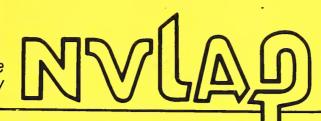


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National Voluntary Laboratory Accreditation Program

# **PROGRAM HANDBOOK**

# PERSONNEL RADIATION DOSIMETRY

NISTIR 89-4125

JULY 1989



U. S. Department of Commerce National Institute of Standards and Technology Gaithersburg, Maryland 20899

QC 100 .U56 89-4125 1989 C.2 NATIONAL INSTITUTE OF STANDARDS & TECHNOLOGY Research Information Center Gaithersburg, MD 20899

# NVLAP PROGRAM HANDBOOK PERSONNEL RADIATION DOSIMETRY REQUIREMENTS FOR ACCREDITATION

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National Voluntary Laboratory Accreditation Program

NISTIR 89-4125

July 1989

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### U.S. DEPARTMENT OF COMMERCE

National Institute of Standards and Technology Gaithersburg, Maryland 20899

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#### I. PROGRAM SUMMARY

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

The Dosimetry Program was established in 1984 in response to a request from the Nuclear Regulatory Commission (NRC). The purpose of the Program is (1) to provide periodic evaluation of dosimetry processors, including review of quality assurance programs to improve the quality of personnel dosimetry processing, 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 N13.11-1983).

Definitions of terms used in the Program 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 refer to ANSI N13.11-1983; and (2) the term "dose" means "dose equivalent."
- Processing covered: Any personnel dosimeter (TLD, film etc.) used to monitor whole body and skin dose in any of the eight radiation categories of ANSI N13.11 (also see appendix C).

Period of accreditation: One year

On-site visit frequency: Two years

Proficiency testing according to: ANSI N13.11 - 1983

Proficiency testing frequency: once prior to accreditation, once every other year thereafter.

Fees: Annual administrative fee, on-site assessment fee based on the number of facilities involved, biennial proficiency testing fee based on the number of dosimeter types and radiation categories selected for each dosimeter.

Assessors: Peers selected from the field of dosimetry.

#### II. INTRODUCTION

#### Background

The U.S. Department of Commerce, National Institute of Standards and Technology (NIST), formerly the 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 A).

This document is intended for information and use by staff of accredited laboratories, those seeking accreditation, other laboratory accreditation systems, and others needing information on the requirements for accreditation under this NVLAP program. 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 accreditation program and should be retained and be readily accessible to laboratory personnel.

#### NVLAP Accreditation

NVLAP accreditation is available to commercial laboratories, manufacturers' in-house laboratories, university laboratories, Federal, State, and local government laboratories. Foreign-based laboratories may be accredited by NIST if they meet the same requirements as domestic laboratories and pay any additional fees required (see Appendix D).

NVLAP is self-supporting and operates on a cost reimbursable basis by charging fees to those who pursue accreditation. The program receives no appropriated public funds.

Accreditation is granted only after thorough evaluation of the applicant has demonstrated that all NVLAP criteria have been met. Laboratories which successfully demonstrate compliance with the criteria are issued two documents to attest to that compliance: (1) a Certificate of Accreditation, and (2) a Scope of Accreditation which states the specific test methods and services for which the laboratories has been accredited (see Appendix I).

#### Why NVLAP Accreditation?

A laboratory may wish to be accredited for many reasons such as; legal requirements, regulations or codes, contract specifications, or the desire to be recognized as demonstrably competent to meet the needs of its clients.

NVLAP provides formal recognition of the competence of accredited laboratories to the user community. Information about accredited laboratories, including the name and scope of accreditation, is disseminated in various media. 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 "testing laboratory" as an organization that provides services to measure, examine, test, calibrate, or otherwise determine the characteristics or performance of materials, products or systems. See Appendix E for information about laboratory main and sub facilities.

#### Accreditation Defined

NVLAP accreditation signifies 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 all been evaluated and found to meet NVLAP criteria. NVLAP accreditation <u>does not mean</u> a guarantee (certification) of laboratory performance or of product test data; it is solely a finding of laboratory competence.

#### NVLAP Programs

Laboratories may participate in as many NVLAP programs as they wish, provided that they meet all NVLAP criteria for each program. Programs currently available are:

Acoustical Testing Services Asbestos in Bulk Insulation and Air Carpet Commercial Products Testing Paints and Coatings Paper and Related Products Plastics Seals and Sealants Computer Interface Protocols Construction Testing Services Electromagnetic Compatibility and Telecommunications Personnel Radiation Dosimetry Thermal Insulation Materials Wood Stoves

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

NVLAP National Institute of Standards and Technology \* Bldg 411 Room A124 Gaithersburg, MD 20899 Phone: (301) 975-4016 FAX: (301) 975-3839

\* formerly the National Bureau of Standards (NBS)

#### III. OPERATIONAL INFORMATION AND REQUIREMENTS

The information and requirements presented in this section are generally applicable to all NVLAP programs. The requirements specified in Sections 7.31 and 7.32 of the NVLAP Procedures (Appendix A) and those specified in this section must be met in order to gain accreditation.

#### Laboratory Code Number (LAB CODE)

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. The Lab Code number is cross-referenced with the laboratory name and location in the NVLAP Directory of Accredited Laboratories.

#### Accreditation Period

Accreditation is granted for a period specified in the Accreditation 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 both expires and is renewed on that date.

#### Approved Signatory

The laboratory must designate one or more staff members as Approved Signatories. The name of at least one Approved Signatory must appear on all test reports endorsed with the NVLAP logo (see section <u>Use of the NVLAP Logo</u> elsewhere in this Handbook). This person is responsible for the technical contents of the report and is the one to be contacted by NVLAP, laboratory clients, or others in case of questions or problems with the report.

There is no formal requirement for nomination or approval of persons designated as Approved Signatories. The laboratory must inform NVLAP of its appointments by completing the appropriate sections in the General Application for accreditation. Approved Signatories should be persons with adequate responsibility or authority within the organization, with adequate and appropriate technical capabilities, and without conflict of interest.

Laboratory <u>test reports carrying the NVLAP logo need not be signed individually</u> 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.

#### Authorized Representative

The laboratory must designate an Authorized Representative to sign the application form and commit the laboratory to fulfill the NVLAP requirements. The Authorized Representative is the only one who can authorize a change in the scope or nature of the laboratory's application. The Authorized Representative may also be an Approved Signatory.

#### 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 technical requirements and fees for renewal are generally the same as for initial accreditation.

The application and fees must be received by NIST prior to expiration of the laboratory's current accreditation to avoid a lapse in accreditation. If an onsite assessment is required, the application and fees must be received to allow sufficient time for the visit to be completed and deficiencies corrected prior to expiration of accreditation. In addition, any current proficiency testing requirements must be met.

#### Keeping NVLAP Informed

During the accreditation period, a laboratory must inform NVLAP:

of any major changes involving the location, ownership, management structure, authorized representative, technical director, approved signatories, or facilities;

if it wishes to delete a test method; or

if it is no longer capable of performing test methods or services for which it is accredited.

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 NVLAP in writing.

#### Additions to Scope of Accreditation

During the accreditation period, a laboratory may request the addition of test methods or services to its Scope of Accreditation. The laboratory must meet all NVLAP criteria for the additional test methods or services such as fees, proficiency testing, technical requirements, etc. The need for an additional on-site assessment will be determined on a case-by-case basis.

#### NVLAP Directory

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.

#### Referencing Your Accredited Status and Use of the NVLAP Logo

Accredited laboratories are encouraged, within specified limits, to announce their accredited status. The NVLAP logo may be used in such announcements. Photographic copies of the logo are available from the NVLAP office.

A laboratory must limit the representation of the scope of its accreditation to only those tests or services for which accreditation has been granted. The following statement is recommended: "Accredited by the National Institute of Standards and Technology, National Voluntary Laboratory Accreditation Program for selected test methods or services."

#### In Advertising

Laboratory advertising of accredited status must be limited to professional, technical, trade, or other laboratory services publications. Letterhead referencing NVLAP accreditation may be used in 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.

News stories and advertising by laboratories of their accredited status in the trade press is permissible and encouraged. The use of advertisements in the trade press is consistent with NVLAP procedures.

Laboratories may not reference their accredited status in consumer media, in product advertising, or on product labels, containers and packaging. 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. Advertising must not imply product certification by NVLAP, NIST, or the U.S. Government.

#### On Laboratory Documents

As long as a laboratory is NVLAP accredited, it may use the NVLAP logo on letterhead and brochures, preferably with the qualifying quote given above. The logo may be used on test reports that are within the scope of accreditation. These reports must bear the name of an Approved Signatory in accordance with the guidelines given in the <u>Approved Signatory</u> section of this Handbook. Policy Guides 11 and 12 (see Appendix) describe additional test report requirements.

#### 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.

#### IV. TECHNICAL EXPERTS

NVLAP uses Technical Experts (TEs) as assessors and evaluators. 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.

<u>Assessors</u> 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.

<u>Evaluators</u> 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.

#### V. 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. The process is described in the following sections.

#### Application and Fees

An Application Package is sent to a laboratory on request. It includes: General Application Forms, Fee Calculation forms, and the program Handbook. The General Application Form must be completed and signed by the authorized representative of the laboratory. Before completing and signing the application, the authorized representative should review all documents and become familiar with NVLAP requirements.

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 program. The total accreditation fee must be paid before accreditation can be granted. The individual parts of the accreditation fee include, <u>as appropriate</u>: an Administrative and Technical Support fee, a Test Method fee, a Proficiency Testing fee, the cost of reference materials and quality assurance samples, and an On-Site Assessment fee. The fees for this accreditation program are shown in the **Fee Calculation Sheet** included in the **Application Package**.

