

NBS Special Publication 739

Directory of Federal Government Certification Programs

## Maureen Breitenberg, Editor

IS N N N N 35 B  $\mathbf{S}$ R ational Bureau of Standards NB 25 IBS NB QC-100 NBS NBS NB  $\nabla BS$  $\mathbf{V} \mathbf{R}$ VRN58 ·U57 No.739 1988 c.2

he National Bureau of Standards' was established by an act of Congress on March 3, 1901. The Bureau's overall goal is to strengthen and advance the nation's science and technology and facilitate their effective application for public benefit. To this end, the Bureau conducts research to assure international competitiveness and leadership of U.S. industry, science and technology. NBS work involves development and transfer of measurements, standards and related science and technology, in support of continually improving U.S. productivity, product quality and reliability, innovation and underlying science and engineering. The Bureau's technical work is performed by the National Measurement Laboratory, the National Engineering Laboratory, the Institute for Computer Sciences and Technology, and the Institute for Materials Science and Engineering.

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Provides the national system of physical and chemical measurement; coordinates the system with measurement systems of other nations and furnishes essential services leading to accurate and uniform physical and chemical measurement throughout the Nation's scientific community, industry, and commerce; provides advisory and research services to other Government agencies; conducts physical and chemical research; develops, produces, and distributes Standard Reference Materials; provides calibration services; and manages the National Standard Reference Data System. The Laboratory consists of the following centers:

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Provides technology and technical services to the public and private sectors to address national needs and to solve national problems; conducts research in engineering and applied science in support of these efforts; builds and maintains competence in the necessary disciplines required to carry out this research and technical service; develops engineering data and measurement capabilities; provides engineering measurement traceability services; develops test methods and proposes engineering standards and code changes; develops and proposes new engineering practices; and develops and improves mechanisms to transfer results of its research to the ultimate user. The Laboratory consists of the following centers:

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Conducts research and provides scientific and technical services to aid Federal agencies in the selection, acquisition, application, and use of computer technology to improve effectiveness and economy in Government operations in accordance with Public Law 89-306 (40 U.S.C. 759), relevant Executive Orders, and other directives; carries out this mission by managing the Federal Information Processing Standards Program, developing Federal ADP standards guidelines, and managing Federal participation in ADP voluntary standardization activities; provides scientific and technological advisory services and assistance to Federal agencies; and provides the technical foundation for computer-related policies of the Federal Government. The Institute consists of the following divisions:

## The Institute for Materials Science and Engineering

Conducts research and provides measurements, data, standards, reference materials, quantitative understanding and other technical information fundamental to the processing, structure, properties and performance of materials; addresses the scientific basis for new advanced materials technologies; plans research around cross-cutting scientific themes such as nondestructive evaluation and phase diagram development; oversees Bureau-wide technical programs in nuclear reactor radiation research and nondestructive evaluation; and broadly disseminates generic technical information resulting from its programs. The Institute consists of the following Divisions:

- Basic Standards<sup>2</sup>
- Radiation Research
- Chemical Physics
- Analytical Chemistry

- Applied Mathematics
- Electronics and Electrical Engineering<sup>2</sup>
- Manufacturing Engineering
- Building Technology
- Fire Research
- Chemical Engineering<sup>3</sup>
- Information Systems Engineering
- Systems and Software Technology
- Computer Security
- Systems and Network Architecture
- Advanced Computer Systems
- Ceramics
- Fracture and Deformation<sup>3</sup>
- Polymers
- Metallurgy
- Reactor Radiation

<sup>&</sup>lt;sup>1</sup>Headquarters and Laboratories at Gaithersburg, MD, unless otherwise noted; mailing address Gaithersburg, MD 20899.

<sup>&</sup>lt;sup>2</sup>Some divisions within the center are located at Boulder, CO 80303. <sup>3</sup>Located at Boulder, CO, with some elements at Gaithersburg, MD

Research Information Center National Bureau of Standards Gaithersburg, Maryland 20899

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**NBS Special Publication 739** 

# Directory of Federal Government Certification Programs

Maureen Breitenberg, Editor

Office of Standards Code and Information Office of the NBS Associate Director for Industry and Standards National Bureau of Standards Gaithersburg, MD 20899

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#### FOREWORD

This directory is the first revision of the National Bureau of Standards (NBS) publication, NBS SP 714, Federal Government Certification Programs for Products and Services, edited by Robert B. Toth and published in April 1986. Additional federal certification programs have been identified and changes have been made to reflect organizational or programmatic changes. This directory, a joint effort of the U.S. Department of Agriculture (USDA) and NBS, is designed to provide updated information on certification programs conducted by the federal government for products and services.

Interest in certification arises from many sectors and may be motivated by economic, procurement, safety, or other considerations. Certification has also increased in significance due to its impact on free trade. Federal, state, and local government officials, manufacturers, distributors, and others may find the information contained in this directory of use in identifying pertinent federal certification programs and the details of such programs, as well as in finding a contact point within the appropriate agency.

> Dr. Stanley I, Warshaw Associate Director for Industry and Standards

#### ACKNOWLEDGMENTS

This directory is based on an earlier publication by Robert B. Toth, who was responsible for much of the work in establishing the format of this publication and its predecessor.

Special thanks are due to Carolyn Wilson and Audrey Talley at the U. S. Department of Agriculture (USDA), who oversaw the collection and review of information on certification programs within USDA. I would also like to thank the managers of federal certification programs who provided the information contained in this directory, without which this publication would not have been possible.

Maureen Breitenberg Editor

#### ABSTRACT

This directory, which represents a joint effort of the U.S. Department of Agriculture (USDA) and the National Bureau of Standards (NBS), is designed to provide updated information on federal certification programs for products and services. This directory is a revision of NBS SP 714, <u>Federal Government</u> <u>Certification Programs for Products and Services</u>, edited by Robert B. Toth and published in April 1986.

This directory is part of ongoing NBS/USDA efforts to establish and maintain comprehensive databases on standards, regulations, certification programs and related information in accordance with the requirements of the Trade Agreements Act of 1979. This material has been compiled to meet the needs of government, industry, and the public for information on U.S. Government certification programs.

Key Words: approved products; certification; grading; inspection; listing; premarket evaluation; qualification; qualified products; specifications; standards; testing

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#### INTRODUCTION

#### Background

In April 1986, the National Bureau of Standards (NBS) published a directory of federal certification programs, NBS SP 714, <u>Federal Government Certification</u> <u>Programs for Products and Services</u>, edited by Robert B. Toth. Since that time, additional federal certification programs have been identified and some agencies have undergone reorganizations or program changes. This directory, which represents a joint effort of the U.S. Department of Agriculture (USDA) and the National Bureau of Standards (NBS), is designed to provide updated information on certification programs which are conducted by the federal government for products and services. It contains information on the date that programs were initiated; the authority under which they are conducted; their aims, benefits and requirements; availability of documentation; and other related information.

#### Format

The entries in this directory are organized into ten sections: Section I-Agricultural Products and Services; Section II - Consumer Products and Services; Section III - Construction Products and Services; Section IV - Electronic and Telecommunications Products and Services; Section V - Government Procurements, Section VI - Testing, Measurement and Laboratory Services; Section VII - Medical Products and Services; Section VII - Medical Products and Services; Section IX - Transportation-Related Products and Services; and Section X-Miscellaneous Products and Services. Indices are provided by product at the beginning of each section, as well as references to related other sections of possible interest. In addition, there is a cumulative product index at the end of the entries, followed by indices by agency acronym, department and agency, and by agency name alone. A description of the format used for each entry is contained in Appendix III.

#### Directory Changes

U.S. Government agencies are encouraged to notify NBS of any changes in their certification programs or of new programs. Such information should be sent to:

National Center for Standards and Certification Information (NCSCI) National Bureau of Standards Administration Building, Room A629 Gaithersburg, MD 20899 (301) 975-4031

### Other References

Additional NBS and USDA documents of possible interest are contained in Appendices I and II.

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### AGRICULTURAL PRODUCTS AND SERVICES



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Products or Services	Meats, Prepared Meats, and Meat Products (Beef, Lamb, Veal, Calf, and Pork)
Department/Agency	U.S. Department of Agriculture (USDA) Agricultural Marketing Service (AMS) Livestock and Seed Division Meat Grading and Certification (MGC) Branch, Room 2638-S P. O. Box 96456 Washington, D.C. 20090-6456 (202) 382-1246 FAX: (202) 447-7271
Initiated	1946
Compliance	Voluntary
Authority	Agricultural Marketing Act of 1946 (as amended)
Aim	To facilitate the marketing of livestock and meat.
Benefits	Through uniform grade standards, the meat grading system provides reliable identification of the value-determining factors of meat and a common language to facilitate trading. From producer to consumer, this system makes buying and selling more efficient and meaningful. The certification program assists large scale buyers by providing impartial evaluation and certification that meat purchases meet their contract specifications.
Agency Function	The MGC Branch provides on-site grading and certification of meats and meat products by the physical examination of product characteristics during the production process prior to the purchase.
Methodology	Inspection by MGC Branch personnel.
Testing	Required tests are preformed in Government labs.
Inspection	MGC Branch personnel.
Conformity Identification	Approved USDA stamps and roller brands are applied in compliance with applicable standards or specifications.

Enforcement	USDA certification is withheld from products not complying with approved standards or specifications.
Term	Continuous inspection on a voluntary basis.
Reciprocity	None.
Standards, Codes or Regulations	The agency develops and maintains its own USDA approved standards and specifications for the various meat items.
Keywords	<pre>beef; certification; grading; lamb; meat; meat products; pork; veal</pre>

Products or Services	Raw Cotton
Department/Agency	U.S. Department of Agriculture (USDA) Agricultural Marketing Service (AMS) Cotton Division, Rm. 2641-S P. O. Box 96456 Washington, D.C. 20090-6456 (202) 447-2145 FAX: (202) 472-9718
Initiated	1916
Compliance	Required for cotton delivered on Futures Contracts.
Authority	7 CFR Part 27 and U. S. Cotton Futures Act.
Aim	To certify quality of cotton delivered on Futures Contracts according to official U. S. Standards.
Benefits	Orderly settlement of cotton Futures Contracts.
Agency Function	Certifier.
Type of Program	Cotton grading and certification.
Methodology	Government agency classes (grades) cotton samples taken from bales expected to be tendered on the futures market and issues certificates certifying quality.
Testing	Government labs.
Inspection	Government.
Conformity Identification	Grade certificates.
Availability of Documentation	List of government cotton classing offices available from above address.

Obligations of Manufacturer/Vendor	To order samples taken and transported to government classing offices.
Enforcement	Decertification.
Term	One year from date of original certification.
Reciprocity	Other federal agencies.
Standards, Codes or Regulations	The agency prepares all criteria documents.
Keywords	certification; classing; cotton quality; grading

.

Products or Services	Dairy Products
Department/Agency	U.S. Department of Agriculture (USDA) Agricultural Marketing Service (AMS) Dairy Division, Rm. 2750-S P. O. Box 96456 Washington, D.C. 20090-6456 (202) 382-9382 FAX: (202) 447-7271
Initiated	1925
Compliance	Voluntary
Authority	7 CFR Part 58 and the Agricultural Marketing Act of 1946 (as amended).
Aim	Orderly trade in processed dairy products and assurance of consistent quality of such commodities.
Benefits	Identification of qualified producers. Grading of selected dairy products. Consistent nomenclature for buying and selling processed dairy products.
Agency Function	Certifier and program administrator.
Type of Program	Pre-marketing evaluation. Assessment prior to government purchase.
Methodology	Government agency provides testing, inspection, audit and site approval. State governments cooperate in some phases.
Testing	Government labs. Government accredited labs.
Inspection	Government. State government.
Conformity Identification	List of approved dairy plants. Authorized grading marks are applied on products for which grading standards are established.

Availability of Documentation	List of approved dairy plants is updated quarterly and is available from the above address.
Obligations of Manufacturer/Vendor	Approved dairy plants must maintain quality control.
Enforcement	Delisting. Product recall.
Term	Dairy plants are reinspected two to four times per year.
Reciprocity	Other federal agencies. State agencies.
Standards, Codes or Regulations	The agency prepares all criteria documents.
Keywords	butter; cheese; dairy products; food quality; grading

Products or Services	Fresh Fruits, Vegetables, Nuts, and Related Products
Department/Agency	U.S. Department of Agriculture (USDA) Agricultural Marketing Service (AMS) Fruits and Vegetables Division, Rm. 2077-S P. O. Box 96456 Washington, D.C. 20090-6456 (202) 447-6393 FAX: (202) 447-7271
Initiated	1917
Compliance	Voluntary
Authority	Agricultural Marketing Act of 1946 (as amended).
Aim	Orderly trade in fresh fruits and vegetables based on standard nomenclature. Common basis for settling market disputes over quality of products
Benefits	Improve efficiency in buying and selling produce based on official and standardized grading which is consistent throughout the nation. Inspection certificates are accepted in court as prima facie evidence of produce condition at the time of inspection.
Benefits Agency Function	based on official and standardized grading which is consistent throughout the nation. Inspection certificates are accepted in court as prima facie evidence of produce
	based on official and standardized grading which is consistent throughout the nation. Inspection certificates are accepted in court as prima facie evidence of produce condition at the time of inspection.
Agency Function	<ul> <li>based on official and standardized grading which is consistent throughout the nation. Inspection certificates are accepted in court as prima facie evidence of produce condition at the time of inspection.</li> <li>Certifier and program administrator.</li> <li>Voluntary pre-marketing evaluation.</li> <li>Voluntary post-marketing assessment.</li> </ul>
Agency Function Type of Program	<ul><li>based on official and standardized grading which is consistent throughout the nation. Inspection certificates are accepted in court as prima facie evidence of produce condition at the time of inspection.</li><li>Certifier and program administrator.</li><li>Voluntary pre-marketing evaluation.</li><li>Voluntary post-marketing assessment.</li><li>Assessment prior to government purchase.</li></ul>

Availability of Documentation	There are no lists of participating producers.
-	Must have a financial interest in the product. Pay assessed fee for service rendered.
Enforcement	Although nearly all aspects of this program are voluntary, a full range of enforcement options apply to shippers who practice fraud.
Term	Certification is done on a lot by lot basis.
Reciprocity	USDA grade marking is recognized nation-wide and world-wide in both private and public sectors.
Standards, Codes or Regulations	Grading criteria are established by AMS.
Keywords	food quality; fruits; grading; nuts; vegetables

Products or Services	Processed Fruits and Vegetables
Department/Agency	U.S. Department of Agriculture (USDA) Agricultural Marketing Service (AMS) Fruits and Vegetables Division, Rm. 0709-S P. O. Box 96456 Washington, D.C. 20090-6456 (202) 447-4693 FAX: (202) 447-7271
Initiated	1931
Compliance	Voluntary, except for products covered by federal or state marketing orders.
Authority	7 CFR Part 52 and the Agricultural Marketing Act of 1946 (as amended).
Aim	Provide an objective evaluation of quality and condition of various processed food products and conditions under which they are produced.
Benefits	Provide a uniform basis for nation-wide trade in processed fruits and vegetables.
Agency Function	Provide voluntary grading and inspection service.
Type of Program	Pre-market evaluation. Post-market assessment. Assessment prior to government purchase.
Methodology	Government, testing, inspection, audit, site approval, compliance with good manufacturing practices (GMPs).
Testing	Government lab. Manufacturer's lab under review by government inspectors. State labs if state is cooperating in program. Third party labs may be used by manufacturer for quality control.

Inspection Federal government inspection. Inspection by cooperating state government inspectors. Conformity Authorized grade and/or inspection marks applied by Identification manufacturer. Government applied mark is restricted to officially sampled lots. Availability List of processing plants under contract is published of Documentation annually and is available from the above address. Obligations of Make product accessible for sampling. Produce product in Manufacturer/Vendor accordance with the good manufacturing practices (GMPs) as defined in the Food and Drug Administration's regulations. Enforcement Since bulk of program is voluntary, means of enforcement is withdrawal of labeling privilege or withdrawal of service. When Marketing Orders are in effect, agency sponsoring the order has authority for product recall or marketing ban. Term is set by contract; activity may be renewed and/or Term may provide for continuous inspection. Reciprocity Certificates are recognized by other federal agencies for procurement. Certificates of Sampling from states are recognized by Agency under certain cooperative agreements. Most acceptance criteria are based on requirements or Standards, Codes specifications developed by federal or state agencies; or Regulations however, sometimes buyer specifications are used. agricultural marketing orders; food quality; fruits; good Keywords manufacturing practices; grading; in-plant inspection; processed foods; sanitation; vegetables

Products or Services	Tobacco and Naval Stores
Department/Agency	U.S. Department of Agriculture (USDA) Agricultural Marketing Service (AMS) Tobacco Division, Rm. 502 Annex Building 300 12th Street, SW P. O. Box 96456 Washington, D.C. 20090-6456 (202) 447-2567 FAX: (202) 447-2567
Initiated	Tobacco — 1935 Naval Stores — 1923
Compliance	<u>Tobacco</u> : Mandatory only for domestic tobacco sold on designated auction markets and all imported tobacco, except cigar and oriental, offered for importation into the U.S. <u>Naval Stores</u> : Voluntary.
Authority	The Tobacco Inspection Act. The Dairy and Tobacco Adjustment Act. The Naval Stores Act.
Aim	Protection of producers and others against speculation, manipulation, control and unreasonable price fluctuations.
Benefits	Helps producers move commodities to consumers quickly, fairly and efficiently.
Agency Function	Certifier and program administrator.
Type of Program	Pre-market evaluation.
Methodology	Government grading in accordance with U.S. Official Standard Grades and Specifications.

i.

TestingNaval Stores:Government lab certifies results of manufacturer's lab.

Inspection <u>Tobacco</u>: Federal government inspection.

> <u>Naval Stores</u>: Official inspectors. Licensed inspectors.

Conformity Identification <u>Tobacco</u>: Government certificates.

<u>Naval Stores</u>: Government certificates and authorized mark by manufacturer.

Availability I of Documentation

Documentation is confidential.

Obligations of Proper lighting and adequate space. Manufacturer/Vendor

Enforcement <u>Tobacco</u>: Reduction of sales opportunity or withdrawal of inspection.

> <u>Naval Stores</u>: Withdrawal of inspection.

Term Continuous inspection.

**Reciprocity** Recognition of certification by other federal agencies and international organizations.

Standards, Codes7 CFR Part 29, Subpart C - Standards.or Regulations7 CFR Part 160, Regulations and Standards for Naval Stores.ASIM Designation D 233, Sampling and Testing Turpentine.

Keywords agricultural marketing orders; food quality; good manufacturing practices; inspection; naval stores; rosin; sanitation; tobacco; turpentine

Products or Services	Poultry, Shell Eggs, Egg Products, and Rabbits
Department/Agency	U.S. Department of Agriculture (USDA) Agricultural Marketing Service (AMS) Poultry Division, Rm. 3938-S P. O. Box 96456 Washington, D.C. 20090-6456 (202) 447-3271 Telex: 89-491 TWX: 710-822-9424 and 710-822-1104 FAX: (202) 447-9016
Initiated	1917
Compliance	Mandatory for all products cited if service is rendered. However, grading of poultry, shell eggs, and rabbits is not mandatory and is provided only to plants requesting the service.
Authority	Laws:
	Agricultural Marketing Act of 1946 (as amended) (60 Stat. 1087-1091; USC 1621-1627). Egg Products Inspection Act (84 Stat. 1620-1635; 21 USC 1031-1056).
	Regulations:
	Poultry and rabbit grading - Regulations Governing the Voluntary Grading of Poultry Products and Rabbit Products and U. S. Classes, Standards, and Grades (7 CFR Part 70).
	Voluntary egg products inspection - Regulations Governing the Voluntary Inspection and Grading of Egg Products (7 CFR Part 55).
	Shell egg grading - Regulations Governing the Grading of Shell Eggs and United States Standards, Grades, and Weight Classes for Shell Eggs (7 CFR Part 56).
	Mandatory egg products inspection - Regulations Governing the Inspection of Eggs and Egg Products (7 CFR Part 59).

Aim	Voluntary: To develop and improve standards of quality, condition, quantity, grade, and packaging, and recommend and demonstrate such standards in order to encourage uniformity and consistency in commercial practices and enhance the orderly and efficient marketing of poultry and poultry products. Mandatory: To assure that the health and welfare of consumers is protected by adoption of measures for assuring that eggs and egg products distributed to them and used in products consumed by them are wholesome and labeled properly.
Benefits	Third party evaluation. Easier dispute settlement. More accurate market price reporting. More equitable competition. Fewer rejections at destination. Established buying guides (specifications). Reduced illness. Upgraded product quality.
Agency Function	Certifier and regulator.
Type of Program	Pre-market evaluation. Post-market evaluation. Assessment prior to government purchase. Specification development. Inspection & grading.
Methodology	Government: Sampling. Organoleptic laboratory testing. Evaluation against standard. Certification by third party certifiers.
Testing	Government laboratories. Approved state laboratories. Third party laboratories. Manufacturer's laboratories.
Inspection	Federal government inspection. Inspection by approved state agencies.

Conformity Identification	Stamps (authorized marks). Certificates. Labeling. Seals.
Availability of Documentation	Single copies of regulations may be obtained from the Agency. Multiple copies may be obtained from the Superintendent of Documents, U.S. Government Printing Office.
Obligations of Manufacturer/Vendor	Operate in a sanitary manner. Maintain volume records. Comply with regulations. Perform required laboratory tests. Reimburse Government for cost of voluntary inspections and gradings. Provide access to products. Provide access to equipment and facilities necessary for accomplishing official duties.
Enforcement	Product retention. Product recall. Withdrawal of service. Laboratory comparison samples. Removal/withhold official identification. Reinspection/regrading. / Interruption of operations (mandatory only). Judicial system.
Term	Continuous mandatory inspection. Continuous or intermittent voluntary inspection.
Reciprocity	Use of licensed State employees. Recognition of certification of ingredients by manufacturer. Recognition of certification by approved government laboratory. Recognition of inspection stamp of "Agriculture Canada" for egg products produced in specifically approved Canadian plants.
Standards, Codes or Regulations	See "Authority."
Keywords	contract acceptance; egg products; eggs; grading branch; grading; poultry; rabbits; shell eggs;

Products or Services	Plants and Unprocessed Plant Products for Export
Department/Agency	U.S. Department of Agriculture Animal and Plant Health Inspection Service (APHIS) Plant Protection and Quarantine National Program Planning Staff Regulatory Services Staff, Federal Building 6505 Belcrest Road Hyattsville, MD 20782 Telephone: (301) 436-8537 Telex: 89607 ADEHVLE FAX: (301) 436-8794
Initiated	1913
Compliance	Voluntary
Authority	Department of Agriculture Organic Act of 1944, as amended. 7 CFR Part 353.
Aim	To assist in foreign marketing of American agricultural products.
Benefits	Most foreign countries require that shipment of plants and
	unprocessed or unmanufactured plant products be accompanied by phytosanitary (plant health) certificates certifying conformity with the receiving country's plant quarantine import regulations. The certificates are issued to exporters based upon physical inspection and and the determination that the commodity is free from insect pests, plant diseases, and other organisms considered harmful by the receiving country. Phytosanitary certificates are not issued to satisfy letters of credit or other commercial contract terms and are not certifications of grade or quality.
Agency Function	unprocessed or unmanufactured plant products be accompanied by phytosanitary (plant health) certificates certifying conformity with the receiving country's plant quarantine import regulations. The certificates are issued to exporters based upon physical inspection and and the determination that the commodity is free from insect pests, plant diseases, and other organisms considered harmful by the receiving country. Phytosanitary certificates are not issued to satisfy letters of credit or other commercial contract terms and
	unprocessed or unmanufactured plant products be accompanied by phytosanitary (plant health) certificates certifying conformity with the receiving country's plant quarantine import regulations. The certificates are issued to exporters based upon physical inspection and and the determination that the commodity is free from insect pests, plant diseases, and other organisms considered harmful by the receiving country. Phytosanitary certificates are not issued to satisfy letters of credit or other commercial contract terms and are not certifications of grade or quality.

