National Voluntary
Laboratory Accreditation
Program

NVLAP

U.S. DEPARTMENT OF COMMERCE
National Bureau of Standards

Dosimetry LAP Handbook

OPERATIONAL AND TECHNICAL REQUIREMENTS
OF THE
LABORATORY ACCREDITATION PROGRAM
FOR
PERSONNEL DOSIMETRY PROCESSORS

NBSIR 85-3170

U.S. DEPARTMENT OF COMMERCE
National Bureau of Standards
Office of Product Standards Policy
Gaithersburg, Maryland 20899

May 1985

DOSIMETRY LAP HANDBOOK
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U.S. DEPARTMENT OF COMMERCE
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U.S. DEPARTMENT OF COMMERCE, Malcolm Baldrige, *Secretary*
NATIONAL BUREAU OF STANDARDS, Ernest Ambler, *Director*

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I. THE DOSIMETRY LAP AT A GLANCE

This document describes operational and technical requirements for the Laboratory Accreditation Program (LAP) for Personnel Dosimetry Processors (Dosimetry LAP). All of the steps leading to accreditation are discussed. Technical requirements are explained indicating how the NVLAP criteria are applied.

The Dosimetry LAP was established in 1982 in response to a request from the Nuclear Regulatory Commission (NRC). The purpose of the LAP is to (1) improve the accuracy of reported dose measurements made by Personnel Dosimetry Processors and, (2) to give recognition to competent processors.

Accreditation is available to any organization (processor) that processes personnel radiation dosimeters used to monitor individual exposure to any of the ionizing radiation categories specified in American National Standard N13.11 "Criteria for Testing Personnel Dosimetry Performance", (ANSI N13.11).

Definitions of terms used in the LAP are consistent with those stated in ANSI N13.11. The following are restated here since they are used extensively in this document.

Processor - A supplier of personnel dosimetry services. In relation to this document "processor" is synonymous with "laboratory".

Dosimeter - Radiation sensitive element(s) in a holder (the holder being considered a part of the dosimeter) used to provide a lifetime cumulative personnel irradiation record of an individual.

Note: (1) References made throughout this document to ANSI N13.11 refer to the 1983 version; and (2) the term "dose" as used in this document means "dose equivalent."

Processing covered: All personnel dosimeters (TLD, film etc.) used to monitor whole body and skin dose in any of the eight radiation categories of ANSI N13.11

Period of accreditation: Two years

On-site visit frequency: Two years

Proficiency testing according to: ANSI N13.11

Proficiency testing frequency: once prior to accreditation, once during each accreditation period thereafter.

Fees: Based on the number of processing facilities involved, the number of dosimeter types and the number of radiation categories for each dosimeter.

Assessors: Peers selected from the field of dosimetry.

II. INTRODUCTION

Background

The U.S. Department of Commerce, National Bureau of Standards (NBS) administers the National Voluntary Laboratory Accreditation Program (NVLAP). NVLAP's function is to accredit public and private testing laboratories based on evaluation of their technical qualifications and competence for conducting specific test methods in specified fields of testing. Accreditation is granted on the basis of conformance with criteria published in the Code of Federal Regulations as part of the NVLAP procedures (15 CFR Part 7). (See Appendix.)

This document is intended for use by staff of accredited laboratories, those seeking accreditation, other laboratory accreditation systems, and others needing information on the requirements for NVLAP accreditation under this LAP. This document is generally included in the **NVLAP Application Package** along with **General Application Forms, Test Method Selection Lists**, and other materials needed to apply for or renew accreditation. It presents the administrative and operational procedures and technical requirements of the LAP and should be retained and be readily accessible to laboratory personnel.

NVLAP Accreditation

Accreditation is granted only after thorough evaluation of the applicant has demonstrated that all NVLAP criteria have been met. The accreditation is formalized through issuance of a Certificate of Accreditation, Scope of Accreditation and publicized by announcement in various government and private media.

NVLAP accreditation is available to commercial laboratories, manufacturer's in-house laboratories, university laboratories, Federal, State, and local government laboratories. Foreign- based laboratories may also be accredited by NBS if they meet the same requirements as domestic laboratories and pay any additional fees required.

Why NVLAP Accreditation ?

The reasons why a laboratory may wish to be accredited include: legal requirements such as regulations or codes, contract specifications, and the desire to be recognized as being demonstrably competent to meet the needs of its clients.

For accreditation to be meaningful, it must be granted by a clearly credible organization. NVLAP provides an unbiased third party evaluation and recognition of performance as well as expert technical assistance to upgrade laboratory performance.

Testing Laboratory Defined

NVLAP defines a "testing laboratory" as an organization that provides services to measure, examine, test, calibrate, or otherwise determine the characteristics or performance of products or systems.

Accreditation Defined

NVLAP accreditation means recognition of a testing laboratory's competence to perform specific test methods in specified fields of testing. It means that the laboratory's quality system, staff, facilities and equipment, calibration procedures, test methods and procedures, records, and test reports, have been evaluated and found to meet NVLAP criteria. NVLAP accreditation does not mean a guarantee (certification) of laboratory performance or product test data; it is a finding of laboratory competence.

For further information about NVLAP, or assistance in understanding and meeting the NVLAP requirements and criteria, please write or call:

NVLAP
National Bureau of Standards
ADMIN A531
Gaithersburg, MD 20899

Phone: 301-921-3431

III. ADMINISTRATIVE AND OPERATIONAL REQUIREMENTS

Note: Administrative and operational requirements presented here are generally applicable to all NVLAP programs. Technical and proficiency requirements are specifically applicable to this LAP.

LABORATORY CODE NUMBER

Each participating laboratory is assigned a four-digit laboratory code number. The code number is used by the NVLAP staff for identification, filing, recordkeeping, and database management. Participants are requested to put their Lab Code number on all correspondence with NVLAP.

ACCREDITATION PERIOD

Accreditation is granted for a period specified in the LAP Application Package (usually one year). The accreditation period begins on one of four dates: January 1, April 1, July 1, or October 1. Once a laboratory has been assigned an accreditation date, it retains that date as long as it remains in the program. Accreditation expires and is renewed on that date.

