

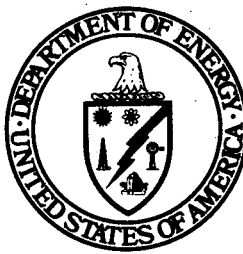
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HANDBOOK FOR THE DEPARTMENT OF ENERGY LABORATORY ACCREDITATION PROGRAM FOR PERSONNEL DOSIMETRY SYSTEMS

**DOE Laboratory Accreditation Program
for Personnel Dosimetry Systems**

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MASTER

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FOREWORD

The program contained in this Handbook provides a significant advance in the field of radiation protection through a structured means for assuring the quality of personnel dosimetry performance. This program culminates an effort initiated by DOE's predecessor in early 1963. Since personnel dosimetry performance is directly related to the assurance of worker safety, it has been of key interest to the Department of Energy (DOE) (and its predecessor agencies). Studies conducted over the past three decades have clearly demonstrated a need for personnel dosimetry performance criteria, related testing programs, and improvements in dosimetry technology. In responding to these needs, the DOE Office of Nuclear Safety (EH) has developed and initiated a DOE Laboratory Accreditation Program (DOELAP) which is intended to improve the quality of personnel dosimetry through (a) performance testing, (b) dosimetry and calibration intercomparisons, and (c) applied research.

In the interest of improving dosimetry technology, the DOE Laboratory Accreditation Program (DOELAP) is also designed to encourage cooperation and technical interchange between DOE laboratories. Dosimetry intercomparison programs have been scheduled which include the use of transport standard instruments, transport standard radioactive sources and special dosimeters. The dosimeters used in the intercomparison program are designed to obtain optimum data on the comparison of dosimetry calibration methodologies and capabilities. This data is used in part to develop enhanced calibration protocols. In the interest of overall calibration update, assistance and guidance for the calibration of personnel dosimeters is available through the DOELAP support laboratories.

To further the efforts in dosimetry upgrade we are also encouraging a closer cooperation and working relationship between the researcher and those involved in performance testing. Feedback to the DOE dosimeter processors on dosimeter performance and applied research efforts will be provided by DOELAP.

The relationship between the DOELAP and the NVLAP (National Voluntary Laboratory Accreditation Program) which services NRC licensees has also been established. The DOE recommended to the Interagency Policy Committee on Personnel Dosimetry, a program, which integrates the DOELAP and NVLAP under the National Dosimetry Accreditation Upgrade Program through an efficient flow of information between the programs. The DOELAP and NVLAP utilize similar methodology. However, the DOELAP is more comprehensive through necessity because of the complexities of the DOE programs to be accredited and the need for more restrictive performance testing.

The DOELAP is basically contained in four documents:

1. "DOE Order 5480 Series,"
2. "Department of Energy Standard for the Performance Testing of Personnel Dosimetry Systems" (provides testing criteria to accredit personnel dosimeters) - DOE/EH-0027,
3. "Handbook for the Department of Energy Laboratory Accreditation Program for Personnel Dosimetry Systems" (provides operating procedures for program), and
4. "Quality Assurance Manual for the Department of Energy Laboratory Accreditation Program for Personnel Dosimetry Systems" (applies to the performance testing laboratory only) - DOE/ID-12105.

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HANDBOOK FOR THE DEPARTMENT OF ENERGY LABORATORY ACCREDITATION PROGRAM FOR PERSONNEL DOSIMETRY SYSTEMS

1. INTRODUCTION

The Department of Energy (DOE) and its predecessor agencies have been concerned about personnel dosimetry performance since the late 1950s. Studies conducted over the past three decades have clearly demonstrated DOE needs both performance criteria for personnel dosimetry and a testing program to determine the criteria have been met.¹⁻¹³

In 1973, the Conference of Radiation Control Program Directors recommended establishing a program for continually testing personnel dosimetry performance throughout the United States. The Conference appointed a task force with state and federal participants to implement this recommendation. The task force concluded that existing standards were inadequate for the purpose. It asked the Health Physics Society Standards Committee (HPSSC) to develop a new Standard to establish criteria for testing personnel dosimetry performance. In 1975, HPSSC charged a working group with writing such a Standard for the American National Standards Institute as ANSI Standard N13.11.¹⁴

In 1976, the Conference of Radiation Control Program Directors, the Nuclear Regulatory Commission (NRC), predecessor agencies of DOE, and the National Center for Devices and Radiological Health (NCDRH) jointly sponsored a public meeting. This meeting was held to discuss the problems associated with personnel dosimetry. At that meeting copies of the draft standard *Criteria for Testing Personnel Dosimetry Performance*, which HPSSC had developed, were distributed. Many of those attending the meeting strongly recommended a pilot study be undertaken to evaluate the draft standard. As a result of that recommendation, the University of Michigan conducted three rounds of personnel dosimetry proficiency testing from 1977 to 1982. Upon completion of the University of Michigan studies, the standard was adopted as a Health Physics Society Standard. The Board of Standards Review of ANSI accepted it as a final American National Standard.¹⁴ The National Voluntary Laboratory Accreditation Program (NVLAP) is using it as a

basis for an accreditation program for personnel dosimeters.¹⁵

Independent of the University of Michigan testing program, DOE conducted a program to evaluate ANSI N13.11 for use in its DOE/DOE contractor personnel dosimetry programs. The studies DOE conducted have demonstrated ANSI N13.11 is not adequate for testing the personnel dosimeters used at DOE/DOE contractor facilities.¹² Accordingly, DOE developed a comprehensive Standard for performance testing its personnel dosimetry systems.¹⁶ The Standard is a modification of ANSI N13.11¹⁴ and is based on recommendations made while evaluating the ANSI Standard. Moreover, DOE wanted a testing program that would encourage further research and promote communication among the DOE/DOE contractor organizations. This kind of program would bring about new developments and procedures to be used to improve dosimetry performance. Therefore, DOE decided to establish a dosimetry testing program consistent with its needs. The program is called the DOE Laboratory Accreditation Program (DOELAP). DOE intends to eventually coordinate its testing program with that of NVLAP. Therefore, DOELAP follows NVLAP methods and procedures as much as possible.

Accreditation is the assessment of whether or not a personnel dosimetry system meets specific criteria. The assessment includes dosimeter performance and the associated quality assurance and calibration programs. The accreditation process includes the development of recommendations for any improvements needed to ensure continuing quality. DOELAP's objective is to accredit the personnel dosimetry systems of DOE/DOE contractors, regardless of whether the dosimeter processing is conducted at commercial or in-house facilities. The term "DOE contractor" will refer to the DOE/DOE contractor facility eligible for accreditation. The term "processor" is limited to the facility handling and evaluating the personnel dosimeters.

This handbook describes the procedures for obtaining accreditation. In general, to obtain accreditation, contractors must:

1. Meet the test criteria in the DOE Standard
2. Pass an onsite assessment of the documentation, quality assurance, and technical adequacy associated with personnel dosimetry systems.

A performance testing laboratory determines the ability to meet the test criteria. Members of a team of experts in personnel dosimetry conduct onsite assessments. The Standard is consistent with the current capabilities of dosimetry systems. However, it will be upgraded as improved dosimetry capabilities become available. This particularly applies to beta-particle and neutron dosimetry.

2. SCOPE OF ACCREDITATION PROGRAM

The DOELAP for personnel dosimetry systems applies to the technical aspects of personnel dosimetry systems at DOE/DOE contractor facilities and to the documentation of those aspects. During the accreditation:

1. A performance testing laboratory evaluates the technical performance of dosimetry systems
2. An onsite assessment studies the quality assurance, documentation, and technical adequacy of such systems.

