



REFERENCE



National  
Voluntary  
Laboratory  
Accreditation  
Program

# Ionizing Radiation Dosimetry

Paul R. Martin

**NIST** HANDBOOK 150-4

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and Technology

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- Computer Services<sup>2</sup>
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- Information Systems

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<sup>1</sup>At Boulder, CO 80303.

<sup>2</sup>Some elements at Boulder, CO 80303.

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**National  
Voluntary  
Laboratory  
Accreditation  
Program**

**Ionizing  
Radiation  
Dosimetry**

Paul R. Martin

August 1994



**U.S. Department of Commerce**  
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Technology Administration  
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## PREFACE

NIST Handbook 150-4 presents the technical requirements of the National Voluntary Laboratory Accreditation Program (NVLAP) for Ionizing Radiation Dosimetry (formerly called the Personnel Radiation Dosimetry program). It is intended for information and use by staff of accredited laboratories, those laboratories seeking accreditation, other laboratory accreditation systems, users of laboratory services, and others needing information on the requirements for accreditation under the Ionizing Radiation Dosimetry program (hereinafter referred to as the Dosimetry program).

This publication supplements NIST Handbook 150, "NVLAP Procedures and General Requirements," which contains Part 285 of Title 15 of the U.S. Code of Federal Regulations (CFR) plus all general NVLAP procedures, criteria, and policies. The criteria in NIST Handbook 150 encompass the requirements of ISO/IEC Guide 25 and the relevant requirements of ISO 9002 (ANSI/ASQC Q92-1987). Handbook 150-4 contains information that is specific to the Dosimetry program and does not duplicate information contained in the Procedures and General Requirements. The numbering of the sections of this handbook is patterned after Handbook 150; for example, Section 285.3 of Handbook 150 presents the description and goal of NVLAP, whereas Section 285.3 of Handbook 150-4 presents the description of the Dosimetry program. Where there is no material specific to the field of accreditation, the section number is omitted.

Any questions or comments on this handbook should be submitted to the National Institute of Standards and Technology/NVLAP, Building 411, Room A162, Gaithersburg, MD 20899; phone (301) 975-4016; FAX (301) 926-2884.

## ACKNOWLEDGMENTS

The preparation of this document is a combination of the work of the original developers and supporters of the Dosimetry program and the work of the NVLAP staff in recent years to bring the program into compliance with the current international quality system concepts and ANSI N13.11. It is impossible to list all of the individuals who provided input to this document, but their efforts are greatly appreciated.

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## SUMMARY

Accreditation is available to any laboratory (processor) that processes personnel radiation dosimeters used to monitor individual exposure to the ionizing radiation categories specified in American National Standard N13.11, *Criteria for Testing Personnel Dosimetry Performance*, (ANSI N13.11). To be granted accreditation, a processor must satisfy the NVLAP requirements contained in NIST Handbook 150 and this handbook, and must demonstrate proficiency according to ANSI N13.11 in processing each dosimeter model/type that the laboratory intends to use in each radiation category for which accreditation is desired.

The Dosimetry program was established in 1984 in response to a request from the U.S. Nuclear Regulatory Commission (NRC). The NRC regulation 10 CFR Part 20, "Standards for Protection Against Radiation," Vol. 56, No. 98; Subpart F states the requirement that NRC licensees use NVLAP-accredited dosimeter processors. 10 CFR Part 20 was revised on 5/21/91.

The purpose of this NVLAP program is to provide periodic evaluation of dosimetry processors, including an assessment of processors' quality systems; to improve the quality of personnel dosimetry; and to recognize competent processors.

Note: This NVLAP program currently bases the proficiency testing on ANSI N13.11-1983. NVLAP is moving towards making use of ANSI HPS N13.11-1993. The laboratories will be notified of the implementation schedule for conversion to the revised N13.11. This handbook does, however, address the new requirements of ANSI HPS N13.11-1993.

***Processing services 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. NVLAP is currently working on expanding the program to include extremity dosimeters tested to ANSI N13.32.

***Period of accreditation:*** One year, renewable annually.

***On-site assessment:*** Visit by a technical expert(s) to determine compliance with the NVLAP criteria before initial accreditation and every two years thereafter. Additional monitoring visits as required.

***Assessors:*** Technical experts with experience in the appropriate field of testing.

***Proficiency Testing:*** Each laboratory is required to demonstrate its capabilities by performing the specified proficiency test in accordance with ANSI N13.11; once prior to accreditation; every two years thereafter.

***Granting Accreditation:*** Based upon satisfactory on-site assessment and resolution of deficiencies, proficiency testing, and technical evaluation of applicable laboratory information.

***Fees:*** Payments are required as listed on the NVLAP fee schedule, including the administrative/technical support fee, on-site assessment fee, proficiency testing fee, and test method fee.



## Sec. 285.1 Purpose

The purpose of this handbook is to set out procedures and technical requirements for NVLAP accreditation of laboratories which perform ionizing radiation dosimetry processing. It complements and supplements the NVLAP programmatic procedures and general requirements found in NIST Handbook 150. The interpretive comments and additional requirements contained in this handbook make the general NVLAP criteria specifically applicable to the Dosimetry program. This handbook also identifies the requirements for proficiency testing to ANSI N13.11, the specific on-site assessment criteria, and the requirements for a quality system. The quality system requirements are designed to comply with the requirements of ISO Guide 25 and ISO 9002.

## Sec. 285.2 Organization of procedures

(a) The handbook is organized to cross-reference with NIST Handbook 150, *NVLAP Procedures and General Requirements*.

(b) In addition, the handbook contains five appendices:

(1) Appendix A provides examples of a Scope of Accreditation and a Certificate of Accreditation for the Dosimetry program;

(2) Appendix B provides the General Operations Checklist, which NVLAP assessors use during an on-site technical assessment to evaluate a laboratory's ability to conduct testing in general;

(3) Appendix C provides the Specific Operations Checklist, which NVLAP assessors use during an on-site technical assessment of a laboratory that processes personnel radiation dosimeters;

(4) Appendix D contains a sample proficiency test report; and

(5) Appendix E contains the NVLAP proficiency testing data summary for 1993.

## Sec. 285.3 Description of NVLAP Ionizing Radiation Dosimetry accreditation program

Accreditation is available to any organization that processes personnel radiation dosimeters used to

monitor individual whole body exposure to ionizing radiation. NVLAP is currently working on the requirements for accreditation of processors of 1) extremity dosimeters with proficiency testing to ANSI N13.32, and 2) Electronic Personal Dosimeters (EPDs) with proficiency testing to ANSI N13.11, as additions to this program.

The processor should seek accreditation for the type of monitoring service it provides, including the radiation type monitored and the type and model of dosimeter utilized for each radiation category. Accreditation is not applicable to the processing of pocket ionization chambers. Nothing in this program is intended to preclude a processor from providing additional services outside the scope of its accreditation.

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

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 considered to provide results that are not 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 has been demonstrated in accordance with ANSI N13.11.

## Sec. 285.4 References

The following documents are referenced or cited in this handbook:

(a) American National Standards Institute (ANSI) standards:

(1) ANSI N13.11-1983, *Criteria for Testing Personnel Dosimetry Performance*;

(2) ANSI HPS N13.11-1993, *Standard for Dosimetry-Personnel Dosimetry Performance-Criteria for Testing*; and

(3) ANSI N13.32-draft, *Standard for the Performance Testing of Extremity Dosimeters*.

ANSI standards may be ordered from:

American National Standards Institute  
11 West 42 Street, 13th Floor  
New York, NY 10036

Order Phone: (212) 642-4900  
Order FAX: (212) 302-1286.

(b) NIST Handbook 150, *NVLAP Procedures and General Requirements*; available from:

NIST/NVLAP  
Building 411, Room A162  
Gaithersburg, MD 20899

Phone: (301) 975-4016  
FAX: (301) 926-2884.

(c) ISO/IEC Guide 25, *General Requirements for the Competence of Calibration and Testing Laboratories*; available from the American National Standards Institute (ordering information is provided under 285.4(a)).

(d) ANSI/IEEE Standard 730, *IEEE Standard for Software Quality Assurance Plans*; available from:

Institute of Electrical and Electronics Engineers  
445 Hoes Lane  
P.O. Box 1331  
Piscataway, NJ 08855-1331

Order Phone: (800) 678-4333  
Order FAX: (908) 981-9667.

## Sec. 285.5 Definitions

**Absorbed dose, D:** The energy absorbed per unit mass at a specific place in a material. The special name for the unit of dose is the gray (Gy) which has units of Joules per Kilogram (J/kg). Formerly, the special unit of absorbed dose was the rad -  $1 \text{ J/kg} = 1 \text{ Gy} = 100 \text{ rad}$ .

**Angular dependence:** The performance of a dosimeter irradiated under nonperpendicular radiation incidence.

**Dose equivalence, H:** The product of D and Q at the point of interest in tissue, where D is the absorbed

dose, Q is the Quality Factor. The special unit of dose equivalent is sievert (Sv);  $1 \text{ Sv} = 100 \text{ rem}$ . Formerly, the special unit of dose equivalent was rem; whereas D is expressed in rads, H is expressed in rems.

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

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

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

**Quality Assurance:** All those planned and systematic actions necessary to provide adequate confidence that a product or service will satisfy given requirements for quality.

**Quality Control:** The operational techniques and activities that are used to fulfill requirements for quality.

**Thermoluminescence dosimeter (TLD):** A dosimeter made of a material that stores energy when irradiated by ionizing radiation and then releases that energy in the form of visible light when heated. The light output of heated TLD is measured photometrically. Examples of commonly available TLDs include lithium fluoride (LiF), calcium fluoride with various trace activators (such as  $\text{CaF}_2\text{:Mn}$  and  $\text{CaF}_2\text{:Dy}$ ), and calcium sulfate ( $\text{CaSO}_4\text{:Mn}$  and  $\text{CaSO}_4\text{:Dy}$ ).

**Whole body:** The whole body is defined as everything except extremities.

## Sec. 285.6 NVLAP documentation

Checklists contain definitive questions about all aspects of the NVLAP criteria for accreditation. NVLAP programs incorporate two types of checklists: (a) a General Operations Checklist and (b) a Specific Operations Checklist. For the former, the questions are applicable to evaluating a laboratory's ability to conduct testing in general. They address factors such as the laboratory's organization, management, and quality system in addition to its testing competency. The Specific Operations Checklist's questions are specific to the test method(s) in the given program and focus on the



testing requirements, including the assessor's observations of test demonstrations.

(a) The NVLAP General Operations Checklist is contained in Appendix B. The questions in the General Operations Checklist follow and are numbered to correspond to the requirements in NIST Handbook 150.

(b) The Specific Operations Checklist for the Ionizing Radiation Dosimetry program is contained in Appendix C, along with a comment sheet used by the assessor in conjunction with this checklist. The comment sheet is used primarily to explain deficiencies noted on the checklist. Additionally, the assessor may use the sheet to make comments on aspects of the laboratory's performance other than deficiencies. A similar comment sheet is provided to the assessor for use with the General Operations Checklist.

## **Sec. 285.22 Assessing and evaluating a laboratory**

### **(a) On-Site Assessment**

(1) The NVLAP assessor will request the quality manual and/or procedures in advance of the on-site assessment to reduce time at the laboratory. The laboratory should be prepared for conducting test demonstrations, have equipment in good working order, and be ready for examination according to the requirements identified in this handbook, NIST Handbook 150, and the laboratory's quality manual. The assessor will need time and work space to complete assessment documentation during the time at the laboratory.

(2) An assessor performs the following activities during a typical on-site assessment:

(i) Conducts an entry briefing with the laboratory manager to explain the purpose of the on-site visit and to discuss the schedule for the day(s). At the discretion of the laboratory manager, other staff may attend the briefing.

(ii) Reviews laboratory quality manual and records, including the following:

- sample identification and tracking procedures and copies of completed radiation dose reports;

- records of periodic internal audits and use of quality control procedures and participation in interlaboratory comparisons or other similar programs; and

- personnel records, including résumés and job descriptions of key personnel and competency evaluations for all staff members who routinely perform the procedures for which accreditation is sought.

At least one laboratory staff member must be available to answer questions; however, the assessor may wish to review the documents alone. The assessor does not usually ask to take any laboratory documents with him and documents previously supplied will be returned.

(iii) Physically examines equipment and facilities, determines whether appropriate environmental conditions are maintained, and observes the demonstration of selected procedures by appropriate personnel assigned to conduct the tests, and interviews the personnel. The assessor may select and trace the history of one or more dosimeters from receipt to final issuance of the radiation dose reports or dose data transfer.

The assessor examines hardware and software for appropriateness and function, and reviews software validation and verification procedures and the dose algorithm for the function and calculations it performs.

The assessor observes demonstrations of dosimeter processing techniques and discusses them with the technical personnel to assure their understanding of the procedures.

(iv) Completes an On-Site Assessment Report, which contains the minimum requirements prescribed in NIST Handbook 150, Sec. 285.22(b)(2), as well as copies of the completed checklists. At the exit briefing, the first page of the report is signed by the assessor and the laboratory's Authorized Representative to acknowledge the discussion but does not

necessarily indicate agreement; appeals may be made through NVLAP. All observations made by the NVLAP assessor are held in the strictest confidence.

**(b) Proficiency Testing**

**(1) Conducting proficiency testing**

In order to be eligible for accreditation, each processor must demonstrate satisfactory performance in accordance with ANSI N13.11 "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 2 years thereafter.

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. After initial accreditation the proficiency testing schedule for each processor is determined by NVLAP in consultation with the laboratory and PTL. A participant may start a test sequence only at the beginning of a quarter.

**A processor will be expected to begin testing on the accreditation renewal 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 NVLAP Technical Expert (TE), that normal processing is done in a manner consistent with that employed in the proficiency test.

A processor has 1 year from the date of application to demonstrate satisfactory

performance for initial accreditation. If satisfactory performance is not demonstrated within one year or if a retest is required, an additional administrative fee may be charged.

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

(i) 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 five each, 1 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. Each shipment should arrive at the PTL by the first day of the month in which testing is to be done.

(ii) The PTL will irradiate each dosimeter to a known dose and return groups of five to the processor at 1-month intervals.

(iii) The processor must read each dosimeter and determine a dose for each 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.

(iv) The processor must report the determined doses to the PTL within 30 days of receipt of the third set of dosimeters.

**(2) Data analysis and reporting**

At the completion of a testing quarter, the PTL will compare each processor's data with the known irradiation data, analyze the results, and send a detailed report containing its individual test results and pass/fail evaluation to each participant. Copies of the report will be sent to NVLAP for use in the evaluation of the processor and for use by the on-site

assessor. An example of the report format is included in Appendix D.

NVLAP maintains computer files of all proficiency test results in order to analyze and/or monitor individual as well as group trends, problems or other factors. NVLAP distributes a yearly summary of the proficiency testing results. The yearly summary also contains 5-year cumulative statistics for each category of testing. The 1993 summary is provided in Appendix E.

### (3) Proficiency test failures and retests

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:

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

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

Processors participating in three or fewer categories and failing the proficiency test in at least one of them will be required to retest in all categories attempted or as determined by NVLAP. Processors participating in four or five 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.

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

## Sec. 285.23 Granting and renewing accreditation

Laboratories granted NVLAP accreditation are provided with two documents: a Certificate of Accreditation and a Scope of Accreditation. Samples of these accreditation documents for the Dosimetry program are shown in Appendix A.

The Scope of Accreditation will specify the model(s)/type(s) of dosimeters and radiation category(ies) for which accreditation has been granted. 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.

## Sec. 285.33 Criteria for accreditation

### (b) Organization and management

(1) As stated in Sec. 285.5 of NIST Handbook 150, *Definitions*: "NVLAP previously differentiated between *main facilities* and *sub-facilities*. This distinction is no longer recognized. (Exception: As long as there is no break in accreditation, any laboratory previously accredited as a sub-facility may request to be 'grandfathered' in its accreditation renewal under the former classification as a sub-facility, including the unique conditions associated with that classification.)"

A NVLAP accreditation extends to temporary site facilities if they are due to be in operation for a short period of time and the laboratory has sufficient quality assurance procedures in place for the temporary facility.

(2) Main laboratory facilities and sub-facilities are defined as follows:

(i) A *main laboratory facility* permanently maintains staff, equipment, procedures, documentation, and facilities necessary to perform the tests for which it seeks accreditation; implements all quality assurance procedures; and maintains and retains all records, and issues test reports.



(ii) A *sub-facility* is physically separate from, but considered an extension of, the main facility. Although it may have all staff, equipment, procedures, and documentation necessary to perform the requisite tests, it receives technical direction and quality management from the main facility. A sub-facility shall maintain staff, equipment, procedures, documentation, and facilities necessary to perform the tests for which it seeks accreditation.

(3) NVLAP will renew the accreditation of a sub-facility (in addition to the main facility) if:

(i) the laboratory was accredited as a sub-facility prior to October 1, 1993;

(ii) the laboratory main facility meets all NVLAP accreditation criteria;

(iii) the laboratory main facility satisfactorily documents and maintains quality assurance procedures addressing the applicable sub-facility; and

(iv) the sub-facility complies with all applicable NVLAP criteria.

(4) NVLAP requires that sub-facilities undergo on-site assessments.

(c) **Quality system, audit and review**

(1) A *quality system* is defined as the organizational structure, responsibilities, procedures, processes and resources for implementing quality management. Quality systems are developed by the laboratory for specific testing services by tailoring the generic guidelines for a quality system. The NVLAP requirements for a quality system are contained in the NIST Handbook 150, *NVLAP Procedures and General Requirements*, and Part 285 of Title 15 of the U.S. Code of Federal Regulations.

The quality system includes the following major components: the organization and management, including a corporate quality

policy; technical and quality managers, personnel training and quality audits; the facilities and equipment used in performing the specific testing functions; the calibration of test equipment, reference materials, and measurement traceability to the national standards; the laboratory operating procedures for performing the test method/process and maintaining quality control; and the records and test/radiation dose reports.

The laboratory must have a method for identifying dosimeters that have been received by the laboratory for testing. This identification number can be used for verification of the test report and tracking the progress of the test item from receipt until the test report is sent to the client.

The quality system requirements are designed to promote laboratory practices which ensure technical integrity of the analyses and adherence to quality assurance. This information will be reviewed by NVLAP assessors during on-site assessments.

(2) Under its quality system, the laboratory shall develop and implement procedures covering all the technical requirements of this handbook. Periodic reviews of the quality system shall reflect adherence to NVLAP requirements and the laboratory's quality objectives. These reviews should reflect positive aspects of the quality system as well as deficiencies.

(3) The most recent editions of the documents listed in Sec. 285.4 *References* should be available as references in maintaining the quality system. There should, also, be available in the laboratory general reference texts on statistics and quality assurance.

(4) The *quality manual* is generally one manual that documents and describes the quality system. It contains references to other supporting documents such as calibration records, equipment inventory and status records, operating procedures for performing the specific test, proficiency testing, quality control functions and statistical methods for controlling the quality of the laboratory function.

In addition to the information specified in NIST Handbook 150, Sec. 285.33(c)(2), the quality manual and/or supporting quality assurance procedures must include:

- (i) processing facilities and scope of services offered;
- (ii) processing equipment inventory including radiation sources used for calibration;
- (iii) processing equipment calibration, verification, and maintenance practices;
- (iv) a test plan (processing procedure) for each test category processed;
- (v) dosimeter models and design specifications;
- (vi) acceptance criteria for dosimeter holders and materials;
- (vii) procedures for handling and storing sensitive components and materials;
- (viii) assembly/disassembly techniques for all dosimeter models used;
- (ix) procedures for periodic checks on in-service dosimeters;
- (x) dosimeter calibration techniques and procedures;
- (xi) identification and tracking of dosimeters;
- (xii) handling, control and storage of in-service dosimeters;
- (xiii) actions concerning damaged dosimeters;
- (xiv) instructions to operate all processing equipment, including any operational checks;
- (xv) data handling and reporting;

(xvi) actions when test data indicate a possible problem exists; and

(xvii) policy for utilizing subcontractors.

The documentation must be readily accessible to all staff members and must be in a format and style which can be easily understood by all staff members.

(d) **Personnel**

(1) The laboratory shall maintain records on each staff member, including a résumé, assigned duties, laboratory procedures for which they are qualified, training, quality assurance activities, and proficiency testing information.

(2) The personnel dosimetry **technical director** shall be a professional experienced in applied radiation dosimetry who is knowledgeable in the design and operation of the dosimetry system(s) currently utilized. This individual must have the technical competence and the supervisory capability to direct the work of professionals and technicians in the dosimetry area.

(3) The laboratory shall have a detailed documented description of its training program for new and current staff members. 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.