RENEWAL

Each participating laboratory will be sent a renewal Application Package, well in advance of the expiration date of its accreditation, to allow sufficient time to complete the renewal process. The renewal application contains the same forms used for initial application, and the laboratory need only indicate where changes have occurred from the previous period in personnel, equipment, facilities, or the scope of accreditation desired.

With the exception of an initiation fee for new applicants, the technical requirements and fees are the same as for initial accreditation. The application and fees must be received by NBS prior to expiration of the laboratory's current accreditation to avoid a lapse in accreditation.

PUBLICIZING ACCREDITATION STATUS

BY NVLAP

NVLAP publishes an annual Directory of Accredited Laboratories. The Directory contains the name and address, scope of accreditation, contact person, and the accreditation renewal date for each accredited laboratory. Supplements to the Directory are published quarterly to cover interim accreditation actions including initial accreditations, renewals, suspensions, terminations, and revocations. The Directory is distributed nationally and internationally to manufacturers, suppliers, retailers, professional and trade associations, code groups, and government agencies.

BY LABORATORIES

Accredited laboratories are encouraged, within specified limits, to publicize their accredited status. The major restriction is that advertising must not imply product certification by NBS or the U.S. Government. Laboratories and their clients may not reference their accredited status in consumer media, in product advertising, or on product labels, containers or packaging.

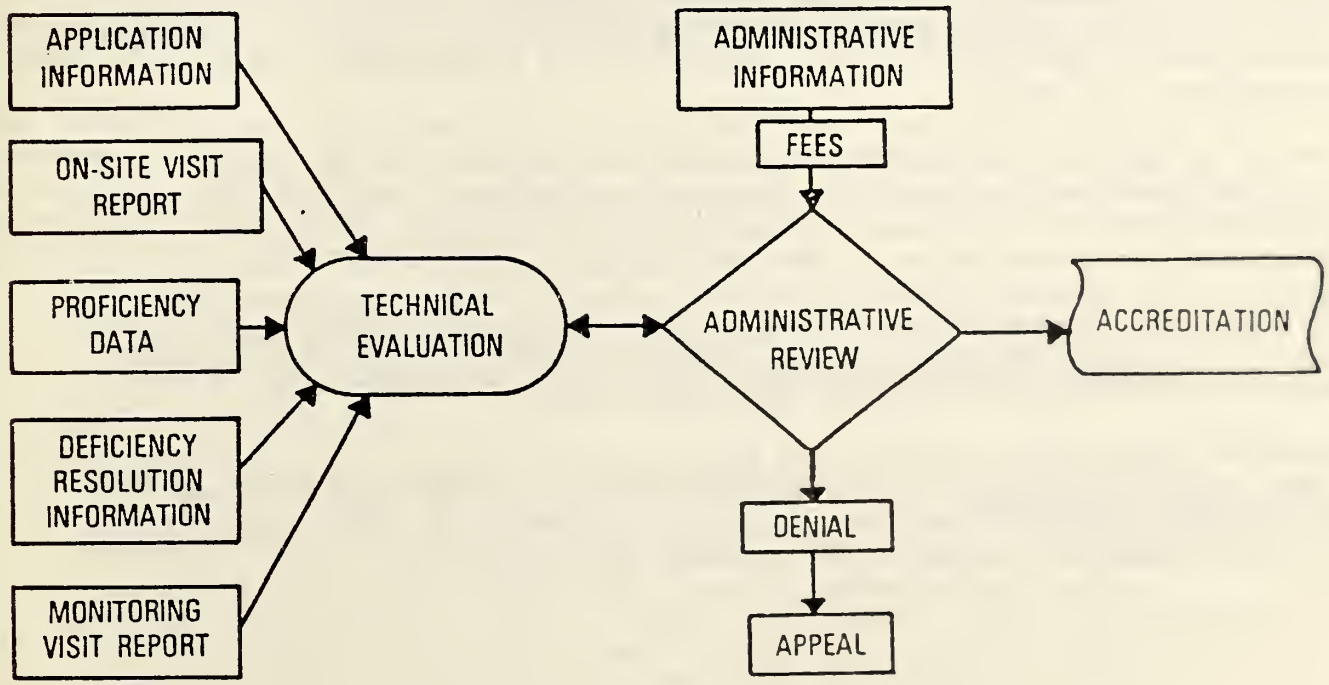
A laboratory may cite its accredited status and use NVLAP logos on reports, stationery, and in business and trade publications provided that it is clearly indicated that it is the laboratory which is accredited. NVLAP Lab Bulletin No. 3A provides more detailed guidance on how a laboratory may publicize its accredited status and the statements which may be made. (See Appendix.)

COMPLIANCE WITH EXISTING LAWS

Accreditation does not relieve the laboratory of the need to observe and comply with existing Federal, State, and local statutes, ordinances, or regulations that may be applicable to its operations, including consumer protection and antitrust laws.

ACCREDITATION PROCESS

Accreditation is granted following successful completion of a process which includes submission of an application and payment of fees by the laboratory, an on-site assessment, resolution of deficiencies identified during the on-site assessment, participation in proficiency testing, technical evaluation, and administrative review. A diagram of the accreditation process is shown in the figure below.



APPLICATION AND FEES

An Application Package is sent to a laboratory on request. It includes: General Application Forms, a Fee Calculation Sheet, and this document. The General Application Form must be completed and signed by an authorized representative of the laboratory. The authorized representative is one who can act on behalf of the laboratory and commit it to fulfill the NVLAP requirements. Before completing and signing the application, the authorized representative should review all documents and become totally familiar with NVLAP requirements. Although other laboratory staff may be designated to perform activities, such as handling proficiency testing or receiving an assessor, the authorized representative is the only one who can authorize a change in the scope or nature of the application.

In general, the accreditation fee is composed of several parts, some of which are fixed while others depend on the scope of accreditation desired and the specifics of the LAP. The total accreditation fee must be paid before accreditation can be granted. The individual parts of the accreditation fee include, as appropriate: a one-time LAP initiation fee for new applicants, an administrative fee, test method fees, an assessment fee, and proficiency testing fees. The fees for this LAP are shown in the Fee Calculation Sheet included in the LAP Application Package.

The laboratory will be scheduled for an on-site assessment after payment of all required fees and will be notified of any additional information which must be supplied and of any applicable proficiency testing requirements which must be completed for the technical evaluation.