The laboratory will be contacted to schedule a mutually acceptable date for the on-site assessment <u>after payment</u> 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.

#### 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 some latitude to make judgments about a laboratory's compliance with the NVLAP criteria.

Each laboratory will be contacted to arrange a mutually agreeable date for an assessment. An assessment normally takes one to three days depending on the extent of the laboratory's application. 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:

- 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 for appropriateness, capability, adherence to specifications, etc.

At the conclusion of the assessment, the assessor will conduct an exit briefing to discuss observations with responsible laboratory staff. A written assessment report will be left with the laboratory. The assessor will forward the assessment forms and a copy of the report to NVLAP.

#### Monitoring Visits

In addition to regularly scheduled assessments, monitoring visits may be conducted by assessors or by NIST staff at any time during the accreditation period. The scope of a monitoring visit may range from checking a few designated items to a complete review. 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.

#### 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 a complete evaluation of laboratory competence. The actual performance of tests and reporting of results using special proficiency testing samples provides NVLAP with a way to determine the overall effectiveness of the laboratory (see Appendix C).

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

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 Program are included elsewhere in this document.

#### Deficiency Notification and Resolution

A deficiency is the failure of a laboratory to meet a NVLAP criterion. Deficiencies may be determined during on-site assessments, monitoring visits, proficiency testing, NVLAP staff review, and Technical Evaluation. Laboratories are informed of deficiencies during the on-site assessment and through other correspondence.

When a laboratory is notified by NVLAP of deficiencies, the laboratory must respond in writing to NVLAP within 30 days of the notification. The response must provide documentation, signed by the authorized representative, that the specified deficiencies have either been corrected or that specific actions are being taken to make corrections. A timetable for completion of corrections should be included.

A laboratory which is currently accredited must correct all deficiencies noted within 30 days of notification or face possible revocation, suspension, or expiration without renewal of its accreditation.

Test equipment that is identified as deficient should not be used until corrective action has been completed. Evidence of correction must be sent to NVLAP.

If substantial deficiencies have been cited, NVLAP may conduct an additional onsite assessment prior to granting accreditation. All deficiencies and resolutions will be subject to thorough review and corrective actions verified during subsequent assessments and technical evaluations.

#### Technical Evaluation

When a laboratory 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, signed by the authorized representative, that the specified deficiencies have been corrected. Clarification of some issues may be requested by telephone. <u>All deficiencies must be corrected before accreditation can be granted or</u> <u>renewed.</u>

#### 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 requirements have been satisfied.

#### Accreditation Actions

The following accreditation actions may be taken by NIST:

- <u>Accreditation</u> If accreditation is recommended, the recommendation forms the basis for granting accreditation. A Certificate of Accreditation and a Scope of Accreditation will be issued to the laboratory.
- <u>Denial</u> If denial is recommended, the laboratory is notified of a proposal to deny accreditation and the reason(s) therefor.
- <u>Suspension</u> 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, correspondence, or advertising.

If denial or revocation has been proposed, the laboratory may request, in writing, 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.

When accreditation has been terminated, whether voluntarily or through adverse action, the accreditation certificate must be returned to NVLAP.

#### VI. TECHNICAL REQUIREMENTS

Section 7.33 of the NVLAP Procedures, found in appendix A, contain the <u>Criteria</u> <u>for Accreditation</u> expressed in general terms. The following comments and additional requirements make the criteria specifically applicable to the Personnel Radiation Dosimetry Program. <u>The requirements listed in section 7.33</u> and those specified in this section must be met in order to gain accreditation.

#### SCOPE OF THE PROGRAM

Accreditation is available to any organization that processes personnel radiation dosimeters used to monitor individual whole body exposure to ionizing radiation (processor). A processor may be accredited to process specific dosimeters of its choice in any one or more radiation categories listed below (see ANSI N13.11 for sources used and irradiation ranges):

- 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 Program is intended to preclude a processor from providing additional, non-accredited services or research related to improved dosimetry.

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) for which accreditation has been granted (see appendix D). 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 to provide accredited dosimetry 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 (see appendix C).

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.

#### TYPES OF FACILITIES

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 (see appendix B).

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;
- exerts technical direction and quality assurance management of all its processing activities or those in the system;
- has available processing equipment and dosimeters which are the same as or provide results that are technically equivalent to, those employed at each facility in a system of which it is a part.

QUALITY SYSTEMS (see Sec. 7.33a, appendix A)

To qualify for accreditation a processor must have a documented system of procedures and practices which assure the quality of its services. During the on-site assessment, an applicant must demonstrate that the quality systems used ensure the technical integrity of the work.

#### Documentation

The documentation must be up-to-date and thoroughly describe all 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 must 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 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
- Actions when test data indicate a possible problem exists
- Procedures for utilizing subcontractors

The documentation must be arranged in such a way that it is readily accessible to all staff members. It may be in the form of a single manual or may be distributed , in sections, to various locations throughout the facility. If separate sections are used, a central reference document must be available to indicate where the individual sections may be found. The documentation must be in a format and style which can be easily understood by all staff members.

#### STAFF (see Sec. 7.33b, Appendix A)

#### <u>Technical Director:</u>

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 must have the technical competence and the supervisory capability to direct the work of professionals and technicians in the dosimetry area.

#### Quality Assurance:

The processor must name a staff member who has overall responsibility for the quality assurance program. This may be the technical director or 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.

#### Technical Staff:

The processor shall maintain a staff which is technically capable of conducting the required processing functions and has a sufficient number of persons to adequately handle the quantity of dosimeters processed.

#### 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 training for assigned duties either through on-the-job training, formal classroom sessions or through certification programs recognized by NVLAP.

#### Competency:

In addition to training, the competency of each staff member must be evaluated 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.

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, or substantial change in staff) shall be reported to NVLAP within 30 calendar days of such change.

#### FACILITIES AND EQUIPMENT (see Sec. 7.33c, Appendix A)

A processor must have adequate facilities and equipment 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.

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

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
- 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
- System to characterize dose-TLD reading relationship for each TLD or TLD batch in each radiation category used

#### Changing Processing Equipment

If an accredited 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 must be notified. Depending on the nature and extent of the changes, the processor will be advised as to any required testing or if an on-site assessment is necessary.

When a new dosimeter or system is to replace another, all new items must 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 tested so that the processor does not lose accreditation.

#### Backup Systems

The processor must maintain 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 in an emergency (see appendix B).

#### CALIBRATION (see Sec. 7.33d, Appendix A)

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.

Calibration of all equipment 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 NIST or by an equivalent foreign national standards authority. Traceability means that it can be shown 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 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.

#### <u>RECORDS</u> (see Sec. 7.33f, Appendix A)

A processor must maintain a functional recordkeeping system. All records must be easily accessible, in a logical order, and containing 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
- Tracking and logging of dosimeters processed

Dosimeter tracking and logging records must 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 dosimeter and personnel involved should all be included.

#### TEST REPORTS (see Sec. 7.33g, Appendix A, and Policy Guide 12, Appendix B)

In the report to a client, a processor is not required to state results in terms of particular quantities or units. However, it must be made completely clear what the reported numbers mean so that they can be used appropriately.

The final report to the client must include:

- Name and address of processor and client
- Pertinent dates
- 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
- Adequately defined data resulting from the processing

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

#### VII. PROFICIENCY TESTING

In order to be eligible for accreditation, 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 and in each test category for which accreditation is desired. Satisfactory proficiency must be demonstrated prior to initial accreditation and every two years thereafter (see Appendix B). A processor will be expected to begin testing on the accreditation anniversary date every other year. Failure to begin testing on the specified date may result in suspension or denial of renewal of accreditation.

Although demonstration of proficiency for the desired dosimeter/category combinations is required to gain accreditation, ANSI N13.11 has no requirements regarding a processor's normal day-to-day processing. However, the NVLAP criteria require that a processor document and demonstrate to the satisfaction of a TE, that normal processing is done in a manner consistent with that employed in the proficiency test (see Appendix C).

Proficiency testing will be administered by a proficiency testing laboratory (PTL) contracted by NIST. Specific instructions on participation in proficiency testing are included with the accreditation application package. Testing is conducted on a quarterly basis and is conducted over a three month period (test sequence) beginning the first day of January, April, July and October. A participant may start a test sequence only at the beginning of a quarter.

A processor has two years to demonstrate satisfactory performance for initial accreditation. If satisfactory performance is not demonstrated within two years, an additional administrative fee may be charged.

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

- A processor must submit a total of 15 dosimeters of each model to be used in each category in which testing is desired. The dosimeters shall be submitted to the PTL in three separate groups of 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 each dosimeter and return groups of 5 to the processor at one-month intervals.
- The processor must read each dosimeter and determine a dose for each applicable category. 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, it will be the responsibility of the processor to determine the dose applied in each radiation category to each dosimeter.
- The processor must report the determined doses to the testing laboratory within 30 days.
- The PTL will compare the reported data with the known irradiation data to ascertain if the processor demonstrated satisfactory performance.

#### Data Analysis and Reporting

At the completion of a test, the PTL will compare each processor's data to the irradiation data, analyze the results, and send a detailed report to participant's containing their individual test results (see appendix E). Copies of the report will also be sent to NVLAP for use in the evaluation of the processor and for use by the on-site assessor.

A summary report giving overall statistics for each quarterly test will be sent by NVLAP to all interested parties. Confidentiality of participants is maintained.

NVLAP maintains a computer file of all proficiency test results in order to analyze and/or monitor individual as well as group trends, problems or other factors.

#### Test Failures and Retest

If a processor fails to demonstrate satisfactory performance in one or more categories during a test, the processor must submit additional dosimeters for a retest in accordance with the following 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 those will require retest in the failed category and in two additional categories. Failure in two or more categories will require retest in all of the categories attempted.

