

ICIAL RECORD COPY



UNITED STATES  
NUCLEAR REGULATORY COMMISSION

WASHINGTON, D.C. 20555-0001

October 24, 1995

Stephen D. Floyd, Director  
Licensing and Performance-  
Based Regulation  
Nuclear Energy Institute  
1776 I Street, NW  
Suite 400  
Washington, DC 20006-3708

SUBJECT: REVIEW OF NUCLEAR ENERGY INSTITUTE (NEI) PROPOSED  
IMPROVEMENTS TO QUALITY ASSURANCE PROGRAMS (REFERENCE  
NEI LETTER, DATED JANUARY 30, 1996)

Dear Mr. Floyd:

We have reviewed the improvements proposed by NEI to quality assurance (QA) programs regarding the processes for qualifying lead auditors and conducting annual evaluations of suppliers as described in your letter of January 30, 1996. In general, we consider some of the proposals acceptable alternatives to existing QA program commitments. However, because these acceptable alternatives may represent reductions in QA program commitments (as compared to typical licensee commitments to NRC regulatory guides), they may need to be processed by licensees in accordance with the requirements of Section 50.54(a) of Title 10 of the Code of Federal Regulations (10 CFR). The enclosure to this letter comments specifically on the alternatives you propose to existing NRC regulatory guide positions and NRC-endorsed American National Standards Institute (ANSI) provisions for lead auditor qualification and annual supplier evaluations. We have also elaborated on the staff's opinion about what types of QA program changes constitute a reduction in commitment.

Your January 30, 1996, letter also stated that the selection and scheduling of audits based on performance is still the subject of discussion among industry, specific utilities, and the NRC. We are presently evaluating several acceptable alternatives to existing NRC regulatory guides and ANSI standard QA program commitments for the scheduling of audits and will provide you the results of our evaluations when they are completed.

Should you have any comments or questions regarding this letter or its enclosure, please contact Mr. Robert Gramm at (301) 415-1010 or Mr. Larry Campbell at (301) 415-2976.

Sincerely,

A handwritten signature in cursive script that reads "Suzanne C. Black".

Suzanne C. Black, Chief  
Quality Assurance and Maintenance Branch  
Division of Reactor Controls  
and Human Factors  
Office of Nuclear Reactor Regulation

PROJECT NO. 689

Enclosure: As stated

NEI Alternatives to NRC Regulatory Guide Positions and ANSI Provisions for  
Lead Auditor Qualification and Annual Supplier Evaluations

1. Reduction in Commitment

The staff believes that if the quality assurance (QA) program description commitment being changed defined a requirement for a specific activity and if that particular requirement was being eliminated by the change, the resulting change would constitute a reduction in commitment and would need NRC approval prior to implementation in accordance with 10 CFR 50.54(a). The staff further believes that if the QA program commitment being changed permits new or alternative options to be used, the change would also constitute a reduction in commitment and the staff would have to evaluate its acceptability. However, if a new requirement is added that clearly does not reduce existing QA program requirements (such as by expanding the current commitments to make them more restrictive), then this change would not constitute a reduction in commitment and it would not require NRC review.

2. Lead Auditor Qualification Process

Section 2.3.4, "Audit Participation," of ANSI N45.2.23-1978, "Qualification of QA Program Audit Personnel for Nuclear Power Plants," as endorsed by Regulatory Guide 1.146, "Qualification of Quality Assurance Audit Personnel for Nuclear Power Plants," dated August 1980, states the following:

The prospective Lead Auditor shall have participated in a minimum of five (5) quality assurance audits within a period of time not to exceed three (3) years prior to the date of qualification, one audit of which shall be a nuclear quality assurance audit within the year prior to the individual's qualification.

The NRC agrees, in part, with NEI's proposed alternative to the existing provisions of Section 2.3.4 of ANSI N45.2.23-1978. However, it is noted that we believe the original intent of Section 2.3.4 was to have the prospective lead auditor participate in several (5) quality assurance audits, one of which would be a nuclear quality assurance audit, in order to demonstrate the ability to effectively implement the audit process and to lead an audit team. NEI's proposal does not describe the process for such a performance-based demonstration of the prospective lead auditor's ability. The NRC considers the following to be an acceptable alternative to Section 2.3.4 of ANSI N45.2.23-1978:

Prospective lead auditors shall demonstrate their ability to effectively implement the audit process and effectively lead an audit team. The employer shall describe this demonstration process in written procedures or instructions and shall evaluate and document the results of the demonstration. Regardless of the methods used for the demonstration, the prospective lead auditor shall have participated in at

least one nuclear quality assurance audit within the year preceding the individual's effective date of qualification. Upon successful demonstration of the ability to effectively implement the audit process and effectively lead audits, and having met the other provisions of Section 2.3 of ANSI N45.2.23-1978, the individual may be certified as being qualified to lead audits.

### 3. Annual Supplier Evaluation

ANSI N45.2.12-1977, "Requirements for Auditing of Quality Assurance Programs for Nuclear Power Plants," as endorsed by NRC Regulatory Guide (RG) 1.144, "Auditing of Quality Assurance Programs for Nuclear Power Plants," Revision 1, dated September 1980, describes a method acceptable to the NRC staff for complying with regulations concerning auditing of quality assurance programs for nuclear power plants. Section 3.5.2 of ANSI N45.2.12-1977 requires that audits of quality assurance activities be regularly scheduled to ensure that the quality assurance program is adequate and that activities are being performed in accordance with the quality assurance program. Regulatory Position C.3 of RG 1.144 discusses what the NRC staff considers acceptable audit scheduling. Regulatory Position C.3.b(2) specifically addresses the auditing of a supplier's quality assurance program and permits an audit frequency of 3 years provided that the licensee performs an annual evaluation of the supplier's performance as follows:

A documented evaluation of the supplier should be performed annually. Where applicable, this evaluation should take into account (1) review of supplier-furnished documents such as certificates of conformance, nonconformance notices, and corrective actions, (2) results of previous source verifications, audits, and receiving inspections, (3) operating experience of identical or similar products furnished by the same supplier, and (4) results of audits from other sources (e.g., customer, ASME, or NRC audits).

NEI has proposed an alternative to the preceding position and has recommended that a continuous or ongoing evaluation of the supplier's performance be conducted rather than a delayed annual evaluation.

The alternative proposed by NEI is generally considered acceptable as long as the results of the ongoing evaluation are documented and the evaluation findings are reviewed in order to determine if any corrective action is required. The NRC considers the following to be an acceptable alternative to the existing regulatory position for conducting annual evaluations:

A documented ongoing evaluation of the supplier should be performed. Where applicable, this evaluation should take into account (1) review of supplier-furnished documents such as certificates of conformance, nonconformance notices, and corrective actions, (2) results of previous source verifications,

audits, and receiving inspections, (3) operating experience of identical or similar products furnished by the same supplier, and (4) results of audits from other sources (e.g., customer, ASME, or NRC audits). The results of the evaluations should be reviewed and appropriate corrective action should be taken. Adverse findings resulting from these evaluations should be periodically reviewed in order to determine if, as a whole, they result in a significant condition adverse to quality and to provide input to support supplier audit activities conducted by the licensee or a third party auditing entity.