

[QA Assessment Plan Template]
[DOE G 414.1-2A, Attachment 1, 6-17-05]

Quality Assurance Assessment Plan
For _____

Office of

Department of Energy
Office of _____

Date: _____

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1. SCOPE

This assessment is considered a preliminary assessment of the implementation of QA policies and principles in _____ operations related to _____ activities. The areas of interest or activities to be assessed are identified in Section ____.

- (1) Program – _____ ;
- (2) Personnel Training and Qualification – _____ ;
- (3) Quality Improvement – _____ ;
- (4) Documents and Records – _____ ;
- (5) Work Processes – _____ ;
- (6) Design – _____ ;
- (7) Procurement – _____ ;
- (8) Inspections and Acceptance Testing – _____ ;
- (9) Management Assessment – _____ ;
- (10) Independent Assessment – _____ ;
- (11) Software Quality Assurance – _____ ;
- (12) Suspect/Counterfeit Items Prevention – _____ ;
- (13) Corrective Action Management Program – _____ ;
- (14) Integrated Safety Management – _____ ;

A follow-up assessment, pending the outcome of this assessment, is anticipated on or about _____.

2. OBJECTIVE

To provide feedback for continuous improvement: A process is established and effectively implemented to continuously improve safety and improve the efficiency and quality of operations. Procedures and mechanisms are in place to implement integrated safety management and quality assurance programs through approved program plans.

3. REQUIREMENTS

- DOE O 414.1C, Quality Assurance
- 10 CFR 830, Nuclear Safety Management
- DOE P 450.4, Safety Management System Policy
- Site-specific QA documentation
- Site-specific ISM documentation
- Organization or Site-specific FRAM/FRA

4. ASSESSMENT TEAM

The Assessment team will be composed of the following individuals:

_____ – Team Leader

_____ (Observer)

Brief biographical information for each team member is provided in Appendix 1-A.

5. ACTIVITIES TO BE ASSESSED

The Assessment Team will review the implementation of Quality Assurance (QA) and Integrated Safety Management Systems (ISMS) by evaluating some of the primary _____ functions and high-risk _____ activities. The Team will focus on _____ function(s) and a selected set of high-risk (hazard) activities. The Team will choose which activities to evaluate from a list of activities prioritized by risk provided by _____ prior to or at the initial briefing. For a chosen activity, the _____ topics will be evaluated by “drilling down” into the activity by lines of inquiry. Personnel interviews and observations may be utilized as determined by the Team while on-location.

As lines of inquiry are being pursued, the Team will also evaluate a number of general QA and ISMS topics, including _____. Spot-checks of QA and/or ISMS implementation in _____ may also be conducted during the assessment of the major activities.

The initial lines of inquiry listed below will be utilized during evaluation of specific work processes.

Review Area 1—Program

1. Review the organization and reporting chain (Criterion 1, DOE O 414.1C) to ensure clear lines of authority are established and utilized.
 - What is the organization structure of this activity?
 - Are functional responsibilities for QA defined and implemented for this activity?
 - What is the organization structure of the QA oversight of this activity?
 - Is the QA organization independent of the line management organizations?
 - What is the commitment of upper, middle, and lower management to the QA program and its implementation?
 - How is Quality policy promulgated and Quality improvement implemented throughout the organization associated with this activity?
 - Are QA audits, surveillances, and nonconformance reports part of the QA program?
 - What are the QA interface points with organizations that support this activity, and how is QA communicated to and implemented through them?
 - What is the process for determining the QA requirements for _____ and/or its contractors for this activity, and what is the review/approval/ implementation status of this process?
 - How are quality problems identified, documented, corrected, and prevented in the future for this activity?
 - How are Readiness Assessment and Operational Readiness Review results integrated with quality improvement and operational efficiency?
 - How are quality and efficiency improvements implemented, and how are lessons learned applied to this activity?

2. Review the graded approach and any criteria for determining what QA management requirements are implemented for various types of work.
 - What are the levels of risk associated with an activity?
 - What is the process for grading the application of QA requirements for activities? Does it identify consequences, requirements, and depth/extent/rigor necessary in application of those requirements?
 - What is the level of commitment of this activity's senior management to QA?
 - What are the greatest concerns regarding QA and ISMS implementation?
 - Are controls and verifications applied to this activity consistent with their importance to safety, cost, schedule, and success of this mission?
 - Are controls documented and communicated to personnel involved in this activity to ensure appropriate application and implementation?

