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# LABORATORY ACCREDITATION ACTIVITIES IN THE UNITED STATES

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# Foreword

The Standards Code and Information Program periodically develops and publishes standards related documents as a service to producers and users of standards, both in government and in the private sector. This report is a sequel to NBSIR 87-3576, The ABC's of Standards-Related Activities in the United States, and NBSIR 88-3821, The ABC's of Certification Activities in the United States, and is designed to provide the reader with additional information on one standards-related activity --laboratory accreditation. This document is an introduction to laboratory accreditation for those not fully familiar with the subject. We intend that this material be informative and serve to stimulate wider interest in this field. Readers interested in this area may wish to review NIST SP 808, Directory of Federal Government Laboratory Accreditation/Designation Programs, which provides updated information on federal government laboratory accreditation and similar type programs conducted by the federal government. Companion volumes on state and local government and private sector laboratory accreditation programs are currently in preparation.

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# Abstract

This paper, another in a series, which includes NBSIR 87-3576, The ABC's of Standards-Related Activities in the United States, and NBSIR 88-3821, The ABC's of Certification Activities in the United States, is designed to provide information on laboratory accreditation to readers not entirely familiar with this topic. This report highlights some important aspects on the topic, furnishes information necessary to make informed decisions on the selection and use of laboratories, and serves as background for using other available documents and services. Readers interested in this area may also wish to review NIST SP 808, Directory of Federal Government Laboratory Accreditation/Designation Programs, which provides updated information on federal government laboratory accreditation and similar type programs conducted by the federal government. Companion volumes on state and local government and private sector laboratory accreditation programs are currently in preparation.



Key Words: accreditation; calibration; conformance testing; laboratory accreditation; NVLAP; quality assurance; testing

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## INTRODUCTION

Testing laboratories support billion dollar industries and affect the operation of our entire regulatory system. Major corporate and regulatory decisions are made daily on the basis of data produced by such testing laboratories. Test data are used in many tasks including: product design and research; quality control prior to acceptance of incoming materials and components, during production, and prior to shipment/sale; in insurance underwriting; meeting contractual agreements; satisfying government regulatory requirements; certification and labeling; buyer protection and information; product comparisons; building and structure design, construction and related engineering tasks; medical and health services; environmental protection; product operation, maintenance and repair; legal proceedings; and forensic work. Flawed test data can result in defective products or services being sold or operated which are capable of causing serious injury to the product's or service's user or harm to the environment. Defective products, such as fire detection and mitigation equipment, security alarms, aircraft, and autos can also result in serious injury or death to unsuspecting bystanders.

One method to assure the quality and accuracy of such data is through the accreditation of laboratories. Laboratory accreditation provides some assurance of the technical proficiency and competence of a laboratory to assess a product's or service's conformance to a set of prescribed standards. Laboratory accreditation is defined in the International Organization for Standardization (ISO) and the International Electrotechnical Commission (IEC) Guide 2 [1] as: "formal recognition that a testing laboratory is competent to carry out specific tests or specific types of tests." A footnote to this ISO/IEC definition indicates that laboratory accreditation "may cover the recognition of both the technical competence and impartiality of a testing laboratory or only its technical competence." The inclusion or exclusion of a requirement for impartiality is only one of many differences between the approval criteria used in various U.S. laboratory accreditation schemes. Such differences in requirements or criteria for accreditation must be considered in evaluating a particular scheme.

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[1] The International Organization for Standardization (ISO) is a worldwide federation of 89 national standards bodies. ISO covers standardization in all fields, except the electrical and electronics fields which are covered by the International Electrotechnical Commission (IEC). IEC has members from over 40 countries which represent some 80% of the world's population. Together ISO and IEC form the world's largest nongovernmental system for voluntary industrial and technical collaboration in the field of standardization.

It should be noted that not being accredited does not necessarily imply that the laboratory is not technically competent since not all laboratories seek or require accreditation, and accreditation programs may not exist in the laboratory's field of operation.

Since most U.S. laboratory accreditation/designation schemes were designed to meet particular governmental or private sector needs, such schemes tend to take distinctive forms and use different sets of procedures to assure that a laboratory has sufficient competence to perform the specified testing. Some schemes involve only a simple review of data submitted by a laboratory with no attempt at verification. Others require a full scale on-site evaluation of the laboratory's facilities, staff and equipment including audits, quality system review, and proficiency testing. Comparable programs, even those which are conducted by the same organization or government agency, may include different types or number of assessment procedures and may provide differing degrees of assurance regarding a laboratory's competency.

While a close interrelationship exists among accreditation, standardization, quality system registration, and certification, these areas are distinct. Certification is the process of providing assurance that a product or service conforms to a standard or specification. Some (but not all) certification programs mandate that accredited laboratories conduct any required testing. However, laboratory accreditation schemes exist which are not associated with a certification program. Certification and laboratory accreditation programs both use standards, but not all standards are intended for these uses. An evaluation of a manufacturer's or laboratory's quality system may be included in the certification and laboratory accreditation process; however, quality system evaluations and registrations are also conducted independently from such programs.

Because accreditation, standardization, quality system registration, and certification are linked; strengths as well as deficiencies in any one area can have significant consequences for the other areas. For example, improvements in test method standards can significantly increase the capability of a laboratory to produce valid test data.

This paper is intended to be an introduction to some of the important aspects of laboratory accreditation. Interested readers are encouraged to increase their knowledge of the field by taking advantage of other available publications and services described in the paper, footnotes and appendix.

