

3078

memorandum

DATE: December 23, 2010

REPLY TO

ATTN OF: EM-961: White

SUBJECT: **EM PROCEDURE EM-2.7, REVISION 0, "NUCLEAR QUALITY ASSURANCE AUDITOR AND LEAD AUDITOR QUALIFICATION AND CERTIFICATION PROGRAM" - APPROVED**

TO: Environmental Management Staff, EM-90

The subject Nuclear Quality Assurance Auditor and Lead Auditor Qualification and Certification Program, see attached, is issued for your use. Please read and familiarize yourself with it. It will be placed onto the Office of Environmental Management's Office Policies and Procedures Webpage, (see <http://www.oakridge.doe.gov/External/Default.aspx?tabid=120>) as soon as possible and will be available there for future reference.

If you have questions or if we can be of any further assistance, please contact me at 576-0742 or Brenda Hawks at 576-2503.

John R. Eschenberg
Assistant Manager for
Environmental Management

Attachment:

EM 2.7 Nuclear Quality Assurance Auditor and Lead Auditor

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Date	12/23/10
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SSB 12/21/10

memorandum

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REPLY TO

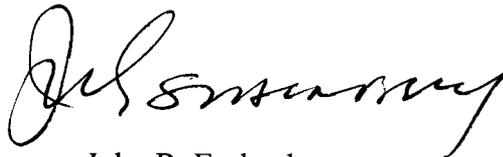
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John R. Eschenberg
Assistant Manager for
Environmental Management

Attachment:

EM 2.7 Nuclear Quality Assurance Auditor and Lead Auditor

Department of Energy
Oak Ridge Office
Environmental Management
Procedure

NUCLEAR QUALITY ASSURANCE AUDITOR AND
LEAD AUDITOR QUALIFICATION AND CERTIFICATION PROGRAM

EM-2.7
Revision 0

Prepared: *Aaron White* 23 Dec 2010
Aaron White, Preparer Date

Approved: *John R. Eschenberg* 12/25/2010
John R. Eschenberg, Date
Assistant Manager for Environmental Management

U. S. Department of Energy Oak Ridge Office Office of Environmental Management	Procedure No. EM-2.7, Revision 0 Nuclear Quality Assurance Auditor and Lead Auditor Qualification and Certification Program Effective Date: 1/3/2011 Page ii of 22
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Revision Log

Revision	Description of the Revision	Issue Date
0	Initial Issue.	1/3/2011

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List of Acronyms

AMEM	Assistant Manager for Environmental Management
DOE	Department of Energy
EM	Environmental Management
NQA	Nuclear Quality Assurance
NQA-1	American Society of Mechanical Engineers (ASME) national standard, <i>Quality Assurance Requirements for Nuclear Facility Applications</i>
ORO	Oak Ridge Office
QA	Quality Assurance
DD	Division Director
PADD	Performance Assurance Division Director

1.0 PURPOSE

The purpose of this procedure is to establish requirements and responsibilities for the qualification and certification Nuclear Quality Assurance (NQA) Lead Auditors and Auditors for the U.S. Department of Energy (DOE) Oak Ridge Office (ORO) Office of Environmental Management (EM) It is imperative for ORO EM that its personnel who participate in the auditing of its nuclear programs and operations have the necessary skills, knowledge, and abilities to successfully perform those duties. The successful performance of audit activities provides EM with the necessary information on the condition of its own and EM contractor's programs and operations including deficiencies so that corrective and continual improvement efforts can be effective. Documentation of the training, qualification and certification ensures that only personnel having the necessary qualification and certifications lead audits of quality assurance programs required to meet the American Society of Mechanical Engineers (ASME) national standard, *Quality Assurance Requirements for Nuclear Facility Applications*, NQA-1.

2.0 SCOPE

This procedure applies to all ORO EM management and non-management staff who serve on nuclear quality assurance (NQA) audits of quality management systems, or parts thereof, conducted against the requirements of ASME NQA-1, 2004 with addenda through 2007(NQA-1, 2004). This standard has been selected as the national consensus standard by the DOE EM for implementation by field office EM organizations and EM contractors. This procedure can also be used to qualify/certify staff from other organizations as needed. The scope of this procedure also includes establishing a qualification/certification program for personnel participating in NQA audits

However, based upon the importance or rigor associated with other assessments, the audited or auditing organization may elect to utilize personnel who have been qualified/certified via this procedure.

