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Report to the Chairman, Committee on Science, Space, and Technology, House of Representatives

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LABORATORY ACCREDITATION

Requirements Vary Throughout the Federal Government

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Resources, Community, and
Economic Development Division

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The Honorable Robert A. Roe
Chairman, Committee on Science, Space,
and Technology
House of Representatives

Dear Mr. Chairman:

As requested in your June 3, 1988, Committee report, we examined laboratory accreditation requirements of the federal government. You were particularly interested in any overlapping and burdensome requirements among the various programs and ways they could be streamlined. As agreed with your office, we also included information on other issues associated with laboratory accreditation, including the potential for more universal charging of user fees and possible focusing of accreditation at the national level in the interest of U.S. competitiveness.

As agreed, the basis for our review was a 1984 National Bureau of Standards, now National Institute of Standards and Technology (NIST), study. That study identified 13 agencies having 33 accreditation programs, and loosely defined laboratory accreditation as "a more or less formal recognition of a laboratory's competence based on some more or less formal assessment."[1] Of the 33 programs identified in the study, 10 either were cancelled or did not fit the definition. Of the 23 remaining, officials for 6 programs told us that the programs were combined into 3 programs, leaving 20 active programs. Our review addresses these 20 programs. Appendix IV lists the 20 programs and gives a brief description of each.

Results in Brief

Federal laboratory accreditation programs contain varying requirements that laboratories must meet to be accredited. In addition, the requirements differ in degree of specificity.

Few federal accreditation programs overlap because they are in different fields of testing. Two programs that do overlap involve NIST and the Federal Communications Commission (FCC) programs in the area of electronic devices. However, burdensome requirements were generally identified to be within, rather than between, specific programs.

[1]Accreditation should not be confused with certification. Certification is the procedure by which written assurance is given that a product or service conforms to a standard or specification.

Accreditation programs can be a source of revenues through charging user fees. User fees can be charged because the beneficiaries of the programs can be identified.

Laboratory and other officials believe that accreditation focused at the national level may have some important implications for increasing U.S. competitiveness in future years.

Background

Laboratory accreditation in the federal government encompasses many different types of testing and related activities, from inspecting grain to certifying maritime cargo gear. Although the programs use different terminology for "accredited," such as "accepted," "approved," and "qualified," they usually were developed because the agencies believed there was a need to assure themselves of the competency of the laboratories and of organizations doing testing on products or services where federal funds were involved. For example, NIST defines an accredited laboratory as one that is competent to carry out specific tests or types of tests. The Customs Service defines accreditation as the determination of the applicant's competence, independence, and reputation. Appendix V lists the terms and the agency's definition of accreditation or accredited laboratory.

The agencies use these accredited laboratories or other organizations in different ways. While a majority accredit laboratories to assure themselves that the laboratories' test results meet their standards, others delegate their authority either to issue certifications or to inspect or to accredit others. Examples of those that directly accredit or approve laboratories to do particular testing include NIST's National Voluntary Laboratory Accreditation Program and the Department of Defense's Defense Electronic Supply Center Qualification Testing of Manufactured Products. Examples of those that accredit others with the agency's authority to inspect or issue certificates include the Department of Agriculture's Federal Grain Inspection Service Designated/Delegated Grain Inspection and Weighing Program and the Occupational Safety and Health Administration's Maritime Cargo Gear Accreditation Program. Examples of those that delegate authority to states or other organizations to do accrediting include the Department of the Interior's Office of Surface Mining Small Operator Assistance Program and the Occupational Safety and Health Administration's Blood Lead Analysis Program. Appendix VI contains a listing of the approaches to accreditation and the programs under each.

Some programs have been established pursuant to statute. For example, under the Clinical Laboratory Improvement Amendments of 1988, administered by the Department of Health and Human Services' Health Care Financing Administration, laboratories engaged in testing material derived from the human body must meet the requirements of Section 353 of the Public Health Service Act in order to be issued a certificate for testing. Other accreditation programs were initiated by the agency. For example, the Toxicology Laboratory Monitoring Program under the Food and Drug Administration was established in response to a need to ensure accurate test results, involving laboratory studies of products, such as drugs and food additives, regulated by the Food and Drug Administration.

Accreditation Requirements

Requirements for federal accreditation programs fit into certain common categories, including organizational information, quality control, personnel, facilities and equipment, test methods and procedures, records and recordkeeping, test reports, and proficiency testing. However, the requirements call for different degrees of specificity. For example, for organizational information, one agency may ask only for name and address of the laboratory or organization, while another may ask for place of incorporation, description of the organization, managerial structure, basic technical services, and a description of clients being served. (See app. II.)

Overlapping Programs

The federal programs generally do not overlap because they tend to be in different fields of testing. For example, the Food Safety and Inspection Service at the U.S. Department of Agriculture accredits for testing meat and poultry for moisture, fat, salt, and protein content, and the Health Care Financing Administration at the Department of Health and Human Services accredits for testing materials derived from the human body for disease. (See app. IV for other examples of the diversity of federal accreditation programs.)

Two programs, however, do overlap—NIST's National Voluntary Laboratory Accreditation Program for electromagnetic compatibility and FCC's Description of Measurement Facilities Program. Under FCC's program, laboratories that test devices for electromagnetic compatibility must submit a physical description of their testing site and facilities to FCC. FCC maintains a list of laboratories that have submitted this information. Any laboratory that submits the description can be on the list.

NIST establishes laboratory accreditation programs on the basis of request and demonstrated need from federal agencies and/or the private sector. It developed a laboratory accreditation program in electromagnetic compatibility at the request of and with assistance from five private laboratories. FCC officials told us that they also contributed to the development of the laboratory accreditation program. Its stated purpose is to recognize and accredit laboratories that produce reliable test data for electromagnetic compatibility and telecommunications equipment. To be accredited, a laboratory must, in addition to other requirements, provide a description of its open field test site.

According to FCC officials, although their list indicates laboratories accredited by the National Laboratory Voluntary Accreditation Program, they do not accept that accreditation in lieu of the description of facilities because the laboratory accreditation program does not cover all the electronic devices that are required to be tested under FCC regulations. They said that in the future they would consider eliminating the filing requirements for National Voluntary Laboratory Accreditation Program accredited laboratories when the program covers all the devices that FCC requires to be tested. A NIST official told us that the program could be expanded to cover all devices.

Burdensome Requirements

The burden from accreditation requirements and procedures placed on participating laboratories varies by agency. For example, for some agencies, the submission of paperwork is sufficient to be placed on their lists of approved or accredited laboratories; in other cases, the agency also requires an on-site visit of the laboratory for the laboratory to be accredited or approved. About 70 percent require both paperwork and on-site reviews.

For particular programs, laboratories reported that burdensome procedures or requirements appear to be within the program itself. For example, the Environmental Protection Agency's Drinking Water Laboratory Certification Program has state primacy under which each state is responsible for accrediting local laboratories. But laboratory accreditation from one state may not be accepted by another state; that is, there is a lack of reciprocity resulting in a laboratory being accredited by many states.

Potential Revenues From Accreditation

Accreditation is a potential area for recouping federal costs through charging user fees. When federal agencies provide goods, services, and privileges that benefit identifiable recipients, charging recipients for these benefits may be considered. In each case the beneficiary of the accreditation program can be specifically identified—the laboratory or other organization.

