PT Standard Operating Procedure 1

for

OWM PT Planning, Operating, Analyzing, and Reporting PT Results

1. Purpose

The purpose of this Standard Operating Procedure (SOP) is to provide a procedure for planning, operating, analyzing, reporting, and following up on proficiency tests and their reports as a part of the NIST Office of Weights and Measures, Proficiency Testing (PT) Program. This SOP provides an overview of how the various types of proficiency tests (PTs) are conducted and an explanation of how laboratory performance is evaluated. This SOP can be used for any of the interlaboratory comparisons operated through the OWM PT Program, whether for use as official proficiency tests or not. It may also be used for training, completion of Laboratory Auditing Program problems, method validation activities, or other unique interlaboratory or intralaboratory comparisons. PTs are usually coordinated through the Regional Measurement Assurance Program (RMAP) regions or nationally, either by OWM staff or by a national PT Coordinator.

2. Overview of Required Components

The items identified in this section are required components of the OWM PT program to ensure compliance with the requirements of ISO/IEC 17043:2023. Specific guidance is identified during the planning and analysis procedure in Sect. 3.

2.1. Scope

This procedure is not limited to official OWM or accreditation body proficiency tests (PTs) and may be used for special interlaboratory comparisons (ILCs), intralaboratory comparisons, mini-measurement assurance program (Mini-MAP) evaluations, method validation, or any other suitable and applicable purpose using the OWM PT planning and analysis tools.

2.2. PT Process Policies, Procedures, and Tools

All of the National Institute of Standards and Technology (NIST) Office of Weights and Measures (OWM) PT quality management system (QMS) (including: NISTIR 7082, "Proficiency Test Policy and Plan" and NISTIR 7214 “Office of Weights and Measures Quality Manual for Proficiency Testing and Interlaboratory Comparisons”) policies, procedures, and tools shall be used in addition to the following items.

2.2.1. The **PT Plan** template spreadsheet shall be used for PT planning to ensure that a consistently developed and documented PT plan is in place that includes PT objectives, purposes, and schemes including the items listed in the following sections and noting if there are any reasons for exclusions.

2.2.2. All PT participants shall meet the participation criteria and shall be qualified or approved to participate at the planned level of work during the planning stage and

all participants are required to waive anonymity and comply with confidentiality restrictions (per NISTIR 7082);

2.2.3. All participants and OWM Laboratory Metrology Program staff shall review PT Plans and OWM Laboratory staff shall approve each **PT Plan** prior to beginning the PT**;**

2.2.4. All participants shall submit official calibration certificates and any requested supplemental forms or information determined as part of the **PT Plan**;

2.2.5. The *draft* PT analysis may be developed by the PT Analyst or NIST OWM staff and shall use the OWM **PT Analysis** template spreadsheet(s). PT participants must review and confirm data entry accuracy during the conduct or analysis of the PT; and

2.2.6. The *final* **PT Analysis** and **PT Report** may be developed by the PT Analyst but shall be reviewed and approved by the NIST OWM, Laboratory Metrology Program staff prior to issuance to PT participants.

2.3. Measurement Parameters, Quantities, and Ranges to be Determined

This procedure may be used for any measurement parameter, range, or level of uncertainty. Specific parameters, ranges, and uncertainties are determined during the PT planning stage.

2.4. Selection of the Item(s) to be Calibrated

Suitable history, stability, resolution, availability of an independent reference value, sufficient accuracy, and sufficiently small uncertainties for use with the reference value are critical for all PTs. The selection of a suitable reference value with metrological traceability is addressed in Sect. 3.3.5. Items to be calibrated in an OWM PT generally reflect the same type and range of items submitted for routine calibrations among participating laboratories.

OWM maintains an inventory of standards that are regularly used throughout the U.S. and Regional Measurement Assurance Programs. In general, items in circulation have demonstrated adequate stability, homogeneity (where applicable), and robustness for the intended applications. New standards introduced into the OWM PT inventory receive extra assessments before, during, and after use as needed. Items belonging to participants may occasionally be used in a PT if and when additional historical data (e.g., from calibration history and control chart data) are available for evaluating the reference value and its stability throughout the PT.

Selection of the standards (PT artifacts) requires special consideration when they are not part of the NIST OWM inventory and especially when there are a small number of participants.

2.5. Participant and Laboratory Qualifications

All participating laboratories shall comply with requirements for participation published in NISTIR 7082, Policy and Plan, NIST Handbook 143, Program Handbook, and with ISO/IEC

17025:2017, *General Requirements for the Competence of Testing and Calibration Laboratories* through recognition by the NIST Office of Weights and Measures or through accreditation by an accreditation body (AB) that is an ILAC Signatory and be members of one of the Regional Measurement Assurance Program regions. Laboratories that are not recognized or accredited are expected to comply with NIST Handbook 143 and ISO/IEC 17025:2017 standard to ensure integrity of the PT scheme, PT items, and submission of compliant calibration certificates.

All participants shall have adequate training prior to participating in PTs to ensure that standards are not damaged, contaminated, or degraded and that specified procedures are followed. Formal and informal training, qualifications, and experience shall be documented within OWM for each participant. (OWM Training Records and transcripts of the prospective PT participant are used when available). Additional records may be requested from potential participants to validate compliance with the participant qualification requirements. PT policies regarding training and participation shall be followed; exceptions for participants who have not completed applicable or recognized OWM training shall be submitted to OWM for approval and records will be retained in OWM. Exceptions will be made for State weights and measures laboratories where participation is required to complete Laboratory Auditing Program (LAP) problems and/or laboratory recognition. However, introductory training or on the job (OJT) training records for the measurement parameter shall be available to ensure the integrity of the PT.

State laboratories and each Approved Signatory are required to comply with the NISTIR 7082 Policy and Plan for regular participation in proficiency tests in all areas of their Scope on a periodic basis (where practical and available). A five-year interval is specified for the regional PT plans, as PTs are planned and available either nationally, or within the Regional Measurement Assurance Program (RMAP). Failure to participate when PTs are available on a regional basis may impact laboratory recognition or accreditation (see NIST Handbook 143, Program Handbook and accreditation body policies and requirements). Laboratories that are not weights and measures laboratories recognized through OWM have the option to participate or not (as long as they meet all participation requirements).

Special PT arrangements may be made for individuals in the State weights and measures laboratories to participate in a unique, non-regional PT, to assist laboratories in regaining signatory approval status for staff or laboratory recognition. Special LAP problem PTs will only be coordinated when the RMAP-coordinated PTs are not adequate/timely enough.

2.6. Equipment, Including Technical Performance Requirements

All participants shall have suitable equipment, reference standards, and suitably small uncertainties for the parameters or levels of calibration in question. Laboratories shall have evidence of metrological traceability to the SI for all participating measurements to meet the most basic objectives of traceability in OWM PTs. In general, the laboratory will already have the measurement parameter, range, and uncertainty (Calibration and Measurement Capability, CMC) on their scope of recognition or accreditation. Approval is required from OWM for any laboratory that wishes to participate with the intent of adding measurement capabilities to their

laboratory scope. OWM approvals may include additional recommendations or requirements prior to participation.

2.7. Laboratory Procedures

Use of internationally or nationally published Standard Operating Procedures (SOPs) is required (where available for that parameter and scope). For compliance with the NIST OWM PT program, it is expected that NIST SOPs are used when available. NIST SOPs are normally specified as part of the PT Plan when available. Procedures shall be specified or referenced in the PT Plan. If specified procedures are not available (e.g., in the case of new technology or method validation efforts), or there are participants from laboratories that do not use OWM procedures, procedures shall be submitted for review upon request. A document review of non-NIST procedures may be included in the final PT Report. In the case of alternative procedures, comparable measurement uncertainties are required for equivalent statistical comparisons of data.

OWM procedures include specifications for standards, environmental conditions, equilibration, methods, calculations, and uncertainty budget components that are to be followed by all participating laboratories even if they are using other procedures or laboratory-developed methods. In general, the PT Plan specifies that participants agree to use the same procedure(s) to avoid potential discrepancies from irregular measurement results or dissimilar uncertainty values that challenge troubleshooting and PT analysis efforts.

3. Proficiency Testing Procedure

There are four stages of each PT: 1) Planning, 2) Operation, 3) Analysis, and 4) Reporting with subtasks in each section. The PT Plan template spreadsheet includes an overall outline for planning and coordinating PTs with separate worksheets for planning phases identified as P1, P2, P3, and P4, operating phases O1 and O2, plus cover pages for the PT as worksheet R1. The PT Analysis template spreadsheet(s) is/are used to check the validity of data entry, data transfer, statistical analysis, and record participant performance evaluations. A combination of the reporting section, R1, of the PT Plan and the PT Analysis tools are used for reporting. An OWM Supplemental PT Report is used for explanations of the data, analysis, and performance assessments. The PT Plan template documents and includes the PT schemes, objectives, purposes, and identifies all information needed in the planning and operational stages of each PT. Note: A separate procedure (PT Standard Operating Procedure 2 for Operating a Mini-Measurement Assurance Program (Mini-MAP) is available for a “Mini Measurement Assurance Program” (MiniMAP) that can be used among two or three laboratories for small, or unique, applications and laboratory requirements. It also requires the use of the PT Plan template and PT Analysis template tools and additional statistical analysis of laboratory data to ensure statistical validity of the outcome analysis.

PTs are usually coordinated and maintained within the Regional Measurement Assurance Programs (RMAPs). The RMAPs maintain 4-year or 5-year PT Plans which include annual reviews, inputs, and updates determined during planning sessions with OWM staff, PT coordinators, PT analysts, and participants. Laboratory participants are obligated to ensure that measurements on their Scope are addressed in the RMAP plans to the extent possible. National

PTs may be coordinated when there are not a significant number of laboratories within the RMAP regions to ensure an adequate number of participants for statistical validity of the PT scheme and data analysis.

