



## Environmental Management Office of Standards and Quality Assurance

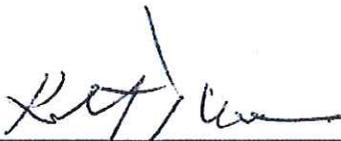
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### Quality Procedure

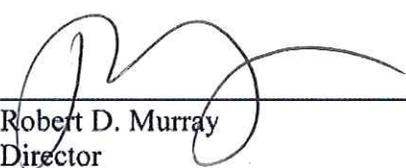
Subject Area: *Audits*

QP-10.1, Revision 0

Effective Date: 8/31/2015

Preparer:   
Robert A. Toro  
Office of Standards and Quality Assurance

8/28/2015  
Date

Approved:   
Robert D. Murray  
Director  
Office of Standards and Quality Assurance

8/31/2015  
Date

1. PURPOSE

This procedure establishes the responsibilities and process for scheduling, planning, performing, and reporting Quality Assurance (QA) audits of EM-QA-001, *Environmental Management Quality Assurance Program* implementation at EM Headquarters and Field Office programs, facilities and projects.

2. SCOPE

The scope of this procedure is to assess the effective implementation of the EM Corporate Quality Assurance Program requirements through audits.

3. APPLICABILITY

This procedure applies to EM personnel and contractors involved with the functions of audits of programs related to the EM Corporate QA Program activities as conducted by the Office of Standards and Quality Assurance.

4. REQUIREMENTS & REFERENCES

The most current version of the following requirements and references are applicable to this procedure.

Requirements

- 4.1 DOE Order O 414.1D, *Quality Assurance*
- 4.2 ASME NQA-1-2008/2009, *Quality Assurance Requirements for Nuclear Facility Applications*
- 4.3 EM-QA-001, *EM Quality Assurance Program*

References

- 4.4 DOE-EM-SRP-2010, *Standard Review Plan (SRP) Protocol for EM Review/Field Self-Assessment of Site-Specific Quality Assurance Programs (QAPs)/Quality Implementation Plans (QIPs)*
- 4.5 QP-2.1, *Personnel Training and Qualification*
- 4.6 SSQ-3.1, *Corrective Action*
- 4.7 QP-4.3, *Records Management*
- 4.8 QP-5.2, *Memo/Correspondence Control and Tracking*
- 4.8 QP-5.3, *Stop Work*
- 4.9 DOE Environmental Management Correspondence Guidance Handbook

5. DEFINITIONS

5.1. 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. (NQA-1-2009)

## 6. RESPONSIBILITIES

### 6.1. Deputy Assistant Secretary (DAS) for Safety, Security and Quality Programs

- 6.1.1 Approves the annual Office of Standards and Quality Assurance Assessment and Activities Schedule.
- 6.1.2 Concurs on and issues the approved audit plan and notification memorandum notifying the organization to be audited of a scheduled or unscheduled audit.
- 6.1.3 Concurs on and issues the memorandum and the final report resulting from completed audits to the EM Field Office or to the audited organization.

### 6.2. Director, Office of Standards and Quality Assurance

- 6.2.1. Responsible for the preparation, revision, and approval of this procedure.
- 6.2.2. Responsible for the development and issuance of the Office of Standards and Quality Assurance Assessment and Activities Schedule.
- 6.2.3. Responsible for providing the necessary resources needed to implement the audit.

Note: The Office of Standards and Quality Assurance staff personnel assigned as the lead responsible for coordinating with a particular EM Field Office can be assigned as the Audit Team Lead and qualified per Procedure QP-2.1, *Personnel Training and Qualification*.

- 6.2.4. Verifies that activities or QA criteria evaluated through the conduct of audits are satisfactorily implemented at EM Headquarters and Field Office programs, facilities and projects.
- 6.2.5. Approves the audit plan.
- 6.2.6. Approves the audit report.

### 6.3. Audit Team Lead, Office of Standards and Quality Assurance

- 6.3.1. Selects the audit team members.
- 6.3.2. Develops the audit plan and associated notification memorandum.
- 6.3.3. Prepares an audit checklist or Criteria Review and Approach Documents (CRADs) based upon the applicable standards and requirements to which the audit is being conducted. Often used criteria can be developed into standardized checklists for repeat usage. Checklist development can also be assigned by the Audit Team Lead to the audit team

members for their areas of evaluation. Examples of audit checklists are shown in Forms 10.1-1A and 10.1-1B of this procedure.

