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## 1.0 PURPOSE:

This procedure establishes the methodology used for independent assessments (IA) that are performed by Jefferson Lab. Independent assessments identify improvement opportunities and provide management and staff with an independent overview of laboratory performance. Corrective actions in response to issues, or opportunities to share lessons learned are identified by assessments. Any identified actions, whether an issue or observation, are tracked to completion/closure and evaluated for effectiveness as detailed in the Jefferson Lab Issues Management Procedure.

The JSA/DOE Contract incorporates various DOE directives which require an effective assessment program. These include DOE O 414.1C, *Quality Assurance* and DOE O 226.1, *Implementation of DOE Oversight Policy*. In addition, both Jefferson Lab's *ISMS Program Description* and *Quality Assurance Plan* require an effective assessment program. This procedure addresses these requirements in part by defining a process for conducting the independent assessment component of the assessment program.

## 2.0 SCOPE:

This procedure applies to all independent assessments planned or carried out at Jefferson Lab by staff or sub contractors. It applies to IAs that include, as assessment team members, DOE or other non-lab staff if Jefferson Lab staff plan the assessment.

It may be used for IAs planned and carried out independent of Jefferson Lab staff by DOE or other external entities, but is not required in those cases. In particular, this procedure is not required for audits conducted by the JSA Internal Audit office.

When audits and surveillances are conducted, rather than assessments, the extent of the documentation and of the reviews should be modified appropriately. Appropriate alternate format reports, pre-approved by Quality Assurance/Continuous Improvement (QA/CI) Department are acceptable (example: lockout/tagout assessment report).

## 3.0 RESPONSIBILITIES:

**NOTE:** Management responsibility may be delegated at the discretion of the responsible manager.

### 3.1 Laboratory Director:

3.1.1 Approves all completed IAs.

3.1.2 Forwards the approved IA Report to the QA/CI Manager.

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- 3.2 Chief Operating Officer or Chief Scientist:**
  - 3.2.1 Reviews IA report.
  - 3.2.2 Forwards the accepted IA report to the Laboratory Director for approval.
  - 3.2.3 Presents/discusses identified concerns with the QA/CI Manager.
  
- 3.3 Associate Director, ESH&Q**
  - 3.3.1 Reviews IA report.
  - 3.3.2 Forwards the accepted IA report to the Chief Operating Officer and/or the Chief Scientist for approval as appropriate.
  - 3.3.3 Presents/discusses identified concerns with the QA/CI Manager.
  
- 3.4 Quality Assurance /Continuous Improvement (QA/CI) Manager**
  - 3.4.1 Coordinates with the appropriate Division/Department Head prior to an organization's scheduled IA.
  - 3.4.2 Assigns appropriate staff and/or engages subcontractors (and/or other interested parties, such as the DOE Site Office) to plan and conduct an IA.
  - 3.4.3 Reviews all IA reports for quality, comprehensiveness, and credibility; and provides appropriate endorsement.
  - 3.4.4 Presents/discusses identified concerns with the Lead Assessor.
  - 3.4.5 Reports IA results to involved parties.
  - 3.4.6 Reports trend analyses of IA results as required.
  - 3.4.7 Forwards the endorsed IA report to the AD, ESH&Q.
  - 3.4.8 Provides the final, director approved, IA Report to QA/CI Lead Assessment Specialist.
  
- 3.5 Lead Assessors** assigned by QA/CI Manager to conduct an IA:
  - 3.5.1 Maintains qualifications required to perform assessments at Jefferson Lab.
  - 3.5.2 Selects appropriate staff members to comprise the IA Team.
  - 3.5.3 Assures all members of the IA team are qualified. (Qualification is obtained by completing the on-line "Assessment Qualification Training Course" (see Section 6 - References for URL).)
  - 3.5.4 Completes the IA in accordance with this procedure.
  - 3.5.5 Prepares and distributes a draft final report to the assessed organization(s). (Allows five business days for comment or request for review.)
  - 3.5.6 Develops and includes a Corrective Action Plan (CAP) for all observations and findings within the IA Report. (Refer to the Issues Management Procedure for guidance in development of corrective actions, if required.)

