



Lead also ensures that planned and periodic independent assessments are conducted to measure item and service quality, process implementation, effectiveness, and to promote improvement.

An Audit Team Leader (ATL) is a lead auditor who has been assigned to lead an audit team. The ATL is responsible for ensuring that the audit activity meets the requirements of Section 2.2.2 of this procedure.

Lead auditors and auditors shall have sufficient authority and organizational freedom from activities being assessed to carry out their responsibilities. These personnel shall be technically qualified and knowledgeable of the items and activities assessed. The type and frequencies of independent assessments shall be based on relevant control levels assigned to the items or activities under the organization's responsibility.

Source verifications may be required based on the relative importance, complexity, and quantity of items or services being procured to support a work activity. The purchaser may accept an item or service by monitoring, auditing, surveilling, witnessing, or observing activities performed by the supplier. Source verifications shall be accomplished as early as possible prior to the start of those activities.

### **2.1.3 Qualifications**

#### **2.1.3.1 Auditor Qualification**

Auditors shall be technically qualified in their assigned roles (areas of audit responsibility), and shall have appropriate training or orientation to develop their competence for performing audits. Competence of personnel performing various audit functions shall be developed by one or more of the following methods:

- A. Orientation to provide a working knowledge and understanding of the requirements of the SNL WIPP QA Program and implementing procedures used to perform audits and report audit results.
- B. Training programs that provide general and specialized training in audit performance. General training includes auditing fundamentals, objectives, characteristics, organization, performance and results. Specialized training includes methods of examining, methods of interviewing and questioning, evaluation of audit items, document specific audit results, and methods of evaluating effective corrective action and closing out conditions adverse to quality and CDAs.
- C. On-the-Job training, instruction, guidance, and counseling under the direct supervision of a lead auditor. Such training shall include planning, performing, reporting, and follow-up actions.

Auditor qualifications shall be documented on the Auditor Qualifications Form, Form NP 18-1-1 (Appendix A).

#### **2.1.3.2 Technical Specialist Qualification**

When the scope of the audit includes auditing technical processes, a technical specialist may be included on the audit team to determine the adequacy of the technical processes. Technical specialists selected for audit assignments shall be indoctrinated and trained as auditors in accordance with Section 2.1.3.1 of this procedure, and shall have a level of experience commensurate with the scope, complexity, or special nature of the work being audited.

### 2.1.3.3 Lead Auditor Qualification

Lead auditors shall have project management skills necessary to organize and direct audits, report audit results, and evaluate planned and implemented corrective actions. Lead auditors shall be certified as meeting education and experience requirements, communication skills, training, audit participation, and successful completion of a lead auditor examination as provided in this section. The basis for certification of a lead auditor shall be documented on a Record of Lead Auditor Qualifications Form, Form NP 18-1-2 (Appendix B). The Lead Auditor shall have verifiable evidence that a minimum of 10 credits have been accumulated.

#### Education

Prospective lead auditors shall provide objective evidence of formal academic training documented in the Education Section of Form NP 18-1-2 (Appendix B).

#### Experience

The SNL QA Team Lead shall document accumulated points for education and experience. Lead auditors shall have participated in a minimum of five QA audits or equivalent verifications (such as management assessments, pre-award surveys, or comprehensive surveillances, as long as the parameters of the audit process are met) within three years prior to certification. One of these audits shall have been a nuclear QA audit within the year prior to certification.

#### Training

Lead auditor candidates shall be trained to the extent necessary to ensure their competence in audit skills as established by the organization responsible for performing audits. Training in the following areas shall be completed and verified based upon management evaluation of the particular needs of each prospective lead auditor:

- Knowledge and understanding of the SNL WIPP QA Program and other program-related procedures, codes, standards, regulations, DOE orders, and regulatory guides.
- General structure of QA plans and implementation procedures.
- Auditing techniques of examining, questioning, evaluating, and reporting.
- Methods of identifying, following up, and closing corrective action items.
- Audit planning in functional areas of nuclear QA.
- On-the-job training to include applicable elements of the audit program.

#### Lead Auditor Examination

A lead auditor shall pass an examination that evaluates comprehension of the audit knowledge described in this section, and the ability to apply this knowledge. The examination shall be oral, written, practical, or any combination.

The development and administration of a lead auditor examination is the responsibility of the SNL WIPP Assessment Task Lead. The SNL QA Team Lead shall administer and proctor a lead auditor examination (or delegate this activity to an independent certifying agency). The integrity of the examination shall be maintained through confidentiality of files, and where applicable, proctoring of examinations. Objective evidence shall be developed and maintained regarding the type and content of the examination.

## Communication Skills

The candidate's manager (or the SNL QA Team Lead) shall evaluate the ability of the lead auditor candidate to communicate effectively, both orally, and in writing. This evaluation shall be documented on Form NP 18-1-2 (Appendix B).

