

NISTIR 7214

**Office of Weights and Measures
Quality Manual
for
Proficiency Testing and
Interlaboratory Comparisons**

Georgia L. Harris
Second Author
Third Author
Fourth Author
Etc.

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Office of Weights and Measures
Physical Measurement Laboratory

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U.S. Department of Commerce
Gina M. Raimondo, Secretary

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*Laurie E. Locascio, Under Secretary of Commerce for Standards and Technology &
Director, National Institute of Standards and Technology*

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Preface

NISTIR 7214 is intended to provide the quality management system for ensuring the validity of measurement results and uncertainties as a part of operating a PT program for Proficiency Tests (PT) and Interlaboratory Comparisons (ILC) developed, managed, and overseen by the NIST Office of Weights and Measures (OWM). This 2023 edition has been updated to ensure compliance with NIST Handbook 143, State Weights and Measures Laboratories Program Handbook, 7th Edition, 2023, current policies of the International Laboratory Accreditation Cooperation (ILAC) related to traceability, uncertainty, and proficiency testing, and compliance with ISO/IEC 17043 (TBD 2022-04), Conformity assessment — General Requirements for the Competence of Proficiency Testing Providers, and International Standard, ISO 13528, Third edition, 2022-08, Statistical Methods for use in Proficiency Testing by Interlaboratory Comparison.

Reviewers of NISTIR 7214, 2023 edition include the following:

- Georgia L. Harris, NIST/Office of Weights and Measures
-

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- <https://nvlpubs.nist.gov/nistpubs/hb/2023/NISTIR.7217> (TBD links removed)

Publication History

The first edition of this document was published in 2005 and was prepared by Jeff C. Gust (Quametec Corp. at the time, under contract) in collaboration with Georgia L. Harris, in the NIST Office of Weights and Measures (OWM) to enable State Weights and Measures Laboratories to comply with criteria for proficiency testing as noted in NIST Handbook 143 and as needed for accreditation programs. The 2005 quality manual was based on ISO/IEC Guide 43 and NCSLI Recommended Practice 15 to formalize “round robin” practices within OWM that began in the 1980s. Original reviewers of the document included:

- Richard Cote, New Hampshire Department of Agriculture
- Doug Faison, NIST/National Voluntary Laboratory Accreditation Program
- Ken Fraley, Oklahoma Bureau of Standards
- Elizabeth Gentry, Oklahoma Bureau of Standards
- Tom Hale, Pennsylvania General Services Administration
- Georgia L. Harris, NIST/Office of Weights and Measures
- Carol Hockert, Minnesota Department of Commerce, Weights and Measures Division
- Van Hyder, NC Department of Agriculture & Consumer Services, Standards Laboratory
- G. Diane Lee, NIST/Office of Weights and Measures

- Val Miller, NIST/Office of Weights and Measures
- Steve Schultz, Nevada Department of Agriculture, Bureau of Weights and Measures

This edition (2023) cancels and replaces edition (NISTIR 7214:2005) and has been technically updated. The main changes compared to the previous edition are as follows:

- harmonization with the revision of ISO/IEC 17043, including technical requirements and structure; and
- harmonization with the revision of ISO 13528 in terms of terminology and statistical analysis.

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<https://www.surveymonkey.com/s/customer-satisfaction-pub>
or by email to owm@nist.gov

Abstract

NISTIR 7214, Office of Weights and Measures (OWM) Quality Manual for Proficiency Testing and Interlaboratory Comparisons, provides the management system for the planning, implementation, analysis, ensuring the validity, and reporting of measurement results and uncertainties for Proficiency Tests (PT) and Interlaboratory Comparisons (ILC) conducted under the auspices of OWM. PTs and ILCs in the OWM program are coordinated with and for State Weights and Measures Laboratories and other members of the Regional Measurement Assurance Programs (RMAPs) supported by NIST OWM. This document is used in conduction with OWM policies as published in NISTIR 7082, Proficiency Test Policy Plan, **January 2018, Draft November 2023**. Appendices in NISTIR 7214 include PT Standard Operating Procedures (SOPs), Good Laboratory Practices (GLPs), Standard Administrative Procedures (SAPs) and references to Excel spreadsheet templates used for PT planning, PT analysis and PT reporting which are validated and published online for use in the OWM PT program.

Key words

Accreditation; interlaboratory comparisons; ISO 13528; ISO/IEC 17043; legal metrology; proficiency test; quality manual; recognition; weights and measures.

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1. Scope

This document is the Quality Manual for the NIST Office of Weights and Measures (OWM), Laboratory Metrology Program, proficiency testing (PT) activities – hereafter called the OWM PT program. OWM PT activities reinforce laboratory application of procedures that are covered in OWM training seminars, measure and assess levels of procedure compliance in participating laboratories, and support laboratory recognition and accreditation activities as required in ISO/IEC 17025:2017, section 7.7 and NIST Handbook 143, State Weights and Measures Laboratories Program Handbook. The OWM PT program is limited in scope to calibrations that support legal metrology in U.S. weights and measures laboratories and other U.S. calibration laboratories where staff have completed OWM training and are also members of and regularly participate in the Regional Measurement Assurance Programs (RMAPs) ongoing training and development sessions. PT program services may be provided upon request to other NIST programs such as the National Voluntary Laboratory Accreditation Program (NVLAP) provided resources are available. Participation in OWM PT program activities is not available to laboratories outside the narrow scope described here.

Additional policies and plans associated with the OWM PT program are published in NISTIR 7082, Proficiency Test Policy and Plan for State Weights and Measures Laboratories (current edition). [Appendix A](#) summarizes additional procedures and resource materials associated with the operation of the OWM PT Quality Management System in Table 1.

OWM staff may support additional PT activities of accreditation bodies (AB) such as the National Voluntary Laboratory Accreditation Program (NVLAP), but in those cases are usually obligated to follow the AB and ILAC policies. In the absence of alternative instructions or policies, the policies and procedures of this manual will apply to all PT activities conducted by the OWM Laboratory Metrology Program.

2. Normative References (*mandatory*)

The following documents are referred to in the text in such a way that some or all their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies. A master list of all applicable references for the OWM PT program quality management system is maintained in a single document and is reviewed at least once every two years with updates as changes are identified (major mandatory documents are duplicated here). See SAP 1, Standard Administrative Procedure for Document and Record Management, Appendix, Master Document List for the OWM PT program. The Master Document List includes all applicable internal and external reference documents and notes the latest valid edition used in the OWM PT program.

- ISO/IEC Guide 99, International vocabulary of metrology — Basic and general concepts and associated terms (VIM). Latest version is also known as: JCGM 200:2012.
- ISO 13528, Third edition, 2022-08, Statistical methods for use in proficiency testing by interlaboratory comparison.
- ISO/IEC 17000, Conformity assessment — Vocabulary and general principles.

- ISO/IEC 17025:2017, General requirements for the competence of testing and calibration laboratories.
- ISO/IEC DIS 17043, 2022-04, Conformity assessment - General requirements for the competence of proficiency testing providers.
- NIST Handbook 143, State Weights and Measures Laboratories Program Handbook, 2023.
- NISTIR 7082, 2023, Proficiency Test Policy and Plan for State Weights and Measures Laboratories.

3. Terms and Definitions

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

- ISO Online browsing platform: available at <https://www.iso.org/obp>; and
- IEC Electropedia: available at <http://www.electropedia.org/>.

For the purposes of this document, the terms and definitions given in ISO/IEC Guide 99 (JCGM 200:2012), NIST Handbook 143, State Weights and Measures Laboratories, Program Handbook and the following apply. Sources and edits are provided in definition brackets. Dates are given in this section to identify specific source documents used for definitions.

- *Assigned value*: value attributed to a particular property of a proficiency test item. [Source: ISO 13528:2022, 3.3]
- *Confidentiality*: property that information is not made available or disclosed to unauthorized individuals, entities, or processes. OWM PTs are not confidential, but PT data and PT reports have usage restrictions. PT reports are available through the Freedom of Information Act.
- *Consensus value*: value derived from a collection of results in an interlaboratory comparison; Note 1 to entry: The phrase ‘consensus value’ is typically used to describe estimates of location and dispersion derived from participant results in a proficiency testing round of a proficiency testing scheme but may also be used to refer to values derived from results of a specified subset of such results or, for example, from a number of expert laboratories. [Source: ISO 13528:2022, 3.11, ISO/IEC 17043:2022 modified – Changed "test" to "testing"].
- *Customer*: organization or individual for which a proficiency testing scheme is provided through a contractual arrangement; Note 1 to entry: The term ‘client’ is an alternative term for ‘customer’ used in parts of this document and these terms are regarded as having the same definition. [Source: ISO/IEC 17043:2022]. OWM Note: OWM does not maintain contractual agreements, charge fees for services, nor does it maintain customers or clients as a part of its PT program; customers or clients in the context of this management system are called participants; see *participants*.
- *Impartiality*: presence of objectivity. Note 1 to entry: Objectivity means that conflicts of interest do not exist, or are resolved so as not to adversely influence subsequent activities of the laboratory. Note 2 to entry: Other terms that are useful in conveying the element of impartiality include “freedom from conflict of interests”,

- “freedom from bias”, “lack of prejudice”, “neutrality”, “fairness”, “open-mindedness”, “evenhandedness”, “detachment”, “balance”.
- *Interlaboratory comparison*: design, performance and evaluation of measurements or tests on the same or similar items by two or more laboratories in accordance with predetermined conditions [Source: ISO 13528:2022, 3.1; ISO/IEC DIS 17043:2022 modified organization to design. The Notes have been added]; Note 1 to entry: The term ‘laboratories’ is used in this document to cover all organizations that provide information on items based on experimental observation, including measurement, testing, calibration, examination, sampling, and inspection; Note 2 to entry: the term ‘measurements or tests’ is used throughout this document to apply to any activities undertaken by the proficiency testing participants that are subject to the proficiency testing, whether quantitative, qualitative or interpretative, unless otherwise qualified. Note 3 to entry: Interlaboratory comparisons that involved measurements convey more insight regarding performance when measurement uncertainty is considered. OWM Note: Inclusion of measurement uncertainties with calibration results is mandatory as a part of the OWM PT program.
 - *Outlier*: member of a set of values which is inconsistent with other members of that set; Note 1 to entry: An outlier can arise by chance from the expected population, originate from a different population, or be the result of an incorrect recording or other gross error. Note 2 to entry: Many proficiency testing schemes use the term outlier to designate a result that generates an action signal. However, this is not the intended use of the term. While outliers will usually generate action signals, it is possible to have action signals from results that are not outliers. [Source: ISO 13528:2022, 3.12; ISO/IEC DIS 17043 modified to change the word “blunder” to “gross error” in Note 1 to entry. Original source noted in ISO 13528:2022: ISO 5725-1:1994, with notes added].
 - *Participant (PT participant)*: person or organization undertakes activities related to proficiency testing and submits their results for performance evaluation by the proficiency testing provider. [Source: ISO/IEC 17043:2022, 3.6].
 - *Proficiency testing (PT)*: evaluation of participant performance against pre-established criteria by means of interlaboratory comparisons; Note 1 to entry: Further information regarding design of various proficiency testing schemes is provided in OWM procedures. [Source: ISO/IEC DIS 17043:2022, 3.7, modified to specify OWM procedures in lieu of Annex references].
 - *Proficiency testing administrative team (PT administrative team)*: the collection of OWM Laboratory Metrology Program staff, and PT volunteers such as PT regional coordinators, PT coordinators, PT analysts, and any other NIST technical staff engaged in the planning and/or evaluation of a PT in the OWM PT program.
 - *Proficiency testing analyst (PT analyst)*: Assigned person who is responsible for handling data related activities for the proficiency test, including initial review, data entry in analysis tools, initial assessments and selection of reference values, and recommendations to OWM regarding final evaluation and assessment.
 - *Proficiency testing coordinator (PT coordinator)*: Assigned person who is responsible for implementation of the PT, including preparation and submission of the PT plan for participant review and OWM approvals, managing the flow and

oversight of the schedule, shipping, intervening on problems that arise to notify OWM and ensure completion of the PT round in a timely manner.

