NVLAP LAB CODE: _____

CHEMICAL CALIBRATION: CERTIFIERS OF SPECTROPHOTOMETRIC NTRMS SPECIFIC OPERATIONS CHECKLIST

Instructions to the Assessor: This checklist addresses specific accreditation criteria prescribed in applicable sections of NIST Handbook 150-21.

Place an "X" beside any of the checklist items which represent a deficiency. Place a "C" beside each item on which you are commenting for other reasons. Record the item number and your written deficiency explanations and/or comments on this list or on the comment sheet(s). Place a check beside all other items you observed or verified at the certifier's facility.

1 Organization and management

(See General Operations Checklist.)

2 Quality system, audit and review

_____ 2.1 The laboratory has the current edition of the following documents available for reference:

_____ 2.1.1 NIST Handbook 150, *NVLAP Procedures and General Requirements*;

_____ 2.1.2 NIST Handbook 150-21, *NVLAP Certifiers of Spectrophotometric NTRMs*;

_____ 2.1.3 NIST Special Publication SP 260-140, *Technical Specifications for Certification of Spectrophotometric NTRMs*;

_____ 2.1.4 ANSI/NCSL Z540-2-1997, *U.S. Guide to the Expression of Uncertainty in Measurement*, 1997; or NIST Technical Note 1297, *Guidelines for Evaluating and Expressing the Uncertainty of NIST Measurement Results*, 1994 edition;

_____ 2.1.5 ISO Guide 31, *Contents of certificates of reference materials*;

_____ 2.1.6 ISO Guide 34, *Quality system guidelines for the production of reference materials*; and,

_____ 2.1.7 ISO Guide 35, *Certification of reference materials – General and statistical principles*.

_____ 2.2 The laboratory's quality documentation contains procedures or instructions describing the following:

_____ 2.2.1 training of staff and quality assurance of technical staff member performance;

_____ 2.2.2 material custody and handling procedures;

_____ 2.2.3 facility maintenance, and equipment maintenance, calibration and verification as a certifier of filter NTRMs, in accordance with the technical specifications set forth in the appropriate NIST SP 260;

_____ 2.2.4 data processing for measurements and generation of certificates; and

_____ 2.2.5 back-up and security of data and reports.

_____ 2.3 The laboratory conducts an internal audit not less than annually to verify that its operations are in compliance with its quality manual and this program.

_____ 2.4 The laboratory participates in proficiency testing established by NIST. (See Appendix D of NIST Handbook 150-21.)

_____ 2.5 The laboratory quality documentation shall include all the technical requirements of NIST Handbook 150-21 and the appropriate NIST SP 260 document.

3 Personnel

_____ 3.1 The laboratory ensures that staff members are aware of the extent of their area of responsibility.

_____ 3.2 The laboratory maintains documentation for each staff member as follows:

_____ 3.2.1 staff member's title and description of that job position;

_____ 3.2.2 job and quality assurance responsibilities;

_____ 3.2.3 résumé;

_____ 3.2.4 training;

_____ 3.2.5 assigned laboratory procedures and duties; and

_____ 3.2.6 results of periodic testing performance reviews.

_____ 3.3 The laboratory has a description of its staff training program including its criteria for successful completion.

_____ 3.4 Technical staff members and technical supervisors participate in some form of continuing education, such as formal course work, in-house education, and technical meetings, and have access to journals and other information that describe advances in the field.

_____ 3.5 The laboratory has available for the assessor results of its staff testing program.

_____ 3.6 Laboratory schedules indicate that time pressures do not detract from staff performance.

4 Accommodation (facilities) and environment

_____ 4.1 The certifier maintains a facility that:

_____ 4.1.1 provides a safe work environment for all employees;

_____ 4.1.2 permits safe handling of chemicals used for any purpose; and,

_____ 4.1.3 prevents contamination or degradation of proficiency test materials and of the raw materials from which they are prepared.

_____ 4.2 Laboratory space where filter NTRMs are tested and measured meets the following minimum requirements:

_____ 4.2.1 ventilation and lighting suitable to the tasks conducted;

_____ 4.2.2 class 100,000 particle containment;

_____ 4.2.3 temperature between 20 °C and 22 °C;

_____ 4.2.4 humidity 70% or lower; and

_____ 4.2.5 access limited to trained staff.

5 Equipment and reference materials

_____ 5.1 The certifier can demonstrate that equipment is properly maintained.

_____ 5.2 A "transfer spectrophotometer" has been "qualified" per NIST SP 260-140, 2.2.1.

_____ 5.3 Appropriate Standard Reference Materials from NIST are available for use, together with the certificates that accompany the SRMs. At a minimum this includes one current set each of SRMs 930, 1930, and 2034.

_____ 5.4 SRMs are properly stored and used according to the instructions that accompany them.

_____ 5.5 Procedures are available for validating any automated test systems. Currently used versions of operating systems, and measurement and data reduction software are validated and documented.

_____ 5.6 The algorithms contained in any measurement related software are known and have demonstrated validity and applicability.

6 Measurement traceability and calibration

_____ 6.1 Calibrations or verifications, including maintenance of control charts, are performed by properly trained staff using standard reference materials traceable to NIST, when available.

_____ 6.2 The transfer spectrophotometer is verified weekly against SRMs from NIST and the data are archived in hard copy and electronic form. Control charts will be available for assessor review.

