

NIST HANDBOOK 150-4
2019 Edition

National
Voluntary
Laboratory
Accreditation
Program

IONIZING
RADIATION
DOSIMETRY

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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 Laboratory Accreditation Programs (LAPs) under NVLAP.

The program-specific handbooks are not standalone documents, but rather are companion documents to NIST Handbook 150 and the referenced ISO/IEC 17025 requirements. Each program-specific handbook tailors the general criteria referenced in NIST Handbook 150 to the specific test methods, calibrations, or types of tests or calibrations covered by a LAP.

NIST Handbook 150-4, *NVLAP Ionizing Radiation Dosimetry*, presents the technical requirements and guidance for the accreditation of laboratories under the NVLAP Ionizing Radiation Dosimetry LAP. The 2019 edition incorporates changes resulting from the release of the newest edition of ISO/IEC 17025:2017, *General requirements for the competence of testing and calibration laboratories*, and NIST Handbook 150 (2016), as well as editorial improvements. The 2019 edition of NIST Handbook 150-4 supersedes and replaces the 2005 edition.

The handbook was revised with the participation of technical experts in the field of ionizing radiation dosimetry and was approved by NVLAP. The following main changes have been made to this handbook with respect to the previous edition:

- the numbering has been aligned to ISO/IEC 17025:2017, *General requirements for the competence of testing and calibration laboratories* (hereafter referred to as ISO/IEC 17025);
- requirements that closely duplicated existing requirements in either ISO/IEC 17025 or NIST Handbook 150 have been removed;
- all references to applicable international guides and standards have been updated.

This handbook is also available on the NVLAP website (<https://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.

Introduction

The laboratory accreditation program for Ionizing Radiation Dosimetry was established in 1984 in response to a request from the U.S. Nuclear Regulatory Commission (NRC). The purpose of the NVLAP Ionizing Radiation Dosimetry Program is to recognize competent dosimetry processing laboratories and to improve the quality of personnel dosimetry by providing periodic evaluations of each laboratory, including an assessment of the laboratory's management system.

Accreditation is available to any laboratory that processes radiation dosimeters used to monitor individual exposure to ionizing radiation. 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 associated with the on-site assessment.

The processing laboratories are referred to as dosimetry processors. In this handbook, the terms *laboratory* and *processor* are used interchangeably.

The ionizing radiation dosimetry standards were developed by the American National Standards Institute (ANSI) and the Health Physics Society (HPS). The dosimetry processors follow the current versions (unless noted by a NVLAP laboratory bulletin) of ANSI/HPS N13.11, *Personnel Dosimetry Performance – Criteria for Testing*, for whole body dosimeters, and ANSI/HPS N13.32, *Performance Testing of Extremity Dosimeters* for extremity dosimeters.

To be granted accreditation, a dosimetry processor shall satisfy the NVLAP requirements contained in ISO/IEC 17025, NIST Handbook 150 and this handbook, and shall demonstrate proficiency in processing each dosimeter model/type that the laboratory intends to use in each radiation category for which accreditation is desired.

1 General information

1.1 Scope

1.1.1 NIST Handbook 150-4 specifies the technical requirements and provides guidance for the accreditation of laboratories under the Ionizing Radiation Dosimetry LAP. This handbook supplements the NVLAP programmatic procedures and general requirements found in NIST Handbook 150.

1.1.2 This handbook also identifies the requirements for a management system, the specific on-site assessment criteria and requirements for proficiency testing to ANSI/HPS N13.11 and ANSI/HPS N13.32. The interpretive comments and additional requirements contained in this handbook make the general NVLAP criteria specifically applicable to the Ionizing Radiation Dosimetry LAP.

1.1.3 This handbook is intended for information and use by accredited dosimetry processors, 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 Ionizing Radiation Dosimetry LAP.

1.1.4 The requirements of NIST Handbook 150 and the referenced ISO/IEC 17025 requirements, the interpretations and specific requirements in this handbook, and the requirements of the test standards for which the laboratory seeks accreditation (i.e., ANSI/HPS N13.11, ANSI/HPS N13.32, etc.) must be combined to produce the criteria for accreditation in the Ionizing Radiation Dosimetry LAP.

1.2 Organization of handbook

The numbering and titles of the first three clauses of this handbook match those of NIST Handbook 150. However, unless there is an additional requirement, only the top-level numbering (e.g., 1, 2, and 3) is listed.

