Response to Request for Additional Information Regarding Review of NEI 11-04, "Nuclear Generation Quality Assurance Program Description," Draft Revision 0

The following responses are provided with respect to the request for additional information concerning Nuclear Energy Institute 11-04, "Nuclear Generation Quality Assurance Program Description," Draft Revision 0 communicated by the NRC by letter on February 8, 2012.

RAI-1

The Nuclear Energy Institute (NEI) 11-04 Quality Assurance Program Description (QAPD) template commits to compliance with NQA-1-2008, Requirement 2 with the following clarification:

> As an alternative to Section 303.3 that prospective Lead Auditors have participated in a minimum of five (5) audits in the previous three (3) years the following may be used for qualification of experienced individuals: "A Prospective Lead Auditor that has related industry experience and previously demonstrated ability to properly implement the audit process shall participate in one nuclear quality assurance audit within the year prior to qualification." [NOTE: This alternative is not allowed for Lead Auditors conducting audits of activities involving Section III, Article NCA-4000 of the American Society of Mechanical Engineers (ASME) Boiler and Pressure Vessel Code; including supplier qualification audits.]

However, NQA-1-2008, Requirement 2, Section 303.3 provides for participation in independent assessments as another means of satisfying the requisite number of quality assurance audits, and supplies the acceptance criteria for use of these activities toward lead auditor qualification.

As such, the U.S. Nuclear Regulatory Commission (NRC) staff was unable to ascertain why this clarification to NQA-1-2008 is necessary for NEI 11-04 given that NQA-1-2008, Requirement 2, Section 303.3, already contains an alternative means for qualifying prospective lead auditors beyond participation in a minimum of five audits in the previous three years. Please provide a justification for this clarification and for the bracketed text.

RAI-1 Response

NEI 11-04 Section 2.7 will be revised to remove the Lead Auditor qualification alternative defined in Section 303.3 which will result in full implementation of the quality standards as described in NQA-1-2008, Requirement 2, Sections 100 through 500, without any exceptions.

RAI-2

The NEI 11-04 QAPD template commits to compliance with NQA-1-2008, Requirement 2 with the following exception:

> Section 400 (a) (8) requires the date of certification expiration be included on the qualification record. [CA] considers the certification expiration date to be the date from the certification or recertification date plus the certification interval time and its inclusion on the qualification record is optional.

The NRC staff was unable to ascertain why this clarification to NQA-1-2008 is necessary for NEI 11-04, please provide a justification for this exception.

RAI-2 Response

The inclusion of this exception in NEI 11-04 is a clarification for changes to the NQA-1 Standard as a result of the consolidation of Requirement 2 that introduced data that was slightly different from the individual personnel documentation requirements. The date of certification establishes the expiration date, when combined with the certification interval. The certification interval is normally a function of a code or standard and is identified in the organization's procedures. Therefore, to have both dates on the form is redundant.

Additionally, in NQA-1-2008, Part III, Nonmandatory Appendix 2A-3, Figure 2A-3.1 Sample Form for Record of Lead Auditor Qualification, the form does not contain a blank for the inclusion of certification expiration date. Therefore, if this form were used "as is" it would not be in strict compliance with NQA-1-2008, Requirement 2, Section 400(a)(8). This information has been sent to the NQA Committee by NEI and the NQA Committee is addressing the issue in a future revision of the Standard.

RAI-3

The NEI 11-04 QAPD template commits to compliance with NQA-1-2008 and NQA-1a-2009 Addenda, Requirement 3, Subpart 2.7 for computer software[, and Subpart 2.20 for subsurface investigation requirements]. [NOTE: Subpart 2.20 does not apply to an Operation –only QAP].

The dedication of commercial grade items or services for use as safety-related applications is a design control activity. Subpart 2.14, “Quality Assurance Requirements for Commercial Grade Items and Services” provides the requirements for commercial-grade items and services and should be committed to in Section 3 of the NEI 11-04 QAPD template.

Based on the above, please add Subpart 2.14 to Section 3.5, NQA-1 Commitment.

RAI-3 Response

NEI 11-04 Section 3.5 will be revised to reference to NQA-1-2008 and NQA-1a-2009 Addenda, Requirement 3, Subpart 2.14 for Quality Assurance requirements for commercial grade items and services.