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

The processor will be notified by mail of any required retesting due to failure or unsatisfactory proficiency testing.

#### 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. If the processor does not use a phantom, 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

- A NVLAP Procedures, Subpart D,"Conditions and Criteria for Accreditation "
- B NVLAP Policy Guides
  - #10 "Main laboratory facilities and subfacilities"
  - #11 "Use of Subcontractors By Accredited Laboratories"
  - #12 "Test Reports Issued By Accredited Laboratories"
  - #13 "Satisfactory Proficiency Testing Is a Requirement for Accreditation"
  - #14 "Accreditation of Foreign Laboratories"
- C NVLAP Lab Bulletins #18 - Algorithms
- D Sample Certificate of Accreditation Sample Scope of Accreditation
- E Sample Proficiency Test Report
- F Assessor Checklist



#### APPENDIX A

#### NVLAP PROCEDURES



NVLAP PROCEDURES - TITLE 15, PART 7, CODE OF FEDERAL REGULATIONS

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:

- 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) <u>Quality System</u>.
- (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) <u>Staff</u>.
- (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) <u>Calibration</u>. 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) <u>Test Methods and Procedures</u>. 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;

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- (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) <u>Records</u>. The laboratory shall:
- 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) <u>Test Reports</u>.
- (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.



APPENDIX B

NVLAP POLICY GUIDES





National Voluntary Laboratory Accreditation Program

# **POLICY GUIDE**

Number 10 June 1988 (Reprinted June 1989)

This Policy Guide presents NVLAP definitions of the types of laboratory facilities which may be granted NVLAP accreditation, the requirements and conditions that must be satisfied in order to achieve accreditation, and procedures that NVLAP will follow in evaluating various types of facilities for their conformance to accreditation criteria.

#### Definitions:

a. <u>Main (laboratory) facility:</u>

- permanently (at all times) maintains staff, equipment, procedures, documentation, and facilities necessary to perform the tests, for which it seeks accreditation;
- (2) implements all quality assurance procedures;
- (3) maintains and retains all records, and issues test reports; and
- (4) may be a permanently fixed site or a permanent mobile facility.

b. <u>Sub-facility</u> is physically separate from, but considered an extension of, its main facility. Although it may have all staff, equipment, procedures, and documentation necessary to perform the requisite tests, it receives technical direction and quality assurance management from the <u>main facility</u>.

- 1. A <u>permanent sub-facility</u> maintains staff, equipment, procedures, documentation, and facilities necessary to perform the tests, for which it seeks accreditation, at all times. It may be a permanently fixed site or a permanent mobile facility and is expected to remain in operation for at least one year.
- 2. A <u>temporary sub-facility</u> is provided with staff, equipment, procedures, documentation, and facilities necessary to perform the tests, for which it seeks accreditation, on an interim basis, to meet the needs of the <u>main facility</u>. A <u>temporary sub-facility</u> may be established at a fixed site or in a mobile facility and is expected to remain in operation less than one year.

#### Conditions for Accreditation:

NVLAP accreditation of a laboratory <u>main facility</u> does not extend to accreditation of <u>sub-facilities</u> unless the <u>sub-facilities</u> have been separately evaluated. These facilities are uniquely identified in the NVLAP accreditation

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#### NVLAP Policy Guide 10 - continued

documents. A NVLAP-accredited laboratory must not present or report test data, produced at any non-accredited, <u>sub-facility</u> as having been produced under the status of NVLAP accreditation.

NVLAP offers accreditation to laboratories that are found competent to perform specific test methods or types of tests in specified fields of testing. Competence is defined as the ability to meet specific technical criteria relating to quality assurance, staff, equipment, facilities, procedures, records, and reports. Technical criteria may or may not be equally applicable to <u>main facilities</u> and <u>sub-facilities</u>. Accreditation of <u>sub-facilities</u> may require NVLAP criteria that address the use and maintenance of equipment and facilities, and the implementation of procedures, that are particularly applicable to the performance of specific test methods in <u>sub-facilities</u>. NVLAP must develop specific technical criteria upon which to base an objective evaluation of staff, facilities, equipment, and procedures employed in applicable <u>sub-facilities</u>.

NVLAP will accredit a <u>main facility</u> if the facility complies with all applicable NVLAP criteria.

NVLAP will accredit a sub-facility (in addition to the main facility) if:

a. the laboratory main facility meets all NVLAP accreditation criteria;

b. the laboratory <u>main facility</u> satisfactorily documents and maintains quality assurance procedures addressing the applicable <u>sub-facility</u>; and,

c. the sub-facility complies with all applicable NVLAP criteria.

#### Procedures:

In principle, NVLAP will require that <u>sub-facilities</u>, to be included in a laboratory's accreditation, undergo on-site assessments and participate in proficiency testing. NVLAP staff, with the guidance of NVLAP technical experts, will determine the need for and extent of such evaluations based on the number and location of similar <u>sub-facilities</u> managed by the laboratory, the nature of the quality assurance system, and any special technical considerations. Decisions on the need for and extent of the evaluations may not be made until after the accreditation of the <u>main facility</u>. The conditions and requirements for evaluation of sub-facilities providing specific testing services are described in NVLAP documents pertaining to the relevant accreditation program.

Laboratories seeking NVLAP accreditation should clearly state, on the NVLAP Application Form, what type(s) of <u>sub-facilities</u> are to be included in the accreditation. NVLAP fees for on-site assessments and proficiency testing will be based on the number of facilities seeking accreditation that are required to undergo on-sites and participate in proficiency testing. A single administrative/technical support fee is charged to the laboratory (<u>main</u> <u>facility</u>).



National Voluntary Laboratory Accreditation Program

# **POLICY GUIDE**

Number 11 March 1989

USE OF SUBCONTRACTORS BY ACCREDITED LABORATORIES

When a laboratory accredited by NVLAP issues a test report containing the NVLAP logo or other indication of NVLAP accreditation, it is implied that the report reflects work performed, and results obtained, by the personnel, equipment, and procedures of that laboratory. However, in some cases a laboratory may require the use of another facility (subcontractor) e.g., due to equipment failure, need for specialized equipment, work overload, or to perform tests outside the laboratory's scope, etc., in order to meet contractual obligations.

The following policy applies whenever the NVLAP logo or other reference to a laboratory's accredited status is used on a test report.

<u>NVLAP POLICY</u>. Whenever a laboratory accredited by NVLAP subcontracts to another laboratory the performance of any test or portion of a test it must clearly identify in its records, and in the report to the client, specifically which test method(s) or portion of a test method(s) were performed by the accredited laboratory and which were performed by the subcontractor. The laboratory must also inform the client, before the fact, that subcontracting will be necessary.

<u>Definition of SUBCONTRACTOR</u>: Any facility not covered under a laboratory's NVLAP accreditation, as defined in the accreditation documents, utilized by the laboratory to produce test data, e.g., laboratories not affiliated with the NVLAP laboratory, facilities within the same corporate structure that are not included in the accreditation, such as franchises, or subsidiaries.

<u>REQUIREMENTS</u> NVLAP policy regarding an accredited laboratory subcontracting any test or portion of a test which will reference the laboratory's accredited status requires the following of an accredited laboratory.

- 1. The laboratory's policy regarding the use of subcontractors must be included in the Quality Assurance Manual.
- 2. The laboratory must notify the client that some testing will be subcontracted (identity of subcontractor not required in advance).

3. Any test report issued that contains data produced by a subcontractor and displays the NVLAP logo or other indication of NVLAP accreditation, must include:

Subcontractor ACCREDITED by NVLAP

- a statement at the begining of the report prominently indicating "This report contains data which was produced by a subcontracted
- laboratory accredited by NVLAP for the test methods performed";
- clear indication of which data was produced by the subcontractor;
- name, address, and contact person of the subcontracted facility(ies);
- the NVLAP lab code of the subcontractor(s);
- a description of the test(s) performed, and results obtained.

Subcontractor NOT ACCREDITED by NVLAP

- a statement at the begining of the report prominently indicating
   " This report contains data which was produced by a subcontracted laboratory which is not accredited by NVLAP ";
- clear indication of which data was produced by the subcontractor;
- name, address, and contact person of the subcontracted facility(ies);
- a description of the test(s) performed; and results obtained;



Laboratory Accreditation Program

# **POLICY GUID**

Number 12 April 1989

#### TEST REPORTS ISSUED BY ACCREDITED LABORATORIES

When a laboratory accredited by NVLAP issues a test report containing the NVLAP logo or other indication of NVLAP accreditation, it is implied that the report reflects work performed, and results obtained, under the conditions of the accreditation. Frequently however, laboratories perform other testing which is not covered by the NVLAP accreditation.

NVLAP POLICY. Whenever a laboratory accredited by NVLAP issues a test report which contains data from the performance of any test or portion of a test not covered by the accreditation it must clearly identify in its records, and in the report to the client, specifically which test method(s) or portion of a test method(s) were not covered by the accreditation. The laboratory must also inform the client, before the fact, when tests requested are not covered by the accreditation.

**REQUIREMENTS**. NVLAP policy regarding test reports issued by an accredited laboratory which references the laboratory's accredited status, requires the following.

- 1) Any test report that contains data from tests which are not covered by the accreditation must include:
  - a statement at the beginning of the report prominently indicating " This report contains data which is not covered by the NVLAP accreditation";
  - clear indication of which data is not covered by the accreditation
- 2) A description of the laboratory's policy regarding the use of the NVLAP logo must be included in the Quality Assurance Manual.
- 3) The laboratory must not misrepresent its accreditation. When a client requires or requests accredited services and any of the requested services are not covered by the accreditation, the client must be so advised.