We noted that only 2 of the 20 programs currently charge fees for participation in their programs—the National Voluntary Laboratory Accreditation Program and the Department of Housing and Urban Development's Technical Suitability of Building Products Program. The National Voluntary Laboratory Accreditation Program charges a yearly fee of from $2,000 to $5,000 for each accreditation, and the Department charges a laboratory or organization a one-time fee of $500 for each type of building product it administers. In addition, in accordance with the recently enacted Clinical Laboratory Improvement Amendments Act of 1988, the Health Care Financing Administration will begin charging fees for issuance of certificates under the program. The act requires that the fees be sufficient to cover general costs of administering the program, including evaluating and monitoring approved proficiency testing programs and implementing and monitoring compliance with program requirements. Other accreditation programs could follow the examples of these programs.

Continued Need for Accreditation

Laboratory officials we spoke with believed that accreditation at the national level, especially federal accreditation, provides greater credibility for their services and is of growing importance to international trade and the competitiveness of U.S. industry. In addition, a NIST official commented on the importance of focusing on accreditation at the national level, through public and private cooperation, to gain greater credibility and acceptance of U.S. products for trading in international markets. The National Voluntary Laboratory Accreditation Program currently has bilateral agreements with several countries to recognize each country's accredited laboratories. Laboratory officials would like to see more of these agreements.

Conclusions

Although few federal accreditation programs overlap, two that do involve NIST and FCC in the area of electronic devices. FCC requires laboratories accredited by the National Voluntary Laboratory Accreditation Program to provide a description of the facilities because the program's accreditation does not cover all the devices FCC requires to be tested. We

believe that since the National Voluntary Laboratory Accreditation Program's purpose is to establish accreditation programs based on requests and demonstrated need, FCC and NIST should work together to eliminate the overlap.

User fees can be an important source of revenues to the government, particularly in budget deficit situations, and accreditation programs are a potential candidate for such fees. User fees would seem appropriate since the beneficiaries of the accreditation programs can be specifically identified.

Recommendations

We recommend that:

- The Chairman, FCC, and the Director, NIST, work together to streamline federal accreditation requirements by eliminating the overlaps in their programs for testing electronic devices. This could be done by FCC and NIST officials working more closely together to determine how the National Voluntary Laboratory Accreditation Program can best meet FCC requirements.
- The Director, Office of Management and Budget, examine federal accreditation programs to determine where user fees can and should be appropriately charged.

Scope and Methodology

We spoke with officials at all 13 agencies identified in the National Bureau of Standards study. We also contacted officials at 15 organizations that are accredited under one or more of the accreditation programs to get their opinions on burdensome and overlapping programs and requirements. We made our review from July 1988 to January 1989 in accordance with generally accepted government auditing standards.

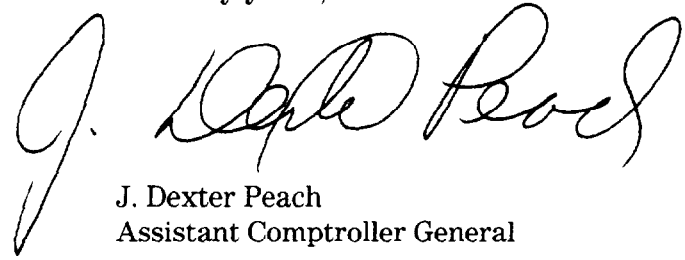
We discussed the results of our review with appropriate agency officials, and they generally agreed with our findings. However, as agreed, we did not obtain official agency comments on a draft of this report.

Appendix I provides additional background information and details concerning our objectives, scope, and methodology. Appendix II contains details of accreditation requirements of federal programs. Appendix III discusses the financial and credibility aspects of accreditation. Appendix IV lists the active programs and provides a brief description of each,

and appendix V lists the programs by terminology and definition of accredited laboratory. Appendix VI lists the programs and their approach to accreditation.

We are sending copies of this report to the Secretaries of Agriculture, Commerce, Defense, Health and Human Services, Housing and Urban Development, Interior, Labor, Transportation, Veterans Affairs and Treasury; the Administrators of the General Services Administration and the Environmental Protection Agency; and the Chairman of the Federal Communications Commission. We are also sending copies to the House Committees on Budget and Ways and Means and the Senate Committees on Budget and Finance. Copies will also be made available to others upon request. The work was performed under the direction of Flora H. Milans, Associate Director. Major contributors to this report are listed in appendix VII.

Sincerely yours,



J. Dexter Peach
Assistant Comptroller General

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Abbreviations

APHIS	Animal and Plant Health Inspection Service
CLIA	Clinical Laboratory Improvement Act
DOD	Department of Defense
EPA	Environmental Protection Agency
FCC	Federal Communications Commission
FDA	Food and Drug Administration
FGIS	Federal Grain Inspection Service
FSIS	Food Safety and Inspection Service
GAO	General Accounting Office
HCFA	Health Care Financing Administration
HHS	Department of Health and Human Services
HUD	Department of Housing and Urban Development
NIST	National Institute of Standards and Technology
NVLAP	National Voluntary Laboratory Accreditation Program
OSHA	Occupational Safety and Health Administration
USDA	Department of Agriculture

Introduction

In its June 3, 1988, report on the National Bureau of Standards Authorization Act for fiscal year 1989, the House Committee on Science, Space, and Technology requested GAO to prepare a report enumerating the requirements of various accreditation programs of the federal government and recommending ways they could be streamlined. The request was in response to comments from private laboratory officials at hearings held in March 1988. At that time, officials noted that the federal government as a whole imposes many overlapping and time-consuming accreditation requirements costing laboratories money and efficiency. As agreed with the Committee staff, we also examined other issues associated with laboratory accreditation, including the potential for more universal charging of user fees and possible focusing of accreditation at the national level in the interest of U.S. competitiveness.

Background

The federal government has many programs that require the laboratory or organization performing the tests to demonstrate its competency to do those tests. Many kinds of laboratories and organizations perform testing to ensure compliance with government requirements, including clinical laboratories that test human tissue for disease; environmental laboratories that test water for chemicals and bacteria; food laboratories that test meat and poultry for moisture, fat, protein, and salt; and commercial gauger laboratories that test petroleum products and other merchandise for composition and/or characteristics. In some cases, a laboratory may be accredited or approved by more than one federal agency if its field of testing encompasses more than one type of testing.

A study, sponsored by the National Bureau of Standards[1] entitled Principal Aspects of U.S. Laboratory Accreditation Systems - Revised 1984, identified 13 agencies having 33 programs for accreditation. The study defined laboratory accreditation as "a more or less formal recognition, based on some more or less formal assessment of a laboratory's competence."[2]

The number of programs was reduced to 30 because agency officials told us that 6 of the programs had been combined to become 3 programs. Of the 30 programs, 20 programs in 11 agencies currently accredit or

[1]The National Bureau of Standards was changed to the National Institute of Standards and Technology in 1988.

[2]Accreditation should not be confused with certification. A certification program is the procedure by which written assurance is given that a product or service conforms to a standard or specification.

approve. They are distributed as shown in table I.1. Appendix IV describes each program.

