




PROGRAM HANDBOOK
for the
ACCREDITATION OF
SUPPLIERS OF CALIBRATED RADIOACTIVE SOURCES
by the
HEALTH PHYSICS SOCIETY



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1. INTRODUCTION


This handbook provides a comprehensive description of the program under which the Health Physics Society (HPS) accredits laboratories that produce NIST-Traceable radioactivity sources. This is the primary informational document for that program, and is intended for general distribution and reference. It contains statements of the policy under which the program operates. It also describes program operating procedures in a general sense, as well as general requirements for accreditation.

This handbook does not contain detailed program operating procedures or the detailed criteria used to evaluate a laboratory for accreditation. Those are found in the CRITERIA for Accreditation document available from the HPS.

1.1 Background

The need for maintaining traceability of radioactivity standards to the National Institute of Standards and Technology (NIST) has been widely recognized and accepted in the United States. Regulatory agencies, quality assurance organizations, and radio-analytical laboratories have adopted this concept. The quality of radiochemical measurements is directly impacted by the accuracy of radioactivity sources used for calibration of instrumentation. Many of these measurements are used to meet guidelines for the protection of the public and workers from radioactive effluents and for remediation of contaminated sites. In spite of the need for assuring the traceability of radioactivity sources, the mechanism for demonstrating NIST traceability has been somewhat ambiguous at best. The publication of ANSI Standard N-42.22 "Traceability of Radioactivity Standards to the National Institute of Standards and Technology (NIST) and Associated Instrument Quality Control in November 1995 provides a defined method for laboratories to establish NIST-Traceability for radionuclide sources that are certified for alpha, beta, x-, or gamma-ray emission rate. Although this standard provides for proficiency testing and implementation of a quality assurance program, there is no mechanism to assure implementation of the standard. The ANSI-42RM Subcommittee on Radioactivity Measurements recommended that an accreditation program be established to ensure that manufacturers claiming NIST-Traceability are implementing the standard. The Health Physics Society recognized the need for accreditation and agreed to sponsor the accreditation program.

Proficiency testing for this program is currently provided by the Nuclear Energy Institute (NEI) /NIST Measurements Assurance Program (MAP). This MAP was developed in 1987 by the nuclear power industry to provide a means for laboratories to demonstrate measurement traceability with NIST. The NEI/NIST program is funded and managed by a steering committee, which includes representatives from all participating laboratories. If NIST develops other proficiency testing programs that meet ANSI N42.22 requirements, these may also be used. This program is not limited to commercial or private laboratories although all participants must be members of NEI. Exceptions may be made for government laboratories or agencies that prohibit membership in NEI due to agency policies.

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The goal for the accreditation program is to verify that laboratories are implementing ANSI-N42.22 and are participating in the NEI/NIST proficiency testing program in accordance with requirements. This requires that: (1) documented performance criteria be met; (2) periodic proficiency testing of the laboratory with NIST are satisfactorily completed, (3) documented QA procedures are followed; and (4) documented procedures are used to provide services to customers.

Steps in the accreditation process include submittal of an application with supporting information, review of the laboratory procedures manual (also called the quality manual), proficiency tests with NIST, on-site assessment by peer assessors, resolution of deficiencies (if any), and final review and decision.

A calibration laboratory that has been accredited under this program has demonstrated a high level of competence, which has been formally acknowledged through the HPS program. Customers who use the accredited services of such laboratories are making the most meaningful link to the national physical measurement standards maintained by NIST. The periodic (usually annual) proficiency testing of accredited laboratories provides the strongest possible form of what is commonly called “traceability”. That, along with the required routine quality control procedures, provides reasonable assurance that high-quality performance is consistently available from an accredited laboratory.

1.2 Program Summary

The program developed by the HPS became operational in 2004. It was developed by the private sector but is available to any laboratory desiring to produce NIST-traceable radioactivity sources. Two HPS committees administer the program, assisted by a headquarters staff person and a technical director. The Policy Committee has responsibility to establish and maintain the policy and procedures for operation of the program, to provide independent oversight, and to develop and maintain the criteria used for assessment of laboratories. The Assessment Committee performs assessments of applicant laboratories and grants accreditation, subject to concurrence by the Policy Committee and the HPS Board.

