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Examination of Laboratory Accreditation Programs in the United States and the Potential Role for a National Laboratory Accreditation System

Janice S. Jablonski
Consultant

Prepared for:

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ABSTRACT

On January 7, 1997, the National Institute of Standards and Technology (NIST), the American National Standards Institute (ANSI), and ACIL (formerly the American Council of Independent Laboratories) convened an open forum to present a proposed infrastructure for a U.S. laboratory accreditation system. The proposal, which would establish the National Council for Laboratory Accreditation (NACLA), is the result of a two-year effort by the three cosponsoring organizations to examine the viewpoints of industry, government and the public, characterize stakeholder concerns regarding the current system of laboratory accreditation in the United States, determine the need for a national system of laboratory accreditation, and develop a proposed infrastructure and implementation approach that would benefit users of laboratory accreditation and the public.

This report presents an initial study of existing U.S. laboratory accreditation programs, with a focus on government programs, particularly at the Federal level. The study was conducted in two phases: Phase I established categories of existing laboratory accreditation programs in the Federal government, at the state and local level, and in the private sector; Phase II compared technical standards used by five Federal government laboratory accreditation programs with general standards for laboratory accreditation established by the International Organization for Standardization (ISO).

The purpose of the study was to provide an initial assessment of the potential benefits of a national system for laboratory accreditation, particularly to existing Federal programs. The study supports two general conclusions:

- There are significant areas of overlapping scope, inconsistent program components, and application of highly variable accreditation terminology in laboratory accreditation programs in the United States; and

- Existing Federal government laboratory accreditation programs differ considerably in the extent to which they evaluate the general aspects of laboratory performance common to all testing and calibration laboratories.

Based on these conclusions, the study recommends that the NACLA Interim Board of Directors emphasize certain areas as it proceeds to develop a detailed plan for implementation.

EXAMINATION OF LABORATORY ACCREDITATION PROGRAMS IN THE UNITED STATES AND THE POTENTIAL ROLE FOR A NATIONAL LABORATORY ACCREDITATION SYSTEM

1.0 INTRODUCTION AND BACKGROUND

This report presents the results of a study of laboratory accreditation programs operating in the United States. The study was conducted for the National Institute of Standards and Technology (NIST) to support the initial planning stages for a comprehensive national program for laboratory accreditation.

1.1 Background

The services of analytical testing and calibration laboratories support nearly every aspect of commerce and government oversight in the United States. Laboratory test data document the safety and efficacy of consumer products, foods and drugs, goods and materials used by public institutions, and of electronic and other devices used by the general public and by the government. For example, laboratory test data allow doctors to evaluate patient health and make diagnoses. They allow industry and the government to ensure that our water and air are not polluted, and they allow consumers to purchase products that are safe for use in their homes, schools and workplaces. Consequently, the reliability of laboratory test data affects virtually all aspects of public health and safety, and hence is an important public concern.

Laboratory accreditation programs have long been recognized as one means for providing uniform assurance that testing and calibration laboratories have the basic facilities, equipment, operating practices, and other characteristics necessary to generate reliable test data. Both industry and the government have recognized the benefits of accreditation programs, and many such programs now exist in both the public and private sectors.

The development of laboratory accreditation programs in the United States has occurred in response to specific needs in specific areas of commerce or government regulation. Programs are designed to address specific domestic or international problems and reflect the resource and other practical constraints of their specific industry, market, or government program. Consequently, there is not a single model nor a set of models for laboratory accreditation programs. Programs differ in terms of their administrative aspects, the scope and specificity of their standards, and the significance of the approval, certification or accreditation status conferred on laboratories. This independent "system" for laboratory accreditation in the United States has led both industry and the government to recognize that there is significant redundancy and inefficiency in the status quo. There is now a growing body of literature which addresses the trade and economic consequences of the current system and the need for a more coordinated approach to conformity assessment and laboratory accreditation.

Prompted in part by this growing recognition and in response to the American Technology Preeminence Act of 1991 (P.L. 102-245), the National Research Council (NRC) in 1994 convened a committee on International Standards, Conformity Assessment, and U.S. Trade Policy. The

Committee's final report, published in 1995,[1] called for steps to be taken to establish a comprehensive program for conformity assessment in the United States. Following publication of the NRC report, Congress and the President charged the National Institute of Standards and Technology (NIST) with responsibility for coordinating conformity assessment activities in the United States, under the National Technology Transfer and Advancement Act of 1995.

NIST in 1994 began working with the American National Standards Institute (ANSI) and ACIL (formerly the American Council of Independent Laboratories) to examine the issues and concerns associated with the current system for laboratory accreditation. The three organizations formed an informal public-private partnership to cosponsor the Laboratory Accreditation Working Group (LAWG), with the goal of developing an infrastructure for a national laboratory accreditation system that would meet the needs of both government and industry. Efforts were made to ensure participation by all government and private sector organizations with an interest in laboratory accreditation. In October of 1995, LAWG conducted its first open forum on national laboratory accreditation. The purpose of this forum was to receive public comment concerning identified problems caused by the current laboratory accreditation environment and the potential need for a national system. As a result of the 1995 open forum, several themes emerged to guide the work of LAWG:

- The present patchwork of laboratory accreditation activities in the United States is inefficient and costly.
- There is a general lack of confidence in U.S. accreditation systems in both the public and private sectors.
- There is a lack of widespread use of international standards as common baseline criteria by U.S. laboratory accreditation programs.
- Domestic acceptance of U.S. test data is complicated by the existing patchwork of multiple accreditation systems.
- International acceptance of test data generated in the United States is an important competitive issue.
- There is a compelling need to address these problems in a comprehensive and meaningful way.

During 1996, LAWG further examined the issues and concerns of the public and private sectors and began to develop a preliminary proposed structure and operating procedures for the National Council for Laboratory Accreditation (NACLA). LAWG completed a draft proposal for NACLA in

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1 See: National Research Council. 1995. *Standards, Conformity Assessment, and Trade Into the 21st Century.* National Academy Press. Washington, D.C.

the Fall of 1996.[2] The draft NACLA proposal reflects three principal problems with the current system, as follows:

Laboratory accreditation programs in the United States have developed independently over time. U.S. programs do not reflect a uniform minimum standard for design and operation; they do not utilize uniform terminology to describe the status of laboratories, nor do they utilize selected accreditors; and, typically, they do not recognize other accreditations through reciprocal agreements. As a result, there is considerable confusion with respect to the meaning or significance of different accreditations, certifications, approvals, and recognitions. There is also considerable overlap among programs. The inconsistency and overlap in programs and terminology creates inefficiencies and unnecessary costs and is a barrier to achieving international recognition of U.S. programs.

There is no focal point for laboratory accreditation programs in the United States. Lacking a central source of information and a forum for information sharing, cooperation, and reciprocity, government programs have invested in tools or systems that are redundant. Cases where government programs have achieved cost savings as a result of cooperative efforts are rare.

Some U.S. laboratory accreditation programs are not designed to meet international standards. Consequently, the process of achieving international recognition of testing data generated by U.S. laboratories is unnecessarily complicated and, in some cases, impossible. Establishing a focal point for laboratory accreditation in the United States would create the basis for coordinated participation in international laboratory accreditation cooperatives and would provide a single point of entry to the U.S. laboratory accreditation system for laboratories and accrediting authorities outside the United States. The overall effect would be a more accessible system of laboratory accreditation with broad international recognition.

In January of 1997, LAWG held a second open forum to present and discuss the NACLA proposal with a broad audience representing the range of public and private interests in laboratory accreditation. The 1997 open forum was attended by some 300 representatives of government, industry, the laboratory community and the private sector laboratory accreditation community. At the close of the forum, the participants agreed by a large majority that implementation of NACLA should proceed through the initial steps proposed by LAWG. Consequently, in February of 1997, LAWG elected an Interim Board of Directors for NACLA, with representation from industry, testing and calibration laboratories, the government, private sector accrediting bodies, and general interests. The Interim Board of Directors is expected to work for one year to develop an expanded proposal for NACLA's organizational structure and function, including a proposed constitution and bylaws. These documents are expected to be presented in a third open forum during 1998.

1.2 Purpose and Scope of This Study

The study described in this report involved collecting and analyzing information on existing laboratory accreditation programs. It was conducted to assist NIST and the future NACLA Interim

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2 See: Collins, Belinda. *Laboratory Accreditation: The Need for a National Infrastructure.* CalLab, November-December, 1996.

Board of Directors in developing an organizational structure and operating procedures for NACLA that:

- Take into account the missions and goals of individual laboratory oversight programs operated in the United States.

- Provide clear benefits to laboratory oversight programs in the public and private sectors so that maximum participation in and endorsement of NACLA by public and private stakeholders can be achieved.

- Serve as the basis for a system of continuous improvement in the conformity assessment process, both from the standpoint of cost-effectiveness and technical reliability.

The study involved two phases. Phase I resulted in an analysis of laboratory accreditation programs previously documented by NIST, which characterizes their purpose and scope and identifies the principal benefits that NACLA can offer them. Based on the information compiled in Phase I, five programs were selected for further analysis in Phase II. In this second phase, the five selected programs were examined to determine the extent to which their technical standards for accreditation are consistent with International Organization for Standardization/International Electrotechnical Commission (ISO/IEC) Guide 25: *"General Requirements for the Competency of Calibration and Testing Laboratories."* This second phase provides an initial indication of the potential benefit to existing programs that would result from a NACLA accreditation based on the standards in ISO/IEC Guide 25.

1.3 Conclusions

The 1997 open forum provided a clear message from representatives of the private sector that there is strong support for a national system of laboratory accreditation. Supporters in the private sector cite the removal of international trade barriers and the potential for reduced costs and increased efficiency as reasons for establishing such a system. The potential benefits of a national system to government programs at the Federal and state levels are less well recognized, however.