(4) In addition to training, the competency of each staff member shall be evaluated by observing the performance of each processing procedure each staff member is authorized to conduct. The performance observation shall be conducted at least annually by the immediate supervisor or a designee appointed by the laboratory director. A record of the staff member's review must be placed in the personnel file, dated and signed by the supervisor.

(5) Reference documents, texts and current scientific and industry periodicals should be made available to all technical personnel to keep their knowledge up to date. An ongoing process of training and professional development is essential to the improvement of technical expertise.

(6) The laboratory shall be organized so that staff members are not subjected to undue pressure or inducement that might influence their judgment or results of their work.

(7) Employees shall be aware of the extent of their area of responsibility. This information should be available in the required job descriptions found in the quality documentation and individual files.

**(f) Equipment and reference materials**

(1) 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.

(2) Examples of equipment, facilities and materials required for film processing include:

(i) fresh chemicals to develop and fix film;

(ii) adequate darkroom;

(iii) proper storage facility to eliminate environmental, chemical or radiation damage of unexposed film;

(iv) densitometer(s) adequate to support workload; and

(v) system to characterize dose-density relationship for each film type and film emulsion batch in each radiation category used.

(3) Examples of equipment, facilities and materials required for TLD processing include:

(i) proper annealing equipment;

(ii) adequate apparatus to read thermoluminescent level;

(iii) proper storage facilities to eliminate environmental, chemical or radiation damage of TLD's; and

(iv) system to characterize dose-TLD reading relationship for each TLD or TLD batch in each radiation category used.

(4) 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 proficiency 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 proficiency tested so that the processor does not lose accreditation.

The processor may request that NVLAP evaluate the technical equivalence of more than one algorithm and/or dosimeter used by a processor to monitor the same radiation type. If NVLAP determines two or more dosimeters to be technically equivalent, only one of the dosimeters will require proficiency testing.

(5) 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.

**(g) Measurement traceability and calibration**

**(1) Equipment calibration**

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.

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 compared to reference standards that are traceable to national standards maintained by NIST or by an equivalent foreign national standards authority.

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.

**(2) Measurement quality assurance and system calibration**

The ANSI N13.11 standard specifies radiation sources and irradiation conditions used by the proficiency testing laboratory. The radiation sources used by the PTL are well-characterized, calibrated, traceable and regularly monitored by the National Institute of Standards and Technology/Ionizing Radiation

Division, as a requirement for use in the proficiency testing program. The calibration facilities at NIST provide the measurement quality assurance for the proficiency testing laboratory.

A processor may obtain better results in a proficiency test by using a reader system that has been calibrated with similar 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 processor's neutron dosimeters which will be used for category VIII testing.

**(3) Software and algorithms**

The laboratory is required to have procedures for software validation and verification; including process control software (dosimeter handling and identification), dose algorithms, data processing (data analysis and reporting) and recordkeeping. The IEEE Standard 730 for "Software Quality Assurance Plans" can be used as a reference for software validation and verification. In addition, software version control should be included in the laboratory document control procedures for all software.

The proficiency tests are performed under controlled conditions and may not precisely reflect the radiation exposure monitored in the field. Algorithms used by a processor to pass proficiency testing may need to have special factors for specific radiation applications. However, the use of special workplace factors must be done with great care, and the use of algorithms specifically tailored to the proficiency tests is discouraged unless they are shown to be adequate for radiation fields monitored. The dose algorithm used for proficiency testing should be as similar as possible to the one used during normal operations.



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

(h) **Calibration and test methods**

(1) **Summary of ANSI N13.11 (Categories and Performance Criteria)**

The categories for performance testing and the associated tolerance limits for proficiency testing are based on the requirements of ANSI Standard HPS N13.11-1993. (Note: The proficiency testing requirements were originally based on ANSI N13.11-1983). Table 1 (page 13), which was taken from the ANSI HPS N13.11-1993 standard, is a summary of the radiation categories, tolerance limits and sources that will be used by the proficiency testing laboratory for testing the dosimetry processors. The ANSI HPS N13.11-1993 revised standard contains additional categories and requirements not included in ANSI N13.11-1983.

The performance criterion for testing fifteen dosimeters in each category is determined as follows:

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B = performance testing bias  
 L = tolerance limit  
 P = performance quotient  
 S = standard deviation of P, where n=15  
 H' = dose equivalent delivered by testing lab  
 D' = dose delivered by testing lab  
 H'' = dose equivalent reported by processor  
 D'' = dose reported by processor  
 (D is used for categories I & II)

$$B = \bar{P} = \frac{\sum (P)}{n}$$

$$P = \frac{(H'' - H')}{H'} \quad \text{or} \quad P = \frac{(D'' - D')}{D'}$$

where n=15

---


$$\text{Performance criterion} = |B| + S \leq L$$


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The tolerance limits for each category are listed in table 1. This standard provides a procedure for testing the performance of suppliers of personnel dosimetry for exposure to ionizing radiation. The ANSI standard is applicable to the performance of all processors that provide dose or dose-equivalent estimates for a permanent record of external personnel exposure. The original ANSI N13.11-1983 standard was revised to include an additional testing category for angular dependence of a dosimeter.

NVLAP is planning to add extremity processing to the accreditation program. The Nuclear Regulatory Commission (NRC) defines extremities and extremity dose limits in 10 CFR Part 20. When adopted, the processing of extremity dosimeters will be tested under the ANSI N13.32 "Standard for the Performance Testing of Extremity Dosimeters." This standard establishes the criteria for acceptable performance of the processing of extremity dosimeters and a procedure for testing their performance. See table 2 on page 14.

There are additional limits of 0.35 placed individually on |B| and on S, as shown in table 1. The additional limits are not required by every category. Categories I, II, V-C and the neutron reporting section of VIII are exempt from the additional limits.

Except as noted below, the requirements of ANSI HPS N13.11-1993 will be implemented as they are defined in the standard. NVLAP has modified the requirements of the following categories in order to implement the standard without excessive cost or burden to the laboratories.

**Category III** has been divided into categories III-A. General, and III-B. High-energy techniques. Also, in the revised standard the requirements for testing category III have changed. A primary source and one other source from the NIST beam codes in category III-A or III-B will be used to irradiate a group of five dosimeters. At least three of the five dosimeters will be irradiated to the primary source and the other two will be irradiated to a different x-ray beam code. The testing will include at least one of the higher energy x-ray codes.

*Category V* has been divided into categories V-A. High-energy, V-B. Low-energy, and V-C. General. The processor should select category V-C, if it monitors both high- and low-energy beta radiation. Sub-category V-C will be either a high-energy beta source or a low-energy beta source randomly chosen for each dosimeter. The  $^{204}\text{Tl}$  will be added to the proficiency testing program to implement this change.

*Category VIII* has been divided into categories VIII-A and VIII-B. NVLAP will not add the AmBe source to the proficiency testing program at this time and will limit proficiency testing to category VIII-A. Therefore, the only change to category VIII will be the requirement for the processor to report both the dose equivalent due to neutrons and the total dose equivalent (neutrons + photons). The category VIII-B may be added at a later date.

## (2) Angular Dependence

The dosimeter response to radiation incident at nonperpendicular angles may be proficiency tested if a processor requests accreditation for either category III or IV and for each model of dosimeter that a processor submits for performance testing in these categories. The angular dependence will only be tested once but will be retested if the dosimeter design is changed, including changes in the holder and filters. Although category IX will not be a category for accreditation, it will be a performance requirement for the dosimeter model.

The procedure for testing in category IX follows (subject to change):

- (i) The processor shall supply 15 badges to the proficiency testing laboratory the first month of testing for each model of dosimeter to be tested.
- (ii) The badges will be irradiated by the proficiency testing laboratory from .10 to 5 rem deep dose equivalent, using sources from category III-B and IV at 0,  $\pm 40$ ,  $\pm 60$  degrees, in both the horizontal and vertical plane of the dosimeter.

- (iii) The processor will analyze the performance of the dosimeter and report the dose equivalent back to the PTL.

## (j) Records

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

- (1) staff training dates and results;
- (2) staff competency review dates and results;
- (3) processing equipment calibration and maintenance;
- (4) results of incoming inspection of dosimeter materials;
- (5) comprehensive logs of processing activities;
- (6) results of internal and external equipment checks, measurement quality assurance programs, internal audits, etc.;
- (7) test data and reports; and
- (8) 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.

## (k) Certificates and reports

NVLAP does not require a processor to state results in terms of particular quantities or units in the report to a client. However, the processor should meet the requirements specified by the appropriate regulatory authority in the region they are operating or by contract. It must be made completely clear what the reported numbers mean so that they can be used

appropriately. The NRC requirements for reporting dose are specified in 10 CFR Part 20.

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

The final report to the client must include:

- (1) name and address of processor and client;
- (2) pertinent dates;
- (3) description or identification of each dosimeter and/or elements;
- (4) "Occupational Radiation Exposure Report" or a similar title;
- (5) an explanation of any deviation from the procedures routinely used in processing dosimeters which may affect the reported results;
- (6) identification of anomalies;
- (7) signature or reference to person having technical responsibility; and
- (8) adequately defined data resulting from the processing.

**(m) Outside support services and supplies**

The laboratory must test incoming supplies that affect the accuracy of the processing service. This includes testing film and characterizing new TLD chips before initial use.

It is the responsibility of the processor to use only appropriate, characterized, tested materials, including: film, TLD, chemicals, badge holders, filters, and validated software.



Table 1. American National Standard HPS N13.11-1993

Test Category	Test Irradiation Range	Tolerance Limit (L)		Additional Limit on  B  and on S
		Deep	Shallow	
I. Accidents, low-energy photons (M150)	0.1 to 5 Gy (10 to 500 rad)	0.30	No test	None
II. Accidents, high-energy photons ( $^{137}\text{Cs}$ gamma rays)	0.1 to 5 Gy (10 to 500 rad)	0.30	No test	None
III. Low-energy photons A. General (M30, M60, M100, M150, H150)  B. High-energy techniques (M100, M150, H150)	0.3 to 100 mSv (0.03 to 10 rem)	0.50	0.50	0.35
IV. High-energy photons ( $^{137}\text{Cs}$ gamma rays) ( $^{60}\text{Co}$ )	0.3 to 100 mSv (0.03 to 10 rem) 662 keV 1.25 MeV	0.50	No test	0.35
V. Beta particles A. High-energy only ( $^{90}\text{Sr}/^{90}\text{Y}$ )  B. Low-energy only ( $^{204}\text{Tl}$ )  C. General ( $^{90}\text{Sr}/^{90}\text{Y}$ or $^{204}\text{Tl}$ )	1.5 to 100 mSv (0.15 to 10 rem)	No test	0.50	0.35  0.35  None
VI. Photon mixture (a combination of Categories III and IV)	0.50 to 50 mSv (0.05 to 5 rem)	0.50	0.50	0.35
VII. Beta-photon mixtures (a combination of Categories IV and V)	2 to 50 mSv (0.2 to 5 rem)	0.50	0.50	0.35
VIII. Neutron-photon mixtures (a combination of $^{137}\text{Cs}$ gamma rays with the following neutrons) A. $^{252}\text{Cf}$ fission neutrons, moderated by 15 cm of $\text{D}_2\text{O}$ covered with Cd  *B. $^{241}\text{AmBe}$ ( $\alpha, n$ ) neutrons (Pb filtered)	1.5 to 50 mSv (0.15 to 5 rem)	Total 0.50 Neutron 0.50	No test No test	0.35 None
**IX. Angles of incidence photons (a combination of categories III-B and IV)	1 to 50 mSv (0.1 to 5 rem)	0.50	0.50	None

\* VIII-B will not be included in the NVLAP proficiency test.

\*\* See section on angular dependence test.

Table 2. Proficiency Testing Categories (Extremity Dosimeters)  
ANSI N13.32\*

Test Category	Energy	Test Range	Irradiation Tolerance Limit	Additional Limit on  B  and on S
I. Accidents, low-energy photons (M150)	70 keV (average)	0.1 to 5 Gy (10 to 500 rad)	0.30	None
II. Accidents, high-energy photons ( <sup>137</sup> Cs)	662 keV	0.1 to 5 Gy (10 to 500 rad)	0.30	None
III. Low-energy photons A. General (M30, M60, M100, M150, H150)	20 keV, 34 keV, 51 keV, 70 keV, (120 keV effective)	0.0025 to 0.1 Sv (0.25 to 10 rem)	0.50	0.35
B. High-energy techniques (M100, M150, H150)	51 keV, 70 keV, 120 keV	0.0025 to 0.1 Sv (0.25 to 10 rem)	0.50	0.35
IV. High-energy photons <sup>137</sup> Cs <sup>60</sup> Co	662 keV 1.25 MeV	0.0025 to 0.1 Sv (0.25 to 10 rem)	0.50	0.35
V. Beta particles A. High-energy only ( <sup>90</sup> Sr/ <sup>90</sup> Y)	662 keV and 1.25 MeV	0.0025 to 0.1 Sv	0.50	0.35
B. Low-energy only ( <sup>204</sup> Tl)	2.3 MeV (Max)	0.0025 to 0.1 Sv	0.50	0.35
C. General ( <sup>90</sup> Sr/ <sup>90</sup> Y and <sup>204</sup> Tl)	2.3 MeV (Max) 0.76 MeV (Max)		0.50	None
D. Slab uranium	2.3 MeV (Max)			0.35
VI. Mixtures, photons (any combination of Categories III and IV)	One energy from each category	0.0025 to 0.1 Sv	0.50	0.35
VII. Mixtures, photons and beta particles (any combination of Categories IV and V)	One energy from each category	0.0025 to 0.1 Sv	0.50	0.35

\* Category III-C is not included in this table. There may be other differences between this table and the table in ANSI N13.32.

**APPENDIX A**

**SAMPLE ACCREDITATION DOCUMENTS**



United States Department of Commerce  
National Institute of Standards and Technology



ISO/IEC GUIDE 25:1990  
ISO/IEC GUIDE 58:1993  
ISO 9002:1994

Certificate of Accreditation


LABORATORY NAME  
ANYTOWN, USA

*is recognized under the National Voluntary Laboratory Accreditation Program for satisfactory compliance with criteria established in Title 15, Part 285 Code of Federal Regulations. These criteria encompass the requirements of ISO/IEC Guide 25 and the relevant requirements of ISO 9002 (ANSI/ASQC Q92-1987) as suppliers of calibration or test results. Accreditation is awarded for specific services, listed on the Scope of Accreditation for:*

IONIZING RADIATION DOSIMETRY

January 1, 19--

Effective until

  
For the National Institute of Standards and Technology

NVLAP LAB CODE: 0000

National Institute  
of Standards and Technology



National Voluntary  
Laboratory Accreditation Program

ISO/IEC GUIDE 25:1990  
ISO/IEC GUIDE 58:1993  
ISO 9002:1994

## Scope of Accreditation



Page 1 of 1

IONIZING RADIATION DOSIMETRY

NVLAP LAB CODE 0000

LABORATORY, INC.  
Anytown, USA 00000-0000  
John Doe Phone: 000-000-0000

This facility has been evaluated and deemed competent to process the radiation dosimeters listed below through employing a Panasonic automatic reader model UD710A.

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

Panasonic TLD model UD802-AS in a Panasonic UD875AT holder for ANSI-N13.11 categories II, III, IV, V, VI, VII, VIII.

Combination Panasonic TLD model UD813-AS8 in a Panasonic UD886AT holder for ANSI-N13.11 category VIII.

Panasonic TLD model UD808-AS in a Panasonic UD879-AT holder for ANSI-N13.11 categories V, VII.

January 1, 19--

Effective until

A handwritten signature in dark ink, appearing to read "Albert R. Holm".

For the National Institute of Standards and Technology

**APPENDIX B**

**GENERAL OPERATIONS CHECKLIST**





## GENERAL OPERATIONS CHECKLIST

**Instructions to the Assessor:** This checklist addresses general accreditation criteria prescribed in applicable sections of NIST Handbook 150, *NVLAP Procedures and General Requirements*.

This checklist follows and is numbered to correspond to the *NVLAP Procedures and General Requirements*, Subsection 285.33. The numbers in square brackets identify related checklist items. A small black triangle appears in the left-hand margin of selected lines of text throughout this checklist; the marked text applies only to the Calibration Laboratory Accreditation Program (LAP).

Place an "X" beside each checklist item which represents a deficiency. Place a "C" beside each item on which you are commenting for other reasons. Record the item number and your written deficiency explanations and/or comments in this list or on the attached comment sheets. Place a check beside all other items you observed or verified at the laboratory.

### SEC. 285.33 CRITERIA FOR ACCREDITATION

#### (b) *Organization and management*

(1) The laboratory shall be:

(i) legally identifiable;

Legal name of laboratory ownership: \_\_\_\_\_

(ii) organized and shall operate in such a way that its permanent, temporary and mobile facilities meet the NVLAP requirements [see also (b)(2)(i), (c)(2)(ii)];

(iii) properly identified on the NVLAP Application.

(2) The laboratory shall:

(i) have managerial staff with the authority and resources needed to discharge their duties [see also (b)(1)(ii), (c)(2)(ii)];

(ii) have policies to ensure that its personnel are free from any commercial, financial and other pressures which might adversely affect the quality of their work;

(iii) be organized in such a way that confidence in its independence of judgment and integrity is maintained at all times;

- 
- \_\_\_\_\_ (iv) specify and document the responsibility, authority and interrelation of all personnel who manage, perform or verify work affecting the quality of calibrations and tests;
  - \_\_\_\_\_ (v) provide supervision by persons familiar with the calibration or test methods and procedures, the objective of the calibration or test, and the assessment of the results. The ratio of supervisory to non-supervisory personnel shall be such as to ensure adequate supervision;
  - \_\_\_\_\_ (vi) have a technical manager (however named) who has overall responsibility for the technical operations;  
  
Name of person: \_\_\_\_\_
  - \_\_\_\_\_ (vii) have a quality manager (however named) who has responsibility for the quality system and its implementation. The quality manager shall have direct access to the highest level of management at which decisions are taken on laboratory policy or resources, and to the technical manager. In some laboratories, the quality manager may also be the technical manager or deputy technical manager;  
  
Name of person: \_\_\_\_\_
  - \_\_\_\_\_ (viii) nominate deputy(ies) in case of absence of the technical or quality manager;  
  
Name(s): \_\_\_\_\_
  - \_\_\_\_\_ (ix) have documented policy and procedures to ensure the protection of clients' confidential information and proprietary rights [see also (c)(2)(xviii)];
  - \_\_\_\_\_ (x) where appropriate, participate in interlaboratory comparisons and proficiency testing programs [see also (c)(2)(xiv), (c)(6)(ii), (g)(3)];
  - \_\_\_\_\_ (xi) have documented policy and procedures to ensure that its clients are served with impartiality and integrity.

**(c) *Quality system, audit and review***

- (1) The laboratory shall:
  - \_\_\_\_\_ (i) have an established and maintained quality system appropriate to the type, range and volume of calibration and testing activities it undertakes;

- 
- \_\_\_\_\_ (ii) have the elements of the quality system documented;
  - \_\_\_\_\_ (iii) ensure that the quality documentation is available for use by the laboratory personnel;
  - \_\_\_\_\_ (iv) define and document its policies and objectives for, and its commitment to, good laboratory practice and quality of calibration or testing services;
  - \_\_\_\_\_ (v) have the laboratory management which ensures that these policies and objectives are documented in a quality manual and communicated to, understood, and implemented by all laboratory personnel concerned;
  - \_\_\_\_\_ (vi) ensure that the quality manual is maintained current under the responsibility of the quality manager [see also (c)(2)(iv)].