- *Proficiency testing item (PT item)*: sample, product, artifact, reference material, piece of equipment, measurement standard, object, image, data set or other information used for proficiency testing [Source: ISO/IEC 17043:2022, 3.8].
- *Proficiency testing provider (PT provider)*: organization which takes responsibility for all activities in the development and operation of a proficiency testing scheme [Source: ISO/IEC DIS 17043:2022]. In this document the NIST Office of Weights and Measures (OWM) is the PT provider.
- *Proficiency testing round (PT round)*: single complete sequence of proficiency testing, including the evaluation and reporting of participants' performance [Source: ISO/IEC DIS 17043:2022, 3.10].
- *Proficiency testing scheme (PT scheme)*: proficiency testing designed and operated in one or more proficiency testing rounds for a specified area of measurement, testing, calibration, examination, sampling, or inspection; Note 1 to entry: A proficiency testing scheme might cover a particular type of activity or a number of activity types within the same area. [Source: ISO/IEC DIS 17043:2022, 3.11].
- *Standard deviation for proficiency assessment*: measure of dispersion used in the evaluation of results of proficiency testing, based on the available information; Note 1 to entry: This can be interpreted as the population standard deviation of results from a hypothetical population of participants performing exactly in accordance with requirements; Note 2 to entry: The standard deviation for proficiency assessment applies only to ratio and interval scale results; Note 3 to entry: Not all proficiency testing schemes evaluate performance based on the dispersion of results. [ISO 13528:2022, 3.4, added “based on the available information” and notes to entries are edited in ISO/IEC DIS 17043:2022].

4. General Requirements

4.1. Impartiality

- 4.1.1. OWM PT activities are undertaken to ensure impartial analysis and reporting for laboratories and staff who are authorized to participate. Participation in the OWM program is restricted based on the Scope described earlier and the PT Policy Plan.
- 4.1.2. The OWM PT program is structured and managed to safeguard impartiality. NIST policies and performance plans specifically address impartiality, conflict of interest, ethics, and scientific integrity.
- 4.1.3. OWM is responsible for the impartiality of its PT activities and does not allow commercial, financial, or other pressures to compromise its impartiality.
- 4.1.4. OWM monitors its activities and its relationships to identify threats to its impartiality. This monitoring includes the relationships of its personnel, PT coordinators, PT analysts, and participants. Participants, PT coordinators, and PT analysts are generally required to comply with impartiality policies and requirements as a part of recognition or accreditation to ISO/IEC 17025; associated laboratory measurement

activities extend to proficiency testing. Annual strategic planning reviews strengths, weaknesses, opportunities, and threats (SWOT analysis) of the PT program.

- 4.1.5. If any threats to impartiality are identified, the effects are eliminated or minimized so that impartiality is not compromised. Actions to eliminate or minimize impartiality are taken as soon as possible when identified. Any complaints to impartiality are addressed as soon as practical.
- 4.1.6. OWM maintains management commitment to impartiality through adoption of this publication and policies, through regular program evaluations, and through accepting program feedback and complaints. Requests or opportunities for program feedback is specified on each PT final report.

Applicable Forms, Policies and References:

- NISTIR 7082, Proficiency Test Policy Plan. Additional policies related to impartiality and participant restrictions are published in the OWM PT Policy and Plan
- Form 1: OWM PT Feedback and Inquiry and Complaint Form
- SAP 2, Standard Administrative Procedure for Handling PT-Related Action Items

4.2. Confidentiality – Participation Requires Waiver of Confidentiality

- 4.2.1. OWM is responsible for the management of all information obtained or created during the performance of PT activities. OWM informs all participants regarding any information it intends to place in the public domain, keeping in mind that all publications and documents within the NIST OWM are subject to the Freedom of Information Act (FOIA) or other related requests. No assurances of confidentiality are maintained in the OWM program and participants are advised of this policy as part of the published OWM policies. OWM does not distribute information or PT Reports beyond the participants, participant laboratories, or accreditation bodies without formal requests or notification to participants and participant laboratories. PT data and reports are considered confidential to the extent possible, other than specific distribution as noted, with the exception of written public requests.
- 4.2.2. Information about participants from a source other than the participant (e.g., complainant or regulator) is kept confidential by OWM whenever possible. The identity of the source is kept confidential by OWM and is not shared with the participant, unless agreed by the source other than through a FOIA request.
- 4.2.3. OWM PT program staff, including any participants, contractors, personnel of external bodies, PT coordinators, PT analysts, or persons acting on the behalf of the OWM PT program, record all information obtained or created during the performance of the PT activities as a part of the official PT records and maintained by OWM. Information regularly included in the PT report such as measurement results, uncertainties, other calibration certificate data, planned reporting data, and possible corrective actions and improvement actions as reported by participants are included in the final reports. Sharing of interim data, falsification of data, and collusion is expressly prohibited by

policy. Findings of collusion, falsification, or significant participant operational failures are handled with standard administrative procedures.

- 4.2.4. The identity of participants in a OWM PT rounds or PT schemes is not confidential (see OWM policies) and all participants are openly reported within each PT report. According to the OWM policies, participants in OWM PTs waive all expectations of confidentiality as a condition of participation.
- 4.2.5. Draft PT reports or draft data entry summaries are distributed to NIST staff and participants for review prior to finalizing reports. Final reports are distributed to participants and members of the applicable Regional Measurement Assurance Program or national group(s). Final PT reports include a statement regarding distribution restrictions. Participants are limited to sharing PT reports with their laboratory management, laboratory customers (upon request), and their associated accreditation or legal oversight bodies. Restrictions regarding use of PT reports in “marketing,” “publication,” or sharing results of another laboratory are prohibited as part of the OWM PT participation policies without the express approval of OWM and all participants. Complaints regarding improper sharing of reports may be submitted to the Office of Weights and Measures.

Applicable Policies and References:

- NISTIR 7082, Proficiency Test Policy Plan. OWM policies regarding openness and confidentiality as well as participant open communication rights and waivers are published as part of the OWM PT Policy Plan.
- PT Plan Template (Excel file). The planning file transfers planning information to the PT cover reports and includes language regarding confidentiality and distribution restrictions.
- SAP 5, Standard Administrative Procedure for Handling PT Related Collusion, Falsification, and Participant Operational Failures
- Form 1: OWM PT Feedback and Inquiry and Complaint Form
- Form 4, OWM PT Action Form

5. Structural Requirements

5.1. Legal Entity

The Office of Weights and Measures (OWM) is an office within the National Institute of Standards and Technology, an official government agency. NOTE: According to ISO/IEC 17043, for the purposes of compliance, a governmental PT provider is deemed to be a legal entity on the basis of its governmental status.

5.2. Operational Responsibilities

The OWM Laboratory Metrology Program and Program Leader maintain overall oversight and responsibility for its PT program and associated activities, including compliance to the documented policies, procedures, and this quality management system. Responsibilities are carried out with additional OWM Laboratory Metrology Program staff in cooperation and

collaboration with PT Administrative Teams comprised of members of the Regional Measurement Assurance Programs (RMAPs) as assigned during PT planning for each proficiency test.

Feedback or complaints regarding any aspect of the PT program or a specific PT report may be submitted by any staff member, a member of the PT Administrative Team, or a PT Participant using official forms. Appeals regarding decisions made by OWM program staff, PT coordinators, or PT analysts must be submitted in writing and will be considered and resolved by delegated staff members, with appeals raised to the OWM Laboratory Metrology Program, Program Leader. Appeals to decisions made by the Laboratory Metrology Program, Program Leader can be directed in writing to the Chief of the Office of Weights and Measures.

5.3. PT Schemes and Procedures

OWM defines and documents the PT rounds or PT schemes for which it conforms as integrated within this document and associated procedures. OWM PT rounds or PT schemes and approaches are documented in OWM PT standard operating procedures and are integrated in the PT Plan template document(s). Procedures are designed and implemented to ensure conformity with this quality management system document.

5.4. PT Operations

OWM carries out PT activities in such a way so as to meet the requirements of this document and address the requirements of the participants, regulatory authorities, and organizations providing recognition and accreditation. These activities include PT activities performed in its permanent facilities, at sites away from its permanent facilities, and at sites maintained by NIST OWM and the PT Administrative Teams. PT participant selection and approval processes help ensure PT program integrity and quality to the extent possible.

5.5. OWM Management and Staff

- a) define its organization and management structure and its place within the organizational structure of NIST. Relationships between OWM management, technical operations, and support services are defined by the NIST Administrative Manual, OWM operations, the OWM organization chart, and individual position descriptions and performance plans. See the NIST and OWM organizational chart for relationships;
- b) specify the responsibility, authority, and interrelationships of all personnel who manage, perform, or verify work affecting the result of its PT activities, including staff, the PT Administrative Team comprised of PT coordinators, PT analysts, and PT participants in documented OWM PT policies. See the national organization structure of the PT program and its operations in the national PT program organizational chart. Responsibilities and authorities of all parties in the PT Administrative Teams and PT participants are defined in the OWM PT Standard Operating Procedures;
- c) documents its procedures to the extent necessary to ensure the consistent application and validity of its PT activities.