This study provides an initial examination of existing government laboratory accreditation programs with the purpose of identifying some potential benefits to those programs that would result from a national system. While additional study and consideration of the implications of a national system are needed, this study supports some preliminary conclusions that may guide the deliberations of the NACLA Interim Board of Directors. They are as follows:

Some significant areas of overlapping scope, inconsistent program components, and application of highly variable accreditation terminology exist in laboratory accreditation programs. NACLA should include a process for addressing these aspects of the current system in a way that will strengthen and improve the overall U.S. laboratory accreditation system. Areas of overlap and inconsistency to be addressed should include:

- In the category of Federal programs supporting government oversight of product testing or certification, programs differ considerably in the

terminology used and the status granted to laboratories. Documentation of laboratory review procedures and criteria varies from program to program and program-qualifying procedures vary from simple review of written applications to comprehensive programs requiring written applications, on-site assessments, and routine laboratory proficiency testing.

- In the category of state and local programs supporting oversight of product testing/certification, preliminary information shows considerable overlap among state/local programs and Federal programs. Provisions for reciprocal recognition between programs were found in only a limited number of settings.

- Also in the area of product testing and certification, a large number of private sector programs appear to duplicate or overlap programs conducted at the Federal and state/local levels. Indications of cooperative or reciprocal relationships were identified in only a very few areas.

- In the area of state/local government programs supporting regulatory compliance, preliminary information shows that considerable overlap may exist between Federal and state programs and among state programs. Little evidence was found of reciprocal arrangements between state programs that accredit or certify for the same purpose. In the area of environmental testing, the National Environmental Laboratory Accreditation Conference (NELAC) has begun to address issues of overlap and to promote reciprocity among state programs. Similar problems in the area of occupational safety and health remain unaddressed, however.

Existing Federal government laboratory accreditation programs differ considerably in the extent to which they address the general aspects of laboratory performance common to all testing and calibration laboratories. These general areas include: laboratory organization and management, laboratory quality systems and audits, laboratory personnel, laboratory facility considerations, equipment and reference materials, measurement traceability and calibration, testing and calibration methods, handling of test items and specimens, laboratory record keeping, laboratory reports, subcontracting practices, and laboratory practices for addressing client complaints. NACLA should include a process designed to gain consensus among Federal government agencies concerning the value of ensuring that, at a minimum, all laboratory accreditation programs address these basic elements. NACLA should further set a goal of implementing such a minimum standard governmentwide reasonably soon. Ensuring that U.S. programs at a minimum address the components of ISO/IEC Guide 25 or its equivalent will improve the overall U.S. system and have both domestic and international benefits.

The NACLA Interim Board of Directors should consider NACLA to be an important leadership resource for the U.S. laboratory accreditation community in the future. For example, NACLA should develop and promote the application of the model used by NELAC and the National Conference on Weights and Measures (NCWM) to achieve consensus among existing, overlapping programs in other areas, particularly where state and Federal government programs overlap. There are many other examples of areas where NACLA leadership can be applied to improve

laboratory accreditation in the United States. For example, NACLA should serve as a forum for addressing issues common to numerous Federal government laboratory accreditation programs, such as:

- Proper procedures for ensuring due process in the suspension or revocation of an accreditation.
- Issues related to liquidated damages resulting from a loss of accreditation status for laboratories or loss of recognition status for accrediting bodies.
- Uniform standards for professional ethics in the accreditation process and in the laboratory industry.
- Appropriate roles for private accrediting bodies in areas typically addressed by government organizations.
- Appropriate relationships between private and public sector programs where they overlap.
- Uniform standards for maintaining confidentiality in the accreditation process and for identifying and addressing confidentiality violations.

Leadership within the Federal government would also provide a forum for identifying areas where cooperation among government programs or the establishment of public-private partnerships might be used to make existing laboratory accreditation programs more efficient and effective. Example areas include:

- Laboratory proficiency testing and related information management and dissemination needs.
- Development and distribution of reference materials for use by laboratories.
- Application of automated information management systems.
- Development and use of training programs.

The NACLA operating plan should therefore include provisions for bringing together representatives from all stakeholder groups to address these and other issues and develop consensus approaches to their resolution.

2.0 PHASE I: CATEGORIES OF EXISTING LABORATORY ACCREDITATION PROGRAMS IN THE UNITED STATES

This phase of the study consisted of a preliminary review of laboratory oversight programs conducted by the Federal government, state and local governments, and in the private sector. Individual programs in the public and private sectors were identified, briefly described and

categorized according to their common elements related to mission and purpose. This phase of the study was based on information from three principal sources:

- *Directory of Federal Government Laboratory Accreditation/Designation Programs*, NIST Special Publication 808 (February, 1991).
- *Directory of State and Local Government Laboratory Accreditation/ Designation Programs*, NIST Special Publication 815 (July, 1991).
- *Directory of Professional/Trade Organization Laboratory Accreditation/ Designation Programs*, NIST Special Publication 831 (March, 1992).

Information on each program listed in the directories was reviewed to identify: the purpose of the program, the scope of the program, the user community for the program, the laboratory community addressed by the program, and funding sources for the program. For each program in the Federal government, applicable Federal regulations were identified, searched and reviewed to further define the program's scope and purpose and to understand the roles of the government and private sector stakeholders in the program. In addition, conversations were conducted with representatives from some agencies to obtain information not otherwise available. Based on the information collected, programs in each major category (Federal government, state and local governments, and the private sector) were assigned to one of a series of categories based on their common mission-related elements.

Program Categories

Exhibit 1 summarizes the categories established for laboratory oversight programs operated by the Federal government, state and local governments, and the private sector. The remainder of this Phase I report provides a description of each category and lists the programs in each.

2.1 Federal Government Programs

Laboratory oversight programs operated by the Federal government have been established for three general purposes:

- To support procurement practices by government agencies.
- To support development of Federal regulations and enforcement of those regulations.
- To facilitate the international movement and/or sale of goods manufactured in the United States.

These three basic functions serve as the basis for the six Federal government program categories listed in Exhibit 1.

EXHIBIT 1
List of Categories for
Laboratory Accreditation Programs

Federal Programs

1. Programs supporting government procurement of analytical services
2. Programs supporting government procurement of goods and materials
3. Programs supporting generation of data for regulatory compliance demonstrations and regulatory decision making
4. Programs supporting government oversight of analytical services used by the general public
5. Programs supporting government oversight of product testing or certification
6. Programs supporting U.S. participation in international treaties or international trade interests

State and Local Programs

1. Programs supporting regulatory compliance determinations
2. Programs supporting oversight of product testing/certification

Private Sector Programs

1. Programs that overlap in scope with Federal or state government programs
2. Programs that have a unique scope and purpose

Programs supporting government procurement of analytical services

Numerous agencies of the Federal government purchase analytical services to support the implementation of their programs. The procedures by which contract laboratories are selected, laboratory performance is monitored, and laboratory reports are inspected and accepted constitute a laboratory oversight function which has all or nearly all of the components of a laboratory accreditation program.

The 1991 NIST Federal Directory lists only one such program. However, it is believed that this category is larger than indicated by the NIST Directory. One reason is that programs in this category may not be defined as formal laboratory "accreditation" or "approval" programs although they involve evaluation of laboratories against stated criteria for purposes of approval or acceptance. There are many examples of such programs in various stages of development and implementation. For example, in the past few years, efforts to remedy environmental hazards at Federal facilities have increased rapidly within the Department of Defense, the Department of Energy, and the Department of Interior. Each of these departments is in the process of establishing a system to oversee procurement of environmental analytical services needed to support their installation restoration efforts. While each department is at a different stage of designing and implementing a program that is tailored to its specific needs, these programs share

a common focus on evaluating laboratory quality systems to ensure that the necessary elements for reliable performance are present.

Environmental programs at EPA, DOD, DOE, and DOI are coordinated through a variety of intra-agency task forces and through the National Environmental Laboratory Accreditation Conference (NELAC). Through participation in NACLA, these agencies can benefit from working with their Federal and state peers who operate similar programs for different fields of testing by exploring opportunities for enhanced cost-effectiveness and identifying new tools and resources that may improve program efficiency and effectiveness.

The NIST Federal Directory identifies one formal program for accreditation or designation of laboratories to support government purchasing of analytical testing services:

> **The Department of Veterans Affairs Oversight Program for Veterans Administration Clinical Laboratories**, which assesses and oversees physicians' diagnostic skills, histopathological services, and chemical, nuclear, and biological testing of clinical samples at VA facilities. Under this program, the College of American Pathologists inspects and accredits VA laboratories, working under contract to the Department of Veterans Affairs. The Veterans Administration Pathology Service oversees the contract. Physicians' diagnostic skills are monitored through the CheckPath quality control program operated by the American Society of Clinical Pathologists. In addition, the Armed Forces Institute of Pathologists monitors the VA histopathology program using a peer review approach involving physicians and medical technologists from the government and private sector to conduct assessments.

Presumably, every Federal government organization that purchases laboratory services conducts a formal or informal program for overseeing the performance of its participating laboratories. Examples of such programs include:

> **The Environmental Protection Agency's Superfund Contract Laboratory Program (CLP)**, which procures analytical testing services to support investigation and remediation of abandoned hazardous materials sites listed on the National Priorities List, under the Comprehensive Environmental Response, Compensation, and Liabilities Act (CERCLA). For this program, EPA qualifies laboratories responding to Invitations for Bid (IFBs), conducts periodic on-site assessments of laboratories performing under contract, and implements a regular program of quarterly laboratory performance evaluation testing. Contractors support certain administrative and technical program functions, such as routine screening of data packages delivered by the laboratories, invoice verification, and operation of the quarterly performance evaluation testing program. EPA staff are responsible for conducting laboratory assessments and inspecting/accepting deliverables. The CLP is EPA's largest program for procurement of analytical services. Other smaller programs conducted by the Agency generally do not have formal, documented procedures for laboratory oversight because they involve only a small number of laboratories.