## TESTING

Testing can be performed by laboratories differing widely in size, legal status, purpose, range of testing services offered, and

technical competence. Such laboratories can be government regulatory laboratories, government research laboratories, or government supported laboratories -- at the federal, state or local levels. They can also be college/university laboratories, independent private sector laboratories; laboratories affiliated with or owned by industrial firms, or manufacturers' in-house laboratories. Test laboratories can be for-profit or nonprofit. Laboratories can operate facilities in one or more than one location; and may, in fact, operate laboratories in more than one country. Laboratories can offer a limited range of testing services, or may offer services in many fields. There are almost as many different types of laboratories providing testing services as there are different types of users of the test data they produce.

A test is defined by ISO/IEC Guide 2 as a: "technical operation that consists of the determination of one or more characteristics of a given product, process or service according to a specified procedure." Test data result from the performance of a test. If the test method procedure or standard is well written, it is sufficient that the test data comply with the standard's accuracy and variability requirements.

Accuracy (or bias) refers to the degree of departure of the test result from the "true value." For example, if a product is weighed and the result is 5.1 kg (when the actual weight is 5.0 kg), the test or measurement is inaccurate by .1 kg. The degree of accuracy needed will depend on the characteristic being tested and the impact of errors on the ability of the product, process, or service being tested to perform in an acceptable manner.

Variability (or precision) refers to the degree of difference between the results from several repetitions of the same test. For example, if that same product (weighing 5.0 kg) were measured three times and the weights were recorded as 5.1 kg, 4.9 kg, and 5.0 kg. These results vary less than measurements for that product of 4.5 kg, 5.0 kg and 5.5 kg.

Variability can be further defined in terms of repeatability, which is a measure of the variation among the test results when the same or similar test is repeated within ONE laboratory, and reproducibility (or replicability), which is a measure of variation of test results from similar tests conducted in DIFFERENT laboratories.

Problems in the accuracy and variability of test results occur not only because of errors by the laboratory staff performing the test or defects in the test equipment used; but may also result from other factors, such as flaws or variables in the test method or in the sample selection process.

## BENEFITS TO A LABORATORY FOR PARTICIPATING IN AN ACCREDITATION SCHEME

Meeting regulatory requirements is probably one of the primary reasons for a laboratory to participate in an accreditation program. Congress, state and local governments can mandate by law that testing be done by an accredited laboratory. Federal, state and local government agencies may also impose such a requirement through regulations issued under their own legal authority. Laboratories may also have to be accredited to meet testing requirements imposed by foreign governments on products imported into their countries.

However, laboratories may also wish to participate in an accreditation program as an outside check of their internal quality control program, as proof of competence to higher level management within the organization, as a competitive advantage over other unaccredited laboratories, as a means of protection in liability proceedings, or as a means of establishing credibility with the public. Contracts or procurement requirements sometimes mandate the use of an accredited laboratory to conduct any required testing. A laboratory desiring to compete for such work would also seek accreditation. Laboratories can sometimes secure reduced medical care and related insurance rates by providing proof of a safe working environment though accreditation. An accreditation requirement could also be imposed as a condition of sale by a laboratory's purchaser.

The reasons for and benefits of seeking accreditation are as diverse as the laboratories themselves. In general, however, laboratories participate in accreditation programs in expectation of some type of economic return on the resources they invest in obtaining the accreditation.

## ELIGIBILITY REQUIREMENTS FOR ACCREDITATION

Eligibility requirements for accreditation vary among programs. Some federal programs restrict eligibility to state government laboratories, such as NIST's program to accredit state weights and measures laboratories. Other programs place different restrictions on eligibility. For example, the U.S. Department of Agriculture (USDA) program for inspecting grain for export restricts the number of approved laboratories in a particular geographical area to assure that each approved laboratory has an adequate market share.

Some accreditation programs are restricted to laboratories operated by the body doing the accreditation, such as the Department of Veterans Affairs' (VA) program to accredit the laboratories of its medical centers. This type of program falls into a categorical gray area that exists somewhere between laboratory accreditation and internal quality assurance -- since elements of both are present. In other programs, eligibility may be restricted to those holding membership in the accrediting organization. It is generally

desirable that a program imposes as few restrictions on eligibility as possible.

## TERMINOLOGY

The terminology used to refer to a laboratory which satisfies the criteria established by a laboratory evaluation type program varies greatly. Some programs use the term "accredited," while others use the term "designated." Other programs refer to such a laboratory as "inspected," "accepted," or even "nationally recognized." Even the same term, such as "accredited," can be used by different programs to mean very different types of assessments and assessment procedures. Different terms may also have different legal implications or may reflect differences between various agencies' or organizations' legal authority to conduct specific programs.

The term laboratory "designation" is increasingly being used rather than "accreditation" for schemes in which government agencies, public authorities, certification bodies, and others identify or "designate" one or more laboratories to perform specific types of testing for their own use or the purpose of implementing regulations, standards, or specifications in which the organization or agency has an interest. Regulators, certifiers and others sometimes designate test laboratories through a contractual or similar relationship with the laboratory. The use of the term "designation" may be preferable, particularly if the depth of technical competence assessment is less than what is usually encompassed under accreditation. (See Reference 1.)

