

**NIST HANDBOOK 150-21**  
2011 Edition

**National  
Voluntary  
Laboratory  
Accreditation  
Program**

**CHEMICAL  
CALIBRATION:  
CERTIFIERS OF  
SPECTROPHOTOMETRIC  
NTRMs**

Barbara Belzer

National Voluntary Laboratory Accreditation Program  
Physical Measurement Laboratory

June 2011



U.S. Department of Commerce  
Gary Locke, Secretary

National Institute of Standards and Technology  
Patrick D. Gallagher, Director

## NVLAP AND THE NVLAP LOGO

The term *NVLAP* and the NVLAP logo are registered marks of the Federal Government, which retains exclusive rights to control the use thereof. Permission to use the term and symbol (NVLAP logo with approved caption) is granted to NVLAP-accredited laboratories for the limited purpose of announcing their accredited status, and for use on reports that describe only testing and calibration within the scope of accreditation. NVLAP reserves the right to control the quality of the use of the NVLAP term, logo, and symbol.

# Contents

Foreword.....	v
Introduction.....	vi
1 General information.....	1
1.1 Scope.....	1
1.2 Organization of handbook.....	1
1.3 Program description.....	1
1.4 References.....	2
1.5 Terms and definitions.....	2
1.6 Program documentation.....	3
2 LAP establishment, development and implementation.....	4
3 Accreditation process.....	4
3.1 General.....	4
3.2 Management system review.....	4
3.3 On-site assessment.....	4
3.4 Proficiency testing.....	4
4 Management requirements for accreditation.....	5
4.1 Organization.....	5
4.2 Management system.....	5
4.3 Document control.....	5
4.4 Review of requests, tenders and contracts.....	5
4.5 Subcontracting of tests and calibrations.....	6
4.6 Purchasing services and supplies.....	6
4.7 Service to the customer.....	6
4.8 Complaints.....	6
4.9 Control of nonconforming testing and/or calibration work.....	6
4.10 Improvement.....	6
4.11 Corrective action.....	6
4.12 Preventive action.....	6
4.13 Control of records.....	6
4.14 Internal audits.....	6
4.15 Management reviews.....	7
5 Technical requirements for accreditation.....	7
5.1 General.....	7
5.2 Personnel.....	7
5.3 Accommodation and environmental conditions.....	7
5.4 Test and calibration methods and method validation.....	7
5.5 Equipment.....	8
5.6 Measurement traceability.....	8
5.7 Sampling.....	8
5.8 Handling of test and calibration items.....	8
5.9 Assuring the quality of test and calibration results.....	9

5.10	Reporting the results .....	9
6	Additional requirements .....	9
Annex A (normative)	Procedures for testing the proficiency of certifiers.....	10
A.1	Direct proficiency testing.....	10
A.2	Indirect proficiency testing.....	11

## Foreword

The NIST Handbook 150 publication series sets forth the procedures, requirements, and guidance for the accreditation of testing and calibration laboratories by the National Voluntary Laboratory Accreditation Program (NVLAP). The series is comprised of the following publications:

- NIST Handbook 150, *NVLAP Procedures and General Requirements*, which contains the general procedures and requirements under which NVLAP operates as an unbiased third-party accreditation body;
- NIST Handbook 150-xx program-specific handbooks, which supplement NIST Handbook 150 by providing additional requirements, guidance, and interpretive information applicable to specific NVLAP laboratory accreditation programs (LAPs).

The program-specific handbooks are not stand-alone documents, but rather are companion documents to NIST Handbook 150. They tailor the general criteria found in NIST Handbook 150 to the specific tests, calibrations, or types of tests or calibrations covered by a LAP.

NIST Handbook 150-21, *NVLAP Chemical Calibration: Certifiers of Spectrophotometric NTRMs* presents the technical requirements and guidance for the accreditation of laboratories under the NVLAP Chemical Calibration: Certifiers of Spectrophotometric NTRMs LAP. The 2011 edition incorporates changes resulting from the release of the newest editions of ISO/IEC 17025, *General requirements for the competence of testing and calibration laboratories*, and NIST Handbook 150, as well as editorial improvements. The 2011 edition of NIST Handbook 150-21 supersedes and replaces the 2000 edition.

