

**NIST Handbook 150-23**

**NVLAP**  
**Homeland Security Applications:**  
**Radiation Detection Instruments**

Bradley Moore  
Leticia Pibida

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**Homeland Security Applications:**  
**Radiation Detection Instruments**

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## Foreword

The National Institute of Standards and Technology (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 comprises 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. Each program-specific handbook tailors the general criteria found in NIST Handbook 150 to the specific test methods, calibrations, or types of tests or calibrations covered by a LAP.

NIST Handbook 150-23, *NVLAP Homeland Security Applications: Radiation Detection Instruments*, presents the technical requirements and guidance for the accreditation of laboratories that test radiation detection instruments used in homeland security applications and detection of illicit trafficking of radioactive materials. Due to the existence of both Institute of Electrical and Electronics Engineers, Inc. (IEEE) and International Electrotechnical Commission (IEC) standards that cover the instrument performance requirements for this type of equipment (i.e., they cover the same instruments, and requirements are similar) and the fact that instrument manufacturers that supply this equipment world-wide are the same, and the number is limited, this accreditation program covers both sets of standards.

The 2022 edition of NIST Handbook 150-23 supersedes and replaces all previous editions.

The handbook was revised with the participation of technical experts in the field of ionizing radiation detection instrumentation and was approved by NVLAP. The primary revision to this handbook is to include reference to the IEC standards used for detection of illicit trafficking of radioactive materials.

The numbering of the handbook has also been restructured to reflect that used by the ISO/IEC 17025:2017, *General requirements for the competence of testing and calibration laboratories* (hereafter referred to as ISO/IEC 17025) standard.

This handbook is available on the NVLAP web site (<http://www.nist.gov/nvlap>) and also at the NIST Research Library (<https://doi.org/10.6028/NIST.HB.150-23-2022>).

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 laboratory accreditation program for Radiation Detection Instruments (RDI) used in homeland security applications was established in 2006 in response to a request from the United States Department of Homeland Security (DHS). In 2014 the scope of the program was expanded to include test methods used by the Department of Defense in response to the request from the Assistant Deputy Under Secretary of the Army for Test and Evaluation as well as the IEC standards used for detection of illicit trafficking of radioactive materials. The purpose of this laboratory accreditation program is to recognize competent radiation detection instrument testing laboratories and to improve the quality of radiation detection instruments used by first responders, radiation instrument users, the federal government, and instrument manufacturers by providing periodic evaluations of each laboratory, including an assessment of the laboratory's management system. The testing program is divided into four types of testing: radiological, environmental, electromagnetic, and mechanical.

The radiation detection instrument testing standards used in homeland security applications were developed by the IEEE Standard Association (SA) Instrumentation and Measurement Society (IMS) (labeled as N42.XX standards)<sup>1</sup>. The International Electrotechnical Commission (IEC) standards for detection of illicit trafficking of radioactive materials were developed under the Technical Committee (TC) 45 Subcommittee B Working Group 15. The laboratories must follow the current versions (unless noted by a NVLAP laboratory bulletin) of applicable standards.

These standards provide requirements and test methods for a large variety of instruments, including personal radiation detectors, hand-held gamma-ray and neutron detectors, radionuclide identification detectors, backpack-type radiation detectors, radiation portal monitors, and mobile systems among others.

Accreditation is available to any laboratory that tests radiation detection instrument in accordance with standards for these instruments and this handbook. A foreign-based laboratory may also be accredited by NVLAP if the laboratory meets the same requirements as domestic laboratories and pays any required additional fees.

To be granted accreditation, a laboratory shall satisfy the NVLAP requirements contained in NIST Handbook 150 and this handbook and shall demonstrate proficiency in the testing of radiation detection instrumentation used in homeland security applications.

NVLAP accreditation implies neither a guarantee (certification) of laboratory performance or test/calibration data nor product certification. NVLAP accreditation is solely a finding of laboratory competence.

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<sup>1</sup> The ANSI N42 committee where the ANSI/IEEE standards were originally developed are now housed under the IEEE SA IMS TC 45. These standards were published by the IEEE even when developed under the ANSI N42 committee.

# 1 General information

## 1.1 Scope

**1.1.1** NIST Handbook 150-23 specifies the technical requirements and provides guidance for NVLAP accreditation of laboratories that test radiation detection instruments.