Programs similar to EPA's Contract Laboratory Program are conducted by the Department of Defense and the Department of Energy to support oversight of laboratories that provide environmental analytical testing services for cleanup of Federal facilities in accordance with CERCLA. One such program is:

> **The Naval Engineering and Environmental Support Activity, Naval Facility Engineering Command Analytical Quality Assurance Program**, which supports the Navy Installation Restoration (IR) program. Under the QA Program, NAVFAC assures the quality of environmental testing data collected to support cleanup of Navy facilities for purposes of compliance with CERCLA. As part of this program, NAVFAC operates an analytical laboratory evaluation program consisting of laboratory on-site assessments, proficiency testing, and data validation. All laboratories working under subcontract to engineering firms engaged in installation restoration activities for the Navy are required to participate in the program. Participating laboratories are evaluated to establish compliance with applicable Navy and EPA quality control and quality assurance requirements, as specified in a NEESA guidance manual (NEESA 20.2-047B).

The U.S. Army Corps of Engineers operates a similar program in conjunction with its Commercial Laboratory Assurance/Inspection Program (see category 2), and the Air Force Center for Environmental Excellence (AFCEE) also conducts a program for oversight of laboratories providing environmental testing services to support environmental clean-up activities at Air Force bases. The DOD and DOE programs rely on EPA's contract-specified methods and criteria to a significant extent and considerable coordination between the three agencies occurs routinely. Some coordination of these programs with EPA and with the states is occurring through NELAC.

Programs supporting government procurement of goods and materials

To ensure that goods purchased for the military meet specified standards, the Department of Defense has established centers such as the Defense Logistics Agency (DLA) and the Defense Electronics Supply Center (DESC). Laboratory oversight functions performed by these organizations are designed to identify testing laboratories capable of reliably performing routine specific tests designed to demonstrate that products meet standards for safety and durability. Many Federal government organizations require that goods and materials used by their programs meet published technical specifications to ensure the safety of users. These programs are often the Federal government equivalent of programs conducted at the state and local levels to ensure the safety of electrical equipment, building and construction materials and equipment, and fire prevention devices used by the general public.

The NIST Directory identifies such programs in the Department of Defense and the Department of Housing and Urban Development. Similar programs may exist in the Department of Energy, the Department of Interior, and other agencies of the Federal government. Identified programs include:

> **The U.S. Army Corps of Engineers District-Level Project and Commercial Laboratory Assurance/Inspection Program**, which ensures that laboratories performing materials testing for the Corps of Engineers have the necessary capabilities. Under this program, District Engineers are responsible for ensuring

that the laboratories used in support of projects conducted by their Districts have the necessary capabilities. Corps of Engineers District Laboratory staff inspect and approve commercial laboratories working under contract. Corps of Engineers District Laboratories are evaluated regularly by the NIST Cement and Concrete Reference Laboratory. The scope of the program includes determination of capabilities for mechanical and chemical testing of soil, aggregates, stone, sand, cement-based products including lime, concrete and gypsum, building constructions (including foundations), water, air and other environmental media.

The DOD Defense Electronics Supply Center, which conducts a program to determine the suitability of laboratories equipped to perform specific testing for manufacturers listed on its Qualified Product/Qualified Manufacturers List (QPL/QML). Under this program, DESC engineers assess laboratories seeking to test military devices for compliance with applicable specifications. The scope of the program includes electrical, nonionizing radiation, metrology, nondestructive optical, and photometric testing of military devices.

The DOD Defense Logistics Agency Qualified Laboratory List identifies laboratories capable of performing specification tests for clothing, textiles, footwear, and equipage-type items used by the military. Under this program, personnel from the Defense Personnel Support Center testing facility conduct assessments of private laboratories to determine whether they qualify for the list. The list is intended to assist DOD contractors in identifying qualified laboratories performing chemical, electrical, nondestructive, optical, photometric, thermal and physical testing of textiles and equipage/apparel products to ensure compliance with military standards.

The HUD Federal Housing Administration Technical Suitability of Building Products Program accredits third parties that validate manufacturers' certifications of building materials used in all HUD projects. Independent validation of product certifications is required for all manufacturers that supply HUD projects. Under the program, HUD authorizes independent organizations as program administrators qualified to issue accreditations to independent laboratories. Approved administrators conduct their own accreditation programs for commercial laboratories. All Carpet Administrators are required to use laboratories approved for carpet testing by NIST's National Voluntary Laboratory Accreditation Program (NVLAP). As of 1990, there were approximately 30 approved administrators and 40 accredited laboratories.

There may be similar programs in other agencies that conduct extensive construction projects or purchase electronic and equipment and machinery, such as the Department of Energy, the U.S. Postal Service and the National Aeronautics and Space Administration (NASA).

<u>Programs supporting generation of data for regulatory compliance demonstrations and regulatory decision making</u>

Various agencies of the Federal government are empowered by Congress to implement regulatory programs designed to protect public health and welfare. These include the Department of Agriculture, the Department of Health and Human Services, the Department of Labor, and the Environmental Protection Agency, among others. These agencies require analytical testing data to support their regulatory programs for two purposes:

- Supporting the process by which the government determines what regulations are necessary and at what level to establish regulatory standards or criteria.

- Supporting the process by which compliance with regulations is monitored, violations are identified, and enforcement cases are developed.

Data required for these two purposes must achieve an established level of reliability and must be representative of conditions in the system being examined (e.g., the environment, a drinking water delivery system, or an industrial workplace). Consequently, laboratory oversight programs designed to support such regulatory functions are generally concerned with the broadest scope of data quality and may take into account the design and execution of sampling schemes and procedures, for example. Materials or media sampled and tested may be highly variable (e.g., wastewater effluent or hazardous waste) or sampling procedures may be complex and designed to capture a high degree of variability and/or very low and difficult to measure concentrations of analytes (e.g., ambient air). For these programs, laboratory accreditation is generally interpreted as a certification that an analytical system is capable of generating data of the required quality. Accreditation in this category generally does not provide any assurance of the reliability of individual measurements or data reports.

The Department of Agriculture, the Department of Health and Human Services, the Department of Labor, the Department of Commerce/National Institute of Standards and Technology, and the Environmental Protection Agency all implement laboratory oversight programs that address data generated to demonstrate regulatory compliance and/or to be used to support regulatory decision making. The NIST Directory identifies the following programs in this category:

The Department of Agriculture Food Safety and Inspection Service (FSIS) Laboratory Accreditation Program, which accredits domestic, nonfederal analytical chemistry laboratories that test meat and poultry products for moisture, protein, fat, salt, and chemicals, including chlorinated hydrocarbons, polychlorinated biphenyls, sulfonamides, nitrosamines, and arsenic for purposes of demonstrating compliance with Department of Agriculture regulations. FSIS personnel conduct laboratory inspections and laboratories are required to participate in a periodic proficiency testing program. Laboratories must demonstrate compliance with published requirements for personnel qualifications, test methods, quality assurance and record keeping (9 CFR 318.21). Analyses are conducted in accordance with methods published by the Association of Official Analytical Chemists. Data generated by laboratories in this program are used to support state and Federal enforcement programs. The program is open to all U.S. laboratories.

The Department of Health and Human Services National Laboratory Certification Program (NLCP), which certifies laboratories that provide drug-testing services to employers that are required to comply with Federal regulations regarding employee drug and alcohol testing programs. For example, the Department of Transportation requires that recipients of certain funding from the Federal Transit Administration (including railroads operated by the National Railroad Administration) maintain mandatory employee drug testing programs. The Nuclear Regulatory Commission requires that licensees authorized to operate nuclear power reactors or to possess, use or transport formula quantities of strategic special nuclear materials, implement programs for periodic testing of employees for drugs and/or alcohol. All laboratories used for drug-testing services by DOT and NRC units are required by Federal regulation to be certified under the NLCP (49 CFR Part 40 and 10 CFR Part 26).

The NLCP is open to all domestic and foreign government and private laboratories that seek to provide drug-testing services to support employee drug-testing programs required by Federal regulation. DHHS contracts with a private consulting firm for services to operate the program. The private firm conducts all administrative and technical aspects of the certification process. Laboratories pay a fee for certification directly to the contractor. DHHS staff oversee the performance of the contractor.

The DHHS/Food and Drug Administration Toxicology Laboratory Monitoring Program, which is designed to ensure the quality and integrity of safety data on drugs, food and food additives, human biological products and medical devices. Under the program, FDA staff inspect nonclinical laboratories to monitor and ensure compliance with its Good Laboratory Practices standards (21 CFR 58). Participation in the program is mandatory for laboratories that generate data for manufacturers of products requiring FDA approval. Under this program, FDA also performs laboratory assessments for EPA' s laboratory oversight program conducted to support implementation of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA).

The Environmental Protection Agency Lead Laboratory Certification Program, which certifies laboratories analyzing lead in paint, dust and soil samples to support elimination of lead-based paint hazards in housing. The program was implemented under authority of the Residential Lead-Based Paint Hazard Reduction Act of 1992. As directed by the statute, EPA has established performance standards for laboratories analyzing lead in paint, dust and soil samples. EPA utilizes third party accreditors to evaluate laboratories for certification and periodically publishes a list of accredited laboratories. The program supports regulatory compliance and enforcement activities conducted by EPA, HUD and the Department of Labor.

