

**SAP 4**  
**OWM PT Standard Administrative Procedure**  
**for**  
**Audits and Reviews**

1 Introduction

1.1 Purpose of the Procedure

The purpose of this procedure is to ensure a regular audit program for the OWM PT program to ensure the planning, establishing, implementing, and maintaining an auditing program including regular internal audits and regular management reviews.

1.2 Scope

The scope of this procedure applies to the internal auditing and management review of all aspects of the OWM PT Program to ensure compliance with applicable sections its quality management system and ISO/IEC 17043.

1.3 Applicable Documentary References.

1.3.1 All documentary references for this procedure are listed and controlled in SAP 1, Document and Record Management. SAP 1 is explicitly referenced in the NISTIR 7214, Quality Manual.

1.4 Responsibility and Authority

1.4.1 OWM Laboratory Metrology Program staff are assigned responsibilities for conducting the internal audit and management review functions as described in this procedure and use the specified Forms to ensure all components of the PT program quality system are consistently and thoroughly addressed.

1.4.2 All assigned staff are knowledgeable about quality systems in general, the PT-program quality system specifically, and have a demonstrated history of auditing knowledge and skills (resume, training records, or performance plan reviews). Because the PT program has a limited number of staff, independence is accomplished to the extent possible by alternating staff assignments and reviews.

1.4.3 The PT Administrative Team, comprised of the Regional PT Coordinators, PT Coordinators, PT Analysts and any mentors or observers for the PT are solicited to submit any applicable inputs to the ongoing operations of the PT program, its effectiveness, and compliance to the OWM policies and procedures, including impartiality, technical quality, and any observed nonconformities.

## 2 Methodology and Frequency

2.1 Conduct the Internal Audit using Form 5. Internal audits are required on planned intervals to ensure compliance to the quality management system documents (see SAP 1, Document and Record Management) and to ensure that the program is effectively implemented and maintained. The Laboratory Metrology Program leader will schedule and assign the internal audit or portions of the audit to staff during annual strategic planning sessions and include tasks in staff performance plans as appropriate a document review is conducted in odd-numbered years and a horizontal application review is conducted in even-numbered years as noted in the following sections.

2.1.1 Define the Scope: Conduct a “document/reference” review in alternating odd-numbered years, completing the Document Reference columns on Form 5.

2.1.1.1 In this assessment, the objective evidence column identifies which documents were observed along with their reference dates, status, or need for updating to ensure compliance. The objective evidence of the document review must be more explicit than simply restating and listing the documents. It is the availability and demonstration of compliance that all documents are in place (where are they located) and that they are up to date and readily available for the PT program. Following SAP 1, all referenced documents are reviewed at least every two years to ensure compliance with national and international documentary standards. (I.e., this includes a review of all ISO, ISO/IEC, ILAC, and accreditation or recognition body documents). Compliance with SAP 1, Document and Record Management is assessed as well.

2.1.1.2 Complete draft Action Item forms (see SAP 2 and Form 4) when nonconformities are identified and reference the form identification number in the internal audit Form 5. Review all prior action items for their application to program documentation. SAP 2 provides guidance on timeliness of action item reviews.

2.1.2 Define the Scope: conduct a horizontal “application” internal audit in alternating even-numbered years, completing Form 5 to identify objective evidence that the entire PT program is fully implemented and complies with PT-program quality system documents as identified in SAP 1 for Document and Record Management.

2.1.2.1 Additional tasks include but are not limited to reviewing the following items, and any other records or objective evidence of PT-program compliance for the two years prior to the audit:

- Completed forms and records;
- Directories of saved feedback and other PT operation communications;
- Directories of completed PT Plans and PT Analysis templates;
- Analysis and summary of all completed PTs and their success rates for pass/fail (as also used in the alternating year State Laboratory Workload Survey conducted by NCSLI Legal Metrology Committee).
- Analysis of all action items and their effectiveness (see SAP 2); and
- Final PT Reports.

2.1.2.2 Complete draft Action Item forms (see SAP 2 and Form 4) as nonconformities are identified and reference the action item number in the internal audit form. Review all prior action items for their application to program implementation. SAP 2 provides guidance on timeliness of action item reviews.

2.1.3 The completed internal audits are discussed by the Laboratory Metrology Program staff and completed Form 5 is submitted to the Program Leader and retained in the applicable program network directories. Outputs from the Internal Audit are reviewed as part of the annual Management Reviews. Action items are reviewed according to SAP 2.

2.2 Conduct the Management Review using Form 6 (outline). Management reviews are conducted at planned intervals to ensure continuing suitability, adequacy, and effectiveness of the program operations. The review includes evaluation of program policies and procedures to ensure compliance to the ISO/IEC 17043 standard and the OWM PT-program documents. The OWM PT program schedules management reviews annually prior to strategic planning sessions or integrates the review and discussion as an integrated part of strategic evaluation and planning.

2.2.1 Complete a draft Form 6. A staff member is assigned to complete the draft outline using outputs from the internal audit and other program data, using Form 6. Form 6 identifies all the required sections of a management review and the scope of the review. The assigned staff member will solicit inputs for the management review outline sections from other OWM staff and the PT Administrative Teams as described earlier.

