



SOP TITLE	TNI Internal Audits
SOP NO.	1-124
REVISION NO.	1.1
PROGRAM	Administration

SOP Approval Dates

	Initial Approval	Last Revision Date	Last Review Date
Committee: Policy	11-02-2018	05-21-2021	
Program	NA	NA	
Policy Committee Review	NA	NA	
TNI Board of Directors Endorsement	11-14-2018	06-09-2021	
Effective Date	01-01-2019	05-21-2021	

1.0 Purpose and Applicability

This Standard Operating Procedure (SOP) describes The NELAC Institute’s (TNI) process for developing internal audit checklists, scheduling and performing internal audits of TNI committee operations and reporting of internal audit results as required by the TNI Quality Management Plan. This SOP applies to all TNI committees except for the Finance Committee. The Finance Committee operations are overseen and monitored by the TNI Board of Directors.

2.0 Summary

This SOP describes the processes related to the TNI Internal Audit program. Internal audit checklists are prepared and approved by the Policy Committee (Section 5). These checklists are then used to perform internal audits using the TNI Internal Audit Database (Section 6). Nonconformities are corrected using corrective action procedures (Section 7). A summary of the internal audit results is presented at the TNI winter meeting and subsequently submitted to the TNI Board of Directors. Appendix A contains instructions for using the TNI Internal Audit Database.

The Policy Committee releases an Internal Audit schedule for the year by the start of the TNI Fiscal Year.

Example: Internal Audit Schedule

Action	Due Date
Update audit checklists	November 15
Policy review checklists	January 15
IT posts updated checklists to database	Due March 1
Internal Audits complete	May 15
Corrective Action Complete	October 1

3.0 Related Documents

None.

4.0 Definitions

Term	Definition
Self-audit	Self-audits are based on the TNI Internal Audit Database checklists and are conducted by a committee’s Program Administrator, a committee’s Chair, or both.
Five Year Audit	An independent committee audit conducted at least every five years by a TNI Program Administrator, Chair, or both, that has no conflict of interest with the mission of the committee to be reviewed. These audits are based on the TNI Internal Audit Database checklist.
TNI Internal Audit Database	A database that contains the TNI Internal Audit Checklists and is used to document TNI Internal Audits and corrective actions.

5.0 Internal Audit Checklists

5.1 Each TNI committee develops an internal audit checklist that contains auditable items.

5.1.1 Each checklist is prepared from a template that can be obtained from the Policy Committee. There are two templates: CSDP Committees and Other Committees.

5.1.2 The checklist is completed by the Program Administrator and Chair for the committee. In some cases, a TNI Staff person may prepare a first DRAFT for the committee to review and finalize.

5.1.3 The checklist templates are divided into two portions.

- 5.1.3.1 The upper portion of the checklist contains requirements that apply to all relevant committees. This portion is prepared and approved by the Policy Committee.
 - 5.1.3.2 The lower portion of the checklist contains requirements specific to a particular committee. The requirements included in this section are pulled from the committee's SOPs and policies.
 - 5.1.3.3 All items included in the checklist take into account the requirements that must be audited for compliance because there is a risk to TNI's reputation or contractual requirements if not met.
 - 5.1.4 Each audit checklist item must reference the section of the TNI document from which it was taken. All documents referenced in the checklist must also be included in the "SOPs/Policies Referenced" summary located at the top of the checklist. This summary must include the revision number of the document.
 - 5.1.5 Checklist items will be audited annually and/or every five (5) years. The frequency of assessment for each checklist item needs to take into consideration the legal, financial, recognition (by external organizations) and reputation risks incurred by TNI from committee activities.
NOTE: A committee can choose to audit an item less frequently than annually and more frequently than every 5 years.
- 5.2 The checklists are updated as referenced TNI documents are updated or removed, or as new relevant documents are developed.
- 5.2.1 The committee will update its internal audit checklist as committee procedures referenced in the lower portion of checklist are updated.
 - 5.2.1.2 The committee's internal audit checklist must be current prior to the start of the internal audit.
 - 5.2.1.2
 - 5.2.2 The Policy Committee will update the upper portion of the checklist templates as procedures referenced in the upper portion of the checklist are updated or as new documents are developed that are relevant to a particular template.
 - 5.2.2.1 These updates may be made by TNI staff or members of the Policy Committee.
 - 5.2.2.2 The CSDP template may be updated by the CSDP Executive Committee.
- 5.3 All new and updated checklists must be approved by the Policy Committee before they can be used.

