# NIST Special Publication 831

# Directory of Professional/Trade Organization Laboratory Accreditation/Designation Programs

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#### **FOREWORD**

This directory is a guide to laboratory accreditation and similar types of programs conducted by private sector professionals and trade organizations. These programs accredit or designate laboratories or other entities to conduct testing to assist certification bodies in carrying out their responsibilities. This accreditation, or designation, is based on formal assessment of the capability of the laboratory to conduct the testing. The nature of such assessments varies considerably from agency to agency.

Laboratory accreditation and related efforts provide some assurance regarding the technical proficiency and competence of an entity to assess a product's or service's conformance to a set of prescribed standards. Many sectors of the economy may be interested in laboratory accreditation and related programs for a variety of economic, procurement, safety, or other considerations. Mutual acceptance of laboratory test results among private sector professional and trade organizations, states, local jurisdictions, and at the national and international levels can remove barriers to trade.

This directory (prepared under a contract with the Office of Standards Services, NIST) is an update of information contained in NIST Special Publication 831 of edition 1992, Principal Aspects of U.S. Laboratory Accreditation Systems. This directory identifies professional and trade organization laboratory accreditation/designation programs and notes the appropriate contact points within each organization. It is a reference for all who operate, use, or rely on laboratory services. Entries in this directory are based on information provided by each organization and reflect the organization's view of its activities. Parties interested in this subject may wish to review NIST SP 808, Directory of Federal Government Laboratory Accreditation/Designation Programs (a summary of programs conducted by the federal government).

#### **ACKNOWLEDGMENTS**

This directory is based on my earlier publications in the field; its format was expanded to be consistent with "NIST Special Publication 808, Directory of Federal Government Laboratory Accreditation/Designation Programs," edited by Maureen Breitenberg. Maureen Breitenberg of NIST's Office of Standard Services has provided important help and cooperation while monitoring this effort for NIST.

Special thanks are due Ruth Schreiber for her help in compiling this directory and managing all aspects of information processing, and to all the program officials who provided the information contained in this directory, without which this publication would not have been possible.

Charles W. Hyer Vice President The Marley Organization, Inc.

Editor

#### ABSTRACT

This directory is a guide to laboratory accreditation and similar types of programs conducted by professional and trade organizations. These programs accredit or designate laboratories or other entities to assist private sector professional societies, trade associations, related certification bodies, their membership, as well as government agencies, in carrying out their responsibilities. This accreditation or designation is based on an assessment of the capability of the laboratory to conduct the testing. However, the nature of the assessment varies considerably by organization and program.

Entries in this directory are based on information provided by each organization and reflect the organization's view of its activities. Parties interested in laboratory accreditation are referred to NIST SP 808, Directory of Federal Government Laboratory Accreditation/
Designation Programs, and NIST SP 815, Directory of State and Local Government Laboratory Accreditation/Designation Programs, which contain information on similar programs conducted at the federal, state and local government levels.

Publication of this directory is part of ongoing NIST efforts to establish and maintain comprehensive information on standards, regulations, laboratory accreditation, certification programs, and related information. This material answers the needs of government, industry, and the public for information on private sector laboratory accreditation and related programs.

**Key Words:** accreditation; conformity assessment; certification; designation; laboratory accreditation; laboratory designation; listing; proficiency testing; qualified laboratories; quality systems; standards; testing

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# INTRODUCTION

## Background:

Laboratory<sup>1</sup> accreditation has taken on increased worldwide significance as recognition and acceptance of test results from domestic and foreign laboratories have assumed greater importance in facilitating domestic and international trade. To accept such results, one must have confidence in the competence of the laboratory that produced them. Laboratory accreditation is one means of providing some assurance of the technical competence of a laboratory to assess a product's or service's conformance to a set of prescribed standards or other requirements.<sup>2</sup>

Laboratory accreditation helps increase confidence in certification program results. While laboratory accreditation and product/service certification are two distinct areas, laboratory accreditation can be vital in increasing the reliability of certification program results and in the confidence that can be placed in that program. The competence of laboratories that perform the required testing within a certification or approval system (e.g., building codes) can be as vital to securing acceptance of that certification/approval as is the adequacy of the standards on which the certification is based. It should be noted that not all laboratory accreditation programs are associated with a certification program and not all certification programs rely on accredited laboratories.