National Voluntary Laboratory Accreditation Program

# **POLICY GUIDE**

Number 13 July 1989 (Replaces Policy Bulletin No. 19)

SATISFACTORY PROFICIENCY TESTING IS A REQUIREMENT FOR ACCREDITATION

Accreditation by the National Institute of Standards and Technology, under the National Voluntary Laboratory Accreditation Program (NVLAP), requires that a laboratory meet all performance requirements and criteria as determined by on-site assessments and proficiency testing.

If, as the result of on-site assessments, deficiencies are found, the laboratory must satisfactorily resolve those deficiencies, in order to obtain initial accreditation or maintain accreditation.

<u>Unsatisfactory participation in any NVLAP proficiency testing program is a</u> <u>technical deficiency which must be resolved in order to obtain initial</u> <u>accreditation or maintain accreditation.</u>

Unsatisfactory participation in NVLAP proficiency testing programs is defined as, but not limited to, one or more of the following:

1. Failure to meet specified proficiency testing performance requirements prescribed by a standard or test method for which the laboratory is seeking accreditation. (Example: ANSI Standard N13.11 for the Dosimetry Program.)

2. Failure to participate in a regularly scheduled "round" of proficiency testing for which the laboratory has received instructions and/or materials.

3. Failure to submit laboratory control data as required.

4. Performance as a statistically outlying laboratory in two successive rounds of proficiency testing or showing a general pattern of outlying test results over three or more rounds.

5. Failure to produce test data within acceptable limits of error when testing NIST Standard Reference Materials or special artifacts whose properties are well characterized and known to NIST/NVLAP.

NVLAP will notify the laboratory of proficiency testing deficiency(s) and actions to be taken to resolve the deficiency(s). Denial or suspension of accreditation will result from failure to resolve deficiencies.



U.S. Department of Commerce National Institute of Standards and Technology

National Voluntary Laboratory Accreditation Program

# **POLICY GUIDE**

Number 14 July 1989 (Replaces Policy Bulletin No. 4)

#### ACCREDITATION OF FOREIGN LABORATORIES

Foreign laboratories, located outside of the continental United States, may be accredited by NVLAP on the same basis as U.S. domestic laboratories. Foreign laboratories must meet the same requirements and criteria as domestic laboratories. The criteria are defined in the NVLAP Procedures and technical Handbooks provided to all applicants. Accreditation is granted based on compliance with all NVLAP criteria as determined by on-site assessments and the results of proficiency testing programs.

Since NVLAP is a cost-reimbursable program, the fees charged foreign laboratories must cover all costs in excess of those associated with the accreditation of domestic laboratories. Additional fees will be charged to foreign laboratories for travel by assess outside of the United States and for shipment of proficiency testing materials to the laboratories.

Upon application, a foreign laboratory must forward payment of NVLAP fees (as calculated on the Fee Calculation Sheet) in U.S. currency. The laboratory will be notified of additional travel and proficiency testing costs which must be paid to NVLAP before an assessor leaves to perform the on-site assessment.

In cases where laboratory documents are not in English, or laboratory personnel do not speak English, it is the responsibility of the laboratory to provide a translator to assist the NVLAP assessor during the inspection. The translator will assist the assessor to converse directly with laboratory management and technical staff and to review laboratory documentation. Documents such as quality control manuals, protocols, standards, and test reports need not be translated into English solely for NVLAP purposes.

An export license, issued by the U.S. Department of Commerce, may be required for certain equipment to be sold outside the United States. If a foreign laboratory applying for NVLAP accreditation must own the required equipment, the laboratory must have a valid export license. For export license information call (202) 377-4811 or write to: U.S. Department of Commerce, Export Administration, Exporter Assistance, P.O. Box 273, Washington, DC 20230.



## APPENDIX C

## NVLAP LAB BULLETINS

U.S. Department of Commerce National Institute of Standards and Technology



National Voluntary Laboratory Accreditation Program

# LAB BULLETIN

Lab Bulletin No. 18

August 1986

DOSIMETRY LAP - ALGORITHMS

There has been much confusion expressed about the proper usage of algorithms in processing dosimeters under the terms of NVLAP accreditation.

The proficiency testing required by NVLAP is conducted in accordance with ANSI N13-11. This document is a performance test method which NVLAP utilizes to evaluate the performance of participants under laboratory controlled conditions. The standard cites specific sources and irradiation conditions to be used. Any calibration/correction factors needed in the processing algorithms(s) used for these tests are readily developed from calibration irradiations (provided by the PTL in the case of neutrons).

In normal everyday processing, the fields to which dosimeters are exposed may or may not be the same as specified in ANSI N13.11, or as well characterized. When fields known to be different from the sources and irradiation conditions used by the PTL are being monitored, different factors may have to be applied in the processing algorithm.

This is not only perfectly acceptable to NVLAP, it is the preferred way to conduct processing. The purpose of the NVLAP program is to promote good dosimetry, not to simply have participants pass a carefully specified test.

During the on-site assessment the assessor will be looking to see that appropriate processing procedures are being used and understood by participants and that when different fields are monitored, suitable correction are made in the algorithms.

For information, please contact Robert L. Gladhill, Project Leader, NIST, Bldg. 411, Room A124, Gaithersburg, MD 20899. 301 975-4016



### APPENDIX D

## SAMPLE CERTIFICATE AND SCOPE OF ACCREDITATION





National Institute of Standards and Technology



National Voluntary Laboratory Accreditation Program

# **SCOPE OF ACCREDITATION**

PERSONNEL DOSIMETRY PROCESSING

NVLAP LAB CODE 0000

LABORATORY, INC. 1 Main Street, Anytown, MD 00000 John Doe Phone: 301-555-1212

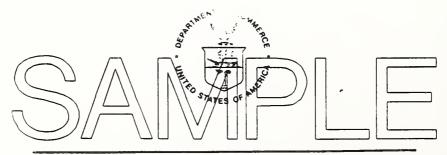
Accreditation Renewal Date: January 1, 19--

This facility has been evaluated and deemed competent to process the radiation dosimeter listed below through employing an Xxxxx Automatic reader model A and Manual Reader B.

This facility is accredited to process the following dosimeters by virtue of actual demonstration of compliance with ANSI-N13.11-1983 through testing.

Xxxxx TLD model Z for ANSI-N13.11 categories I, II, III, IV, V, VI, VII, VIII.

Xxxxx Film for ANSI-N13.11 categories I and II.



APPENDIX E

SAMPLE PROFICIENCY TEST REPORT (ABRIDGED)



### PERSONNEL DOSIMETRY PERFORMANCE TESTING

#### CONDUCTED FOR :

### NATIONAL VOLUNTARY LABORATORY ACCREDITATION PROGRAM NATIONAL BUREAU OF STANDARDS U.S. DEPARTMENT OF COMMERCE

CONDUCTED AT :

### BATTELLE, PACIFIC NORTHWEST LABORATORY P.O. BOX 999 RICHLAND, WASHINGTON 99352

PROCESSOR NAME :

PROCESSOR CODE NO. :

TYPE OF DOSIMETER :

TEST RESULTS FOR QUARTER : 1988-1

TESTING STATUS : RENEWAL

REPORT PRINTED : 27 APR., 1988

CHECKED BY :

DATE : . 27 APR.88

ON THE FRONT PAGE, "PROCESSOR CODE" IS A FOUR-DIGIT CODE PLUS A LETTER FOR PROCESSORS WITH MORE THAN ONE MODEL OF DOSIMETER. "TESTING STATUS" REFERS TO TESTING FOR INITIAL ACCREDITATION, RETEST FOR CASES OF FAILURE, OR RENEWAL OF ACCREDITATION FOR THIS DOSIMETER.

FOR EACH DOSIMETER, A PERFORMANCE QUOTIENT IS CALCULATED BY :

 $P = (H^* - H)/H$ 

WHERE : H = DELIVERED QUANTITY H\* = REPORTED QUANTITY

FOR EACH DEPTH OF A TEST CATEGORY, AN AVERAGE PERFORMANCE QUOTIENT, P, AND ITS STANDARD DEVIATION, S, ARE CALCULATED FOR N DOSIMETERS. A PROCESSOR PASSES A CATEGORY IF, FOR EACH RELEVANT DEPTH, /P/ + S IS LESS THAN OR EQUAL TO THE APPROPRIATE TOLERANCE LIMIT, L.

FOR CATEGORIES I AND II, WHICH INVOLVE ACCIDENT DOSES, L = 0.3. FOR CATEGORIES III THROUGH VIII, WHICH INVOLVE PROTECTION DOSES, L = 0.5.

IF A DOSIMETER IS LOST, NOT REPORTED BY THE PROCESSOR, IRRADIATED IMPROPERLY, ETC., DOSIMETERS ARE LISTED UNDER "DOSIMETERS VOIDED" AND ARE NOT INCLUDED IN THE PASS/FAIL CALCULATIONS.

SOME INCONSISTENCIES CAN BE NOTED IN THE TABLES DUE TO THE FACTORS WHICH ARE APPLIED TO INDIVIDUAL DELIVERED DOSES. THE RATE IS THE SOURCE CALIBRATION AT THE CENTER OF THE FRONT PHANTOM SURFACE. A FIELD UNIFORMITY FACTOR IS APPLIED TO EACH DELIVERED DOSE TO REFLECT DOSIMETER PLACEMENT ON THE PHANTOM. FOR X-RAYS, THE DELIVERED EXPOSURE IS DETERMINED FROM THE OUTPUT OF A TRANSMISSION CHAMBER. CORRECTIONS ARE APPLIED FOR AIR DENSITY AND FOR THE ELECTROMETER RANGE.