The numbering and titles of clauses four through eight of this handbook mirror those of ISO/IEC 17025. For clarity, the top-level and first sub-level clauses (e.g., 4, 5, 4.1, 4.2, etc.) are also numbered and titled to correspond with ISO/IEC 17025, even when there are no additional requirements given in this handbook.

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 process ionizing radiation dosimeters.

1.3.2 Accreditation is available to any organization that processes personnel radiation dosimeters used to monitor individual whole body or extremity radiation dose received from exposure to ionizing radiation.

1.3.3 Processors who provide dosimetry services to internal clients (i.e., dosimeters are issued to workers under the same organization, such as a utility company with a dosimetry processing division) shall ensure that the laboratory's scope of accreditation is appropriate to meet state and federal requirements for the worker who was issued a dosimeter.

1.3.4 Processors who provide dosimetry services to external clients shall clearly communicate to the client the scope of the processor's accreditation, including radiation categories for each type and model of dosimeter provided.

1.3.5 NVLAP does not prohibit a processor from providing additional services outside the scope of its accreditation, but those services shall be clearly identified in client reports as not being in the scope of the laboratory's NVLAP accreditation.

1.3.6 Processors may utilize dosimeters and processing techniques of their choice. However, once accredited, the dosimeters and processing techniques used to provide accredited dosimetry in the normal conduct of work shall be the same as those that were used in demonstrating proficiency.

1.3.7 The processor shall notify the NVLAP Program Manager of any changes or deviations from the specified dosimeters or processing techniques and provide evidence of satisfactory proficiency testing for those dosimeters or processing techniques before the new dosimeters and techniques can become a part of the processor's scope of 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.

- ISO/IEC 17025, *General requirements for the competence of testing and calibration laboratories*
- NIST Handbook 150, *NVLAP Procedures and General Requirements*
- ANSI/HPS N13.11:2009, *Personnel Dosimetry Performance - Criteria for Testing*
- ANSI/HPS N13.32:2008, *Performance Testing of Extremity Dosimeters*
- IEEE Standard 1012:2012, *IEEE Standard for Software Verification and Validation*
- Code of Federal Regulations, 10 CFR Part 20, *Standards for Protection Against Radiation*

1.5 Terms and definitions

For the purposes of this handbook, the terms and definitions given in NIST Handbook 150, ANSI N13.11, ANSI N13.32, and the following definitions apply.

1.5.1

absorbed dose, D

The energy absorbed per unit mass at a specific point in a material. The unit of dose is the gray (Gy), which has units of joules per kilogram (J/kg). Formerly, the special unit of absorbed dose was the rad; 1 J/kg = 1 Gy = 100 rad.

1.5.2

angular dependence

The performance of a dosimeter irradiated under non-perpendicular radiation incidence.

1.5.3

dosimeter

Radiation sensitive element(s) in a holder (the holder being considered a part of the dosimeter) used for personnel monitoring.

1.5.4

extremities

The extremities are defined as the portions of the body from the elbow to the fingers and the knees to the toes (including the knee).

1.5.5

processor

A supplier of personnel dosimetry services. In relation to this document, *processor* is synonymous with *laboratory*.

1.5.6

whole body

The whole body is defined as everything except extremities.

1.5.7

PTL

The proficiency-testing laboratory.

1.5.8

TLD

The thermo-luminescent dosimeter.

1.6 Program documentation

1.6.1 General

NVLAP 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 ISO/IEC 17025, NIST Handbook 150, and this program-specific handbook. 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).

1.6.2 NVLAP General Criteria Checklist (ISO/IEC 17025:2017)

All NVLAP programs use the NVLAP General Criteria Checklist (ISO/IEC17025:2017) (formerly called the NIST Handbook 150 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, B and E of NIST Handbook 150.

1.6.3 NIST Handbook 150-4 Checklist

The NIST Handbook 150-4 Checklist addresses the requirements specific to the Ionizing Radiation Dosimetry LAP. The checklist items are numbered to correspond to clauses 4 through 8 of NIST Handbook 150-4. The current version of the checklist is available from the NVLAP website at <https://www.nist.gov/nvlap>.

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

3.1.1 This clause discusses the assessment and accreditation process for laboratories in the Ionizing Radiation Dosimetry LAP.

3.1.2 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.