**1.1.2** The requirements of ISO/IEC 17025, NIST Handbook 150, NIST Handbook 150-23, and the requirements of the test standards for which the laboratory seeks accreditation constitute the collective body of requirements combined to produce the criteria for accreditation in the NVLAP RDI LAP.

**1.1.3** This handbook is intended for information and use by accredited radiation detection instrument testing laboratories, assessors conducting on-site assessments, laboratories seeking accreditation, other laboratory accreditation systems, users of laboratory services, and others needing information on the requirements for NVLAP accreditation under the Radiation Detection Instruments LAP.

## 1.2 Organization of handbook

The numbering and titles of the first eight clauses of this handbook are patterned after NIST Handbook 150, *NVLAP Procedures and General Requirements*, and ISO/IEC 17025 *General requirements for the competence of testing and calibration laboratories* to allow easy cross-reference. The primary subclauses in clauses 4 through 8 (e.g., 4.1, 4.2, etc.) are also numbered and titled to correspond with those of ISO/IEC 17025, even when there are no additional requirements.

## 1.3 Program description

**1.3.1** This accreditation program is designed to satisfy the requirements of contractors, state and local governments, and federal agencies specifying accreditation for laboratories that conduct type testing of radiation detection instruments.

**1.3.2** Accreditation is available to any organization that conducts type testing or validation testing of radiation detection instruments in accordance with this handbook and corresponding standards referenced as part of the criteria for accreditation. Accreditation is offered in the categories of radiological, environmental, electromagnetic, and mechanical testing. Laboratories can be accredited all or part of the available test methods.

**1.3.3** Laboratories that test radiation detection instruments shall clearly communicate the scope of the laboratory's accreditation.

## 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.



- NIST Handbook 150, *NVLAP Procedures and General Requirements*
- IEEE Standard 1012, *IEEE Standard for Software Verification and Validation*
- ISO/IEC 17025, *General requirements for the competence of testing and calibration laboratories*

## **1.5 Terms and definitions**

For the purposes of this handbook, the relevant terms and definitions given in NIST Handbook 150 apply unless a term is redefined in this handbook. The definitions provided in this handbook are specific to the RDI LAP, and when applicable, they supersede the definitions given in NIST Handbook 150. Test-specific terms, defined in other technical publications referenced in this document, supersede the definitions given in this handbook.

### **1.5.1**

#### **detector**

A device or component designed to produce a quantifiable response to ionizing radiation normally measured electronically.

### **1.5.2**

#### **instrument**

A complete system consisting of one or more assemblies designed to quantify one or more characteristics of ionizing radiation or radioactive material.

### **1.5.3**

#### **type test**

Initial test of instruments representative of production made to a specific design to show that the design meets defined specifications.

### **1.5.4**

#### **validation test**

Evaluation or measurement of performance characteristics of the laboratory's equipment to verify that certain stated specifications and contractual requirements are met.

## **1.6 Program documentation**

### **1.6.1 General**

NVLAP checklists enable assessors to document the assessment of a laboratory against the NVLAP requirements found in NIST Handbook 150, this handbook, and in some cases, 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). Use of checklists helps to ensure the completeness, objectivity, and uniformity of the on-site assessment process. The current version of each checklist is available on the NVLAP web site, <https://www.nist.gov/nvlap>.

### **1.6.2 NVLAP General Criteria Checklist**

All NVLAP programs use the NVLAP General Criteria Checklist, which contains the requirements published in ISO/IEC 17025 and NIST Handbook 150. The checklist items are numbered to correspond to clauses 4 through 8 of ISO/IEC 17025 and annexes A and B, and E of NIST Handbook 150.

### **1.6.3 NIST Handbook 150-23 Checklist**

The NIST Handbook 150-23 Checklist addresses the requirements specific to the Radiation Detection Instruments LAP. The checklist items are numbered to correspond to clauses 3 through 8 of NIST Handbook 150-23.

### **1.6.4 Test Method Review Summary**

The assessors use the Test Method Review Summary (TMRS) to review a laboratory's ability to perform the radiation detection instrument tests within each standard for which the laboratory seeks accreditation. The laboratory will choose for accreditation the specific tests of the applicable standards. In addition, the laboratory must show compliance with the general considerations and fulfill the documentation requirements in of the applicable standards. The review of the test method details by the assessor includes observing tests and having laboratory staff describe the test procedures. The assessor notes on the Test Method Review Summary the depth into which each part of the test method was reviewed (Observed Test, Walked/Talked Through Test, Listened to Description of Procedures, Examined Apparatus).