3.0 REFERENCES AND DEFINITIONS

3.1 References

- 3.1.1 ASME NQA-1-2004 with Addendum through 2007, *Quality Assurance Requirements for Nuclear Facility Applications*.
- 3.1.2 DOE O 414.1C, Quality Assurance
- 3.1.3 Office of Environmental Management Procedure EM 3.3, Integrated Assessment Program
- 3.1.4 10 CFR 830, Nuclear Safety Management and 830 Subpart A, Quality Assurance
- 3.1.5 Office of Environmental Management Procedure EM 2.4, Startup and Restart of Nuclear Facilities

3.2. Definitions

- 3.2.1 Assessment: A review, evaluation, inspection, test, check, surveillance, or audit to determine and document whether items, processes, systems, or services meet specified requirements and perform effectively.
- 3.2.2 Audit: a planned and documented activity performed to determine by investigation, examination, or evaluation of objective evidence the adequacy of and compliance with established procedures, instructions, drawings, and other applicable documents, and the effectiveness of implementation. An audit should not be confused with surveillance or inspection activities performed for the sole purpose of process control or product acceptance (per NQA-1, 2004).
- 3.2.3 NQA Auditor: Individual performing NQA-1 audits.
- 3.2.4 Certification: The act of determining, verifying and attesting in writing to the qualifications of personnel, processes, procedures, or items in accordance with specified requirements.
- 3.2.5 Lead NQA Auditor: Organizes and directs audits, reports audit findings, and evaluates corrective action and is certified as a Lead Auditor by NQA-1, 2004 standards.
- 3.2.6 Qualification: The characteristics or abilities gained through education, training, or experience, as measured against established requirements, Such as standards, or tests, that qualify an individual to perform a required function.

4.0 POLICY

The Nuclear Quality Assurance Auditor and Lead Auditor Qualification and Certification Program ensures that auditors of quality management systems in nuclear facilities are knowledgeable of the following before performing an audit:

- Assessment/audit methodology
- ORO EM Quality Assurance Program
- ORO EM Procedure - EM 3.3 Integrated Assessment Program

- ASME NQA-1-2004 with Addendum through 2007, *Quality Assurance Requirements for Nuclear Facility Applications*.
- *Other requirement documents, as appropriate.*

The qualification of lead auditors and auditors shall be certified in writing by the PAD Director (PADD). The PAD shall also maintain a list of all certified NQA lead auditors and NQA auditors. There shall be requirements for maintenance of proficiency and requalification if proficiency is not maintained. Qualification/certification of NQA audit personnel shall conform to requirements from NQA-1 (2004).

5.0 GENERAL REQUIREMENTS

5.1. Requirements for the Certification of NQA Auditors and Lead NQA Auditors under NQA-1

- 5.1.1. The lead NQA auditor and NQA auditor candidate must have received both formal and on- the-job training addressing the following:
- Knowledge and understanding of DOE and nuclear industry standards, regulations, and orders including, ASME NQA-1 (latest revision); 10 CFR 830, "Nuclear Safety Management"; DOE O 414.1C, Quality Assurance; and other codes, standards, and regulations in the area of QA applicable to ORO programs and projects.
 - General structure of QA programs.
 - Audit techniques (such as examining, reviewing, questioning, evaluating, interviewing, inspecting, and measuring; methods of identifying and follow-up on corrective action items; and closing out audit findings).
 - Audit planning, conduct, and reporting.
 - On-the-job training to include practical application of the ORO assessment program and audits.

These skills shall be evaluated, documented, and certified on Attachment A.

- 5.1.2. The lead NQA auditor and NQA auditor candidate shall have effective written and oral communication skills relative to performing and reporting audits. These skills shall be evaluated, documented, and certified on Attachment A.

- 5.1.3. The lead NQA auditor and NQA auditor candidate's educational background, experience, and relevant professional technical qualifications shall be evaluated and reviewed. The results shall be rated using "credits" awarded for each of the specified areas.