The Department of Labor Occupational Safety and Health Administration Blood Lead Program, which approves laboratories shown to be capable of meeting OSHA-specified accuracy requirements for analysis of lead in blood to support compliance with OSHA standards for lead exposures in the workplace (29 CFR

1910.1025). Under this program, OSHA approves laboratories based on their performance in a quarterly laboratory proficiency testing program. The program is open to all U.S. and foreign laboratories.

The NIST National Voluntary Laboratory Accreditation Program (NVLAP), which is a voluntary program to accredit public and private laboratories for conducting specified test methods or calibrations in several specific fields of testing and calibration, including accreditation for bulk and airborne asbestos fiber analysis, in support of EPA's asbestos program. NIST conducts the program for EPA in accordance with an Interagency Memorandum of Understanding.

The Environmental Protection Agency Drinking Water Laboratory Certification Program, under which laboratories that analyze drinking water to support compliance with the Safe Drinking Water Act are certified either by EPA or delegated state authorities. Under this program, EPA 's Office of Research and Development National Exposure Research Laboratory certifies EPA's ten Regional Office laboratories for drinking water analysis. EPA Regional Certification Officers certify state laboratories and commercial laboratories located in states that do not have delegated programs. Delegated state Certification Officers certify commercial and utility laboratories that supply compliance data for drinking water systems within their boundaries. The program includes an annual mandatory program for laboratory proficiency testing.

Other EPA laboratory oversight programs which support regulatory and regulatory compliance programs include:

The FIFRA/TSCA Good Laboratory Practices Program, which assures the quality of data submitted by manufacturers requesting approval of chemical products under the Toxic Substances Control Act or pesticide products under the Federal Insecticide, Fungicide and Rodenticide Act. Under this program, FDA conducts audits of selected laboratories and studies for EPA. EPA also conducts its own audits of selected studies performed by laboratories not participating in the FDA program. In 1995, EPA committed to expanding this program to a full laboratory accreditation program by the year 2000.

The Discharge Monitoring Report Quality Assurance (DMRQA) Program, which conducts annual mandatory laboratory proficiency testing for laboratories supplying monitoring data in accordance with discharge permits issued under authority of the Clean Water Act. This program includes proficiency testing for chemical analysis and whole effluent toxicity testing. The program is designed to monitor compliance with the analytical testing and quality assurance requirements established under the Clean Water Act (40 CFR 136).

The ICR Laboratory Approval Program for drinking water laboratories participating in the Agency's Information Collection Requirements (ICR) Rule drinking water monitoring program. This program is operated by EPA's Office of Ground Water and Drinking Water separate from the Drinking Water Laboratory

Certification Program. It involves approving chemistry laboratories to perform specific chemical tests for disinfectants and disinfection by-products and approving microbiological laboratories for identification and quantification of *Giardia* and *Cryptosporidium* in drinking water samples, in accordance with EPA-specified methods. It includes a regular proficiency testing program. The ICR program was newly-established by EPA in 1995, and will run for a limited duration of approximately 2 years.

Programs supporting government oversight of analytical services used by the general public

In a few instances, Federal government programs have been established to oversee the quality of services provided by laboratories that serve the needs of the general public. The most significant example of this type of program is the Department of Health and Human Services program for certification of medical testing laboratories, which was established under the Clinical Laboratory Improvement Act of 1988. The most significant characteristic of these programs is that they encompass very large communities of laboratories that vary widely in terms of size and the range of services provided. Consequently, in addition to technical and scientific issues of quality control, these programs must address issues related to the impact of accreditation on both small and large laboratories, the wide range of compliance scenarios posed by diverse laboratory populations, and the administrative infrastructure required to oversee a large population. These programs require streamlined, efficient administrative and information management systems and must be based on policies reflecting trade-offs between financial and logistical considerations and quality objectives.

The NIST Directory identifies two Federal government programs established specifically to evaluate and approve laboratories that provide services to the general public:

The Department of Agriculture Animal and Plant Health Inspection Service Contagious Equine Metritis Program, which approves laboratories for conducting diagnostic procedures for venereal disease in horses (contagious equine metritis). Under the program, USDA Field Veterinary Medical Officers evaluate and approve laboratories. The program is open to all U.S. public and private laboratories.

The Department of Health and Human Services Health Care Finance Administration Clinical Laboratory Approval Program, which certifies all laboratories in the United States engaged in the testing of human specimens, under authority of the Clinical Laboratory Improvements Act of 1988. Originally, CLIA required the licensing of medical testing laboratories engaged in interstate commerce and certification of medical testing laboratories for Medicare or Medicaid payment status. In 1988, CLIA was broadened significantly to include all laboratories engaged in medical testing. This expanded program affects an estimated 300,000 to 600,000 laboratories.

Programs supporting government oversight of product testing or certification

This category is the largest of Federal government laboratory oversight programs. Programs in this category are generally designed to oversee independent testing laboratories that

perform specific, routine tests on designated products or types of products, such as electrical equipment, safety equipment and radio frequency emitting devices. Issues of sampling and sampling variability are less important (although not absent) in these programs. Programs in this category vary widely in terms of the terminology used and the "status" of laboratories reviewed. Some grant a formal accreditation or delegate authority to act on behalf of the government to qualified laboratories; others utilize only a "listing" process with no official relationship between the government and the laboratory (i.e., the applicable Federal regulations establish a process for manufacturers to apply for approval without provisions for a formal laboratory oversight or approval program). Consequently, this category provides an important opportunity for NACLA to serve as a vehicle for improving consistency and reliability in the conformity assessment community.

A large number of Federal agencies require that products or materials used for specific purposes be tested and certified to meet specific technical standards. For example, the Federal Communications Commission authorizes radio frequency emitting devices, the U.S. Coast Guard approves a variety of safety and other equipment used on board commercial and recreational vessels, the Department of Labor approves numerous types of electrical and other equipment as safe for use in the workplace, and EPA approves wood-burning stoves for use in the United States. All of these programs involve testing of products, generally by independent laboratories, to certify that they meet regulatory specifications. Such programs typically involve examination of test data and test facilities to determine that the laboratory is qualified to conduct the subject tests. In some cases, laboratories are specifically certified or accredited for the purpose; in others, the government maintains a list of qualified laboratories, but does not issue a specific certification or accreditation. This category of Federal government programs is by far the largest. The following 16 programs have been identified from the NIST Directory and other sources:

The Department of Agriculture Federal Grain Inspection Service, which approves private and government units to inspect and weigh grains and to test equipment and weights under the U.S. Grain Standards Act and approves Federal units to inspect and weigh commodities under the Agricultural Marketing Act. Under the program, USDA delegates authority to approved entities for purposes of conducting grain and commodity inspections and calibrating weighing equipment. The program is recognized by the National Conference on Weights and Measures.

The Department of Commerce National Conference on Weights and Measures State Laboratory Approval Program, which certifies state laboratories for compliance with standards established by the National Conference on Weights and Measures as part of a national program for uniform standards applicable to weighing and measuring devices. Through the NCWM, states develop uniform national standards which they then implement at the state level, by agreement. NIST evaluates state laboratories for compliance with the national standards, in accordance with the NCWM constitution and bylaws. Participation in NCWM is voluntary for states.

The Department of Commerce/NIST National Voluntary Laboratory Accreditation Program (NVLAP), which is a voluntary program to accredit public and private laboratories for conducting specific test methods or calibrations in specific fields of testing and calibration. NVLAP includes accreditation of

laboratories for conducting standard tests on products such as carpet, building materials (such as thermal insulation materials, concrete, cement, and aggregates), road/paving materials, radiation dosimetry devices, paint, paper, sealants, plastic, plumbing fixtures, and telecommunications equipment. NVLAP accreditation in these areas supports government programs for oversight of product testing or certification. NVLAP has other components (such as asbestos testing and fasteners and metals) that support regulatory programs.

The Environmental Protection Agency Wood Stoves New Source Performance Standards (NSPS) Laboratory Accreditation Program, which accredits laboratories for testing wood stoves to demonstrate their ability to meet New Source Performance Standards established by EPA under the Clean Air Act (40 CFR Part 60). Under the program, EPA staff conduct on-site laboratory inspections and award accreditation to qualified laboratories. Laboratories are then accredited to test and certify new wood-burning stoves, in accordance with EPA-specified methods. The program also includes an annual laboratory proficiency testing program.

The Environmental Protection Agency Program for Recognition of Independent Laboratories for Retrofit Device Evaluation, which recognizes independent laboratories as capable of performing screening tests on vehicles for assessing emissions and fuel economy benefits devices (including fuel additives). This program is intended to identify laboratories for use by manufacturers in conducting screening evaluations of products in advance of emissions testing conducted by the EPA laboratory. EPA staff evaluate written information received from laboratories. No on-site evaluation or proficiency testing is conducted. Laboratories having facilities and equipment similar to those of the EPA Motor Vehicle Emissions Laboratory are identified.

The Federal Communications Commission Program for Authorization of Radio Frequency Emitting Devices, which includes a program for listing laboratories capable of performing tests required for FCC authorization of equipment. Under FCC regulations (at the time of report preparation) governing the marketing of radio frequency devices, manufacturers are required to provide a description of the measurement facilities used to conduct the required tests (47 CFR 2.948). To support the review of measurement facilities information, FCC personnel maintain a list of qualified measurement facilities. Manufacturers use facilities listed by FCC to conduct required tests. FCC regulations provide for on-site inspections and witnessing of test procedures by FCC personnel; however, no routine program of on-site evaluations is conducted. Decisions to list laboratories are based on review of written information provided by laboratories. Laboratories are required to update the information on file with FCC as appropriate. Laboratories are "re-listed" every three years.

The Department of Health and Human Services, Food and Drug Administration Center for Food Safety and Applied Nutrition Evaluation of Milk Laboratories Program, which evaluates and endorses laboratories that

monitor milk and dairy products for biological and chemical contaminants. This program supports a voluntary consortium of FDA, the states, and the National Conference of Interstate Milk Shippers with the goal of ensuring the safety of dairy products sold in interstate commerce. Under the program, FDA and the states inspect milk laboratories periodically (every two or three years). Recognized laboratories participate in an annual split sample analysis program.