There is also a distinction between the acceptance body (the organization responsible for accepting and using the data produced by an accredited laboratory) and the accrediting body (the body that administers the laboratory accreditation program and issues the accreditation). For example, the accreditation body for a laboratory which tests radiation dosimeters might be NIST's National Voluntary Laboratory Accreditation Program (NVLAP), but the acceptance body -- the body which uses the data to regulate dosimeters -- would be the Nuclear Regulatory Commission (NRC). This is an important difference that the reader be aware of when reviewing information on laboratory accreditation programs.

## SCOPE OF ACCREDITATION

Laboratories can be accredited in a number of ways. One way is for the laboratory to be accredited to test in an entire field of testing. The American Society for Testing and Materials (ASTM) Standard E 1224-88: Standard Guide for Categorizing Fields of Testing for Laboratory Accreditation defines a field of testing as a "broad sphere of science, engineering, or technology used to describe a general area of testing for classification purposes." ASTM E 1224 lists these

fields as acoustic and vibration testing, biological testing, chemical testing, construction materials testing, electrical testing, geotechnical testing, mechanical testing, medical testing, metrology, non-destructive testing, optics and photometry, and thermal testing. A laboratory can also be accredited in a scientific discipline, such as biochemistry, or for a specific technology (such as gene splicing), or in relation to specific products, such as blood product testing or concrete sample testing. Accreditation can also be limited to the conduct of specified test methods.

In general, the broader the scope of approval, the more difficult and time consuming it is for the accrediting body to thoroughly assess the laboratory's ability to perform all test methods within that scope. However, the narrower the scope of accreditation, the more likely it is that a laboratory performing a broad range of testing will have to obtain multiple accreditations.

## CRITERIA FOR EVALUATING/ACCREDITING LABORATORIES

Standards organizations have recognized the importance of laboratory competence and accreditation. The Organization for Economic Cooperation and Development (OECD) has published a "Code of Good Laboratory Practice." ISO and IEC have published Guide 25, "General Requirements for the Competence of Calibration and Testing Laboratories," which establishes general requirements for laboratory competency to conduct specific calibrations or tests. In the area of laboratory accreditation, ISO and IEC have published Guide 38: General Requirements for the Acceptance of Testing Laboratories; Guide 54: Testing Laboratory Accreditation Systems - General Recommendations for the Acceptance of Accreditation Bodies; and Guide 55: Testing Laboratory Accreditation Systems - General Recommendations for Operation. [2]

In the United States, a number of organizations have attempted to address the issue of judging technical competence through standards documents, such as the American Society for Testing and Materials (ASTM) E 994, "Standards Guide for Laboratory Accreditation Systems,"

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[2] The European Committee for Standardization (CEN) has published a series of standards or European Norms (EN) (referred to as the EN 45000 series) based on the ISO Guides listed above. The series includes EN 45001 - General Criteria for the Operation of Testing Laboratories (1989), EN 45002 - General Criteria for the Assessment of Testing Laboratories (1989), EN 45003 - General Criteria for Laboratory Accreditation Bodies (1989), and prEN 45019 - Guidance on Specific Aspects of Testing and Certification of Personnel (1989).

and ASTM E 548, "Practice for Generic Criteria for Use in Evaluation of Testing Laboratories and Inspection Agencies." Federal agencies have published guides and related manuals in this area, such as the Food and Drug Administration's (FDA) Good Laboratory Practice (GLP) guidelines.

The following list contains general criteria which may be used in evaluating laboratories. Any or all of these general criteria may be used during the assessment process. In addition, criteria specific to the type of laboratory being accredited, the nature of the work being performed, and the purpose for which the accreditation program was established may be imposed.

**1. Laboratory Organization/Independence (No Conflict-of-Interest)**

The laboratory should be a legal entity organized in a manner which permits the performance of all required functions in a satisfactory fashion. In addition, a requirement may be imposed that the laboratory be impartial or independent, that is free from any outside influence -- monetary, organizational, or otherwise -- which might bias the integrity of the work performed.

**2. Financial Stability**

The laboratory may be required to have sufficient resources to enable it to properly use and maintain the test equipment and facility, to satisfactorily perform all required functions, and to adequately indemnify itself against financial liabilities/penalties resulting from its operations.

**3. On-site Inspection**

The laboratory may be required to pass an on-site evaluation by assessors appointed by the accrediting body. The evaluation should include a review of all relevant information concerning the ability of the applicant to comply with the accreditation criteria.

**4. Staff Qualifications Requirements**

The laboratory may be required to demonstrate that its personnel are qualified or licensed (where necessary). Each staff member should have the education, training, knowledge, and experience necessary to perform the tasks assigned and an appropriate level of supervision should be maintained. The training of each staff member should be kept current and should be documented.

**5. Adequate Quality System**

An operational quality system may be required which is appropriate to the type and amount of work performed by the laboratory. The system should be reviewed on a periodic basis by management and

revised as needed to ensure continued acceptable performance. A quality system should be suitably documented in a comprehensive, up-to-date quality manual, which is readily available for consultation by staff.

## 6. Sampling Requirements

Where test materials are received by the laboratory in quantities larger than the amount required for the test, the laboratory may be required to sample the material in such a manner as to ensure that the sample tested is representative of the entire quantity of material received. Where sample selection is the responsibility of the test laboratory, appropriate sampling methods and/or techniques should be used.