The handbook was revised with the participation of technical experts from the NIST Biochemical Science Division and has been approved by NVLAP. The following main changes have been made to this handbook with respect to the previous edition:

- all references to applicable international guides and standards have been updated;
- on-site assessment checklists and the test method selection list are no longer included in order that they may be provided as separate documents, which may be updated at different intervals than the handbook;
- the body of the handbook has been restructured to conform with internationally accepted rules for the structure and drafting of standards, where appropriate, to promote ease of use and understanding.

Annex A forms a normative part of this handbook, meaning that it is an integral part of the handbook and contains provisions to which it is necessary to conform in order to claim compliance with the handbook requirements.

This handbook is also available on the NVLAP web site (<http://www.nist.gov/nvlap>).

Questions or comments concerning this handbook should be submitted to NVLAP, National Institute of Standards and Technology, 100 Bureau Drive, Stop 2140, Gaithersburg, MD, 20899-2140; phone: 301-975-4016; fax: 301-926-2884; e-mail: [nvlap@nist.gov](mailto:nvlap@nist.gov).

## Introduction

The National Institute of Standards and Technology (NIST) operates the National Voluntary Laboratory Accreditation Program (NVLAP®) as a means to accredit laboratories that are competent to conduct specific laboratory functions. While the program does not guarantee the individual results of any given laboratory operation, it does assure users that an accredited laboratory has been assessed and found capable of conducting work to the extent listed in its scope of accreditation.

NIST Handbook 150-21 presents the additional technical requirements of NVLAP for accreditation of laboratories that design, prepare, characterize, certify, and distribute NIST-traceable reference materials (NTRMs™) for spectrophotometric filters. NIST Special Publication SP 260-140 defines an NTRM as a “commercially produced reference material with a well-defined traceability linkage to existing NIST chemical measurement standards.” The program may be referred to by the short title “filter NTRMs™.” This handbook is intended for information and use by staff of accredited laboratories, those laboratories seeking accreditation, other laboratory accreditation systems, laboratory assessors, users of laboratory services, and others needing information on the accreditation requirements.

Technical specifications for use by laboratories that design, prepare, characterize, certify, and distribute spectrophotometric filter NTRMs are found in the NIST Special Publications (SP) 260 series. Each SP 260 and the present document will be reviewed periodically and revised as necessary to accommodate new technology and revised protocols. Whenever possible, changes to operational procedures will be implemented at the anniversary of an accreditation.

NTRM™ is a trademark of the National Institute of Standards and Technology. It can be applied to certified reference material filters only by certifiers who are accredited under this program. Assessment for accreditation will be administered by NVLAP of NIST, while proficiency evaluation and examination for traceability of certifier measurements to NIST measurements will be conducted by the Biochemical Science Division (BSD) of NIST. The BSD will provide technical oversight for this program and will be the sole authority for determining which laboratories meet the technical requirements to be certifiers of NTRMs™. NVLAP will be the sole authority for granting accreditation to laboratories. Accreditation will be granted only after all administrative and technical requirements have been met.

# 1 General information

## 1.1 Scope

**1.1.1** NIST Handbook 150-21 specifies the technical requirements and provides guidance for the accreditation of laboratories under the NVLAP Chemical Calibration: Certifiers of Spectrophotometric NTRMs (Filter NTRMs Program). It supplements the NVLAP procedures and general requirements found in NIST Handbook 150 by tailoring the general criteria found in NIST Handbook 150 to the specific tests and types of tests covered by the Filter NTRMs Program.

**1.1.2** NIST Handbook 150, this handbook, and their respective checklists (see 1.6), as well as the technical requirements of the relevant NIST SP 260 series document, constitute the collective body of requirements that must be met by a laboratory seeking NVLAP accreditation for the Filter NTRMs Program.

**1.1.3** Any laboratory (including commercial, manufacturer, university, or federal, state, or local government laboratory) that designs, prepares, characterizes, certifies, and distributes spectrophotometric filters may apply to NVLAP for accreditation.