### 2.1.3.4 Lead Auditor Certification

Lead auditors shall be certified by the auditing organization responsible for the auditing program through completion of Form NP 18-1-2. The basics of certification (such as education, experience, professional competence, rights of management, communication skill, and training) will be documented (Appendix B).

### 2.1.3.5 Maintenance of Lead Auditor Proficiency

An annual evaluation of lead auditor qualifications shall be performed by the SNL WIPP Assessment Task Lead to determine if their proficiency has been maintained through one or a combination of the following:

- Regular and active participation in the audit process.
- Review and study of codes, standards, implementing procedures, instructions, and other documents related to QA program auditing.
- Participation in QA training programs.
- Based on this evaluation, the SNL WIPP Assessment Task Lead shall extend the qualification, require retraining, or require requalification. Lead auditor annual evaluations shall be documented on the Maintenance of Lead Auditor Form, Form NP 18-1-3 (Appendix C).

Lead auditors who fail to maintain their proficiency for a two-year period (two years from the date of their last documented evaluation) or longer, shall require retraining and requalification to the requirements of section 2.1.3.3 of this procedure. Participation as an auditor in only one nuclear audit is required.

## **2.2 Audits**

A program of audit activities shall be planned, performed, documented, and reported to appropriate management. The Audit Team Leader shall be responsible for all activities of the audit process. The Audit Team Lead shall be a Certified Lead Auditor. Audit teams shall consist of personnel who have qualified as lead auditors or auditors under the assessment program.

### **2.2.1 Scheduling**

Audits shall be scheduled as early in the life of the work activity as practicable, and in a manner which will provide coverage and coordination with ongoing quality assurance program activities. An internal audit of the overall SNL WIPP QA program shall be conducted annually. Regularly scheduled audits shall be supplemented with additional audits or surveillances, when deemed appropriate by the SNL WIPP Assessment Task Lead to assess the quality of selected work products and work processes.

## 2.2.2 Performance

The SNL WIPP Assessment Task Lead is responsible for coordinating lead auditor resources and assigning audit activities to Audit Team Leaders (ATLs). Each Audit Team Leader is selected based upon his/her availability, expertise, and independence from the activities to be audited.

### Preparation

The ATL shall be responsible for planning the audit activity, and for performing the following:

- Selecting the audit team prior to the start of the audit activity.
- Ensuring that team members are selected based on their technical qualifications, or knowledge of the item or process being audited, and independent of the work to be audited.
- Completing a review of past assessment results to determine the nature of problems that have occurred.
- Ensuring that, in the case of an internal audit, personnel having direct responsibility in the activity being audited, shall not be involved with the selection of the audit team.
- Including technical evaluations of applicable procedures, instructions, and activities.
- Preparing a QA audit checklist (should be completed prior to start of the audit).
- Ensuring that the scope includes related corrective actions taken and it's effectiveness in preventing recurrence since the previous assessment.
- Develop and sign audit plan upon review and approval by the Assessment Task Lead which should include the scope, requirements, audit personnel, activities to be audited, organizations to be notified, applicable documents, schedule, and written procedures or checklists to be used.
- Develop audit plan transmittal letter

### Audit Conduct

The ATL shall ensure that the audit is performed as per the audit plan, and that selected work areas are evaluated against specified requirements. Objective evidence shall be examined to the depth necessary to determine if those elements are being satisfactorily implemented. Audit results and conditions requiring immediate corrective action shall be reported to management of the audited organization. Conditions adverse to quality (findings) shall be documented and corrected according to the requirements specified by NP 16-1, Corrective Action. Conditions that are identified as Corrected During the Audit (CDA) require remedial actions only and will be verified prior to audit close-out. Observations are concerns identified during the course of an audit or surveillance, that if left unaddressed could develop into a QA program deficiency. Observations are considered closed at the conclusion of an audit. However, at the discretion of the lead, a written response to an observation may be required. If a response is required, it will be communicated to the responsible organization in the audit report or cover letter. Recommendations maybe offered to management as suggestions to improve a process. Commendable Practices are activities or products that exceed customer expectations. Conditions adverse to quality, CDAs, observations, recommendations and commendable practices/areas will all be documented in the audit report.

### Reporting

The ATL shall prepare an audit report which shall be distributed to the management of the audited organization and any affected organizations. The audit report shall include the following:

- Title page.
- Table of contents,
- A description of the audit scope and identification of the members of the audit team.
- Identification of personnel contacted during the audit.

- A summary of audit results including a statement of QA program adequacy (when evaluated as part of the scope of the audit), a statement of implementation and effectiveness, a description of each audit finding (condition adverse to quality), CDAs, observations, recommendations and commendable practices/areas.
- Appendices identifying the objective evidence reviewed, equipment examined, and personnel interviewed.
- Findings categorized based on their relative importance and degree of impact on compliance application, repository performance assessment and waste isolation.