## 7. Sample Control/Integrity Requirements

The laboratory may be required to have an effective system which ensures both the identity and integrity of the test samples. Maintaining the integrity of the sample involves preventing it from being damaged during any stage of its collection, shipping, storage, or handling. Such damage can include: physical damage; loss of part of the sample due to leakage; contamination by foreign materials; failure to maintain the sample within appropriate temperature or atmospheric conditions; or other deterioration, such as that which can occur if samples are held too long before testing. Where the sample may be used as legal evidence, a complete record may be required on who had custody of the sample from collection through testing, and (when needed) up until its disposal.

## 8. Statistical Methods Requirements

The statistical methods used to interpret or to provide additional information about test data should be appropriate and adequate for the type and level of testing undertaken. Control charts, which help distinguish random errors from systematic (assignable cause) errors or variations, should be employed as needed to alert laboratory personnel to potential problems in test procedures or equipment.

## 9. Recordkeeping Requirements

A laboratory may be required to maintain all test records, observations, calculations and derived data for all tests it performs for a given number of years. ISO/IEC Guide 38 recommends a guideline period of at least 6 years or as otherwise required by law or by the accrediting body.

## 10. Test Report Content/Format Requirements

Test reports should include all information relevant to sample selection, test performance, and test results. Such information

should be displayed in a format that is easy to read and understand. Data included in such reports should be routinely audited and validated, that is checked for questionable values and accepted or rejected based on an established set of criteria. Audit levels (the amount of work subject to review and the extent of those reviews) should be appropriate for the type and amount of work being performed as well as the skill of the analyst or technician conducting the tests.

**11. Available Operational Manuals/Instructions**

The laboratory may be required to have readily available instructions on the operation and maintenance of all materials and equipment, copies of the test methods and standards employed with any additional instructions needed as to their application, sample selection and handling procedures, and other relevant information needed to ensure the quality of the work performed.

**12. Periodic Re-audit of Facilities**

An accredited laboratory may be subject to periodic reassessment to insure its continued compliance with all accreditation requirements. Any significant changes in the laboratory's operations should be reported as soon as possible to the accrediting body, which should then promptly decide whether the accreditation should be continued or terminated.

**13. Participation in Proficiency Testing Program**

Proficiency testing evaluates the competency of a laboratory by comparing that laboratory's results with results obtained from other laboratory(s) from tests performed on the same or similar items. Applicants may be required to satisfactorily complete specified proficiency tests, particularly in the application of test methods critical to the evaluation of the product or service.

**14. Adequacy of Facilities and Equipment**

The laboratory should own or have access to all equipment required to correctly perform all test methods for which accreditation is sought. In addition, the facility should permit test methods to be conducted in a controlled environment to prevent any adverse effects on the accuracy of the test result. Specifically, the testing environment should be free from excessive temperatures, temperature fluctuations, dust, moisture, dryness, vibration, and electromagnetic or other interference. The laboratory should also have adequate lighting, heating and ventilation. When needed, specialized facilities, such as clean rooms, should be available.

## 15. Equipment Maintenance/Repair/Calibration Requirements

Equipment calibration, preventative maintenance and repair procedures and the choice of reference materials [3] used for calibration should be appropriate for the nature and amount of the work being performed. Equipment calibrations should be traceable [4] to some ultimate or national reference standard. [5] Complete records should be maintained on all calibration, maintenance and repair procedures performed.

## 16. Adequate Control over Subcontractors

The laboratory may be required to have a system to assure that testing and related work performed by another party under contract is of acceptable quality. The nature of the system should be appropriate for the type and amount of work being performed by the subcontractor. The laboratory should also be able to provide to the accrediting body or other interested parties adequate evidence of the competency of all subcontractors.

## 17. Appeals Procedure

The laboratory may be required to have a mechanism to deal with technical questions, appeals, complaints and challenges, originating either from the customer or from interested regulatory or accrediting bodies.

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[3] Reference materials are defined by ISO Guide 30 as a "material or substance one or more properties of which are sufficiently well established to be used for the calibration of an apparatus, the assessment of a measurement method, or for assigning values to materials."

[4] "Traceability means the ability to relate individual measurement results to national standards or nationally accepted measurement systems through an unbroken chain of comparisons." Examples of traceability include: equipment calibrated by NIST; equipment calibrated using NIST transfer standards (materials previously measured by NIST); or equipment calibrated using other NIST calibrated equipment. For further information on traceability, see Reference 7.

[5] Reference standards include those involving dimension (i.e., length, diameter, angle, or volume and density), mechanical properties (i.e. flow rate or airspeed), ionizing radiation measurements, time and frequency, etc.

**Note: Accreditation programs do not necessarily include all of the above technical criteria in their evaluation process. The choice of criteria depends on the degree and type of assurance sought by the accrediting body regarding a laboratory's stability and competence, the cost associated with the adoption of each criterion, and the complexity of the test method(s) included in the accreditation. Differences can also exist between programs using the same technical criteria but varying the frequency and intensity of their application. For example, a requirement for proficiency testing can be imposed annually or monthly, for all test methods or only the most important ones. Depending on these factors, an on-site inspection may vary from a one day inspection conducted by one assessor to a week-long inspection conducted by a team.**

## U.S. ACCREDITATION PROGRAMS

The U.S. laboratory accreditation system is different from that of most foreign countries. The majority of foreign accreditation bodies are public organizations or organizations with some direct government involvement. There is also a growing tendency in foreign countries to run laboratory accreditation schemes in a coordinated fashion. In the United States, on the other hand, laboratory accreditation schemes are operated by all levels of government and by the private sector as well. There is no centralized coordinating body, though some coordination does take place between specific programs on their own initiative or through the intervention of other interested bodies, such as trade associations or professional societies. The different types of U.S. programs are briefly described below.

