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|  | <i>HPS INSTRUMENT CALIBRATION ACCREDITATION HANDBOOK</i> | Issue Date: | Rev. #1 |
| REVISION 1 was approved by the HPS BOD on 7/22/2004 | | 7/22/2004 | Page 1 of 12 |

PROGRAM HANDBOOK

for the

ACCREDITATION OF INSTRUMENT CALIBRATION LABORATORIES

by the

HEALTH PHYSICS SOCIETY



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|---|--|----------------|--------------|
|  | HPS INSTRUMENT CALIBRATION ACCREDITATION HANDBOOK | Issue Date: | Rev. #1 |
| | REVISION 1 was approved by the HPS BOD on 7/22/2004 | 7/22/2004 | Page 2 of 12 |

Table of Contents

| | |
|---|----|
| 1. INTRODUCTION | 3 |
| 1.1 Background | 3 |
| 1.2 Program Summary | 4 |
| 1.3 Evolution of the Program | 5 |
| 2. POLICY AND PROCEDURES | 6 |
| 2.1 Definition of Accreditation | 6 |
| 2.2 Scope of Accreditation | 6 |
| 2.3 Levels of Accreditation | 6 |
| 2.4 Basic Conditions for Accreditation | 7 |
| 2.5 Accreditation Period | 7 |
| 2.6 Proficiency Test | 7 |
| 2.7 Authorized Representative | 8 |
| 2.8 Keeping the HPS Informed | 8 |
| 2.9 Additions to the Scope of Accreditation | 8 |
| 2.10 Fee Structure | 8 |
| 2.11 Damage or Loss of Instruments | 8 |
| 3. THE ACCREDITATION PROCESS | 90 |
| 3.1 Application for Accreditation | 10 |
| 3.2 Review of the Quality Manual | 10 |
| 3.3 Proficiency Testing | 10 |
| 3.4 On-Site Assessment | 11 |
| 3.5 Deficiency Notification and Resolution | 11 |
| 3.6 Evaluation and Recommendations | 11 |
| 3.7 Accreditation Decision and Notification | 12 |
| 3.8 Monitoring Visits | 12 |
| 3.9 Renewal of Accreditation | 12 |
| 3.10 Termination or Revocation | 13 |
| 4. REFERENCES | 13 |

| | | | |
|---|--|----------------|--------------|
|  | <i>HPS INSTRUMENT CALIBRATION ACCREDITATION HANDBOOK</i> | Issue Date: | Rev. #1 |
| | REVISION 1 was approved by the HPS BOD on 7/22/2004 | 7/22/2004 | Page 3 of 12 |

1. INTRODUCTION

This handbook provides a comprehensive description of the program under which the Health Physics Society (HPS) accredits laboratories that calibrate portable radiation protection instruments. 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 following companion documents available from the HPS:


- Accreditation Criteria for Health Physics Society Accredited Calibration Laboratories, American Health Physics Society Document, Laboratory Policy Accreditation Committee
- Program Operating Procedures, Health Physics Society Document

The HPS operates a separate accreditation program for the accreditation of “Suppliers of Calibrated Radioactive Sources.” This program became active in 2004 and is described in a separate handbook and separate supporting documentation. However, a single criteria document with appendices covers the two areas of accreditation.

1.1 Background

In 1981 the National Institute of Standards and Technology (then called the National Bureau of Standards), after broad concurrence from the radiation measurement community, published the results of a study that showed that secondary laboratories were needed in three distinct sectors: state, private, and federal (NBS Special Publication 603, Requirements for an Effective National Ionizing Radiation Measurements Program). Expressed reasons for maintaining this sector distinction included: (1) the system had already developed along those lines; (2) regulatory relationships; and (3) the desire to avoid possible conflicts of interest. It was felt, for example, to be inappropriate for a regulatory agency to have its instruments calibrated by a licensee who would then be inspected with those same instruments. Some members of the measurement community felt that only a program developed by a particular sector would be sufficiently responsive and effective in satisfying the specific needs of that sector. In response to such concerns, three programs were developed that now constitute the national system. The state-sector program is operated by the Conference of Radiation Control Program Directors (CRCPD), the program developed by and for the federal sector is operated by the National Voluntary Laboratory Accreditation Program (NVLAP), and the program aimed at the private sector is operated by the HPS.

Although the programs were developed and are operated in three distinct sectors, they have in common the four basic elements considered to be essential for measurement quality assurance (MQA) in a secondary laboratory: (1) documented performance criteria that must be met; (2) periodic proficiency testing of the

| | | | |
|---|--|----------------|--------------|
|  | <i>HPS INSTRUMENT CALIBRATION ACCREDITATION HANDBOOK</i> | Issue Date: | Rev. #1 |
| | REVISION 1 was approved by the HPS BOD on 7/22/2004 | 7/22/2004 | Page 4 of 12 |

secondary laboratory by NIST; (3) documented quality assurance procedures that are routinely followed; and (4) documented procedures used to provide services to customers. Further commonality exists because each program was developed in close collaboration with, and with guidance from, the NIST Office of Radiation Measurement.