**1.1.4** The reference materials produced under this program are recognized by NIST as NIST Traceable Reference Materials™, or NTRMs™. They may also be referred to as “filter NTRMs” to differentiate them from other types of NTRMs™.

**1.1.5** The standards and specifications used by the certifiers are those published by NIST in the NIST SP 260 series of publications, by consensus standards organizations, and where appropriate, by the certifier, in the areas of material sampling, material preparation and packaging, spectrophotometric characterization, uncertainty analysis, certification, storage, and distribution.

## 1.2 Organization of handbook

The numbering and titles of the first five clauses of this handbook match those of NIST Handbook 150. The primary subclauses in clauses 4 and 5 (e.g., 4.1, 4.2, etc.) are also numbered and titled to correspond with those of NIST Handbook 150, even when there are no requirements additional to those in NIST Handbook 150.

Annex A provides the procedures that NIST uses for testing the proficiency of certifiers of spectrophotometric filter NTRMs.

## 1.3 Program description

**1.3.1** This program provides accreditation to those laboratories that can demonstrate their capabilities and competence as certifiers of spectrophotometric filter reference materials that meet the technical specifications and requirements as published. See NIST SP 260-140, *Technical Specifications for Certification of Spectrophotometric NTRMs*. Laboratories that have received NVLAP accreditation are permitted to distribute, with the designation NTRM™, filter reference materials that they have designed, prepared, characterized, and certified, and that meet all the technical specifications and other requirements set forth in this program.

**1.3.2** To achieve and maintain accreditation, laboratories must demonstrate their competence by periodically participating in proficiency testing. The required proficiency testing programs are operated by the NIST BSD on a cost recovery basis.

**1.3.3** To be accredited under the program described in this handbook, certifiers of spectrophotometric filter NTRMs must undergo periodic on-site assessment of their management system and technical competence. Also, periodically they must demonstrate their proficiency in accurately characterizing the filter materials they distribute. The procedures for conducting these assessments and demonstrations are found in this handbook.

## **1.4 References**

The following documents are referenced in this handbook. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) shall apply within one year of publication or within another time limit specified by regulations or other requirement documents.

- ANSI/NCSL Z540-2-1997, *U.S. Guide to the Expression of Uncertainty in Measurement*
- ISO Guide 30, *Terms and definitions used in connection with reference materials*
- ISO Guide 31, *Reference materials—Contents of certificates and labels*
- ISO Guide 34, *General requirements for the competence of reference materials producers*
- ISO Guide 35, *Reference materials—General and statistical principles for certification*
- JCGM 200:2008, *International vocabulary of metrology – Basic and general concepts and associated terms (VIM)*
- NIST Handbook 150, *NVLAP Procedures and General Requirements*
- NIST Special Publication SP 260-140, *Technical Specifications for Certification of Spectrophotometric NTRMs*
- NIST Technical Note 1297, *Guidelines for Evaluating and Expressing the Uncertainty of NIST Measurement Results*, 1994 Edition

## **1.5 Terms and definitions**

For the purposes of this handbook, the terms and definitions given in NIST Handbook 150 and the following apply.

### **1.5.1 accuracy of measurement**

Closeness of the agreement between the result of a measurement and a true value of the measurand. [*International Vocabulary of Basic and General Terms in Metrology (VIM)*, 3.5]



## **1.5.2**

### **assigned value**

Value attributed to a particular quantity and accepted, sometimes by convention, as having an uncertainty appropriate for a given purpose. [See VIM, 1.20.] Assigned value is formally named “conventional true value (of a quantity)” in the VIM.

## **1.5.3**

### **Certifiers of Spectrophotometric NTRMs; for short, “Certifiers”**

Laboratories that design, prepare, characterize, certify and distribute NTRM filter reference materials.

## **1.5.4**

### **proficiency test (PT)**

A means of evaluating a laboratory’s performance under controlled conditions relative to a given set of criteria through measurement and reporting of results on unknown materials provided by an external provider of proficiency testing (NIST) or by NIST’s examining materials and certified measurements provided by the laboratory under test.