Sampling/testing, accreditation, product or service certification/ approval, assessment and registration of a producer's management system by an assessment body, as well as recognition of an accreditation body's competence can all be elements of what is now generally termed a "conformity assessment" scheme. When evaluating a conformity assessment scheme, one must look at each of the various elements that comprise the scheme and assess the competence with which each is likely to be performed. If each element is performed properly, overall confidence in the results of a conformity assessment are enhanced and can serve as a basis for increased international trade.

<sup>&</sup>lt;sup>1</sup> The International Organization for Standardization and the International Electrotechnical Commission (ISO/IEC) Guide 25-1990 *General Requirements for the Competence of Calibration and Testing Laboratories* defines "laboratory" as a "body that calibrates and/or tests." It further notes: "1) In cases where a laboratory forms part of an organization that carries out other activities besides calibration and testing, the term 'laboratory' refers only to those parts of that organization that are involved in the calibration and testing process. 2) As used herein, the term 'laboratory' refers to a body that carries out calibration or testing at or from a permanent location, at or from a temporary facility, or in or from a mobile facility."

<sup>&</sup>lt;sup>2</sup> ISO/IEC Guide 58-1993 General Requirements for Operation and Recognition – *Calibration and Testing Laboratory Accreditation Systems* defines "laboratory" as a "body that calibrates and/or tests." The Guide defines "accreditation" as a "procedure by which an authoritative body gives formal recognition that a body or person is competent to carry out specific tasks."

<sup>&</sup>lt;sup>3</sup> ANSI Z34.1-1993 *Third-Party Certification Program* and its companion ANSI Z34.2-1987 *Self-Certification by Producer or Supplier* defines "producer" as "the manufacturer, distributor, supplier or other party providing the product or service who is responsible for assuring conformity to all requirements of the referenced standards or specifications."

<sup>&</sup>lt;sup>4</sup>ISO Guide 48-1986 *Guidelines for Third-party Assessment and Registration of a Supplier's Quality System* defines an "assessment body" as a "third-party body which assesses and registers the Quality Systems of Suppliers with respect to published Quality Systems Standards."

#### Purpose and Content:

This directory provides information on private sector professional/trade organization laboratory accreditation and similar types of programs (schemes). These programs designate a set of laboratories or related entities as qualified to conduct testing to assist private sector professional societies, trade associations, related certification bodies, and government agencies in carrying out their responsibilities. The programs or schemes include an assessment of the laboratory's/entity's capability to conduct specified testing. However, the type and degree of rigor of such assessments vary greatly among programs. Entries in this directory are based on new and updated information provided by professional/trade organizations, which conduct such programs. The information reflects each organization's view of its program. In the course of compiling this information, some laboratories report an inconsistency in the manner in which some accreditation programs apply various portions of their formal assessment criteria and procedures. No attempt has been made either to confirm or refute such allegations. It should be noted that the criteria of some programs are applied on an optional or discretionary basis based on: the type of approval sought; past experience with the laboratory; fields of testing included in the accreditation scope; or the requirements/needs of the organizations relying on the accreditation.

The editor is unaware of any harmonized set of federal or state government criteria for evaluating private sector laboratory accreditation/ designation programs. In the absence of such criteria, this directory should only be used as one source of information for assessing individual programs. Parties interested in conformity assessment should also review NIST SP 903, Directory of U.S. Private Sector Product Certification Programs, which contains information on a number of closely related programs.