- 6.3.4. Ensures that the audit team members are qualified per Procedure QP-2.1, *Personnel Training and Qualification*, and prepared for the conduct of the audit. Assigns areas of evaluation to audit team members.
- 6.3.5. Leads the performance of the audit and conducts briefings with the management of the audited organization.
- 6.3.6. Documents the results of the audit in a report with input from the audit team members on their assigned areas of evaluation. Provides the audit report to the Deputy Assistant Secretary, Safety, Security, and Quality Programs for concurrence. Provides the audit report to the Director, Office of Standards and Quality Assurance, for approval and issuance.
- 6.3.7. Ensures that the approved audit report and associated documents (audit plan, audit checklists, memoranda, for example) are uploaded to the specific Assessment folder in the Issues Management System. Ensures that results of the audit including findings/deficiencies, observations, recommendations, and noteworthy practices have been added to the specific Assessment folder in the Issues Management System per Procedure SSQ-3.1, *Corrective Action*.

Note: Final disposition of records resulting from audits and implementation of this procedure is based on the EM Records Disposition process.

#### 6.4 Audit Team Member

- 6.4.1 Responsible for becoming qualified and prepared for the audit in their assigned area of evaluation by reviewing applicable QA requirements, programmatic and implementing documents pertaining to the organization to be audited, previous audit reports and associated corrective actions, checklists, and participating in pre-audit conference calls.
- 6.4.2 Responsible for evaluating the assigned audit area(s).
- 6.4.3 Provides input to the Audit Team Lead documenting the evaluation for their assigned area(s) or audited QA program element and input to the audit report.

### 7. GENERAL INFORMATION

Methods used to conduct audits may include examination, evaluation, investigation, review, analysis, interview, and direct observation. See definition of Audits in Section 5 of this procedure.

### 8. AUDIT PROCESS

#### 8.1. Developing the Annual Assessment and Activities Schedule

- 8.1.1 After coordination with the Field Office representatives by the Office of Standards and Quality Assurance personnel on projected assessments and activities at the Sites, the Director for the Office of Standards and Quality Assurance develops an annual Assessment and Activities Schedule in accordance with Attachment A. A real-time

schedule is also developed to accommodate updates to the schedule; a sample format is provided as Attachment B.

- 8.1.2 The Director, Office of Standards and Quality Assurance, submits the annual Schedule to the Deputy Assistant Secretary for Safety, Security, and Quality Programs for approval.
- 8.1.3 Once the Schedule is approved, the Director, Office of Standards and Quality Assurance, distributes the approved annual schedule to Field QA representatives and its respective Site managers.

Note: The approved annual Assessment and Activities Schedule is uploaded onto the Office of Standards and Quality Assurance website. The real-time assessment schedule which captures real-time updates is maintained in the Issues Management System, <http://correctiveactionhub.em.doe.gov/CAP/default.asp>

## 8.2 Planning an Audit

- 8.2.1 The Director, Office of Standards and Quality Assurance, ensures that the Audit Team Lead has no direct responsibility for the area being audited and is qualified as a Lead Auditor in accordance with QP-2.1, *Personnel Training and Qualification*.
- 8.2.2 The Audit Team Lead identifies an appropriate number of Audit Team Members who collectively have the experience or training commensurate with the scope, complexity, or special nature of work to be evaluated.
- 8.2.3 The Audit Team Lead ensures that each assigned Audit Team Member is qualified in accordance with QP-2.1, *Personnel Training and Qualification*, and independent of the assigned area(s) to be evaluated.
- 8.2.4 The Audit Team Lead ensures that the audit team is prepared for the audit through team meetings and/or calls to discuss audit scope, assignments, and logistics; obtaining points of contact for the audited organization(s); and having available access to review the applicable QA requirements, including programmatic and implementing documents of the organization(s) to be audited.
- 8.2.5 After coordinating with the audited organization to discuss scope for the audit, the Audit Team Lead develops and signs the audit plan and prepares a notification memorandum for approval by the Director, Office of Standards and Quality Assurance, in accordance with Attachment C, Scoping Activities and Audit Plan Development.

Note: The notification memorandum is developed in accordance with the latest EM Correspondence Guidance Handbook. Internal Office forms, such as a Justification Page, Concurrence Sheet and Informal Note (from the DAS to the Assistant Secretary for Environmental Management), are also processed for administrative purposes in accordance with Procedure QP-5.2, *Memo/Correspondence Control and Tracking*.

- 8.2.6 The Director, Office of Standards and Quality Assurance reviews and approves the audit plan with concurrence and issuance along with the notification memorandum by the Deputy Assistant Secretary for Safety, Security, and Quality Programs to the audited organization at least 30 days prior to conduct of the audit. Timeframes less than 30 days may be required for emerging issues. At the discretion of the Director, Office of

Standards and Quality Assurance, audit plans may be issued less than 30 days prior to conduct of the audit.

8.2.7 The Audit Team Lead directs the team to develop a QA Checklist as needed (Forms 10.1-1A and 10.1-1B as examples) for the audit using the generic lines of inquiry obtained from the latest version of the *Standard Review Plan – Protocol for QAP/Quality Assurance Implementing Plan (QIP) Review*. The Audit Team Lead may also direct the team to customize a checklist commensurate with the applicable requirements, scope, complexity, or special nature of work to be evaluated as needed using the Criteria Review and Approach Document (CRAD) methodology.

