

NBS Special Publication 739

Directory of Federal Government Certification Programs

Maureen Breitenberg, Editor

ational Bureau of Standards -QC-100 · U57 No.739 1988

he National Bureau of Standards¹ 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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- Chemical Physics
- Analytical Chemistry

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- Electronics and Electrical Engineering²
- Manufacturing Engineering
- Building Technology
- Fire Research
- Chemical Engineering³

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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:

- Information Systems Engineering
- Systems and Software Technology
- Computer Security
- Systems and Network Architecture
- Advanced Computer Systems

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:

- Ceramics
- Fracture and Deformation³
- Polymers
- Metallurgy
- Reactor Radiation

¹Headquarters and Laboratories at Gaithersburg, MD, unless otherwise noted; mailing address Gaithersburg, MD 20899.

²Some divisions within the center are located at Boulder, CO 80303.

Located at Boulder, CO, with some elements at Gaithersburg, MD

Research Information Center National Bureau of Standards Gaithersburg, Maryland 20899

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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.

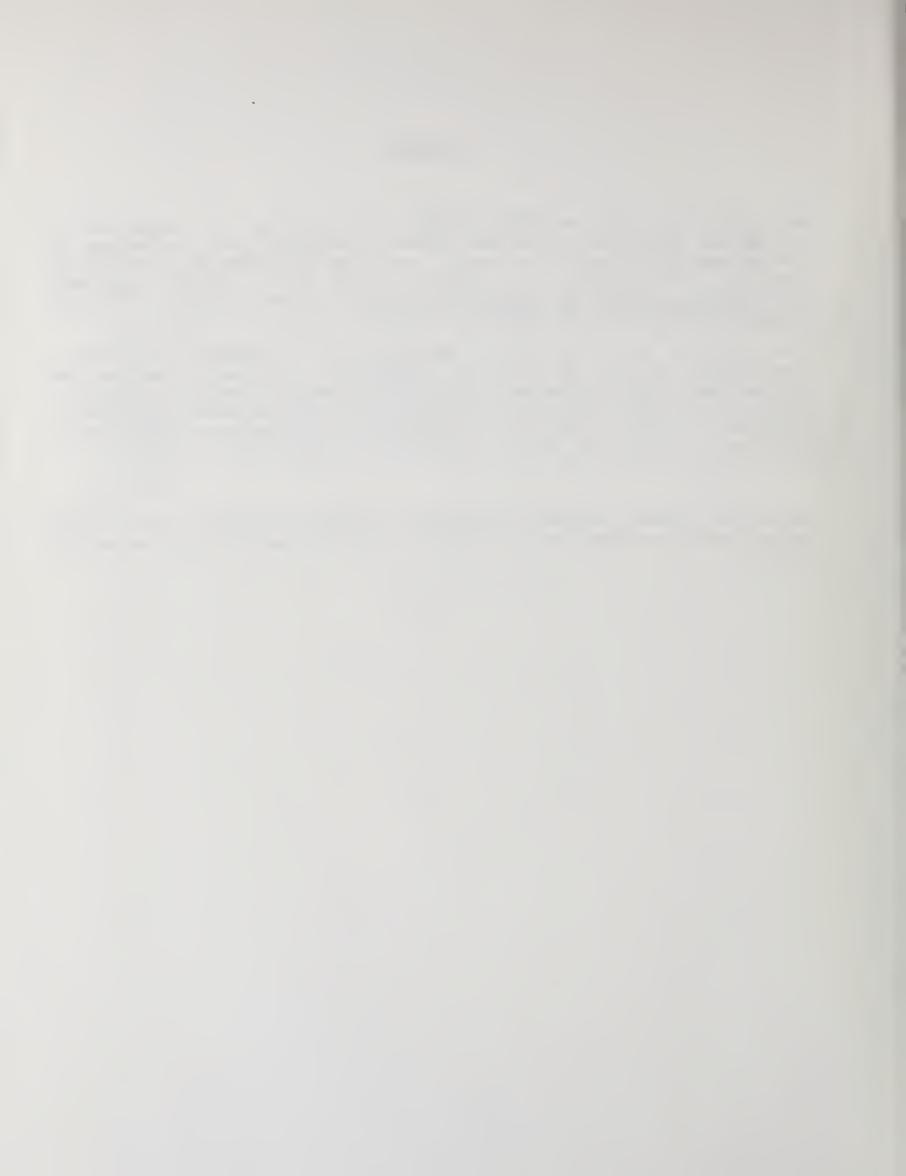
Maureen Breitenberg Editor

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, Federal Government Certification Programs for Products and Services, 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, Federal Government Certification Programs for Products and Services, 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 VIII - Mining, Drilling and Industrial Equipment; 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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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 beef; certification; grading; lamb; meat; meat products;

pork; veal

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

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

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.

Agency Function

Certifier and program administrator.

Type of Program

Voluntary pre-marketing evaluation. Voluntary post-marketing assessment. Assessment prior to government purchase.

Methodology

Federal or state inspection.

Inspection

Federal government inspection.

Inspection by state government inspectors trained by USDA.

Conformity
Identification

Certificate of inspection.

Availability of Documentation There are no lists of participating producers.

Obligations of

Must have a financial interest in the product. Pay Manufacturer/Vendor 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

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
Identification

Authorized grade and/or inspection marks applied by manufacturer. Government applied mark is restricted to officially sampled lots.

Availability of Documentation

List of processing plants under contract is published annually and is available from the above address.

Obligations of Manufacturer/Vendor

Make product accessible for sampling. Produce product in 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

Term is set by contract; activity may be renewed and/or 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.

Standards, Codes or Regulations Most acceptance criteria are based on requirements or specifications developed by federal or state agencies; however, sometimes buyer specifications are used.

Keywords

agricultural marketing orders; food quality; fruits; good manufacturing practices; grading; in-plant inspection; processed foods; sanitation; vegetables

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

Tobacco:

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.

Naval Stores: 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.

Testing Naval Stores:

Government lab certifies results of manufacturer's lab.

Inspection Tobacco:

Federal government inspection.

Naval Stores:

Official inspectors. Licensed inspectors.

Conformity Identification Tobacco:

Government certificates.

Naval Stores:

Government certificates and authorized mark by manufacturer.

Availability of Documentation Documentation is confidential.

Obligations of Manufacturer/Vendor Proper lighting and adequate space.

Enforcement

Reduction of sales opportunity or withdrawal of inspection.

Naval Stores:

Tobacco:

Withdrawal of inspection.

Term Continuous inspection.

Recognition of certification by other federal agencies and Reciprocity

international organizations.

