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

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MEMORANDUM FOR Students Completing Fundamentals of Metrology Laboratory Auditing Program (LAP) problems

From: Isabel Chavez Baucom, Micheal Hicks, and Elizabeth Koncki
NIST/Office of Weights and Measures/Laboratory Metrology Program

Subject: Updated Laboratory Auditing Program Problems for Participants of Fundamentals of Metrology Seminar

Problem Assignment and Approved Signatory Status

These Laboratory *Auditing* Program (LAP) problems have been developed to provide new metrologists in the NIST Office of Weights and Measures (OWM) State Laboratory Program a mechanism for recognition of Approved Signatory status, once they have completed both the Mass and Volume seminars. These problems MAY be completed and submitted prior to attending the Mass and Volume seminars (they are not *required* prior to attendance).

Successful completion of these LAP problems requires that a Mass and a Volume PTs are successfully completed with all analyses that are described on the next page. A detailed summary must be generated for EACH Mass and Volume segment that covers all the required analyses (template included here). The problem summary should include a statement of the purpose of the problem, an explanation of what data was evaluated and from what source it came, what analyses were performed, what action items were identified, how action items were integrated into the normal laboratory operations, and any conclusions the participant has developed about their laboratory measurement system based on the data and analyses.

Note: As these are AUDITING problems, the observations, findings, recommended improvements, and corrective actions need to flow into the laboratory's internal audit and management reviews. It also needs to include the plans/results of corrective action, preventive action, or improvement action that resulted from the problems – as used as an AUDIT. If you don't have the authority to assign and complete action items in your laboratory, you will need to coordinate with your laboratory management to accomplish these goals.

Step 1: Complete the Proficiency Tests (PTs)

Complete a Mass and a Volume PTs (through your regularly scheduled Regional Measurement Assurance Program PT Plan is preferred; you may contact Micheal Hicks if one is not available within the required time period.) Completion of a PT means performing the measurements, submitting a calibration certificate, and getting feedback on the results. When coordinated through the RMAPs, you may need to work with the coordinator, who will also work with OWM staff, to provide interim results to OWM for review and to provide you with interim feedback.

Step 2: Complete the Internal Audit Assessments

Complete all of the additional assessments and PT follow-up forms as described in the below LAP Problem Assessment section. These items can be completed in parallel and do not need to wait until the PT results are final.

Step 3: Write the LAP Problem Summary

Write your Summary of the Process and Results, including the status of Action Items (Action Plan form. https://www.nist.gov/document/8-9-action-plan-form-log) and how they have been handled and expected due dates on completion of the action items.

Step 4: Submission

Submit the problems to NIST OWM as a single submission (do not send them as pieces) in some form of electronic media (not paper). NIST Box (https://nist.app.box.com/f/db9b1525ebd24a21a4676cf6843cf57a) is the preferred method for submitting. Submissions are also acceptable via USB memory sticks that will not be returned. If it is needed, contact Isabel Chavez Baucom for uploading/login instructions to NIST Box. Be sure to put your name, state, title, and date on zipped submission file or USB media!!! E.g. BaucomIsabel_LAP problems-NIST-YYMMDD. ISO/IEC 17025 and NIST HB 143 require that all Laboratory documentation be complete and this will become part of your laboratory documentation: internal audit, action items, and management review. INCLUDE OBJECTIVE EVIDENCE FOR EVERYTHING!!!

a) Submit all PT results to Micheal Hicks (micheal.hicks@nist.gov) for **initial** feedback. These can be sent via email.
b) Submit all files to NIST Box (preferred) or mail to Isabel Chavez Baucom as ONE complete package for review:

NIST Office of Weights and Measures
Attn.: **Isabel Chavez Baucom**
100 Bureau Drive, MS 2600
Gaithersburg, MD 20899

Training Requirements

1. Internal on-the-job training (OJT) on your laboratory Quality Management System (including administrative procedures).
2. Fundamentals of Metrology – do not *start* the problems until you have successfully completed this class.
3. Mass: Completion of NIST Mass Seminar or equivalent
4. Volume: Completion of NIST Volume Seminar or equivalent