## Compilation of this Directory:

In compiling this information, organizations whose laboratory accreditation/designation programs and systems were last reported in the 1992 edition of NIST Special Publication 831, Directory of Professional/Trade Organization Laboratory Accreditation/ Designation Programs, were contacted to update their entries. Most of the organizations listed in NIST SP 903 were also contacted to advise them that SP 831 was being updated and to request information on any relevant programs. In addition, other sources were also used to develop a list of potential organizations that might operate laboratory accreditation programs, and they too were contacted.

The private sector accreditation/designation programs listed in this directory are generally recognized as third-party programs conducted by professional/trade societies, associations and other related types of organizations. There are also numerous first-party (producer/supplier) and second-party designation programs, many of which employ similar criteria. These were not included in this directory.

#### Directory Format:

The professional and trade organization entries in this directory are organized alphabetically by organization/title. Each entry contains: a description of the program; the date that the program was initiated; the authority under which the program is conducted; the fields of testing being accredited or designated, (employing where applicable ASTM 1224-94 Standard Guide for Categorizing Fields of Capability for Laboratory Accreditation Purposes Testing; the products directly or indirectly affected by the testing; program requirements; availability of related publications; and other information. Programs or systems included within this directory are updated or newly acquired listings based primarily on the 1992 directory, Directory of Professional/Trade Organization Laboratory Accreditation/ Designation Programs.<sup>5</sup>

Appendix I contains several indices, including a product index. A copy of the questionnaire and a description of the format used for each entry are contained in Appendix II. Appendix III, Reconciliation of Professional/Trade Organization Accreditation Systems Appearing in the 1992 Edition of NIST SP 831, provides information on programs which were included in the 1992 edition; but which, for one reason or another, are no longer listed. Appendix IV contains information on other organizations which provided data on their activities in the accreditation area, but which did not qualify for inclusion in the main body of the directory. Appendix V contains a list of acronyms, abbreviations and initializations used in the directory. Appendix VI contains a list of other NIST publications of potential interest to the reader.

#### Program Differences:

Requirements for private sector professional/trade organization laboratory accreditation/designation programs vary substantially among programs. American Association for Laboratory Accreditation (A2LA) programs for providing assurance of the competence of its accredited laboratories include: a review of a laboratory's structure; personnel; equipment and facilities; equipment calibration and maintenance procedures; quality control program; record keeping procedures; availability and use of operational/quality manuals; content and quality of actual test reports; testing conditions, methods and procedures; sample handling and selection procedures; an on-site inspection of the laboratory's equipment and facilities and/or the use of a proficiency testing program. On the other hand, programs intended to designate laboratories that primarily test products and equipment for procurement purposes (procurements requiring product conformity to specified standards and specifications) tend to concentrate on conducting an initial assessment and have fewer program follow-up or monitoring requirements.

<sup>5</sup> NIST Special Publication 831 *Directory of Professional/Trade Organization Laboratory Accreditation/ Designation Programs*, Charles W. Hyer, Editor, National Institute for Standards and Technology, Department of Commerce, Gaithersburg, MD 20899.

<sup>&</sup>lt;sup>6</sup> Laboratory proficiency testing is defined by ISO/IEC Guide 2 as the: "determination of laboratory testing performance by means of interlaboratory test comparisons."