The three programs also use the same procedures for evaluation of candidate laboratories. Steps in that process include submittal of an application with supporting information, review of the laboratory procedures manual (also called the quality manual), proficiency test by NIST, on-site assessment by peer assessors, resolution of deficiencies (if any), and final review and decision.

Thus, with regard to the essential MQA elements and the evaluation procedures, the three programs are similar. A calibration laboratory that has been accredited under any of these three programs has demonstrated a high level of competence, which has been formally acknowledged. 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 secondary laboratories by NIST and, as in the HPS program, testing of tertiary laboratories by secondary 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 1987. It is aimed at the private sector but is available to any laboratory that calibrates portable instruments used for radiation protection. 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 accreditations, subject to concurrence by the Policy Committee and the HPS Board.

Important characteristics of the program are as follows:


Scope. Calibration of portable radiation protection instruments using gamma rays, x rays, beta particles, neutrons, and alpha particles.

Levels of Accreditation. Secondary and tertiary (i.e., one and two steps removed from NIST, which is the national primary level).

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

Proficiency Testing. Performed annually. Secondary laboratories are tested by NIST, and tertiary laboratories are tested by secondary laboratories.

Criteria. HPS document entitled “Accreditation Criteria for Health Physics Society Accredited Calibration

| | | | |
|---|--|----------------|--------------|
|  | <i>HPS INSTRUMENT CALIBRATION ACCREDITATION HANDBOOK</i> | Issue Date: | Rev. #1 |
| | REVISION 1 was approved by the HPS BOD on 7/22/2004 | 7/22/2004 | Page 5 of 12 |

Laboratories,” which is consistent with the international standard ISO/IEC 17025, “General requirements for the competence of testing and calibration laboratories.”

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.

1.3 Evolution of the Program

The initial program was based on criteria developed by an ad hoc committee of experts in the field of instrument calibration. In 1991 the program was re-evaluated and specific changes were made to strengthen it. The responsibilities of the two committees were better defined and detailed in operational procedures, the need for the two committees was reaffirmed, and a technical director (TD) position was created to ease the burden on the volunteer committee members and to improve responsiveness. The criteria were also changed at this time to incorporate guidance from ISO/IEC Guide 25, “General requirements for the competence of testing and calibration laboratories.” This included changes in format of the criteria document and in some of the general requirements, but no changes were made to the technical requirements.

In 2002 the criteria document was upgraded and reformatted to include requirements from the international standard ISO/IEC 17025, “General requirements for the competence of testing and calibration laboratories.” The new standard links the accredited laboratories closely to the widely accepted quality standards ISO 9000, 9001, and 9002 through cross compatibility of requirements. This change was undertaken to upgrade the program to an approved standard (ISO/IEC Guide 25 was withdrawn when 17025 was approved) and to prepare the program for recognition by NACLA, the National Cooperation for Laboratory Accreditation. NACLA accredits accrediting programs using guidance in ISO Guide 58. The recognition by NACLA will bring acceptance of the program by both national and international bodies. Thus, the work of HPS-accredited laboratories will be widely accepted for its quality.

The application, operating procedures, and program handbook were reviewed and revised at the same time. Minor changes were made to the technical criteria, including the addition of criteria for calibration of instruments at low dose rates. These criteria had previously been approved as a separate document.

| | | | |
|---|--|----------------|--------------|
|  | <i>HPS INSTRUMENT CALIBRATION ACCREDITATION HANDBOOK</i> | Issue Date: | Rev. #1 |
| | REVISION 1 was approved by the HPS BOD on 7/22/2004 | 7/22/2004 | Page 6 of 12 |

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 HPS Criteria for Accreditation of Calibration Laboratories. It means that all of the required elements were present at the laboratory for carrying out the calibration 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 calibration procedures and competence at the time of evaluation.


2.2 Scope of Accreditation

A laboratory may be accredited to calibrate instruments over a range of ionizing radiation types, energies, and intensities. The extent of this range is described in the pertinent parts of the Criteria for Accreditation of Calibration Laboratories. An individual laboratory is accredited for a particular set of radiation types, energies, intensities, 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 calibration laboratories that satisfy criteria for either of two possible levels: secondary or tertiary (i.e., one or two steps removed, respectively, from NIST, which is the national primary level). The Criteria for Accreditation as a secondary accredited laboratory (SAL) are more stringent than the corresponding Criteria applicable to a tertiary accredited laboratory (TAL). In addition, the accreditation process for the SAL is more elaborate and expensive than the comparable process for the TAL.

2.4 Basic Conditions for Accreditation

| | | | |
|---|--|----------------|--------------|
|  | <i>HPS INSTRUMENT CALIBRATION ACCREDITATION HANDBOOK</i> | Issue Date: | Rev. #1 |
| | REVISION 1 was approved by the HPS BOD on 7/22/2004 | 7/22/2004 | Page 7 of 12 |

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 the “Accreditation Criteria for Health Physics Society Accredited Calibration Laboratories.”