5.6. OWM Staff and PT Administrative Team Authority and Resources

OWM has personnel who, irrespective of other responsibilities, have the authority and resources needed to carry out their duties through documented policies and allocated time defined in performance plans, including:

- a) implementation, maintenance, and improvement of the PT management system through periodic audits, reviews, strategic planning, and solicitation of feedback;
- d) identification of deviations from the PT management system or from the procedures for performing PT activities through normal PT operations and through internal auditing;
- e) initiation of actions to prevent or minimize such deviations through procedures for handling action items;
- f) reporting to management on performance of the PT management system and any need for improvement as identified during review of normal PT operations, complaints, internal audits, management reviews, and strategic planning;
- g) ensuring the effectiveness of PT activities.

Each Regional Measurement Assurance Program (RMAP) has a Regional Coordinator, and each PT has an Administrative Team consisting of a PT Coordinator, PT Analyst, and possible mentors and observers who are assigned during the PT planning. Each of these persons is provided the authority to initiate, request, or support as delegated the actions on the list in this section.

5.7. OWM, Laboratory Metrology Program management and the PT Administrative Team ensure that:

- a) communication takes place regarding the effectiveness of the management system and the importance of meeting the requirements of participants, customers, regulatory authorities, and organizations providing recognition or accreditation through training and regular communication with the PT Administrative Team and PT participants;
- h) the integrity of the PT management system is maintained when changes to the management system are planned and implemented through regular document reviews, internal audits to identify and ensure compliance, and strategic evaluations to identify need for changes and improvements.

Applicable Policies and References:

- Office of Weights and Measures Organization Chart (posted online, managed by OWM office staff and chief)
- National PT program Organization Chart (posted online, managed by the Laboratory Metrology Program)
- NISTIR 7082, Proficiency Test Policy and Plan. OWM policies, roles, responsibilities, and authorities for PT coordinators, PT analysts, and PT participants are published as part of the OWM PT Policy and Plan and as a part of the PT Standard Operating Procedures. They are also reviewed as part of the Regional Measurement Assurance Program PT planning sessions

- PT Standard Operating Procedure (SOP) 1 for OWM PT Planning, Operating, Analyzing, and Reporting of PT Results (OWM PT)
- PT Standard Operating Procedure 2 for Operating a Mini-Measurement Assurance Program (Mini-MAP)
- SAP 1, Standard Administrative Procedure for Document and Record Management for OWM PT program
- SAP 2, Standard Administrative Procedure for Handling PT-Related Action Items
- SAP 4, Standard Administrative Procedure for PT program Audits and Reviews
- Form 1: OWM PT Feedback and Inquiry and Complaint Form
- Form 4, OWM PT Action Form – used to implement and track actions related to complaints
- Form 5, OWM PT Internal Audit
- Form 6, OWM PT program Management Review Outline

6. Resource Requirements

6.1. General

6.1.1. OWM has access to the personnel, facilities, equipment, standards, systems, and support services necessary to manage and perform its PT activities. OWM operates the PT program in cooperation and collaboration with designated PT Administrative Teams assigned for each proficiency test either nationally or through the Regional Measurement Assurance Programs (RMAPs):

- Caribbean Measurement Assurance Program (CaMAP) (inactive);
- MidAmerica Measurement Assurance Program (MidMAP);
- Northeast Measurement Assurance Program (NEMAP);
- Southeast Measurement Assurance Program (SEMAP);
- Southwest Assurance Program (SWAP); and
- Western Regional Assurance Program (WRAP).

6.1.2. Testing and calibration activities conducted under the responsibility of OWM, related to PT item characterization or for assessing homogeneity and stability, is conducted in accordance with the relevant requirements of ISO/IEC 17025 and OWM PT procedures. Characterization of PT standards and artifacts, including suitability and metrological traceability, is discussed as a part of PT planning. Stability of the standards is considered during planning and further evaluated during PT analysis. Stable, well characterized artifacts are selected for PTs. Analysis methods consider observed trends, damage, or instability of standards.

Homogeneity of samples is generally not an applicable characterization for the physical type of standards used in the scope of this PT program (see policies and plan for OWM PT program scope).

6.1.3. OWM does not conduct PTs for reference materials, standard reference materials, or certified reference materials. Therefore, compliance with ISO 17034, General Requirements for the Competence of Reference Material Producers is not applicable.

6.2. Personnel

- 6.2.1. OWM has access to a sufficient number of competent personnel to perform its PT activities for which they are responsible and to evaluate the significance of deviations. Primary responsibility for the validity of all issued PT reports is maintained by the OWM Laboratory Metrology Program. OWM makes use of and develops voluntary PT Administrative Teams made up of technical experts as PT Regional Coordinators, PT Coordinators, PT Analysts, and PT Participants through training and mentoring efforts where these trained and experienced volunteers take on additional roles – all having OWM Laboratory Metrology Program oversight.
- 6.2.2. OWM has a process for managing competence of its staff and volunteers. NIST policies, job descriptions, and performance plans are written to ensure accuracy of PT draft and final reports. OWM oversees volunteers for each PT round or PT scheme to ensure competency, ongoing training, mentoring, and development.
- 6.2.3. All personnel of the OWM PT program, either staff or volunteers, who could influence the PT activities act impartially, are competent, and work in accordance with OWM's management system. Impartiality and competence are overseen by OWM Laboratory Metrology Program staff. Identification of concerns regarding impartiality or competence are brought to the attention of the OWM Laboratory Metrology Program Leader for follow-up and action.
- 6.2.4. OWM has documented information demonstrating competence of its personnel, that can influence the results of PT activities, including requirements for education, qualification, training, technical knowledge, skills, and experience. In addition to NIST hiring practices, OWM publishes training requirements for State weights and measures laboratories that must be met prior to participating in OWM PTs, and in addition to training, successful completion of previous PTs is required prior to coordinating, analyzing, or reporting on any specific measurement parameters.
- 6.2.5. OWM authorizes personnel and volunteers in the PT Administrative Team to perform specific activities within PT rounds or PT schemes, including but not limited to the following responsibilities:
 - a) plan PT rounds or PT schemes in the PT draft plan;
 - b) assess data/information to determine stability and homogeneity, if applicable, as well as assigned values and associated uncertainties of the characteristics of the PT item (during planning, when possible, possibly during analysis);
 - c) prepare, handle, and distribute PT standards according to appropriate handling and shipping procedures for each type of PT standards;
 - d) operate the data processing system including data entry and PT analysis using OWM PT analysis tools;
 - e) conduct statistical analysis using the OWM PT procedures and analysis tools;
 - f) draft the evaluation of the PT participant performance;
 - g) give opinions and interpretations as well as advice to the participants; and
 - h) issue draft PT reports.

All responsibilities noted on this list are included, as applicable within each documented PT Plan, PT Analysis, and PT Final Report. Final approvals for items on this list are only made by OWM Laboratory Metrology Program staff.

- 6.2.6. OWM management communicates to 1) OWM staff their duties, responsibilities, and authorities through job descriptions, work assignments, performance plans 2) PT Administrative Team members, PT coordinators, PT analysts, and PT participants, their duties, responsibilities, and authorities as part of the OWM published policies.

Applicable Policies and References:

- Office of Weights and Measures Organization Chart (posted online, managed by OWM office staff and chief)
- National PT program Organization Chart (posted online, managed by the Laboratory Metrology Program)
- NISTIR 7082, Proficiency Test Policy and Plan. OWM policies, roles, responsibilities, and authorities for PT coordinators, PT analysts, and PT participants are published as part of the OWM PT Policy and Plan and as a part of the PT Standard Operating Procedures. They are also reviewed as part of the Regional Measurement Assurance Program PT planning sessions
- PT Standard Operating Procedure (SOP) 1 for OWM PT Planning, Operating, Analyzing, and Reporting of PT Results (OWM PT)
- PT Standard Operating Procedure 2 for Operating a Mini-Measurement Assurance Program (Mini-MAP)
- PT Plan Template (Excel file). The planning file lists PT Administrative Team and PT participants.
- Good Laboratory Practice for Proficiency Test Follow-ups with Form

6.3. Facilities and Environmental Conditions

- 6.3.1. OWM ensures that there is appropriate accommodation for the operation of the PT scheme. This includes facilities and equipment for PT item handling, calibration, testing, storage, dispatch, data processing, communications, and retrieval of documents and records. OWM is not involved with manufacturing PT items. OWM specifies facilities and environmental conditions in published procedures that are commonly adopted and used by most PT participants and in compliance to ISO/IEC 17025. Environmental requirements are discussed during PT planning.
- 6.3.2. OWM ensures that the environmental conditions do not compromise the PT activities by specifying applicable environmental conditions during PT planning through selecting appropriate procedures. Particular care is taken when operations are undertaken at sites away from OWM's permanent facilities or participant laboratories. OWM does not use external providers and all PT participants are required to comply with ISO/IEC 17025 facility and environmental requirements. Technical requirements for accommodation and environmental conditions that can affect the PT are documented during PT planning or are explicitly documented in the

applicable/specified PT Standard Operating Procedure (SOP) designated in the PT Plan.

- 6.3.3. Access control to and use of areas affecting the PT activities is managed. OWM determines the extent of access control for its laboratories based on its particular circumstances. PT standards are maintained in secure locations within NIST. During the operation of a PT, each participant facility is expected to comply with environmental conditions and security as required by ISO/IEC 17025 and recognition or accreditation requirements.
- 6.3.4. OWM identifies environmental conditions that can influence the validity of the PT items and any testing and calibration carried out, including conditions that are required by relevant specifications and measurement procedures. OWM controls and monitors these conditions and records all relevant monitoring activities when participating in PTs. PT participants are required to monitor relevant conditions as a part of ISO/IEC 17025 compliance. Relevant PT activities are to be halted in any laboratory when environmental conditions jeopardize the operations of the PT scheme. Similar requirements are published in procedures designated during PT planning. Additional environmental ranges and equilibration requirements are including in the PT Plan template.

NOTE Conditions can include, for example, biological sterility, dust, electromagnetic disturbances, radiation, illumination (light), humidity, electrical supply, temperature, and sound and vibrations levels, as appropriate to the technical activities concerned.

- 6.3.5. Within OWM, there is effective separation between neighboring areas in which there are incompatible activities. Action is required to be taken by participant laboratories to ensure ongoing stability, suitable care, and handling, and to prevent cross-contamination with requirements of participant compliance to ISO/IEC 17025.