Date of quality manual: \_\_\_\_\_

Date of latest update: \_\_\_\_\_

- (2) The quality manual, and related quality documentation, shall state the laboratory's policies and operational procedures established in order to meet the NVLAP requirements. The quality manual and related quality documentation shall contain:
  - \_\_\_\_\_ (i) a quality policy statement, including objectives and commitments, by top management;
  - \_\_\_\_\_ (ii) the organization and management structure of the laboratory, its place in any parent organization and relevant organizational charts;
  - \_\_\_\_\_ (iii) the relations between management, technical operations, support services and the quality system;
  - \_\_\_\_\_ (iv) procedures for control and maintenance of documentation [see also (c)(1)(vi), (j)(1)];
  - \_\_\_\_\_ (v) job descriptions of key staff and reference to the job descriptions of other staff;

- 
- \_\_\_\_\_ (vi) identification of the laboratory's approved signatories (list here or in the comments section): \_\_\_\_\_  
\_\_\_\_\_
  - \_\_\_\_\_ (vii) the laboratory's procedures for achieving traceability of measurements;
  - \_\_\_\_\_ (viii) the laboratory's scope of calibrations and/or tests;
  - \_\_\_\_\_ (ix) written procedures for ensuring that the laboratory reviews all new work to ensure that it has the appropriate facilities and resources before commencing such work;
  - \_\_\_\_\_ (x) reference to the calibration, verification and/or test procedures used;
  - \_\_\_\_\_ (xi) procedures for handling calibration and test items;
  - \_\_\_\_\_ (xii) reference to the major equipment and reference measurement standards used;
  - \_\_\_\_\_ (xiii) reference to procedures for calibration, verification and maintenance of equipment;
  - \_\_\_\_\_ (xiv) reference to verification practices including interlaboratory comparisons, proficiency testing programs, use of reference materials and internal quality control schemes [see also (b)(2)(x), (c)(6)(ii), (g)(3)];
  - \_\_\_\_\_ (xv) procedures to be followed for feedback and corrective action whenever:
    - \_\_\_\_\_ a) testing discrepancies are detected, or
    - \_\_\_\_\_ b) departures from documented policies and procedures occur;
  - \_\_\_\_\_ (xvi) the laboratory management policies for departures from documented policies and procedures or from standard specifications;
  - \_\_\_\_\_ (xvii) procedures for dealing with complaints [see also (n)];
  - \_\_\_\_\_ (xviii) procedures for protecting confidentiality and proprietary rights [see also (b)(2)(ix)];
  - \_\_\_\_\_ (xix) procedures for audit and review;
  - \_\_\_\_\_ (xx) a description of the laboratory's policy regarding the use of the NVLAP logo;
  - ▶ \_\_\_\_\_ (xxi) a statement of the laboratory's policy for establishing and changing calibration intervals for equipment it controls; and
  - ▶ \_\_\_\_\_

- 
- ▶ \_\_\_\_\_ (xxii) a statement of the laboratory's policy concerning the technique(s) to be used
  - ▶ for determining measurement uncertainty and calibration/verification
  - ▶ adequacy.

- \_\_\_\_\_ (3) The laboratory shall arrange for audits of its activities at appropriate intervals to verify that its operations continue to comply with the requirements of the quality system. Such audits shall be carried out by trained and qualified staff who are, wherever possible, independent of the activity to be audited. Where the audit findings cast doubt on the correctness or validity of the laboratory's calibration or test results, the laboratory shall take immediate corrective action and shall immediately notify, in writing, any client whose work may have been affected.

The audits shall be objective and be conducted internally or on contract. The audits shall include both general criteria (documents, records and policies) and technical compliance (test methods and practices and calibration procedures).

- \_\_\_\_\_ (4) The quality system adopted to satisfy the NVLAP requirements shall be reviewed at least once a year by the management to ensure its continuing suitability and effectiveness and to introduce any necessary changes or improvements.

- \_\_\_\_\_ (5) All audit and review findings and any corrective actions that arise from them shall be documented. The person responsible for quality shall ensure that these actions are discharged within the agreed timescale.

(6) In addition to periodic audits the laboratory shall ensure the quality of results provided to clients by implementing checks. These checks shall be reviewed and shall include, as appropriate, but not be limited to:

(i) internal quality control plans, such as control charts and other available statistical techniques;

**NOTE:** Measurement assurance techniques are acceptable means to control the measurement process and consistently produce the highest quality measurements.

(ii) participation in proficiency testing or other interlaboratory comparisons [see also (b)(2)(x), (c)(2)(xiv), (g)(3)];

(iii) regular use of certified reference materials and/or in-house quality control using secondary reference materials;

(iv) replicate testings using the same or different methods;

(v) retesting of retained items;

(vi) correlation of results for different characteristics of an item.

**(d) Personnel** [see also (c)(2)(v)]

(1) The testing laboratory shall have sufficient personnel, having the necessary education, training, technical knowledge and experience for their assigned functions.

(2) The testing laboratory shall ensure that the training of its personnel is kept up-to-date.



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- \_\_\_\_\_ (3) Records on the relevant qualifications, training, skills and experience of the technical personnel shall be maintained by the laboratory.

**(e) Accommodation (facilities) and environment** [see also (i)(3)]

- \_\_\_\_\_ (1) Laboratory accommodation, calibration and test areas, energy sources, lighting, heating and ventilation shall be such as to facilitate proper performance of calibrations or tests.

**NOTE:** Laboratory design will be, to the maximum extent practical, in accordance with the guidelines found in the NCSL Recommended Practice #7, *Laboratory Design*, July 25, 1993.

- \_\_\_\_\_ (2) The environment in which these activities are undertaken shall not invalidate the results or adversely affect the required accuracy of measurement. Particular care shall be taken when such activities are undertaken at sites other than the permanent laboratory premises.

**NOTE:** It is expected that environments which do not meet generally accepted norms, such as those found in NCSL Recommended Practice #7, yet which exhibit the stability required to apply necessary correction factors, will be specified by the laboratory for the purpose of assessment of compliance with its own procedures to achieve its stated uncertainties.

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- \_\_\_\_\_ (3) The laboratory shall provide facilities for the effective monitoring, control and recording of environmental conditions as appropriate. Due attention shall be paid, for example, to biological sterility, dust, electromagnetic interference, humidity, voltage, temperature, and sound and vibration levels, as appropriate to the calibrations or tests concerned.
- \_\_\_\_\_ (4) There shall be effective separation between neighboring areas when the activities therein are incompatible.
- \_\_\_\_\_ (5) Access to and use of all areas affecting the quality of these activities shall be defined and controlled.
- \_\_\_\_\_ (6) Adequate measures shall be taken to ensure good housekeeping in the laboratory.

**NOTE:** While it is the laboratory's responsibility to comply with relevant health and safety requirements, this is outside the scope of this assessment.

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**(f) *Equipment and reference materials***

- (1) The laboratory shall:
  - \_\_\_\_\_ (i) be furnished with all items of equipment (including hardware, software, and reference materials) required for the correct performance of calibrations and tests;
  - \_\_\_\_\_ (ii) in those cases where the laboratory needs to use equipment outside its permanent control, including rented, leased and client-owned equipment, ensure that the relevant NVLAP requirements are met.
  
- \_\_\_\_\_ (2) All equipment shall be properly maintained. Maintenance procedures shall be documented. Any item of the equipment which has been subjected to overloading or mishandling, or which gives suspect results, or has been shown by verification or otherwise to be defective, shall be taken out of service, clearly identified and wherever possible stored at a specified place until it has been repaired and shown by calibration, verification or test to perform satisfactorily. The laboratory shall examine the effect of this defect on previous calibrations or tests.
  
- \_\_\_\_\_ (3) Each item of equipment including reference materials shall, when appropriate, be labelled, marked or otherwise identified to indicate its calibration status.
  
- \_\_\_\_\_ (4) Records shall be maintained of each item of equipment and all reference materials significant to the calibrations or tests performed. The records shall include:
  - \_\_\_\_\_ (i) the name of the item of equipment, software or reference material;

\_\_\_\_\_ (ii) the manufacturer's name, type identification, and serial number or other unique identification;

\_\_\_\_\_ (iii) date received and date placed in service;

**NOTE:** For initial accreditation, the date received and the date placed in service are not considered mandatory requirements for inclusion in laboratory records, although this is encouraged as good laboratory practice.

\_\_\_\_\_ (iv) current location, where appropriate;

\_\_\_\_\_ (v) condition when received (e.g., new, used, reconditioned);

\_\_\_\_\_ (vi) copy of the manufacturer's instructions, where available;

\_\_\_\_\_ (vii) dates and results of calibrations and/or verifications and date of next calibration and/or verification;

\_\_\_\_\_ (viii) details of maintenance carried out to date and planned for the future;

\_\_\_\_\_ (ix) history of any damage, malfunction, modification or repair;

► \_\_\_\_\_ (x) measured value observed for each parameter found to be out of tolerance during calibration/verification.

#### **(g) *Measurement traceability and calibration***

\_\_\_\_\_ (1) All measuring and testing equipment having an effect on the accuracy or validity of calibrations or tests shall be calibrated and/or verified before being put into service. The laboratory shall have an established program for the calibration and verification of its measuring and test equipment. The program will ensure the recall or removal from service of any standard or equipment which has exceeded its calibration interval or is otherwise judged to be unreliable.

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- (2) The overall program of calibration and/or verification and validation of equipment shall be designed and operated so as to ensure that, wherever applicable, measurements made by the laboratory are traceable to national standards of measurement where available. Calibration certificates shall, wherever applicable, indicate the traceability to national standards of measurement and shall provide the measurement results and associated uncertainty of measurement and/or a statement of compliance with an identified metrological specification.

**NOTE:** Traceability to national standards includes traceability to standards maintained or defined at national laboratories in foreign countries where applicable. In these cases, traceability is achieved via international standards. This includes intrinsic standards of measurement where available.

Where applicable, the methodology of the *Guide to the expression of uncertainty in measurement*: 1993, shall be used as the basis for expression of uncertainty of the measurement. NIST Technical Note 1297; January 1993, *Guidelines for Evaluating and Expressing the Uncertainty of NIST Measurement Results*, is a practical application document written around the *Guide to the expression of uncertainty in measurement*. Where detailed procedures are not used to quantify and combine uncertainties (i.e., use of test accuracy ratio concepts), the sources of uncertainty shall be tabulated and demonstrated to be acceptable for the measurement undertaken.

**NOTE:** A significant number of intrinsic standards, such as the Josephson Array Voltage Standard and the Iodine-Stabilized Helium-Neon Laser Length Standard, have been developed and are now being used by many national standards laboratories and some industrial laboratories. These standards are based on well-characterized laws of physics, fundamental constants of nature, or invariant properties of materials, and make ideal stable, precise, and accurate measurement standards if properly designed, characterized, operated, monitored and maintained. Where intrinsic standards are used, the laboratory should demonstrate by measurement assurance techniques, interlaboratory comparisons, or other suitable means, that its intrinsic standard measurement results are correlated with those of national or international standards.



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- \_\_\_\_\_ (3) Where traceability to national standards of measurement is not applicable, the laboratory shall provide satisfactory evidence of correlation of results, for example by participation in a suitable program of interlaboratory comparisons or proficiency testing [see also (b)(2)(x), (c)(2)(xiv), (c)(6)(ii)].

**NOTE:** Traceability requirements may also be satisfied by:

- (i) internationally accepted standards in the field concerned;
- (ii) suitable reference materials;
- (iii) ratio or reciprocity measurements; or
- (iv) mutual consent standards which are clearly specified and mutually agreed upon by all parties concerned.

- \_\_\_\_\_ (4) Reference standards of measurement held by the laboratory shall be used for calibration only and for no other purpose, unless it can be demonstrated that their performance as reference standards has not been invalidated.

- \_\_\_\_\_ (5) Reference standards of measurement shall be calibrated by a body that can provide traceability to a national standard of measurement. There shall be a program of calibration and verification for reference standards.

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- \_\_\_\_\_ (6) Where relevant, reference standards and measuring and testing equipment shall be subjected to in-service checks between calibrations and verifications.
- \_\_\_\_\_ (7) Reference materials shall, where possible, be traceable to national or international standards of measurement, or to national or international standard reference materials.

**(h) *Calibration and test methods***

- \_\_\_\_\_ (1) The laboratory shall have documented instructions on the use and operation of all relevant equipment, on the handling and preparation of items and for calibration and/or testing, where the absence of such instructions could jeopardize the calibrations or tests. All instructions, standards, manuals and reference data relevant to the work of the laboratory shall be maintained up-to-date and be readily available to the staff.

- [illegible]

- (i) Calibration procedures shall contain the required range and tolerance or uncertainty of each item or unit parameter being calibrated or verified. In addition, the procedures shall contain the generic description of the measurement standards and equipment needed with the required parameter, range, tolerances or uncertainties, and specifications for performing the measurement of the calibration or verification, and/or representative types (manufacturer, model, option) that are capable of meeting the generic description for the measurement standards. The procedures shall be consistent with the accuracy required, and with any standard specifications relevant to the calibrations/verifications concerned.
- (ii) The laboratory shall ensure that the calibration uncertainties are sufficiently small so that the adequacy of the measurement is not affected. Well-defined and documented measurement assurance techniques or uncertainty analyses may be used to verify the adequacy of a measurement process. If such techniques are not used, then the collective uncertainty of the measurement standards shall not exceed 25% of the acceptable tolerance (e.g., manufacturer's specification) for each characteristic of the measuring and test equipment being calibrated or verified.

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- \_\_\_\_\_ (4) Where it is necessary to employ methods that have not been established as standard, these shall be subject to agreement with the client, be fully documented and validated, and be available to the client and other recipients of the relevant reports [see also (k)(2)(x)].
- \_\_\_\_\_ (5) Where sampling is carried out as part of the test method, the laboratory shall use documented procedures and appropriate statistical techniques to select samples [see also (k)(2)(ix)].
- \_\_\_\_\_ (6) Calculations and data transfers shall be subject to appropriate checks.
- \_\_\_\_\_ (7) Where computers or automated equipment are used for the capture, processing, manipulation, recording, reporting, storage or retrieval of calibration or test data, the laboratory shall have written procedures which ensure that:
- \_\_\_\_\_ (i) the NVLAP requirements are complied with;
- \_\_\_\_\_ (ii) computer software, computers or automated equipment is documented and adequate for use;
- \_\_\_\_\_ (iii) procedures are established and implemented for protecting the integrity of data; such procedures shall include, but not be limited to, integrity of data entry or capture, data storage, data transmission and data processing;
- \_\_\_\_\_ (iv) computer and automated equipment is maintained to ensure proper functioning and provided with the environmental and operating conditions necessary to maintain the integrity of calibration and test data [see also (f)(1)];

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- \_\_\_\_\_ (v) it establishes and implements appropriate procedures for the maintenance of security of data including the prevention of unauthorized access to, and the unauthorized amendment of, computer records.
- \_\_\_\_\_ (8) Documented procedures shall exist for the purchase, reception and storage of consumable materials used for the technical operations of the laboratory [see also (m)(2)].

**(i) *Handling of calibration and test items***

- \_\_\_\_\_ (1) The laboratory shall have a documented system for uniquely identifying the items to be calibrated or tested, to ensure that there can be no confusion regarding the identity of such items at any time [see also (k)(2)(v)].
- \_\_\_\_\_ (2) Upon receipt, the condition of the calibration or test item, including any abnormalities or departures from standard condition as prescribed in the relevant calibration or test method, shall be recorded. Where there is any doubt as to the item's suitability for calibration or test, where the item does not conform to the description provided, or where the calibration or test required is not fully specified, the laboratory shall consult the client for further instruction before proceeding. The laboratory shall establish whether the item has received all necessary preparation, or whether the client requires preparation to be undertaken or arranged by the laboratory.

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- \_\_\_\_\_ (3) The laboratory shall have documented procedures and appropriate facilities to avoid deterioration or damage to the calibration or test item, during storage, handling, preparation, and calibration or test; any relevant instructions provided with the item shall be followed. Where items have to be stored or conditioned under specific environmental conditions, these conditions shall be maintained, monitored and recorded where necessary. Where a calibration or test item or portion of an item is to be held secure (for example, for reasons of record, safety or value, or to enable check calibrations or tests to be performed later), the laboratory shall have storage and security arrangements that protect the condition and integrity of the secured items or portions concerned [see also (e)].
- \_\_\_\_\_ (4) The laboratory shall have documented procedures for the receipt, retention or safe disposal of calibration or test items, including all provisions necessary to protect the integrity of the laboratory.
- \_\_\_\_\_ (5) Tamper-resistant seals shall be affixed to operator-accessible controls or adjustments on measurement standards or measuring and test equipment which, if moved, will invalidate the calibration. The laboratory's calibration system shall provide instructions for the use of such seals and for the disposition of equipment with damaged or broken seals.

**NOTE:** Tamper-resistant seals are sometimes affixed to equipment to prevent unauthorized access to areas where adjustments or critical components are located.



(j) *Records*

\_\_\_\_\_ (1) The laboratory shall maintain a record system to suit its particular circumstances and comply with any applicable regulations. It shall retain on record all original observations, calculations and derived data, calibration records and a copy of the calibration certificate, test certificate or test report for an appropriate period. The records for each calibration and test shall contain sufficient information to permit their repetition. The records shall include the identity of personnel involved in sampling, preparation, calibration or testing [see also (c)(2)(iv)].

▶ **EXCEPTION:** The retention of all original observations, calculations, and  
 ▶ derived data in the calibration record system is not a mandatory requirement  
 ▶ for calibration laboratories, although it is encouraged as good laboratory  
 ▶ practice.

\_\_\_\_\_ (2) All records (including those listed in (f)(4) pertaining to calibration and test equipment), certificates and reports shall be safely stored, held secure and in confidence to the client [see also (b)(2)(ix), (c)(2)(xviii)].

**NOTE:** The period of retention shall be specified in the quality manual.

Record retention time specified: \_\_\_\_\_

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**(k) Certificates and reports**

- \_\_\_\_\_ (1) The results of each calibration, test, or series of calibrations or tests carried out by the laboratory shall be reported accurately, clearly, unambiguously and objectively, in accordance with any instructions in the calibration or test methods. The results should normally be reported in a calibration certificate, test report or test certificate and should include all the information necessary for the interpretation of the calibration or test results and all information required by the method used [see also (k)(4)(i)].

► **NOTE:** It is recognized that the results of each calibration do not always  
 ► result in the production of a calibration certificate or report. Whenever a  
 ► certificate or report is produced, the above requirements shall be met.

- (2) Each certificate or report shall include at least the following information:

- \_\_\_\_\_ (i) a title, e.g., "Calibration Certificate," "Test Report" or "Test Certificate";
- \_\_\_\_\_ (ii) name and address of laboratory, and location where the calibration or test was carried out if different from the address of the laboratory;
- \_\_\_\_\_ (iii) unique identification of the certificate or report (such as serial number) and of each page, and the total number of pages;
- \_\_\_\_\_ (iv) name and address of client, where appropriate;
- \_\_\_\_\_ (v) description and unambiguous identification of the item calibrated or tested [see also (i)(1)];
- \_\_\_\_\_ (vi) characterization and condition of the calibration or test item;
- \_\_\_\_\_ (vii) date of receipt of calibration or test item and date(s) of performance of calibration or test, where appropriate;
- **EXCEPTION:** Although it is encouraged as good laboratory practice, the  
 ► requirement for inclusion of the date received is not mandatory for  
 ► calibration laboratories.
- \_\_\_\_\_ (viii) identification of the calibration or test method used, or unambiguous description of any non-standard method used;
- \_\_\_\_\_ (ix) reference to sampling procedure, where relevant [see also (h)(5)];

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- \_\_\_\_\_ (x) any deviations from, additions to or exclusions from the calibration or test method, and any other information relevant to a specific calibration or test, such as environmental conditions [see also (c)(2)(xv), (h)(4)];
  - \_\_\_\_\_ (xi) measurements, examinations and derived results, supported by tables, graphs, sketches and photographs as appropriate, and any failures identified;
  - \_\_\_\_\_ (xii) a statement of the estimated uncertainty of the calibration or test result, where relevant;
  - \_\_\_\_\_ (xiii) a signature and title, or an equivalent identification of the person(s) accepting responsibility for the content of the certificate or report (however produced), and date of issue [see also (c)(2)(vi)];
  - \_\_\_\_\_ (xiv) where relevant, a statement to the effect that the results relate only to the items calibrated or tested;
  - \_\_\_\_\_ (xv) a statement that the certificate or report shall not be reproduced except in full, without the written approval of the laboratory;
  - \_\_\_\_\_ (xvi) a statement that the report must not be used by the client to claim product endorsement by NVLAP or any agency of the U.S. Government;
  - \_\_\_\_\_ (xvii) the signature of an approved signatory for all test and calibration reports endorsed with the NVLAP logo;
  - ▶ \_\_\_\_\_ (xviii) special limitations of use; and
  - ▶ \_\_\_\_\_ (xix) traceability statement.
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- \_\_\_\_\_ (3) Where the certificate or report contains results of calibrations or tests performed by subcontractors, these results shall be clearly identified [see also (I)].

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\_\_\_\_\_ (4) Particular care and attention shall be paid to the arrangement of the certificate or report, especially with regard to presentation of the calibration or test data and ease of assimilation by the reader. The format shall be carefully and specifically designed for each type of calibration or test carried out, but the headings shall be standardized as far as possible [see also (k)(1)].

\_\_\_\_\_ (5) Material amendments to a calibration certificate, test report or test certificate after issue shall be made only in the form of a further document, or data transfer including the statement "Supplement to Calibration Certificate (or Test Report or Test Certificate), serial number ... (or as otherwise identified)," or equivalent form of wording. Such amendments shall meet all the relevant requirements of item (j).

\_\_\_\_\_ (6) The laboratory shall notify clients promptly, in writing, of any event such as the identification of defective measuring or test equipment that casts doubt on the validity of results given in any calibration certificate, test report, or test certificate or amendment to a report or certificate.