Standards, Codes or Regulations

7 CFR Part 29, Subpart C - Standards.

7 CFR Part 160, Regulations and Standards for Naval Stores. ASTM Designation D 233, Sampling and Testing Turpentine.

Keywords agricultural marketing orders; food quality; good

manufacturing practices; inspection; naval stores; rosin;

sanitation; tobacco; turpentine

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;



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

Certifier and program administrator.

Type of Program

Pre-export inspection.

Methodology

Inspection by federal government and state government

cooperators.

Testing

Testing in government labs and recognized state and

university labs.

Conformity Identification Federal Phytosanitary Certificate.

Availability of Documentation Information regarding foreign country plant quarantine 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 or Regulations

Criteria for certification are established by each foreign country.

Keywords export certification; export; phytosanitary; plant health;

plant quarantine; plant products; plant; re-export

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
Identification

Valid import permit number.

Availability of Documentation

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

Obligations of the Manufacturer/Vendor

Importer must make written application for permit.

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, Codes, or Regulations Criteria for permits are established by the Acts and the regulations promulgated therefrom.

Keywords

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

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

In some cases, exporters must enter a cooperative Manufacturer/Vendor 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

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 Valid import permit and certificates. Identification

Availability Copies of regulations may be obtained from the Agency.

Of Documentation Information on permit holders available only through the

Freedom of Information process.

Obligations of the Comply with regulations and conditions of permits, Manufacturer/Vendor 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, See "Authority."
Codes, or
Regulations

Keywords import; organisms; permit; vectors

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



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

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.

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 Valid import permit and certificates. Identification

Availability Copies of regulations may be obtained from the Agency.

of Documentation Information on permit holders available only through the

Freedom of Information process.

Obligations of the Comply with regulations and conditions of permit.

Manufacturer/Vendor 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.

Regulations

Standards, See "Authority."
Codes, or

Keywords animal product; import; meat; milk; permit

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

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.

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 quidelines 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

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

The exporter must submit a written permit application, provide a valid health certification for imports, reimburse the Department for quarantine and special services provided under cooperative agreements.

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.

Term

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



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 Must Manufacturer/Vendor fee.

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

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

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 semiannually; 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

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 semiannually; 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;

condemnation of meat or poultry products; withdrawal of

inspection; criminal prosecution.

Term

Indefinite term.

Reciprocity

Inspection program recognized by:

Other federal agencies.

State agencies.

Private sector organizations. Foreign government agencies. International organizations.

Standards, Codes or Regulations 9 CFR Parts 350-362.

Keywords

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

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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; f

fish quality; fish; fishery products; plant inspection; PUFI; quality standards; sanitation; seafood specifications;

seafood; SIFE

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

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 government 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

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

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

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.

Recognition by other federal agencies, state agencies, and Reciprocity

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

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

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
Identification

Certified labs are issued certificates identifying areas of competency. Certifying authorities maintain lists of labs

which have been issued certificates.

Availability of Documentation

Lists are available from certifying authorities and EPA

Regional Offices.

Obligations of Manufacturer/Vendor

Certified labs must complete periodic performance 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, or Regulations

EPA develops standards methods.

Agency recognizes methods prepared by others.

Keywords chemistry; drinking water; microbiology; on-site evaluation;

performance evaluation; pollution; quality assurance;

radiochemistry; water quality

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.

Conformity
Identification

Certifying states issue identification numbers to individual certified applicators.

Availability of Documentation

Each state maintains a controlled list of certified 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 Manufacturer/Vendor

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, Regulations 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

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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Appliances

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

Initiated

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.

Agency Function Administers a program to establish procedures to

evaluate the energy use of products, establish/revise maximum use levels, and to analyze new products to

determine if the "Act" applies.

Type of Program Pre-marketing evaluation and post-marketing assessment.

Methodology Manufacturer's self-certification.

Testing Manufacturer's lab.

Third party labs.

Inspection Government.

Identification

Conformity Policy/requirements not established at this time.

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.

Term Indefinite term.

Reciprocity

National Appliance Energy Conservation Act (NAECA)

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

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.

Methodology

Following rulemaking proceedings as required by EPCA, the 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. FTC 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 Manufacturer/Vendor

The Rule requires manufacturers to label covered appliances with information indicating their estimated annual energy costs and related information. Manufacturers base required label information on tests they perform using procedures prescribed by DOE. The Rule also contains specific requirements concerning the duty of manufacturers to make reports to the Commission, to maintain records and to have substantiation for required disclosures or other representations they make.

Term

Indefinite term.