3.1.3 The assessment process consists of a NVLAP review of the application and laboratory management system documentation, an on-site assessment visit, and proficiency testing.

3.1.4 Proficiency testing is required before initial accreditation and every two years thereafter.

3.1.5 NVLAP management may consider a pre-assessment on-site visit to better define the laboratory's requested scope of accreditation. In such cases, the pre-assessment costs will be charged to the laboratory in addition to the actual On-Site Assessment Fee.

3.2 Management system review

3.2.1 When NVLAP receives the application, management system documents, and required procedures, one or more NVLAP assessors are assigned to review the management system documentation. The assigned assessors will review the documents to ensure they cover all aspects of the management system related to quality and, if followed, satisfy the requirements in ISO/IEC 17025 clauses 4 through 8, NIST Handbook 150-4, NIST Handbook 150 Annexes A, B and E, as applicable, and the requirements of the test

standards for which the laboratory seeks accreditation (i.e., ANSI/HPS N13.11, ANSI/HPS N13.32, etc.). Prior to conducting the on-site assessment, the NVLAP assessor may request a copy of the laboratory's management system documentation and cross-reference documentation that verifies that all the requirements of ISO/IEC 17025 and NIST Handbook 150 are addressed.

3.2.2 During the review, the NVLAP assessor may identify nonconformities and require changes to the management system so that it meets the requirements. A NVLAP assessor may ask for additional management system documents related to quality.

3.3 On-site assessment

3.3.1 When the management system review has been completed and nonconformities resolved, NVLAP schedules the on-site assessment.

3.3.2 The assessment will take place at the laboratory site. The NVLAP assessor typically conducts the on-site assessment over a time period of three days. The assessment time may be longer depending on the number of dosimeter types and test categories for which a laboratory is accredited. Efforts will be made to minimize disruption to the normal working routines during the assessment. The NVLAP assessor will need time and workspace to complete assessment documentation during their time at the laboratory site.

3.3.3 The processor shall have its facilities and equipment in good working order and be ready for examination according to the requirements identified in this handbook, ISO/IEC 17025, NIST Handbook 150, and the laboratory's management system documentation.

3.3.4 The processor shall make available, at the beginning of the on-site assessment, all supporting technical information in a format that is conducive to a detailed review.

3.3.5 The NVLAP assessor will use the NVLAP General Criteria Checklist (ISO/IEC 17025:2017) and the NIST Handbook 150-4 Checklist. The checklists and the technical specifics contained in this handbook ensure that the assessment is complete and that all assessors cover the same items at each laboratory.

3.3.6 The activities covered during a typical on-site assessment are described below. A NVLAP assessor, prior to the visit, will provide a preliminary agenda, which may change due to findings observed during the on-site assessment.

- a) *Opening meeting:* The NVLAP assessor 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 NVLAP assessor will ask the laboratory manager to assist in arranging times for individual interviews with laboratory staff members. The NVLAP assessor 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 NVLAP assessor does not need to talk to all staff members; however, the NVLAP assessor will select staff members representing all aspects of the laboratory. These interviews are conducted to determine whether the staff members are properly trained, assigned, and supervised, and are technically competent for the tasks assigned to them.

- c) *Records review:* The NVLAP assessor will review laboratory documentation, including the management system, quality policies, 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 NVLAP assessor may request additional information to clarify issues regarding nonconformities or to delve more deeply into technical issues.

Processor staff shall be available to answer questions; however, the NVLAP assessor may wish to review the documents and records in private. The NVLAP assessor usually does not ask to remove any laboratory documents or records from the laboratory premises.

