

August 16, 2010

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

From: Georgia L. Harris, Laboratory Metrology Group Leader
 Weights & Measures Division

Subject: **Annual Submission for 2011 and 2011-2012 NIST Laboratory Recognition**

The following information is provided to assist you in preparing for the 2011 and 2011-2012 review cycles. Please submit all items electronically in any format *except* e-mail: CD, DVD, or USB sticks are all acceptable formats (please note if you want the USB stick back). Please put the laboratory name (two-digit state codes) and date in all file names that you submit. E.g., "Appendix B.doc" could be "MD Appendix B 10.doc" as well as on any forms you complete. As a reminder: we do *not* track items submitted by e-mail.

Review Cycle and Deadlines

In order to maintain or obtain NIST/WMD Recognition for your laboratory, you must submit materials each year between October 1 and November 15. The due date is November 15 each year. We will consider items post-marked by the deadline to be compliant.

Materials that are not submitted on time 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.

Table 1 – Items to Submit for All Laboratories (exceptions noted in next section)

Review the attached Table 1 for items that need to be submitted by all laboratories. If you have a certificate that expires in 2010, or you do not have a certificate for 2010, or your current 2010 certificate is conditional, you will need to submit everything on the list. If the laboratory status is Conditional, you will also need to provide a status update related to the reasons for the conditional status. Modifications were made to Table 1 during the most recent update to Handbook 143 in 2007. You may complete a self-assessment using the table and submit it with your assessment.

Detailed descriptions of the information on Table 1 can be found in NIST Handbook 143, Program Handbook, 2007 edition, (available on line: <http://www.nist.gov/labmetrology>, State Laboratory Program). Blank forms can be downloaded in Word format from the site listed above. See exceptions for laboratories with 2-year certificates that do not expire this year.

Current Two-Year Certificates (expiring 2011)

Laboratories with *current* 2-year certificates that do not expire this year must submit:

1. Appendix B (application). Please use the integrated Appendix B and D contact information for laboratory staff.
2. Updated Uncertainty tables to include Precision assessment (P_n).
3. Proficiency Testing Follow-up Forms for PTs/ILCs completed this year (you do not need to submit forms for the PTs completed during the RMAP sessions, but do include them on your PT/ILC Log).
4. Your latest Management Review (conducted within the past 12 months).
5. Measurement Assurance Assessment, Inventory, and Control Charts for all measurement parameters on your Scope.
6. Software Verification and Validation documents as requested in our last review letter (or complete assessment if you did not receive a review; contact our office for details).

Keep in mind that, even though some items are not requested in the submission this year, internal assessments, technical audits, and management reviews are REQUIRED to be completed within your laboratory on an annual basis. These items *may* be requested during our review to verify conditions as needed.

New Two-Year Certificates (including those expiring 2010)

If a number of conditions are met during this review cycle, WMD will issue 2-year certificates. The benefit of this certificate is that only Appendix B, Uncertainty tables, Proficiency Testing forms and “special request” items and updates are required during the next submission cycle in 2011 for the 2012 cycle. To be eligible for a 2-year certificate, the following conditions must be met:

- Must submit a COMPLETE package on time (Use Table 1 as a checklist). Incomplete submissions will either be converted to a one-year certificate or you will get a notice that we are not reviewing your submission until the missing items are completed.
- Must have a *current* certificate from the latest cycle (i.e., 2010 or 2009-2010).
- Must have a record of submitting on time (3 of last 5 years, latest 2) or be NVLAP accredited.
- Current certificate must not be “conditional.”
- Must not have any unresolved deficiencies; deficiencies identified in previous reviews may be resolved with this submission. Review previous letters to make sure all reviewed items have been resolved.
- Must be up to date with LAP problems, Quality Manual, Administrative Procedures, and PT participation, reporting, and corrective action. During the 2008 reviews for 2009 certificates we requested a number of updated sets of laboratory documents.

