

THE HPS ACCREDITATION PROGRAM

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INTRODUCTION

The quality of a radiation protection program can be no better than the quality of the measurements made to support it. In many cases the measurement quality is unknown, and is merely assumed on the basis of the calibration of a measuring instrument. If that calibration is inappropriate, performed improperly, or based on an out-of-calibration standard, the measurement result will be inaccurate and misleading. Assurance of measurement quality can be achieved by participation in one of the national measurement assurance programs; often referred to as measurement quality assurance (MQA) programs. Such a program evaluates the appropriateness of procedures, facilities and equipment plus include periodic actions that demonstrate adequate performance. These actions include internal consistency checks, proficiency tests, and site visits by technical experts to review operations. Basically, these requirements are fulfilled by an accredited calibration laboratory as described in ISO/IEC Guide 25, and the superceding standard ISO/IEC Standard 17025, "General requirements for the competence of testing and calibration laboratories." [1] The requirements in the standard must be supported by specific technical requirements. U. S. efforts toward the establishment of accredited programs precede the two international documents.

Activities leading to the establishment of present day measurement assurance programs (MAP) were initiated in the early 1970's. The only national MAP program functioning at that time was the program for radiation therapy dosimetry calibration laboratories operated by the American Association of Physicists in Medicine. [2] In May of 1973 the Conference of Radiation Control Program Directors (CRCPD) held a workshop which led to the establishment of accreditation programs for personnel dosimetry. [3] In response to a congressional inquiry, during 1977 NBS staff (now NIST) prepared a document describing a need for a national system of secondary laboratories. This led to a Senate recommendation for a broad study in cooperation with the states. In collaboration with CRCPD the needs for state, federal, and private (commercial) sector secondary laboratories were studied along with alternatives for developing a national system. The conclusions of this study were published in early 1981 [4] and included a long-range plan for the development of a proposed laboratory system. The first sector chosen for development was the states. This effort was funded by Congress and intended to result in several regional laboratories plus a model for use by other sectors of the national measurement support system. [5] This effort along with the personnel dosimetry effort identified many of the critical elements needed in a successful MAP program. Programs are operating which serve the four sectors: medical (AAPM), states (CRCPD), commercial (HPS) and federal (NVLAP). The purpose of this note is to discuss the HPS program; its status, and expected changes.

BACKGROUND

In July of 1984, a meeting, "Workshop on Radiation Survey Instruments and Calibrations," was held at the National Bureau of Standards in Washington, D.C. The workshop considered the need for performance requirements for instruments and the need for a system of secondary calibration laboratories in the commercial sector to control the calibration of radiation protection instruments. Discussions indicated that the Health Physics Society (HPS) was the logical choice to undertake a program to accredit commercial calibration of radiation protection instruments. As a result an ad hoc committee was established by the HPS to review the logistic, financial and legal issues and provide a recommendation to the Board of Directors. The committee, chaired by F. X. Masse, provided a proposal to the Board in 1987 which was approved.

The initial program was designed to handle a large number of laboratories (20-50) with diverse capabilities. This resulted in a two tier system, secondary and tertiary laboratories, with only the secondary laboratories expected to have direct interaction with NBS (NIST). Three functional groups were established in the recommendations. The first was the "Standing" committee with the responsibility for developing the accreditation criteria, the operating procedures and providing program overview. The second committee,

the “Operations” committee, was responsible for the actual accreditation review of applicant laboratories and development of recommendations for accreditation. The third group was expected to consist of representatives of the accredited laboratories who would nominate a representative to the operations committee. The purpose was to ensure orderly growth of the program and a program that would meet the needs of the industry. The program was expected to be self supporting through fees charged the accredited laboratories. The only significant costs were expected to be the operations committee which it was felt would have to meet more frequently for training and review of laboratories along with the secretariat expenses for maintaining files and distributing documents.

Liability was an important issue with the program. As with all accreditation programs, the intent is to document the capability of the laboratory to adequately perform an activity (calibration). There is no intent to monitor laboratory activities to the extent that such calibrations can be guaranteed by the HPS. Hence, the liabilities for individual calibrations and for possible damage to instruments rest solely with the accredited laboratory. Another concern is unequal treatment of candidate laboratories or disclosure of accreditation activities (proficiency test results, failure of applicant, etc.) that could impact business. It was because of these concerns that the multi-committee structure was established and a coding system developed for the laboratories with the true identity of candidate laboratories known only by selected individuals within the “Operations” committee until the applicant was successful (recommendation for accreditation sent to the Board). Vendors often consider elements of their calibration operations proprietary and the procedures and operational structure are designed to respect this confidence.