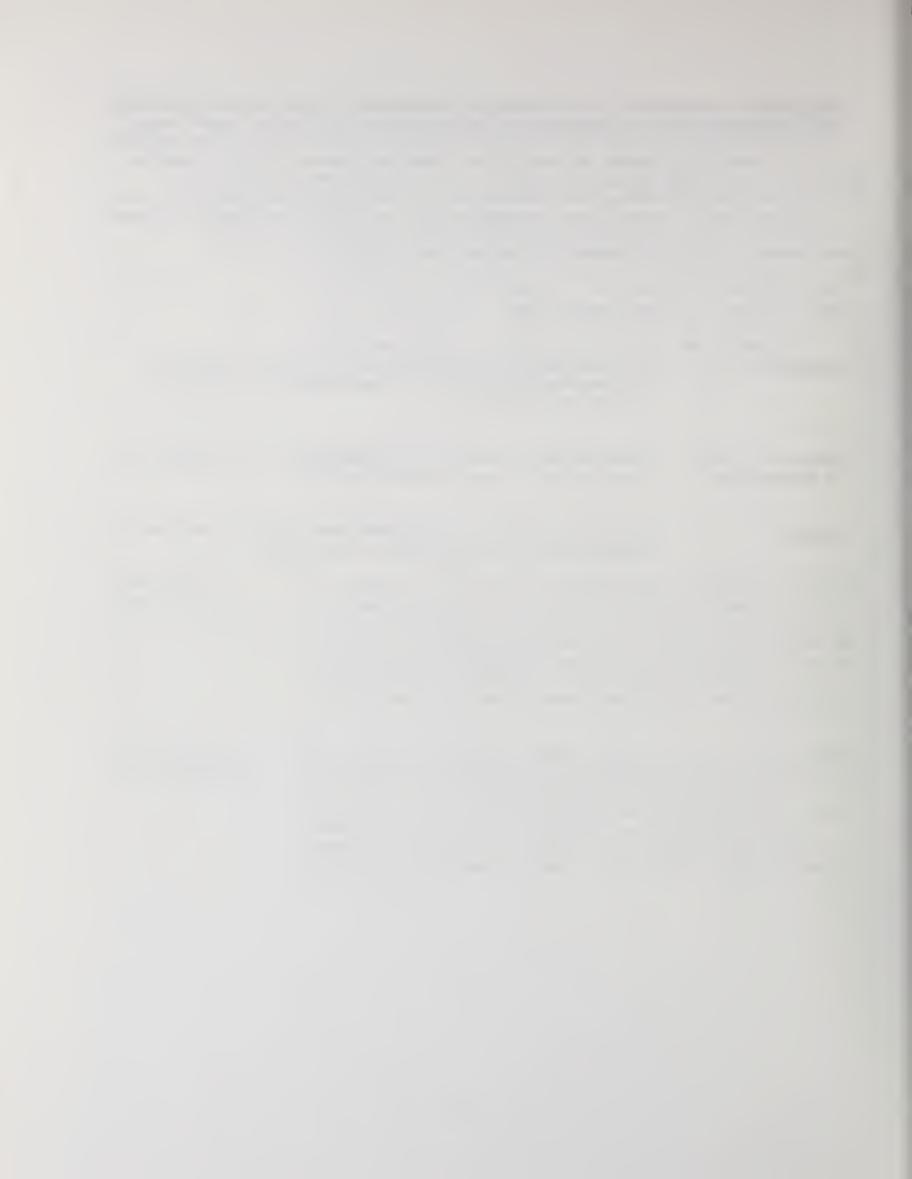
Reciprocity

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

Standards, Codes or Regulations Standard test procedures are prescribed by the DOE. Label format is prescribed by the FTC.

Keywords

appliance labeling; energy efficiency rating; energy conservation; estimated annual energy cost



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 of Documentation

Lists of manufacturers or private branders subject to certification rules or banning orders can be obtained from CPSC.

Obligations of Manufacturer/Vendor 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, 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 reduce risks of injury.

Keywords

audit testing; banned products; consumer products; imminent hazard; mandatory standards; product recall; product safety

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

June 1953

Compliance

Initiated

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.

Availability of Documentation No list of certified suppliers or products is prepared.

Obligations of

Manufacturer may comply with the Act by guaranteeing Manufacturer/Vendor 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

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

Manufacturer/Vendor 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, Agency 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



SECTION III CONSTRUCTION PRODUCTS AND SERVICES INDEX

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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 Manufacturers are obligated to cease marking products Manufacturer/Vendor which do not meet required standards.

Enforcement

The principal means of enforcement is delisting of manufacturers. 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

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.

Conformity
Identification

Authorized label affixed by manufacturer. Lists of approved third party agencies are issued by HUD.

Availability of Documentation

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

Obligations of the Manufacturer/Vendor

Manufacturers and dealers must keep accurate data by unit 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, or Regulations

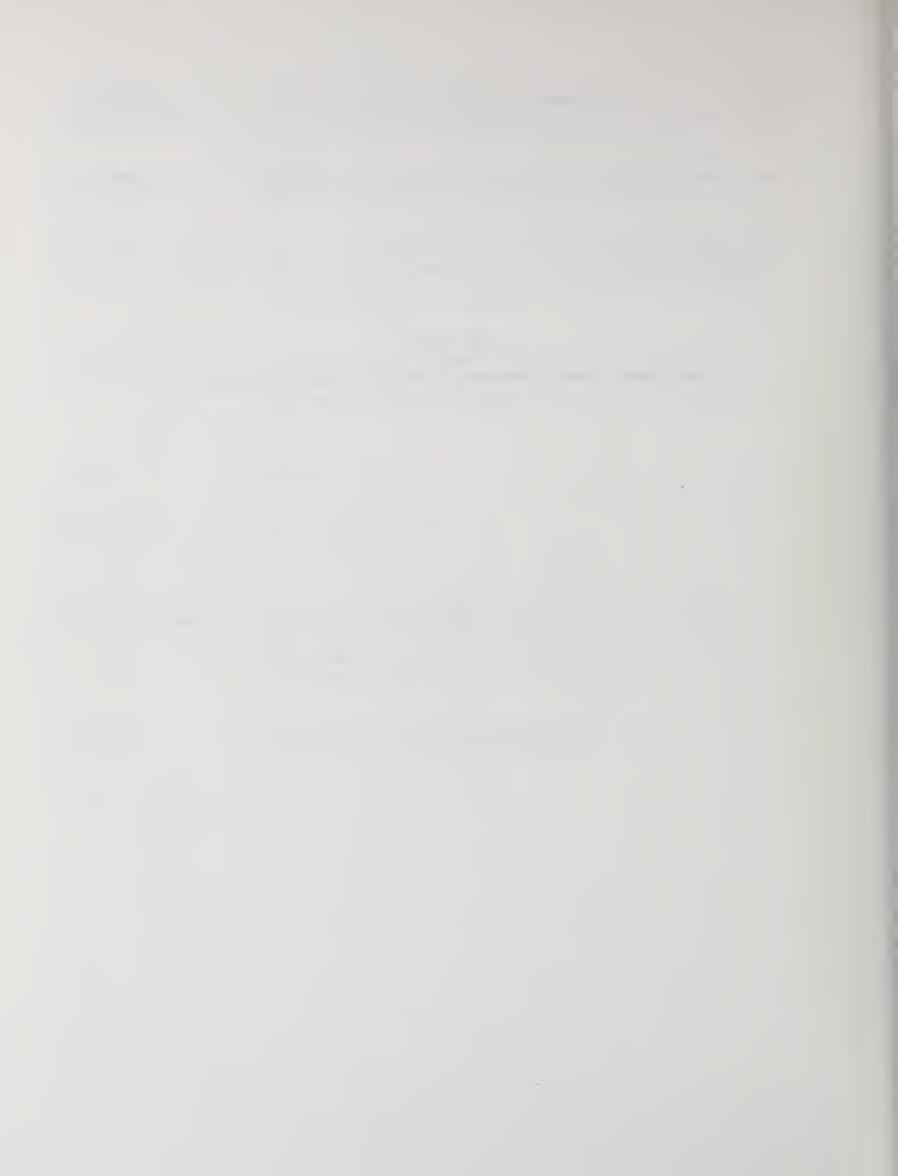
Agency references standards prepared by others and incorporates requirements in the Federal Manufactured Home Construction Safety Standards (24 CFR Part 3280). Enforcement is in accordance with Procedural and Enforcement Regulations (24 CFR Part 3282).