NVLAP assessors do not need access to employee 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 is often stored together with technical information that a NVLAP assessor will need to check (e.g., job descriptions, resumes, and technical performance reviews). In these cases, a NVLAP 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 NVLAP assessor 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 management system procedures, the audit findings, the results of the management review, and the actions taken to resolve problems identified.
- e) *Equipment and software:* The NVLAP assessor will examine equipment and facilities and determine whether appropriate environmental conditions are maintained. The NVLAP assessor will examine hardware and software for function and appropriateness, review software validations and verification procedures and review the function of the dose algorithm and calculations performed. All equipment required to process ionizing radiation dosimeters shall be available for examination.
- f) *Demonstrations:* The NVLAP assessor will observe demonstrations of dosimeter processing techniques and discuss them with the technical personnel to assure their understanding of the procedures. The NVLAP assessor may select and trace the history of one or more dosimeters from receipt to final issuance of the radiation dose reports of dose data transfer.
- g) *Proficiency testing:* The NVLAP assessor will discuss all aspects of proficiency testing results with appropriate staff. Test methodology and records documenting the laboratory's execution of the testing will be reviewed and discussed. Unusual trends and outlying results will be discussed.
- h) *On-site assessment report:* A NVLAP assessor will complete an on-site assessment report, which summarizes the findings. This report normally consists of the On-Site Report, the NVLAP General Criteria Checklist (ISO/IEC 17025:2017), and the NIST Handbook 150-4 Checklist. The first page of the report will be signed by the NVLAP assessor and the NVLAP Authorized Representative to acknowledge the discussion, but this does not necessarily indicate agreement by the laboratory. The assessor will submit the report through the NVLAP Interactive Web System, which will allow the laboratory to have access to the report documentation.

- i) *Closing meeting:* The NVLAP assessor will conduct a closing meeting with the laboratory management, supervisory personnel, and other staff members at the discretion of the laboratory's management to discuss findings. During the visit a NVLAP assessor will have categorized each finding identified as either a nonconformity or a comment. These will be discussed at the closing meeting. The NVLAP assessor will specifically note items that have been corrected during the on-site assessment along with any requirements for additional action. Any disagreements between the laboratory and a NVLAP assessor may be referred to NVLAP for resolution.

3.3.7 The processor shall address all nonconformities and provide, within 30 days from the date of the on-site assessment, a response to NVLAP. The laboratory shall use the NVLAP Interactive Web System (NIWS) for submitting the resolution of nonconformities identified during the on-site assessment.

3.3.8 The processor shall review all comments for potential improvements in the dosimetry measurement system.

3.4 Proficiency testing

3.4.1 Conducting proficiency testing

3.4.1.1 Each processor shall demonstrate satisfactory performance in accordance with ANSI N13.11, *Personnel Dosimetry Performance – Criteria for Testing*, and ANSI/HPS N13.32, *Performance Testing of Extremity Dosimeters*, for each dosimeter model it intends to use and in each test category for which accreditation is desired. Satisfactory proficiency-test results shall be demonstrated prior to initial accreditation and every two years thereafter.

3.4.1.2 The proficiency-test review during the on-site assessment includes:

- a) The processor shall demonstrate to a NVLAP assessor that normal day-to-day processing is done in a manner consistent with that employed in the proficiency test.
- b) If, for technical reasons, the processor needs to void a reported result in the proficiency test, all the corresponding objective evidence shall be documented and reviewed by the NVLAP assessor during the on-site assessment.

3.4.1.3 A processor has one year from the date of application to demonstrate satisfactory performance for initial accreditation. If satisfactory performance is not demonstrated within one year or if retesting is required, additional test and/or administrative fees may be charged.

3.4.1.4 Proficiency testing will be administered by a proficiency-testing laboratory (PTL) that has been qualified by NVLAP. Specific instructions on participation in proficiency testing are included with the accreditation application package. Testing is conducted on a quarterly basis and is conducted over a three-month period (test sequence) beginning the first day of January, April, July and October. After initial accreditation, the proficiency testing schedule for each processor is determined by NVLAP management in consultation with the laboratory and PTL. A participant may start a test sequence only at the beginning of a quarter.

3.4.1.5 A summary of the procedure for participation in the proficiency test follows:

- a) The processor shall submit a total of 15 dosimeters of each model to be used in each category in which testing is desired. The dosimeters shall be submitted to the PTL in three separate groups of five each, one month apart. Each shipment will also require, for each model being tested, at least one shipping control and six extra dosimeters to be used as spares. The first shipment shall include two additional dosimeters of each model to be used for photos (dosimeters may have to be destroyed). All dosimeters will be returned when the test is complete.
- b) Each shipment should arrive at the PTL at least two days prior to the first day of the month in which testing is to be done. Shipments arriving at the PTL after the first of the month in which testing is to be done may be returned unirradiated.
- c) The PTL will irradiate each dosimeter to a known dose and return groups of five to the processor at one-month intervals.
- d) The processor shall read each dosimeter and determine a dose for each category.
- e) The processor shall report the determined doses to the PTL within 30 days of receipt of each dosimeter set. The final report of determined doses, including any changes to previously reported data, shall be provided to the PTL within 30 days of receipt of the third set of dosimeters.