Important characteristics of the program are as follows:


Scope. Accreditation of manufacturers to produce NIST-traceable radioactivity sources calibrated for alpha, beta, x-, and gamma-ray emission rate.

Levels of Accreditation. Secondary only (i.e. one step removed from NIST which is the national primary level)

Period of Accreditation. Three years, renewable for additional three-year periods.


Proficiency Testing. Accredited laboratories are tested annually by NIST.

Criteria. HPS document entitled "Criteria for Accreditation of Calibration Laboratories by the HPS" which is consistent with ISO/IEC 17025.

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On-Site Assessment. Conducted before initial accreditation and before renewal of accreditation. Monitoring visits may be conducted randomly or in response to perceived need. Assessors are technical peers.

Fees. At cost, based on the requested scope of accreditation.

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2. POLICY AND PROCEDURES

This part of the handbook describes the general policy and procedures used for operation of the program. The specific, sequential actions taken during the accreditation process are described in the next part of this handbook.

2.1 Definition of Accreditation


Accreditation is a formal recognition of a laboratory's competence at a specified time. It means that the laboratory was evaluated and was found to satisfy the pertinent parts of the documented ANSI-N42.22 standard and "Criteria for Accreditation of Calibration Laboratories by the HPS". It means that all of the required elements were present at the laboratory for carrying out the functions for which accreditation was granted, in terms of staff, equipment, procedures, quality control, and all the other items covered by the Criteria. Accreditation does not guarantee (i.e., certify) that a laboratory's services are or always will be provided with the level of accuracy it claimed and demonstrated, and for which it was accredited. The HPS does not monitor the daily operations of an accredited laboratory, and therefore is not responsible for the quality of the work performed. The process of evaluation described in this handbook has the purpose of determining and recognizing the soundness of a laboratory's procedures and competence at the time of evaluation.

2.2 Scope of Accreditation

A laboratory may be accredited to calibrate radioactivity sources over a range of ionizing radiation types, energies, and geometries. The extent of this range is described in the pertinent parts of the "Criteria for Accreditation of Calibration Laboratories by the HPS". An individual laboratory is accredited for a particular set of radiation types, energies, and procedures, as requested by the laboratory and specified in the Scope of Accreditation granted by the HPS.

2.3 Levels of Accreditation

The HPS accredits laboratories that produce NIST-Traceable sources at the secondary level (i.e. direct traceability to NIST).

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2.4 Basic Conditions for Accreditation

To become a candidate for and maintain accreditation, the management of a laboratory must agree to the following conditions:

- 2.4.1 To meet and maintain compliance with applicable parts of ANSI N42.22 and "Criteria for Accreditation of Calibration Laboratories by the HPS"
- 2.4.2 To participate in required proficiency testing through NIST MAP for achieving or maintaining accreditation initially and on a periodic basis.
- 2.4.3 To claim or imply (including advertising) accreditation only for those characteristics and procedures listed in the Scope of Accreditation. The Scope of Accreditation can be amended to add radionuclides or calibration techniques prior to a triennial review by providing the HPS evidence of a successful proficiency test with NIST for the radionuclide or technique of interest. The laboratory shall also claim accreditation only for radionuclides calibrated in accordance with the laboratory's approved Quality Manual.
- 2.4.4 To report to the HPS the details of major challenges regarding the quality of services provided including audit findings by clients that require corrective action.
- 2.4.5 To include in radionuclide certificates to external clients a statement that the user of the laboratory's services may contact the HPS to report any problems with radioactivity sources.

2.5 Accreditation Period


A laboratory is granted accreditation for a period of three years beyond the date of notification.

2.6 Proficiency Test

The nature of the proficiency test will be commensurate with the scope of accreditation desired. Each applicant laboratory will be tested before initial accreditation. Each accredited laboratory will be tested annually for comparative calibration techniques and triennially for absolute calibration techniques

Although it is desirable that each radionuclide/technique be included in the testing program, it is not feasible that an initial or subsequent annual proficiency tests include every radionuclide that is certified by the laboratory. Instead, tests for calibration of radionuclides can be performed by radiation type, instrument type, and procedure. It is expected that as many radionuclides/techniques as possible will be tested over time. Additional details and requirements for proficiency tests are given in "Criteria for Accreditation of Calibration Laboratories by the HPS".