Testing Testing in government labs and recognized state and university labs. Conformity Federal Phytosanitary Certificate. Identification Availability Information regarding foreign country plant quarantine of Documentation import requirements is maintained at above address and at Agency offices at major points of entry into the United States. Obligations of the Exporter must make written application for inspection and Manufacturer/Vendor make commodity available for physical inspection. Applications for active growth field inspections must be directed to the appropriate state plant regulatory agency in advance of the planting season. Federal certification is withheld from commodities not Enforcement complying with the plant quarantine import requirements of the foreign country. Term Inspections normally not valid if conducted more than 14 days prior to commodity export. Reciprocity Certification is recognized by foreign plant protection services and by regional plant protection organizations. Standards, Codes Criteria for certification are established by each foreign or Regulations country. Keywords export certification; export; phytosanitary; plant health; plant quarantine; plant products; plant; re-export

Products or Services	Plants and Unprocessed Plant Products for Import
Department/Agency	U.S. Department of Agriculture Animal and Plant Health Inspection Service (APHIS) Plant Protection and Quarantine National Program Planning Staff Regulatory Services Staff, Federal Building 6505 Belcrest Road Hyattsville, MD 20782 Telephone: (301) 436-8645 Telex: 89607 ADEHVLE FAX: (301) 436-8794
Initiated	1912
Compliance	Mandatory
Authority	Plant Quarantine Act of 1912, as amended.
	Federal Plant Pest Act of 1957, as amended.
Aim	To assist in preventing the introduction and dissemination of exotic plant pests and pathogens into and throughout U.S. agriculture.
Benefits	The permit system serves to notify prospective importers of the entry status and special entry requirements for their imports. This aids in preventing the arrival on U.S. shores of plant material potentially infested with exotic plant pests. The permit system also provides the agency with a list of importers of plants and plant products.
Agency Function	Reviews applications, issues permits, and provides information on entry requirements and regulatory changes.
Type of Program	Pre-import evaluation of entry requirements.
Methodology	Review of regulations and evaluation of pests associated with product in country of origin.
Testing	None.

Conformity Val: Identification

Valid import permit number.

Availability Lists of approved commodities and entry requirements of Documentation from each country available from above address. Information on permit holders available only through the freedom of information process.

Obligations of the Importer must make written application for permit. Manufacturer/Vendor

Term Permits issued for varying time periods ranging from 1 day to 5 years, depending on the product.

Reciprocity Import permit is recognized by foreign plant protection services and by state plant protection organizations.

Standards,Criteria for permits are established by the Acts and theCodes, orregulations promulgated therefrom.RegulationsRegulations

Keywords

import; permit; plant health; plant quarantine; plant
products; plant

Products or Services	Animal By-products for Export
Department/Agency	U.S. Department of Agriculture Animal and Plant Health Inspection Service (APHIS) Veterinary Services Program Planning and Development Import-Export Emergency Planning Staff Federal Building, Rm. 810 6505 Belcrest Road Hyattsville, MD 20782 Telephone: (301) 436-8017 Telex: 89607 ADEHVLE FAX: (301) 436-8794
Initiated	1946
Compliance	Voluntary
Authority	Laws: Agricultural Marketing Act of 1946, Sections 203 and 204. Regulations: 9 CFR Part 156.
Aim	To assist U.S. exporters in complying with import requirements of foreign countries.
Benefits	Most foreign countries require shipments of certain inedible animal by-products to be accompanied by certificates indicating the class, quality, and condition of the by-product and the U.S. status relative to certain livestock diseases. The certificates are issued to exporters based upon physical inspection, Department policy regarding the absence of certain diseases in the U.S., and endorsement of certain certifications made by state or accredited veterinarians.
Agency Function	Certifier and program administrator.
Type of Program	Pre-export inspection.
Methodology	Inspection by federal government and/or state government cooperators.

Testing	None.
Conformity Identification	USDA: export certificate, stamp endorsement, or letterhead certification.
Availability of Documentation	There are no lists of participating exporters. Copies of regulations may be obtained from the Agency.
Obligations of the Manufacturer/Vendor	In some cases, exporters must enter a cooperative agreement with Veterinary Services (VS); make written application to the Deputy Administrator, VS; and make product available for inspection.
Term	No specific term; based on time limits set forth by importing country.
Reciprocity	None.
Standards, Codes, or Regulations	Criteria for certification are established by each foreign country.
Keywords	animal by-product; export; export certification; inedible

Products or Services	Organisms and Vectors - Imported Livestock
Department/Agency	U.S. Department of Agriculture Animal and Plant Health Inspection Service (APHIS) Veterinary Services Program Planning and Development
·	Import-Export Emergency Planning Staff Federal Building, Rm. 810 6505 Belcrest Road Hyattsville, MD 20782 Telephone: (301) 436-8017 Telex: 89607 ADEHVLE FAX: (301) 436-8025
Initiated	1913
Compliance	Mandatory
Authority	Laws:
	Virus-Serum-Toxin Act of 1913, as amended (21 USC 111, 151-158) (7 USC 430).
	Act of June 17, 1930 (Tariff Act Section 201) (19 USC 1202) (46 Stat. 673).
	Act of June 17, 1930 (Tariff Act-Section 306) (19 USC 306) (46 Stat. 689).
	Act of July 2, 1962 - P.L. 518 (21 USC 134) (76 State 129).
	Act of May 6, 1970 - P.L. 91-239 (21 USC 135) (84 Stat. 202).
	Regulations:
	9 CFR Chapter I, Subchapter D, Parts 92, 94, 97, and 122.
Aim	To assist in preventing the introduction and dissemination of exotic animal diseases into the U.S. livestock population.
Benefits	The permit system serves to notify importers about special entry requirements and handling procedures for imports. Uniform central control of imports.

Agency Function	Review applications, issue permits, and provide information on entry requirements and regulatory changes.
Type of Program	Pre-import evaluation.
Methodology	Review of applications and evaluation of the importer's ability to handle the organisms or vectors in a safe manner.
Testing	None.
Inspection	Government.
Conformity Identification	Valid import permit and certificates.
Availability of Documentation	Copies of regulations may be obtained from the Agency. Information on permit holders available only through the Freedom of Information process.
Obligations of the Manufacturer/Vendor	Comply with regulations and conditions of permits, maintain records, provide access to facilities and records for inspection.
Enforcement	Revocation of permit, judicial system, refuse entry of imports.
Term	Permits are issued for 1 year.
Reciprocity	None.
Standards, Codes, or Regulations	See "Authority."
Keywords	import; organisms; permit; vectors

Products or Services	Animal Biological Products
Department/Agency	U.S. Department of Agriculture Animal and Plant Health Inspection Service (APHIS) Veterinary Services Rm. 320-E Washington, D.C. 20250 Telephone: (202) 447-5193 Telex: 89607 Ans: ADEHVLE FAX: (202) 472-5686
Initiated	1913
Compliance	Mandatory
Authority	Laws: Virus-Serum-Toxin Act of 1913, as amended (21 USC 151-159) (7 USC 430). Regulations: 9 CFR Chapter I, Subchapter E, Parts 101-117
Aim	To assure that animal biological products imported into or prepared in the United States are pure, safe, potent, and efficacious.
Benefits	Uniform central control. Prevention of the introduction and spread of animal diseases. Avoidance of risk to public health and well-being. Improved product quality.
Agency Function	Certifier and regulator.
Type of Program	Pre-license product evaluation. Post-license product evaluation. Specification development. Inspection. Export certification.

Methodology	Government Laboratory testing Evaluation against standard Inspection Export certification.
Testing	Manufacturer's laboratories. Government laboratories. Third party laboratories.
Inspection	Government.
Conformity Identification	Labeling and certificates.
Availability of Documentation	Single copies of regulations may be obtained from the Agency. Multiple copies may be ordered from the Superintendent of Documents, U. S. Government Printing Office.
Obligations of the Manufacturer/Vendor	Comply with regulations. Maintain detailed records. Operate in a sanitary manner. Perform manufacturing steps and tests in accordance with requirements. Submit samples to government laboratory. Provide access to facilities and records.
Enforcement	Government release to market of each serial of each product. Market suspension. Reinspection. Judicial system.
Term	Continuous market release. Periodic inspection of facilities and records.
Reciprocity	None.

Standards, Codes, or Regulations See "Authority."

Keywords

export certificates; licenses; standard requirements; veterinary biological products

Products or Services	Meat, Milk, and Poultry Products for Import
Department/Agency	U.S. Department of Agriculture Animal and Plant Health Inspection Service (APHIS) Veterinary Services Program Planning and Development Import-Export Emergency Planning Staff Federal Building, Rm. 810 6505 Belcrest Road Hyattsville, MD 20782 Telephone: (301) 436-8017 Telex: 89607 ADEHVLE FAX: (301) 436-8025
Initiated	1890
Compliance	Mandatory
Authority	<pre>Laws: Act of August 30, 1890 (Animal Quarantine Acts; 21 USC 102 through 105) (26 Stat. 414). Act of February 2, 1903 (21 USC 111) (32 Stat. 792). Act of June 17, 1930 (Tariff Act Section 201) (19 USC 1202) (46 Stat. 673). Act of June 17, 1930 (Tariff Act-Section 306) (19 USC 306) (46 Stat. 689). Act of July 2, 1962 - P.L. 518 (21 USC 134) (76 State 129). Act of May 6, 1970 - P.L. 91-239 (21 USC 135) (84 Stat. 202). Regulations: 9 CFR Chapter I, Subchapter D, Parts 94, 95, and 96.</pre>
Aim	To assure that imported animal products are properly cooked and handled in a manner to prevent the entry and dissemination of exotic animal diseases into the U.S. livestock population.

Benefits	The permit system serves to notify importers about special entry requirements and handling procedures for imports. Uniform central control of imports.
Agency Function	Review applications, issue permits, and provide information on entry requirements and regulatory changes.
Type of Program	Pre-import evaluation.
Methodology	Review of applications and evaluation of the importer's ability to meet criteria for import.
Testing	None.
Inspection	Government.
Conformity Identification	Valid import permit and certificates.
Availability of Documentation	Copies of regulations may be obtained from the Agency. Information on permit holders available only through the Freedom of Information process.
Obligations of the Manufacturer/Vendor	Comply with regulations and conditions of permit. Maintain records and provide access to facilities and records for inspection.
Enforcement	Revocation of permit, judicial system, refuse entry of imports.
Term	Permits are issued for 1 month to 1 year.
Reciprocity	None.
Standards, Codes, or Regulations	See "Authority."
Keywords	animal product; import; meat; milk; permit

Products or Services	Specified Animals for Export
Department/Agency	U.S. Department of Agriculture Animal and Plant Health Inspection Service (APHIS) Veterinary Services, Domestic Programs Import-Export Operations Staff Federal Building, Rm. 764 6505 Belcrest Road Hyattsville, MD 20782 Telephone: (301) 436-8695 Telex: 89607 ADEHVLE FAX: (301) 436-8025
Initiated	1884
Compliance	Mandatory
Authority	<pre>Laws: Act of May 29, 1884 (21 USC 112, 113, 120). Act of May 29, 1884 (21 USC 114a). Act of February 2, 1903 (21 USC 121). Act of July 2, 1962 (21 USC 134, 134f). Act of March 4, 1907 (21 USC 612, 613, 614, 618). Regulations: 9 CFR Chapter I, Subchapter D, Part 91.</pre>
Aim	To assure the exportation of healthy livestock and poultry in a humane manner.
Benefits	Provide a means for exporting healthy animals from the United States which enhances the U.S.'s image and aids in the balance of trade with foreign nations.
Agency Function	Inspection, certification and regulation.
Type of Program	Inspection and certification of health for livestock exports.

Methodology	Government: Diagnostic testing Inspection of documents and animals Certification
Testing	Government laboratories and government quarantine personnel.
Inspection	Government.
Conformity Identification	Valid health certification matching individual animal identification.
Availability of Documentation	Copies of regulations, specific health conditions, and guidelines for approved export facilities available on request from the above address.
Obligations of the Manufacturer/Vendor	The exporter must submit an international health certificate issued by an accredited veterinarian to the Department for endorsement. The enclosed health certificate must accompany the animals to a port of embarkation.
Enforcement	The health certificates are not endorsed unless the specific health requirements have been met. The importing country is notified if the exporter chooses to export the animals without USDA endorsement.
Term	Health certificates are valid for 30 days.
Reciprocity	None.
Standards, Codes, or Regulations	U.S. export requirements are based upon criteria developed by experts in the field of preventative veterinary medicine and accepted by the Department. The importing country's health requirements are also enforced by the Department.
Keywords	animals; export; health certificate; inspection; livestock; permit; poultry; quarantine; testing

Products or Services	Specified Animals for Import
Department/Agency	U.S. Department of Agriculture Animal and Plant Health Inspection Service (APHIS) Veterinary Services, Domestic Programs Import-Export Operations Staff Federal Building, Rm. 764 6505 Belcrest Road Hyattsville, MD 20782 Telephone: (301) 436-8590 Telex: 89607 ADEHVLE FAX: (301) 436-8567
Initiated	1890
Compliance	Both mandatory and authorized to act.
Authority	Laws:
	Act of August 30, 1890 (Animal Quarantine Acts; 21 USC 102 through 105) (26 Stat. 414).
	Act of February 2, 1903 (21 USC 111) (32 Stat. 792).
	Act of June 17, 1930 (Tariff Act-Section 201) (19 USC 1202) (46 Stat. 673).
	Act of June 17, 1930 (Tariff Act-Section 306) (19 USC 306) (46 Stat. 689).
	Act of July 2, 1962- P.L. 518 (21 USC 134) (76 Stat. 129).
	Act of May 6, 1970-P.L. 91-239 (21 USC 135) (84 Stat. 202).
	Regulations:
	9 CFR Chapter I, Subchapter D, Parts 92, 94, 97, and Subchapter G, Part 151.
Aim	To prevent the introduction and dissemination of animal diseases of foreign origin.
Benefits	Allows the U.S. livestock and poultry industries access to genetic materials to improve the national herd/flock and increase its productivity.

Agency Function	Provides an inspection and quarantine service, issues permits for entry and certifies the health status of animals and poultry released from quarantine.
Type of Program	Pre-import evaluation of permit applications, inspection of imported animals and re-evaluations of import requirements on a continuing basis.
Methodology	Government: Diagnostic testing Inspection of documents and animals Certification.
Testing	Government laboratories and government quarantine personnel.
Inspection	Government.
Conformity Identification	Valid health certification matching individual animal identification.
Availability of Documentation	Copies of regulations, specific health conditions, and guidelines for approved import facilities available on request from the above address.
Obligations of the Manufacturer/Vendor	
Enforcement	Animals and poultry not meeting U.S. requirements for entry are rejected and must be taken out of the country or be destroyed at importer's expense. Violators of Federal Import Laws are subject to legal action.
Tem	Permits are valid for periods from 2 weeks to 3 days. In a very few cases, blanket permits for up to one year are issued.
Reciprocity	None.

Standards, Codes, or Regulations Criteria based on norms developed by experts in the field of preventative veterinary medicine and accepted by the Department.

Keywords

animals; entry; health certificate; import; inspection; livestock; permit; poultry; quarantine; testing

Products or Services	Rice, Beans, Whole and Split Peas, Lentils, Processed Grain Products, and Related Products
Department/Agency	U.S. Department of Agriculture Federal Grain Inspection Service (FGIS) Field Management Division, Room 1641-S P. O. Box 96454 Washington, D.C. 20090-6454 Telephone: (202) 382-0262 Telex: 760 7351 ANS:FGIS UC. FAX: (202) 447-4628
Initiated	1916
Compliance	Voluntary
Authority	Agricultural Marketing Act of 1946.
Aim	Orderly trade in rice, pulses, processed grain products, and related products. Common basis for settling market disputes over quality of products.
Benefits	Improved efficiency in the buying and selling of rice and pulses based on official and standardized grading and of processed grain products and related products based on user's specification. Inspections are uniform throughout the nation. Inspection certificates are accepted in court as prima facie evidence of product condition at time of inspection.
Agency Function	Certifier, regulator, and program administrator.
Type of Program	Pre-marketing evaluation. Post-marketing assessment. Assessment prior to government purchase.
Methodology	Accreditation of third party laboratories.
Testing	FGIS laboratory. Government accredited laboratory.
Inspection	FGIS, state government, or third party.

Conformity Identification	Certificates of inspections.
Availability of Documentation	There are no lists of participating companies.
Obligations of the Manufacturer/Vendor	Must have financial interest in products and pay assessed fee.
Term	Continuous or intermittent voluntary inspection on a lot basis.
Reciprocity	Certificates are required by federal agencies, state agencies, private sector organizations, foreign governments, and international organizations buying and selling rice, pulses, processed grain products, and related products.
Standards, Codes or Regulations	U.S. Standards for Rough Rice, Brown Rice for Processing, Milled Rice; United States Standards for Beans; United States Standards for Whole Dry Peas, Split Peas, and Lentils; and related handbooks. Acceptance criteria for processed grain products and related products are based on requirements or specifications developed by federal and state agencies and/or FGIS inspection handbooks. In some instances, buyer or seller specification are used.
Keywords	beans; good manufacturing practices; in-plant inspection; lentils; peas; pulses; rice; sanitation

Products or Services	Grain Inspection and Weighing
Department/Agency	U.S. Department of Agriculture Federal Grain Inspection Service (FGIS) Field Management Division, Room 1641-S P. O. Box 96454 Washington, D.C. 20090-6454 Telephone: (202) 382-0262 Telex: 760 7351 ANS:FGIS UC. FAX: (202) 447-4628
Initiated	1916 (inspection). 1976 (weights).
Compliance	Mandatory for exports. Voluntary for domestic products.
Authority	U.S. Grain Standards Act, as amended.
Aim	Provide for the establishment of Official United States Standards for Grain, promote the uniform application of the official standards by official inspection personnel, provide for an official inspection systems for grain, and to regulate the certification of the weight of grain shipped in interstate and foreign commerce.
Benefits	Facilitate the marketing and trading of grain in an orderly and timely manner.
Agency Function	Certifier, regulator, and program administrator.
Type of Program	Pre-performance evaluation. Post-performance assessment. Assessment prior to government purchase.
Methodology	Third party laboratory.
Testing	FGIS laboratory. Delegated state laboratory. Designated local government agency laboratory.

Inspection	FGIS, state government, or third party.
Conformity Identification	Certification of inspection and/or weight.
Availability of Documentation	List of official inspection and weighing agencies and list of export elevators may be obtained from:
	U.S. Department of Agriculture Federal Grain Inspection Service (FGIS) Compliance Division, Room 1647-S P. O. Box 96454 Washington, D.C. 20090-6454 Telephone: (202) 382-0262 Telex: 760 7351 ANS:FGIS UC. FAX: (202) 447-4628
Obligations of the Manufacturer/Vendor	Must submit application for inspection or weighing.
Term	Continuous or intermittent, mandatory or voluntary inspection and weighing services on a lot basis.
Reciprocity	Certificates are recognized by federal agencies, state agencies, private sector organizations, foreign governments, and international organizations buying and selling grain.
Standards, Codes or Regulations	U.S. Grain Standards Act, as amended, and the regulations thereunder; Official United States Standards for Grain; FGIS Inspection Handbooks; and FGIS Weighing Handbook.
Keywords	grain elevators; grain scales; grain weights; grain bins; load cells; loading plans; official grain standards

Products or Services	Meat/Poultry Products (Mandatory Inspection)
Department/Agency	U.S. Department of Agriculture Food Safety and Inspection Service (FSIS) 14th and Independence Ave., SW Washington, D.C. 20250 (202) 447-7025
Initiated	1901 (Meat); 1958 (Poultry).
Compliance	Mandatory
Authority	21 USC 601 et seq. (meat). 21 USC 451 et seq. (poultry).
Aim	Assure that meat and poultry products moving in interstate commerce for use as human food are safe, wholesome, and accurately labeled.
Benefits	The risk of adulterated or misbranded meat and poultry products entering commerce has been minimized.
Agency Function	Program administrator.
Type of Program	Pre-marketing evaluation.
Methodology	Government inspection.
Testing	Government labs. Government approved/accredited labs. Manufacturer's labs. State/local government labs.
Inspection	Federal or state government.
Conformity Identification	Government applied marks; pre-marketing label approval.

Availability of Documentation	"Meat and Poultry Inspection Directory" published semi- annually; for sale by the Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402.
Obligations of the Manufacturer/Vendor	Make application for inspection; meet requirements for issuance of establishment number; operate under inspection in conformance with Agency rules (9 CFR Parts 301-381).
Enforcement	Condemnation of meat animals or birds before slaughter; condemnation of carcasses or product; withdrawal of inspection; criminal prosecution.
Term	Continuous inspection for slaughtering plants, and the frequency of inspection for processing plants to be determined by the Secretary of Agriculture.
Reciprocity	Inspection results recognized by: Other federal agencies. State agencies. Private sector organizations. Foreign government agencies. International organizations.
Standards, Codes or Regulations	9 CFR Parts 301-381; compatibility with FDA regulations issued under authority of the Federal Food, Drug, and Cosmetic Act.
Keywords	adulterated product; humane slaughter; livestock; meat inspection; misbranded product; poultry inspection

Products or Services	Meat/Poultry Products (Voluntary Inspection)
Department/Agency	U.S. Department of Agriculture Food Safety and Inspection Service (FSIS) 14th and Independence Ave., SW Washington, D.C. 20250 (202) 447-7025
Initiated	1958
Compliance	Voluntary
Authority	7 USC 1622(h).
Aim	Provide identification service for meat or other federally inspected products; food inspection service relating to manufacture of a food article; reindeer slaughter inspection service; certification of technical animal fats for export; buffalo slaughter inspection service; rabbit slaughter inspection service; certification of products for dogs, cats, and other carnivores; and, migratory water fowl, game bird, or squab slaughter inspection and/or other poultry or poultry products.
Agency Function	Certifier and program administrator.
Type of Program	Pre-marketing evaluation.
Methodology	Government inspection.
Testing	Government labs. Government approved/accredited labs.
Inspection	Federal or state government.
Conformity Identification	Government applied mark.
Availability of Documentation	"Meat and Poultry Inspection Directory" published semi- annually; for sale by the Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402.

Obligations of the Make application for inspection; meet requirements for issuance of establishment number; operate under inspection in conformance with Agency rules (9 CFR Parts 301-381).

Enforcement Condemnation of meat animals or birds; condemnation of meat or poultry products; withdrawal of inspection; criminal prosecution.

Indefinite term.

Reciprocity Inspection program recognized by: Other federal agencies. State agencies. Private sector organizations. Foreign government agencies. International organizations.

Standards, Codes or Regulations

Term

9 CFR Parts 350-362.

Keywords buffalo inspection; game birds; identification service; meat inspection; pet food; poultry inspection; rabbit inspection; reindeer inspection; squab

Products or Services	Processed Fish and Shellfish
Department/Agency	U.S. Department of Commerce National Oceanic and Atmospheric Administration National Marine Fisheries Service Science and Technology Office of Utilization Research National Seafood Inspection Program Room 814, Universal Building South 1825 Connecticut Ave., NW Washington, D.C. 20235 (201) 673-5374
Initiated	1958
Compliance	Voluntary
Authority	Agricultural Marketing Act of 1946 (as amended), 50 CFR Parts 260-266.
Aim	Increase consumer confidence in products which bear inspection marks and grade shields and provide technical services to the participating industry.
Benefits	Established quality control for seafood processing operations has improved the wholesomeness of fishery products. The quality and value of these products is communicated to consumers through grading of major types of seafood sold for human consumption. The program also helps processors prepare processing specifications for non-standard fishery products and provides mechanisms for settling trade disputes.
Agency Function	Certifier and program administrator.
Type of Program	Pre-marketing evaluation of both processing plant and processed products. Entire program is operated on a fee-for-service basis.
Methodology	Government inspection of plant and products, testing, and certification.

Testing	Testing in government labs, recognized state labs, and Federally accredited private labs.
Inspection	Inspection by licensed government agents and state agents operating with a license agreement.
Conformity Identification	Lists of approved suppliers and certified products. Government applied mark.
Availability of Documentation	Lists of Sanitary Inspected Fish Establishments (SIFE) and seafood Packed under Federal Inspection (PUFI) or which participate in grade marking. Lists of seafood products covered by these services may be obtained from:
	U.S. Department of Commerce, NOAA National Marine Fisheries Service National Seafood Inspection Laboratory P. O. Drawer 1207 Pascagoula, MS 39567-0112 (601) 762-4591
Obligations of the Manufacturer/Vendor	Producers must comply with sanitary, quality control, and inspection requirements in addition to providing office, laundry and temporary lab space.
Enforcement	Delisting.
Term	Indefinite.
Reciprocity	Certification is recognized by: other federal and state agencies private organizations, foreign government agencies (inspection service available for both import and export), international organizations. At present no reciprocity exists with similar agencies in other countries.
Standards, Codes or Regulations	Agency prepares all criteria documents including the Fishery Products Inspection Manual.
Keywords	fish quality; fish; fishery products; plant inspection; PUFI; quality standards; sanitation; seafood specifications; seafood; SIFE

Products or Services	Color Additives
Department/Agency	U.S. Department of Health and Human Services Food and Drug Administration (FDA) Center for Food Safety and Applied Nutrition Office of Physical Sciences Division of Color Technology (HFF-430) Colors Certification Branch Room 4034, FOB 8 200 C Street, SW Washington, D.C. 20204 (202) 245-1141
Initiated	1977 (latest authority)
Compliance	Mandatory
Authority	P.L. 94-295, 21 CFR Parts 70 through 82.
Aim	To assure public health and safety in use and consumption of foods, drugs, and cosmetics to which specified colors have been added.
Benefits	Color additive certification monitors conformance of additives to existing requirements and identifies the need for new limitations.
Agency Function	Certifier.
Type of Program	Pre-marketing evaluation.
Methodology	Government testing.
Testing	Government labs.
Inspection	Government.
Conformity Identification	A list of approved colors and certified products.

