

SAP 1
OWM PT Standard Administrative Procedure
for
Document and Record Management

1 Introduction

1.1 Purpose of the Procedure

The purpose of this procedure is to ensure uniform, consistent, timely and effective management of PT program documents and records and to ensure compliance with applicable reference documents. All procedures, forms, and records relevant to the PT program are kept up to date and made readily available to personnel.

1.2 Scope

The scope of this procedure is applicable to the PT program documents and records. Some of the same practices are used in maintaining documents and records for the OWM Laboratory Metrology Program, but this procedure is specific to the PT program.

1.3 Applicable Documentary References – See Appendix A, Master List

1.3.1 Files are organized on the master list based on status as Internal or External documents as well as whether they are controlled and updated by the OWM Laboratory Metrology Program staff. The latest valid date is included with each document and its full title and possible URL link for accessibility. Documents are all uniquely identified by Title.

1.3.2 All program staff have, have access to, or can obtain, the latest version of the publications on the Master List.

1.3.3 Copies of current versions may be printed for staff or PT participant use, but the official copies will be retained electronically and posted online (with the exception of Form 5 which contains copyrighted content).

1.4 Responsibility and Authority

1.4.1 All Laboratory Metrology Program staff are responsible for implementing this procedure and have authority to accept and store PT technical records, update PT program documents and templates as directed and as approved by the Program Leader, and complete and retain records related to PT program administrative operations as assigned (e.g., complaint handling, internal audits, management

reviews). The Program Leader has overall programmatic authority and responsibility to ensure compliance.

1.4.2 NIST publishes IT security protocols used by many if not all government agencies. NIST Information Technology staff are responsible for maintaining the NIST network for file storage, backup, security, retention, and recovery should the need arise. The system is maintained to ensure the integrity of documents and technical records for all staff, associates, and contractors who have network access. Staff are responsible for complying with IT security policies which is reinforced through annual training. No specialized software systems other than Excel templates are used in the OWM PT program.

2 Methodology

2.1 For Laboratory Metrology Program controlled documents and files, OWM follows the NIST “Editorial Review Board” (ERB) approval process for publication reviews and publications prior to adoption. All applicable forms and records are retained as part of the internal NIST policies and procedures related to publication approvals. All versions of the applicable PT Program documents, with the exception of Form 5 which contains copyrighted information, are posted on the NIST OWM website.

2.2 Good file-naming practices are used in the Laboratory Metrology Program following the “Electronic File Organization Tips” that are provided as guidance to State Weights and Measures Laboratories. As a minimum, the file name includes the latest revision date in the file name, the document has a meaningful title, the date (and possibly filename) is included in the footer, and the “page x of y” format is used for pagination. Documents must comply with NIST style guides and requirements for publication.

2.3 The Master List is reviewed at least every two years as part of the OWM PT Program, Internal Audit (see SAP 4, Audits and Reviews) when the document review and assessment is conducted in odd-numbered years. The list may be updated any time a staff member identifies or is alerted that a publication has been updated; when that happens, staff are assigned to review the implications for the PT program, and if appropriate, add changes and save a “track change” version of the Master List for interim use until this Standard Administrative Procedure is updated.

2.4 The following OWM-controlled files may be updated by the OWM Laboratory Metrology Program staff as interim versions and approved for use by the Program Leader and posted online, as appropriate:

2.4.1 Excepted interim updates. Appendices in NISTIR 7214 including Standard Administrative Procedures, Forms, and Excel Templates may

be updated as needed or improved, and approved by the Laboratory Metrology Program, Program Leader. Approved updates are posted online and kept with master publication documents for subsequent publications.

2.4.2 Excel templates used for calculations and analysis must be reviewed using NISTIR 8250, GLP 15, Software Quality Assurance to the extent necessary prior to posting or use. Reviewed Excel templates must be approved by the Laboratory Metrology Group, Program Leader prior to use or posting.

2.4.3 All other updates to the NISTIR 7082, Policies and Plan, and all non-excepted portions of NISTIR 7214 require obtaining approval through the ERB process as described earlier. Drafts may be approved by the Program Leader and posted for soliciting comments from PT Administration Teams and affected PT participants.