Keywords

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

SECTION IV

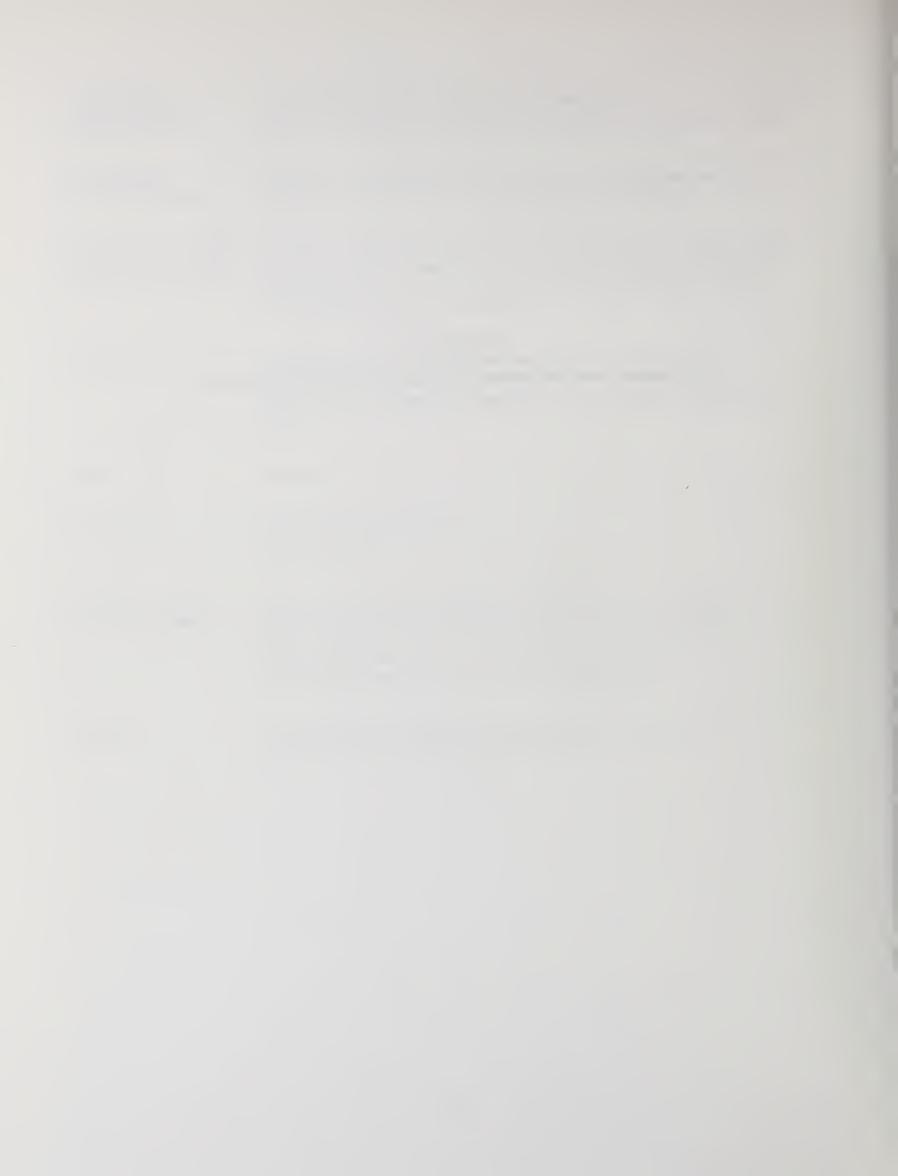
ELECTRONIC AND TELECOMMUNICATIONS PRODUCTS AND SERVICES



SECTION IV

ELECTRONIC AND TELECOMMUNICATIONS PRODUCTS AND SERVICES INDEX

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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 Electrification 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;

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.

Certification

- -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 Identification Agency maintains lists of producers of approved products, but lists are not published.

Producers are licensed to apply approval markings in accord with regulations.

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

Obligations of the

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

Enforcement

Marketing ban.

Term

Indefinite term.

Reciprocity

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

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 electronically 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

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

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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.

Term

Indefinite.

Reciprocity

Some states have used the Verification List in their procurement process.

Standards, Codes or Regulations

Federal Information Processing Standards Publications (FIPS PUBs) 60-1, I/O Channel Interface; 61, Channel Level Power Control Interface; 62, Operational Specifications for Magnetic Tape Subsystems; 63, Operational Specifications for Rotating Mass Storage Subsystems.

Keywords

ADP; computer systems; data processing; I/O; verification

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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.

Inspection

Follow-up inspection is not an integral part of this 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 Identification

Listing on QPL's.

Availability of Documentation Federal QPL's and specifications are distributed by GSA 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.

Term

Indefinite for most products; certain products may require 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.

Standards, Codes, or Regulations

Program is based on qualification requirements specified in federal specifications.

Keywords

government procurement; procurement; QPL; quality control; testing

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

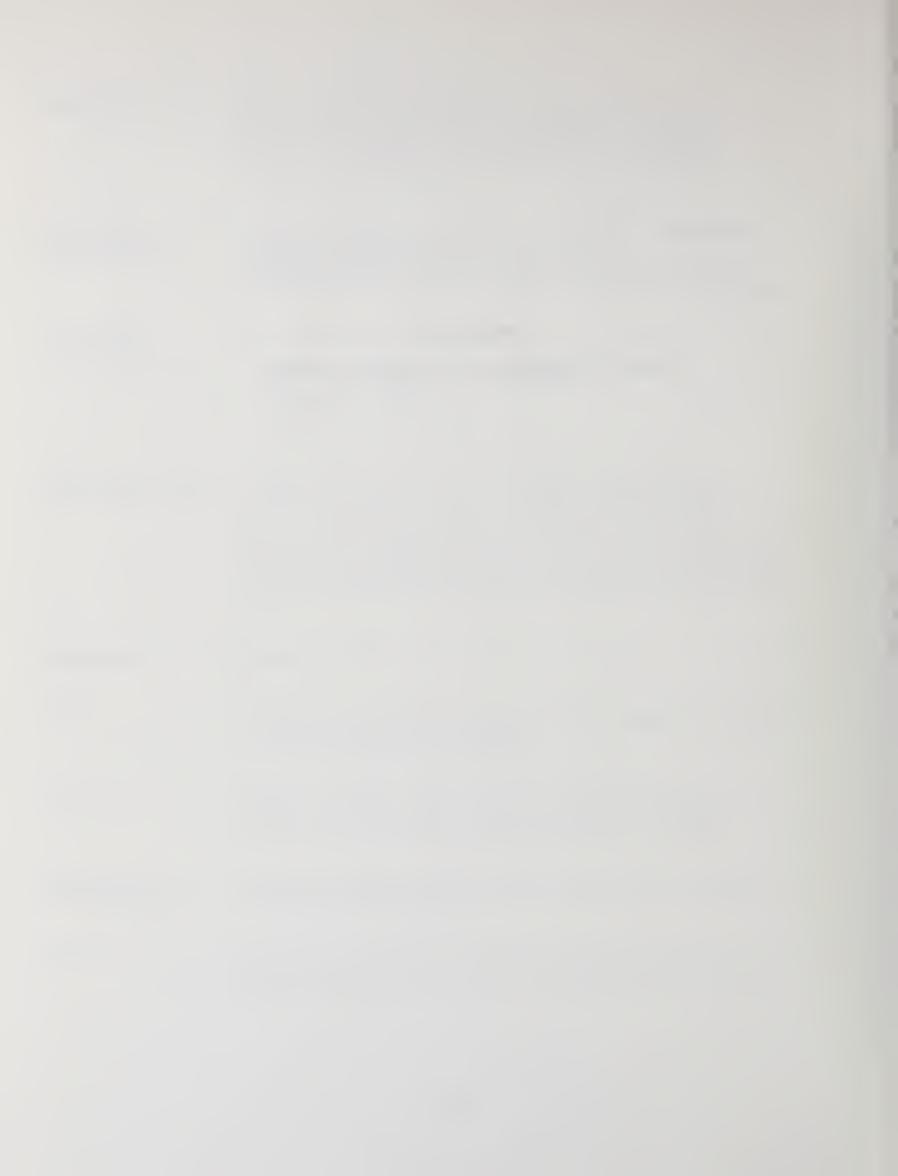
Program is based on qualification requirements specified in Military Specifications.

