OWM Traceability Reviews

The OWM Recognition Certificate states that you can provide traceable measurements.... be able to prove it! Ensure that your lab documents support it.

Submit full "traceability assessment" and "objective evidence" any time there is a change in Scope requests. This assessment is also needed for:

- Technical audit: Appendix C or D in GMP 13
- Lab QMS documents
- Internal Audits
- LAP Problems
- Future Annual Submissions?

Traceability Assessments: Quality Management System (QMS)

- Terminology and Definitions - Review QMS documents. Be sure to use the latest VIM definition! It is in GMP 13, Section 1.2! Make sure your document references and terminology lists include the latest VIM (2008 with 2012 corrections)!
- Reference is: "International Vocabulary of Metrology – Basic and General Concepts and Associated Terms (VIM 3rd edition), JCGM 200:2012 (JCGM 200:2008 with minor corrections)"
- Make sure all implementation of 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 alone are not enough. NOTE: OWM has observed examples of lab submissions during last "traceability assessment" or with "LAP problems" where files appear complete at that time of review, but are not part of full set of laboratory QMS documents (QM, SAP, Appendices) and/or referenced as Records.... failure to have up to date calibrations will result in NO recognition for those parameters/ranges. If referencing these items as Records - they are examples of Objective Evidence for those sections of the Internal Audit and need to be noted in the QMS or SAP (e.g., "see Traceability-20xx.XLSX file" or "see QM Appendix MX").

What is a Full "traceability assessment" and what "objective evidence" gets submitted?

Best practice: Use Appendix C or D as the technical audit and as an outline of the objective evidence that needs to be referenced/included in the QMS or referenced records and submitted for OWM reviews. Review GMP 13, Section 1.5.

- 1.5.1 - Realization of SI Units - reference use of SI units in QM, on calibration certificates (show example certificate as part of package), and include SI units on hierarchies (included in QMS files) (Observation: In all places where units are represented, follow the manuscript review checklist in SP 811!!!)
    - Submit: hierarchies (QMS or QMS referenced record) and calibration certificates

- 1.5.2 - Unbroken chain of comparisons - need hierarchies for all measurements on the scope (also need them for environmental standards.) - Supporting evidence includes calibration certificates for each level on the hierarchy and supplier evaluations for each outside provider - and have that level on your scope or supported if done internally.
    - Submit: calibration certificates and supplier evaluations

- 1.5.3 - Documented "calibration program" - Adoption of GMP 11 and due dates, appropriate intervals, extension of calibration intervals ONLY done with supporting data and evidence/analysis. GMP 11 notes that it is a template and may reference laboratory documents (or databases) in section 4.1. Example inventory as job aid posted with GMP 11 and GMP 13. GMP 11 and the sample Excel file includes environmental standards and equipment like balances. See also Appendix B of GMP 13 or use the Excel file job aid or database. There must be a document or record and it needs to be submitted as evidence. If a record, it needs to be referenced in the QMS. No standards that are out of date will be put on a lab Scope. Expanding Scope requires adding standards and equipment to the inventory with appropriate suppliers and due dates.
    - Submit: inventory of standards and equipment that shows suitable calibration dates, intervals, and due dates. If a database is used in the lab, then export a report of the standards/equipment.

- 1.5.4 - Documented measurement uncertainty - uncertainties need to be updated to expand a Scope. Reference the laboratory uncertainty files as a record in the QMS (e.g., "Lab Uncertainty 20XX.XLSX".)
    - Submit: updated uncertainty file; ensure all applicable components addressed and passing P(n) values.

- 1.5.5 - Reference NIST SOP OR submit 1) copy of SOP with 2) reference Validation Procedure (like GLP 14 (2019) - or BETTER; 3) record of validation. Note: most older SAPs on Method Validation are NOT adequately covering traceability assessments.)
    - Submit: if lab-developed methods include the SOP, validation procedure or reference to GLP 14, and records of validation per GLP 14 appendix (if NIST SOP, simply reference it on assessment).

- 1.5.6 - Accredited technical competence.
    - Submit: evidence of training (logs, transcripts, OJT - example OJT worksheets are on the new website shown in recent Info Hour), and successful PT - or discuss options with OWM for unique areas not covered in RMAPs

- 1.5.7 - Measurement assurance.
    - Submit: Measurement Assurance System Assessment (2010) posted with SOP 30 - DO that assessment; include applicable control charts and/or standard deviation charts.

As noted before – do this assessment and submit request and evidence to OWM any time there is a requested Scope addition or change, with an updated APPLICATION form.