### **1.6.5 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**

**3.1.1** 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.

**3.1.2** A laboratory interested in accreditation for any of the types of tests offered under the RDI LAP shall review and become familiar with all requirements listed in ISO/IEC 17025, NIST Handbook 150, and in this handbook, review the RDI LAP website at <https://www.nist.gov/nvlap/radiation-detection-instruments-lap>, and contact NVLAP for the most current updates on the requirements and application process.

**3.1.3** The assessment process consists of a NVLAP review of the application and laboratory management system documentation, assessment visit, and proficiency testing, when available.

**3.1.4** NVLAP may consider a preassessment on-site visit to better define a laboratory's requested scope of accreditation. In such cases, the preassessment costs will be charged to the laboratory in addition to the onsite assessment fee.

## **3.2 Management system review**

**3.2.1** The management system documentation provided to NVLAP during the application for accreditation process will be reviewed by a NVLAP assessor(s) prior to the onsite assessment. The assessors will review the management system documents to ensure the accreditation requirements are satisfied. Prior to conducting the assessment, the NVLAP assessor(s) may request a copy of the laboratory's cross-reference documentation verifying the requirements of ISO/IEC 17025, NIST Handbook 150, and this handbook are addressed in the laboratory's management system

**3.2.2** The NVLAP assessor may also ask for additional management system documents as necessary to confirm compliance to requirements.

## **3.3 Onsite assessment**

**3.3.1** The assessment normally takes 3 days. The assessment may be longer depending on the number of radiation detection instrument types and test categories for which a laboratory is seeking accreditation. Efforts will be made to minimize disruption to normal working routines during the assessment. The lab shall make available proper workspace to the assessor(s) to review documentation and complete the assessment report.

**3.3.2** The laboratory shall have its facilities and equipment in good working order and be readily available during the assessment.

**3.3.3** The laboratory shall make available to the assessors, at the beginning of the assessment, all supporting technical information in a format that is conducive to a detailed review.

**3.3.4** The activities of a typical on-site assessment are described below. The assessor, prior to the visit, shall provide a preliminary agenda.

- a) *Opening meeting:* The NVLAP assessor(s) will meet with laboratory management and supervisory personnel, and other personnel at the discretion of the laboratory's management, to explain the purpose of the on-site assessment and to discuss the schedule for the assessment activities. Information provided by the laboratory on its application form may be discussed during this meeting.
- b) *Staff interviews:* The assessor(s) will ask the laboratory manager to assist in arranging times for individual interviews with laboratory staff members. The assessor(s) will interview staff members filling key positions (e.g., Laboratory Manager, Technical Director, Quality Manager, Authorized Representative) and staff members who have an effect on the outcome of the testing. The assessor(s) do not need to talk to all staff members; however, the assessor(s) will select staff members representing all aspects of the laboratory. These interviews are conducted to determine

if the staff members are properly trained, assigned, and supervised, and are technically competent for the tasks assigned to them.

- c) *Records review:* The assessor(s) will review laboratory documentation, including the management system, equipment and maintenance records, record-keeping procedures, testing procedures, laboratory test records and reports, personnel competency records, personnel training plans and records, and safeguards for the protection of sensitive and proprietary information. The assessor(s) may request additional information to clarify potential nonconformities.

Laboratory staff shall be available for interviews with the assessor(s); however, the assessor(s) may wish to review documents and records alone. The assessor(s) do not typically ask to remove laboratory documents or records from the laboratory premises.

Assessors do not need access to information that may be considered sensitive or private such as salary, medical information, or performance reviews for work done outside the scope of the laboratory's accreditation. However, this information may often be stored together with technical information that an assessor will need to check (e.g., job descriptions, resumes, and technical performance reviews). In these cases, the assessor will work with the laboratory to ensure the review is performed without violating individual privacy. At the discretion of the laboratory, a member of the human resources department may be present during the review of personnel information.