## **1.5.5**

### **Standard Reference Material® (SRM®)**

A reference material certified and distributed by the National Institute of Standards and Technology (NIST).

## **1.6 Program documentation**

### **1.6.1 General**

Assessors use NVLAP checklists to ensure that each laboratory receives an assessment comparable to that received by others. Checklists assist assessors in documenting the assessment to the NVLAP requirements found in NIST Handbook 150, this handbook, and the checklists themselves. Checklists contain definitive statements or questions about all aspects of the NVLAP criteria for accreditation, and form part of the On-Site Assessment Report (see NIST Handbook 150). The current version of each checklist is available on the NVLAP web site <<http://www.nist.gov/nvlap>>.

### **1.6.2 NIST Handbook 150 Checklist**

All NVLAP programs use the NIST Handbook 150 Checklist, which contains the requirements published in NIST Handbook 150. The checklist items are numbered to correspond to clauses 4 and 5 and annexes A and B of NIST Handbook 150.

### **1.6.3 NIST Handbook 150-21 Checklist**

The NIST Handbook 150-21 Checklist (also referred to as the Filter NTRMs Program-Specific Checklist) addresses the requirements given in this handbook and may contain requirements expressed at a more detailed level than found in the handbook.

### **1.6.4 NVLAP Lab Bulletins**

NVLAP Lab Bulletins are issued to laboratories and assessors, when needed, to clarify program-specific requirements and to provide information about program additions and changes.

## **2 LAP establishment, development and implementation**

This clause contains no information additional to that provided in NIST Handbook 150, clause 2.

## **3 Accreditation process**

### **3.1 General**

An overview of the laboratory accreditation process is provided in NIST Handbook 150, clause 3, and includes information pertaining to application for accreditation; on-site assessment; proficiency testing; accreditation decision; granting accreditation; renewal of accreditation; changes to scope of accreditation; monitoring visits; and suspension, denial, revocation, and voluntary termination of accreditation.

### **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. These documents become part of the official laboratory file. Documentation is requested to be supplied in electronic format whenever possible.

### **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. The assessor may request additional information to clarify issues regarding nonconformities or to delve more deeply into technical issues.

**3.3.3** The NIST Handbook 150 Checklist, the Filter NTRMs Program-Specific Checklist, and the technical specifications found in the appropriate NIST SP 260, will be used by the assessor, or assessment team, to help assure the completeness, objectivity, and uniformity of the on-site assessment. The assessment will include a review of the certifier's ability to perform appropriate measurement and testing procedures. The assessor notes the depth into which each part of the operational procedure was reviewed and records the results of the review on the specific operations checklist comment sheet.

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

### **3.4 Proficiency testing**

**3.4.1** The proficiency testing program for evaluation of certifiers of spectrophotometric NTRMs will be conducted by the Biochemical Science Division (BSD) of the National Institute of Standards and Technology. The tests will be conducted according to the specifications found in the appropriate NIST

SP 260 and the provisions of Annex A of this handbook, and with the support of the NIST Statistical Engineering Division.

**3.4.2** Proficiency testing will follow one or both of two models, as required by the BSD and as described in Annex A of this handbook. The two models are briefly described as follows:

- a) *Direct Proficiency Testing:* In this model, filters will be sent by NIST BSD to certifiers of spectrophotometric NTRMs as unknowns for measurement. After completion of the measurements, each certifier will return its results to NIST BSD for evaluation of the certifier's proficiency.
- b) *Indirect Proficiency Testing:* In this model, each certifier of filter NTRMs will submit to NIST BSD a portion of each lot of material produced. NIST BSD can then judge the proficiency of the certifier by checking the validity of the certifier's claims regarding assigned values.

## **4 Management requirements for accreditation**

### **4.1 Organization**

There are no requirements additional to those set forth in NIST Handbook 150.

### **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.

### **4.3 Document control**

There are no requirements additional to those set forth in NIST Handbook 150.

### **4.4 Review of requests, tenders and contracts**

There are no requirements additional to those set forth in NIST Handbook 150.