Keywords

government procurement; military; military specifications; military systems; procurement; QPL; qualification; quality control; testing

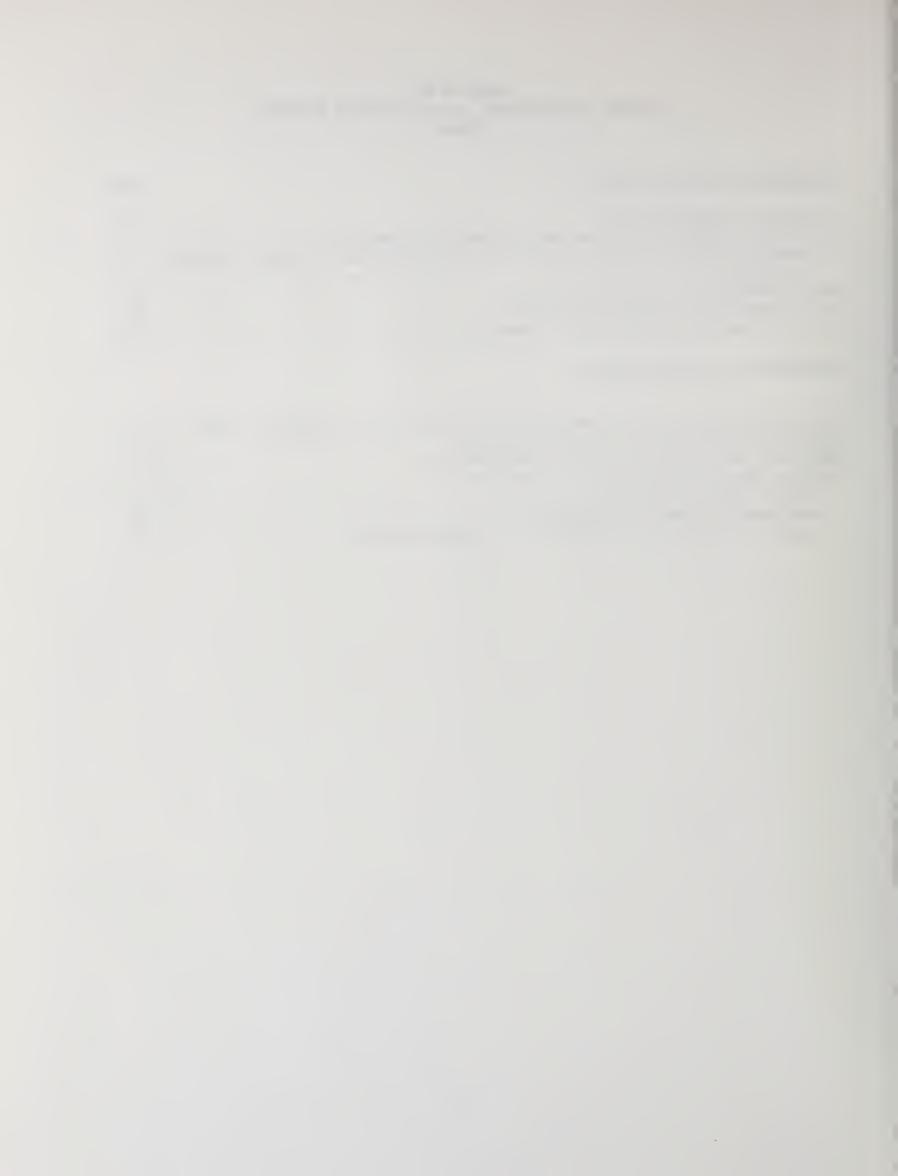
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TESTING, MEASUREMENT, AND LABORATORY SERVICES



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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

Agency Function

Accreditor.

performance.

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

Laboratories are obligated to maintain adequate quality Manufacturer/Vendor 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

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

Accredited laboratories must continue to operate under the Manufacturer/Vendor 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

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 of Documentation

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

Obligations of Manufacturer/Vendor 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, or Regulations

Internal Revenue Procedure 69-22 (Distilled Spirits).

ATF Procedure 86-3 (Wines).

ATF prepares criteria documentation.

Keywords

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

wines

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
Identification

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 of Documentation

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

Obligations of the Manufacturer/Vendor

State laboratories are obligated to participate in 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 or Regulations Criteria documents are developed by NBS. See NBS Handbook 143 available from NBS.

Keywords

frequency; length; mass; measurement instruments; quality control; state laboratories; temperature; volume

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.

Methodology

Government design approval, performance testing,

inspection, and site approval.

Testing

FGIS laboratory.

Government laboratory. Manufacturer's laboratory.

State laboratory.

Inspection

FGIS or state government.

Conformity Identification NTEP Certificate of Conformance (CC).

FGIS CC.

FGIS Report of Test (ROT).

NBS ROT.

Government applied approval seal.

Availability of Documentation List of approved equipment may be obtained from:

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.

