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DOE-STD-1095-YR

DOE STANDARD

DEPARTMENT OF ENERGY LABORATORY ACCREDITATION PROGRAM FOR PERSONNEL DOSIMETRY

U.S. Department of Energy **AREA SAFT**

Washington, DC. 20585

FOREWORD

The Department of Energy (DOE) implemented the DOE Laboratory Accreditation Program (DOELAP) for external dosimetry in 1986. The objective of the DOELAP external dosimetry program is to assure the competency of dosimetry measurements through calibration intercomparisons, performance testing, site assessments, and encourage applied research in areas where there is a technology shortfall. DOE also expects the program to enhance cooperation and technical information exchange among its sites and facilities to provide a more standardized and uniform radiation dosimetry capability. DOE sites and facilities are expected to use standards and other technical guidance from the Department to ensure that the performance of personnel dosimetry and radiobioassay measurements are adequate to meet the requirements of Title 10, Code of Federal Regulations, Part 835, *Occupational Radiation Protection* and related documents.

This standard establishes the technical basis for the Performance Testing Laboratory (PTL) that administers the external dosimeter program for DOE site dosimetry programs seeking DOELAP accreditation. The performance testing categories for whole body dosimetry are based on ANSI/HPS N13.11, *American National Standard for Dosimetry – Personnel Dosimetry Performance – Criteria for Testing*, and for extremity dosimetry from ANSI/HPS N13.32, *American National Standard for Performance Testing of Extremity Dosimeters*.

Throughout this standard, the word “shall” is used to denote an action that is to be performed if the objectives of this standard are to be met, and the word “should” is used to denote an action that is expected to be performed unless documentation is provided showing technical equivalence.

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1 PURPOSE AND SCOPE

This technical standard describes the U.S. Department of Energy Laboratory Accreditation Program (DOELAP) for external dosimetry, in support of worker health and safety. DOELAP accreditation involves performance testing of dosimeters in a laboratory setting and the documentation of program elements important to the long-term quality assurance of a dosimetry program and its ability to accurately measure, record, and report occupational whole body and extremity dose. DOELAP, however, does not evaluate the adequacy of a dosimetry program to accurately measure occupational dose in actual work environments encountered at DOE sites. The information in this technical standard is intended for use by accredited programs, programs seeking accreditation, the Performance Testing Laboratory, DOELAP Assessors, and subcontracted vendors for implementation of the DOELAP requirements, including the technical and quality assurance aspects of the accredited program.

2 APPLICABILITY

This technical standard applies to DOE Headquarters, field organizations, and contractors working to the individual monitoring requirements of 10 CFR Part 835. For the purposes of accreditation, external dosimetry includes both whole body and extremity dosimeters.

3 ACCREDITATION PROCESS

To be granted accreditation, the following is required:

- Timely submittal of an application in accordance with the timeline set by the External Dosimetry Senior Technical Manager (STM);
- Compliance with DOELAP requirements contained in this standard;
- Demonstration of proficiency in processing each dosimeter model and type applied for; and
- Successful passing of an on-site assessment conducted by DOELAP Assessors.

3.1 Application

Consideration for DOELAP accreditation requires the submission of an application, a program self-assessment, and the documented quality assurance program.

The program self-assessment is an internal review conducted by the applicant, which compares the program's compliance status to the requirements set forth in this standard. Lines of inquiry for the self-assessment can be obtained through the STM.

3.2 Performance Testing

Proficiency in processing shall be demonstrated for each model and type of dosimeter that the program intends to use to demonstrate compliance with 10 CFR Part 835.402. The radiation categories selected in the application for which accreditation is desired shall be representative of the radiation type and energy encountered at the location where the dosimeter will be used.

