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July 29, 1997

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Standard Practice for Assessments

Approved by


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Hanford Analytical ServicesAuthor:
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Quality Systems

1.0 PURPOSE

The Hanford Analytical Services (HAS) laboratories expect to be the subject of audits and assessments conducted by clients, regulatory bodies receiving HAS analytical data, and internal audits conducted by the HAS Quality Systems group. HAS recognizes the role of the auditing group to determine the scope and direction of the audit. HAS has established the expectations of the conduct of the audit. These expectations are intended to:

- allow auditors complete access to the laboratory and staff
- permit work to proceed safely with the minimum interruption during the audit
- provide the laboratory with the advantages associated with a neutral, third party, evaluation of the laboratory.

2.0 SCOPE

This standard practice establishes the expectations for advance notification, level of formality, interfaces and identifies the points of contact for the assessors.

3.0 REQUIREMENTS

The HAS expectations for assessment and audits are outlined below. They are consistent with professional audit certification programs.

1. The auditing group is expected to notify via formal correspondence the HAS Manager of their intent to audit the laboratory. The notice is expected to identify the point of contact of the organization requesting the audit, reasons for the audit including the use of the audit findings, the scope and subject of the audit, criteria for the audit, the roles, identity, and professional backgrounds of the audit team, and a proposed schedule.

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2. The HAS Manager will assign an Audit Coordinator to serve as the focal point for the laboratory. Prior to arriving at the laboratory, the auditing group is expected to request and review documentation from the laboratory that cover the practices, procedures, and results that will be the subject of the audit. At a minimum, the auditing organization is expected to be familiar with the quality system requirements of the HAS Quality Assurance Requirements Document DOE/RL-96-68 which governs all analytical work conducted for the DOE at the Hanford Site.
3. The audit team is expected to conduct an entry briefing with the Audit Coordinator and, as appropriate, any others who will assist the audit. During the briefing, the auditors are expected to explain: the scope of the audit and its purpose; how the practices, procedures, and results for assessment have been chosen; how the daily debriefings and exit briefing will be conducted; how the formal findings will be documented and forwarded to the laboratory and others; the length of time allocated to the laboratory to respond to the findings; and how the auditing group will be involved in the corrective action process.

The audit team and laboratory staff are expected to resolve any questions about the appropriateness of the laboratory QA documentation to the standards that will be the basis of the audit at this time. If there are areas where disagreements still exist after discussion, these areas are to be noted in the audit report. During the course of the audit, if findings are based on the auditors' standards which are in disagreement with the laboratory QA practices, the auditors are expected to indicate in their findings if the laboratory is in compliance with its own QA policies. All aspects of these findings should then be documented against the auditors' standards.

A mutually agreed upon agenda will be finalized at this time.

4. All safety standards and requirements of the laboratory will be observed by the auditors including safety training, if necessary. At all times, members of the audit team will immediately notify the Audit Coordinator if any conditions contrary to worker health and safety are observed. This should be done with discretion unless an emergency situation exists.
5. During the assessment activities, the auditors are expected to develop documentation supporting all practices, procedures, and results that were examined. If deficiencies are found against applicable standards, the standards need to be cited (give specifics) and the facts describing the deficiency captured in sufficient detail that a third party reviewer could understand the exact basis of the deficiency and the laboratory can proceed with appropriate corrective actions.
6. At the end of each day, sufficient time is expected to be set aside to conduct a verbal debriefing on the day's findings. The practices, procedures, and results that were examined during the day should be listed. Specifics of any deficiencies are expected to be provided. During the debriefing or at any time prior to the conclusion of the exit briefing, the laboratory may engage the auditors in discussion of the findings and may present information verbally or in writing for the auditor's consideration prior to the preparation of final audit findings.

Standard Practice for Assessments

7. Auditors are encouraged to offer opinions to laboratory management personnel during the course of the audit pertaining to enhancements of operations, safety of workers, and where improvements could be made.
8. Conduct an exit briefing. At a minimum, the details of all deficiencies (citation of standard not met, details of non-compliance) are expected to be provided in writing to the Audit Coordinator and other designated laboratory representatives no later than the beginning of the meeting. If any changes in the findings are made based on the exit briefing, make and initial the changes on the lead auditor and Audit Coordinator copies. Inform the laboratory of how and when the formal audit report will be prepared and circulated prior to formal release and outline the expectations and the role of the auditing group in the corrective action process.
9. The organization requesting the audit and/or the audit team is expected to respond in a timely fashion to laboratory follow up activities as appropriate.