- d) *Internal audit and management review:* The assessor(s) will review and discuss with the laboratory staff the laboratory's internal audit and management review activities, which are separate and distinct activities. The discussion will include all aspects of those activities including the quality system procedures, the audit findings, the results of the management review, and the actions taken to resolve problems identified.
- e) *Equipment and software:* The assessor(s) will examine the suitability of all equipment and facilities required to perform the standard test methods for which the laboratory is accredited (or is seeking accreditation). The assessor(s) will examine radiological-type testing equipment including required validation tests, test sources, environmental chambers, calibration ranges, and associated computer hardware and software for function and compliance with this handbook and all associated standards. In particular, the assessor(s) will evaluate whether there are any limitations on the size and/or type of radiation detection instruments that the laboratory can test with its available equipment and facilities. The assessor(s) will also review any associated software validations and verification procedures used as part of the testing and the data report formatting.
- f) *Demonstrations:* The demonstrations requested may be selective or all-inclusive. The assessor(s) will observe selected or all-inclusive radiation detection-type testing of instruments in different classes as they apply to the standards requested for accreditation and discuss them with the laboratory personnel to assure their understanding of the procedures. The assessor(s) may select and trace the history of one or more instruments from receipt to final issuance of the test results.

The environmental, electromagnetic, and mechanical test methods require verification of the radiological response for the instruments under test. Therefore, the laboratory shall demonstrate proper performance of environmental, electromagnetic, and mechanical tests in combination with radioactive sources.

- g) *Proficiency testing (PT)*: The assessor(s) shall discuss all aspects of proficiency testing results with appropriate staff. Test methodology and any PT (if applicable) records documenting the laboratory's execution of the testing will be reviewed.
- h) *Assessment report*: The assessor(s) will complete an assessment report, summarizing the findings. This report consists of the NVLAP Onsite Assessment Signature Sheet with Narrative Summary, NVLAP General Criteria Checklist (ISO/IEC 17025:2017), NIST Handbook 150-23 Checklist, and Test Method Review Summary (TMRS). The assessor(s) will also enter any nonconformities and/or comments into the NVLAP interactive website (NIWS). All observations made by the assessor will be held in confidence as stated in the declaration signed by all assessors and NVLAP staff.
- i) *Closing meeting*: The lead assessor conducts a closing meeting with the laboratory management, supervisory personnel, and other staff members at the discretion of the laboratory's management to discuss the overall findings of the assessment. The assessor(s) categorize assessment findings as nonconformities and comments. These will be discussed at the closing meeting and resolutions may be mutually agreed upon. The assessor(s) will specifically note items that have been corrected during the on-site assessment. The first page of the on-site assessment report is signed by the assessor(s) and the laboratory's Authorized Representative. The lead assessor will give a copy of the assessment report to the laboratory's Authorized Representative for retention and send the original report to NVLAP. The process for resolving nonconformities identified during the on-site assessment is documented in NIST Handbook 150. Any disagreements between the laboratory and an assessor may be referred to NVLAP for resolution.

**3.3.5** Although comments do not necessitate a corrective action response to NVLAP, the laboratory shall review all comments for potential improvements in the testing of radiation detection instruments used for homeland security and detection of illicit trafficking of radioactive materials.

## **3.4 Proficiency testing**

### **3.4.1 Conducting proficiency testing**

**3.4.1.1** NVLAP will require proficiency testing rounds as needed to evaluate a laboratory's proficiency.

**3.4.1.2** Laboratories shall participate in proficiency testing when NVLAP announces plans to conduct a proficiency test.

### **3.4.2 Analyzing and reporting proficiency data**

The laboratory shall analyze the proficiency testing results, identify all outliers and follow the requirements of NIST Handbook 150 for the control of nonconforming work.

### **3.4.3 Proficiency testing nonconformities**

The laboratory shall initiate corrective action for performance outside the acceptance criteria in proficiency testing or any nonconforming work discovered from the outlying proficiency testing results. The laboratory's accreditation may be suspended if the proficiency testing results indicate continued poor or unsatisfactory performance on consecutive proficiency testing rounds.

## **4 General requirements**

There are no requirements additional to those set forth in ISO/IEC 17025.

## **5 Structural requirements**

There are no requirements additional to those set forth in ISO/IEC 17025.

## **6 Resource requirements**

### **6.1 General**

There are no requirements additional to those set forth in ISO/IEC 17025.

### **6.2 Personnel**

**6.2.1** The laboratory shall maintain a list of personnel designated to fulfill NVLAP requirements including Laboratory Director, Technical Director, Team Leaders, NVLAP Authorized Representative, and NVLAP Approved Signatories.

**NOTE** The Technical Director should be professionally experienced in radiation detection instrumentation and be familiar with the radiation detection instrumentation the laboratory tests.

**6.2.2** The laboratory shall maintain responsibility for and control of any work performed within its scope of accreditation. The laboratory shall ensure all individuals performing radiation detection instrument testing activities satisfy all accreditation requirements, irrespective of the means by which personnel are compensated (e.g., the laboratory must ensure all test personnel receive proper training and are subject to performance reviews, etc.).