6.0 Committee Internal Audit

- 6.1 Internal audits are performed at the frequency stated in the internal audit checklist.
- 6.1.1 Self-audits are performed annually by the committee's Program Administrator, a committee's Chair, or both.
 - 6.1.2 The five (5) year audits are performed by a TNI Program Administrator or a TNI committee Chair external to the committee and that has no conflict of interest with the committee's mission.
 - 6.1.2.1 The audit performed by the American National Standards Institute (ANSI) is considered sufficient to qualify as the five year independent audit of the CSDP Executive Committee and CSDP Expert Committees. ANSI follows their own auditing procedures during their audits. TNI will keep copies of all records received and provided to ANSI and keep corrective action records related to the ANSI audit following the procedures outlined in SOP 1-104 (Control of TNI Documents). Any five year internal audit checklist items that are not covered by the ANSI audit must be added to the self-audit performed that year.

- 6.1.3 Committees may have checklist items that are checked at a frequency greater than annually but at least every five years. These checklist items are considered part of the self-audits and are audited at the appropriate time frame.
- 6.1.4 The internal audits are scheduled by the committee and can be performed at one time or over time.
- 6.2 The internal audits are documented electronically using the TNI Internal Audit Database. Instructions for using the database can be found in Appendix 1.
- 6.3 The nonconformities of the internal audit will be shared with the committee and briefly summarized in the committee minutes.
 - 6.3.1 The committee meeting minute summary will include at a minimum, the date the internal audit was completed, the number of auditable items and the number of nonconformities with a brief summary of each.
 - 6.3.2 TNI members may request a copy of the completed checklist after corrective action (see Section 7) is completed. These requests should be submitted to the committee's Program Administrator in writing.

7.0 Corrective Action

- 7.1 Each committee must address the nonconformities ("No" responses) found in its internal audit by preparing a corrective action response/plan.
 - 7.1.1 The corrective action process is coordinated by the Program Administrator and committee Chair.
 - 7.1.2 The Internal Audit Database includes three columns that track responses to each nonconformity that include root cause evaluation, proof of correction or a plan for correction with a due date and a verification that the corrective action has been implemented. Corrective action responses are due by September 30 each year.
 - 7.1.3 The Internal Audit Database corrective action columns include:
 - 7.1.3.1 "What factors contributed to "No" response?"
 - This question leads to a root cause analysis. It is important to evaluate what lead to the nonconformity so that the relevant process can be repaired. The committee should consider all factors that may have contributed to the issue.
 - 7.1.3.2 "What will or has been done to correct issue – Corrective Action (CA)?"
 - Provide a summary of what was done or what the committee plans to do to correct the issue. The completion date or the expected completion date must be included in the response.
 - In some cases, a committee may find that the checklist item is out of the committee's control and another committee is responsible for correcting the issue. In these cases the committee must state in this column that the correction has been transferred to a named committee and include the date the other committee was notified.
 - The need to update written procedures should be taken into consideration when preparing corrective action plans.
 - Corrective action plans are tracked by each committee using its procedure for tracking action items.
 - The committee must notify the next level of organizational management within TNI when the corrective action responses are complete.

7.1.3.3 “CA Verified (Name/Date)”

- Verification takes place approximately 60 days after completion of the corrective action task and is performed by the Program Administrator or committee Chair. If the corrective action is not found to be implemented, the committee places the task into its action item listing and the task is looked at again for verification approximately 60 days after the task is completed

7.1.4 The corrective action response is reviewed by the next level of organizational management within TNI (*i.e.*, an Executive Committee or TNI Board of Directors).

7.1.4.1 The review by the next level of organizational management shall be documented by stating “Approved” or “Not Approved” in the same corrective action response box. Responses that are not approved will be reconsidered by the committee and a new response will be written for approval.

7.1.4.2 The committee that wrote the response must be notified once the corrective action responses have been reviewed.

7.2 Corrective action documentation will be maintained by the Program Administrator following SOP 1-104 (Control of TNI Documents).

7.2.1 The corrective action responses/plans are considered Class III documents.

7.3 The data compiled from the internal audits will be summarized in a short summary to be presented at the TNI winter meeting.

8.0 References

TNI Quality Management Plan
SOP 1-104: Control of TNI Documents

9.0 SOP Approved Changes

Revision No.	Effective Date	Description of Change
0	1/1/19	New SOP
1	3/6/20	Update Corrective Action procedures and include new columns in the Internal Audit Database to document corrective action.
1.1	5/7/21	Changed audit schedule in Section 2.