APPROVED SIGNATORY

Under NVLAP criteria, an accredited laboratory must have one or more individuals or laboratory positions designated as having responsibility for signing "all test reports endorsed with the NVLAP logo." This is the person(s) to whom NVLAP, laboratory clients, or others would go in case of questions or problems with the report.

There is no formal requirement for nomination or approval of persons or laboratory positions designated as approved signatories. The laboratory should inform NVLAP of its appointments by completing the appropriate sections in the application for accreditation. Approved signatories should be: persons or positions with adequate responsibility or authority within the organization, with adequate and appropriate technical capabilities, and without conflict of interest. The approved signatory may be the authorized representative who is responsible for signing the NVLAP Application Form.

Laboratory test reports carrying the NVLAP logo need not be signed individually by the approved signatory. Test report forms may be preprinted with the required information. Forms that are electronically or computer generated may have the information printed along with the test results.

TECHNICAL EXPERTS

NVLAP uses Technical Experts (TEs) as assessors and evaluators. These are individuals knowledgeable in the testing field being evaluated. They may be engineers or scientists currently active in the field, consultants, college professors or retired persons. They are selected on the basis of their professional and academic achievements, experience in the field of testing, management experience, and tact in dealing with people. Their services are generally contracted as required; they are not NVLAP staff members.

Assessors are TEs selected to conduct an on-site assessment of a particular laboratory on the basis of how well their individual experience matches the type of testing to be assessed, as well as absence of conflicts of interest. The laboratory has the right to appeal the assignment of an assessor and may request an alternate.

Evaluators are TEs selected to review the record of the laboratory as a whole, including the application, assessment report, deficiencies, corrections to deficiencies, and proficiency test results and, based on this record, to recommend whether or not a laboratory should be accredited. The evaluators are matched to the type of testing being evaluated and are selected to avoid conflicts of interest.

ON-SITE ASSESSMENT

Before initial accreditation and periodically thereafter, an on-site assessment of each laboratory is conducted to determine compliance with the NVLAP criteria. The assessment is conducted by one or more NVLAP assessors selected on the basis of their expertise in the field of testing to be reviewed. Assessors use checklists developed by NVLAP so that each laboratory receives an assessment comparable to that received by others. However, assessors have considerable latitude to make judgments about a laboratory's compliance with the NVLAP criteria, depending on the assessor's experience and the unique circumstances of the laboratory.

Each laboratory will be contacted to arrange a mutually agreeable date for an asessment. The time needed to conduct an assessment varies, but two days is the norm. Every effort is made to conduct an assessment with as little disruption as possible to the normal operations of the laboratory. During the assessment the assessor will carry out the following functions:

- meet with management and supervisory personnel responsible for the laboratory's activities (for which accreditation is being sought) to review the assessment process with the individuals involved and to set the assessment agenda.

- examine the quality assurance system employed by the laboratory. The assessor may select and trace the history of one or more samples from receipt to final issuance of test reports. The assessor will conduct a thorough review of the laboratory's quality manual or equivalent, evaluate the training program, examine notebooks or records pertaining to the samples, check sample identification and tracking procedures, determine whether the appropriate environmental conditions are maintained, and examine copies of completed test reports.

- review records of periodic internal audits, use of check samples or participation in round robin testing or other similar programs.

- review personnel records including resumes and job descriptions of key personnel, competency evaluations for all staff members who routinely perform the testing for which accreditation is sought, calibration or verification records for apparatus used, test reports, and sample control records.

- observe demonstrations of testing techniques and discuss them with the technical personnel to assure their understanding of the procedures.

- examine major equipment, apparatus, and facilities.

At the conclusion of the assessment, the assessor will conduct an exit briefing to discuss his or her observations with appropriate laboratory staff and call attention to any deficiencies uncovered. A written summary of any deficiencies discussed will be left at the laboratory. The assessor will forward the assessment forms and a written summary to NBS.

> If deficiencies have been noted, the laboratory must, within 30 days of the date of this notification provide NVLAP with documentation or certification, by the authorized representative, that the specified deficiencies have been corrected or that specific actions are being taken to correct the deficiencies.

A laboratory applying for initial accreditation may request an extension to complete required corrections.

If any deficiencies are noted at laboratories which are currently accredited, such deficiencies must be corrected within 30 days after notification or the laboratory may face possible revocation, suspension, or expiration of its accreditation. Any test equipment that is identified as out-of-calibration, should not be used until corrective action has been completed. All deficiencies noted for corrective action will be subject to thorough review and verification during subsequent assessments and technical evaluations.

MONITORING VISITS

In addition to regularly scheduled assessments, monitoring visits may be conducted by assessors or by NBS staff at any time during the accreditation period. Monitoring visits may occur for cause or on a random selection basis. These visits serve to verify reported changes in the laboratory's personnel, facilities, and operations or to explore possible reasons for poor performance in proficiency testing.

The scope of a monitoring visit may range from checking a few designated items to a complete review. Failure to cooperate with NVLAP assessors will be grounds for initiation of adverse accreditation action. No additional fee is required for the monitoring visit.

PROFICIENCY TESTING

Proficiency testing is an integral part of the NVLAP accreditation process. Demonstration of appropriate facilities, equipment, personnel, etc. is essential, but may not be sufficient for the evaluation of laboratory competence. The actual determination of test data using special proficiency testing samples provides NVLAP with a way to determine the overall effectiveness of the laboratory.

Proficiency testing is a process for checking actual laboratory testing performance, usually by means of interlaboratory comparisons. Each LAP has unique proficiency testing requirements. The data are analyzed by NVLAP and summary reports of the results are sent back to the participants.

For many test methods, results from proficiency testing are very good indicators of a laboratory's testing capability. Information obtained from proficiency testing helps to identify problems in a laboratory. When problems are found, NVLAP staff members work with the laboratory staff to solve them. If problems with the test method are suspected, NVLAP provides information to the appropriate standards-writing bodies.

The specific proficiency testing requirements for this LAP are included in Section V of this document.

TECHNICAL EVALUATION

After a laboratory has completed all the technical requirements of a LAP and is ready for an accreditation action, a final technical evaluation is conducted by experts chosen for their experience and knowledge of the pertinent test methods. They review records on each applicant laboratory and base their evaluation on:

- information provided on the application;
- on-site assessment reports;
- actions taken by the laboratory to correct deficiencies;
- results of proficiency testing; and
- information from any monitoring visits of the laboratory.