Performance testing compares the results from the applicant's measurement values to the dose delivered to the applicant's dosimeters using the criteria established in the ANSI/HPS N13.11 and ANSI/HPS N13.32 standards. The delivered doses are not revealed to the program until after their results are reported for all three rounds of irradiations. Comparing the reported experimental results from the applicant's measurement process with the delivered doses provides evidence of the program's proficiency in terms of both accuracy and precision. A variation beyond established acceptance criteria provides a means for denying accreditation or granting only accreditation for use of categories and dosimeters that successfully passed performance testing.

The applicant shall review the performance testing data for potential improvements in the dosimetry measurement system.

Performance testing shall be defined and consistent with routine processing procedures. The same dosimeter model, type, and sensitive element used to assess occupational exposures shall also be used during performance testing.

Performance Testing of additional dosimeter models and types not currently used in the program may be requested through the Performance Testing Laboratory.

3.2.1 Whole Body Dosimeter Performance Testing

Performance testing of whole body dosimeters is conducted in accordance with ANSI/HPS N13.11.

Retesting is required if the performance testing results for any selected category from the Test Category column do not meet criteria. The retest sequence is listed in Table 3-1. If a dose algorithm was modified in response to a category failure, then retesting in all applied-for categories is required.

Table 3-1. Retesting Requirements for Whole Body Dosimeter Performance Testing

Test Category	Required Retesting*
I. Accidents, photons	I. Accident, Photons II. Photons/photon mixtures
II. Photons/photon mixtures	II. Photons/photon mixtures III. Betas IV. Photon/beta mixtures
III. Betas	II. Photons/photon mixtures III. Betas IV. Photon/beta mixtures
IV. Photon/beta mixtures	II. Photons/photon mixtures III. Betas IV. Photon/beta mixtures
V. Neutron/photon mixtures	II. Photon/photon mixtures V. Neutron/photon mixtures

An applicant is allowed a maximum of 2 retests, irrespective of which whole body performance testing category failed. Failure of the second retest will result in failure of the application for whole body dosimetry accreditation.

3.2.2 Extremity Dosimeter Performance Testing

Performance testing of extremity dosimeters is conducted in accordance with ANSI/HPS N13.32.

Retesting is required if the performance testing results for any selected category in the Test Category column do not meet criteria. The request sequence is listed in Table 3-2. If a dose algorithm was modified in response to a category failure, then retesting in all applied-for categories is required.

Table 3-2. Retesting Requirements for Extremity Dosimeter Performance Testing

Test Category	Required Retesting*
I. High-dose, photons	I. High-dose, photons II. Photons (IIA, IIB, or IIC)
II. Photons	II. Photons III. Betas IV. Beta/photon mixtures
III. Betas	II. Photons

	III. Betas IV. Beta/photon mixture
IV. Beta/photon mixtures	II. Photons III. Betas IV. Beta/photon mixture

An applicant is allowed a maximum of 2 retests, irrespective of which extremity performance testing category failed. Failure of the second retest will result in failure of the application for extremity dosimetry accreditation.

3.3 On-site Assessment

An on-site assessment of an applicant's program is conducted initially and triennially thereafter to ensure a program meets the quality assurance requirements prescribed in this standard. For initial accreditation, an on-site assessment is conducted after performance testing is completed. A monitoring visit may also be conducted approximately one year after implementation of a new program or if major deficiencies were identified during an on-site assessment of an established program. .

4 QUALITY ASSURANCE

4.1 Quality Assurance Program

The program shall have a documented quality assurance program describing the internal management structure, system of procedures, and practices to ensure dosimetry results are accurate, repeatable, verifiable, and properly recorded.

The program's quality assurance manual or supporting documentation shall include

- statement of quality policy and quality objectives;
- documented processes, procedures, and instructions;
- documents needed to ensure effective planning, operation, and control of processes;
- records required to demonstrate compliance with the quality assurance program;
- dosimetry specifications and Technical Basis Documentation;
- acceptance criteria for dosimeter materials and holders;
- training objectives and processes for maintaining proficiency; and
- practices for handling and resolving contested dosimetry data and test reports.