Term

Continuous or intermittent, mandatory or voluntary

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; NTEP; railway track; ROT; scale; state weights and measures officials



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

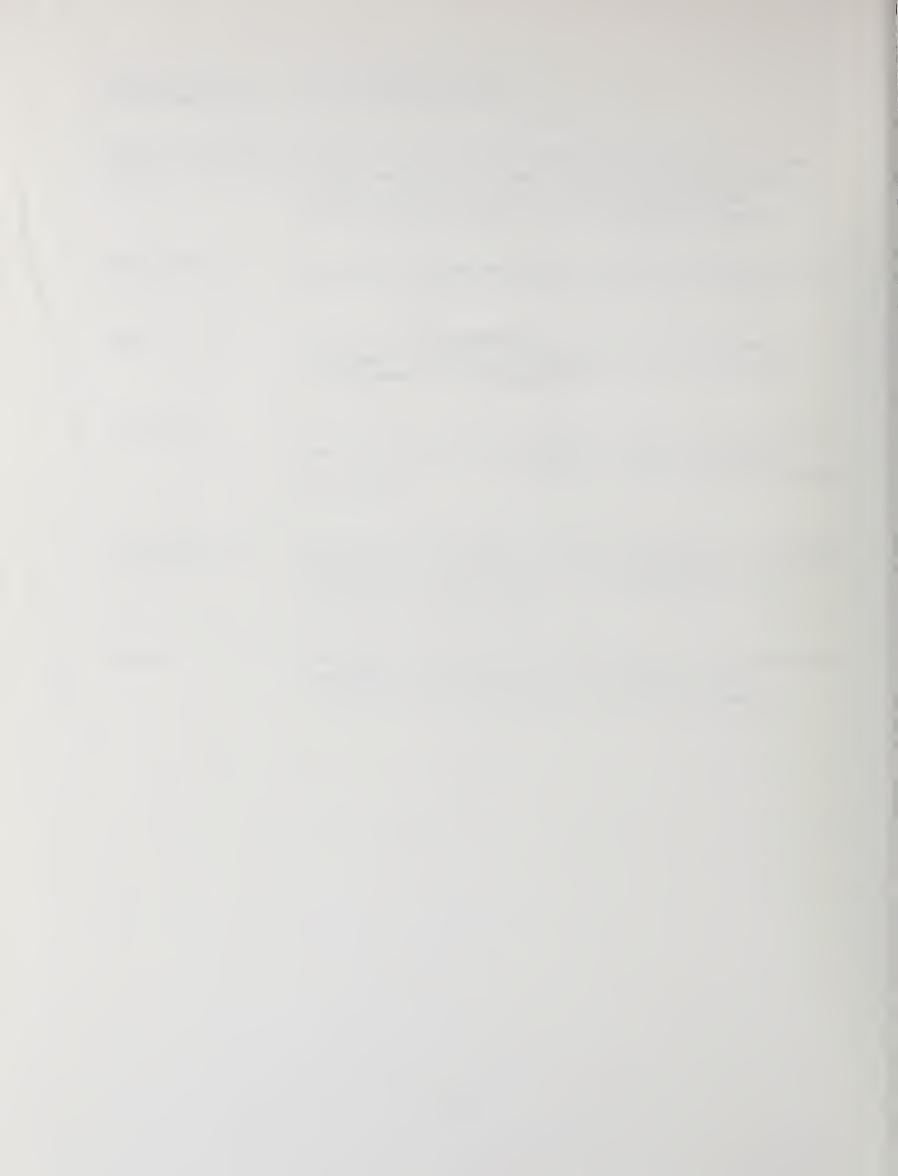
Other federal agencies and state agencies. This program is the U.S. basis for recognition of approved measuring instruments within an international system currently being established.

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



SECTION VII MEDICAL PRODUCTS AND SERVICES INDEX

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Health Care Providers and Suppliers: Hospitals,
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.

Authority

Social Security Act, P.L. 92-603.

Clinical Laboratories Improvement Act of 1967 (CLIA), P.L. 90-174.

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).

42 CFR Part 74 (Interstate (CLIA) licensed laboratories).

Aim

To establish minimum health and safety standards which must be met by providers and suppliers participating in the Medicare and Medicaid programs.

Benefits

Improved quality of health care for Medicare/Medicaid beneficiaries.

Agency Function

Certifies facilities for Medicare reimbursement, licenses 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.

Methodology

Certification/licensure is granted to a provider/supplier 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 Identification

An identification number is given to the provider/supplier when it is determined that federal requirements are met.

Availability of Documentation A list of approved suppliers/providers is available from 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.

Reciprocity

Hospitals accredited by the Joint Commission on Accreditation of Hospitals (JCAH) or the American Osteopathic Association (AOA) are deemed to meet the Federal Medicare requirements.

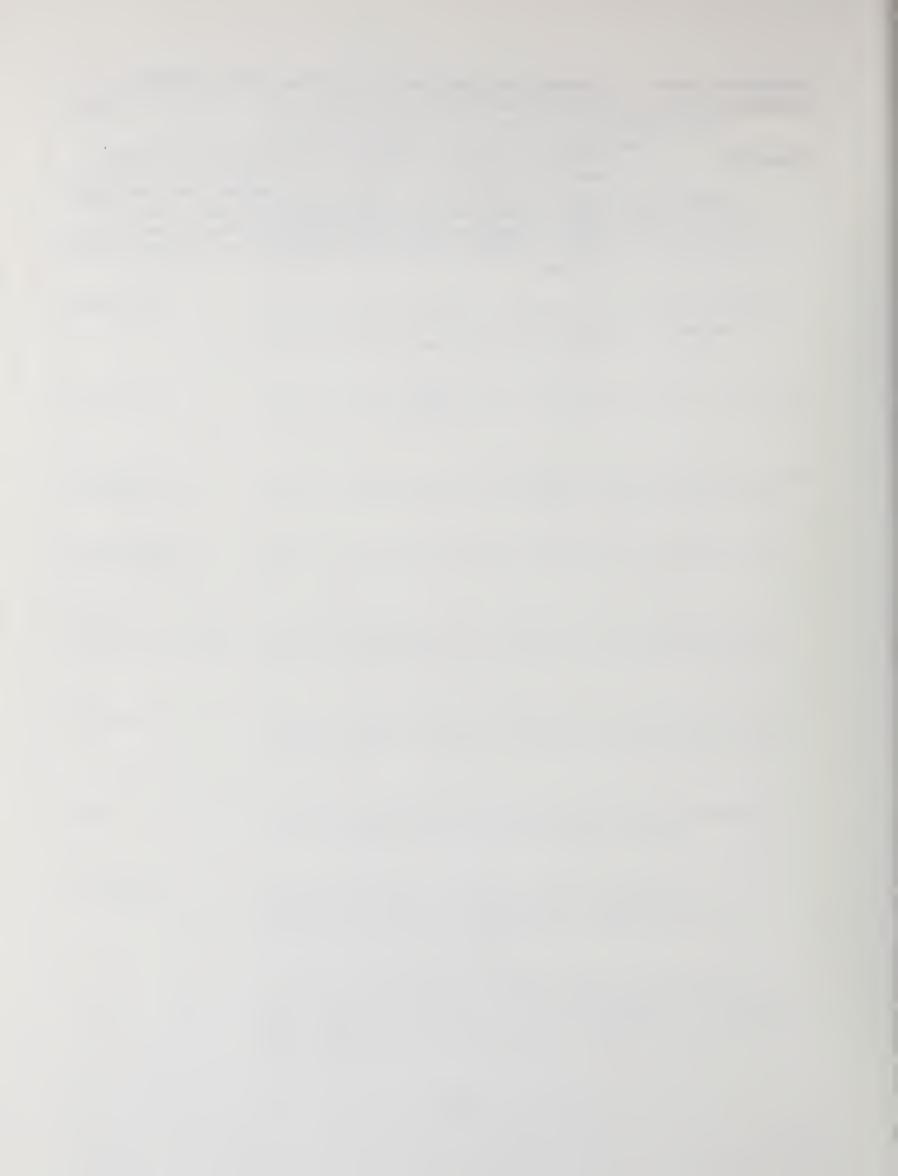
Clinical laboratories performing tests in interstate commerce may apply for a College of American Pathologists (CAP) Exemption (if the lab is CAP accredited), a New York State Exemption, or a Low Volume Exemption in lieu of a CLIA license.