Common audit findings shall be grouped in the report so that related or systemic problems in the QA program can be identified. The ATL shall submit the completed and signed audit report to the SNL WIPP Assessment Task Lead for review and approval. The ATL shall transmit the audit report to responsible management, the principal investigator, and to the Sandia Delegated Representative (SDR) if the activity was an external audit.

### Follow-Up

SNL management of the audited organization shall investigate conditions adverse to quality documented in accordance with NP 16-1, and ensure appropriate corrective actions are taken. The ATL shall evaluate the adequacy of audit responses, and take follow-up action to verify that corrective action(s) are accomplished as scheduled.

## **2.3 Surveillances**

Surveillances shall be planned, performed, documented, and reported to appropriate management. The frequency of surveillances shall be commensurate with the status and importance of the activity.

The surveillance process consists of monitoring or observing to verify that an item, activity, system, or process conforms to specified requirements. Personnel who perform surveillances shall be qualified auditors.

Surveillances are conducted to accomplish the following:

- Monitor work in progress.
- Document compliance or non-compliance with established requirements and procedures.
- Identify actual and potential conditions adverse to quality, including conditions Corrected During the Surveillance (CDS), observations, recommendations, and commendable areas/practices.
- Obtain timely corrective action commitment from cognizant managers for identified conditions adverse to quality.
- Provide notification to responsible managers of the status and performance of work under surveillance.
- Verify timely implementation of corrective action.

Surveillances are less formal than audits, and generally more narrow in scope. They may be documented using the audit report format, or if the surveillance is very focused and brief, it may be documented on a Limited-Scope Surveillance Report Form, Form NP 18-1-4 (Appendix G). The Limited-Scope Surveillance process is designed to simplify planning and documentation to facilitate short duration or "walk-through" evaluations of items, activities, or processes. A limited-scope surveillance may be conducted without notice, and a surveillance plan is not required.

### 3.0 Records

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The following QA records, generated through implementation of this procedure, shall be prepared and submitted to the SNL WIPP Records Center in accordance with NP 17-1 (Records):

<u>QA Record</u>	<u>Preparer</u>	<u>Records Submitter</u>
• Auditor Qualifications, Form NP 18-1-1	Auditor Candidate	SNL WIPP Assessment Task Lead
• Lead Auditor Qualifications, Form NP 18-1-2	Lead Auditor Candidate	SNL WIPP Assessment Task Lead
• Maintenance of Lead Auditor Form NP 18-1-3	Lead Auditor	SNL WIPP Assessment Task Lead
• Limited-Scope Surveillance Report, Form NP 18-1-4	Lead Auditor/Auditor	SNL WIPP Assessment Task Lead
• Certificates of Completion of Training	Lead Auditor/Auditor	Lead Auditor/Auditor
• Certificates of Passing an Examination	Lead Auditor/Auditor	Lead Auditor/Auditor
• Lead Auditor Examination (written, oral, or practical internal document)	SNL WIPP Assessment Task Lead	SNL QA Team Lead
• Audit and Surveillance Schedules	SNL WIPP Assessment Task Lead	SNL WIPP Assessment Task Lead
• Audit/Surveillance Plan with Notification Letter	Audit Team Leader	SNL WIPP Assessment Task Lead
• Audit and Surveillance Checklist (contains questions only)	Audit Team Leader	SNL WIPP Assessment Task Lead
• Audit/Surveillance Report with Transmittal Letter	Audit Team Leader	SNL WIPP Assessment Task Lead
• Audit Response	Auditee	Audit Team Leader

Note: Documentation associated with Corrective Action Requests issuance, follow-up and closure are processed as QA records in accordance with NP 16-1.

### 4.0 Appendices

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- Appendix A: Form NP 18-1-1, Auditor Qualifications
- Appendix B: Form NP 18-1-2, Lead Auditor Qualifications
- Appendix C: Form NP 18-1-3, Maintenance of Lead Auditor
- Appendix D: Lead Auditor Certification Auditor Qualification Process Flow Chart
- Appendix E: Maintenance of Lead Auditor Certification Process Flow Chart
- Appendix F: Audit and Surveillance Process Flow Chart
- Appendix G: Form NP 18-1-4, Limited-Scope Surveillance Report



### Appendix A

<p style="text-align: center;"><b>NUCLEAR WASTE MANAGEMENT PROGRAM</b></p> <p>Sandia National Laboratories</p>	<h2>Auditor Qualifications</h2>	<p><b>Form Number: NP 18-1-1</b></p> <p><b>Page 1 of 1</b></p>
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Name: \_\_\_\_\_ Employer: \_\_\_\_\_

**Education** (degree, discipline, institute, year) \_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

**Experience** \_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

**Audit/Surveillance Participation (if any)** \_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

See Section 2.1.3.1 for details on training requirements.