Note: The QA Checklist can be based on:

- A review of requirements of the EM-QA-001 and/or the audited organization's QA Program, including programmatic and implementing documents;
- Previous assessment results;
- Programmatic and technical documents; and
- Other related activity reports.

8.2.8 The Audit Team Lead reviews and approves the audit checklist or CRADs.

8.2.9 The Audit Team Lead directs the performance of the audit team throughout the audit process.

### 8.3 Conducting an Audit

8.3.1 The Audit Team Lead conducts a pre-audit (entrance) meeting with representatives of the organization to be audited, and other participants, such as observers, to address the following elements:

- Purpose, scope, and schedule for the audit
- Introduction of the audit team and personnel from the organization to be audited
- QA program elements and activities to be evaluated
- Support required from the affected organization.

Participation of attendees to this meeting is documented on an attendance sheet. An example is provided as Form 10.1-2, Attendance Sheet.

Note: An observer may also attend this meeting. The role of the observer participating in an audit is described in Attachment E, Protocol for Observers.

8.3.2 Each Audit Team Member monitors work or program activities in progress, conducts interviews, and reviews applicable records and documents to evaluate their assigned area(s) of evaluation.

- Use the written procedure being evaluated and/or checklist or CRADs as a guide to determine compliance, observe work activities, and determine effectiveness.

- Examine, collect, and document objective evidence for compliance with program and implementation requirements.
- Document name, title, and organization of all personnel interviewed.
- Determine effectiveness of requirements flow-down and program implementation for the assigned area.

8.3.3 The Audit Team Member immediately notifies the Audit Team Lead of a potential Significant Condition Adverse to Quality (SCAQ). A discussion is initiated with management of the organization being audited and the Director, Office of Standards and Quality Assurance, of the potential SCAQ.

Note: The definition and instructions for processing an SCAQ are shown in QP-5.3, *Stop Work*.

8.3.4 The Audit Team Lead conducts a daily caucus with the audit team to discuss results of each day's evaluation and each team member's progress. At this time, each team member also provides any issues identified during the conduct of the audit. Issues can be classified as findings/deficiencies, observations, recommendations, or noteworthy practices.

8.3.5 The Audit Team Lead conducts daily briefings, as needed, with management representatives of the organization being audited to report audit status and progress including discussion of potential findings/deficiencies, observations, recommendations, or noteworthy practices and to coordinate required interfaces involved in the audit. Participation of attendees to this meeting can be documented on an attendance sheet. An example is provided as Form 10.1-2, Attendance Sheet.

8.3.6 The Audit Team Lead conducts a post-audit (exit) meeting to provide audit results and overall QA program effectiveness to the management of the audited organization. Participation of attendees to this meeting can be documented on an attendance sheet. An example is provided as Form 10.1-2, Attendance Sheet.

#### 8.4 Post-Audit Activities and Report Development

8.4.1 The Audit Team Lead prepares the audit report in accordance with Attachment D, Audit Report Format and Content, and requests input from the Audit Team Members for their assigned areas. A second week may be required to complete the audit report on-site with assistance from a select group of team members.

8.4.2 Each Audit Team Member submits input to the audit report. Input to the audit report requires a write-up for each assigned area or activity, providing a description and results of the evaluation. Findings/deficiencies, if discussed, must include a reference to a specific programmatic or procedural requirement. Observations and recommendations do not require a reference to requirements. Noteworthy practices are also included in the write-up if identified.

8.4.3 If an audit checklist or CRAD is used and required to be completed as directed by the Audit Team Lead, the Audit Team Member records the following information on the audit checklist:

- Personnel contacted or interviewed
- Documents and objective evidence reviewed
- Issues classified as findings/deficiencies, recommendations, and noteworthy practices
- A description of the results of the evaluation for each checklist item
- Results of evaluation (satisfactory, unsatisfactory, or not applicable)

Note: Instructions for completing the checklist, if required, for an audit are shown in Form 10.1-1A or Form 10.1-1B, EM Quality Assurance Checklist.

- 8.4.4 The Audit Team Lead prepares, signs, and submits the audit report with a transmittal memorandum to the Director, Office of Standards and Quality Assurance, for review and approval not to exceed more than thirty (30) days after the audit is completed. The Audit Team Lead informs and provides a justification to the Director, Office of Standards and Quality Assurance, if the report cannot be issued within this timeframe.

Note: The transmittal memorandum is developed in accordance with the latest EM Correspondence Guidance Handbook.

- 8.4.5 The Director, Office of Standards and Quality Assurance, reviews and signs the audit report and forwards to the Deputy Assistant Secretary for Safety, Security, and Quality Programs for concurrence and issuance along with transmittal memorandum to the evaluated organization.