3.4.2 Analyzing and reporting proficiency data

3.4.2.1 Reporting and analyzing the proficiency data includes:

- a) At the completion of a testing quarter, the PTL will compare the processor's data with the known irradiation data, analyze the results, and send a detailed report containing the individual test results and pass/fail evaluation to the processor.
- b) If, for technical reasons, the processor needs to void a reported result in the proficiency test, all the corresponding objective evidence shall be documented and submitted to the PTL prior to the completion of a testing quarter.

3.4.2.2 Copies of the report will be sent to NVLAP to be used in the evaluation of the processor and for use by the NVLAP assessor.

3.4.2.3 The processor shall review the proficiency testing data for potential improvements in the dosimetry measurement system.

3.4.3 Proficiency testing nonconformities

3.4.3.1 If a processor fails to demonstrate the expected performance for whole body dosimetry processing during a proficiency test, the processor shall submit additional whole-body dosimeters for a retest at the next available round of proficiency testing in accordance with the following requirements:

Requirements for retest of whole body dosimeters

Failed in category	Retest in failed category	Retest in failed category + two additional categories
Accident photons	✓	
Protection level photons		✓
Betas		✓
Photon mixtures		✓
Beta/Photon mixtures		✓
Neutron/Photon mixtures	✓	

3.4.3.2 A failure in extremity dosimeter categories will require a retest in each failed category.

3.4.3.3 If satisfactory proficiency test results are not received by NVLAP within six months, NVLAP will remove each failed dosimeter and associated category from the laboratory's scope of accreditation. When the laboratory demonstrates satisfactory proficiency testing, the dosimeter(s) and category(ies) will be added back to the laboratory's scope of accreditation.

3.4.3.4 In the event that a processor fails a category test more than once, fails other categories previously passed, or generally exhibits an erratic pattern in testing, NVLAP management will review all current and previous proficiency testing results and advise the processor on how to proceed. These situations will be handled on a case-by-case basis. Simply passing a category test after multiple attempts may not qualify as satisfactory proficiency.

4 General requirements

4.1 Impartiality

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

4.2 Confidentiality

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 processor shall document the required qualifications for each staff position. The staff information may be kept in the official personnel folders or in separate, official folders that contain only the information that the NVLAP assessor need to review.

6.2.2 The processor shall maintain a list of personnel designated to fulfill NVLAP requirements including: Laboratory Director, NVLAP Authorized Representative, and NVLAP Approved Signatories.

6.2.3 At least one of the personnel dosimetry Approved Signatories shall be experienced in applied radiation dosimetry and knowledgeable in the design and operation of the dosimetry system(s) currently utilized.

6.2.4 The training program and the training materials shall be updated when procedures change.

6.2.5 Staff members shall be retrained when procedures change, or when the individuals are assigned new responsibilities. Each staff member may receive training for assigned duties either through on-the-job training, formal classroom study, attendance at conferences, or another appropriate mechanism.

6.2.6 When key personnel are added to the staff, the notification to NVLAP of key personnel changes shall include a current resume for each new staff member.

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

6.2.8 Individuals hired to perform testing activities are sometimes referred to as "subcontractors." NVLAP does not make a distinction between full-time laboratory employees and individuals hired on a contract. NVLAP requires that the dosimetry laboratory maintain responsibility for and control of any work performed within its scope of accreditation. The processor shall ensure all individuals performing dosimetry processing activities satisfy all NVLAP requirements, irrespective of the means by which individuals are compensated (e.g., the processor must ensure all test personnel receive proper training and are subject to annual performance reviews, etc.).

6.2.9 Training materials that are maintained within the processor shall be kept up-to-date.

6.3 Facilities and environmental conditions

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

6.4 Equipment

6.4.1 The processor shall have adequate facilities and equipment to perform the type(s) of processing for which capability is claimed. Adequate facilities and equipment shall include the following:

- a) sufficient space to perform the processing;
- b) proper shielding of areas from unwanted radiation;
- c) necessary environmental controls;
- d) radiation sources and processing equipment;
- e) safety systems; and
- f) properly calibrated equipment.

6.4.2 When a new dosimeter or system is to replace another, all new items shall be tested and assessed prior to retiring the old items from service. Depending on the timing, this may require that both systems, the old and the new, undergo proficiency testing so that the processor maintains accreditation.