### CATEGORY I : ACCIDENTS,LOW-ENERGY PHOTONS RADIATION SOURCE : M150 (MFI) IRRADIATION DISTANCE : 100.0 CM TO THE FRONT FACE OF PHANTOM

PROCESSOR NAME : PROCESSOR CODE NO. : TYPE OF DOSIMETER : TEST RESULTS FOR QUARTER : 1988-1 TESTING STATUS : RENEWAL REPORT PRINTED : 27 APR., 1988

			ION INFORM		DEEP ABSORB		CX = 1.38
DOSIMETE		RATE	CHARGE	TOTAL	DELIVERED		
NUMBER	IRRADIATED	(mR/nCOUL	) (nCOUL)	(R)	(RAD)	(RAD)	P
40154	88-01-20	2.3850	9862.0	23.57	32.53	32.14	0118
40158	88-01-20	2.3850	20303.0	48.61	67.08	62.06	0749
40157	88-01-20	2.3850	81479.0	195.07	269.20	297.78	.1062
40151	88-01-21	2.3850	93503.0	220.11	303.75	319.43	.0516
40156	88-01-21	2.3850	7746.0	18.51	25.55	22.90	1038
40064	88-02-18	2.3850	35927.0	84.41	116.49	98.27	1564
40068	88-02-18	2.3850	14404.0	33.84	46.70	45.95	0161
40067	88-02-18	2.3850	10034.0	23.58	32.53	30.31	0684
40062	88-02-18	2.3850	6186.0	14.53	20.06	20.65	.0296
40069	88-02-18	2.3850	40244.0	94.49	130.40	116.19	1090
30014	88-03-15	2.3850	60433.0	144.22	199.02	161.64	1878
30012	88-03-16	2.3850	4830.0	11.41	15.74	15.22	0333
30013	88-03-16	2.3850	19379.0	45.77	63.17	52.49	1690
30008	88-03-16	2.3850	20585.0	48.62	67.10	56.29	1612
30003	88-03-16	2.3850	24671.0	58.27	80.42	67.82	1567

N = 15 P = -.07 S = .09 /P/ + S = .16L = .30

### CATEGORY II : ACCIDENTS, HIGH-ENERGY PHOTONS RADIATION SOURCE : CESIUM-137 IRRADIATION DISTANCE : 100. CM TO THE FRONT FACE OF PHANTOM

	PROCESSOR NAME	:	
	PROCESSOR CODE NO.	:	
	TYPE OF DOSIMETER	•	
TEST	RESULTS FOR QUARTER	•	1988-1
	TESTING STATUS	:	RENEWAL
	REPORT PRINTED	:	27 APR., 1988

DOCIMENED		IRRADIATI	ON INFORM TIME	ATION TOTAL	DEEP ABSORB	ED DOSE, REPORTED	
DOSIMETER NUMBER	DATE IRRADIATED	RATE (MR/MIN)	(MIN)	(R)	(RAD)	(RAD)	P,
NUMBER	IRRADIATED	(MR/MIN)	(MIN)	(R)	(RAD)	(RAD)	F '
40161	88-01-14	457.87	99.00	45.33	46.69	43.08	0772
40168	88-01-15	457.87	151.10	69.19	71.26	71.26	0000
40160	88-01-15	457.87	26.59	12.18	12.54	14.88	.1865
40163	88-01-15	457.87	48.65	22.28	22.94	23.67	.0316
40159	88-01-19	457.87	276.46	126.58	130.38	137.43	.0541
40056	88-02-12	457.03	105.35	48.15	49.59	46.74	0576
40058	88-02-16	457.03	160.81	73.49	75.70	64.21	1517
40054	88-02-16	457.03	82.74	37.81	38.95	35.52	0879
40055	88-02-18	456.86	26.65	12.18	12.54	13.71	.0929
	88-02-19			78.07		70.52	1231
40057	88-02-19	457.03	170.82	/8.0/	80.41	70.52	1231
30035	88-03-11	456.31	51.11	23.32	24.02	22.91	0462
30034	88-03-11	456.31	57.67	26.32	27.11	26.46	0239
30016	88-03-14	456.31	69.13	31.55	32.49	29.15	1029
30029	88-03-14	456.31	78.01	35.60	36.67	31.30	1463
30030	88-03-16	456.31	353.23	161.18	166.02	142.26	1431

N = 15 P = -.04 S = .10 /P/ + S = .14 L = .30\*\*\*\*\* PASS \*\*\*\*\*

CATEGORY III : LOW-ENERGY PHOTONS PAGE 1 OF 2 RADIATION SOURCE : M30 (LG) IRRADIATION DISTANCE : 100.0 CM TO THE FRONT FACE OF PHANTOM

PROCESSOR NAME	:	
PROCESSOR CODE NO.	:	
TYPE OF DOSIMETER	:	
TEST RESULTS FOR QUARTER	:	1988-1
TESTING STATUS	:	RENEWAL
REPORT PRINTED	:	27 APR., 1988

DOCIMENE		IRRADIATI				SE EQUIV, (	CX = .40
DOSIMETER NUMBER	R DATE IRRADIATED	RATE (mR/nCOUL)	CHARGE (nCOUL)	TOTAL (MR)	DELIVERED (MREM)	(MREM)	P
NOMBER			(110001)	(111)	(IIII)	(IIIZEII)	*
40186	88-01-24	2.6810	4870.0	13030.6	5212.24	4762.00	0864
40177	88-01-24	2.7010	276.8	738.87	295.55	326.00	.1030
40185	88-01-24	2.6810	2842.0	7604.31	3041.72	2745.00	0976
40174	88-01-24	2.6810	2172.0	5811.60	2324.64	2055.00	1160
40193	88-01-24	2.6810	8342.0	22320.6	8928.24	8032.00	1004
40083 40087 40086 40084 40085	88-02-18 88-02-18 88-02-18 88-02-18 88-02-18	2.7010 2.7010 2.6810 2.6810 2.6810	253.0 277.0 5895.0 3763.0 8437.0	674.80 738.81 15600.9 9958.62 22328.2	269.92 295.53 6240.35 3983.45 8931.27	332.00 354.00 6730.00 4367.00 9694.00	.2300 .1979 .0785 .0963 .0854
30045 30075 30050 30063 30053	88-03-16 88-03-16 88-03-16 88-03-16 88-03-16	2.7010 2.6810 2.6810 2.7080 2.6810	273.2 6423.0 5871.0 86.5 4102.0	740.69 17060.1 15594.0 235.12 10895.3	296.28 6824.05 6237.58 94.05 4358.13	361.00 7467.00 6392.00 102.00 4468.00	.2185 .0942 .0248 .0845 .0252

N = 15 P = .06 S = .11 /P/ + S = .17L = .50

CATEGORY III : LOW-ENERGY PHOTONS PAGE 2 OF 2 RADIATION SOURCE : M30 (LG) IRRADIATION DISTANCE : 100.0 CM TO THE FRONT FACE OF PHANTOM

PROCESSOR NAME : PROCESSOR CODE NO. : TYPE OF DOSIMETER : TEST RESULTS FOR QUARTER : 1988-1 TESTING STATUS : RENEWAL REPORT PRINTED : 27 APR., 1988

DOSIMETER DATE NUMBER IRRADIATED	IRRADIATION INFOR RATE CHARGE (mR/nCOUL) (nCOUL)	TOTAL	SHALLOW DOS DELIVEREI (MREM)	SE EQUIV, C REPORTED (MREM)	X = .92 P
4018688-01-244017788-01-244018588-01-244017488-01-244019388-01-24	2.68104870.02.7010276.82.68102842.02.68102172.02.68108342.0	13030.6 738.87 7604.31 5811.60 22320.6	679.76 6995.96 5346.67	10952.0 751.00 6315.00 4727.00 18473.0	0864 .1048 0973 1159 1004
4008388-02-184008788-02-184008688-02-184008488-02-184008588-02-18	2.7010 253.0 2.7010 277.0 2.6810 5895.0 2.6810 3763.0 2.6810 8437.0	674.80 738.81 15600.9 9958.62 22328.2	679.71 14352.8 9161.93	764.00 815.00 15479.0 10045.0 22297.0	.2306 .1990 .0785 .0964 .0854
3004588-03-163007588-03-163005088-03-163006388-03-163005388-03-16	2.7010 273.2 2.6810 6423.0 2.6810 5871.0 2.7080 86.5 2.6810 4102.0	740.69 17060.1 15594.0 235.12 10895.3	15695.3 14346.4 216.31	831.00 17174.0 14701.0 235.00 10276.0	.2195 .0942 .0247 .0864 .0252
				N = - P = S =	15 .06 .12
				- /P/ + S =	.17

L = .50

CATEGORY V : BETA PARTICLES RADIATION SOURCE : Amersham Sr-90 50 mCi IRRADIATION DISTANCE : 35.0 CM TO THE FRONT FACE OF PHANTOM

PROCESSOR NAME : PROCESSOR CODE NO. : TYPE OF DOSIMETER : TEST RESULTS FOR QUARTER : 1988-1 TESTING STATUS : RENEWAL REPORT PRINTED : 27 APR., 1988

		IRRADIATI	ON INFO	RMATION	SHALLOW DO	DSE EQUIVA	LENT
DOSIMETER	DATE	RATE	TIME	TOTAL	DELIVEREI	D REPORTED	
NUMBER	IRRADIATED	(MRAD/MIN)	(MIN)	(MRAD)	(MREM)	(MREM)	Р
40172	88-01-18	9.74	20.96	195.89	195.89	208.00	.0618
40189	88-01-20	289.64	15.60	4519.38	4519.38	4920.00	.0886
40169	88-01-20	289.64	21.58	5981.70	5981.70	5812.00	0284
40178	88-01-21	289.64	13.71	3803.28	3803.28	3917.00	.0299
40202	88-01-21	289.64	6.72	1867. <b>61</b>	1867.61	1925.00	.0307
40094	88-02-17	289.01	3.75	1041.35	1041.35	1220.00	.1716
40109	88-02-17	289.01	23.07	6387.34	6387.34	7174.00	.1232
40095	88-02-17	289.01	6.30	1743.83	1743.83	1906.00	.0930
40107	88-02-17	289.01	13.73	3968.54	3968.54	4481.00	.1291
40093	88-02-19	9.72	17.29	161.31	161.31	189.00	.1717
30093	88-03-11	9.70	16.22	152.72	152.72	152.00	0047
30062	88-03-11	9.70	45.09	420.02	420.02	384.00	0858
30067	88-03-11	9.70	51.33	498.14	498.14	489.00	0183
30046	88-03-14	288.64	28.07	7778.98	7778.98	7715.00	0082
30036	88-03-14	288.64	16.71	4615.79	4615.79	4341.00	0595
						,	

