UNITED STATES DEPARTMENT OF COMMERCE
National Institute of Standards and Technology
Gaithersburg, Maryland 20899-

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MEMORANDUM For: State Laboratory Authorized Representatives and Metrologists

From: Georgia L. Harris, Program Leader, Office of Weights and Measures (OWM)
Elizabeth Gentry, Office of Weights and Measures

Subject: General Feedback for All State Laboratories Regarding 2017 Recognition Certificates of Metrological Traceability

The NIST Office of Weights and Measures, Laboratory Program assesses laboratories against the quality management system and technical requirements that are published in NIST Handbook 143, Program Handbook. Handbook 143 adopts and supplements requirements in ISO/IEC 17025:2005. Specific assessments are conducted each year, may include on-site assessments, and include review of and section of the Handbook, and often specifically these sections:

- Laboratory management reviews;
- Calibration and measurement capabilities (reported uncertainties);
- Proficiency testing results;
- Laboratory staff and demonstrated competency through training and proficiency testing;
- Suitability of laboratory equipment, facilities, standards, and procedures; and
- Suitability of laboratory quality management systems.

Management Review Observations

Management reviews provide a wonderful opportunity to review the suitability and effectiveness of ongoing laboratory operations on a periodic and planned basis. It also provides an occasion to identify and communicate success stories and resource needs to ensure ongoing quality operations. Outputs of the management review should feed into the laboratory planning system and include the goals, objectives and action plans for the coming year. Findings from management reviews and the actions that arise from them need to be recorded with assigned responsibility for ensuring actions take place by specified deadlines. All changes need to be monitored for effectiveness and assessed during the subsequent audits to ensure that changes and improvements contribute to quality operations. This year, during the overall assessment of Management reviews from all laboratories, several examples of best practices were noted:

- Inclusion of topics from the Regional Measurement Assurance Program (RMAP) training sessions such as "Risk Management" and changes to the 17025:2017 standard have been shared with laboratory management;
- Discussion of the Quality Management System and policy updates;
- Summarized overviews of proficiency testing results;
- Discussion of feedback from OWM as an "external audit" (which it is);
- Planning and scheduling for recalibration of laboratory standards on a timely basis;
- Planned efforts and balance replacements for those balances that no longer have parts, or in some cases service, available; and
- Planned efforts for integrating and documenting on-the-job training (another topic covered at the 2016 RMAP training sessions).

Laboratory management reviews document ongoing evidence of corrective action, preventive action, and continual improvement action. OWM encourages the ongoing support to complete action items that are identified during internal audits, laboratory assessments, and in the

management reviews as well as follow-up evaluations of effectiveness as required. Continual improvement is an essential quality practice and is required by Handbook 143.

Quality Management System (QMS) Analyses and Updates (General Feedback)
During this annual submission review cycle, laboratories were asked to submit a special Quality Management System assessment as well as updated Quality Management System. A lengthy memorandum was provided by Elizabeth Gentry in March 2016 covering a National Annual Assessment Summary – Quality Management System Topics (that included reviews of the 2014 to 2015 submissions). Special hands-on training sessions were held at all of the 2016 Regional Measurement Assurance Program events on this topic to given laboratories a head start on accomplishing the assessment. Additionally, a Laboratory Metrology *Info Hour* webinar was held on August 2, 2016.

Conducting the QMS assessment and ensuring that the laboratory QMS is current prior to the introduction of the NEW ISO/IEC 17025 documentary standard is *critical* to ensuring a smooth transition to the new standard that has undergone a *major* update! The new ISO/IEC 17025 standard, which has been significantly reorganized and contains new requirements, is expected to be published and implemented in 2017. Additional training and resources will be provided during 2017 regarding changes to this standard and to Handbook 143.

Laboratories with certificates that do not expire until the end of 2017 were given the option to submit this extra QMS assessment during the 2017 submission cycle; however, laboratories who chose to wait are encouraged to conduct this assessment and update laboratory documents as soon as possible to avoid being at a disadvantage later in 2017.

