PT Standard Operating Procedure 2

for

Operating a Mini-Measurement Assurance Program (MiniMAP)

1. Scope or Range of Test

This procedure is for the operation of a *small* interlaboratory comparison, where there are few laboratories (typically between two or three) where a full proficiency test among a regional group or a national assessment is not readily available to meet the needs of the laboratory or where there is a very small number of laboratories with similar capabilities. Integrated "measurement assurance" assessments with additional evaluations of internal control charts and uncertainties to supplement the data used for statistical analysis are a key part of conducting small proficiency tests, hence the idea for calling them Mini-Measurement Assurance Programs, or "MiniMAPs". Given the limitations in the statistical validity of a small number of participants in a MiniMAP, the additional assessments of internal data as specified in this procedure, in addition to the proficiency testing (PT) components, are essential.

This procedure is especially useful for ensuring objective evidence is available to support claims of metrological traceability, consistency among laboratories, effective corrective action, evidence for adding a new range of calibrations to a laboratory scope of accreditation or scope of recognition, or meeting needs where other proficiency tests are not currently or readily available. Reasons for conducting such interlaboratory comparisons include comparing measurement results among small numbers of laboratories where other PTs are not available, adding something to the laboratory scope, completing Laboratory Auditing Program (LAP) problems, validating procedures, and for conducting follow-up from a previously failed PTs. See the Reporting section for the additional analyses that are part of a complete MiniMAP report. In general, full participation in Regional Measurement Assurance Program (RMAP) or National PTs are preferred where available.

1.1. PT Process – Required Components

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

1.1.1. PT Plan Template;
1.1.2. Laboratory and staff must be qualified to participate at the planned level of work;
1.1.3. Review (and approval) of the PT Plan by all participants and by the NIST Office of Weights and Measures Laboratory Metrology staff;
1.1.4. Completion of a draft PT Analysis file (using NIST PT software tools) with confirmation of data entry by all participants;
1.1.5. Review and approval of the Final PT Report by the NIST Office of Weights and Measures Laboratory Metrology staff;

1.1.6. Completed PT Follow Up forms for each laboratory;
1.1.7. Submission of participant calibration certificates for the standards used in the MiniMAP (included with the final report); and
1.1.8. Supplemental reporting as noted in Section 6.

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

This procedure may be used for any measurement parameter and is not limited by measurement parameter or range. However, the measurement parameter (the measurand) must be defined prior to circulation of the artifact.

1.3. Description of the Item to be Calibrated

Selection of the standards (PT artifacts) require special consideration when they are not part of the NIST OWM inventory or when there are a small number of participants. Suitable history, stability, resolution, availability of an independent reference value, sufficient accuracy, and sufficiently small uncertainties for use with the reference value are critical due to the small number of participants in this procedure. The availability of calibrated measurement values for the standards used by each laboratory supplements, or reinforces, values selected for the PT analysis.

1.4. Equipment, Including Technical Performance Requirements

All participants must have suitable equipment and reference standards that can provide suitably small uncertainties to meet the objectives of the MiniMAP. At least one of the participants must have the measurement parameter, range, and uncertainty (Calibration and Measurement Capability, CMC) on their Scope of Accreditation. See additional assessments required in the Reporting Section.

1.5. Reference Standards and Reference Materials

Suitable independence of reference standard values and working standard values are required. I.e., if laboratory B participates in an interlaboratory comparison with laboratory A, where laboratory A calibrated the reference standards for laboratory B, there is limited value for the two participants. Special care must be taken to avoid comparisons among laboratories that could lead to a circular calibration, which would provide traceability to other laboratories over the SI. There may be exceptions when selecting participants if a prior calibration was from another laboratory and "before and after" calibrations are done based on a calibration of reference standards that are being obtained in the process. Artifact and standards history is an important part of the MiniMAP process and analysis. If the current certification is circular, there may still be adequate history and analysis of data that demonstrates equivalency to an adequate level. Thus, increasing the credibility of comparisons.

1.6. Participant Qualifications

Participating staff must have adequate training prior to the conduct of PTs to ensure that standards are not damaged, and that procedures are followed. Qualifications, experience, and

training must be documented for each participant (e.g., OWM training transcripts and laboratory on-the-job and other training records, and a resume are examples of documented requirements. See also Form 2: OWM PT Participation Request – Training/Qualification Form. PT policies regarding training and participation must be followed and all participants contact information and participating data (even if corrected later) is to be included in the analyses and reports.

2. Procedures, Environmental Conditions, Stabilization Periods, and Handling

Use of internationally or nationally published Standard Operating Procedures (SOPs) is expected where available. For compliance with the NIST OWM PT program, NIST SOPs are to be used if available. Procedures must be specified or referenced in the PT Plan. If published SOPs are not available, all participants must agree to use the same procedures to avoid having discrepancies introduced that are procedure dependent. Where method validation is the purpose of the MiniMAP, a comparison of the procedures is required as part of the analysis and all procedures must be submitted with the report. (This also means that laboratories with proprietary procedures are not permitted to participate in a MiniMAP unless they are willing to submit procedures.) A document review of non-NIST procedures should be included in the supplementary report. Procedures or MiniMAP instructions must include environmental requirements and stabilization periods.