4.2 Program Management

Managerial and technical personnel shall have the resources needed to carry out their duties, including the implementation of the Quality Assurance Program.

A technical lead (however named), who is experienced in applied radiation dosimetry and knowledgeable in the design and operation of the dosimetry system(s) currently used, shall be assigned. The technical lead is responsible for ensuring that dosimetry data are approved and making decisions regarding questionable data.

A quality assurance (QA) lead (however named), who has responsibility and authority for ensuring that the quality assurance program is implemented, shall be assigned. The QA lead shall have authority to communicate quality assurance issues directly with the technical lead and other organizational management. The program technical lead may function as the quality manager as long as the responsibilities are clearly defined.

Responsibilities for the implementation of the quality assurance program shall be defined, including the organizational structure and functional responsibilities of key personnel.

The individuals responsible for the implementation of the quality assurance program may delegate work to others but shall retain responsibility.

Management and personnel shall be free from undue internal and external influences that may adversely impact the quality of their work.

Senior management shall conduct a formal review of the External Dosimetry Quality Assurance Program at the midpoint of the DOELAP assessment cycle. The review shall include assessing opportunities for improvement and the need for changes to policies or processes. At minimum, the review shall take account of

- comparison of quality objectives and standards against achievements;
- assessment and test results;
- non-conformances and corresponding corrective actions, preventative measures, and deficiency trends;
- results from external and internal audits; and
- other relevant factors, such as quality control activities, resources, and training.

A program shall have a documented plan for continuity of operations. This includes service contracts, in-house maintenance, spare parts capabilities, and unexpected loss of key personnel.

When more than one organization is involved in the implementation of the requirements for DOELAP accreditation (e.g., major equipment maintenance, calibration, document control and

records); the responsibilities, interfaces, and authority of each organization shall be clearly defined and documented.

When a vendor or subcontractor is involved in the implementation of the requirements for DOELAP accreditation, the accredited program shall have a procedure describing how they will ensure that all of the DOELAP requirements are maintained.

External audits of a vendor or subcontractor's quality assurance plan shall be performed initially and at least once during the DOELAP accreditation period. Audits should be performed at least one year prior to the DOELAP on-site assessment to allow assessors to evaluate the program's progress in assigning issues to staff for tracking corrective actions through to completion. The audits shall be supplemented by an ongoing evaluation of the performance of the vendor or subcontractor through blind audits, which are outlined in section 4.7.2.

4.3 Personnel Training and Qualifications

All personnel performing accredited activities shall have the training, qualifications, and competence to perform their assigned tasks effectively.

A training program commensurate with the complexity and scope of the assigned responsibilities shall be documented. Training shall be provided to achieve initial proficiency, maintain proficiency, and adapt to changes in job responsibilities, new technologies, or policies and procedures. Training to maintain proficiency shall be conducted at least annually.

The technical lead shall initially and at least annually evaluate and document the proficiency of each staff member authorized to perform dosimetry related functions. This proficiency assessment shall include an observation of performance.

In the event that proficiency is not achieved or maintained, any person's work duties that affects the quality of accredited activities shall be under the direction or supervision of a properly trained and qualified individual. Personnel shall not be the primary signatory on dose processing records or QA/QC reports until proficiency is demonstrated.

4.4 Documents and Records

A system shall be in place which clearly describes which records are kept and practices followed through the entire dosimetry cycle.

All documents that form the quality assurance program shall be controlled to ensure that the correct documents are being employed. Documents shall be reviewed for accuracy and

approved by authorized personnel in accordance with documented review frequencies.

A comprehensive record of processing activities shall be maintained. Records shall contain sufficient identification to allow correlation with calibration and quality control records.

Procedures shall be established and maintained for the identification, collection, indexing, access, filing, storage, maintenance, and disposal of quality and technical records.