Applicable Policies and References:

- SAP 1, Document and Record Management, Appendix Master Document List. See Table 2. NIST OWM Documents – Related to Calibrations and PT Analyses, where PT Standard Operating Procedures provide examples of facility and environmental requirements within procedures designated during PT planning.

6.4. External Products and Services

- 6.4.1. OWM does not engage external service providers for the following activities:
 - a) the planning of PT rounds or PT schemes;
 - b) the evaluation of performance; or
 - c) the final authorization of reports.

- 6.4.2. OWM uses volunteer technical experts to make up a PT Administrative Team for each PT consisting of PT coordinators, PT analysts (may be the same person as the PT coordinator), and PT participants as a part of developing a 4-year PT Plan for each Regional Measurement Assurance Program (RMAP) group, for developing, and for implementing individual PT plans and schemes whether regional or national. OWM Laboratory Metrology Program staff maintain approval for the selection of the PT Administrative Team and maintain oversight for all members and activities related to PT operations. Members identified in this section are considered integral to the operation of and are not considered “external” to the OWM PT program.
- 6.4.2. OWM ensures that only suitable externally provided products and services are used when such products and services are:
- a) intended for incorporation into the OWM PT program activities;
 - b) provided, in part or in full, directly to the participant or customer by OWM, as received from the external provider;
 - c) used to support the operations of the OWM PT program.
- 6.4.3. 6.4.3. OWM informs participants, in advance and in writing, of services that are, or may be provided externally, when they affect the production or characterization of the PT items or services provided (infrequent). PT participants are integral to the planning and selection of standards and calibrations used in each PT round or PT scheme and are notified as part of the PT planning process.
- 6.4.4. OWM has a procedure and retains records for:
- a) defining, reviewing, and approving OWM’s requirements for externally provided products and services (covered by NIST procurement policies and practices);
 - b) defining the criteria for selection, of the external provider, and for monitoring and evaluating their performance (covered by NIST procurement technical requests);
 - c) ensuring that externally provided products and services conform to OWM’s established requirements, or when applicable, to the relevant requirements of this document, before they are used or directly provided to the customer (covered by NIST procurement technical requests);
 - d) taking any actions arising from the performance monitoring and evaluation of the external providers.
- 6.4.5. OWM communicates its requirements to external providers through documented procurement requests for any additional:
- a) products and services to be provided;
 - b) acceptance criteria;
 - c) competence, including any required qualification of the organization or personnel involved;
 - d) activities that the proficiency testing provider or its customers intend to perform at the external provider’s premises.

- 6.4.6. OWM is responsible to the participants or customers for the work of externally provided services, except in the case where the customer or a regulatory authority specifies which service provider is to be used.

Applicable Policies and References:

- SAP 3, Standard Administrative Procedure for Supplier Evaluation

7. Process Requirements

7.1. Establishing, Contracting, and Communicating the PT Round or PT Scheme Objectives

7.1.1. Review of Requests, Tenders, and Contracts (Participant Review and Requests)

- 7.1.1.1. OWM does not solicit or accept requests outside of the PT Planning process coordinated only with the Regional Measurement Assurance Program (RMAP) members, the regional or national planning process, as support to the U.S. legal metrology system. There are no contracts or tenders as a part of the OWM PT program. Participants requesting special PTs to be approved outside the regional or national PTs must follow the same procedure as those coordinated through RMAPs and complete and submit a PT plan proposal to OWM for review and approval. The scope of OWM PTs is limited to support of the U.S. legal metrology system. The PT procedures ensure that:
- a) objectives of the PT round or PT scheme are sufficiently defined and in agreement with the customers' needs;
 - b) the requirements, including those for test, calibration and sampling methods, measuring equipment and PT items to be used, are adequately defined, documented, and understood;
 - c) OWM has the capability and resources to meet the requirements; and
 - d) the PT round or PT scheme is technically appropriate considering the needs of the given application, field of application, and OWM PT program scope.
- 7.1.1.2. The PT planning process and review covers all aspects of the PT plan and request, including any externally provided services.
- 7.1.1.3. Records of such reviews, including any significant changes, are retained. Records are also be retained of pertinent discussions with PT participants relating to their requirements, or the results of the PT activities.
- 7.1.1.4. The PT participants are informed of any modification or deviation in the agreed PT plan and scheme design or operations.
- 7.1.1.5. If a PT plan is underway, the PT plan review is repeated (if necessary for technical reasons), and any updates are communicated to all affected personnel and participants.

7.1.2. PT Scheme Communication

- 7.1.2.1. OWM makes detailed information available about the PT plan to all participants. This includes:
- objectives and relevant details of the PT scheme;
 - criteria to be met for participation;
 - criteria for determining the assigned value and the evaluation of performance;
 - confidentiality arrangements and waiver requirements for OWM PTs;
 - critical timelines;
 - any fees for participation (there are no fees as part of OWM PT program operations); and
 - details of how to apply if not already a member of the RMAP (application is only open to qualified members of the RMAP groups).
- 7.1.2.2. Participants are advised promptly by the PT Coordinator or OWM of any changes in PT round or PT scheme design or operation.
- 7.1.2.3. Relevant records of communications with participants are maintained and retained, as appropriate.

Applicable Policies and References:

- NISTIR 7082, Proficiency Test Policy and Plan. OWM policies, roles, responsibilities, and authorities for PT coordinators, PT analysts, and PT participants are published as part of the OWM PT Policy and Plan and as a part of the PT Standard Operating Procedures. Requests and reviews of PT plans are conducted through the Regional Measurement Assurance Program PT planning sessions. State weights and measures laboratories are automatically included in PT rounds or PT schemes based on laboratory calibration scopes. Industry members must be members of the RMAPs or approved to be new members of the RMAPs and industry PT participants must complete forms to document qualifications for participating
- PT Standard Operating Procedure (SOP) 1 for OWM PT Planning, Operating, Analyzing, and Reporting of PT Results (OWM PTs) – covers aspects of planning, organizing, implementing, and analyzing PT rounds or PT schemes
- PT Standard Operating Procedure 2 for Operating a Mini-Measurement Assurance Program (Mini-MAP) – uses the SOP for OWM PTs plus additional planning and analysis required by participants
- Form 2, OWM PT Participation Request – Training/Qualification Form
- Form 3, RMAP Associate Membership Application

7.2. Design and Planning of a PT Round or PT Scheme

7.2.1. General

- 7.2.1.1. OWM, in conjunction with the PT Administrative Team, including all PT participants and PT coordinators, identifies and plans activities which directly affect the validity of the PT round or PT scheme and ensures that they are carried out in accordance with prescribed procedures including the “PT Plan”. OWM approves all PT plans prior to implementation.
- 7.2.1.2. When significant changes to activities are proposed which could affect the validity of the results of a PT scheme, the influence or risk of such changes is determined and approved by OWM if acceptable to ensure that the validity of the PT results are not jeopardized.
NOTE Examples of significant changes are new approaches for PT item preparation, determination of stability, determination of assigned values, statistical approach, new types of proficiency testing activities endorsed by other proficiency testing providers, by PT coordinators, by PT participants, or by any other external provider.
- 7.2.1.3. OWM, in conjunction with the PT Administrative Team, PT coordinators, and PT participants, develops a documented PT Plan before beginning all PT rounds or PT schemes to address the objectives, purpose, and basic design of the PT scheme, including the following information and, where appropriate, reasons for its selection or exclusion:
- a) Identification, name, address, and affiliation of OWM Point of Contact, PT Administrative Team, including the PT Coordinator, PT Analyst, any observers/mentors, and all PT participants;
 - b) the activities to be provided by any identify external service providers and the names and addresses of the external service providers involved in the operation of the PT round or PT scheme (this is rare if ever in the OWM PT program);
 - c) criteria to be met for participation (including membership in the RMAP, evidence of training, compliance with other OWM policies);
 - d) the number and type of expected participants in the PT scheme;
 - e) definition of calibration activities to be performed and submitted by participants, including selection of the measurand(s), characteristic(s) or sampling methodology of interest, including information on what the participants are to identify, measure, test, and report in the specific PT scheme;
 - f) a description of the range of values or characteristics, or both, to be expected for the PT items;
 - g) the potential major sources of errors involved in the area of the PT scheme;
 - h) requirements for the selection, production, quality control, storage, and distribution of PT items;
 - i) arrangements to prevent collusion between participants or falsification of results, and procedures to be employed if collusion or falsification of results is suspected (see OWM policies);
 - j) a description of the information which is to be supplied to participants and the time schedule for the various phases of the PT scheme;

- k) for continual PT schemes, the frequency or dates upon which PT items are to be distributed to participants, the deadlines for the return of results by participants and, where appropriate, the dates on which testing, or measurement is to be carried out by participants;
- l) any information on methods or procedures which participants need to use to store, handle, prepare or dispose of the PT item and perform the measurements;
- m) procedures for the test or measurement methods to be used for the homogeneity and stability testing of PT items (biological viability is not applicable in OWM PT program scope);
- n) preparation of any standardized reporting formats to be used by participants (in general, laboratories are required to submit certificates compliant with ISO/IEC 17025:2017 and may include additional forms for special evaluations as documented during planning;
- o) a detailed description of the statistical analysis to be used;
- p) the origin, metrological traceability, and measurement uncertainty of any assigned reference values;
- q) the treatment of results from different methods if/when permitted by the PT scheme;
- r) criteria for the evaluation of performance of participants;
- s) a description of the data, interim reports, or information to be returned to participants;
- t) a description of the extent to which participant results, and the conclusions that will be based on the outcome of the PT scheme, are to be made public or shared; and
- u) actions to be taken in the case of lost, delayed, or damaged PT items.

7.2.2. Statistical Design

- 7.2.2.1. Statistical designs are documented and selected to meet the objectives of the scheme, based on the type of the data (quantitative or qualitative, including ordinal and nominal), statistical assumptions, the type of errors, and the expected number of results. Tentative analyses are selected during the planning phase and continually evaluated during the collection, final analysis, and reporting as needed, considering the selected reference values and associated uncertainties.
- 7.2.2.2. OWM documents the statistical design and data analysis methods to be used to determine the assigned value, evaluate participant results, and documents the reasons for their selection and assumptions upon which they are based. OWM demonstrates that statistical assumptions are reasonable and that statistical analyses are carried out in accordance with prescribed procedures, as needed.
- 7.2.2.3. In designing the PT statistical analysis, OWM considers the following:
 - a) the accuracy, precision and the measurement uncertainty required or expected for each characteristic in the PT scheme;
 - b) the minimum number of participants in the PT round or PT scheme needed to meet the objectives of the statistical design. In cases where there is an insufficient number of participants to meet these objectives or to produce statistically

- meaningful analysis of results, OWM documents, and provides to participants, details of the alternative approaches used to assess participant performance;
- c) the relevance of significant figures to the reported result, including the number of decimal places;
 - d) the number of PT items to be tested or measured and the number of repeat tests, calibrations, or measurements to be conducted on each PT item or for each determination;
 - e) the procedures used to establish the standard deviation, and adjusted standard deviations when data is trimmed, for proficiency assessment or other evaluation criteria;
 - f) the treatment of results from different methods, where permitted by the PT scheme;
 - g) how the participant's measurement uncertainty is reported and used to evaluate performance;
 - h) procedures used to identify or handle outliers, or both;
 - i) where relevant, the procedures for the evaluation of values excluded from statistical analysis (all data in the OWM PT program is included in reports, but some may not be used as part of the assessment when in selecting consensus reference values or performing other statistical assessments); and
 - j) where appropriate, the objectives to be met for the design and the frequency of PT rounds.