Availability of Documentation	Lists available from FDA.
Obligations of the Manufacturer/Vendor	Manufacturers must conform with Good Manufacturing Practices (GMP) and report any known ill effects associated with certified additives.
Enforcement	Marketing ban Product recall Delisting.
Term	Certification is provided on a batch basis.
Reciprocity	Certification is recognized by other federal agencies, state agencies, and private sector organization.
Standards, Codes or Regulations	Agency prepares criteria for certification. Agency adopts the test methods prepared by others such as the Association of Official Analytic Chemists.
Keywords	additives; adulteration; carcinogens; certification; color additives; cosmetics; drugs; foods; misbranding

Products or Services	Food for Humans
Department/Agency	U.S. Department of Health and Human Services Food and Drug Administration (FDA) Center for Food Safety and Applied Nutrition Office of Compliance Regulatory Guidance Division Room 5001, FOB 8 200 C Street, SW Washington, D.C. 20204 (201) 485-0187
Initiated	1938
Compliance	Mandatory
Authority	Food, Drug and Cosmetic Act of 1938, as amended.
Aim	To assure that foods are pure and wholesome, safe to eat, and produced under sanitary conditions.
Benefits	The appearance of adulterated and misbranded products in the market has been minimized.
Agency Function	Program administrator.
Type of Program	Pre-marketing evaluation.
Methodology	Government inspection.
Testing	Government labs Manufacturers' labs Third party labs State/local labs
Inspection	Government State/local government

Conformity Identification	Proper informative labeling; identification of processing plant where such are specifically inspected, such as shellfish packers.
Availability of Documentation	FDA publicizes only firms known to be not complying with required standards.
Obligations of the Manufacturer/Vendor	Producers must advise FDA any time a violation of good manufacturing practices occurs. Misbranded, adulterated products should be destroyed, but may be seized by govern- ment agents.
Enforcement	Marketing ban. Product recall.
Term	Continuous inspection.
Reciprocity	Program is recognized by: Other federal agencies. State agencies. Private sector organizations.
Standards, Codes or Regulations	Agency prepares all criteria documents.
Keywords	adulterated product; dietary foods; fill of container standard; good manufacturing practices; infant formula; misbranded product; nutrition labeling; sanitation; standard of identity; standard of quality

Products or Service	Fresh and Frozen Molluscan Bivalves (Oysters, Clams, and Mussels)
Department/Agency	U.S. Department of Health and Human Services Food and Drug Administration (FDA) Center for Food Safety and Applied Nutrition Office of Compliance Shellfish Sanitation Branch (HFF-344) Room 3092, FOB 8 200 C Street, SW Washington, D.C. 20204 (201) 485-0149
Initiated	1925
Compliance	Voluntary/cooperative
Authority	Food, Drug and Cosmetic Act of 1938, (Sections 402, 403, 701(a)), as amended. Public Health Service Act (Sections 301, 308, 311, 361), as amended.
Aim	To identify actual or potential sources of pollution that may contaminate shellfish growing areas; prevent the harvesting of shellfish from contaminated waters; and maintain sanitary conditions during the handling and processing of shellfish.
Benefits	Shellfish products marketed in interstate commerce are safe for human consumption.
Agency Function	Administers program; evaluates state shellfish control programs; and develops program guidelines and standards.
Type of Program	Pre-marketing control of product through classification of shellfish growing areas, prevention of illegal harvesting, and inspection of harvesting and processing operations.
Methodology	State shellfish agencies have the responsibility for classifying growing waters and assuring industry maintains adequate sanitary operating procedures. FDA evaluates state programs to determine program compliance through field visits and office file reviews.

Testing	FDA evaluates state and local laboratories used for the examination of sea water and shellfish. The laboratories are only evaluated for compliance with American Public Health Association (APHA) procedures for the examination of sea water and shellfish, not approved or certified.
Inspection	State shellfish control officials conducts all shellfish activities through field surveys and inspection of harvesting and processing operations. State programs are evaluated by FDA shellfish specialists.
Conformity Identification	FDA publishes monthly the "Interstate Certified Shellfish Shippers List" (ICSSL) containing the names and certification numbers of state certified shellfish firms.
Availability of Documentation	The ICSSL is provided free to all states, the shellfish industry and other interested individuals upon request.
Obligations of the Manufacturer/Vendor	Shellfish industry is required to meet state shellfish sanitary requirements for harvesting, handling and processing operations, and conform to National Shellfish Sanitation Program (NSSP) criteria and Good Manufacturing Practice Regulations.
Enforcement	State decertifies firm. FDA is notified and removes firm from the ICSSL.
Term	Indefinite term; reinspection after correction of deficiencies.
Reciprocity	FDA certification is recognized by other federal agencies, states and foreign government agencies.
Standards, Codes or Regulations	NSSP Manual of Operations Part I and II; Laboratory Procedures for the Examination of Seawater and Shellfish, Fifth Edition, 1985 by APHA. FDA develops and revises manual of operations. Manual revisions are approved by state shellfish control agencies.
Keywords	clams; interstate shipment; mussels; National Shellfish Sanitation Program; NSSP; oysters; seafood; shellfish

Products or Services	Infant Formula
Department/Agency	U.S. Department of Health and Human Services Food and Drug Administration (FDA) Center for Food Safety and Applied Nutrition Office of Compliance Regulatory Guidance Division Room 5001, FOB 8 200 C Street, SW Washington, D.C. 20204 (201) 485-0187
Initiated	1980
Compliance	Mandatory
Authority	Infant Formula Act of 1980, 21 USC 412, 21 CFR Chapter 1, Subchapters A and B.
Aim	To establish minimum nutrition requirements for infant formula.
Benefits	Virtually all domestically produced infant formula now complies with this rule.
Agency Function	Program administrator
Type of Program	Pre-marketing evaluation.
Methodology	Manufacturer self-certification. Compliance with Good Manufacturing Practices (GMP).
Testing	Manufacturers lab.
Inspection	Government.

Conformity Identification	Lists of approved suppliers and certified products.
Availability of Documentation	Lists available from FDA.
Obligations of the Manufacturer/Vendor	Quarterly recertification by each producer. Prompt notification to FDA of any suspected batch non-compliance, adulteration, or misbranding.
Enforcement	Marketing ban. Product recall by agency or producer.
Term	Audit testing/inspection to assure conformance with quality control requirements prescribed by agency.
Reciprocity	FDA certification is recognized by other federal agencies, states and private sector organizations.
Standards, Codes or Regulations	Technical requirements are specified in the Act.
Keywords	adulteration; good manufacturing practices; infant formula; misbranding; nutrition requirements; product recall; quality control

Products or Services	Food Inspection Personnel
Department/Agency	U.S. Department of Health and Human Services Food and Drug Administration (FDA) State Training Branch (HFC-153) 5600 Fishers Lane Rockville, MD 20857 (301) 443-5871
Initiated	1976
Compliance	Voluntary
Authority	Public Health Service Act, as amended.
Aim	Achieve a high degree of uniformity throughout the nation in the inspection of sanitation for the selling of food.
Benefits	Program has provided uniform methods of training, examination, and review of food inspection personnel.
Agency Function	Certifier.
Type of Program	Evaluation of individual's competence.
Methodology	Government testing and audit.
Testing	Federal and state examination and training facilities.
Inspection	Federal and state government.
Conformity Identification	Lists of certified inspectors are kept by participating state health departments.
Availability of Documentation	List must be obtained at the state level.
Term	Retesting every three years.

Reciprocity	Recognition by other federal agencies, state agencies, and private sector organizations.
Standards, Codes or Regulations	Agency prepares all criteria documents.
Keywords	food inspection personnel; model ordinance; personnel certification practices; retail sales; sanitation; standard of quality; standard of identity; training

Products or Services	Food and Drugs for Animals
Department/Agency	U.S. Department of Health and Human Services Food and Drug Administration (FDA) Center for Veterinary Medicine
	For new animal drugs: Office of New Animal Drug Evaluation 5600 Fishers Lane Rockville, MD 20857 (301) 443-4313
	For animal foods: Office of Surveillance and Compliance Animal Feeds Division 5600 Fishers Lane Rockville, MD 20857 (301) 443-4438
Initiated	1938
Compliance	Mandatory
Authority	Food, Drug and Cosmetic Act, Title 21 USC, as amended by P.L. 90-399.
Aim	To assure that foods, feeds, additives and medicines intended for animal use are safe and effective for intended use.
Benefits	Low-risk preparations with uniform quality and predictable performance have been developed for animal use.
Agency Function	For new animal drugs (NAD): certifier. For all other products: program administrator.
Type of Program	Pre-marketing evaluation.
Methodology	For NAD, government design approval, inspection, site approval. For other products, manufacturer self-certification. For all products, compliance with Good Manufacturing Practices (GMP).

Testing	Manufacturer's lab or third party lab.
Inspection	Government.
Conformity Identification	Lists of approved products and qualified producers are maintained by FDA.
Availability of Documentation	Lists are available from the Center.
Obligations of the Manufacturer/Vendor	For all products, manufacturers are required to register establishments annually; maintain sanitary conditions, provide adequate labeling; and comply with GMPs. For NADs, substantial evidence to demonstrate safety and effectiveness must be provided. Proof that residues unsafe for human consumption are not left over specified time periods is required for drugs or medicated feeds intended for animals which are used as human food.
Enforcement	Marketing ban and product recall.
Term	No specific term; retesting is based on changes in product characteristics or use. A major consideration is any misbranding or adulteration.
Reciprocity	Certifications are recognized widely in the U.S. Many states require a "Guaranteed Analysis" for minimum protein, fat, fiber, and moisture content. There is no reciprocity among countries for these products.
Standards, Codes or Regulations	Agency prepares regulatory requirements including the GMPs, but draws some technical input from the National Academy of Sciences.
Keywords	additives; adulteration; animal drugs; animal feed; good manufacturing practices; misbranding; pet food; registration; veterinary medicine

Products or Services	Drinking Water
Department/Agency	Environmental Protection Agency (EPA) Office of Drinking Water Criteria and Standards Division Science and Technology Branch 401 M Street, SW Washington, D.C. 20460 (202) 382-3040
Initiated	1974
Compliance	Mandatory. Act requires states seeking primacy to implement a certification program based on federal standards; otherwise EPA will certify laboratories in remaining areas.
Authority	Safe Drinking Water Act (42 USC 300); National Interim Primary Drinking Water Regulations (40 CFR Parts 141 and 142).
Aim	To broaden the base of testing facilities competent to analyze drinking water in disciplines of chemistry, microbiology, and radiochemistry.
Benefits	Easier access to competent testing facilities for all regulated and interested parties.
Agency Function	Certifier (in nonprimary states, territories, and Indian reservations). Program administrator elsewhere.
Type of Program	Pre-market evaluation. (Act requires that data from a laboratory be acceptable only after laboratory is certified; however, laboratory must be in operation before it can be certified).
Methodology	Government design of certification program testing, inspection, audit, and site approval plus compliance with Good Laboratory Practice Regulations.

Testing Government labs. State labs.

Inspection Government. State labs.

Conformity Certified labs are issued certificates identifying areas Identification of competency. Certifying authorities maintain lists of labs which have been issued certificates.

Availability Lists are available from certifying authorities and EPA of Documentation Regional Offices.

Obligations of Certified labs must complete periodic performance Manufacturer/Vendor evaluations satisfactorily, maintain competency in approved methods, notify certifier of changes in staff or equipment and submit to periodic on-site evaluations.

Enforcement Delisting.

Term Three years if certified by EPA or most states; some states recertify more frequently.

Reciprocity Direct EPA certification is recognized by other federal agencies and some states. States are expected to develop procedures for recognizing certifications among themselves.

Standards, Codes, EPA develops standards methods. or Regulations Agency recognizes methods prepared by others.

Keywords chemistry; drinking water; microbiology; on-site evaluation; performance evaluation; pollution; quality assurance; radiochemistry; water quality

Products or Services	Certification of Private and Commercial Applicators of Restricted Use Pesticides
Department/Agency	Environmental Protection Agency (EPA) Pesticide Applicator Certification and Training Program Office of Pesticides and Toxic Substances 401 M Street, SW Washington, D.C. 20460 (202) 475-9582
Initiated	1972
Compliance	Mandatory. Act requires states to perform certification to federal guidelines, but permits EPA to perform the function if state is unable to do so.
Authority	The Federal Fungicide, Insecticide, and Rodenticide Act (FIFRA) P.L. 94140 and P.L. 95396. 40 CFR Part 171.1171.11; and various state laws and regulations.
Aim	To minimize misuse of pesticides by both private and commercial applicators.
Benefits	Greater awareness by regulated community of the hazards associated with pesticide misuse.
Agency Function	Certifier in Colorado and Nebraska; state facilities in all other states and territories.
Type of Program	Pre-market evaluation; applicator may not offer services for hire until competency is demonstrated by examination or attendance at an approved training program.
Methodology	Government facilities in Colorado and Nebraska; state facilities in all other states and territories.
Testing	Personnel testing is conducted by the certifying agency.
Inspection	Same basis as testing.

- ConformityCertifying states issue identification numbers to individualIdentificationcertified applicators.
- Availability Each state maintains a controlled list of certified of Documentation applicators. Contacts in states are available from the states or EPA. Lists of certified applicators in Colorado and Nebraska are available from the EPA.
- Obligations of Certified applicators and/or their employees are obligated to limit applications to those restricted pesticides for which they have been certified.
- Enforcement Delisting or limitation of certification by certifying agency.
- Term State certification terms vary from one to six years; the term for federal certification is four years for private applicators and three for commercial applicators.
- Reciprocity Reciprocity among states is based on state agreements which are on file with the EPA. No formal list of reciprocal relations is available.
- Standards, Codes, Certification standards are promulgated by the states and must be as stringent as required by FIFRA.
- Keywords chemicals; environmental hazards; fungicides; insecticides; pesticides; registered chemicals; restricted use; rodenticides

Products or Services	The Testing of Cigarettes for "Tar," Nicotine and Carbon Monoxide (PROGRAM WAS MODIFIED IN 1987)
Department/Agency	Federal Trade Commission Bureau of Consumer Protection Division of Advertising Practices 6th and Pennsylvania, NW Washington, D.C. 20580 (202) 326-3150
Initiated	1966
Compliance	Voluntary
Aim	To inform the smoking public about the "tar," nicotine, and carbon monoxide of cigarettes so that they can make an informed choice in buying cigarettes.
Benefits	See above.
Agency Function	Program administrator.
Type of Program	Post-marketing assessment.
Methodology	Cigarettes which used to be tested in a government owned laboratory are now tested by the industry using a government approved method. Results are reported to the FTC for publication. A consultant to the FTC monitors the testing.
Testing	See above.
Inspection	Advertisements are reviewed continually.
Conformity Identification	A report on the test results are published in the Federal Register and provided to Congress.
Availability of Documentation	A copy of the report is available from the FTC.

Reciprocity There are no reciprocal agreements.

Keywords carbon monoxide; cigarettes; CO; nicotine; tar; tobacco; TPM SECTION II

CONSUMER PRODUCTS AND SERVICES

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						-
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AMERICAN IN	DIAN, ESKIMO	, AND ALEUT	ENTERPRISES	5 THAT MARKET	INDIAN,	ESKIMO,
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Department/Agency U.S. Department of Energy Building Equipment Division Office of Buildings and Community Systems Office of Conservation and Renewable Energy Deputy Assistant Secretary for Conservation Mail Station CE-132 100 Independence Ave., SW Washington, D.C. 20585 (202) 586-9127 (202) 586-5100

Appliances

#### Initiated

Products or

Services

Standards will be established and made effective as follows:

January 1, 1987: Dishwashers, Clothes Washers, Clothes Dryers

January 1, 1990: Refrigerators, Refrigerator-Freezers, Freezers, Room Air Conditioners, Water Heaters, Pool Heaters, Direct Heating Equipment, Kitchen Ranges, Ovens

January 1, 1992: Central Air Conditioners, Furnaces

Compliance Mandatory for all manufacturers and importers of the 11 types of covered products.

Authority Energy Policy Conservation Act (EPCA) as amended, P.L. 94-163, 89 Stat. 917, 42 USC 6295.

Aim Reduce energy consumption through the use of more efficient appliances.

Benefits By establishing technically feasible minimum energy efficiency or maximum energy use levels of various appliances covered (generally used in residential applications) the consumer will save on utility bills while reducing the need for utility companies to construct additional facilities or consume larger quantities of fuel.

Administers a program to establish procedures to Agency Function evaluate the energy use of products, establish/revise maximum use levels, and to analyze new products to determine if the "Act" applies. Pre-marketing evaluation and post-marketing assessment. Type of Program Methodology Manufacturer's self-certification. Manufacturer's lab. Testing Third party labs. Inspection Government. Conformity Policy/requirements not established at this time. Identification Availability Policy/requirements not es' blished at this time. of Documentation Obligations of the Policy/requirements not established at this time. Manufacturer/Vendor Enforcement Policy/requirements not established at this time. Indefinite term. Term National Appliance Energy Conservation Act (NAECA) Reciprocity of 1987 (which amended the EPCA) preempts all state legislation unless a waiver is granted by DOE or the state complies with ecific requirements established in NAECA. Standards, Codes 10 CFR Part 430. or Regulations Keywords appliances; central air conditioners; clothes dryers; clothes washers; direct heating equipment; dishwashers; energy efficiency; EPCA; freezers; furnaces; kitchen ranges; ovens; NAECA; pool heaters; refrigerator-freezers; re\_rigerators; room air conditioners; water heaters

Products or Services	Categories of Major Home Appliances
Department/Agency	Federal Trade Commission Bureau of Consumer Protection Division of Enforcement 601 Pennsylvania Ave., NW Washington, D.C. 20580 (202) 326-3035
Initiated	1980
Compliance	Mandatory for categories of covered appliance products.
Authority	The Energy Policy and Conservation Act (EPCA) P.L. 94-163, 89 Stat. 871 (1975), as amended by the National Energy Conservation Policy Act, P.L. No.95-619, 92 Stat. 3258 (1978). 16 CFR Part 305 (Rule for Using Energy Costs and Consumption Information Used in Labeling and Advertising for Consumer Appliances Under the Energy Policy and Conservation Act (Rule)).
Aim	To encourage consumers to comparison shop for energy efficient household appliances in order to reduce the amount of energy they use in their homes.
Benefits	The availability of energy consumption information should enhance consumer demand for appliances that save energy. In turn, competition should be generated among manufacturers to meet this demand by producing more energy efficient appliances. Consumers will be able to save money by reducing their energy costs and can help to promote the national goal of energy conservation.
Agency Function	Program administrator.
Type of Program	Pre-sale disclosure.

Following rulemaking proceedings as required by EPCA, the Methodology FTC has adopted labeling rules for several appliance categories. The appliance labels will give consumers the estimated yearly energy cost or energy efficiency of competing products before they buy an appliance. The labels will also provide consumers with a range of estimated annual energy costs for comparable appliances. Under the EPCA, only appliances for which the DOE has prescribed final test procedures can be covered by the FTC's Rule. Manufacturers must base required label information on the results of tests performed in accordance with the procedures prescribed by DOE. Additionally, the FTC prescribed the required layout, type size, setting, colors, paper stock and contents of the appliance labels. FIC representatives are allowed to observe any testing required by the Rule and to inspect the results of the testing if requested.

Testing

Commercial lab. Manufacturer's lab.

Inspection

Government.

Conformity Identification The Commission's Appliance Labeling Rule mandates a uniform disclosure scheme (in the form of appliance labels) for energy consumption information. All energy labels for each category of covered appliance use the same size, colors and typefaces with consistent positioning of headline, copy and charts. Such uniformity in the disclosure format facilitates immediate consumer recognition and readability.

Availability of Documentation The range of estimated annual energy costs for each covered appliance is taken from the appropriate appendix to the Rule in effect at the time the labels are affixed to the products. The FTC publishes revised ranges annually in the Federal Register, if appropriate, or a statement that specific prior ranges are still applicable. Ranges are changed if the upper or lower limit of the range changes by 15% or more. Obligations of the<br/>Manufacturer/VendorThe Rule requires manufacturers to label covered appliances<br/>with information indicating their estimated annual energy<br/>costs and related information. Manufacturers base required<br/>label information on tests they perform using procedures<br/>prescribed by DOE. The Rule also contains specific<br/>requirements concerning the duty of manufacturers to make<br/>reports to the Commission, to maintain records and to have<br/>substantiation for required disclosures or other<br/>representations they make.TermIndefinite term.

Reciprocity	The Commission's Appliance Labeling Rule is recognized by other federal agencies, state agencies, and private
	sector organizations.

Standards, CodesStandard test procedures are prescribed by the DOE.or RegulationsLabel format is prescribed by the FTC.

Keywordsappliance labeling; energy efficiency rating; energy<br/>conservation; estimated annual energy cost

Products or Services	Consumer Products (Personal use devices intended for household, school, or recreational use)
Department/Agency	Consumer Product Safety Commission (CPSC) Office of the General Counsel 5401 Westbard Avenue, Room 200 Bethesda, MD 20207 (202) 492-6980
Initiated	October 1972
Compliance	Mandatory
Authority	P.L. 92-573 as amended by P.L. 94-284, 95-319, 95-631, 96-373, 97-35.
Aim	To reduce the number of consumer products which present unreasonable risks.
Benefits	Specific products covered by CPSC Standards are now certified by manufacturers to conform with legal requirements.
Agency Function	Program administrator.
Type of Program	Post-marketing assessment.
Methodology	Manufacturer's self-certification. Government audit.
Testing	Manufacturer's lab. Third party labs.
Inspection	Government.
Conformity Identification	Government authorized mark or label by manufacturer or private brander.

- Availability Lists of manufacturers or private branders subject to certification rules or banning orders can be obtained from CPSC.
- Obligations of Manufacturers, private branders, and distributors shall keep such records as the Commission directs to assist in the enforcement of the Act, such as known non-conformance to applicable standards or known defects which could present an unreasonable risk of injury whether or not covered by a standard.
- Enforcement Marketing ban. Product recall.
- Term Periodic retesting in a testing program acceptable to the CPSC is usually required.
- Reciprocity None.
- Standards, Codes, Criteria for standards are cited in the Act; agency itself prepares Consumer Product Safety Standards; Commission recognizes the use of voluntary standards to reduce risks of injury.
- Keywords audit testing; banned products; consumer products; imminent hazard; mandatory standards; product recall; product safety

Products or Services	Fabrics Used in Wearing Apparel and Interior Furnishings
Department/Agency	Consumer Product Safety Commission (CPSC) Office of the General Counsel 5401 Westbard Avenue, Room 200 Bethesda, MD 20207 (202) 492-6980
Initiated	June 1953
Compliance	Mandatory
Authority	P.L. 83-88.
Aim	To reduce the risk of fire and injury or death related to fire, in or on fabric articles.
Benefits	Compliance with applicable standards and associated labeling have reduced the covered risks.
Agency Function	Program administrator.
Type of Program	Post-marketing assessment.
Methodology	Manufacturer's self-certification. Government audit inspection/testing.
Testing	Government labs. Government approved labs. Third party labs. Manufacturer's lab.
Inspection	Government. State/local government. Third party.
Conformity Identification	Authorized label by manufacturer.

of Documentation	
Obligations of Manufacturer/Vendor	Manufacturer may comply with the Act by guaranteeing conformance with applicable standards based on test data.
Enforcement	Product condemnation and destruction.
Term	Periodic audit testing/inspection is required to maintain certification.
Reciprocity	Conformity is recognized by other federal agencies, state governments, and private organizations.
Standards, Codes, or Regulations	Criteria for standards are cited in the Act; agency itself prepares Consumer Product Safety Standards; Commission recognizes the use of voluntary standards to accomplish the purpose of the Act.
Keywords	apparel; bedding; fabrics; flammability; furnishings; interior furnishings; product testing; voluntary standards; wearing apparel

No list of certified suppliers or products is prepared.

Availability

Products or Services	American Indian, Eskimo, and Aleut Enterprises that Market Indian, Eskimo, or Aleut Handicrafts
Department/Agency	Indian Arts and Crafts Board U.S. Department of the Interior Room 4004, North Interior Building Washington, D.C. 20240 (202) 343-2773
Initiated	1943
Compliance	Voluntary
Authority	P.L. 74-355; 25 CFR Part 308.
Aim	To improve the competitiveness of genuine products which are marketed in competition with imitations.
Benefits	See above.
Agency Function	Certifier and program administrator.
Type of Program	Pre-marketing evaluation.
Methodology	Government inspection and evaluation of product quality.
Inspection	Products and facilities are inspected by the federal government.
Conformity Identification	Facilities are licensed to use the certification mark. Products are marked.
Availability of Documentation	A free list of approved enterprises is available from the Board.
Obligations of Manufacturer/Vendor	The certification mark may be applied only to products that meet the Board's standards.