- **NOTE:** Such notification shall quantify the magnitude of error created in the calibration results. The laboratory shall notify customers promptly, in writing, of any customer's measuring and test equipment found significantly out of tolerance during the calibration/verification process. Measurement data shall be reported so that appropriate action can be taken.
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- \_\_\_\_\_ (7) The laboratory shall ensure that, where clients require transmission of calibration or test results by telephone, telex, facsimile or other electronic or electromagnetic means, staff will follow documented procedures that ensure that the NVLAP requirements are met and that confidentiality is preserved.
- \_\_\_\_\_ (8) Whenever a laboratory accredited by NVLAP issues a calibration or test report which contains data covered by the accreditation and also data not covered by the accreditation, it must clearly identify in its records, and in the report to the client, specifically which calibration or test method(s), or portion of a calibration or test method(s), was not covered by the accreditation. The laboratory must also inform the client, before the fact, when calibrations or tests requested are not covered by the accreditation.

NVLAP policy regarding calibration and test reports issued by an accredited laboratory, which reference the laboratory's accredited status, requires that any calibration or test report containing data from calibrations or tests which are not covered by the accreditation include:

- \_\_\_\_\_ (i) a statement at the beginning of the report prominently indicating, "This report contains data which are not covered by the NVLAP accreditation"; and
- \_\_\_\_\_ (ii) a clear indication of which data are not covered by the accreditation.

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.

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(I) ***Subcontracting of calibration or testing*** [see also (k)(3)]

- \_\_\_\_\_ (1) Where a laboratory subcontracts any part of the calibration or testing, this work shall be placed with a laboratory complying with these requirements. The laboratory shall ensure and be able to demonstrate that its subcontractor is competent to perform the activities in question and complies with the same criteria of competence as the laboratory in respect of the work being subcontracted. The laboratory shall advise the client in writing of its intention to subcontract any portion of the testing to another party.
- \_\_\_\_\_ (2) The laboratory shall record and retain details of its investigation of the competence and compliance of its subcontractors and maintain a register of all subcontracting.
- \_\_\_\_\_ (3) A NVLAP-accredited laboratory intending to subcontract testing or calibration work that will be performed and reported as meeting NVLAP procedures and criteria must:
- \_\_\_\_\_ (i) have in its quality manual a subcontracting policy compatible with the NVLAP policy, with a description of the procedures for administering and implementing those actions to demonstrate the conformance and consistency of the subcontracted laboratory to perform according to NVLAP procedures;
- \_\_\_\_\_ (ii) place the subcontracted work with a laboratory that maintains accreditation established by NVLAP shown by a current NVLAP Lab Code, or provide and maintain current records that demonstrate that the subcontracted laboratory is competent to perform the test(s) or calibration(s) and that it operates in a manner consistent with and in conformance to NVLAP criteria for accreditation;
- \_\_\_\_\_ (iii) clearly identify in its records, and in the report to the client, exactly which data were obtained by the NVLAP-accredited laboratory and which data were obtained by the subcontractor, NVLAP-accredited or not;
- \_\_\_\_\_ (iv) inform its client, before the fact, that it intends to subcontract for completion of all or a portion of the client's work; and



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- \_\_\_\_\_ (v) include at the beginning of the report the name, address, and contact person of the subcontracted laboratory(ies), and one of the following statements, as appropriate:

*if NVLAP-accredited*

"This report contains data which were produced by a subcontracted laboratory **ACCREDITED (NVLAP LAB CODE)** for the calibration or test methods performed"

*if not NVLAP-accredited*

"This report contains data which were produced by a subcontracted laboratory **NOT ACCREDITED** for the calibration or test methods performed."

The requirements of this section do not supersede any regulation, law, contract specification, or other related conditions which require NVLAP accreditation.

**(m) *Outside support services and supplies***

- \_\_\_\_\_ (1) Where the laboratory procures outside services and supplies in support of calibrations or tests, the laboratory shall use only those outside support services and supplies that are of adequate quality to sustain confidence in the laboratory's calibrations or tests.

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- \_\_\_\_\_ (2) Where no independent assurance of the quality of outside support services or supplies is available, the laboratory shall have procedures to ensure that purchased equipment, materials and services comply with specified requirements. The laboratory should, wherever possible, ensure that purchased equipment and consumable materials are not used until they have been inspected, calibrated or otherwise verified as complying with any standard specifications relevant to the calibrations or tests concerned [see also (h)(8)].
- \_\_\_\_\_ (3) The laboratory shall maintain records of all suppliers from whom it obtains support services or supplies required for calibrations or tests.

**(n) Complaints** [see also (c)(2)(xvii)]

- \_\_\_\_\_ (1) The laboratory shall have documented policy and procedures for the resolution of complaints received from clients or other parties about the laboratory's activities. A record shall be maintained of all complaints and of the actions taken by the laboratory.
- \_\_\_\_\_ (2) Where a complaint, or any other circumstance, raises doubt concerning the laboratory's compliance with the laboratory's policies or procedures, or with the NVLAP requirements or otherwise concerning the quality of the laboratory's calibrations or tests, the laboratory shall ensure that those areas of activity and responsibility involved are promptly audited in accordance with item (c)(3).

▶ (o) *Measuring and test equipment (M & TE)*

▶ **NOTE:** This section applies to the control of measuring and test equipment (M & TE) used to assure that supplies and services comply with prescribed customer requirements. It is based in large part on the requirements found in government audit standards such as MIL-STD 45662A, and is found in Part II of the ANSI/NCSL Z540-1-1994 (Draft) standard.

▶ (1) General requirements for M & TE

- ▶ \_\_\_\_\_ (i) The supplier shall establish and document a system to control the calibration/verification of M & TE.
- ▶ \_\_\_\_\_ (ii) M & TE used to determine compliance with customer technical specifications shall be calibrated or verified in accordance with sections 285.33(b) through (n).
- ▶ \_\_\_\_\_ (iii) The supplier shall have a program to recall for calibration or verification, or remove from service, M & TE that has exceeded its calibration interval, has broken calibration seals, or is suspected to be malfunctioning because of mishandling, misuse, or unusual results.
- ▶ \_\_\_\_\_ (iv) All operations performed by the supplier in compliance with these requirements shall be subject to customer verification at unscheduled intervals.
- ▶ \_\_\_\_\_ (v) The supplier shall carry out, or arrange to have carried out, periodic quality auditing of the calibration and verification system in order to ensure its continuing effective implementation and compliance with these requirements.
  - ▶ - Based on the results of the audits and any other relevant factors, such as customer feedback, the supplier shall review and modify the system as necessary.
  - ▶ - Plans and procedures for the audits shall be documented. The conduct of the audit and any subsequent corrective action shall also be documented.

▶ (2) Detailed requirements for M & TE

▶ (i) Calibration system description: The supplier shall provide and maintain a written description of the calibration/verification system covering M & TE and measurement standards. The description shall be sufficient to satisfy each requirement of section 285.33(o) and any deviations shall be submitted with supporting documentation to the customer for approval.

▶ (ii) Adequacy of measurement standards: Measurement standards used by the supplier for calibrating M & TE and other measurement standards shall comply with the requirements of items (f)(1), (g)(1), and (h)(2).

▶ (iii) Environmental conditions: M & TE shall be used in an environment controlled to the extent necessary to ensure valid results. Due consideration shall be given to temperature, humidity, lighting, vibration, dust control, cleanliness, electromagnetic interference and any other factors affecting the results of measurements. Where pertinent, these factors shall be monitored and recorded and, when appropriate, correcting compensations shall be applied to measurement results.

▶ (iv) Intervals of calibration and verification: M & TE requiring calibration shall be calibrated or verified at periodic intervals established and maintained to assure acceptable reliability, where reliability is defined as the probability that M & TE will remain in-tolerance throughout the interval. Intervals shall be established for all M & TE requiring calibration unless the equipment is regularly monitored through the use of check standards in a documented measurement assurance process. Check standards must closely represent the item parameters normally tested in the process and the check standard must be verified periodically. Where intervals are used to ensure reliability, the interval setting system must be systematically applied and shall have stated reliability goals and a method of verifying that the goals are being attained. Intervals may be based on usage or time since last calibration or verification. All exemptions from periodic calibration or verification shall be documented. The recall system may provide for the temporary extension of the calibration due date for limited periods of time under specified conditions that do not unreasonably impair the satisfaction of the customer's requirements.

▶ (v) Calibration procedures: Procedures used to calibrate/verify the supplier's M & TE shall comply with the requirements of items (h)(1) and (h)(2).

▶ (vi) Out-of-tolerance conditions: If any M & TE is found to be significantly out of tolerance during the calibration/verification process, the supplier's system shall provide for notification to the user and to the supplier's quality element, if appropriate, of the out-of-tolerance condition with the associated measurement data so that appropriate action can be taken.

- ▶ \_\_\_\_\_ (vii) Adequacy of calibration system: The supplier shall establish and maintain documented procedures to evaluate the adequacy of the calibration system and to ensure compliance with these requirements.
- ▶ \_\_\_\_\_ (viii) Calibration sources: M & TE requiring calibration shall be calibrated or verified by laboratories that comply with sections 285.33(b) through (n).
- ▶ \_\_\_\_\_ (ix) Records: These requirements shall be supported by records documenting that established schedules and procedures are followed to maintain the adequacy of all M & TE. The records for M & TE requiring calibration shall include an individual record of calibration or verification, or other means of control, providing a description or identification of the item, calibration interval, date calibrated, identification of the calibration source, calibration results (data and/or condition status) and calibration action taken (adjusted, repaired, new value assigned, derated, etc.).
- ▶ \_\_\_\_\_ (x) Calibration status: M & TE shall be labeled to indicate calibration or verification status. The label shall identify specific date calibrated (day, month, year, Julian date, or equivalent) and the specific calibration due date or usage equivalent. Items not calibrated to their full capability or which have other limitations of use, shall be labeled or otherwise identified as to the limitations. When it is impractical to apply a label directly to an item, the label may be affixed to the instrument container or some other suitable means may be used to reflect calibration status. Tamper-resistant seals are affixed to operator accessible controls or adjustments which if moved will invalidate the calibration. The quality system shall provide instructions for the disposition of equipment with broken tamper-resistant seals.
- ▶ \_\_\_\_\_ (xi) Control of subcontractor calibration: The supplier is responsible for assuring that the subcontractor's calibration system conforms to section 285.33 (I) to the degree necessary to assure compliance with contractual requirements. NVLAP accreditation of the subcontractor's laboratory can serve as the basis for compliance with this requirement.
- ▶ \_\_\_\_\_ (xii) Storage and handling: M & TE shall be handled, stored, and transported in a manner which shall not adversely affect the calibration or condition of the equipment.

## GENERAL OPERATIONS CHECKLIST - COMMENTS AND DEFICIENCIES

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

Item No.	Comments and/or Deficiencies
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[illegible]



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

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**APPENDIX C**

**SPECIFIC OPERATIONS CHECKLIST**



## SPECIFIC OPERATIONS CHECKLIST

### IONIZING RADIATION DOSIMETRY (formerly called Personnel Radiation Dosimetry)

**Instructions to the Assessor:** Examine staff members' notebooks, calibration/verification records, equipment maintenance logs, and other records where necessary to verify discussion with staff members and observation of their performance in processing selected dosimeters. Be particularly observant for inconsistencies among records, procedures, observations, and responses. Note and discuss any inconsistencies with the Technical Director. In completing this checklist, indicate N/A for those items not applicable to the processor's dosimetry system or processing procedures.

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

Place an "X" beside any of the following items which represent a deficiency. Place a "C" beside each item on which you are commenting for other reasons. Record the item number and your deficiency explanations and/or comments on the comment sheet(s). Place a check beside all other items you observed or verified at the laboratory.

#### 1 *Personnel*

- ☐ 1.1 The qualifications of the individual who has overall technical responsibility are consistent with the position description.
- ☐ 1.2 The individual having technical responsibility demonstrated technical knowledge and management control of processing operations and services.
- ☐ 1.3 A qualified individual exercises authority in assignment of processing tasks and the timely processing of dosimeters.
- ☐ 1.4 Staff personnel are generally qualified and competent.
- ☐ 1.5 Communication seems adequate between technical and supervisory staff.
- ☐ 1.6 Staff are not subjected to undue pressure or inducement that can influence their judgement or the results of their work.
- ☐ 1.7 Staff members are aware of the extent of their area of responsibility.
- ☐ 1.8 Staff members are not assigned duties beyond their demonstrated competence.
- ☐ 1.9 Staff size is sufficient to handle the workload.

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- \_\_\_\_\_ 1.10 Job descriptions (Authorized Representative, Technical Director, Approved Signatory, individuals that conduct processing protocols, and individuals that review and approve the processing results) are current and reflect duties. Equivalence or exceptions to the required qualifications are documented.
- \_\_\_\_\_ 1.11 Staff responsibility is clearly assigned for:
- \_\_\_\_\_ a) overall technical direction;
  - \_\_\_\_\_ b) routine maintenance, verification and service of equipment;
  - \_\_\_\_\_ c) periodic calibration of major equipment;
  - \_\_\_\_\_ d) final review and approval of data; and
  - \_\_\_\_\_ e) review and resolution of questionable data.
- \_\_\_\_\_ 1.12 The staff training program is implemented as documented.
- \_\_\_\_\_ 1.13 The training program includes:
- \_\_\_\_\_ a) a period of close supervision until competency is demonstrated;
  - \_\_\_\_\_ b) a mechanism for evaluating and informing staff members of the adequacy of their performance in conducting assigned processing protocols;
  - \_\_\_\_\_ c) documentation of specialized skills required to perform duties;
  - \_\_\_\_\_ d) provisions for retraining staff members when protocols are revised;
  - \_\_\_\_\_ e) adequate training of high turnover or temporary staff; and
  - \_\_\_\_\_ f) a record of training courses completed by each staff member.
- \_\_\_\_\_ 1.14 The procedures for ensuring the competency of staff members are implemented as documented.
- \_\_\_\_\_ 1.15 Competency of staff members is reviewed at least annually.
- \_\_\_\_\_ 1.16 Records of the competency reviews, including dates and findings, for the staff members are maintained.
- \_\_\_\_\_ 1.17 Appropriate action is taken when competency is not demonstrated, such as retraining, until competency is obtained.

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## 2 Dosimeter Handling (General)

### 2.1 Procedures are documented and implemented as written for:

- \_\_\_\_\_ a) satisfactory acceptance of dosimeter materials to verify that dosimeter materials meet the criteria/specifications for type, size, or other significant parameters, such as sensitive elements and filter materials type and proper size (area, thickness), correct dosimeter holder material;
- \_\_\_\_\_ b) checking the proper assembly of dosimeters such as placement of filters and sensitive elements;
- \_\_\_\_\_ c) a system for identification of dosimeters;
- \_\_\_\_\_ d) ensuring that in-service dosimeters are checked on a defined schedule or frequency to ensure that all necessary components are in place;
- \_\_\_\_\_ e) monitoring environmental parameters including background radiation in all areas where dosimeters are handled or stored; and
- \_\_\_\_\_ f) ensuring that dosimeters are suitably packaged for issuance to clients to prevent damage or unknown exposure during transit.

### 2.2 Procedures are documented and implemented as written for the receipt of in-service and background control dosimeters at the processor's facility including:

- \_\_\_\_\_ a) individual dosimeter identification, associated dosimeter type, and appropriate processing protocols to be followed;
- \_\_\_\_\_ b) identification of internal and external control dosimeters;
- \_\_\_\_\_ c) a mechanism for tracking individual dosimeters and/or sensitive elements through the processing cycle;
- \_\_\_\_\_ d) a mechanism for identifying dosimeters which have not been returned from clients for processing;
- \_\_\_\_\_ e) method for screening incoming dosimeters or sensitive elements for radioactive contamination prior to readout;
- \_\_\_\_\_ f) method for identifying mishandled background control dosimeters.
- \_\_\_\_\_ g) handling/storage areas which are commensurate with types and numbers of dosimeters handled/stored and categorized by stage of operation; and
- \_\_\_\_\_ h) the handling of late returned dosimeters.

### 2.3 Records indicate that clients are promptly notified in writing, if applicable, of any radioactive contamination found on dosimeters received for processing.



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- \_\_\_\_\_ 2.4 Clients are supplied the same dosimeter types or models (sensitive elements and holder), as were proficiency tested.
  - \_\_\_\_\_ 2.5 Written information is exchanged with the external client regarding dosimetry services provided, including as applicable:
    - \_\_\_\_\_ a) radiation type to be monitored;
    - \_\_\_\_\_ b) dose definition (terminology);
    - \_\_\_\_\_ c) responsibility for handling dose of record;
    - \_\_\_\_\_ d) calibration procedures used in dose determination quality control;
    - \_\_\_\_\_ e) special processing procedures to be used as part of the dosimetry service;
    - \_\_\_\_\_ f) directions for handling and use of background control dosimeters;
    - \_\_\_\_\_ g) identification of anomalies noted during processing; and
    - \_\_\_\_\_ h) precautions to avoid contamination of dosimeters.

### ***3 Dosimeter Identification***

- \_\_\_\_\_ 3.1 Sufficient information is contained in the dosimeter identification code to allow correlation with the processor's record system.
- \_\_\_\_\_ 3.2 The identification system is adequate to assure correct identification of demountable (non-fixed) as well as fixed dosimeter elements and the relationship of each element to a position or filter in the dosimeter.

### ***4 Dosimetry - General***

- \_\_\_\_\_ 4.1 Documentation of the dosimetry system is available to the staff which contains:
  - \_\_\_\_\_ a) lower and upper limits of reliability for the dosimetry system in each radiation category of interest;
  - \_\_\_\_\_ b) specifications with a minimum and maximum level of exposure which each model dosimeter is capable of recording during routine processing;
  - \_\_\_\_\_ c) established criteria/specifications for all systems and dosimeter materials;
  - \_\_\_\_\_ d) the energy and dose response of each type or model of dosimeter used;
  - \_\_\_\_\_ e) procedures to be implemented when any processing equipment fails to meet performance specifications; and

- 
- \_\_\_\_\_ f) procedures for system calibration.
  - \_\_\_\_\_ 4.2 All necessary items of equipment for the correct performance of processing activities are on hand.
  - \_\_\_\_\_ 4.3 Physical facilities, e.g., benchspace, utility services, and safety equipment, are adequate to accommodate processing activities.
  - \_\_\_\_\_ 4.4 No environmental interference is apparent from other nearby activities especially those involving radiation.
  - \_\_\_\_\_ 4.5 There is agreement between assigned processing responsibilities and those technical areas addressed in the training program.
  - \_\_\_\_\_ 4.6 All written and approved procedures are available to the staff.
  - \_\_\_\_\_ 4.7 Each processing protocol is documented in sufficient detail to allow performance by a competent technician.
  - \_\_\_\_\_ 4.8 All staff follow written processing procedures.
  - \_\_\_\_\_ 4.9 Dosimetry processing equipment is sufficiently identified to correlate with calibration records.
  - \_\_\_\_\_ 4.10 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.
  - \_\_\_\_\_ 4.11 Records are available for all processing equipment showing preventive and repair maintenance conducted to ensure stability of equipment performance.
  - \_\_\_\_\_ 4.12 Continuity of equipment operation has been adequately provided for through service contracts or in-house maintenance capability and parts inventory.
  - \_\_\_\_\_ 4.13 A record is maintained of processing activities (e.g., dated log) with sufficient identification to allow correlation with calibration/verification and control system records.
  - \_\_\_\_\_ 4.14 The dosimeter tracking system assures that each measurement is identified and recorded at the time of determination.
  - \_\_\_\_\_ 4.15 Each processing protocol provides for the interspersing of quality control (QC) dosimeters for each set of dosimeters processed (should be a minimum of three).
  - \_\_\_\_\_ 4.16 Irradiation of quality control dosimeters is conducted with suitable sources and records indicate good reproducibility for the method of irradiation.

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- \_\_\_\_\_ 4.17 Appropriate safeguards are used to prevent subversion of quality control dosimeter audits.
  - \_\_\_\_\_ 4.18 The processor has documented and established the frequency of the use of either irradiated or non-irradiated dosimeters based upon total number of dosimeters processed, equipment stability, type of quality control checks used or other suitable means.
  - \_\_\_\_\_ 4.19 A procedure is documented and implemented as written for conducting a detailed review of data produced between the last successful quality control dosimeter and the first quality control dosimeter which fails to meet established control limits.
  - \_\_\_\_\_ 4.20 The procedures system identifies how procedures will be controlled, revised, deleted, and issued. A system for controlling program requirements will be in place within the procedures system.
  - \_\_\_\_\_ 4.21 Dosimeters are processed and reports issued objectively without influence from other areas within the organizational structure.