6.4.3 The processor shall maintain adequate backup equipment or systems for key processing steps to be used in the event of failure of primary systems or shall have provisions to utilize the services of another NVLAP-accredited processor in an emergency.

6.4.4 The processor shall notify NVLAP if the processor wishes to change its processing system (e.g., upgrade present system, entirely replace with a new system, or add a new system in addition to the current system). NVLAP management will advise the processor of the required proficiency testing and if an on-site assessment is necessary.

6.4.5 Any equipment used for measurement, dosimeter processing, or quality control shall be periodically calibrated or documented as to indicate the lack of need for periodic calibration.

6.4.6 The reference standards used and the environmental conditions at the time of calibration shall be documented for all calibrations.

6.4.7 Calibration records and evidence of the traceability of the reference standards used shall be made available for inspection during the on-site assessment.

6.4.8 In addition to the information specified in ISO/IEC 17025 and NIST Handbook 150, processing equipment calibration records 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 error;
- d) calibration/verification date and schedule;

- e) identity of the laboratory individual or external service responsible for calibration; and
- f) source of reference standard and traceability.

6.5 Metrological traceability

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

6.6 Externally provided products and services

6.6.1 The processor shall test, in accordance with standard sampling procedures, incoming supplies that affect the accuracy of the processing service. For example, the sampling of incoming supplies would include testing film and characterizing new TLD chips before initial use.

6.6.2 The processor shall use only appropriate, characterized, tested materials, including the following:

- a) dosimeter materials;
- b) badge holders;
- c) filters;
- d) chemicals; and
- e) validated software.

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 Selection and verification of methods

7.2.1.1 The processor shall develop and implement procedures covering all the technical requirements of this handbook.

7.2.1.2 The most recent editions of the documents listed in 1.4 shall be available as references in maintaining the management system.

7.3 Sampling

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

7.4 Handling of test or calibration items

Received dosimeters shall be surveyed for radioactive contamination prior to processing.

7.5 Technical records

7.5.1 Records shall be maintained for at least three years.

7.5.2 Records shall be reviewed by the NVLAP assessor during the on-site assessment either in total or by selected sampling.

7.6 Evaluation of measurement uncertainty

The processor shall develop measurement uncertainty analyses for all dosimeters and radiation types for which it is accredited.

7.7 Ensuring the validity of results

7.7.1 ANSI/HPS N13.11 and ANSI/HPS N13.32 require that the PTL make the test irradiations on a specified phantom. However, the standard does not specify that a processor use such a phantom when making calibration irradiations. If the processor does not use a phantom, suitable factors shall be applied to convert from free-air calibration to on-phantom calibration.

7.7.2 The PTL will provide each participating processor with emission rate, spectrum, and backscatter information on the neutron source used, and calibration irradiation of a set of the processor's neutron dosimeters, which shall be used for ANSI/HPS N13.11 neutron/photon mixtures category.

7.7.3 Data from monitoring activities includes:

- a) The processor shall have procedures for software verification and validation, including process control software (dosimeter handling and identification), dose algorithms, data processing (data analysis and reporting), and record keeping. The IEEE Standard 1012-1998, *IEEE Standard for Software Verification and Validation Assurance Plans* shall be used as a reference. In addition, software version control shall be included in the laboratory document control procedures for all software.
- b) The proficiency tests are performed under controlled conditions and may not precisely reflect the radiation exposure monitored in the field. Algorithms used by a processor to pass proficiency testing may need to have special factors for specific radiation applications. However, the use of special workplace factors shall be done with great care, and the use of algorithms specifically tailored to the proficiency tests is discouraged unless they are shown to be adequate for the radiation

fields monitored by the laboratory. The dose algorithm used for proficiency testing shall be as similar as possible to the one used during normal operations.

- c) Calibration/correction factors used in the dose algorithm(s) can be developed from calibration irradiations provided by the PTL or other laboratories, such as in the case of neutrons. The algorithm shall be available to the assessor for review in order to determine appropriateness and verification of calculations and function.

7.8 Reporting of results

7.8.1 General

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

7.8.2 Common requirements for reports (test, calibration or sampling)

The processor shall meet contract requirements for reporting dose and the requirements specified by appropriate regulatory authorities. The NRC requirements for reporting dose are specified in the Code of Federal Regulations, 10 CFR Part 20, *Standards for Protection Against Radiation*.