In general, the following observations were noted during the QMS reviews:

- Many best practices noted in the memorandum from Elizabeth Gentry in March 2016 have been implemented in many laboratories. Unfortunately, many laboratories have not implemented some essential best practices that will help as quality management systems need to be updated in the very near future. Be sure to review that memorandum that is posted on the OWM website. One best practice that will significantly help is the following:

  Combine Quality Manual chapters (form one document) and Standard Administrative Procedures (SAPs, form one document) for easy maintenance. Headers and footers are uniform throughout each file. One version control identifier is applied to the entire document even if individual sections are updated during the year and noted in the revision control or adoption section (e.g., Adopted April 2016).

  A recommended "first step" is to combine individual quality manual chapter files into one document, create uniform headers/footers, and use one version control throughout the document. Update the master list to reflect the change. The same can then be done to combine individual SAP files. The ultimate goal is to have a QM and SAPs with consistent version control, headers, and footers. Each year a single review and new adoption date keeps both documents current. Appendices or other reference files often have multiple updates during/throughout the year and rather than completely updating the QMS each time a change is documented, simply referencing these additional files. Include the current date in each file name to ensure that the latest version is available and used (e.g., Standards_Inventory_2016_11_25.xlsx).

Quality Manuals and Administrative Procedures that are still in individual chapters need filenames that include the Title of that Section and the Revision date as a minimum for laboratory efficiency and effectiveness. Ideally, these files will be combined into one document each, but progress toward good document control will speed along the updating process that will be required in the coming years due to implementing the new ISO/IEC 17025 standard.

- Thirty-four laboratories completed and submitted the QMS assessment and the laboratory QMS (eleven did not complete the QMS assessment yet, although a few still submitted updated Quality Management Systems);
- Laboratory Quality Manuals *in general* have taken one of the following three forms:
    1. Original quality manual (from the NISTIR 5802 template that was based on a combination of ISO 9001, ISO Guide 25, and Baldrige Quality criteria) that has been updated based on changes to ISO/IEC 17025 over the years) WITH a crosswalk table highlighting the location of ISO/IEC 17025:2005 (Handbook 143) criteria within the management system – seven (7) laboratories;
    2. Original quality manual with NO crosswalk table for ISO/IEC 17025:2005 (Handbook 143) – seventeen (17) laboratories; and
    3. Quality manuals that are closely aligned with the current organizational structure of ISO/IEC 17025:2005 (Handbook 143) – ten (10) laboratories.

Recommendation Regarding the QMS Assessments
Make every effort to ensure that all identified action items are completed during the coming year as that will help your laboratory be prepared for the coming changes due to the ISO/IEC 17025: 2017 updates. OWM did not conduct thorough assessments of all Quality Management Systems to ensure that all proposed corrective actions identified in the QMS Assessments were implemented. Keep in mind that it is the responsibility of laboratory staff to ensure that action items are completed in a timely manner.

- To simplify efforts in updating manuals during the coming phase-in period, please consider the following additional recommendations:
    - Make every effort to ensure the current laboratory QMS is up to date;
    - If you have a quality manual and standard administrative procedures based on the original templates, the simplest update will be to make sure a crosswalk of the new ISO/IEC 17025 standard is inserted and clearly identifies applicable sections. Having this crosswalk will help identify gaps between the current QMS and the new standard during external assessments and internal audits.
    - If you have a quality manual based on ISO/IEC 17025:2005, inserting a crosswalk table against the new standard is possible.
    - OWM does NOT recommend rewriting quality manuals based on the outline of the current ISO/IEC 17025 standard nor the draft of the ISO/IEC 17025: 2017 standard! Ensuring a limited number (two) of quality manual formats within the state laboratories will help upcoming working groups identify which sections need to be updated in which versions of the manuals and will assist in providing uniformity and subsequent training.