Dosimeter types or models used to determine whole-body and skin dose for personnel are included in the scope of the Accreditation Program. Accreditation currently does not apply to extremity dosimeters, pocket ionization chambers, thermal neutron dosimetry, and high-energy neutron dosimetry. The program scope does not forbid a laboratory to provide additional dosimetry services (i.e., personnel, extremity, environmental, or area monitoring). Nor does it preclude a laboratory from operating research programs to improve the

dosimetry services. Calibration services are accessible, for a fee, to laboratories requiring characterization of dosimetry systems in routine use or under development.

The DOELAP allows abbreviated testing for dosimeter types known or suspected to be noncompliant in certain categories. The dosimeter type will be considered adequate or accreditable only if it is used in those environments covered by the categories for which it was successfully tested.

The DOELAP test standard scope is limited. Approximate energy intervals covered are: 15 keV to 2 MeV for photons; above 0.3 MeV for beta particles; and 1 keV to 2 MeV for neutrons. Additional test categories covering other energy ranges are being developed as the need arises and time permits. DOELAP does not currently cover occupational environments containing significant contributions outside these ranges. Processors are not required to test dosimeters used for these environments.

Every two years, each DOE contractor must maintain its accreditation by demonstrating compliance with DOELAP criteria.

3. ADMINISTRATION OF THE PROGRAM

The DOELAP is managed by the DOE Office of Nuclear Safety. The DOE Headquarters (HQ) DOELAP Administrator provides for the overall program management. An Oversight Board technically reviews DOELAP protocol and makes recommendations concerning accreditation. The Oversight Board consists of five DOE/DOE contractor personnel. Each serves a 2-year term. An Appeals Board considers contractor appeals concerning accreditation denial. It consists of six DOE/DOE contractor personnel. The performance evaluation program at the DOE Radiological and Environmental Sciences Laboratory (RESL) at the Idaho National Engineering Laboratory (INEL) coordinates the accreditation

process. The Performance Evaluation Program Administrator at RESL is responsible for conducting the performance testing and site assessment programs and for maintaining all documentation associated with DOELAP.

The HQ DOELAP Administrator will periodically request nominations for a pool of technical experts to serve in this accreditation program. The experts are selected by evaluating their professional and academic achievements and their experience in dosimetry. The onsite assessors, members of the Oversight Board, and of the Appeals Board are selected from this pool. Each board will select its own chairman.

4. ACCREDITATION PROCESS

The Performance Evaluation Program Administrator coordinates the accreditation process for personnel dosimetry systems. To obtain accreditation, a DOE contractor must first submit an application through the field office. The contractor must then satisfy both the performance testing and the onsite assessment requirements. The Performance Evaluation Program Administrator prepares an administrative report documenting the test results and recommendations for accreditation. The Oversight Board evaluates the report and the recommendations and, if approved, sends them to the HQ DOELAP Administrator. The HQ DOELAP Administrator makes the final decisions on accreditation and issues the Certificates of Accreditation. A Certificate of Accreditation specifies the model(s) or type(s) of dosimeters accredited for specific radiation categories.

If a dosimetry system, or part of a dosimetry system, is found noncompliant with DOELAP criteria, the contractor and field office prepare a remedial action plan to implement immediately. The plan is sent through the DOE field office to the HQ DOELAP Administrator with a copy to the Performance Evaluation Program Administrator. The contractor and field office may appeal to the Appeals Board at any point in the accreditation process. In the meantime, the dosimetry system may be partially accredited. If the system has demonstrated satisfactory performance in a subset of the DOELAP irradiation categories and if the remedial action plan is initiated, the accreditation process may continue in those categories. When more than one dosimeter design is used to meet the special needs at a laboratory, it is possible for a portion of a dosimetry system to receive final accreditation while the remaining part requires a remedial action plan.

If a DOE contractor uses the services of a commercial processor, both the contractor and processor facilities will be visited. If more than one DOE contractor is using the same commercial processor, only one site visit to the processor may be required. More than one DOE contractor may use performance test data for a commercial processor if each contractor facility uses the identical dosimeter design and if the appropriate test categories are included. Site-specific calibration factors and response algorithms are required if used for routine evaluations. The Performance Evaluation Program

Administrator must approve combined evaluations, and the Oversight Board must review them.

The following sections describe the phases of the accreditation process in more detail.

4.1 Application

The contractor initiates the accreditation process by submitting an application form (Appendix A) through the appropriate field office. To expedite the process, a designated representative of the applying laboratory management (e.g., the laboratory's head health physicist) should complete the application as thoroughly as possible and sign it. The designated representative should be familiar with all DOELAP requirements. The representative reviews all documents and acts as liaison between DOE/DOE contractor management and the Performance Evaluation Program Administrator. Other staff members may be designated to perform specific activities (e.g., handling proficiency testing or receiving an assessor). Yet, only one designated individual should be responsible for requesting a change in the scope or nature of the accreditation.

The application requires each applicant to describe the particular processing system employed. The description should include the specific apparatus and protocols used and whether processing is done manually or automatically. It should also identify the equipment and procedures to be used for the appropriate testing categories. The information submitted should describe the system used as thoroughly as possible without divulging proprietary information.

The application is used to:

- Enroll the DOE/DOE contractor facility in the program
- Determine the dosimeter types or models and test categories desired for accreditation
- Gather information about the DOE/DOE contractor's facility and organizational structure for evaluation purposes
- Select assessors with the proper technical background for the onsite visit
- Gather information necessary to prepare for an onsite visit.

The contractor sends the application to the appropriate field office. There, it is reviewed and, if approved, sent to the Performance Evaluation Program Administrator.

4.2 Performance Test

Performance testing is the first requirement of the DOELAP accreditation process. The procedures contained in the DOE Standard are briefly highlighted in this section.

A dosimeter type may be accredited in one or more of the radiation categories shown in Table 1. This table contains the source specification, energies, and dose range for each category. The contractor must specify the exposure categories and the types or models of the dosimeters submitted for accreditation.

The test period is three to six months. The contractor must submit three shipments of dosimeters during this test period to the performance testing laboratory for irradiation. The contractor shall normally submit five dosimeters in each test category with each shipment. The contractor will be required to include a specified number of additional dosimeters of each design in each shipment to be used as controls and when necessary as replacements. The Standard specifies certain cases where 10 dosimeters per category per shipment may be submitted for irradiation. These cases must be coordinated with the DOELAP Performance Evaluation Program Administrator.

The dosimeters are then irradiated and returned to the contractor. The contractor must read each one and determine a dose or dose equivalent. The testing laboratory will identify all dosimeters irradiated in Categories I and II and those irradiated for the neutron tests (Categories VI & VII). Dosimeters irradiated in the mixture categories Categories III, IV, and V and VII (not including neutron irradiations) are not identified by category. In these cases, the processor must determine the dose for each dosimeter without knowing the irradiation category. Pretest calibration exposures for neutron categories are recommended and will be provided upon request. The contractor will identify the neutron field(s) to be used for the performance testing. Besides identifying the dosimeters irradiated by the neutron sources to the contractor, the testing laboratory will provide the ratio of responses of a BF₃ detector in a 9-in.-dia sphere and in a 3-in.-dia sphere covered with 10-mil-thick cadmium. The ratio gives the contractor a relative

calibration for albedo dosimeters. This information may be useful to relate the test fields to the neutron fields in the occupational environment.