Table I.1: Government Agencies With Accreditation Programs

Agency	Number of programs
Department of Agriculture	3
Department of Commerce	1
Department of Defense	2
Environmental Protection Agency	2
Federal Communications Commission	1
Department of Health and Human Services	3
Department of Housing and Urban Development	1
Department of the Interior	1
Department of Labor	3
Department of Transportation	2
Treasury Department	1
Total	**20**

Two programs have been cancelled since 1984, and eight do not both recognize and assess laboratories per the definition of laboratory accreditation. Table I.2 lists the reasons the 10 programs were not included in our review.

Table I.2:Programs That Have Either Been Cancelled or Do Not Fit Accreditation Definition

Agency	Program	Reason
Department of Agriculture		
Animal and Plant Health Inspection Service	National Poultry Improvement Plan	No accreditation program. Certifies that flocks test negative for disease.
Rural Electrification Administration	Timber Products Accreditation Program	Cancelled 3 or 4 years ago because of lack of staff.
Department of Defense		
Army Corps of Engineers	Quality Assurance of Laboratory Testing Procedures	No accreditation program. Inspection of laboratories as part of quality assurance on a contract-by-contract basis.
Defense Logistics Agency	Commercial Testing Laboratories	Cancelled in 1988 because program was redundant of other work and not used.
General Services Administration		
Federal Supply Service	(No name)	No accreditation program. Supplier must show evidence of compliance with safety standards. Usually, source for standards is Underwriters Laboratory.

(continued)

Agency	Program	Reason
Department of Labor		
Mine Safety and Health Administration	Underground Mining Equipment Testing	No accreditation program. Looks at products to see that they meet specifications.
Department of Transportation		
Federal Aviation Administration	Qualified Equipment Approval Program	No accreditation program. Administration observes manufacturers' testing.
Federal Aviation Administration	Designated Airworthiness Representative	No accreditation program. Representatives inspect aircraft for airworthiness.
National Highway Traffic Safety Administration	Qualified Testing Organizations	No accreditation program. Contracts with laboratories to do testing.
Department of Veterans Affairs	Automotive Adaptive Equipment	No accreditation program. Manufacturer must show that equipment meets Veterans Administration standards.

Accreditation Terms and Delegations of Authority

Each agency has developed its own terms and methods for accrediting laboratories. Terms used for accreditation include "qualified," "authorized," "approved," "listed," "accepted," and "accredited." Agencies either directly accredit laboratories or delegate to others their authority to inspect or issue certificates or to accredit laboratories.

Terms for Accreditation Vary

Agencies have various terms for accreditation. Six programs use the term "accreditation," including the National Institute of Standards and Technology's (NIST) National Voluntary Laboratory Accreditation Program (NVLAP), the Food and Drug Administration's (FDA) Evaluation of Milk Laboratories Program, and the Occupational Safety and Health Administration's (OSHA) Maritime Cargo Gear Accreditation Program. The remaining 14 use other terms. As table I.3 shows, there is little uniformity of terminology for accreditation across the agencies. (App. V discusses the terms and the agencies and programs that use them.)

Table I.3: Agency Terms for Accreditation

Term	Number of agencies
Accredited	6
Approved	2
Designated/delegated	2
Suitable	1
Qualified	2
Certified	1
Recognized	2
Description	1
Good laboratory practices	1
Accepted	2
Total	**20**

Although the terms for accreditation vary, the definitions for accredited laboratories are similar for the 18 programs that have defined an accredited laboratory. For example, the NIST NVLAP definition of an accredited laboratory is "formal recognition that a testing laboratory is competent to carry out specific tests or types of tests." The Defense Electronics Supply Center, Department of Defense (DOD), defines suitable laboratories as those found "to be suitably equipped and staffed for performing qualification testing for manufacturers." (See app. V for other definitions.) Although two programs do not state a definition for accredited laboratory, the requirements for participation in these programs include the qualifications of the laboratory personnel and the availability of facilities and equipment.

Approaches to Accreditation Vary

Agencies accredit laboratories through several methods:

- The majority of programs directly accredit laboratories to do particular testing using either their own personnel or consultants and technical experts (11 programs).
- Other programs use accreditation to delegate agency authority to laboratories or other organizations to issue certifications or to do inspections (six agencies).
- Other programs delegate agency authority to others, such as states or private accrediting agencies, to do accreditation. They use two methods:
- State primacy, whereby states have the responsibility for accrediting laboratories within agency guidelines (two agencies).
- Third party, whereby a third party is designated to certify laboratory results (one agency).

Appendix VI has a complete listing of the programs under each category.

Direct Accreditation

Agencies use direct accreditation for 11 of the programs. In some cases the agency does all the assessment work and in other cases some of the assessment work is done by consultants or contractors. Examples of agencies that do the assessment work themselves include:

- The U.S. Customs Service Commercial Gaugers and Laboratories Program. Under this program, Customs uses its petroleum chemists to inspect laboratories applying for accreditation. Customs also has its Office of Investigations do a background investigation.
- The Defense Personnel Supply Center Qualified Laboratory Program. Under this program, Supply Center investigative chemists survey the laboratories to determine whether the laboratory is capable of performing specification testing on clothing, textiles, footwear, and equipage-type items.

Examples of agencies that use contractors or consultants to assess the laboratories include:

- The Department of Health and Human Services' (HHS) Health Care Financing Administration (HCFA) Clinical Laboratory Improvement Amendments Program. Under this program, HCFA contracts with states to have state employees do the laboratory inspections on behalf of the federal government. HCFA reimburses the states for this activity. On the basis of the documentation from the inspections, HCFA certifies the laboratory to participate in the program.
- NIST's NVLAP contracts with technical experts to do on-site inspections of the laboratories. The technical expert reports to NIST on the results of the inspection, and the NIST staff reviews the report.

Delegation of Authority to Inspect or to Issue Certificates

Six programs use accreditation to delegate agency authority to others to do inspections or to issue certificates. In these cases, the agencies have authority to inspect laboratories or organizations to determine whether they are meeting the agency's standards. This authority is delegated to private agencies that carry out the inspections or certifications.

One program that uses the private sector to do inspections and evaluations of private laboratories is FDA's Evaluation of Milk Laboratories Program. This program uses a combination of direct accreditation and

state agency participation through the National Conference of Interstate Milk Shipments, a voluntary organization directed and controlled by its state membership. FDA's memorandum of understanding with the Conference states that the program is operated primarily by the states, with FDA providing varying degrees of scientific, technical, and inspection assistance. FDA issues certificates of accreditation to state central laboratories, and the state milk laboratory control agency issues a certificate of accreditation to each commercial and industry laboratory.

Under the Department of Housing and Urban Development's (HUD) Technical Suitability of Building Products Program, organizations acceptable to HUD validate manufacturers' certifications that certain building products or materials meet applicable standards. These organizations, called accepted administrators, can also review and approve laboratories that apply for participation in HUD's building products program.

OSHA's Maritime Cargo Gear Accreditation Program grants agencies accreditation to perform certification functions under its cargo gear regulations. The accredited organizations inspect and test maritime cargo gear handling devices, such as cranes and derricks, and issue certificates that the devices meet or do not meet OSHA requirements.

Delegation of Authority to Accredit Others

Agencies can also use accreditation to authorize state or private agencies to do laboratory accreditation. One method of doing this is through state primacy, whereby states are responsible for accrediting local laboratories. Another method is through third-party accreditors, whereby a private organization accredits the laboratory. Two programs use state primacy and one uses a third party to do accreditation.