3.1. Planning Stages

The PT Plan template spreadsheet follows the steps in this SOP and includes the PT Plan requirements. The PT Plan is usually initiated and completed by a PT Coordinator; it may be completed by OWM staff for national PTs who may also serve as a PT Coordinator. All PT Plans are to be reviewed and followed by PT participants and shall be submitted to OWM for final approval before proceeding with the PT scheme (reference NISTIR 7082). OWM will ensure that the PT is adequately defined, documented, technically and administratively appropriate. Updates to the PT Plan shall be approved by OWM and circulated to PT participants during the course of the PT operations as needed, especially if risks to the PT are identified, schedules are updated, the procedures for calibration or analysis are updated, the validity of PT result/data is suspect, or PT shipping and handling must be modified.

Key sections of the PT Plan template include the following planning stages and worksheets, with each section having multiple steps:

- P1 – Organize the PT;
- P2 – Objectives and Details;
- P3 – Artifact and Shipping; and
- P4 – Addresses and Contacts.

3.1.1. Stage P1: Worksheet P1; Organize the PT

3.1.1.1. Define the Scope and Title: Parameter, Range, Uncertainty and PT Name

During the P1 step, the need for the measurement parameter, range, and level of calibration or level of uncertainty to be expected for the PT are defined. The need and scope may be defined during the RMAP 4-year planning process as well. PTs are named based on the region, year of planned reporting, measurement parameter, and expected level of calibration and uncertainty. PT plans for the regions will sample different parameter ranges and units from year to year to meet the variable Scopes of the laboratories.

The PT Plan template includes a drop down list of options to define the parameter, range, and level of calibration (e.g., echelon or class) for the PT. The use of standardized drop-down choices helps ensure consistency among all PTs and is used to name the PT:

Region:	
Reporting Year:	
Parameter:	

Unit System:	
PT Sequence Number:	
Range or Nominal:	

For example, the following selection identifies the region, year, parameter/level of work, units, and PT number (to allow for multiple PTs meeting that criteria):

Region:	MidMAP
Reporting Year:	2025
Parameter:	Mass Echelon III
Unit System:	Metric
PT Sequence Number:	01
Range or Nominal:	5 kg to 10 g

The PT name for this example is: "MidMAP-25-MIII-M-01". The PT Plan template and the PT Analysis template tools shall indicate this name as part of the file name.

3.1.1.2. Identify the PT Administrative Team

The personnel involved in the design, operation, and analysis of a PT are integral to the PT administrative team. This step includes the identifying the PT Coordinator(s), PT Analyst(s), and OWM staff Points of Contacts (responsible staff for oversight, trouble shooting, final analysis). Each PT may have observers who wish to learn about PT administrative actions. The PT may also include mentors who are experienced PT Coordinators who agree to assist a new PT Coordinator with the planning and coordination of a PT. The PT may also include mentor or observer PT Analysts who are responsible for the data entry and initial data analysis of the PT using the PT Analysis template. The responsible PT Administrative Team and their contact information are all identified during the planning stage. The roles of each administrator are defined below.

- PT Coordinator: The coordinator is one or more individuals with responsibility for organizing and managing all of the activities involved in the operation of a proficiency testing scheme. Coordinators document observations, feedback, and complaints related to the PT, and provide input to the analyst for drafting the final report. They do not provide reference value information to participants.
- PT Analyst: The analyst provides initial data entry, analysis, conduct inquiries for problematic data, and may provide interim pass/fail feedback to participants. They do not provide reference value information to participants. They draft the PT analysis and report with input from the PT coordinator, confirm data entry with

participants, and submit the draft PT analysis and PT report to OWM for final review and approval.

- PT Mentor: The mentor is an experienced PT Coordinator or Analyst who provides one-on-one guidance to a coordinator or analyst with less experience. Having a separate mentor is optional for OWM PTs, otherwise the regional coordinator acts as the default mentor.
- Observer: The observer role allows a participant to observe how the coordinator and analyst plan, operate, analyze, and report a PT. This allows them to gain valuable experience before volunteering as a coordinator or analyst in the future. The observer must be an integrated part of all communications for the PT. Having an observer is optional for OWM PTs.
- Regional Coordinator: Each RMAP group is assigned at least one regional coordinator. This position requires an experienced and effective PT coordinator and analyst. They manage and document the PT participation planning schedule process for their RMAP. They mentor and assist, as needed, all the coordinators and analysts for the PTs in their group and make sure all PTs are kept on schedule to meet the PT plan. They serve as backup to take over a PT if the coordinator or analyst is no longer able to perform their duties. They regularly report to OWM and participant laboratories on the status of PTs in their region.
- Technical Point of Contact: may be a PT Coordinator, PT Analyst, mentor, or assistant: A NIST point of contact, coordinator or analyst provides guidance and support to the PT Administrative Team and PT participants. OWM staff approve the PT Plan before a PT may be started and finalize the PT analysis and evaluations included in the final PT Report. Some PT coordinators and PT analysts are reluctant to be critical of metrology peers when it is necessary to identify and address deficiencies in analyzing a PT and including evaluations and feedback in the final PT Report. The NIST coordinator and analyst provides any additional feedback necessary regarding the performance of participants and serves as the final arbitrator for all PTs performed under the OWM PT program guidelines.
- NIST (or other) Technical Advisor: The NIST technical advisor provides subject matter expert guidance and support for a PT. Having a technical advisor is based on the parameter and unique needs of the PT. This person may or may not assist the PT Coordinator, PT Analyst, or in the PT Final Report generation, but is available as a technical advisor if any issues arise during the PT that would benefit from an experienced technical staff member. This person may or may not be a member of the Office of Weights and Measures. For example, a member of the Statistical Engineering Division, the Mass and Force Group, a retired staff member, or contractor (if specified in their contract role) may meet the technical advisor role. Having a NIST Technical Advisor is optional for OWM PTs; although this role may be added after the PT Plan has been approved depending on the needs of the PT.
- Pivot Laboratory: If one participant will provide intermediate calibrations or beginning/ending values for the PT, they shall be designated during planning and

approved by OWM. The purpose of using a pivot laboratory shall be defined (most often for monitoring trends in the data but may be included to participate with a procedure that produces smaller uncertainties to assist in defining or validating the reference value(s)). Pivot laboratories are not necessarily considered "expert" laboratories for the purpose of identifying and selecting the assigned reference values.

3.1.1.3. Identify High Level Scheduling Overview (Critical Timelines)

Identify the planned completion dates, how long the standard(s) (artifacts) will be available and how long each lab will be given to complete the calibrations. The program goal is to complete each PT within a one-year period so that final reports can be issued at subsequent RMAP meetings. OWM may supply the coordinator information on when and how long PT artifacts are available, the due date for submitting a draft analysis and report to OWM, and any logistical considerations that must be considered.

3.1.1.4. Circulation Plans - Identify Laboratories, Participants and Training Details and Set Initial Schedule for Review

Include a list of all laboratories and all participants on the planned scheduled list. All intended participants shall be included in the plan. All participants shall comply with Sect. 2.5, Participant and Laboratory Qualifications and OWM will verify training qualifications or oversight requirements as a part of reviewing and approving a PT Plan. If a proposed non-legal metrology participant is not a regular attendee at the RMAP training or has not completed OWM training requirements, then Form 2 must be completed and submitted for that staff member. When a participant requires a completed PT to finish LAP problems, that shall be flagged on the scheduled list and in the PT Objectives section to enable OWM staff to obtain interim data and analyses if/as needed. Additions to this list once a PT has begun shall be approved by the NIST OWM Point of Contact prior to participation. When a petal scheme or opening and closing measurements will be made by a designated laboratory, the pivot laboratory shall be approved by OWM and listed multiple times in the schedule as applicable.

The PT coordinator creates a preliminary schedule that is sent out for laboratories to identify any conflicts before the schedule is set. Special consideration is required when participants are required to transport the PT item(s) to other participants. Laboratories that have been historically slow at finishing PTs, who have planned downtimes or moves, or who have previously received warnings from OWM regarding schedule compliance, are scheduled at the end of the routing. This way, the PT can be finalized even if that lab keeps the artifact too long, doesn't complete measurements, or submit a calibration certificate.

A planned PT must have a balance between enough participants to enable statistical validity of the data analysis and too many participants that would prevent completion during the planned PT scheme and scheduled dates. In some cases, too few participants will lead to merging plans with other regions up to and including a national PT instead of a regional PT.

Laboratories that "hard schedule" their work or have planned any extended periods of time that temporarily prohibit them from making measurements (e.g., vacations, standard calibrations, new laboratory or equipment installations, holiday closures, etc.), communicate this with the coordinator before the schedule is created or as soon as they are aware.

3.1.2. Stage P2: Worksheet P2; Objectives and Details

3.1.2.1. Unique Considerations

Identify any unusual or unique issues associated with the PT that is not a standard calibration approach defined in the applicable specifications and tolerances for the standard to be used or by the procedures that will be designated. Any unique calibration or test methods or issues related to the standards to be used or calibrated shall be identified, determined, documented, and approved during the planning stages.

3.1.2.2. Establish PT Objectives

Select the PT objectives by checking the applicable selection boxes for each of the following options. Clearly identify any additional objectives entered in the "other" category. The most common items are selected by default in the PT Plan template. When a participant was identified in the P1 worksheet as needing LAP problems, LAP problems need to be selected on this checklist as well. The following are specific objectives listed in the PT plan template:

- Demonstration of Competency for Accreditation or Recognition;
- Validation of Expanded Uncertainties;
- Evaluation of Calibration Certificates;
- Method Validation (New Methods/Procedures ONLY);
- Laboratory Auditing Program (LAP) problems (For State employees/participants);
- Demonstration of Effective Corrective Action from previously failed PTs;
- Conformance or Suitability Evaluation of Artifact;
- Identifying Artifact Characteristics (stability, material, density, etc.);
- Customer Service & Contract Review (e.g., timeliness, following instructions); and/or
- Other (requires explicit description).

3.1.2.3. Identify PT Evaluation Methods (Performance Statistics)

Select the planned PT Evaluation Methods by checking the applicable selection boxes for each of the following options. The default evaluations will include an assessment of the overall statistics to identify any values outside the initial two standard deviation limits for the PT including all data and observations which is used for the analysis of the reference value with metrological traceability (See 3.3 Analysis). The difference (bias), normalized error, E_n, the normalized precision, P_n , the Z score, and 2 standard

deviation evaluations are selected by default. When other evaluation methods are used, they shall be explicitly defined when selected. Difference from Reference Value (Bias);

- Normalized Error (E_n);
- Precision Assessment (P_n);
- Z Score;
- 2 Standard Deviations;
- SOP 1 Calibration Certificate Review Checklist (qualitative review for ISO/IEC 17025 compliance);
- SP 811 Check List for Reviewing Manuscripts (qualitative review); and/or
- Other.