The radiation sources and geometries are described fully in the Standard. A brief description of them follows:

1. A sealed ¹³⁷Cs gamma-ray source
2. X-ray machine(s) producing continuous spectra using the techniques of the National Bureau of Standards,¹⁸ and capable of generating nearly monoenergetic low-energy photon beams (15 to 20 keV and 55 to 65 keV).
3. A sealed ⁹⁰Sr/⁹⁰Y beta particle source with a 100-mg/cm² filter (nominal) to remove the ⁹⁰Sr component - The residual maximum energy, as defined in the International Standard ISO 6980,¹⁹ shall equal or exceed 1.80 MeV. The in-phantom dose rate at 100 mg/cm² divided by the dose rate at 7 mg/cm² shall be 1.01 ± 0.03 . The in-phantom dose rate at 1000 mg/cm² shall be less than 1% of the dose rate at 7 mg/cm². The measurement specifications take precedence over the irradiation geometry specifications.
4. A sealed ²⁰⁴Tl source filtered by 50 mg/cm² (nominal) - The residual maximum energy, as defined in ISO 6980, shall equal or exceed 0.53 MeV. The in-phantom dose rate at 20 mg/cm² divided by the in-phantom dose rate at 7 mg/cm² shall be 0.80 ± 0.05 . The measurement specifications take precedence over the irradiation geometry specifications.
5. A natural or depleted uranium slab - The source protective covering shall be in the range between 3 mg/cm² and 7 mg/cm² inclusive. The dose rate at 100 mg/cm² divided by the dose rate at 7 mg/cm² shall be 0.58 ± 0.04 . The measurement specifications take precedence over the geometry specifications. The dimensions of the source must exceed the dimensions of irradiated dosimeters.
6. A ²⁵²Cf neutron source used unmoderated and moderated by 15 cm of D₂O covered by 0.05 cm of cadmium.¹⁷

The Standard of performance for DOELAP is based on achievable standards consistent with the goals of health protection. The criteria were chosen to be both economically and technologically

Table 1. Irradiation categories

Category	Energy	Test Range	Test Depths
I. Low-Energy Photons (X Ray) - High Dose		10-500 rad	Deep
NBS Filtered Technique			
M150 ^a	70 keV ^b		
II. High-Energy Photons - High Dose		10-500 rad	Deep
¹³⁷ Cs ^a	662 keV		
IIIA. Low-Energy Photons (X Ray) - General		0.03-10 rem	Shallow Deep
NBS Filtered Techniques			
M30 ^a	20 keV ^b		
S60 ^a	36 keV ^b		
M150 ^a	70 keV ^b		
H150	120 keV ^c		
IIIB. Low-Energy Photons (X Ray) - Plutonium Environments		0.03-5 rem	Shallow Deep
Monoenergetic	15 to 20 keV		
Monoenergetic	55 to 65 keV		
²⁴¹ Am ^d	59 keV		
IV. High-Energy Photons		0.03-10 rem	Shallow Deep
¹³⁷ Cs ^a	662 keV		
VA. Beta Particles - General (Point Geometry)		0.15-10 rem	Shallow
²⁰⁴ Tl ^e	0.76 MeV ^f		
⁹⁰ Sr/ ⁹⁰ Y (filtered) ^a	2.3 MeV ^f		
VB. Beta Particles - Special (Slab Geometry)		0.15-5 rem	Shallow
Uranium	2.3 MeV ^f		

Table 1. (continued)

Category	Energy	Test Range	Test Depths
VC. Beta Particles - Special (Point Geometry)		0.15-10 rem	Shallow
$^{204}\text{Tl}^e$ $^{90}\text{Sr}/^{90}\text{Y}$	0.76 MeV ^f 2.3 MeV ^f		
VI. Neutron		0.2-5 rem	Deep
^{252}Cf (moderated) ^g ^{252}Cf (unmoderated)			
VII. Mixture Categories			
III & IV ^a	One energy from each category	0.05-5 rem	Shallow, Deep
III & V		0.2-5 rem	
IV & V ^a		0.2-5 rem	Deep Deep
III & VI ^h		0.3-5 rem	
IV & VI ^a		0.3-5 rem	

a. This category or a subset of this category is also specified in Reference 14.

b. Average.

c. Effective.

d. The ^{241}Am source is optional. At the option of the testing laboratory, it may be used in lieu of the 55- to 65-keV monoenergetic source.

e. A modified performance algorithm is recommended.

f. Maximum.

g. Moderated by 15 cm of D_2O (see Reference 17).

h. For work environments containing plutonium, use the monoenergetic or ^{241}Am sources.

achievable based on the data collected during the intercomparison of dosimeter system performance for DOE laboratories.¹³ A test criterion:

$$|B| + S \leq 0.30^a \quad (1)$$

can be interpreted as providing approximately 70% confidence a dosimeter response would be within 30% of a conventionally true value. For workers using four dosimeters annually and receiving approximately the same dose on each, the criterion provides approximately 95% confidence the annual reported dose equivalent would be within 30% of a conventionally true value.

The criterion in Equation (1) is consistent with the recommendations of the National Council on Radiation Protection and Measurement (NCRP), the International Commission on Radiation Units and Measurements (ICRU), and the International Commission on Radiological Protection (ICRP). Reference 16 points out the following caveats:

- The NCRP and ICRU recommend 30% for the accuracy with 95% confidence. To meet these requirements, at least four dosimeters receiving approximately equal doses must be used to determine the annual dose.
- The recommendation by the ICRP of accuracy within a factor of 1.5 at the 95%

a. Bias (B) - the average of the performance quotients, P_i , for n dosimeters, for a specific irradiation category and depth.

$$B = \frac{1}{n} \sum_{i=1}^n P_i \quad (1a)$$

where

$$P_i = \frac{(\text{Reported})_i - (\text{Delivered})_i}{(\text{Delivered})_i}$$

Standard Deviation (S) - The standard deviation of the performance quotients, P_i , calculated for n dosimeters for a specified irradiation category and depth.

$$S = \left[\frac{\sum_{i=1}^n (P_i - B)^2}{n - 1} \right]^{1/2} \quad (1b)$$

confidence level is approximately met for each dosimeter (and thus for each worker). However, the uncertainty due to angular response included in the ICRP accuracy recommendations is neglected in the test criteria. The criterion in Equation (1), using quarterly exchange rates to achieve 95% confidence, is the approximate equivalent of reserving up to 20% additional bias for angular response variations.

- The NCRP recommends 20% accuracy at high doses. The ICRU and ICRP favor a special effort to increase accuracy on a case-by-case basis.
- Inaccuracies resulting from field use under partially unknown conditions are neglected in the test criterion. Examples of such unknowns are the position of dosimeter relative to source distribution or its location on the body of the wearer.

The criterion in Equation (1) was modified to reduce the probability of a failure due to the imprecise delivery of dose equivalent to the test dosimeters and to permit more time for fine adjustments in the mixture categories. The DOELAP Test criterion is:

$$|B| + S - |E| \leq L \quad (2)$$

where

$$L = 0.30 \text{ for Categories I through VI}$$

$$L = 0.40 \text{ for Category VII}$$

and E is the estimated fractional uncertainty in the delivered dose or dose equivalent rate. The performance testing laboratory determines the value of E. It will typically be in the range between 1% and 4%.

The test for the low-energy beta source listed in Table 1 does not require using Equation (2) because of the technological and practical limitations of current dosimeter designs. Instead, this less stringent test is used for ²⁰⁴Tl:

$$|B| - |E| \leq 0.40 \quad (3)$$

This criterion was chosen based on the low-energy beta performance of current DOE dosimetry systems, as discussed in the Standard.¹⁶ The ²⁰⁴Tl source is not used in any mixture categories unless requested by a participant. The performance criteria for Category VII and for the ²⁰⁴Tl tests will be upgraded to that of the other categories and sources two years after the effective date of the DOE Order.²⁰

The dose interpretation algorithms used for reporting occupational doses should be used for the performance tests, if practical. If changing an algorithm to meet the DOE Standard specifications increases the error of reported occupational doses, that algorithm should not be changed. Using different calibration factors for the tests and for various occupational environments is justified if it results in an improved dose estimation. The contractor must document the relationship between the algorithms used for the test and the reported worker doses. The contractor must also justify the use of environment-dependent factors.

