SAP 2

OWM PT Standard Administrative Procedure

for

Handling PT-Related Action Items

1   Introduction

1.1   Purpose of the Procedure

The purpose of this procedure is to provide documented guidance for operating the OWM Laboratory Metrology Program – PT Program and for activities leading to possible action items for changes, whether corrective, minimizing risks, or improvements. The procedure is designed to consolidate all activities of the PT program in one place that might lead to these specified actions.

1.2   Scope and References

The scope of this procedure is to cover any PT-program related activities that might lead to an Action Item including but not limited to the following listed items. Numbers in parenthesis relate to ISO/IEC 17043 and related sections in NISTIR 7214, Quality Manual. Unless alternative Standard Administrative Procedures (SAP) are referenced, this SAP covers the procedure leading to action items as well as processing the action items themselves.

- Nonconforming work – may arise from any portion of the PT-program operations or other items on this list and leads to corrective actions (7.5.4);
- Complaints – from PT analysts, PT coordinators, or PT participants (7.6);
- Appeals – from PT participants who are dissatisfied with PT-program operations including decisions regarding PT analyses or other failures (7.7);
- Actions to address risk and opportunities – preventive action identified by any party or process (8.5);
- Improvement actions – identified by any party or process (8.6);
- Feedback and/or inquiries – solicited or unrequested (8.6.2);
- Corrective actions – from any party or PT-program operation (8.7);
- Internal audits – operation internal to OWM to assess program compliance to requirements (see also SAP 4 for Audits and Reviews and Form 5) (8.8);
- Management reviews – operation internal to OWM periodically conducted to assess overall PT program operations (see also SAP 4 for Audits and Reviews and Form 6) (8.9); and
- Staff or participant observations identified during any PT-program operations and/or strategic planning using a SWOT analysis (Strengths, Weaknesses, Opportunities, Threats);

1.3   Responsibility and Authority

1.3.1 OWM Laboratory Metrology Program staff members are responsible for receiving, identifying, documenting, managing, reviewing effectiveness, and archiving actions arising from PT-program tasks on the list in 1.2. Staff have a responsibility to resolve action items in a timely manner as assigned or delegated.

1.3.2 OWM Laboratory Metrology Program staff collaboratively review all inputs, observations, proposed action items, proposed resolutions, assignments, and proposed deadlines to ensure the PT program operates according to the PT program quality management system documents and to ensure that all action items are resolved in a timely manner.

1.3.3 Feedback, complaints, or appeals lead to immediate receipt notifications regarding receipt (within one week) by the receiving staff member (assigned staff member in the case that more staff are included in original communications).

1.3.4 Final resolution and approval of action item completion and assessment of effectiveness reside with the Laboratory Metrology Program Leader after suitable team reviews. Resolutions related to a complaint, inquiry, or appeal will be communicated to any interested or affected party by the Program Leader. In the case of an appeal that was raised to a higher level than the Laboratory Metrology Program, the communication may be drafted by the Laboratory Metrology Program staff with communications sent by the OWM Chief.

2   Methodology

2.1   All inputs are documented on Form 4, even if not leading to an Action Item. Exception: See item 2.3.1.

2.2   Enter the name and date of the person completing the form as well as the Source of the information to be used.

2.3   Identify the Action Type as Corrective, Risk Minimization (Preventive), Improvement, or Not Applicable as an action item.

2.3.1 Not Applicable. Feedback or inquiries submitted as PT-program feedback might simply be praise – and in that case, the item is marked as Not Applicable. Feedback is passed on to OWM management and saved electronically in a PT-program feedback directory. Responses regarding the feedback and inquiries are saved as well. Criteria should be noted as Meets Criteria or Comment. The remainder of the form should be considered, as even positive feedback might provide a useful item in the Management Review, opportunities for identifying program strengths in strategic planning SWOT analyses, promotional newsletter articles or papers and so on. Inquiries require return communications and are evaluated to determine if program documents, criteria, or reports

should be further clarified to explain some aspect of the PT program. (All feedback is not required to be documented on Form 4 but shall be saved to a PT program feedback directory. This is the only Action Type deemed Not Applicable that does not require completion of Form 4. Full analysis of feedback is required for the Management Review.)

2.3.2 Corrective Action. Nonconforming work requires corrective action, whether identified by staff observations, participant complaints, appeals, internal audits, management reviews, or any other program operation.

2.3.3 Risk Minimization (Preventive Action). Potential failures or potential corrective action are identified as risks or preventive action.

2.3.4 Improvement Action. Areas or items for improvement might include items like improving document formatting, timing on reviews, opportunities in strategic planning, audits, and management reviews.