All quality assurance and technical records shall be legible, easily retrievable, and stored in a suitable environment to prevent damage, deterioration, or loss. Records shall be available for review during the on-site assessment.

Electronic records shall be protected and regularly backed-up on a pre-determined schedule to prevent unauthorized access, amendment, or loss.

4.5 Work Processes

All accredited activities that can influence the assignment of dose to an individual shall be conducted in accordance with established procedures, which shall include the following:

- work methods and sequence;
- equipment to be used;
- work environment;
- quality control;
- acceptance criteria;
- inspection points; and
- recordkeeping.

Work process procedures shall control the preservation of identification of dosimeters, measurements, dose records, and other data on which the dose is based, and maintain their traceability to the individual concerned.

Work process procedures shall prescribe specifications and precautions to control the processing, handling, issuing, storage, retrieval, and shipment of dosimeters.

4.6 Quality Improvement

Quality control procedures shall be implemented to ensure that the equipment performs at the levels of precision and accuracy defined in the processing protocols. Quality control data shall be recorded in such a way that trends are detectable.

When quality control data is found to be outside pre-defined acceptance criteria, corrective actions to correct the problem and to prevent incorrect results from being reported shall be document. Reevaluation of all dosimeters processed since last acceptance shall be performed.

Software verification and validation shall be performed in accordance with an appropriate software quality assurance plan. V and V shall include process control software, dose algorithms, data processing, and record keeping. In addition, software version control shall be included in the programs documented control procedures for all software.

When computer or laboratory information systems are used to input, store, calculate, or retrieve data in relation to key dosimeter processing steps, the program shall

- establish and maintain procedures describing the processes;
- validate the accuracy of data entry; and
- verify the accuracy of any calculations performed.

The variability of test results among staff, equipment, and locations shall be assessed to ensure consistency.

Internal audits shall be conducted at least annually. The audits shall cover compliance with all DOELAP requirements. New programs shall complete at least one internal audit of its management system prior to the first on-site assessment. All audits and actions taken for correcting identified problems and preventative actions implemented to prevent recurrence shall be documented.

4.7 Facilities and Equipment

Facilities and equipment shall be adequate to perform the type(s) of processing for which it is accredited. A list and description of facilities and equipment which have the potential to impact the quality of dose results shall be available for review.

Adequate facilities and equipment shall have the following:

- sufficient space to perform processing;
- proper shielding of areas from unwanted radiation;
- environmental monitoring and controls, including background radiation; and
- properly calibrated equipment.

Adequate backup equipment shall be possessed and maintained in the event the primary systems fail. If backup equipment or systems are not available, the program shall have documented provisions to utilize the services of another DOELAP accredited laboratory in an

emergency.

4.7.1 Dosimeters

A design specification shall be established for each dosimeter model and configuration. The specification shall include dosimeter holders, any filter material used, the areal density (mg/cm^2) of the material, and the positions of the dosimetric material within the dosimeter.

Dosimeter materials and holders shall be acceptance tested before being placed into service.

The impacts of the following system characteristics shall be determined. Documentation shall clearly indicate algorithm name and version used to generate the results.

- lower limit of detection;
- useful dose range;
- background contribution to dose equivalent;
- processing system measurement uncertainty;
- repeatability/precision;
- residual Signal;
- angular dependence;
- self irradiation; and
- batch homogeneity.

Fading of dosimeter materials under normal conditions shall be determined for two times the period of intended use. For example, fading of quarterly dosimeters shall be documented and accounted for over the period of 6 months.

Dosimeters placed into service shall be checked according to a defined schedule or frequency to ensure all necessary components are in place. A screening procedure shall be used to ensure dosimetry materials, including sensitive elements, are consistent with the dosimeter design. Procedures shall include the phosphor type and sensitivity.

Loading of dosimeters shall be carried out in a well-defined order to ensure the dosimeter is in compliance with the design specification and prevent confusion in handling visually similar elements. Precautions shall be taken to avoid optical fading and non-radioactive contamination of the phosphor or the detector.