Enforcement	Delisting as well as the imposition of criminal penalties for the willful misuse of the mark.			
Term	Indefinite term with occasional re-inspection.			
Reciprocity	No reciprocal agreements.			
Standards, Codes, or Regulations	Agency prepared standards/criteria.			
Keywords	Aleut; American Indian; crafts; Eskimo; handicrafts; Indian; jewelry; native American artists; native American craftsmen			

SECTION III

# CONSTRUCTION PRODUCTS AND SERVICES

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Products or Services	Building Products for Construction
Department/Agency	U.S. Department of Housing and Urban Development Federal Housing Administration Manufactured Housing Construction and Regulatory Functions Division, Room 6270 451 Seventh Street, SW Washington, D.C. 20410-8000 (202) 755-5929
Initiated	1965
Compliance	Voluntary
Authority	24 CFR Part 200.935.
Aim	To prevent product failures and misrepresentations of products. To expedite introduction of new or innovative building materials. Alleviate safety hazards associated with building materials, long term durability problems, and misleading test results.
Benefits	Better assurance that the building products arriving at the job site comply with the designated standards.
Agency Function	Program administrator.
Type of Program	Ongoing validation of private certification of products included under a HUD mortgage insurance program.
Methodology	Third party certification. Manufacturer's self-certification.
Testing	Government accredited labs. Third party validating labs. Manufacturer's lab. State/local government labs. Agency accredited labs.
Inspection	Third party.

Conformity Identification	Authorized mark or label affixed by manufacturer or third party validator. More than seventy third party validators participate in the HUD Building Products Certification program for building products including: solid fuel type heaters, fireplace stoves, plastic bathtub units, plastic shower receptors and stalls, plastic lavatories, plastic water closet bowls and tanks, aluminum windows, storm doors, sliding glass doors, storm windows, wood window units, wood sliding patio doors, sealed insulating glass units, carpet, carpet with attached cushion, PVC window units, and lumber.
Availability of Documentation	All documentation is published in the Federal Register, 24 CFR Part 200.
Obligations of the Manufacturer/Vendor	
Enforcement	The principal means of enforcement is delisting of manufac- turers. Laboratories whose quality control is inadequate may be disapproved. Administrators may be suspended under rules 24 CFR Part 200.935.
Term	All parties may operate indefinitely in these programs. Laboratories are subject to periodic reaccreditation.
Reciprocity	Products in these programs enjoy a wide degree of reciprocal recognition, including other federal agencies, state agencies, private sector organizations, foreign governments, and international organization. There are participating organizations in Canada for certain building products.
Standards, Codes, or Regulations	HUD adopts standards prepared by others, and prepares criteria documents where necessary. Documents defining acceptance are in 24 CFR Part 200.935.
Keywords	acceptance criteria; administrators; building products; certification; construction; housing; mortgage insurance; third party validation

Products or Services	Manufactured Housing
Department/Agency	U.S. Department of Housing and Urban Development Federal Housing Administration Manufactured Housing Construction Division, Rm. 6270 451 Seventh Street, SW Washington, D.C. 20410-8000 (202) 755-6590
Initiated	1976
Compliance	Mandatory
Authority	National Manufactured Housing Construction and Safety Standards Act, P.L. 93-382, 42 USC 5407; 24 CFR Part 3280.
Aim	To reduce the number of personal injuries and deaths, cost of insurance, and property damage resulting from manufactured home accidents and to improve the quality and durability of manufactured homes.
Benefits	Uniform nation-wide certification program has accomplished the stated purposes of the Act and improved interstate commerce in manufactured housing.
Agency Function	Program administrator.
Type of Program	Pre-emptive, mandatory, national regulation.
Methodology	Third party certification of manufactured housing designs and quality assurance manuals, and in-plant inspection to assure compliance with standards.
Testing	Third party labs. Manufacturer's lab.
Inspection	Third parties. State government inspection agencies.

ConformityAuthorized label affixed by manufacturer.IdentificationLists of approved third party agencies are issued by HUD.

Availability Lists are maintained by HUD, HUD's Monitoring Agent, and of Documentation Approved State Administrative Agencies (SAA's).

Obligations of the Manufacturers and dealers must keep accurate data by unit Manufacturer/Vendor serial number of each manufactured housing unit so that purchasers can be notified if an imminent safety hazard or serious defect is alleged.

Enforcement Marketing ban on unlabeled homes; notification and correction of defective units; removal of approval of third party inspection agencies for repeated inadequate performance.

Term

Indefinite term.

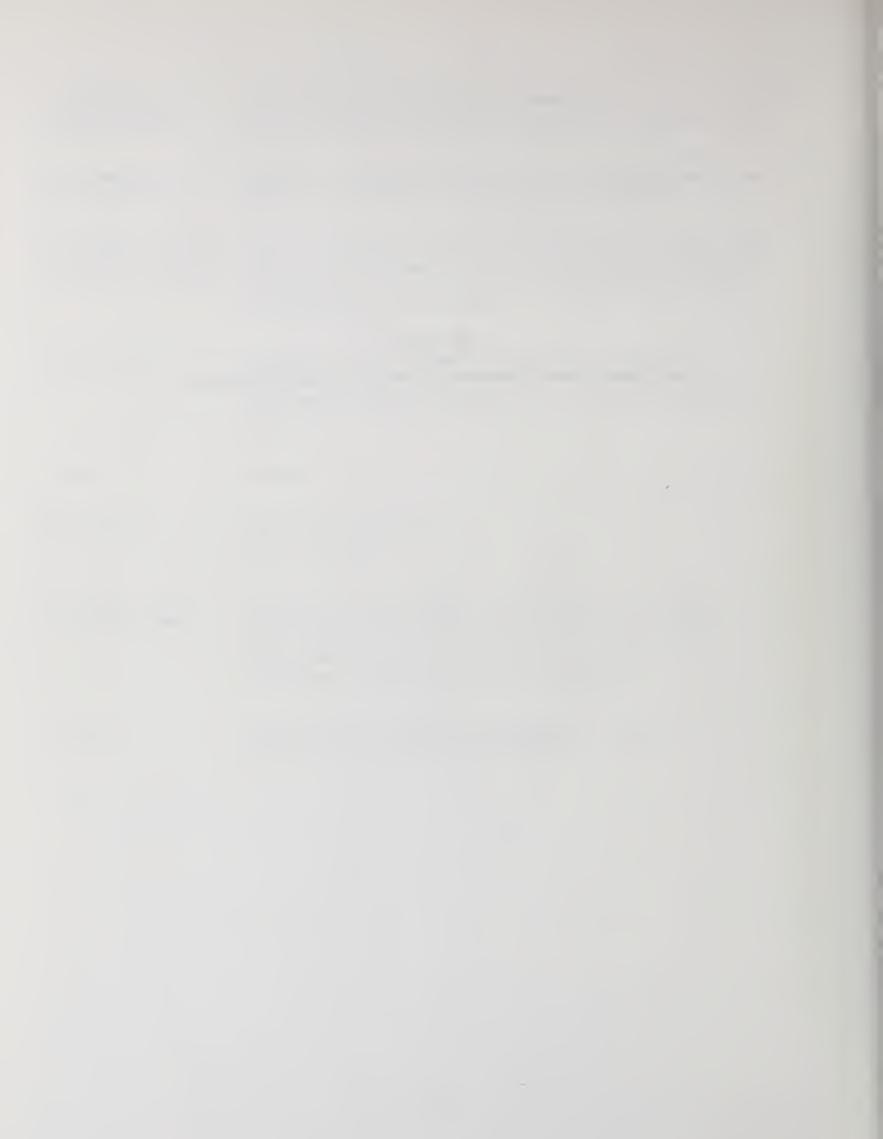
- Reciprocity Other federal agencies. State agencies.
- Standards, Codes, Agency references standards prepared by others and incorporates requirements in the Federal Manufactured Home Construction Safety Standards (24 CFR Part 3280). Enforcement is in accordance with Procedural and Enforcement Regulations (24 CFR Part 3282).

Keywords design approval; housing requirements; inspection; manufactured housing; product safety

#### SECTION IV

# ELECTRONIC AND TELECOMMUNICATIONS PRODUCTS AND SERVICES

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Products or Services	Parts, Materials and Equipment for Rural Electric and Telephone Systems	
Department/Agency	U.S. Department of Agriculture Rural Electrification Administration (REA) 14th and Independence Ave., SW Washington, D.C. 20250	
	Chairman, Technical Standards Committee "A" (Electric) (202) 382-9080	
	Chairman, Technical Standards Committee "A" (Telephone) (202) 382-8698	
Initiated	1938	
Compliance	Mandatory only for designated parties using REA loans.	
Authority	7 CFR Part 1702.	
Aim	To minimize capital requirements and control the quality of materials and equipment incorporated into rural electric and telephone systems. The evaluation and listing of material and equipment insures the availability of suitable products at reasonable costs and, together with REA standards for construction and installation, provides an important element of loan security.	
Agency Function	Certifier.	
Type of Program	Electric and telephone systems receiving financing administered by REA shall use materials and equipment evaluated and listed by REA.	
Methodology	Government design review and testing.	
Testing	Government labs. Manufacturers' labs.	

Conformity Identification	Approved manufacturers and suppliers for rural electric systems are included in REA Bulletin 43-5, "List of Materials Acceptable for Use on Systems of REA Electri- fication Borrowers." The 1986 issue contains over 185 categories of material and equipment from over 200 manufacturers.
	Approved manufacturers and suppliers for rural telephone systems are listed in REA Bulletin 344-2, "List of Materials Acceptable for USe on Telephone Systems of REA Borrowers."
Availability of Documentation	Bulletins 43-5 and 344-2 are available on a subscription basis from the Superintendent of Documents, Government Printing Office, Washington, D.C. 20402.
Enforcement	Delisting.
Term	Indefinite term. Bulletin 43-5 is published yearly and supplements are issued quarterly. Bulletin 344-2 is printed every two years followed by eleven supplements.
Standards, Codes or Regulations	REA prepares product standards which define performance and design requirements together with acceptance criteria.
Keywords	acceptable materials; approved product lists; central office equipment; components; distribution; electric systems; electronic; microwave; private branch exchanges; radio-telephone; telecommunications; telephone; transmission;

Products or Services	Electrical and Electronic Devices that Generate Radio Frequency Energy
Department/Agency	Federal Communications Commission (FCC) Authorization and Standards Division Columbia, MD 21045 (301) 725-1585
Initiated	1940 (Marine equipment was the earliest type approved).
Compliance	Mandatory
Authority	Federal Communications Act of 1934 as amended. 47 CFR Part 2, Subpart J.
Aim	Reduce uncontrolled radio frequency interference first observed in connection with medical diathermy equipment in the 1940's.
Benefits	Broad decrease in spurious radio frequency energy in the environment in spite of tremendous increases in the types and quantity of devices in general use that have the potential for creating radio frequency interference.
Agency Function	Certifier and program administrator.
Type of Program	Generally FCC procedures provide for pre-marketing evaluation and/or post-marketing assessment. Authorization procedures reflect the requirements of particular categories of equipment which are summarized here:
	Type Approval
	-Applies to some non-licensed devices.
	-Testing of sample by FCC prior to issuance of grant is mandated by FCC Rules.
	-Grant of authorization is issued by FCC.
	Type Acceptance

- -Applies to some compulsory installed marine safety-of-life equipment, and to transmitting equipment used in many of the radio services under a radio station license issued by the FCC.
- -Based on desk review and evaluation of written application and test report submitted by applicant
- -Testing of samples at FCC Laboratory is not required by FCC Rules, but FCC has authority to request samples for testing either before or after issuance of grant.

-Grant of authorization is issued by FCC.

# <u>Certification</u>

- -Applies to non-licensed devices, mostly low power radio frequency devices and, in addition, to certain categories of receivers which tune in the band from 30 to 901 MHz and 935 to 940 MHz, personal computers and peripherals, citizen band receivers, and some other kinds of industrial, scientific and medical equipment.
- -Based on desk review and evaluation of written application and test report submitted by applicant.
- -Testing of samples at FCC Laboratory is not required by FCC Rules, but FCC has authority to request samples for testing either before or after issuance of grant.

-Grant of authorization is issued by FCC.

#### Notification

- -Applies to certain categories of receivers which tune in the 30 to 901 MHz or 935 to 940 MHz bands (including cordless telephone receivers) in addition to certain licensed transmitters and associated devices employed mostly in fixed point to point microwave and broadcast services. The Commission will add equipment to this category as it determines that additions are warranted.
- -Manufacturer submits brief application for authorization of device. Application is not required to include test data.
- -FCC may sample device or review the manufacturer's test data before or after issuance of grant.

-Grant of authorization is issued by FCC.

#### Verification

- -Applies to all computing devices except personal computers, personal peripherals and exempt computing devices (Section 15.801 (e)); also applies to FM broadcast and television broadcast receivers, in addition, certain categories of industrial, scientific and medical devices and ship earth stations.
- -Manufacturer tests device prior to marketing for compliance with applicable FCC regulations and retains test data.
- -No filing with FCC is required. However, manufacturer's test data may be required by FCC for subsequent review.

-FCC may sample devices, at its option

-No grant of authorization is issued by FCC.

### Registration

- -Applies to subscriber owned and common carrier owned telephone devices interconnected to the public telephone network. Objective of registration is to assure that device will not cause "harm" (as defined in FCC Rules) to telephone network. Radio frequency devices which connect to the public telephone network may be subject to registration as well as to one or more of the other procedures.
- -Based on desk review and evaluation of written application and test report submitted by applicant. Administrative review is done by FCC Laboratory. Other aspects of application are handled by FCC Common Carrier Bureau, including issuance of grant.

-Grant of authorization is issued by FCC.

-Subpart L or Part 2 and Part 68 of FCC Rules provides further information on this procedure.

Methodology

#### Program uses:

- -Government lab for testing, inspection and audit. -manufacturer and third party labs.
- -Government recognition of private labs.

Testing

Testing may be performed by: -FCC laboratory. -Manufacturer's laboratory. -Third party laboratory.

- Inspection Agency accredits independent labs, but does not inspect production facilities.
- Conformity Agency maintains lists of producers of approved products, Identification but lists are not published. Producers are licensed to apply approval markings in accord with regulations.

Availability Above lists must be requested from FCC through Freedom of Information Information procedures.

Obligations of the Maintain design of approved equipment. Explain maintenance Manufacturer/Vendor requirements to users.

Enforcement Marketing ban.

Term Indefinite term.

Reciprocity None. Test data from counterpart agencies is taken into consideration, but no reduction of test requirements is provided.

Radio frequency devices must have the required form of equipment authorization before being imported into the United States and must be accompanied by a properly executed copy of FCC Form 740.

There are some specified exceptions to this requirement as given in Part 2 of the FCC Rules, Sections 2.806, 2.809, 2.811 and 2.813. Also, there are a few categories of devices which are not subject to technical standards in the FCC Rules. These devices must meet the applicable standards before importation.

Standards, Codes, or Regulations Criteria promulgated by FCC; private sector standards are considered in preparing rules. Keywords broadcast equipment; cable TV equipment; certification;

broadcast equipment; cable TV equipment; certification; communications equipment; computer peripherals; computers; medical electronics; radio frequency energy; transmitters; TV equipment; type approval

Products or Services	Electronic Fund Transfer Authentication Devices
Department/Agency	U.S. Department of the Treasury Deputy Assistant Secretary for Departmental Information Systems 1500 Pennsylvania Ave., NW Washington, D.C. 20220 (202) 566-5847
Initiated	1984
Compliance	Mandatory for all Government bureaus that receive or send funds or securities electronically through the U.S. Treasury.
Authority	Treasury Order 16-02.
Aim	To assure that equipment which authenticates electronic fund transfers complies with designated standards to minimize exploitation of Electronic Fund Transfer (EFT) Systems.
Benefits	It is a major milestone toward unifying the protection and audit of the billions of dollars transferred electron- ically every day.
Agency Function	Program administrator and certifier. Evaluation for compliance with Treasury standard conducted by the National Bureau of Standards (NBS), Institute for Computer Sciences and Technology (ICST). Security evaluation guidance provided by the National Security Agency (NSA).
Type of Program	Pre-marketing evaluation. Assessment prior to government purchase.
Methodology	Testing by NBS and NSA.
Testing	Testing by NBS and NSA.
Inspection	Treasury.

Conformity Identification	A list of certified equipment and software is maintained by the Department of the Treasury.	
Availability of Documentation	List and other technical documentation is available from the Deputy Assistant Secretary for Departmental Information Systems, Department of the Treasury.	
Obligations of Manufacturer/Vendor	To comply with criteria.	
Enforcement	Delisting.	
Term	Indefinite term.	
Reciprocity	No reciprocal agreements.	
Standards, Codes, or Regulations	Federal Information Processing Standard (FIPS) 46, FIPS 113, Federal Standard 1027, ANSI X9.9 and X 9.17. Criteria documents are coordinated by Treasury.	
Keywords	authentication devices; communications security; computer security; cryptolography; EFT; electronic fund transfer; encryption standard; financial institutions; interface requirements; validation	

Products or Services	Electronic Products for Radiation Protection
Department/Agency	U.S. Department of Health and Human Services Food and Drug Administration (FDA) Center for Devices and Radiological Health Office of Compliance Radiological Products Division 8757 Georgia Ave. Silver Spring, MD 20910 (301) 427-7175
Initiated	1968
Compliance	Mandatory
Authority	Radiation Control for Health and Safety Act, 42 USC 2636; 21 CFR 1000-1050.
Aim	To protect the public from unnecessary exposure to radiation from electronic products.
Benefits	Through enforcement, as well as product improvement and user education, public exposure to ionizing and non-ionizing radiation has been reduced significantly.
Agency Function	Program administrator.
Type of Program	Pre-marketing evaluation.
Methodology	Manufacturer self certification.
Testing	Manufacturer's lab. Third party lab. Government lab.
Inspection	Government.
Conformity Identification	Manufacturer applied label.

Availability of Documentation	No lists are published or maintained in this program.
Obligations of the Manufacturer/Vendor	Manufacturers must keep production and distribution records; notify buyers of nonconforming equipment and recall such equipment for repair.
Enforcement	Marketing ban.
Term	Certification applies for the life of each distinctive model.
Reciprocity	No known reciprocity.
Standards, Codes or Regulations	Agency sets criteria and publishes performance standards.
Keywords	electronic radiation; lasers; mercury vapor lamps; microwave ovens; product labeling; sunlamps; television receivers; ultrasonic therapy equipment; x-ray equipment

Products or Services	Input/Output Channel Level Interfaces for Information Processing Equipment	
Department/Agency	U.S. Department of Commerce National Bureau of Standards (NBS) Institute for Computer Sciences and Technology Advanced Systems Division Technology Bldg., Room A216 Gaithersburg, MD 20899 (301) 975-2904	
Initiated	1979	
Compliance	Mandatory for applicable information processing equipment to be purchased by federal agencies.	
Authority	15 CFR Part 200.	
Aim	To verify the ability of information processing equipment from one manufacturer to function successfully with equipment of other manufacturers.	
Benefits	Federal agencies are able to purchase information processing equipment that has the necessary level of compatibility. This enables systems to be assembled or expanded more readily and with considerably less time for troubleshooting. This program also enables all suppliers to compete on an equitable basis.	
Agency Function	Certifier and program administrator.	
Type of Program	Verification of compliance prior to consideration for purchase by the federal government.	
Methodology	NBS verification of compliance to specified standards by review of documentation, or demonstrated use with verified equipment.	
Testing	Any testing is ordinarily accomplished by the manufacturer to fulfill requirements of the applicable standards or the NBS Verification Checklist.	

Inspection	By purchasing agency.
Conformity Identification	A verification certificate is issued for equipment having no significant deviation from the applicable standard.
	A Verification List of equipment conforming to standards is published and maintained by NBS.
Availability of Documentation	Verification List and Checklist are available from the NBS. Applicable standards are available through the National Technical Information Service, Springfield, VA 22161.
Obligations of the Manufacturer/Vendor	Suppliers desiring a verification review must make a request to NBS, identify the make and model, provide
,	required documentation, and reimburse the agency for cost incurred.
Enforcement	Delisting.
Enforcement Term	Delisting. Indefinite.
Term	Indefinite. Some states have used the Verification List in their

SECTION V

# GOVERNMENT PROCUREMENTS

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Products or Services	Parts, Materials, and Equipment
Department/Agency	General Services Administration (GSA) Federal Supply Service (FSS) Office of Quality and Contract Administration Quality Assurance Division Room 1122, Crystal Mall Bldg.4, Jefferson Davis Highway Arlington, VA Mailing Address: Washington, D.C. 20406 (703) 557-8515
Initiated	1944
Compliance	Mandatory for those products defined by Federal Specifications which have been designated for the Qualified Products List (QPL) certification program because conformance demonstration at each procurement would necessitate extensive testing.
Aim	As a means of expediting contract awards and deliveries of designated products, manufacturers are required to have these products pre-tested to determine if the products conform to all specified requirements. Subsequently, assurance that proper quality is being maintained is achieved by normal acceptance inspection of selected samples of a shipment, rather than a detailed lot inspection.
Benefits	The availability of products known to be qualified reduces the cost and time to select products for inclusion in equipment and systems that must perform reliably. Helps control purchase lead times and increases the quality of equipment using these products. The majority of these QPL's are for adhesives, paint, safety equipment, and security office equipment - safes, vault doors, filing cabinets, and padlocks.
Agency Function	Program administrator.
Type of Program	Pretesting prior to government purchase.

Testing Government or private laboratories, including the manufacturer's lab, may be used if acceptable to the GSA and the designated preparing activity. Labs are not formally accredited by GSA. Follow-up inspection is not an integral part of this Inspection program. Listing on a QPL does not waive requirements for either in-process or other inspection by the manufacturer, or inspection by the buyer. Conformity Listing on QPL's. Identification Federal QPL's and specifications are distributed by GSA Availability of Documentation Business Service Centers. Obligations of the Manufacturers and distributors must supply test samples, Manufacturer/Vendor ordinarily bear the cost of testing, maintain quality and notify of design changes. Reference may be made to listing of QPL's in advertising and related publicity, provided there is no claim or implication of government preference or endorsement, or that the product is the only one of its type that has passed the prescribed tests. Indefinite for most products; certain products may require Term retesting at periodic intervals. Reciprocity Federal and state agencies recognize and use federal QPL's. There are no bilateral or multilateral arrangements with other countries. Program is based on qualification requirements specified in Standards, Codes, or Regulations federal specifications. Keywords government procurement; procurement; QPL; quality control; testing

Products or Services	Parts, Materials and Components Used in Military Systems
Department/Agency	U.S. Department of Defense Director of Standardization and Data Management The Pentagon, Room 2A-318 Washington, D.C. 20301 (202) 695-0121
Initiated	1949
Compliance	Mandatory for those products defined by procurement specifications and having qualifications requirements. Equipment supplied to the Department of Defense may not contain products from other than qualified sources for those commodities for which Qualified Products Lists (QPL's) have been developed.
Authority	Federal Acquisition Regulations, General Provisions, Part 9. Defense Standardization Manual, DOD 4120, 3-M. Defense Standardization Document SD-6.
Aim	Maintain a high level of quality for critical products through pre-procurement evaluation of prospective vendors.
Benefits	The QPL Program normalizes the selection of possible vendors in several hundred critical technical commodities which are sufficiently standardized to permit a stringent, common, advanced assessment of supplier capability.
Agency Function	Program administrator.
Methodology	Pretesting prior to purchase by government or its contractors.
Testing	Any type of laboratory acceptable to DOD sponsoring activity may be used; labs are not formally accredited by DOD.