RAI-4

The NEI 11-04 QAPD template commits to compliance with NQA-1-2008, Requirement 4, with the following clarifications and exceptions:

> Section 203 requires the purchaser to specify the quality assurance requirements in the procurement documents. To meet this requirement, [CA] may require suppliers to have a documented QAP that meets the applicable requirements of Title 10 of the Code of Federal Regulations Part 50, Appendix B, as appropriate to the circumstances of the procurement.

Technical and quality requirements are provided in Sections 202 and 203 of NQA-1-2008, Requirement 4, respectively. As such, it is not clear to the staff why an exception or clarification to NQA-1-2008, Requirement 4, Section 203, is necessary given that provisions regarding the information are contained in NQA-1-2008 and NQA-1a-2009 Addenda, please provide a justification for this clarification.

RAI-4 Response

NEI 11-04 Section 4.1 will be revised to remove the Section 203 exception noted.

RAI-5

Section 6, "Document Control," of NEI 11-04, states the following:

> [CA] has established the necessary measures and governing procedures to control the preparation, issuance, and revision of documents that specify quality requirements or prescribe how activities affecting quality, including organizational interfaces, to ensure that correct documents are employed. The following controls, including electronic systems used to make documents available, are applied to documents and changes thereto:

The above section in the previous revision, NEI 06-14A REV 7, states the following:

> [CA] has established the necessary measures and governing procedures to control the preparation of, issuance of, and changes to documents that specify quality requirements or prescribe how activities affecting quality, including organizational interfaces, are controlled to assure that correct documents are being employed. The control systems (including electronic systems used to make documents available) are documented and provide for the following:

Please provide clarification of the correct paragraph to be used for this section.

RAI-5 Response

The noted difference is the result of efforts to improve wording in this revised section to be clearer and grammatically correct. There is no change of intent.

RAI-6

The NEI 11-04 QAPD template commits to compliance with NQA-1-2008 and NQA-1a-2009, Requirement 7, with the following clarifications and exceptions:

> A documented review of the supplier's accreditation will be performed and will include a verification of the following:
>
> > The calibration laboratory holds a domestic (United States) accreditation by any one of the following accrediting bodies, which are recognized by the International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement (MRA):
> >
> > (1) National Voluntary Laboratory Accreditation Program (NVLAP)
> > (2) American Association for Laboratory Accreditation (A2LA)
> > (3) ACLASS Accreditation Services (ACLASS)
> > (4) International Accreditation Service (IAS)
> > (5) Laboratory Accreditation Bureau (L-A-B)

The NRC has approved other laboratory accrediting bodies not listed above. Please provide clarification if it is the intent to only account for the five above or to also include "other NRC-approved Laboratory accrediting bodies."

RAI-6 Response

NEI 11-04 Section 7.2 exception will be revised to state the following:

- A documented review of the supplier's accreditation will be performed and will include a verification of the following:

  The calibration laboratory holds a domestic (United States) accreditation by an NRC-approved accrediting body recognized by the International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement (MRA).

RAI-7

The NEI 11-04 QAPD template commits to compliance with NQA-1-2008, Requirement 10 and Subparts 2.4, 2.5 and 2.8 for establishing appropriate inspection requirements with the following clarifications;

> Subpart 2.4 commits [CA] to Institute of Electrical and Electronics Engineers (IEEE) 336-1985, which refers to IEEE 498-1985. Both IEEE 336-1985 and IEEE 498-1985 use the definition of "Safety Systems" from IEEE 603-1980. [CA] commits to the definition of Safety Systems in IEEE 603-1980, but does not commit to the balance of that standard. This definition is only applicable to equipment in the context of Subpart 2.4.
>
> An additional exception to Subpart 2.4 is addressed in Part II, Section 12 of the QAPD.