The categories for low-energy photon and beta particles offer a choice of sources. The "A" categories are for general sources, the "B" or "C" categories for specific occupational environments or applications. For example, Category IIIA is for general low-energy photon environments. Category IIIB applies specifically to plutonium environments. Testing in both subgroups of Category III is appropriate for a dosimeter used in both plutonium and nonplutonium environments with significant x-ray fields. Different dose interpretation algorithms may be used for Categories IIIA and IIIB if they are the same ones used to estimate the occupational doses.

The beta particle categories are for general beta environments (⁹⁰Sr/⁹⁰Y and ²⁰⁴Tl point sources—Category VA), environments containing uranium sources (slab uranium—Category VB), and environments having predominantly high-energy or low-energy betas (a ⁹⁰Sr/⁹⁰Y or a ²⁰⁴Tl point source—Category VC). The sources in Category VA have energy spectra suitable for an energy response test for beta fields. According to Reference 19, an energy response test may include ¹⁴⁷Pm, ²⁰⁴Tl, and ⁹⁰Sr/⁹⁰Y sources. These are contained in the ISO series 1 sources, designed for dose rate uniformity over large areas. The Category VB source may be preferable in a dosimetry system designed to monitor uranium fields when a similar source is routinely used for beta dose standardization.

The exposure geometry from contact with a slab produces a different depth dose curve from the curve obtained at a distance from a point source. Present dosimeter designs may require calibration factors for occupational environments that are significantly different from the slab uranium source factors. The contractor is responsible for demonstrating that calibration obtained from the slab uranium source is appropriate. Category VC may be preferable if the occupational environment contains only limited beta energy ranges. The limited range must be identified as being closer to the energy of ⁹⁰Sr/⁹⁰Y or of ²⁰⁴Tl. The contractor chooses the beta source in Category VC before initiating the test. If more than one of Categories VA, VB, and VC are chosen, the contractor may use different dose-interpretation algorithms when those same algorithms are used for specific occupational environments.

After each shipment of dosimeters is returned, the contractor determines the dose for each dosimeter and reports the doses to the performance testing laboratory. When all three rounds have been completed, the performance testing laboratory mails the results of the proficiency testing to the contractor. If the contractor does not demonstrate satisfactory performance in one or more categories during a test sequence, the laboratory will send the contractor a notice of required retesting with the test results.

For each dosimeter type, the retest sequence is as follows:

1. Categories I and II - When a contractor tests in both high-dose categories and the test result is not satisfactory in one or both, retesting in both is required. When a contractor tests in only one high-dose category and the test result is not satisfactory, retesting in that category is required. Whenever the test result is not satisfactory for a high-dose category, retesting in the corresponding protection level category (III or IV) is also required.
2. Categories III, IV, V, VI, and VII - When a contractor tests in three or fewer protection level categories and the test result is not satisfactory in one of these, the contractor must retest in all of them. A second case occurs when a contractor tests in more than three protection level categories, and the test result is not satisfactory in one of these tests. Then the contractor must retest in that category and in two additional

protection level categories for which their performance was satisfactory. The contractor will not know which two additional categories are chosen. Finally, when performance is not satisfactory in two or more protection level categories, retesting is required in all protection level categories for which accreditation is sought.

4.3 Onsite Assessment

To become accredited, a contractor must demonstrate the ability to conduct a credible personnel dosimetry program. For initial accreditation, an onsite visit is required after the performance testing has been satisfactorily completed. This visit shall assess the quality assurance, documentation, and technical aspects of the personnel dosimetry program. Appendix B contains the assessment criteria. Assessors may use them with considerable latitude according to their experience and as the unique conditions at each processing facility may dictate. The onsite assessment is repeated at least every two years.

Two assessors are assigned to visit each facility. Assignments are based on how well the assessors' individual experience matches the type of processing to be assessed. Assignments also are made to avoid conflicts of interest. The contractor is told of the assignments and has the right to appeal the assignment of an assessor to the Performance Evaluation Program Administrator. If the contractor and the Program Administrator cannot agree on an assessor, they may ask the Appeals Board to resolve the difference. When the assessors have been assigned, the Program Administrator contacts the contractor to arrange a mutually agreeable date for the visit. The field office is notified of the dates of the site visit. The time needed to conduct an onsite visit varies. A two-man team typically requires two to three days.

The assessors:

1. Begin the visit by meeting with the management and the supervisory personnel responsible for the dosimetry activities for which accreditation is being sought. The assessors acquaint management with the assessment process and set the agenda for the visit.
2. Evaluate the contractor's quality assurance system.

3. Select and trace the history of a sample batch of dosimeters from when the dosimeters are received to the time a dose report is issued.
4. Thoroughly review the contractor's performance test results.
5. Review the contractor's quality assurance documentation.
6. Examine technicians' notebooks for records about the selected group of dosimeters.
7. Check dosimeter identification and tracking procedures.
8. Determine if the appropriate environmental conditions are maintained.
9. Examine copies of completed reports.
10. Evaluate documentation.
11. Evaluate technical aspects. These include: personnel training and competency, facilities and equipment, equipment calibration and maintenance, and record-keeping systems.
12. Conduct a close-out meeting with management and supervisory personnel to explain their findings and to clarify the contractor's responsibilities.
13. Leave a copy of their reports with the contractor.
14. Conduct monitoring visits between the biennial assessments.

The following subsections discuss some of these activities. Subsections 4.3.1 through 4.3.3 provide a general overview of the program elements assessors are likely to consider important components of a satisfactory dosimetry program. Subsections 4.3.4 through 4.3.6 discuss the close-out meeting, procedures for correcting deficiencies, and monitoring visits.

4.3.1 Quality Assurance Program. The key to a properly functioning organization is an ongoing quality assurance (QA) program. A QA program is an organization's internal system of procedures and practices to ensure the quality control of its services. A QA manual should document this program. To qualify for accreditation, a contractor must demonstrate its QA program during the onsite visit. Criteria for the QA program are contained in Appendix B.

4.3.2 Documentation. A contractor must have up-to-date documentation thoroughly describing all of its significant procedures and practices. These

written descriptions should contain such items as: (a) personnel requirements and responsibilities, (b) a system for maintaining necessary records, (c) operating procedures, (d) procedures to employ in the event of unusual or nonstandard circumstances, and (e) scheduling. Written descriptions should cover at least these topics:

Personnel

- Organizational chart
- Job/position description for all dosimeter-processing and records-management personnel
- Procedures for training personnel
- Assurance of personnel competency

Equipment

- Processing-equipment inventory, including radiation sources used for calibration
- Practices for processing-equipment calibration, verification, and maintenance
- A test plan (processing protocol) for the conduct of the performance tests for each dosimeter design processed
- Instructions for operating all processing equipment, including instructions for performing operational quality assurance checks

Dosimeters

- Dosimeter models and design specifications
- Acceptance criteria for incoming dosimeter holders and materials
- Procedures for handling and storing sensitive dosimeter components and materials
- Assembly/disassembly techniques for all dosimeter models used
- Procedures for periodic checks of in-service dosimeters
- Identification and tracking of dosimeters
- Procedures for handling and storing in-service dosimeters
- Actions to repair or replace damaged dosimeters

Calibration

- Relationship(s) between dosimeter calibrations and field spectra

- Dosimeter calibration techniques and procedures, including traceability paths

Reporting

- Data handling and reporting
- Actions to be taken when variations in test data indicate a problem.

4.3.3 Technical Adequacy. Contractors must ensure employees do their jobs well by having adequate procedures for training and utilizing employees. Contractors must also provide adequate equipment, facilities, and maintenance procedures.

4.3.3.1 Personnel Training. The contractor must ensure each new staff member is trained for the processing duties assigned. The competency of staff members should be verified and documented annually. In addition, all staff members should be retrained when processing equipment and protocols are changed or when the staff members are assigned new responsibilities.

Each staff member must receive (or have had) training for the assigned duties through on-the-job training, formal classroom sessions, or a technician certification program. This training should be documented in the personnel file.