3. Review and approval of contractor QAPs for selected high-risk activities.
 - What is the QA Plan?
 - Is the QA Plan approved? If not, when will it be approved?
 - What is the review process for the approval of the QAP for this activity?
 - What is the process for determining the QA requirements for _____ and its contractor(s) for this activity, and what is the review/approval/implementation status of this process?
 - What is/are the major contractor's QA Plan(s), and is it/are they implemented?

Review Area 2—Personnel Training and Qualification

Evaluate the status of implementation of a training and qualification program that ensures personnel are capable of performing their assigned work.

- What is the organization's documented training plan? Is it adequate and effective? How are training requirements established? What is the review and approval process?
- Does the organization have adequate resources, processes, and responsible elements to support the selection, training, and qualification of personnel conducting work?
- Does the training and qualification program describe the positions and functions to which it applies?
- How are certifications and special qualifications (e.g., auditors, subject matter experts, nondestructive examination personnel, welders, etc.) established and maintained current?
- How is proficiency established and maintained for operational positions and/or functions?
- How is on-the-job training established and maintained?
- How is the required reading program established and maintained?

Review Area 3—Quality Improvement

1. Evaluate the status of implementation of a quality improvement process to detect and prevent quality problems.
 - Do established work processes and procedures adequately identify and report quality problems?
 - Does senior management policy encourage problem detection and prevention?
 - What are the existing processes for communicating lessons learned and performance information? Are they adequate? Are they effective?
 - How is the significance of quality problems categorized and prioritized?
 - Does this quality improvement process provide for the identification of the causes of problems? Does it require identification of actions to prevent recurrence? Are both of these required as part of the problem correction process? Is implementation effective?
 - How are cause, extent, and remedial and preventative actions for quality problems addressed?
2. Evaluate the approach to identification, control, and correction of items, services, and processes that do not meet established requirements (nonconforming).
 - What procedures determine which disciplines or functions evaluate and disposition the nonconforming item, service, or process? Are they adequate?
 - What procedures identify and control nonconforming items to prevent their inadvertent use? Are these procedures adequate?
 - How are quality problems associated with services and processes documented and corrected?
3. Evaluate the process to review item characteristics, process implementation, and other quality-related information to identify items, services, and processes needing improvement.
 - What quality performance analysis system is in place (e.g., six sigma, metrics and indicators, trending)? Is it adequate?
 - How does the performance analysis system provide for feedback to affected and related organizations or groups?

Review Area 4—Documents and Records

1. Evaluate the process for preparation, review, approval, issue, use, and revision of documents that prescribe processes, requirements, and design.
 - What is the approved and documented document control system providing the above functions? Is it documented? Does it clearly describe responsibilities and functions? Is it adequate?
 - Are key functions related to the quality criteria (e.g., design, procurement, work control, inspection, testing) described in reviewed and approved documents such as procedures?
 - Are key work processes and associated activities and functions in the FRA supported

by documentation?

2. Evaluate the process for specification, preparation, review, approval, and maintenance of records.
 - What is the approved and documented records management system providing the above functions? Is it adequate?
 - Are the requirements of the National Archives and Records Administration addressed?
 - What is the quality records standard applied to the applicable contract(s), and is it fully implemented?

Review Area 5—Work Processes

Evaluate the implementation of quality management principles in work processes.

- Are the methods adequate for ensuring that work is performed consistent with technical standards, administrative controls, and other hazard controls?
- Are the core functions and guiding principles of ISM addressed in work processes?
- Do the approved instructions, procedures, and other appropriate means for the work processes meet regulatory or contract requirements?
- What are the methods that identify and control items to ensure their proper use? What are the methods that maintain items to prevent their damage, loss, or deterioration? Are these methods adequate? (See Review Area 3, items 2 and 3)
- What are the requirements for and methods of ensuring adequate calibration and maintenance for equipment used for process monitoring or data collection? Are they adequate?
- Is there an adequate system in place for use and control of software in accordance with DOE G 414.1-4?

Review Area 6—Design

Evaluate the implementation of quality management principles in design.

- How has this office determined whether it performs actual design work? If not, how is oversight of contractor design addressed and documented? How is the training and qualification of personnel carried out for this oversight of design?
- Are appropriate standards and sound engineering and scientific principles applied to design items and processes? How is this documented? Is the graded approach utilized properly?
- Is the use of software in the design and safety analysis process controlled in accordance with DOE G 414.1-4?
- What method is used to incorporate applicable requirements and design bases in design work?
- Are design changes controlled at the same level as the design?
- How are design interfaces identified and controlled, within the design authority and externally with customers and suppliers, including subcontractors?
- What is the process for design verification and/or validation for design products? Is it

- adequate? Are individuals other than those performing the design work utilized?
- Is the design work verified/validated before approval and implementation of design?
- What is the system for engineering involvement in the identification, analysis, and control of suspect/counterfeit items that could affect safety? Is it documented? Is it adequate?

