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DOE STANDARD

DEPARTMENT OF ENERGY LABORATORY ACCREDITATION FOR EXTERNAL DOSIMETRY

U.S. Department of Energy
Washington, D.C. 20585

AREA SAFT

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FOREWORD

The Department of Energy (DOE) implemented the DOE Laboratory Accreditation Program (DOELAP) for external dosimetry in 1987. The radiobioassay portion of DOELAP is described in standard DOE-STD-1112-98, *Department of Energy Laboratory Accreditation Program for Radiobioassay*. DOELAP evaluates the quality of DOE external dosimetry programs through performance testing, evaluations of program-specific calibrations traceable to national standards organizations, and onsite assessments.

This standard supersedes technical standards DOE/EH-0026 and DOE/EH-0027, *Department of Energy Standard for the Performance Testing of Personnel Dosimetry Systems*. Guidance information contained in those documents will be updated and made available as a guidance supplement. This DOELAP technical standard defines performance testing and onsite assessment criteria to be met by DOE site dosimetry programs seeking DOELAP accreditation in whole body and extremity dosimetry. Further, DOELAP, in recognition of the use of commercial vendors for dosimetry services, is developing a qualification process similar to accreditation for these vendors. Additional information regarding Qualified Vendor status will be available in the revision of technical standard DOE-STD-1111-98, *Department of Energy Laboratory Accreditation Program Administration*.

DOE has a long history of active participation to improve external dosimetry and in the development of national consensus standards for evaluating the performance of external dosimetry systems. Technical studies and staff, supported by DOE programs, were instrumental in defining and testing dosimeter performance criteria at least as early as 1962 when the existing Pacific Northwest National Laboratory was contracted to conduct a national intercomparison test. DOE programs continue to support technical evaluations of national external dosimetry standards. Ongoing revisions to American National Standards Institute (ANSI) external dosimetry standards are anticipated in response to technological improvements and efforts to improve consistency between U.S. and international dosimetry performance testing criteria.

This standard establishes the technical basis for the Performance Testing Laboratory (PTL) that administers the external dosimeter testing program for DOE site dosimetry programs seeking DOELAP accreditation. The performance testing categories for whole body dosimetry are based on ANSI/HPS N13.11-2009, *American National Standard for Dosimetry – Personnel Dosimetry Performance – Criteria for Testing*, and for extremity dosimetry from ANSI/HPS N13.32-2008, *An American National Standard, Performance Testing of Extremity Dosimeters*.

In this standard, the terms used for quantities and units are compliant with those of the International Commission on Radiation Units and Measurements in Report 51, *Quantities and Units in Radiation Protection Dosimetry*. In 2007, DOE adopted the dosimetric quantities and units specified in International Commission on Radiological Protection (ICRP) Publication 60, *1990 Recommendations of the International Commission on Radiological Protection*. The ICRP Publication 60 dosimetric quantities adopted in 10 C.F.R. 835, *Occupational Radiation Protection*, have been designated by ICRP as “protection quantities” that are intended for defining and calculating the numerical limits and action levels used in radiation protection standards such as 10 C.F.R. 835. Protection quantities are not measureable but rather are used to provide a way to relate the magnitude of a radiation exposure to the risk of a health effect that is applicable to an individual and that is largely independent of the type and source

(internal or external) of the radiation. Protection quantities used in 10 C.F.R. 835 include: equivalent dose, effective dose, committed equivalent dose, committed effective dose, total effective dose, and cumulative total effective dose.

In lieu of the protection quantities, this standard uses the measurable quantities called "operational quantities." For almost all situations considered, doses determined with the operational quantities were equal to or greater than the doses determined using protection quantities. Refer to chapter 6 of *Implementation Guide for Use with 10 CFR 835* (DOE G 441.1-1C) for a detailed discussion of the use of operational versus protection quantities.

DOE will use this technical standard and other guidance to ensure that personnel whole body and extremity dosimetry measurements comply with the occupational dosimetry requirements in 10 C.F.R. 835. Throughout this standard, the word "shall" is used to denote an action that is 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.

This DOE technical standard is approved for use by all DOE components and their contractors. Beneficial comments (recommendations, additions, and deletions) and any pertinent data that may be of use in improving this document should be addressed to the Office of Health, Safety and Security (HS-30), U.S. Department of Energy, Washington, DC, 20585, by letter or by following the instructions in the Technical Standards Program Procedures on the DOE Technical Standards Program web site (www.hss.energy.gov/nuclearsafety/ns/techstds/).