7.2.3. Determining Assigned Values

- 7.2.3.1. OWM documents the procedure for determining the assigned values for the characteristics in its PT rounds or PT schemes. The procedure ensures the metrological traceability and measurement uncertainty required to demonstrate that the PT round or PT scheme is fit for its purpose.
- 7.2.3.2. PT rounds or PT schemes in the area of calibration all have assigned values with metrological traceability and associated measurement uncertainties. The OWM PT Final Reports include statements of metrological traceability.
- 7.2.3.3. PT rounds or PT schemes in areas other than calibration are not applicable for the OWM PT program.
- 7.2.3.4. When a consensus value is used as the assigned value, OWM documents the reason for that selection and provides an estimate of the uncertainty of the assigned value as described in the PT plan for the PT scheme. Details of the reference or assigned values are included in the PT report(s).
- 7.2.3.5. OWM has a policy regarding the disclosure of assigned values. The policy ensures that participants cannot gain advantage from early disclosure. In addition, the policy addresses collusion and falsification of data.

Applicable Policies and References:

- NISTIR 7082, Proficiency Test Policy and Plan. OWM policies, roles, responsibilities, and authorities for PT coordinators, PT analysts, and PT participants are published as part of the OWM PT Policy and Plan and as a part of the PT Standard Operating Procedures. Requests and reviews of PT plans are conducted through the Regional Measurement Assurance Program PT planning sessions

- PT Standard Operating Procedure (SOP) 1 for OWM PT Planning, Operating, Analyzing, and Reporting of PT Results (OWM PTs) – covers aspects of planning and designing PT rounds or PT schemes
- PT Standard Operating Procedure 2 for Operating a Mini-Measurement Assurance Program (Mini-MAP) – uses the SOP for OWM PTs plus additional planning and analysis required by participants
- SAP 5, Standard Administrative Procedure for Handling PT Related Collusion, Falsification, and Participant Operational Failures
- PT Plan Template (Excel file). The planning file documents all design and planning requirements.
- PT Analysis Template (Excel file). The analysis file provides statistical analysis, evaluation of selected reference values, participant performance evaluation, and participant summary statistics.

7.3. Operations Related to the Preparing, Selecting, and Handling of PT Items

7.3.1. Preparing and Selecting PT Items

- 7.3.1.1. OWM does not produce PT items. OWM establishes and implements procedures to ensure that PT items are prepared or selected according to the plan described in 7.2 and fit for the PT rounds or PT schemes' purpose.
- 7.3.1.2. OWM establishes and implements procedures to ensure appropriate selection, acquisition, collection, identification, preparation, handling, storage and, where required, disposal of all PT items. OWM does not purchase materials for manufacturing PT items. All purchases of PT equipment, standards, and services are similar in type and design from those routinely encountered in normal calibration activities. Purchases of supplies, equipment, and standards used in PTs comply with relevant regulatory requirements and are consistent with appropriate ethical considerations.
- 7.3.1.3. OWM does not conduct any PT rounds or PT schemes that require participants to sample, prepare or manipulate, or both, the PT item and submit it to OWM.

7.3.2. Assessing Homogeneity and Stability of PT items

- 7.3.2.1. Criteria for suitable homogeneity and stability are established and are based on the risks that inhomogeneity and instability can impact the evaluation of the participants' performance. OWM does not batch or package PT items and homogeneity is not generally applicable for the calibration items considered in the scope of the OWM PT program as there are usually not "samples".
- 7.3.2.2. The procedures for the assessment of stability are documented and conducted, where applicable, in accordance with appropriate statistical designs.
- 7.3.2.3. The assessment of stability is performed as a part of the PT analysis for every PT.
- 7.3.2.4. Where experimental evidence is needed to assess stability, OWM uses appropriate methods to assess the stability of the PT item (this is not common except for standards that are damaged during the conduct of the PT or in the rare cases where standards exhibit drift).

- 7.3.2.5. PT items are selected and demonstrated to be sufficiently stable to ensure that they will not undergo any significant change throughout the conduct of the PT, including storage and transport conditions. When this is not possible, the stability is quantified and considered as an additional component of the measurement uncertainty associated with the assigned value of the PT item, and/or considered in the evaluation criteria.
 - 7.3.2.6. When PT items from previous rounds are retained for another PT round, the property values to be determined in the PT round or PT scheme is confirmed by OWM prior to distribution (would have been confirmed in prior PT final reports) and prior reports and confirmed data is generally not shared with the PT Analyst until that laboratory has submitted data for the current PT round.
 - 7.3.2.7. In circumstances where stability testing is not conducted on every PT item, OWM demonstrates during the PT analysis that the procedures used for handling, shipping, and calibration of the PT items are sufficient for the purpose of the PT scheme. Each final PT report includes a section for OWM evaluation of stability.
- 7.3.3. Handling and Storing PT items
- 7.3.3.1. OWM ensures that PT items are appropriately identified and segregated and cannot become contaminated or degraded, from the time of selection or preparation to their distribution to participants.
 - 7.3.3.2. OWM provides secure storage areas to prevent damage or deterioration of any PT item between selection, preparation, and distribution. Appropriate procedures for authorizing dispatch to, and receipt from, such areas is defined by NIST shipping procedures.
 - 7.3.3.3. When appropriate, the condition of stored or stocked PT items is assessed prior to use in a PT round or PT scheme to avoid use of any standard that exhibits possible deterioration.
 - 7.3.3.4. Potentially hazardous PT items are not used in the PT program.
- 7.3.4. Packaging, Labelling and Distributing PT items
- 7.3.4.1. OWM controls or supports packaging and labelling processes to the extent necessary to ensure conformity with relevant national, regional, or international safety and transport requirements (which is reinforced through the NIST and vendor shipping process and procedures).
 - 7.3.4.2. OWM specifies relevant environmental conditions for the transport of proficiency test items if applicable (though this is generally not applicable). Where relevant, OWM monitors the pertinent environmental conditions of the PT item during transport and assess the impact of environmental influences on the PT item.
 - 7.3.4.3. In PT rounds or PT schemes where participants are required to transport the PT items to other participants, or return them to OWM, documented instructions for this transport are supplied.
 - 7.3.4.4. OWM ensures that labels are securely attached to the packaging of individual PT items and are designed to remain legible and intact throughout the PT round.

7.3.4.5. OWM follows PT monitoring methods with the PT Coordinators and PT participants to enable the confirmation of shipping and delivery of the PT items.

7.3.5. Instructions for Participants

7.3.5.1. OWM and PT Coordinators give participants sufficient notice before sending PT items, providing the date on which the PT items are likely to arrive or to be dispatched, unless the design of the PT round or PT scheme makes it inappropriate to do so.

7.3.5.2. OWM and PT Coordinators give detailed documented instructions to all participants. Instructions to participants include:

- a) the necessity to treat PT items in the same manner as the routinely calibrated items, unless there are particular requirements of the PT round or PT scheme which require departure from this principle;
- b) details of factors which could influence the measurement or calibration of the PT items, e.g., the nature of the PT items, conditions of storage, whether the PT round or PT scheme is limited to selected test methods, and the timing of the testing or measurement;
- c) detailed procedure for preparing, conditioning, or equilibrating, the PT items before conducting measurements or calibrations, unless this is part of the PT scheme;
- d) any appropriate instructions on handling the PT items, including any safety requirements;
- e) any specific environmental conditions for the participant to conduct tests or calibrations, or both, and, if relevant, any requirement for the participants to report relevant environmental conditions during the time of the measurement;
- f) specific and detailed instructions on the manner of recording and reporting results and associated uncertainties. When the instructions include reporting of the uncertainty of measurement, this includes compliance with the Guide to the Expression of Uncertainty in Measurement and reporting the coverage factor and the coverage probability – in general, OWM PTs require submission of a calibration certificate that is fully compliant with ISO/IEC 17025 (exceptions would be noted in the instructions);

NOTE This instruction usually includes parameters such as the units of measurement, the number of significant figures or decimal places and reporting basis (e.g., on dry weight, or “as received”).

- g) Specific instructions on providing details concerning the measurement methods used by the PT participant when a specific procedure is not identified during planning;
- h) the latest date for OWM or the PT Coordinator or PT Analyst to receive the results from the participants; and
- i) information on the contact details of OWM for enquiries.

Applicable Policies and References:

- NISTIR 7082, Proficiency Test Policy and Plan. OWM policies, roles, responsibilities, and authorities for PT coordinators, PT analysts, and PT participants

- are published as part of the OWM PT Policy and Plan and as a part of the PT Standard Operating Procedures. Requests and reviews of PT plans are conducted through the Regional Measurement Assurance Program PT planning sessions
- PT Standard Operating Procedure (SOP) 1 for OWM PT Planning, Operating, Analyzing, and Reporting of PT Results (OWM PTs) – covers aspects of selection, handling, and shipping PT items
 - PT Standard Operating Procedure 2 for Operating a Mini-Measurement Assurance Program (Mini-MAP) – uses the SOP for OWM PTs plus additional planning and analysis required by participants
 - SAP 3, Standard Administrative Procedure for Supplier Evaluation for PT Supplies and Calibration Services

7.4. Evaluating and Reporting PT Results

7.4.1. Data Analysis

- 7.4.1.1. Results received from participants are recorded and analyzed by appropriate methods. Procedures are in place and implemented to check the validity of data entry, data transfer, statistical analysis, and reporting.
- 7.4.1.2. Data analysis generates summary statistics and performance statistics, and associated information consistent with the statistical design of the PT scheme.
- 7.4.1.3. The influence of outliers on summary statistics is minimized by the use of appropriate statistical approaches.
- 7.4.1.4. OWM has documented procedures for treatment of results with different methods where the PT plan allows for use of different methods, providing reported uncertainties are equivalent to those specified in the PT plan. In the event that measurement results and uncertainties are not consistent with the PT plan, data may be included and analyzed but not used in the PT round or PT scheme group analysis.
- 7.4.1.5. OWM has documented criteria and procedures for dealing with test results that may be inappropriate for statistical evaluation, e.g., miscalculations, transpositions, and other gross errors.
- 7.4.1.6. OWM has documented criteria and procedures to identify and manage situations where PT items that have been distributed and data subsequently found to be unsuitable for performance evaluation, e.g., because of inhomogeneity, instability, damage, or contamination.