A.  **Orientation** – Training which provides a working knowledge of QA requirements and NP 18-1 Audits and Surveillances.

B.  **Training Program**

Course description and date: \_\_\_\_\_

Sponsor: \_\_\_\_\_

C.  **On-the-Job-Training** - Training, guidance, and counseling during the conduct of audit(s) under the direction of Lead Auditor.

The Auditor Candidate or Technical Specialist named above is qualified as a Quality Assurance Auditor within the SNL WIPP QA Program

\_\_\_\_\_  
SNL WIPP Assessment Task Lead (Signature) \_\_\_\_\_  
Date Qualified

\_\_\_\_\_  
SNL WIPP Assessment Task Lead (Print)



## Appendix B, continued

## Instructions for Qualification Points

Form Number:

NP 18-1-2

Page 2 of 2

Education (Highest degree only) from an Accredited Institution	Maximum 4 Credits
Associate Degree in: _____ _____	=1
Associate Degree in Engineering, Physical Sciences, Mathematics, or Quality Assurance _____	=2
Bachelor Degree in: _____ _____	=2
Bachelor Degree in Engineering, Physical Sciences, Mathematics, or Quality Assurance _____	=3
Master Degree in Engineering, Physical Sciences, Business Management, or Quality Assurance - additional credit _____	=1
Experience	Maximum 9 Credits
Technical (engineering, manufacturing, construction, operation, or maintenance) - one credit for each year, up to 5, maximum _____	=5
Nuclear Industry* - including either Nuclear Power Industry, Navy Nuclear experience, Nuclear Weapons complex experience, or _____	=1
Quality Assurance* or _____	=2
Auditing* or _____	=4
Nuclear Quality Assurance or _____	=3
Nuclear Quality Assurance Auditing _____	=4
* Additional credit if two (2) or more years or technical experience have been in this area	
Professional Certification in Engineering, Science, or Quality Assurance	Maximum 2 Credit
Professional Engineer (Registered by State Agency)	=2
National Professional or Technical Society	=2
Rights of Management**	Maximum 2 Credits
** Based on performance factors such as leadership, sound judgment, maturity, analytical ability, tenacity, past performance, and QA training courses beyond those specifically required by this procedure	

### Appendix C

<b>NUCLEAR WASTE MANAGEMENT PROGRAM</b> Sandia National Laboratories	<h2>Maintenance of Lead Auditor</h2>	<b>Form Number: NP 18-1-3</b>  <b>Page 1 of 1</b>
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Name \_\_\_\_\_ Employer \_\_\_\_\_  
 Previous Qualification Date \_\_\_\_\_