N = 15 P = .05 S = .08 /P/ + S = .13L = .50

PROCESSOR NAME	:	
PROCESSOR CODE NO.	:	
TYPE OF DOSIMETER	:	
TEST RESULTS FOR QUARTER	:	1988-1
TESTING STATUS	:	RENEWAL
REPORT PRINTED	:	27 APR., 1988

DOSIMETER		LLOW DOSE REPORTED	EQUIVALENT		EEP DOSE EQ REPORTED	DUIVALENT
NUMBER	(MREM)	(MREM)	P	(MREM)	(MREM)	Р
		(,	-	(	(,	-
40188	3773.9	4220.0	.1182	3443.1	3035.0	1185
40179	435.0	480.0	.1034	404.2	351.0	1316
40206	342.4	454.0	.3258	307.3	311.0	.0120
40170	1835.1	2134.0	.1629	1684.5		0881
40194	580.7	858.0	.4774	505.2	549.0	.0866
40100	3548.0	3680.0	.0372	3208.8	3357.0	.0462
40118	299.9	317.0	.0570	264.5	257.0	0285
40108	320.2	305.0	0476	284.6	269.0	0548
40116	2760.4	2736.0	0088	2414.4	2417.0	.0011
40105	745.1	672.0	0981	670.6	593.0	1158
						•
30060	386.7	333.0	1389	353.3	307.0	1311
30058		464.0	0031	436.2	435.0	0027
30038	3770.2	3978.0	.0551	3439.2	3840.0	.1165
30090	656.5	587.0	1058	580.7	527.0	0924
30061	438.1	441.0	.0067	407.0	409.0	.0048
				•		

N	3	15	N	=	15
-		0.0	-		0.2
P	=	.06	P	=	03
S	3	.16	S	=	.08
- (D ( ) C			- /P/ + S		1 1
/P/ + S		.23	/ [/ + ]	-	. 11
L	-	.50	L	-	.50

### CATEGORY VII : SUMMARY OF PHOTONS PLUS PAGE 3 OF 3 BETA PARTICLES

PROCES	SOR NAME	:		
PROCESSOR	CODE NO.	:		
TYPE OF D	OSIMETER	:		
TEST RESULTS FOR	QUARTER	:	1988-1	
TESTIN	G STATUS	:	RENEWAL	
REPORT	PRINTED	:	27 APR.,	1988

DOSIMETER		LLOW DOSE REPORTED	EQUIVALENT		EP DOSE EQ REPORTED	UIVALENT
NUMBER	(MREM)	(MREM)	P	(MREM)	(MREM)	P
WONDER	(11(211))	(11(211))	•	(11(211))	(11(211))	•
40191	643.6	716.0	.1125	221.7	216.0	0257
40181	3586.2	3990.0	.1126	1731.6	1683.0	0281
40203	569.9	572.0	.0037	146.7	144.0	0187
40200	204.3	209.0	.0230	63.4	60.0	0529
40196	977.4	950.0	0280	264.8	255.0	0368
40101	2551.5	2617.0	.0257	1673.9	1646.0	0166
40097	384.1	437.0	.1377	148.3	142.0	0424
40120	2019.1	2148.0	.0638	836.1	830.0	0073
40098	2433.6	2615.0	.0746	1478.5	1386.0	0626
40115	1140.5	1195.0	.0478	469.9	450.0	0424
30071	520.3	503.0	0332	347.1	335.0	0350
30041	290.8	285.0	0199	174.3	164.0	0593
30049	2073.9	2035.0	0188	977.2	949.0	0288
30051	423.5	392.0	0743	204.3	197.0	0356
30086	3075.2	3046.0	0095	1052.4	1067.0	.0139

N	=	15		N	=	15
- P		.03		P	=	03
s	. =	.06	_	S	3	. 02
- /P/ + S	=	.09	- /P/ +	S	=	.05
L		.50		L	=	.50

PROCESSOR NAME	:			
PROCESSOR CODE NO.	:			
TYPE OF DOSIMETER	:			
TEST RESULTS FOR QUARTER	:	1988-1		
TESTING STATUS	:	RENEWAL		
REPORT PRINTED	:	27 APR.,	1988	

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		EP DOSE EQL	IVALENT
DOSIMETER			
NUMBER	(MREM)	(MREM)	P
40210	4451.4	4451.0	0001
40213	2258.3	2531.0	.1208
40214	2455.3	2595.0	.0569
40215	199.9	195.0	0244
40209	563.2	510.0	0945
40072	2130.7	2098.0	0153
40074	1572.1	1708.0	.0864
40075	1490.1	1584.0	.0630
40076	714.0	751.0	.0519
40073		2459.0	.0497
30095	1571.5	1528.0	0277
30103	217.5	201.0	0761
30105	1761.9	1489.0	1549
30106	824.6	844.0	.0235
30099	590.4	545.0	0769

		N	2	15
		P	-	00
		S	-	.08
- /P/	+	S	=	.08
		L	=	. 50

## NATIONAL VOLUNTARY LABORATORY ACCREDITATION PROGRAM PERSONNEL DOSIMETRY PERFORMANCE TESTING

\*\*\*\*\*\*\*\* SUMMARY OF STATISTICAL RESULTS \*\*\*\*\*\*\*\*\*

PROCESSOR NAME :

PROCESSOR CODE NO. :

TYPE OF DOSIMETER :

TEST RESULTS FOR QUARTER : 1988-1

TESTING STATUS : RENEWAL

REPORT PRINTED : 27 APR., 1988

		SHALLOW	DEPTH			DEEP	DEPTH	
CATEGORY	- P	S	- /P/+S	L	P	S	- /P/+S	L
I		NO T	EST		071	.090	.161	.300
II		NO T	EST		040	.098	.138	.300
III	.056	.115	.171	.500	.056	.115	.171	.500
IV		NO T	'EST		037	.038	.074	.500
v	.046	.081	.128	.500		NO	TEST	
VI	.063	.164	.227	.500	033	.080	.113	.500
VII	.028	.062	.0 <b>9</b> 0	.500	032	.020	.052	.500
VIII		NO	TEST		001	.076	.077	. 500

\*\*\*\* PROCESSOR DID NOT PARTICIPATE IN THIS CATEGORY. NATIONAL VOLUNTARY LABORATORY ACCREDITATION PROGRAM PERSONNEL DOSIMETRY PERFORMANCE TESTING

\*\*\*\*\*\*\*\* SUMMARY OF PASS/FAIL RESULTS \*\*\*\*\*\*\*\*\*

PROCESSOR NAME :

PROCESSOR CODE NO. :

TYPE OF DOSIMETER :

TEST RESULTS FOR QUARTER : 1988-1

TESTING STATUS : RENEWAL

REPORT PRINTED : 27 APR., 1988

CATEGORY I,	ACCIDENT, LOW-ENERGY PHOTONS	PASS
CATEGORY II,	ACCIDENT, HIGH-ENERGY PHOTONS	PASS
CATEGORY III,	LOW-ENERGY PHOTONS	PASS
CATEGORY IV,	HIGH-ENERGY PHOTONS	PASS
CATEGORY V,	BETA PARTICLES	PASS
CATEGORY VI,	PHOTON MIXTURES	PASS
CATEGORY VII,	PHOTONS PLUS BETA PARTICLES	PASS
CATEGORY VIII,	PHOTONS PLUS NEUTRONS	PASS

## APPENDIX F

## ASSESSOR CHECKLIST



NVLAP Lab Code #

### DOSIMETRY LAP GENERAL OPERATIONS CHECKLIST

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		Covered Attached
1.	The functional organization including key management and supervisory positions is consistent with that reported by the processor and appears adequate to support the required processing activities.	
2.	Authority, responsibility, and reporting relationships are clearly defined and appropriate for the processing services offered considering the processor's capabilities.	
3.	The qualifications of the individual who has technical responsibility are consistent with the position description.	
4.	The individual having technical responsibility generally exhibits technical knowledge and management control of processing operations for services identified in the application for accreditation.	
5.	The qualifications of the individual having responsibility for quality assurance are consistent with the position description.	
6.	Staff personnel are generally qualified and competent in areas observed.	;
7.	Communication seems adequate between technical and supervisory staff.	
8.	No significant management problems are apparent which might impair operation or customer relations.	
9.	Facilities including benchspace, utility services, and safety equipment are adequate to accommodate processing in the requested categories and no interfe- rence is apparent from other activities especially those involving radiation.	
10.	Please note the period for which the processor retains records of dosimetry processing and supporting raw data.	years
11.	When the processor deviates from the use of documented processing procedures, equipment, or facilities, records are adequate to show that no degradation of performance occurs.	
12.	The processor treats data, records, and dosimetry reports as proprietary information or as agreed upon in writing with the client.	
13.	The processor's Quality Assurance (QA) documentation outlines practices for handling and resolving contested dosimetry data and test reports.	
14.	The processor appears to process dosimeters and render reports objectively without influence from external sources.	
15.	An independent organizational relationship appears to exist between processing and other activities conducted within the same corporate framework.	
16.	Available equipment, facilities, and personnel seem adequate with respect to the workload indicated in the processor's record system.	
17.	Interviews indicate that allocations exist for securing and maintaining resources required for the processing activities for which accreditation is requested.	