4.0 RESPONSIBILITIES**4.1 HAS Manager**

Negotiate time frame, scope, subject, and closure of the audit. Suspend audit due to safety concerns, operational hazards, inappropriate behavior of the assessment team. Provide resources to support audit and response.

4.2 Assessment/Audit Team

The responsibilities of the assessment team are as follows:

1. Document assessment preparation activities.
2. Prepare an Assessment Plan describing the objectives. The Assessment Plan must identify the following:
 - a. Area of the laboratory to be assessed (refer to scope, Section 2.0, areas to be assessed)
 - b. Laboratory Assessment/Audit number that will be tracked by HATS
 - c. Assessment team members
 - d. Assessment scope and objectives
 - e. Source/reference documents
 - f. Listing of assessment documentation requirements or tools, that is, assessment checklist, outlines, line of questioning, details process flowchart, and so forth.

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- g. Forward a copy of the assessment plan to the lead assessor for review
3. Perform the assessment field work
4. Record observations, and gather information and evidence through interviews, witnessing the activity, or document reviews
5. Inform the Lead Assessor of the progress of the assessment, particularly upon discovery of conditions which may result in an observation or finding
6. Prepare the draft Assessment/Audit Report
7. Review assessment report and provide concurrence.

4.3 Audit Coordinator

- Ensure time frame can be supported by Operations, Quality Systems, and subject support groups.
- Assign escorts and primary points of contact.
- Arrange for work space and requested resources for the audit team.
- Facilitate the entrance, daily and exit briefings.
- List all materials provided to or requested from the audit team.
- Prepare summary of events.
- Acquire or assign an assessment number from the Hanford Action Tracking System (HATS). The format shall be LMA-YR-### (for example, LMA-95-001).
- Ensure entry into the HATS database for tracking and closure of corrective action. The corrective action process will follow WHC-CM-1-4, *Corrective Action Management Manual*.

4.4 Lead Assessor

The Lead Assessor shall report to the Laboratory Manager on all phases of the management assessment. Other responsibilities of the Lead Assessor are as follows.

1. Coordinate the planning of the assessment/audit.
2. Coordinate the preparation of the assessment/audit plan.

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3. Conduct pre-assessment/audit conference. Document attendees and date of meeting.
4. Meet with the assessment/audit team, as required, to:
 - a. Review assessment/audit progress
 - b. Resolve questions and identify concerns
 - c. Establish observations/findings based on activities witnessed and evidence gathered.
5. Conduct the post-assessment/audit conference. Include the Laboratory Manager, the Operations Manager of the Laboratory, and the Laboratory QA Officer. Document attendees and date of meeting.
6. Prepare the Assessment/Audit Report.
7. Sign the Assessment/Audit Report and transmit to the Manager, Hanford Analytical Services, with copies to the appropriate Laboratory Managers and Laboratory QA Officer.

NOTE: Follow-up of laboratory corrective action commitments ensures that the laboratory has completed and implemented the corrective actions identified in the response to the assessment observation and WHC-CM-5-4, Section 8.8. Follow-up and closure of corrective actions includes review and verification of submitted documents. Additional follow-up actions may include on-site laboratory inspections if warranted.

4.5 Laboratory Personnel

Interface professionally with audit personnel, truthfully answer questions, respond to areas of responsibility, and support assessment team.

5.0 RECORDS

Any records generated as a result of activities described in this section will be managed in accordance with applicable Records Inventory and Disposition Schedules.

6.0 DESIGNATED REVIEWERS

Designated Reviewing Organizations

POC

Hanford Analytical Services (Champion)

J. E. Hyatt

Operations Support

T. F. Dale

Quality Systems

S. L. Huggins

7.0 REFERENCES

DOE/RL-96-68, *Hanford Analytical Services Quality Assurance Requirements Document*,

WHC-CM-1-4, *Corrective Action Management Manual*.

WHC-CM-5-4, *Laboratories Administration*, Section 8.8, "Corrective Action Management."