### 1. Federal Government Laboratory Accreditation Programs in the United States

Requirements for laboratory accreditation/designation programs within the federal government vary greatly by program. While some programs, such the National Voluntary Laboratory Accreditation Program (NVLAP), are quite comprehensive; others involve only minimal review of a laboratory's qualifications. The requirements and scope of each program have generally been tailored to meet specific agency needs; and, except for NVLAP, laboratory accreditation/ designation is not the primary program goal. In some cases, the accredited or designated laboratories provide only an initial product screening service, with federal laboratories maintaining final responsibility for producing the test data used in enforcing regulations, such as the Mine Safety and Health Administration's (MSHA) programs for conformity assessment of mining products and equipment.

Eligibility requirements for accreditation also vary among programs. Some programs restrict applications to state laboratories only, such as NIST's program for accrediting state weights and measures laboratories. As noted above, one USDA program restricts the number

of laboratories that can be approved in a particular geographical area, and the VA program accredits only the laboratories of its medical centers. Some agencies, such as DOD's Defense Logistics Agency (DLA), designate or accredit laboratories found to be capable of performing specific tests on products procured by that agency. Such programs are open only to potential government suppliers.

Terminology also varies by program. A 1989 GAO report noted the use of 10 different terms for accreditation with at least 18 different meanings by the 20 programs it reviewed. The same term, such as "accredited," used by different programs can mean very different types of assessments and assessment procedures. Different terms may also have different legal implications or may reflect differences between various agencies' legal authority to conduct specific programs. [6]

**2. State/Local Government Laboratory Accreditation Programs in the United States**

States administer many laboratory accreditation programs for a variety of reasons. In most cases, state and local government agencies accredit laboratories to test products regulated indirectly by requiring that such products be inspected and/or tested by an approved body. An example of the latter is the regulation of building and electrical products at the state or local government level by requiring that the products be tested/inspected and bear the mark of a recognized or approved testing laboratory. In other cases, the state or local government programs, like some federal programs, accredit or designate laboratories that provide a surveillance/ screening service for testing product compliance. In such cases, state/local government laboratories will usually maintain responsibility for producing the test data used in enforcement situations.

States also evaluate laboratories for other purposes, such as to assist them in enforcing federal regulations. For example, states have primary enforcement responsibility for the national requirements for ensuring the quality of public water systems. In carrying out this obligation, states accredit local laboratories to test drinking water. State and local authorities also accredit or designate laboratories to test products prior to their procurement by a state agency.

As with federal programs, state and local requirements for laboratory accreditation/designation vary greatly by program. Some programs are quite comprehensive, while others involve only minimal review of

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[6] Information on each agency's legal authority is contained in NIST SP 808 - Directory of Federal Government Laboratory Accreditation/Designation Programs.

a laboratory's capabilities. The terminology used for accreditation also varies extensively.

### 3. Private Sector Laboratory Accreditation Programs in the United States

Private sector accrediting bodies also administer laboratory accreditation programs for a variety of reasons. These reasons range from assisting laboratories in defending their competence in professional malpractice matters to assisting an industry to avoid government regulation by undertaking self-policing efforts. Many private sector programs are operated as an integral part of a private sector certification program. In addition, programs can be established to assist government agencies in enforcing regulations, such as in the testing of building and construction products. The criteria and terminology used in private sector laboratory accreditation/designation schemes again vary greatly among programs.

Private sector programs also differ in size and scope. The American Association of Blood Banks (AABB) operates an accreditation program for blood bank and transfusion services which is recognized by many state authorities. The College of American Pathologists (CAP) program accredits hospitals and independent medical laboratories, and their program is used by the VA to assure the competence of VA medical facilities. The American Association for Laboratory Accreditation (A2LA) operates an accreditation program which accredits laboratories in a number of testing fields.

At the international level, the IEC Quality Assessment System for Electronic Components (IECQ) accredits testing facilities capable of demonstrating compliance of electronic components to prevailing requirements and standards, which are based on IEC standards. This accreditation program is part of a reciprocal worldwide certification system, in which certificates of conformity issued by an approved laboratory in one participating country are accepted by all other participating countries.

The IEC also operates the IEC System for Conformity Testing for Safety of Electrical Equipment (IECEE). The IECEE's objective is the reciprocal recognition of test results (not certification marks or certificates of conformity) among the participating countries. Equipment is tested by approved laboratories against prevailing specifications and requirements, including safety, based on IEC standards. Any electrical products for which there are appropriate IEC standards can be included within the program. If the product is found to conform to relevant IEC standards, the test certificate, accompanied by the test report, can then be presented to National Certification Bodies (NCB's) in other countries where certification is desired.

**INTERNATIONAL/REGIONAL COOPERATION IN TESTING/LABORATORY ACCREDITATION**

There are a number of mechanisms used to facilitate the acceptance of test data produced by laboratories in more than one country. In some cases, a laboratory in one country will buy or establish a subsidiary within the physical boundaries of a foreign country. Test data can then be exchanged and accepted between the parent laboratory and its subsidiary. In other cases, an agreement can be established between two or more organizations located in different countries to accept each other's test data.