The previous version of NEI 11-04, NEI 06-14A Rev 7, in addition to the above also contains the following clarification:

> *[NOTE: This in an optional alternative for those sites where the reporting independence of NQA-1-1994, Supplement 10S-1, Section 3.1 may not be met. Refer to accession number ML052490337.] Where inspections at the operating facility are performed by persons within the same organization (e.g., Maintenance group), [CA] takes exception to the requirements of NQA-1-1994, Supplement 10S-1, Section 3.1, the inspectors report to the [quality control management] while performing those inspections.]*

Although NQA-1-2008 no longer contains a specific section for reporting independence it still provides the following in Section 100, which states, "Inspection for acceptance shall be performed by qualified persons other than those who performed or directly supervised the work being inspected." This was the original basis for the acceptance of the alternative as refer to in accession number ML052490337.

The NRC staff was unable to ascertain why this clarification to NQA-1-2008 is not included for NEI 11-04 as in its previous version, please provide a justification for this clarification.

RAI-7 Response

The reason for the Alternative Position has been removed in NQA-1-2008. As a result, there is no reason to take an exception to a position that is no longer applicable. The wording in Section 100 of NQA-1-2008 applies in all cases.

RAI-8
The NEI 11-04 QAPD template commits to compliance with NQA-1-2008, Requirement 12, with the following clarification and exception:

> The out of calibration conditions described in Section 303.2 refers to when the M&TE is found out of the required accuracy limits (i.e., out of tolerance) during calibration and not overdue for calibration.

Previous excepted alternatives for this requirement have not included "not overdue for calibration." The NRC staff was unable to ascertain why this clarification to NQA-1-2008 is necessary for NEI 11-04, please provide a justification for this exception.

RAI-8 Response
NEI 11-04 Section 12.2 will be revised to remove the exception noted. The clarification is no longer needed due to the distinction has been appropriately addressed in NQA-1-2008 between expired due dates and out of tolerance conditions for measuring and test equipment.

RAI-9
The NEI 11-04 QAPD template commits to compliance with NQA-1-2008, Requirement 12, with the following clarification and exception:

> Measuring and test equipment are not required to be marked with the calibration status, as described in section 303.6, where it is impossible or impractical due to equipment size or configuration (such as the label will interfere with operation of the device) provided the required information is maintained in suitable documentation traceable to the device. This exception also applies to the calibration labeling requirement stated in NQA-1-2008, Subpart 2.4 (See Section 7.2.1 of ANSI/IEEE Std. 336-1985).

The NRC staff notes that NQA-1-2008 and NQA-1a-2009 Addenda, Requirement 12, Section 303.6, as written, already provides for measuring and test equipment to be "otherwise identified" to indicate calibration status and establish traceability to calibration records. As such, it is not clear to the staff why an alternative to NQA-1-2008, Requirement 12, Section 303.6 is necessary. Please provide a justification for this clarification.

RAI-9 Response
NEI 11-04 Section 12.2 will be revised to add the following exception:

- NQA-1-2008, Subpart 2.4 refers to ANSI/IEEE Std. 336-1985 for the installation, inspection, and testing requirements for power, instrumentation, and control equipment at nuclear facilities. Where ANSI/IEEE Std. 336-1985 makes reference to the use of IEEE Std. 498-1985 for measuring and test equipment control, *[CA]* will implement the QA requirements of NQA-1-2008, Requirement 12.

RAI-10
The NEI 11-04 QAPD template commits to compliance with NQA-1-2008, Requirement 13. The NEI 11-04 QAPD template also commits, during the construction and operational phase of the plant, to compliance with the requirements of NQA-1-2008 and NQA-1a-2009, Subpart 2.1, Subpart 2.2, Subpart 2.3, and

Subpart 3.2, Appendix 2.1, with the following clarifications and exceptions: *[NOTE: This commitment and the following clarifications and exceptions do not apply to an ESP-only QAPD.]*

> [As an alternative to Subpart 2.2, Section 405, Shipments from Countries outside the United States, [CA] may elect to establish special requirements that address the appropriate quality requirements and applicable United States Customs and Border Protection/Department of Homeland Security requirements.]

The NRC staff was unable to ascertain why this clarification to NQA-1-2009a is included, please provide a justification for this clarification.

RAI-10 Response

NEI 11-04 Section 13.2 will be revised to delete the reference to NQA-1a-2009, Subpart 2.2, Subpart 2.2, Section 405, "Shipments from Countries Outside the United States" until further resolution is provided by the NQA Committee.