In the case of model code organization laboratory accreditation designation programs, such programs have arisen from the adoption of the codes by state, local, and municipal authorities having jurisdiction. Code officials, who are familiar with the details and intention of specific code requirements, are employed as assessors to review and evaluate laboratories. The depth of such reviews are based on the laboratory's scope of operations. They are also based on the authority's dependence upon test report data to identify products, which conform to code requirements and which are thus acceptable for installation and use. Code organization laboratory accreditation/designation programs are an outgrowth of product evaluation schemes. Participation in such programs is often inappropriately assumed to be equivalent to achieving laboratory approval directly by governmental authorities. That is, such programs are sometimes assumed by laboratories and users of laboratory services to be comparable to such programs as the U.S. Department of Labor's Occupational Safety and Health Administration's Nationally Recognized Testing Laboratory (NRTL) program. In fact, such laboratory accreditations can more appropriately be considered as "recommendations" to some approval authority or authorities. The authority having jurisdiction to recognize/accept a laboratory relies on the recommendation (accreditation/designation) of a private sector assessor organization (code organization) known to be familiar with the requirements of the adopted code. Recognition or acceptance of the accreditation remains the responsibility of the authority (state or local government agency) having jurisdiction. Code organization laboratory accreditation/designation is the responsibility of the code organization, while laboratory recognition, acceptance of test results and product certifications (products that conform to code) are governmental responsibilities. Comprehending the differences among these functions and recognizing who has responsibility for each of them are crucial steps in understanding how the approval process really operates in the building and construction area.

Another difference among listed programs is the importance and use of international standards in the program. Included in the questionnaire, were two specific questions that provided some indication of the importance of international guides and standards concerning conformity assessment activities. The first asked: "Does your program conform to ISO/IEC Guide 58?" The second asked: "Are your requirements for laboratories comparable to ISO/IEC Guide 25?"

In each case, the 38 respondents were able to check "Yes," "No," or "Don't Know." Fourteen respondents indicated that their programs conformed to ISO/IEC Guide 58, while an almost equal number (twelve) indicated that either their program did not conform or they didn't know. For ISO/IEC Guide 25, 22 respondents indicated that their programs' requirements were comparable, while five said they were not and 11 didn't know. As a general observation, use of international conformity assessment guides and standards has grown since the last edition of this directory, though further education in this area is still needed.

The following chart summarizes the number of programs requiring each of 25 assessment criteria or procedures, out of a total of 38 programs:

	38 Programs Reports	
REQUIREMENT	WITH	WITHOUT
Must Be A Legal Entity	28	10
Must Be Financially Stable	24	14
Must Be Independent of Manufacturers/Suppliers Of Products Tested	23	15
Must Have An Effective Quality System	33	5
Must Have Procedures To Prevent Conflicts-Of-Interest	26	12
Must Have A Document Control System	31	7
Must Have A Contract Review Process	20	18
Must Have Procedures for Sub-Contracting Tests and Calibrations	21	17
Must Have A Documented Procurement Process	21	17
Must Have A Complaints/Appeals Process	18	20
Must Have A System to Control Nonconforming Testing and/or Calibration Work	22	16
Must Have A Corrective/Preventive Action Process	23	15
Must Have An Effective Recordkeeping Process	32	6
Must Have Documented Record Retention Requirements	23	15
Must Conduct Internal Audits of Its Quality System	28	10
Laboratory Management Must Review Results of Internal Audits	22	16
Must Have Qualified Personnel	35	3
Laboratory Measurements Must Be Traceable To National Standards	25	13
Must (Where Applicable) Use Effective Sampling Techniques	19	19
Must Have a Process for Handling/Transport of Test/Calibration Items	20	18
Must Participate In A Proficiency Testing Program	22	16
Must Have Adequate Instrumentation Facilities and Equipment	30	8
Must Ensure Adequate Equipment Maintenance/Calibration	31	7
Must Attend Program Laboratory Workshops/Conferences	8	30
Must Maintain Other or Related Accreditations/Approvals	7	31

Some programs have additional requirements not included in the above chart. For example, the American Oil Chemists' Society (AOCS), Page 25, requires an AOCS approved chemist to be on the full-time staff of laboratories applying for accreditation. Other requirements (not listed above) include membership by the laboratory in the association. Many of AOCS's formal procedures allow non-member laboratories, such as government laboratories, to be accredited. However, in reality all accreditations are held by members.

