# SECONDARY CALIBRATION LABORATORY FOR IONIZING RADIATION LABORATORY ACCREDITATION PROGRAM NATIONAL INSTITUTE OF STANDARDS AND TECHNOLOGY NATIONAL VOLUNTARY LABORATORY ACCREDITATION PROGRAM

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*Abstract* - This paper presents an overview of the procedures and requirements for accreditation under the Secondary Calibration Laboratory for Ionizing Radiation Program (SCLIR LAP). The requirements for a quality system, proficiency testing and the onsite assessment are discussed. The purpose of the accreditation program is to establish a network of secondary calibration laboratories that can provide calibrations traceable to the primary national standards.

## INTRODUCTION

The National Voluntary Laboratory Accreditation Program (NVLAP) is administered by the National Institute of Standards and Technology (NIST). NVLAP follows the procedures contained in the U.S. Code of Federal Regulations, Title 15, Part 7, when establishing a laboratory accreditation program and accrediting laboratories which participate in that program. NVLAP is moving towards the adoption of the ISO Guide 25 in its requirements for evaluation of laboratory competence.

NVLAP currently has eleven laboratory accreditation programs (LAPs) including the Ionizing Radiation Dosimetry Program, formally the Personnel Radiation Dosimetry Program. The SCLIR LAP was established in response to a request from representatives of federally owned laboratories engaged in the calibration of devices or instruments for measuring ionizing radiation.

## CRITERIA FOR ACCREDITATION

The criteria for this program is contained in the NVLAP Program Handbook and NIST Special Publication 812 "Criteria For the Operation of Federally Owned Secondary Calibration Laboratories

(1) National Institute of Standards and Technology.

for Ionizing Radiation." The technical criteria in NIST SP-812 were developed by a group of 26 representatives of federally owned calibration laboratories.

## NVLAP ACCREDITATION

Accreditation by NVLAP signifies formal recognition of a testing laboratory's competence to perform calibrations or specific test methods in specified fields of calibration or testing. It means that NVLAP has evaluated the laboratory's quality system, staff, facilities and equipment, calibration procedures, test methods and procedures for calibrations, records, and test reports. The laboratory must also demonstrate its competence through proficiency testing, which in this program involves the comparison of calibrations performed by the laboratory and the primary standard calibration performed by the NIST Ionizing Radiation Division.

## SCOPE OF THE PROGRAM

Accreditation is available to any organization that can demonstrate the competence to perform the calibration services covered by the program. A laboratory may be accredited to calibrate specific instruments or sources of its choice in any one or more of the areas listed below.

Survey Instruments
- Gamma ray
- X-ray
- Beta particle
- Neutron
- Alpha particle

Irradiation of Personnel Dosimeters
- Gamma ray
- X-ray
- Neutron
- Beta particle

Source Calibrations
- Gamma ray

Diagnostic Instruments
- X-ray

Reference Class Instruments
- Gamma ray
- X-ray

## ACCREDITATION PROCESS

The accreditation process is divided into two stages. Stage I is a preliminary technical evaluation of the laboratory and includes a thorough review of the quality manual. To initiate this evaluation, a laboratory must submit an application with the stage one fee of $2120, currently, and three copies of its quality manual. The application requires a description of the laboratory facilities and proposed scope of accreditation. An Application Package containing the necessary forms, a Program Handbook, program criteria document, and fee information is sent to a laboratory upon request.

Stage II is the full evaluation of the laboratory which includes proficiency testing, an onsite assessment, deficiency resolution, and a technical review by a panel of technical experts. Figure 1 is a flow diagram of the Secondary Calibration Laboratory for Ionizing Radiation LAP accreditation process.

## QUALITY SYSTEM

The Quality System is defined as the organizational structure, responsibilities, procedures, processes, and resources for implementing quality management. Quality Systems are developed by the laboratory for the type of calibration or testing service performed, by tailoring the generic guidelines for a Quality System. The NVLAP requirements for a Quality System are contained in ISO Guide 25 and the NVLAP procedures in the U.S. Code of Federal Regulations, Title 15, Part 7, Section 7.33. ISO Guide 25 is an international guide for the evaluation of the competence of laboratories.