2.2.2 Schedule and conduct a PT-program management review meeting. Conduct the PT program management review meeting prior to the annual Laboratory Metrology Program strategic planning sessions so that the output of the PT program is included as a part of the SWOT

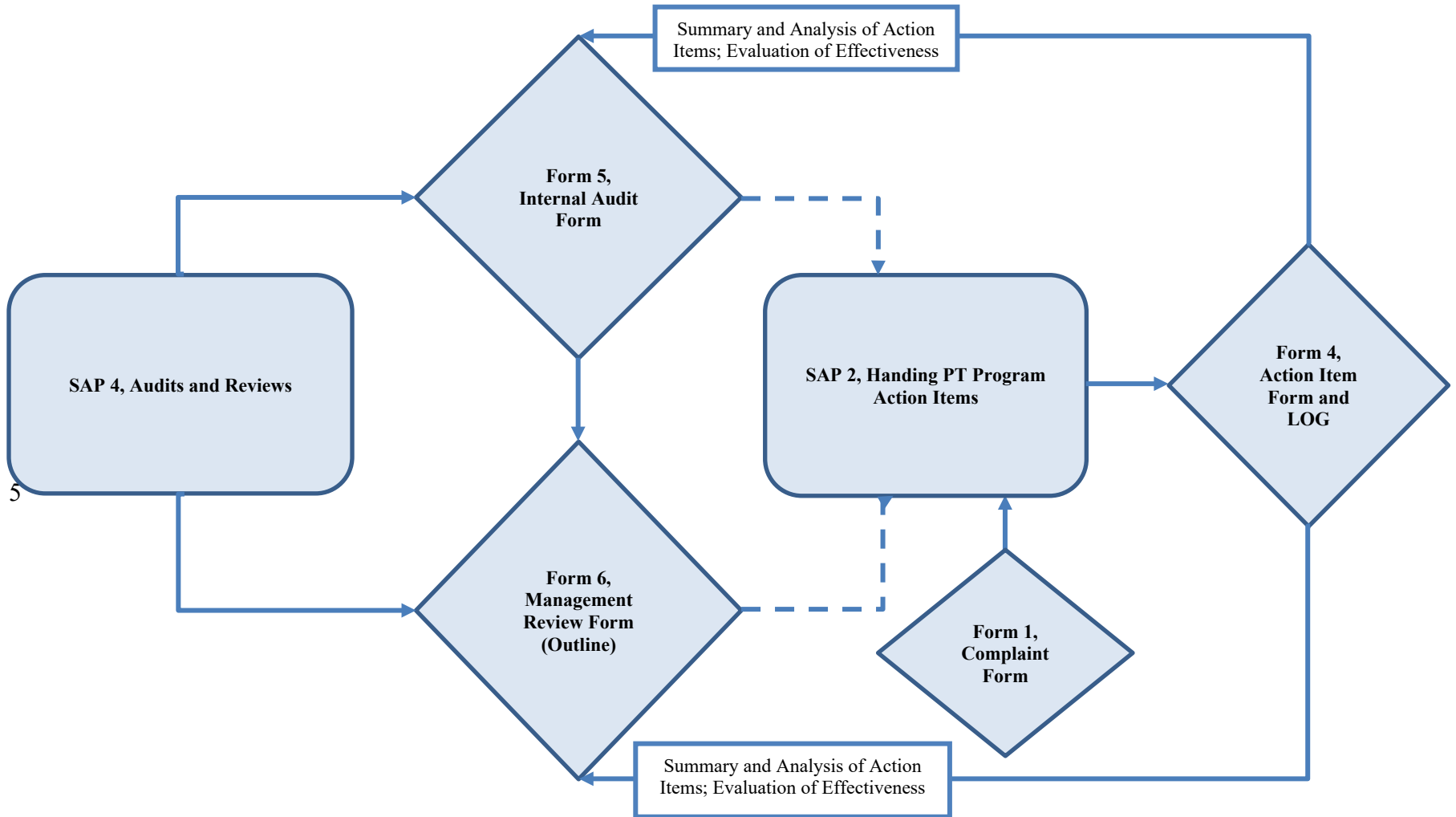
(strengths, weaknesses, opportunities, and threats) analyses and discussions.

- 2.2.3 Complete the Summary of Management Review Outputs at the end of Form 6. Minutes of the management review meeting and high level summary of action items that are identified during the management review must be documented in the last section of the management review. Some of the items in this output section may also be summarized in the overall Executive Summary which is completed after the meeting is held.
- 2.2.4 Complete any applicable draft Action Item forms (see SAP 2 and Form 4) as corrective actions, risk minimization, or opportunities for improvement are identified and reference the action item number in the internal audit form.
- 2.2.5 Complete the Executive Summary. Outlined items in the Executive Summary section guide the staff member in a high level review. SWOT assessments are included as part of the management review executive summary to integrate this effort into planned activities and to ensure it is a part of setting short-term and long-term goals.

### 3 Records

- 3.1 Communications and input received from the PT Administrative Team and other OWM staff members during the preparation of the internal audit and management review will be retained as objective evidence.
- 3.2 Forms 5 and 6, when completed, provides the full record of the internal audit and management review that are completed annually.
- 3.3 Follow up Action Item forms (Form 4) are completed as identified during both the internal audit and the management review. Action items are also entered into the action item log.

4 Workflow for Auditing and Management Reviews Related to Action Items



This publication is available free of charge from: [Link to be provided when approved for publication](#)