**NOTE 1** Full-time laboratory employees and individuals hired on contract are both considered laboratory personnel.

**NOTE 2** When key personnel are added to the staff, the notification of change to NVLAP should include a current resume for each new staff member.

**6.2.3** The laboratory training program shall be updated at the time when a test procedure is updated. The laboratory's training materials shall also be updated at that time.

**6.2.4** Laboratory staff shall be retrained when procedures are updated or when the individuals are assigned new roles and/or responsibilities.

**NOTE** Personnel training may include on-the-job training, formal classroom study, attendance at conferences, or another appropriate mechanism.

**6.2.5** For each staff member, the staff member's immediate supervisor, or a designee appointed by the Laboratory Director, shall conduct an annual assessment and observation of performance.

### **6.3 Facilities and environmental conditions**

There are no requirements additional to those set forth in ISO/IEC 17025.

### **6.4 Equipment**

A laboratory shall have adequate facilities and equipment to perform the radiation detection instrumentation tests for which capability is claimed. All equipment required to conduct radiological type testing shall be available for review. Adequate facilities and equipment shall include the following:

- a) sufficient space to perform the tests;
- b) proper shielding of areas from unwanted radiation;
- c) necessary environmental chambers for conducting environmental tests;
- d) radiation sources that are traceable to the International System of Units (SI) through a national metrology institute (e.g., NIST or an equivalent organization);
- e) properly characterized radiation detection instruments to determine the radiation fields used in the radiological tests;
- f) safety systems;
- g) properly calibrated test equipment;
- h) electromagnetic and mechanical test equipment for conducting electromagnetic and mechanical tests.

### **6.5 Metrological traceability**

**6.5.1** The radiation sources and reference standards used and the environmental conditions at the time of measurements shall be documented for all measurements. The laboratory shall also document how radiation fields are characterized and shall include a description of the calibration of reference instruments, sources, and measurement methods used. For low-level radiation fields, calculations may be required to make this determination, and in this case information about the method used and validation of the method shall be documented.

**6.5.2** The radiation sources and reference standards used and the environmental chamber conditions at the time of the test shall be documented for all type tests.

**6.5.3** Calibration records, type testing records, and certificates providing evidence of the traceability of the radiation sources and reference standards used shall be made available for inspection during the on-site assessment.

**6.5.4** Calibration records for equipment used for measurements and evaluation of radiation detection instruments shall include the following:

- a) notation of all equipment variables requiring calibration or verification;
- b) range of calibration/verification;
- c) resolution of the instrument and its allowable uncertainty;
- d) calibration/verification date and schedule;
- e) identity of the laboratory, individual or external service responsible for calibration;
- f) traceability of radiation sources, radiation fields, and reference standards.

## **6.6 Externally provided products and services**

There are no requirements additional to those set forth in ISO/IEC 17025.

## **7 Process requirements**

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

There are no requirements additional to those set forth in ISO/IEC 17025.

### **7.2 Selection, verification, and validation of methods**

**7.2.1** A laboratory may be accredited to standard test methods in their entirety or to only certain sections of the test methods.

**7.2.2** The laboratory shall have written procedures for laboratory personnel to follow when conducting tests.

**NOTE** Environmental, electromagnetic compatibility (EMC), and mechanical test methods require verification of the radiological response for the items under test. Therefore, the laboratory will be required to show for environmental, electromagnetic, and mechanical testing that they can properly perform the tests in combination with radioactive sources.

**7.2.3** The procedures shall also address any information not specifically contained in the standard method and any deviations implemented by the laboratory.

**NOTE** Although a laboratory may become accredited for the EMC portions of the relevant test methods for radiation detection instruments used in homeland security, and detection of illicit trafficking of radioactive materials, the RDI laboratory is not considered to be accredited in the NVLAP Electromagnetic Compatibility and Telecommunications (ECT) Laboratory Accreditation Program. Accreditation in that program requires a separate application and Scope of Accreditation.



**7.2.4** The procedures shall include equipment operation, and the usage of calibration checks and quality control checks within the laboratory.

**7.2.5** The laboratory shall develop validation methods to ensure test fields and relevant quantities used for equipment testing are within acceptable tolerances as defined in the relevant standards.

### **7.3 Sampling**

There are no requirements additional to those set forth in ISO/IEC 17025.

