

Standard Operating Procedure for Operating a Mini-Measurement Assurance Program (Mini-MAP)

1. Scope or Range of Test

This procedure is for the operation of a small interlaboratory comparison, typically only between two or three laboratories 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 are a key part of conducting small proficiency tests, hence the idea for calling them Mini-Measurement Assurance Programs, or “mini-MAPs”. Given the constraints in the usual small number of participants for a Mini-MAP, additional assessments in addition to the proficiency testing (PT) components are essential to provide additional data validity.

This procedure is especially useful for ensuring effective corrective action, 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, and conducting follow-up from a previously failed PTs. See the Reporting section for the additional analyses that are expected as part of a complete Mini-MAP 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 system (NISTIR 7082, "Proficiency Test Policy Plan" and NISTIR 7214 “Weights and Measures Division Quality Manual for Proficiency Testing and Interlaboratory Comparisons” policies, procedures, and tools must be used, including:

- 1.1.1. PT Planning Checklist;
- 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 Planning Checklist by all participants and by the NIST Office of Weights and Measures, Laboratory Metrology staff;
- 1.1.4. Submission of participant calibration certificates (with the final report);
- 1.1.5. Completion of a draft PT analysis report (using NIST PT software tools) with confirmation of data entry by all participants;
- 1.1.6. Review and approval of the Final PT Report by the NIST Office of Weights and Measures, Laboratory Metrology staff;
- 1.1.7. Completed PT Follow Up forms for each laboratory; 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 (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.

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 Mini-MAP. 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., participating in an interlaboratory comparison with the laboratory that is calibrating or has calibrated your reference standards that were used to provide your own calibration results has limited value for the participants. Special care must be taken to avoid comparisons among laboratories that could lead to a circular calibration where traceability to the SI is limited. There may be exceptions 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 this 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

Staff must have adequate training prior to participating in PTs to ensure that standards are not damaged and procedures are followed. Formal qualifications, experience, and training must be documented for each participant. PT policies regarding training and participation must be followed and all participant information and data 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, it is expected that NIST SOPs are used when available. Procedures must be specified or referenced in the planning documents. If 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 should be included in the supplementary report. Procedures or Mini-MAP instructions must include environmental requirements and stabilization periods.

Standards circulated for a Mini-MAP may require special handling in addition to the normal laboratory Standard Administration Procedures. If special handling is required, it must be documented in the instructions. 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 tools and resources must be used for all Mini-MAP calculations and analyses.

4. Measurement Assurance

Laboratory control charts for the measurement process need to be current, have sufficient data, and need to 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 service or replacement of equipment, it should be done before the Mini-MAP 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 based on technical assessments. See Supplemental Reporting Requirements.

6. Reporting

A complete reporting package is required for all participants for a Mini-MAP 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 on which to base statistical determinations without additional technical assessments.

6.1. Calibration certificates.

Submission of participant calibration certificates is required.

6.2. Draft PT analysis report.

Completion of a draft PT analysis report (using NIST PT software tools) with confirmation of data entry by all participants is required.

6.3. OWM Review and Approval.

Review and approval of the PT Report by the NIST Office of Weights and Measures is required.

6.4. A Supplemental Data Analysis Report is required.

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 should be considered in writing up a supplemental assessment to go with a Mini-MAP report. There is obvious overlap among the questions, so a final supplemental report should be complete, yet as concise as possible. (E.g., 2 or 3 pages would be maximum expected with supporting evidence like traceability hierarchies or control charts, but 6 sentences are too brief).

6.4.1. Purpose(s) –

- The purpose description may repeat information in the PT planning checklist, and may also 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 an assessment of the HISTORY 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 Mini-MAP 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. If 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.

6.4.5. Complete uncertainty analysis

- The updated uncertainties will need to be submitted with the package requesting addition to a Scope.
- Special care must be taken with SOP 29, Step 7 for the evaluation of the uncertainties to make sure the Mini-MAP results are useful for both/all parties.

6.4.6. Calibration Certificate Assessment

- Given that many of the Mini-MAPs 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 or need to be updated based on changes due to 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.

6.4.7. PT Follow-up Form

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