7.8.3 Specific requirements for test reports

7.8.3.1 The final report from processors who provide dosimetry services to internal clients (i.e., dosimeters are issued to workers under the same organization, such as a utility company with a dosimetry processing division) shall include the following:

- a) facility name and/or location where dosimeter was issued/worn;
- b) pertinent dates (date dosimeters irradiated, date dosimeters processed, report date, etc.);
- c) description or identification of each dosimeter and/or elements;
- d) explanation of any deviation from the procedures affecting the reported results;
- e) identification of anomalies;
- f) well defined data resulting from the processing; and
- g) name of NVLAP signatory who reviewed, validated, and authorized the individual's dose measurement.

7.8.3.2 The final report from processors who provide dosimetry services to external clients shall include the following:

- a) name and address of processor and client;
- b) pertinent dates;
- c) description or identification of each dosimeter and/or elements;

- d) "Occupational Radiation Exposure Report" or a similar title;
- e) explanation of any deviation from the procedures affecting the reported results;
- f) identification of anomalies;
- g) adequately defined data resulting from the processing; and
- h) signature or reference to person having technical responsibility.

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.

7.11 Control of data and information management

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 system documentation

8.2.1 If the processor uses a computer-based documentation system, the processor should consider the ease of usability by the staff. The processor shall ensure that the requirements of ISO/IEC 17025 are met so that staff is knowledgeable of the online documentation system and can readily retrieve appropriate information.

8.2.2 The processor shall have a method for identifying dosimeters that the processor has received for testing. This identification can be used for verification of the test report and tracking the progress of the test item from receipt until the test report is sent to the client.

8.3 Control of management system documents

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

8.3.2 The processor shall create a cross-reference document allowing the laboratory and the assessors to verify that all requirements of ISO/IEC 17025 and NIST Handbook 150 Annexes A, B and E, as applicable, are addressed in the management system documentation.

8.3.3 A general reference text on statistics shall be available in the laboratory.

8.3.4 The processor shall have copies of applicable referenced standards, practices and procedures.

8.3.5 In addition to the information specified in ISO/IEC 17025, the quality management system and/or supporting management procedures shall include the following:

- a) processing facilities and scope of services offered;
- b) processing equipment inventory including radiation sources used for calibration;
- c) processing equipment calibration, verification, and maintenance practices;
- d) dosimeter models and design specifications;
- e) acceptance criteria for dosimeter holders and materials;
- f) procedures for handling and storing sensitive components and materials;
- g) assembly/disassembly techniques for all dosimeter models used;
- h) procedures for periodic checks on in-service dosimeters;
- i) dosimeter calibration techniques and procedures;
- j) identification and tracking of dosimeters;
- k) handling, control and storage of in-service dosimeters;
- l) actions concerning damaged dosimeters;
- m) instructions to operate all processing equipment, including any operational checks;
- n) data handling and reporting;
- o) actions when test data indicate a possible problem exists; and
- p) policy for utilizing subcontractors.

8.4 Control of records

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

8.5 Actions to address risks 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 actions

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

8.8 Internal audits

8.8.1 The most recent internal audit report shall be available for review during NVLAP on-site assessments.

8.8.2 Previous internal audit reports, as far as three years back, shall be available for review if requested by the NVLAP assessor.

8.8.3 The internal audit shall cover compliance with NVLAP, laboratory management system, regulatory, and contractual requirements.

8.8.4 The processor shall perform at least one complete internal audit of its management system prior to the first on-site assessment. The records will be reviewed before or during the on-site assessment visit.

8.8.5 The processor shall perform at least one complete internal audit of its management system annually.

8.9 Management reviews

8.9.1 Periodic reviews of the management system shall reflect adherence to NVLAP requirements and the laboratory's quality objectives.

8.9.2 The periodic management reviews shall reflect positive aspects of the management system as well as nonconformities.

8.9.3 The most recent management review report shall be available for review during NVLAP on-site assessments.

8.9.4 Previous management review reports, as far as three years back, shall be available for review if requested by the NVLAP assessor.

8.9.5 The processor shall perform at least one complete management review prior to the first on-site assessment. The records will be reviewed before or during the on-site assessment visit.

8.9.6 The processor shall perform at least one complete management review annually.

9 Additional requirements

There are no additional requirements beyond ISO/IEC 17025, NIST Handbook 150 and its associated normative annexes, and any other normative references previously cited in this handbook.