The two agencies that use state primacy are the Environmental Protection Agency (EPA), for its Drinking Water Laboratory Certification Program, and Interior, for its Office of Surface Mining Small Operator Assistance Program. Under the EPA program, EPA certifies the primary state laboratory and the states with primacy can certify local laboratories. All but two states, Wyoming and Indiana, have primacy. Under the Interior program, the state program administrator selects and pays qualified laboratories to determine the probable hydrologic consequences of surface mining and reclamation operations.

OSHA uses third-party accreditors for its blood lead analysis program. To compile a list of laboratories meeting its requirements for blood lead analysis, OSHA relies on the College of American Pathologists, a national

medical specialty society, the New York State Department of Health, and the State Laboratory of Hygiene at the University of Wisconsin to provide proficiency testing results from private laboratories. Prior to relying on these organizations, OSHA relied on HHS' Centers for Disease Control to monitor laboratory performance.

Basis for Accreditation Programs

Laboratory accreditation programs have been established pursuant to statute or agency regulation. The regulations usually contain the requirements and procedures for carrying out the accreditation programs.

Examples of programs that have been established pursuant to statute include the EPA Drinking Water Laboratory Certification Program, which is required under the Safe Drinking Water Act, as amended.[3] Under section 1413 of the amended act, a state has primary enforcement responsibility for public water systems and accredits local laboratories to test drinking water. Another program is the Clinical Laboratories Improvement Amendments (CLIA) of 1988, administered by HCFA. Under CLIA, laboratories engaged in testing materials derived from the human body must meet the requirement of Section 353 of the Public Health Service Act in order to be issued a certificate for testing.

A program that was initiated by an agency is the NIST NVLAP which was initiated in 1976 at the request of the private sector to provide national recognition for competent laboratories. Another program that was initiated by an agency is the Toxicology Laboratory Monitoring Program administered by FDA. According to FDA officials, the program was initiated because the results from laboratories doing toxicology studies on food and drugs were questionable and FDA needed to assure itself that study results were accurate.

Objectives, Scope, and Methodology

Our objective in this review was to examine laboratory accreditation requirements of the various federal government programs and determine which, if any, have overlapping requirements and whether those requirements can be streamlined. To carry out this objective, we contacted officials at the 13 agencies identified in the National Bureau of Standards study Principal Aspects of U.S. Laboratory Accreditation Systems -Revised 1984. Because of time constraints, we agreed with the Committee to limit our review to the laboratory programs identified in

[3]Although called a certification program, it actually accredits laboratories.

this study and did not attempt to determine whether other accreditation programs exist in the federal government. We used the study's definition of laboratory accreditation.

We also agreed to include information on other issues associated with accreditation, including the potential for charging user fees and possible focusing of accreditation at the national level in the interest of U.S. competitiveness. To carry out this objective, we discussed user fees and international accreditation issues with appropriate agency officials.

We requested from each program official a list of laboratories accredited or approved under their program and a description of the program and its requirements. In addition, we chose a judgmental sample of 12 laboratories from the lists and surveyed these laboratories by telephone using a structured interview. We tried to choose laboratories that appeared on more than one list. We asked questions concerning whether the laboratory was accredited by more than one federal agency and whether the program's requirements were overlapping and/or burdensome. We also interviewed officials of the American Association for Laboratory Accreditation, the American Council of Independent Laboratories, the College of American Pathologists, and three testing laboratories to obtain their comments on burdensome and/or overlapping requirements.

We performed our review from July 1988 to January 1989 in accordance with generally accepted government auditing standards.

Federal Requirements for Laboratory Accreditation

Although some accreditation programs have specific, detailed requirements and others state their requirements in general terms, these requirements can be placed into the same general categories. Most of the programs also have procedures for carrying out their requirements, including application and assessment procedures. Generally, the programs are in different fields of testing or other certifying activity, but we did find overlap in two programs. In addition, burdensome requirements were reported to occur within some of the programs.

Accreditation Requirements Vary

Program requirements include those for organizational information, quality control, personnel, facilities and equipment, test methods and procedures, records and recordkeeping, test reports, proficiency testing, and fees (if any). Table II.1 shows the categories of accreditation requirements and the number of agencies that include these requirements in their regulations.

Table II.1: Federal Requirements for Laboratory Accreditation

Requirement	Number of programs
Organizational information	12
Quality control or assurance system	7
Personnel	18
Facilities and equipment	19
Test methods and procedures	16
Records and recordkeeping	12
Test reports	11
Proficiency testing	8
Fees	2
No conflict of interest	6
Financial stability	3

Note: These data reflect information from a total of 20 agencies.

Organizational Information

Twelve accreditation programs require that the applicant for accreditation provide one or more of the following: name of the organization, address, ownership, organization chart, and description of the laboratory. Some program requirements request only the name and address and others request more detailed information. For example, the only organizational information the Defense Electronic Supply Center Program requires is the name and address of the laboratory.

An example of a program that requests detailed organizational information is the Coast Guard's Safety Approval of Cargo Containers Program which requires, among other things, name and address (including place of incorporation, if a corporation); a description of the organization, including the ownership; managerial structure, organizational components and directly affiliated agencies and their functions utilized for supporting technical services; a listing of the basic technical services offered; and a general description of the clients being served or intended to be served. Another program is OSHA's Nationally Recognized Testing Laboratories Program, which states that the description of the organization should include its legal name and address, the names of its principal officers, its principal ownership, all relevant organizational components, all relevant organizational affiliates with the names of their principal officers and directors, external organizations utilized for technical support and their functions, and a brief history of the organization.

Quality Control or Assurance

Quality control or assurance system requirements are designed to ensure the required degree of accuracy and precision of the laboratory work. Seven programs require the laboratory to have a quality assurance program, which may include having a quality assurance manual and a periodic review of the quality assurance system. For example, the FDA Toxicology Laboratory Monitoring Program regulations require, among other things, that ". . . a testing facility shall have a quality assurance unit composed of one or more individuals who shall be responsible for monitoring each study to assure that the facilities, equipment, personnel, methods, practices, records, and controls are in conformance with the regulations in this part . . . ." Another example is EPA's Drinking Water Laboratory Certification Program requirements, which state that it is essential that all laboratories analyzing drinking water compliance samples adhere to defined quality assurance procedures to ensure that routinely generated analytical data are scientifically valid and defensible and are of known and acceptable precision and accuracy. EPA also enumerates the items that should be addressed in each quality assurance plan.

Personnel

Personnel qualifications may include one or more of the following: education, training, technical knowledge, and experience. Of the 20 programs, 18 have personnel requirements. Some programs require specific staff qualifications. For example, OSHA's Maritime Cargo Gear Accreditation Program requires the applicant to provide a list of its personnel, both supervisory and managerial, and include any surveyors, with

resumes of their individual experience in the testing, examination, inspection, and heat treatment of cargo gear.

Another program that specifies staff qualifications is the Department of Agriculture's (USDA) Food Safety and Inspection Service Accredited Laboratory Program, which accredits laboratories that test meat and poultry for chemical residues and food chemistry. The requirements for a laboratory conducting residue analysis state that the laboratory must be supervised by a person holding as a minimum a bachelor's degree in either chemistry, food science, food technology, or related field, and either the supervisor or the analyst assigned to analyze the sample must have 3 years' experience in analyzing for that type of chemical residue.