The program was approved by the Board in 1987 and the first two laboratories were accredited in 1988; Eberline operated both laboratories. Eberline later elected to not maintain accreditation at both laboratories. Over the life of the program there have been five candidate laboratories; two are presently accredited. The program resulted in a lot of interest when first announced. Inquiries were received from 71 U.S. and foreign facilities and sporadic inquiries continue to be received.

In 1990, an ad hoc committee was formed to review the liability issue and the structure of the accreditation program. The committee concluded that liability issues were not a great concern and affirmed the initial structure with some slight modifications. The Standing committee became the Laboratory Accreditation Policy Committee (**LAPC**), with the responsibility of establishing the accreditation criteria and operating policy. The operations committee became the Laboratory Accreditation Assessment Committee (**LAAC**) and had the responsibility for performing accreditation reviews in accordance with the criteria and policy established by the LAPC and to develop a recommendation for accreditation to the Board. The LAPC still had an overview function on the accreditation activities and concurs on recommendations of the LAAC. A technical director (**TD**) position was also established at this time. This was to assist the committees with the large amount of administrative details and to ensure continuity of the program. The immediate job of the TD was to assist in revising the original criteria to be compatible with the guidance set forth in ISO/IEC Guide 25 and to complete a set of operational policies. Documented policies produced within the committees were not in a consistent format or complete. The new criteria based on Guide 25 were completed and approved in 1994. The HPS was the first group to revise criteria to meet Guide 25.

Some additional highlights for the program are noted below.

- In 1987 the AAPM dropped the survey instrument accreditation criteria at the request of Frank Masse and Robert Loevinger.
- Criteria for the Federal Laboratories program (NVLAP) were developed in 1987. The criteria were based on and nearly identical to the HPS criteria. The need for a separate program was based on the inappropriateness of having the regulatory agencies accredited by HPS members who they oversee.
- K & S Associates were accredited in 1994.
- In 1995 a meeting was held under the auspices of the Council on Ionizing Radiation Measurements and Standards to discuss the comparability of the HPS, AAPM, and CRCPD programs and the feasibility of combining programs. The conclusion was that the technical areas served were different and that different expertise was needed; particularly from the assessors. Thus they could not be effectively combined; however, it was recommended that all programs come into compliance with ISO/IEC Guide 25. [n.b., this has occurred.]

- In 1996 the Laboratory Accreditation Working Group (LAWG) met at NIST and formed the National Cooperation for Laboratory Accreditation (NACLA). The meetings were attended by HPS representatives of the accreditation program since they had important implications for the future of the HPS program.
- In 1999 K & S Associates requested that criteria be developed for accreditation at low dose rates (environmental levels). This resulted from the CIRMS National Needs Report [7], (MPD B.2) and a workshop sponsored by NIST, CIRMS, CRCPD and the DOE held in conjunction with the CRCPD annual meeting on May 3, 1999 [8]. NIST does not presently support environmental level calibrations.
- In 2001 the Board approved accreditation of K & S for low dose rates. This activity required that a proficiency test be arranged through the National Physical Laboratory (NPL) in Great Britain. NIST is now developing capability in this area.
- In 1997 the LAPC began consideration of criteria for the accreditation of source manufacturers at the request of Society membership.

EXPECTED CHANGES

The basic document that the present criteria are based on (ISO/IEC Guide 25) has been replaced by an international standard ISO/IEC 17025 which makes upgrading of the HPS program important. The standard relies heavily on other quality standards and includes cross-references to ISO 9001 and ISO 9002. The standard was adopted by ANSI as an American National Standard in November 2000. Approval as an American National Standard was through the American Society for Quality, the American Society for Testing and Materials and NCSL International. Compliance with the new standard will lead to changes in the general quality system requirements in the HPS criteria, but the technical requirements for calibrations are not expected to change significantly.

In addition, recommendations resulting from the formation of NACLA (see Appendix) provide opportunities to strengthen the value of the program to the community. NACLA recognition of the HPS accreditation program will bring national and international recognition to the Society and its programs and establish the HPS program on a level equal to that of the NVLAP program. It will add significant value to the HPS accreditation program and thus attract calibration laboratories into the HPS program, especially those that sell products and services to foreign countries. The committees are working at bringing the HPS program into compliance with ISO/IEC Guide 58, "Calibration and testing laboratory accreditation systems – General requirements for operation and recognition."

