



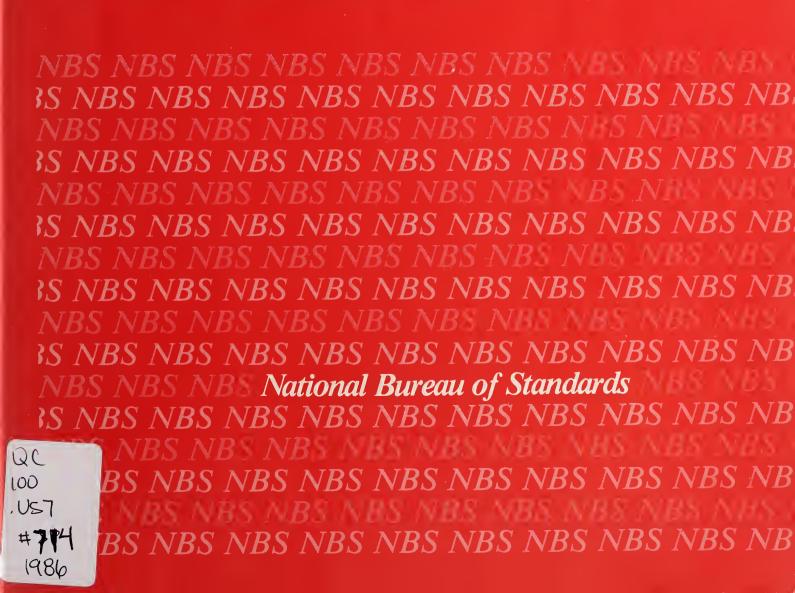
NIST PUBLICATIONS

U.S. DEPARTMENT OF COMMERCE National Bureau of Standards

NBS Special Publication 714

Federal Government Certification Programs for Products and Services

Robert B. Toth, Editor



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 and provides: (1) a basis for the nation's physical measurement system, (2) scientific and technological services for industry and government, (3) a technical basis for equity in trade, and (4) technical services to promote public safety. 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.

The National Measurement Laboratory

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; and provides calibration services. The Laboratory consists of the following centers:

- Basic Standards²
- Radiation Research
- Chemical Physics
- Analytical Chemistry

The National Engineering Laboratory

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

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

The Institute for Computer Sciences and Technology

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 centers:

- Programming Science and Technology
- Computer Systems Engineering

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-country 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 Deformation ³
- Polymers
- Metallurgy
- Reactor Radiation

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

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

Federal Government Certification Programs for Products and Services

Prepared for: Office of Product Standards Policy National Bureau of Standards Gaithersburg, MD 20899

Robert B. Toth, Editor R. B. Toth Associates

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U.S. Department of Commerce Malcolm Baldrige, Secretary National Bureau of Standards Ernest Ambler, Director

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Foreword

This volume is the second of three listings of certification programs in the United States. NBS Special Publication 703, published in August 1985, provided information on private sector programs; the current work is devoted to Federal government programs; and a compilation of state programs is under way. These databases will combine to furnish a comprehensive source of information to respond to the needs of a vast and broad array of public and private sector organizations.

Interest in product certification stems from any of a number of economic, procurement, health and safety, equity, or other considerations. Federal agencies, manufacturers, distributors, state government officials, and others may find this directory to be of value for identifying pertinent programs, the nature of the certification activities, program requirements, standards used, and other relevant information.

Dr. Stanley I. Warshaw, Director Office of Product Standards Policy

Acknowledgements

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Special thanks are due the staff of R. B. Toth Associates who acquired and organized this volume for publication.

Robert B. Toth Editor

Abstract

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.