The Quality System includes the following major components: the organization and management, including a corporate quality policy, Technical and Quality Managers, personnel training and quality audits; the facilities and equipment used in performing the specific calibration or testing functions; the calibration of test equipment, reference materials, and measurement traceability to the national standards; the laboratory operating procedures for performing the calibrations and maintaining quality control; and the records and calibration certificates documenting these functions.

There must be a documented procedure for identifying items that have been received by the laboratory for calibration. This identification can be used for tracking the item from receipt until it is returned to the client with the calibration report. The reports and records that a laboratory maintains for a specific instrument calibration should be retained for at least 5 years. The test reports must contain the necessary information to verify the calibration of the instrument, and to recreate the calibration of the instrument if needed.

The Quality Manual is used to document the Quality System. It is generally one manual that describes the Quality System. It contains references to other supporting documents such as calibration records, equipment inventory and status, operating procedures for performing the specific calibration or test, proficiency testing, quality control functions, and statistical methods for controlling the quality of the laboratory function. The requirements for the Quality Manual are contained in the Program Handbook, Section 6.4, and in the ISO Guide 25, Section 5.2.

## PROFICIENCY TESTING

In order to be eligible for accreditation, each laboratory must demonstrate the calibration of an instrument by proficiency testing. The proficiency test requirements for the SCLIR LAP are contained in Appendix A of NIST SP-812. Proficiency testing is performed once prior to accreditation and then annually thereafter. If the laboratory has requested accreditation for more than one instrument category and the same radiation type, proficiency testing will only be required for the higher accuracy category. The laboratory must perform a calibration at the accuracy and uncertainty level specified for each category in NIST SP-812, in order to receive that uncertainty limit on their scope of accreditation.

The laboratory is required to perform an uncertainty error analysis for the calibration procedures for which they are seeking accreditation by NVLAP.

## ONSITE ASSESSMENT

Before initial accreditation and periodically (every 2 years) thereafter, an onsite assessment of each laboratory is conducted to determine compliance with the NVLAP criteria. The assessment is

conducted by two assessors selected on the basis of their expertise in the appropriate field(s) of calibration. One assessor is a NIST employee from the Ionizing Radiation Division, the other is a NVLAP peer assessor. An assessment normally takes 2 to 3 days depending on the extent of the laboratory's calibration services. During the assessment, the assessor will examine the quality system, calibration records, test procedures, personnel competency records, calibration reports and other quality assurance procedures. The assessor will examine equipment and facilities, and will ask to have selected procedures demonstrated.

Assessors use checklists, based on the specific criteria, during the assessment to ensure that each laboratory receives an assessment comparable to that received by others. Onsite assessments are conducted every two years, but the accreditation is renewed annually. Monitoring visits may occur between scheduled onsite assessments.

## DEFICIENCY NOTIFICATION AND RESOLUTION

A deficiency is the failure of a laboratory to meet a NVLAP criterion. Deficiencies may be determined during onsite assessments, monitoring visits, proficiency testing or technical review for initial accreditation. Laboratories are informed of deficiencies either during an onsite assessment or through other correspondence and are given an opportunity to resolve the deficiency.

## CONCLUSION

The review of the Quality Manual, proficiency testing and error analysis, and the onsite assessment, together form the basis for determination of competence leading to accreditation of laboratories that calibrate ionizing radiation measurement instruments. Laboratories accredited under this program will be at the level of a secondary standard calibration laboratory.

## REFERENCES

ISO Guide 25. 1990. "General Requirements for the Competence of Calibration and Testing Laboratories." International Organization for Standardization.

Martin, P., J. Horlick. September 1991. NVLAP Program Handbook Secondary Calibration Laboratory For Ionizing Radiation. Draft. U.S. Department of Commerce, National Institute of Standards and Technology.

Ratliff, T. A. 1990. The Laboratory Quality Assurance System. Van Nostrand Reinhold, New York.