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								Comments Covered Attached
18.	qual	ity assura	nce documenta	tion, and ot	ther relate	d documents a	ecifications, are available utine processin	g
19.							st version of ssing procedure	s
20.	Resp	onsibility	for maintain	ing and rev	ising QA do	cumentation .	is clearly assi	gned
21.	Resp equi	ionsibility	for the main learly assign	tenance and ed.	service of	environment	al and processi	ng
22.	Resp	onsibility	for periodic	calibratio	n of major	equipment is	clearly assign	ed
23.			for final ap tionable data				ions	
fin	dings	s pertinent	e Assessor: to any of th priate questi	e questions	of the gen	eral operati	comments, obse ons checklist.	ervations, or Make sure to
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## DOSIMETRY LAP QUALITY ASSURANCE CHECKLIST -

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			Comments
1.	The processor's Quality Assurance (QA) documentation describes practices for ensuring the competency of staff members.	Covered	Attached
2.	The processor assures competency of staff members at least annually, through one or more of the following methods:		
	<ul> <li>(a) observation of the conduct of processing protocols by technically qualified individuals.</li> <li>(b) written available individuals.</li> </ul>		
	(b) written examination based on the processing protocol.		
3.	The processor's QA documentation describes the training program which prepares staff members to conduct these processing protocols.		_
4.	The documentation has provisions for retraining assigned staff members when protocols are revised.		
5.	Specialized skills required in the conduct of all processing protocols are documented and included in the training program for individuals who conduct these protocols.		
6.	The training program includes:		
	<ul> <li>(a) a period of close supervision until competincy is demonstrated.</li> <li>(b) a mechanism for evaluating and informing staff members of the adequacy of their performance in conducting assigned processing processing.</li> </ul>	<u> </u>	
	(c) a mechanism for retraining on a periodic basis and correcting any deficiencies in performance between these periods of retraining.		
7.	A record of dates and findings of the competency review for all staff members is available.		
8.	A record of training courses completed by each staff member is available.		
9.	Calibration and verification practices for dosimetry systems for all processing protocols are outlined in the QA documentation identifying calibration services, reference materials, and measurement assurance programs used.		
10.	Dosimetry systems are calibrated to known doses from radioactive sources or radiation generating machines. The dose in a radiation field is measured using an N8S-calibrated instrument or is based on the measurement of flux or emission rate of a source traceable to primary radiation standards.		
11.	Calibration sources used are appropriate for the radiation dose to be interpreted by the dosimeter.		
12.	Calibration/verification records for major equipment items for dosimetry processing include the following: (a) equipment name or description		
	(b) manufacturer name		
	(c) model, style, serial number, or other identifying mark		
	(o) notation of equipment variables requiring calibration/verification		
	(c) range of ouse measurements for which calibrations have been conducted		
	coincide with requirements of each processing protocol		
	(g) schedule for periodic calibrations including calibration/verification date (h) date and result of last calibration/verification including assessed uncertainty of measurement		
	(i) identification of staff member or position responsible for equipment calibration or external service performing calibration		
	(j) identity of reference standards used	·	

	· _	Covered Attached
13.	Calibration of equipment is verified at regular intervals which are determined by equipment type, manufacturing specification, accumulated stability data, or other reasonable plan such that a high degree of confidence is demonstrated in measurements made by the processor.	
14.	The processor has established procedures for bringing back-up equipment into routine service or using the services of another NVLAP-accredited processor to assure continuity of service when dosimetry systems or personnel fail to perform within limits of control.	
15.	The dosimetry system documentation includes a specification with a minimum and maximum level of exposure which the dosimeter is capable of recording during routine processing.	
equ men obs dis	tructions to the Assessor: Examine staff members' notebooks, calibration/verifi- ipment maintenance logs, and other records where necessary to verify discussion bers and observation of their performance in processing selected dosimeters. Be servant for inconsistencies among records, procedures, observations, and respons- scuss any inconsistencies with the Technical Director. In completing this check a for those items not applicable to the processor's dosimetry system or processi	with staff particularly es. Note and list, indicate
Dos	simeter Acceptance	
16.	. The processor has established satisfactory acceptance criteria/specifications for all dosimeter materials.	
17	. These acceptance criteria are documented in the processor's QA documentation.	

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18. The processor uses a screening procedure to ensure that dosimeter materials (sensitive elements) to be used are consistent with the dosimeter design including phosphor type and sensitivity.

- 19. The processor has implemented an acceptance procedure to verify that film received meets applicable specifications and that the film's expiration date is sufficiently far in advance for the film to be unexpired at the anticipated time of processing.
- 20. The processor has documented a procedure for checking the proper assembly of dosimeters.
- 21. Check procedures are used to verify that filter materials are consistent with the dosimeter design and that filters are properly placed in dosimeters.
- 22. The processor verifies that dosimeter holders meet required specifications.
- 23. Fading of the TL materials, under normal conditions, is documented and accounted for over the period of intended use.
- 24. TL material for each dosimeter type or model is capable of withstanding heat treatment required in processing.
- 25. Dosimeters placed in-service are checked according to a defined schedule or frequency to ensure that all necessary components are in place.

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### Comments -Covered Attached

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## Dosimeter Handling prior to Issue

26.	The processor's QA documentation contains procedures for dosimeter handling prior to issue.		
27.	Dosimeters are suitably packaged for issue to clients to prevent damage or unknown exposure during transit.		
	Film		
28.	Prior to issue, film is stored unopened in a cool, dry, low background location which is free from chemical vapors or other deleterious agents.		
29.	Film is current and is stored in such a manner so as to reduce build-up of density due to natural background and/or old age deterioration.		
30.	The film emulsion batch number is noted; and prior to issue, each batch is tested to check that fog-level, dose-density, and spectral characteristics are satisfactory.		
	<u>د</u> .		
	Thermoluminescent Dosimeters (TLD)	;	
31.	TLD or phosphors are subject to an adequate annealing cycle which is reproducible regarding time, temperature, cooling rate, humidity, and light prior to issue.		
32.	The processor takes precautions to minimize light exposure of light-sensitive TL materials.		
33.	The processor takes precautions to avoid contamination of TL elements (e.g., chalk, dust, grease, or any radioactive material) and advises clients to take these precautions.		
34.	Loading of sensitive elements is carried out in a well-defined order to prevent confusion in handling visually-similar elements of different TL materials and prevent contamination of TL material in powder <sup>3</sup> form.		
Dos	imeter Identification		
35.	The processor has a positive system for identification and tracking for all dosimeters.		
36.	Sufficient information is contained in the dosimeter identification code to allow correlation with the processor's record system.		
37.	The identification system is adequate to assure correct identification of demountable (non-fixed) as well as fixed TL elements and the association of each TL element with a position or filter in the dosimeter.		
38.	The processor supplies the same or technically equivalent dosimeter types or models, including sensitive elements, to clients that were proficiency tested.		

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	Comments Covered Attached
Dosimeter Handling and Storage In-service	
39. The processor's QA documentation details practices for the r and storage of in-service dosimeters.	receipt, handling,
<ul> <li>40. The processor communicates with his client regarding dosimeter provided including as applicable: <ul> <li>radiation type</li> <li>dose definition (terminology)</li> <li>responsibility for handling dose of record</li> <li>calibration procedures used in dose determination</li> <li>quality control</li> <li>special processing procedures to be used as part of the dote directions for handling and use of background control dost</li> <li>identification of anomalies noted during processing</li> </ul></li></ul>	osimetry service
<ul> <li>41. A procedure and assignment of responsibility exists for the and background control dosimeters at the processor's facility - individual dosimeter identification, its associated dosimeter appropriate processing protocol to be followed</li> <li>- identification and coding of internal and external control.</li> <li>- a mechanism for tracking an individual dosimeter and/or set through the processing cycle</li> <li>- a mechanism for identifying dosimeters which have not been clients for processing</li> <li>- method for screening dosimeters or TL elements for radioar prior to readout</li> <li>- method for identifying mishandled background control dosing</li> </ul>	ty including: eter type, and 1 dosimeters ensitive element n returned from ctive contamination
42. Dosimeter storage areas are commensurate with types and num stored.	bers of dosimeters
43. Environmental parameters including background radiation are dosimeter storage areas to assure adequate conditions.	monitored in
44. Observed practices for dosimeter handling and storage appea provisions outlined in the QA documentation.	r consistent with
45 Records indicate that alignets are potified in writing of ra	diaactive

45. Records indicate that clients are notified in writing of radioactive contamination found on dosimeters received by the processor.

Instructions to the Assessor: Where practical, observe a demonstration of critical processing activities for requested radiation categories. Examine required equipment and instrumentation. Interview staff members responsible for routine processing as well as those conducting the demonstration.

#### Dosimeter Processing Equipment

- 46. Dosimetry processing equipment is sufficiently identified to correlate with calibration records.
- 47. Adequate controls are in place to assure the performance of equipment to those levels of precision and accuracy defined by the processor in each processing protocol.
- 48. The processor has documented operating procedures to be implemented when the equipment fails to meet the criteria of question 47.