Laboratory Staffing, Training and Proficiency Tests (Handbook 143, Sections 4.1.5, 5.2, and 5.9)
Handbook 143, Section 4.1.5 notes that "the laboratory shall have managerial and technical personnel who, irrespective of other responsibilities, have the authority and resources needed to carry out their duties, including the implementation, maintenance and improvement of the

management system, and to identify the occurrence of departures from the management system or from the procedures for performing tests and/or calibrations, and to initiate actions to prevent or minimize such departures (see also 5.2)." A number of laboratories have current staffing shortages and do not have adequate resources to fully carry out the duties and responsibilities of the laboratory. This is especially true regarding the management of the laboratory Quality Management Systems! Staffing shortages should be identified as a non-conformity during the laboratory internal audits, with corrective action efforts discussed in Management Reviews, and with evidence of corrective actions initiated.

Good succession planning is a critical laboratory function. In the past few years, OWM has observed numerous laboratories fail to have adequate staff resulting dire consequence: loss of Recognition and Accreditation, including the inability to perform calibrations to support State legal weights and measures activities.

An up to date memorandum and list of training requirements is posted on the OWM website. As a note for staff who previously have completed all training requirements, ongoing performance of measurements in the laboratory and completion of proficiency tests on a regular basis is essential to keeping your metrology skills up to date and proficient! Approved signatories should never pass up the opportunity to participate in a proficiency test that is scheduled for the laboratory. After the "on-the-job" training (OJT) provided at the 2016 RMAPs, OWM will be offering several opportunities during 2017 to gain guidance regarding updating Standard Administrative Procedures regarding staff training to include minimum training requirements, training on the QMS, and documentation of OJT within the laboratory. Examples of best practices and updated procedures and templates will be shared.

Consider registering for the following Laboratory Metrology *Info Hour* (webinars) that have already been scheduled for 2017 for ongoing professional development and to increase awareness of program changes and opportunities:

- January 24, 2017, Course 2970; Class: 5477: ISO/IEC 17025 - 2017 Updates, (With Warren Merkel, NIST – co-convener of the ISO/IEC 17025 Working Group) – Hear about the latest draft of the ISO/IEC 17025 standard as it is getting updated and find out how to review and submit input comments.
- February 21, 2017, Course: 2980; Class: 5479: Risk Assessments and the New 17025, (with Georgia Harris) – Review of the concepts covered at the 2016 RMAP sessions, get and discuss the follow up survey that compiled examples of risk assessments, and get an example of a "Risk Management Policy" statement that can be inserted into your Quality Manual.
- March 21, 2017, Course: 2981; Class: 5482: Risk Assessments for the Essentials of Traceability, (with Georgia Harris) – Review the Essential Elements of Metrological Traceability (GMP 13), review proposed changes to the ISO/IEC 17025 standard related to evidence of traceability, and consider and discuss RISK Management related to each of the 7 essential elements.
- April 18, 2017, Course: 2941; Class: 5480: Best Practices of Laboratory On the Job Training (OJT), (with Georgia Harris) – review examples of best practices from at least one laboratory within each RMAP region, see and discuss an updated Administrative Procedure, see and hear about OJT documentation best practices, and briefly reinforce training conducted at the 2016 RMAPs on learning objectives and documentation of OJT.

A training flier for OWM metrology seminars was circulated by our office in November 2016 and regular updates to seminars are posted on the website under Events. OWM staff regularly add

seminars and webinars based on observed needs and based on specific OWM Contacts System requests when there are sufficient requests to hold the seminar/webinar. Requests for current and potential training may be submitted via the OWM Contacts System at any time (not via email). Please ensure that upcoming RMAP training and any training gaps are identified and included in your training plans and are approved for the coming year.

Please remember that Laboratory Auditing Program (LAP) problems are due within one year of completion of the Fundamentals of Metrology seminar and within two years of the Advanced Mass seminar or refresher training may be required. These problems are required for laboratory staff to become Approved Signatories for the laboratory.