Note: The transmittal memorandum is developed in accordance with the latest EM Correspondence Guidance Handbook. Internal Office forms, such as a Justification Page, Concurrence Sheet and Informal Note (from the DAS to the Assistant Secretary for Environmental Management), are also processed for administrative purposes in accordance with Procedure QP-5.2, *Memo/Correspondence Control and Tracking*

- 8.4.6 Once the report and transmittal memorandum are scanned, the Deputy Assistant Secretary for Safety, Security, and Quality Programs issues the report via email to the responsible management of the audited organization.
- 8.4.7 The Audit Team Lead assembles and processes the records per Section 12.0 of this procedure and is responsible for entering the final report, completed checklists if applicable, and associated findings/deficiencies, observations, recommendations, and noteworthy practices identified during the audit into the Issues Management System.

## 9 RECORDS

Records listed below are collected per QP-4.3, *Records Management*, as individual records or included in a records package, as specified. Final disposition of QA records resulting from audits is based on the EM Records Disposition process.

Lifetime QA Record: None

Nonpermanent Records:

- Approved Annual Audit Schedule
- Audit Plan and Notification Memorandum,
- Audit Report and Transmittal Memorandum
- Completed QA Checklist (if applicable)

Non-QA Records: Attendance Sheets

10. FORMS

Forms 10.1-1A and B, Environmental Management Quality Assurance Checklist (Examples)

Form 10.1-2, Attendance Sheet (Example)

11. ATTACHMENTS

Attachment A – Annual Assessment and Activities Schedule

Attachment B – Assessment and Activities Schedule

Attachment C – Planning an Audit - Scoping Activities and Audit Plan Development

Attachment D – Audit Report Format and Content

Attachment E – Protocol for Observers

**RECORD OF REVISION**

DOCUMENT: QP-10.1 Revision 0 Subject Area: *Audits*

<b>Revision Number</b>	<b>Description of Changes</b>	<b>Revision on Pages</b>	<b>Effective Date</b>
0	Original	All	8/31/2015

## Environmental Management Quality Assurance Checklist

Form Number: 10.1-1A  
Audit Number:

1. Organization Evaluated:

2. Assessment
- Audit
  - Surveillance
  - Review

3. Prepared by: \_\_\_\_\_

Printed Name

Signature: \_\_\_\_\_ Date: \_\_\_\_\_

4. Dates of Evaluation:

5. Controlled Document:

6. Activity Evaluated:

7. Item No. 8. QA Criterion/Characteristics to be Evaluated

9.

Remarks

10. Results  
(SAT, UNSAT, or N/A)

[Reference Document and Section]

**Form 10.1-1, Environmental Management Quality Assurance Checklist**

7. Item No.	8. QA Criterion/Characteristics to be Evaluated	9. Remarks	10. Results

## Form 10.1-1A – General Instructions (Example)

Document the following information on Form 10.1-1A, ENVIRONMENTAL MANAGEMENT QUALITY ASSURANCE CHECKLIST:

**Audit Number** (located at top right corner of form): Indicate the audit number that corresponds to the use of this QA checklist. (Note: the audit number is assigned by the custodian of the Assessment and Activities Schedule.)

1. **Organization Evaluated:** Indicate the organization to be evaluated.
2. **Checkboxes:** Check the appropriate box to indicate if the checklist is being used for an audit, surveillance, or review.
3. **Prepared by, Signature, and Date:** Print the team leader for the audit, surveillance, or review. The team leader signs and dates the checklist after the checklist has been completed.
4. **Dates of Evaluation:** Indicate the dates that the evaluation occurs in the field, job site, office location, etc.
5. **Controlled Document:** Indicate the requirements document(s) that is/are the basis for the requirements that provide the characteristics to be evaluated.
6. **Activity Evaluated:** Indicate the activity being evaluated during this audit, surveillance, or review.
7. **Item Number:** Sequence the checklist items in a format appropriate to the controlled document. For example, EM-QA-001 has 10 Criteria. A numbering scheme that could be used would be 1-2 for EM-QA-001 Criterion 1, checklist question or line of inquiry 2.
8. **QA Criterion/Characteristics to be Evaluated:** This is the block for the checklist question to be answered during the audit, surveillance, or review process. Consider using the latest EM Standard Review Plan Review Module as guidance for developing each checklist item.
9. **Remarks:** This is the block where the team member documents the result of his/her evaluation using the audit, surveillance or review. The following categories are recommended to be inputted in this section: Personnel Contacted (name, organization, and title), Documents Reviewed (document number, revision number, title), and Discussion (narrative of results, including a description of the finding/deficiency, recommendation, or noteworthy practice).
  - Personnel Contacted: Provide list of personnel contacted during the audit or surveillance. (Indicate name and title)
  - Documents Reviewed: Provide list of documents reviewed during the audit or surveillance. (Indicate document number, revision number, title)
  - Discussion: narrative format providing results of evaluation of specific checklist item
10. **Results:** Indicate where the evaluation of the characteristic to be evaluated is Satisfactory (SAT), Unsatisfactory (UNSAT), or Not Applicable (N/A). As a general rule, following guidance should be used:
  - a. **UNSAT:** There is a finding/deficiency documented onto a Corrective Action Report as a result of the evaluation.
  - b. **N/A:** There is no evidence of implementation to evaluate for that characteristic or the characteristic was not audited.
  - c. **SAT:** The evaluation demonstrates the characteristic has been satisfied
  - d. Under the result, indicate person responsible for evaluating the checklist item (use initial of first name and full last name; signature is not needed). For example: J. Smith