2.5 PT Records are collected throughout the year as each Regional Measurement Assurance Program meeting is held and as the PTs are being conducted. Records are filed as noted in Section 3. Staff receiving information will file materials and files within the designated area of the PT Program records.

2.6 PT program operational activity records are completed on PT program forms and retained as records according to the applicable procedure.

2.7 Files are maintained in the OWM network chronologically and the latest version will have the most current date. Archived versions may be noted with “archive” at the beginning of the directory name if within a directory.

3 Records

3.1 Forms – There are no applicable forms published with this Standard Administrative Procedure for document approvals. OWM follows the NIST “Editorial Review Board” (ERB) approval process for publication reviews and publications prior to adoption. All applicable forms and records are retained as part of the internal NIST policies and procedures. As internal or external publications are included in the Master List and this Administrative Procedure or Appendix A are published, updated, and posted, the versions on the Master List are automatically adopted.

3.2 PT Operational (Administrative) Records and Completed Forms)

Ongoing quality management system records and forms from feedback, complaints, appeals, internal audits, management reviews, action items, and strategic planning are retained with the PT quality management system records

and tracked chronologically. Some records (e.g., a completed complaint form) may be duplicated with a specific PT if it is applicable to the technical operation or analysis of that PT. A master log of action items may cross over multiple annual cycles and be retained at a higher level in the filing structure so that it is readily available. Official files are retained electronically. Scanned files retained with records must be legible.

3.3 PT Technical Records

3.3.1 Records retained by OWM are maintained on the NIST OWM network files that are regularly backed up and protected by NIST Information Technology staff. Directories are organized by region, year, and name of the PT so information is organized and readily available to all OWM Laboratory Metrology Program staff members.

3.3.2 PT Plans. Draft, approved, updated, and final PT plans files are maintained with OWM PT records. The draft PT plan contains all information about the standard to be calibrated and instructions for care, handling, equilibration, shipping, and calibration. The PT Coordinator may keep the approved and updated versions as they are monitoring and controlling the operation of the PT. Because the final PT report introduction pages are based on this file, the must be kept up to date as the PT commences and is completed. OWM reviews and approves the draft PT plans and the final PT plans that are used to generate PT draft and Final Reports. Regional PT plans are maintained by OWM and by the Regional PT Coordinator. State laboratories may also submit copies of their regional PT Plans as part of their annual OWM recognition submissions.

3.3.3 PT Analyses. The PT Analysis Template is used by the PT Analyst or NIST staff to analyze submitted PT data according to appropriate procedures. The PT Analyst may keep NIST staff copied on interim drafts or communications as a PT progresses. The PT Analyst may use the interim Summary Report worksheet to share interim E_n and P_n results with participants to monitor shipping plans or immediate corrective actions if needed. The final PT Analysis will be approved by NIST OWM and used to generate the summary report, tables, and graphs for the PT Final Report. All copies of the PT Analysis files or Final Reports are maintained with applicable OWM PT records.

3.3.4 PT Final Reports – Draft, Final, Amended, and Appended Reports are retained in applicable OWM electronic directories and distributed to participants to 1) review draft data entry for accuracy and 2) review final analysis and assessments (most often presented at the Regional Measurement Assurance Program meetings and provided electronically prior to or at the meetings). In the event that errors or discrepancies are

identified, OWM maintains records of the investigation and amends the PT Final Report if appropriate. An Amended PT Final Report is maintained with the rest of the PT records.

3.3.5 PT Materials Submitted by Participants. Copies of all requested data, forms, communications, calibration certificates, amended calibration certificates, and interim records of corrected action identified during the PT are retained with the OWM PT records.

3.4 PT Standard Artifact Records – Inventory and Calibration Certificate records are retained for standards used in PTs as long as the PT standard artifacts are in service.

3.5 PT Record Retention – All files are retained in the PT records. In the event that NIST retention policies intervene with storage of records, the longer of either the latest ten years or all PTs related to a specific standard/artifact that remains in use will be retained. For example, the 100 gallon prover has been in circulation consistently since 1989 and all records will be retained for that standard artifact as well as PTs continuously conducted with that standard since that time. In cases where standards are no longer available, records will be retained for at least ten years.

4 Appendix A – Master List