The educational background, experience, and professional technical qualifications of the lead auditors and auditors shall be documented and certified on Attachment B.

The minimum credits required to be certified are:

- NQA Auditor - 7 credits
- NQA Lead Auditor - 10 credits

Credits shall be assigned using the following criteria:

a. Education (4 credits maximum) from an accredited institution

- 1 Credit - Associate degree (any discipline), or
- 2 Credits - Associate degree in engineering, physical science, mathematics, or QA, or
- 2 Credits - Bachelor's degree (any discipline), or
- 3 Credits - Bachelor's degree in engineering, physical science, mathematics, or QA
- 1 Credit* - Graduate degree (Masters or Ph.D.) in engineering, physical science, business management, or QA

*Additional 1 Credit

b. Experience (9 credits maximum)

Technical experience in engineering, manufacturing, operations, maintenance, or construction equals one credit per year with a maximum of five credits. Additional credits can be awarded as follows:

- 1 credit - if two years of experience has been in the nuclear field, or
- 2 credits - if at least two years of experience have been in QA, or
- 3 credits - if at least two years of experience have been in nuclear QA, or
- 3 credits - if at least two years of experience have been in auditing, or
- 4 credits - if at least two years of experience have been in nuclear QA auditing

c. Professional Technical Qualifications and Achievement (2 credits maximum)

Two credits for certification of competency in engineering, science, or QA issued and approved by a state agency, national professional/technical society (e.g., Professional Engineer, Certified Quality Auditor), or the DOE Technical Qualification Program.

d. Rights of Management (2 credits maximum)

Up to 2 credits for the individual's other performance factors applicable

to auditing not explicitly called out above. Examples of these factors are leadership, sound judgment, maturity, analytical ability, past performance, and QA training.

These skills shall be evaluated, documented, and certified on Attachment B

- 5.1.4. NQA auditor candidate shall have participated in at least five QA audits within three years of the date of certification. One of these audits shall have been a NQA-1 audit performed within one year prior to certification.

Participation in independent assessments including team assessments and regulatory inspections/surveys by the prospective lead auditor may be used to satisfy up to four of the five required quality assurance audits, provided that the activities can demonstrate the following:

- a. Independence from the functional areas being assessed.
 - b. Planning that establishes the scope of the activities and associated evaluation criteria.
 - c. Performance by technically qualified and experienced personnel.
 - d. Results that are documented and reported to management.
 - e. Appropriate corrective action initiated and tracked to resolution.
- 5.1.5. NQA auditor candidate shall have participated in at least one QA audit or assessment within three years of the date of qualification. Audit participation evaluation shall be documented and certified on Attachment B.
- 5.1.6. Lead NQA auditor candidates shall pass an examination evaluating his/her comprehension and ability to apply the body of knowledge identified above. The examination may be oral, written, practical, or any combination of the three types and be focused on audit methodology, as well as knowledge and understanding of NQA-1, EM 3.3, and the structure of NQA-1 based QA programs. Lead NQA auditor and NQA auditor examinations administered by the ORO shall be administered and controlled as follows:
- a. The integrity of the examination shall be maintained through confidentiality of files and, where applicable, the examinations shall be proctored.
 - b. Objective evidence regarding the type and content of the examination shall be developed and maintained.

The examination results shall be documented and certified on Attachment B.

- 5.1.7. The lead NQA auditor and NQA auditor candidate shall be certified in writing. The PADD verifies that all activities necessary for qualification have been completed, including training; communications; education, experience, and professional qualifications; audit participation qualifications; and examination requirements.

Note: Once verified PADD documents and certifies the results on Attachment B. The PADD approval completes the individual's certification for a 5-year period.