APPENDIX A

Instructions for Use of TNI Internal Audit Database

To access the Internal Audits database, visit the following URL:

<http://apps.nelac-institute.org/audit>

Home Page:

The screenshot shows the top navigation bar with 'Internal Audit Database', 'Home', 'Register', and 'Log in' links. Below is a large grey box with the title 'TNI Internal Audit Database'. Underneath are two columns: 'Getting started' with instructions on account creation and a 'Start' link, and 'About TNI' with a description of the organization and a 'Go to TNI »' button. At the bottom, there is a copyright notice: '© 2018 - The NELAC Institute (TNI)'.

If this is the first time you are logging into the database, click on REGISTER in the upper right corner.

Register.

Create a new account

Full Name	<input type="text"/>
Email	<input type="text"/>
Organization	<input type="text"/>
Password	<input type="password"/>
Confirm password	<input type="password"/>
	<input type="button" value="Register"/>

Complete the registration information and click on the REGISTER box. A message will flash at the top of the screen: *An email has been sent to your account. Please view the email and confirm your account to complete the registration process.* Confirm your account by clicking on the link in your email.

When you have an account set-up, click on “LOG IN” in the upper right corner of the home page and log in with the credentials you created – your email address and password.

Once you have logged in and are ready to document your audit, click on START. The database is very intuitive and simple to use.



A My Checklists box will be displayed containing all the internal audits you are working on. It will be empty until you start your first new checklist.

My Checklists

Audit #	By	Committee Name	Date	Complete?	
1	Ilona Taunton	Admin and Support	6/20/2018	<input type="checkbox"/>	Chg Name
3	Ilona Taunton / Paul Junio	Quality Systems	10/15/2018	<input checked="" type="checkbox"/>	Chg Name

Start New Checklist

Continue Checklist

Remove Checklist

You have a choice to **START NEW CHECKLIST**, **CONTINUE CHECKLIST** or **REMOVE CHECKLIST**.

- To start a new checklist (**START NEW CHECKLIST**), use the down arrow in the Audit Checklist line to find which committee audit you want to start. All the available checklists are in the list.

A screenshot of a software interface showing a dropdown menu for 'Audit Checklist'. The menu is open, displaying a list of audit categories. 'Quality Systems' is highlighted in green at the top of the list. Other categories include Admin and Support, Advocacy, Asbestos, Chemistry, CSDP Executive Committee, Field Activities, Information Technology, Laboratory Accreditation Body, Microbiology, NEFAP Executive Committee, NELAP Accreditation Council, Policy, PT Expert, PTP Executive Committee, Radiochemistry, Stationary Source Audit Sample, and WETT. To the right of the dropdown is a 'Save and Continue' button.

- Type in the name of the person(s) performing the audit and the audit date.

A screenshot of the audit form. The 'Audit Checklist' dropdown is set to 'Quality Systems'. The 'Audit Performed By' text box contains 'Ilona Taunton / Paul Junio'. The 'Audit Date' text box contains '10/15/18' and has a calendar icon to its right. At the bottom of the form are 'Cancel' and 'Save and Continue' buttons.

- Then click Save and Continue.

- The checklist will pop up and then you can click in the Yes, No or N/A box to respond to the questions. You can click in a box to place a check mark in it. You can remove the checkmark by clicking on it again.

#	Item	Ref	Freq	Yes	No	N/A	Comments
1	All Committee Members and Associate Committee Members have individual TNI membership, or are Affiliates as defined in the Policies Governing Standards Development, Section 1.3.1 (SOP 2-100).	SOP 2-101: 2.3.2	Self - Annual External - 5 Years	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
2	For purposes of determining balanced representation, the default stakeholders are ABs, laboratories and other organizations directly involved in providing sampling and environmental measurement, and all others. (The Board of Directors must approve the use of any other stakeholder groups.)	Bylaws: Article XI, Section 4	Self - Annual External - 5 Years	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

- The comments box can be used to add additional notes or provide detail requested in a box. You can see more than two lines of notes in the box by clicking on the triangle in the bottom right corner of the box.
- Once you have made your additions to the checklist, you can choose to SAVE it or COMPLETE it. You can also CANCEL the work you have done. These choices are at the bottom of the page.

93	All records, including those relating to the approval, revision, or reaffirmation of a standard are retained for a minimum of five (5) years or one complete standards cycle, whichever is longer. All records related to the withdrawal of a standard are retained for five years from the date of withdrawal. (Sect 10)	SOP 2-100: 10	Self - Annual External - 5 Years	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
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- o If you choose to SAVE it, you will find it in your My Checklists box and it can be opened to continue the next time you are ready to work on it. Highlight the checklist by clicking on the line of the checklist and then click **CONTINUE CHECKLIST**.