7.4.2. Evaluating Participant Performance

- 7.4.2.1. OWM uses valid methods of evaluation which meet the objectives of the PT scheme. The methods are documented and include a description of the basis for the evaluation. Valid methods of evaluation are described in OWM procedures, following guidance from ISO 13528.
- 7.4.2.2. Where applicable for the purpose of the PT scheme, OWM provides expert commentary on the performance of participants with regard to the following:
 - a) overall performance against prior expectations, taking measurement uncertainties into account;
 - b) variation within and between participants, and comparisons with any previous PT rounds, similar PT rounds or PT schemes, or published data;

- c) variation between methods or procedures where appropriate;
- d) possible sources of error (with reference to outliers) and suggestions for improving performance;
- e) advice and educational feedback to participants as part of the continual improvement procedures of participants;
- f) situations where unusual factors make evaluation of results and commentary on performance impossible;
- g) any other suggestions, recommendations, or general comments; and
- h) conclusions.

Interim individual summary sheets are often provided for participants periodically during or after completion of a particular PT round or PT scheme in the OWM PT program. These can include opportunities for data entry evaluations as well as interim feedback. Updated summaries of performance for individual participants may also be provided over successive evaluations or PT rounds of the PT schemes. Summaries may be further analyzed, and trends highlighted, if required.

7.4.3. PT reports

- 7.4.3.1. OWM PT reports are clear, accurate, objective, and comprehensive and include data covering the results of all participants, together with an indication of the performance of individual participants. When it is not practical to report all original data to participants, a summary of the results, e.g., in tabulated or graphical form, may be supplied (unusual).
- 7.4.3.2. OWM PT Final Reports include the following, unless it is not applicable or OWM has valid reasons for not doing so:
 - a) the name and contact details of OWM;
 - b) the name(s), function(s), and signature(s) or equivalent identification of person(s) authorizing the report;
 - c) an indication of which activities are provided by external providers when they affect the production or characterization of the PT items, or the services provided (generally not applicable in OWM PT program);
 - d) the date of issue and status (e.g., preliminary, interim, or final) of the report;
 - e) unique identification that all its components are recognized as a portion of a complete report, with page numbers and a clear indication of the end of the report;
 - f) a statement to the extent to which results are confidential or may be shared (restricted usage is noted);
 - g) the report name/number and clear identification of the PT scheme;
 - h) a clear description of the PT items used, including necessary details of the PT item's selection, preparation and homogeneity and stability assessment;
 - i) participant results including the reported uncertainties;
 - j) methods used to statistically analyze the data (see OWM Supplemental Report or procedures);
 - k) statistical data and summaries, including assigned values and range of acceptable results and graphical displays;
 - l) procedures used to establish assigned reference value(s) (see OWM Supplemental Report);

- m) details of the metrological traceability and measurement uncertainty of any assigned value;
- n) procedures used to establish the standard deviation for proficiency assessment, or other criteria for evaluation (see OWM Supplemental Report or procedures);
- o) assigned values and summary statistics for test methods/procedures used by each group of participants (if different methods are used by different groups of participants);
- p) comments on participants' performance;
- q) information about the design and implementation of the PT scheme;
- r) advice on the interpretation of the statistical analysis; and
- s) comments or recommendations based on the outcomes of the PT round.

For many OWM PT reports, the OWM Supplemental Report provides the procedures and bases for analysis used for all OWM PT analyses and reporting. The OWM Supplemental Report is provided with all other reports and readily available online to all participants.

- 7.4.3.3. Reports are made available to participants within planned timescales. In sequential PT schemes, e.g., where the turn-around time may be very long, and in schemes involving perishable materials, preliminary or interim results may be provided before final results are disclosed to allow for early investigation of possible errors or troubleshooting by the PT participant(s).
- 7.4.3.4. OWM has a policy for the use of reports by individuals and organizations.
- 7.4.3.5. When it is necessary to issue a new or amended report for a PT round or PT scheme and or round, the amendment includes the following:
 - a) a unique identification;
 - b) a reference to the original report that it replaces or amends; and
 - c) identification of the amendment and a statement concerning the reason for the amendment or re-issue.
- 7.4.3.6. Amended reports (fixed to correct errors) are renamed with “amended” noted in the file name and are issued to all participant(s). The analysis considers the potential impact on all participants for that scheme and/or round.
- 7.4.3.7. Appended reports to add participants or data are renamed as a PT Final Report with “addendum” added to the file name. Addendum reports are only issued to applicable PT participants.
- 7.4.3.8. If OWM issues a statement of participation or performance in addition to the PT report, the statement contains only information that is as clear and accurate as possible (not misleading).

Applicable Policies and References:

- NISTIR 7082, Proficiency Test Policy and Plan. OWM policies, roles, responsibilities, and authorities for PT coordinators, PT analysts, and PT participants are published as part of the OWM PT Policy and Plan and as a part of the PT Standard Operating Procedures. Requests and reviews of PT plans are conducted through the Regional Measurement Assurance Program PT planning sessions

- PT Standard Operating Procedure (SOP) 1 for OWM PT Planning, Operating, Analyzing, and Reporting of PT Results (OWM PTs) – covers aspects of data analysis, participant evaluation, and PT reporting
- PT Standard Operating Procedure 2 for Operating a Mini-Measurement Assurance Program (Mini-MAP) – uses the SOP for OWM PTs plus additional planning and analysis required by participants.
- PT Plan Template (Excel file). The planning file documents baseline information that is required in the PT report and transfers applicable information to the leading pages of the PT final reports.
- PT Analysis Template (Excel file). The analysis file provides statistical analysis, evaluation of selected reference values, participant performance evaluation, and participant summary statistics.
- Good Laboratory Practice for Proficiency Test Follow-ups with Form
- NISTIR 8250, Good Laboratory Practice for Software Quality Assurance

7.5. Monitoring and Control of the PT Scheme Process and Records

7.5.1. Technical Records

- 7.5.1.1. OWM ensures that technical records for each PT activity contain the results, reports, and sufficient information to facilitate, if possible, identification of factors affecting the PT performance evaluation and its associated characteristics and enable the repetition of the PT activity under conditions as close as possible to the original. The technical records include the date and the identity of personnel responsible for each PT activity and for checking data and results.
- 7.5.1.2. Data used to verify the PT items, instructions to participants, participants' original responses, any other information included in the PT plans, PT final reports, and all final documents submitted by PT participants. Information is recorded at the time measurements, observations or analyses are made and is identifiable with the specific task.
- 7.5.1.3. OWM ensures that amendments to technical records can be tracked to previous versions or to original information submitted by participants. Both the original and amended data and files are retained, including the date of alteration, an indication of the altered aspects and the personnel responsible for the alterations.

7.5.2. Control of Data and Information Management

- 7.5.2.1. OWM has access to the data and information needed to perform its activities (whether computerized or non-computerized).
- 7.5.2.2. OWM information management system used for the collection, processing, recording, reporting, storage, or retrieval of data is validated for functionality, including the proper functioning of interfaces before introduction following referenced procedures for verification and validation. Whenever there are any changes, including PT provider software configuration or modifications to

commercial off-the-shelf software, they are authorized, documented, and validated before implementation.

7.5.2.3. OWM information management system (network and software templates) is:

- a) protected from unauthorized access;
- b) safeguarded against tampering and loss;
- c) operated in an environment that complies with provider or PT Provider specifications or, in the case of non-computerized systems, provides conditions which safeguard the accuracy of manual recording and transcription;
- d) maintained in a manner that ensures the integrity of the data and information;
- e) include recording system failures and the appropriate immediate, corrective actions.

7.5.2.4. The information and management systems are not maintained outside of NIST compliant IT requirements to ensure adequate maintenance, backup, and recovery.

7.5.2.5. OWM ensures that instructions, manuals, and reference data, including calibration history, and PT item inventories relevant to OWM information management system are made readily available to staff and volunteers as needed.

7.5.2.6. Calculations and data transfers is checked in an appropriate and systematic manner. PT participants have opportunities to assist in the validation of data entry and review of the PT analysis.

7.5.3. Surveillance of the Processes

7.5.3.1. OWM monitors all related processes that affect the validity of the results of the PT rounds or PT schemes and PT final reports. The resulting data (results) of this monitoring is recorded in such a way that trends are detectable and, where practicable, statistical/appropriate techniques is applied to review the results.

7.5.3.2. All PT plans, coordination, analysis, and reporting are monitored as a part of implementing OWM procedures. (Monitoring is planned and reviewed for 100 % of all PT rounds or PT schemes as a part of implementing the OWM procedures.)

7.5.4. Nonconforming Work

7.5.4.1. OWM has a procedure that is implemented when any aspect of its PT activities does not conform to its procedures (customer requirements must comply with the OWM PT plan). The procedure(s) ensures that:

- a) the responsibilities and authorities for the management of nonconforming work are defined;
- b) actions (including halting work of ongoing PT schemes and or rounds and withholding PT schemes and or round reports, as necessary) are defined and are based upon the risk levels established by OWM;
- c) an evaluation of the significance of the nonconforming work is made, including an impact analysis on previous activities;
- d) a decision on the need for action and timescale is taken immediately, together with any decision about the acceptability of the nonconforming work;

- e) PT round or PT scheme participants and customers, as appropriate, are informed and the nonconforming PT items or reports already sent to participants are recalled or disregarded;
- f) the responsibility for authorization of the resumption of work is defined.

NOTE Nonconforming work may be identified in many ways and includes but is not limited to the following: participant complaints, staff observations, management reviews and internal or external audits, quality control, preparations of proficiency test items, homogeneity and stability evaluations, data analysis, instructions to participants, and materials handling and storage.

7.5.4.2. OWM retains records of nonconforming work and actions as specified in 7.5.4.1 bullets b) to f).

7.5.4.3. Where the evaluation indicates that nonconforming work could recur or that there is doubt about the compliance of OWM with their own procedures, the corrective action procedure in 8.7 is promptly followed.