The Department of Labor Occupational Safety and Health Administration Nationally Recognized Testing Laboratories (NRTL) Program, which recognizes U.S. and foreign organizations capable of performing tests for safety on equipment and materials that meet OSHA-specified criteria. The program covers electrical and fire protection tests on electrical and related products used in the workplace. Criteria are specified as Federal regulation (29 CFR 1910). OSHA staff conduct all on-site laboratory evaluations. Accreditations are renewed every five years.

The OSHA Maritime Cargo Gear Accreditation and Certification Program, which approves third parties for purposes of inspecting maritime materials handling devices, such as cranes and derricks. This program covers mechanical, electrical, and nondestructive testing in accordance with specified methods and criteria. OSHA staff perform all laboratory evaluations. Laboratory approvals are renewed every one to three years. The program has international recognition through the International Labor Organization Convention.

The Department of Transportation/U.S. Coast Guard Merchant Vessel Inspection and Equipment Testing Program for Recreational and Commercial Vessels, which accredits laboratories for purposes of testing lifesaving, engineering, fire protection, and pollution prevention equipment used on recreational and commercial vessels to demonstrate compliance with Coast Guard standards. This program includes biological, chemical, mechanical, photometric, and thermal testing of safety, survival, fire protection and pollution prevention equipment. U.S. Coast Guard engineers assess and accredit laboratories to test and certify equipment in accordance with Coast Guard regulations.

The U.S. Coast Guard Program for Approval of Equipment Used in Hazardous Areas Aboard Commercial Vessels, which recognizes independent testing laboratories for testing of electrical equipment used in hazardous areas on Coast Guard certified vessels. This program involves approval for conducting electrical, mechanical and nondestructive tests on electrical enclosures, wiring and cabling, in accordance with standards established by the National Electrical Code and the National Fire Protection Association. Under this program, U.S. Coast Guard engineers conduct all laboratory evaluations.

The Department of Treasury U.S. Customs Service Petroleum Laboratory Accreditation Program, which accredits laboratories for the purpose of conducting chemical testing of petroleum, petroleum products, and bulk organic chemicals upon entry to the United States to determine that they meet standards established by U.S. Customs (19 CFR 151.13). All tests are performed in accordance with ASTM

and American Petroleum Institute methods and standards. U.S. Customs personnel conduct all laboratory evaluations.

Programs supporting U.S. participation in international treaties or international trade interests

In a small number of cases, agencies of the Federal government have established laboratory oversight programs in response to requirements imposed by the international community related to products exported from the United States. In these cases, in order to maintain the position of U.S. commerce abroad, the government has entered into formal treaties that require establishment of a laboratory accreditation or certification program or simply created a government program to certify laboratories in response to import restrictions implemented by foreign governments.

The NIST Directory identifies three laboratory certification programs which are conducted for purposes of testing products exported from the United States or used in export activities. These are:

The Department of Agriculture Program for Certification of ATP Test Stations and Laboratories, which certifies facilities that test trucks, trailers, rail cars, freight containers, refrigeration units, and other equipment used for international transport of perishable foods, as required by the Agreement on International Carriage of Perishable Foodstuffs. Department of Agriculture staff conduct all evaluations under this program. Certified facilities are authorized to issue ATP certificates for equipment determined to meet established standards. As of 1990, 20 countries were signatories to the Agreement.

The U.S. Coast Guard Cargo Container Safety Approval Program, which approves organizations to conduct mechanical tests on cargo containers used in international shipping for purposes of compliance with the International Convention for Safe Containers. Under this program, Coast Guard personnel review and approve third parties to receive delegated authority from the Commandant of the Coast Guard to approve containers for use in international shipping. The program is open to all U.S. laboratories and laboratories in foreign countries that are not parties to the Convention.

The Department of Treasury Bureau of Alcohol, Tobacco, and Firearms Laboratory Certification Program for Analysis of Wines and Distilled Spirits, which certifies laboratories that analyze wine and distilled spirits to meet the requirements of foreign governments for exported products to be accompanied by a chemical analysis generated by an ATF-certified laboratory. Analyses are required to be conducted in accordance with Internal Revenue Service and ATF procedures. ATF personnel assess written documentation from laboratories. No on-site evaluation or proficiency testing is required.

2.2 State and Local Government Programs

Programs Supporting Regulatory Compliance Determinations

Under numerous Federal statutes, regulatory programs may be delegated to states upon a finding that the state program is equivalent to the Federal program. In cases where the Federal program includes a laboratory oversight function, state programs must also include an equivalent laboratory function. Under all of the major regulatory programs implemented by EPA, for example, authority is delegated to equivalent state programs to enforce the Federal program. In the case of drinking water programs, all delegated states are required to certify laboratories that provide drinking water monitoring data for compliance purposes. State certification programs must be based on Federal guidance and may rely on EPA's national laboratory proficiency testing program, or they may rely on another, equivalent proficiency testing program that meets their specific needs. Under the Clean Water Act, state programs must require that all facilities classified as Major Dischargers participate in EPA's annual laboratory proficiency testing program for chemistry and whole effluent toxicity testing. In the areas of hazardous waste and air quality, EPA's Federal programs do not have specific provisions for laboratory accreditation. States with delegated programs in these areas are therefore not required to certify laboratories for hazardous waste or air analysis. However, many states have developed certification programs in these areas, especially where they can be easily added as an expansion to existing drinking water laboratory certification programs. All of these environmental programs are coordinated on a national level through the National Environmental Laboratory Accreditation Conference.

States also implement their own occupational safety and health programs. All regulated industries are required to comply with the Federal regulations established by OSHA. Some states also have their own additional requirements. All equipment testing laboratories used by manufacturers of workplace equipment must be recognized by OSHA's NRTL Program, at a minimum. State programs may rely on the NRTL Program or may have their own mandatory, independent laboratory approval or accreditation process.

In addition to regulatory programs delegated by the Federal government, states operate regulatory programs in accordance with authorities established solely by state statutes. Such programs may also include laboratory accreditation or oversight programs. For example, state programs for oversight of weights and measures activities (i.e., those participating in the National Conference on Weights and Measures).

The following laboratory oversight program types have been identified at the state and local level to support enforcement of regulatory programs:

Drinking Water Laboratory Certification Programs: All states having delegated authority to enforce the Federal Safe Drinking Water Act certify laboratories that analyze drinking water for compliance purposes. States have designed their own laboratory certification programs, developed their own standards and criteria for certification, and require the use of either an EPA-operated laboratory proficiency testing program or an alternative program. All state programs are based on technical guidance provided by EPA. State Certification Officers are required to

attend an EPA training program and state drinking water laboratories are certified by the EPA Regional Laboratories.

Wastewater Laboratory Certification Programs: Some states with delegated authority to enforce the Clean Water Act operate certification programs for wastewater laboratories. These programs are typically administered in conjunction with the state's drinking water laboratory certification program and utilize EPA proficiency testing programs for wastewater analysis. Because there is no national laboratory accreditation program for wastewater laboratories (the DMRQA program noted previously only requires participation in an annual laboratory proficiency testing study), no EPA guidance is provided for such programs. Guidance addressing laboratory inspections is available from EPA, however.

Hazardous Waste Laboratory Certification Programs: A smaller number of states operate laboratory certification programs for laboratories conducting analyses to document compliance with state Resource Conservation and Recovery Act (RCRA) programs (with delegated authority from EPA) and for state programs designed to provide for remediation of abandoned hazardous materials sites that are not listed on the National Priorities List. Since EPA does not operate laboratory certification programs in either the RCRA or Superfund areas, there are no Federal requirements or guidance for such state programs. Analytical method guidance is provided by EPA for RCRA compliance and the methods used by EPA's Superfund Contract Laboratory Program are often used by state programs. EPA does not conduct a national laboratory proficiency testing program for hazardous waste analysis. States may use results from the drinking water and/or wastewater proficiency testing programs, or they may require that laboratories purchase studies from private vendors. In a small number of cases, states produce and distribute their own performance evaluation studies.

Air Quality Laboratory Certification Programs: A small number of states also operate laboratory certification programs for laboratories conducting analyses to support compliance with the Clean Air Act. These programs exist only in the few states that have comprehensive environmental laboratory accreditation programs. EPA does not have a national program for accreditation of air quality laboratories, and state programs are designed to meet the needs of the state program, utilizing analytical methods guidance published by EPA. EPA does operate national proficiency testing and reference materials programs for air quality laboratories, which are utilized by state programs.

Comprehensive Laboratory Certification Programs Supporting Implementation of State Sanitary Codes: Several states operate comprehensive laboratory accreditation programs to support areas regulated under state sanitary codes. These programs oversee, for example, veterinary laboratories, animal research laboratories, and certain product testing laboratories. Many also include the state drinking water laboratory certification program under the umbrella sanitary code program.

Programs supporting oversight of product testing/certification

Nearly all states have laboratory oversight programs for laboratories that test products and materials for certification under state and local laws. Some of these programs overlap with programs at the Federal level. For example, while the majority of occupational safety and health programs at the state and local levels rely on OSHA's Nationally Recognized Testing Laboratory (NRTL) Program, some jurisdictions have their own laboratory accreditation or recognition programs that are specified in addition to the OSHA NRTL Program. Others evaluate laboratories for the same fields of testing as Federal programs, such as the Department of Defense program for certification of electrical equipment and the Department of Housing and Urban Development program for certification of building and construction materials. This overlap represents another significant opportunity for NACLA to make the current system of laboratory accreditation and conformity assessment in the United States more consistent and efficient. Following is a listing of types of programs in this category that have been identified at the state and local level from the initial information sources.