2.7 Authorized Representative

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Each applicant laboratory shall designate an individual who will serve as its authorized representative. That individual will be the principal contact for the HPS with the laboratory during the accreditation process. The authorized representative shall also sign the application form, thereby committing the laboratory to the basic conditions for accreditation listed in section 2.4.

2.8 Keeping the HPS Informed

An applicant or accredited laboratory shall promptly inform the HPS of any changes that may have adverse impact on the quality of its services. Such changes include organizational structure, management, facilities, technical manager, laboratory supervisor, and calibration procedures. The HPS will make an assessment of the resultant impact, and determine what actions, if any, need to be taken regarding the accredited status of the laboratory.

2.9 Additions to the Scope of Accreditation

An accredited laboratory may at any time request an addition to its scope of accreditation. That request shall be submitted as an application for accreditation, and will be processed in the same manner as the original accreditation. The need for an additional proficiency test or on-site assessment will be examined and determined in consultation with the laboratory.

2.10 Fee Structure


The fee structure is designed to cover HPS expenses related to accreditation of a laboratory. Information concerning the current fee structure may be obtained from the HPS Secretariat.

Complications in the accreditation process, such as difficulty in achieving a successful proficiency test, or deficiencies noted during an on-site assessment that require an extended first visit or a second visit, can increase the cost of accreditation.

The estimated overhead expenses are intended to recover the Society's costs for operation of this program. At the end of each operating year, an accounting of all such expenses will be made and each laboratory accredited and charged in that year will be credited with properly apportioned surplus funds, or will be required to pay a properly apportioned share of any deficit. It shall be the responsibility of the Assessment Committee to limit this deficit such that no secondary assessment levied will exceed 20 percent of the original accreditation fees.

2.11 Damage or Loss of Radioactivity Sources

The HPS assumes no liability for damage or loss of radioactivity sources submitted to NIST for calibration or testing while at the laboratory or in transit.

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3. THE ACCREDITATION PROCESS

This part of the handbook describes the specific actions taken during the accreditation process. This process applies to both the initial accreditation and each renewal of accreditation.

Accreditation will be granted upon successful completion of the following sequential actions that constitute the process: application for accreditation; review of the quality manual; proficiency testing; on-site assessment; deficiency notification and resolution; evaluation and recommendations; accreditation decision and notification.

3.1 Application for Accreditation

An application package that includes an application form, the criteria for accreditation, and the program handbook may be requested from the HPS by telephone or mail. A laboratory interested in becoming accredited shall submit a properly completed application form to the HPS. The applicant shall specify the scope of calibrations for which accreditation is sought.

The application will be reviewed to determine the nature of the candidate laboratory's organizational structure, personnel, facilities, and radiation sources.

3.2 Review of the Quality Manual


When it has been determined that the applicant meets the preliminary organizational and facility requirements, the laboratory will be requested to submit its quality manual for review. The manual will be reviewed to determine whether it contains all the information required by the "Criteria for Accreditation of Calibration Laboratories by the HPS". Emphasis will be placed on review of the procedures used by the laboratory for quality control and production of sources. When the quality manual is found to be satisfactory, proficiency test data will be supplied for review.

3.3 Proficiency Testing

The candidate laboratory will participate in proficiency testing conducted through a NIST MAP within one year from the date of application for accreditation. Proficiency test that were performed prior to application for accreditation can be submitted subject to the following provisions: the tests were performed not earlier than one year prior to application, and the sources were manufactured in accordance with the quality manual submitted with the accreditation package.

A candidate laboratory that fails its first proficiency test will receive priority for a second test. If the second test is also failed, the accreditation process shall be discontinued. If the laboratory continues to be interested in becoming accredited, it shall reapply by submitting a properly completed application form to the HPS.

When results have been obtained that are within the appropriate limits prescribed in the "Criteria for Accreditation of Calibration Laboratories by the HPS" an on-site assessment of the candidate laboratory will be scheduled.

