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

July 1, 2018

MEMORANDUM FOR State Directors
State Metrologists (including GIPSA/USDA, LA County)

From: Georgia L. Harris, Laboratory Metrology Program
Office of Weights and Measures (OWM)

Subject: **Annual Submission for 2019 for NIST OWM Laboratory Recognition**

This memorandum is the annual solicitation request for OWM Laboratory Recognition per NIST Handbook 143, Program Handbook. Required submission materials are identified in Handbook 143, Table 1 (updated each year). The required 2019 Recognition technical request is detailed in this memo. OWM will only issue one year Certificates of Metrological Traceability as participating laboratories transition through the implementation of ISO/IEC 17025:2017.

Deadlines and Reviews

To maintain or obtain NIST OWM Laboratory Recognition, materials must be submitted each year between October 1 and November 1. The deadline is **November 1.** Materials that are not submitted on time or that are submitted incomplete may not be reviewed prior to the expiration of the current laboratory Recognition certificate. We will make no commitments of timely reviews for late submissions. Items that are significantly late may not be reviewed until the next review cycle. Materials may be submitted during the year to update a Recognition measurement scope. However, they may not be reviewed in a timely manner or until the next review cycle, pending OWM training schedules and other program commitments and priorities.

Please MAIL complete submissions with attention to:

NIST Office of Weights and Measures
Attn: Georgia Harris
100 Bureau Drive, MS 2600
Bldg 222, Rm A 264
Gaithersburg, MD 20899-2600

Submission Method and Content

Note that Federal Express, UPS, or other couriers do not get to us any faster than Priority Mail because items are delivered to a different location at NIST, where they are scanned and inspected. Often these packages take two to three additional days to be delivered to the OWM office. Please submit all items electronically in any format *except* e-mail. CD and USB sticks are acceptable formats. E-mail submissions will not be accepted, except where an item is missing and specific guidance is provided. We do *not* track items submitted by e-mail unless we specifically request them once we are conducting reviews. We have sent USB sticks to all primary laboratory contacts with this memorandum so that you can submit files on the NIST-provided USB. *We will not return the USB sticks after they are submitted.* (If you have removable media policies that have banned use of these materials, contact Georgia Harris directly for alternative solutions).

Please use Document Control best practices in all your files and in file-naming conventions. Review the *Electronic File Organization Tips* available on the State Lab Program Resources page before sending your submission files: http://www.nist.gov/pml/wmd/labmetrology/lab-resources.cfm.

Summary Table for 2018 Annual Submission for 2019 Recognition

ISO/IEC 17025:2017 Section or Reference	Item	To be submitted by all laboratories as appropriate	Sent
*Application	HB 143, Recognition Application (2018) *This has been updated! Use the new application!*	Yes	
*ALL	Previous Non-conformities (*review and complete action items related to prior year OWM feedback, onsite assessments, and internal audits*).	As identified in previous audits and reviews and OWM feedback	
6.2	Laboratory Auditing Program (LAP) Problems.	If applicable	
6.6	Calibration Certificates for all Standards Calibrated by Other Laboratories, with your Supplier Evaluations and Certificate Assessment.	If applicable	
7.2	Laboratory Developed Calibration Procedures (and include Validation Procedure and Evidence of Validation).	New procedures only	
*7.6	Uncertainties for all Measurement Parameters 1. Make sure components match applicable SOP uncertainty budget tables; 2. Update all standard deviations consistent with your control charts; 3. Evaluate all uncertainties with appropriate precision assessment (P_n) and if there are any P_n failures, include appropriate comments and evidence of corrective action or pending corrective action. Your uncertainties must match your proposed Recognition Application. *Excel Versions preferred.*	Yes	
*7.7	Proficiency Testing Follow Up Forms (*only for PTs that are completed for your lab*). ONE per PT!!!	Yes	
*7.7	Control Chart and Measurement Assurance Assessments 1. Inventory of Control Charts and Standard Deviation Charts – by Parameter and Range 2. Copies of Control Charts 3. Measurement Assurance Assessments for each Parameter (and Range if appropriate) – assessment forms and Excel file analysis (can be integrated in control charts) See the next section for additional guidance.	Yes	
8.2	Submit your Quality Manual/Management System Manual, Appendices, Forms, Administrative Procedures, and Lab Developed Methods. *ONLY if updated!*	Only if updated.	
*8.9	Management Review *(less than 6 months old!).* *Management Review Outline (2018) has been updated! Use the new outline!*	Yes	
**Minimum number of items to be submitted for all laboratories.*			

NOTE: If you have any specific questions about content, please contact Georgia Harris or Elizabeth Gentry.