Mutual acceptance of test data also results from the establishment of bilateral or multilateral agreements between governmental authorities. These agreements require each party to accept test results from laboratories accredited by the other party or parties. Mutual confidence in the competence of the other party's testing laboratories is vital to the success of such agreements.

One example of such a multilateral agreement is the Agreement on the International Carriage of Perishable Foodstuffs and on the Special Equipment to be Used for Such Carriage (ATP). The ATP is an international agreement which sets standards for the testing and uses of equipment which carry perishable foodstuffs. USDA certifies test stations and laboratories in accordance with requirements of the ATP. These bodies can then issue U.S. ATP certificates, which are recognized by other ATP signatories including: Austria, Belgium, Czechoslovakia, Denmark, Finland, France, Germany, Hungary, Ireland, Italy, Luxembourg, Morocco, Netherlands, Norway, Poland, Portugal, Spain, Sweden, the United Kingdom, and Yugoslavia.

NIST's National Voluntary Laboratory Accreditation Program (NVLAP) has established bilateral agreements between the United States and the National Association of Testing Authorities (NATA) in Australia, the Testing Laboratory Registration Council (TELARC) in New Zealand, and the Standards Council of Canada (SCC). Under these agreements, test results from laboratories accredited by each party are recognized by the other party to the agreement.

The European Community (EC) has established a regional mutual recognition scheme for regulated products. Under the so-called "new approach to technical harmonization of standards," each EC country is to provide to the EC a list of laboratories and other bodies (referred to as "notified bodies"), which can declare that a regulated product conforms to the "essential requirements" spelled out in the applicable directive. Acceptable methods for conformity assessment are also listed in each directive. The test results of any notified body and subsequent product approval marking must be accepted by all other EC countries, unless there is cause to believe that the product was improperly tested. Each EC country is responsible for assuring

that the bodies it notifies comply with the criteria for competence spelled out in the EN 45000 series.

In some mutual recognition schemes, the test results or report are mutually accepted as opposed to certification marks. Provision may be made for the test report prepared in one participating country to be accepted in other participating countries for the purpose of obtaining certification or government marketing approval by the importing country. Examples are the programs coordinated by the European Free Trade Association (EFTA) for pressure vessels, ships' equipment, agricultural equipment and tractors, liquid fuel heating equipment, lifting apparatus (such as hoists, elevators, etc.) and gas appliances.

The required test report may have to establish conformity with applicable standard(s) which have been harmonized (made technically identical or equivalent in practice) between the importing and exporting countries or the report may have to show compliance with technical requirements specified by the importing country alone. In the latter case, the requirements of the importing country may differ significantly from the requirements of the exporting country.

In some more advanced forms of mutual recognition arrangements, there is a mutual recognition of each other's marks or certificates of conformity, or the granting of a license to each party to label a conforming product with the other's certification mark, or with a mark common to all parties to the agreement. A laboratory accreditation scheme is usually an integral part of such an arrangement. An example of this type of scheme at the regional level is the European Committee for Electrotechnical Standardization (CENELEC) HAR Agreement -an agreement on the use of a common marking scheme for electrical cables and cords complying with harmonized specifications. Cables and cords that have been tested by an accredited/designated body in one country and bear the common HAR mark or a colored thread marking must be accepted without further testing or certification by the approval organizations of participating countries.

**ILAC**

One of the major events in international cooperation in the field of laboratory accreditation occurred in 1977 when Denmark and the United States convened an international conference on the mutual recognition of test results in Copenhagen. Ultimately this became the International Conference on Laboratory Accreditation (ILAC). ILAC's purpose is to promote the development of national programs for accrediting test laboratories and the use of harmonized accreditation criteria. Over forty countries have participated in ILAC, which has been the motivating force for the publication of eight ISO/IEC Guides on the subject of testing and laboratory accreditation.

## IMPORTANCE OF LABORATORY ACCREDITATION TO TRADE

Laboratory accreditation has taken on increased significance as international recognition and acceptance of test data across national boundaries have assumed greater importance in the reduction of technical barriers to trade. As traded products become more complex, it is no longer possible to assess their quality or performance merely by looking at them. Such decisions are now generally based on test data. Laboratory accreditation provides some assurance of the technical proficiency and competence of a laboratory to assess a product's or service's conformance to a set of prescribed standards. The competence of laboratories which perform testing within an evaluation/approval system is vital in securing acceptance of their test results by other countries. Mutual acceptance of laboratory test results between countries can reduce the need for unnecessary retesting and serve as a basis for increased opportunities for international trade.

The international General Agreement on Tariffs and Trade (GATT) has as one of its major components the Agreement on Technical Barriers to Trade (usually referred to as the Standards Code). The framers of the Standards Code, including the United States, recognized that activities such as laboratory accreditation and the mutual acceptance of test results by countries can either expedite or seriously hinder the free flow of goods in international commerce. However, the Code does not obligate signatories to recognize test results or certification marks from another country. The Code established a mechanism to enable signatories to the Code to enter into bilateral negotiations to discuss the reciprocal acceptance of test results. One method for insuring test data acceptance is the mutual recognition of the scheme or schemes which exist in each country for the accreditation of testing laboratories. Assurance that there is an adequate laboratory accreditation scheme can provide another country with some degree of confidence in test results of laboratories accredited under that scheme. Further multilateral trade negotiations are continuing, and one goal is to broaden the scope of the Code in this very important area.