If the technical evaluation reveals additional deficiencies, written notification describing them will be made to the laboratory. The laboratory must respond within 30 days of such notification and provide documentation or certification by the authorized representative that the specified deficiencies have been corrected. Clarification of some issues may be requested by telephone. All deficiencies must be corrected before accreditation can be granted or renewed.

ADMINISTRATIVE REVIEW

After the technical evaluation has been completed, the NVLAP staff prepares an administrative recommendation that the laboratory either be granted or denied accreditation. This recommendation is based on a review of the technical evaluation and other records to ensure that all NVLAP technical, financial and administrative obligations have been satisfied.

ACCREDITATION ACTIONS

Acting for the Director of NBS, the Director of the NBS Office of Product Standards Policy makes the following decisions.

Accreditation — If accreditation is recommended, the recommendation forms the basis for granting accreditation. A **Certificate of Accreditation** will be issued to the laboratory.

Denial — If denial is recommended, the laboratory is notified of a proposal to deny accreditation and the reason(s) therefor.

Suspension — If a laboratory is found to have violated the terms of its accreditation, the accreditation can be suspended. The laboratory will be notified of the reasons for and conditions of the suspension and the action(s) that the laboratory must take to have accreditation reinstated.

Revocation — If a laboratory is found to have violated the terms of its accreditation, the laboratory is notified of a proposal to revoke accreditation and the reasons therefor. The laboratory may be given the option of voluntarily terminating accreditation. If accreditation is revoked, the laboratory must return its **Certificate of Accreditation** and cease use of the NVLAP logo on any of its reports, other correspondence, or advertising.

If denial or revocation has been proposed, the laboratory may request a hearing, under United States Code 5 U.S.C. 556, within 30 days of the date of receipt of the notification. If a hearing is not requested, the action becomes final upon the expiration of that 30-day period.

After a participant's accreditation has been terminated, whether voluntarily or through adverse action, the accreditation certificate must be returned to NVLAP. If a laboratory elects not to renew or wishes to voluntarily terminate its accreditation at any time, the notification of such intention should be forwarded to NBS in writing.

IV. TECHNICAL REQUIREMENTS

The requirements discussed in this section interpret the NVLAP criteria for application to the Dosimetry LAP. These requirements do not supersede the published NVLAP criteria which are included in the Appendix.

SCOPE OF THE LAP

A processor may be accredited to process specific dosimeters of its choice in any one or more of the radiation categories listed below:

I. Accidents, Low energy photons
II. Accidents, High energy photons
III. Protection, Low energy photons
IV. Protection, High energy photons
V. Protection, Beta particles
VI. Protection, Photon mixtures (any combination of categories III & IV)
VII. Protection, Mixtures photons and beta particles (any combination of categories IV & V)
VIII. Protection, Mixtures fission neutrons and high energy photons

Only dosimeter types/models which document whole body and skin dose may be included under the accreditation. Accreditation is not applicable to the processing of extremity dosimeters or pocket ionization chambers. Nothing in this LAP is intended to preclude a processor from providing additional, non-accredited services or research related to improved dosimetry such as personnel extremity or environmental or area monitoring.

To be granted accreditation, a processor must satisfy the NVLAP criteria and must also demonstrate proficiency in processing each dosimeter model/type it intends to use in each radiation category for which accreditation is desired, according to ANSI N13.11. The scope of accreditation will specify the model(s)/type(s) of dosimeters and radiation category(ies) which are covered. Additional models/types of dosimeters may be added to the scope of accreditation after proficiency is demonstrated for the additional dosimeter(s) in the category(ies) desired.

Processors may utilize dosimeters and processing techniques of their choice. However, once accredited, the processing technique(s) and dosimeters used in the normal conduct of work must be the same as were used in demonstrating proficiency. If a processor encounters radiation fields from sources other than those specified in ANSI-N13.11, the evaluation procedures used may be different from that used in the proficiency testing. In such cases the assessor will review the actions taken.

If any changes or deviations from the specified dosimeters or processing techniques occur, it will be the responsibility of the processor to provide evidence that such changes lead to results that are technically equivalent to the accredited processing activities. Determination of technical equivalence will be made by technical experts.

If the changes or deviations in the dosimeters or techniques are not considered to provide results that are technically equivalent the new dosimeters and/or techniques will not be covered by the accreditation until they have been fully evaluated and/or satisfactory performance demonstrated in accordance with ANSI N13.11.

In some instances, an organization may have more than one facility in which processing functions are performed. When this situation occurs a decision must be made as to whether the processing facilities are to be accredited separately or as one "system of facilities".

To facilitate the decision, NVLAP will use the following definition of a "main facility". Any facility meeting all of the criteria in this definition will require a separate accreditation. A facility which does not meet all these criteria and is subservient to a main facility will be considered a sub-facility and may be included with the main facility in the accreditation of a system. A selected number of a systems sub-facilities will receive an on-site visit.

A main facility is a facility that:

- Accepts full responsibility for all personnel dosimeter processing done by itself or a system of which it is a part; and,

- Exerts technical direction and quality assurance management of all its processing activities or those in the system; and,

- Has available processing equipment and dosimeters which are the same or provide results that are technically equivalent to those employed at each processing facility in a system of which it is a part.

QUALITY ASSURANCE SYSTEM

The key to a properly functioning organization is that it follows a documented system of procedures and practices which assure the quality of its services. To qualify for accreditation, an applicant must demonstrate that the quality systems used ensure the technical integrity of the work.

DOCUMENTATION

A processor must have up-to-date documentation which thoroughly describes all its procedures and practices. The written descriptions should contain such items as the method of implementation, responsible personnel, recordkeeping system, operating procedures, procedures to employ in the event of unusual or non-standard circumstances, and scheduling. Written descriptions should include at least the following topics:

- Organizational chart;
- Processing facilities and scope of services offered;
- Job/position description for all processing personnel;
- Personnel training procedures;
- Personnel competency assurance procedures;

- Processing equipment inventory including radiation sources used for calibration;
- Processing equipment calibration, verification, and maintenance practices;
- A test plan (processing procedure) for each test category processed;
- Dosimeter models and design specifications;
- Acceptance criteria for dosimeter holders and materials;
- Procedures for handling and storing sensitive dosimeter components and materials;
- Assembly/disassembly techniques for all dosimeter models used;
- Procedures for periodic checks on in-service dosimeters;
- Dosimeter calibration techniques and procedures;
- Identification and tracking of dosimeters;
- Handling, control and storage of in-service dosimeters;
- Actions concerning damaged dosimeters;
- Instructions to operate all processing equipment including any operational checks;
- Data handling and reporting; and
- Actions when test data indicate a possible problem exists.