4.3.3.2 Personnel Competency. The technical director of the personnel dosimetry program should be a professional experienced in applied radiation dosimetry. He/she should be knowledgeable in the design and operation of the dosimetry system(s) currently utilized. This individual should have the technical competence to establish any required dosimetry programs. He/she should also have the supervisory capability to direct the work of professionals and technicians in the dosimetry area. The technical director may be responsible for the quality assurance program. If not, responsibility is assigned to another individual. This person should have knowledge and experience in quality assurance. He/she will communicate directly to the technical director and other organizational management. If a second individual has responsibility for the QA program, the description for that position should be included in the organization description. There should be enough trained staff members to provide program continuity.

In addition to providing for staff training, the technical director must annually evaluate the competency of each staff member authorized to perform

dosimeter evaluations. These staff evaluations should be available for review.

The DOELAP Performance Evaluation Program Administrator must be informed of any organizational or personnel changes that could affect the performance of the contractor's dosimetry program. Changes such as technical supervision or responsibility for quality assurance program should be reported to this Administrator within 60 calendar days of the change.

4.3.3.3 Facilities and Equipment. The contractor or dosimeter processor must have facilities and equipment adequate to perform the type(s) of processing for which it claims capability. Proper shielding should be provided to protect areas from unwanted radiation, and environmental controls should be maintained. The equipment should include adequate processing equipment and radiation sources. If properly calibrated (NBS-traceable) laboratory-standard equipment for determining dose equivalent is not available, the contractor should have access to the services of a competent calibration laboratory.

Adequate backup equipment or systems for key processing steps should be available for use in the event the primary systems fail. The backup system could be arranging for the services of another DOE-accredited contractor on an emergency basis.

4.3.3.4 Equipment Maintenance and Calibration. The contractor must maintain a preventive maintenance program for equipment used to process dosimeters and to perform quality control checks. When equipment—used for measurement, dosimeter processing, or quality control—is inherently subject to change due to use or the passage of time, it must be calibrated periodically. Calibration is comparing the equipment with a reference standard. This comparison determines the performance of a measuring instrument or the output of a radiation source with sufficient accuracy.

The proper performance of the dosimetry processing system must be verified periodically. Dosimeters irradiated in well-characterized radiation fields are used for this purpose.

Either the contractor or an external calibration service should calibrate equipment or the dosimetry system and characterize radiation fields. All calibrations and characterizations must be performed using reference standards traceable to NBS national standards¹⁸ or to standards maintained by an equivalent foreign national standards authority. Being trace-

able means being able to show that appropriate documented actions were taken to compare (either directly or indirectly) a reference standard with a national standard.

The transfer standards used and the environmental conditions at the time of calibration must be documented for all calibrations. Calibration records must be made available for inspection during the assessors' onsite visit. The traceability of the reference standards used are verified at that time.

4.3.3.5 Recordkeeping. The contractor must maintain functional records on the dosimetry system. This means the records should be easily accessible, in some logical order, and complete. Records covering the following items are required and are reviewed during the onsite visit:

- Staff training dates and results
- Staff competency review
- Processing-equipment calibration and maintenance
- Data used to develop dosimeter processing algorithms
- Results of inspection of incoming dosimeter materials
- Logs of processing activities
- Results of internal and external equipment checks, measurement quality assurance programs, audits, etc.
- Performance test data and reports
- Tracking and logging dosimeters.

Processing-equipment calibration (or verification) records should include the following: equipment name or description; model, style, or serial number; manufacturer; notation of all equipment variables requiring calibration or verification; the range of calibration/verification; the resolution of the instrument and its allowable error; calibration or 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.

Dosimeter-tracking and -logging records should trace the movement of each dosimeter through the processing facility, from its receipt through all the tests performed to the final report.

The final dose report the contractor developed for the permanent record should include or reference the location of the following:

- Name and address of contractor

- Pertinent dates and identification of dosimeter, including contractor and corresponding processor identification codes
- Description and identification of the dosimeter and/or elements
- An explanation of any deviation from the protocol routinely used in processing dosimeters that may affect the reported dose (e.g., mishandling of background control dosimeters)
- Identification of anomalies
- Signature of or a reference to the person having technical responsibility
- All additional items identified in the contractor's test plan.

4.3.4 Close-Out Meeting. At the conclusion of the visit, the assessors will discuss their observations with appropriate members of management and identify any findings or deficiencies. A written summary of any deficiencies discussed is left with the contractor's authorized representative. The assessors forward the assessment forms and the written summary to the DOELAP Performance Evaluation Program Administrator for use in the technical evaluation. The contractor is requested to forward within 30 days a written plan for resolving identified deficiencies. This plan should be sent through the field office to the Performance Evaluation Program Administrator.

4.3.5 Deficiencies: Deficiencies identified during the initial onsite visit may require some time to correct. These corrections must be completed before accreditation is granted. Deficiencies noted during subsequent biennial onsite assessments of an accredited contractor should be corrected within 60 days of the close-out meeting. If a contractor disagrees with a part of the assessors' findings, the contractor may request that the Performance Evaluation Program Administrator review and reverse the findings in question. A further appeal may be directed in writing to the Appeals Board if the assessors' findings are upheld. When out-of-calibration apparatus is cited, the apparatus should not be used until corrective action has been completed. Any deficiencies noted for corrective action are reviewed during subsequent onsite visits and technical evaluations.

4.3.6 Monitoring Visits. In addition to regularly scheduled onsite assessments, assessors may be assigned to make monitoring visits at any time during the two-year accreditation period. Monitoring

visits may occur for cause or on a random basis. These visits may serve to verify reported changes in the contractor's processing facilities and/or operations. The visits may also explore possible reasons for poor performance in proficiency testing. The scope of a monitoring visit may range from checking a few designated items to making a complete review.

4.4 Granting Accreditation

When the technical evaluation has been completed or at the end of the accreditation period, the Performance Evaluation Program Administrator prepares an administrative report and recommendation for the DOE Headquarters DOELAP Administrator and the Oversight Board. The Board evaluates the report and recommendation and proposes one of two options:

- **Accreditation** - The HQ DOELAP Administrator completes the accreditation process by issuing a certificate of accreditation to the contractor.
- **Remedial Action Required** - The contractor is notified that remedial action is required and of the reason(s) for the remedial action. The contractor must immediately identify and implement a remedial action plan within 45 days of receiving the notification. This plan is sent to the HQ DOELAP Administrator through the DOE field office with a copy to the Performance Evaluation Program Administrator. A contractor may request an Appeals Board review.

Dosimetry systems may be partially accredited if a system is demonstrated to be satisfactory in a particular subset of the DOELAP irradiation categories. If a system has not satisfactorily demonstrated compliance with the test criterion in a particular subset of categories and if a remedial action plan is initiated, the accreditation process may continue in all other categories.

The contractor has the responsibility to inform the Performance Evaluation Program Administrator whenever any changes are made in dosimeters or processing techniques. The contractor must provide evidence supporting a conclusion that the system is technically equivalent to the accredited system. The Performance Evaluation Program Administrator with the Oversight Board's approval makes a determination of technical equivalence. If they decide the

changed dosimeters or techniques are not technically equivalent, the accreditation does not cover the dosimeters or techniques. They must be fully evaluated and/or demonstrate a satisfactory dosimeter performance in accordance with DOELAP requirements before they are covered.

If a change in the type or quality of radiation fields occurs, or is anticipated, the contractor shall inform the Performance Evaluation Program Administrator. The contractor shall also justify either that the existing accreditation is adequate, or that additional accreditation testing is required.

The Performance Evaluation Program Administrator will recommend approval or disapproval. The justification with the recommendation is forwarded to the Oversight Board for action. The contractor may request a review of the results by the Appeals Board. If the current dosimetry system is not adequate, the contractor may: (a) apply to accredit either the current system, a new system; or a supplemental system including the new radiation field(s), or (b) obtain dosimetry services from a DOE contractor currently accredited for the radiation field(s) involved.

