OWM Traceability Review Guidance

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The NIST Office of Weights and Measures maintains a laboratory Recognition program that "recognizes" the ability of State weights and measures laboratories (and a limited number of additional legal metrology laboratories) to provide metrologically traceable measurements and comply with the requirements of ISO/IEC 17025:2017 (through NIST Handbook 143 processes). The guidance provided in this article is specifically directed to the laboratories encompassed by the OWM legal metrology program; however, all laboratories that are accredited may benefit from considering guidance provided here.

The OWM Recognition Certificate states that weights and measures laboratories can provide metrologically traceable measurements. All laboratories claiming compliance to ISO/IEC 17025 should be able to do this and stand ready to provide objective evidence to customers and to onsite assessors of accreditation bodies! Any accredited or recognized laboratory must ensure that the laboratory documents support statements of traceability.

To provide objective evidence supporting metrological traceability, OWM requires laboratories under the Recognition program to submit a full "traceability assessment" and objective evidence any time there is a change in Scope requests. This assessment is also required for:

- Technical audits: Appendix C or D in NISTIR 6969 Good Measurement Practice (GMP) 13;
- Lab Quality Management System (QMS) documents;
- Internal Audits;
- Laboratory Auditing Program (LAP) Problems; and
- Future Annual Submissions.

Traceability Assessments: Reviewing Quality Management System (QMS) Documents

Laboratories need to be sure that all laboratory documents and their quality management system are up to date and use the latest applicable reference documents.

Examples of items to review include the following:

- Terminology and Definitions - Laboratories need to be sure and use the latest definitions from the International Vocabulary of Metrology (VIM)! The latest definition is also published in GMP 13, Section 1.2. Laboratory document references and terminology must include the latest VIM (2008 with 2012 corrections).
- The correct reference to include is: "International Vocabulary of Metrology – Basic and General Concepts and Associated Terms (VIM 3rd edition), JCGM 200:2012 (JCGM 200:2008 with minor corrections)"
- The laboratory needs to make sure all implementation of standards hierarchies, calibration intervals and due dates, and inventory files are complete, referenced, and up to date in QMS documents. Adoption of GMP 11 and GMP 13 as written are not enough. NOTE: OWM has observed examples of "traceability assessment" or "LAP problems" submissions where files appear complete at the time of review, but are not part of the full set of laboratory QMS documents (QM, SAP, Appendices) and/or not referenced as Records. All relevant documents must be incorporated into the QMS. Also, failure to have up to date calibrations will result in a nonconformity in the traceability assessment for those parameters/ranges. When referencing these files as Records, they are examples of Objective Evidence for applicable sections of the Internal Audit and need to

be noted in the QMS or Standard Administrative procedures (e.g., "see Traceability-20xx.XLSX file" or "see QM Appendix MX").

What is a full "traceability assessment"? What "objective evidence" is submitted for OWM review?

To complete a full traceability assessment, it is a best practice to use Appendix C or D of GMP 13 as a technical audit and an outline to identify all objective evidence that must be referenced/included in the QMS or referenced. The following list of seven essential elements of traceability looks at the GMP 13, section 1.5, and provides guidance for each item. The list of seven essential elements correlates with the requirements of ISO/IEC 17025, sections 6.4, 6.5, and Annex A. Figure 1, Seven Essential Elements of Metrological Traceability provides a graphic representation and handy resources at a glance.

- 1.5.1 – Realization of SI Units. Laboratories must reference use of the International System of Units in the quality manual, on calibration certificates (show example certificates as part of the objective evidence) and traceability hierarchies (included in QMS files). NOTE: In all places where units are represented, follow the manuscript review checklist in NIST Special Publication 811. The definition of traceability requires evidence of traceability to the SI unit (not to NIST or another national metrology institute). Example hierarchies are provided in GMP 13, but it is important to note that the hierarchies presented are examples and hierarchies specific to each laboratory requires essential objective evidence.

    - Laboratories submit the following for OWM evaluations: measurement hierarchies that outline traceability to the SI units (either within the QMS or as a QMS referenced record) and sample calibration certificates that would be issued to customers or weights and measures officials.