This documentation should be in the form of a manual but may be individual sheets in various locations throughout the facility. If individual sheets are used, a central reference document must be available to indicate where the sheets may be found. The documentation must be in a format and style which can be easily understood by technicians. It must be readily accessible to all staff members.

PERSONNEL

Training:

Each new staff member must be trained for assigned duties and existing staff members must be retrained when processing equipment and/or procedures are changed or they are assigned new responsibilities. Each staff member must receive (or have had) training for assigned duties either through on-the-job training, formal classroom sessions or through technician certification programs.

Competency:

In addition to training, the supervisor must evaluate the competency of each staff member by observing the performance of each processing procedure each staff member is authorized to conduct. The performance observation must be conducted at least annually by the immediate supervisor or his designee. A record of the staff member's performance must be placed in the personnel file, dated and signed by the supervisor.

Technical Director:

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. This individual should have the technical competence to establish dosimetry programs (if required) and the supervisory capability to direct the work of professionals and technicians in the dosimetry area. Responsibility for the quality assurance program may reside with the technical director or with another individual having knowledge and experience in quality assurance and who has a direct line of communication to the technical director and other organizational management.

The assessor will review resumes or other information to substantiate the qualifications of the technical director and all key individuals.

Any organizational or personnel changes that could affect the performance of the dosimetry processing service (e.g., change of Technical Director, technical supervision, responsibility for quality assurance program) shall be reported to NVLAP within 30 calendar days of such change.

EQUIPMENT AND FACILITIES

A processor must have adequate equipment and facilities to perform the type(s) of processing for which capability is claimed. This includes adequate space to perform the processing, proper shielding of areas from unwanted radiation, environmental controls, adequate processing equipment and radiation sources, adequate safety systems, and either properly calibrated laboratory standard equipment for verifying system performance or access to the services of a competent calibration laboratory.

There also must be adequate backup equipment or systems for key processing steps, to be used in the event of failure of primary systems, or provisions to utilize the services of another NVLAP accredited processor on an emergency basis.

Examples of equipment required for film processing include:

- Fresh chemicals to develop and fix film;
- Adequate darkroom;
- Proper storage facility to eliminate environmental, chemical or radiation damage of unexposed film;
- Densitometer(s) adequate to support workload; and
- System to characterize dose-density relationship for each film type and film emulsion batch in each radiation category used.

Examples of equipment required for TLD processing include:

- Proper annealing equipment;
- Adequate apparatus to read thermoluminescent level;
- Proper storage facilities to eliminate environmental, chemical or radiation damage of TLD's; and
- System to characterize dose-TLD reading relationship for each TLD or TLD batch in each radiation category used.

EQUIPMENT MAINTENANCE AND CALIBRATION

All equipment used to process dosimeters and to perform quality control must be adequately maintained so that it can accomplish the required function.

Any equipment used for measurement, dosimeter processing, or quality control that is inherently subject to change due to use or passage of time, must be periodically calibrated. Calibration means comparison with a reference standard so that the performance of a measuring instrument, or the output of a radiation source, may be determined with sufficient accuracy.

Proper performance of the dosimetry processing system must be periodically verified using dosimeters that have been irradiated in well-characterized radiation fields.

Calibrations of all equipment including the dosimetry processing system, and characterization of radiation fields, may be performed by the processor or by an external calibration service. All calibrations and characterizations must be done against reference standards that are traceable to national standards maintained by NBS or by an equivalent foreign national standards authority. To be traceable means the ability to show that appropriate documented actions were taken to compare (either directly or indirectly) a reference standard with the national standard.

The reference standards used and the environmental conditions at the time of calibration must be documented for all calibrations. Calibration records and evidence of the traceability of the reference standards used must be made available for inspection during the on-site visit.

Processing equipment calibration (or verification) records should include the following: equipment name or description; model, style, or serial number; manufacturer; notation of all equipment variables requiring calibration or verification; the range of calibration/verification; the resolution of the instrument and its allowable error; calibration/verification date and schedule; date and result of last calibration; identity of the laboratory individual or external service responsible for calibration; source of reference standard and traceability.

RECORDKEEPING

A processor must maintain a functional recordkeeping system. This means that records must be easily accessible, in some logical order and contain complete information on the subject. Records covering the following items are required and will be reviewed during the on-site visit either in total or by selected sampling:

- Staff training dates and results;
- Staff competency review dates and results;
- Processing equipment calibration and maintenance;
- Results of incoming inspection of dosimeter materials;
- Comprehensive logs of processing activities;

- Results of internal and external equipment checks, measurement quality assurance programs, internal audits, etc.;
- Test data and reports; and
- Tracking and logging of dosimeters processed

Dosimeter tracking and logging records should trace the movement of each dosimeter through the processing facility from its receipt through all the tests performed to the final test report. Dates, times, condition of item and personnel involved should all be included.

FINAL REPORT

In the report to the client it must be made completely clear exactly what the reported numbers mean so that they can be used appropriately. A processor does not have to report the processing results in terms of specific quantities or specific units.

The final report to the client must include:

- Name and address of processor;
- Pertinent dates and identification of dosimeter including client and corresponding processor identification codes;
- Client name;
- Description or identification of each dosimeter and/or elements;
- "Occupational Radiation Exposure Report" or a similar title;
- An explanation of any deviation from the procedures routinely used in processing dosimeters which may affect the reported results;
- Identification of anomalies;
- Signature or reference to person having technical responsibility; and
- Adequately defined data resulting from the processing.

Records of these reports must be maintained for at least three years.

V. PROFICIENCY TESTING

In order to be eligible for accreditation under the Dosimetry LAP, each processor must demonstrate satisfactory performance in accordance with ANSI N13.11-1983, "Criteria for Testing Personnel Dosimetry Performance" for each dosimeter model it intends to use, in each test category for which accreditation is desired. Proficiency must be demonstrated prior to initial accreditation and prior to renewal.