One example of another method that might be used is that of a Youden Plot analysis (Using the PT Analysis Youden template) that also includes an evaluation of random and systematic components of variability. The evaluation methods are further defined in the PT Analysis section of this procedure (Sect. 3.3) and uses the PT Analysis template to ensure uniform and consistent analyses and performance assessments.

3.1.2.4. Select the Design Pattern and Pivot Laboratory (if appropriate)

Identify the design pattern to be used in the PT. The same pattern is used to establish the overall schedule in stage P1. The circular pattern is selected by default and is most common. Pivot laboratories may be used to monitor trends and stability or to provide interim reference values for interim evaluation and feedback but are not required. All pivot laboratories must be approved by OWM with documented and planned roles and responsibilities with respect to use of data in final analyses. Any available reference values will not be provided to pivot laboratories prior to submission of calibration certificates to prevent undue advantages or collusion in analyses.

3.1.2.4.1. Circular Design

The PT moves in a circle from beginning to end and may start and end with a pivot lab (the pivot lab is not required). Each laboratory ships the PT to the next lab without returning it to a pivot lab for intermediate measurements. This version of the design leads to the common term “round robin.”

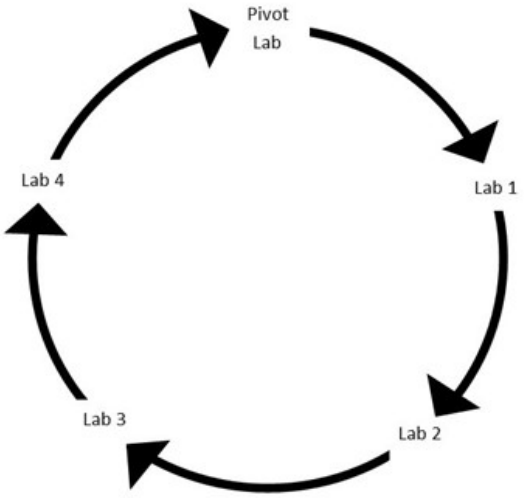

Figure 1. Circular Design

3.1.2.4.2. Petal Design

The pivot lab makes initial measurements, then one of the participating labs makes measurements, then the pivot lab gets the PT back and makes intermediate measurements before sending the PT to the next lab. This is repeated for every laboratory.

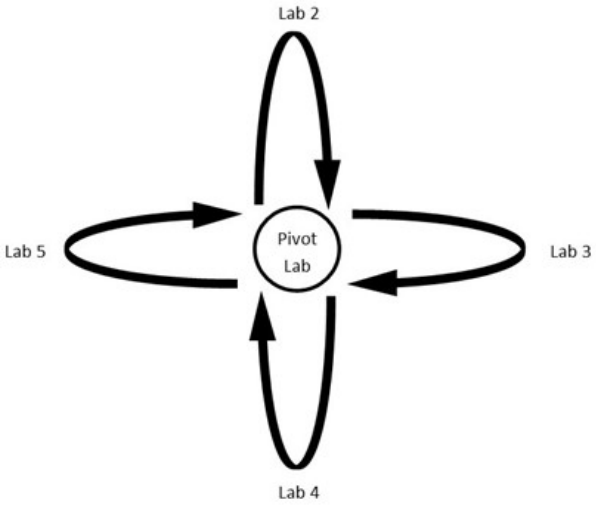

Figure 2. Petal Design

3.1.2.4.3. Modified Petal Design

This design is similar in concept to the Petal Design, with the difference being that the PT does not return to the pivot lab after each lab. The number of labs a PT is passed through before returning to the pivot lab is optional based on the objectives and stability of the artifact.

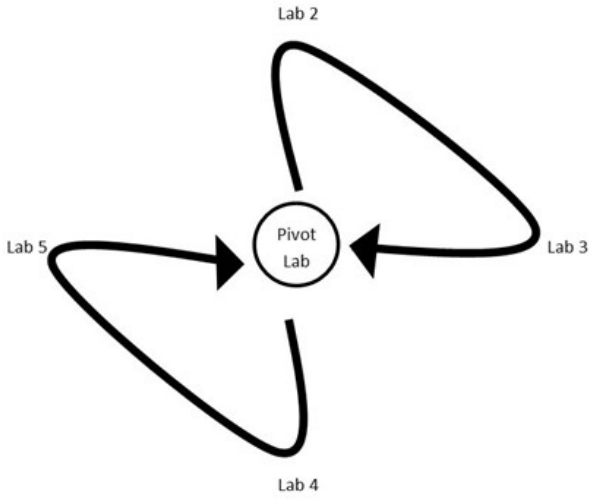

Figure 3. Modified Petal Design

3.1.2.5. Calibration Procedure

It is expected that NIST Standard Operating Procedures (SOPs) are used in the OWM PTs. When there is no NIST SOP available, use of internationally or nationally published SOPs is expected. Enter the calibration procedure participants are to use and include the entire reference document and date for the procedure. See also Section 2.7. Be specific with full document, title, and date of SOP: "NISTIR 7383 (2019 Ed), NIST SOP 19 (March 2019) Calibration of Graduated Neck-Type Metal Provers" versus "SOP 19". Note whether any laboratories request alternative procedures to be approved by OWM. Alternative procedures may be requested for OWM evaluation, may not be proprietary or restricted for distribution, and must provide equivalent uncertainties to the selected procedure. Alternative analyses may need to be implemented when uncertainties are not equivalent.

3.1.2.6. Environmental Conditions During Storage, Handling, and Calibrations

The default terminology is: “As outlined in the designated calibration procedure(s) which are followed to ensure PT standard(s) artifacts are not compromised. Conditions to be specified on calibration certificate (ranges acceptable).”

Environmental conditions, equilibration, and uncertainty budget components identified in the NIST SOPs must be followed by all participating laboratories, even if they are using other procedures or laboratory-developed methods. Environmental conditions for calibrations must not negatively impact the measurement results or uncertainty of the

calibrations and must not negatively impact the stability of the standard items being calibrated in the PT.

3.1.2.7. Equilibration Procedures and Time

The default terminology is: “As outlined in the designated calibration procedure and as routinely managed for similar types of calibrations (unless additional requirements specified here). Equilibration conditions to be included on calibration certificate if supplemental to the calibration procedure.” The equilibration requirements of the designated SOP are used by all participants and restated if/as needed.

If the chosen calibration procedure or documentary standards for handling do not cover equilibration requirements, a consensus decision must be made during the PT planning process. Modifying the default entry is also required when the PT Plan is used for method validation, especially if laboratories are using differing approaches for equilibration. In the case of differing approaches, a supplemental data sheet to document differences may be used, or the equilibration procedures may be included on the calibration certificate. Whatever approach will be used is to be specified during the PT planning phase.

3.1.2.8. Required Equipment

The default terminology is: “Participants will use equipment that they typically use for this measurement parameter ensuring that accuracy and repeatability requirements of the procedure and this PT are met.” When new technology, equipment, or standards, are being evaluated, additional specific requirements must be discussed during planning and documented in this field. If any special equipment is required as a part of the calibration and/or shipped with the standard, it should be noted here. For example, if a support stand is to be shipped with a “special J” type prover for calibration, make sure the equipment is listed in this section.

3.1.2.9. Measurand and/or Characteristics of Interest

Specific reference conditions and references for the measurement parameter and item(s) *intended to be measured* must be specified during the PT planning phase. Instructions in the PT Plan template note the following as examples: Conventional Mass correction, Volume at the '0' graduation mark, Volume at the '0' graduation mark and 4 neck scale intervals, length between 7 inch and 13 inch graduations. Volume might need to be specified at 20 °C or 60 °F or Volume to be Delivered (TD) or Volume to be Contained (TC). The explicit measurand must be defined during planning so that participants report correct measurement results and references in their calibration certificates and so analyses are evaluating like references. Other characteristics of interest could be something for the participant to identify, such as the material, coefficient of cubical expansion, or the density and are often specified in the Reporting section of the chosen Standard Operating Procedure.

3.1.2.10. Units to be Reported

There is a standardized drop down field of possible measurement units. Measurement results and uncertainties may need to be reported in different units. The PT Analyst can often convert reported values on certificates, but that is an extra step and an opportunity for conversion errors that can be avoided or minimized if participants report values as planned. When a data entry sheet is circulated to PT participants for data entry, the PT coordinator or PT analyst must ensure appropriate labels are specified and indicated to ensure all values are subsequently analyzed using the specified measurement units.

3.1.2.11. Number of Significant Figures

The default for OWM PTs is two significant digits unless otherwise noted in the instructions. This follows the NISTIR 6969, Good Laboratory Practice 9, for Rounding Measurement Results and Uncertainties. To comply with special applications, the instructions might state "at most, 2 significant digits."

3.1.2.12. Specify Any Supplemental Data Sheets

The default for supplemental data sheets is "no" for OWM PTs. In some cases, for larger numbers of standard items to be measured, a supplemental data entry sheet may be used to assist the PT Analyst so they can copy/paste from the participant-created data sheet. In that case, the confirmation of data entry is conducted during data entry by the participant and/or participating laboratory representative. A spreadsheet version of the PT Analysis spreadsheet may be used to simply the analysis effort; the "data entry" sheet of the PT Analysis spreadsheet may be used for this application. There are often supplemental data sheets and forms on specialty PTs, and national PTs, or international comparisons. The PT coordinator or PT analyst must ensure the extra data sheet has correct labeling of the intended measurement units!

A supplemental data sheet is an option for the PT Analyst but does not replace the requirement for calibration certificates to be submitted. When a supplemental data sheet is used, the format must match the first data entry row and headings in the Data Entry tab of the PT Analysis template. The PT Analyst is expected to still do a quality check and *sample* the data entry and calibration certificate(s) to verify that the values match.