Compliance with a DOE Technical Standard is not mandatory unless it is adopted as a requirement in a contract or subcontract with DOE or in an applicable regulation.
Title 10 C.F.R. § 835.402(b) requires that "External dose monitoring programs implemented to demonstrate compliance with § 835.402(a) . . . shall be: (1) Accredited, or excepted from accreditation, in accordance with the DOE Laboratory Accreditation Program for Personnel Dosimetry; or (2) Determined by the Secretarial Officer responsible for environment, safety and health matters to have performance substantially equivalent to that of programs accredited under the DOE Laboratory Accreditation Program for Personnel Dosimetry." Consequently, because this technical standard prescribes the means by which persons or entities subject to 10 C.F.R. Part 835 satisfy the requirement to be accredited or excepted from accreditation "in accordance with the DOE Laboratory Accreditation Program for Personnel Dosimetry," persons or entities required to comply with 10 C.F.R. § 835.402 must (1) comply with this technical standard in order to be accredited or excepted from accreditation under DOE's Laboratory Accreditation Program for Personnel Dosimetry; or (2) be determined "by the Secretarial Officer responsible for environment, safety and health matters to have performance substantially equivalent to that of programs accredited under the DOE Laboratory Accreditation Program for Personnel Dosimetry."

This technical standard's effective date is April 1, 2011.

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ACRONYMS/ABBREVIATIONS

ANSI	American National Standards Institute
CFR	Code of Federal Regulations
DOE	U.S. Department of Energy
DOELAP	Department of Energy Laboratory Accreditation Program
HPS	Health Physics Society
PEPA	Performance Evaluation Program Administrator
PTL	Performance Testing Laboratory

1. SCOPE

1.1. This technical standard describes the U.S. Department of Energy Laboratory Accreditation Program for external dosimetry, in support of worker health, safety, and security. DOELAP accreditation involves performance testing and 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. Accreditation involves:

1.1.1. Performance testing a dosimetry system using radiation sources, dose levels, and categories of irradiation specified in these national standards:

a. ANSI/HPS N13.11-2009, *American National Standard, Personnel Dosimetry Performance - Criteria for Testing*, and

b. ANSI/HPS N13.32-2008, *American National Standard, Performance Testing of Extremity Dosimeters*.

1.1.2. Onsite assessment of dosimetry quality assurance, staffing, facilities, equipment, documentation, records, etc., by DOELAP assessors using information contained in this and other DOELAP technical standards and guidance.

References herein to ANSI standards pertain to the above versions. However, as these consensus standards are subject to change, the references may be revised as appropriate. Notice will be given in the *Federal Register* when a new ANSI standard is to be implemented, along with an appropriate timeframe for implementation.

1.2. Dosimeter types or models used to routinely measure whole body and extremity dose are included in the scope of DOELAP for external dosimetry. Accreditation under this standard applies to dosimeters that are used to determine a dose of record to demonstrate compliance with 10 C.F.R. 835; it does not apply to nonroutine dosimetry. This standard is limited as follows:

1.2.1. Approximate energy intervals are: 15 keV to 2 MeV for photons; above 0.3 MeV to 1 MeV (average) for beta particles; and epithermal to 3 MeV for neutrons (extremity dosimetry excluded).

1.2.2. Approximate dose intervals are: 0.05 rem to 500 rad for photons; 0.25 rem to 25 rem for beta particles; and 0.15 rem to 5 rem for neutrons.

1.3. Radiation fields used to calibrate an external dosimetry system and the radiation fields to which personnel are exposed may differ from the reference calibration sources specified in this performance testing standard. Where such differences exist, the method for determining a dosimeter's response per unit of delivered dose (or dose equivalent) for the occupational radiation fields shall be documented by the applicant.

1.4. This standard is specific to the technical characteristics of and quality assurance program supporting an external dosimetry program at a DOE site. No consideration is given to any administrative aspect such as report format, field use, or compliance with requirements outside of 10 C.F.R. Part 830, *Nuclear Safety Management*, and 10 C.F.R. Part 835. In addition, no consideration is given to the placement of dosimeters or the assessment of dose from multiple dosimeters.

2. REFERENCES

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

U.S. Code of Federal Regulations, Title 10, Part 830, *Nuclear Safety Management.*

U.S. Code of Federal Regulations, Title 10, Part 835, *Occupational Radiation Protection*.

U.S. Department of Energy, *Laboratory Accreditation Program Administration*, DOE-STD-1111-98, Washington, DC.

U.S. Department of Energy, *Implementation Guide for Use with 10 C.F.R. 835*, DOE G 441.1-1C, Washington, DC.

ANSI/HPS N13.11-2009, *American National Standard, Personnel Dosimetry Performance - Criteria for Testing*, Health Physics Society, McLean, VA.

ANSI/HPS N13.32-2008, *American National Standard, Performance Testing of Extremity Dosimeters*, Health Physics Society, McLean, VA.