Although demonstration of proficiency for the desired dosimeter/category combinations is required to gain accreditation, there is nothing in ANSI N13.11 which requires that a processor's normal day to day processing be conducted in any specific way. However, the NVLAP criteria do require that a processor adequately demonstrate to the satisfaction of the TEs, that normal processing is done in a manner consistent with that employed in the proficiency test.

Proficiency testing will be administered by a proficiency testing laboratory (PTL) contracted by NBS. Materials included with the accreditation application package will provide specific instructions on participation in proficiency testing. The PTL will offer an opportunity to participate in a test sequence at least once every three months. A processor has two years to demonstrate satisfactory performance. If satisfactory performance is not demonstrated within two years reapplication will be necessary and an additional administrative fee will be required.

A summary of the procedure for the proficiency test is as follows:

- A processor must submit 15 dosimeters of each model to be used in each category in which testing is desired. The dosimeters must be submitted to the PTL in three separate groups of 5 each, one month apart. Each shipment will also require at least one shipping control and three spares. All dosimeters will be returned when the test is complete.

- The PTL will administer a known dose to dosimeters and return them to the processor in groups of 5 at one-month intervals.

- The processor must read each dosimeter and determine a dose. Dosimeters irradiated in categories I, II, and VIII will be identified by category by the PTL. Dosimeters irradiated in categories III, IV, V, VI and VII will not be identified by category, and it will be the responsibility of the processor to determine the dose for each dosimeter without prior knowledge of irradiation category.

- The processor must report the determined doses to the testing laboratory.

- The PTL will analyze the reported data and compare them with the known irradiation data to ascertain if the processor demonstrated satisfactory performance.

RETEST

If a processor fails to demonstrate satisfactory performance in one or more categories during a test sequence, the processor must submit additional dosimeters for a retest sequence in accordance with the following retest requirements:

- A failure in Categories I, II or VIII will require retest in the failed category(ies) only.

- A failure in Categories III, IV, V, VI or VII will require retest as follows:

  Processors participating in 3 categories or less and failing the proficiency test in at least one of them will be required to retest in all categories attempted. Processors participating in 4 or 5 categories and failing in any one of these will require retest in the failed category and in two additional categories unknown to the processor. Failure in two or more categories will require retest in all of the categories attempted.

Each processor who fails a test will be notified by mail of any required retesting and of the cost.

SYSTEM CALIBRATION

All testing (and calibration) irradiations are done with perpendicular incidence only. In order for a processor to process dosimeters for the proficiency test, the system used will need to be calibrated with the same source types, incidence, and spectra as used by the PTL. ANSI N13.11 requires that the PTL make the test irradiations on a specified phantom. However, the standard does not specify that a processor must use such a phantom when making calibration irradiations. The processor has the option to use a phantom in making calibration irradiations. If the processor does not use a phantom then suitable factors must be applied to convert from free-air calibration to on-phantom calibration.

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 processors neutron dosimeters which will be used for category VIII testing.

APPENDICES

NVLAP Accreditation Criteria

NVLAP Lab Bulletin No.3A

NVLAP Accreditation Criteria

SUBPART D - CONDITIONS AND CRITERIA FOR ACCREDITATION

Sec. 7.31 Application of accreditation conditions and criteria.

(a) To become accredited and maintain accreditation, a laboratory must meet the conditions for accreditation set out in Section 7.32 and the criteria set out in Section 7.33 as tailored for specific LAPs.

(b) The conditions leading to accreditation include acceptance of the responsibilities of an accredited laboratory and requirements for information disclosure.

(c) The criteria are tailored and interpreted for the test methods, types of test methods, products, services or standards of the relevant LAP. These tailored criteria are the technical requirements for accreditation developed through the procedures of Section 7.15.

(d) In applying the conditions, criteria, and technical requirements for accreditation, the Director of OPSP shall not:

(1) Prohibit accreditation solely on the basis of a laboratory's affiliation or nonaffiliation with manufacturing, distributing, or vending organizations, or because the laboratory is a foreign firm; or

(2) Develop, modify, or promulgate test methods, standards, or comparable administrative rules.

Sec. 7.32 Conditions for accreditation.

(a) To become accredited and maintain accreditation, a laboratory shall agree in writing to:

(1) Be assessed and evaluated initially and on a periodic basis;

(2) Demonstrate, on request, that it is able to perform the tests representative of those for which it is seeking accreditation;

(3) Pay all relevant fees;

(4) Participate in proficiency testing as required.

(5) Be capable of performing the tests for which it is accredited according to the latest version of the test method within one year after its publication or within another time limit specified by the Director of OPSP;

(6) Limit the representation of the scope of its accreditation to only those tests or services for which accreditation is granted;

(7) Limit all its test work or services for clients to those areas where competence and capacity are available;

(8) Limit advertising of its accredited status to letterheads, brochures, test reports, and professional, technical, trade, or other laboratory services publications, and use the NVLAP logo under guidance provided by the Director of OPSP;

(9) Inform its clients that the laboratory's accreditation or any of its test reports in no way constitutes or implies product certification, approval, or endorsement by NBS;

(10) Maintain records of all actions taken in response to testing complaints for a minimum of one year;

(11) Maintain an independent decisional relationship between itself and its clients, affiliates, or other organizations so that the laboratory's capacity to render test reports objectively and without bias is not adversely affected;
(12) Report to the Director of OPSP within 30 days any major changes involving the location, ownership, management structure, authorized representative, approved signatories, or facilities of the laboratory; and
(13) Return to the Director of OPSP the certificate of accreditation for possible revision or other action should it:
(i) be requested to do so by the Director of OPSP;
(ii) voluntarily terminate its accredited status; or
(iii) become unable to conform to any of these conditions or the applicable criteria of Section 7.33 and related technical requirements.

(b) To become accredited and maintain accreditation, a laboratory shall supply, upon request, the following information:
(1) Legal name and full address;
(2) Ownership of the laboratory;
(3) Organization chart defining relationships that are relevant to performing testing covered in the accreditation request;
(4) General description of the laboratory, including its facilities and scope of operation;
(5) Name and telephone number of the authorized representative of the laboratory;
(6) Names or titles and qualifications of laboratory staff nominated to serve as approved signatories of test reports that reference NVLAP accreditation; and
(7) Other information as may be needed for the specific LAP(s) in which accreditation is sought.