Laboratory approval related to fire safety products/materials certification (pertaining to products listed by state/local Fire Marshals)

Laboratory approval related to testing buildings (including foundations) for compliance with earthquake standards (identified in California only)

Laboratory approval related to products or equipment used in the workplace

Laboratory approval related to testing solar collection devices (identified in Florida only)

Laboratory approval for testing dairy products

Laboratory approval for testing other types of foods

Laboratory approval for testing electrical materials, devices and appliances based in the National Electrical Code

Laboratory approval for testing products covered by state sanitary codes, including disinfectants, soaps, detergents, biocides and water treatments

2.3 Programs Operated by the Private Sector

The NIST 1992 *Directory of Professional/Trade Organization Laboratory Accreditation/Designation Programs* identifies laboratory accreditation programs addressing 28 different industry and product areas. Nearly all of these programs accredit or recognize laboratories that perform specific routine tests on products. Programs in half of the industry/product areas overlap in scope with laboratory oversight programs conducted by the Federal government or state/local governments. The largest area by far is construction materials, with 19 different organizations identified that accredit laboratories performing tests on materials or products used in construction. Many of these programs duplicate each other and programs

conducted by the Federal government (e.g., the Department of Housing and Urban Development and the NIST National Voluntary Laboratory Accreditation Program). Consequently, providing a framework within which to achieve increased uniformity and reciprocal recognition within this group of programs is an important opportunity for NACLA.

Following is a listing of private sector programs that fall into the two categories identified in Exhibit 1: Programs that overlap in scope with Federal or state government programs and Programs that have a unique scope and purpose, organized by industry or product area.

Programs that overlap in scope with Federal or state government programs

Agricultural Products:

American Oil Chemists Society
National Soybean Processors Association

Blood and Human Tissue:

American Association of Blood Banks

Boating Equipment:

National Marine Manufacturers Association

Construction Materials:

American Architectural Manufacturers Association
American Association of Laboratory Accreditation
American Institute of Steel Construction, Inc.
Associated Laboratories, Inc.
Board of Accreditation of Concrete Testing Laboratories of North Carolina
Building Officials and Code Administrators, Inc.
Cellulose Industry Standards Enforcement Program
Council of American Building Officials/National Evaluation Service
ETL Testing Laboratories, Inc. Laboratory Approval Programs for Certification Program Testing
International Association of Plumbing and Mechanical Officials
International Conference of Building Officials
Kitchen Cabinet Manufacturers Association
MTL Certification Services
American Society of Mechanical Engineers/National Board of Boiler and Pressure Vessel Inspection
National Certified Testing Laboratories, Inc.
National Electrical Testing Association
NSF International
National Wood Window and Door Association
Southern Building Code Congress International, Inc.

Drinking Water, Drinking Water Additives and Water Handling Devices:

American Association of Laboratory Accreditation
NSF International

Electrical Equipment:

American Association of Laboratory Accreditation
International Electrotechnical Commission Quality Assessment System for Electronic Components
MET Electrical Testing Company, Inc./Approval of Laboratories for use in MET Certification Program
The United States National Electronic Components Quality Assessment System, Electronic Components Certification Board

Environmental Testing:

American Association of Laboratory Accreditation

Industrial Hygiene Laboratory Analysis and Product Testing:

American Industrial Hygiene Association
National Association of Independent Laboratories for Protective Equipment Testing

Laboratory Animal Care Facilities:

American Association for the Accreditation of Laboratory Animal Care

Medical Testing:

American Association of Laboratory Accreditation
College of American Pathologists Laboratory Accreditation Program

Road and Paving Materials:

American Association of State Highway Transportation Officials (Accreditation in conjunction with NIST)
American Association of State Highway Transportation Officials/Materials Reference Laboratory
American Society of Testing Materials/Cement and Concrete Reference Laboratory

Solar Collectors and Solar Domestic Water Heaters:

Solar Rating and Certification Corporation

Transportation Containers:

National Safe Transit Association, Technical Verification Program

Programs that have a unique scope and purpose

Air Movement and Control Equipment:

Air Movement and Control Association

Computers and Communications Equipment:

Corporation for Open Systems International
MET Electrical Testing Company, Inc./Approval of Laboratories for use in MET Certification Program

Dental Devices:

National Association of Dental Laboratories National Board for the Certification of Dental Laboratories

Glass and Glass Products:

Insulating Glass Certification Council
Safety Glazing Certification Council/Approved Testing Laboratories for Testing in the ANSI and Consumer Product Safety Commission

Lubricating Oil:

American Society of Testing Materials

Medical Devices:

MET Electrical Testing Company, Inc./Approval of Laboratories for use in MET Certification Program

Motor Vehicles:

American Association of Laboratory Accreditation
American Association of Motor Vehicle Administration

Offshore Oil and Gas Operations:

American Society of Mechanical Engineers Safety and Pollution Prevention Equipment Program

Railroad Equipment and Materials:

Association of American Railroads

Treated Wood:

American Wood Preservers Bureau

3.0 PHASE II: COMPARISON OF SELECTED EXISTING FEDERAL LABORATORY ACCREDITATION STANDARDS WITH ISO/IEC GUIDE 25

This phase of the study consisted of a comparison of laboratory accreditation standards used by five selected Federal government programs with the standards included in: *"General Requirements for the Competency of Calibration and Testing Laboratories (ISO/IEC Guide 25-1990),"* hereinafter referred to as ISO 25. The purpose of this comparison analysis was to provide NIST and the National Conference on Laboratory Accreditation (NACLA) with an initial assessment of the extent to which laboratory accreditation programs in the Federal government utilize standards that examine the same characteristics as do the ISO standards. NIST and NACLA can use this analysis to consider the extent to which a NACLA-recognized accreditation based on the ISO 25 standards might serve as a uniform national standard common to all U.S. laboratory accreditation programs.

The analysis compared the standards published by five Federal programs with ISO 25. The documents used for the comparison were:

1. The **National Environmental Laboratory Accreditation Conference (NELAC)** standards for accreditation of environmental testing laboratories (published by the U.S. Environmental Protection Agency as of July 24, 1996);

2. The Department of Health and Human Services, Alcohol, Drug Abuse, and Mental Health Administration's **Mandatory Guidelines for Federal Workplace Drug Testing Programs**, published in the *Federal Register* on April 11, 1988 (53 FR 11970 - 11989) and amended on June 9, 1994 ;

3. The Department of Health and Human Services, Food and Drug Administration's standards for **Good Laboratory Practice for Nonclinical Laboratory Studies (GLP)**, as published on April 1, 1996 (21 CFR Part 58);

4. The National Institute of Standards and Technology procedures and general requirements for the **National Voluntary Laboratory Accreditation Program**, published in March of 1994 (NIST Handbook 150); and

5. The U. S. Environmental Protection Agency laboratory quality systems requirements for the **National Lead Laboratory Accreditation Program**, published on April 30, 1993.

The standards included in each of these references were compared, line by line, to ISO 25, to determine the extent to which they are identical or substantially similar.

Results

Exhibit 2 summarizes the extent of overlap between the ISO 25 standards and each of the five Federal programs examined. Of those, only the NELAC and NVLAP standards include all the requirements of ISO 25. During 1996, NELAC made a deliberate effort to ensure that the quality systems requirements of the NELAC standards are as consistent with ISO 25 as possible. Consequently, the NELAC standards include all of ISO 25 requirements and, in most cases, utilize the same language as ISO 25. Similarly, the NVLAP procedures and general requirements have been specifically designed to include all aspects of ISO 25. Both the NELAC and NVLAP standards also include requirements that address laboratory performance characteristics beyond the scope of ISO 25. Consequently, a NACLA-recognized accreditation based on ISO 25 would provide both NELAC accrediting authorities (principally environmental programs at the state level) and NVLAP with an initial assessment of general laboratory characteristics. By relying on a NACLA recognition process, NELAC and NVLAP could focus the scope of their laboratory assessments on those performance characteristics unique to their programs.

Overlap between the ISO 25 standards and each of the Federal Workplace Drug Testing Program, the Good Laboratory Practices (GLP) program, and the National Lead Laboratory Accreditation program[3] was less than for NELAC and NVLAP. In all three cases, most of the principal topics covered by ISO 25 were also addressed by the program standards. In many instances, however, the program standards were less specific and detailed than ISO 25. For example, while all three programs included requirements for the contents of laboratory reports, none included all the items explicitly required by ISO 25. The ISO Guide lists 16 items which must be included in all reports:

1. A title
2. Name and address of the laboratory
3. Unique identification of the report and of each page, and the total number of pages
4. Name and address of the client, where appropriate
5. Description/identification of the item tested or calibrated
6. Characterization of the item tested or calibrated
7. Condition of the item

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[3] To implement the National Lead Laboratory Accreditation program, EPA maintains a Memorandum of Agreement with both the American Association for Laboratory Accreditation (A2LA) and the American Industrial Hygiene Association (AIHA) to conduct laboratory assessments and recommend laboratories for accreditation. A2LA evaluates all laboratories against ISO 25 as well as the specific requirements of the National Lead Laboratory Accreditation Program.

8. Date of receipt of the item and date of testing

9. Identification of the test method used

10. Reference to sampling procedures used, if any

11. Any deviations from the published method

12. The results of testing and any supporting data

13. A statement of the estimated uncertainty

14. Signature and title of the responsible individual, and date of issue

15. A statement that the results apply only to the item tested, where appropriate

16. A statement that the report or certificate shall not be partially duplicated without the written approval of the laboratory.