**List below participation in assessment activities (audits and surveillances)**

Activity Assessed/SNL Organization/Contract	Audit/Surveillance Number	Date

**List below participation in other Quality Assurance Program Activities (Procedure Author, Perform QA Review, etc)**

Activity	Date

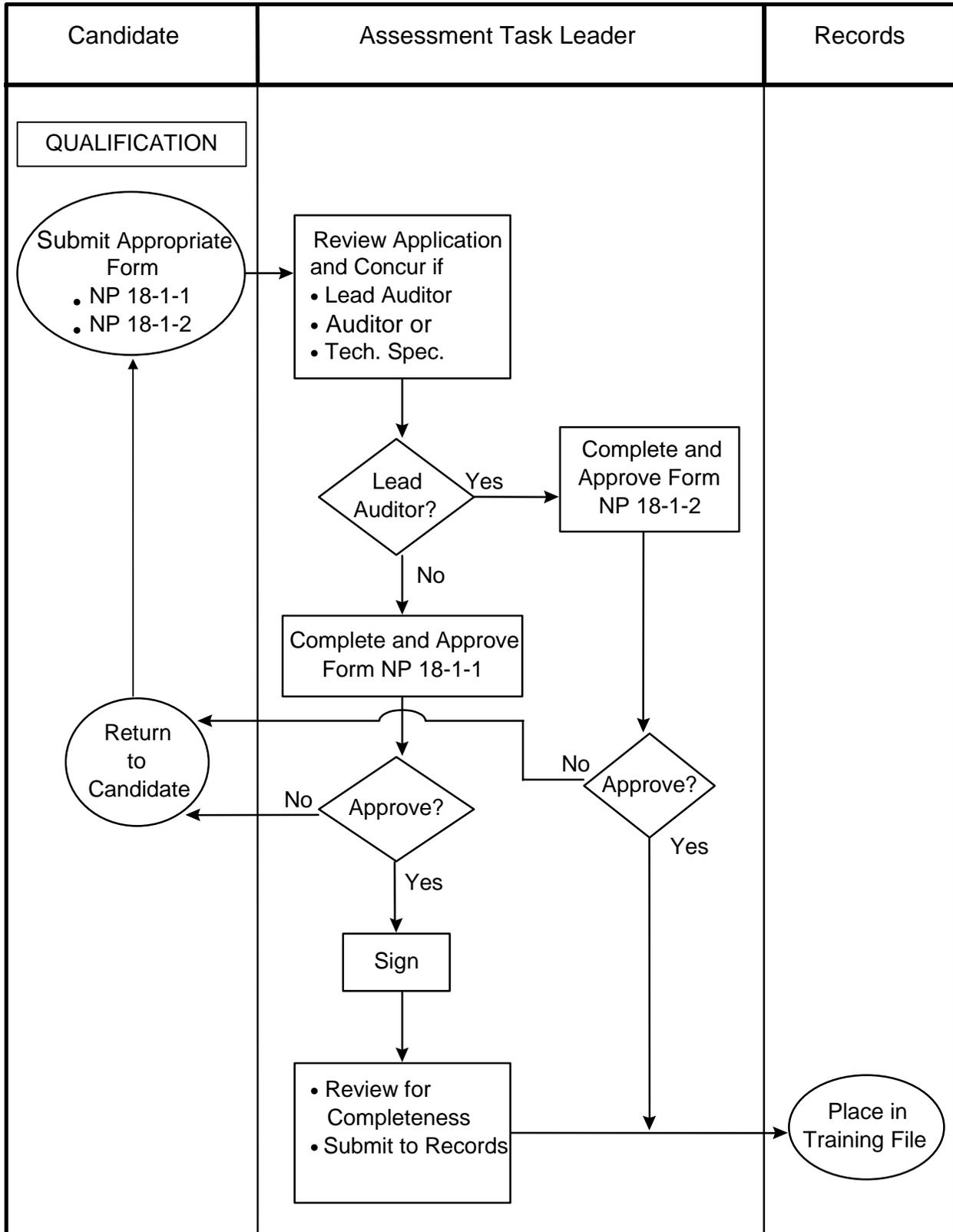
**Participation in Lead Auditor/Auditor Training**

Name of Trainer/Company	Title of Training	Date

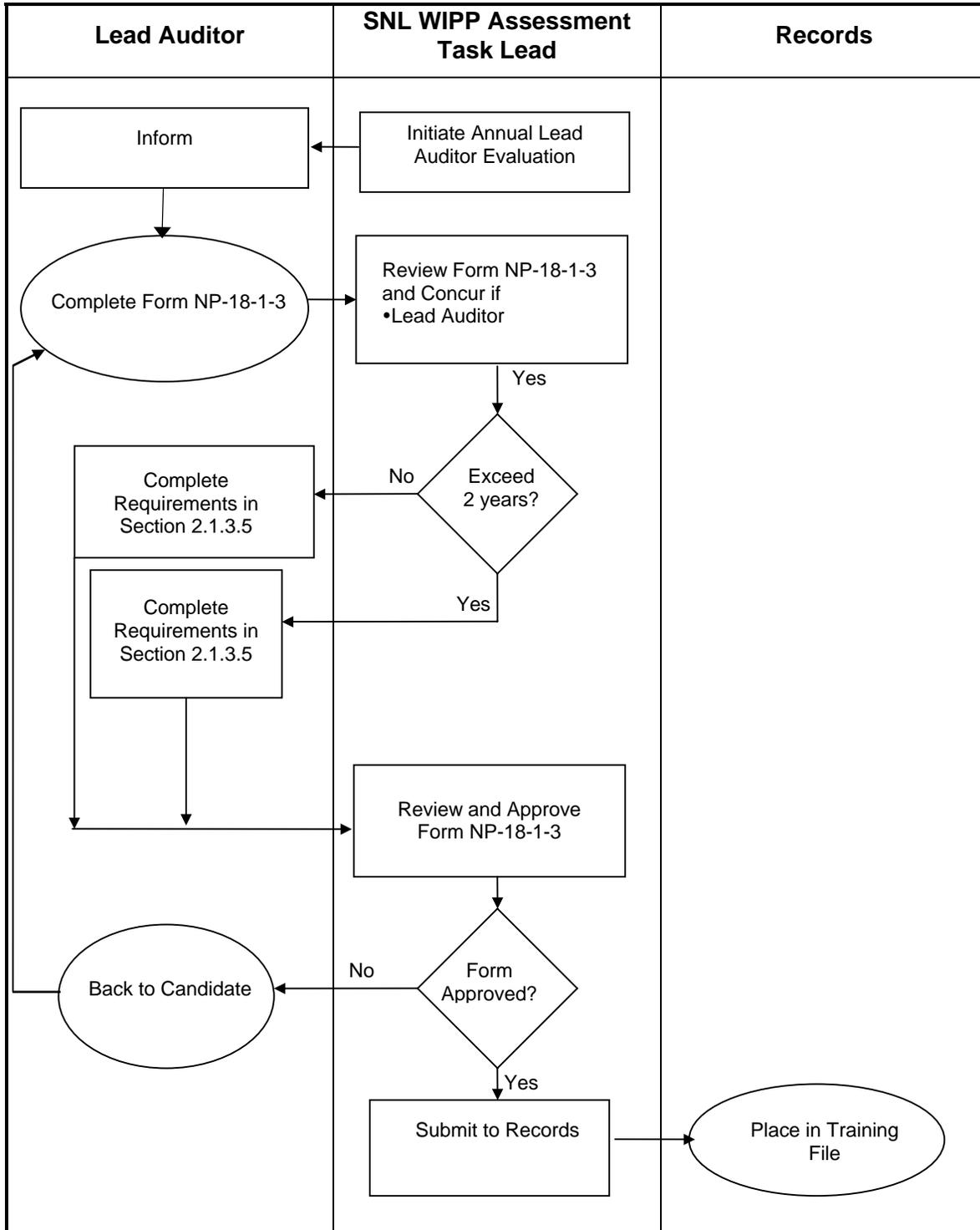
Approval signature below authorizes extension of qualification for one year.