5. EXCEPTIONS

DOELAP excepts some B-Clause contractors from these requirements. These B-Clause contractors do not perform in-house dosimetry and do not routinely report significant doses received by personnel (e.g., small university

contracts). In these cases, the B-Clause contractor may choose to obtain accreditation from either DOELAP or NVLAP. Field offices may apply for additional exceptions to the HQ DOELAP Administrator.

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APPENDIX A

DEPARTMENT OF ENERGY APPLICATION FOR ACCREDITATION IN PERSONNEL DOSIMETRY

APPENDIX A

DEPARTMENT OF ENERGY APPLICATION FOR ACCREDITATION IN PERSONNEL DOSIMETRY

1. DOE site or facility _____
2. DOE Field Office _____
3. Other DOE facilities using your personnel dosimetry services (specify dosimeter designs and applicable categories required). _____

4. Vendor identification, if outside vendor used:

5. Name of authorized representative of management for DOELAP accreditation

Name _____

Title _____

Department _____

Contractor _____

Address _____

Street or P.O. Box

City

State

Zip Code

Telephone _____

6. List all dosimeters, by name and model number, for which accreditation is sought and place an (x) under each dosimeter listed, opposite the appropriate category (see DOELAP Handbook and DOE Standard for a detailed explanation of each category).

Category	Dosimeter Designation
I.	Low-Energy Photon ^a (High Dose)
II.	High-Energy Photon ^b (High Dose)
IIIA.	Low-Energy Photon
IIIB.	Low-Energy Photon (Plutonium)
IV.	High-Energy Photon
VA.	Beta
VB.	Beta (Uranium)
VC.	Beta (Special) ^c
VI.	Neutron ^d

a. Automatically entered if entered in Category IIIA or IIIB.

b. Automatically entered if entered in Category IV.

c. Please specify whether a high energy beta source (⁹⁰Sr/⁹⁰Y) or a low energy beta source (²⁰⁴Tl) more nearly approximates the beta spectra of your facility.

d. Please specify one or both of the neutron sources. Use only the source(s) that more closely represent the energy spectra found in the occupational environments covered by your service. If the energy spectra vary significantly, both sources may be necessary.

NOTE: If a dosimeter is entered in two or more single categories (III-VI), it is automatically entered into all of the appropriate mixture categories (VII). A combination dosimeter with physically separate parts should be listed as one dosimeter. A separate neutron dosimeter should be considered part of a general beta-gamma-neutron dosimeter and submitted together with the beta-gamma dosimeter to the neutron/photon mixture categories. The Performance Evaluation Program Administrator will inform you of the required number of dosimeters to be submitted for each of the three irradiation periods.

7. Which of the dosimeters listed in the table above are currently in use? Planned for future use? Under study? (No additional information is required for dosimeters under study.)
8. For each dosimeter listed in the preceding table, describe important design features, including: type of dosimeter material, type of badge or dosimeter holder used, dosimeter placement inside the holder, and type and arrangement of absorbers. Diagrams are helpful. (Proprietary information should not be included.)
9. For each dosimetry system listed in the table, attach a short statement to justify not seeking accreditation in any of the listed categories.
10. For each dosimeter, state whether it is processed in-house, in a commercial laboratory, or in another government facility.
11. Describe in-house dosimeter processing, including readout apparatus and procedures and protocols for the handling, storage, and preparation of dosimeters. Indicate whether processing is manual or automatic. Indicate procedures that may differ for different categories.
12. If an angular dependence study of dosimeter performance and a determination of the lower limit of detectability have been performed, results should be included with this application. If not, results will be required prior to the granting of accreditation (see DOE Standard for the Performance Testing of Personnel Dosimetry Systems).
13. If field calibrations of dosimeters are used to determine occupational exposures, the dosimeter calibration documentation for each field type should be included with this application.

I hereby authorize this application and attest that all statements made are true, complete, and correct to the best of my knowledge and belief and are made in good faith.

Authorized Representative:

Printed Name _____

Signature _____

Title _____

Date _____

By authorizing this application you affirm that you are aware that if accreditation is granted to your organization, the accreditation applies to dosimetry processing services using the specific dosimeter models/types in the categories requested and using the processing techniques that were used to demonstrate satisfactory performance in accordance with the DOE Standard. You will be expected to use the same dosimeter(s) and techniques in the normal processing activities you perform.

If any changes are made or deviations occur in these dosimeters or techniques, it will be the responsibility of your organization 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 the DOE Oversight Board.

If the changes or deviations to the dosimeters or processing techniques are not considered to provide results that are technically equivalent, the new dosimeters and/or techniques will not be covered by the accreditation until they have been fully evaluated and/or their performance has been demonstrated in accordance with the DOE Standard.

In authorizing this application you declare that you commit the applicant contractor to:

- Be examined and audited, initially and on a continuing basis during the accreditation period
- Permit the onsite assessors to review and examine records or other documents required by the DOELAP Handbook
- Maintain compliance with applicable handbook criteria
- Participate in proficiency testing programs that may be required for maintaining accreditation.
Field Office Review: (to be completed before application is submitted)

Printed Name _____

Signature _____

Title _____

Date _____

APPENDIX B
CRITERIA FOR ONSITE ASSESSMENT

APPENDIX B

CRITERIA FOR ONSITE ASSESSMENT

The site assessors are given considerable latitude in evaluating a contractor's personnel dosimetry program. To help each contractor receive a fair assessment, the assessors are provided with this list of criteria covering the main points of a good program.

General

The contractor shall have the latest versions of the processing protocols, dosimeter specifications, quality assurance manual, and other related documents (equipment manufacturer instructions, etc.) available at the facility. The latest version of these documents must be used in conducting all routine processing.

Personnel

1. The functional organization must be consistent with the current organizational chart for the personnel dosimetry program.
2. The qualifications of the individual who has technical responsibility for the personnel dosimetry program must be consistent with the position description.
3. The individual who has technical responsibility must generally exhibit adequate technical knowledge and management control for personnel dosimetry.
4. The individual who has technical responsibility must ensure all dosimetry data are approved.
5. The qualifications of the individual responsible for personnel dosimetry quality assurance (QA) must be consistent with the position description.
6. The responsibility for maintaining and revising the QA manual must be clearly assigned.
7. All personnel dosimetry program staff members must be familiar with and implement the documented quality control program.
8. Communication between technical and supervisory staff members must be adequate.
9. An independent organizational relationship must exist between dosimeter processing and other contractor activities.
10. A designated individual must exercise the authority to assign processing tasks and to ensure timely dosimeter processing.
11. The responsibility for major equipment maintenance, calibration, and servicing major equipment must be clearly assigned.
12. Assigned staff members must be knowledgeable about dosimeter processing equipment and competent in performing assigned processing tasks.
13. The QA manual must describe practices for ensuring staff member competency.
14. The QA manual must describe the training program to prepare staff members to conduct processing protocols.
15. The QA manual must have provisions for retraining assigned staff members when protocols are revised.
16. The competency of staff members should be verified annually, through one or both of these methods:
 - Observation of the conduct of processing protocols by technically qualified individuals
 - Written examination based on the processing protocols.
17. A record of the dates and findings of competency reviews must be available for review.
18. Specialized skills required to conduct all processing protocols must be documented. The training program for individuals who conduct the protocols must include these skills. In addition, the training must include:
 - A period of close supervision until competency is demonstrated
 - A mechanism to evaluate and inform staff members of the adequacy of their performance in conducting assigned processing protocols
 - A mechanism to retrain periodically and to correct any deficiencies in performance between the retrainings.
19. Agreement between assigned processing responsibilities and the technical areas

- addressed in the training program must be apparent.
20. A record of training courses completed by each staff member must be available for review.