## 5 TLD Dosimetry

- \_\_\_\_\_ 5.1 Procedures are documented and implemented as written to ensure that:
  - \_\_\_\_\_ a) TLD's are subject to an adequate annealing cycle which is reproducible regarding time, temperature, cooling rate, humidity, and light prior to issue;
  - \_\_\_\_\_ b) precautions are taken to minimize light exposure of TL materials;
  - \_\_\_\_\_ c) precautions are taken to avoid contamination of TL elements (e.g., chalk, dust, grease, or any radioactive material);
  - \_\_\_\_\_ d) loading of sensitive elements is performed in a well-defined order to prevent confusion in handling visually-similar elements of different TL materials;
  - \_\_\_\_\_ e) fading of TL materials, under normal conditions, is documented and accounted for over the period of intended use; periodic rechecks on fading are conducted, if necessary (fading may vary among TL material, manufacturing batches, or following changes in heating cycle); and
  - \_\_\_\_\_ f) TL material for each dosimeter type or model is capable of withstanding heat treatment required in processing.
- \_\_\_\_\_ 5.2 Sufficient measurements have been made and documented to establish the relationship of the TL emission characteristics and the conversion factor between instrument reading and dose equivalent.

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- \_\_\_\_\_ 5.3 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.
- \_\_\_\_\_ 5.4 Equipment for reading out and annealing TL elements is appropriate.
- \_\_\_\_\_ 5.5 The annealing oven or furnace is reserved for dosimetry annealing.
- \_\_\_\_\_ 5.6 Procedures are documented and implemented as written for:
- \_\_\_\_\_ a) 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;
  - reproducible heating cycle which ensures readout of a consistent fraction of relevant stored energy;
  - glow curve output;
  - inert gas purging;
  - digital readout;
  - fading, linearity;
- \_\_\_\_\_ b) removing TL sensitive elements from the dosimeter case which minimizes the potential for loss of information from the sensitive element;
- \_\_\_\_\_ c) checking the TLD reader operation and stability at least daily, when used, using pre-irradiated dosimeters or light sources;
- \_\_\_\_\_ d) loading/unloading the TLD reader;
- \_\_\_\_\_ e) review of selected dosimetry data during the processing cycle;
- \_\_\_\_\_ f) checking to ensure that adequate annealing is accomplished;
- \_\_\_\_\_ g) review of glow curves, if they are captured.

## 6 Film Dosimetry

- 6.1 Procedures are documented and implemented as written to ensure that:
- \_\_\_\_\_ a) prior to issue, film is stored unopened in a cool, dry, low radiation background location which is free from chemical vapors or other deleterious agents;
- \_\_\_\_\_ b) film is current and is stored in a manner to reduce build-up of density due to natural background and/or old age deterioration;
- \_\_\_\_\_ c) each film emulsion batch received is tested to check that fog level, dose-density, and spectral characteristics are satisfactory, and a record is maintained by film emulsion number; and

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- \_\_\_\_\_ d) acceptance procedures verify that film received meets specifications and ensures that the film's expiration date is sufficient for the film to be used at the anticipated time of processing.
- \_\_\_\_\_ 6.2 Adequate equipment, facilities, and materials to support the film processing operations including developing, stop bath, fixing, washing, drying, and densitometry are in place.
- \_\_\_\_\_ 6.3 Film processing darkroom is temperature-controlled, has adequate ventilation, properly installed safelights, and preferably has incandescent lighting.
- \_\_\_\_\_ 6.4 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.
- \_\_\_\_\_ 6.5 Tanks and equipment which hold or are exposed to processing solutions are chemically inert and kept clean.
- \_\_\_\_\_ 6.6 Densitometry equipment capable of measuring appropriate film densities is in place and adequate to support the workload.
- \_\_\_\_\_ 6.7 Records demonstrate the accuracy and reliability of all instruments used to determine gross density of field and control films:
- \_\_\_\_\_ a) densitometer performance is checked before use; and
- \_\_\_\_\_ b) densitometers are calibrated at a frequency recommended by the manufacturer, every 6 months, or as directed in the processing protocol, whichever is more frequent.
- \_\_\_\_\_ 6.8 Quality control films are used to establish the dose density characteristics of each film emulsion batch.
- \_\_\_\_\_ 6.9 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.
- \_\_\_\_\_ 6.10 At least two unexposed films of the same emulsion/lot are included in each processed batch.
- \_\_\_\_\_ 6.11 Records show that temperatures and times for development, stop bath, fixing, washing, and drying are controlled and consistent with processing protocols.
- \_\_\_\_\_ 6.12 Developer/fixer solutions are maintained under cover to reduce oxidation and exclude contamination.

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- \_\_\_\_\_ 6.13 During development, the developing solution is agitated to provide for uniform development of all film.
- 6.14 Procedures are documented and implemented as written for:
- \_\_\_\_\_ a) ensuring that processing chemicals are dated, are properly stored, and discarded upon expiration of shelf life;
  - \_\_\_\_\_ b) defining the frequency for replenishing processing solutions according to time in use or number of films processed;
  - \_\_\_\_\_ c) controlling all chemistry and processing conditions;
  - \_\_\_\_\_ d) for use and renewal of a stop bath;
  - \_\_\_\_\_ e) fixing and washing films;
  - \_\_\_\_\_ f) maintaining the temperatures in processing solutions;
  - \_\_\_\_\_ g) defining and maintaining drying temperatures;
  - \_\_\_\_\_ h) removing film from wrappers in the darkroom and maintaining them in identifiable order for processing;
  - \_\_\_\_\_ i) taking precautions to prevent accidental exposure of the films to light while being processed;
  - \_\_\_\_\_ j) use of control films to verify that processing meets control limits during routine processing activities;
  - \_\_\_\_\_ k) storing films after processing to minimize damage to the emulsion; and
  - \_\_\_\_\_ l) examining films for non-uniform blackening and defining a special measurement procedure for those showing significant non-uniform blackening.

## **7 Track Etch**

- \_\_\_\_\_ 7.1 Track detectors are evaluated using optical or counting equipment appropriate for the anticipated macro- or microscopic track dimension.
- \_\_\_\_\_ 7.2 Chemicals used are of the appropriate solution and quality.
- \_\_\_\_\_ 7.3 Voltage stability and automatic shutdown in case of "sheeting" is utilized when electro-chemical track etch is performed.
- \_\_\_\_\_ 7.4 If multiple staff operators or instruments are used, appropriate intercomparisons are performed to ensure equivalency.



## 8 Dose Assessment and Reporting

- 8.1 Satisfactory documentation of the algorithm exists to indicate its validity for dose interpretation:
  - \_\_\_\_\_ a) algorithm was created and tested using fundamental data which are retrievable;
  - \_\_\_\_\_ b) sources of uncertainty arising from the use of the algorithm are understood and documented;
  - \_\_\_\_\_ c) process controls were considered and documented in the development of the algorithm;
  - \_\_\_\_\_ d) attributes and limitations of the algorithm are documented;
  - \_\_\_\_\_ e) algorithm changes are tested, recorded, and documented; and
  - \_\_\_\_\_ f) a revision log is maintained.
- \_\_\_\_\_ 8.2 Differences, if any, between the algorithm(s) used for proficiency testing and those used for client dose reporting are documented.
- \_\_\_\_\_ 8.3 Differences between algorithms used for different clients are documented.
- \_\_\_\_\_ 8.4 Protocols for routine processing are defined and can be shown to be consistent with NVLAP proficiency testing procedures.
- \_\_\_\_\_ 8.5 Data are reviewed by the Technical Director or his designee prior to being reported to the client.
- \_\_\_\_\_ 8.6 A procedure exists for the investigation, documentation and resolution of anomalies.
- 8.7 An adequate report of dose is sent to the client and includes as applicable:
  - \_\_\_\_\_ a) name and address of processor;
  - \_\_\_\_\_ b) pertinent dates and identification of dosimeter including client and corresponding processor identification codes;
  - \_\_\_\_\_ c) client name;
  - \_\_\_\_\_ d) identification of the dosimeter and/or elements including the radiation category;
  - \_\_\_\_\_ e) "Occupational Radiation Exposure Report" or a similar title;
  - \_\_\_\_\_ f) 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);

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- \_\_\_\_\_ g) identification of anomalies, including contamination of the dosimeter;
  - \_\_\_\_\_ h) signature or reference to person having technical responsibility (NVLAP "approved signatory" when report references NVLAP); and
  - \_\_\_\_\_ i) all additional items required by the processor's test plan appear in the test report.

## **9 Quality Assurance Implementation**

- \_\_\_\_\_ 9.1 Internal audits are performed to assure that no degradation of performance occurs.
- \_\_\_\_\_ 9.2 The quality assurance program includes processing checks, such as:
  - processing controls (e.g., light source readings, microprocessor controls);
  - blind audit dosimeters unknown to the technician;
  - unexposed dosimeters;
  - intercomparison programs.
- \_\_\_\_\_ 9.3 Technicians are familiar with and perform the quality control program.
- \_\_\_\_\_ 9.4 The quality assurance program is organized to assess variability of test results among staff members, or separate equivalent systems at the same or different locations (subfacilities).
- \_\_\_\_\_ 9.5 Results of audits are examined by the Technical Director or designee, and action is taken to correct any deficiencies.
- \_\_\_\_\_ 9.6 Records of participation in intercomparison programs or external measurement assurance programs demonstrate consistency with practices documented.
- \_\_\_\_\_ 9.7 Records and practices observed from the point of dosimeter receipt through to final delivery of data to the user indicate consistency with documented procedures.
- \_\_\_\_\_ 9.8 The processor has an established written plan for bringing back-up equipment into 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.
- \_\_\_\_\_ 9.9 Record retention duration and locations will be specified in writing.
- \_\_\_\_\_ 9.10 Records of prior performance tests should be analyzed for trends and degradation of test performance.

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## 10 Calibration

- \_\_\_\_\_ 10.1 Dosimetry systems are calibrated to known doses from radioactive sources or radiation generating machines. The dose in a radiation field is measured using an NIST-traceable instrument or is based on the measurement of flux or emission rate of a source traceable to primary radiation standards.
- \_\_\_\_\_ 10.2 Calibration sources used are appropriate for the type of radiation to be interpreted by the dosimeter.
- \_\_\_\_\_ 10.3 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;
  - \_\_\_\_\_ d) notation of equipment variables requiring calibration/verification;
  - \_\_\_\_\_ e) range of dose measurements for which calibrations have been conducted;
  - \_\_\_\_\_ f) allowable error (taking into consideration instrument tolerance) to 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; and
  - \_\_\_\_\_ j) identity of reference standards used.
- \_\_\_\_\_ 10.4 Calibration and verification practices for dosimetry systems for all processing protocols are described in the QA documentation identifying calibration services, reference materials, and measurement assurance programs used.
- \_\_\_\_\_ 10.5 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.

## 11 Computer Operations

- \_\_\_\_\_ 11.1 All computer software used in the processing cycle is properly validated and verified prior to use and periodically thereafter.

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- \_\_\_\_\_ 11.2 Data transfers between processing and computing equipment are accomplished without loss of data, and verification is performed.
  - \_\_\_\_\_ 11.3 All computer software associated with the processing system(s) is fully documented.
  - \_\_\_\_\_ 11.4 Integrity of data files are protected by systematic redundancies, such as adequate back up at regular intervals.
  - \_\_\_\_\_ 11.5 Appropriate controls are in place for software and data security, and to preclude inadvertent or unauthorized changes.

## **12 Subfacilities**

- \_\_\_\_\_ 12.1 The main facility maintains all QA documentation and procedures and assures that all subfacilities are consistent in their processing activities.
- \_\_\_\_\_ 12.2 Comparative tests are conducted to assure consistency of dosimetry data developed between the main facility and the subfacility.
- \_\_\_\_\_ 12.3 The subfacility receives all QA and procedural direction from the main facility.

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

[illegible]

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

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## **APPENDIX D**

### **SAMPLE PROFICIENCY TEST REPORT**

**(NOTE: This sample does not cover each category.)**



PERSONNEL DOSIMETRY PERFORMANCE TESTING

CONDUCTED FOR :

NATIONAL VOLUNTARY LABORATORY ACCREDITATION PROGRAM  
NATIONAL INSTITUTE OF STANDARDS AND TECHNOLOGY  
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 :

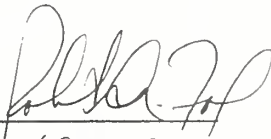
TEST RESULTS FOR QUARTER : 1991-4

TESTING STATUS : RENEWAL

REPORT PRINTED : Feb 4, 1992

CHECKED BY :

DATE :

  
4 FEB 92

'PROCESSOR CODE', on the front page, is a five character code that consists of a four digit processor identifier number plus a single letter to identify each of the processor's dosimeter models.

'TESTING STATUS' indicates whether the testing is for initial accreditation, for retesting in cases of prior failure, or for renewal of accreditation of this dosimeter.

A performance quotient is calculated for each dosimeter by:

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

where : H = delivered quantity  
H\* = reported quantity

For each appropriate depth of a test category, an average performance quotient ( $\bar{P}$ ), and its standard deviation (S) are calculated for 'N' dosimeters. A processor passes a category if, for each relevant depth,  $|\bar{P}| + S$  is less than or equal to the appropriate tolerance limit (L). For categories I and II, which involve accident level doses,  $L = 0.3$ . For categories III through VIII, which involve protection level doses,  $L = 0.5$ .

If a dosimeter is not reported by the processor, is irradiated improperly, is lost, etc., the dosimeter is listed as 'VOIDED' and is not included in the pass/fail calculations.

NOTE: Some of the dose rates in this report have additional correction factors which are applied to individual delivered doses. The rate printed in this report is the source calibration at the center of the phantom's front surface. A field non-uniformity factor is applied to each delivered dose to reflect the dosimeter placement on the phantom. For x-rays, the delivered exposure is determined from the charge collection of a transmission chamber. Corrections are applied for air density and electrometer range. The dosimeters are shimmed on the phantom so they are parallel with the front surface of the phantom.

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 : 1991-4  
 TESTING STATUS : RENEWAL  
 REPORT PRINTED : Feb 4, 1992

DOSIMETER NUMBER	DATE IRRADIATED	IRRADIATION INFORMATION			DEEP ABSORBED DOSE, CX = 1.38		P
		RATE (mR/nCoul)	CHARGE (nCoul)	TOTAL (R)	DELIVERED (rad)	REPORTED (rad)	
6	91-10-15	2.3100	17603.0	40.79	56.29	77.00	.3680
42	91-10-15	2.3100	8358.0	19.39	26.75	24.70	-.0767
10	91-10-15	2.3100	130370.0	301.91	416.63	410.00	-.0159
15	91-10-15	2.3100	34676.0	80.34	110.88	130.00	.1725
27	91-10-16	2.3100	4354.0	10.21	14.09	13.00	-.0770
81	91-11-20	2.3100	46718.0	107.90	148.90	169.00	.1350
67	91-11-20	2.3100	25668.0	59.40	81.98	91.00	.1101
75	91-11-20	2.3100	9830.0	22.70	31.33	33.00	.0533
83	91-11-20	2.3100	26708.0	61.69	85.13	88.00	.0338
49	91-11-20	2.3100	39768.0	91.85	126.75	169.00	.3333
97	91-12-17	2.3100	4448.0	10.31	14.23	12.50	-.1217
103	91-12-17	2.3100	3254.0	7.54	10.41	8.70	-.1644
113	91-12-17	2.3100	7675.0	17.80	24.56	20.80	-.1530
92	91-12-18	2.3100	31468.0	73.77	101.81	99.00	-.0276
128	91-12-18	2.3100	22529.0	52.82	72.89	68.00	-.0671

N = 15

$\bar{P}$  = .03

S = .16

$|\bar{P}| + S = .20$

L = .30

\*\*\*\*\* PASS \*\*\*\*\*



CATEGORY II : ACCIDENTS,HIGH-ENERGY PHOTONS  
 RADIATION SOURCE : CESIUM-137  
 IRRADIATION DISTANCE : 100.0 CM TO THE FRONT FACE OF PHANTOM

PROCESSOR NAME :  
 PROCESSOR CODE NO. :  
 TYPE OF DOSIMETER :  
 TEST RESULTS FOR QUARTER : 1991-4  
 TESTING STATUS : RENEWAL  
 REPORT PRINTED : Feb 4, 1992

DOSIMETER NUMBER	DATE IRRADIATED	IRRADIATION INFORMATION			DEEP ABSORBED DOSE, CX = 1.03		P
		RATE (mR/min)	TIME (min)	TOTAL (R)	DELIVERED (rad)	REPORTED (rad)	
25	91-10-11	420.20	29.83	12.53	12.91	14.00	.0844
19	91-10-14	420.20	386.92	162.59	167.46	160.00	-.0446
11	91-10-16	420.20	1009.99	424.40	437.13	390.00	-.1078
12	91-10-17	420.10	918.76	385.97	397.55	360.00	-.0945
34	91-10-19	420.20	572.88	240.73	247.95	240.00	-.0321
72	91-11-19	419.15	67.67	28.36	29.22	32.00	.0953
71	91-11-20	419.15	612.93	256.91	264.62	310.00	.1715
62	91-11-21	419.15	392.21	164.39	169.32	200.00	.1812
65	91-11-21	419.15	25.14	10.54	10.85	11.50	.0596
58	91-11-25	419.15	339.60	142.34	146.61	170.00	.1595
126	91-12-21	418.33	507.52	212.31	218.68	245.00	.1204
99	91-12-21	418.33	34.98	14.63	15.07	14.50	-.0380
118	91-12-21	418.33	63.47	26.55	27.35	29.00	.0604
124	91-12-22	418.33	392.17	164.06	168.98	175.00	.0356
120	91-12-25	418.33	287.87	120.43	124.04	130.00	.0481

N = 15

$\bar{P}$  = .05

S = .09

$|\bar{P}| + S = .14$

L = .30

\*\*\*\*\* PASS \*\*\*\*\*

CATEGORY III : LOW-ENERGY PHOTONS

PAGE 1 OF 2

RADIATION SOURCE : S60 (MFC)

IRRADIATION DISTANCE : 100.0 CM TO THE FRONT FACE OF PHANTOM

PROCESSOR NAME :

PROCESSOR CODE NO. :

TYPE OF DOSIMETER :

TEST RESULTS FOR QUARTER : 1991-4

TESTING STATUS : RENEWAL

REPORT PRINTED : Feb 4, 1992

DOSIMETER NUMBER	DATE IRRADIATED	IRRADIATION INFORMATION			DEEP DOSE EQUIV, CX = .98		P
		RATE (mR/nCoul)	CHARGE (nCoul)	TOTAL (mR)	DELIVERED (mrem)	REPORTED (mrem)	
32	91-10-11	1.9120	2791.0	5317.41	5211.06	6000.00	.1514
33	91-10-14	1.9120	713.0	1346.25	1319.32	1300.00	-.0146
8	91-10-14	1.9120	162.3	306.41	300.28	270.00	-.1008
31	91-10-14	1.9120	108.9	205.64	201.53	190.00	-.0572
14	91-10-14	1.9120	1212.1	2288.62	2242.85	1900.00	-.1529
73	91-11-19	1.9120	531.9	1024.37	1003.88	990.00	-.0138
80	91-11-19	1.9120	203.1	391.14	383.32	355.00	-.0739
82	91-11-19	1.9120	209.6	403.66	395.59	365.00	-.0773
54	91-11-19	1.9120	4080.0	7857.54	7700.39	8000.00	.0389
46	91-11-19	1.9120	1527.5	2941.76	2882.93	3500.00	.2140
109	91-12-20	1.9120	1114.8	2119.53	2077.14	2350.00	.1314
114	91-12-20	1.9120	187.3	356.07	348.95	305.00	-.1259
94	91-12-20	1.9120	50.1	95.27	93.37	90.00	-.0361
89	91-12-20	1.9120	1119.4	2128.27	2085.71	2320.00	.1123
96	91-12-20	1.9120	128.8	244.94	240.04	220.00	-.0835

N = 15

$\bar{P}$  = -.01

S = .11

$|\bar{P}| + S = .12$

L = .50

\*\*\*\*\* PASS \*\*\*\*\*

CATEGORY III : LOW-ENERGY PHOTONS

PAGE 2 OF 2

RADIATION SOURCE : S60 (MFC)

IRRADIATION DISTANCE : 100.0 CM TO THE FRONT FACE OF PHANTOM

PROCESSOR NAME :

PROCESSOR CODE NO. :

TYPE OF DOSIMETER :