Approval: \_\_\_\_\_  
 Signature, SNL WIPP Assessment Task Lead \_\_\_\_\_ Date \_\_\_\_\_

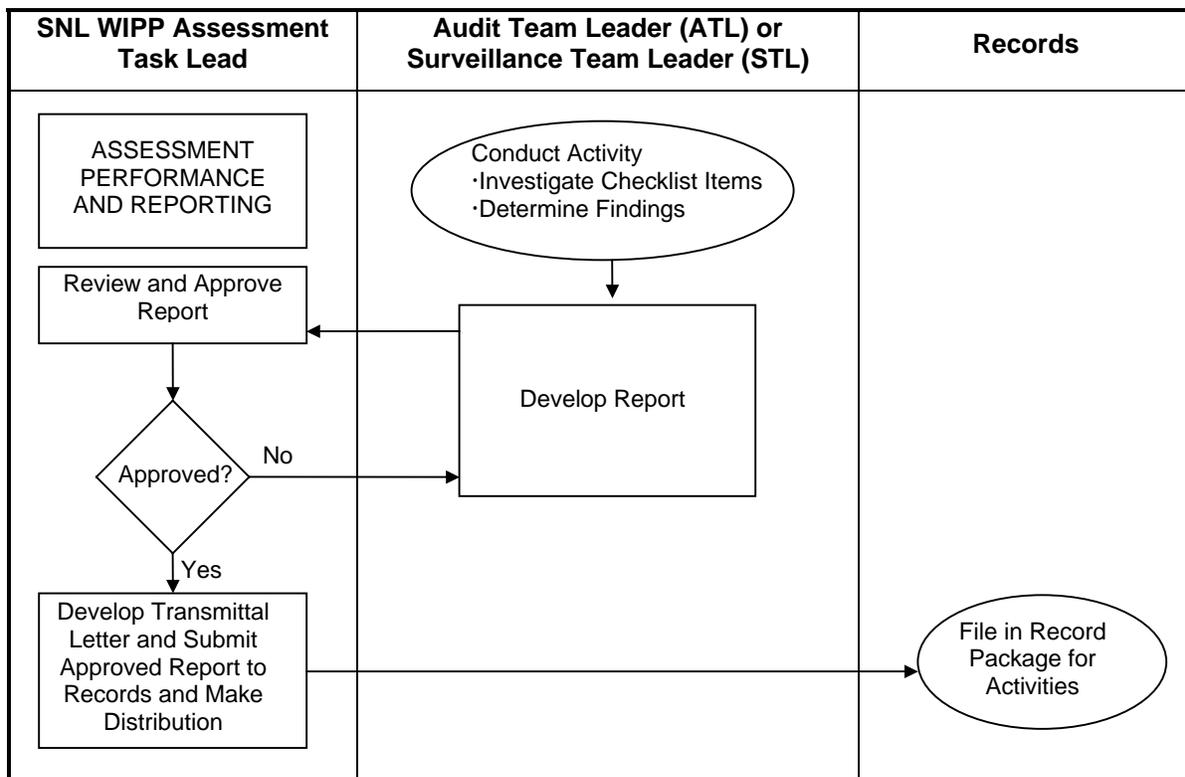
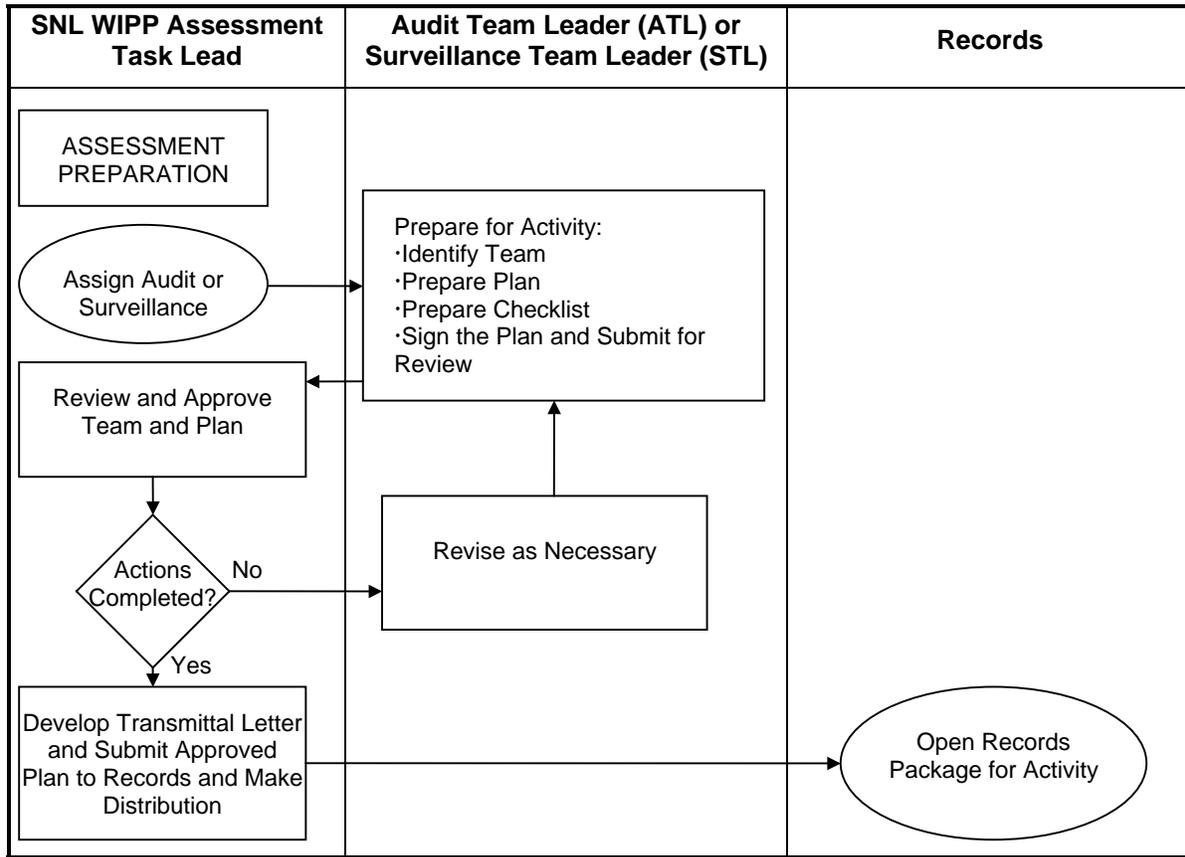
### Appendix D Lead Auditor Certification/Auditor Qualification Process Flow Chart