- 5.1.8. The PADD will use Attachment C to document the lead NQA auditor or NQA auditor candidate's certification. Once the PADD signs and dates Attachment C, the candidate has met the requirements of this procedure; the PADD will submit the completed Attachments A, B, and C forms to ORO Document Control as official records and maintain a copy for their records.
- 5.1.9. Lead NQA auditors and NQA auditors shall maintain their certification through one or more of the following:
- a. Regular and active participation in the audit process.
 - b. Review and study of codes, standards, procedures, and instructions related to QA program and program auditing or assessments, including active participation in national or international QA, conformity assessment, or management system standards bodies.
 - c. Participation in training programs.
- 5.1.9.1 An annual review shall be conducted of each NQA auditor's and lead NQA auditor's qualification to determine if the certification is to be extended. Based on the annual review results, the PADD extends the qualification and recertification or requires retraining or requalification and recertification.
- 5.1.9.2 NQA lead auditors and auditors who fail to maintain their qualification for 2 years or more shall re-qualify to the requirements of this procedure.
- 5.1.9.3 The review and maintenance of certification shall be documented and certified on Attachment B.
- 5.1.10. Limited certification of personnel that have received qualification as an NQA Lead Auditor under another program may be granted and documented in Attachment C if
- a. Justified on a case-by-case basis by the PADD based on evaluation of the candidate qualifications and evaluation of the adequacy of the program granting such qualification in Attachment C.
 - b. An individual is knowledgeable in the area being assessed but has auditing/assessment training and experience less than equivalent to this procedure.
- 5.1.10.1 Individuals having equivalent qualifications can be allowed to work independently under the Team Lead.
- 5.1.10.2 Individuals who are less than equivalently qualified shall have a review team member assigned to assist them.

5.2. Extension and/or Recertification of Lead Auditor and Auditor Certification

- 5.2.3. At least once each calendar year, the PADD will reevaluate each NQA auditor or lead NQA Auditor certification and will extend the certification for another year if appropriate. Each NQA auditor or lead NQA auditor maintains his/her qualification through participation in at least one assessment, reading updates of

Attachment A documents, and/or participation in relevant training. The NQA auditor or lead NQA auditor will discuss the applicable items with the PADD and obtain the PADD's initials and date on Attachment A, if used to demonstrate continued proficiency.

NOTE: A calendar year consists of 12 months, with a 30+ day window for completion of the recertification.

- 5.2.4. The NQA auditor or lead NQA auditor will provide documentation of qualification maintenance activities along with the applicable form (Attachment A and/or D) to the PADD for signatures and dates. The NQA auditor or lead NQA auditor will submit the completed forms to ORO Document Control as official records and maintain a copy for his/her records.

6.0 RECORDS

The following records are generated during the performance of the procedure:

Record Description	QA Record Y/N	QA Record Retention L/NP	Responsibility for Submittal
QA Auditor Qualification List	Y	L	PADD
Record of Lead NQA Auditor and NQA Auditor Qualification & Certification Form	Y	L	PADD

L = Lifetime

NP = Non permanent

The identified records shall be processed and maintained in accordance with the ORO program for Records Management.

7.0 ATTACHMENTS

- A. NQA Auditor Qualification List
- B. Record of Lead NQA Auditor and NQA Auditor Qualification & Certification Form
- C. Lead NQA Auditor or NQA Auditor Certification Approval Form
- D. Lead NQA Auditor or NQA Auditor Certification Extension Approval Form

Attachment A

NQA AUDITOR QUALIFICATION LIST

NQA AUDITOR QUALIFICATION LIST

Assessor's/QA Auditor's Name: _____

Qualification Type (Assessor/QA auditor or lead assessor/QA auditor): _____

Quality Assurance Division Director

I. INITIAL FORMAL TRAINING	ASSESSOR'S/AUDITORS INITIALS/DATE	PADD OR DESIGNEE'S INITIAL/DATE
Nuclear Quality Assurance Lead Auditor Certification Training	EG/9/30/20XX	BD
Conduct of Operations Training	EG/8/30/20XX	BD
Safety Basis Training	EG/7/15/20XX	BD
Other formal training		