3.1.2.13. Tolerance Source and Class

Select the applicable documentary standard and tolerance that will be used to evaluate participant data as this is normally applicable for PTs supporting legal metrology. The evaluation approach may differ from the classification for the PT items. A drop-down of the most common tolerances used in OWM PTs is provided for this field. When a tolerance is specified, it implies conformity assessment and decision rules be followed in the PT reporting process. The participant calibration certificate will then list tolerances, how the uncertainty was applied in making decisions, and an assessment of compliance to specifications and tolerances (or what was not evaluated) as required by ISO/IEC 17025 conformity assessments.

3.1.2.14. The Percentage or Fraction of Tolerance used for Assessing P_n

This value is used in the normalized precision calculations and is related to published decision rules in the standards referenced in the Tolerance Source and Class. A drop-down option provides either 1/3 (as used in mass specification decision rules) or 100 % which will compare the uncertainty to the tolerance on a one to one basis (as is the case for most volume calibrations). When a laboratory volume standard is calibrated in the PT scheme, the ratio of 1/3 will be used to ensure that laboratory standards are fit for purpose and have sufficiently small uncertainties for use when calibrating field standards.

3.1.2.15. Expected Uncertainties from Participants

The default terminology is: "Uncertainties must represent the actual uncertainties used by the laboratory. The expected value is small enough to pass the P_n statistical test and includes the components identified in the NIST SOPs."

Uncertainties must represent the actual uncertainties calculated by the laboratory and not be a function of the specified tolerances or portion of tolerances. The expected value must be small enough to pass the P_n statistical test and includes the components identified in the NIST SOPs. The reported uncertainty must be generally consistent with other laboratories using the same or similar procedures and significant differences among participants may be investigated during analysis. Reported uncertainties may not be smaller than those published by accreditation bodies and are expected to be reasonably close to published or submitted values that would be obtained during normal or routine calibrations. Note: A precision assessment should be a routine part of each laboratory ensuring the validity of laboratory results and uncertainties reported to customers. Having precision failures in a PT indicates that laboratories have not sufficiently evaluated their uncertainties with respect to documentary standards and taken suitable corrective actions.

3.1.2.16. Expected Range of Values from the Participants

Default terminology is: "The expected range of values from participants is less than the tolerance." The normal variation of a selected PT item is that its measurement values stay within tolerances during circulation with proper (normal) care and handling. The range is defined as the maximum value minus the minimum observed or reported value. When all participants claim metrological traceability to the SI with suitable uncertainties compared to the defined tolerance, it is typical that all reported measurement results will be within the tolerance limits unless there are other gaps in the participant's calibration program (e.g., standards not calibrated according to schedules; inappropriate equipment used for the calibration; environmental controls outside of prescribed limits.) In most OWM PTs, only major errors, problems with reference values or standards, major blunders and mistakes, personnel competency issues, or outliers are likely to be observed outside the tolerance range specified in the PT plan.

3.1.2.17. Expected Limits of Stability

The default terminology is: “When there is no significant observed shift or drift, and the first and last measurements are not outliers, the comparison between initial and closing measurements should result in an E_n value of less than 1”. A stability assessment may be conducted during the PT analysis, with Pivot Laboratory values or with the first and last participant values. A visual assessment of the data might show shifts or trends, in which case additional analyses of the PT may be required. If there was a major change in a standard during the conduct of the PT, multiple analyses may be required in the final analysis and documented in the PT Report. The stability of the standard(s) also must be addressed in the final report by the PT Analyst and/or OWM.

3.1.3. Stage P3: Worksheet P3; Artifact and Shipping

3.1.3.1. Artifact Owner and Description

3.1.3.1.1. Owner Name and Address

Ownership information is supplied by OWM or the owner when a stable PT item is loaned for an RMAP PT or national PT. Artifact characteristics (e.g., 4 in neck vs 3 in neck, or stainless steel vs cast iron) that are being requested for the PT are documented by the PT coordinator during the planning stage. Once an artifact is selected, the other relevant characteristics are identified on the artifact (or case) or supplied by OWM or the owner.

3.1.3.1.2. Unique Description and Characteristics of the Selected Standards

Document all applicable characteristics about the standard(s), including (as applicable) but not limited to:

- Manufacturer;
- Serial Number;
- Description;
- Range (largest to smallest) or Nominal;
- Number of Pieces;
- Model / Design;
- Tolerance classification as manufactured;
- Material;
- Density;
- Coefficient of Expansion;
- Neck Graduation Size; or
- Other.

3.1.3.2. Handling

The PT coordinator provides sufficient details on handling requirement of the artifact and references any applicable procedures. Some items to consider are cleaning (or not), gloves/weight handlers, drying before packing for the next laboratory, storage, or safety

requirements. Participants must be fully trained or supervised by a trained metrologist for proper handling when participating in PTs (see section 2.5.)

3.1.3.3. Packing

Artifacts must be packaged to avoid damage. The PT coordinator includes a description with sufficient details of the case (and acceptable methods of securing), packing material, and how the artifact(s) are packaged. Any PT specific instructions or pictures are documented here. This section includes the following or similar statement: "Any participant that receives the artifact packaged in a manner that is not appropriate or mishandling by the shipper is evident, must contact the coordinator and OWM."

3.1.3.4. Shipping

OWM informs the PT coordinator if alternative shipping methods are designated for a PT, but PTs are generally shipping using a default method to reduce transport time, lost, or damaged PTs. The required default shipping method is FEDEX Express, 2nd Day Air (2nd Business Day). This section includes the following or similar statement: "If your laboratory is unable to use this shipping method, contact OWM for alternative methods and approval."

OWM pays the shipping costs for state laboratories. In these instances, the billing is "3rd Party" with the specified account number (not included in the PT Plan or this procedure due to prior fraudulent use by outside parties. In the billing reference or internal comment section, indicate "NIST Div. 680.02 (and the RMAP group, e.g., NEMAP)". OWM does not pay for shipping costs for non-state laboratories unless the PT Coordinator is a volunteer from that other laboratory. The OWM Federal Express account number is not published in procedures or templates that are posted online due to prior fraudulent access.

3.1.3.5. Insurance Reference Information (for Shipping)

The PT coordinator completes the insurance field and shipping weight estimates by locating the corresponding values provided.

3.1.4. Stage P4: Worksheet: P4; Addresses and Contacts

OWM provides full RMAP member lists and attendance lists to the PT coordinator for completing the contact list and shipping addresses. This information must be reviewed by the laboratories during the PT Plan review to ensure PT items are correctly shipped and not lost in shipping. The shipping address and contact information on this sheet is used by participants in coordinating shipping to the next participant in the PT once they have completed their calibrations.

The list on P4 sheet must match with the list of laboratories provided in sheet P1 and is not automatically completed. However, the detailed list of participants on the P1 sheet *is* used as an automatic reference in the PT Report sheet (R1) that is part of the PT Plan template. Be sure to double check spelling accuracy for organizations and names. Ensuring a

complete list of participants during the planning phase is important to ensure the PT Report includes all participants and does not inadvertently omit someone. The laboratory and name columns may be copied/pasted as values on the P4 sheet, with additional shipping address details and contact information completed.

3.1.5. PT Plan Review and Approval

Once the PT Plan sections P1, P2, P3, and P4 have been completed, and reviewed by all participants with any updates or participant additions resolved, the PT Coordinator submits the PT Plan to OWM for approval to proceed. OWM may fill in or modify sections of the PT Plan if the information was not initially available to the PT Coordinator or if it needs to be adjusted. OWM will communicate approval and/or return the approved PT Plan to the PT Coordinator to circulate a final copy to all participants.

3.2. Operation Stage

3.2.1. Roles of the PT Coordinator(s), Mentor(s), Observer(s)

The operation stage of the PT Plan template includes two worksheets, O1, for tracking progress of the PT against the planned schedule and O2, for recording and documenting any problems, delays, damage, or complaints that arise during the PT. These records are completed by the PT coordinator during operation of the PT and shared with the PT Analyst and OWM. Any issues that are required to be resolved by OWM require additional communications and status to be documented. The following sections cover the tasks conducted during the PT operation phase.

3.2.1.1. Start the PT

Email the OWM approved PT Plan to all participants, lab contacts, and the RMAP regional coordinator. Coordinate with OWM to provide the artifact and ensure it is shipped to the opening laboratory. Ensure a printed copy of the PT Plan is included with the PT items and label the PT Plan to keep it with the PT items. Request OWM to send available initial or historical reference values to the PT analyst after the analyst has performed their initial measurements and submitted a calibration certificate.

3.2.1.2. Monitor the PT Progress and Report Status

The Monitoring of the Progress and Reporting Status is documented in the PT Workbook, Section O1: Coordinator Tracking. The coordinator is responsible to always know where the PT items are located and be able to report the status of the PT to OWM when requested. The status is tracked by the PT coordinator as the PT moves from laboratory to laboratory. The coordinator actively communicates with the PT participants and PT analyst to keep the PT on schedule, report any delays or problematic laboratories to OWM before delays could interfere with the critical timelines. A laboratory in the planned schedule may need to be skipped to get the PT item(s) to a “hard scheduled” laboratory and return to the schedule later when there are delays. PT shipments should not proceed until the shipping laboratory confirms with

the receiving laboratory that they are available and prepared to participate in a timely manner.

3.2.1.3. Feedback and Complaints

Feedback and complaints are documented in the PT Plan, Section O2: Coordinator Feedback. The coordinator records feedback, recommendations, observations, and complaints throughout the course of the PT.

3.2.1.4. End the PT Round, Submit all Records, and Prepare for the Analysis Phase

If there are any question on the stability of the artifact as determined by the PT Analysis, additional ending measurements may be needed. After all measurements are completed, the PT coordinator notifies OWM and the PT analyst. The PT coordinator identifies the final shipping location for the PT items and informs the last participant to ship to the final location. AT that time, the PT Coordinator notifies the PT Analyst and OWM that all measurements are completed.

The coordinator sends electronic copies of all the calibration certificates or supplemental data sheets submitted by the participants with the completed coordinator tracking and feedback sections O1 and O2 of the PT Plan to OWM. The coordinator prepares a draft summary based on their observations, feedback, and complaints (formal or informal) from participants and OWM, and forwards it to the PT analyst for inclusion in the PT draft and final reports.