Standards, Codes or Regulations

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



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 or Regulations

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

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

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.

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

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

Federal Register, Vol. 40, No. 65 - April 3, 1975, defines

standards for driving aids.

Requirements for wheelchair lifts are specified in Federal Register, Vol. 43, No. 96 - May 17, 1978.

Keywords

adaptive equipment; automotive; driving aids; hand control;

handicapped aids; prosthetic aids; quality; safety;

wheelchair lifts

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

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, College of American Pathologists Laboratory Accreditation

or Regulations Program (CAPLAP).

Keywords clinical laboratories; laboratories; limited special

function laboratories; nuclear medicine; pathology

SECTION VIII MINING, DRILLING, AND INDUSTRIAL EQUIPMENT



SECTION VIII MINING, DRILLING, AND INDUSTRIAL EQUIPMENT INDEX

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Respirators and Other Breathing Apparatus; Personal Coal 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

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.

Obligations of Manufacturer/Vendor Traceability.

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

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/Vendor

Manufacturer must maintain production according to typeapproved 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.

Indefinite. Term

Other international, federal and state agencies, and Reciprocity

private organizations.

Standards, Codes or Regulations

Agency prepares criteria documents.

Keywords diesel-powered equipment; dust collectors; electrical

components; exhaust gasses; flammable atmosphere; mining machines; non-coal mines; safety; transporters; ventilators

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 typeapproved 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.

Indefinite. Term

Other international, federal and state agencies, and Reciprocity

private organizations.

Standards, Codes or Regulations

Agency prepares criteria documents.

battery powered equipment; coal mines; electrical equipment; Keywords

fans compressors; illumination; intrinsically-safe

equipment; mining equipment; pumps; safety; shuttle cars;

signalling devices

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

Cooperate with employers and recognized certification Manufacturer/Vendor 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

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

Occupational Safety and Health Act of 1970, PL 91-596.

29 CFR Part 1910 -- Occupational Safety and Health Standards

for General Industry.

29 CFR Part 1915 -- Occupational Safety and Health Standards

for Shipyard Employment.

29 CFR Part 1917-1918 -- Occupational Safety and Health

Standards for Marine Terminals; Longshoring.

29 CFR Part 1926 -- Construction Safety and Health

Standards.

29 CFR Part 1928 -- Occupational Safety and Health Standards

for Agricultural Employment.

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.

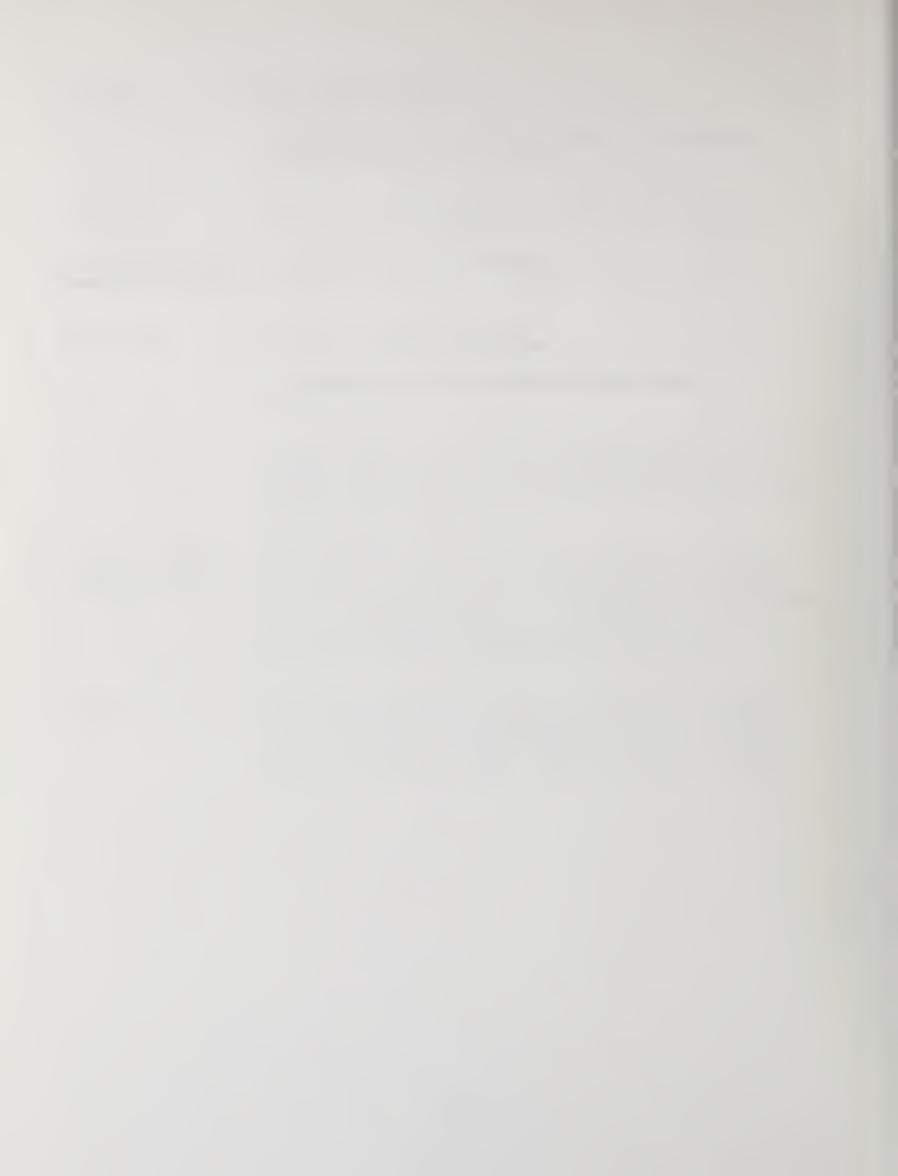
Standards, Codes or Regulations OSHA standards include extensions of federal standards and federal and non-government standards incorporated by reference. These include numerous standards of the American National Standards Institute, the American Society of Mechanical Engineers, the National Fire Protection 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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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.