Facilities and Equipment

Accreditation programs also establish requirements to ensure that the laboratory has adequate facilities and equipment, including specifications for the maintenance of the equipment and its records and specifications for calibration. This type of requirement is common to 19 of the 20 programs. The only program that does not include such a requirement is OSHA's Blood Lead Analysis Program because this program relies solely on proficiency testing and not on inspections or on-site visits of laboratories. Some programs state specific requirements for the equipment and facilities. For example, USDA's Animal and Plant Health Inspection Service (APHIS) Program for Approval of Laboratories to Conduct Diagnostic Procedures for Contagious Equine Metritis includes specific requirements such as ". . . adequate bench space available to perform the tests—at least 2.5 M (8 feet)."[1]

Another example of a program with specific equipment and facilities requirements is USDA's Federal Grain Inspection Service (FGIS) Designated/Delegated Weighing and Inspection Program. FGIS requirements state that FGIS examine each unit of equipment used in the official weighing, sampling, testing, or grading of grain, or in monitoring the official inspection of grain to determine whether the equipment is functioning in an approved manner and that FGIS test each unit of equipment for which official performance requirements have been established for accuracy every 6 months. In addition, only equipment from an FGIS-approved list can be used.

[1]Contagious equine metritis is a highly transmissible venereal disease of horses.

Some programs state facilities and equipment requirements in general terms. For example, under HUD's Technical Suitability of Building Products Program, the administrator shall "Have facilities and capabilities for communications with manufacturers, laboratories, and HUD, including publication of a directory of certified products and a list of accredited laboratories, if required by the program."

Test Methods and Procedures

Test methods and procedures requirements may include that the laboratory perform testing following methods and procedures established by the agency and may also include that the laboratory maintain a plan for implementing testing standards and procedures, measures for detecting discrepancies, and a system for identifying samples. Of the 20 programs, 16 include test methods and procedures. The Defense Electronics Supply Center states this requirement in general terms—"Testing procedures, tests reports, and qualification procedures also will be discussed during the audit. At the conclusion of the audit, any deficiencies will be discussed with appropriate company personnel." An example of a program with a specific and detailed requirement and guidance is EPA's Drinking Water Laboratory Certification Program. The program's "Manual for the Certification of Laboratories Analyzing Drinking Water" contains criteria and procedures for quality assurance, approved methodology, and recommended practices.

Records and Recordkeeping

Records and recordkeeping requirements generally state that the laboratory should maintain adequate records, including sufficient information to permit verification, that should be held secure and in confidence, as required. Of the 20 programs, 12 have records and recordkeeping requirements.

Records and recordkeeping requirements can be stated in general terms but may include such details as how long the records should be kept. The Defense Electronics Supply Center states that "Data should be presented in sufficient detail to substantiate, to interested parties not witnessing the test, the test procedures used and the results obtained in the testing. Failure to submit data in sufficient detail will subject reports to the risk of being rejected and create the possibility of extensive retesting being required." Under the U.S. Grain Standards Act, as amended, USDA's FGIS requires each delegated agency, state agency, or person to maintain samples of officially inspected grain up to 90 days. FGIS requires records to be kept for 5 years after the inspection, weighing, or transaction.

Test Reports

Test report requirements state how the laboratory should issue reports on test results. Of the 20 programs, 11 have test report requirements. NIST's NVLAP program states that the reports should ". . . accurately, clearly, and unambiguously present the specified test results and all required information . . ." and prescribes a list of all the information that should be included in the reports. USDA's FSIS Accredited Laboratory Program states that prior to notifying any other party, the laboratory must telephone FSIS and report the analytical chemical results of the official samples. The laboratory must report the analytical chemical residue results from official samples, weekly, on designated forms to the FSIS. The FDA's Toxicology Laboratory Monitoring Program requires that study results should include such information as name and address of facility, objectives and procedures, description of methods used, and statistical methods employed for analyzing the data.

Proficiency Testing

Proficiency testing refers to checks of laboratory testing performance using comparisons of interlaboratory test results. Of the 20 programs, 8 have a proficiency testing requirement. NVLAP states that one of its requirements is participating in proficiency testing as required. Customs Service states that commercial gaugers and laboratories have to agree to allow their performance to be evaluated by Customs Service personnel on a periodic basis by such means as on-site inspections, demonstrations of gauging procedures, reviews of submitted records, and proficiency testing through check samples. EPA's Drinking Water Laboratory Certification Program manual states that

> "It is essential that the laboratory analyze an unknown performance evaluation sample (when available) once per year for all regulated contaminants measured. Results need to be within the control limits established by USEPA [U.S. Environmental Protection Agency] for each analysis for which the laboratory wishes to be certified."

OSHA's list of laboratories approved for blood lead analysis is based on proficiency testing and states that the ". . . list is comprised of laboratories that have met OSHA requirements for blood lead analysis, scoring at least 8 out of 9, or 89% in the three most recent quarterly proficiency surveys."

Fees

Two programs charge fees for a laboratory to be accredited. These programs are NIST's NVLAP, whose fees range from $2,000 to $5,000, and HUD's Technical Suitability of Building Products Program, which charges

each laboratory or organization a one-time fee of $500 for each type of building product it administers. See appendix III for further information on fees.

Conflict of Interest

Of the 20 programs, 6 have a no-conflict-of-interest requirement. OSHA's Nationally Recognized Testing Laboratory Program requires the applicant to present evidence of the independence needed to achieve objectivity and preclude conflict of interest. Laboratories applying for accreditation under the Customs Service Commercial Gaugers and Laboratories Program must include a written agreement to avoid conflict of interest situations. The applicant has to agree to have no financial interest in or other connection with any business or other activity that might affect the unbiased performance of its duties as a Customs-approved (accredited) commercial gauger (laboratory). The Coast Guard's Approval of Equipment and Materials Program has as one of its requirements that the laboratory not be owned or controlled by the manufacturer or vendor of the equipment or material to be inspected or tested, or by the supplier of materials to the manufacturer. The Coast Guard's Safety Approval of Cargo Containers Program uses as part of its criteria for selection of approval authorities that the person or organization is independent of manufacturers and owners.

Financial Stability

Three programs require that the applicant have financial stability. The Customs Service's Commercial Gaugers and Laboratories Program asks in the application for a statement of financial condition. The Coast Guard's Safety Approval of Cargo Containers Program uses as part of its criteria for selection of approval authorities that the person or organization has an acceptable degree of financial security.

Accreditation Procedures

Accreditation programs usually have procedures for implementing accreditation requirements. These procedures differ from program to program. Application and assessment procedures usually determine whether a laboratory can comply and is complying with program requirements. Other procedures generally include granting and renewal; denial, suspension, and revocation; and voluntary termination.

Applying for and Maintaining Accreditation

Under application and assessment procedures, the agency evaluates the laboratory's ability to comply and compliance with the conditions for accreditation set out in the criteria and requirements.

Of the 20 programs, 16 state their application procedures. The FSIS Accredited Laboratory Program states that ". . . application for accreditation shall be made in writing by the owner or operator of the non-Federal analytical laboratory" and sent to FSIS. FSIS officials told us that the laboratory must stipulate whether it wants to be accredited for chemical residues or for food chemistry. HUD's program states that any organization desiring HUD acceptance as a qualified administrator to conduct a certification program shall make application in writing and also enumerates the information that should be included in the application.