3.2.2. Roles of the PT Participants

PT Participants have a responsibility to review the PT plan and follow the schedule and designated procedures in a timely manner and to the extent possible to avoid introducing problems that must be resolved. They must also submit calibration certificates and supplemental data sheets if requested to the PT Coordinator or PT Analyst (however designated) so that interim feedback is possible and so that reporting can be completed according to the planned critical timelines. PT Participants must also report delays, damage, conflicts, and shipping issues as soon as possible to the PT Coordinator so that alternative plans can be implemented if needed.

3.2.2.1. Follow the Schedule and Ensure Approved Participation

The PT schedule is developed by the coordinator based on input from participants, the OWM, the logistics of shipping the PT, and the time allotment for each laboratory. NIST OWM PTs typically have multiple metrologists from several laboratories participating, to minimize disruptions and costs, follow the schedule as designed. Only metrologists approved on the PT Plan may participate unless additional approvals are granted by OWM and communicated to the PT coordinator and PT analyst.

3.2.2.2. Report Delays or Conflicts Immediately

When a laboratory is in possession of the PT and experiences an unexpected event that may cause a delay of the PT, they immediately communicate this with the coordinator. This allows the coordinator to make timely informed decisions on the progression of the PT.

When a laboratory is not in possession of the PT and identifies a potential conflict with the schedule of the PT, they immediately communicate this with the coordinator. This allows the coordinator to make timely informed decisions on the progression of the PT.

3.2.2.3. Receive PT Shipments

When a laboratory receives the PT, they shall inform the PT coordinator of the date of receipt, visual inspection observations, any damage to the artifact or case, and whether PT items were packaged in an inappropriate manner.

3.2.2.4. Perform Measurements

PTs must be treated as priority calibrations. Measurements must be performed in a timely manner to keep the PT on schedule. Unless otherwise directed by the PT Plan, measurements are made as per routing customer calibrations. PTs are not treated as special calibrations by changing the process normally performed. PT items and associated equipment (e.g., cases, trailers) are not permitted to be used for purposes not defined in the approved PT Plan.

3.2.2.5. Submit Calibration Certificates

Participants are required to report their values to the coordinator using an official calibration certificate that is ISO/IEC 17025 compliant. Amended values or uncertainties resulting from corrective action or new measurements are submitted in an official amended calibration certificate, with reasons for amendment noted on the certificate per ISO/IEC 17025 requirements. Calibration certificates must be submitted in a timely manner so the PT coordinator or PT analyst can supply initial feedback and keep the PT on schedule.

Before receiving initial feedback, each laboratory selects one participant to represent their laboratory's "official values". These values are used in the analysis of the PT.

If a participant uses a non-NIST procedure, they may be requested to submit a copy of the procedure to the PT analyst or OWM along with their calibration certificate.

3.2.2.6. Report Valid Uncertainties

Laboratories are required to report their actual uncertainties based on officially reported uncertainties per their Scope as noted earlier. Uncertainties that are reported based on guard-banding, test-uncertainty ratios, or fractions of tolerances or maximum permissible errors are not permitted and will result in "failure" notices in the PT final report.

3.2.2.7. Repackage and Ship PT Items

PT artifacts are repackaged in the same manner as received (if appropriate) to prevent damage to the PT items. The participating laboratory should have informed the PT coordinator if packaging instructions were not followed upon the initial receipt and inspection. If deviations occurred, if artifacts were damaged, or if the instructions and packing needs improvement, the PT coordinator and OWM may need to investigate and resolve issues further.

When the laboratory receives approval to ship the PT to the next laboratory, they email the coordinator the date of shipment, the tracking number, and which laboratory they shipped it to. Additional shipping information (e.g., carrier used, method used) that deviates from the Section P3: Artifact and Shipping, is emailed to the PT coordinator.

A PT should never be shipped to a laboratory without confirming with the PT coordinator or the receiving laboratory, that they are available and prepared to participate in a timely manner.

3.2.3. Roles of the PT Analyst (during the Operations Phase)

The PT analysis may be started during the Operation Stage, but final analyses are completed after the PT measurements have all been completed with all calibration certificates submitted. The exception for interim analysis is to monitor and problems or trends in the data and to provide interim feedback to laboratories. Laboratories may be asked to validate the data entry in the PT Analysis templates and to identify major discrepancies or possible blunders. When an initial or historical reference value is known, the PT analyst may complete the data entry and interim analysis as data is submitted during the operations phase; keeping up with the data entry will also save time during the final Analysis and Reporting phases. Specific analysis tasks that can be conducted during the operations stage are detailed in this section; more in depth statistical analyses are covered in the Analysis Stage, Section 3.3.

3.2.3.1. Data Entry

The analyst shall use the OWM PT Analysis template(s) for evaluation of submitted data. PT analysts should be sure to read the Instructions worksheet prior to performing any data entry. The file is to be named with the name of the PT as designated during the PT planning stage with “analysis” kept in the file name along with the latest date it is updated. E.g., from the Planning stage, the example given was MidMAP-25-MIII-M-01. That file name would be saved as “MidMAP-25-MIII-M-01-Analysis-20230301.”

Information about the PT items, tolerances, and identification are entered on the Data Entry worksheet in the fields labeled. The PT analyst must be sure to select applicable tolerances as identified in the PT Plan. Hover over any cell that has a red triangle in the upper right corner for additional instructions during data entry.

Data is entered in chronological order by calibration date. Timely submission of participant calibration certificates is essential to conduct real-time analysis and to give interim feedback.

For each participant from the PT plan, one row will represent data from their submitted calibration certificate. Information for each participant includes the 1) date of calibration; 2) participant identification (see notes below); 3) whether or not the participant has submitted the laboratory's official value (in laboratories with more than one staff member, they must designate which certificate is to be used as the official result for their laboratory); 4) which SOP was used (usually a number of the SOP that was designated in the PT Plan); and 5) measurement results and uncertainties for each PT item in the PT scheme.

The Participant ID on the Data Entry worksheet consists of the Lab Code and the initials of the participant (e.g., NH-JD, represents New Hampshire – John Doe). For non-state laboratories, there are designated organizational codes in the PT Analysis template.

The PT Analysis template, Data Entry worksheet may be exported and sent to PT participants to entire data into the worksheet themselves. PT analysts will then sample the submitted data entry worksheet for accuracy against the submitted calibration certificates and copy/paste the data into the master PT Analysis file.

3.2.3.2. Interim Feedback if Problems are Observed or Initial Data Analysis if an Initial Reference Value is Provided

For values that appear to be marginal or outliers, laboratories are advised to validate their measurements and reported results. After the laboratory has checked their results and their values still appear significantly out of line, OWM is contacted for guidance.

Analyst feedback does not include specific or general details on performance (e.g., no reference values are provided in interim feedback). Final performance statistics are not known until final analysis is conducted with all participant data and the analysis is approved by OWM.

The analyst maintains the integrity of the PT by not informing participants of reference values, or how close a participant is to the reference value. Feedback is not provided on values submitted via phone, fax, email, or in person. The only acceptable forms of data submission are an official calibration certificate or an official amended calibration certificate.

For certain unique PTs that are slow moving and are continuous in nature (e.g., national trailer based PTs), interim reports may be provided by OWM.

3.2.3.3. Data Entry Validation

The analyst offers an opportunity for the participant to evaluate data entry by copying only those data entry rows for that laboratory to review and verify accuracy of the data entry. The PT analyst may conduct initial analysis and provide "go/no go" feedback.

3.2.3.4. Preparing for the Draft Analysis and Report

Once the PT round is completed, any remaining data is input into the OWM PT Analysis template. If the PT analyst has entered data as it is received in a timely manner, there should be very little remaining data entry required. Laboratories may again be sent the Data Entry rows so they can confirm there are no data entry errors. No other sections of the analysis tool are sent to participants prior to the final reporting. To prevent lengthy delays, it is helpful to provide a deadline (e.g., 1 week) for the review period.

Data entry errors made by the analyst are corrected. Data entry errors made by participant calibration certificates or submitted data sheets must be retained, though are not included in the statistical analysis. Data entry errors by the participant are considered failures and must be corrected with an amended certificate. All data is retained for the final report with corrections and amendments noted in the final report.

The data entry file is submitted to OWM for review to provide any necessary input/suggestions on data points to be questioned further prior to the analysis stage.

3.2.3.5. Prepare Draft Analysis and Report

After receiving any inputs or feedback from OWM at the end of the operations stage, continue on to the Analysis stage, section 3.3

3.3. Analysis Stage: Data Analysis and Calculations

The OWM PT Analysis templates are used for data analysis and participant performance assessments.

3.3.1. Complete the Data Entry worksheet using only the official calibration certificate(s) for all participants if this was not already done during the Operations stage. Either the PT analyst or PT participants enter the following information on the PT Analysis template Data Entry worksheet:

- Enter the calibration date;
- Enter the laboratory name code (from the table in the spreadsheet or the two digit State abbreviation) and participant initials;
- Enter the reported SOP;
- Enter the Measurement Result(s) and Uncertainty(ies);
- Do a visual assessment for data entry errors or potential blunders (mistakes);
- Select the "official" tag for the staff member who has been designated as the official value by the participating laboratory (only one value may be selected per laboratory to avoid weighting results) and deselect others from that lab as appropriate; and
- Request the laboratory evaluate and confirm the data entry values.

3.3.2. Visually Assess the Data and Graph Worksheets for Stability and Outliers for all PT Items

Visually review the graphs and look for stability, measurement result shifts or changes, trends or drift in measurement values, and significant data outliers. Look for outliers that might be blunders/typos or possible measurement errors and contact the PT participant and ask them to verify their submitted data and double check the data entry if not already done. Especially look for unit or conversion errors made during recording or data entry. The final report needs to include a stability assessment from OWM. The R1 Report section of the PT Plan includes a field for OWM staff to complete after reviewing the data. Stability observations may be drafted by the PT analyst but must be reviewed and approved by OWM. OWM may conduct a visual assessment and stability evaluation as a part of the Operation stage if alerted by the PT coordinator or PT analyst of any concerns.