If a dosimeter is used in radiation fields it is not designed for (e.g., a photon dosimeter being used in a mixed photon/neutron field) the effect of the radiation not intended to be measured shall be determined.

4.7.2 Processing

A positive system for identifying and tracking all dosimeters through the processing cycle shall be established.

Dosimeter reader operation and stability shall be verified before use with quality control dosimeters and measurement of system internal parameters (e.g., PMT sensitivity, dark counts, light source counts). Records shall indicate that dose measurements are made only with stable equipment.

Annealing of dosimeters shall be conducted in a reproducible manner regarding time, temperature, cooling rate, humidity, and light. For TLDs, it is preferred that thermal erasing procedures be carried out in ovens reserved strictly for dosimeter annealing; however, in-reader annealing can be done when very low irradiation doses have been measured and when the in-reader annealing has been demonstrated to be reproducible. The in-reader annealing technical basis shall be documented to demonstrate the upper dose range limit for which in-reader annealing may be performed.

Mechanisms and procedures shall be in place to routinely identify reader processing problems, such as the use of Quality Control and unirradiated dosimeters. Each processing protocol shall provide for interspersing quality control dosimeters. These dosimeters shall have a predetermined relationship to the primary calibration dosimeters as follows:

- NIST traceable or equivalent sources shall be used to irradiate quality control dosimeters.
- Records shall indicate good reproducibility for the irradiation method.
- Unirradiated and quality control dosimeter shall be determined, based upon the total number of dosimeters processed, equipment stability, type of quality control checks, or other suitable method.

Blind audits shall be conducted to validate the overall performance of the dosimetry system. The audit program shall consist of the use of dosimeters irradiated by a NIST Traceable isotopic source or x-ray beam to a dose that is unknown to the processor. Procedures describing steps to be taken in the event that blind audits are outside of pre-established criteria shall be documented. Blind audit dosimeters should be incorporated into every dosimeter change out.

The dosimetry algorithm shall be documented in sufficient detail to indicate its validity for dose interpretation. Documentation shall indicate algorithm name and version, and include

- Fundamental data for creating and testing;

- Uncertainty analysis of the algorithm;
- Process controls used for algorithm development; and
- Attributes and limitations of the algorithm.

Deviations from processing procedures, equipment or facilities shall be verified to ensure no degradation of performance has occurred.

4.7.3 Interim Processing

Although interim processing of Optically Stimulated Luminescence (OSL) dosimeters is not for the dose of record, decisions are made based on interim results which may impact the overall dose to the worker. For interim processing, the following is required:

- Technical basis document determining signal depletion as a function of the number of times the dosimeter is processed.
- Calibration of processing equipment shall not be less restrictive than the manufacturer's prescribed requirements.
- All personnel performing interim processing activities shall meet the requirements of section 4.3. Personnel Training and Qualifications.

4.8 Maintenance and Calibration

A preventative maintenance program for equipment used to process dosimeters or perform quality control checks shall be implemented.

Equipment used for dosimeter processing or quality control shall be periodically calibrated or whenever the accuracy of the equipment is suspect. Calibration procedures shall identify required accuracy and define the methods and frequency for checking accuracy. Calibration procedures shall not be less restrictive than the manufacturer's prescribed requirements. A technical basis shall be developed when calibration techniques differ from manufacturer recommendations or when calibration frequency is not prescribed by the manufacturer.

Processing-equipment calibration or verification records shall include

- Equipment name or description;
- Model, style, and serial number;
- Manufacturer;
- Notation of all equipment variables requiring calibration or verification;
- The range of the calibration or verification;
- The resolution of the instrument and its allowable error;

- Calibration or verification date and schedule;
- Date and result of last calibration;
- Identity of the laboratory individual and external service responsible for calibration;
- Source of reference standard and traceability; and
- Environmental conditions.