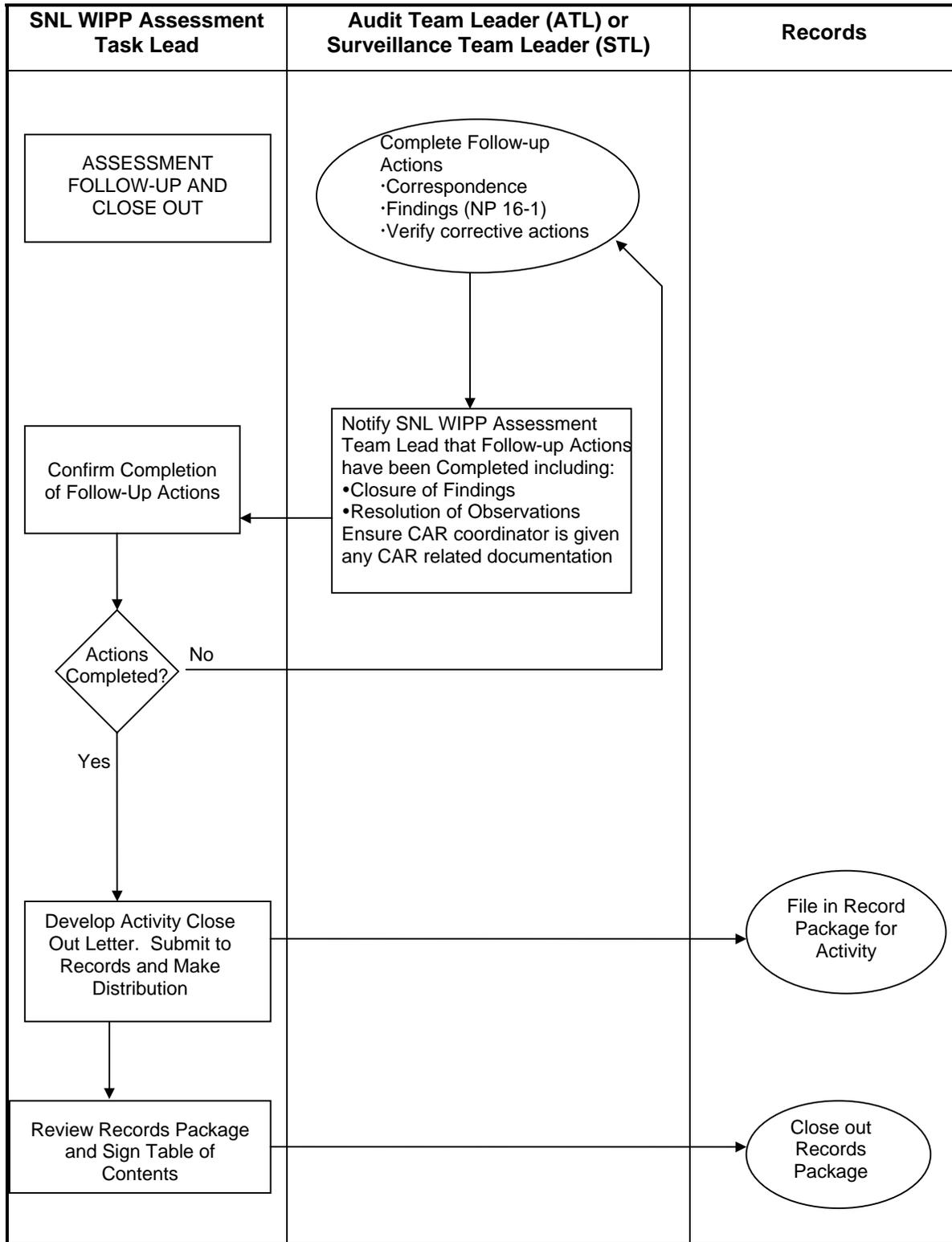
## Appendix E Maintenance of Lead Auditor Certification Process Flow Chart



## Appendix F Audit and Surveillance Process Flow Chart



**Appendix F, continued**



**Appendix G**

<p style="text-align: center;"><b>NUCLEAR WASTE MANAGEMENT PROGRAM</b></p> <p style="font-size: small;">Sandia National Laboratories</p>	<h2 style="margin: 0;">Limited-Scope Surveillance Report</h2>	<p><b>Form Number: NP 18-1-4</b></p> <p><b>Page 1 of 1</b></p>												
<b>1.</b>	<p>Surveillance No.: _____ Date of Surveillance: _____</p> <p>Auditor: _____</p> <p>Area/Activity Examined: _____</p> <p>_____</p> <p>_____</p> <p>_____</p>													
<b>2.</b>	<p>Surveillance Results:</p> <div style="text-align: center; font-size: 48px; opacity: 0.3; transform: rotate(-15deg); font-family: cursive;">             Sample Form         </div>													
<b>3.</b>	<p>Findings: <input type="checkbox"/> NO <input type="checkbox"/> YES (initiate CAR in accordance with NP 16-1, unless it was CDS as documented below)</p> <p style="margin-left: 100px;">↓</p> <p>Brief Description of Deviation: _____ (include requirement violated)</p> <p style="margin-left: 100px;">Car No.: _____</p> <p>Corrected During the Surveillance (CDS) (describe remedial action taken):</p> <p>_____</p>													
<b>4.</b>	<p>Authentication:</p> <table style="width: 100%; border: none;"> <tr> <td style="width: 60%; border: none;">_____</td> <td style="width: 20%; border: none;">Signature</td> <td style="width: 20%; border: none;">Date: _____</td> </tr> <tr> <td style="border: none;">Printed Name of Auditor</td> <td style="border: none;"></td> <td style="border: none;"></td> </tr> <tr> <td style="border: none;">_____</td> <td style="border: none;">Signature</td> <td style="border: none;">Date: _____</td> </tr> <tr> <td style="border: none;">Printed Name SNL WIPP Assessment Task Lead</td> <td style="border: none;"></td> <td style="border: none;"></td> </tr> </table>		_____	Signature	Date: _____	Printed Name of Auditor			_____	Signature	Date: _____	Printed Name SNL WIPP Assessment Task Lead		
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Printed Name SNL WIPP Assessment Task Lead														

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