According to NIST Handbook 143, Program Handbook, and the published training memorandum, attendance at the Regional Measurement Assurance Program (RMAP) training and proficiency testing planning and reviews are *required* annually for ongoing laboratory Recognition. The training, agenda, and learning objectives for 2017 RMAPs have been posted on the OWM website. Upcoming RMAP training is scheduled as follows:

Region	**Dates**	**City, State** *(City may change)*	**Host Contact**
SEMAP	April 3 to 6, 2017	Raleigh, North Carolina	Van Hyder Van.Hyder@ncagr.gov 919-733-4411
WRAP	May 1 to 4, 2017	Helena, MT	Dave Fraser dafraser@mt.gov 406-449-2582
NEMAP	September 18 to 21, 2017	Charleston, WV	Tony O'Brien Anthony.P.OBrien@wv.gov 304-722-0602
SWAP	October 2 to 5, 2017	Topeka, KS	Kevin Uphoff Kevin.uphoff@kda.ks.gov 785-296-2938
MidMAP	October 16 to 19, 2017	Lansing, MI	Nick Santini santinin@michigan.gov 517-655-8202 x316

2017 Annual Submission Planning – Traceability Assessments (Handbook 143, Section 5.6)
Additional technical information will be requested in 2017 for the next annual review cycle regarding Metrological Traceability (Handbook 143, Section 5.6). If your laboratory calibration program for standards and instruments is well documented and up to date, all calibrations are current, and supplier evaluation records are up to date, the technical assessment to be submitted should be relatively simple.

There is no reason to wait until the Fall to ensure that documentation of traceability and calibration intervals are reviewed and current. Early evaluation will provide an opportunity to arrange for any calibrations (e.g., corrective action) where you observed gaps in your system before the NIST submission deadline. It is also important to ensure that all supplier evaluation records are up to date for the laboratories from which calibrations are obtained. A good best practice is to download the Accreditation Scope for the laboratory providing the calibration at the time plans are made for obtaining the calibration. If not already completed, NIST recommends

updating the SAP to note that supplier evaluations are conducted initially and immediately prior to obtaining calibrations (instead of "annually" as was in the original wording of the template procedures).

The checklists included in GMP 13 may be used to assess laboratory documents and ensure they are complete and sufficiently well documented. The following specific items will be requested during the 2018 Annual Submission cycle for all measurements associated with the laboratory Scope:

1. Documented Traceability Hierarchy of Standards (be sure to include associated environmental measurements; this may be a part of GMP 11 and GMP 13 documents, but preferably a separate document that is referenced and kept up to date);
2. Standards Inventory (including Reference, Working, and Check standards based on the hierarchies) with Calibration Dates, Intervals, and Calibration Sources (Ensure that there is not duplication between Inventories of standards maintained in Excel and historical appendices in the Quality Manual.);
3. A complete Inventory of Calibration Certificates (named with suitable file names and dates of calibration, organized according to the Scope, Level or the GMP 11/13 references); and
4. Copies of Good Measurement Practices (GMP) 11 and 13 that are edited/tailored for your laboratory (which can reference the external hierarchy and inventory files).

Best practices for item #4 will likely reference laboratory files from items #1 and #2 rather than duplicating information in GMP 11, GMP 13, or Quality Manual Appendices. This best practice has been covered in multiple training sessions, so if you still have questions, be sure to attend upcoming sessions at your earliest convenience. Additional guidance will be provided on this topic through Laboratory Metrology *Info Hours* and webinar training during 2017. Be sure to participate in these scheduled training events as this material will NOT be covered during the 2017 Regional Measurement Assurance Program training.

If you have any questions or comments, please feel free to contact us by phone or e-mail at (301) 975-4014 or *georgia.harris@nist.gov* for Georgia Harris and (301) 975-3690 or *elizabeth.gentry@nist.gov* for Elizabeth Gentry.