_____ 6.3 Wavelength calibration is verified and archived monthly by means of a full spectrum scan of SRM 2034.

_____ 6.4 NTRM certifier standards are maintained in accordance with NIST SP 260-140, 5.3.

_____ 6.5 Reference materials are stored according to the instructions given on their certificates and guarded from degradation and contamination during storage and use. Care is given to verifying that the correct certificate is available for each reference material and that the expiration date given on the certificate for the material has not passed.

_____ 6.6 Testing equipment records indicate calibration requirements, ranges, allowable error, and staff member(s) responsible for the required calibrations.

7 Calibration and test methods

_____ 7.1 Copies are available of all uncertainty criteria, specifications, and validated test methods employed in the certification of filter NTRMs.

_____ 7.2 The certifier can demonstrate conformance to all filter cleaning, calibration and testing requirements set forth in the technical specifications for producing filter NTRMs (appropriate NIST SP 260s.)

_____ 7.3 The certifier follows written procedures regarding critical aspects of filter NTRM production, including:

_____ 7.3.1 material preparation;

_____ 7.3.2 verification of surface flatness, opposite face parallelism, and transmittance uniformity according to NIST SP 260-140, 2.2.2;

_____ 7.3.3 nominal transmittance conformance;

_____ 7.3.4 material measurement and certification, meeting all requirements of the appropriate NIST SP 260 document, with certificates being in conformance with NIST Handbook 150 and ISO Guide 31;

_____ 7.3.5 material storage;

_____ 7.3.6 verification of stability;

_____ 7.3.7 assignment of uncertainties according to NIST SP 260-140, 2.4; and,

_____ 7.3.8 recertification of filter NTRMs.

8 Handling of calibration and test items

_____ 8.1 The laboratory has a material log system used to identify filter NTRM materials and their components uniquely, and to document the source, processing, storage, and use of the materials. The log includes:

_____ 8.1.1 the source and date of receipt of the material;

_____ 8.1.2 the condition of the material;

_____ 8.1.3 documentation of acceptance or rejection of material, including reasons in any case of rejection;

_____ 8.1.4 a unique laboratory identification number for each material and for each test sample, thereof (having all coding and marking in accordance with NIST SP 260-140, 3.4); and,

_____ 8.1.5 the initials of the person making the above entries in the material log book.

_____ 8.2 Where there is any doubt as to the material's suitability for use (e.g., a mismatch between identification and description), the laboratory has a procedure for resolving the problem. Such action is documented and all out-of-tolerance filters are rejected.

_____ 8.3 The laboratory can demonstrate that proper shipping procedures are employed including:

_____ 8.3.1 adherence to all applicable shipping and safety regulations;

_____ 8.3.2 provision of material safety data sheets, where applicable;

_____ 8.3.3 assurance that shipment mode does not comprise filter NTRM stability; and,

_____ 8.3.4 the ability to track custody of material, in the event a recall is needed.

9 Records

_____ 9.1 The laboratory's quality system documentation follows written procedures for the storage and retrieval of records.

_____ 9.2 Records are stored in a logical fashion allowing retrieval within one working day.

_____ 9.3 The laboratory has documentation, either electronic backup or "paper" hard copy, to assure survival of original data if computer systems are used for primary data retention.

_____ 9.4 The laboratory ensures that the technical staff member signs (or initials) and dates the original data.

_____ 9.5 The following records are maintained for a minimum of 3 years:

_____ 9.5.1 materials log;

_____ 9.5.2 original data collected by technical staff member(s);

_____ 9.5.3 identity of personnel involved in material preparation and measurement;

_____ 9.5.4 measurement data accompanied by its metadata as required in NIST SP 260-140, 5.7;

_____ 9.5.5 quality control activities and results including spectrophotometer calibration and control of environmental factors in accordance with NIST SP 260-140, 4.2 and 5.4 (Control Charts);

_____ 9.5.6 filter NTRM test results and summary reports;

_____ 9.5.7 equipment and maintenance;

_____ 9.5.8 certification reports (noting that certification data for each filter must be retained for the life of the filter);

_____ 9.5.9 recertification documentation, filter condition, and recertification data; and,

_____ 9.5.10 records of all actions taken in response to customer complaints.

_____ 9.6 The certifier provides, in electronic format, data to NIST in accordance with NIST SP 260-140, 4.6 and 5.7.

_____ 9.7 Filled-in examples are available for all standardized forms and reports.

10 Certificates and Reports

_____ 10.1 Certificates accompanying filter NTRMs are found to be in conformance with ISO Guide 31.

_____ 10.2 Any necessary supplementary information is clearly labeled and described.

_____ 10.3 Clear instructions are given that certificates and associated documentation are to be available to the personnel who use the filter NTRMs.

11 Subcontracting of calibration or testing

(See General Operations Checklist.)

12 Outside support services and supplies

(See General Operations Checklist.)

13 Complaints

(See General Operations Checklist.)

SPECIFIC OPERATIONS CHECKLIST - COMMENTS AND DEFICIENCIES

Instructions to the Assessor: Use this sheet to document comments and deficiencies. For each, identify the appropriate item number from the checklist. Identify comments with a "C" and deficiencies with an "X." If additional space is needed, make copies of this page (or use additional blank sheets).

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