Enter Date: **Enter NVLAP Lab Code:**

NIST HANDBOOK 150-21 CHECKLIST
Chemical Calibration:
Certifiers of Spectrophotometric NTRMs

Instructions to the Assessor: This checklist addresses specific accreditation requirements prescribed in NIST Handbook 150-21, *Chemical Calibration: Certifiers of Spectrophotometric NTRMs*.

- All items on this checklist shall be addressed.
- Select "X" for each item that represents a nonconformity.
- Select "C" for each item on which you are commenting for other reasons.
- Select "OK" for each item you observed or verified as compliant at the laboratory.
- Record the item number and the nonconformity explanation and/or comment on the appropriate comment sheet.

Note: The numbering of the checklist items correlates to the numbering scheme in NIST Handbook 150-21, clauses 3, 4, and 5.

3 Accreditation process

3.2 Management system review

___ The applicant certifier shall provide NVLAP with management system documentation including pertinent manuals, documented procedures and uncertainty budgets with the application for accreditation.

3.3 On-site assessment

___ 3.3.1 The certifier shall be prepared for conducting demonstrations of spectrophotometric measurements. Key personnel and requisite equipment, in good working order, shall be ready for examination according to the technical specifications found in the NIST SP 260, and the requirements identified in this handbook, NIST Handbook 150, and the certifier's quality manual.

___ 3.3.2 The certifier shall make available all supporting technical information in a format that is conducive to a detailed review.

___ 3.3.4 The certifier shall review all comments for potential improvements in its operations as a certifier of filter NTRMs.

4 Management requirements for accreditation

4.2 Management system

___ 4.2.1 The certifier shall define and document its management procedures for obtaining accurate and precise measurement data and for conducting its operations as a certifier of filter NTRMs in accordance with the technical specifications set forth in the appropriate NIST SP 260. These procedures shall be the benchmarks by which certifier management assesses overall and individual performance.

___ 4.2.2 Under its management system, the certifier shall develop and implement procedures covering all technical requirements of this handbook and the NIST SP 260. Professional staff shall be able to obtain enough information from the certifier's management system documentation to perform their work in the absence of the manager. Periodic management reviews of the management system shall reflect adherence to NVLAP requirements and the certifier's management procedures. These reviews shall reflect positive aspects of the management system as well as nonconformities.

4.13 Control of records

___ The period of retention shall be three years, unless a longer period is required by the client, regulation, or the certifier's own procedures. Records of certification data shall be retained for the life of each certified filter.

5 Technical requirements for accreditation

5.4 Test and calibration methods and method validation

___ 5.4.1 The certifier shall have a copy of all specifications and validated test methods that it uses in the filter NTRM certification programs for which it seeks accreditation.

___ 5.4.3 The certifier's laboratory shall conform in all respects with the validated method employed to assign a value to a filter NTRM. A certifier shall validate each method used by comparison with Standard Reference Materials (SRMs) certified and issued by the National Institute of Standards and Technology, unless appropriate SRMs are not available, or the certifier can show an alternative and convincing demonstration of traceability to the international system of units (SI).

___ 5.4.4 The certifier shall follow written procedures to address all aspects of producing filter NTRMs (e.g., material preparation and assessment, measurement, certification, packaging, storage, and stability verification, etc.).

___ 5.4.5 Filter measurement and certification shall meet all requirements of the appropriate NIST SP 260 document.

5.5 Equipment

In addition to the information specified in NIST Handbook 150, 5.5.5, testing equipment records shall include the following:

___ a) notation of all equipment variables requiring calibration;

___ b) the range of calibration;

___ c) as appropriate, the resolution, detection limit, and sensitivity of the instrument and its allowable error;

___ d) identity of the person or company responsible for service and calibration of the instrument; and

___ e) source of reference standards and traceability.

5.6 Measurement traceability

___ 5.6.1 The certifier shall have the reference materials and any associated certificates used in evaluation of personnel and calibration of equipment. At a minimum this will include one current set of SRMs 930, 1930, and intrinsic standards.