International Commission on Radiological Protection Publication 60*, 1990 Recommendations of the International Commission on Radiological Protection*, 1991, Pergamon Press, New York, NY.

International Commission on Radiation Units and Measurements Report 51, *Quantities and Units in Radiation Protection Dosimetry*, 1993, Bethesda, MD.

3. DEFINITIONS

Accident Dosimetry. As used in this standard, accident dosimetry refers to whole body dosimeter performance testing category (I). Analogous testing of extremity dosimetry under ANSI N13.32-2008 uses the term “high-dose dosimetry” in its category (I).

Accreditation. The certification through DOELAP that an external dosimetry program meets the criteria in this standard for specified measurements. The process of accreditation includes testing dosimetry system performance and an onsite assessment of associated quality assurance, records, calibration programs, and any corrective actions. The objective of DOELAP is to accredit external dosimetry and radiobioassay programs at DOE sites.

Angular Dependence. The response of a dosimeter as a function of the nonperpendicular angle of incidence of the radiation field to the dosimeter compared to its response to the same radiation field from perpendicular frontal irradiation.

Applicant. A DOE site dosimetry program that has submitted an application for DOELAP accreditation and is participating in the accreditation process. While a DOE contractor is usually the “applicant,” the cognizant DOE Site Office is a partner in the application and accreditation processes. An applicant may also be a commercial vendor who has applied to DOELAP to be designated a Qualified Vendor.

Assessment. An onsite review undertaken by DOELAP to assess the competence of an external dosimetry program, based on this standard, for a defined scope of accreditation.

NOTE: Assessing the competence of a program involves assessing the entire dosimetry operations of a contractor or vendor, including the competence of the personnel, the validity of the dose assessment methodology, and the validity of the dosimetry results.

Assessor. An individual with appropriate experience in external dosimetry who has been trained and qualified by DOELAP to perform an onsite assessment of a dosimetry program or a qualified vendor.

Designated Representative. A person identified by the applicant who provides a single point of contact for coordinating participation in performance testing and the onsite assessment.

Dosimeter. A combination of absorber(s) and radiation-sensitive element(s) packaged in a holder (the holder being considered as part of the dosimeter). The dosimeter is used to provide a cumulative record of radiation dose or dose equivalent received by the individual wearing the dosimeter.

Dosimetry Program. The personnel, management, quality assurance, operation, and dosimetry system(s) used for assessing occupational external exposure to ionizing radiation.

Dosimetry System. The dosimeter(s), associated apparatus, and analytical method(s) used for measuring external exposure to ionizing radiation.

Performance Testing Laboratory. A laboratory independent of the applicant's operation and authorized by DOE to conduct performance testing specified by this standard.

Processing. The physical, chemical, and analytical means used to determine a dosimeter's response to radiation and the interpretation or evaluation of the response.

4. GENERAL REQUIREMENTS

4.1 Specific information supporting accreditation to be submitted to the PTL is described in the application. For example, the applicant shall provide the following information:

4.1.1. Confirmation that the dosimeters submitted for each test are a subset of the population of dosimeters either in use or those to be provided to the users.

4.1.2. The performance category or categories to be tested in.

4.1.3. A brief description of dosimeter design, construction, and processing, including a reference to the software version of the dose algorithm(s).

4.1.4. A description of the method(s) used to validate that dosimeter construction conforms to its design.

4.1.5. A brief description of how the dosimeter is to be oriented on the test phantom.

4.2. A DOE site dosimetry program shall maintain accreditation by demonstrating satisfactory performance through biennially performance testing and onsite assessment.

4.2.1. A site dosimetry program that successfully passes its performance testing cycle and receives no deficiencies or concerns during that cycle's onsite assessment may be exempted from the next onsite assessment. This exemption is explained in the *Laboratory Accreditation Program Administration* technical standard.

4.3. A dosimeter shall be tested if it is used to demonstrate compliance with 10 C.F.R. 835.

4.3.1. The applicant, in conjunction with the cognizant DOE Site Office, as appropriate, shall determine the dosimeter(s) to undergo performance testing, and shall select the testing category or categories for each dosimeter.

4.3.2. Careful consideration should be given as to whether a dosimeter requires testing. The following should be taken into consideration:

a. Multiple configurations of the same dosimeter may or may not require testing. The DOELAP Performance Evaluation Program Administrator should be consulted for assistance in this determination.

b. Methods used to derive doses from radiation fields with spectra and dose levels beyond those in use by DOELAP are not within the scope of this standard. A dosimetry system using multiple algorithms (exclusive of field-specific algorithms or corrections) shall be tested for each algorithm.

4.4. The PEPA coordinates all aspects of performance testing with the designated representative. Testing is typically conducted in sessions that include dosimeters submitted by several applicants.