My Checklists

Audit #	By	Committee Name	Date	Complete?	
1	Ilona Taunton	Admin and Support	6/20/2018	<input type="checkbox"/>	Chg Name
3	Ilona Taunton / Paul Junio	Quality Systems	10/15/2018	<input checked="" type="checkbox"/>	Chg Name

Start New Checklist

Continue Checklist

Remove Checklist

- o If you chose to mark it COMPLETE, it will also show up in your My Checklists box. You will see a check mark in the Complete column. You can still modify the checklist by

clicking on the line of the checklist and then click **CONTINUE CHECKLIST**. (Note: The date of the internal audit remains the same. To change the date after you re-SAVE or re-COMplete the checklist, click on CHG NAME and you can change the date and/or change the name(s) of the internal auditor(s). The Date is the last date the checklist was saved or completed.)

My Checklists

Audit #	By	Committee Name	Date	Complete?	
1	Ilona Taunton	Admin and Support	6/20/2018	<input type="checkbox"/>	Chg Name
3	Ilona Taunton / Paul Junio	Quality Systems	10/15/2018	<input checked="" type="checkbox"/>	Chg Name

Start New Checklist

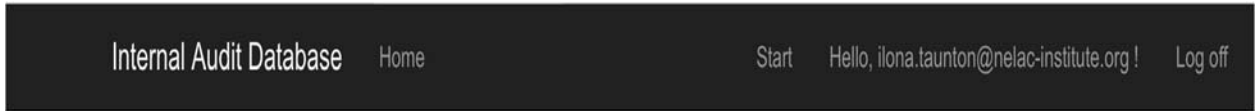
Continue Checklist

Remove Checklist

- A checklist can be removed from your list and permanently deleted by clicking on the line of the checklist and then click **REMOVE CHECKLIST**. This only deletes the checklist you worked on and not the template from the Start menu.

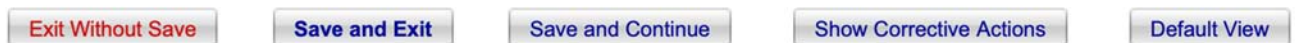
The screenshot shows the 'My Checklists' interface with a table of checklists. A dialog box is overlaid on the interface, displaying a warning message: 'WARNING: You are about to delete the selected checklist. This action cannot be undone. To confirm the deletion, type "delete" (without the quotes) into the box below and click the DELETE button:'. Below the text is a yellow input field containing the word 'DELETE' and a 'DELETE' button. There are also 'Cancel' and 'DELETE' buttons at the bottom of the dialog box. The background interface shows a table with columns 'Audit #', 'By', 'Committee Name', 'Date', 'Complete?', and 'Chg Name'. The second row is highlighted in green. Below the table are buttons for 'Start New Checklist' and 'Continue Checklist'. At the bottom left, there is a copyright notice: '© 2018 - The NELAC Institute (TNI)'.

- When you are finished with your work – click on Log off in the upper right corner.



- Corrective Action

When you are ready to input corrective action, log-in and choose to “Continue Checklist” on the checklist you would like to update. The following options become available at the top of the checklist:



Choose “Show Corrective Actions”. The figure below is an example of a corrective action form for completion. Any items marked “No” are included in this form. The comments made during the internal audit are also included.

#	Item	Ref	Yes	No	N/A	Comments	What factors contributed to 'No' response?	What will or has been done to correct issue - Corrective Action (CA)	CA Verified (Name/Date)
8	A committee application form was submitted by every committee member prior to their acceptance for membership.	SOP 1-101: 7.2.2, QMP: 5.1	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>				
20	Documents are labeled following the naming conventions in SOP 1-100 and SOP 1-116.	SOP 1-104: 6.6.1	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>				
28	All Provisional Policies and SOPs are clearly marked as “Provisional” in parentheses after the effective date on the cover page and header of each page.	SOP 1-116: 5.2.2	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>				
31	The principles of openness for committee meetings are followed.	POL 1-110: III	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>				
34	Superseded documents are traceable and maintained for the appropriate time (choose 3-5 documents to trace back).	SOP 1-104: 6.4	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>				
35	Superseded and obsolete documents are removed from public access.	SOP 1-104: 6.5	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>				



When the updates are complete, you can choose to “Save and Exit” for “Save and Continue”. This form may also be exported into Excel to share with others.