Information used to assess the laboratory may be derived from on-site visits, laboratory responses to identified deficiencies, and laboratory performance on proficiency tests. Of the 20 programs, 19 have these types of procedures. Table II.2 shows the procedures and the number of programs that use them.

Table II.2:Number of Programs Requiring Paperwork, On-Site Reviews, and Proficiency Testing

Requirements	Number of programs
Paperwork submission and on-site reviews	14
On-site only	2
Paperwork submission only	3
Neither paperwork nor on-site reviews	1
Have proficiency testing requirements	8

Note: These data reflect information from a total of 20 agencies.

An example of a program that requires both paperwork submission and on-site reviews is NIST's NVLAP program. An example of a program that requires paperwork only is the Federal Communications Commission's (FCC) Description of Measurement Facilities. Under this program an applicant for equipment authorization submits, among other things, such information as the location of the testing site; a physical description of the test site accompanied by photographs; and a list of measuring equipment used. In many instances, a testing laboratory submits this information on the applicant's behalf.

A program that requires on-site inspections only is FDA's Evaluation of Milk Laboratories. Under this program the evaluator makes a visit to the laboratory and reviews the facilities, equipment, materials, procedures, results, and records. The program with neither paperwork submission nor on-site visits is Interior's Office of Surface Mining Small

Operator Assistance Program. Under this program, states act as program administrators. As such they are responsible for qualifying laboratories to determine the probable hydrologic consequences of and prepare a statement on the chemical and physical properties of rocks overlying coal for owners of mines producing less than 100,000 tons of coal a year.

In our survey of 12 laboratories, 8 reported that agencies ask for similar paperwork for application and assessment, and 3 reported that the paperwork is not similar. One of the eight reported that the paperwork for one agency was more involved than the paperwork for the other. The question did not apply to the laboratory accredited by only one agency.

Laboratory Reactions to Application and Assessment Procedures

All the laboratories reported having at least one on-site visit from one of the accrediting agencies. However, a laboratory was not necessarily visited by each of the agencies that accredit it, because not every agency makes on-site visits. For example, one laboratory reported having on-site visits once a year by one accrediting agency and having no visits by another accrediting agency because that agency does not make on-site visits. NVLAP was reported as making on-site visits once a year by one laboratory and once every 2 years by another laboratory. Laboratories under the same programs reported different intervals for on-site visits. For example, one laboratory accredited by USDA's FSIS reported on-site visits once every 2 years, another under the same program reported on-site visits once every year, and a third reported being visited only once. FSIS officials told us that laboratories that they determine through proficiency testing to be deficient are visited more often than those that are not.

Other Program Procedures

Under granting and renewal procedures, the agency determines if a laboratory's accreditation will be granted or renewed. Six out of the 20 programs have granting and/or renewal procedures. Some programs, such as APHIS' Program for Approval of Laboratories to Conduct Diagnostic Procedures for Contagious Equine Metritis and EPA's Motor Vehicle Emission Device Testing Program, do not have renewal procedures because the term of accreditation is indefinite. The procedures vary for the programs that have renewal processes. For example, in the FGIS program, delegated states have ongoing authority unless revoked by FGIS or voluntarily terminated by the state, and designated agencies have to renew their authority every 3 years. Under OSHA's Maritime Cargo Gear Accreditation Program, the renewal process is every 3 years.

Denial is the action in which the agency does not grant accreditation to the applicant. Revocation is eliminating the laboratory's accreditation; in order for the laboratory to be accredited again it has to reapply for accreditation. Suspension is eliminating the laboratory's accreditation for a certain period of time in which the laboratory must correct the deficiencies if it wishes to regain its accreditation. Of the 20 programs, 15 have denial, suspension, and/or revocation procedures. For example, EPA's Drinking Water Laboratory Certification Program states that certification will be reinstated when and if the laboratory can demonstrate to the certifying authority that the deficiencies which produced Provisionally Certified status have been corrected.

Voluntary termination is when a laboratory at any time terminates its participation and responsibilities as an accredited laboratory. Six out of the 20 programs have voluntary termination procedures.

Overlapping Programs and Burdensome Requirements

The federal programs generally do not overlap because they tend to be in different fields of testing. For example, under the FSIS Accredited Laboratory Program, laboratories are accredited for testing meat and poultry for moisture, fat, salt, and protein content. Under HCFA's Clinical Laboratory Improvement Act Amendments, laboratories are accredited for testing materials derived from the human body for disease. Appendix IV provides other examples of the diversity of federal accreditation programs.

However, we identified two programs that overlap—NIST's NVLAP program for electromagnetic compatibility and FCC's Description of Measurement Facilities Program. Burdensome requirements were generally reported to be within rather than between programs.

Two Programs That Overlap

FCC and NIST administer programs that involve laboratories that test the same type of electronic devices. Under FCC's program, applicants for equipment authorization for radio frequency devices submit, among other things, a description of the laboratory's facilities for testing the devices to show FCC where the devices are being tested. FCC maintains a list of laboratories that have submitted a description of their facilities. Any laboratory that submits the information can be on the list. FCC charges no fees.

NIST establishes laboratory accreditation programs on the basis of requests and demonstrated need from federal agencies and/or the private sector. The NVLAP laboratory accreditation program for electromagnetic compatibility was developed at the request of five private laboratories to recognize and accredit laboratories that produce reliable test data for electromagnetic compatibility and telecommunications equipment. FCC contributed input to the development of this program, but it was actually developed by NIST with assistance from the private laboratories. The program covers computing devices and telephone terminal equipment.

According to FCC officials, although their list indicates NVLAP-accredited laboratories, they do not accept NVLAP accreditation in lieu of the laboratory providing a description of facilities because NVLAP accreditation does not cover all the devices that FCC regulations require to be tested. The officials said that in the future they would consider eliminating the filing requirements for NVLAP accredited laboratories when NVLAP covers all the devices that FCC requires to be tested. A NVLAP official told us that NVLAP could be expanded to cover all devices.

Although the FCC and NVLAP programs overlap, officials we spoke with at two laboratories that participate in both programs did not believe that this overlap was a burden. They said that the FCC requirements are minimal. However, they would like to see FCC accept NVLAP accreditation because FCC does ask for the same information that is required by NVLAP.

Cross-Governmental Acceptance of Accreditation Programs

Programs recognized by other federal agencies include NVLAP, HUD's Technical Suitability of Building Products Program, and FDA's Toxicology Laboratory Monitoring Program. HUD accepts the test results from NVLAP-accredited carpet testing laboratories. HUD's building products program is accepted by the Department of Veterans Affairs and the Farmers Home Administration. FDA officials told us that FDA shares with EPA the results of inspections of about 30 toxicology laboratories that also test for pesticides and environmental contaminants.

Burdensome Requirements

Laboratory officials commenting on overlapping and burdensome requirements stated that the burden was from requirements of a particular program and not necessarily from overlapping or duplicative requirements of other programs. One laboratory official believed that far too much staff time was spent on NVLAP requirements and that there was a burden in obtaining and maintaining the records. An official of a

laboratory that was accredited by both FSIS and EPA stated that the programs are in different areas of testing and are not duplicative, but believed that the proficiency requirements of the programs were excessive.