The importance of mutual recognition of test data and laboratory accreditation schemes has also been recognized in other international arenas. The Organization for Economic Cooperation and Development (OECD) has worked extensively on developing its Code of Good Laboratory Practice to facilitate the international exchange of data on most chemical products. Events such as the formation of a European Single Market and the signing of the Free Trade Agreement between the United States and Canada and the undertaking of free trade negotiations with Mexico have further recognized and emphasized the need to address laboratory accreditation issues. Mutual recognition of test data is vital in the prevention of trade barriers resulting from unnecessary repetitive testing.

## SOME FACTORS FOR CONSIDERATION

Not all laboratory accreditation programs are equally thorough and not all laboratory accrediting bodies are equally competent. The users of accreditation, accredited laboratories, and the test data produced by accredited laboratories should be aware of the following factors when evaluating a laboratory's accreditation or an accreditation process. These factors may affect the ability of the accreditation process to provide assurance that an accredited laboratory is capable of producing accurate and precise test data.

### 1. Standards/Test Methods Used

The choice of standards and test methods used in a laboratory accreditation scheme has a significant impact on the validity of the scheme and the accuracy, representativeness, and reproducibility of the results. To test a product or service against a standard, a test procedure or method must be used. A test result can only have value if the method used to generate it is capable of producing accurate and precise results.

It is almost impossible to avoid all possible misinterpretations in the writing of a standard. Many standards developers, however, design a standard but fail to test and adjust the standard to accommodate problems encountered during implementation, particularly during testing situations. Conformance to characteristics specified in a standard may not be able to be accurately assessed using any kind of practical test method.

The standards may not cover all essential characteristics of the product necessary to ensure a given level of quality or safety or the standard may contain specifications that are unnecessary and not based on well documented research or information. The specifications may be inadequate or set too low to ensure an acceptable level of product quality or safety. If such problems with test methods and standards are significant, the test result can be misleading or useless.

### 2. Open Access to the System

In general, participation in the accreditation process should not be conditional upon a laboratory's membership in any association or organization. It is usually not desirable for the accrediting body to have any relationship with the test laboratory which might influence the accreditation process. Laboratories, holding membership in the accrediting organization, could develop sufficient influence over the accrediting body to affect the accreditation decision. In addition, unjustified fees, financial requirements, or other conditions for application, which restrict participation and are not relevant to the competency of the laboratory, should be avoided.

**3. Conflicts-of-Interest**

If the accreditation process is to be credible, the accrediting body and its assessors should be free from any outside influence which might bias the results of the accreditation process. The body should have sufficient financial resources to allow it to refuse accreditation should that prove necessary. No relationship should exist between the laboratory and the accreditation body or its assessors which might influence the objectivity and outcome of the accreditation process.

**4. Effective Quality System**

The presence of an effective quality system in the accreditation scheme is important in maintaining confidence in the accreditation process. ISO/IEC Guide 54 notes that the system should be "appropriate to the type, range and volume of work performed." The system should be documented and should include "quality assurance procedures specific to each step of the accreditation process." Procedures for ensuring adequate feedback, taking corrective actions, and appeals should also be included. Such documentation should be available to the accreditation staff, and responsibility for the system should be assigned to a person having access to the highest management levels. The quality system should be periodically reviewed and revised as needed to ensure the continued effectiveness of the system.

**5. Staff Training, Experience, and Records**

Assessors should have the knowledge and experience necessary to perform all required assessments in the accreditation process, including detailed knowledge of the assessment criteria and the standards, test methods and equipment involved. Financial benefit accruing to the accreditation body from the training of assessors should be avoided to discourage the training of marginally qualified assessors. The accrediting body should also have a means of assuring fair and equitable selection and assignment of assessors. Assessor reports and recommendations should be submitted without editing to the accrediting body. A proposed standard for selecting qualified assessors is currently under consideration by ISO.

**7. Adequate Records**

The accrediting body should maintain adequate records on the data collected, findings and reports related to all assessments performed; the qualifications, training and experience of each assessor; the assessment procedures used; and the laboratories accredited. All documentation regarding a laboratory should be restricted to persons or organizations considered by the accreditation body as having a legal right to such records.

## 8. Adequate Follow Up and Enforcement

The accrediting body should have mechanisms in place which minimize the potential for fraud or deception on the part of a laboratory regarding its accreditation status or the meaning of that status. This includes arrangements for periodic reassessments of each accredited laboratory to assure its continued compliance with the accreditation criteria. The accrediting body should also have procedures which permit the swift withdrawal of accredited status from laboratories which fail to comply with the terms and requirements for accreditation, as well as procedures for notifying other interested parties of the change in accreditation status.

## 9. Lack of Recognition of Laboratory Accreditation Schemes

Lack of recognition or acceptance of a laboratory accreditation scheme by other parties can result in the need for extensive retesting of a product or service at considerable expense in terms of both time and money. In some cases, lack of recognition is the result of inadequate knowledge or information on the program and/or the vested interests of others, rather than problems in the program itself. Lack of recognition can result in the need for a laboratory to obtain multiple accreditations of the same or essentially the same testing services, sometimes based on all or most of the same accreditation criteria. For example, based on information collected by Mr. Charles Heyer, laboratories desiring to be accredited/designated nationwide to conduct electrical safety-related testing of construction materials have to gain the acceptance of at least 43 states, over 100 local jurisdictions, the International Conference of Building Officials (ICBO), the Building Officials and Code Administrators (BOCA), the Southern Building Code Congress International (SBCCI), a number of federal agencies, as well as by several large corporations.