#### **4.5 Subcontracting of tests and calibrations**

There are no requirements additional to those set forth in NIST Handbook 150.

#### **4.6 Purchasing services and supplies**

There are no requirements additional to those set forth in NIST Handbook 150.

#### **4.7 Service to the customer**

There are no requirements additional to those set forth in NIST Handbook 150.

#### **4.8 Complaints**

There are no requirements additional to those set forth in NIST Handbook 150.

#### **4.9 Control of nonconforming testing and/or calibration work**

There are no requirements additional to those set forth in NIST Handbook 150.

#### **4.10 Improvement**

There are no requirements additional to those set forth in NIST Handbook 150.

#### **4.11 Corrective action**

There are no requirements additional to those set forth in NIST Handbook 150.

#### **4.12 Preventive action**

There are no requirements additional to those set forth in NIST Handbook 150.

#### **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.

#### **4.14 Internal audits**

There are no requirements additional to those set forth in NIST Handbook 150.

#### **4.15 Management reviews**

There are no requirements additional to those set forth in NIST Handbook 150.

### **5 Technical requirements for accreditation**

#### **5.1 General**

There are no requirements additional to those set forth in NIST Handbook 150.

#### **5.2 Personnel**

There are no requirements additional to those set forth in NIST Handbook 150.

#### **5.3 Accommodation and environmental conditions**

There are no requirements additional to those set forth in NIST Handbook 150.

#### **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.

**5.4.2** Testing conducted in the Certifiers of Spectrophotometric NTRMs program may include:

- a) transmittance measurement;
- b) wavelength measurement;
- c) stray radiation measurement; and
- d) optical testing for such properties as flatness, wedge and transmittance uniformity.

**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.

**5.4.6** Uncertainties will be assigned according to procedures given in NIST SP 260-140, 2.4.

## **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.

**5.6.3** Control charts will be developed in accordance with NIST SP 260-140, 5.4.

## **5.7 Sampling**

There are no requirements additional to those set forth in NIST Handbook 150.

## **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.

**5.8.3** The certifier should be able to demonstrate that all applicable shipping and safety regulations are met.

**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**

**5.10.1** Certificates and reports accompanying filter NTRMs will conform to NIST Handbook 150 and ISO Guide 31.

**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.

## **6 Additional requirements**

There are no additional requirements beyond NIST Handbook 150 and its associated normative annexes, and any other normative references previously cited in this handbook.

**Annex A**  
(normative)  
**Procedures for testing the proficiency of certifiers**

**A.1 Direct proficiency testing**

**A.1.1** The direct proficiency testing program will be conducted by the National Institute of Standards and Technology (NIST). The work will be carried out by the Biochemical Science Division (BSD) of the Material Measurement Laboratory (MTL) with the support of the Statistical Engineering Division of the Information Technology Laboratory (ITL). Proficiency testing materials are chosen to test the certifier's ability to follow a method and to achieve results at or exceeding the required level of accuracy found in the appropriate NIST SP 260.

**A.1.2** Certifiers will be sent test materials, data sheets, and instructions for performing the test and reporting the results. 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. Failure to return the proficiency testing data by the deadline equals failure to participate. See A.1.10.

**A.1.3** On occasion, the on-site assessor may hand carry proficiency test materials to the certifier. These proficiency test materials, like all others measured by the laboratory, are to be listed or entered into the laboratory's normal material tracking and identification system for control and data recording. In these cases, the samples may be returned to the on-site assessor rather than stored at the laboratory.

**A.1.4** The results of the proficiency testing program will be reported to the participants and in appropriate documents and reports. The identity and performance of individual certifiers will remain confidential. The results of proficiency testing will be made available to on-site assessors for use during laboratory visits. Any problems indicated by proficiency testing will be discussed with appropriate laboratory personnel, who will then be responsible for developing and implementing plans for resolving the problems. Accreditation decisions will be based in part on satisfactory resolution of proficiency testing nonconformities.

**A.1.5** A proficiency test will use statistical and graphical techniques to examine the performance of each certifier based on the results obtained on test materials provided by NIST/BSD. If a laboratory exceeds the critical limit for the test sample it will fail the proficiency test.