Inspection	Periodic follow-up inspection. Plant visits are part of the overall management of the program. Listing on a QPL does not waive the requirements for in-process or other inspection by the manufacturer or receiving inspection by the buyer.
Conformity Identification	Listing on Qualified Product Lists (QPL's). Authorized designation (JAN Mark) may be applied by manufacturer/distributor to qualified semiconductors, microelectronic, and products with established reliability.
Availability of Documentation	DOD specifications and QPL's are distributed by: Naval Publications and Forms Center 5801 Taylor Avenue Philadelphia, PA 19120
Obligations of the Manufacturer/Vendor	Manufacturer/distributor must supply test samples, ordinarily bear the cost of testing, maintain quality, notify of design or process changes, and mark only approved types. Advertising and publicity may refer to listing on QPL's provided there is no claim or implication of government preference or endorsement or that the product is the only one of its type that has passed the prescribed tests.
Enforcement	Delisting.
Term	Validated every two years; most critical components require retesting at periodic intervals.
Reciprocity	There is limited reciprocity with counterpart agencies in Canada, Australia, and Ireland as well as specific procedures for products complying with QPL's of NATO.
Standards, Codes or Regulations	Program is based on qualification requirements specified in Military Specifications.
Keywords	government procurement; military; military specifications; military systems; procurement; QPL; qualification; quality control; testing

# SECTION VI

TESTING, MEASUREMENT, AND LABORATORY SERVICES

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LABORATORY TESTING PROCEDURES IN VA MEDICAL CENTERS	

Products or Services	Laboratory Accreditation
Department/Agency	U.S. Department of Commerce National Bureau of Standards (NBS) National Voluntary Laboratory Accreditation Program (NVLAP) Administration Bldg., Room A531 Gaithersburg, MD 20899 (301) 975-4016
Initiated	1976
Compliance	Voluntary
Authority	Section 2, Stat. 1449 as amended (15 USC 272); Reorg. Plan No. 3 of 1946, Part VI; 15 CFR Part 7.
Aim	To accredit laboratories found competent to perform specific tests or types of tests.
Benefits	Provides a national recognition for competent laboratories; helps regulatory and procurement agencies to identify competent laboratories; fosters international acceptance of test data produced in U.S. laboratories; provides laboratory management with a quality assurance check of their performance; and provides laboratories with guidance from technical experts to aid in reaching a higher level of performance.
Agency Function	Accreditor.
Type of Program	Laboratory accreditation.
Methodology	Technical requirements, including test methods, standards and the products or services to be covered, are established for each laboratory accreditation program. Laboratories may then request that their performance be assessed by NVLAP against these requirements.
Testing	Government.
Inspection	Government.

Conformity Identification	A certificate of accreditation is provided to the laboratory. Directories of accredited laboratories are published annually.
Availability of Documentation	General requirements are set forth in 15 CFR Part 7. Requirements for specific laboratory accreditation programs are available from NVLAP.
Obligations of the Manufacturer/Vendor	Laboratories are obligated to maintain adequate quality control programs and to abide by the terms of its accreditation.
Enforcement	Suspension or revocation of accreditation.
Term	Certificates of Accreditation are valid for one year.
Reciprocity	NBS accreditation of a laboratory is recognized by many federal and state agencies, as well as some foreign government bodies.
Standards, Codes or Regulations	General requirements are set forth in 15 CFR Part 7. Specific requirements for each laboratory accreditation program are established by NBS in conjunction with technical experts from the federal, state and local levels; academia; and from industry.
Keywords	accreditation; laboratories; NVIAP; quality control; test methods; testing

Products or Services	Meat/Poultry/Food Products (Accreditation of laboratories)
Department/Agency	U.S. Department of Agriculture Food Safety and Inspection Service (FSIS) Science, Chemistry Division Room 302 Annex Washington, D.C. 20250 (202) 447-7723
Initiated	1962, Final Rule 9 CFR Parts 318 and 381, 1/20/87.
Compliance	Voluntary
Authority	9 CFR Parts 318 and 381.
Aim	This program allows the acceptance of official sample results from accredited laboratories which service the meat and poultry food industry and provides faster service than can be provided by FSIS laboratories.
Benefits	Provides faster analytical service to the meat and poultry food industry. This allows for a better inspection program.
Agency Function	Accreditor and program administrator.
Type of Program	Pre-marketing evaluation.
Methodology	Government accreditation; on-site laboratory review; proficiency samples and ongoing split samples that serve as a continuing check on the laboratory's analytical capability.
Testing	Government accredited labs.
Inspection	Government.
Conformity Identification	Government applied mark.

Availability of Documentation	The lists of USDA-FSIS accredited laboratories are published in the "Meat and Poultry Inspection Directory."
Obligations of the Manufacturer/Vendor	Accredited laboratories must continue to operate under the Accredited Laboratory Rules as documented under 9 CFR Parts 318.21 and 381.153.
Enforcement	Delisting.
Term	Indefinite term.
Reciprocity	Recognition of Accreditation by: State agencies. Private sector organizations.
Standards, Codes or Regulations	9 CFR Parts 318.21 and 381.153.
Keywords	accredited/laboratory coordinator; initial accreditation sample check; laboratory accreditation; laboratory; meat testing; official sample; ongoing accreditation check sample; poultry testing; probation; split sample

Products or Services	Certification of U.S. Laboratories for the Analysis of Wines and Distilled Spirits for Export
Department/Agency	U.S. Department of the Treasury Bureau of Alcohol, Tobacco and Firearms Office of Laboratory Services 1401 Research Boulevard Rockville, MD 20850 (301) 294-0410 Telex: 710-822-9229 ATF HQ WSH
Initiated	Distilled spirits beverages: 1969 Wines: 1973
Compliance	Mandatory only for laboratories wishing to be certified by the Bureau of Alcohol, Tobacco and Firearms.
Authority	Internal Revenue Procedure 69-22 (Distilled Spirits). ATF Procedure 86-3 (Wines).
Aim	To meet the requirements of certain countries which require that U.S. wines and/or distilled spirits beverages exported to those countries be accompanied by a chemical analysis performed by a laboratory certified by ATF.
Benefits	Enables U.S. industry to comply with foreign government requirements.
Agency Function	Program administrator and certifier.
Type of Program	Pre-certification evaluation.
Methodology	Government review of applicant's qualifications.
Testing	ATF certifies laboratories qualified for the analysis of wines and distilled spirits beverages.
Inspection	Government inspection.
Conformity Identification	A list of certified laboratories.

Availability	The list of laboratories certified by ATF are available
of Documentation	and may obtained at the address indicated above.

Obligations of Exporters of U.S. wines and distilled spirits beverages obligated to use the services of laboratories certified by ATF, but only if the importing country so requires.

Enforcement Delisting.

Term Retesting after 4 years.

Reciprocity No reciprocal agreements.

Standards, Codes, Internal Revenue Procedure 69-22 (Distilled Spirits). or Regulations ATF Procedure 86-3 (Wines). ATF prepares criteria documentation.

Keywords alcohol; ATF certified laboratory; beverages; chemical analyses; distilled spirits; laboratory accreditation; wines

Products or Services	Measurement Calibration Services
Department/Agency	U.S. Department of Commerce National Bureau of Standards (NBS) Office of Weights and Measures Administration Bldg., Room A617 Gaithersburg, MD 20899 (301) 975-4004
Initiated	1965
Compliance	Voluntary
Authority	NBS Organic Act (P.L. 81-619).
Aim	Provide certification of state measurement laboratories capabilities to calibrate standards and equipment for measuring mass, length, volume, temperature, and frequency-based devices.
Benefits	Provides basis for uniform requirements and consistent results in metrological calibration and tolerance testing among states.
Agency Function	Program administrator.
Type of Program	A joint on-going activity between federal and state governments to: (1) maintain traceability to national standards; and (2) evaluate, up-grade, and train measurement technicians in official state weights and measures laboratories.
Methodology	Inspection and site approval of new laboratory facilities. Installation and maintenance of measurement control programs. Program requirements in NBS Handbook 143. Technical standards in NBS Handbook 145.
Testing	All services within this program are performed by state laboratories accredited by NBS.

Inspection

#### Government.

Conformity State laboratories receive certificates of accreditation and are identified in a list, NBS SP 686. Instruments and standards certified by state laboratories may be identified by a state government-applied mark.

Availability NBS SP 686, NBS Handbook 143, and NBS Handbook 145 are available from NBS.

Obligations of the State laboratories are obligated to participate in Manufacturer/Vendor external control programs based on geographical regions which include controlled sample testing, round robin experiments, and continuing education for technicians.

- Enforcement NBS exercises influence over state laboratories through provision of traceability to NBS standards, provision of training and by sponsoring the Regional Measurement Management Programs. State programs may ban the use of uncalibrated measurement equipment in their regulatory programs.
- Term Indefinite term. NBS Certificates of Accreditation are valid for up to 3 years.
- Reciprocity NBS certification of a state laboratory carries recognition within that state and among states and recognition by federal government agencies and private organizations.
- Standards, Codes Criteria documents are developed by NBS. See NBS or Regulations Handbook 143 available from NBS.
- Keywords frequency; length; mass; measurement instruments; quality control; state laboratories; temperature; volume

Products or Services	Grain Scale Testing and Certification
Department/Agency	U.S. Department of Agriculture Federal Grain Inspection Service (FGIS) Field Management Division, Room 1641-S P. O. Box 96454 Washington, D.C. 20090-6454 Telephone: (202) 382-0262 Telex: 760 7351 ANS:FGIS UC. FAX: (202) 447-4628
Initiated	1976
Compliance	Mandatory only for official certification of grain weight.
Authority	U.S. Grain Standards Act, as amended.
Aim	Provide for the certification of grain weight and the testing and certification of the weighing systems used for official grain weighing and inspection. FGIS and delegated states must test all grain scales at facilities which have requested official weight certification. FGIS conducts evaluations of automatic bulk weighing systems and vehicle, railway track, and grain inspection scales to determine compliance with FGIS regulations and the applicable National Type Evaluation Program (NTEP) type evaluation examination criteria and test procedures as adopted by the National Conference on Weights and Measures (NCWM). Only those scales that have been approved, and Class II, III, IIIL scales that have been evaluated by FGIS or the National Bureau of Standards (NBS) and approved under the NTEP may be used for official weighing and inspection purposes.
Benefits	Ensure the accuracy of weighing systems used to officially weigh grain and provide uniformity in the inspection and testing of weighing devices used for that purpose.
Agency Function	Certifier, regulator, and program administrator.
Type of Program	Pre-performance evaluation. Post-performance assessment. Assessment prior to government purchase.

Government design approval, performance testing, Methodology inspection, and site approval. Testing FGIS laboratory. Government laboratory. Manufacturer's laboratory. State laboratory. Inspection FGIS or state government. Conformity NTEP Certificate of Conformance (CC). Identification FGIS CC. FGIS Report of Test (ROT). NBS ROT. Government applied approval seal. Availability List of approved equipment may be obtained from: of Documentation U.S. Department of Agriculture Federal Grain Inspection Service (FGIS) Equipment Branch Room 0623-South Building P. O. Box 96454 Washington, D.C. 20090-6454 Index of NTEP device evaluations and NTEP criteria and test procedures may be obtained from : NCWM/OWM National Bureau of Standards Administration Building Room A617 Gaithersburg, MD 20899 Obligations of the Must provide instruments under the CC exactly as specified Manufacturer/Vendor and provide installation, maintenance, and operating instructions consistent with the evaluation report. Modifications affecting accuracy, reliability or integrity must be approved by the FGIS Equipment Branch before implementation. Continuous or intermittent, mandatory or voluntary Term inspection on a scale.

Reciprocity	Certificates are required by federal agencies, state agencies, private sector organizations, foreign governments, and international organizations buying and selling grain.
Standards, Codes or Regulations	U.S. Grain Standards Act, as amended, and the regulations thereunder; FGIS Equipment Handbook; FGIS Weighing Handbook; NBS Handbook 44; and NTEP device evaluation criteria.
Keywords	automatic bulkweighing systems; grain test; NIEP; railway track; ROT; scale; state weights and measures officials

Products or Services	Evaluation of Commercial Weighing and Measuring Instruments
Department/Agency	U.S. Department of Commerce National Bureau of Standards (NBS) Office of Weights and Measures Administration Bldg., Room A617 Gaithersburg, MD 20899 (301) 975-4004
Initiated	1984
Compliance	Voluntary
Authority	Resolution of the National Conference on Weights and Measures (NCWM) and NBS Organic Act (P.L. 81-619).
Aim	Provide an evaluation service for producers of specified kinds of weighing and measuring instruments used in commercial trade prior to acceptance for sale or use within the U.S.
Benefits	Provides a uniform means of evaluating the performance of specific devices/systems for conformance to legal requirements.
Agency Function	Certifier and program administrator.
Type of Program	Pre-marketing evaluation.
Methodology	NBS provides performance evaluation and testing either directly or jointly with an NBS authorized laboratory.
Testing	Government approved labs. (Authorized laboratory indicated above is most likely to be an authorized state measurement laboratory).
Inspection	NBS or state government.
Conformity Identification	Certificates of Conformance issued to manufacturer. List of qualified manufacturers.

Availability of Documentation	List published by NBS.
Obligations of the Manufacturer/Vendor	Manufacturers must mark instruments marketed under the Certificate of Conformance exactly as specified and provide installation, maintenance, and operating instructions consistent with the evaluation report.
Enforcement	Delisting. States may require Certificate of Conformance before allowing device to be marketed in the state.
Term	Certificate is valid as long as the type and model of instrument is produced consistent with the evaluation report.
Reciprocity	Other federal agencies and state agencies. This program is the U.S. basis for recognition of approved measuring instruments within an international system currently being established.
Standards, Codes or Regulations	NCWM prepares acceptance criteria, taking advice from NBS, device manufacturers and participating laboratories and international organizations. The NCWM adopts these criteria by consensus vote.
Keywords	commercial measuring devices; legal metrology; measurement instruments; production control; prototype; state laboratories; type evaluation; weighing instruments

# SECTION VII

# MEDICAL PRODUCTS AND SERVICES

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Products or	Health Care Providers and Suppliers: Hospitals,
Services	Psychiatric Hospitals, Hospices, Skilled Nursing Facilities (SNF), Intermediate Care Facilities (ICF), Intermediate Care Facilities for the Mentally Retarded (ICF/MR), Home Health Agencies (HHA), Ambulatory Surgical Centers (ASC), Rural Health Clinics (RHC), End Stage Renal Disease Facilities (ESRD), Outpatient Physical Therapy or Speech Pathology Services (OPT/OSP), Physical Therapists in Independent Practice (PTIP), Comprehensive Outpatient Rehabilitation Facilities (CORF), Independent Laboratories, Interstate Licensed Laboratories, Portable X-Ray Services.
Department/Agency	U.S. Department of Health and Human Services (DHHS) Health Care Financing Administration (HCFA) Health Standards and Quality Bureau
	Office of Survey and Certification 6325 Security Boulevard Baltimore, MD 21207 (301) 934-5547 (FTS)
Initiated	1966
Compliance	Voluntary for Medicare Certification. Mandatory licensure for laboratories performing work in interstate commerce.
Compliance	Mandatory licensure for laboratories performing work in
Compliance	Mandatory licensure for laboratories performing work in
-	Mandatory licensure for laboratories performing work in interstate commerce.
-	Mandatory licensure for laboratories performing work in interstate commerce. Social Security Act, P.L. 92-603. Clinical Laboratories Improvement Act of 1967 (CLIA),
-	<ul> <li>Mandatory licensure for laboratories performing work in interstate commerce.</li> <li>Social Security Act, P.L. 92-603.</li> <li>Clinical Laboratories Improvement Act of 1967 (CLIA), P.L. 90-174.</li> <li>42 CFR Part 416 (ASC), Part 418 (Hospices), Part 442 (ICF, ICF/MR), Part 481 (RHC), Part 482 (Hospitals), Part</li> </ul>
-	<ul> <li>Mandatory licensure for laboratories performing work in interstate commerce.</li> <li>Social Security Act, P.L. 92-603.</li> <li>Clinical Laboratories Improvement Act of 1967 (CLIA), P.L. 90-174.</li> <li>42 CFR Part 416 (ASC), Part 418 (Hospices), Part 442 (ICF, ICF/MR), Part 481 (RHC), Part 482 (Hospitals), Part 488 (CORF), Part 405 (remaining facilities).</li> </ul>

Certifies facilities for Medicare reimbursement, licenses Agency Function laboratories under CLIA, administers programs, and develops program standards and quidelines. Type of Program Assesses a provider's or supplier's ability to meet federal requirements in order to participate in the Medicare program or to perform laboratory testing in interstate commerce. Certification/licensure is granted to a provider/supplier Methodology by passing an on-site inspection process to assure compliance with the federal regulations. Inspection Annual on-site inspection by State Survey Agency acting for the federal government. Conformity An identification number is given to the provider/supplier Identification when it is determined that federal requirements are met. Availability A list of approved suppliers/providers is available from of Documentation HCFA. Obligations of the Providers/suppliers must continue to meet the appropriate Manufacturer/Vendor federal requirements and to notify the government of any changes in their operation. Enforcement Medicare decertification/termination or revocation of CLIA license if provider/supplier fails to comply with program requirements. Term Providers/suppliers must undergo annual on-site inspection to assure compliance with program requirements. Hospitals accredited by the Joint Commission on Reciprocity Accreditation of Hospitals (JCAH) or the American Osteopathic Association (AOA) are deemed to meet the Federal Medicare requirements. Clinical laboratories performing tests in interstate commerce may apply for a College of American Pathologists (CAP) Exemption (if the lab is CAP accredited), a New York State Exemption, or a Low Volume Exemption in lieu of a CLIA license.

 Standards, Codes
 Standards are specified in the Acts and in the Code of Federal Regulations.

 Keywords
 ambulatory surgical centers; CLIA/interstate licensure;

health care facility; health care providers; home health agencies; hospices; hospitals; intermediate care facilities; laboratories; Medicare certification; physical therapy; portable x-ray services; rehabilitation facilities; rural health clinics; skilled nursing facilities; speech pathology services

Products or Services	Drugs Containing Insulin
Department/Agency	U.S. Department of Health and Human Services Food and Drug Administration (FDA) Center for Drugs and Biologics Office of Biologics Research and Review 5600 Fishers Lane Rockville, MD 20857 (301) 443-3490
Compliance	Voluntary
Authority	21 CFR Part 429.
Aim	To provide insulin users with assurance of a uniform quality drug.
Benefits	Virtually all producers participate in this certification program.
Agency Function	Certifier.
Type of Program	Pre-marketing evaluation.
Methodology	Government inspection. Compliance with Good Manufacturing Practices (GMP).
Testing	Manufacturer's lab. Government lab.
Inspection	Government.
Conformity Identification	Lists of qualified producers and certified products are maintained by FDA.
Availability of Documentation	Lists are available from FDA.

Obligations of the Producers are required to keep production records for two Manufacturer/Vendor years after batch shipment.

Enforcement Marketing ban (under the requirement that any misbranded drug is banned by law).

Term Certification is provided on a batch basis.

Reciprocity Certification is recognized by other federal agencies, state agencies, and private sector organizations.

Standards, Codes Agency prepares certification criteria. Agency adopts test methods of the U.S. Pharmacopoeial Convention and the National Formulary.

Keywords certification; color coding; drugs; insulin; labeling; market ban; packaging

Products or Services	Drugs for Human Use
Department/Agency	U.S. Department of Health and Human Services Food and Drug Administration (FDA) Center for Drugs and Biologics Office of Compliance Regulatory Affairs Division Legislative, Consumer and Professional Affairs Branch Metro Park North 7520 Standish Place Rockville, MD 20855 (301) 295-8012
Compliance	Mandatory
Authority	Food, Drug and Cosmetic Act of 1938 as amended, Title 21 USC, 21 CFR Parts 200-212 and 300-315.
Aim	To assure that drugs and antibiotics are both safe and effective for intended use.
Benefits	Virtually all covered products consumed in the U.S. are made in registered establishments and produced under Good Manufacturing Practices (GMP).
Agency Function	Certifier.
Type of Program	Pre-marketing evaluation.
Methodology	Government design approval, inspection, site approval and compliance with GMP.
Testing	Manufacturer's lab. Third party lab.
Inspection	Government.
Conformity Identification	Lists of qualified producers and approved products are maintained by FDA.

Availability of Documentation	Official lists may be obtained from: Drug Listing Branch (HFN-315) Center for Drugs and Biologics Food and Drug Administration (FDA) 7520 Standish Place Rockville, MD 20855 (301) 295-8077
Obligations of the Manufacturer/Vendor	Producers are required to register establishments, maintain sanitary conditions, provide substantial clinical evidence of safety and effectiveness, prepare adequate labeling and instructions for use, submit advertising for approval, comply with GMP, use approved packaging, and advise FDA of known adverse reactions.
Enforcement	Marketing ban. Product recall.
Term	No specific term; retesting is based on changes in product characteristics, composition, or intended use. A major consideration is any misbranding or adulteration.
Reciprocity	Certification is recognized widely in the U.S., but no foreign reciprocity.
Standards, Codes or Regulations	FDA prepares all standard requirements including GMP Rules, except that specifications of official drug components are prepared by private organizations, i.e., the U.S. Pharmacopeia, the Homeopathic Pharmacopeia, or the National Formulary.
Keywords	adulteration; antibiotics; drug registration; drugs; good manufacturing practices; labeling; misbranding; packaging; pre-market evaluation; recall; sanitation

Products or Services	Medical Devices
Department/Agency	U.S. Department of Health and Human Services Food and Drug Administration (FDA) Center for Devices and Radiological Health Office of Device Evaluation 8757 Georgia Ave. Silver Spring, MD 20910 (301) 427-7004
Initiated	1976
Compliance	Mandatory
Authority	Medical Device Amendments, P.L. 94-295 to Food, Drug and Cosmetic Act, Title 21 USC.
Aim	To assure that medical devices are both safe and efficacious in their intended use.
Benefits	For Class III devices, the program provides a more thorough design review.
	For Class I and II devices, the program provides clear public expectations.
Agency Function	For Class III devices, certifier.
Agency Function	For Classes I and II devices, program administrator.
Type of Program	Pre-marketing evaluation.
Methodology	For Class III, government design approval, audit
	inspection, and site approval; manufacturers supply test data.
	For Classes I and II, manufacturer self-certification and compliance with Good Manufacturing Practices (GMP).
Testing	Manufacturer's lab or third party lab. Audit testing may be done by labs under contract to government.

Inspection	Government.
Conformity Identification	For Class III devices only, list of approved products is maintained by FDA. For Classes I and II, manufacturer self-certification is evidenced through information required in product labeling
Availability of Documentation	Lists are available from the: FDA Devices Registration and Listing Branch Product Surveillance Division 8757 Georgia Ave. Silver Spring, MD 20910 (301) 427-7190
Obligations of the Manufacturer/Vendor	Manufacturers of all classes of medical devices are required to be registered and to collect data on patient/ practitioner experience and report any hazardous events or noncompliances with Class III or Class II certification.
Enforcement	Marketing ban, product recall, delisting are all applicable to medical devices.
Term	No specific term; retesting is based on changes in product characteristics or use. A major consideration is any misbranding or adulteration.
Reciprocity	Certifications are recognized widely in the U.S., but no foreign reciprocity.
Standards, Codes or Regulations	Agency prepares requirements for Class III; standards for Class II may be from private sector; FDA develops and maintains GMP rules.
Keywords	adulteration; good manufacturing practices; investigational use; medical devices; medical device classification; misbranding; pre-market notification; recall

Products or Services	Automotive Driving Aids and Automatic Wheelchair Lifts
Department/Agency	Veterans Administration Prosthetic & Sensory Aids Service (121) 810 Vermont Ave., NW Washington, D.C. 20420 (202) 233-2011
Initiated	Driving aids, March 27, 1975; wheelchair lifts, May 10, 1978.
Compliance	Mandatory only for purchases funded by the Veterans Administration (VA).
Authority	P.L. 91-666.
Aim	To provide quality equipment and assure the safety of veteran passengers and drivers as well as the general public.
Benefits	Since developing the Quality Products List for hand controls and van lifts, manufacturers of these units have been assisted by the VA in improving the quality of their products. Establishment of standards has fostered competition.
Agency Function	Certification is made by the VA sponsored Automobile Adaptive Equipment Committee.
Type of Program	Assessment prior to government purchase.
Methodology	Compliance is assured by government testing/inspection or third party government approved certification, and manufacturers' self-certification.
Testing	Testing results are accepted from government laboratories, government approved labs, third party labs and manufacturers' labs.
Inspection	Government.

Conformity Identification	Listing in VA Circular 10-86-54.
Availability of Documentation	The VA Compliance List, DM&S Circular 10-86-54, dated April 24, 1986, lists certified suppliers of wheelchair lift systems and hand controls.
Term	Testing of new products is on-going. Listings are updated annually.
Reciprocity	Certification by other agencies is accepted when current standards are applied.
Standards, Codes, or Regulations	<u>Federal Register</u> , Vol. 40, No. 65 - April 3, 1975, defines standards for driving aids.
	Requirements for wheelchair lifts are specified in <u>Federal Register</u> , Vol. 43, No. 96 - May 17, 1978.
Keywords	adaptive equipment; automotive; driving aids; hand control; handicapped aids; prosthetic aids; quality; safety; wheelchair lifts

Products or Services	Self-Propelled and Motorized Wheelchairs
Department/Agency	Veterans Administration Prosthetic & Sensory Aids Service (121) 810 Vermont Ave., NW Washington, D.C. 20420 (202) 233-2011
Initiated	Self-propelled wheelchairs, December 7, 1977; Motorized wheelchairs, December 15, 1981
Compliance	Mandatory only for purchases funded by the Veterans Administration (VA).
Authority	Title 38 USC 4101(c)(2).
Aim	Avoid hazardous conditions for disabled persons caused by inferior products.
Benefits	Product quality and safety has improved and competition has increased. Federal Supply Schedule Contracts have been established to enforce compliance.
Agency Function	Certification is made by the VA sponsored Prosthetic Technology Equipment Committee.
Type of Program	Assessment prior to government purchase.
Methodology	Compliance is assured by government testing/inspection or third party government approved certification, and manufacturers' self-certification.
Testing	Testing results are accepted from government laboratories, government approved labs, third party labs and manufacturers' labs.
Inspection	Government.