- 1.5.2 – Unbroken chain of comparisons. Laboratories must show an unbroken chain of calibrations as a part of the measurement hierarchies. Demonstration of unbroken chains of calibrations are essential for all measurements on a laboratory scope. Hierarchies are also needed for equipment and things like environmental standards that are used for corrections during other calibrations. Supporting evidence includes ensuring that calibration certificates are readily available for each set of standards and levels presented on the measurement hierarchy. Supplier evaluations are also required to support evaluation and compliance to the standard for each outside provider. Measurements completed internally require supporting evidence for the capability, even if it is not included on the published Scope.

    - Laboratories submit the following additional items to OWM for evaluation: calibration certificates for standards that are used, along with supplier evaluations to show that all suppliers are compliant with ISO/IEC 17025:2017.

- 1.5.3 − Documented "calibration program". Laboratories must have a suitable calibration program for standards and equipment used to provide calibrations. Adoption of GMP 11 includes having a clear process for evaluating due dates on a regular basis to ensure no past-due standards are used, ensuring appropriate calibration intervals for all equipment and standards, and extending calibration intervals ONLY with supporting data and evidence/analysis. GMP 11 also notes that it is a template and may reference laboratory documents (or databases) according to section 4.1. An example inventory job aid is posted with both GMP 11 and GMP 13 that shows example items, calibration dates, calibration intervals, due dates, supplier references, and so on. It includes conditional formatting to clearly identify standards or equipment that is past due. A regular review of these records and a system for preventing use of past due standards is also required. That might include a review of the standards prior to issuing each calibration certificate, or a monthly or annual review of calibration due dates where items are flagged in the laboratory calendar to ensure that no standards are used after their calibration due dates. GMP 11 and the sample Excel file includes environmental standards and equipment like balances because section 6.4 of the ISO/IEC 17025:2017 standard places laboratory equipment in the same category as measurement standards that must be assessed and monitored. Appendix B of GMP 13, the Excel file job aid, or a suitable database system can be used for inventory tracking. However, there must be a document or record available and it needs to be provided as evidence when proving traceability. If the calibration program files are part of a record, it needs to be referenced in the QMS. OWM will not put measurements on a laboratory Scope if standards are out of date. Expanding a

laboratory Scope often requires adding standards and equipment to the inventory with appropriate suppliers and due dates.

- Laboratories submit the following additional items to OWM for evaluation: Up to date inventory of standards and equipment that shows suitable calibration dates, intervals, and due dates. Best practice is to include suppliers and accreditation codes, maybe even dates of supplier reviews. If a database is used in the lab, an exported report of the standards/equipment may be submitted.

- 1.5.4 – Documented measurement uncertainty. Calibration uncertainties are a critical essential element of the definition of traceability and are required to comply with the Guide to the Expression of Uncertainty in Measurement (GUM), as noted in ISO/IEC 17025:2017. Uncertainties must be provided for each measurement parameter and nominal value for the laboratory Scope. Laboratory uncertainty files and records should be referenced in the QMS (e.g., "Lab Uncertainty 20XX.XLSX".)

  - Laboratories submit the following additional items to OWM for evaluation: Updated uncertainty files; ensuring that all applicable components are addressed, components are compliant with the standard operating procedure uncertainty budgets, calculations are performed according to the GUM, appropriate degrees of freedom and coverage factors are used, and appropriate documentary standards and tolerances are used to assess conformity assessment and decision risk rules, using passing P_n values. (The P_n assessment uses a ratio of Uncertainty divided by the applicable tolerance to calculate a value that must be less than one to pass. It is also used in all OWM proficiency tests as a component of pass/fail statistics.)

- 1.5.5 - Reference documented and validated procedures used to conduct calibrations (e.g., NIST SOP or internally developed SOP with a record of its validation). NOTE: many laboratory administrative procedures for method validation do not adequately cover traceability assessments. Weights and measures laboratories in the OWM program are expected to use the NIST OWM published calibration procedures that are also covered in OWM training seminars. The latest version of the procedures also must be referenced in the laboratory QMS documents.