The problems are due within one year of completing the Fundamentals of Metrology seminar. *If you are not able to complete the Mass and/or Volume training requirements or options within that one-year period, you can request an extension of the due date from OWM.*

Potential for Conditional Recognition

If there are no other approved signatory staff available in the laboratory, successful completion of these problems *may* also enable Conditional NIST OWM Recognition of a laboratory prior to participating in Mass and Volume Seminars. By completing the LAP problems, the associated SOP 7/8 and SOP 18/19 preliminary training, and successfully completing the prescribed proficiency tests, a laboratory may be granted Conditional Recognition to support State weights and measures activities. The Conditional Recognition will be valid for one year only, no extension will be granted. The participant will be required to complete the Mass and Volume seminars in that year.

LAP Problem Assessments

1. **Perform a Proficiency Test (PT).**

   Complete a PT on artifact(s) provided by NIST or another RMAP PT as instructed and submit a formal/signed Calibration Certificate for **each** (**mass and volume**). Objective Evidence: laboratory data and observations, any hand calculations, computer print-out or file(s) used in the process, and the certificates. Submit an interim report for evaluation; submit a final or amended report with the full set of LAP problems if needed. Be sure to record this as an action item and follow your laboratory administrative procedure if/when amending certificates!!! Include a copy of the PT report that shows your results. If the PT has failures, there will be additional action items!

2. **Conduct a "certificate review" of the Calibration Certificate(s) in item 1.**

   During the certificate review, identify any corrective actions that are needed. Use the job aid with SOP 1 and the Manuscript evaluation included with SP 811: http://www.nist.gov/pml/wmd/labmetrology/sops.cfm and https://www.nist.gov/pml/special-publication-811/nist-guide-si-check-list-reviewing-manuscripts. Submit amended reports as required (follow the lab procedure; best practice: make sure your lab procedure for amending certificates complies with 17025 while you're at it!). Objective evidence will include a certificate that is marked up and scanned to PDF. Be sure to identify and document action items!

3. **Conduct a "traceability assessment".**

   Conduct traceability assessments of the measurement processes for the standards used in your PTs for item 1. Use the job aid Traceability Assessment Form in GMP 13, Appendix C: https://www.nist.gov/pml/weights-and-measures/laboratory-metrology/good-measurement-practices. Be sure to identify and document action items!

   The objective evidence will include the completed GMP 13, Appendix C form as well as items listed below:

   a. Submit copies of all *relevant* calibration certificates for the standards used within your laboratory that were used for the PT and that demonstrate/establish metrological traceability.

   b. Submit copies of the *relevant* traceability hierarchies that support item 1 (see Appendix A in GMP 13 for examples).

4. **Conduct a "measurement assurance" assessment.**

   Evaluate the control charts, range charts, or standard deviation charts and associated analyses used to obtain standard deviations of the measurement process that are included in the uncertainty analysis for these PTs. If you don't have a control chart for the process at this time, you will need to perform at least 7 measurements to create control charts (following SOP 9, 17/20) – and remember you need 25 to 30 for valid uncertainties. There are TWO assessments for this. The objective evidence will include the completed form of a and b below. Be sure to identify and document action items!

   a. Use Appendix A included in SOP 9 to evaluate the charts themselves.

   b. Use the job aid for measurement assurance assessments that is posted with SOP 30 (Measurement Assurance System Assessment (Latest Date-2010)) to assess the measurement assurance system in your laboratory. You will also need to review the SOP used for the PTs to make sure that it is followed in your laboratory!