TEST RESULTS FOR QUARTER : 1991-4

TESTING STATUS : RENEWAL

REPORT PRINTED : Feb 4, 1992

DOSIMETER NUMBER	DATE IRRADIATED	IRRADIATION INFORMATION			SHALLOW DOSE EQUIV, CX = 1.14		
		RATE (mR/nCoul)	CHARGE (nCoul)	TOTAL (mR)	DELIVERED (mrem)	REPORTED (mrem)	P
32	91-10-11	1.9120	2791.0	5317.41	6061.84	7000.00	.1548
33	91-10-14	1.9120	713.0	1346.25	1534.72	1500.00	-.0226
8	91-10-14	1.9120	162.3	306.41	349.31	310.00	-.1125
31	91-10-14	1.9120	108.9	205.64	234.43	210.00	-.1042
14	91-10-14	1.9120	1212.1	2288.62	2609.03	2200.00	-.1568
73	91-11-19	1.9120	531.9	1024.37	1167.78	1130.00	-.0324
80	91-11-19	1.9120	203.1	391.14	445.90	405.00	-.0917
82	91-11-19	1.9120	209.6	403.66	460.17	420.00	-.0873
54	91-11-19	1.9120	4080.0	7857.54	8957.60	9200.00	.0271
46	91-11-19	1.9120	1527.5	2941.76	3353.61	4000.00	.1927
109	91-12-20	1.9120	1114.8	2119.53	2416.26	2700.00	.1174
114	91-12-20	1.9120	187.3	356.07	405.92	350.00	-.1378
94	91-12-20	1.9120	50.1	95.27	108.61	105.00	-.0332
89	91-12-20	1.9120	1119.4	2128.27	2426.23	2660.00	.0964
96	91-12-20	1.9120	128.8	244.94	279.23	250.00	-.1047

N = 15

$\bar{P}$  = -.02

S = .11

$|\bar{P}| + S$  = .13

L = .50

\*\*\*\*\* PASS \*\*\*\*\*

CATEGORY IV : HIGH-ENERGY PHOTONS  
 RADIATION SOURCE : CESIUM-137  
 IRRADIATION DISTANCE : 100.0 CM TO THE FRONT FACE OF PHANTOM  
 300.0 CM TO THE FRONT FACE OF PHANTOM

PROCESSOR NAME :  
 PROCESSOR CODE NO. :  
 TYPE OF DOSIMETER :  
 TEST RESULTS FOR QUARTER : 1991-4  
 TESTING STATUS : RENEWAL  
 REPORT PRINTED : Feb 4, 1992

DOSIMETER NUMBER	DATE IRRADIATED	IRRADIATION INFORMATION			DEEP DOSE EQUIV, CX = 1.03		
		RATE (mR/min)	TIME (min)	TOTAL (mR)	DELIVERED (mrem)	REPORTED (mrem)	P
26	91-10-17	420.07	6.03	2533.04	2609.03	3100.00	.1882
18	91-10-17	420.07	2.02	848.55	874.00	950.00	.0870
40	91-10-17	46.12	1.83	84.55	87.09	90.00	.0334
7	91-10-18	46.11	1.93	88.84	91.50	90.00	-.0164
3	91-10-18	46.11	1.05	48.65	50.11	50.00	-.0022
70	91-11-21	419.10	8.63	3618.89	3727.46	4100.00	.0999
61	91-11-21	419.10	6.32	2650.08	2729.59	3050.00	.1174
45	91-11-21	419.10	10.56	4424.95	4557.70	4900.00	.0751
53	91-11-21	419.10	2.38	999.54	1029.53	1040.00	.0102
84	91-11-21	419.10	1.26	529.46	545.34	570.00	.0452
119	91-12-24	418.33	2.64	1104.40	1137.53	1140.00	.0022
125	91-12-24	418.31	9.17	3837.26	3952.38	4150.00	.0500
101	91-12-24	418.33	4.64	1942.46	2000.73	2130.00	.0646
123	91-12-25	418.33	10.91	4562.61	4699.49	4700.00	.0001
111	91-12-25	45.93	10.57	485.38	499.95	510.00	.0201

N = 15

$\bar{P}$  = .05

S = .06

$|\bar{P}| + S$  = .11

L = .50

\*\*\*\*\* PASS \*\*\*\*\*

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

PROCESSOR NAME :  
 PROCESSOR CODE NO. :  
 TYPE OF DOSIMETER :  
 TEST RESULTS FOR QUARTER : 1991-4  
 TESTING STATUS : RENEWAL  
 REPORT PRINTED : Feb 4, 1992

DOSIMETER NUMBER	DATE IRRADIATED	IRRADIATION INFORMATION			SHALLOW DOSE EQUIVALENT		P
		RATE (mrad/min)	TIME (min)	TOTAL (mrad)	DELIVERED (mrem)	REPORTED (mrem)	
5	91-10-16	264.69	5.45	1385.29	1385.29	1550.00	.1189
29	91-10-16	264.69	13.72	3521.35	3521.35	3200.00	-.0913
20	91-10-17	8.90	26.08	222.80	222.80	240.00	.0772
37	91-10-17	264.69	14.81	3762.87	3762.87	3400.00	-.0964
21	91-10-17	264.69	16.94	4484.77	4484.77	3900.00	-.1304
79	91-11-15	264.17	3.97	1016.44	1016.44	990.00	-.0260
52	91-11-15	264.17	6.93	1757.89	1757.89	1830.00	.0410
66	91-11-15	264.17	15.62	4002.97	4002.97	3400.00	-.1506
51	91-11-15	264.17	1.42	373.80	373.80	360.00	-.0369
47	91-11-19	8.88	20.89	180.01	180.01	175.00	-.0278
107	91-12-18	8.86	24.56	208.96	208.96	195.00	-.0668
110	91-12-18	8.86	21.40	182.05	182.05	170.00	-.0662
98	91-12-19	263.56	1.18	310.56	310.56	280.00	-.0984
115	91-12-19	263.60	1.28	323.49	323.49	300.00	-.0726
105	91-12-19	263.60	17.77	4496.75	4496.75	3800.00	-.1549

N = 15

$\bar{P}$  = -.05

S = .08

$|\bar{P}| + S$  = .13

L = .50

\*\*\*\*\* PASS \*\*\*\*\*

CATEGORY VI : PHOTON MIXTURES

PAGE 1 OF 3

RADIATION SOURCE : CESIUM-137

IRRADIATION DISTANCE : 100.0 CM TO THE FRONT FACE OF PHANTOM  
300.0 CM TO THE FRONT FACE OF PHANTOM

PROCESSOR NAME :

PROCESSOR CODE NO. :

TYPE OF DOSIMETER :

TEST RESULTS FOR QUARTER : 1991-4

TESTING STATUS : RENEWAL

REPORT PRINTED : Feb 4, 1992

DOSIMETER NUMBER	DATE IRRADIATED	IRRADIATION INFORMATION			DELIVERED DOSE EQUIVALENT	
		RATE (mR/min)	TIME (min)	TOTAL (mR)	SHALLOW CX = 1.03 (mrem)	DEEP CX = 1.03 (mrem)
39	91-10-16	420.10	1.67	700.9	721.9	721.9
16	91-10-16	46.13	1.09	50.3	51.8	51.8
28	91-10-16	420.10	7.48	3140.9	3235.2	3235.2
35	91-10-16	46.12	7.32	337.5	347.7	347.7
38	91-10-16	46.12	8.13	375.0	386.2	386.2
55	91-11-19	46.03	1.36	62.5	64.3	64.3
68	91-11-19	419.28	1.56	655.5	675.1	675.1
59	91-11-19	419.28	2.23	935.7	963.8	963.8
69	91-11-19	419.28	2.99	1252.3	1289.8	1289.8
60	91-11-19	419.28	2.20	923.1	950.8	950.8
116	91-12-19	418.38	4.42	1848.6	1904.0	1904.0
127	91-12-19	418.38	1.56	653.4	673.0	673.0
106	91-12-19	418.38	3.44	1440.6	1483.9	1483.9
104	91-12-19	418.38	1.80	753.1	775.7	775.7
117	91-12-19	418.38	3.49	1460.9	1504.7	1504.7



CATEGORY VI : PHOTON MIXTURES

PAGE 2 OF 3

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 : 1991-4  
 TESTING STATUS : RENEWAL  
 REPORT PRINTED : Feb 4, 1992

DOSIMETER NUMBER	DATE IRRADIATED	IRRADIATION INFORMATION			DELIVERED DOSE EQUIVALENT	
		RATE (mR/nCoul)	CHARGE (nCoul)	TOTAL (mR)	SHALLOW CX = 1.43 (mrem)	DEEP CX = 1.38 (mrem)
39	91-10-14	2.3100	617.00	1408.2	2013.8	1943.4
16	91-10-14	2.3100	22.52	51.5	73.6	71.0
28	91-10-14	2.3100	345.60	788.8	1128.0	1088.5
35	91-10-14	2.3100	133.84	305.9	437.5	422.2
38	91-10-14	2.3100	113.65	259.8	371.5	358.5
55	91-11-19	2.3100	38.91	90.1	128.8	124.3
68	91-11-19	2.3100	92.06	213.6	305.5	294.8
59	91-11-19	2.3100	135.43	314.3	449.4	433.7
69	91-11-19	2.3100	147.10	340.4	486.8	469.8
60	91-11-19	2.3100	213.30	493.8	706.2	681.5
116	91-12-19	2.3100	592.40	1362.7	1948.7	1880.6
127	91-12-19	2.3100	75.03	172.6	246.8	238.2
106	91-12-19	2.3100	666.00	1532.0	2190.8	2114.2
104	91-12-19	2.3100	206.30	474.6	678.6	654.9
117	91-12-19	2.3100	187.66	431.7	617.3	595.7

PROCESSOR NAME :  
 PROCESSOR CODE NO. :  
 TYPE OF DOSIMETER :  
 TEST RESULTS FOR QUARTER : 1991-4  
 TESTING STATUS : RENEWAL  
 REPORT PRINTED : Feb 4, 1992

DOSIMETER NUMBER	TOTAL SHALLOW DOSE EQUIVALENT			TOTAL DEEP DOSE EQUIVALENT		
	DELIVERED (mrem)	REPORTED (mrem)	P	DELIVERED (mrem)	REPORTED (mrem)	P
39	2735.7	3200.0	.1697	2665.2	3100.0	.1631
16	125.4	145.0	.1563	122.8	140.0	.1398
28	4363.1	4900.0	.1230	4323.7	4700.0	.0870
35	785.1	1000.0	.2737	769.8	950.0	.2340
38	757.7	950.0	.2538	744.7	900.0	.2085
55	193.1	250.0	.2947	188.6	240.0	.2725
68	980.6	1200.0	.2237	970.0	1150.0	.1856
59	1413.2	1650.0	.1676	1397.5	1580.0	.1306
69	1776.7	2160.0	.2158	1759.6	2070.0	.1764
60	1657.0	1980.0	.1949	1632.3	1900.0	.1640
116	3852.7	3800.0	-.0137	3784.6	3650.0	-.0356
127	919.8	1080.0	.1742	911.2	1040.0	.1414
106	3674.7	3100.0	-.1564	3598.1	3000.0	-.1662
104	1454.3	1620.0	.1139	1430.6	1560.0	.0905
117	2122.0	2760.0	.3007	2100.4	2650.0	.2617

N =	15	N =	15
$\bar{P}$ =	.17	$\bar{P}$ =	.14
S =	.12	S =	.11
$ \bar{P}  + S$ =	.29	$ \bar{P}  + S$ =	.25
L =	.50	L =	.50

\*\*\*\*\* PASS \*\*\*\*\*

\*\*\*\*\* PASS \*\*\*\*\*

CATEGORY VII : PHOTON AND BETA MIXTURES

PAGE 1 OF 3

RADIATION SOURCE : CESIUM-137

IRRADIATION DISTANCE : 100.0 CM TO THE FRONT FACE OF PHANTOM  
300.0 CM TO THE FRONT FACE OF PHANTOM

PROCESSOR NAME :

PROCESSOR CODE NO. :

TYPE OF DOSIMETER :

TEST RESULTS FOR QUARTER : 1991-4

TESTING STATUS : RENEWAL

REPORT PRINTED : Feb 4, 1992

DOSIMETER NUMBER	DATE IRRADIATED	IRRADIATION INFORMATION			DELIVERED DOSE EQUIVALENT	
		RATE (mR/min)	TIME (min)	TOTAL (mR)	SHALLOW CX = 1.03 (mrem)	DEEP CX = 1.03 (mrem)
24	91-10-17	420.05	1.53	644.8	664.1	664.1
1	91-10-17	420.05	1.92	808.6	832.8	832.8
36	91-10-18	420.02	4.56	1914.6	1972.0	1972.0
9	91-10-18	420.02	1.36	569.8	586.9	586.9
22	91-10-18	46.11	6.63	305.8	315.0	315.0
64	91-11-14	419.28	5.24	2196.3	2262.2	2262.2
74	91-11-14	419.28	2.12	888.2	914.8	914.8
77	91-11-14	419.28	2.61	1095.7	1128.6	1128.6
56	91-11-15	46.04	2.20	101.4	104.5	104.5
86	91-11-15	46.03	5.34	246.0	253.3	253.3
121	91-12-20	45.93	10.28	472.1	486.2	486.2
91	91-12-20	45.93	10.22	469.4	483.5	483.5
112	91-12-23	418.33	1.20	503.4	518.5	518.5
122	91-12-23	418.33	3.18	1331.0	1370.9	1370.9
93	91-12-23	418.33	7.23	3023.1	3113.8	3113.8

CATEGORY VII : PHOTON AND BETA MIXTURES

PAGE 2 OF 3

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 : 1991-4  
 TESTING STATUS : RENEWAL  
 REPORT PRINTED : Feb 4, 1992

DOSIMETER NUMBER	DATE IRRADIATED	IRRADIATION INFORMATION			DELIVERED DOSE SHALLOW	EQUIVALENT DEEP
		RATE (mrad/min)	TIME (min)	TOTAL (mrad)	(mrem)	(mrem)
24	91-10-17	264.67	2.86	755.6	755.6	.0
1	91-10-17	264.67	9.09	2310.5	2310.5	.0
36	91-10-18	264.66	8.62	2213.3	2213.3	.0
9	91-10-21	264.66	1.48	380.8	380.8	.0
22	91-10-21	8.90	21.27	183.6	183.6	.0
64	91-11-19	264.17	3.24	822.1	822.1	.0
74	91-11-19	264.17	2.96	757.2	757.2	.0
77	91-11-20	264.17	8.39	2149.5	2149.5	.0
56	91-11-19	8.88	16.30	140.4	140.4	.0
86	91-11-19	8.88	12.82	113.9	113.9	.0
121	91-12-23	263.54	3.46	876.7	876.7	.0
91	91-12-23	8.86	30.31	257.8	257.8	.0
112	91-12-23	8.86	27.95	237.7	237.7	.0
122	91-12-23	263.54	7.05	1784.5	1784.5	.0
93	91-12-23	263.54	5.40	1424.0	1424.0	.0

CATEGORY VII : SUMMARY OF PHOTONS PLUS  
BETA PARTICLES

PAGE 3 OF 3

PROCESSOR NAME :  
PROCESSOR CODE NO. :  
TYPE OF DOSIMETER :  
TEST RESULTS FOR QUARTER : 1991-4  
TESTING STATUS : RENEWAL  
REPORT PRINTED : Feb 4, 1992

DOSIMETER NUMBER	TOTAL SHALLOW DOSE EQUIVALENT			TOTAL DEEP DOSE EQUIVALENT		
	DELIVERED (mrem)	REPORTED (mrem)	P	DELIVERED (mrem)	REPORTED (mrem)	P
24	1419.8	1600.0	.1270	664.1	750.0	.1293
1	3143.4	3200.0	.0180	832.8	950.0	.1407
36	4185.4	4000.0	-.0443	1972.0	2250.0	.1410
9	967.7	1100.0	.1367	586.9	650.0	.1075
22	498.6	550.0	.1031	315.0	340.0	.0794
64	3084.3	3290.0	.0667	2262.2	2360.0	.0432
74	1672.0	1800.0	.0765	914.8	920.0	.0057
77	3278.1	3300.0	.0067	1128.6	1140.0	.0101
56	244.9	250.0	.0210	104.5	105.0	.0050
86	367.2	395.0	.0757	253.3	255.0	.0065
121	1362.9	1420.0	.0419	486.2	490.0	.0078
91	741.3	760.0	.0253	483.5	470.0	-.0279
112	756.2	790.0	.0447	518.5	540.0	.0415
122	3155.4	3150.0	-.0017	1370.9	1380.0	.0066
93	4537.9	4650.0	.0247	3113.8	3350.0	.0758

N =	15	N =	15
$\bar{P}$ =	.05	$\bar{P}$ =	.05
S =	.05	S =	.06
$ \bar{P}  + S$ =	.10	$ \bar{P}  + S$ =	.11
L =	.50	L =	.50

\*\*\*\*\* PASS \*\*\*\*\*

\*\*\*\*\* PASS \*\*\*\*\*

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 : 1991-4  
TESTING STATUS : RENEWAL  
REPORT PRINTED : Feb 4, 1992

CATEGORY	SHALLOW DEPTH				DEEP DEPTH			
	$\bar{P}$	S	$ \bar{P} +S$	L	$\bar{P}$	S	$ \bar{P} +S$	L
I		NO TEST			.033	.164	.197	.300
II		NO TEST			.047	.093	.140	.300
III	-.020	.112	.132	.500	-.006	.111	.117	.500
IV		NO TEST			.052	.055	.107	.500
V	-.052	.080	.132	.500		NO TEST		
VI	.166	.120	.286	.500	.137	.113	.250	.500
VII	.048	.050	.098	.500	.051	.057	.108	.500
VIII		NO TEST				****		

\*\*\*\* 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 : 1991-4

TESTING STATUS : RENEWAL

REPORT PRINTED : Feb 4, 1992

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	****



**APPENDIX E**

**NVLAP PROFICIENCY TESTING DATA SUMMARY**



National Voluntary Laboratory Accreditation Program (NVLAP)  
Ionizing Radiation Dosimetry (Personnel)

Proficiency Testing - 1993 Year Summary

ANSI N13 Category	1993			1989 thru 1993	
	Number of category tests Attempted /Passed	Average $ \bar{P}  + S$ , category tests Passed	S for category tests Passed, Median/Maximum	Grand Average $ \bar{P}  + S$ , Passed	Number of Category Tests Attempted/ Passed (% PASS)
I	40/37 (93)	0.12	0.06/0.21	0.13	187/172 (92)
II	39/39 (100)	0.10	0.06/0.19	0.11	207/200 (97)
IIId IIIs	40/38 (95)	0.17 0.17	0.06/0.25 0.06/0.23	0.17 0.16	193/183 (95)
IV	44/44 (100)	0.11	0.05/0.20	0.11	217/217 (100)
V	40/40 (100)	0.16	0.07/0.28	0.15	200/200 (100)
VIId VIIs	39/37 (95)	0.15 0.16	0.07/0.20 0.07/0.15	0.15 0.15	185/180 (97)
VIId VIIs	40/40 (100)	0.13 0.13	0.05/0.17 0.05/0.17	0.12 0.13	204/201 (99)
VIII	33/31 (94)	0.09	0.05/0.12	0.11	169/166 (98)

Column 1: Radiation categories per ANSI N13.11. "s" indicates shallow dose and "d" indicates deep dose.

Column 2, 3, 4: Includes data for 1993 only. Category tests passed includes initial, retest, and renewal testing.

Column 2: Category tests attempted, passed, percent passed.

Column 3: Arithmetic average of the calculated  $|\bar{P}| + S$  for category tests that were passed in 1993.