Aim

To promote the development of civil aviation and to provide

for safe and efficient use of the airspace.

Benefits

The FAA certification system has helped to produce one of the safest and most efficient air transportation systems in

the world.

National Transportation Safety Board data demonstrate that surface travel results in approximately 170 times more fatalities than air travel, not only in total, but in rate

per passenger mile traveled.

Agency Function

Program administrator and certifier.

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 Type Certificate 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.

Parts Manufacturer Approval (PMA) 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 or Regulations

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

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 observa-

tions 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 or Regulations

Agency prepares examination and performance criteria and incorporates related criteria prepared by DOD, FAA,

and Canadian Atmospheric Environmental Service.

Keywords

aviation weather; computer data entry; eyesight examination; radar observation; radiosonde observation; vision standards;

weather observation

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

(IIO) 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 of Documentation

Agency maintains a list of accredited inspectors. Such firms are not required to publicize a list of their clients.

Obligations of the Manufacturer/Vendor

Cooperate with a specific third party certifier regarding design, fabrication, and installation data and maintenance requirements.

Enforcement

Delisting or ban on usage.

Term

Annual retesting.

Reciprocity

Recognition of certification by:

Other federal agencies

State agencies.

Standards, Codes or Regulations

Agency adopts standards prepared by others.

Keywords

accreditation; cranes; derricks; marine equipment; materials handling equipment; naval equipment; safe working loads;

wire rope

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-MTH-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

Compliance

Mandatory for equipment required to be used on recreational

boats and commercial vessels.

Authority

33 CFR Part 159; 46 CFR Parts 2, 159-164.

Aim

To approve equipment which meets minimum safety and performance standards.

Benefits

Approved equipment is intended to reduce the loss of life in marine accidents, and to prevent oil and sewage pollution of

waterways by ships and boats.

Agency Function

Program administrator and certifier.

Type of Program

Pre-market evaluation, inspection, and testing.

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.

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

Manufacturer/Vendor 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

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

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. Obligations of the

Owner and lessees are responsible for maintaining each Manufacturer/Vendor 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

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

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.

Conformity Identification Authorized label by manufacturer. List of certified products.

Availability of Documentation Lists available from EPA.

Obligations of

Manufacturer must qualify new engine designs, new emission Manufacturer/Vendor 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, or Regulations

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

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 of Documentation

Agency maintains list of vehicle and equipment manufacturers who have undertaken product recalls for the purpose of achieving compliance with Federal Motor Vehicle Safety Standards.

Obligations of the Manufacturer/Vendor

Manufacturers must inform the Agency, owners, purchasers, and dealers of known defects and the plans to correct the defect(s).

Enforcement

Marketing ban.
Product recall.

Term

Indefinite.

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 or Regulations Agency prepares criteria documents.

Keywords

automobiles; compliance; motor vehicle equipment; product recall; safety; school buses; trucks; used vehicles

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 Manufacturer/Vendor construction.

Manufacturer is obligated to use approved welders during

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

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

Manufacturer/Vendor 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

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 maintain quality control. Vendors must Manufacturer/Vendor cycle inventory. Users must 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 or Regulations

Agency has integrated product requirements based on industry test methods.

Keywords

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

Packages and Containers for Radioactive Material

Department/Agency

Nuclear Regulatory Commission

Office of Nuclear Material Safety and Safequards

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

Report defects or noncompliance.

Manufacturer/Vendor Report significant reduction of effectiveness during use.

Enforcement

Order, denial, fine.

Term

5 year renewable.

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, or Regulations

U. S. Nuclear Regulatory Commission Regulatory Guides

(Division 7).

10 CFR Part 71 and 10 CFR Part 21.

Keywords

environment; nuclear; packaging; radioactive material;

safety

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.

Conformity
Identification

Certificates are provided to shippers and/or manufacturers by approval agencies.

Enforcement

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

Term

Indefinite.

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 or Regulations 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

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

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 Documentation

Certification of welders by the American Welding Society; comparable program by the installing contractor may be acceptable to DOT. List of approved pipelines kept by DOT.

Obligations of Manufacturer/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 or Regulations Agency mainly adopts standards of other organizations.

Keywords

certified welder; hazardous materials; pipelines; pressure-limiting devices; qualified plastic pipe assembler; safety; welding

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 Documentation

Agency maintains list of firms authorized to manufacture

such tanks.

Obligations of Manufacturer/Vendor

Manufacturer must maintain integrity of design, quality 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 or Regulations Agency integrates standards of other organizations into

the program.

Keywords

hazardous materials; hydrotesting; pressure relief devices;

quality control; safety valves; tanks; transportation

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 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 must mai Manufacturer/Vendor changes for approval.

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

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.

Methodology

Manufacturer's guarantee that serially-produced equipment 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 Identification

Approved equipment requires an authorized ATP certification plate and distinguishing mark along with a manufacturers plate.

Availability of Documentation

Lists of approved test facilities and fees for 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 Manufacturer/Vendor

Approved test facilities must be open to the public, 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.

Term

Approval of test stations and laboratories is good for 5 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



SECTION X MISCELLANEOUS PRODUCTS AND SERVICES



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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

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.

Conformity
Identification

Qualified manufacturers are listed on a Conforming Products List (CPL).

Availability of Documentation

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.

Obligations of the Manufacturer/Vendor

Manufacturers must submit a unit for testing.

Term

Indefinite.

Standards, Codes or Regulations Acceptance criteria have been developed by NHTSA in collaboration with NBS.

Keywords

alcohol; analysis; blood alcohol; breath alcohol; calibration; highway safety; law enforcement; legal evidence; tester

Hazardous Household Substances

(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.

227

Availability of Documentation

List of banned hazardous substances may be obtained from

CPSC.

Obligations of Manufacturer/Vendor designated substances.

Carriers must keep records of interstate shipment of

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.

banned products; corrosive; flammability; hazardous Keywords

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.

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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.

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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 KWIC Index (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 tbt news

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 Report to the United States Congress on the Agreement on Technical Barriers to Trade - "Standards Code"

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 CATT Hotline. A telephone hotline provides current information received from the CATT 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. The hotline number is (301) 975-4041 (not toll-free).
- 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 Export Briefs 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, contact: Carolyn Wilson, 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, postmarket 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
Identification

The method, if any, that the agency uses to identify that the product/service has been certified.

Availability of Documentation

How information on lists of approved products/suppliers or 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.

Term

The length of time the certification is valid.

Reciprocity

Any recognition of the certification by other federal or state agencies, private sector organizations, foreign governments, or international organizations.

Standards, Codes, or Regulations

The documents which define the acceptance criteria for the certification.

Keywords

Words describing key characteristics of the program.

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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.

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