Some federal agency laboratory accreditation programs have gained recognition by other agencies. These include the NVLAP program -- currently required by the Department of Housing & Urban Development (HUD), the Federal Communications Commission (FCC), the Federal Trade Commission, the Environmental Protection Agency (EPA) the Nuclear Regulatory Commission (NRC) and parts of the Department of Defense (DOD). Additional agencies are likely to require NVLAP accreditation as new laboratory accreditation programs (LAPs) are established. Reports on laboratories (that also test pesticides and environmental contaminants) from the Food and Drug Administration's (FDA) toxicology laboratory monitoring program are shared with the Environmental Protection Agency (EPA). In some cases, private sector laboratory accreditation programs are recognized and accepted by federal, state and local government authorities for regulatory, procurement or other purposes. Programs that are well accepted are usually more cost effective since the need for multiple and duplicative assessments is reduced.

## 10. Mutual Recognition Agreements (MRAs)

Lack of recognition can be overcome through mutual recognition agreements (MRAs) -- agreements by two or more parties in which each party agrees to recognize the competence of laboratories accredited by the other party(s). There can be many problems with mutual recognition agreements, however, including lack of clarity or the inclusion of poorly defined terms and responsibilities in the written agreement. One of the least understood problems involves the identity and authority of the signatories to the agreement. For example, two accrediting bodies can agree to recognize each other's laboratory accreditation system. If the acceptance bodies for the test data produced by the accredited laboratories are not parties to the agreement, the acceptance bodies may not be willing to accept data generated from laboratories accredited under either system. The value of the agreement is then questionable. This problem can be overcome if each accrediting body is willing to extend its own accreditation to a laboratory that has been accredited by the other party. However, under this arrangement, each party may be assuming responsibility for and the liability and risks associated with the other party's work. Therefore, the establishment of effective MRAs can be a very complex undertaking.

## 11. Multiple Accreditations

Laboratories involved in multiple types of testing may need to obtain accreditation from more than one U.S. agency or organization. The 1989 GAO report noted that it was unlikely that a laboratory would be designated/accredited to perform the **same** type of testing by more than one federal government agency, but it was quite possible that a laboratory must be accredited by more than one agency for different types of testing. For example, it may need accreditation by one agency to test human tissue for disease; by another to test water for chemicals and bacteria; and by yet another to test meat and poultry for moisture, fat, protein, and salt. However, as noted above, it is not uncommon for a laboratory to need multiple state and local government accreditations/designations to conduct the same type of testing.

Laboratory accreditation programs are frequently narrow in their scope -- designating or accrediting laboratories to test only a narrowly defined range of products or services within the agency's or organization's area of responsibility. The results of laboratory assessments from these programs are usually of only limited use to other federal agencies and organizations. A laboratory which offers a broad range of testing services may need multiple accreditations which can increase the lab's cost of doing business and may restrict entrance into additional testing areas.

## 12. An Adequate Appeals System

Disagreements may occasionally arise among parties involved in an accreditation program. Provision should be made within the program for an impartial appeals mechanism to handle disagreements that cannot otherwise be resolved. Procedural requirements should be in writing with minimal limitations on the timing of appeals, and on who may file.

## 13. Lack of Failures

If all applicants are accredited, the effectiveness of the accreditation program should be reviewed. It is possible that the accreditation program has been effective and unqualified testing laboratories have not applied. It is, however, also possible that the accreditation program has not been effective in uncovering weaknesses in laboratory operations and the program's methods and criteria need to be overhauled. Causes for the lack of failures should be investigated to determine if the program is still effective.

## 14. Accreditation Costs

The costs involved in accreditation can be cause for serious concern for all laboratories, particularly for smaller laboratories or laboratories that offer a broad range of testing services. Such costs must be balanced against the amount of new testing work likely to result.

Multiple accreditations can be required to perform testing for different countries, or even for more than one state and/or local jurisdiction. Multiple accreditations may also be required for different products or testing fields -- all of which can considerably increase total accreditation costs. These costs must ultimately be passed on to the users of the testing services.

## SUMMARY

It is important to realize that laboratory accreditation does not necessarily give any guarantees about the test results obtained from the performance of any specific test procedures. Laboratory accreditation means that the laboratory is **capable** of performing specified test methods and procedures correctly, not that the laboratory has competently tested all products in each and every instance. In addition, accreditation provides assurance only about a laboratory's capability within the scope or areas for which accreditation was granted. If a laboratory is accredited to test concrete, no assurance is provided regarding that laboratory's ability to test any product other than concrete. It should also be noted that not being accredited does not necessarily imply that the laboratory is not technically competent since not all laboratories

seek or require accreditation, and accreditation programs may not exist in the laboratory's field of operation.

Users of test results must understand the laboratory accreditation process, the criteria used, and the scope of accreditation to assess the value of that accreditation before intelligent choices can be made regarding the use of the test results produced by laboratories accredited under that process. While laboratory accreditation, standardization, quality system registration, and certification are distinct activities, the four together can serve as a basis for increased or diminished opportunities for national and international trade. Mutual acceptance of laboratory test results among entities in the United States and between the United States and other countries reduces the need for repetitive and costly retesting and is an important step towards facilitating national and international commerce.

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