Conformity Identification	Self-propelled wheelchair suppliers and motorized wheelchair suppliers are currently listed.
Availability of Documentation	The General Services Administration's (GSA) Federal Supply Schedule for wheelchairs provides particulars.
Term	Testing of new products is on-going. Listings are updated annually and GSA contracts are negotiated annually.
Reciprocity	Certification by other agencies is accepted when current standards are applied.
Standards, Codes, or Regulations	<u>Federal Register</u> , Vol. 42, No. 239 - December 13, 1977, defines standards for propelled wheelchairs. Requirements for motorized wheelchairs are specified in <u>Federal Register</u> , Vol. 46, No. 240 - December 15, 1981.
Keywords	handicapped aids; prosthetic aids; quality; safety; wheelchair

Products or Services	Tests and Procedures Performed by Veterans Administration Medical Center Laboratories
Department/Agency	Veterans Administration Pathology Service, Dept. of Medicine and Surgery 810 Vermont Ave., NW Washington, D.C. 20420 (202) 233-2464
Initiated	1970
Compliance	Voluntary
Aim	Standardization and uniformity in laboratory test performance throughout 204 clinical laboratories, 63 nuclear medicine laboratories, 159 special purpose laboratories of the Veterans Administration system.
Benefits	Improved quality of care for patients. Peer-reviewed process provides cross-educational benefits for all laboratories.
Agency Function	Certifier and program administrator.
Type of Program	Quality Control. Physician peer review.
Methodology	Third party certification - College of American Pathologists (CAP).
Inspection	Third party.
Conformity Identification	Authorized certificate issued by third party - College of American Pathologists.
Availability of Documentation	Maintained by Pathology Service and local laboratories, and at CAP.
Enforcement	Pathology Service, Veterans Administration Central Office.

Term	Indefinite term.
Reciprocity	Recognition of certification by Joint Council of American Hospitals.
Standards, Codes, or Regulations	College of American Pathologists Laboratory Accreditation Program (CAPLAP).
Keywords	clinical laboratories; laboratories; limited special function laboratories; nuclear medicine; pathology

# SECTION VIII

# MINING, DRILLING, AND INDUSTRIAL EQUIPMENT

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Products or	Respirators and Other Breathing Apparatus; Personal Coal
Services	Dust Samplers
Department/Agency	U.S. Department of Health and Human Services National Institute for Occupational Safety and Health Appalachian Laboratory for Occupational Safety and Health Certification Branch 944 Chestnut Ridge Road Morgantown, WV 26505-2888 (304) 291-4331
Initiated	1972
Compliance	Voluntary
Authority	30 CFR Part 11. 30 CFR Part 74.
Aim	To assure a minimum level of performance and quality for respiratory protective devices in the marketplace and provide an independent review of manufacturer's designs.
Benefits	The certifying laboratory evaluates approximately 2000 samples of respiratory protective devices from a population of 21 domestic manufacturers and five importers. These evaluations combined with an extensive defect notification program, including both users and manufacturers, assures that nearly all potentially life- threatening problems with respiratory protective equipment are detected and corrected before equipment-related injuries occur.
Agency Function	Certifier.
Type of Program	Pre-marketing evaluation and post-marketing assessment, in the form of defect investigation.
Methodology	Federal design approval and testing.
Testing	Government laboratory and manufacturers labs.

Inspection	Federal agency representatives only.
Conformity Identification	Approved product lists and government-approved labels applied by the manufacturer.
Availability of Documentation	Approved product lists are available to users at the above address.
Obligations of the Manufacturer/Vendor	Manufacturer must conduct pre-submittal tests; establish a quality control plan for agency approval; notify agency of possible or actual equipment or component defects; participate in agency-sponsored investigations; and cease labeling if approval is suspended.
Enforcement	Delisting. Product recall (voluntary by the manufacturer). Notification to users.
Term	Indefinite term.
Reciprocity	Other federal agencies (e.g. the NRC). State agencies. Government of Canada and its counterpart agencies.
Standards, Codes or Regulations	Agency prepares criteria documents. Agency adopts standards prepared by others for quality plans and respirator maintenance.
Keywords	air samplers; breathing apparatus; coal mine dust; design approval; face pieces; gas masks; mining equipment; pesticides; respirators

Products or Services	Surface and Subsurface Safety Valves for Oil and Gas Operations
Department/Agency	Minerals Management Service Offshore Operations Offshore Rules and Operations Division, Room 6A116 U.S. Department of the Interior 12203 Sunrise Valley Drive Reston, VA 22091 (703) 648-7813
Initiated	1980
Compliance	Mandatory
Authority	30 CFR Part 250.11. Outer Continental Shelf (OCS) Orders.
Aim	To prevent major oil spills that cause pollution.
Benefits	Decreased pollution and accidents and improved consistency of manufacturing and testing.
Agency Function	Program administrator.
Type of Program	Pre-marketing evaluation.
Methodology	Third party inspection.
Inspection	Federal inspection of drilling/production operations. Valves subject to ASME-approved, third party inspection.
Conformity Identification	Authorized mark or label by manufacturer.
Availability of Documentation	Available from ASME at 345 E. 47th Street, New York, NY 10017.

Traceability. Obligations of Manufacturer/Vendor

Enforcement	Delisting.
Term	Three years.
Reciprocity	No reciprocal agreements.
Standards, Codes, or Regulations	ANSI/ASME - SPPE-1, Quality Assurance and Certification of Safety and Pollution Prevention Equipment Used in Offshore Oil and Gas Operations. ANSI/ASME - SPPE-2, Accreditation of Testing Laboratories for Safety and Pollution Prevention Equipment Used in Offshore Oil and Gas Operations.
Keywords	environmental protection; gas pollution; OCS; offshore drilling; oil pollution; petroleum pollution; pollution prevention; safety valves; valves

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Products or Services	Diesel-Powered Equipment for Gassy Mines
Department/Agency	U.S. Department of Labor Mine Safety and Health Administration (MSHA) Approval and Certification Center Box 251 Triadelphia, WV 26059 (304) 547-0400
Initiated	1977
Compliance	Mandatory for certain areas of non-coal mines where methane may be present.
Authority	P.L. 91-173; 30 USC 957. P.L. 95-164; 30 USC 961, 951; 30 CFR Part 36.
Aim	To provide a uniform means for evaluating diesel-powered equipment used in non-coal mines for mining and transportation.
Benefits	Accidents and deaths related to diesel-powered mine machinery have been minimized.
Agency Function	Certifier.
Type of Program	Pre-market evaluation.
Methodology	Government design approval, testing, and inspection.
Testing	Government labs or other labs under government monitoring.
Inspection	Government.
Conformity Identification	Agency designated and issued mark.
Availability of Documentation	Agency publishes lists of certified and approved equipment.

- Obligations of the Manufacturer must maintain production according to type-Manufacturer/Vendor approved drawings, including modifications to design required for approval, and employ acceptable quality control plan.
- Enforcement Marketing ban; removal from mine use of non-conforming equipment; legal action.

Term Indefinite.

**Reciprocity** Other international, federal and state agencies, and private organizations.

Standards, Codes Agency prepares criteria documents.

or Regulations

Keywordsdiesel-powered equipment; dust collectors; electrical<br/>components; exhaust gasses; flammable atmosphere; mining<br/>machines; non-coal mines; safety; transporters; ventilators

Products or Services	Electrical Equipment for Mines
Department/Agency	U.S. Department of Labor Mine Safety and Health Administration (MSHA) Approval and Certification Center Box 251 Triadelphia, WV 26059 (304) 547-0400
Initiated	1977
Compliance	Mandatory
Authority	P.L. 95-164; 30 USC 961, 951; 30 CFR Part 18. P.L. 91-173; 30 USC 957.
Aim	To provide a uniform means for evaluating electrical equipment used in gassy mines for mining, illuminating, and measuring in order to reduce work place hazards.
Benefits	Accidents and deaths related to electrically-powered mine machinery have been minimized.
Agency Function	Certifier.
Type of Program	Pre-market evaluation.
Methodology	Government design approval, testing, and inspection.
Testing	Government labs or other labs under government monitoring.
Inspection	Government.
Conformity Identification	Agency designated and issued mark.
Availability of Documentation	Agency publishes lists of certified and approved equipment.

Obligations of the Manufacturer/Vendor	Manufacturer must maintain production according to type- approved drawings, including modifications to design required for approval, and employ acceptable quality control plan.
Enforcement	Marketing ban; removal from mine use of non-conforming equipment; legal action.
Term	Indefinite.
Reciprocity	Other international, federal and state agencies, and private organizations.
Standards, Codes or Regulations	Agency prepares criteria documents.
Keywords	battery powered equipment; coal mines; electrical equipment; fans compressors; illumination; intrinsically-safe equipment; mining equipment; pumps; safety; shuttle cars; signalling devices

Products or Services	Systems Using Presence Sensing Devices for Initiating Mechanical Power Presses (PSDI)
Department/Agency	U.S. Department of Labor Occupational Safety and Health Administration (OSHA) Directorate of Technical Support Office of Variance Determination, Room N3656 200 Constitution Ave., NW Washington, D.C. 20210 (202) 523-7193
Initiated	Final Rule to be issued in 1987.
Compliance	Mandatory for employers planning to use such systems.
Authority	29 CFR Part 1910.217; 29 CFR Part 1910 General Industry; P.L. 91-596 Occupation Safety and Health Act of 1970.
Aim	To provide protection for employees using presence sensing devices for initiation of mechanical power presses.
Benefits	The overall press and control system safety are enhanced by certification to ensure a higher degree of equipment capability and reliability than was provided for in the former standard.
Agency Function	Program administrator.
Type of Program	Regulatory compliance.
Methodology	OSHA recognizes third party certification program(s) to validate certifications by manufacturer or employer. Certifications include design, installation and annual recertification.
Testing	Laboratory selected by recognized certification program.
Inspection	Recognized third party certification program.

Conformity Identification	Mark or label authorized by recognized certification program.
Availability of Documentation	Available from recognized certification program, manufacturer, or employer.
Obligations of the Manufacturer/Vendor	Cooperate with employers and recognized certification programs to develop, install and maintain safe devices for presses.
Enforcement	As required by OSHA Act; periodic inspection of employers under OSHA inspection program; written report on mechanical power presses also required.
Term	Retesting after one year by recognized certification program.
Reciprocity	Recognition of certification by: Other federal agencies State agencies.
Standards, Codes or Regulations	Recognized certification program adopts and uses standards prepared by others.
Keywords	industrial safety; light curtain; machine guarding; mechanical power press; Presence Sensing Device Initiation (PSDI); presses; safety distance

Products or Services	Equipment and Materials Used in the Workplace
Department/Agency	U.S. Department of Labor Occupational Safety and Health Administration (OSHA) Directorate of Safety Standards Programs 200 Constitution Ave., NW Washington, D.C. 20210 (202) 523-8061
Initiated	1971
Compliance	Mandatory
Authority	<ul> <li>Occupational Safety and Health Act of 1970, PL 91-596.</li> <li>29 CFR Part 1910 Occupational Safety and Health Standards for General Industry.</li> <li>29 CFR Part 1915 Occupational Safety and Health Standards for Shipyard Employment.</li> <li>29 CFR Part 1917-1918 Occupational Safety and Health Standards for Marine Terminals; Longshoring.</li> <li>29 CFR Part 1926 Construction Safety and Health Standards.</li> <li>29 CFR Part 1928 Occupational Safety and Health Standards.</li> <li>29 CFR Part 1928 Occupational Safety and Health Standards for Agricultural Employment.</li> </ul>
Aim	To provide protection to the nation's workers on their job by reducing or eliminating the various hazards to which workers may be exposed. Certain equipment because of its nature or the types of hazards that may develop while in use is required to be listed, labelled, or approved by third party laboratories.
Benefits	The certification program enables employers to install equipment which has demonstrated compliance with applicable standards and regulations. OSHA workplace inspections can also be expedited when certified equipment is used.
Agency Function	Program administrator.
Type of Program	Post-marketing assessment.
Methodology	Third party certification.

Testing	Third party test labs.
	Accreditation of laboratories proposed in the Federal Register Notice of March 6, 1984.
Inspection	OSHA inspectors can inspect equipment in the workplace.
Obligations of the Manufacturer/Vendor	Comply with applicable standards.
Enforcement	Ban from the workplace.
Term	Indefinite term.
Reciprocity	Listing, labelling, or approval by foreign certification agencies is recognized by OSHA so long as evaluation criteria are equal to or more stringent than applicable OSHA standards and regulations.
Standards, Codes or Regulations	OSHA standards include extensions of federal standards and federal and non-government standards incorporated by reference. These include numerous standards of the American National Standards Institute, the American Society of Mechanical Engineers, the National Fire Protection Association, Underwriters Laboratories, and others.
Keywords	agriculture; construction; diving; electrical; equipment; fire protection; hazardous materials; health; job safety; machinery; material handling; medical services; personal protective equipment; safety; tools; ventilation; welding

# SECTION IX

## TRANSPORTATION-RELATED PRODUCTS AND SERVICES

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Products or Services	Civilian Aircraft, Aircraft Engines, Propellers, and their Components and Parts
	In addition to these products, the comprehensive FAA system provides for certification of pilots, flight instructors, crew members, mechanics, parachute riggers, control tower operators, dispatchers, air carriers in interstate or overseas air transportation, air taxi operators, agricultural aircraft operators, navigational facilities, airports and heliports serving certificated air carriers, repair stations, parachute lofts and schools for pilots and mechanics. Certificates of designation and certificates of authority are issued to aviation medical examiners, examiners of pilots and technical personnel, designated manufacturing inspection representatives.
Department/Agency	U.S. Department of Transportation (DOT) Federal Aviation Administration (FAA) Office of the Associate Administrator for Aviation Standards (AWS-1) 800 Independence Ave., SW Washington, D.C. 20591 (202) 267-3131
Initiated	1926
Compliance	Mandatory
Authority	Federal Aviation Act of 1958 (49 USC). 49 CFR Part 1-199.
	Federal Aviation Act of 1958 (49 USC).
Authority	Federal Aviation Act of 1958 (49 USC). 49 CFR Part 1-199. To promote the development of civil aviation and to provide

Type of Program	Initial design assessment; initial product evaluation; assessment of design, manufacturing, and quality control practices; approval of maintenance periods; and monitoring of all service discrepancy reports.
Methodology	A <u>Type Certificate</u> is granted by the FAA after an applicant has identified and demonstrated compliance with applicable regulations. A Type Certificate is issued for a specific make and model (type) of aircraft, engine, or propeller. Special Conditions may be issued for novel or unusual design features.
	A <u>Production Certificate</u> is issued to holders of type certificates upon demonstration that their quality control system assures that products conform to the type certificate.
	An <u>Airworthiness Certificate</u> is granted for a specific aircraft that meets the approved type design and is in condition for safe operation. Airworthiness certificates are also issued for engines that are exported.
	<u>Parts Manufacturer Approval (PMA)</u> is required for the manufacture of parts, materials, processes and equipment to be installed on a type certificated product. This requires demonstration of compliance with applicable regulations, directives, and standards, and operation of an effective quality control system.
	Authorization to manufacture and designate products, in accordance with FAA Technical Standard Orders (TSO's), requires demonstration of compliance with performance and quality control requirements specified in the respective TSO's.
Testing	Compliance with the applicable requirements is usually accomplished by the applicant and the FAA will review, witness and test as appropriate, prior to approval of the design. Certain flight testing is performed by FAA personnel. Test data for PMA and TSO's are submitted to the FAA for review and approval. The FAA does not approve or accredit test laboratories; however, a manufacturer must possess, or have access to facilities that will enable it to test and inspect products to the requisite levels.

Inspection Inspection is accomplished by FAA specialists and designated representatives.

Conformity Identification	Airworthiness Certificates are issued for each approved aircraft. Engines and propellers must list the Type Certificate and Production Certificate numbers on their data plates. Products conforming to PMA are marked "FAA-PMA". Those manufactured in accordance with a TSO authorization are marked with the applicable TSO number.
Availability of Documentation	No lists of approved or qualified products or suppliers are published for general distribution by FAA.
Obligations of the Manufacturer/Vendor	Each manufacturer or user of certified products, including TSO items, shall report any accident, failure, malfunction, or defect that could result in fire, engine failure, primary structural defect, loss or more than one electrical or hydraulic power generating system, and similar critical occurrences. FAA personnel shall be provided access to inspect any products manufactured under authorization, and to inspect the manufacturing facilities, quality control inspection and test, and technical data files.
Enforcement	Various civil penalties are provided for under section 901 of the Federal Aviation Act of 1958. Under section 903, a state or federal law enforcement officer, or an FAA safety inspector may summarily seize an aircraft involved in a violation. If it is determined that the public interest and safety requires it, the FAA may issue an order amending, suspending or revoking, all or in part of any Type Certificate, Production Certificate, Airworthiness Certificate or Air Carrier Operating Certificate or Air Navigation Facility Certificate. Other enforcement options include cease and desist orders, orders of denial and injunctions.
Term	Type Certificates and Production Certificates are effective until surrendered, suspended, revoked, or a termination date is otherwise established. Airworthiness Certificates are effective as long as maintenance, and alterations are performed in accordance with established regulations and procedures, and the aircraft are registered in the U.S. A PMA or TSO authorization is not transferable and is effective until surrendered or withdrawn.
Reciprocity	The International Civil Aviation Organization (ICAO) sets general guidelines for airworthiness certification systems in Annex 8 to the Chicago Convention. The Federal Aviation Regulations implement ICAO guidelines in the U.S. The U.S. Dept. of Defense and the Coast Guard require that certain of their aircraft and equipment be FAA certified.

A Type Certificate may be issued for a product manufactured in a foreign country with which the U.S. has a bilateral agreement for acceptance of these products for export and import if the country in which the product was manufactured certifies that the product has been examined, tested, and found to meet applicable FAA requirements and the manuals, placards, and instrument markings are in English. Depending on the design and any unique features, Special Conditions may be identified for approval.

An Airworthiness Certificate is granted to imported aircraft for which a Type Certificate has been issued if the country in which the aircraft was manufactured certifies, and the FAA finds, that the aircraft conforms to the type design and is in condition for safe operation.

The FAA need not issue Production Certificates, PMA's, or TSO authorizations if the manufacturing facilities are located outside the U.S., unless there is no undue burden in administering the applicable requirements of the Federal Aviation Act of 1958.

Standards, Codes Applicable design, performance, and quality requirements are specified in 49 CFR Parts 1 to 199. Nongovernment standards are primarily standards developed by the Society of Automotive Engineers, Radio Technical Commission for Aeronautics, and the Aerospace Industries Association.

Keywords air taxi operators; aircraft repair; aircraft; airports; airworthiness; aviation medical examiners; aviation; avionics; control tower operators; dispatchers; engines; flight crew; flight instructors; flight mechanics; heliports; navigational facilities; parachute schools; parachute riggers; pilots; PMA; production certificate; propellers; safety; TSO; type certificate

Products or Services	Weather Observation
Department/Agency	U.S. Department of Commerce National Oceanic and Atmospheric Administration National Weather Service 8060 13th Street Silver Spring, MD 20910 (301) 427-7792
Initiated	1983
Compliance	Mandatory
Authority	Organic Act of the National Weather Service, 15 USC 311.
Aim	Codify the basis for training, examination, and certification of human weather observers.
Benefits	Assures consistent, minimum performance expectations for manual weather observations used for the preparation of forecasts and warnings and the support of aviation operations.
Agency Function	Certifier and program administrator.
Type of Program	Pre-performance assessment.
Methodology	Government testing, inspection, and audit.
Testing	Government.
Inspection	Government.
Conformity Identification	Government-issued certificates and master list of validated observers.
Availability of Documentation	Master List is maintained at the FAA Academy, Oklahoma City, OK.

Obligations of the Certificate holder is required to maintain skill level Manufacturer/Vendor through experience (taking a minimum number of observations throughout the year). Enforcement Certificate suspension. Term Audit testing keyed to individual performance, eyesight, and current experience. Reciprocity Other federal agencies. State agencies. Private organizations. Canadian government agencies. Standards, Codes Agency prepares examination and performance criteria or Regulations and incorporates related criteria prepared by DOD, FAA, and Canadian Atmospheric Environmental Service. aviation weather; computer data entry; eyesight examination; Keywords radar observation; radiosonde observation; vision standards; weather observation

Products or Services	Maritime Cargo Handling Equipment
Department/Agency	U.S. Department of Labor Occupational Safety and Health Administration (OSHA) Directorate of Field Operations Office of Construction & Maritime Compliance Assistance Room N3108 200 Constitution Ave., NW Washington, D.C. 20210 (202) 523-8136
Initiated	1971
Compliance	Mandatory
Authority	29 CFR Part 1915-1919.
Aim	Assure that all covered equipment complies with regulatory requirements. Most of the equipment is at marine terminals and shipyards. Cargo gear on board U.S. inspected vessels is under the jurisdiction of the U.S. Coast Guard.
Benefits	Safety of longshoremen, seamen, and dock workers has been improved by this program which fulfills U.S. responsibilities for International Labor Organization (ILO) Convention No. 32.
Agency Function	Program administrator.
Type of Program	Post-marketing assessment.
Methodology	Third party certification.
Testing	Government accredited lab.
Inspection	Third party.
Conformity Identification	List of certified products made on OSHA official forms.

Availability Agency maintains a list of accredited inspectors. Such of Documentation firms are not required to publicize a list of their clients. Obligations of the Cooperate with a specific third party certifier regarding Manufacturer/Vendor design, fabrication, and installation data and maintenance requirements. Enforcement Delisting or ban on usage. Annual retesting. Term Reciprocity Recognition of certification by: Other federal agencies State agencies. Standards, Codes Agency adopts standards prepared by others. or Regulations accreditation; cranes; derricks; marine equipment; materials Keywords handling equipment; naval equipment; safe working loads; wire rope

Products or Services	Lifesaving, Engineering, Fire Protection, and Pollution Prevention Equipment for Recreational Boats and Commercial Vessels
Department/Agency	U.S. Department of Transportation (DOT) U.S. Coast Guard Office of Marine Safety, Security and Environmental Protection 2100 2nd Street, SW Washington, D.C. 20593 Telex: 892427
	For electrical, pneumatic, and hydraulic equipment: Marine Technical and Hazardous Materials Division Engineering Branch, G-MIH-2 Room 1218D (202) 267-2206
	For all other equipment: Merchant Vessel Inspection and Documentation Division Survival Systems Branch, G-MVI-3 Room 1404 (202) 267-1444
Initiated	1946
Initiated Compliance	1946 Mandatory for equipment required to be used on recreational boats and commercial vessels.
	Mandatory for equipment required to be used on recreational
Compliance	Mandatory for equipment required to be used on recreational boats and commercial vessels.
Compliance Authority	Mandatory for equipment required to be used on recreational boats and commercial vessels. 33 CFR Part 159; 46 CFR Parts 2, 159-164. To approve equipment which meets minimum safety and
Compliance Authority Aim	<ul><li>Mandatory for equipment required to be used on recreational boats and commercial vessels.</li><li>33 CFR Part 159; 46 CFR Parts 2, 159-164.</li><li>To approve equipment which meets minimum safety and performance standards.</li><li>Approved equipment is intended to reduce the loss of life in marine accidents, and to prevent oil and sewage pollution of</li></ul>

Methodology	Government design approval and audit testing and inspection.
	Third party pre-approval testing and production testing and inspection.
	Manufacturer self-certification and/or production testing and inspection on selected items.
Testing	Coast Guard accredited laboratory. Manufacturer inspection on selected items.
Inspection	Coast Guard accredited laboratory. Manufacturer inspection on selected items.
Conformity Identification	List of approved/certified products and suppliers.
identification	Items are marked with Coast Guard approval number.
	Laboratory listing or classification marking required on some items.
Availability of Documentation	Publication "Equipment Lists" (U.S. Coast Guard COMSTINST M16714.3A) available for sale through Government Printing Office.
Obligations of the Manufacturer/Vendor	Manufacturer is required to produce approved item exactly as described in approved plans. Some record keeping required.
Enforcement	Delisting. Civil and criminal penalties are also available in certain cases.
Term	Five year term; renewal generally available on request.
Reciprocity	None.
Standards, Codes or Regulations	33 CFR Part 159.15 and 46 CFR Part 160-164 define applicable requirements and criteria.
Keywords	boats; commercial vessels; marine safety; marine equipment; marine pollution prevention; recreational boats; ships

Products or Services	Shipboard Navigational Aides
Department/Agency	U.S. Department of Transportation (DOT) U.S. Coast Guard Office of Navigation, Room 1422 2100 2nd Street, SW Washington, D.C. 20593 Telex: 892427 (202) 267-2267
Initiated	January 1985
Compliance	Mandatory
Authority	33 CFR Part 164; Port and Tanker Safety Act of 1978.
Aim	To approve the standards of collision avoidance at sea.
Benefits	Awareness and performance of observers is enhanced through automatically acquired information.
Agency Function	Program administrator.
Type of Program	Pre-market evaluation.
Methodology	Manufacturer self-certification.
Testing	Manufacturer's laboratory.
Inspection	Government.
Conformity Identification	Authorized label by manufacturer.
Availability of Documentation	No lists of conforming products are published.