Applicable Policies and References:

- NISTIR 7082, Proficiency Test Policy and Plan. OWM policies, roles, responsibilities, and authorities for PT coordinators, PT analysts, and PT participants are published as part of the OWM PT Policy and Plan and as a part of the PT Standard Operating Procedures. Requests and reviews of PT plans are conducted through the Regional Measurement Assurance Program PT planning sessions
- PT Standard Operating Procedure (SOP) 1 for OWM PT Planning, Operating, Analyzing, and Reporting of PT Results (OWM PTs) – covers monitoring the PT operations as well as collection and management of data during the conduct of the PT
- PT Standard Operating Procedure 2 for Operating a Mini-Measurement Assurance Program (Mini-MAP) – uses the SOP for OWM PTs plus additional planning and analysis required by participants
- SAP 1, Standard Administrative Procedure for Document and Record Management, contains the document and record management authority, policies, and procedures used in the OWM PT program.
- SAP 2, Standard Administrative Procedure for Handling PT-Related Action Items
- PT Plan Template (Excel file). The planning file documents monitoring and actions during the PT implementation.
- Form 1: OWM PT Feedback and Inquiry and Complaint Form
- Form 4, OWM PT Action Form

7.6. Handling Complaints

7.6.1. OWM has a documented procedure for handling complaints that includes at least the following:

- a) a description of the process for receiving, substantiating, and investigating the complaint, and deciding what actions is taken in response;
- b) tracking and recording the complaint, including the actions undertaken to resolve it;

- c) ensuring that any appropriate action is taken in a timely manner.
- 7.6.2. A description of the process for handling complaints is publicly available.
- 7.6.3. Upon receipt of a complaint, the PT provider confirms whether the information received is feedback, inquiry, or complaint and if it relates to PT program activities; if related to the PT program, the feedback, inquiry, or complaint is resolved according to OWM procedures.
- 7.6.4. The proficiency PT Administrative Team and/or OWM staff receiving the complaint is responsible for gathering all necessary information to determine whether the complaint is substantiated.
- 7.6.5. Whenever possible the PT provider acknowledges receipt of the feedback, inquiry, or complaint, and provides the complainant with the outcome and, if applicable, progress reports.
- 7.6.6. Investigation and resolution of complaints is performed to prevent discriminatory actions.
- 7.6.7. The resolution of complaints is made by, or reviewed and approved by, persons not involved in the subject of the complaint in question. Where resources do not permit this, any alternative approach is selected to ensure impartiality is not compromised.
- 7.6.8. Whenever possible, OWM gives formal notice at the end of the handling process to the complainant and any other applicable party; and
- 7.6.9. OWM is responsible for all decisions at all levels in the handling process for feedback, inquiries, and complaints.

Applicable Policies and References:

- SAP 2, Standard Administrative Procedure for Handling PT-Related Action Items – this procedure specifically addresses action items related to complaints
- Form 1: OWM PT Feedback and Inquiry and Complaint Form – may be used by PT participants to provide feedback, direct an inquiry or complaint, or appeal OWM analyses and decisions
- Form 4, OWM PT Action Form – used to implement and track actions related to complaints

7.7. Handling Appeals

- 7.7.1. OWM has a documented procedure for handling appeals that includes at least the following:
 - a) a description of the process for receiving and investigating the appeal, and deciding what actions is taken in response;
 - b) tracking and recording the appeal, including the actions undertaken to resolve it;
 - c) ensuring appropriate action is taken.
- 7.7.2. A description of the process for handling appeals is publicly available.
- 7.7.3. OWM acknowledges receipt of appeals, and provide the appellant with the outcome and, if applicable, progress reports.
- 7.7.4. OWM staff are responsible for gathering all necessary information to determine whether the appeal is valid.
- 7.7.5. OWM staff are responsible for all decisions during the process for handling appeals.

- 7.7.6. The decision on the appeal is made by, or reviewed and approved by, persons not involved in the decision that is the subject of the appeal in question, whenever possible.
- 7.7.7. Investigation and decision on appeals will be performed in such a way as to prevent any discriminatory actions.

Applicable Policies and References:

- SAP 2, Standard Administrative Procedure for Handling PT-Related Action Items – this procedure specifically addresses action items related to appeals.
- Form 1: OWM PT Feedback and Inquiry and Complaint Form – may be used by PT participants to provide feedback, direct an inquiry or complaint, or appeal OWM analyses and decisions
- Form 4, OWM PT Action Form – used to implement and track actions related to appeals

8. Management System Requirements

8.1. General Requirements

- 8.1.1. OWM has established, documents, implements, and maintains this management system to support and demonstrate the consistent fulfilment of the requirements of the normative references specified in this document and its scope of activities, including the type, range and volume of PT that are provided.
- 8.1.2. The OWM management system includes the following items:
 - policies;
 - responsibilities;
 - management system documentation (see 8.2);
 - control of management system documents (see 8.3);
 - control of records (see 8.4);
 - actions to address risks and opportunities (see 8.5);
 - improvement (see 8.6);
 - corrective action (see 8.7);
 - internal audits (see 8.8);
 - management reviews (see 8.9).
- 8.1.3. OWM meets 8.1.1 by establishing, publishing, implementing, and maintaining a quality management system as published in this document with associated policies and procedures, administrative procedures, forms, and associated templates. This quality management system support and demonstrate the consistent fulfilment of the requirements of sections 4 through 7 in this document.

8.1.4. OWM management provides evidence of commitment to the development and implementation of the Laboratory Metrology Program, PT program quality management system and to continually improving its effectiveness as demonstrated by approving this document for publication and authorizing staff time in performance plans for its implementation.

8.2. Management System Documentation

8.2.1. The policies and objectives identified in this quality management system address the competence, impartiality, and consistent operation of the OWM PT program.

8.2.2. All documentation, processes, systems, and records related to the fulfilment of the requirements of this document is included in or referenced from this quality management system. See the “Applicable Policies and References” in each section of this document for specific references applicable to that particular section and see the Appendices of this document for the full list of all documents. Processes, systems, and records are addressed in the listed supporting documents. Additional reference documents are noted in SAPs and appendices.

8.2.3. All personnel involved in PT activities have access to the parts of the management system documentation and related information that are applicable to their responsibilities. Official NIST publications and current updated components are posted online to ensure that PT coordinators, PT analysts, and PT participants have access to all applicable documents and files (with the exception of Form 5, Internal Audit Form, which contains copyrighted language). Back-up final versions are maintained in controlled areas of the NIST internal network. NIST staff have access to both online and network versions of the quality management system documents and resources as well as all copyrighted/referenced external standards. In the case of copyrighted documentary standards, the link for obtaining references is provided. NIST staff obtain applicable documentary standards as needed following internal NIST procedures.

Applicable Policies and References:

- NISTIR 7214, Appendix A, Supplemental Procedures and Resources includes a list of all publications and resources that are included in the OWM PT program quality management system.
- Standard Administrative Procedure (SAP) 1, Document and Record Management, Appendix, includes a Master List of all applicable internal and external publications related to the operation of the OWM PT program.

8.3. Control of Management System Documents

8.3.1. OWM controls the documents (internal and external) that relate to the fulfilment of this document.

8.3.2. OWM ensures that:

- a) documents are approved for adequacy prior to issue;
- b) documents are periodically reviewed, and updated as necessary;
- c) changes and current revision status of documents are identified;
- d) relevant versions of applicable documents are available at points of use and their distribution is controlled;
- e) documents are uniquely identified;
- f) the unintended use of obsolete documents is prevented, and suitable identification is applied to them if they are retained for any purpose. Any obsolete or older documents retained online are noted appropriately.

Applicable Policies and References:

- NISTIR 7214, Appendix A, Supplemental Procedures and Resources includes a list of all publications and resources that are included in the OWM PT program quality management system.
- SAP 1, Standard Administrative Procedure for Document and Record Management, contains the document and record management authority, policies, and procedures used in the OWM PT program. SAP 1, Appendix, includes a Master List of all applicable internal and external publications related to the operation of the OWM PT program.

8.4. Control of Records

8.4.1. OWM establishes and retain legible records to demonstrate fulfilment of the requirements in this document. In general, records are developed electronically and retained in electronic format. In the case of hand-written scanned records, efforts are made to ensure legibility and electronic retention.

8.4.2. OWM implements the controls needed for the identification, storage, protection, back-up, archive, retrieval, retention time, and disposal of its PT records. OWM back-up files are managed by the Information Technology system at NIST and the OWM data management plan. See additional record controls in section 7.5.1.

8.4.3. OWM retains proficiency testing records at least as long as allowed with NIST retention policies and as defined in the OWM PT program procedures. Access to these records is consistent with the confidentiality commitments and records are readily available to OWM staff. Applicable requests for past records by the PT Administrative Team or PT Participants are assessed as needed depending on application and intended use.

Applicable Policies and References:

- SAP 1, Standard Administrative Procedure for Document and Record Management, contains the document and record management authority, polices, and procedures used in the OWM PT program. It explicitly lists examples of technical and administrative records maintained in the PT program.

8.5. Actions to Address Risks and Opportunities

- 8.5.1. OWM considers the risks and opportunities associated with the PT activities during evaluation of action items, internal audits, management reviews, and during annual strategic planning sessions. Annual strategic planning sessions use SWOT analysis methods to identify strengths, weaknesses, opportunities, and threats. The strategic planning output is integrated into performance plan development in order to:
- a) give assurance that the management system achieves its intended results;
 - b) enhance opportunities to achieve the purpose and objectives of OWM;
 - c) prevent, or reduce, undesired impacts and potential failures in the PT activities; and
 - d) achieve improvement.
- 8.5.2. OWM plans and prioritizes :
- a) actions to address risks and opportunities;
 - b) how to integrate and implement these actions into its management system; and
 - c) how to evaluate the effectiveness of these actions.
- 8.5.3. Actions taken to address risks and opportunities are prioritized according to the potential probability and impact on the validity and reputation of the OWM Laboratory Metrology Program PT activities.

Applicable Forms, Policies and References:

- SAP 2, Standard Administrative Procedure for Handling PT-Related Action Items
- Form 4, OWM PT Action Form
- SAP 4, Standard Administrative Procedure for Audits and Reviews
- Form 5, OWM PT program Internal Audit Form

8.6. Improvement Actions

- 8.6.1. OWM identifies and selects opportunities for improvement and implement any necessary actions through internal auditing, management reviews, strategic planning, staff identification of opportunities during regular program operations, and through evaluations from PT participants, PT coordinators, and PT analysts during planning, analysis, and reporting discussions with all participants.