FLOW CHART FOR: SECONDARY CALIBRATION LABORATORY FOR IONIZING RADIATION LAP

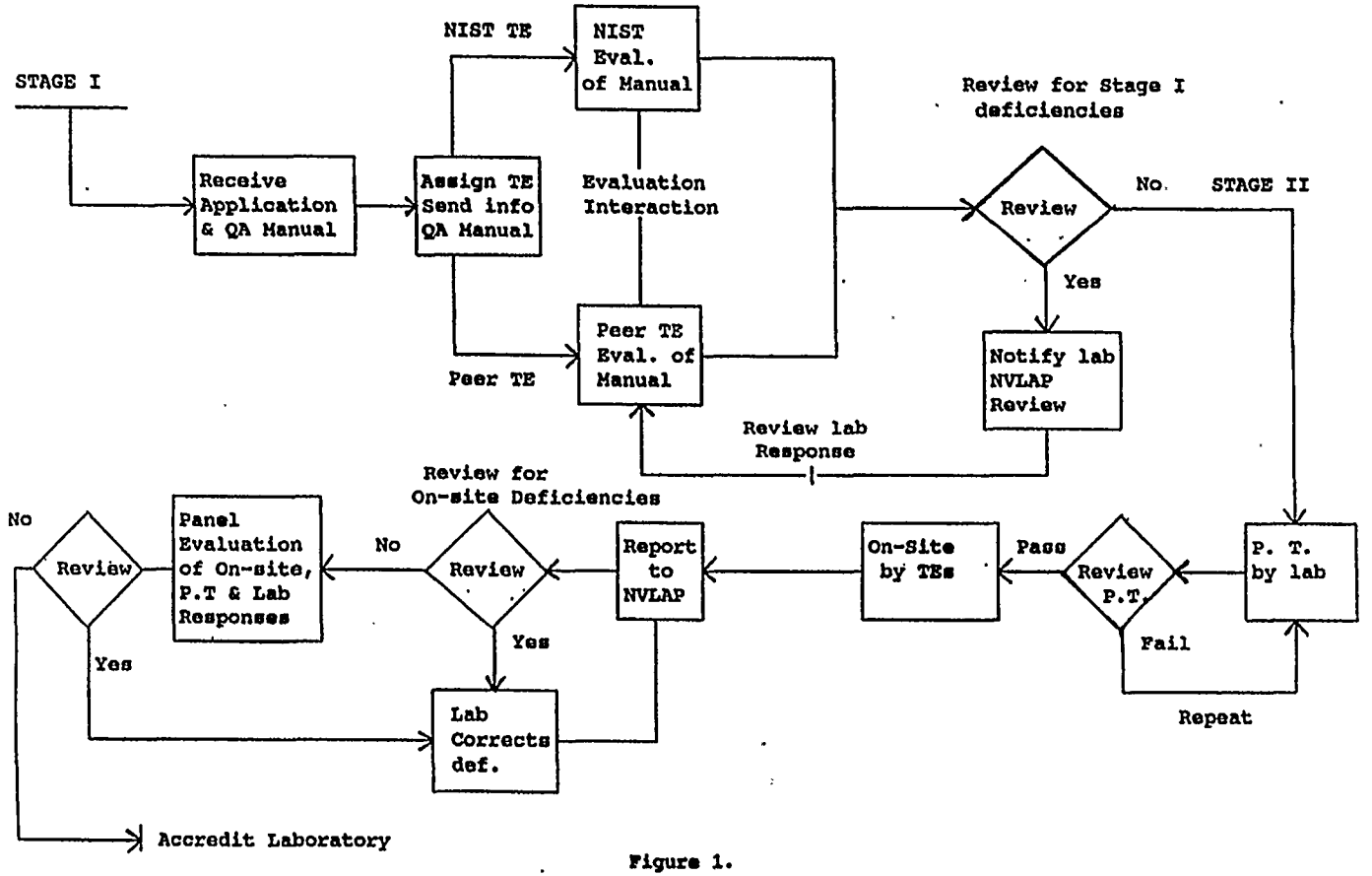


Figure 1.