## Environmental Management Quality Assurance Checklist (Example)

Form Number: 10.1-1B  
Audit Number:

<b>Organization Evaluated:</b>	<div style="display: flex; justify-content: space-between; align-items: center;"> <div style="text-align: center;"> <input checked="" type="checkbox"/> Audit   <input type="checkbox"/> Surveillance                 </div> <div style="text-align: right;">                     Prepared by: _____                 </div> </div>
<b>Activity Evaluated:</b>	
<b>Controlled Document:</b>	
<b>Item No.</b>	<b>Characteristics to be Evaluated</b>
<b>QA Criterion (title)</b>	
7-1	Provide line of inquiry consistent with the Verify that procurement documents include the following provisions to ensure quality as applicable to the item (including spare parts and replacements) or service being procured: Statement of the scope of work to be performed; technical and QA program requirements; right of access to supplier facilities and records; Provisions for hold points beyond which work cannot proceed without purchaser authorization; schedule for submittal of documents to purchaser for information, review and approval; reporting of non-conformances, dispositioned as use-as-is or repair to the purchaser for approval of the disposition; identification of spare and replacement parts or assemblies, and instructions relative to the performance of special processes; and controls to mitigate procurement and installation of counterfeit or fraudulent items. Verify that changes to procurement documents are subject to the same degree of control as used in the preparation of the original documents.(EM QAP 7.7.1, 7.7.2)
<b>Remarks</b>	SAT
<b>Personnel Contacted (name/title):</b> <ul style="list-style-type: none"> <li>• Documents Reviewed (Document Number, Revision number, Title):</li> <li>• Discussion:</li> </ul>	

## Form 10.1-1B – General Instructions (Example)

Document the following information on Form 10.1-1B, ENVIRONMENTAL MANAGEMENT QUALITY ASSURANCE CHECKLIST:

**Audit Number:** Indicate the audit number that corresponds to the use of this QA checklist. (Note: the audit number is assigned by the custodian of the Assessment and Activities Schedule.)

1. **Organization Evaluated:** Indicate the organization to be evaluated.
2. **Checkboxes:** Check the appropriate box to indicate if the checklist is being used for an audit or surveillance.
3. **Prepared by, Signature, and Date:** Print the team leader for the audit, surveillance, or review. The team leader signs and dates the checklist after the checklist has been completed.
4. **Activity Evaluated:** Indicate the activity being evaluated during this audit, surveillance, or review.
5. **Controlled Document:** Indicate the requirements document(s) that is/are the basis for the requirements that provide the characteristics to be evaluated.
6. **Dates of Evaluation:** Indicate the dates that the evaluation occurs in the field, job site, office location, etc.
7. **Item Number:** Sequence the checklist items in a format appropriate to the controlled document. For example, EM-QA-001 has 10 Criteria. A numbering scheme that could be used would be 1-2 for EM-QA-001 Criterion 1, checklist question or line of inquiry 2.
8. **QA Criterion/Characteristics to be Evaluated:** This is the block for the checklist question to be answered during the audit, surveillance, or review process. Consider using the latest EM Standard Review Plan Review Module as guidance for developing each checklist item.
9. **Remarks:** This is the block where the team member documents the result of his/her evaluation using the audit, surveillance or review. The following categories are recommended to be inputted in this section: Personnel Contacted (name, organization, and title), Documents Reviewed (document number, revision number, title), and Discussion (narrative of results, including a description of the finding/deficiency, recommendation, or noteworthy practice).
10. **Results:** Indicate where the evaluation of the characteristic to be evaluated is Satisfactory (SAT), Unsatisfactory (UNSAT), or Not Applicable (N/A). As a general rule, following guidance should be used:
  - a. **UNSAT:** There is a finding/deficiency documented onto a Corrective Action Report as a result of the evaluation.
  - b. **N/A:** There is no evidence of implementation to evaluate for that characteristic or the characteristic was not audited.
  - c. **SAT:** The evaluation demonstrates the characteristic has been satisfied
  - d. Under the result, indicate person responsible for evaluating the checklist item (use initial of first name and full last name; signature is not needed). For example: J. Smith