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**3.5.7** Forwards completed report to QA/CI Manager.

**3.6 Assessed Organization(s) Management and Staff:**

**3.6.1** Cooperates with Lead Assessor during the IA.

**3.6.2** Conducts a factual and technical accuracy review of the draft final report.

**3.6.3** Provides comments to Lead Assessor within five business days. If no communication is provided the IA report is considered acceptable as written.

**3.7 QA/CI Lead Assessment Specialist**

**3.7.1** Maintains a log of scheduled IAs and assigns a unique number to each when an IA is initiated.

**3.7.2** Maintains completed IA reports electronically.

**3.7.3** Facilitates CAP meetings with affected personnel and subject matter experts (SMEs).

**3.7.4** Cross references CAP with Automated Quality Information System/Corrective Action Tracking System (AQIS/CATS or CATS) action links.

**3.7.5** Verifies all corrective actions are entered into the CATS.

**3.7.6** Reports verification to the Manager, QA/CI.

**3.7.7** Provides a copy of the final, director approved, IA report to the Lead Assessor.

**3.7.8** Coordinates feedback, as appropriate, to the organization(s) assessed. (The assessment report is one form of feedback, but one-on-ones, department meetings, etc. may also be used to communicate IA results.

**4.0 PROCESS STEPS & EXPECTATIONS**

**4.1** Upon receipt of a request for an independent assessment or according to the Integrated Assessment Schedule, the QA/CI Manager will assign a Lead Assessor to conduct the assessment. Requests can be generated from Laboratory personnel or external oversight organizations. Resource constraints may limit the number of independent assessments that can be completed. A decision not to honor a request for an independent assessment must be made by the QA/CI Manager.

**4.2** IAs are planned using Attachment B - IA Plan as a guide.

**4.2.1** When available, Criteria and Review Approach Documents (CRADs) form the basis of the IA plan. CRADs define objectives,

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performance criteria and lines of inquiry appropriate to the process being assessed.

- 4.2.2 When CRADs are not available before planning begins, development of CRADS is part of the planning process.
  - 4.2.3 The completed plan for a scheduled IA is submitted for QA/CI review at least 30 days before the scheduled start of the MSA.
  - 4.2.4 The plan is submitted and maintained with the completed assessment. QA/CI will maintain a log of IAs and assign a unique number to each. This number should be obtained when the planning phase is initiated.
- 4.3 Jefferson Lab personnel or Jefferson Lab contractors performing assessments must be qualified as detailed in the "Auditor/Assessor Qualification Procedure". Records of qualification are maintained in the "ASPEN" system.
  - 4.4 IAs are performed in accordance with this procedure. Typically a team will perform the IA, but a single person is allowed.
  - 4.5 Results of the IA, including findings, observations and noteworthy practices, are formatted in accordance with Attachment C - IA Report.
  - 4.6 Findings and observations are documented using Attachment D - IA Corrective Action Form or similar and included with the final report.
  - 4.7 Upon completion of the assessment, the assessor will prepare and distribute to the assessed organizations a draft final report.
  - 4.8 The assessed organization(s) will be given five (5) business days to conduct a factual and technical accuracy review of the draft report. If comments are not received by close of business on the 5<sup>th</sup> day, the report is considered acceptable as written.
  - 4.9 After the organizational factual review of the assessment report is complete, the assessor will submit the report to the QA/CI Manager for final management review and director approval.
  - 4.10 Corrective actions for each finding and observation will be documented using the CAP template available from QA/CI.
  - 4.11 Items requiring corrective action will be documented on Attachment D, *IA Corrective Action Form* or other appropriate form. The form will be used

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to develop an Assessment CAP. All CAP items shall be entered into CATS. The CAP shall be maintained with the final assessment report.

**4.12** Final approved Independent Assessment Reports and associated documentation will be maintained by the QA/CI Department.

**4.13** Issues identified in IAs should be a focus of management observations, walk-a-rounds, surveillances, etc. just as the results suggest topics for future IAs.

## 5.0 DEFINITIONS AND ABBREVIATION/ACRONYMS

**Audit** – an evaluation of a system, organization, process, project or process to ascertain the validity and reliability of information about the thing being audited.

**CATS** – The Jefferson Lab Corrective Action Tracking System is used to document, track, and trend; findings, observations, and proposed corrective actions to completion.

**Compensatory Measures** – short-term measures that are implemented when findings have high risk and when the long term corrective action will take an immoderate amount of time to put in place. An example of a compensatory measure is putting a fire watch in place in a building that does not have an approved sprinkler system.

**Corrective Actions** – actions taken to correct the deficiencies identified in the report of findings and observations.

**CRAD** – Criteria and Review Approach Document which is a detailed compilation of documentation titles, positions/titles of interviewees, locations and work functions to observe and questions to ask to perform the assessment.

**Factual Accuracy Review** – an opportunity for the organization that was assessed to review the draft report to determine if assessment findings, observations and discussion in the report are accurate as recorded.

**Findings** – detected non-compliances with mandatory requirements.

**IA** – Independent Assessment.

**Managers** – personnel responsible for a process, a program, or an organization.

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**Noteworthy Practices** – positive aspects of a program that could be used as a model for other similar programs across the Lab

**Observations/Opportunities for Improvement** – deviations from best management practices or minor deviation from procedural requirements that are isolated and considered to be a "quick fix."

**Surveillance** – the process of monitoring systems or processes for conformity to expected or desired performance.

**Validation**— the QA activity of reviewing and assessing the effectiveness of completed corrective and preventive actions.

**Verification**— the QA activity of reviewing actions reported complete to ensure they were adequately completed.

## 6.0 REFERENCES

- [Jefferson Lab Quality Assurance Plan](#)
- [Jefferson Lab Issues Management Procedure](#)
- ISO 9001:2000
- DOE O 226.1
- DOE O 414.1C
- [Jefferson Lab Assessment Qualification Training Course \(QAC-001\)](#)

## 7.0 ATTACHMENTS

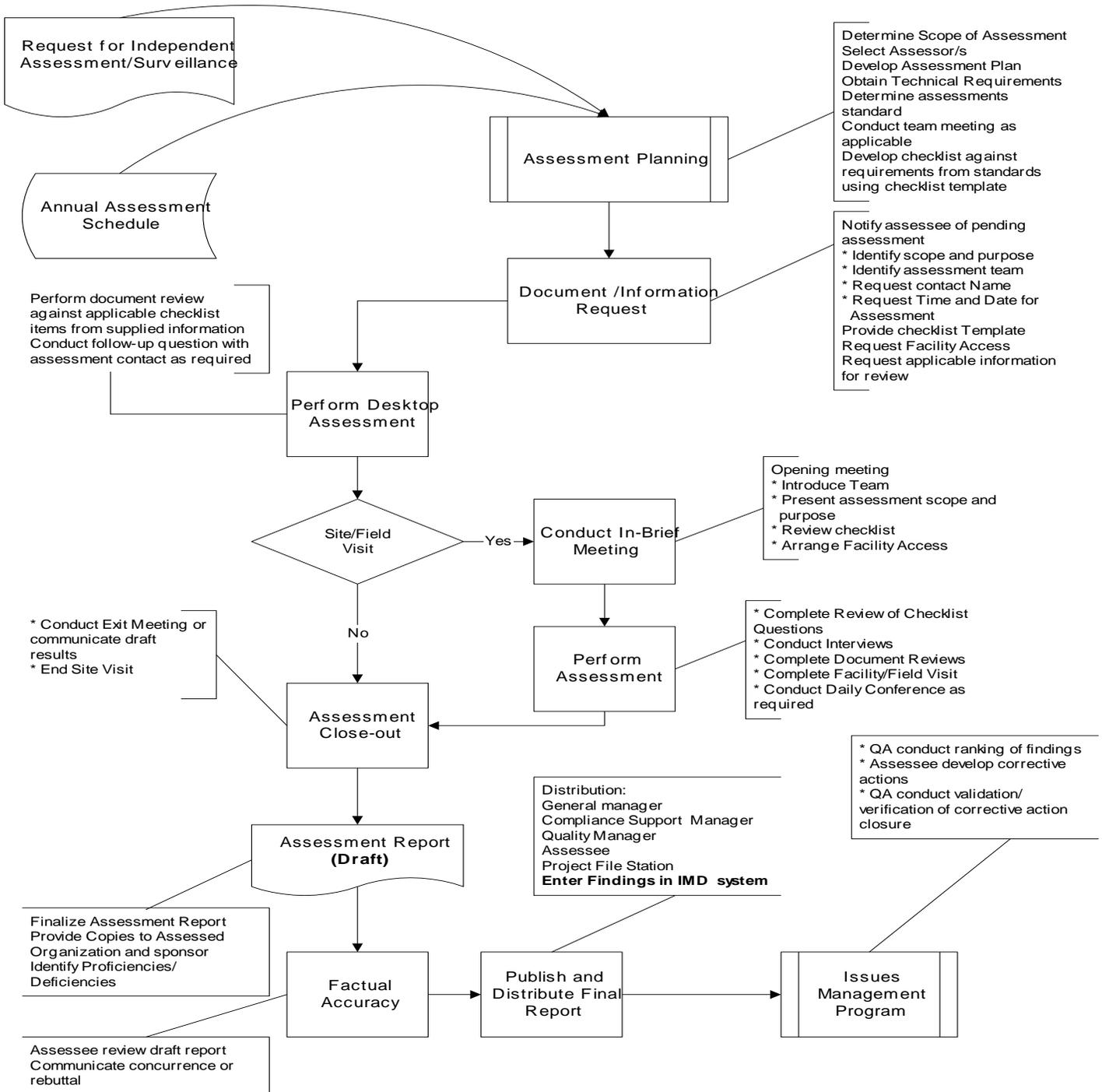
- Attachment A** – Flowchart of Independent Assessment Process
- Attachment B** – Independent Assessment Plan (Template)
- Attachment C** – Independent Assessment Report (Template)
- Attachment D** – Independent Corrective Action Form

## 8.0 REVISION SUMMARY

REVISION	DESCRIPTION	EFFECTIVE DATE

 <b>Jefferson Lab</b> Thomas Jefferson National Accelerator Facility		TITLE: <b>INDEPENDENT ASSESSMENT PROCEDURE</b>			
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**ATTACHMENT A  
FLOWCHART OF INDEPENDENT ASSESSMENT PROCESS**



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 <small>Thomas Jefferson National Accelerator Facility</small>	TITLE:	<b>INDEPENDENT ASSESSMENT PLAN</b> ATTACHMENT B to IA Procedure	
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ASSESSMENT TITLE		DATE	