3.3.3. Assess the Automatic Statistics Calculations for the Mean and Standard Deviation on Each "Data (n)" Worksheet

The initial mean and standard deviation are calculated using all of the participating laboratory's official reported values and uncertainties. Visually scan the tabulated data and review the data entry to ensure all official values are identified and that no values stand out as significantly different.

3.3.4. Review and Deselect Values Outside of Two Standard Deviations of the Mean Value (Trim the Mean) to Create the Adjusted Statistics Shown in the Data Analysis Block

Review the suggested "adjustment" instructions and identify any outlier or suspect values. Deselect all values outside of the two standard deviation limits is used as a first step to create the Adjusted Mean and Adjusted Standard Deviation statistics that may be used when selecting the reference value and reference uncertainties. The values will be signified by HIGH or LOW (above or below two standard deviations). This step may be performed only ONCE. Sequential de-selection of data is inappropriate. No data is physically deleted from the data entry, data analysis tables, or graphs. All data will have performance statistics calculated and reported. After this step, the "adjusted mean and adjusted standard deviation" can be reviewed in the statistics on the top of each "Data (n)" worksheet.

The adjusted standard deviation for the PT is used in the Z Score calculations.

3.3.5. Assess and Determine Reference Value and Uncertainty Options

Several valid statistical approaches may be used for determining suitable reference values and they must comply with requirements in ISO/IEC 17043, Annex B and/or ISO 13528. The most common methods that have been used by OWM are listed below. Someone with suitable technical expertise in the measurement parameter and level of work shall be involved with assessing and determining the final and most suitable reference value(s) for each PT item. The selection of the reference value may be different among PT items even within a set of multiple standards depending on the data and analysis of the reference values. Selection option 4A from Table 1 is set as the default selection in the OWM PT Analysis template and is identified as the "Wt'd Mean±Trm'd Avg U". Options 4A and 4B are the most commonly used reference values in OWM PTs. Uncertainties for reference

values are always reported and used in the E_n assessments and plotted on the associated analysis graphs. The PT analyst may select reference values based on this table or additional analyses, but final approval of the PT reference value(s) will be made by OWM staff.

Choices in the PT Analysis template spreadsheet include the following options in a drop down cell for selecting reference values:

- Adjusted mean (will be identical to the calculated mean value when no data is deselected; this approach helps to identify values that might have gross errors or are outlier values);
- Adjusted mean with μ_b (uncertainty of bias must be reported and entered during analysis; this will be used in the reference value uncertainty) – rarely used;
- Calibration Source from one laboratory such as NIST or an approved pivot laboratory (this selection value defaults to zero in the selection list if no values are entered in the PT Analysis template spreadsheet);
- Mean of accredited laboratories and average uncertainty (a formula must be entered to calculate the mean of specific accredited laboratory values and also the mean of their uncertainties) – rarely used; and
- Weighted mean and trimmed average uncertainty (set as the default) – this value weights the selection of the reference value based on the reported uncertainty and uses the mean of uncertainties nearest the median uncertainty.

Several of these choices might be used to evaluate the impact on the final PT analysis for all participants; however, the final selection of assigned reference values is evaluated and approved by OWM prior to release of a final report. Criteria used by PT Analysts and OWM staff have been evaluated by NIST statisticians to ensure appropriate values are selected for standards used in each PT. All choices should be considered and compared to other options in the spreadsheet as a part of ensuring the validity of the selected reference value.

3.3.5.1. Reference Value and Uncertainty from a Single Laboratory (Externally Derived Criteria) – ISO 13528, section 7.5. ISO/IEC 17043, B.3.1. item c.

A reference value from a single laboratory may be one from an NMI, such as one from NIST. This might be considered an ideal reference value to use when there is also evidence of stability, and the uncertainties are sufficiently small relative to the participant values. This source is not always an option due to the high cost and the time associated with obtaining this value. Stability of the standard may also make this value less desirable due to the lack of long-term stability of reference values in some measurement areas. In some cases, where standards have demonstrated stability over a long period of time, these values may be used. (Examples: 100 gal prover, 500 lb reference standards). The uncertainty associated a single-laboratory reference value is taken from the calibration certificate. It is critical that this value be compared to all other reference options to ensure stability and ongoing validity of the chosen reference value(s). Given that all participating laboratories are required to maintain traceability

of measurement results to the SI, this option is not essential for most legal metrology applications and proficiency tests.

3.3.5.2. Accredited Laboratory, Pivot Laboratory, PT Coordinator Laboratory or Groups of Expert Laboratories Initial Reference Value and Uncertainty (Externally Derived Criteria) – ISO 13528, sections 7.5, 7.6 Consensus value from expert laboratories; ISO/IEC 17043, B.3.1. items c or d.

As a part of the PT Plan, OWM and the PT Administrative Team and PT participants may have discussed and approved using an initial measurement result and uncertainty and possibly ending values from an Accredited laboratory, a Pivot Laboratory, or a PT Coordinator. This is Choice 2 shown in Table 1. Unless measurement results at this level have uncertainties that are significantly smaller than other laboratories in the group, exceptional care must be taken to ensure suitable agreement in the final measurement results to avoid conflict among participants and disagreements about assigned reference value(s). This avoidance of perceived conflict is especially important given that OWM PTs are not anonymous, and participants are familiar with the other laboratories' facilities and staff, and their capabilities and scopes.

Using a single laboratory (often called a Pivot Laboratory) with a "better procedure" is sometimes chosen and may be used to monitor for trends/drift during the course of the scheme, often with before and after measurements, however the evaluation and selection of the reference value must include assessment against other options. The risk with this option may include challenges or appeals to the pivot laboratory value(s) where a laboratory that fails one or more of the statistics used in the analysis. This approach must be compared to other options in the spreadsheet as a part of ensuring the validity of the reference value.

This approach may be suitable in some instances, for example:

- Where more than one level of calibration will be performed in the PT, with some laboratories performing a higher-level procedure (lower uncertainty) and the remaining laboratories performing a lower level procedure, a mean value from these laboratories may be used to select a best assigned reference value. Calculations of the mean values and uncertainties of the better subgroup of procedures could be used.
- Where the standard to be used in the PT belongs to one of the participants and significant history of calibrations and stability is available the "owner" may be selected to provide initial and closing measurement results and the value from that laboratory used as the initial assigned reference value.

3.3.5.3. Historical Reference Value and Uncertainty (Externally Derived Criteria)

An historical reference value can be an individual value or a collection of values from a variety of sources including past NMI calibrations, past RMAP calibrations, or past accredited lab calibrations. The uncertainty is often a mean of the uncertainty of the selected values (average uncertainty from contributing values). These values can often

be used to assess stability of the standard artifacts over time or to validate another chosen reference value. When this data is available, it is often used as a quick check of participant data as it is being collected and entered during the proficiency test.

3.3.5.4. Mean of "Official" Participants and Uncertainty (Consensus Value) (Comparison Derived Criteria) – ISO 13528, 7.7 Consensus value from participant results; ISO/IEC 17043, B.3.1. item e.

When all official values agree with no need for omitting data as part of the analysis, and when the associated uncertainty is acceptable for the assessment needed, the mean value of all official participant results may be used. This value is most often used when there is no other good alternative, or when the tolerances are sufficiently large that the use of this value no significant negative impact on the analysis. The uncertainty is from the standard deviation of values used, multiplied by *k* as a coverage factor. OWM PTs are coordinated among laboratories that all have demonstrated traceability to the International System of Units (SI) and any or all of the laboratory values could conceivably be used in demonstrating traceability for the reference value (provided robust statistics support the selection decisions). This approach must be compared to other options in the spreadsheet as a part of ensuring the validity of the reference value.

3.3.5.5. Weighted Mean and Average Trimmed Uncertainty – ISO 13528, 7.7 Consensus value from participant results, ISO/IEC 17043, B.3.1. item e.

This is the default method selected in the OWM PT Analysis spreadsheet. After the initial data is reviewed and initial failures are flagged and removed from the analysis used in selecting the assigned reference value, the values and statistics that are remaining are considered the adjusted, trimmed, or Winsorized mean and include an associated uncertainty. The weighted mean and average trimmed uncertainty are then used to ensure that laboratories with smaller uncertainties contribute a greater proportion of the assigned values. This approach may underestimate the uncertainty of the reference value thus could impact the normalized error calculations. Again, this approach must be compared to other options in the spreadsheet as a part of ensuring the validity of the reference value.

3.3.5.6. Simulations and Monte Carlo Assessments

Although not widely used for OWM PT analyses, this tool generates simulated values based on an inputted distribution and variables for the PT data set. Simulation iterations can run in the tens of thousands, hundreds of thousands, or more depending on the computing capabilities. When this analysis is conducted, the values are often entered as additional participant data point(s) for reference when reviewing the graphs and the selection of reference values. This approach has been considered in a number of PTs although it is not explicitly referenced in either ISO/IEC 17043 or ISO 13528, though the standards do reference alternative rigorous statistical approaches that must be documented.

3.3.5.7. Multiple assigned reference values.

Selection of different reference values may be required for each standard within a set of standards circulated for a given PT. Typically this approach is reserved for problem artifacts that seem to be trending in a consistent pattern or direction. Problematic data could include situations where standards are cleaned or damaged in some way during the PT where an obvious shift in the data occurred. Combinations of other reference value and uncertainty options may be used for each subgrouping of data. Use of alternative methods by participants is normally assessed according to method without mixing results for analysis. The summary data chart for standard/artifact in the PT designates the value that was used and selected as the assigned reference value. All other statistics and uncertainties performed for that standard will then be based on the selected reference value.

Table 1. Summary Table for Reference Values and Uncertainty Choices.

