NIST HANDBOOK 150-4 CHECKLIST

IONIZING RADIATION DOSIMETRY

Instructions to the Assessor: This checklist addresses specific accreditation criteria prescribed in NIST Handbook 150-4, Ionizing Radiation Dosimetry (DOS). Included also are instructions and comments sheets used for observing actual demonstrations of the performance of selected test methods. These criteria do not supersede the *Criteria for Accreditation* based on NIST Handbook 150, which are addressed in the NIST Handbook 150 Checklist.

Place an “X” beside any of the following items that represent a nonconformity. Place a “C” beside each item on which you are commenting for other reasons. Record the item number and your nonconformity explanation and/or comments on the comment sheet(s). Place a check beside all other items you observed or verified at the laboratory. Indicate N/A for items not applicable to the laboratory's management system.

Note: The numbering of each item correlates to the numbering scheme of the clauses in NIST Handbook 150-4.

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 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 supplies and services

_____ 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 this handbook.

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 Proper performance of the dosimetry processing system *shall* be verified using dosimeters that have been irradiated in well-characterized radiation fields that are traceable to a national standard; such that, over a two-year cycle at least five dosimeters have been tested in each category in the laboratory's scope of accreditation.

_____ 5.6.3 NVLAP proficiency test results *shall* not be used to fulfill the performance verification requirements.

_____ 5.6.4 The dosimeters *shall* not be specially selected or processed for performance verification so that the tests are representative of normal processing.

_____ 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 items

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 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

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 comments with a "C" and nonconformities with an "X." If additional space is needed, make copies of this page (or use additional blank sheets).

Item No.	Comments and/or Nonconformities