Submitted results that are incomplete or that fall outside the critical limits will be considered as failing.

**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.1.7** If a certifier fails the same type of proficiency testing twice in succession or generally exhibits an erratic pattern in testing, NVLAP will review all current and previous proficiency testing results. Failure to correct the nonconformity may result in suspension of accreditation.

**A.1.8** To regain lost accreditation, the certifier may be required to undergo a complete on-site reassessment to determine the cause of the nonconformities and to determine that effective corrective actions have been implemented. 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. Failure to perform fully satisfactorily in the on-site reassessment will result in accreditation remaining suspended.

**A.1.9** The full cost of any on-site reassessment shall be paid in advance by the certifier. NVLAP staff will make every effort to expedite these extraordinary assessments to give a certifier every reasonable opportunity to demonstrate competence to perform the test method and regain accreditation.

**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.2.1** The indirect proficiency testing program will be conducted by NIST and the work will be carried out by BSD with the support of the Statistical Engineering Division. Competence of the certifier will be tested based on materials and certificates produced by that certifier.

**A.2.2** For every lot of filter NTRMs issued by a certifier, the certifier will send to NIST/BSD, a unit, or units, of the filter NTRM together with certificates and additional pertinent documents, such as instructions and shipping documents. Initially, a certifier will be required to provide to NIST/BSD one test unit from each group of 30 certified filter NTRM units. The proportion of test units to be provided to NIST/BSD will be reconsidered at each renewal of accreditation and adjusted as necessary. Additionally, NIST/BSD may obtain specimens of a specific certifier's output through purchase, or by loan from a third party who has purchased the material. These last two options are intended to provide NIST with the possibility of making "blind," unannounced tests of filter quality.

**A.2.3** As part of its evaluation of the certifier's competence, NIST may measure the submitted material or otherwise use the material in any way it deems useful.

**A.2.4** Whenever a filter NTRM is recalibrated, recalibration data will be made available electronically to NIST/BSD for use in assessment of long-term material stability. The data obtained by NIST/BSD will be considered, within the technical limits of accounting for user treatment of the filters, in judging the certifiers proficiency in distributing filter NTRMs of suitable stability. Decisions regarding certifier proficiency with respect to stability will be based on broad patterns of success or failure—not individual instances related to one or a few filter NTRM units.

**A.2.5** The results of the proficiency testing program will be reported to the participants and in appropriate documents and reports. The identity and performance of individual certifiers will remain confidential. The results of proficiency testing will be made available to on-site assessors for use during visits to the certifier. Any problems indicated by proficiency testing will be discussed with appropriate certifier personnel, who will then be responsible for developing and implementing plans for resolving the problems. Accreditation decisions will be based in part on satisfactory resolution of proficiency testing nonconformities.

**A.2.6** Testing by NIST/BSD may take either of two forms:

- a) A material submitted, with assigned values and standard deviations, by a certifier may be measured by NIST/BSD, with the results being compared to the values and standard deviations assigned by the certifier being examined.
- b) A material submitted as in A.2.6 a) may be held for future measurement pending the outcome of customer experience using filter NTRMs from the given lot, or pending review of filter NTRM recertification data collected on specimens from the given lot. The material may be tested later, at the discretion of NIST/BSD. It will be tested in the event anomalous results arise in the use of a specific lot of filter NTRMs.

**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.2.8** If a certifier fails an indirect proficiency test twice in succession or generally exhibits an erratic pattern in testing, NVLAP will review all current and previous proficiency testing results. Failure to correct the nonconformity may result in suspension of accreditation.

**A.2.9** To regain lost accreditation, the certifier may be required to undergo a complete on-site reassessment to determine the cause of the nonconformities, and to determine that effective corrective actions have been implemented. 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. Failure to perform fully satisfactorily in the on-site reassessment will result in accreditation remaining suspended.

**A.2.10** The full cost of any on-site reassessment shall be paid in advance by the certifier. NVLAP staff will make every effort to expedite these extraordinary assessments to give a certifier every reasonable opportunity to demonstrate competence to perform the test method and regain accreditation.

**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.