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	<u>C</u>	overed	Comments Attached
49.	Duties are assigned for the maintenance and routine verification that all processing equipment is in proper working order.		<del></del>
50.	Records are available for each piece of processing equipment showing preventive and repair maintenance conducted to evaluate stability of equipment performance.		
51.	The processor has adequately provided for continuity of equipment operation thro service contracts or in-house maintenance capability and parts inventory.	ugh 	
	Thermoluminescent Dosimeters		
52.	The processor has equipment for reading out and annealing TL elements as appropriate for the system.	,	
53.	The annealing oven or furnace is reserved for dosimetry annealing.		0
54.	A written procedure and responsibility exists for establishing and checking appropriate operating conditions for instrumentation which may include: - reproducible positioning of the TL element in the reader - stabilization against voltage change or drift in dark current when applicable - reproducible heating cycle which ensures readout of a consistent fraction of relevant stored energy - glow curve output - inert gas purging - digital readout	 ,	
	Film		
55.	The processor has adequate equipment, facilities, and materials to support the film processing operations for which accreditation has been requested including developing, stop bath, fixing, washing, drying, and densitometry.		
56.	Film processing darkroom(s) is temperature-controlled with preferably incandescent lights and properly installed safelights.		
57	. Safelights used in darkrooms are tested at prescribed intervals to measure the fog-level of films exposed at the normal working distance from the safelights for a period comparable in length to maximum processing time.		
58	. Precautions are taken to prevent accidental exposure of the films to light while being processed.	e	
. <b>5</b> 9	. Processing chemicals are dated, appear to be properly stored, and a procedure exists to preclude use upon expiration of shelf life.		
60	<ul> <li>Tanks and equipment which hold or are exposed to processing solutions are chemically inert.</li> </ul>		
61	. The processor has equipment capable of measuring film densities appropriate to his processing protocols (typical optical densities would fall between 0.01 to with a resolution of $\pm 10\%$ or $\pm 0.01$ density units whichever is greater) and this equipment is adequate to support the workload.	5	
62	<ul> <li>Records demonstrate the accuracy and reliability of all instruments used to determine gross density of specimen and control films.</li> <li>Densitometer performance is checked for consistency before use.</li> <li>Densitometers are calibrated at a frequency recommended by the manufacturer, every 6 months, or as directed in the processing protocol, whichever is more frequency.</li> </ul>		

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	Comments
Covered	Attached

Pro	cessing (General)	
63.	The supervisor or a designated individual exercises authority in assignment of processing tasks and the timely processing of dosimeters.	
64.	There is agreement between assigned processing responsibilities and those technical areas addressed in the training program.	
65.	A written test plan (processing protocol) is available to the processing staff for each radiation category for which accreditation is sought.	
66.	Each processing protocol is documented in sufficient detail to allow performance of instructions by a competent technician.	
67.	All processing personnel follow processing procedures defined in processing protocols.	
	A record is maintained of processing activities (e.g., dated log) with sufficient identification to allow correlation with calibration/verification and control system records. This record is available for inspection in the processor's facility.	
69.	Staff members appear competent in performing assigned processing tasks.	
70.	The energy and dose response of each type or model of dosimeter used, is known by the processor.	
71.	The processor establishes and documents lower and upper limits of reliability for the dosimetry system in each radiation category of interest.	
72.	Procedures for dosimetry system calibration are documented and are available for use by staff members at least on a "need to know" basis.	
73.	The processor's tracking system is adequate such that each measurement is identified and recorded at the time of determination.	
74.	<ul> <li>Each processing protocol provides for the interspersing of quality control (QC) dosimeters for each set of dosimeters processed and/or blank dosimeters:</li> <li>irradiation of quality control dosimeters is conducted with suitable sources and records indicate good reproducibility for the method of irradiation;</li> <li>appropriate safeguards are used to prevent subversion of quality control dosimeter audits;</li> </ul>	
	- the processor has established the frequency of the use of blank and quality control dosimeters based upon total number of dosimeters processed, equipment stability, type of quality control checks used or other suitable means;	
75	A documented procedure exists for conducting a detailed review when data produced between the last successful quality control dosimeter and the first quality control dosimeter which fails to meet established control limits.	
76	. Data are reviewed for anomalies by the technical director or his designee prior to being reported to the client and a procedure for this review is documented.	

#### Comments Covered Attached

- Name and address of processor. - Pertinent dates and identification of dosimeter including client and corresponding processor identification codes. - Client name. - Identification of the dosimeter and/or elements including the radiation category. - "Occupational Radiation Exposure Report" or a similar title. - An explanation of any deviation from the protocol routinely used in processing dosimeters which may affect the reported dose (i.e., mishandling of background control dosimeter by client). - Identification of anomalies. - Signature or reference to person having technical responsibility. - All additional items required by the processor's test plan appear in the test report. Processing (Thermoluminescent) 78. The processor has a documented method for removing TL sensitive elements from the dosimeter case which minimizes the potential for loss of information from the sensitive element. 79. Procedures are established to ensure that TLD reader operation and stability are checked at least daily, when used, using pre-exposed dosimeters or light sources. Procedures ensure that no measurements are made until equipment conditions have stabilized.

77. An adequate report of dose is sent to the client and includes as applicable:

- 80. Sufficient measurements have been made to establish the relationship of the TL emission characteristics and the conversion factor between instrument reading and dose equivalent.
- 81. Technicians appear to understand operating conditions and critical functions of TLD processing equipment such as heating/temperature cycle, inert gas purging, annealing cycle, and recognition and resolution of equipment failure.
- 82. Procedures for loading/unloading the TLD reader are implemented as documented.
- 83. The processing protocol provides for review of selected dosimetry data during the processing cycle.
- 84. Checks are made to ensure that the annealing is accomplished.

Processing - (Photographic Film)

- 85. Films are removed from wrappers in the darkroom and maintained in identifiable order for processing.
- 86. The processor, through quality control films, establishes the dose density characteristics of each film emulsion batch.
- 87. Groups containing at least three quality control films of the same emulsion/lot exposed to known doses which bracket exposure ranges of the dosimeters to adequately check the response curve of the dosimeter type are included in each processed batch. Such group controls are positioned at the beginning and end of each processing batch and at intervals as defined in the processing protocol.
- 88. At least two unexposed films of the same emulsion/lot are included in each processed batch.
- 89. Processing of control films verifies that processing meets control limits during routine processing activities.

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# Comments Covered Attached 90. The processor has procedures for controlling chemistry and processing conditions. 91. Records show that temperatures and times for development, stop bath, fixing, washing, and drying are controlled and consistent with processing protocols. 92. Developer/fixer solutions are maintained under cover to reduce oxidation and exclude contamination. 93. During development, the developing solution is agitated to provide for uniform development of all film. 94. Procedures address the frequency for replenishing processing solutions according to time in use or number of films processed. 95. Procedures are documented and followed for use and renewal of a stop bath. 96. Fixing and washing procedures are documented and implemented according to processing protocols. 97. The temperatures in processing solutions are maintained according to processing protocols. £ 98. Orying temperatures are in accordance with the processing protocol. 99. After processing, films are stored so as to minimize damage to the emulsion. 100. Films are examined for non-uniform blackening and a special measurement procedure is defined for those showing significant non-uniform blackening. 101. All measurements made are recorded against film identification codes. 102. Track detectors are evaluated using optical or counting equipment appropriate for the anticipated macro- or microscopic track dimension. Dose Assessment 103. Satisfactory documentation of the algorithm exists to indicate its validity for dose interpretation: - algorithm was created and tested using fundamental data which are retrievable - sources of uncertainty arising from the use of the algorithm are understood and documented. - process controls were considered and documented in the development of the algorithm - attributes and limitations of the algorithm are documented. 104. The processor has documented differences, if any, between calibration and algorithms used for proficiency testing in comparison to routine dosimetry processing. 105. The processor has documented differences between algorithms used for different clients based upon information supplied by the client. Instructions for the Assessor: Evaluate the processor's quality assurance practices through discussion with the staff and examination of records. 106. The processor audits each processing protocols to assure that no degradation of performance occurs.

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			Comments Attached
107.	The processor's quality assurance program includes processing checks such as: - processing controls (i.e., light source readings, microprocessor controls) - blind audit dosimeters unknown to the technician - unexposed dosimeters - intercomparison programs		
108.	Technicians are familiar with and perform (as applicable) the documented quality control program.		
109.	This quality control program is also organized to assess variability of test results among staff members, or separate equivalent systems.		
110.	Results of audit practices are examined by the supervisor and action is taken to correct any deficiencies.		
111.	Records of the laboratory's participation in intercomparison programs or external measurement assurance programs are consistent with practices defined in the QA documentation.		
112.	If processing activities are conducted in multiple locations within the processor's facility, comparative tests are conducted to assess consistency of dosimetry data.	<del></del>	
113.	The documented quality assurance system clearly describes and is consistent with records and practices observed from the point of dosimeter receipt throu to final delivery of data to the user.	gh	

<u>Instructions for the Assessor</u>: Use the space below to record your comments, observations, or findings pertinent to any of the above questions. Make sure to identify the appropriate question number for each comment.

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Number Comments

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NIST-114A	U.S. DEPARTMENT OF COMMERCE	1. PUBLICATION OR REPORT NUMBER NISTIR 89-4125
REV. 3-89)	NATIONAL INSTITUTE OF STANDARDS AND TECHNOLOGY	2. PERFORMING ORGANIZATION REPORT NUMBE
	BIBLIOGRAPHIC DATA SHEET	
		JULY 1989
TITLE AND SUBTITLE		
	Program Handbook - Personnel Radiation Dosimetr	cy
	10081 mm 11001101	
AUTHOR(S)		
Rober	t L. Gladhill	
PERFORMING ORGAN	IZATION (IF JOINT OR OTHER THAN NIST, SEE INSTRUCTIONS)	7. CONTRACT/GRANT NUMBER
U.S. DEPARTMENT OF	COMMERCE	
GAITHERSBURG, MO		8. TYPE OF REPORT AND PERIOD COVERED
	TATION MANE AND COUDULTE ADDRESS (STREET CITY STATE TIM	
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