Obligations of the Manufacturer/Vendor	Conformity obligations rest on the equipment user who must perform and document tests specified in Coast Guard regulations.
'Enforcement	Product recall (i.e. user would be required to replace equipment not in compliance.)
Term	Indefinite term.
Reciprocity	Other Federal agencies. Foreign government agencies. International organizations.
Standards, Codes or Regulations	Agency adopts standards prepared by the International Maritime Organization and the U.S. Maritime Administration.
Keywords	alarms; automatic radar plotting aids; bearing encoders; boats; collision avoidance systems; depth sounding devices; gyro compasses; loran receivers; marine safety; marine equipment; ships; speed indicators; steering gear; vessels

Products or Services	Shipping Containers
Department/Agency	U.S. Department of Transportation (DOT) U.S. Coast Guard Office of Marine Safety, Security and Environmental Protection Merchant Vessel Inspection and Documentation Division 2100 2nd Street, SW Washington, D.C. 20593 Telex: 892427 (202) 267-2978
Initiated	1977
Compliance	Mandatory
Authority	International Safe Container Act.
Aim	To provide procedures to certify containers as conforming to the International Convention for Safe Containers.
Benefits	International transport of containers is safer.
Agency Function	Program administrator and enforcement agency.
Type of Program	Container must be certified before it can be entered into international traffic.
Methodology	Third party certification.
Testing	Manufacturer or owner and Certifying Authority witness tests for container design type approval.
Conformity Identification	Containers must display a safety approval plate from the Certifying Authority in the country of registry.
Availability of Documentation	List of approved manufacturers may be obtained from the Certifying Authority in each signatory country. Coast Guard can identifying Certifying Authorities.

-	Owner and lessees are responsible for maintaining each container in a safe condition.
Enforcement	Detention of unsafe and noncomplying containers.
Term	Individual containers and vehicles are subject to re-inspection every 30 months.
Reciprocity	Certification is recognized by foreign governments and international organizations.
Standards, Codes or Regulations	Standards are included in the International Convention for Safe Containers, regulations in 49 CFR Part 450-453.
Keywords	ACEP; Approved Continuous Examination; cargo container; commercial vessels; container; CSC; design approval; International Convention for Safe Containers; marine equipment; ships

Products or Services	Automotive After Parts
Department/Agency	Environmental Protection Agency (EPA) Manufacturers Operations Division Technical Support Branch 401 M Street, SW Washington, D.C. 20460 (202) 382-2487
Initiated	1980. Modification to current procedures are expected to be proposed.
Compliance	Voluntary
Authority	Section 207 (a) of the Clean Air Act, 42 USC 7541; 40 CFR Part 85.
Aim	To enable vehicle owners to identify replacement parts that would not void the vehicle's emission warranty
Benefits	Vehicle owners have benefited from the availability of parts from competitive sources. Parts suppliers are able to compete with original equipment and vehicle manufacturers for aftermarket sales by being able to assure vehicle owners that their products are in compliance with EPA standards and the vehicle manufacturer's warranty for emission applies.
Agency Function	Program administrator.
Type of Program	Self-certification by supplier.
Methodology	Testing and certification by supplier after notifying EPA of intent to certify.
Testing	By supplier.
Conformity Identification	The part or its packaging shall bear the statement "Certified by (name of manufacturer or warranter) to EPA Emission Standards."

Availability of Documentation	Requirements are set forth in 40 CFR Part 85.
Obligations of Manufacturer/Vendor	Suppliers are required to establish and maintain records of all certification tests as well as other information related to the integrity of the parts and the certification procedures.
Enforcement	Decertification.
Term	Indefinite term.
Standards, Codes, or Regulations	Test procedures and criteria for certification of catalytic converters, positive crankcase ventilation valves, air filters, spark plugs, distributors and other ignition and carburetor components are specified in 40 CFR Part 85.
Keywords	aftermarket; air pollution; automotive parts; environment treatment; pollution control; replacement parts; vehicle emissions; warranty

Products or Services	Motor Vehicle Engines, Gasoline and Diesel
Department/Agency	Environmental Protection Agency (EPA) Office of Mobile Sources Certification Division Certification Branch 2665 Plymouth Road Ann Arbor, MI 48105 (313) 668-4280
Initiated	1972
Compliance	Mandatory for producers and distributors of motor vehicle engines, automobiles, light duty trucks, and motorcycles.
Authority	The Clean Air Act as amended in 1977, 42 USC 1857.
Aim	To control emissions from motor vehicles and engines in the interest of public health.
Benefits	The atmospheric environment has become cleaner through progressively more restrictive emissions of carbon monoxide, hydrocarbons, oxides of nitrogen, and particulates from internal combustion engines.
Agency Function	Both certifier and program administrator.
Type of Program	Pre-market evaluation; regulations provide for design evaluation, pre-production testing, and production auditing.
Methodology	Government design approval, testing, and audit in conjunction with manufacturer self-certification.
Testing	Government lab. Government accredited lab. Manufacturer's labs.
Inspection	Government. Third party.

ConformityAuthorized label by manufacturer.IdentificationList of certified products.

Availability Lists available from EPA. of Documentation

Obligations of Manufacturer must qualify new engine designs, new emission control system designs, and existing engine and emission control system designs when emission regulations change.

- Enforcement Marketing ban. Product recall.
- Term Annual with audit testing.

Reciprocity Federal certification is recognized in all states except California.

Standards, Codes, EPA prepares all criteria documents; some test methods prepared by others are referenced.

Keywords aftermarket; carbon monoxide; diesel engines; environmental treatment; evaporative emissions replacement; exhaust emissions; gasoline engines; hydrocarbons; light duty trucks; motor vehicles; motorcycles; oxides of nitrogen; pollution control; vehicles; warranty

Products or Services	Motor Vehicle Safety
Department/Agency	U.S. Department of Transportation (DOT) National Highway Traffic Safety Administration (NHTSA) Office of Vehicle Safety Compliance 400 Seventh Street, SW Room 6113 Washington, D.C. 20590 (202) 366-2832
Initiated	1966
Compliance	Mandatory
Authority	National Traffic and Motor Vehicle Safety Act of 1966 as amended.
Aim	To regulate design, construction, and performance of motor vehicles to protect the public against unreasonable risk of accidents.
Benefits	Reduction of traffic accidents, and deaths and injuries resulting from traffic accidents.
Agency Function	Program administrator.
Type of Program	Pre-market evaluation.
Methodology	Government audit. Manufacturer self-certification.
Testing	Government laboratories.
Inspection	Government.
Conformity Identification	Authorized label by manufacturer.

Availability Agency maintains list of vehicle and equipment manufacturers of Documentation who have undertaken product recalls for the purpose of achieving compliance with Federal Motor Vehicle Safety Standards. Obligations of the Manufacturers must inform the Agency, owners, purchasers, and dealers of known defects and the plans to correct the Manufacturer/Vendor defect(s). Enforcement Marketing ban. Product recall. Indefinite. Term Reciprocity Other federal agencies and state agencies. Private sector organizations may be paid contractors to the agency for detection of defects or compliance research. Standards, Codes Agency prepares criteria documents. or Regulations Keywords automobiles; compliance; motor vehicle equipment; product recall; safety; school buses; trucks; used vehicles

Products or Services	Railway Tank Cars (Includes pressurized, non-pressurized, multi-unit, and cryogenic types)
Department/Agency	U.S. Department of Transportation (DOT) Research and Special Programs Administration (RSPA) Office of Hazardous Materials Transportation 400 7th St., NW, Room 8100A Washington, D.C. 20590 (202) 366-0656
Initiated	1965 (couplers subject to approval after 1977)
Compliance	Mandatory
Authority	49 CFR 179.100-400.
Aim	To provide safe and reliable tank cars for transport of hazardous materials.
Benefits	Certification minimizes the risk of leakage or rupture of tanks, inadequacy of couplers and the improper use of tanks for designated materials.
Agency Function	Program administrator.
Type of Program	Pre-market evaluation.
Methodology	Third party certification; Association of American Railroads (AAR) provides design approval of couplers which is accepted by DOT under this regulation.
Testing	Third party acceptable to the AAR and to the Bureau of Explosives.
Inspection	Third party acceptable to the AAR and to the Bureau of Explosives.
Conformity Identification	Direct marking on tanks. Certificates of construction issued by Agency.

Availability of Documentation	Certificates of construction are kept by Agency and AAR.
Obligations of Manufacturer/Vendor	Manufacturer is obligated to use approved welders during construction.
Enforcement	Delisting or product recall is defects can be repaired.
Term	Certification is essentially indefinite.
Reciprocity	Other federal agencies. State agencies. Private sector organizations. Canadian government.
Standards, Codes or Regulations	Agency adopts standards of other organizations and provides integrating requirements.
Keywords	certified welder; design approval; hazardous materials; railroads; railway car couplers; welding

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Products or Services	Rear End Marking Devices for Passenger, Commuter and Freight Trains
Department/Agency	U.S. Department of Transportation (DOT) Federal Railroad Administration (FRA) Associate Administrator for Safety Office of Safety Enforcement 400 7th St., NW, Room 8326 Washington, D.C. 20590 (202) 366-9252
Initiated	1978
Compliance	Mandatory
Authority	Section 202, 84 Stat. 971, 45 USC 431 and 49 CFR Part 1.49(n).
Aim	To alleviate the potential for rear end collisions by requiring use of marking devices which have characteristics that assure visibility under adverse conditions encountered in service.
Benefits	Rear end collisions have decreased since implementation of this certification program.
Agency Function	Program administrator and certifier.
Type of Program	Review of self-certification submitted by railways. Review of test data submitted by device manufacturers or railways. Publication of Lists of Approved Rear End Marking Devices.
Methodology	Testing to demonstrate compliance is accomplished by manufacturers and railways in their labs or independent labs that meet specified qualifications. Railways submit a certificate signed by the chief operating officer that devices used on the railway system have been tested and comply with the FRA standard or are devices included in FRA's list of approved devices.

Conformity Identification	Inclusion on FRA's list of approved devices.
Availability of Documentation	49 CFR Part 221, Appendix B.
Obligations of Manufacturer/Vendor	Produce devices that are the same as samples tested for the original approval.
Enforcement	Civil penalties ranging from \$250 to \$2500 for each violation. Each day of each violation constitutes a separate offense.
Term	Indefinite.
Reciprocity	Recognition by state regulators as minimum requirements.
Standards, Codes or Regulations	Guidelines for Testing of FRA Rear End Marking Devices.
Keywords	colorimetric; lights; photometric; railroads; railway car; safety; strobe; transportation

Products or Services	Cylinders for Transportation of Hazardous Materials
Department/Agency	U.S. Department of Transportation (DOT) Research and Special Programs Administration (RSPA) Office of Hazardous Materials Transportation (DHM-1) 400 Seventh Street, SW Room 8100A Washington, D.C. 20590 (202) 366-0656
Initiated	1964
Compliance	Mandatory
Authority	49 CFR Part 178.36-178.68.
Aim	To provide a uniform testing program for cylinders made from a variety of metals and used for many kinds of hazardous materials.
Benefits	Consistent safety and durability of cylinders for intended use.
Agency Function	Program administrator.
Type of Program	Pre-market evaluation.
Methodology	Third party certification or manufacturer self certification.
Testing	Third party lab. Manufacturer's lab.
Conformity Identification	Authorized identity by manufacturer.
Availability of Documentation	No central registry of manufacturers; all cylinders legal for use are marked.

Obligations of the	Manufacturers must maintai	n quality control. Vendors must
Manufacturer/Vendor	cycle inventory. Users mu	ast not use out-of-date cylinders.

Enforcement Product recall.

Term Fifteen year term; regulation has no specific provision for retesting, but tanks in sound physical condition may be tested and recertified.

Reciprocity Marked cylinders are accepted throughout the U.S.

Standards, Codes Agency has integrated product requirements based on industry test methods.

Keywords containers; cylinders; hazardous materials; hydrotest; quality control; safety; transportation

Products or Services	Packages and Containers for Radioactive Material
Department/Agency	Nuclear Regulatory Commission Office of Nuclear Material Safety and Safeguards Washington, D.C. 20555 (301) 427-4122
Initiated	1974
Compliance	Mandatory
Authority	10 CFR Part 71.
Aim/Benefits	Protection of public health and safety and the environment.
Agency Function	Program administrator and certifier
Type of Program	Review and assessment of package designs prior to approval and grant of certificate of compliance. Approximately 220 different designs have been certified.
Methodology	Government design approval, inspection, and audit inspection/testing.
Testing	Applicant/Government
Inspection	Applicant/ Government.
Conformity Identification	Approved packages are assigned an identification number.
Availability of Documentation	Part 71 Docket Files. United States Nuclear Regulatory Commission Public Document Room Washington, D. C. 20555 (202) 634-3273
Obligations of Manufacturer/Vendor	Report defects or noncompliance. Report significant reduction of effectiveness during use.

Enforcement Order, denial, fine. 5 year renewable. Term Inspection prior to each use. Reciprocity Recognition of certification by: - Department of Transportation (DOT). - Foreign governments upon issuance of DOT Competent Authority Certificate. Standards, Codes, U. S. Nuclear Regulatory Commission Regulatory Guides or Regulations (Division 7). 10 CFR Part 71 and 10 CFR Part 21. Keywords environment; nuclear; packaging; radioactive material;

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Products or Services	Packaging of Hazardous Materials for Export
Department/Agency	U.S. Department of Transportation (DOT) Research and Special Programs Administration (RSPA) Office of Hazardous Materials Transportation 400 7th St., NW, Room 8100A Washington, D.C. 20590 (202) 366-0656
Initiated	March 13, 1985
Compliance	Voluntary
Authority	49 USC 1804, 1805, 1808; 49 CFR Part 1.53; Appendix A to Part 1.
Aim	Designate third party testing agencies through which shippers and container manufacturers may demonstrate conformance of packaging designs with United Nations (U.N.) standards.
Benefits	To enhance the use of U.S. packaging in international transportation and facilitate the ability of U.S. companies to compete in export markets.
Agency Function	Program administrator and National Competent Authority in accordance with U.N. Recommendations.
Type of Program	Pre-market evaluation.
Methodology	Materials Transportation Bureau (MTB) designates third party approval agencies to evaluate and issue approval certificates for intermodal portable tanks and certifications of conformance for other types of packaging.
Testing	Testing by third party (manufacturers and shippers labs) is permitted if acceptable to the approval agencies.
Inspection	Subsequent inspection of packaging is not part of this program.

ConformityCertificates are provided to shippers and/or manufacturersIdentificationby approval agencies.

Enforcement Designation of an approval agency to issue certification may be withdrawn for failure to abide by requirements of the program.

Indefinite.

Term

Reciprocity Certification in accordance with U.N. Recommendations is intended to avoid acceptance testing and packaging approval in each country which might have such requirements.

Standards, Codes Standards are set forth in the U.N. Recommendation (Transport of Dangerous Goods), and DOT requirements listed in 49 CFR Part 171, Subchapter C.

Keywords containers; export; hazardous materials; National Competent Authority; safety; transportation; United Nations

Products or Services	Packaging of Radioactive Materials for Transport
Department/Agency	U.S. Department of Transportation (DOT) Research and Special Programs Administration (RSPA) Office of Hazardous Materials Transportation 400 7th St., NW, Room 8100A Washington, D.C. 20590 (202) 366-0656
Initiated	1975
Compliance	Mandatory
Authority	49 USC 1803, 1808 as amended; 49 CFR Part 173.465-173.469.
Aim	To provide packaging for radioactive materials which maintains integrity under mild (Type A) or severe (Type B) fault conditions.
Benefits	Transport of radioactive materials is accomplished with minimum radiation exposure to personnel.
Agency Function	Certifier.
Type of Program	Pre-market evaluation.
Methodology	Government design approval, inspection, and validation of test data submitted by manufacturer based on own or third party tests.
Testing	Third party or manufacturer's lab.
Inspection	Government or third party.
Conformity Identification	Mark on packaging authorized by agency, known as Competent Authority within International Atomic Energy Agency scheme.

Availability of Documentation	Lists of approved manufacturers maintained in each country. Packaging of certain radioactive materials requires acceptance by Competent Authority in both shipping and receiving countries.
Obligations of Manufacturer/Vendor	Maintain specified quality control records; cooperate in investigation of any package failures.
Enforcement	Marketing ban. Product recall.
Term	Indefinite. Certification is based on prototype acceptance.
Reciprocity	Type A packaging for domestic use accepted by other federal, state, and private organizations. Type B packaging for international use, subtype U (unilateral) is accepted with mark from one country. Subtype M (multilateral) requires mark from sending and receiving countries and transit countries for certain materials.
Standards, Codes or Regulations	Agency establishes requirements and procedures.
Keywords	fissile material; IAEA; package approval; packaging; quality assurance; radioactive material; safety; transportation

Products or Services	Pipelines for Hazardous Fluids
Department/Agency	U.S. Department of Transportation (DOT) Research and Special Programs Administration (RSPA) Office of Pipeline Safety 400 7th St., NW, Room 8417 Washington, D.C. 20590 (202) 366-4595
Initiated	1968
Compliance	Mandatory
Authority	49 USC 1803-1809 as amended.
Aim	To provide a mechanism for regulating the installation and maintenance of pipelines for the transportation of hazardous materials.
Benefits	Safety record of such pipelines in the U.S. meets expectations.
Agency Function	Program administrator.
Type of Program	Pre-installation review with periodic testing of safety equipment throughout the useful life of the pipeline.
Methodology	Third party certification: welder and plastic pipe assemblers.
	Manufacturer self-certification: valves, pressure-limiting services, and overall installation to specified standards.
Testing	Third party or manufacturer's lab.
Inspection	Third party.
Conformity Identification	Lists of qualified welders/installers and approved installations are published.

- Availability of Certification of welders by the American Welding Society; Documentation Comparable program by the installing contractor may be acceptable to DOT. List of approved pipelines kept by DOT.
- Obligations of Manufacturer/Vendor Wanufacturer/Vendor Wanufacturer/Vendor Owner of pipeline is responsible for annual tests of pressure-limiting devices and for reports on all accidents related to the use of the pipeline. Accidents involving deaths are investigated by the National Transportation Safety Board.
- Enforcement Delisting; individual welders or installers may be required to undergo additional training; faulty valves or limiting devices may have to be replaced; pipeline could be decommissioned temporarily.
- Term Pressure-limiting devices must be inspected on approximately an annual basis, not to exceed a 17 month interval.
- Reciprocity Approved pipelines are not regulated by any other federal or state agency.
- Standards, Codes Agency mainly adopts standards of other organizations. or Regulations
- Keywords certified welder; hazardous materials; pipelines; pressure-limiting devices; qualified plastic pipe assembler; safety; welding

Products or Services	Special Tanks for Transport of Hazardous Materials
Department/Agency	U.S. Department of Transportation (DOT) Research and Special Programs Administration (RSPA) Office of Hazardous Materials Transportation 400 7th St., NW, Room 8100A Washington, D.C. 20590 (202) 366-0656
Initiated	1964
Compliance	Mandatory
Authority	49 CFR Part 178.270-272. (Special category reauthorized by P.L. 93-633.)
Aim	To provide a uniform means for assuring the reliability of containers for shipping designated hazardous materials.
Benefits	Materials are transported safely and efficiently and personal injuries due to container failure are minimized.
Agency Function	Program administrator.
Type of Program	Pre-market evaluation.
Methodology	Government design approval. Third party certification.
Testing	Third party or manufacturer's lab.
Inspection	Third party.
Conformity Identification	Authorized mark applied by manufacturer.

Availability of Agency maintains list of firms authorized to manufacture such tanks.

Obligations of Manufacturer must maintain integrity of design, quality Manufacturer/Vendor control, and cooperate in investigation of suspected faults.

Enforcement Delisting or product recall.

Term Retest; user/owner to arrange for documented visual inspection at 2 1/2 year intervals; valves and pressure relief devices must be retested at 2 1/2 year intervals; and complete tank must be hydrotested every 5 years.

Reciprocity Other federal agencies. State agencies Private sector organizations. Canadian government.

Standards, Codes Agency integrates standards of other organizations into or Regulations the program.

Keywords hazardous materials; hydrotesting; pressure relief devices; quality control; safety valves; tanks; transportation

Products or	Tanks for Transport of Hazardous Materials
Services	
Department/Agency	U.S. Department of Transportation (DOT) Research and Special Programs Administration (RSPA) Office of Hazardous Materials Transportation 400 7th St., NW, Room 8100A Washington, D.C. 20590 (202) 366-0656
Initiated	1964
Compliance	Mandatory
Authority	49 CFR Part 173.32-34, 49 USC 1803-1809.
Aim	To provide safe and reliable containers for domestic shipment of hazardous materials.
Benefits	Certification minimizes the risk of leakage or rupture of tanks and improper use of tanks for designated materials.
Agency Function	Program administrator.
Type of Program	Pre-market evaluation. (Certain types of tanks in use at time regulation went into effect which were made to specific standards of the Association of American Railroads were approved.)
Methodology	Manufacturer self-certification.
Testing	Third party or manufacturer's lab.
Inspection	Periodic inspection is performed by owner.
Conformity Identification	Certain tanks are identified by marking as specified in the regulation.

Availability of Documentation	Agency maintains list of manufacturers of certified tanks by type.
Obligations of Manufacturer/Vendor	Manufacturer must maintain design control and submit design changes for approval.
Enforcement	Marketing ban (also extends to distributors).
Term	Retest; user/owner to arrange for documented visual inspection at 2 1/2 year intervals; valves and pressure relief devices must be retested at 2 1/2 year intervals; and complete tank must be hydrotested every 5 years.
Reciprocity	Other federal agencies. State agencies. Private sector organizations. Canadian government.
Standards, Codes or Regulations	Agency integrates standards of other organizations into the program.
Keywords	hazardous materials; hydrotesting; portable tanks; pressure relief devices; quality control; safety valves; transportation

Products or Services	Refrigerated Vehicles and Refrigeration Units
Department/Agency	U.S. Department of Agriculture Office of Transportation ATP Manager Washington, D.C. 20250-4500 Telephone: (202) 653-6275 Telex: 89491 FAX: (202) 653-6327
Initiated	1986
Compliance	Mandatory only for equipment transporting perishable foodstuffs between countries in Europe, when the receiving country is a contracting party to the Agreement on the International Carriage of Perishable Foodstuffs Act and on the Special Equipment To Be Used for Such Carriage (ATP). Transport operations involving a movement of more than 150 km by sea are exempt. The Agreement does not apply to carriage in the U.S. or any of its territories.
Authority	7 CFR Part 3300 and the International Carriage of Perishable Foodstuffs Act of 1982, P.L. 97-325.
Aim	The Agreement was developed by the Economic Commission for Europe, of which the U.S. is a member, to improve the conditions of preservation of perishable foodstuffs during their carriage, particularly in international trade.
Benefits	The objective of U.S. participation in the Agreement are to protect and expand trade in perishable foodstuffs transported in U.S. equipment to Europe and improve the sale of U.S. made equipment.
Agency Function	Certifier and program administrator.
Type of Program	Inspection, testing and certification of equipment.