A few other important anomalies should also be considered when reviewing the above chart. The American Society for Testing and Materials (ASTM) Cement and Concrete Reference Laboratory (CCRL), Page 43, is considered to be a designation program. CCRL was started in 1929 as a Research Associate Programs at NIST. CCRL designates some 765 laboratories that have been evaluated using standards and test methods contained in NIST Letter Circular 1133. Though this program is not a true laboratory accreditation program because of its limited requirements, it does provide valuable evidence of testing laboratory competence. Such evidence is useful to others, which accredit/designate laboratories. The CCRL Program pre-dates most testing laboratory accreditation programs as well as most laboratory accreditation standards. However, the CCRL Program is often mistakenly identified as a laboratory accreditation program. With the CCRL program information detailed herein, it is now possible for interested parties to determine what additional requirements, if any, may be appropriate for accrediting laboratories that participate in this program. One can also get a better understanding of the limitations of this program by comparing is requirements with those of NIST's National Voluntary Laboratory Accreditation Program (NVLAP). Information on the NVLAP program is contained in NIST SP 808, Directory of Federal Government Laboratory Accreditation/Designation Programs.

Entries containing information on laboratory designations made by independent testing laboratories that operate third-party certification programs often indicate that "independence (no-conflict-of-interest)" is a requirement. Yet these entries also note that the accreditation of laboratories of participating manufacturers is allowed when such laboratories are needed to perform the in-house quality assurance testing required for certification.

Other anomalies were noted in the category: "Periodic Random Re-audit," which may result from such factors as national security clearance requirements. Some programs may also have checked the requirement, "Participation in Proficiency Testing," when such a requirement may be applicable only to certain types of accreditations or to only limited types of testing within the scope of the accreditation.

# Acceptance of Private Sector Accreditation Program Results by Government Agencies and Certification Programs:

Accreditation decisions made by some private sector laboratory accreditation programs can influence the outcome of applications for laboratory accreditation received by federal, state, local and municipal governments. A few of these are even mentioned by name in the category "Other Recognition." However, until there is some formal uniform governmental procedure for the recognition of private sector testing laboratory accreditation programs, government recognition of private sector laboratory accreditation programs will continue to be a erratic process. Recognition of private sector laboratory accreditation programs raises several major issues:

- Independent third-party private sector accreditation programs may not be needed in specific areas where there is a national government laboratory accreditation program, which can assure the competence of laboratories at a reasonable cost, since government programs are more likely to be widely recognized and accepted than private sector programs.
- Although mutual recognition among comparable programs is desirable to prevent needless, costly duplication, most private sector programs depend upon participating laboratory fees for their existence. Can such programs remain financially viable if mutual recognition among programs occurs?
- Recognition of multiple private sector testing laboratory accreditation programs by certifiers may also be difficult. Most accreditation efforts by certifiers are subtasks, undertaken as part of the operation of product certification programs. Certification programs need to identify laboratories, which are not only competent to conduct the testing, but which are also capable of providing virtually identical test results. The latter requirement is necessary given the competition among participating producers. The need for both types of assurance may cause recognition of multiple accreditation programs by certifiers programs to be infeasible.

Despite these problems, reducing duplicative and unnecessary laboratory accreditation requirements is a worthwhile effort, which should be pursued by government agencies in conjunction with the private sector.

# Directory Changes:

Private sector professional and trade organizations are encouraged to notify NIST of any changes in their laboratory accreditation programs or of new programs. Such information should be sent to:

Global Standards Program
National Institute of Standards and Technology
Administration Building, Room 820, MS 2100
Gaithersburg, MD 20899-2100

Phone: (301) 975-4031 Fax: (301) 963-2871

e-mail: maureen.breitenberg@nist.gov

## Other References:

The Office of Standards Services of the National Institute of Standards and Technology (NIST) periodically develops and publishes conformity assessment related documents as a service to producers and users of standards, both in government and in the private sector. A list of these publications is contained in Appendix IV. Conformity assessment information is also available on the NIST Conformity Assessment Website at:

http://ts.nist.gov/ca