NIST HANDBOOK 150-4 CHECKLIST
IONIZING RADIATION DOSIMETRY TESTING PROGRAM

Instructions to the Assessor: This checklist addresses specific accreditation requirements prescribed in NIST Handbook 150-4, *Ionizing Radiation Dosimetry*.

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

Note: The numbering of the checklist items correlates to the numbering scheme in NIST Handbook 150-4, clauses 1, 3, 4, and 5.

1 General information

1.3 Program description

___ 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.

3 Accreditation process

3.3 On-site assessment

___ 3.3.3 The laboratory shall have its facilities and equipment in good working order and be ready for examination according to the requirements identified in this handbook, NIST Handbook 150, and the laboratory's quality manual.

___ 3.3.4 The laboratory 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.

___ 3.3.6 c) Laboratory staff shall be available to answer questions; however, the NVLAP assessor may wish to review the documents and records alone.

___ 3.3.6 e) All equipment required to process ionizing radiation dosimeters shall be available for review.

___ 3.3.7 The laboratory shall address all nonconformities and provide, within 30 days from the date of the on-site assessment, a response to NVLAP headquarters.

___ 3.3.8 The laboratory 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/HPS 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 must be demonstrated prior to initial accreditation and every two years thereafter.

___ 3.4.1.2 The processor shall demonstrate to the satisfaction of a NVLAP assessor that normal day-to-day processing is done in a manner consistent with that employed in the proficiency test.

3.4.2 Analyzing and reporting proficiency data

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

___ 3.4.3 Proficiency test nonconformities

___ 3.4.3.1 If a processor fails to demonstrate satisfactory 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.

4 Management requirements for accreditation

4.2 Management system

___ 4.2.2 The controlled version of the laboratory management system documentation may be paper-based or computer-based. Version control shall be maintained in either case.

___ 4.2.3 If the laboratory uses a computer-based documentation system, the laboratory should consider the ease of usability by the staff. The laboratory shall ensure that the requirements of NIST Handbook 150 are met so that staff is knowledgeable of the online documentation system and can readily retrieve appropriate information.

___ 4.2.4 The laboratory shall create a cross-reference document allowing the laboratory and the assessors to verify that all requirements of NIST Handbook 150 are addressed in the management system documentation.

___ 4.2.5 The laboratory shall have a method for identifying dosimeters that the laboratory 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.

___ 4.2.6 The laboratory shall develop and implement procedures covering all the technical requirements of this handbook.

___ 4.2.7 The most recent editions of the documents listed in 1.4 shall be available as references in maintaining the management system.

___ 4.2.8 A general reference text on statistics shall be available in the laboratory.

___ 4.2.9 The laboratory shall have copies of applicable referenced standards, practices and procedures.

___ 4.2.10 In addition to the information specified in NIST Handbook 150, the quality manual 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

___ p) policy for utilizing subcontractors

4.6 Purchasing services and supplies

___ 4.6.2 The laboratory 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.

___ 4.6.3 The processor shall use only appropriate, characterized, tested materials, including the following:

___ a) dosimeter materials

___ b) badge holders

___ c) filters

___ d) chemicals

___ e) validated software

4.13 Control of records

___ 4.13.1 Records shall be maintained for at least three years.

4.14 Internal audits

___ 4.14.1 The most recent internal audit report shall be available for review during NVLAP on-site assessments.

___ 4.14.2 Previous internal audit reports, as much as three years back, shall be available for review if requested by the NVLAP assessor.

___ 4.14.3 The internal audit shall cover compliance with NVLAP, laboratory management system, regulatory, and contractual requirements.

___ 4.14.4 The laboratory 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.

4.15 Management reviews

___ 4.15.1 Periodic reviews of the management system shall reflect adherence to NVLAP requirements and the laboratory's quality objectives.

___ 4.15.2 The periodic management reviews shall reflect positive aspects of the management system as well as nonconformities.

___ 4.15.3 The most recent management review report shall be available for review during NVLAP on-site assessments.

___ 4.15.4 Previous management review reports, as much as three years back, shall be available for review if requested by the NVLAP assessor.

___ 4.15.5 The laboratory 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.

5 Technical requirements for accreditation

5.1 General

___ The quality manual shall contain, or refer to, documentation that describes and details the laboratory’s implementation of procedures covering all of the technical requirements in NIST Handbook 150 and in NIST Handbook 150-4.

5.2 Personnel

___ 5.2.1 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.

___ 5.2.2 The personnel dosimetry Technical Director shall be a professional experienced in applied radiation dosimetry who is knowledgeable in the design and operation of the dosimetry system(s) currently utilized.

___ 5.2.3 When key personnel are added to the staff, the notification of changes shall include a current resume for each new staff member.

___ 5.2.4 Laboratories 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 assessors need to review.

___ 5.2.5 The training program shall be updated when procedures change.

___ 5.2.6 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.

___ 5.2.7 Training materials that are maintained within the laboratory shall be kept up-to-date.

___ 5.2.8 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.

___ 5.2.9 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 laboratory shall ensure all individuals performing dosimetry processing activities satisfy all NVLAP requirements, irrespective of the means by which individuals are compensated (e.g., the laboratory must ensure all test personnel receive proper training and are subject to annual performance reviews, etc.).

5.4 Test and calibration methods and method validation

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

5.5 Equipment

___ 5.5.1 A 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

___ f) properly calibrated equipment

___ 5.5.2 The processor shall notify NVLAP headquarters 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.

___ 5.5.3 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, be proficiency tested so that the processor does not lose accreditation.

___ 5.5.4 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.

5.6 Measurement traceability

___ 5.6.1 Any equipment used for measurement, dosimeter processing, or quality control shall be periodically calibrated or documented as to the lack of need for periodic calibration.

5.6.2 - 5.6.4 NIST Handbook 150-4, items 5.6.2 - 5.6.4 are no longer required. See NVLAP Lab Bulletin LB-61-2011 for an explanation of this change.

___ 5.6.5 The reference standards used and the environmental conditions at the time of calibration shall be documented for all calibrations.

___ 5.6.6 Calibration records and evidence of the traceability of the reference standards used shall be made available for inspection during the on-site visit.

___ 5.6.7 In addition to the information specified in 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

___ f) source of reference standard and traceability

5.8 Handling of test and calibration items

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

5.9 Assuring the quality of test and calibration results

5.9.1 Test methods

___ 5.9.1.4 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.

___ 5.9.1.5 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.

5.9.2 Software and algorithms

___ 5.9.2.1 The laboratory is required to 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.

___ 5.9.2.2 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.

___ 5.9.2.3 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.

5.10 Reporting the results

___ 5.10.2 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*.

___ 5.10.3 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

___ c) description of identification of each dosimeter and/or elements

___ d) explanation of any deviation from the procedures affecting the reported results

___ e) identification of anomalies

___ f) adequately defined data resulting from the processing

___ g) name of NVLAP signatory who reviewed, validated, and authorized the individual's dose measurement

___ 5.10.4 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

___ h) signature or reference to person having technical responsibility

NIST HANDBOOK 150-4 CHECKLIST
COMMENTS AND NONCONFORMITIES

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

Item No.	*C or X*	*Comments and/or Nonconformities*

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