8.6.2. OWM seeks feedback, both positive and negative, from participants and laboratories. The feedback is analyzed and used to improve the management system, PT activities and customer service. PT Follow-up forms are reviewed from State weights and measures laboratories each year to identify trends, gaps, or any improvements needed in training or standardizing follow-up evaluations. All PT final reports solicit complaints, appeals, or feedback with language such as the following:

“Complaints or appeals regarding this Proficiency Test, its operation, analysis, or reporting may be submitted to NIST OWM Laboratory Metrology Program staff using Form 1 (available on the NIST OWM website). General PT or program feedback and opportunities for improvement may be submitted to OWM Laboratory Metrology Program staff via email.”

Applicable Forms, Policies and References:

- SAP 2, Standard Administrative Procedure for Handling PT-Related Action Items
- Form 1: OWM PT Feedback and Inquiry and Complaint Form
- Form 4, OWM PT Action Form
- SAP 4, Standard Administrative Procedure for Audits and Reviews
- Form 5, OWM PT program Internal Audit Form

8.7. Corrective Actions

8.7.1. When a nonconformity occurs, OWM:

- a) reacts to the nonconformity and, as applicable:
 - take action to control and correct it;
 - address the consequences;
- b) evaluates the need for action to eliminate the cause(s) of the nonconformity, in order that it does not recur or occur elsewhere, by:
 - reviewing and analyzing the nonconformity;
 - determining the causes of the nonconformity;
 - determining if similar nonconformities exist, or could potentially occur;
- c) implements any action needed;
- d) reviews the effectiveness of any corrective action taken;
- e) updates risks and opportunities determined during planning, if necessary;
- f) makes changes to the management system, if necessary.

8.7.2. Corrective actions are appropriate to the effects of the nonconformities encountered.

8.7.3. OWM retains records as evidence of:

- a) the nature of the nonconformities, cause(s) and any subsequent actions taken;
- b) the results of any corrective action.

Applicable Forms, Policies and References:

- SAP 2, Standard Administrative Procedure for Handling PT-Related Action Items
- Form 4, OWM PT Action Form
- SAP 4, Standard Administrative Procedure for Audits and Reviews
- Form 5, OWM PT program Internal Audit Form

8.8. Internal Audits

- 8.8.1. OWM conducts internal audits at planned intervals to provide information on whether the management system:
- a) conforms to:
 - o OWM's requirements for its management system, including the PT activities;
 - o the requirements of this document;
 - b) is effectively implemented and maintained.
- 8.8.2. OWM:
- a) plans, establishes, implements, and maintains an audit program including the frequency, methods, responsibilities, planning requirements and reporting, which takes into consideration the importance of the PT activities concerned, changes affecting OWM, and the results of previous audits;
 - b) conducts audits by personnel knowledgeable about the PT activities and the OWM PT quality management system, maintaining independence of the specific activities to the extent possible;
 - c) defines the audit criteria and scope for each audit;
 - d) ensures that the results of the audits are reported to relevant management;
 - e) implements appropriate correction and corrective actions without undue delay;
 - f) retains records as evidence of the implementation of the audit programme and the audit results.

Applicable Forms, Policies and References:

- SAP 4, Standard Administrative Procedure for Audits and Reviews
- Form 5, OWM PT program Internal Audit Form
- SAP 2, Standard Administrative Procedure for Handling PT-Related Action Items
- Form 4, OWM PT Action Form
- SAP 1, OWM PT Standard Administrative Procedure for Document and Record Management

8.9. Management Reviews

- 8.9.1. OWM conducts management reviews at planned intervals, in order to ensure its continuing suitability, adequacy and effectiveness, including the stated policies and objectives related to the fulfilment of this document.
- 8.9.2. The inputs to management reviews are recorded and include information related to the following (as included on the management review form.
- a) changes in internal and external issues that are relevant to OWM;
 - b) fulfilment of objectives;
 - c) suitability of policies and procedures;
 - d) status of actions from previous management reviews;
 - e) outcome of recent internal audits;
 - f) corrective actions;
 - g) assessments by external bodies;

- h) changes in the volume and type of the work or in the range of PT activities;
- i) customer, participant, and personnel feedback;
- j) complaints and appeals;
- k) effectiveness of any implemented improvements;
- l) adequacy of resources;
- m) results of risk identification;
- n) outcomes of the surveillance of the processes; and
- o) other relevant factors, such as monitoring activities and training.

8.9.3. The outputs from the management review include the recording of all decisions and actions related to:

- a) the effectiveness of the management system and its processes;
- b) improvement of the activities related to the fulfilment of the requirements of this document;
- c) provision of required resources; and
- d) any need for changes.

Applicable Forms, Policies and References:

- SAP 1, Standard Administrative Procedure for Document and Record Management for OWM PT program
- SAP 4, Standard Administrative Procedure for Audits and Reviews
- Form 5, OWM PT program Internal Audit Form
- Form 6, OWM PT program Management Review Outline
- SAP 2, Standard Administrative Procedure for Handling PT-Related Action Items
- Form 4, OWM PT Action Form

References

A master list of all applicable references for the OWM PT program quality system are maintained in a single document. See SAP 1, Standard Administrative Procedure for Document and Record Management for the OWM PT program. Some of the references were duplicated in Section 2, as Normative (mandatory) References; however, the latest versions are referenced in the Appendix of SAP 1.

Appendix A: Supplemental Procedures and Resources

This table contains a summary of the appendices in this document and the location of official versions. This summary should be used by laboratories participating in OWM proficiency tests to ensure suitable review and document control of the various applicable supplementary resources.

Table 1. Supplemental Resources Associated with NISTIR 7214 and NISTIR 7082

Item	Description	Official Version
Appendix B	PT Standard Operating Procedure (SOP) 1 for OWM PT Planning, Operating, Analyzing, and Reporting of PT Results	Contained within this document (NISTIR 7214) as an official procedure.
Appendix C	PT Standard Operating Procedure (SOP) 2 for Conducting a Mini Measurement Assurance Program	Contained within this document (NISTIR 7214) as an official procedure.
Appendix D	Good Laboratory Practice for Proficiency Test Follow-ups with Form	GLP and Forms as of this publication date; updated versions of the forms and job aids to be posted on the OWM Website.
Appendix E	OWM Supplemental Report for Proficiency Tests	Template as of publication date here; updated versions posted on the OWM Website.
Appendix F: OWM PT program Standard Administrative Procedures (SAP)	SAP 1: Document and Record Management for PT program SAP 2: Handling PT-Related Action Items SAP 3: Supplier Evaluation for PT Supplies and Calibration Services SAP 4: PT program Audits and Reviews SAP 5: Handling PT Related Collusion, Falsification, and	Contained within this document (NISTIR 7214) as official administrative procedures.

Item	Description	Official Version
	Participant Operational Failures	
Appendix G: PT program Forms	<p>External facing Form 1: OWM PT Feedback and Inquiry and Complaint Form Form 2: OWM PT Participation Request – Training/Qualification Form Form 3. RMAP Associate Membership Application Form 7: Examples of Proficiency Test 4-Year Plan and History/Log</p> <p>Internal facing Form 4: OWM PT Action Form (used with Form 1 and SAP 2, 4, and 5)</p> <p>Form 5. OWM PT program Internal Audit Form (may result in using Form 4)</p> <p>Form 6: OWM PT program Management Review Outline (may result in using Form 4)</p>	<p>Contained within this document (NISTIR 7214) as official forms (forms 1 through 3 are also posted online).</p> <p>Form 5 is not published with this document due to copyright constraints.</p>
Excel File: PT Plan Template	<p>Excel file: pt-plan-template-yyyyymmdd.xlsx</p> <p>Includes process flow, planning checklist and requirements, and creates a template for the final report leading pages.</p>	<p>OWM Website: pt-plan-template-20230301.xlsx</p> <p>Updated versions to be posted on the OWM Website.</p>

Item	Description	Official Version
Excel File: PT Analysis Templates	<p>Excel file: PT Analysis Template 35 artifact – 150 participant – yyyyymmdd.xlsx</p> <p>Excel file: PT Analysis Youden Template- yyyyymm-dd.xlsm</p> <p>Includes statistical analysis for all participants according to statistical analysis methods and creates the summary, tables, and graphs to be included in the draft and final reports.</p> <p>Data entry sheet of the PT Analysis template may be exported and is permitted for participant use to aid in PT analysis tasks.</p>	<p>OWM Website: pt-analysis-template-35-artifact-150-participant-20230301.xlsx</p> <p>pt-analysis-youden-template-20230301.xlsm</p> <p>Updated versions to be posted on the OWM Website.</p>

Appendix B: PT Standard Operating Procedure (SOP) 1 for OWM PT Planning, Operating, Analyzing, and Reporting of PT Results

Contained as part of this NISTIR 7214.

Appendix C: PT Standard Operating Procedure (SOP) 2 for Conducting a Mini Measurement Assurance Program

Contained as part of this NISTIR 7214.

Appendix D: Good Laboratory Practice for PT Follow-Up

A Good Laboratory Practice for PT follow-ups with an associated form is contained within this NISTIR 7214; however, flexibility in adapting the form is required in practice and for laboratory accreditation and recognition purposes. Any updated official versions will be located on the OWM website for use with each PT Report. The template form may be integrated into laboratory Quality Management System documents as a part of ensuring the validity of measurement results and evaluation and assessment of interlaboratory comparisons and proficiency tests. The GLP may be adopted by laboratories as part of their official practices.

As this form may be periodically updated, the official version will be located on the OWM website for use by participating laboratories.

Appendix E: Supplemental Report for OWM Proficiency Tests

A template Supplemental Report is contained within this NISTIR 7214; however, flexibility in adapting the report is required in practice and any updated official versions will be located on the OWM website for use with each PT Report.

Appendix F: OWM PT Standard Administrative Procedures (SAP)

- SAP 1: OWM PT Document and Record Management
- SAP 2: OWM PT Handling PT-Related Action Items
- SAP 3: OWM PT Supplier Evaluation for PT Supplies and Calibration Services
- SAP 4: OWM PT Audits and Reviews
- SAP 5: OWM PT Handling Collusion, Falsification, and Participant Operational Failures

Appendix G: OWM PT program Forms

External Facing Forms

- Form 1: OWM PT Feedback and Inquiry and Complaint Form
- Form 2: OWM PT Participation Request – Training/Qualification Form
- Form 3: RMAP Associate Membership Application
- Form 7: Examples of Proficiency Test 4-Year Plan and History/Log

Internal Facing Forms

- Form 4: OWM PT Action Form (used with Form 1 and SAP 2, 4, and 5)
- Form 5: OWM PT program Internal Audit Form (may result in using Form 4)
- Form 6: OWM PT program Management Review Outline (may result in using Form 4)