The GLP standards included explicit requirements for 9 of the 16 elements; the Federal Workplace Drug Testing Program standards included explicit requirements for only 3 of the 16 elements; the National Lead Laboratory Accreditation program standards require 5 of the 16 elements. Other areas of difference in the level of detail include standards for quality systems, laboratory facility environment, maintenance of equipment and reference materials, measurement traceability and calibration, and test methods.

Exhibit 2 provides this analysis for each of the elements of ISO 25. In some cases, notes indicate differences between the program standards and the ISO 25 standards. In these cases, the ISO standards are generally more comprehensive than the program standards. Consequently, laboratories meeting the ISO 25 standard would likely be found to comply with the program standards as well. In one case, a conflict was identified between ISO 25 and the program standards. ISO 25 includes provisions for qualifying subcontractor laboratories to provide services as needed. The Federal Workplace Drug Testing Program standards strictly prohibit the use of subcontractor laboratories and this difference in policy is noted in Exhibit 2. The GLP program standards do not address the use of subcontractor laboratories, presumably because nonclinical drug testing methods generally require that all tests be performed at one site, and hence are not conducive to subcontracting. Standards for the National Lead Laboratory Accreditation Program also do not address subcontracting.

Two areas addressed by ISO 25 are not addressed by the Federal Workplace Drug Testing Program, the GLP Program, and the National Lead Laboratory Accreditation Program. These are standards for procurement of outside support and supplies and standards for addressing client complaints. The current ISO requirements in these areas do not conflict with standards in any of the three Federal programs, however.

EXHIBIT 2
SUMMARY TABLE COMPARING EXISTING STANDARDS WITH ISO 25 FOR SELECTED FEDERAL LABORATORY ACCREDITATION PROGRAMS

Key

NELAC: National Environmental Laboratory Accreditation Conference

DHHS: The Department of Health and Human Services, Alcohol, Drug Abuse, and Mental Health Administration's Federal Workplace Drug Testing Laboratory Accreditation Program

GLP: The Department of Health and Human Services, Food and Drug Administration's Good Laboratory Practices for Nonclinical Laboratories Program

NVLAP: The National Institute of Standards and Technology National Voluntary Laboratory Accreditation Program

Lead: The U. S. Environmental Protection Agency's National Lead Laboratory Accreditation Program

ISO SECTION AND REQUIREMENT	NELAC	DHHS	GLP	NVLAP	Lead	COMMENTS
4. Organization & Management						
4.1 a) managerial staff required	✓	✓	✓	✓		**GLP** standards specify designation of a technically qualified Study Director.
b) personnel free from COI	✓			✓		
c) organized for independence in judgement and integrity	✓			✓		
d) document responsibilities of managers and all personnel affecting quality	✓			✓		
e) supervision by persons familiar with methods and procedures	✓	✓	✓	✓		
f) technical manager responsible for technical operations	✓		✓	✓	✓	

ISO SECTION AND REQUIREMENT	NELAC	DHHS	GLP	NVLAP	Lead	COMMENTS
g) quality manager (QM) responsible for the quality system with direct access to the highest level of management	✓	✓	✓	✓		**DHHS** standards specify that the Quality Manager may be the Laboratory Director. **GLP** standards do not explicitly require direct access to the highest level of management. Standards applicable to internal audits and audit reports include requirements that the QA staff report directly to management.
h) nominate deputies for the QM	✓			✓		
i) document policies and procedures to protect clients' CBI and proprietary rights	✓			✓		
j) participate in interlaboratory comparisons or proficiency testing	✓			✓		
5. Quality System, Audit and Review						
5.1 Establish and maintain a quality system. Document the elements of the system. Make documentation available to staff. Ensure implementation.	✓	✓	✓	✓	✓	
5.2 Quality manual shall state policies and procedures established to meet these standards. It shall contain:	✓			✓	✓	
a) a quality policy statement	✓			✓	✓	
b) laboratory organization & management	✓			✓	✓	
c) relations between management, technical operations, support services and the quality system	✓			✓		
d) procedures for control and maintenance of documentation	✓			✓		

ISO SECTION AND REQUIREMENT	NELAC	DHHS	GLP	NVLAP	Lead	COMMENTS
e) job descriptions for key staff and references to the job descriptions of other staff	✓			✓	✓	
f) identification of laboratory signatories	✓			✓		
g) procedures for achieving traceability of measurements	✓			✓		
h) scope of calibration or testing services	✓			✓		
i) arrangements for reviewing all work to ensure laboratory has required facilities and resources before commencing	✓			✓		
j) reference to calibration, verification and/or test procedures used	✓	✓	✓	✓	✓	
k) procedures for handling calibrations a/o test items	✓			✓	✓	
l) reference to major equipment and reference measurement standards used	✓			✓		
m) reference to procedures for calibration, verification and maintenance of equipment	✓			✓	✓	
n) reference to verification practices including interlaboratory comparisons, proficiency testing, use of reference materials, and internal QC schemes	✓	✓		✓		

ISO SECTION AND REQUIREMENT		NELAC	DHHS	GLP	NVLAP	Lead	COMMENTS
	o) procedures to be followed for feedback and corrective action when discrepancies are detected	✓		✓	✓		
	p) arrangements for exceptionally permitting departures from policies	✓			✓		
	q) procedures for dealing with complaints	✓			✓		
	r) procedures for protecting confidentiality and proprietary rights	✓			✓		
	s) procedures for audit and review	✓		✓	✓	✓	
5.3	arrange for audits at appropriate intervals; audits to be carried out by trained and qualified staff who are independent of the activity; take immediate action where audits indicate a problem, notify clients where audits indicate a problem.	✓		✓	✓		
5.4	review the quality system at least once each year and introduce any necessary changes or improvements	✓		✓	✓		**GLP** standards require periodic review consistent with the study schedule. Some studies are designed to be completed in less than one year.
5.5	document all audits, reviews and corrective actions	✓		✓	✓		
5.6	implement checks to ensure quality, including:	✓			✓		
	a) internal QC schemes	✓	✓		✓		
	b) participation in proficiency testing or interlaboratory comparisons	✓	✓		✓		
	c) use of certified reference materials or secondary reference materials	✓			✓		

ISO SECTION AND REQUIREMENT	NELAC	DHHS	GLP	NVLAP	Lead	COMMENTS
d) replicate testing using different methods	✓	✓		✓		
e) retesting of retained items	✓	✓		✓		
f) correlation of results for different characteristics	✓			✓		
6. Personnel						
6.1 sufficient personnel with necessary education, training, technical knowledge and experience	✓		✓	✓	✓	
6.2 ensure that personnel training is kept up-to-date	✓	✓		✓		
6.3 maintain records on staff qualifications, training, skills and experience	✓	✓	✓	✓	✓	
7. Accommodation and Environment						
7.1 proper areas, energy sources, lighting, heating, and ventilation	✓			✓	✓	
7.2 environment does not invalidate results	✓		✓	✓		
7.3 facilities for effective monitoring, control and recording of environmental conditions	✓			✓		
7.4 effective separation between areas	✓		✓	✓		
7.5 access to and use of all areas affecting quality shall be defined and controlled	✓			✓		

ISO SECTION AND REQUIREMENT	NELAC	DHHS	GLP	NVLAP	Lead	COMMENTS
7.6 adequate measures to ensure good housekeeping	✓		✓	✓		
8. Equipment and Reference Materials						
8.1 furnished with all required equipment	✓		✓	✓	✓	**Lead** program guidance states that all requirements of ISO Guide 25 related to equipment maintenance and calibration apply.
8.2 all equipment properly maintained	✓		✓	✓	✓	
8.3 all equipment and standards marked or labeled to indicate calibration status	✓	✓		✓	✓	**Lead** program guidance states that all requirements of ISO Guide 25 related to equipment maintenance and calibration apply.
8.4 maintain records for all equipment and reference materials significant to all calibrations or tests performed; records shall include:	✓		✓	✓	✓	
a) name of the equipment item	✓			✓	✓	
b) manufacturer's name, type identification, and serial number or other unique identifier	✓			✓	✓	
c) date received and date placed in service	✓	✓		✓	✓	**NVLAP** standards state that this requirement is not mandatory for initial accreditation.
d) current location	✓			✓	✓	
e) condition when received (new, used, reconditioned)	✓			✓	✓	
f) copy of manufacturer's instructions	✓			✓	✓	
g) dates and results of calibrations a/o verifications and date of the next calibration a/o verification	✓	✓	✓	✓	✓	**DHHS** standards include this technical requirement but do not include a specific requirement for maintaining these records.