NQA AUDITOR QUALIFICATION LIST

PART II. REQUIRED READING (Use the latest revision of each document)	ASSESSOR'S/AUDIT- ORS INITIALS/DATE	PADD OR DESIGNEE'S INITIAL/DATE
<u>ORO OPERATING EXPERIENCE PROGRAM</u>		
<u>OAK RIDGE OFFICE - LEVEL III FUNCTIONS, RESPONSIBILITIES, AND AUTHORITIES (FRA)</u>		
<u>ORO MANAGEMENT SYSTEM DESCRIPTION / QUALITY ASSURANCE PROGRAM - PART A (MSD)</u>		
<u>ORO MANAGEMENT SYSTEM DESCRIPTION / QUALITY ASSURANCE PROGRAM - PART B (QAP)</u>		
<u>ENVIRONMENTAL MANAGEMENT QUALITY IMPLEMENTATION PLAN (EM-QIP)</u>		
<u>INTEGRATED SUPPORT CENTER QUALITY MANAGEMENT SYSTEM DESCRIPTION (QMSD)</u>		
<u>ORO INTEGRATED SAFETY MANAGEMENT (ISM) PROGRAM DESCRIPTION</u>		
QUALITY ASSURANCE REQUIREMENTS FOR NUCLEAR FACILITY APPLICATIONS (ASME NQA-1 2004)		
QUALITY ASSURANCE, DOE O 414.1C		
10 CFR PART 820 "PROCEDURAL RULES FOR DOE NUCLEAR ACTIVITIES"*		
10 CFR PART 830, "NUCLEAR SAFETY MANAGEMENT"*		
ORO EM PROCEDURE: <u>EM 3.3 INTEGRATED ASSESSMENT PROGRAM</u>		
OTHER RELEATED DOCUMENTS		
DOE QA GUIDES		

III. JOB PERFORMANCE DEMONSTRATIONS

1. Participation in three assessments (five for the lead QA Auditors):

ASSESSMENT TITLE/DATE	ASSESSOR'S/AUDITORS INITIALS/DATE	PADD OR DESIGNEE'S INITIAL/DATE
a.		
b.		
c.		
d.		
e.		
Other activities		
a.		
b.		
c.		

2. Conduct at least one entrance and one exit meeting

Assessment Title:		
	ASSESSOR'S/AUDITORS INITIALS/DATE	PADD OR DESIGNEE'S INITIAL/DATE
Entrance meeting		
Exit meeting		

3. Prepare at least one complete assessment report

Assessment Title	Date	

I approve the completion of this Qualification List.

Performance Assurance Division Director

Date

IV. ADDITIONAL QUALIFICATION REQUIREMENTS FOR LEAD QA AUDITORS

Date of examination: _____

A. Verification of Communications Skills

The prospective lead QA auditor will demonstrate to the PADD that he or she possesses adequate leadership and communication skills to effectively lead audits. Leadership includes the ability not only to organize an audit team, but also to work effectively with external organizations in the planning and execution of audits. Communication skills include both written and oral communications. The PADD must specifically evaluate the candidate's ability to develop written expositions of audit issues. Oral communication skills may be evaluated through interview, oral examination, or observation of performance over an extended period of time.

I have verified the prospective lead QA auditor's leadership and communication skills:

Performance Assurance Division Director

Date

B. Examination Results Attach documentation of oral, written, and/or practical examination results

1. Knowledge and understanding of DOE and nuclear industry standards, regulations, and orders

Date of examination: _____

Name of organization administering examination: _____

Examination results: Pass/Fail (circle one)

2. General structure of quality assurance programs

Date of examination: _____

Name of organization administering examination: _____

Examination results: Pass/Fail (circle one)

3. Audit techniques

Date of examination: _____

Name of organization administering examination: _____

Examination results: Pass/Fail (circle one)

4. Audit planning

Date of examination: _____

Name of organization administering examination: _____

Examination results: Pass/Fail

I approve the completion of this Qualification List.

Performance Assurance Division Director

Date

Attachment B

RECORD OF LEAD NQA AUDITOR AND NQA AUDITOR
QUALIFICATION & CERTIFICATION FORM

RECORD OF LEAD NQA AUDITOR AND NQA AUDITOR QUALIFICATION & CERTIFICATION FORM

The following table must demonstrate an accumulation of at least ten points for lead auditors and at least seven points for auditors. This document must be attached to the certification documentation.