Some of the key benefits of the program and benefits that we hope to achieve with the changes that are underway include:

- Reduction of audits of the calibration labs when the programs receive national recognition with accreditation of the operating programs.
- International recognition of the calibration labs through international reciprocity agreements when the program receives national recognition through accreditation.
- Regulatory recognition of calibrations as having documented "traceability" when performed by accredited labs.
- Responsiveness to the HPS community. A very important aspect of the HPS program is the ability of the program to meet the special interests of the health physics community. An example of this is the recent development of accreditation for environmental level calibrations that are not presently supported by NIST.
- Improvement in the technical and documentary basis of calibrations.
- More confidence in the basis of radiation protection programs through the public and other groups.
- Compliance of accredited labs with key aspects of the ISO 9000 series of standards.
- Extension of the program to other aspects of radiation measurements such as source manufacturers who provide calibrated sources, to bioassay measurement laboratories, etc.

REFERENCES

1. ISO/IEC 17025:1999, "General requirements for the competence of testing and calibration laboratories." (1999-12-15)
2. Loevinger, R., "The AAPM Accredited Dosimetry Calibration Laboratories," in Proceedings of the Workshop on Radiation Survey Instruments and Calibrations, PNL-SA-113346, CONF-840774, p. 0.11, Pacific Northwest Laboratory, Richland, Washington, November 1985.
3. Gladhill, R. L., Horlick, J., and Eisenhower, E., The National Personnel Radiation Dosimetry Accreditation Program, National Bureau of Standards Internal Report 86—2350, January 1986.
4. National Bureau of Standards, Requirements for an Effective National Ionizing Radiation Measurements Program, NBS Special Publication 603, March 1981.
5. Heaton, H. T. II, "Implementation of CRCPD Accreditation Criteria in State Calibration Laboratories", in Proceedings of the workshop on Radiation Survey Instruments and Calibrations, PNL-SA-13346, CONF-840774, p. 0.22, Pacific Northwest Laboratory, Richland, Washington, November 1985.
6. ISO/IEC Guide 58:1993, "Calibration and testing laboratory accreditation systems -General requirements for operation and recognition."
7. CIRMS, "National Needs in Ionizing Radiation Measurements and Standards", second report, October 1998.
8. CIRMS, "Summary Report - Workshop on mR-Level Measurements and Standards for Public and Environmental Radiation Protection", June 1999

APPENDIX FORMATION OF NACLA

In 1994 the ACIL, ANSI and NIST jointly sponsored an informal Laboratory Accreditation Working Group (LAWG) to examine issues related to laboratory accreditation, national and international recognition US accreditation programs and consider the development of a US accreditation system. In January 1997, LAWG held an open forum at NIST to discuss the official formation of the National Cooperation for Laboratory Accreditation (NACLA). The 400 participants overwhelmingly supported the development of NACLA. In April 1998, NACLA held a workshop on the status of NACLA. The Chairman of the International Laboratory Accreditation Cooperation (ILAC) and the Director of NIST gave unequivocal endorsement to the aims of NACLA. NACLA formed a Board of Directors and incorporated as a non-profit scientific organization shortly after the April meeting.

NACLA is a non-profit corporation established to coordinate laboratory accreditation activities within the US and to serve as the US link to the international laboratory community by developing mutual recognition arrangements (MRA) with the international accreditation community (ILAC). NACLA accomplishes its mission by evaluating accreditation bodies in the US to ISO/IEC Standard 17025, "General Requirements for the competence of testing and calibration laboratories" and ISO/IEC Guide 58, "Calibration and testing laboratory accreditation systems – General requirements for operation and recognition". Laboratories judged to meet the ISO requirements are invited to be signatories to the MRA. In September 2000 NACLA recognized the first three accreditation organizations – National Voluntary Laboratory Accreditation Program (NVLAP), American Association for Laboratory Accreditation (A2LA) and the International Council of Building Officials Evaluation Service (ICBO ES).

In July 2000 a Memorandum of Understanding (MOU) was signed between NIST and NACLA for the purpose of coordinating the process of evaluating the more than 100 accrediting bodies in the US. The MOU will help coordinate the unnecessary duplication and sometimes-contradictory accreditation standards and requirements and improve the efficiency of the recognition process. Terms of the MOU call for NIST to encourage government agencies to use NACLA-recognized accreditation bodies and to

encourage laboratory accreditation bodies to seek NACLA recognition. In addition, NIST will treat NACLA recognition as a suitable alternative to its own laboratory accreditation program (NVLAP).

The AAPM has become a member of NACLA and has already decided to seek NACLA recognition within the next two years. Although the AAPM program only has 4 labs accredited and is not seeking more labs to accredit, the national and international recognition gained by NACLA recognition of the AAPM accreditation program are considered benefits to the Society that justify the cost and effort.