### **7.4 Handling of test items**

There are no requirements additional to those set forth in ISO/IEC 17025.

### **7.5 Technical records**

There are no requirements additional to those set forth in ISO/IEC 17025.

### **7.6 Evaluation of measurement uncertainty**

The laboratory shall document uncertainty of the field quantity (exposure, air kerma, etc.) produced by the radiation fields used for testing, and the traceability to the SI through a national metrology institute (e.g., NIST or an equivalent organization).

### **7.7 Assuring the validity of results**

**7.7.1** The radiation sources and fields used by the testing laboratories shall be traceable to the SI through a national metrology institute (e.g., NIST or an equivalent organization) as a requirement for use in the type testing and when NVLAP announces a proficiency testing program. The testing laboratory shall describe how the field quantity produced by the radiation fields used for testing is determined and show validation of the method used.

**7.7.2** The IEEE Standard 1012, *IEEE Standard for Software Verification and Validation*, shall be used as a reference when developing procedures for verification and validation of software used to acquire data from the instruments used for testing.

**NOTE 1** The categories for performance testing and the associated tolerance limits for both type testing and proficiency testing are based on the requirements of radiation detector performance.

**NOTE 2** The testing standards specify the radiation sources or radiation fields to be used in the radiological detection tests and radionuclide identification tests.

### **7.8 Reporting of results**

The laboratory shall report the test results in accordance with the reporting format required by the specific requirements of the testing program associated with the individual standards.

## **7.9 Complaints**

There are no requirements additional to those set forth in ISO/IEC 17025.

## **7.10 Nonconforming work**

There are no requirements additional to those set forth in ISO/IEC 17025.

# **8 Management system requirements**

## **8.1 Options**

There are no requirements additional to those set forth in ISO/IEC 17025.

## **8.2 Management systems documentation**

**8.2.1** The laboratory shall create a cross-reference document allowing the laboratory and NVLAP assessors to verify that all requirements of ISO/IEC 17025, NIST HB 150, and this handbook are addressed within the management system.

**8.2.2** The laboratory shall have copies of applicable standards and standard operating procedures that are used to fulfill test requirements.

**8.2.3** In addition to the information specified in NIST Handbook 150, the management system documentation shall include the following:

- a) description of the laboratory's facilities and scope of services offered;
- b) equipment inventory for relevant test methods including, but not necessarily limited to:
  - radiation sources used for testing, including source certificates and/or method used to determine the source activity or radiation field strength as applicable;
  - radiation detection instrument models and design specifications for those instruments used in support of type testing, including maintenance and calibration practices;
  - radiation detection instrument calibration, energy response information, and/or mathematical model or calculation used to determine the radiation field strength used for testing;
  - environmental chambers, thermometers, and hygrometers, including maintenance and calibration practices;
  - electromagnetic testing instrumentation, including maintenance and calibration practices;
  - dust and water spray testing instrumentation, including maintenance and calibration practices;

- vibration and mechanical shock testing instrumentation, including maintenance and calibration practices;
- c) instructions to operate all laboratory-owned radiation detection “test equipment” instruments, including any operational checks;
- d) procedures for handling and storing sensitive components and materials;
- e) procedures used for identification and tracking of radiation detection instruments received for testing (i.e., item under test);
- f) actions concerning damaged radiation detection instruments received in shipping;
- g) handling, control, and shipping of radiation detection instruments used in proficiency testing (when applicable);
- h) data handling and reporting that includes information and description of the report data template used to report the results of the tests
- i) actions when test data indicate a possible problem exists when setting up the radiation field or any other test parameter specified in the standards.

### **8.3 Control of management system documentation**

The controlled version of the laboratory management system documentation may be paper-based or computer-based. Version control shall be maintained in either case.

### **8.4 Control of records**

Records shall be maintained for at least three years.

### **8.5 Actions to address risk and opportunities**

There are no requirements additional to those set forth in ISO/IEC 17025.

### **8.6 Improvement**

There are no requirements additional to those set forth in ISO/IEC 17025.

### **8.7 Corrective action**

There are no requirements additional to those set forth in ISO/IEC 17025.

### **8.8 Internal audits**

An applicant laboratory shall perform a complete internal audit per the requirements of ISO/IEC 17025 prior to the initial assessment.

## **8.9 Management reviews**

An applicant laboratory shall perform a complete management review per the requirements of ISO/IEC 17025 prior to the initial assessment.