Equipment and Facilities

1. A list and description of the facilities and equipment used in all the processing protocols for which accreditation is requested must be available in the laboratory. The list allows the facilities and equipment to be correlated with calibration records.
2. Dosimetry readout equipment appropriate for the dosimetry system must be available.
3. When an annealing oven or furnace is necessary, it must be reserved strictly for dosimeter annealing.
4. There must be a method for securing and maintaining the resources required for the processing activities for which accreditation is requested.
5. Procedures should be established to bring backup equipment into routine service, repair equipment on a rapid-response basis, and/or use the services of another DOELAP-accredited contractor. Such procedures ensure continuity of service when personnel or dosimetry systems fail to perform within the control limits.
6. Dosimetry processing equipment must be identified well enough to permit correlation with calibration records.
7. Adequate controls must be in place to ensure equipment performance at the levels of precision and accuracy the contractor defined in each processing protocol. The operating procedures to be implemented when the equipment fails to meet these criteria must be documented.
8. To help evaluate the stability of equipment performance, records of preventive maintenance and repairs must be available for each piece of processing equipment.
9. Service contracts or an in-house capability to maintain equipment and stock parts must be adequate to ensure continuity of equipment operation.
10. Environmental parameters in the processing facility, including background radiation, must be measured and recorded.

11. Calibration and verification records for major equipment used in dosimetry processing must include
 - Equipment name or description
 - Manufacturer's name
 - Model, style, serial number, or other identifying mark
 - Identification of all equipment variables requiring calibration or verification
 - Range of dose measurements for calibrations
 - Allowable error (taking into consideration instrument tolerance) to coincide with the requirements of each processing protocol
 - Schedule for periodic calibrations, including calibration/verification date
 - Date and result of last calibration/verification, including assessed uncertainty of measurement
 - Identification of staff member or position responsible for equipment calibration, or identity of external service performing calibration
 - Identity of reference standard and how the individual dosimetry data relate to national standards or to nationally accepted measurement systems.
12. The calibration of equipment must be verified at regular intervals. These intervals are determined by equipment type, manufacturing specifications, accumulated stability data, or some other reasonable plan. In all cases, the processor must demonstrate the reliability of the measurements performed.
13. Duties are assigned for all processing equipment maintenance and for routinely verifying all equipment is in proper working order.

Quality Assurance

1. Technicians must be familiar with and implement the documented quality control program.
2. The quality control program must be organized to assess the variability of test results among staff members.
3. The supervisor must examine audit results. Action must be taken to correct any deficiencies.
4. Records of the laboratory's participation in intercomparison programs or external measurement assurance programs must be consistent with practices defined in the QA manual.

5. If processing is conducted in multiple locations within the processor's facility, the processor must perform comparative tests to assess the consistency of dosimetry data.
6. The documented QA system must clearly describe records kept and practices followed. These records and practices must cover the process from the point of dosimeter receipt through to the final delivery of data to the user.
7. Records of any deviation from the use of documented processing procedures, equipment, or facilities must be kept to show no degradation of performance occurred.
8. The QA program must incorporate external checks, including:
 - Processing controls (e.g., light source readings, microprocessor controls)
 - Blind-audit dosimeters
 - Unexposed dosimeters.
9. A comprehensive record of processing activities (i.e., a dated log) must be maintained. This record must contain sufficient identification to allow correlation with calibration/verification and control system records. This record must be available for inspection in the processor's facility.
7. Documented procedures must be used to verify:
 - Filter materials are consistent with the dosimeter design
 - Filters are properly placed in dosimeters.
8. A procedure must be established to verify dosimeter holders meet required specifications.
9. The QA manual must document procedures for handling dosimeters before they are issued.
10. Dosimeters placed in service must be checked according to a defined schedule or frequency to ensure all necessary components are in place.
11. A screening procedure must be used to ensure that dosimetry materials (sensitive elements) are consistent with the dosimeter design. The procedure must include phosphor type and sensitivity.
12. The identification system must be adequate to ensure the correct identification of both demountable (nonfixed) and fixed thermoluminescent (TL) elements. The system must also identify the association of each TL element with a position or filter in the dosimeter.
13. The same dosimeter type or model and sensitive elements used during proficiency testing must be used to assess occupational exposures.
14. Information available concerning processed dosimeters should include:
 - Radiation type
 - Dose definition (terminology)
 - Responsibility for handling the dose of record
 - Calibration procedures used in dose determination
 - Quality control
 - Special processing procedures to be used as part of the dosimetry service
 - Directions for handling and using background control dosimeters
 - Identifying anomalies noted during processing.

Dosimeters

General Criteria

1. Practices for receiving, handling, and storing dosimeters must be consistent with provisions in the QA manual.
2. A positive system for identifying and tracking all dosimeters must be in use.
3. A satisfactory acceptance criterion for all dosimetry material must be established. The criteria must be documented in the QA manual.
4. Sufficient information must be contained in the dosimeter identification code to allow correlation with the record system used in processing.
5. The dosimetry system documentation must include a design specification. The specification must show the minimum and maximum exposure level the dosimeter can record during routine processing.
6. A procedure for checking the proper assembly of dosimeter cards and/or film packets must be documented.
15. A person must be assigned responsibility for the receipt of in-service and background control dosimeters. There must also be a procedure to cover this. The procedure must include:
 - The individual dosimeter identification, the dosimeter type, and the appropriate processing protocol to be followed
 - Identifying and coding internal and external control dosimeters
 - A mechanism for tracking an individual dosimeter and/or sensitive element through the processing cycle

- A mechanism for identifying dosimeters that have not been returned by clients for processing
 - A method for screening dosimeters or TL elements for significant contamination prior to readout
 - A method for identifying mishandled background control dosimeters.
16. The location of dosimeters within the laboratory must be documented.
 17. Environmental parameters, including background radiation, must be monitored in dosimeter storage areas to ensure adequate storage conditions.

Thermoluminescence Dosimeters (TLDs)

1. Equipment for reading out and annealing TL elements must be appropriate for the system.
2. A written procedure must exist and responsibility must be designated for establishing and checking appropriate instrumentation operating conditions. This check may include the following:
 - Reproducible positioning of the TL element in the reader
 - Stabilization against voltage change or drift in dark current when applicable
 - Reproducible heating cycle that ensures readout of a consistent fraction of relevant stored energy
 - Glow curve output
 - Inert-gas purging
 - Digital readout.
3. A method for removing sensitive elements from the dosimeter case must be documented and implemented. The method must preclude losing information from the sensitive element.
4. The operation and stability of TLD readers must be checked at least daily using pre-exposed dosimeters or light sources. Records must indicate that no dose measurements are made until equipment conditions have stabilized.
5. Sufficient measurements must have been made to establish the relationship between the TL emission-dose characteristics and the conversion factor. The conversion factor is used to convert instrument reading to dose equivalent.
6. Technicians must understand operating conditions and critical functions of TLD processing equipment, including:
 - Heating/temperature cycle
 - Inert-gas purging

- Annealing cycle
 - Recognition and resolution of equipment failure.
7. Procedures for loading and unloading the TL reader must be implemented as documented.
 8. The processing protocol must include reviewing selected dosimetry data during the readout cycle.
 9. Before they are issued, TLDs or phosphors must be subject to an adequate annealing cycle. The annealing cycle must be reproducible regarding time, temperature, cooling rate, humidity, and light.
 10. Background readings must be checked according to an established procedure before TLDs are issued.
 11. Precautions must be taken to minimize the exposure of light-sensitive TL materials to light.
 12. Precautions must be taken to avoid the contamination of TL elements (e.g., by chalk, dust, grease, or any radioactive material).
 13. Loading sensitive elements must be carried out in a well-defined order. Loading procedures must prevent confusion in handling visually-similar elements of different TL materials and contamination of TL material in powder form.
 14. To prevent damage or unknown exposure during transit, TLDs must be suitably packaged for issue to users.
 15. TL material fading under normal conditions must be documented and accounted for over the period of intended use.
 16. The TL material for each dosimeter type or model must be capable of withstanding heat treatment required in the dosimetry process.