Review Area 7—Procurement

1. Review contract List A/List B requirements for proper flowdown to contractors of DOE O 414.1C and/or 830 Subpart A requirements.

- Review the list of contractors.
- Review _____ contract. (Team will select)
- What is the schedule of assessments for this contractor?
- For this contractor, how are quality problems identified, documented, reported, corrected, and prevented in the future?
- How are past assessment results implemented?
- How are flowdown requirements to subcontractors verified? Tracked?
- How does _____ ensure that the QA Plan and ISM are implemented for all contractors?
- How does the Field Office assessment program of this contractor continuously improve quality and efficiency of operations?
- Review recent Customer Review Survey for activities of this contractor. How are feedbacks relayed to the contractor? What are the follow through activities?
- How are contractor commitments tracked? Enforced?
- How are new QA and ISM requirements incorporated into existing contracts?

2. Evaluate the process for review of proposals and selection of contractors, QA and ISMS requirements flow down, customer requirements flowdown.

- What is the contractor evaluation process used?
- What is the process for determining customer requirements/specifications and how are these requirements captured and incorporated in the contract?
- How are QA and ISMS requirements flowed down to the contractor and subcontractor?
- How is the qualification of persons who evaluated the proposals determined? – compare with training and qualification records in CHRIS.
- Review Contractor Records retained. Are the records complete?
- How are new QA requirements incorporated into new contracts?

Review Area 8—Inspections and Acceptance Testing

Evaluate the process for inspections and acceptance testing of items, services, and processes.

- What is the method for specifying inspections and tests for items, services, and processes? Is it adequate?
- How are acceptance and performance criteria established and utilized? Is the graded approach applied satisfactorily?

- What is the process for inspecting, testing, and accepting software products? Is it adequate? What standards and requirements are invoked?
- Are inspections and acceptance tests planned and controlled? How?
- How are inspections and acceptance tests results documented?
- Is inspection and test equipment calibration established and maintained? How? How is traceability of calibration maintained? Is it adequate?

Review Area 9—Management Assessment

Evaluate the assigned responsibility for _____ implementation of Management Assessment (Criterion 9 DOE O 414.1C) for selected activities.

- What is the schedule of management assessments?
- How was the risk model utilized to determine assessment areas, schedule, and rigor?
- Does the management assessment program include all levels of management? If so, how?
- How are quality problems identified, documented, reported, corrected, and prevented in the future?
- How are past management assessment results implemented?
- How does the management assessment program continuously improve quality and efficiency of operations?
- How was result of the assessment incorporated in the lessons learned Program?

Review Area 10—Independent Assessment

Evaluate the assigned responsibility for _____ implementation of Independent Assessment (Criterion 10, DOE O 414.1C) for selected activities.

- What is the schedule of independent assessments for this activity?
- How was the risk model utilized to determine assessment areas, schedule, and rigor?
- Is the independent assessment program adequately defined and documented?
- By what criteria are assessors chosen for independent assessments?
- What is the process for reporting independent assessment results and required corrective actions to responsible management?
- How are past independent assessment results tracked through completion of corrective actions?
- How are past independent assessment results implemented?
- What performance parameters does the independent assessment program measure?
- How does the independent assessment program continuously improve quality and efficiency of operations?
- How was result of the assessment incorporated in the lessons learned Program?

Review Area 11—Software Quality Assurance

Evaluate the status of implementation of a software QA program.

- What safety-related software packages does the contractor use?
- What DOE SQA policies and requirements exist for these software packages? Are

- these incorporated into a formal QA program by the contractor?
- Is there anything specific in the contract with regard to DOE SQA policy and requirements?
- What are oversight processes/activities for SQA? Has there been any assessment to date either independently or as part of other QA or performance assessments?

Review Area 12—Suspect/Counterfeit Items Prevention

Review the oversight of the S/CI Prevention process implementation.

- Does the contractor have S/CI program in place?
- What is the oversight process for this activity?
- What are the findings/observations of the most recent two assessment of this program?
- What are the corrective actions initiated to address any issues? How are these tracked?

Review Area 13—Corrective Action Management Program

Evaluate the Corrective Action Management Process and current status of corrective actions in tracking systems.