5. **Provide a documented "uncertainty analysis" to support the calibrations in item 1.**

   This uncertainty assessment should be your analysis, not a "laboratory documented solution". Use the job aid Uncertainty Evaluation Form (DOC), SOP 29 Worksheet (DOC) or the Uncertainty Budget Template (Excel) posted with SOP 29. Once you have completed this assessment, evaluate it against the SOP used for the PT to make sure it is complete. Then evaluate your assessment against the Uncertainty Budgets submitted for Laboratory Recognition (latest update) and identify and recommend resolution for any differences. Be sure to identify and document action items! See: http://www.nist.gov/pml/wmd/labmetrology/sops.cfm

6. **Complete the PT Follow-Up Form.**

   Finally, conduct the PT follow-up assessment and complete the PT Follow-up Form for each PT. Note that even if everything passes and was wonderful, there are follow-up action to complete in your laboratory! Submit the completed PT Follow-Up Form as objective evidence along with any other evidence of corrective actions. Use the PT Follow-Up Form: http://www.nist.gov/pml/wmd/labmetrology/lab-resources.cfm

Be sure to include the Summary Assessments and Action Items per the instructions or the problem status will be INCOMPLETE. Each item will include objective evidence. PLEASE consider how you have named files and the "Electronic File Organization Tips" that are posted here. Use descriptive but SHORT FILE names and include the revision dates in the file names. https://www.nist.gov/pml/weights-and-measures/laboratory-metrology/state-lab-program-resources Conduct a final quality check on the files before sending them to NIST OWM!

Assessments and Reviews

OWM will review the problems that are submitted to identify any missing pieces and provide initial feedback as soon as possible. It is standard practice for OWM to identify "something" during the review to ask participants to clarify and answer questions. Action Items that are identified in your assessments do not necessarily need to be completed prior to submitting the problems, but significant gaps may impact laboratory recognition status and significant concerns will need to be immediately resolved. Action items are expected to be resolved by the laboratory (it may involve more OJT training about how your quality management system operates).

The problems are intended to be completed INDEPENDENTLY by each person. However, the summary action items will need to be reviewed with laboratory management and follow the documentation process used in your laboratory for action items (corrective, preventive, improvement, etc.), internal audits, and management reviews.

Summary Report and/or Assessment. This should be about 2 to 3 pages for Mass **and** 2 to 3 pages for Volume (Separate files, one for Mass and one for Volume). Include references to attachments (and their file names) that are included as objective evidence. Below is an example of an outline of a summary report.

1. Purpose of the PT (Mass and Volume)
2. High-level overview and Observations of PTs (Mass and Volume)
3. Certificate Review and Findings (Mass and Volume)
4. Traceability Assessment and Findings (Mass and Volume)
5. Measurement Assurance Assessments and Findings (Mass and Volume)
6. Uncertainty Assessment and Findings (Mass and Volume)
7. PT Follow Up (Mass and Volume)
8. Conclusions (Mass and Volume)

Action Plan Form

Table 1. Action Plan Form.

Created by			**Creation Date**			**Action # or ID**	
Action Type[a]	*Select one*	**Criteria**[b]	Select one	**Priority**[c]	Select one	**Source**[d]	Select one
Title/Short Description	*Create a title or short description that can easily be referenced*						
Finding/ Observation(s)	*Describe in clear terms the finding that needs to be addressed*						
Risk Assessment	*Assess the risk to your laboratory as a result of the finding*						
Root Cause	*Use a common root cause analysis approach to evaluate why this happened (e.g., five whys)*						
Proposed Action(s)	*Describe what action(s) is proposed to resolve the finding(s)*						
Due Date		**Task Assigned To**					
Completion Date		**Task Verified By**					
Final Action(s)	*Describe what was the final action(s) taken to resolve the finding*						
Action Effectiveness	*Describe how was the action evaluated for effectiveness and if it proved to be effective*						
Evaluation Date		**Task Verified By**					

[a]Action Types: Corrective Actions (CA), Risk Minimization (RM), Improvement Actions (IA); [b]Criteria: Meets Criteria (OK), Nonconformity (X), Comment (C); [c]Priority: High = 1, intermediate = 2, Low = 3; [d]Source: Complaint (C), Internal Audit (A), LAP Problems (LAP), Employee Observations (EO)

Action Plan Log

Table 2. Action Plan Log.

Action # or ID	Action Type	Creation Date	Title	Finding/Observation(s)	Proposed Action(s)	Assigned To	Due Date	Actual Completion Date	Evaluation for Effectiveness Date