Sec. 7.33 Criteria for accreditation.

(a) Quality System. (1) The laboratory shall operate under an internal quality assurance program appropriate to the type, range, and volume of work performed. The quality assurance program must be designed to ensure the required degree of accuracy and precision of the laboratory's work and should include key elements of document control, sample control, data validation, and corrective action. The quality assurance program must be documented in a quality manual or equivalent (e.g., operations notebook) which is available for use by laboratory staff. A person(s) must be identified as having responsibility for maintaining the quality manual.
(2) The quality manual must include as appropriate:
(i) The laboratory's quality assurance policies including procedures for corrective action for detected test discrepancies;
(ii) Quality assurance responsibilities for each function of the laboratory;
(iii) Specific quality assurance practices and procedures for each test, type of test, or other specifically delineated function performed;
(iv) Specific procedures for retesting, control charts, reference materials, and interlaboratory tests; and
(v) Procedures for dealing with testing complaints.
(3) The laboratory shall periodically review its quality assurance system by or on behalf of management to ensure it's continued effectiveness. These reviews must be recorded with details of any corrective action taken.

(b) Staff. (1) The laboratory shall:
(i) Be staffed by individuals having the necessary education, training, technical knowledge, and experience for their assigned functions; and
(ii) Have a job description for each professional, scientific, supervisory and technical position, including the necessary education, training, technical knowledge, and experience.
(2) The laboratory shall document the test methods each staff member has been assigned to perform.
(3) The laboratory shall have a description of its training program for ensuring that new or untrained staff are able to perform tests properly and uniformly to the requisite degree of precision and accuracy.
(4) The laboratory shall be organized:
(i) So that staff members are not subjected to undue pressure or inducement that might influence their judgment or results of their work; and
(ii) In such a way that staff members are aware of both the extent and the limitation of their area of responsibility.
(5) The laboratory shall have a technical manager (or similar title) who has overall responsibility for the technical operations of the laboratory.
(6) The laboratory shall have one or more signatories approved by the Director of OPSP to sign test reports that reference NVLAP accreditation. Approved signatories shall:
(i) Be competent to make a critical evaluation of test results; and
(ii) Occupy positions within the laboratory's organization which makes them responsible for the adequacy of test results.

(c) Facilities and Equipment. (1) The laboratory shall be furnished with all items of equipment and facilities for the correct performance of the tests and measurements for which accreditation is granted and shall have adequate space, lighting, and environmental control, and monitoring to ensure compliance with prescribed testing conditions.
(2) All equipment must be properly maintained to ensure protection from corrosion and other causes of deterioration. Instructions for a proper maintenance procedure for those items of equipment which require periodic maintenance must be available. Any item of equipment or component thereof which has been subjected to overloading or mishandling, gives suspect results, or has been shown by calibration or otherwise to be defective, must be taken out of service and clearly labelled until it has been repaired. When placed back in service, this equipment must be shown by test or calibration to be performing its function satisfactorily.
(3) Records of each major item of equipment must be maintained. Each record must include:
(i) The name of the item of equipment;
(ii) The manufacturer's name and type, identification and serial number;
(iii) Date received and date placed in service;
(iv) Current location, where appropriate;
(v) Details of maintenance; and
(vi) Date of last calibration, next calibration due date, and calibration report references.

(d) Calibration. The laboratory shall:
(1) Calibrate new testing equipment before putting it into service;
(2) Recalibrate, at regular intervals, in-service testing equipment with the calibration status readily available to the operator;
(3) Perform checks of in-service testing equipment between the regular calibration intervals, where relevant;
(4) Maintain adequate records of all calibrations and recalibrations; and
(5) Provide traceability of all calibrations and reference standards of measurement where these standards exist. Where traceability of measurements to primary (national or international) standards is not applicable, the laboratory shall provide satisfactory evidence of the accuracy or reliability of test results (e.g., by participation in a suitable program of interlaboratory comparison).

(e) Test Methods and Procedures. The laboratory shall:
(1) Conform in all respects with the test methods and procedures required by the specifications against which the test item is to be tested, except that whenever a departure becomes necessary for technical reasons the departure must be acceptable to the client and recorded in the test report;
(2) Have data to prove that any departures from standard methods and/or procedures due to apparatus design or for other reasons do not detract from the expected or required precision of the measurement;
(3) Maintain a test plan for implementing testing standards and procedures including adequate instructions on the use and operation of all relevant equipment, on the handling and preparation of test items (where applicable), and on standard testing techniques where the absence of such instructions could compromise the test. All instructions, testing standards, specifications, manuals, and reference data relevant to the work of the laboratory must be kept up-to-date and made readily available to the staff;
(4) Maintain measures for the detection and resolution of in-process testing discrepancies for manual and automatic test equipment and electronic data processing equipment, where applicable;
(5) Maintain a system for identifying samples or items to be tested, which remains in force from the date of receipt of the item to the date of its disposal, either through documents or through marking to ensure that there is no confusion regarding the identity of the samples or test items and the results of the measurements made; and
(6) Maintain rules for the receipt, retention, and disposal of test items, including procedures for storage and handling precautions to prevent damage to test items which could invalidate the test results. Any relevant instructions provided with the tested item must be observed.

(f) Records. The laboratory shall:
(1) Maintain a record system which contains sufficient information to permit verification of any issued report;
(2) Retain all original observations, calculations and derived data, and calibration records for one year unless a longer period is specified; and
(3) Hold records secure and in confidence, as required.

(g) Test Reports. (1) The laboratory shall issue test reports of its work which accurately, clearly, and unambiguously present the specified test results and all required information. Each test report must include the following information as applicable:

(i) Name and address of the laboratory;
(ii) Identification of the test report by serial number, date, or other appropriate means;
(iii) Name and address of client;
(iv) Description and identification of the test specimen, sample, or lot of material represented;
(v) Identification of the test specification, method, or procedure used;
(vi) Description of sampling procedure, if appropriate;
(vii) Any deviations, additions to, or exclusions from the test specifications;
(viii) Measurements, examinations, and derived results supported by tables, graphs, sketches, and photographs, as appropriate, and any failures identified;
(ix) A statement of measurement uncertainty where relevant;
(x) Identification of the organization and the person accepting technical responsibility for the test report and date of issue;
(xi) A statement that the report must not be reproduced except in full with the approval of the laboratory; and
(xii) A statement to the effect that the test report relates only to the items tested.