- Does the Field Office incorporate CAMP into its program?
- Has the Office assigned a responsible individual to manage this?
- How are CATS and CAMP reconciled? Is there a responsible individual assigned for CATS? How are corrective actions communicated to or coordinated with HQ?
- Obtain a couple of Nonconformance Records and review.

Review Area 14—Integrated Safety Management

Review the integration of ISMS into the overall quality assurance program for selected high risk activities.

- What is the management system utilized for implementing ISMS for this activity?
- What are the roles and responsibilities for ISMS implementation? Are they clearly defined/documentated? Are they implemented?
- What is the process for feedback and continuous improvement in ISMS implementation?
- How are ISM lessons learned applied to this activity?
- Are ISMS line management responsibilities defined and implemented?
- What work controls are in place to ensure safety?
- What is the process for determining and grading the application of ISMS requirements?
- What is the commitment of upper, middle, and lower management to the ISM program and its implementation?
- How are Readiness Assessment and Operational Readiness Review results integrated with ISM and operational efficiency?
- What are the greatest concerns regarding ISM implementation?

6. ORGANIZATIONS TO BE NOTIFIED

7. APPLICABLE RECORDS, INTERVIEWS, OBSERVATIONS

The Assessment Team will require support from _____ to do an effective assessment. The Team has identified preliminary list of records, interviews, and observations of interest. It should be noted that additional ones may be identified as the assessment progresses. _____ should be prepared to provide the records and documents identified in advance and make the required individuals available for the interviews.

Record Review:

FRAM
Quality Assurance Plan
ISMS Description
Contract List A/List B requirements
Contractor QAP approval
List of current projects and activities
Management Assessment schedule
Independent Assessment schedule

For ISMS:

Oversight Assessment Plan for FY _____
FY _____ Safety Performance Objectives
Current _____ ISMS Description
Contractor ISMS Description
Contract Section I DEAR Clauses 970.5223-1 and 970.5204-2

Interviews:

AMEM (closeout)
Facility and Operations Team Leader
Quality and Safety Division Director
Quality Assurance and Process Management Team Leader
Quality Assurance Subject Matter Expert
Facility and Materials Disposition Division Acting Director
Waste Disposition Division Acting Director
Lead Facility Representative
Facility Engineers
Others as needed

Observations:

- Any Management Assessment in progress
- Any Independent Assessment in progress
- Oversight or surveillance of contractor’s S/CI program implementation
- Corrective action status or planning meeting
- Software QA activity
- Performance measure status meeting
- Effectiveness verification of any ISMS improvement action

8. SCHEDULE

Figure 1 lays out the proposed schedule for the assessment. The Assessment Team will arrive at the site on _____, _____. The briefing shown in Figure 1 below will commence as soon as the team arrives on site, which is expected to be _____.

The activities in the following _____ days will include interviews of key personnel and may include observations of activities. The Assessment Team Leader, in conjunction with _____ management will identify the individuals that need to be invited for discussions and the activities to be observed.

Figure 1: Proposed Assessment Schedule

Date:	
Time:	Travel to
Time:	<ul style="list-style-type: none">▪ Briefing▪ Review list of current high-risk activities▪ Determine schedule for closeout meeting▪ Collect documents▪ Review documents
Date:	
Time:	<ul style="list-style-type: none">▪ ISMS Integration into QA▪ Graded Approach definition, procedures, and implementation▪ Contractor Lists A and B▪ Specific Contracts and Procurement▪ Contractor Oversight<ul style="list-style-type: none">○ QAP review and approval○ S/CI Implementation○ CAMP○ Software QA○ Feedback and lessons learned
Date:	
Time:	Continue oversight elements
Time:	<ul style="list-style-type: none">▪ New Contract(s) – Review Status<ul style="list-style-type: none">○ QA Requirements flowdown○ Technical requirements flowdown○ Bidder questions

Date:	
Time:	Management Assessments Independent Assessment
	Additional Assessment Topics As Required
Time:	<ul style="list-style-type: none"> ▪ Team meeting ▪ Closeout meeting
Date:	
Time:	Travel back to DOE HQ

**APPENDIX 1-A. ASSESSMENT TEAM MEMBERS' BIOGRAPHICAL
INFORMATION**

[Include the following information in the plan for the Team Leader and all members of the Assessment Team]

_____ - **Team Leader – Name & Title:** _____

Experience:

Education:

Personal:

_____ - **Team Member – Name & Title:** _____

Experience:

Education:

Personal:

_____ - **Team Member – Name & Title:** _____

Experience:

Education:

Personal: