

**QUALITY PLAN IMPLEMENTING MATRIX  
 CRITERION 10, “INDEPENDENTASSESSMENT”**

Item No.	Requirement	Source Document*	Implementation Location
<b>General Requirements</b>			
1.	Plan and conduct independent assessments to measure item and service quality, to measure the adequacy of work performance and to promote improvement.	10CFR830.122(j)(1) AND DOE O 414.1C(4)(b)(10)(a)	ISD 328-1.0, <i>Independent Assessments</i> , Section 4.1.3, Planning an Individual Independent Assessment, and Section 4.1.4, Performing an Independent Assessment, address this requirement.
2.	Establish sufficient authority and freedom from line management for independent assessment teams. AND Internal independent assessments will be performed by contractor organizations or personnel that have authority and independence from line management, to support unbiased evaluations.	10CFR830.122(j)(2) AND DOE O 414.1C(4)(b)(10)(b)	ISD 328-1.0, <i>Independent Assessments</i> , Section 1.4, Summary, and Section 4.1, Independent Assessment, describe the independence.
3.	Ensure that persons conducting independent assessments are technically qualified and knowledgeable in the areas to be assessed. AND Independent assessments are performed by technically qualified and knowledgeable personnel with sufficient authority and freedom from the organization being assessed.	10CFR830.122(j)(3) AND DOE O 414.1C(4)(b)(10)(c) AND IP 330.0, LANL Quality Assurance Program, Subsection 10.1, Summary	ISD 328-1.0, <i>Independent Assessment</i> , Section 4.1, Independent Assessment, describes the technical qualifications as “experience and expertise of SMEs”.
4.	Audits shall be performed to verify that performance criteria are met and to determine the effectiveness of the program.	ASME NQA-1-2000, Requirement 18, 100, Basic	ISD 330-3.2, <i>Quality Audits</i> , Section 4.4.1, Quality Audit Report, requires “a statement on the effectiveness of the elements audited.”

\*Black Type = Mandatory QA requirements from Contract DE-AC52-06NA25396: LANL/NMED Order on Consent; DOE Order 414.1C; 10 CFR 830, Subpart A; ASME NQA-1-2000; and LANL QA Program IP 330.0.

\*\*Requirement is not currently in the location specified; however, it will be included within the next revision of the document.

Item No.	Requirement	Source Document*	Implementation Location
5.	These audits shall be performed in accordance with written procedures or checklists by personnel who do not have direct responsibility for performing the activities being audited.	ASME NQA-1-2000, Requirement 18, 100, Basic	ISD 330-3.2, <i>Quality Audits</i> , Section 4.3, Audit Team Members, addresses development of an audit checklist, and Attachment 3 is an example of a quality audit plan checklist.
6.	Audit results shall be documented and reported to and reviewed by responsible management.	ASME NQA-1-2000, Requirement 18, 100, Basic	ISD 330-3.2, <i>Quality Audits</i> , Section 4.4.1, Quality Audit Report, Lead Auditor and Audited Organization Management responsibilities address this requirement.
7.	Follow-up action shall be taken where indicated.	ASME NQA-1-2000, Requirement 18, 100, Basic	ISD 322-4.2, <i>Issues and Corrective Action Management System</i> , Section 5.4, addresses this requirement.
<b>Scheduling of Independent Assessments (Audits)</b>			
8.	Audits shall be scheduled in a manner to provide coverage and coordination with ongoing activities, based on the status and importance of the activity.	ASME NQA-1-2000, Requirement 18, 200, Scheduling	**ISD 330-3.3, <i>Quality Audits</i> , addresses this requirement.
9.	Scheduled audits shall be supplemented by additional audits of specific subjects when necessary to provide adequate coverage.	ASME NQA-1-2000, Requirement 18, 200, Scheduling	**ISD 330-3.3, <i>Quality Audits</i> , addresses this requirement.
<b>Planning of Independent Assessments (Audits)</b>			
10.	The auditing organization shall develop and audit plan for each audit.	ASME NQA-1-2000, Requirement 18, 301, Audit Plan	ISD 330-3.2, <i>Quality Audits</i> , Section 4.2.2, Quality Audit Plan Preparation, addresses this requirement.
11.	This plan shall identify the audit scope, requirements, audit personnel, activities to be audited, organizations to be notified, applicable documents, schedule, and written procedures or checklists.	ASME NQA-1-2000, Requirement 18, 301, Audit Plan	ISD 330-3.2, <i>Quality Audits</i> , Attachment 1, "Example of Quality Audit Plan," and Attachment 2, "Example of Quality Audit Plan Transmittal," address this requirement.

\*Black Type = Mandatory QA requirements from Contract DE-AC52-06NA25396: LANL/NMED Order on Consent; DOE Order 414.1C; 10 CFR 830, Subpart A; ASME NQA-1-2000; and LANL QA Program IP 330.0.

\*\*Requirement is not currently in the location specified; however, it will be included within the next revision of the document.

Item No.	Requirement	Source Document*	Implementation Location
<b>Selection of Independent Assessment (Audit) Team</b>			
12.	Audit personnel shall have sufficient authority and organizational freedom to make the audit process meaningful and effective.	ASME NQA-1-2000, Requirement 18, 302, Personnel	ISD 330-3.2, <i>Quality Audits</i> , Section 4.2.1[3], Quality Audit Team Member Selection, Step [B] addresses this requirement.
13.	An audit team shall be identified prior to the beginning of each audit. [NOTE: This team shall contain one or more Auditors, one being designated Lead Auditor who organizes and directs the audit.]	ASME NQA-1-2000, Requirement 18, 303, Selection of Audit Team	ISD 330-3.2, <i>Quality Audits</i> , Section 4.2.1, Quality Audit Team Member Selection, Note, addresses this requirement.
<b>Performance of Independent Assessments (Audits)</b>			
14.	Elements for audit shall be evaluated against specified requirements.	ASME NQA-1-2000, Requirement 18, 400, Performance	ISD 330-3.2, <i>Quality Audits</i> , Section 4.3[2], Quality Audit Conduct, Step [B], addresses this requirement.
15.	Objective evidence shall be examined to the depth necessary to determine if these elements are being implemented effectively.	ASME NQA-1-2000, Requirement 18, 400, Performance	ISD 330-3.2, <i>Quality Audits</i> , Section 4.3[2], Quality Audit Conduct, Step [B], addresses this requirement.
16.	Conditions requiring prompt corrective action shall be reported immediately to management of the audited organization.	ASME NQA-1-2000, Requirement 18, 400, Performance	ISD 330-3.2, <i>Quality Audits</i> , Section 4.3[2], Quality Audit Conduct, Note between Steps [C] and [D] addresses this requirement.
<b>Independent Assessment (Audit) Reporting</b>			
17.	The audit report shall be signed or otherwise endorsed by the Lead Auditor and issued to the audited organization.	ASME NQA-1-2000, Requirement 18, 500, Reporting	ISD 330-3.2, <i>Quality Audits</i> , Section 4.4.1, Quality Audit Report, Steps [3] and [5] address this requirement.
18.	The contents of the report shall: <ul style="list-style-type: none"> <li>• describe the audit scope;</li> <li>• identify Auditors and persons contacted;</li> <li>• summarize audit results, including a statement of the effectiveness of the elements audited; and</li> <li>• describe each reported adverse audit finding.</li> </ul>	ASME NQA-1-2000, Requirement 18, 500, Reporting	ISD 330-3.2, <i>Quality Audits</i> , Section 4.4.1, Quality Audit Report, and Attachment 4, Executive Summary of Quality Audit Results, address this requirement.

\*Black Type = Mandatory QA requirements from Contract DE-AC52-06NA25396: LANL/NMED Order on Consent; DOE Order 414.1C; 10 CFR 830, Subpart A; ASME NQA-1-2000; and LANL QA Program IP 330.0.

\*\*Requirement is not currently in the location specified; however, it will be included within the next revision of the document.

Item No.	Requirement	Source Document*	Implementation Location
<b>Independent Assessment (Audit) Response and Follow-up</b>			
19.	Management of the audited organization or activity shall investigate adverse audit findings, schedule corrective action, including measures to prevent recurrence of significant conditions adverse to quality, and notify the appropriate organization in writing of action taken or planned.	ASME NQA-1-2000, Requirement 18, 600, Response	ISD 322-4.2, <i>Issues and Corrective Action Management System</i> , Sections 5.4 and 5.7, addresses this requirement.
20.	Audit responses shall be evaluated by or for the auditing organization.	ASME NQA-1-2000, Requirement 18, 600, Response	ISD 330-3.2, <i>Quality Audits</i> , Section 4.4.1, Quality Audit Report, states the Lead Auditor or QA-IA Group Leader evaluates audit responses for concurrence.
21.	Follow-up action shall be taken to verify that corrective action is accomplished as scheduled.	ASME NQA-1-2000, Requirement 18, 700, Follow-up	ISD 322-4.2, <i>Issues and Corrective Action Management System</i> , Sections 5.4 and 5.7, addresses this requirement.
<b>Independent Assessment (Audit) Records</b>			
22.	Audit records shall include audit plans, audit reports, written replies, and the record of completion of corrective action.	ASME NQA-1-2000, Requirement 18, 800, Records	ISD 322-4.2, <i>Issues and Corrective Action Management System</i> , Sections 5.4 and 5.7, addresses this requirement.

\*Black Type = Mandatory QA requirements from Contract DE-AC52-06NA25396: LANL/NMED Order on Consent; DOE Order 414.1C; 10 CFR 830, Subpart A; ASME NQA-1-2000; and LANL QA Program IP 330.0.

\*\*Requirement is not currently in the location specified; however, it will be included within the next revision of the document.