There is a two-hour Annual Submission webinar scheduled that examines the required materials and process. Register in the OWM Contact System as usual and no later than October 1, 2018. Reading this memorandum constitutes the required pre-work for the session:

- Training Event: Webinar - State Laboratory Annual Submission Process (5457)
- When: Thursday, September 6, 2018, 2:00 PM to 4:00 PM Eastern Time.

2018 Technical Audit – Measurement Assurance

Updated control charts and standard deviation (or range) charts are to be submitted for the 2018 annual submission. In addition, an inventory of control charts maintained in your laboratory and a "measurement assurance assessment" for each area of the laboratory Scope will be requested. This is to fulfill a technical audit of Section 5.9 of NIST Handbook 143, Program Handbook (also ISO/IEC 17025:2017, Section 7.7). Measurement assurance activities are one of the most critical methods that can be used, to minimize the risk of bad measurement results being provided on calibration certificates. When considering ways to minimize risk and prevent measurement problems as a part of the updated ISO/IEC 17025 standard, it is important to recognize that most laboratories already have an integrated system of measurement assurance methods in place.

To itemize what is being requested:

1. Inventory list of control charts.

   This is considered part of document control, data management, and/or equipment requirements. The inventory may already be part of the laboratory Quality Manual or is an associated Appendix or another referenced laboratory file. The list may also be part of the laboratory document control Master List. A sample inventory is posted on the NIST website (https://www.nist.gov/pml/weights-and-measures/laboratory-metrology/state-lab-program-resources).

2. All the control charts and/or standard deviation (or range) charts for all measurement parameters on the laboratory Scope.

   OWM requires active or live versions, not a static PDF file and nothing with links unless the linked files are provided in the appropriate associated directory. Please discuss this request with Georgia Harris if your charts are not maintained in Excel spreadsheets (e.g., Access database; or PMAP files). This should be rare since this software has not been maintained for many years. Control charts must designate or comment on all observations of concern or deviation, noting outliers and causes, indicating the date(s) of evaluation, documentation of the resulting action, and available supporting objective evidence (e.g., corrective or improvement actions taken).

   If the control charts have never been internally assessed against the SOP 9 checklist for completeness of required elements, be sure to complete that assessment early in 2018 to ensure adequate time to implement corrective actions before submitting the control charts for OWM review. Control chart files are considered laboratory configured modifications of software, therefore suitable software verification and validation documentation of at least the template version used in the lab is required as well; security controls should be on all copies (provide passwords or reset them to provide OWM access). You do not need to submit the SOP 9 evaluation, or verification and validation documentation (unless it's already integrated in the file). Obvious failures in compliance with SOP 9, Appendix A,

and/or software verification and validation, labeling, and/or security controls will be noted as non-conformities during the OWM review.

3. Measurement assurance assessments for each measurement area of the laboratory Scope.

   There is a Measurement Assurance System Assessment template form on the NIST website (https://www.nist.gov/pml/weights-and-measures/laboratory-metrology/state-lab-program-resources). Job aids for the analysis of control charts were included with the training materials at each 2017 RMAP. These job aids are also posted on the above websites for your reference.

   A NEW tool for analysis is being provided in Excel to assist with ongoing systematic assessments of the laboratory control charts. This approach follows what is in the updated SOP 9 and SOP 30 for evaluation of mean values compared to appropriate calibration reference values. It also incorporates use of t-tests and F-tests following methods taught in the *Fundamentals of Metrology* seminar, which are in Sections 8 and 9 of the NISTIR 6969 – 2018 updates and which were in LAP 26/27 in the 1980s and early 1900s. It is expected that all charts will be assessed by the laboratory staff prior to submission to OWM for review.