<b>ATTENDANCE SHEET (Example)</b>		Form Number: 10.1-2 Page of		
Audit Number:	Organization Evaluated:	<input type="checkbox"/> Pre-Audit Meeting <input type="checkbox"/> Post Audit Meeting		
Summary of Material Covered:				
Audit Team Lead: (Printed Name)		Date:		
Attendee (Print Name)	Signature	Organization/Employer	Position/Title	Phone Number

**Form 10.1-2 – ATTENDANCE SHEET Instructions**

Document the following information on Form 10.1-2, Attendance Sheet:

1. **Audit Number:** Indicate the audit number that corresponds to the use of this form.
2. **Organization Evaluated:** Indicate the organization to be evaluated.
3. **Checkboxes:** Check the appropriate box to indicate is form is being used for a pre-audit or post-audit meeting.
4. **Summary of Material Covered:** Indicate the requirements document that is the basis for this audit.
5. **Audit Team Lead:** Print the name of the team lead for the audit.
6. **Signature:** The audit team lead signs his or her name prior to distribution of the attendance sheet.
7. **Date:** Indicate the date that the meeting or briefing occurred.

The rest of the blocks below are for each attendee to print his or her name, provide signature, their organization/employer, their current position/title and phone number.

**ATTACHMENT A – ANNUAL ASSESSMENT AND ACTIVITIES SCHEDULE**

**EM-43 Assessment and Activities Schedule for Fiscal Year xxxx**

Site/Organization	Federal Point-of-Contact	Assessment or Activity #	Scope	Date	EM-43 Team Lead

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*Name* \_\_\_\_\_ *Date* \_\_\_\_\_  
*Deputy Assistant Secretary for Safety, Security, and Quality Programs*

The EM-43 FY2015 Assessment and Activities Schedule is a listing of assessments, assistance, and meetings requiring travel that are planned within EM-43. The approved and signed annual Schedule can be accessed in the EM QA website. A detailed schedule is provided in real time in the EM Corrective Action Hub at <http://correctiveactionhub.em.doe.gov/CAP/default.asp>. The schedule is arranged chronologically, but is coded by priority for the office. The prioritization of the schedule is obtained by utilization of color coding. The following categories are used to provide the prioritization:

Green	Environmental Management Corporate Quality Assurance Program Implementation Reviews (commitments from EM-1/2 or EM-40)
Blue	High Level Waste/Used Nuclear Fuel QARD Audits
Brown	Special Efforts and Support to EM HQ Offices and Field Offices
Yellow	Meetings and Training Requiring Travel (e.g., QA Corporate Board,, Site Visits)
Dotted/Shaded Cells	Regardless of color – dotted or shaded cells are used to indicate the review is complete and the report is issued

**Legend:** *AST* = Assistance to Field Offices (not a formal assessment); *AU* = Audit; *PA* = Performance Assessment; *S* = Surveillance; *TRN* = Training; *MTG* = Meeting, Site Visit

## ATTACHMENT A – ANNUAL ASSESSMENT AND ACTIVITIES SCHEDULE (cont'd)

### SCHEDULING OF ASSESSMENTS AND ACTIVITIES

The following elements are considered in developing the annual Office of Standards and Quality Assurance Assessment and Activities Schedule:

- a. Assessments are scheduled in a manner to provide coverage, consistency, and coordination with ongoing work.
- b. Each EM site is audited annually, unless a decrease in the frequency of oversight activities of the Site's facilities and projects is determined jointly between EM and the Field/Site based on the scope and complexity of the work, including results of previous assessments.
- c. Audits are scheduled to begin as early in the life of the work as practicable and are scheduled to continue at intervals consistent with the schedule for accomplishing the work.
- d. Regularly scheduled audits are supplemented by additional assessments of specific subjects, when necessary, to provide an adequate evaluation of QA Program compliance or effectiveness, or when requested by the management of the area to be evaluated.
- e. Meetings (MTG), such as the EM QA Corporate Board Meetings and meetings with the QA managers at the Field Offices.
- f. Other activities include, as a minimum, training (TRN) and Site support (AST) not requiring a formal assessment process (document reviews)

For each scheduled assessment, the assessment and activities schedule (working-level document) provides the following detailed information, as a minimum:

- a. **Site/Organization(s):** Field Office/Project/Facility to be audited
- b. **Federal Point of Contact:** Field/Site Office Federal point-of-contact
- c. **Assessment or Activity #:** For assessments, use this designation EM-PA-Year (2-digit)-Number (starts with 01, etc.). For site meetings/visits, i.e., QA Corporate Board, use this designation: EM-MTG-Year (2-digit)-Number (starts with 01). For training which require travel, use this designation (EM-TRN-Year (2-digit)-Number (starts with 01). For activities providing Site assistance, such as document review, use this designation (EM-AST-Year (2-digit)-Number (starts with 01). The custodian of this schedule retains responsibility for providing the number for each assessment/activity on this schedule.
- d. **Type of Assessment/Focus and Scope of Assessment:** Brief description of the type and scope of assessment (audit, surveillance, assist visit, review, etc.) and activity (site meetings, training)
- e. **Date:** Date of assessment
- f. **EM-43 Lead:** Name of EM-43 Team Lead