Another program that was cited as having a burdensome requirement is EPA's Drinking Water Laboratory Certification Program. This program operates under state primacy, whereby each state is responsible for accrediting local laboratories. Although EPA endorses reciprocity, that is, mutually acceptable certification between regions and states, we were told that there is very little reciprocity between states. One laboratory official told us that the laboratory was accredited by 8 to 10 states. EPA officials agreed that there is a lack of reciprocity and stated that because states have been delegated primacy, states have the autonomy to accept or reject other states' certifications. EPA believes that it does not have the legal authority to require reciprocity.

Some Laboratory Accreditation Issues

Some additional aspects of laboratory accreditation we examined are the potential for revenues, the cost of accreditation programs, and the need for federal accreditation to provide credibility. Only two programs currently charge fees for accreditation. In addition, one program has recently been congressionally mandated to charge fees. Other programs could possibly charge fees. Although actual program costs for accreditation could not be determined exactly, program officials could generally estimate the costs. Some laboratory officials we spoke with said that federal accreditation is needed to provide credibility of test results in the international arena.

Potential Revenues From Accreditation

When federal agencies provide goods, services, and privileges that benefit identifiable recipients, charging recipients for these benefits may be considered. In each case the beneficiary of the accreditation program can be specifically identified—the laboratory or other organization. Currently only two agencies charge fees for participation in their programs—NIST and HUD. Under the NVLAP program, the laboratory pays a fee that ranges from $2,000 to $5,000 per year for accreditation. According to NVLAP officials, the fees are meant to cover the costs of the accreditation, including the costs of the technical experts who make the on-site evaluations.

Under HUD's building products program, HUD issues "use of materials bulletins" by which HUD establishes a generic level of acceptability for an individual product or system of products, such as pressure-treated lumber and plywood and plastic bathroom fixtures. Laboratory or private organizations that are accepted by HUD as administrators pay a one-time fee of $500 for each bulletin on which they are listed as a program administrator. Accepted program administrators validate the manufacturer's certification that a particular building material or product meets applicable HUD standards.

In addition, under the Clinical Laboratory Improvement Amendments of 1988, HCFA is now required to charge fees for issuance of certificates under the program. The act requires that the fees be sufficient to cover general costs of administering the program, including evaluating and monitoring approved proficiency testing programs and implementing and monitoring compliance with program requirements. HCFA officials told us that they are currently determining the amount of the fees and how they will be charged.

Program Costs

Agency officials were unable to provide us with exact costs of accreditation. However, two agencies that could state program costs are NIST and HCFA. The budget for NVLAP for fiscal year 1989 is $2.8 million. HCFA's expenditures for laboratory monitoring for fiscal year 1987 were $4.7 million.

Some program officials said that the accreditation program is just a small part of the complete program and, therefore, the cost is not separated out. However, most officials could estimate the program costs either in dollars or in staff time. For example:

- EPA's Motor Vehicle Emission Program officials estimated the cost for operating the laboratory recognition program to be about $1,000 per year.
- OSHA's Maritime Cargo Gear Accreditation Program officials estimated that the cost for operating the program is one full-time employee and one part-time secretary.
- FSIS officials estimated the cost of operating its accredited laboratory program was $363,834 for February 1, 1987, to January 31, 1988. This includes costs for on-site reviews, staff time, clerical support, computer support, and check samples.
- An FDA official estimated that staff time cost for the Toxicology Laboratory Monitoring Program is 10 full-time employees per year.
- HUD officials estimated that one person spends about 10 percent of his time per year to administer the accepted administrator portion of the Technical Suitability of Building Products Program.

Continued Need for Accreditation

A NIST official commented on the importance of focusing accreditation at the national level, through public and private cooperation, to gain greater credibility and acceptance of U.S. products for trading in international markets. Several laboratories expressed the need for federal government accreditation because of the credibility it provides. In addition, some believed that federal accreditation, particularly accreditation under NVLAP, was needed at the national level to increase U.S. competitiveness in areas related to international trade.

One laboratory official told us that foreign governments should accept NVLAP. Currently each government has its own requirements. Another laboratory official told us that NVLAP was needed particularly as a tool for international trade in the telecommunications area.

NVLAP has bilateral agreements with Australia, New Zealand, and Great Britain to recognize each country's accredited laboratories. Also, NIST recently signed an agreement with Canada for mutual recognition of laboratories accredited by NVLAP and the Standards Council of Canada's National Accreditation Program for Testing Organizations.

Other comments from laboratory officials on the need for accreditation to provide credibility concern the lack of a systematic accreditation process and the need for a universal organization to accredit laboratory performance.

Public or Private Accreditation

Private laboratories have raised the question as to whether private organizations can assume the responsibility for accreditation of laboratories. We asked the laboratories we surveyed whether accreditation could be done by one organization, either public or private. Of the 10 laboratories reporting, 7 stated that they believed that accreditation by one body, either public or private, was possible. One laboratory official said that this was possible because one agency could expand to cover all areas of testing if it had experts in each area. Another laboratory official believed that one organization with separate divisions could do all accreditation. Three believed that it was not possible because the fields of testing are different.

We also asked agency officials whether a private organization could do the accreditation they were doing. Generally, they reported that there was not a private sector group available to do the accreditation or what the agency does, or that the program was too small for a private organization to do accreditation. One case where there is a private sector body to do accreditation is the area of clinical laboratories. The College of American Pathologists has a laboratory accreditation program for clinical laboratories that is recognized by HCFA under CLIA. If a laboratory is accredited by the College, it can apply for an exemption to be accredited under CLIA.

Federal Accreditation Programs Reviewed

Agency	Title	Description
Department of Agriculture		
Animal and Plant Health Inspection Service	Approval of Laboratories to Conduct Diagnostic Procedures for Contagious Equine Metritis	Approve laboratories to conduct diagnostic procedures for contagious equine metritis, a highly transmissible venereal disease of horses.
Federal Grain Inspection Service	Delegated/ Designated Grain Inspection and Weighing Program	Delegated states and designated agencies perform official inspection and weighing services for FGIS.
Food Safety and Inspection Service	Accredited Laboratory Program	Accredits non-federal analytical chemistry laboratories to analyze official meat and poultry samples. A single accreditation is offered for moisture, protein, fat, and salt content, while accreditation for chemical residues is done by specific classes of chemicals.
National Institute of Standards and Technology	National Voluntary Laboratory Accreditation Program	System for accrediting testing laboratories found competent to perform specific tests or types of tests. Comprised of a series of laboratory accreditation programs which are established on the basis of requests and demonstrated need.
Department of Defense		
Defense Electronics Supply Center	Qualification Testing of Manufactured Products	Commercial test laboratories are found to be suitably equipped and staffed for performing qualification testing for manufacturers of electrical, mechanical, and environmental equipment.
Defense Personnel Supply Center	Qualified Laboratories Program	Laboratories are found to be capable of performing types of specification tests for clothing, textile, footwear, and equipage-type items.
Environmental Protection Agency	Drinking Water Laboratory Certification Program	Primacy states may certify local laboratories for testing drinking water compliance with the Safe Drinking Water Act.
	Motor Vehicle Emissions Device Testing Program	Evaluation program to determine performance of various retrofit devices and fuel additives applicable to automobile for which fuel economy improvement claims are made.
Federal Communications Commission	Description of Measurement Facilities	Laboratories making measurements of devices that are included in application for FCC equipment authorization provide a description of their facilities.