___ 5.6.2 Certificates, records, and evidence of the traceability of the reference standards used shall be retained and made available for an assessor's inspection during the on-site visit. The certificates shall indicate certified values and uncertainties and traceability of reference standards. If calibration or validation is performed by the certifier, the standard metrological procedures used, the environmental conditions, and the measurement uncertainty shall be documented. Certificates are required for calibrations performed by outside services; they are not required for general purpose testing equipment not directly used for calibration, validation, or filter certification.

5.8 Handling of test and calibration items

___ 5.8.1 The certifier shall follow written criteria for acceptance or rejection of materials.

5.8.2 The certifier shall have a materials record system that documents the following information:

___ a) source of the material;

___ b) location of the material;

___ c) personnel who have handled or worked with the material; and

___ d) what has been done to the material, including rejection of unsuitable material.

___ 5.8.4 The mode of shipment and the procedures for shipment shall be designed to guard the integrity and stability of the material.

___ 5.8.5 Shipping records shall provide adequate information to track custody of the material and to provide for the possibility of recall, if necessary.

5.9 Assuring the quality of test and calibration results

___ The certifier's quality assurance checks shall be performed routinely, covering all time periods, material types, instruments, tasks and personnel. Where appropriate, the specific checks on personnel performance shall be executed without the prior knowledge of the personnel being checked. Quality assurance activities shall not be postponed during periods of heavy workloads.

5.10 Reporting the results

___ 5.10.2 Information supplementary to the certificates may be provided as instructions or reports. Such documents shall be clearly labeled as to their purpose and as to which specific individual filter NTRM they accompany.

___ 5.10.3 Certificates, instructions and reports shall be provided in such manner that it is clear they are to remain with the filter NTRMs through all stages of shipment and handling, until they have reached the personnel who are to use them.

A Annex A: Procedures for testing the proficiency of certifiers

A.1 Direct proficiency testing

___ A.1.2 The test shall be conducted in accordance with a specific test method using specified standard operating procedures. Proficiency testing shall not be contracted out to another laboratory. Any special NIST/BSD instructions shall also be followed. The special instructions are designed to ensure uniformity in procedures among participants. Completed data shall be returned to NIST/BSD, in electronic format, for review by a specified date. See A.1.10.

A.1.6 If an accredited certifier fails a proficiency test, it shall do the following to maintain its accreditation:

___ a) Within 30 days of notification of failure, provide to NVLAP detailed, written documentation that includes an analysis of why the laboratory failed any part of the test, and what corrective actions it has taken (technical staff member training, revised procedures, quality assurance activities, etc.) to resolve its measurement problems so as to avoid similar errors in the future. Documented evidence that the corrective actions have been effectively implemented is required.

___ b) Participate successfully in the next round of proficiency testing.

___ A.1.8 The certifier shall provide NVLAP with documentation within 30 days of the reassessment, adequately demonstrating that any nonconformities noted by the assessor have been satisfactorily resolved.

___ A.1.9 The full cost of any on-site reassessment shall be paid in advance by the certifier.

___ A.1.10 Failure to participate in a round of proficiency testing will result in immediate suspension of accreditation, and the certifier shall successfully participate in the next regularly scheduled round to have its accreditation reinstated.

A.2 Indirect proficiency testing

A.2.7 If an accredited certifier fails an indirect proficiency test, it shall do the following to maintain its accreditation:

___ a) Within 30 days of notification of failure, provide to NVLAP detailed, written documentation that includes an analysis of why the certifier failed each part of the test, and what corrective actions it has taken (technical staff member training, revised procedures, quality assurance activities, etc.) to resolve its measurement problems so as to avoid similar errors in the future. Documented evidence that the corrective actions have been effectively implemented is required.

___ b) Participate successfully in indirect proficiency testing at the time the certifier certifies its next lot of filter NTRMs.

___ A.2.9 The certifier shall provide NVLAP with documentation within 30 days of the reassessment, adequately demonstrating that any nonconformities noted by the assessor have been satisfactorily resolved.

___ A.2.10 The full cost of any on-site reassessment shall be paid in advance by the certifier.

___ A.2.11 Failure to submit the agreed upon filter NTRM unit from each production lot, together with the assigned values, and standard deviations for each certified characteristic will result in immediate suspension of accreditation, and the certifier shall successfully participate in the next regularly scheduled round to have its accreditation reinstated.