**ATTACHMENT B – ASSESSMENT AND ACTIVITIES SCHEDULE (WORKING DOCUMENT - EXAMPLE)**

<u>Site/Org</u>	<u>Federal POC</u>	<u>Status</u>	<u>Type of Assessment or Activity (Including scope)</u>	<u>Assessment or Activity #</u>	<u>Date</u>	<u>EM-43 Lead (L) and Team Members</u>	<u># Feds (EM-43)</u>	<u># Contractors</u>	<u>Remarks</u>

**SCHEDULING OF ASSESSMENTS AND ACTIVITIES**

The following elements are considered in updating the Office of Standards and Quality Assurance Assessment and Activities Schedule maintained in the Issues Management System:

- a. Assessments are scheduled in a manner to provide coverage, consistency, and coordination with ongoing work.
- b. Each EM site is audited annually, unless a decrease in the frequency of oversight activities is determined jointly between EM and the Field/Site based on the scope and complexity of the work, including results of previous assessments.
- c. Audits are scheduled to begin as early in the life of the work as practicable and are scheduled to continue at intervals consistent with the schedule for accomplishing the work.
- d. Regularly scheduled audits are supplemented by additional assessments of specific subjects, when necessary, to provide an adequate evaluation of QA Program compliance or effectiveness, or when requested by the management of the area to be evaluated.
- e. Meetings (MTG), such as the EM QA Corporate Board Meetings and meetings with the QA managers at the Field Offices.
- f. Other activities include, as a minimum, training (TRN) and Site support (AST) not requiring a formal assessment process (document reviews)

For each scheduled assessment, the assessment and activities schedule (working-level document) provides the following detailed information, as a minimum:

- g. **Site/Organization(s):** Field Office/Project/Facility to be audited
- h. **Federal POC:** Field/Site Office Federal point-of-contact
- i. **Status:** Status of assessment or activity – Pending, Planning/Preparation, Ongoing, Complete/Report Preparation, or Complete
- j. **Type of Assessment/Activity (including Scope):** Brief description of the type of assessment (audit, surveillance, assist visit, review, etc.) and scope of the assessment
- k. **Assessment/Activity #:** For assessments, use this designation EM-PA-Year (2-digit)-Number (starts with 01, etc.). For site meetings/visits, i.e., QA Corporate Board, use this designation: EM-MTG-Year (2-digit)-Number (starts with 01). For training which require travel, use this designation (EM-TRN-Year (2-digit)-Number (starts with 01). The custodian of this schedule retains responsibility for providing the number for each assessment/activity on this schedule.
- l. **Date:** Date of assessment
- m. **EM-43 Lead and Team Members:** Name of EM-43 Team Lead and team members
- n. **# Feds (EM-43):** Total number of EM-43 personnel participating in assessment or activity
- o. **# Contractors:** Total number of support contractor personnel participating in assessment or activity
- p. **Remarks:** Additional information not covered in previous categories.

Note: The latest revised Assessment and Activities Schedule is maintained and can be accessed real-time in the EM Corrective Action Hub at <http://correctiveactionhub.em.doe.gov/CAP/default.asp>

## ATTACHMENT C – PLANNING AN AUDIT SCOPING ACTIVITIES AND AUDIT PLAN DEVELOPMENT

### Scoping Activities

1. Scope definition activities (to be coordinated with the organization no later than six weeks prior to scheduled audit date)
  - a. Identify applicable EM QA Program elements to be evaluated.
  - b. Identify new or ongoing work activities and critical processes subject to EM-QA-001 requirements.
  - c. Determine changes planned or in process to QA Program of audited organization. Identify QA program documents or procedures subject to the audit or applicable to a process or activity to be evaluated (e.g., a previous EM assessment report, any conditions issued to the audited organization since completion of the previous EM assessment report, and any important historical documents).
  - d. Obtain current organization chart. Identify key organizations/personnel that may be subjected to the audit.
  - e. Determine any training requirements needed by audit team to get on site.
  - f. Identify badging and security requirements applicable to audit team.
  - g. Determine whether property passes are required for laptops, Personal Digital Assistants, and so forth (items that require a property pass are site specific; check with site security) used on site during audit.
  - h. Determine logistical arrangements (e.g., meeting room, audit teamwork area, computer/administrative support, and lodging).
2. Interface with management of audited organization via teleconference (at least six weeks prior to scheduled audit date)
  - a. Discuss planned scope of audit.
  - b. Confirm tentative schedule for performance of audit.
  - c. Obtain commitments on availability of knowledgeable audited organization personnel to participate in audit.
  - d. Identify anticipated date of audit plan issuance.