<p><b>I. Purpose &amp; Scope:</b></p> <p>Should include a brief, concise statement defining the areas, procedures, processes, etc. that will be assessed. Note any special requirements or limitations. State the planned start and finish date for the assessment.</p>
<p><b>II. Definitions:</b></p> <p>In most assessments it is convenient to categorize results into findings, observations, and noteworthy practices. Whatever categories you plan to use should be defined here, e.g., <u>Finding</u> - non-compliance with a <i>requirement</i>.  <u>Observation/Opportunity for Improvement</u> - deviation from best management practices minor deviation from procedural requirements that are isolated and considered to be a "quick fix."   <u>Noteworthy Practice</u> - Positive aspects of a program that could be used as a model for other similar programs across the Lab.</p>
<p><b>III. Requirements</b></p> <p>Describe the requirements against which the assessment will be made. These could include DOE orders, EH&amp;S Manual chapters, Work Smart Standards, work control documents (SOPs, TOSPs) division or department goals, DOE/SURA contract metrics, etc.</p>
<p><b>IV. Team Members</b></p> <p>A list of the personnel doing the assessment. The lead assessor should be indicated.</p>
<p><b>V. Specific Areas Being Assessed</b></p> <p>This section should include a list of the people to be interviewed, documents to be reviewed, work evolutions to be observed, etc.</p>
<p><b>VI. Final Report</b></p> <p>State who is responsible for writing the assessment report, who will review it and the date it will be forwarded to the cognizant AD.</p>

Prepared by \_\_\_\_\_ Date \_\_\_\_\_

Lead Assessor

Copy to:

 <small>Thomas Jefferson National Accelerator Facility</small>	<b>TITLE:</b>	<b>INDEPENDENT ASSESSMENT REPORT</b>	
		ATTACHMENT C to IA Procedure	
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<p><b>Purpose &amp; Scope:</b></p> <p>Insert the scope and purpose developed during planning. Should include a brief, concise statement defining the area, procedure, work plan, boundaries and any special requirements or limitations. Include the assessment duration and team. If the purpose or scope changed from that stated in the plan, note the differences.</p>
<p><b>Summary of Assessment:</b></p> <p>Provide a narrative summary of areas assessed. Description is to include adequate details to enable an independent reviewer to comprehend the depth and breadth of the assessment. Details to include key elements of the assessed activity or process and the status of their acceptability. When applicable, define the status of implementation of actions related to previous issues relevant to the assessed area.</p>
<p><b>Results:</b></p> <p>Define the issues (findings, observations, noteworthy practices) identified during the assessment. All findings require corrective action to eliminate the non-conformance. Cognizant management will decide whether or not to pursue corrective actions for observations. Issues with corrective actions should be documented on a Corrective Action Form (Attachment D) and entered into CATS; the CATS identification number should be included in the report. Identify the status of each issue (open, pending or closed), issue owner, and estimated completion of required corrective and/or preventive actions. Clearly state all required follow-up actions with due dates and owners.</p>
<p><b>Effectiveness Evaluation:</b></p> <p>State the team's conclusion on effectiveness of the area or activity assessed. When applicable, discuss the implementation of previous corrective or preventive actions in the assessment effectiveness statement.</p>

<p><b>Performed by:</b> _____ <b>Date:</b> _____</p> <p style="margin-left: 40px;">Lead Assessor</p>
<p><b>Reviewed by:</b> _____ <b>Date:</b> _____</p> <p style="margin-left: 40px;">Manager, QA/CI</p>
<p><b>Reviewed by:</b> _____ <b>Date:</b> _____</p> <p style="margin-left: 40px;">Associate Director, ESH&amp;Q</p>

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Approved by: _____ Chief Operating Officer or Chief Scientist	Date: _____
Approved by: _____ Director Jefferson Laboratory	Date: _____

 <b>Jefferson Lab</b> <small>Thomas Jefferson National Accelerator Facility</small>	<b>TITLE:</b>	<b>INDEPENDENT ASSESSMENT CORRECTIVE ACTION FORM</b> ATTACHMENT D to IA Procedure	
	<b>ASSESSMENT #</b> <small>(obtained from QA/CI)</small>		Page 1
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<b>Requirement:</b>
<b>Finding or Observation:</b>
<b>Recommended Corrective Action:</b>

\_\_\_\_\_

**Responsible Person**

\_\_\_\_\_

**Expected Completion Date**

**CATS Issue Number:** \_\_\_\_\_