NEI understands that the recent changes in US shipping law may prevent full compliance with NQA-1 a-2009 Addenda, Subpart 2.2, Section 405, "Shipments from Countries outside the United States," as written. The NRC has brought this topic to the attention of the NQA Committee and a resolution is currently under development by the Committee that may delete or modify Subpart 2.2, Section 405.

RAI-11

The NEI 11-04 QAPD template commits to compliance with NQA-1-2008, Requirement 13. The NEI 11-04 QAPD template also commits, during the construction and operational phase of the plant, to compliance with the requirements of NQA-1-2008 and NQA-1a-2009, Subpart 2.1, Subpart 2.2, Subpart 2.3, and Subpart 3.2, Appendix 2.1, with the following clarifications and exceptions: *[NOTE: This commitment and the following clarifications and exceptions do not apply to an ESP-only QAPD.]*

> Subpart 2.2, Section 701 refers to Subpart 2.15 for requirements related to handling of items. The scope of Subpart 2.15 includes hoisting, rigging, and transporting of items for the nuclear power plant[s] during construction.

Nowhere is subpart 2.15 does it state that the requirements for hoisting, rigging, and transporting of items for the nuclear power plants only apply during construction. The NRC staff was unable to ascertain why this clarification to NQA-1-2009a is included, please provide a justification for this clarification.

RAI-11 Response

NEI 11-04 Section 13.2 will be revised to remove the reference to Subpart 2.15 as this clarification point is no longer needed.

RAI-12
The NEI 11-04 QAPD template commits to compliance with NQA-1-2008, Requirement 17, and regulatory positions stated in Regulatory Guide (RG) 1.28, Rev 4, June 2010, with the following clarifications and exceptions:

> In establishing the provisions for a list of records, [CA] commits to comply with Regulatory Guide 1.28, Revision 4, position C.1.a.(3) with the following clarifications; *[Note: [CA] should use either Option 1 or Option 2 below]*
>
> > *[[Note: Option 1][CA] commits to develop a list of typical QA records and their retention periods using the guidance of NQA-1-2008, Part III, Nonmandatory Appendix 17A-1, Section 200, for the lifetime records recognizing that the record name may vary and the list may not be all-inclusive. For records not listed, the record that most nearly describes the record in question will be followed regarding retention. [CA] commits to maintain sufficient records to furnish evidence of activities affecting quality.]*
> >
> > *[[Note: Option 2][CA] commits to develop a list of QA records and their retention periods and to maintain sufficient records to furnish evidence of activities affecting quality.]*

The NRC staff was unable to ascertain why this clarification to RG 1.28, Rev 4, June 2010 is included, please provide a justification for this clarification.

RAI-12 Response
NEI 11-04 Section 17.3 will be revised to remove the clarification as it is not needed.

RAI 13
The NEI 11-04 QAPD template commits to compliance with NQA-1-2008, Requirement 18, and regulatory positions stated in RG 1.28, Rev 4, with the following clarifications and exceptions:

> *[CA]* annual evaluation of the supplier in NRC position C. 2. b. (4). (a), (b), and (c) shall only be required to consider activities related to *[CA]* procurement activities.

The NRC staff was unable to ascertain why this clarification to RG 1.28, Revision 4, is necessary given that the relationships with suppliers, and the related evaluation requirements, are already based on procurement activities and the associated documentation. Please provide a justification for the clarification.

Furthermore, compliance with NQA-1-2008, Requirement 18 is based on internal audits. External audits/supplier evaluations are described in Section 7 of the NEI 11-04 QAPD template. Please explain why the above clarification, if retained, is listed in Section 18.3 versus Section 7.2.

In addition, please provide a justification for the exclusion of NRC position C. 2. b. (4)(d) from the above clarification.

RAI-13 Response
NEI 11-04 Section 17.3 will be revised to remove the clarification as it is not needed.

RAI-14

Section 18.1 of NEI 11-04 QAPD template provides reference to external and internal audits. External audits or audits of suppliers are described and documented in Section 7 of NEI 11-04, and Requirement 7 of NQA-1-2008. Please provide clarification as to why external audits are mentioned in Section 18.1.

RAI-14 Response

NEI 11-04 Section 18.1 will be revised to remove references to External or Supplier Audits.