2.3.5 Complaints, Appeals, and Staff Observations often require a full assessment before identifying the Action Type as corrective, risk minimization (preventive), or not applicable assigning subsequent priorities. In that case, come back to this identifying step after completing the item description and assessments. In the case of Internal Audits and Management Reviews, the full assessment may be required as well, but in that case see the SAP 4 for Audits and Reviews.

2.4 Identify the assessment. An assessment is made based on all PT-program quality documents and references as OK) Meets Criteria X) Does Not Meet Criteria or C) Comment. The decision regarding OK status must have program staff consensus or third party assessment. The status of an assessment as X is considered a nonconforming and requires explicitly identifying which document or reference is not complying, identifying how compliance is not met, and requires Corrective Action as noted in 2.3.2. Comments are unrelated to documented criteria or may be warnings (risk) or opportunities for improvement that are not currently nonconforming.

2.5 Prioritize the action. Actions are prioritized as 1) High, 2) Medium, or 3) Low. The following examples provide guidance, but each item must be assessed based on the overall PT program operations and output.

2.5.1 Examples of High priorities include many complaints, all appeals, all technical errors in templates for PT analysis, technical amendments required for PT final reports, and any PT-program operations that impact the quality of the program outputs (PT reports).
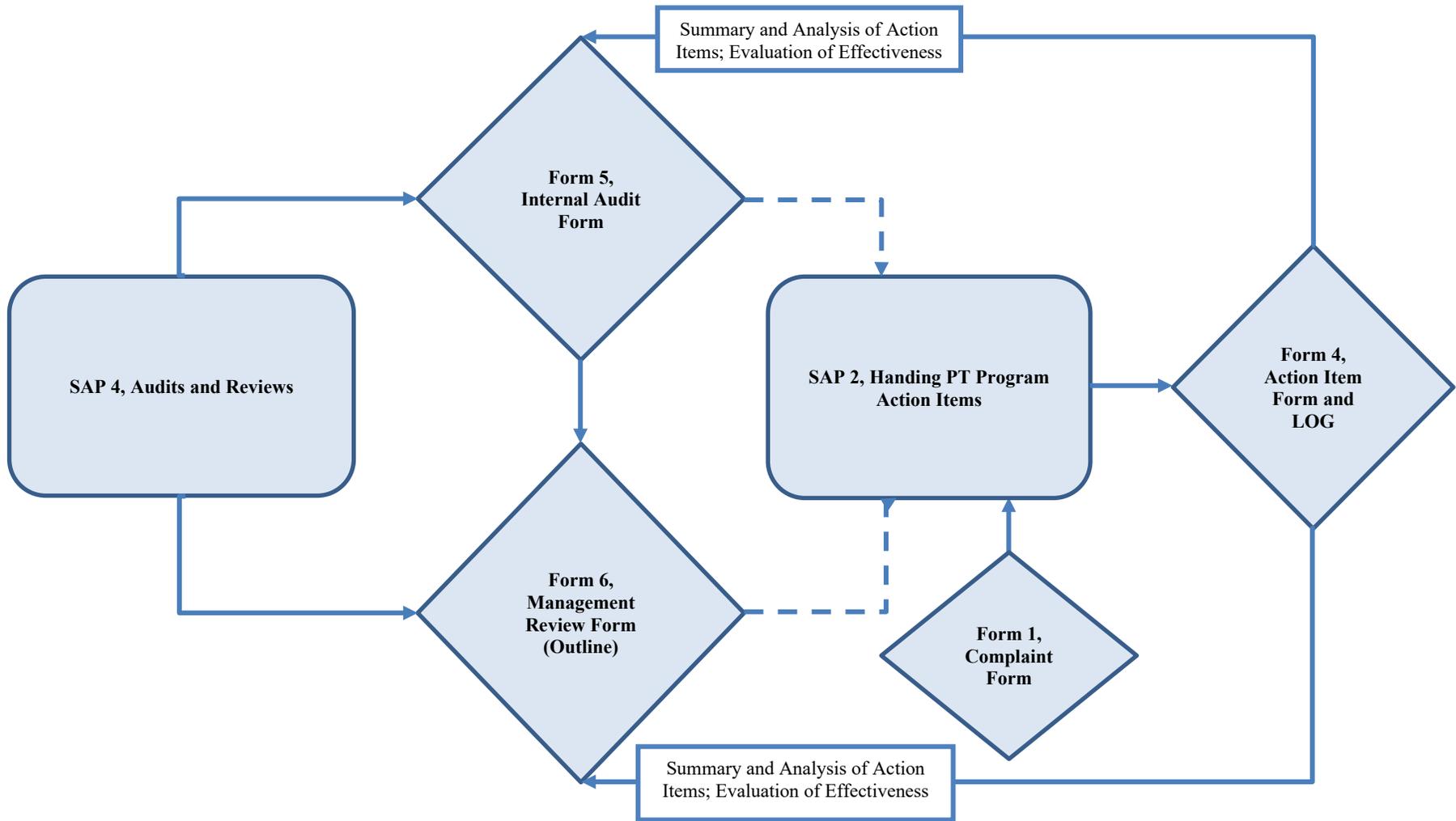
2.5.2 Examples of Medium priorities include all action items that will resolve some complaints that are related to administrative operations or risk minimization actions. Suggested updates to template documents for planning, analysis, and reporting may fall in this category.