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

CONTENTS

| | Page |
|---|------|
| Foreword | iii |
| Acknowledgements | iv |
| Abstract | V |
| Introduction | 1 |
| Alphabetic Listing of Government Departments and Agencies | 9 |
| Index By Product or Service Certified | 141 |

Introduction

Classifying Certification Programs

The public has traditionally looked to government to provide protection and prevent hazardous conditions. In many areas the U.S. Federal Government accomplishes this through laws that establish regulations and standards. In some instances, users need assurance that products or services comply with the regulations or standards. This need usually arises because only sophisticated or expensive assessments - design analysis and/or testing - can provide each user with the necessary level of assurance that a product or service will not harm the user nor the public at large. The process of assessment, then marking or listing the product or service so as to indicate compliance, is generally termed certification.

Federal Government certification programs can be classified into three general categories:

- Certification of products or services which directly affect the health or safety of the user or the public;
- 2. Programs to avoid extensive product testing to demonstrate conformance at each procurement;
- 3. Programs to provide a uniform basis for trade by objective evaluation of the quality and condition of products.

Of the 61 Federal Government certification programs described in this directory, many include elements of more than one category. As listed on the following page, 19 can be classified as Category 2 or 3 programs; the remaining 42 Category 1 programs directly affect health and safety.

Nearly all Category 1 certification programs are mandatory. Affected products cannot be sold or used, except for carefully restricted experimental purposes, until they have been judged safe. In some cases, such as drugs and medical devices, products must not only be harmless, but they must also be effective. Except for eggs and tobacco, Category 3 programs are voluntary. Producers and distributors participate in these certification programs because their products have wider customer acceptance or can command better prices when marked "choice" or "Grade A".

Nearly all Category 2 programs are basically voluntary in that producers or distributors can sell their products in the open market without Government certification. However, if these products are to be

Category 2 Certification Programs

Avoiding Repetitive Extensive Conformance Demonstration

Department of Defense

- Qualified Products Lists

General Services Administration

- Qualified Products Lists

Rural Electrification Administration

- Approved Products Lists

Department of Commerce

- Measuring Instruments

- Input/Output Channel Interfaces

Environmental Protection Agency

- Automotive Aftermarket Parts

Department of Housing and Urban Development

- Building Products

Department of Transportation

- Breath Alcohol Testers

Department of the Treasury

- Electronic Fund Transfer Authentication Devices

Veterans Administration

- Self Propelled and Motorized Wheelchairs

Category 3 Certification Programs

Uniform Grading of Quality and Conditions

Department of Agriculture

- Eggs and Dairy Products
- Fresh and Processed Fruits and Vegetables
- Poultry and Meats
- Turpentine and Rosin
- Tobacco

Department of Commerce

- Processed Fish and Shellfish

bought by Government agencies or with funds provided or guaranteed by the Government, certification is mandatory. The largest program of this type is operated by the Department of Defense. Its Qualified Products Lists (QPL's) are used throughout the world not only by U.S. and foreign military agencies, but many commercial organizations such as aircraft and electronic equipment manufacturers and their customers. Of the more than 38,000 military specifications and standards, fewer than 1300 (3.4%) require qualification testing and establishment of a QPL.

The Department of Defense has strict criteria for its QPL's. One or more of the following must apply:

- (a) Tests to determine compliance with the specification exceed 30 days (720 hours).
- (b) Quality conformance inspection requires special equipment not commonly available.
- (c) The products are emergency life saving equipment or are critical to life survival.

General Services Administration has a similar program, with 80 QPL's (1.3%) among its 6000 Federal specifications, standards, and product descriptions.

While the private sector often uses these QPL's merely as buyer's guides, for a variety of reasons (including product liability) many buyers will purchase products only from sources that have demonstrated their military specification requirements and being listed on the pertinent QPL. Small businesses have found this technique to be particularly cost-effective to gain entry into a market.

Certification for Safety and Health

Category 1 certification programs are the most visible and pervasive. With few exceptions, nearly every certification program in this category has been mandated by Congress in reaction to major disasters or to protect the public from unhealthy or hazardous conditions that could not be controlled adequately by traditional market factors. The oldest Federal certification program illustrates the relationship between legislation and certification.