(2) The laboratory shall issue corrections or additions to a test report only by a further document suitably marked, e.g. "Supplement to test report serial number .....," which meets the relevant requirements of Section 7.33(g)(1).

(3) The laboratory shall retain a copy of each test report issued for one year unless a longer period is specified by the Director of OPSP.

(4) The laboratory shall ensure that all test reports endorsed with the NVLAP logo are signed by an approved signatory.

National Voluntary
Laboratory Accreditation
Program

NVLAP

U.S. Department of Commerce
in cooperation with the
National Bureau of Standards

Bulletin

Lab Bulletin No. 3A

January 1, 1985

INFORMING THE PUBLIC OF YOUR ACCREDITATION STATUS

Summary

This Bulletin supersedes NVLAP Lab Bulletin No. 3 dated October 1, 1981. It reflects significant changes made to the NVLAP procedures (Title 15, Part 7, of the Code of Federal Regulations) which became effective on December 10, 1984.

The Bulletin is addressed primarily to personnel at accredited laboratories who are responsible for communicating the laboratory's accreditation status to clients and the public, through advertising, issuance of test reports, use of the NVLAP logo, etc.

The Bulletin's purpose is to "provide guidance on referencing the laboratory's accredited status, and use of the NVLAP logo by the laboratory and its clients," in accordance with provisions of the NVLAP Procedures.

Background

NVLAP was established to assist industry and government in identifying competent testing laboratories. NVLAP accreditation means that a laboratory is competent to perform specific test methods in selected fields of testing. The NVLAP Procedures are the bases upon which the entire program operates and accomplishes accreditation of laboratories. Parts A and B of the Procedures provide general information and the method by which a new Laboratory Accreditation Program (LAP), in a new field of testing, may be requested and established. Parts C and D of the Procedures , of more concern to accredited laboratories, describe how a laboratory becomes accredited and the conditions and criteria for initial and continued accreditation. This Bulletin is concerned principally with issues in Part D of the Procedures.

Requirements and Guidance

To become accredited and maintain accreditation a laboratory shall:

limit the representation of the scope of its accreditation to only those tests or services for which accreditation is granted

A laboratory accredited by NVLAP may use the following statement on its letterheads and in trade or other publications: "Accredited by the National Bureau of Standards, National Voluntary Laboratory Accreditation Program for selected test methods for --(identify product or service area(s))." This statement could, for example, be placed at the bottom of the laboratory letterhead.

A laboratory's letterhead containing a reference to its NVLAP accreditation may be used in any direct solicitation for business from potential customers. It is recommended that a copy of the NVLAP Certificate and Scope of Accreditation be appended to such a solicitation.

To become accredited and maintain accreditation a laboratory shall:

limit advertising of its accredited status to letterheads, brochures, test reports, and professional, technical, trade, or other laboratory services publications, and use the NVLAP logo under guidance provided by NBS

A statement about NVLAP accreditation and the NVLAP logo may be used on reports and data sheets containing test data obtained by a laboratory provided the tests or services are performed in accordance with the terms of its accreditation. The NVLAP logo may not be used on test reports or data sheets during any period of suspended or expired accreditation or after voluntary or involuntary termination of accreditation.

The nature or type of product advertising prohibited by NVLAP procedures includes any advertising that is intended to encourage a consumer to purchase a product because it was tested by an accredited laboratory, whether that advertising appears in consumer media, the business media, or at a point of sale to consumers.

News stories and advertising by laboratories of their accredited status in the trade press is not only permissible but encouraged. The use of advertisements in the trade press is consistent with NVLAP procedures.

The "consumer media" to be avoided include popular periodicals such as Time, Good Housekeeping, etc., and newspapers such as the Washington Post or the New York Times. The term "consumer media" does not include business publications such as Barron's, or the Wall Street Journal which are oriented to the business community and in which products per se normally are not advertised.

To become accredited and maintain accreditation a laboratory shall:

> **inform its clients that the laboratory's accreditation or any of its test reports in no way constitutes or implies product certification, approval, or endorsement by NBS**

Laboratory accreditation by NBS confers recognition that a laboratory has been found competent to perform specific test methods or services in a selected field(s) of testing. Laboratories must avoid all inference that accreditation under NVLAP carries with it an endorsement, approval, or recommendation of the products tested by the laboratories.

To become accredited and maintain accreditation a laboratory shall:

> **assure that all test reports endorsed with the NVLAP logo are signed by an approved signatory**

An approved signatory is an officer or employee of the laboratory, identified by name or position, who has been accepted by NVLAP as being responsible for the issuance of test reports under this condition of NVLAP accreditation. A laboratory seeking initial accreditation or reaccreditation must specify (a) one or more individuals, or (b) position(s) within the organization for which it requests acceptance as an approved signatory.

Computer or machine generated test reports that contain the NVLAP logo need not be signed but must have the printed name of the approved signatory.

Questions About Accreditation

If you have questions about what is an acceptable method of advertising in areas not specifically covered in this Lab Bulletin or about the propriety or acceptability of a particular statement, advertising media, or use of information about your NVLAP accreditation status, please contact NVLAP before your publicity program is implemented.

Call 301-921-3431 or

Send your questions to:

Harvey W. Berger
Associate Manager, Laboratory Accreditation
National Bureau of Standards
ADMIN A531
Gaithersburg, MD 20899

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☐ Document describes a computer program; SF-185, FIPS Software Summary, is attached.

11. ABSTRACT (A 200-word or less factual summary of most significant information. If document includes a significant bibliography or literature survey, mention it here)

This document explains the operation and technical requirements of the Laboratory Accreditation Program (LAP) for Personnel Dosimetry Processors (Dosimetry LAP). All of the steps leading to accreditation are discussed. Technical requirements are explained indicating how the NVLAP criteria are applied.

It is intended for use by staff of accredited laboratories, those seeking accreditation, other laboratory accreditation systems, and others needing information on the requirements for NVLAP accreditation under this LAP.

12. KEY WORDS (Six to twelve entries; alphabetical order; capitalize only proper names; and separate key words by semicolons)

accreditation; assessment; dosimetry; laboratory; processor; proficiency testing

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