2.5.3 Examples of Low priorities include feedback and opportunities for improvement. Improving clarity in program documents that require extensive writing and approval processes may fall in this category with interim communications and guidance included as a medium priority.

2.6 Create a Title that provides a brief description of the assessment.

2.7 Describe the Finding/Observation. Provide detailed explanations of what the issue or nonconformity is. Be clear and explicit enough so that when coming back to the issue after a period of time, it will still be clear as to the concern(s). Be sure to include additional categories from section 1.2 in this description so that they can be tagged in the action item log.

2.8 Evaluate Risk. Any required or suggested action carries some level of risk. When evaluating risk, clearly identify and document possible risks. Document mechanisms that are already in place to mitigate risk, what additional guidance, job aids or tools can be used to mitigate risk. Identify the probability that a risk will or won't occur and the implications or impact of the occurrence. Identify if other aspects of the PT program are affected and could affect the program systemically. Steps to mitigate high probability, high impact items carry the greatest priority and may require revisiting item 2.5. The level of assessment is conducted based on the level of criteria compliance and priority.

2.9 Root Cause. Consider possible causes for this item using a "five whys" or other applicable (documented) technique. Use the results of the root cause assessment to help identify possible actions after a suitable assessment has been conducted. The root cause assessment should also consider whether there are additional systemic factors to consider. The level of assessment is conducted based on the level of criteria compliance and priority.

2.10 Proposed Action. Suggest possible action that may be taken that align with corrective, risk minimization, improvement actions and associated root causes. The action to be taken must suggest steps to prevent the issue from recurring and not just "fix" the current issue. The proposed action also must assess whether any changes are needed in the quality management system or policies and procedures. Once a list of proposed actions is identified, a team meeting is conducted, or a draft form is circulated soliciting further inputs conducted among Laboratory Metrology Program staff. The purpose of the meeting or circulation of the draft is to discuss, concur, or offer alternatives to the assessment so far. Updates to the form are completed during the team meeting or draft reviews.

2.11 Assign Action Item(s) and Due Date. At this point, the action item(s) is/are assigned to a staff member which may or may not be the person who completed the form so far). Due dates are scheduled and prioritized based on the priority assigned to the action item, to ensure completing action items without undue delay and reasonable allocation of staff time and resources.

2.12 Complete the Action Item(s). Staff member works to complete the task, conducting interim reviews or obtaining additional inputs and feedback if/as needed. A due date may be flagged in the calendar system to track status, consider further evaluation, or request extensions.

2.13 Verify Action Item(s) and Date. Completion of the action item(s) or task(s) is/are verified by another staff member of the Laboratory Metrology Program, a summary of the final action(s) is documented by that staff member and the form is dated. A flag is entered into the calendar system to evaluate effectiveness of the action(s) at some time in the future, for example in 6 months, 1 year, or at the next scheduled Internal Audit or Management Review.

2.14 Evaluation of Effectiveness. At the scheduled time, an evaluation of the effectiveness of the action(s) is/are assessed as a team discussion or group evaluation (may be conducted via documented mechanisms such as email).

3 Records

3.1 Form 4, when completed, provides the full record of the associated Action Item(s). A summary of all action items is maintained in a Log for tracking the status and completion of the actions and to enable sorting for further analysis. The action item forms, and action item log are objective evidence that are analyzed and used during subsequent internal audits and management reviews.

3.1.1 Sorting action items may be completed according to multiple tags for further assessment and more than one tag may be appropriate. E.g., complaints, participant feedback, nonconforming work, and corrective action may all be identified for a given action item.

3.1.2 The regular analysis of action items may identify trends or larger systemic issues that may require PT program corrective or improvement actions. The analysis of action items should be completed and summarized as a part of the internal audit and summarized for the management review (see SAP 4, Audits and Reviews).

4   Workflow for Inputs Related to Action Items

Summary and Analysis of Action Items; Evaluation of Effectiveness

Form 5, Internal Audit Form

SAP 4, Audits and Reviews

SAP 2, Handing PT Program Action Items

Form 4, Action Item Form and LOG

Form 6, Management Review Form (Outline)

Form 1, Complaint Form

Summary and Analysis of Action Items; Evaluation of Effectiveness