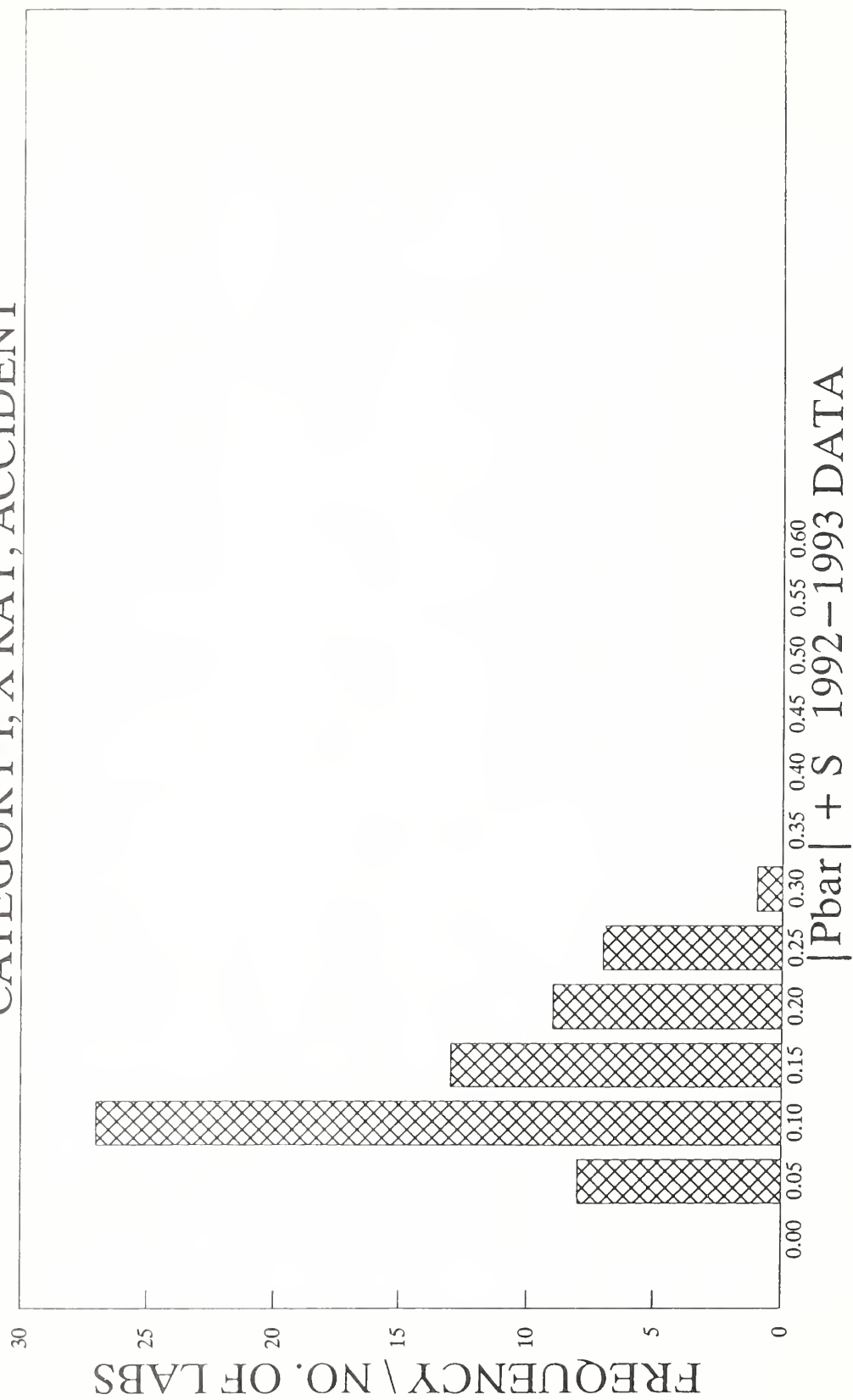
Column 4: Median is defined as half of the values for S are below the median value and half are above. Maximum is the largest value reported.

Column 5: The arithmetic average of all of the  $|\bar{P}| + S$  values for passed category tests from 1989 through 1993. Category tests passed includes initial, retest, and renewal testing.

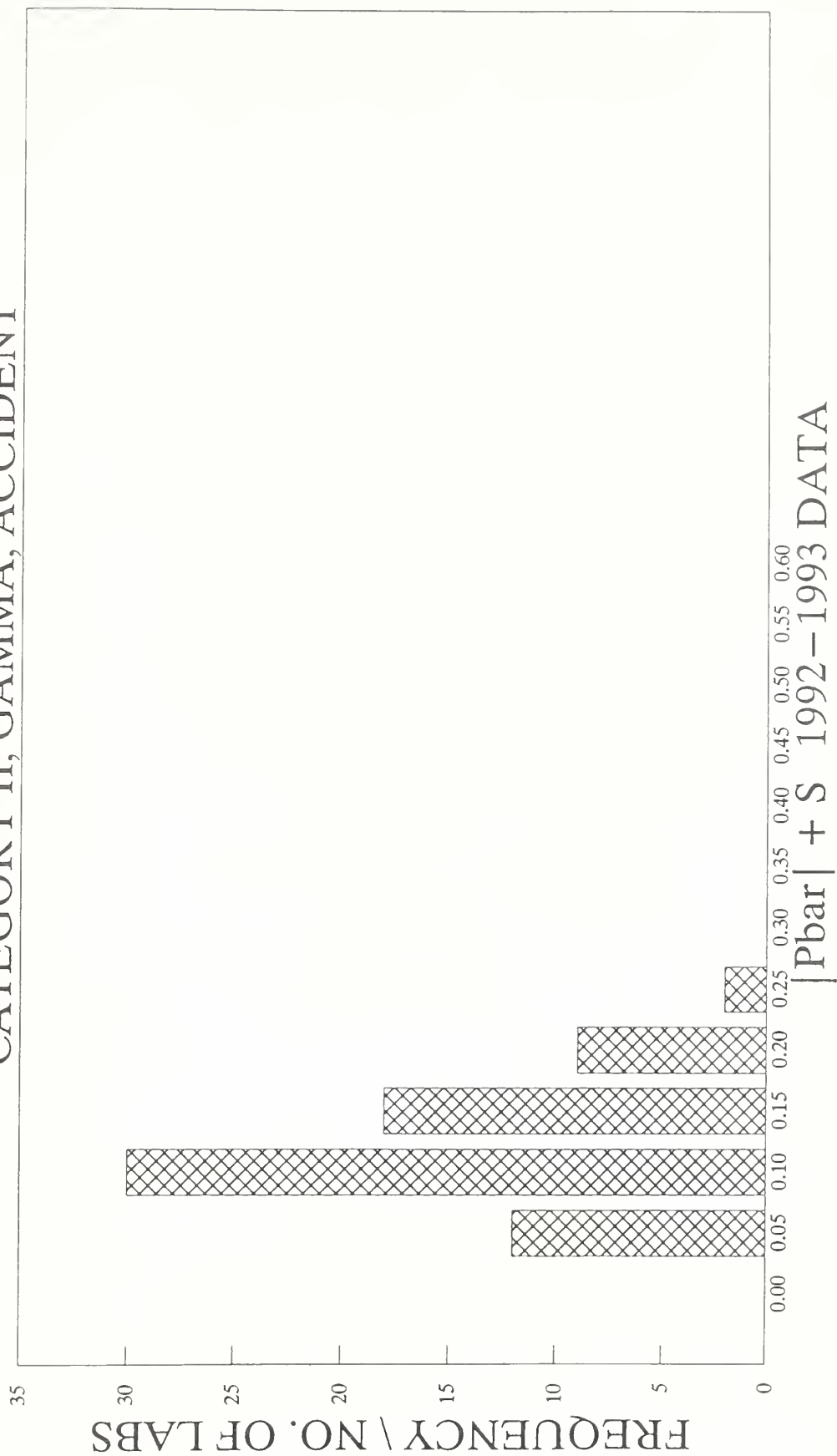
Column 6: Category tests attempted, passed, percent passed.

NOTE: Averages, medians, and other summary statistics calculated on the basis of small samples can differ considerably from values calculated from large samples.