Film Dosimeters

1. An acceptance procedure must be in place to verify film as received meets the manufacturer's specifications. It must further verify the film's expiration date is beyond the anticipated time of use and processing.
2. Equipment, facilities, and materials must be adequate to support the film processing operations for which accreditation has been requested.
3. Film-processing darkroom(s) must be temperature-controlled and have properly installed safelights. They must either use incandescent lights or be able to demonstrate nonincandescent lights do not affect the dosimeter results.

4. Safelights used in darkrooms must be tested at prescribed intervals. Testing shall measure the fog level of exposed films. Exposure shall be at the normal working distance from the safelights for a period comparable to the maximum processing time.
5. Precautions must be taken to prevent accidentally exposing the films to light while they are being processed.
6. Processing chemicals must be dated and properly stored. A procedure must exist for their disposal when their shelf life expires.
7. Tanks and equipment that hold or are exposed to processing solutions must be chemically inert.
8. The equipment must be capable of measuring film densities equivalent to an optical density of 0.01 to 5. Resolution shall be $\pm 10\%$ or ± 0.01 density units, whichever is greater, and the equipment must be adequate to support the workload.
9. Records must demonstrate the accuracy and reliability of all instruments used to determine the gross density of specimen and control films.
 - Densitometer performance must be checked for consistency before use.
 - Densitometers must be calibrated at the most frequent of these three intervals:
 - As the manufacturer recommends
 - Biannually
 - As directed in the processing protocol.
10. Films must be removed in the darkroom and loaded in identifiable order in film racks for processing.
11. Through quality control films, the dose density characteristics of each film emulsion batch must be established. A known relationship with the master algorithm for the dosimeter model must also be established.
12. Quality control films of the same emulsion lot must be included in each processed batch. The quality control films should be exposed to known doses that adequately check the response curve of the dosimeter type. They must be positioned at the beginning and end of each processing batch and at intervals as defined in the processing protocol.
13. At least two unexposed films of the same emulsion lot must be included in each processed batch.
14. Processing control films must be verified as meeting control limits before routine processing activities are initiated.
15. As a minimum, the contractor must follow the film manufacturer's recommendations when adopting chemistry and processing conditions in the processing protocols.
16. Before it is issued, film must be stored unopened. The storage location must be cool, dry, free from chemical vapors or other deleterious agents, and have low background radiation.
17. Film must be current. It must be stored so as to reduce buildup of density due to natural background radiation and/or deterioration with age.
18. Before film is issued, its emulsion lot number must be noted and each lot must be tested. Testing shall check that the fog level, dose density, and spectral characteristics are satisfactory.
19. To prevent damage or unknown exposure during transit, film dosimeters must be suitably packaged for issue to users.
20. Records must show that temperatures and times for development, stop bath, fixing, washing, and drying are reproducible and consistent with processing protocols.
21. Developer/fixer solutions must be kept covered to reduce oxidation and exclude contamination.
22. During development, the developing solution must be agitated to provide for the uniform development of all film.
23. Procedures must be documented and followed to allow the appropriate time lapse between preparing developer and fixer solutions and using them. They must also document and follow the time lapse for discarding or replenishing these solutions according to how long they are used or how many films are processed.
24. If a stop bath is used, procedures must be documented and followed for using and renewing it.
25. Fixing procedures must be documented. They shall be implemented according to the manufacturer's recommendations.
26. Washing procedures after fixing must be as documented.
27. The temperature difference in adjacent processing solutions must not exceed 3°C .
28. Records must indicate the apparatus used to dry film does not exceed the appropriate drying temperatures. Drying temperatures must be documented in the processing protocol.

29. After processing, films must be stored so they may be retrieved without damage to the emulsion.
30. Films must be examined for nonuniform blackening. A special measurement procedure must be defined for those showing significant non-uniform blackening.
31. All measurements made must be recorded with film identification codes.
32. Track detectors must be evaluated using optical or counting equipment appropriate for the anticipated macro- or microscopic track dimension.

Calibration

1. Calibration and verification practices for dosimetry systems must be outlined in the QA manual. The manual must identify the calibration services, reference materials, and measurement assurance programs used.
2. Dosimetry systems must be calibrated to known doses from radioactive sources or radiation-generating machines. The calibration facility radiation fields must be measured with calibrated instruments. Instrument calibrations must be traceable to national standards or based on the measurement of activity of a source. In the latter case, the source must be traceable to primary radiation standards. Care must be taken to maintain a standard source geometry.
3. Calibration protocols used must be appropriate for the sources of radiation at the facility and the potential exposure levels.
4. The energy response of each type or model of dosimeter must be characterized by calibrating each model for all appropriate radiation categories. The dosimeter response must be determined over the exposure range for which it is to be used.

Processing

1. The processing protocol must be documented in sufficient detail that it can be followed by a competent technician.
2. All processing personnel must adhere to processing procedures defined in processing protocols.
3. A comprehensive record of processing activities (i.e., a dated log) must be maintained. The log must contain sufficient identification to

allow correlation with calibration/verification and control system records. This record must be available for inspection in the processor's facility.

4. When any deviation from using documented processing procedures, equipment, or facilities occurs, records must show performance remained satisfactory during the period in which the deviation occurred.
5. The individual technically responsible for dosimetry processing or his/her assigned representative must give final approval of dosimetry data. This person must also make decisions regarding questionable data.
6. The algorithm must be satisfactorily documented to indicate its validity for dose interpretation. Documentation must indicate:
 - The algorithm was created and tested using fundamental data that are retrievable.
 - The uncertainty analysis of the algorithm characterizes the precision and accuracy of the dose interpretation to the dosimeter.
 - Process controls were considered and documented when the algorithm was developed.
 - The attributes and limitations of the algorithm are documented.
7. Computational models or algorithms for calculating dose from raw data must be adequate for the processor's dosimetry system.
8. All processing protocols must be audited to ensure no degradation of performance occurs.
9. Each processing protocol must provide for interspersing quality control dosimeters. These dosimeters must have a predetermined relationship to the primary calibration dosimeters as follows:
 - Suitable sources must be used to irradiate the quality control dosimeters.
 - Records must indicate good reproducibility for the irradiation method.
 - Evaluation of the quality control data must be outside the control of the processing technician.
 - The contractor must have determined how frequently blank and quality control dosimeters shall be used. This determination must be based upon the total number of dosimeters processed, equipment stability, the type of quality control checks used, or other suitable means.
10. The dose of quality control dosimeters must be determined either from measurements using a transfer-standard quality instrument or by

calibration from a source of known activity. Instrument calibration and the activity of the source must be directly traceable to primary standards.

11. A procedure must exist for a detailed review of data produced between the last successful quality control dosimeter and the first quality control dosimeter failing to meet control limits.
12. Dose measurements must be identified and recorded at the time of measurement.
13. The useful dose range for the dosimetry system must be established and documented in each radiation category of interest.
14. Control limits to accept dose measurement data from in-service dosimeters must be defined and implemented.
15. The technical director or a designee must review dosimeter data for anomalies before reporting the dose.

Reports

1. The QA manual must outline practices for handling and resolving contested dosimetry data and test reports.

2. The dose report must include:

- Name and address of processor, if different from contractor
- Name of contractor
- Pertinent dates and the identification of dosimeters, including processor and contractor identification codes, if appropriate
- An explanation of any deviation from routine processing procedures if the deviation could affect the reported dose
- The signature of or a reference to the person having technical responsibility.

Testing

1. Protocols for proficiency testing in accordance with the DOE Standard must be defined. They must be consistent with routine processing procedures.
2. A written test plan for each radiation category for which accreditation is sought must be available to the processing staff.

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