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Agency	Title	Description
Health and Human Services		
Food and Drug Administration	Toxicology Laboratory Monitoring Program	Nonclinical laboratories that are evaluating the safety of FDA-regulated products are inspected to determine whether they are following good laboratory practices.
Food and Drug Administration	Evaluation of Milk Laboratories	Laboratory accreditation and endorsement of sample collection surveillance procedures provides a national base for the uniform collection and examination of milk.
Health Care Financing Administration	Clinical Laboratory Improvement Amendments and Medicare	Independent clinical laboratories receiving payments under Medicare must be accredited under Medicare. Under CLIA, laboratories must meet the requirement of section 353 of the Public Service Health Act.
Department of Housing and Urban Development	Technical Suitability of Building Products Program	Organizations acceptable to HUD validate manufacturers' certifications that certain building materials meet applicable standards.
Department of the Interior		
Office of Surface Mining	Small Operator Assistance Program	Qualified laboratories determine the probable hydrologic consequences and a statement of results of test borings or core samplings.
Department of Labor		
Occupational Safety and Health Administration	Nationally Recognized Testing Laboratories	Third-party testing for safety of equipment and materials for workplace use.
Occupational Safety and Health Administration	Blood Lead Analysis	Laboratories test blood for lead level to comply with OSHA regulations.
Occupational Safety and Health Administration	Maritime Cargo Gear Accreditation Program	Third-party inspection of certain maritime cargo gear handling devices specifically required to be certificated under OSHA maritime safety and health standards.
Department of Transportation		
Coast Guard	Safety Approval of Cargo Container Program	Laboratories approve cargo containers used in international transport in accordance with International Convention for Safe Containers.
Coast Guard	Approval of Equipment and Materials	Laboratories determine that devices meet or exceed the minimally acceptable technical requirements as established in regulations. Devices are of three types: life saving, fire protection, and marine pollution prevention.
Department of Treasury		
Customs Service	Commercial Gaugers and Laboratories Accreditation Program	Commercial laboratories analyze petroleum, bulk liquid organic chemicals, and vegetable and animal oils to determine their composition and/or characteristics.

Terms for Accreditation and Definitions of "Accredited" or "Accredited Laboratory"

Term	Agency	Title	Definition of accredited or accredited laboratory
Accredited	USDA Food Safety and Inspection Service	Accredited Laboratory Program	Nonfederal analytical laboratory that has met the requirements for accreditation . . . and may be used in lieu of an FSIS laboratory for analyzing official regulatory samples.
	National Institute of Standards and Technology	National Voluntary Laboratory Accreditation Program	Formal recognition that a testing laboratory is competent to carry out specific tests or types of tests.
	HHS FDA	Evaluation of Milk Laboratories	Appropriate agency certifies the performance of analysis in milk laboratories.
	HHS HCFA	Clinical Laboratory Improvement Amendments of 1988 and Medicare	A laboratory accredited by an approved accreditation body.
	Department of Labor OSHA	Maritime Cargo Gear Accreditation Program	Applicant for accreditation shall be staffed by individuals technically qualified to conduct the inspection and examinations.
	Treasury Department U.S. Customs Service	Commercial Gaugers and Laboratories Accreditation Program	Determination that the applicant is competent, independent, and reputable.
Approved	USDA APHIS	Approval of Laboratories to Conduct Diagnostic Procedures for Contagious Equine Metritis	Assurance of laboratory's competence to run approved tests and that adequate space and equipment is available.
	Department of Labor OSHA	Blood Lead Analysis	Laboratory that has received a satisfactory grade in blood lead proficiency testing in the prior 9 months.
Designated/ Delegated	USDA Federal Grain Inspection Service	Delegated/Designated Grain Inspection and Weighing Program	Agency or person has adequate facilities and qualifications for the performance of such official inspection and weighing functions and meets other criteria.
	DOT Coast Guard	Safety Approval of Cargo Container Program	A delegate of the Commandant of the Coast Guard authorized to approve containers.
Suitable	DOD Defense Electronics Supply Center	Qualification Testing of Manufactured Products	Laboratories found to be suitably equipped and staffed for performing qualification testing for manufacturers.

(continued)

Term	Agency	Title	Definition of accredited or accredited laboratory
Qualified	DOD Defense Personnel Supply Center	Qualified Laboratories Program	Laboratories found to be capable of performing the types of specification tests for which they are listed.
	Department of the Interior Office of Surface Mining	Small Operator Assistance Program	Designated public agency, private firm, institution, or analytical laboratory which can prepare the required determination of probable hydrologic consequences or statement of results of test borings or core samplings.
Certified	EPA	Drinking Water Laboratory Certification Program	A laboratory that meets the minimum requirements of EPA-approved state certification program.
Recognized	EPA	Motor Vehicle Emissions Device Testing Program	A test facility operated independently of any motor vehicle, motor vehicle engine, or retrofit device manufacturer capable of performing retrofit device evaluation tests.
	Department of Labor OSHA	Nationally Recognized Testing Laboratories	Organization that is recognized by OSHA and tests for safety and lists, labels, or accepts equipment or materials that meet specific criteria.
Description	FCC	Description of Measurement Facilities	None stated.
Good Laboratory Practices	HHS FDA	Toxicology Laboratory Monitoring Program	None stated.
Accepted	HUD	Technical Suitability of Building Products Program	Administrator shall be capable of conducting a certification program through its organization, staff, and facilities and have a reputation for adhering to high ethical standards.
	DOT Coast Guard	Approval of Equipment and Materials	A laboratory must have or have access to the apparatus, facilities, personnel, and calibrated instruments that are necessary to inspect and test the equipment or material.

Accreditation Programs and Delegation of Authority

Primary use for accreditation	Agency and program
Nine programs use agency personnel to accredit laboratories to do particular testing.	USDA/APHIS—Approval of Laboratories to Conduct Diagnostic Procedures for Contagious Equine Metritis USDA/FSIS—Accredited Laboratory Program DOD/Defense Electronic Supply Center—Qualification Testing of Manufactured Products DOD/Defense Personnel Supply Center—Qualified Laboratories Program EPA/Motor Vehicle Emissions Device Testing Program FCC/Description of Measurement Facilities HHS/FDA—Toxicology Laboratory Monitoring Program Department of Labor/OSHA—Nationally Recognized Testing Laboratories Treasury/Customs Service—Commercial Gaugers and Laboratories Accreditation Program
Two programs use agency personnel and outside experts or state personnel to accredit laboratories to do particular testing.	NIST/National Voluntary Laboratory Accreditation Program HHS/HCFA—Clinical Laboratory Improvement Act, Medicare
Six programs use accreditation to delegate agency authority to others to issue certifications or to do inspections.	USDA/FGIS—Designated/Delegated Grain Inspection and Weighing Program HHS/FDA—Evaluation of Milk Laboratories Department of Labor/OSHA—Maritime Cargo Gear Accreditation Program DOT/Coast Guard—Safety Approval of Cargo Container Program HUD—Technical Suitability of Building Products Program DOT/Coast Guard—Approval of Equipment and Materials
Two programs use state primacy where states have the responsibility for accrediting the laboratories within agency guidelines.	Interior/Office of Surface Mining—Small Operator Assistance Program EPA/Drinking Water Laboratory Certification Program
One program uses third parties to do the accrediting.	Department of Labor/OSHA—Blood Lead Analysis
Total Number of Programs:	**20**

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