Choice	Source	Uncertainty	Comments
1	NIST (or other NMI)	As reported	Only used when measurement values are historically stable and have a sufficiently small uncertainty
2	Single laboratory reference value (e.g., approved pivot laboratory)	As reported	May be used when approved in the PT Plan and if values are historically stable with a sufficiently small uncertainty
3	Consensus of "Expert" Laboratories": adjusted mean of approved "expert" laboratories	Mean uncertainty of selected values	E.g., accredited labs; pivot lab; labs with lowest uncertainty from a designated better procedure; separate equation entered in designated cells to calculate values
4	Consensus of Participant Laboratories: adjusted statistics with mean weighted based on reported uncertainties (consensus value)	Option: A) Average uncertainty; or B) Standard deviation of selected values multiplied by *k* selected based on degrees of freedom as a coverage factor for the number of participant values selected.	E.g., the official value from each laboratory is selected after deselecting any values outside of the statistical limits PT Analysis template defaults to this 4A option: "Wt'd Mean±Trm'd Avg U" PT Analysis template option "Adjusted Mean" uses Option 4B.
5	Historically stable reference value(s) for the standard(s) used in the PT	Mean of the uncertainty of the selected values	E.g., other RMAP region, prior reference value, approved by OWM (may also be used for interim evaluation or validation of selected option)
6	Monte Carlo Simulation	Statistics from simulation	Less common

3.3.6. Calculate and Review Participant Performance Statistics

The PT analyst must read the instructions worksheet included with the PT Analysis template spreadsheets to supplement guidance in this SOP and to be sure the analyses are consistently conducted.

The PT analyst double checks the tolerances that were entered for each PT item on the Data Entry worksheet as that value is used in the calculation of performance statistics. The PT analyst also selects the proper percentage or ratio for the uncertainty to tolerance values required based on the documentary standard used in decision risk analysis as that value is also used in the precision assessment.

Calculations of the PT Participant performance statistics are automatic once the tolerance and decision risk ratios are selected and after 1) the official values for each laboratory are selected and reviewed for accuracy, 2) outliers and extreme values are deselected based on analysis of each PT item and 3) the reference value and its associated uncertainty are selected. All values deselected as extreme values are assessed and reported, the deselection process is only used in the process for selecting the reference value(s).

The statistics used in the performance assessment and reported on the PT Summary worksheet are the normalized error, E_n and the normalized precision P_n assessments. The values that are outside of the two standard deviation limit for the PT are also reported, but do not contribute to the pass/fail summary statistics for the PT.

On the Data (n) tables, the detailed performance statistics are automatically calculated and tabulated. They include:

- Difference from the Reference Value (bias). This value is useful for the laboratory when conducting follow-up accuracy assessments;
- Normalized Error, E_n, given as an absolute value and which must be less than one to pass. This value is conditionally formatted to turn the color red when it fails the E_n assessment;
- Normalized Precision, P_n is calculated as a method for quantifying a pass/fail condition where decision risk assessments require the evaluation of the uncertainty when determining tolerance compliance. This value is a simple ratio of the uncertainty to the portion of the applicable tolerance and must be less than one to pass. It is also conditionally formatted to indicate when a failure has occurred; and
- Z Score, is the Difference divided by the adjusted standard deviation, also called the standard deviation of the PT.

The values are calculated using the formulae in the following sections.

3.3.6.1. Difference or Bias from the Reference Value (Offset), 17043, B.4.1.3., item a, Eqn. B.1.

The difference, bias, or offset (however referenced) of each reported value from the selected reference value is calculated and reported as part of the

PT analysis data using Eqn. 1. This value is not used as a pass/fail statistic but is used in the initial assessment of data by the PT Analyst and by OWM to review the overall data for obvious blunders and outliers. The laboratory may use this value as a part of its follow-up assessments of laboratory bias, accuracy assessment, and evaluations of recalibration intervals. E.g., for precision calibrations, a laboratory might want to set recalibration goals such that whenever the bias/offset exceeds some ratio of its reported uncertainty, a recalibration or interim assessment of metrological traceability is conducted. Historical OWM PT statistics (no longer used) included an assessment of this offset as shown in Eqn. 2 with a modification of the *Z*-score that was based on laboratory uncertainties rather than the PT statistics. The laboratory may still wish to conduct this assessment for internal evaluations, but it is no longer reported in the OWM PT Reports.

$$x_{lab} - X_{ref} \qquad \text{Eqn. (1)}$$

$$OWM_{historical}\ Z = \frac{x_{lab} - X_{ref}}{U_{lab}} \qquad \text{Eqn. (2)}$$

3.3.6.2. Normalized Error, E_n , 17043, B.4.1.3., item e, Eqn. B.6

Normalized Error, E_n, is defined in ISO/IEC 17043 as the ratio of the difference between the reference value and the reported value compared to the root sum square of associated expanded uncertainties. The normalized error is an indicator of accuracy/inaccuracy as compared to an assigned reference value with respect to the associated uncertainties. Conceptually, the normalized error asks whether the bias is less than the expanded uncertainties of the laboratory and reference value combined in root sum square as shown in Eqn. 2.

$$E_n \text{ assessment: Is } \left(x_{lab} - X_{ref}\right) < \sqrt{U_{lab}^2 + U_{ref}^2}? \qquad \text{Eqn. (3)}$$

OWM uses the absolute value of the calculated E_n results in order to graph multiple statistics on the same charts and to have a simple pass/fail criteria. Using the absolute value, the value of E_n must be less than one to pass. Values of E_n between 0.7 and 1 are highlighted on the charts to alert laboratories of the possible need to investigate bias with respect to the combined expanded uncertainties.

$$E_n = \left| \frac{x_{lab} - X_{ref}}{\sqrt{U_{lab}^2 + U_{ref}^2}} \right| \text{ Result must be < 1 to pass.} \qquad \text{Eqn. (4)}$$

This equation evaluates the bias of the laboratory value from the reference value relative to the combined uncertainties of the laboratory uncertainty and reference value uncertainty. Values failing the E_n test may be omitted from the calculation of the adjusted statistics in the analysis process, but results are always assessed and reported in the draft and final PT reports.

3.3.6.3. Normalized Precision, P_n, Referenced in ISO/IEC 17043, B.5.1.1.

The Normalized Precision, P_n, is a performance assessment of fitness for purpose (suitability) of the laboratory uncertainty compared to applicable documentary standards and is related to decision rules and conformity assessments as described in ISO/IEC 17025. Where decision rules and conformity limits are provided and reported uncertainty must be considered, the precision assessment, P_n is conducted. The precision assessment asks whether the reported uncertainty is less than the specified limits, as shown in Eqn. 4 where the example is given that uncertainty must be less than one-third of the maximum permissible error (as is the case in mass calibrations according to OIML R111 and ASTM E 617).

$$P_n \text{ assessment: Is } U_{lab} < \frac{1}{3} m.p.e.? \qquad \text{Eqn. (5)}$$

The precision assessment is a ratio of the reported uncertainty versus the decision rule limits. Passing values for the precision assessment are less than one and are graphed with the E_n values. This statistic is unique to OWM assessments but is related to ISO/IEC 17025 decision rules and ISO/IEC 17043 performance assessments. Documentary standards used in legal metrology generally specify appropriate uncertainty to tolerance (or maximum permissible errors, m.p.e.) ratios on which to base decision risks. In this supplemental report, tolerances and m.p.e. terminology is used interchangeably. Documented decision risks and use of uncertainties in making conformity decisions are specified in the ISO/IEC 17025 standard. Many of the OWM published procedures and documentary standards that are referenced for legal metrology include uncertainty to m.p.e. ratios of 1:1 or 1:3, where the uncertainty must be less than the applicable m.p.e. or the uncertainty must be less than one-third of the m.p.e. The 1/3 ratio is common in international legal metrology documentary standards such as those from the International Organization of Legal Metrology (OIML) and a number of the NIST Handbook 150-x series documentary standards. ASTM E617 for mass standards also includes this common ratio of uncertainty to tolerances. In some cases, the ratio will be 1:1, where the uncertainty must simply be smaller than the applicable tolerance or m.p.e.

The formula used for calculating the precision test (P_n) is shown in Eqn. 5. The result shall be less than 1 to pass this statistic.

$$P_n = \left| \frac{U_{lab}}{\frac{1}{3} m.p.e.} \right| \quad \text{Result must be < 1 to pass.}$$

alternative ratios that may be used: Eqn. (6)

$$P_n = \left| \frac{U_{lab}}{m.p.e.} \right|, \; P_n = \left| \frac{U_{lab}}{\text{fraction or \% of } m.p.e.} \right|$$

The precision test evaluates whether the uncertainty of the laboratory value is less than the tolerance or less than a specified ratio of the tolerance. It is used to assess whether the laboratory has the capability to properly determine conformity to specific documentary standards. In some of the documentary standards for legal metrology, conformity assessment requires the uncertainty to be less than one-third of the tolerance or maximum permissible error. In others, the uncertainty shall be less than the tolerance and the normal calibration practice is to adjust standards to their nominal value. Uncertainties shall be sufficiently small to perform proper conformity assessments. The P_n assessment identifies whether the uncertainty is sufficiently small so that the potential error in the value does not significantly impact the value.

Values that are excessively small may also be cause for concern and may signify that uncertainty budgets are incomplete or that inappropriate procedures were used for the planned PT. Values with uncertainties failing the P_n test may be omitted from the calculation of the adjusted statistics.

3.3.6.4. Z Score , ISO/IEC 17043, item B.4.1.3. item b, Eqn. B3.

The statistical evaluation of Z Score comes from ISO/IEC 13528, 3.7 as: *"standardized measure of performance, calculated using the participant result, assigned value and the standard deviation for proficiency assessments"*. The Z score may be used in combination with the adjustment statistics (trimmed mean and associated uncertainty) described earlier.

OWM reports this value in the tables of the PT Report but does *not* use this statistic for pass/fail criteria in PTs because the Z value does not include assessment of the laboratory uncertainty. The value may be used in isolating values outside 2 standard deviations of the accepted reference values. According to ISO/IEC 17043, satisfactory performance on the Z score value is generally indicated as $Z \leq 2$; unsatisfactory performance is indicated as $Z > 3$. and marginal performance is anything between $Z > 2$ and $Z \leq 3$. However, further evaluation of the Z-score requires an assessment of the observed bias from the assigned reference value with respect to the reported

laboratory uncertainty, such as is provided by the E_n assessment. However, the directionality (positive or negative values) of this statistic can provide additional insights to the laboratory for ongoing evaluation of differences, bias, or offsets in measurement results especially when compared to internal measurement assurance data.

$$Z - score = \frac{x_{lab} - X_{ref}}{s_{PT}} \qquad \text{Eqn. (7)}$$

The s_{PT} is the standard deviation for the specific PT round and is automatically calculated based on the robust standard deviation of all selected participant results . However, the PT standard deviation may also be calculated from the following when approved by OWM:

- a fitness for purpose goal for performance, as determined by expert judgement or regulatory mandate (prescribed value) specified in the PT Plan;
- an estimate from previous rounds of proficiency testing or expectations based on experience (by perception) specified in the PT Plan;
- an estimate from a statistical model (general model) specified in the PT Plan; or
- the results of a precision experiment approved by OWM in the PT Plan.