Proficiency Tests

To evaluate measurement assurance and compliance to the published WMD policy, please submit copies of “Laboratory Follow-up and Corrective Action Checklist” forms for all proficiency tests that were completed during 2010 (that have not already been identified in a previous submission). Forms are available on the NIST website: <http://ts.nist.gov/WeightsAndMeasures/Metrology/roundrobins.cfm>. We expect that if corrective action was appropriate, that it was completed, or that it is in progress with a planned completion date. You do not need to submit a “Four Year Assessment,” just the individual PT/ILC forms/assessments.

Software and Computer System Assessment

Please complete the following assessment forms and submit with your package this year IF YOUR FEEDBACK LETTER INDICATED THAT FOLLOW UP WAS NEEDED or if you did not receive a feedback letter last year:

1. Laboratory Computer Systems Assessment.doc (Use and submit the ISO/IEC 17025 Form that highlights Computer System Assessments in orange.)
2. Software Assessment Inventory.xls (This file has been updated based on work in WMD during 2010. Download and submit the updated version.)
3. Technical Assessment of Software Rev1.doc (This file has been updated based on work in WMD this summer. Download and submit the updated version.)
4. Also submit your implemented copy of Standard Administrative Procedure 10 (or equivalent) for Laboratory Software. (This file has been updated based on work in WMD this summer. Download the updated version, review it, and consider adopting it. If you adopt the new version, you do not need to submit it back to us, but do let us know you have adopted it as a part of your SAPs.)

The Laboratory Computer Systems Assessment matches the specific criteria from Handbook 143 for items that are related to computer systems. The Inventory is simply a list of files and authorized access

and validation techniques you have completed. The Technical Assessment of Software is Form A from SAP 10 to use to document your level of assessment for each file used in the laboratory. We covered earlier versions of these items at the Combined RMAP training in April 2009. Additional webinars have been scheduled to cover these topics (see our website for a list).

Measurement Assurance

As a part of the 2009 to 2010 review letters, and during 2010 we advised laboratories that we would be requesting copies of laboratory control charts for all measurement areas on your Scope, an inventory of control charts/programs, and a measurement assurance assessment for each measurement parameter on your Scope. We have held webinars on this topic during the year and two template files are posted on the NIST website: <http://ts.nist.gov/WeightsAndMeasures/resources.cfm>. One is an inventory/status file and the other is an assessment form.

As we noted in review letters, your technical assessment will need to include: 1) a brief description of the measurement assurance methods used for each measurement parameter; 2) a technical review of the control charts or range charts for that measurement parameter with a status report of any (or no) issues that have been noted related to the stability of the measurement process and the stability of the standards; 3) electronic submission of your entire set of control charts.

For item number one, we are not looking for an extended publication; we will expect something more than one sentence, but less than a full page. Think about a high level description of your control charts for a management review. Please use the template file from our website. For item number two, if your quality manual has a list of Control Charts (as in Appendix J in the 1996 Template), the Comments column may be used to address a brief status assessment of the charts. The status should briefly address whether values are in control, whether you have taken any action based on the data, whether all values are within the limits, whether you have conducted an F-test or t-test and how much data is maintained. Feel free to use the new template inventory file from our website. For item number three, please be sure that your submitted set of control charts matches the list in your Quality Manual appendix and your measurement Scope.

Be sure to review your charts against SOP 9, 17, 20, 30, and the Control Chart and Range Chart Review Checklist. Also, be sure that your uncertainty tables are updated with the latest process standard deviations from your control charts. If there are bias components that are evident in the control charts and included in the uncertainty charts, ensure that the assessment described in SOP 29 has been completed and documented in your assessments and note whether any proficiency tests support your observations.

Management Reviews

A copy of the latest management review is to be submitted with all applications. An outline is available on the NIST website here: <http://ts.nist.gov/WeightsAndMeasures/resources.cfm>.

Quality Manuals

Send quality manuals and administrative procedures if there are updates and if updates have been recommended. The quality manuals must comply with the CURRENT version of NIST Handbook 143 (2007)! In some cases, you have been notified that you will not obtain Recognition unless updates are completed.

Calibration Reports

Submit calibration reports only for those standards that were obtained during the year from other laboratories.