Standards circulated for a MiniMAP may require special handling in addition to the normal laboratory administration procedures. If special handling is required, it must be documented in the instructions. If the special handling requires training (safety or other) then arrangements should be made among all participants. Otherwise, good laboratory practices and administrative procedures are followed as for all other calibrations.

3. PT Analyses (Calculations) (include the Measurement Equations)

The standard OWM approved PT Plan and PT Analysis tools and resources must be used for all MiniMAP planning, calculations, and analyses.

4. Measurement Assurance

Laboratory control charts and/or standard deviation charts (where applicable) for the measurement process need to be current, have sufficient data, and cover the range and scope of measurements being considered. Where suitable control charts or standard deviation charts are not available, adequate replications must be performed to assess the repeatability of the measurement process. If corrective action is needed with calibration, service, or replacement of equipment, it should be done before the MiniMAP is conducted. See Supplemental Reporting Requirements.

5. Uncertainties (include an Uncertainty Budget Table)

If this is a new area on the Scope, additional uncertainty analyses need to be reviewed as a part of the laboratory analysis of data prior to issuing the calibration certificate to ensure compliance with SOPs and completeness (inclusion of all significant uncertainty components) based on technical assessments. See Supplemental Reporting Requirements.

6. Reporting

A complete "reporting package" is required for all participants for a MiniMAP and is required where the results are used for accreditation or recognition purposes, evidence of corrective action, demonstration of proficiency, setting or adjusting calibration intervals. Due to the small number of participants, there is not adequate data from the PT alone on which to base statistical determinations without these additional technical assessments. The following items are required to be submitted with the PT Plan (as approved, and with any updates) and PT Analysis files (draft and final).

6.1. Calibration certificates.
Submission of participant calibration certificates for standards used in the calibration is required. Traceability hierarchies may be requested.

6.2. Draft PT Analysis file.
Completion of a draft PT analysis report (using NIST PT software tools) with confirmation of data entry by all participants is required. Submission of the draft PT Analysis file to OWM is required.

6.3. OWM Review and Approval is <u>Required</u>.
Review and approval of the PT Plan, PT Analysis file(s), and PT Final Report are performed by the NIST Office of Weights and Measures.

6.4. A Supplemental Data Analysis Report is <u>Required</u>.
There are many reasons a previous PT might have failed and a number of assessments that should be involved supplemental to a final PT report. There are also a number of assessments that should be conducted when adding something to a laboratory Scope/CMC. What follows is an outline and brief set of questions that are addressed when writing up a supplemental assessment to go with a MiniMAP PT Report. There is obvious overlap among the questions, so a final supplemental report should be complete and as concise as possible. (e.g., 2 or 3 pages would be maximum expected with additional pages of supporting evidence for calibration certificates, traceability hierarchies, and control charts, but 6 sentences are too brief).

6.4.1. Purpose(s) –
- The purpose description may repeat information in the PT Plan and may expand on or expound on some of the background issues, concerns, or laboratory goals.
- Demonstration of Traceability. A full traceability assessment is needed to add something to a laboratory Scope (see the appendices in GMP 13).
- Demonstration of Competency for Accreditation.
- Demonstration of Effective Corrective Action from Previously Failed PTs.

6.4.2. Reference Standards Assessment
- To verify that values on reference standards or working standards (whichever is being considered) continue to be valid requires conducting a calibration history assessment of the measurement results over time. Uncertainties due to instability may need to be considered and incorporated when needed. As noted earlier, an

assessment of the independence of standards used for the MiniMAP must be considered.

- Copies of the traceability hierarchy and relevant calibration certificates need to be included.

6.4.3. Documented Procedures

- Use of NIST published SOPs is expected where available and do not need to be submitted with the final package. If NIST SOPs are not available, all participants must agree to use the same procedures to avoid having discrepancies introduced that are procedure dependent. A document review of non-NIST procedures will be conducted by the participants and/or coordinator and included in the supplementary report.

6.4.4. Equipment Assessments

- The measurement process must be assessed and included in the report; data from the measurement process is integrated into the uncertainties. Where "bias" from the control charts has not previously been included, it must be considered as a part of this report.
- See the "measurement assurance" assessment forms that are available and can be used as evidence for the traceability assessment.
- Where the uncertainty budget includes data from the measurement assurance systems and lists equipment, the evaluation can be simplified.

6.4.5. Complete uncertainty analysis

- The updated uncertainties are to be submitted with the PT package and when requesting addition to a Scope. Any precision assessment (P_n) failures must include corrective action.
- Special care must be taken with SOP 29, Step 7 for the evaluation of the uncertainties to make sure the MiniMAP results are useful for both/all parties.

6.4.6. Calibration Certificate Assessment

- Given that many of the MiniMAPs are conducted to add something to the Scope, it is possible that "template certificates" have not been a part of the laboratory Quality Management System and/or need to be updated based on changes and corrective actions. All participants should review each other's certificates in this effort and ensure compliance with NISTIR 6969, SOP 1; NIST SP 811; ISO/IEC 17025 Section 7.8 and any other applicable requirements of the calibration parameter, including conformity assessments and reference to documentary standards.

6.4.7. PT Follow-up Form

- A PT Follow Up form needs to be completed for each laboratory (not each participant) per the earlier notes.