Equipment shall be properly identified to correlate with calibration records and maintenance logs.

The energy response of each type or model of dosimeter shall be characterized for all radiation categories and exposure ranges for which it is to be used.

All calibrations and characterizations shall be performed using reference standards traceable to the National Institute of Standards and Technology (NIST) national standards or standards maintained by an equivalent national standards authority.

All processing equipment calibration, verification, and maintenance practices shall be documented.

When results are found to be inaccurate, reviews of the equipment used to generate the results shall be conducted to determine the validity of the data and the corrective actions to be taken.

4.9 Reporting

The dose report (initial report from the dosimetry processor or other records) shall include

- Processor name and address if different from contractor;
- Name of contractor;
- Pertinent dates for the wear period and the identification of dosimeters;
- Processor and contractor identification codes, as appropriate;
- An explanation of any deviation from routine processing procedures if the deviation could affect the reported dose;
- The signature of or reference to the technical lead (however named); and
- Software version(s) of the dose algorithm(s) used.

APPENDIX A - REFERENCES

The current versions of the following documents allow for complete implementation of this technical standard:

American National Standards Institute (ANSI). 2009. *Personnel Dosimetry Performance – Criteria for Testing*. ANSI/HPS N13.11-2009. New York, NY.

American National Standards Institute (ANSI). 2008. *Performance Testing of Extremity Dosimeters*. ANSI/HPS N13.32-2008. New York, NY.

U.S. Department of Energy. 2008a. *Radiation Protection Programs Guide for use with Title 10, Code of Federal Regulations, Part 835, Occupational Radiation Protection,* DOE G 441.1-1C, Admin Chg 1. Washington, D. C.

U.S. Department of Energy. 2011. *Department of Energy Laboratory Accreditation Program for Personnel Dosimetry.* DOE-STD-1095-2011. Washington, DC.

U.S. Department of Energy. 2011. Title 10, Code of Federal Regulations, Part 830, *Nuclear Safety Management.* Washington, DC.

U.S. Department of Energy. 2011. Title 10, Code of Federal Regulations, Part 835, *Occupational Radiation Protection*. Washington, DC.

APPENDIX B – GUIDANCE FOR PROGRAMS THAT USE SERVICE PROVIDERS

DOELAP accredited programs may purchase dosimetry services from services providers; however, the DOELAP accredited program has the responsibility for ensuring the requirements of this technical standard are met. The purpose of this appendix is to outline the major considerations of a program that is purchasing dosimetry services from a commercial dosimeter vendor or a DOE dosimeter processor.

A copy of the work agreement with the service provider, including any agreed upon commitments shall be available for review. The work agreement should clearly establish

- Access to relevant documents, including dosimetry technical basis documents, policies and procedures, and the documented quality assurance program;
- Personnel whole body and extremity dosimeters provided for beta and gamma radiation;
- Personnel whole body dosimeters for neutron radiation provided, including calibration that closely represents the workplace neutron spectrum;
- External dosimetry data validation and verification;
- External dosimetry reports (see section 4.9);
- Emergency external dosimetry services; and
- Appropriate packaging and handling of dosimeters.

Staff shall have sufficient qualifications and experience to be able

- Sufficiently assess the capabilities and limitations of the service provider;
- Validate dosimeter results used to determine dose-of-record;
- Provide oversight of the service provider including the review of quality control data and conduct on-sight assessments;
- Identify error trends and anomalous data; and
- Conduct quality assurance assessments.

A technical basis for the selected performance testing categories or subcategories shall be available.

The program shall have a procedure for conducting quality assurance assessments of the service provider; including on-site audits, QC reviews, and blind audit dosimeters. The procedures shall also describe how findings are identified and corrected.

The program shall have a procedure for handling and shipping dosimeters. The procedure shall include details on maintaining dosimeter chain-of-custody and assessment of any transit dose.