Manufacturer's guarantee that serially-produced equipment Methodology conforms to the reference equipment which has been tested. Agency approves test facilities, audits inspections and testing, and provides ATP certificates. Testing Agency approves and monitors test facilities. Inspection Provides for self-inspection of equipment in service by U.S. owners based on reference tests in approved test facilities. Agency issues U.S. ATP certificates based on statements and reports of the owners and the test facilities. Conformity Approved equipment requires an authorized ATP certification Identification plate and distinguishing mark along with a manufacturers plate. Availability Lists of approved test facilities and fees for of Documentation certificates can be obtained from the ATP Manager at the above address. Copies of the Agreement, the Act, and the Senate Report, and 7 CFR Part 3300 are also available. Obligations of the Approved test facilities must be open to the public, Manufacturer/Vendor maintain test records for three years, and permit the ATP Manager to review records and observe tests. Owners of equipment with U.S. ATP certificates have the responsibility to maintain equipment in good repair. Enforcement Delisting of test stations, laboratories, and certificates. Approval of test stations and laboratories is good for 5 Term years. Certificates for new equipment are good for 6 years. Renewal certificates are good for 6 years with a test. Renewals or transfers with an inspection are good for 3 years minimum. Reciprocity U.S. ATP certificates are recognized by the 21 countries that are contracting parties to the Agreement under a reciprocal arrangement.

Standards, Codes or Regulations The Agreement and 7 CFR 3300 define all the acceptance criteria.

Keywords

containers; food; frozen food; international agreement; rail cars; refrigerated; refrigeration units; trailers; transportation

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# SECTION X

# MISCELLANEOUS PRODUCTS AND SERVICES

#### SECTION X MISCELLANEOUS PRODUCIS AND SERVICES INDEX

#### REFERENCES IN THIS SECTION

AIR AND WATER	TREATMENT FA	CILITIES	•••••	
BREATH ALCOHOI	J TESTERS AND	THEIR CALIBRATION	UNITS	
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# REFERENCES IN OTHER SECTIONS

DRINKING WATER
EQUIPMENT AND MATERIALS USED IN THE WORKPLACE
PESTICIDE APPLICATORS, PRIVATE AND COMMERCIAL

Products or Services	Air and Water Treatment Facilities (CHANGES IN THE TAX LAW HAVE ENDED THE NEED FOR THIS CERTIFICATION)
Department/Agency	Environmental Protection Agency (EPA) Contact Appropriate Regional Administrator. Regional Administrators located in Boston, MA; New York, NY; Philadelphia, PA; Atlanta, GA; Chicago, IL; Dallas, TX; Kansas City, KS; Denver, CO; San Francisco, CA; and Seattle, WA.
Initiated	1976
Compliance	Voluntary
Authority	40 CFR Part 20.
Aim	To identify facilities which reduce air or water pollution for the purpose of qualifying for investment tax credit.
Benefits	Increased investment by industries in pollution abatement equipment and facilities.
Agency Function	Certifier; some states also perform a parallel function for local tax purposes.
Type of Program	Tax incentive program.
Methodology	Government design approval.
Testing	No testing.
Inspection	No inspection.
Conformity Identification	Lists of certified facilities maintained by state certifying agencies and EPA Regional Offices.
Availability of Documentation	Lists from states and EPA Regional Offices.

Obligations of Facilities must submit plans for review whenever Manufacturer/Vendor modifications are made.

Enforcement Delisting.

Term Indefinite term.

Reciprocity No reciprocity.

Standards, Codes, or Regulations EPA defines acceptance criteria.

Keywords air quality; depreciation; investment tax credit; pollution control; waste heat removal; waste water treatment; water quality

Products or Services	Breath Alcohol Testers and Their Calibration
Department/Agency	U.S. Department of Transportation (DOT) National Highway Traffic Safety Administration (NHTSA) Office of Alcohol and State Programs Alcohol Programs Division, (NTS-21) 400 Seventh Street, SW Room 5130 Washington, D.C. 20590 (202) 366-9581
Initiated	1984
Compliance	Voluntarily adopted by states and local jurisdictions. Manufacturers voluntarily submit testers for evaluation and listing.
Authority	23 USC 402 and 49 CFR Part 1.50.
Aim	Assist states and local communities by providing a centralized qualification test program for breath-testing devices designed to collect evidence in law enforcement programs.
Benefits	States have adopted the NHTSA model specification for evidential breath testers and a calibration unit developed by the National Bureau of Standards (NBS). This qualification program enables states and local jurisdictions to buy equipment that has demonstrated compliance with these model specifications. They avoid the cost of individual tests and use equipment that is rugged and reliable and bears the scrutiny of challenges in court cases. Manufacturers benefit in not having to arrange for individual tests in numerous jurisdictions.
Agency Function	Certifier.
Type of Program	Qualification testing.
Methodology	Government testing.
Testing	Testing is accomplished by the DOT Systems Center.

Qualified manufacturers are listed on a Conforming Products List (CPL).
Model specifications and CPL's are published in the Federal Register; 49 FR 48854. Currently thirteen manufacturers of breath measurement devices are listed. Four of these are foreign suppliers.
Manufacturers must submit a unit for testing.
Indefinite.
Acceptance criteria have been developed by NHISA in collaboration with NBS.

Products or	Hazardous Household Substances
Services	(Chemicals which are toxic, corrosive, flammable irritating, radioactive or pressure-generating, and devices which are used with these chemicals and may injure intended users.)
Department/Agency	Consumer Product Safety Commission (CPSC) Office of the General Counsel 5401 Westbard Avenue, Room 200 Bethesda, MD 20207 (202) 492-6980
Initiated	July 1960
Compliance	Mandatory
Authority	P.L. 96-613 as amended by the Poison Prevention Packaging Act, P.L. 91-601.
Aim	To reduce the risk of injury to all intended users of designated substances and devices.
Benefits	Informative labeling is now in effect and selected products have been banned.
Agency Function	Program administrator.
Type of Program	Pre-marketing evaluation.
Methodology	Government approval of labeling information to be provided with designated hazardous substances.
Testing	Manufacturer's lab. Government labs.
Inspection	Government.
Conformity Identification	Authorized mark or label by manufacturer.

Availability of Documentation	List of banned hazardous substances may be obtained from CPSC.
Obligations of Manufacturer/Vendor	Carriers must keep records of interstate shipment of designated substances.
Enforcement	Marketing ban. Product recall.
Term	Indefinite term.
Reciprocity	Approved labeling is recognized by other federal agencies, state governments, and private organizations.
Standards, Codes, or Regulations	Criteria for designating substances as hazardous are prepared by the Commission.
Keywords	banned products; corrosive; flammability; hazardous substances; irritant; misbranded substances; radioactivity; toxicity

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This index may be used by readers to learn what certification programs a particular agency operates when only the agency's acronym or other limited designation is known. Agencies are listed alphabetically by acronym/designation.

#### ACRONYM

AMS/USDA
APHIS/USDA
BATF/TREASURY
BIA/DOI
Coast Guard, DOT
Conservation and Renewable Energy/DOE
CPSC
Departmental Information Systems, TREASURY
DSPO/DOD
EPA
FAA/DOT
FCC
FDA/DHHS
FGIS/USDA
FHA/HUD
FRA/DOT
FSIS/USDA
FTC
GSA
HCFA/DHHS
MMS/DOI
MSHA/DOI
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## DEPARIMENT/AGENCY INDEX

This index may be used by readers to learn what certification programs a particular department and/or departmental agency operates when both the department and agency's names are known. Departments are listed alphabetically, followed by a listing of independent federal agencies.

## DEPARIMENT/INDEPENDENT AGENCY

## DEPARIMENTS

DEPARIMENT OF AGRICULTURE Agricultural Marketing Service
DEPARIMENT OF COMMERCE National Bureau of Standards
DEPARIMENT OF DEFENSE Office of Standardization and Acquisition Support
DEPARIMENT OF HEALTH AND HUMAN SERVICES Food and Drug Administration53, 55, 57, 59, 61, 63, 107, 145, 147, 149 Health Care Financing Administration
DEPARIMENT OF HOUSING AND URBAN DEVELOPMENT Federal Housing Administration
DEPARIMENT OF THE INTERIOR Bureau of Indian Affairs
DEPARIMENT OF LABOR Mine Safety and Health Administration
DEPARIMENT OF TRANSPORTATION Coast Guard
Bureau of Alcohol, Tobacco, and Firearms

# INDEPENDENT AGENCIES

CONSUMER PRODUCT SAFETY COMMISSION
ENVIRONMENTAL PROTECTION AGENCY
FEDERAL COMMUNICATIONS COMMISSION
FEDERAL TRADE COMMISSION
GENERAL SERVICES ADMINISTRATION
NUCLEAR REGULATORY COMMISSION
VETERANS ADMINISTRATION

This index may be used by readers to learn what certification programs a particular agency operates when only the agency's name is known. Agency names are listed alphabetically.

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Veterans Administration	

# APPENDIX I

# Information Available From

# Office of Standards Code and Information (OSCI) National Bureau of Standards Administration Building, Room A629 Gaithersburg, MD 20899 (301) 975-4040

# o <u>Directory of International and Regional Organizations Conducting</u> <u>Standards-Related Activities</u> (NBS SP 649)

Directory contains information on 272 international and regional organizations which conduct standardization, certification, laboratory accreditation, or other standards-related activities. Volume describes their work in these areas, as well as the scope of each organization, national affiliations of members, U.S. participants, restrictions on membership, and the availability of any standards in English.

# o Standards Activities of Organizations in the United States (NBS SP 681)

The directory summarizes the standardization activities of more than 750 organizations in the United States, including federal and state agencies and approximately 420 private sector groups that develop standards. It also contains listings of state procurement offices, sources of standards documents and information, a subject index and related listings that cover acronyms and initials, defunct bodies and organizations with name changes.

# o Private Sector Product Certification Programs in the United States (NBS SP 703)

This directory presents information from 109 private sector organizations in the United States which engage in product certification activities. Entries describe the type and purpose of each organization, the nature of the activity, product certified, standards used, certification requirements, availability and cost of services, and other relevant details.

# o <u>Federal Government Certification Programs for Products and Services</u> (NBS SP 714)

This directory presents information on 61 U.S. Government certification programs for products and services. Entries describe the scope and nature of each certification program, testing and inspection practices, standards used, methods of identification and enforcement, reciprocal recognition or acceptance of certification, and other relevant details.

## o <u>KWIC Index</u> (Computer Output Microform (COM) produced)

The KWIC Index contains the titles of more than 25,000 U.S. voluntary product and engineering standards. A standard can be located by means of any significant or key word in the title. Key words are arranged alphabetically. A standard with five key words, for example, would therefore be listed in five different places. To purchase microfiche copies of the 1987 revision of the Index, contact the National Technical Information Service, 5285 Port Royal Road, Springfield, VA 22161; (703) 487-4600. Use order no. PB87-133377; cost \$18.00.

#### o tht news

This newsletter provides information on government programs and available services established in support of the GATT Agreement on Technical Barriers to Trade (Standards Code). <u>tbt news</u> reports on the latest notifications of proposed foreign regulations; bilateral consultations with major U.S. trade partners; programs of interest to U.S. exporters; and availability of standards and certification information. Subscription is free upon request.

## o Technical Barriers to Trade

This booklet explains the basic rules of the international Agreement on Technical Barriers to Trade negotiated during the Tokyo Round of the Multilateral Trade Negotiations (MIN), and describes Title IV of the U.S. Trade Agreements Act of 1979 which implements the United States' obligations under the Agreement. The Agreement, popularly known as the Standards Code, was designed to eliminate the use of standards and certification systems as barriers to trade. The booklet describes the functions of the Departments of Commerce and Agriculture, the Office of the U.S. Trade Representative, and the State Department in carrying out the U.S.'s responsibilities.

#### o "GATT Standards Code Activities"

This brochure gives a brief description of NBS' activities in support of the Standards Code. These activities include operating the U.S. GATT inquiry point for information on standards and certification systems; notifying the GATT Secretariat of proposed U.S. regulations; assisting U.S. industry with trade-related standards problems; responding to inquiries on foreign and U.S. proposed regulations; and preparing reports on the Standard Code.

# o <u>Report to the United States Congress on the Agreement on Technical Barriers to</u> <u>Trade - "Standards Code"</u>

This 2nd triennial report describes the programs and activities established to implement the Standards Code in the United States by the four responsible U.S. government agencies: Office of the U.S. Trade Representative; Department of Commerce (National Bureau of Standards, International Trade Administration); Department of Agriculture and Department of State.

o Free Handout Material. Handouts are available on ADIS, NCSCI and GATT activities, and standards-related information (such as government sources of specifications and standards, use of the KWIC index, foreign and international standards bodies, U.S. standards organizations, state purchasing offices). A NCSCI fact sheet and an ADIS publications list (bibliography) is also available.

In addition to general inquiry services, the following assistance is also available:

o GATT Hotline. A telephone hotline provides current information received from the GATT Secretariat in Geneva, Switzerland, on proposed foreign regulations which may significantly affect trade. The recorded message is updated weekly and gives the product, country, closing date for comments (if any) and Technical Barriers to Trade (TBT) notification number. <u>The hotline number is (301) 975-</u> <u>4041 (not toll-free)</u>.

o Assistance to U.S. and Foreign Exporters. Current regulations and certification information for the manufacture of products in the U.S. for export are obtained from foreign countries. To aid foreign exporters, NCSCI provides directory information to state offices prepared to respond to queries concerning conditions to be met by goods for sale in their state, as well as standards and certification information for export to the U.S.

# APPENDIX II

# Information Available From

Publications Office U.S. Department of Agriculture Foreign Agricultural Service (FAS) 14th & Independence Ave., S.W. Room 5074-South Building Washington, D.C. 20250-1000 (202) 447-7937

## o Food and Agricultural Export Directory

This directory is published by the High Value Products Division, FAS for firms engaged in exporting and marketing U.S. agricultural and food products. It provides up-to-date listings and brief descriptions of federal and state agencies, American embassy personnel abroad, trade associations, and related other organizations that offer services and advice in exporting and marketing U.S. agricultural and food products overseas.

# o Agriculture's Emissaries Overseas

This directory lists the names, addresses, telexes and telephone numbers and descriptions of agricultural counselors and attaches overseas.

# o U.S. Agricultural Trade Offices Overseas

This directory provides the names, addresses, telexes and telephone numbers and descriptions of FAS agricultural trade offices overseas.

#### o The U.S. Farmer's Export Arm

This publication describes services of the Foreign Agricultural Service designed to increase U.S. farm exports.

## o Partners in Trade Promotion

This publication describes the market development cooperator program and lists participants.

#### o How to Get Information on Agricultural Trade

This publication contains a check list and forms to order export publications developed by the U.S. Department of Agriculture.

## o FAS Reports

These are press releases announcing potential sales opportunities resulting from the extension of Commodity Credit Corporation (CCC) or P.L. 480 credit to foreign countries.

## o Foreign Agriculture Magazine

This monthly magazine for U.S. business selling farm products overseas provides tips on how best to break into exporting, descriptions of the markets with the greatest sales potential, and export assistance available from the U.S. Department of Agriculture. These articles are generally accompanied by tables and graphs to let readers know at a glance what is going on overseas. Periodic special issues - such as one devoted to the export of value-added items - provide a more in-depth look at important segments of the overseas market. And every month short wrap-ups of foreign buying trends, new competitors and products, trade policy developments, and promotion activities going on around the world are highlighted.

## o Foreign Agricultural Trade of the United States

This is a bimonthly statistical and analytical review of the U.S. agricultural trade.

# o Foreign Agricultural Circulars

These periodic reports provide agricultural exporters with timely, reliable information on the needs of foreign buyers, changing consumer preferences, and the supply and demand situation in countries around the world. World agricultural information and updates on special FAS export services for the food and agricultural trade are highlighted in the circulars.

# o Weekly Roundup of World Production and Trade

This report presents current news and statistics on various commodities, and a summary of recent developments in world production and trade. This report is available at no cost within the United States.

## o World Crop Production

This monthly report provides the U. S. Department of Agriculture's estimates on the production of wheat, coarse grains, oilseeds, and cotton in major countries and selected regions of the world.

## o The World Agricultural Transportation Report

This is a monthly publication on key transportation issues and developments related to agricultural exports.

## o Ocean Liner Cargo Service Directory

A reference of ocean transportation services available to U.S. exporters.

o Export Handbook for U.S. Agricultural Exports, (No. #593)

This publication is provided by the U.S. Department of Agriculture, Office of Transportation. It gives guidelines on shipping, export packing, and transporting selected agricultural products. o Export Product Review Program (EPR). The EPR program is a fee-based service which provides U. S. exporters and manufacturers of pre-packaged food products with advance information on the general and product specific regulations on product labeling, additive restrictions, ingredient requirements, and product standards for their product in a targeted foreign country. The product evaluation includes an in country review by local government officials to determine whether the product can be admitted or if approval might be given if certain changes were made. An indication of the product's marketability in the country completes the evaluation. For more information, contact: Audrey Talley, Export Product Review Program, HVPD/FAS, Room 4647-South, Washington, D. C. 20250-1000, Telephone: (202) 475-3408.

o Agricultural Information and Marketing Services (AIMS). The AIMS program functions as a liaison between American companies and foreign buyers to help identify market opportunities and promote U.S. agricultural and food products overseas. AIMS is a fee-based program offering the following services:

#### o Export Briefs

This weekly bulletin includes all trade leads processed by FAS each week. These trade leads are processed as they are received from abroad and disseminated through a direct mail service to interested U.S. suppliers. The <u>Export Briefs</u> is targeted toward export agents, trade associations, and companies interested in export opportunities for a wide variety of food and agricultural products. The bulletin also highlights upcoming trade shows and foreign trade developments.

An important feature of the <u>Export Briefs</u> bulletin is the USDA Technical Office's section on foreign countries' proposed changes in agricultural standards and regulations. Foreign countries who are signatories to the General Agreement on Technical Barriers to Trade (GATT) (also known as the Standards Code) are required to notify the GATT Secretariat of these changes and allow time for comments from other signatories on possible impacts on trade. Although the USDA Technical Office was established to inform and collect comments from interested parties on changes in agricultural standards by signatories to the Standards Code, this section in the <u>Exports Briefs</u> also includes information on changes in the regulations and standards of non-signatory countries. For more information on the USDA Technical Office, Building 1072, BARC-East, Beltsville, MD 20705, Telephone: (301) 344-2651

## o Buyer Alert

This service goes a step beyond product introduction. It disseminates actual sales announcements from U.S. suppliers to foreign exporters in the leading value-added export markets for U.S. agricultural and food products.

#### o Contacts for U.S. Agricultural Products

This monthly newsletter for agricultural products assists American firms by introducing their food and agricultural products to foreign markets. Contacts are sent to FAS agricultural offices overseas for distribution to prospective foreign buyers. The newsletter is translated into Japanese, Spanish, French, Italian and Greek and mailed to thousands of buyers worldwide. Product announcements are included on a first-come, first-served basis.

## o International Marketing Profiles

The AIMS program offers two series of International Marketing Profile reports - Product Marketing Profiles and Country Marketing Profiles. Both reports draw from the world's major statistical reporting services to present information and statistics on the trade of particular commodities and specific countries.

To receive information on these or other AIMS services, contact: AIMS, FAS/HVPD, Room 4647-South, Washington, D.C. 20250-1000, Telephone: (202) 475-3408.

# APPENDIX III

# Format Used for Each Entry

Products or Services	The products/services covered by this program.
Department/Agency	The responsible office/agency/department, as well as their address, telephone, telex, and fax numbers if available.
Initiated	The date the program was initiated.
Compliance	Whether the program is mandatory, voluntary, or mandatory only under specified circumstances.
Authority	The public laws, sections in the <u>Code of Federal Regulations</u> or in the <u>Federal Register</u> which authorize the agency to conduct the program.
Aim	The problems or conditions which prompted the program's establishment and how the program will or has remedied them.
Benefits	Information on the benefits (decreased accident rate, improved product quality/safety, improved competition, etc.) of the program.
Agency Function	Information on whether the agency certifies the product or service itself or whether the actual certification is conducted by another specified party and the agency serves as program administrator.
Type of Program	Whether the program requires pre-market evaluation, post- market assessment, assessment prior to government purchase, or some other type of evaluation scheme.
Methodology	The methodology used by the program to ensure compliance with certification criteria, such as government inspection, third party testing, compliance with Good Manufacturing Practices, etc.

Testing Whether the agency or another specified party is responsible for any tests conducted on the product/service. Inspection Whether the agency or another specified party is responsible for any inspections of the product/service. Conformity The method, if any, that the agency uses to identify that Identification the product/service has been certified. Availability How information on lists of approved products/suppliers or of Documentation other documentation on the program can be obtained. Enforcement The remedies (product recall, marketing ban, product seizure, etc.) available to the agency in cases of noncompliance with certification criteria. The length of time the certification is valid. Term Reciprocity Any recognition of the certification by other federal or state agencies, private sector organizations, foreign governments, or international organizations. The documents which define the acceptance criteria for Standards, Codes, or Regulations the certification. Keywords Words describing key characteristics of the program.

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Document describes a computer program; SF-185, FI	PS Software Summary, is attached.	
This directory, which represents Agriculture (USDA) and the Nation provide updated information on fe services. This directory is a re <u>Certification Programs for Produce</u> published in April 1986. This directory is part of ongoing comprehensive databases on standare related information in accordance Act of 1979. This material has h industry, and the public for infor programs.	hal Bureau of Standards ederal certification pro- evision of NBS SP 714, <u>Fo</u> ets and Services, edited of NBS/USDA efforts to estards, regulations, certi- e with the requirements been compiled to meet the	(NBS), is designed to grams for products and ederal Government by Robert B. Toth and tablish and maintain fication programs and of the Trade Agreements e needs of government,
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20402.		15. Price
Order From National Technical Information Service (	NTIS), Springfield, VA. 22161	



# **Periodical**

**Journal of Research**—The Journal of Research of the National Bureau of Standards reports NBS research and development in those disciplines of the physical and engineering sciences in which the Bureau is active. These include physics, chemistry, engineering, mathematics, and computer sciences. Papers cover a broad range of subjects, with major emphasis on measurement methodology and the basic technology underlying standardization. Also included from time to time are survey articles on topics closely related to the Bureau's technical and scientific programs. Issued six times a year.

# Nonperiodicals

Monographs—Major contributions to the technical literature on various subjects related to the Bureau's scientific and technical activities.

Handbooks—Recommended codes of engineering and industrial practice (including safety codes) developed in cooperation with interested industries, professional organizations, and regulatory bodies.

**Special Publications**—Include proceedings of conferences sponsored by NBS, NBS annual reports, and other special publications appropriate to this grouping such as wall charts, pocket cards, and bibliographies.

Applied Mathematics Series—Mathematical tables, manuals, and studies of special interest to physicists, engineers, chemists, biologists, mathematicians, computer programmers, and others engaged in scientific and technical work.

**National Standard Reference Data Series**—Provides quantitative data on the physical and chemical properties of materials, compiled from the world's literature and critically evaluated. Developed under a worldwide program coordinated by NBS under the authority of the National Standard Data Act (Public Law 90-396). NOTE: The Journal of Physical and Chemical Reference Data (JPCRD) is published quarterly for NBS by the American Chemical Society (ACS) and the American Institute of Physics (AIP). Subscriptions, reprints, and supplements are available from ACS, 1155 Sixteenth St., NW, Washington, DC 20056.

**Building Science Series**—Disseminates technical information developed at the Bureau on building materials, components, systems, and whole structures. The series presents research results, test methods, and performance criteria related to the structural and environmental functions and the durability and safety characteristics of building elements and systems.

**Technical Notes**—Studies or reports which are complete in themselves but restrictive in their treatment of a subject. Analogous to monographs but not so comprehensive in scope or definitive in treatment of the subject area. Often serve as a vehicle for final reports of work performed at NBS under the sponsorship of other government agencies.

**Voluntary Product Standards**—Developed under procedures published by the Department of Commerce in Part 10, Title 15, of the Code of Federal Regulations. The standards establish nationally recognized requirements for products, and provide all concerned interests with a basis for common understanding of the characteristics of the products. NBS administers this program as a supplement to the activities of the private sector standardizing organizations.

**Consumer Information Series**—Practical information, based on NBS research and experience, covering areas of interest to the consumer. Easily understandable language and illustrations provide useful background knowledge for shopping in today's technological marketplace.

Order the above NBS publications from: Superintendent of Documents, Government Printing Office, Washington, DC 20402.

Order the following NBS publications—FIPS and NBSIR's—from the National Technical Information Service, Springfield, VA 22161.

**Federal Information Processing Standards Publications (FIPS PUB)**—Publications in this series collectively constitute the Federal Information Processing Standards Register. The Register serves as the official source of information in the Federal Government regarding standards issued by NBS pursuant to the Federal Property and Administrative Services Act of 1949 as amended, Public Law 89-306 (79 Stat. 1127), and as implemented by Executive Order 11717 (38 FR 12315, dated May 11, 1973) and Part 6 of Title 15 CFR (Code of Federal Regulations).

**NBS Interagency Reports (NBSIR)**—A special series of interim or final reports on work performed by NBS for outside sponsors (both government and non-government). In general, initial distribution is handled by the sponsor; public distribution is by the National Technical Information Service, Springfield, VA 22161, in paper copy or microfiche form.

U.S. Department of Commerce National Bureau of Standards Gaithersburg, MD 20899

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