4.5. The PTL will specify the number of dosimeters to be provided for each category or subcategory selected by the applicant as well as the number of replacement dosimeters should a problem occur. Replacement dosimeters as well as control dosimeters to evaluate transit doses should be included for each round. The minimum number of dosimeter results needed for statistical analysis for a 15 dosimeter test is 13, and for a 21 dosimeter test is 18. If the minimum number is not met due to

dosimeters voided by the participant, then analysis will be delayed until replacement dosimeter results have been provided to the PTL.

4.6. A test session generally consists of three separate iterations (rounds) performed over a period of several months. The PTL will return test dosimeters to the applicant at the end of the test round. The applicant shall report the results of evaluations to the PTL by the requested date. Failure by an applicant to submit all dosimeter evaluations by that date may result in failure of the affected test category; failure under this circumstance will not be remedied through a subsequent retest.

4.7. The PTL will report all test results to the applicant after the dosimeter evaluations have been compiled. An estimate of the uncertainty of the assigned values of dose or dose equivalent will be included. The PTL will not accept any request to change or void any reported result after the test results have been compiled.

4.8. If a dosimetry system is to be changed such that a determination of technical equivalence is necessary, then lower limit of detection and angular dependence determinations shall be performed, as described in ANSI/HPS N13.11-2009 or N13.32-2008, following receipt of a technical equivalence determination by the DOELAP Administrator. A request for technical equivalence shall include, for consideration, an explanation for not performing these studies if the requestor believes they are not necessary.

5. WHOLE BODY DOSIMETER PERFORMANCE TESTING

5.1. ANSI/HPS N13.11-2009 is incorporated into this standard. DOELAP may modify any specification as necessary.

5.2. Retesting shall occur if the performance testing results for any selected category do not meet specifications. The retest sequence is as follows:

5.2.1. Accident Category (I) - If a test result is unsatisfactory, retesting in categories (I) and (II) is required.

5.2.2. Protection Categories (II, III, and IV) - If a test result is unsatisfactory for a non-neutron category, retesting in all non-neutron categories selected on the application is required.

5.2.3. If the test result is unsatisfactory for neutron category (V), retesting in categories (V) and (II) is required.

5.2.4. If a dose algorithm was modified in response to a category failure, then retesting in all applied-for categories is required.

5.3. An applicant is allowed a maximum of 2 retests, irrespective of which whole body performance testing category may have been failed. Failure of the second retest will result in failure of the application for whole body dosimetry accreditation. The DOELAP Administrator will provide formal notification to a renewal applicant that the whole body dosimetry accreditation has expired.

6. EXTREMITY DOSIMETER PERFORMANCE TESTING

6.1. ANSI/HPS N13.32-2008 is incorporated into this standard. DOELAP may modify any specification as necessary.

6.2. Retesting shall occur if the performance testing results for any selected category do not meet specifications. The retest sequence is as follows:

6.2.1. High-Dose Category (I) - If a test result is unsatisfactory, retesting in category (I) and in the corresponding protection level category (IIA, IIB, or IIC) is required.

6.2.2. Protection Categories (II, III, and IV) - If a test result is unsatisfactory for any selected protection level category, retesting in all protection level categories selected on the application is required.

6.2.3. If a dose algorithm was modified in response to a category failure, then retesting in all applied-for categories is required.

6.3. An applicant is allowed a maximum of 2 retests, irrespective of which extremity performance testing category may have been failed. Failure of the second retest will result in failure of the application for extremity dosimetry accreditation. The DOELAP Administrator will provide formal notification to a renewal applicant that the extremity dosimetry accreditation has expired.

7. ONSITE ASSESSMENT

To become accredited or a qualified vendor, an applicant shall demonstrate the ability to conduct a credible external dosimetry program in compliance with DOELAP criteria. The onsite assessment will assess the quality assurance, documentation, and technical aspects of the dosimetry program. For initial accreditation, an onsite assessment will occur after performance testing has been satisfactorily completed. An applicant seeking initial accreditation or qualification shall correct any deficiency identified by the onsite assessment, and provide sufficient evidence of having done so, prior to receiving any further consideration. Any identified concern shall be addressed by a corrective action plan and that plan shall be submitted to DOELAP for acceptance. General onsite assessment information may also be found in the *Laboratory Accreditation Program Administration* technical standard and supplemental guidance. An applicant for Qualified Vendor status shall demonstrate that its quality assurance program is reasonably equivalent to the applicable requirements in 10 C.F.R. 830.

CONCLUDING MATERIAL

Review Activity:
National Nuclear Security Administration
Office of Environmental Management
Office of Health, Safety and Security
Office of Nuclear Energy
Office of Science

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Preparing Activity:
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SAFT-0127