



July 1, 2017

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 2017 to 2018 (ongoing Recognition), 2018, and 2018 to 2019  
NIST Laboratory Recognition**

This memorandum is the annual solicitation request for OWM Laboratory Recognition per NIST Handbook 143, Program Handbook. Items that are required are identified in Handbook 143, Table 1. A detailed version of required annual information and specific technical requests for this year is on the next page.

#### Deadlines and Reviews

To maintain or obtain NIST/OWM Laboratory Recognition, materials need to 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 your current 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 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 days extra to be delivered to our 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 a NIST-provided USB. *We will not return the USB sticks after they are submitted.*

Detailed descriptions of the information on the summary table shown on the next page can be found in NIST Handbook 143, *Program Handbook*, 2007 edition (available on line: <http://www.nist.gov/labmetrology>, State Laboratory Program).

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

**Summary Table for Annual Submissions**

Handbook 143 Section	Item	Certificate expires December 31, 2017 (or laboratory does not have a current certificate)	Certificate expires next year: December 31, 2018	Sent
Appendix B and D	Combined Appendix B-D, Application for Recognition ( <i>See website for latest version</i> ).	Yes	Yes	
Appendix E	Uncertainties (Scope must match to Appendix B-D Scope); <i>Excel Versions preferred</i> .	Yes	Yes	
4.15	Management Review ( <i>less than 6 months old!</i> ).	Yes	Yes	
3.3.4, k 5.9 4.15	Proficiency Testing Follow Up Forms ( <i>only for PTs that are completed for your lab</i> ).	Yes	Yes	
3.5.1.	Previous Non-conformities ( <i>review and complete action items related to prior year feedback and internal audits</i> ).	As identified in previous audits and reviews	As identified in previous audits and reviews	
ISO/IEC 17025 Assessment (2016)	Include references to Quality Management System <i>and evidence of implementation assessments</i> ( <i>See website for latest version as updated in 2016</i> ).	Yes	No	
4.2 4.14	Submit your <i>entire</i> Quality Manual/Management System Manual, Appendices, Forms, Administrative Procedures, and Lab Developed Methods. Be sure to <i>include an updated Documents Master List</i> .  <i>Complete a quality management system assessment (using the ISO/IEC 17025 form and these tools) and update your laboratory documents using the memo: "National Annual Assessment Summary (Memo) – Quality Management System Topics (2014 to 2015 Submission)" and the outline: "QMS Analysis-Evaluating Essential Elements", as posted here: <a href="http://www.nist.gov/pml/wmd/labmetrology/lab-resources.cfm">http://www.nist.gov/pml/wmd/labmetrology/lab-resources.cfm</a></i>	Yes – ONLY if it was not already submitted in 2016	NO	
4.14.1	Technical Assessments: Traceability Assessment. See PT Follow Up earlier on this list.	YES	YES	
5.4	Laboratory Developed Calibration Procedures (and include Validation Procedure and Evidence of Validation).	New procedures only	New procedures only	
Table 2	Laboratory Auditing Program (LAP) Problems.	If applicable	If applicable	

Handbook 143 Section	Item	Certificate expires December 31, 2017 (or laboratory does not have a current certificate)	Certificate expires next year: December 31, 2018	Sent
5.6	Calibration Certificates for all Standards Calibrated by Other Laboratories.	See Traceability Assessment	See Traceability Assessment	
5.6	Traceability Assessment. Please submit the items on this checklist as noted below. This material should regularly be reviewed and kept up to date and should not require major additional requirements. It is the major source of evidence to defend traceability for all measurements in your laboratory.	YES	YES	
	1. Legal requirements and authorization for your program (law, statutes, regulations, rules – however named) – including the Director responsibilities for standards and any licensing/registration program requirements.	YES	YES	
	2. Traceability hierarchy for all measurement parameters on your Scope and to match your Scope (whether in Excel, in GMP 13, or in your Quality Manual).	YES	YES	
	3. Calibration certificates for all standards on your hierarchy (reference, working, check, for all levels in the hierarchy). PDF files that are suitably named!	YES	YES	
	4. Supplier Evaluation forms/assessments or Excel file summary for all calibration certificates obtained from outside your laboratory (excluding NIST) with recognition or accreditation status noted.	YES	YES	
	5. Documented Inventory and Calibration Intervals and status of all standards noted above. May be combined with Excel file, included in Quality Manual, or GMP 11. (Note: best practice is to have an Excel file with hierarchy, inventory that includes calibration intervals and status all in one place – that is referenced in your Quality Manual and in GMP 11 and 13).	YES	YES	

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

There is a two-hour webinar scheduled on the Annual Submission materials and process and you can register in the OWM Contact System as usual:

- Training Event: Webinar - State Laboratory Annual Submission Process (5454)
- When: Thursday, September 14, 2017, 2:00 to 4:00 PM Eastern Time.