  - Laboratories submit the following additional items to OWM for evaluation: if the laboratory is using a lab-developed method, they must submit the SOP, the validation procedure or reference NISTIR 8250 GLP 14 (if using GLP 14), and record of their validation per the GLP 14 appendix. If a laboratory is using the NIST SOP, they can simply reference it on their assessment. If the laboratory needs minor instructions or clarification of the NIST procedures, they can simply write a Supplement that may not need full validation. However, validation of the ability to implement the procedures is still required through successful completion of proficiency testing.

- 1.5.6 - Accredited technical competence. Laboratories must be able to demonstrate that they have adequate staff, that staff are trained, and that they have demonstrated competency. Laboratory personnel demonstrate competency through performing procedures during training seminars, as demonstrations for assessors during on-site assessments, and as a part of proficiency tests.

  - Laboratories submit the following additional items to OWM for evaluation: Training records (training logs or databases, transcripts, on-the-job training (OJT) worksheets) and successful proficiency testing results. For unique measurement areas that are not covered by OWM training or PTs, the laboratory needs to have further discussions with OWM staff.

- 1.5.7 - Measurement assurance. Laboratories are required to demonstrate how they ensure the validity of measurements they conduct. All the NIST OWM procedures incorporate measurement assurance methodologies that include things like replicate measurements, control charts, standard deviation charts, use of check standards, and periodic review of the measurement processes. Additional OWM SOPs cover measurement assurance methodologies.

- Laboratories submit the following additional items to OWM for evaluation: A completed Measurement Assurance System Assessment (2010) form (posted with SOP 30), applicable control charts and/or standard deviation charts that demonstrate measurements processes, and standards that are in control or appropriate action items pending completion in a timely manner.

As noted earlier, laboratories are required to have objective evidence for each of the seven essential elements to prove that they can provide metrological traceability for measurements they provide to laboratory customers or other weights and measures officials. Laboratories seeking accreditation are required to demonstrate the same essential elements during their accreditation assessment process. Laboratories recognized by the NIST Office of Weights and Measures must complete this traceability assessment and submit their request and objective evidence to OWM any time there is a requested Scope addition or change with the latest Recognition application. Laboratories that are accredited by ILAC signatory accreditation bodies must follow the detailed procedures required by their accreditation bodies for demonstrating metrological traceability. If you have any questions regarding OWM Traceability Review, please contact Mike Hicks at **Micheal.Hicks@nist.gov**.

Item	Title	Description	17025:2017	NIST or OWM Resource
1	Realization of the SI	*Define: Measurand (VIM)* BIPM SI Brochure	Section 6.5.2 Annex A.2.1, a)	NIST SP 811 – Units, Symbols, Conversions
2	Unbroken Chain of Calibrations	*Define: Calibration (VIM)* *Illustrate Hierarchy*	Section 6.5.1 Annex A.2.1, b)	GMP 13 – Definitions and Example Hierarchies
3	Calibration Program	*Traceability of Standards and Equipment Supplier Evaluation* *Note: suitable intervals and current status; ILAC AB accreditation or compliance evaluation*	Sections 6.4, 6.5, 6.6 Annex A.2.1, b) Annex A, A.3.1	GMP 13 – Process GMP 11 – Calibration Intervals
4	Documented Measurement Uncertainties	*Use: Guide to the Expression of Uncertainty in Measurements (GUM)* *Option: Compliance Assessments*	Section 6.5.1 Section 7.6 Annex A.2.1, c)	SOP 29 SOPs – Each have Uncertainty Budget Tables
5	Documented and Validated Procedures	*Selection hierarchy; validation*	Section 7.2 Annex A.2.1, d)	GMP 12 SOPs – Validated to ensure traceable results GLP (Method Validation)
6	Technical Competence Evidence	*Training, Proficiency Testing, Demonstrations*	Section 6.2 Annex A.2.1, e)	GLP 1 State Labs: training and PT requirements AB: PT Plans
7	Measurement Assurance	*Statistical validation of standards and process; input to uncertainties*	Section 7.7	GLP 1 SOP 30, 9, 17, 20

Figure 1. Seven essential elements of traceability