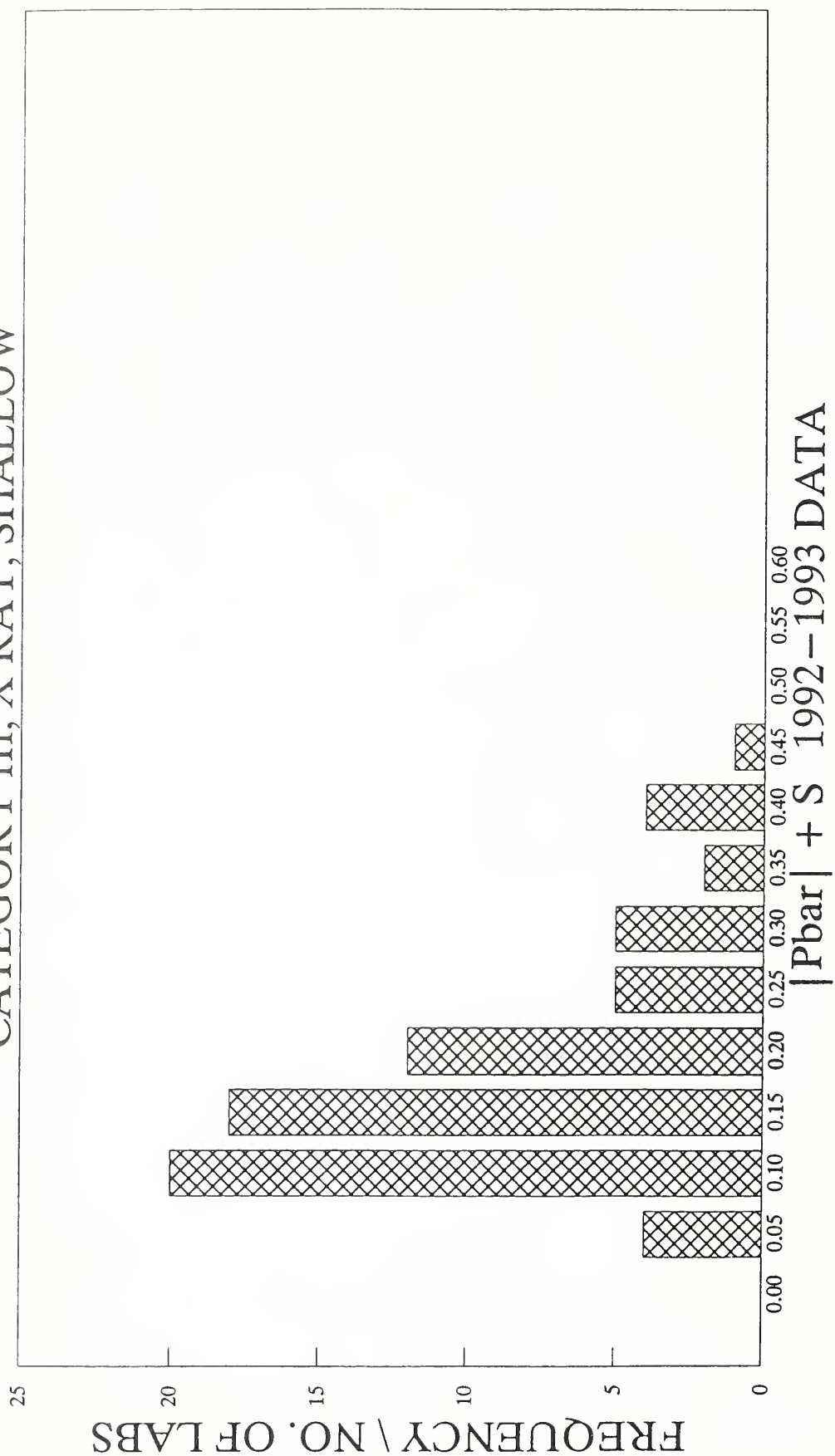
# CATEGORY I, X RAY, ACCIDENT



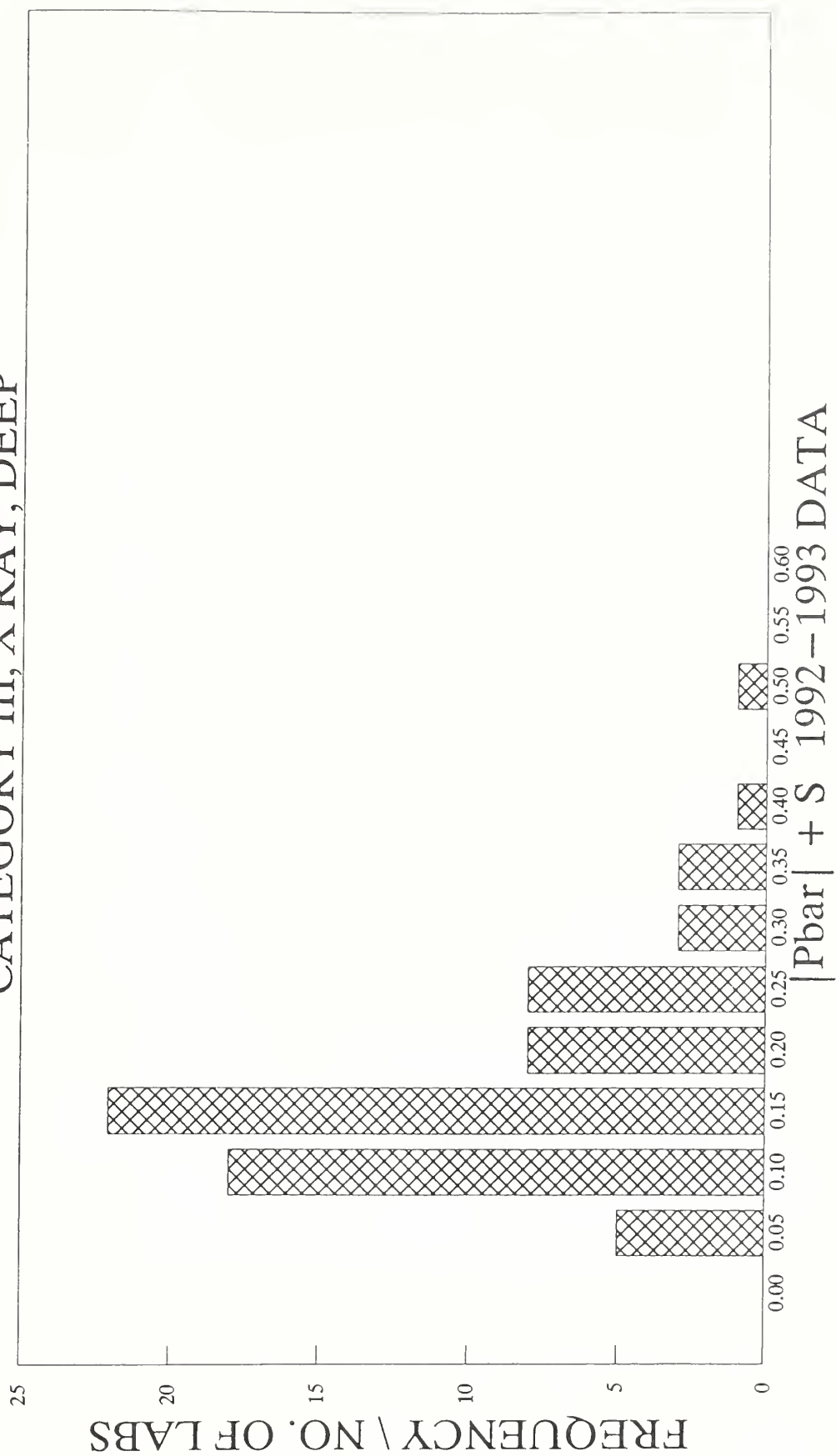
# CATEGORY II, GAMMA, ACCIDENT



# CATEGORY III, X RAY, SHALLOW

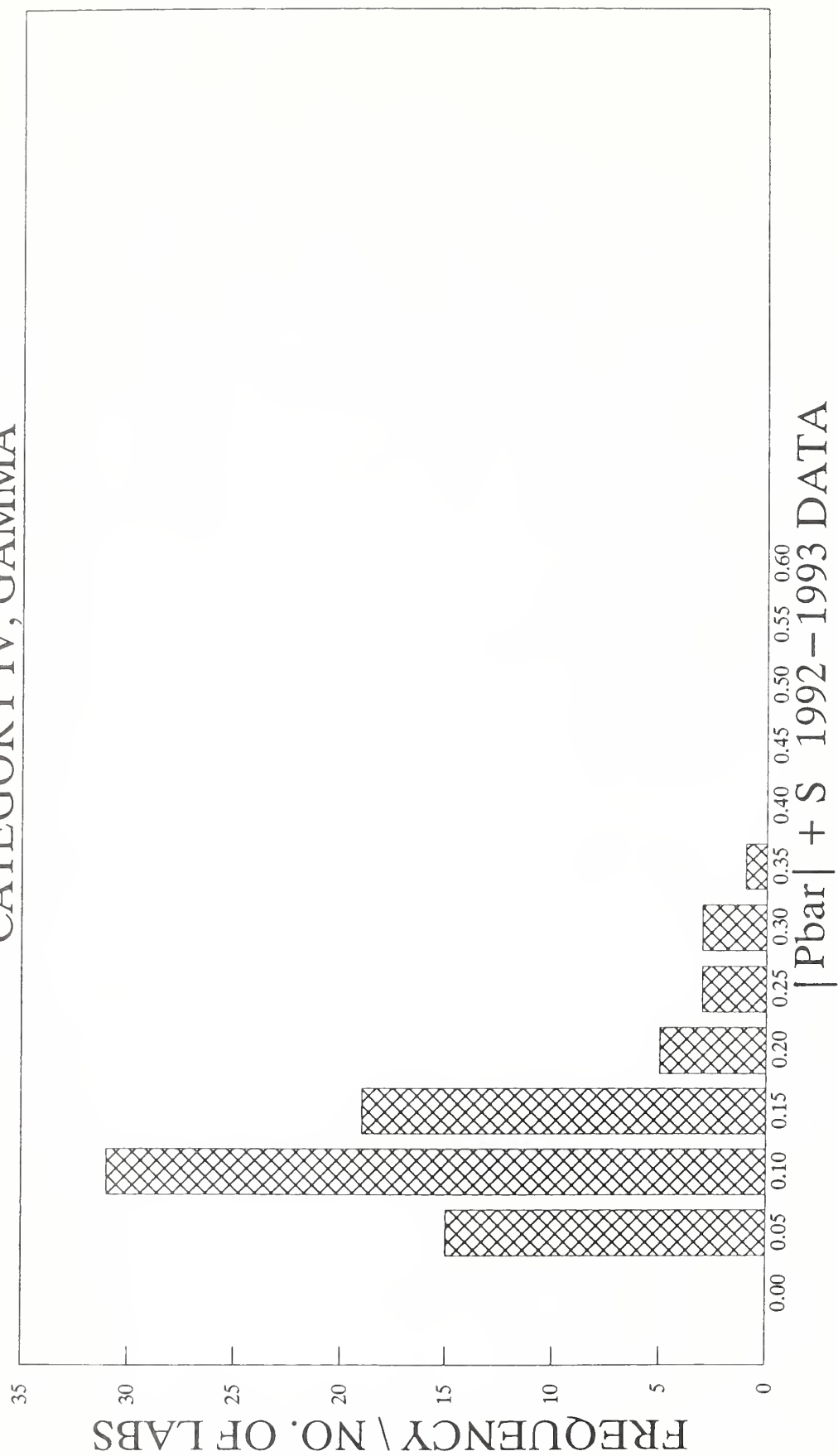


# CATEGORY III, X RAY, DEEP

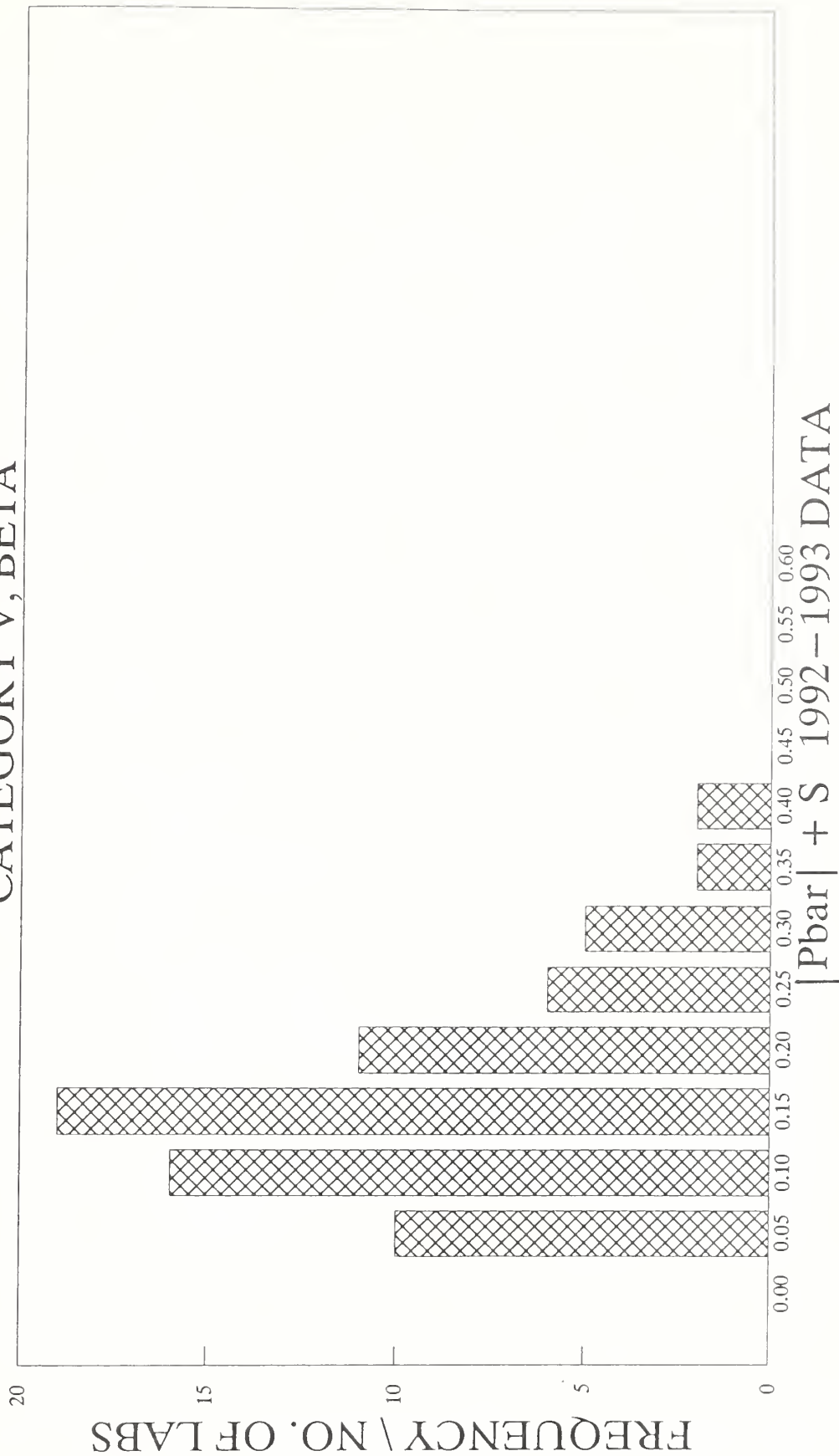




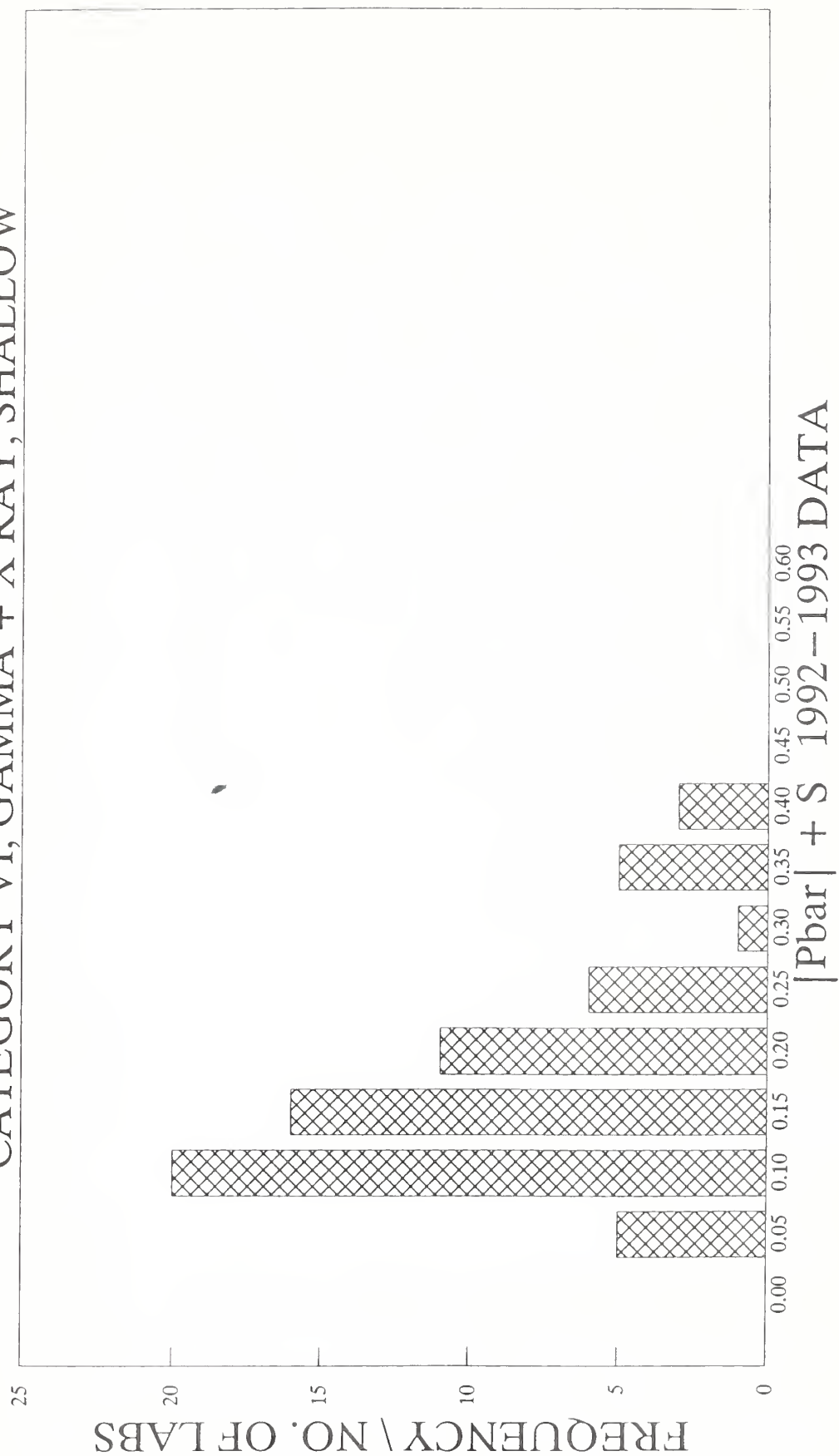
# CATEGORY IV, GAMMA



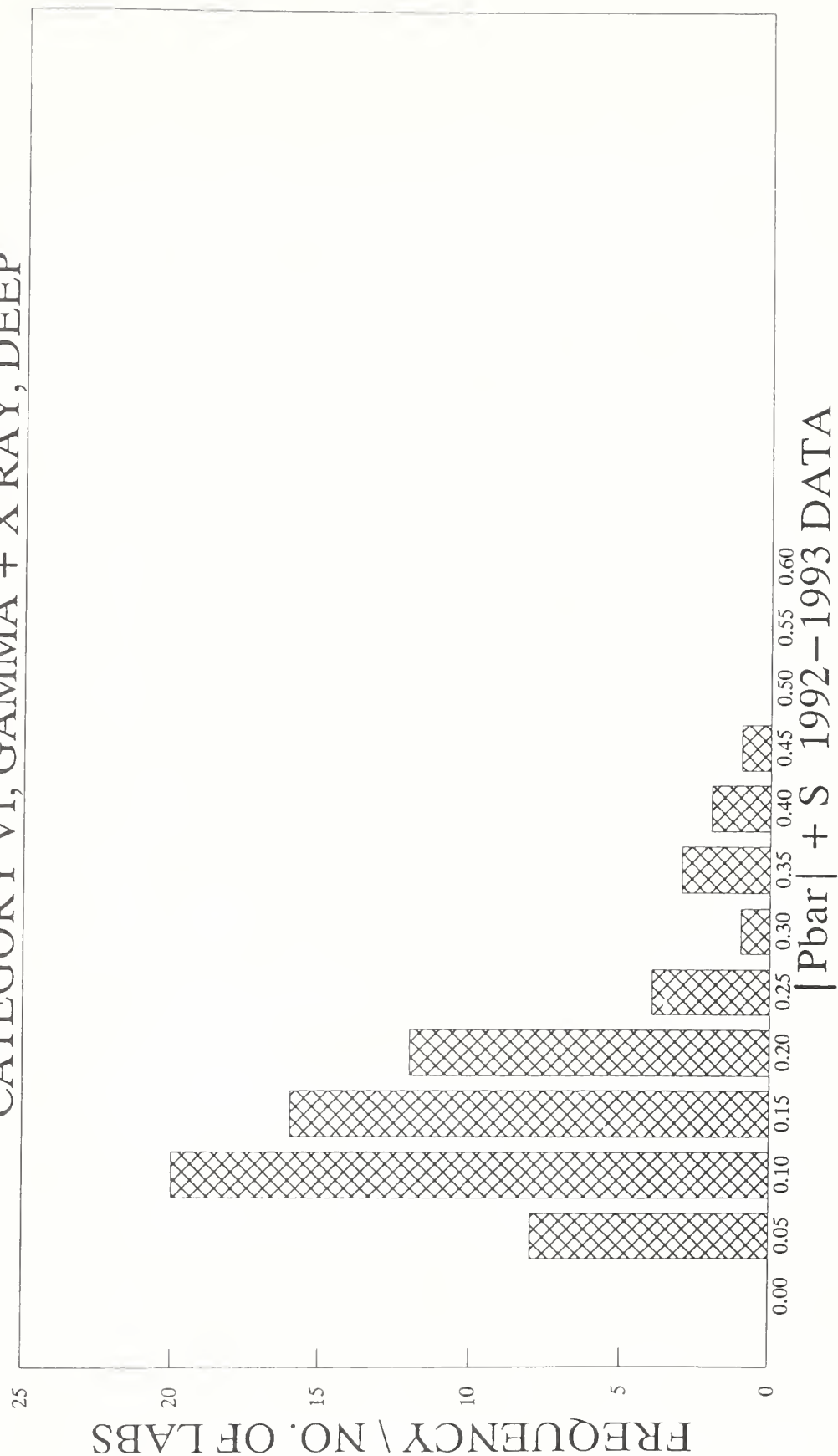
# CATEGORY V, BETA



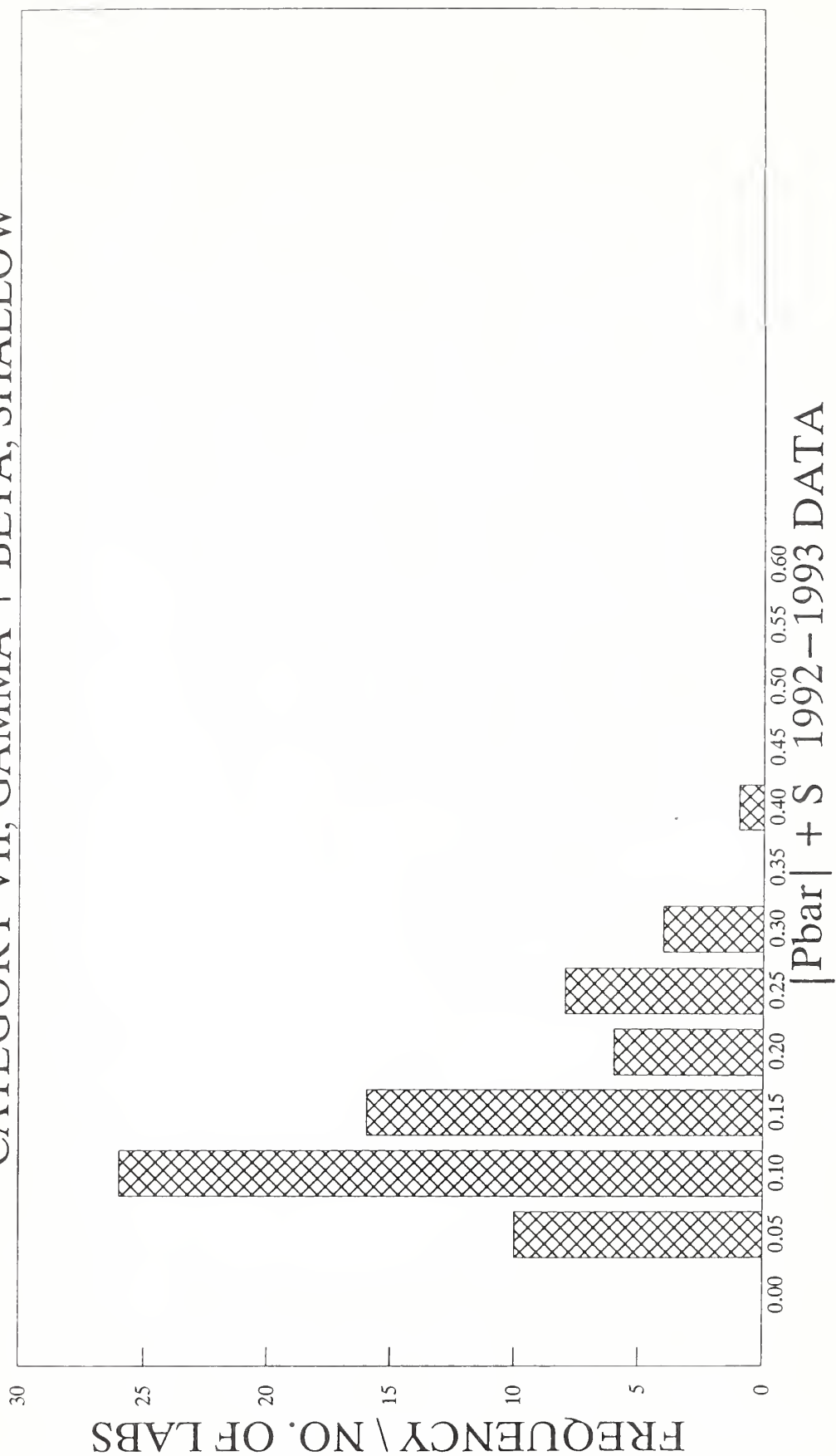
# CATEGORY VI, GAMMA + X RAY, SHALLOW



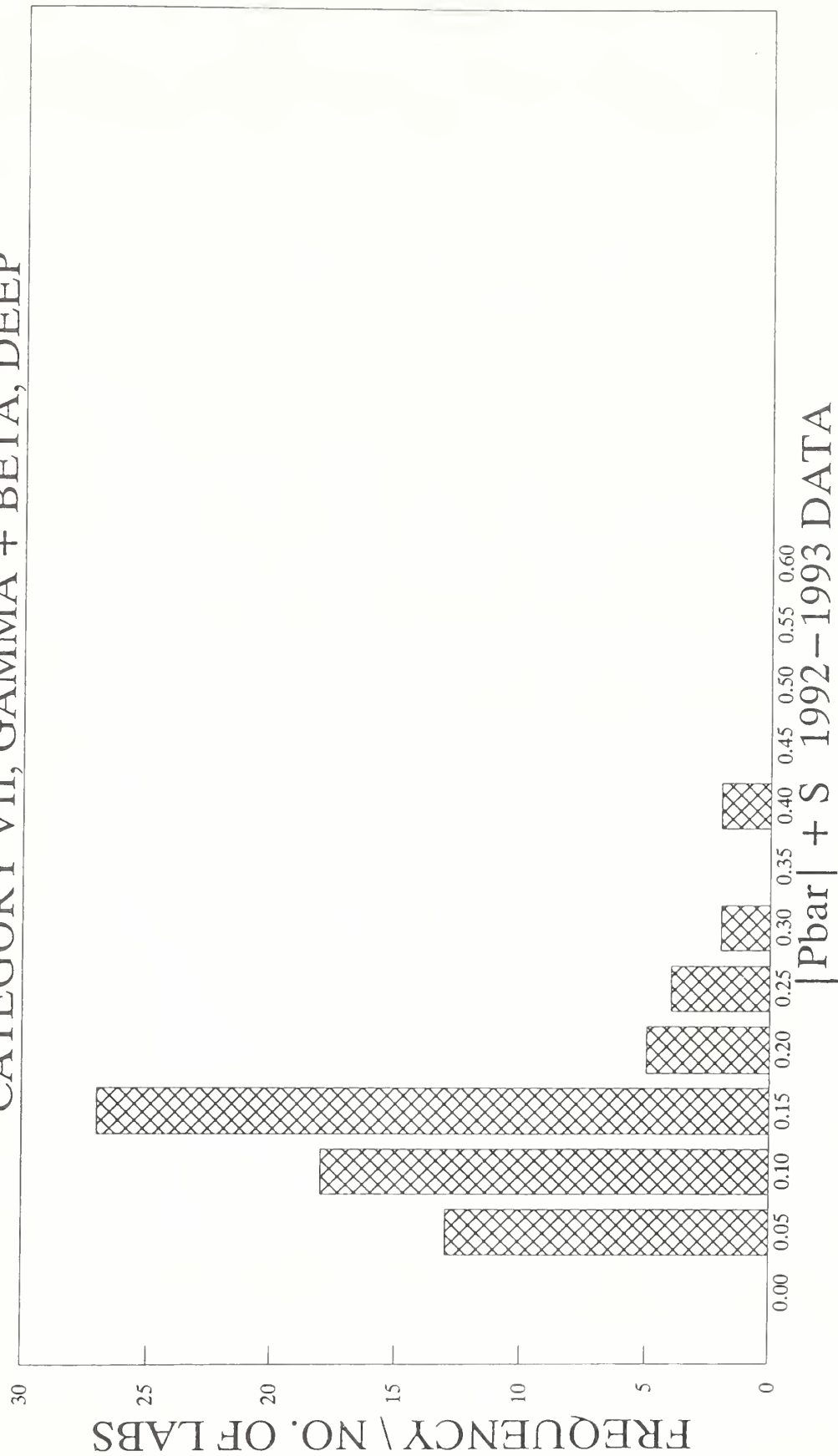
# CATEGORY VI, GAMMA + X RAY, DEEP



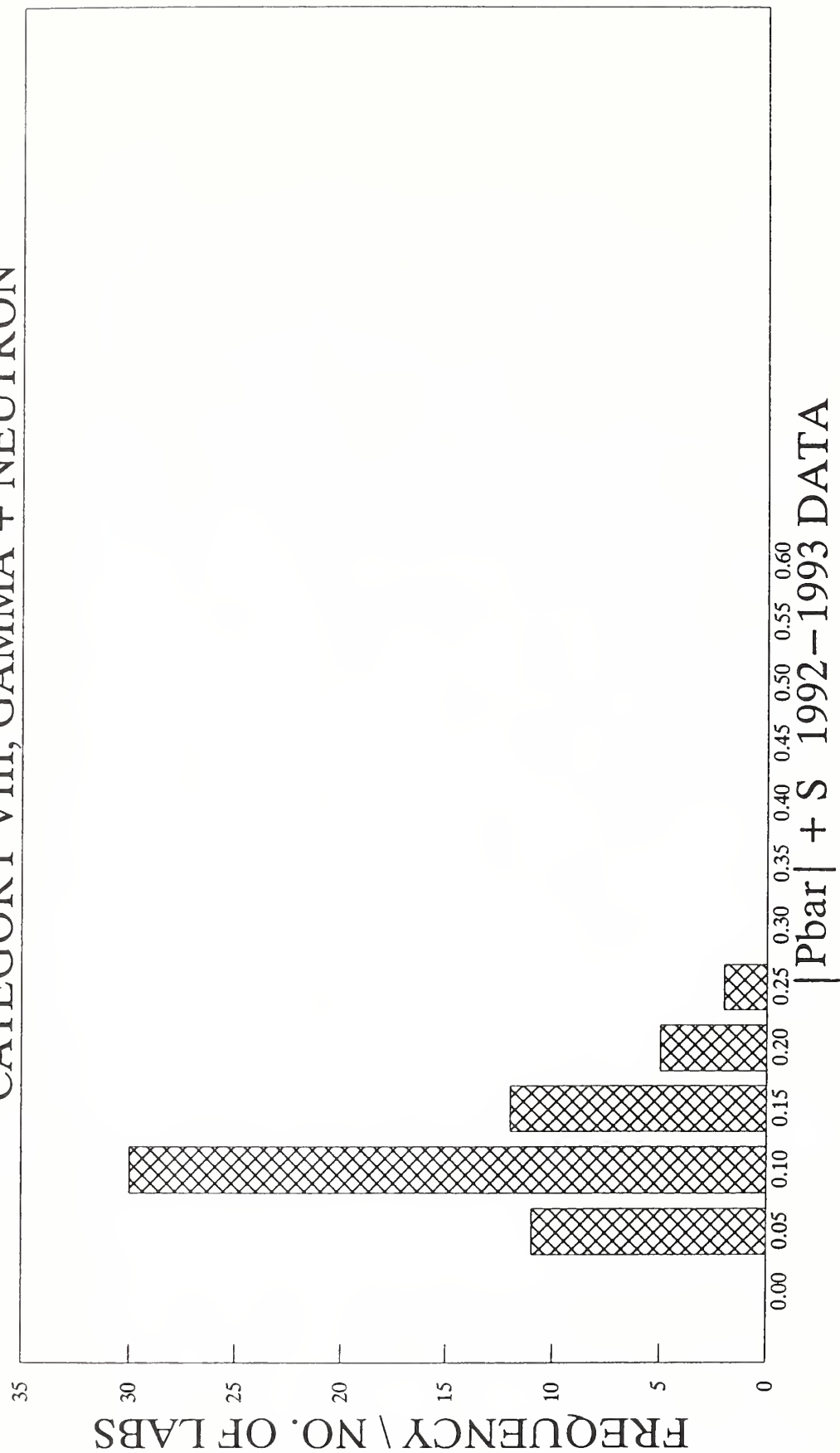
# CATEGORY VII, GAMMA + BETA + SHALLOW



# CATEGORY VII, GAMMA + BETA, DEEP



# CATEGORY VIII, GAMMA + NEUTRON





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