3.3.6.5. Rejection of Observations; Retention of Data

As noted in Section 3.3.5 for selecting of the reference value, data may be deselected when it is outside of two standard deviations of the participant values and depending on the PT and amount of remaining data additional deselections may be done for laboratory values that fail initial E_n and P_n calculations.

However, once the reference value has been selected, each participant value is assessed based on the final PT statistics and performance statistics with pass/fail status noted. Only obvious data entry blunders by the PT Coordinator or PT Analyst are removed or corrected during assessments. Data entry errors by the laboratory in preparing their certificates are reported along with amended certificate data only if the laboratory had an opportunity for advanced corrective action prior to completion of the PT scheme.

3.3.7. Specialized Assessments

A PT Analysis Youden template is available for use when the Youden analysis would be a helpful assessment of random and systematic components of the observed variability. The template requires either two identical procedures to be compared when the purpose is method validation or two identical PT items to be compared when the purpose is a proficiency test. For example, two 5 lb weights, two 20 kg weights, or two 5 gal test measures could all be further evaluated using the PT Analysis Youden template spreadsheet. Follow the instructions in the template for the data entry and analysis and include the appropriate tables and graphs in the PT final report as appropriate.

3.3.8. Uncertainties

3.3.8.1. Laboratory Uncertainties

According to NIST Standard Operating Procedures and OWM Policies, laboratories are required to report official uncertainties per their Scope. Laboratory expanded uncertainties are evaluated for suitability as a part of the precision assessment of the PT (unless not applicable). Laboratory failures may result from normalized precision (P_n) assessments and require corrective action.

Uncertainties that are reported based on guard-banding, test-uncertainty ratios, or fractions of tolerances or maximum permissible errors are not permitted. For example, when P_n values of 0.33 are observed for all standards in mass calibrations, The PT analyst or OWM staff should recommend further investigations of uncertainties and may lead to identification of failures and OWM recommended corrective action in the PT Final Report.

3.3.8.2. Reference Value(s) Uncertainties

The uncertainty (uncertainties) associated with the reference value(s) are clearly communicated within each PT Report on the data tables and on the graphs for each standard. OWM reports uncertainties for all selected reference values.

3.3.9. Ensuring Validity of PT Analysis and PT Reports

3.3.9.1. Verify Data Entry in Draft Reports

The PT Coordinator(s) and PT Analyst(s) should work together to cross-check measurement results as they are submitted and entered on the PT Analysis template data entry worksheets. Once all data has been entered, a draft Excel file worksheet of the data entry may again be circulated to participants to verify/confirm that the data entry is complete (for all participants) and has been accurately entered. (Interim/draft analyses with analyzed measurement results should not be included in draft results to participants at this stage.)

OWM staff also review the draft data entry file and provide input/suggestions (if needed) on data points to be questioned further. Once data entry has been confirmed, the PT Analyst continues to follow the steps to visually assess the data, evaluate the initial statistics, and select the reference value for each calibrated standard to proceed with the analysis. OWM reviews the reference value selection before the Data Analysis and Report are finalized.

Data entry errors made by the PT Coordinator or PT Analyst that initially show up as outliers should be corrected. Data entry errors made by laboratories on their certificates or submitted data sheets shall be retained, though not included in the statistical analysis. Data entry errors by the laboratory are considered failures and shall be represented by an Amended Certificate that identifies the corrective action according

to ISO/IEC 17025 requirements for amended certificates. All data is retained in the final report, although some of the data will not be included in the overall PT statistics.

OWM staff will seek out additional Technical Advisors if/as needed for specialty areas in which they do not have technical expertise and/or if there are any concerns regarding the initial data that requires special analysis.

3.3.9.2. Identification of Corrective Actions and Improvement Actions

Review of draft PTs and corrective actions that are required for final PTs will be recorded and monitored within OWM. PT Coordinators should provide input to the OWM staff regarding any observations for improvement, corrective action, and any informal complaints that were received during the operation of the PT scheme.

3.4. Reporting Stage

The OWM PT Plan template includes cover pages for the PT Final Report to simplify and standardize creation of the PT Draft and Final Reports. The PT Plan template transfers detailed planning data that is required in the PT final report and ensures that all participants are entered correctly.

3.4.1. Calibration Certificates

Submission of participant calibration certificates with measurement results and actual uncertainty values are required. The certificates submitted to the PT Coordinator or PT Analyst are compiled and submitted to OWM for PT record retention.

3.4.2. Preliminary (Draft) PT Analysis Report

A draft PT analysis report is completed using OWM PT templates. Confirmation of data entry by all participants is required. In general, participants should be provided an opportunity to review either all data entry during the interim reviews or review a draft report prior to OWM approving a PT Final Report.

3.4.3. OWM Review and Approval for Final OWM PT Report

The NIST Office of Weights and Measures shall review and approve all OWM PTs before they are considered Final. Amendments to final reports shall be noted as to the corrections and circulated to all participants.

3.4.4. Contents of OWM PT Final Reports

OWM PT Final Reports are designed to comply with all requirements in NISTIR 7214 and ISO/IEC 17043 for report contents. The sections of each of the templates is printed to PDF and compiled in a master PT Final Report. The PT Final Report includes:

- R1 worksheet from the PT Plan – as completed, approved, and signed by OWM staff (taking extra care to expand or condense rows for completeness and legibility;

    - Extra sections to be completed include the stability assessment and OWM recommendations and feedback which often includes recommended or required action items. PT coordinators or PT analysts may complete sections on recommendations or corrective actions, but the final feedback is provided under OWM authority;
- The following worksheets from the PT Analysis templates:
    - Cover (may be eliminated if the R1 worksheet includes all complete information;
    - PT Summary worksheet (includes a summary of E_n and P_n performance statistics for all participants);
    - Data Entry worksheet; and
    - Data (n), Graph (n), and E(n)&P(n) (n) worksheets for all "n" PT items (n representing the number of each item).
- The *OWM Supplemental PT Report* is provided and includes content that is applicable for all OWM proficiency tests.
- Form 1 is referenced in all PT reports to solicit feedback or complaints regarding the conduct of the PT.

3.4.4.1. Calibration Certificate Assessment

If a calibration certificate assessment was part of the PT Plan objectives, and completed, appropriate checklists from NISTIR 6969, SOP 1 or SP 811 manuscript checklist is included in an extra section of the final report to evaluate compliance with ISO/IEC 17025 and correct use of measurement units and symbols.

3.4.4.2. Other Non-statistical Pass/Fail Criteria

Some PTs are planned and designed to assess laboratory participation for performance measures unrelated to specific measurement results and associated uncertainties. Additional non-statistical pass/fail criteria might include any or all of the following items that are explained in the PT Report. These criteria should have been selected as a part of the PT Plan during the original planning phase to ensure that all laboratories are aware of the additional assessments:

- Compliance of the certificate to ISO/IEC 17025, Section 7.8 as noted in section 3.4.4.1;
- Errors on submitted certificates and/or data sheets;
- [Unreasonable] time delays on standard/artifact shipments and/or report submission (e.g., communicating with the coordinator; reports within 2 weeks);
- Improper packaging and shipping (and handling);
- Deviations from the approved and accepted PT Plan (e.g., using a different SOP);
- Switching or substituting standards or PT artifacts with laboratory artifacts;
- Unapproved cleaning, adjustments, or other identified care and handling problems;

- Uncertainty analysis: Detailed uncertainty analysis may be planned as part of the PT Plan. Uncertainty components as specified in the SOP and PT Plan were not included.
- Uncertainty reported on a certificate that is smaller than what is on the published Scope (for Accredited labs).

3.4.5. PT Draft or Final Reports Presented to Participants

Reports should be circulated via email or made available to download for all PT participants prior to the scheduled review. A scheduled review of the results may be conducted online for national PTs but is normally conducted at the regularly scheduled RMAP meeting. The PT coordinator and PT analysts should prepare to present the PT Final Report at the designated RMAP sessions. The OWM point(s) of contact will be available to supplement specific failure assessments, recommendations, or advice to participants, and shall communicate required follow up actions for State laboratories. All data entry errors should have been identified prior to this review session so that PT Final Reports do not need to be further amended.

3.4.6. Amendment and Addendum to PT Final Reports

PT Final reports may be updated through amendments to fix identified errors or perform other corrections; however, thorough data entry review by all parties should normally minimize the need for amended reports. Any amended PT Final Report shall include notations as to what was fixed or corrected, the date will be updated, and the file name shall include "amended". Amended PT Final Reports shall be circulated to all participants. PTs that are appended with new data added for specific purposes (e.g., LAP problems or new staff participation after completion of the PT) will be identified as an addendum and shall be named with "addendum" in the file name. Appended reports are only issued to the applicable added staff. (If a PT has both appended data and amended data, it will be named and handled as amended.)

4. Opportunities for PT Program Feedback or Complaint

Form 1: OWM PT Feedback and Inquiry and Complaint Form is available for all PT participants to submit feedback, inquiries, or complaints and can include suggested opportunities for improvement to OWM. Appeals regarding PT Analysis or analysis of PT participant performance evaluations are handled as complaints.

5. PT Follow-up and Laboratory Analysis

According to ISO/IEC 17025, performing follow up evaluations of proficiency tests is a required step in ensuring the validity of laboratory measurements. The OWM Good Laboratory Practice (GLP) on PT Follow Up Evaluations includes a series of analyses and questions that laboratories should use for conducting further post-PT evaluations. The GLP includes a form that can be used by the laboratory and incorporated into the laboratory quality management system forms. For State Laboratories in the OWM recognition program, conducting PT follow-ups is required annually as a part of OWM evaluations.