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3.4 On-Site Assessment

A visit to the candidate laboratory's facilities will be conducted to assess compliance with the relevant parts of the "Criteria for Accreditation of Calibration Laboratories by the HPS. The laboratory shall demonstrate its operational procedures and shall permit the review and examination of any records or other documents required by the Criteria. An exit interview will be held with the laboratory management at the conclusion of the visit to summarize the findings. The laboratory will be notified of deficiencies discovered and that it will be given an opportunity to correct them before formal accreditation recommendations are made. Failure of the laboratory to cooperate during the visit may be cause for taking adverse accreditation action.

The initial on-site assessment team for a candidate laboratory will consist of three members: a representative of NIST; and two members named by the HPS Assessment Committee. Follow-up assessments shall consist of 2-3 members depending on the scope of accreditation and the needs of the assessment team as determined by the LAAC.

A candidate laboratory may request replacement of an assessor if it can demonstrate that the original assignment of a particular assessor constitutes a conflict of interest.

3.5 Deficiency Notification and Resolution

If deficiencies are identified during the on-site assessment, the laboratory will be given written notification of those deficiencies and a reasonable period in which to correct or resolve them. Because deficiencies vary in degree, and corrections may take various forms, the Assessment Committee shall exercise judgment regarding confirmation of corrections. Options include a letter from the laboratory that explains how corrections were made or a visit to the laboratory for visual confirmation.


3.6 Evaluation and Recommendations

After any deficiencies found during the on-site assessment have been corrected and it appears that all requirements for accreditation have been satisfied, the Assessment Committee will initiate a final technical evaluation before recommending accreditation. The final evaluation will be performed by a team selected for that purpose, and will consider whether these requirements have been satisfied:

- Adequate quality manual
- Satisfactory proficiency tests
- On-site assessment
- Correction of deficiencies (if any)
- Payment of fees.

Satisfactory completion of this final evaluation process results in a recommendation of accreditation.

3.7 Accreditation Decision and Notification

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Based on the recommendation from the Laboratory Accreditation Assessment Committee (LAAC), and subsequent concurrence by the Laboratory Accreditation Policy Committee (LAPC), the HPS Board of Directors may approve or deny the recommended accreditation at its discretion. After the Board has approved a recommended accreditation, the Assessment Committee will send to the applicant laboratory a letter that officially grants accreditation. The effective date and the expiration date will be indicated. A scope of accreditation and a certificate of accreditation will subsequently be issued.

If accreditation is denied, the laboratory will be notified of the reason for denial.

3.8 Monitoring Visits

In addition to scheduled on-site assessments, monitoring visits of limited scope may be used to assure that an accredited laboratory continues to comply with the pertinent Criteria for Accreditation. Monitoring visits may be conducted randomly (without cause) or in response to problems perceived by the Assessment Committee (with cause). A laboratory may or may not be contacted in advance of a monitoring visit.

Accredited laboratories will not be charged the costs of random monitoring visits since a part of the accreditation fee will contribute toward those costs. The expense of a monitoring visit conducted because of a perceived problem will be borne by the accredited laboratory visited.

During the three-year accreditation period, it may become necessary to revisit an accredited laboratory because of significant changes that are directly related to its accredited status. Those changes that may cause a re-assessment of the laboratory include replacement of key personnel, major changes in calibration procedures or quality control, replacement of critical items of equipment or radiation sources, or relocation of the facility. If such a revisit becomes necessary, its cost will be borne by the accredited laboratory.


3.9 Renewal of Accreditation

If an accredited laboratory desires renewal of accreditation, an application in accordance with Section 3.1 must be submitted to the HPS no later than six months before the current accreditation expires. This will allow sufficient time to complete the evaluation for renewal before expiration of the current accreditation.

3.10 Termination or Revocation

An accredited laboratory may voluntarily terminate its accreditation at any time. Likewise, an applicant laboratory may voluntarily withdraw its request at any time prior to the completion of action on the request. The applicant laboratory will be responsible for the costs incurred up to the time of withdrawal.

If the Assessment Committee finds that an accredited laboratory has violated the Basic Conditions for Accreditation, the chair of the Committee, after consultation with the laboratory, may notify the laboratory that revocation of its accreditation is proposed. The laboratory shall have 30 days from receipt of notice in

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which to appeal to the Policy Committee by requesting a hearing. If the hearing is not requested, the revocation becomes final