ISO SECTION AND REQUIREMENT	NELAC	DHHS	GLP	NVLAP	Lead	COMMENTS
h) details of maintenance carried out and planned	✓	✓	✓	✓	✓	**DHHS** standards include this technical requirement but do not include a specific requirement for maintaining these records.
i) history of any damage, malfunction, modification or repair	✓		✓	✓	✓	
9. Measurement Traceability and Calibration						
9.1 all equipment must be calibrated or verified prior to placement in service; laboratory must have a program for calibration/verification of equipment	✓		✓	✓	✓	
9.2 program must ensure that all measurements are traceable to national standards where available	✓			✓	✓	**NVLAP** standards require application of specific procedures included in program guidance.
9.3 where national standards are not available, laboratory must provide evidence of correlation of results (e.g., by participation in an interlaboratory comparison program)	✓			✓	✓	
9.4 reference standards shall be used for calibration only	✓			✓	✓	
9.5 reference standards must be calibrated by a body that can provide traceability to a national standard	✓			✓	✓	
9.6 reference standards and equipment shall be subjected to in-service checks between calibrations/ verifications	✓			✓	✓	
9.7 reference materials shall be traceable to national or international standards	✓			✓	✓	

ISO SECTION AND REQUIREMENT	NELAC	DHHS	GLP	NVLAP	Lead	COMMENTS
10. Calibration and Test Methods						
10.1 laboratory must have documented instructions on operation of equipment, handling and preparation of items for testing; all instructions/manuals must be maintained up-to-date	✓		✓	✓	✓	
10.2 must use proper methods for all calibrations, tests and related activities	✓	✓	✓	✓	✓	
10.3 where no methods are specified, must select methods that have been published in international or national standards published by reputable technical organizations or in relevant scientific periodicals	✓		✓	✓		**Lead** standards state that all methods are specified at 40 CFR 1910.
10.4 where nonstandard methods are used, they must be approved by the client, documented, validated, and available	✓		✓	✓	✓	**Lead** standards state that all methods are specified at 40 CFR 1910. Alternative methods must be documented and validated.
10.5 Documented procedures for sampling and appropriate statistical methods must be used	✓		✓	✓		
10.6 Calculations and data transfers subject to appropriate checks	✓		✓	✓	✓	
10.7 where computers are used to handle data, the laboratory must ensure that: a) all ISO 25 requirements are complied with	✓		✓	✓		**NELAC** standards require compliance with EPA's "Good Automated Laboratory Practices" guidelines. **GLP** standards require a Standard Operating Procedure for data handling. There are no explicit specifications similar to ISO 25.
b) computer software is documented and appropriate	✓			✓	✓	

ISO SECTION AND REQUIREMENT	NELAC	DHHS	GLP	NVLAP	Lead	COMMENTS
c) procedures for protecting data integrity are used	✓			✓		
d) hardware is maintained properly	✓			✓		
e) data security procedures are established and implemented	✓			✓		
10.8 Laboratory must have documented procedures for purchase, reception and storage of consumables	✓			✓		
11. Handling of Calibration and Test Items						
11.1 must have documented system for uniquely identifying items to be tested	✓	✓	✓	✓	✓	
11.2 condition of all items must be documented upon receipt	✓	✓	✓	✓	✓	
11.3 must have documented procedures and facilities to prevent deterioration or damage to test items; environmental conditions must be monitored and documented where appropriate; security must be maintained where necessary	✓	✓	✓	✓		**GLP** standards require a separate storage facility and controlled access.
11.4 must have documented procedures for receipt, retention and safe disposal of test items	✓	✓	✓	✓		
12. Records						
12.1 must maintain an appropriate record system; retain and record all original observations, calculations, etc.	✓	✓	✓	✓		**GLP** standards are more specific than ISO 25. **NVLAP** standards recommend maintenance of original observations, calculations, and derived data but do not require that they be maintained by calibration laboratories.

ISO SECTION AND REQUIREMENT	NELAC	DHHS	GLP	NVLAP	Lead	COMMENTS
12.2 all records, certificates and reports must be safely stored	✓	✓	✓	✓		**GLP** standards are more specific than ISO 25.
13. Certificates and Reports						
13.1 all results must be reported accurately, clearly, unambiguously, and objectively	✓			✓		
13.2 each report or certificate shall include: a) a title	✓			✓	✓	
b) name and address of laboratory	✓		✓	✓		
c) unique identification of the report, and each page and the total number of pages	✓			✓		
d) name and address of client, where appropriate	✓			✓		
e) description/identification of the item tested	✓	✓	✓	✓		**GLP** standards are more specific than ISO 25.
f) characterization and condition of the item	✓		✓	✓		**GLP** standards are more specific than ISO 25.
g) date of receipt of the item and date of test	✓		✓	✓	✓	**NVLAP** standards recommend but do not require calibration laboratories to include date of receipt and test.
h) identification of method used	✓	✓	✓	✓	✓	
i) reference to sampling procedure, where used	✓		✓	✓		
j) any deviations from the method	✓		✓	✓		
k) results and any supporting data	✓	✓	✓	✓	✓	

ISO SECTION AND REQUIREMENT	NELAC	DHHS	GLP	NVLAP	Lead	COMMENTS
l) a statement of estimated uncertainty	✓			✓		
m) signature and title of responsible individual	✓		✓	✓	✓	
n) a statement that the results apply only to the item tested, where appropriate	✓			✓		
o) a statement that the report or certificate shall not be duplicated except in full without written consent of the laboratory	✓			✓		
13.3 any results generated by subcontractors must be identified	✓			✓		**DHHS** standards strictly prohibit the use of subcontractors.
13.4 reports should be designed to be easily read and understood	✓			✓		
13.5 any amendments to reports or certificates must be made in writing and must identify the original report by its unique identifier	✓		✓	✓	✓	
13.6 clients must be notified promptly and in writing of any defects identified	✓			✓		
13.7 electronic transmission of data or reports must be done in accordance with procedures that ensure confidentiality and that ISO 25 is met	✓			✓		
14. Subcontracting of Calibration or Testing						

ISO SECTION AND REQUIREMENT	NELAC	DHHS	GLP	NVLAP	Lead	COMMENTS
14.1 any subcontract laboratories used must comply with ISO 25; laboratories are responsible for determining that their subcontract laboratories meet ISO 25	✓			✓		**NELAC** standards require that all subcontractors be determined to meet NELAC standards. **DHHS** standards strictly prohibit the use of subcontractors.
14.2 laboratories must maintain records of its determinations of the competency of subcontract laboratories and must maintain a register of qualified subcontract laboratories	✓			✓		**DHHS** standards strictly prohibit the use of subcontractors.
15. Outside Support Services and Supplies						
15.1 laboratories must use outside supplies and services that are adequate to sustain confidence in the laboratory's work	✓			✓		
15.2 laboratory must have procedures for ensuring that purchased equipment, materials or services meet requirements and are inspected prior to use	✓			✓		
15.3 laboratory must maintain records of all suppliers and service providers	✓			✓		
16. Complaints						
16.1 laboratory must have documented policies and procedures for resolution of complaints; records of complaints shall be maintained	✓			✓		
16.2 where a complaint raises doubts about the quality of the laboratory's work, an audit must be conducted promptly	✓			✓		

4.0 CONCLUSIONS

This study supports some preliminary conclusions that may guide the deliberations of the NACLA Interim Board of Directors. They are as follows:

Some significant areas of overlapping scope, inconsistent program components, and application of highly variable accreditation terminology exist in laboratory accreditation programs. NACLA should include a process for addressing these aspects of the current system in a way that will strengthen and improve the overall U.S. laboratory accreditation system. Areas of overlap and inconsistency to be addressed should include:

- Federal programs supporting government oversight of product testing or certification differ considerably in the terminology used and the status granted to laboratories. Documentation of laboratory review procedures and criteria varies from program to program and program-qualifying procedures vary from simple review of written applications to comprehensive programs requiring written applications, on-site assessments, and routine laboratory proficiency testing.

- State and local programs supporting oversight of product testing/certification, preliminary information shows considerable overlap among state/local programs and Federal programs. Provisions for reciprocal recognition between programs were found in only a limited number of settings.

- Also in the area of product testing and certification, a large number of private sector programs appear to duplicate or overlap programs conducted at the Federal and state/local levels. Indications of cooperative or reciprocal relationships were identified in only a very few areas.

- In the area of state/local government programs supporting regulatory compliance, considerable overlap may exist between Federal and state programs and among state programs. Little evidence was found of reciprocal arrangements between state programs that accredit or certify for the same purpose. In the area of environmental testing, the NELAC has begun to address issues of overlap and to promote reciprocity among state programs. Similar problems in the area of occupational safety and health remain unaddressed, however.

Existing Federal government laboratory accreditation programs differ considerably in the extent to which they address the general aspects of laboratory performance common to all testing and calibration laboratories. These general areas include: laboratory organization and management, laboratory quality systems and audits, laboratory personnel, laboratory facility considerations, equipment and reference materials, measurement traceability and calibration, testing and calibration methods, handling of test items and specimens, laboratory record keeping, laboratory reports, subcontracting practices, and laboratory practices for addressing client complaints. NACLA should include a process designed to gain consensus among Federal

government agencies concerning the value of ensuring that, at a minimum, all laboratory accreditation programs address these basic elements. NACLA should further set a goal of implementing such a minimum standard governmentwide reasonably soon. Ensuring that U.S. programs at a minimum address the components of ISO/IEC Guide 25 or its equivalent will improve the overall U.S. system and have both domestic and international benefits.

The NACLA Interim Board of Directors should consider NACLA to be an important leadership resource for the U.S. laboratory accreditation community in the future. For example, NACLA should develop and promote the application of the model used by the National Environmental Laboratory Accreditation Conference (NELAC) and the National Conference on Weights and Measures (NCWM) to achieve consensus among existing, overlapping programs in other areas, particularly where state and Federal government programs overlap. There are many other examples of areas where NACLA leadership can be applied to improve laboratory accreditation in the United States. For example, NACLA should serve as a forum for addressing issues common to numerous Federal government laboratory accreditation programs, such as:

- Proper procedures for ensuring due process in the suspension or revocation of an accreditation;
- Issues related to liquidated damages resulting from a loss of accreditation status for laboratories or loss of recognition status for accrediting bodies;
- Uniform standards for professional ethics in the accreditation process and in the laboratory industry;
- Appropriate roles for private accrediting bodies in areas typically addressed by government organizations;
- Appropriate relationships between private and public sector programs where they overlap; and
- Uniform standards for maintaining confidentiality in the accreditation process and for identifying and addressing confidentiality violations.

Leadership within the Federal government would also provide a forum for identifying areas where cooperation among government programs or the establishment of public-private partnerships might be used to make existing laboratory accreditation programs more efficient and effective. Example areas include:

- Laboratory proficiency testing and related information management and dissemination needs;
- Development and distribution of reference materials for use by laboratories;
- Application of automated information management systems; and
- Development and use of training programs.

The NACLA operating plan should therefore include provisions for bringing together representatives from all stakeholder groups to address these and other issues and develop consensus approaches to their resolution.