### Notification Memorandum

3. Prepare and issue notification memorandum with approved audit plan (at least 30 days before audit).  
Note: The transmittal memorandum is developed in accordance with the latest EM Correspondence Guidance Handbook.

### Audit Plan Development

4. Develop an audit plan and include the following information:
  - a. Signature/Approval Page
  - b. Audit Scope that addresses:
    - i. Identification of the organization to be evaluated
    - ii. Timeframe for conducting the audit
    - iii. Summary of audit scope and base requirements
  - c. Schedule for conducting the audit (entrance/exit meetings, assessment activities, management briefings, daily team meetings)
  - d. Requirement(s) to be evaluated and applicable references to implementing documents or checklists to be used.
  - e. Audit Team members (name, organization, title [Audit Team Lead/Audit Team Member/Technical Specialist-Subject Matter Expert])

## ATTACHMENT D – AUDIT REPORT FORMAT AND CONTENT

Team members are responsible for providing report inputs to the Audit Team Lead. The format and content (in parenthesis) shown in this Attachment is used for audits conducted by the Office of Standards and Quality Assurance.

1. Report Transmittal Memorandum (to be signed and issued by the Deputy Assistant Secretary for Safety, Security and Quality Programs )
2. Signature/Approval Page (to be signed by the Audit Team Lead as Preparer, to be approved with by the Director, Office of Standards and Quality Assurance, and concurred by the Deputy Assistant Secretary for Safety, Security and Quality Programs)
3. Report Content
  - a) Executive Summary (**narrative format** providing brief description of the scope, results of the audit, and overall statement of QA program effectiveness)
  - b) Summary of Audit Results

Option 1: Each sub-category noted below can be presented in a **narrative format** which includes a discussion of each QA Program criterion or programmatic element evaluated with accompanying results and findings, observations, recommendations, and/or noteworthy practices

Option 2: Each sub-category noted below can also be presented in a **bulletized format** as follows:

    - 1) Purpose and Scope: Provide description of audit scope and base requirements
    - 2) Audited Organization: Identify organization(s) evaluated.
    - 3) Dates of the Audit: Denote timeframe for conduct of the audit.
    - 4) QA Sections/Activities Evaluated: Provide title of QA Program elements and/or activities evaluated.
    - 5) Audit Team: Indicate name, title, organization/affiliation of audit team member.
    - 6) Results: Describe the findings/deficiencies (Conditions Adverse to Quality and Significant Conditions Adverse to Quality) with reference to the regulatory or procedural requirement(s) and the checklist item. Also, describe observations and recommendations, including noteworthy practices in this section. Observations and recommendations do not need to provide references to regulatory or procedural requirements.
  - c) Conclusion: Provide overall assessment of QA program compliance or effectiveness
  - d) Attachment 1, Personnel Contacted List. Identify individuals interviewed during the conduct of the audit by organization and position title, including those who attended the pre-audit (entrance), post-audit (exit) meetings, and management briefings.
  - e) Attachment 2, Audit Checklist (if required by Audit Team Lead.)

Note: The Environmental Management Quality Assurance Checklist (Form 10.1-1A and Form 10.1-1B), if directed to be completed by the Audit Team Lead, may be included as Attachment 2 of the audit report, but is not required to be issued with the audit report. The report transmittal memorandum and/or the summary report should indicate that the checklist will not be included during issuance of the audit report but is integrated, maintained, and are accessible in the EM Corrective Action Hub.

## **ATTACHMENT E – PROTOCOL FOR OBSERVERS**

An observer assigned to an audit team functions only in a singular role. Specifically, the observer is a passive spectator who reports to the Audit Team Lead. All activities conducted by the observer related to audit or surveillance must be with the full knowledge and endorsement of the Audit Team Lead. The observer is allowed to attend the pre-audit (entrance) and post-audit meetings, the caucuses conducted by the audit team at the end of each day, and the daily briefings with the management of the audited organization. The observer is also allowed to observe any audit team member conducting interviews or reviewing objective evidence of program implementation. The audit team member may allow the observer to ask any questions of the interviewee as long as the audit team member has completed his/her interview. At the conclusion of the audit, the observer may be asked by the Audit Team Lead to provide feedback on the audit process.

Issues involving professional disagreement between the observer and members of the audit team should be escalated to the Director, Office of Standards and Quality Assurance by the observer and to the Audit Team Lead, together if at all possible, as soon as practicable. It is the expectation that most differences of opinion will be resolved through exhibiting behaviors consistent with the EM core values that encourage the open expression and discussion of differing viewpoints.