Employer Name:					
Employer:					
Qualification Point Requirements Education – University/Degree Date				4 Credits Max.	Credits
1. Undergraduate Level	University		Degree Date		
2. Graduate Level	University		Degree Date		
Experience (9 Credits Max.)				Company Dates	
1. Technical (0-5 credits)					
2. Nuclear Industry (1 credit), or Quality Assurance (2 Credits), or Auditing or Nuclear Quality Assurance (3 Credits), or Nuclear Quality Assurance Auditing (4 Credits)					
Professional Accomplishment – Certificate/Date				2 Credits Max.	
1. P.E. Certificate Date					
2. Society Certificate Date					
3. DOE TQP Certificate Date					
Management – Justification/Evaluator/Date				2 Credits Max. Explain: Justification	
TOTAL CREDITS:					
Evaluated By: (Name, Title)			Date:		
Audit Communication Skills					
Evaluated by: (Name, Title)			Date:		
Audit Training Courses					
Course Title or Topic:					
1. _____		Date:			
2. _____		Date:			
Audit Participation Location Audit Date					
1.					
2.					
3.					
4.					
5.					
Examination By: Passed: Yes/ No (Please circle)			Date:		
APPROVALS (check one):				Certified Approved	
<input type="checkbox"/> Lead Auditor Certification				_____ Performance Assurance Division Director	
<input type="checkbox"/> Auditor Qualification & Certification					
Annual Evaluation (Signature and Date)					

Attachment C

LEAD QA AUDITOR, OR QA AUDITOR CERTIFICATION APPROVAL FORM

**LEAD NQA AUDITOR OR NQA AUDITOR CERTIFICATION
APPROVAL FORM**

Certification

On (Date) _____, (Name) _____ completed, and the PADD reviewed, the attached Assessor Qualification List. Following a review of the List and evaluation discussions with the individual, the PADD has determined the individual meets the certification requirements and demonstrates the capability to perform quality assessments as a QA auditor, or lead QA auditor (**circle one**). Therefore, in accordance with the ORO Nuclear Quality Assurance, Auditor Lead Auditor Qualification Program, EM 2.7, the PADD recommends the above named individual be certified as an, auditor, or lead auditor (**circle one**) in the capacity(s) stipulated below.

Type of Certification:

Lead NQA Auditor	NQA Auditor
------------------	-------------

Limited Certification

In accordance with the ORO EM Procedure EM-2.7, the PADD reviewed (Name) _____'s qualifications and related work experience on (Date) _____. Although the individual has not completed the NQA Auditor Qualification List, the PADD determined the individual is suitably qualified to perform as an assessment team member on the upcoming (title of assessment) _____. Based on the justification provided in the attached, the PADD recommends the above named individual be certified to perform (Title of Discipline) _____related assessments in the capacity(s) stipulated below.

Lead NQA Auditor	NQA Auditor
------------------	-------------

Limited Certification Justification

The individual's education and experience is attached and justifies limited certification to perform auditor duties. Example Justification: *"The individual has over 10 years of nuclear industry Quality Assurance (QA) related experience as both an American National Standards Institute Level III certified QA auditor and as a QA manager. In addition, the individual has reviewed the ORO EM Procedure 2.7 and 3.3 in addition to the QA related portions of the authorization basis."*

Recommendation:

Name

Title

Approval:

Name

Title

Attachment D

LEAD NQA AUDITOR, OR NQA AUDITOR CERTIFICATION EXTENSION
APPROVAL FORM

**LEAD NQA AUDITOR OR NQA AUDITOR CERTIFICATION EXTENSION
APPROVAL FORM**

On (Date) _____, (Name) _____ completed, and the PADD has reviewed the attached documents and found evidence that this individual has maintained proficiency as an assessor, lead assessor, QA auditor, or lead QA auditor over the past year. Following a review of the documents and evaluation discussions with the individual, the PADD determined the individual meets the requirements for certification extension and demonstrates the capability to perform ORO EM auditor, or lead auditor (**circle one**). Therefore, in accordance with the ORO EM Procedure 2.7 "Nuclear Quality Assurance Auditor and Lead Auditor Program," the PADD recommends the extension of certification for the above named individual as an ORO NQA Auditor or Lead NQA Auditor (**circle one**) for a period of one year in the capacity(s) stipulated below

<input type="checkbox"/> Lead NQA Auditor	<input type="checkbox"/> NQA Auditor
---	--------------------------------------

Recommendation:

Name **Date**

Approval:

Name **Date**

Attachment:

NQA Auditor and QA auditor Qualification List