2.4.2 To participate in proficiency testing that may be required for achieving or maintaining accreditation.

2.4.3 To be evaluated and audited initially and on a periodic basis.

2.4.4 To claim or imply (including advertising) accreditation only for those characteristics and procedures listed in the Scope of Accreditation.

2.4.5 In the case of services offered by a SAL, to give priority to candidate or accredited tertiary laboratories.

2.4.6 To report to the HPS the details of major challenges regarding the quality of services provided.

2.4.7 To include in calibration reports to external clients a statement that the user of the laboratory’s services may contact the HPS to report any problems with the calibration program.

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. SALs will be tested by NIST, and TALs will be tested by SALs. In addition to a proficiency test initiated by NIST, the program uses intercomparisons among laboratories and tests on the calibration of laboratory instruments to satisfy proficiency testing requirements. These alternatives are detailed in the criteria document.

It is not feasible that an initial or subsequent annual proficiency test for a particular radiation quantity should attempt to cover the entire range of exposure rates, dose rates, dose equivalent rates, fluence rates, or emission rates of interest. Instead, each test will involve only a representative part of the possible range, with the intent of covering the complete range over a period of years. Similarly, if a laboratory uses many of the x-ray beam codes, the initial proficiency test will not involve each code, but all codes will be covered in a period consisting of that and subsequent years.

2.7 Authorized Representative

| | | | |
|---|--|----------------|--------------|
|  | <i>HPS INSTRUMENT CALIBRATION ACCREDITATION HANDBOOK</i> | Issue Date: | Rev. #1 |
| | REVISION 1 was approved by the HPS BOD on 7/22/2004 | 7/22/2004 | Page 8 of 12 |

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

A current fee schedule can be obtained from the secretariat that shows the estimated costs for the accreditation of both secondary and tertiary instrument calibration laboratories. 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% of the original accreditation fees.

2.11 Damage or Loss of Instruments

The HPS assumes no liability for damage or loss of an instrument submitted to an accredited laboratory for calibration, either while at the laboratory or in transit. The accredited laboratory will be responsible for damage or loss that occurs within the laboratory but will not be responsible for damage or loss during transit.

| | | | |
|---|--|----------------|--------------|
|  | <i>HPS INSTRUMENT CALIBRATION ACCREDITATION HANDBOOK</i> | Issue Date: | Rev. #1 |
| | REVISION 1 was approved by the HPS BOD on 7/22/2004 | 7/22/2004 | Page 9 of 12 |

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. Emphasis will be placed on review of the procedures used by the laboratory for quality control and for instrument calibration. When the quality manual is found to be satisfactory, a proficiency test of the candidate laboratory will be conducted.

3.3 Proficiency Testing

The candidate SAL will participate in a proficiency test conducted by NIST, and the candidate TAL will participate in a proficiency test conducted by a SAL.

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 limit prescribed in the criteria for accreditation of calibration laboratories, an on-site assessment of the candidate laboratory will be scheduled.

| | | | |
|---|--|----------------|------------|
|  | <i>HPS INSTRUMENT CALIBRATION ACCREDITATION HANDBOOK</i> | Issue Date: | Rev. #1 |
| | REVISION 1 was approved by the HPS BOD on 7/22/2004 | 7/22/2004 | Page 10 of |

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 "Accreditation Criteria for Health Physics Society Accredited Calibration Laboratories." 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 SAL will consist of three members: a representative of NIST and two members named by the HPS Assessment Committee. Follow-on assessments will consist of a team of two to three members, depending on the scope of operation of the laboratory and recognized needs, and will be defined by the LAAC.

The on-site assessment of a candidate TAL will be conducted by a representative of the SAL assigned this responsibility by the Assessment Committee, or by an individual assigned this responsibility by the Assessment Committee.

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 test
- on-site assessment

| | | | |
|---|--|----------------|------------|
|  | <i>HPS INSTRUMENT CALIBRATION ACCREDITATION HANDBOOK</i> | Issue Date: | Rev. #1 |
| | REVISION 1 was approved by the HPS BOD on 7/22/2004 | 7/22/2004 | Page 11 of |

- 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

Based on the recommendation from the Assessment Committee, and subsequent concurrence by the Policy Committee, 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 termination 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 ensure 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

| | | | |
|---|--|----------------|------------|
|  | HPS INSTRUMENT CALIBRATION ACCREDITATION HANDBOOK | Issue Date: | Rev. #1 |
| REVISION 1 was approved by the HPS BOD on 7/22/2004 | | 7/22/2004 | Page 12 of |

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

4. REFERENCES

Accreditation Criteria for Health Physics Society Accredited Calibration Laboratories, Health Physics Society Document, Laboratory Policy Accreditation Committee.
 ISO/IEC-17025, General Requirements for the Competence of Testing and Calibration Laboratories, Geneva; 1999.