In the early nineteenth century steamboats were a major, easily observed indicator of America's growing industrial and commercial strength. However, boiler explosions were common occurrences and took These disasters made a real impression on the public since many lives. they occurred not on the high seas, or in remote areas, but on heavily trafficked rivers and harbors, often near cities and towns. Harrowing descriptions by spectators and survivors spread throughout the country. Congress was reluctant to act because it would be "...adverse to fetter or discourage the ingenuity and skill for which the artists of this country are so distinguished...." In many circles, including Congress, it was felt that the prudent businessman would see to it that his equipment was properly designed and operated because of the tremendous loss he would incur should there be an accident. Nevertheless, boiler explosions continued at a disastrous rate. In 1832 alone, fourteen percent of this country's steam vessels were destroyed by such occurrences, and over one thousand people were killed. Between 1830

and 1838, Presidents Jackson and Van Buren periodically requested Congress to take action.

In the Spring of 1838 explosions on three steamboats killed more than a thousand. That year Congress enacted legislation which required periodic regulatory inspection and certification of ship boilers and machinery. Subsequent legislation in 1852 and 1871 provided a system of requirements including establishment of maximum permitted steam pressure, instituting hydrostatic overpressure testing, and extending inspection from boiler fabricators to also include boiler materials suppliers. Certification was a basic element of this system.

While steamboat boiler explosions fell off markedly, boilers continued to explode ashore with considerable frequency, but the effects were usually confined to factory sites. The general public was not affected directly as in the case of steamboats, so public clamor for legislation was not raised until 1907, when a catastrophic boiler explosion in a shoe factory in Brockton, Mass. led to legislation by the Commonwealth of Massachusetts. This was the first legal code for steam boiler construction by a state and other states soon followed The American Society of Mechanical Engineers then undertook development of its Boiler Code, which was first published in 1914. This Code has since been adopted by most states, and in 1969 selected sections were adopted by the Coast Guard for application on steamboats. Self-certification by equipment manufacturers and government certification either by a government agency or a designated third-party inspection agency, are basic elements of boiler safety assurance on land and sea.

The most comprehensive Federal certification program is unique in that it was not established as a result of public clamor but at the instigation of the industry that would be regulated. Immediately after World War I, the nascent aircraft manufacturing industry recognized that the public would more likely have sufficient confidence to fly regularly if their airplanes had been tested and certified safe for flying by the Federal Government. A certification program was proposed by industry that included assessment and certification of the detailed design; certification of the production process with special emphasis on quality assurance; and an airworthiness certificate for each aircraft, engine and propeller produced by the certified facility. The first aircraft was certified in 1926. Interestingly, in these early years, the Government delegated certification of airworthiness for production aircraft to Underwriters Laboratories.

The rigorous testing and subsequent certification by the U.S. Government resulted in a level of assurance and confidence which became recognized throughout the world. This product certification program contributed in no small measure to the sales of American aircraft. The preeminent position earned by American aircraft manufacturers in the world market continues to this day. Since those days, the aircraft certification program has encompassed nearly every critical aspect of

aviation. In addition to certification of aviation products, the Federal Aviation Administration certifies pilots and mechanics, their instructors, and their schools, the airlines, airports, repair facilities, and many other elements. This comprehensive approach has been adopted by most countries that manufacture or operate aircraft.

The U.S. Department of Transportation is responsible for the widest range of Federal certification programs. These programs also probably have the largest actual or potential monetary impact. In addition to certifying ships, recreational boats, and aircraft, the Department of Transportation has certification programs for automobiles, all types of containers for shipping hazardous materials, as well as pipelines.

Food and Drug Administration (FDA) no doubt has responsibility for protecting the greatest number of lives. Its certification programs include not only foods and drugs for human consumption, but also those for animals with special attention to those elements that affect the food chain. Medical devices of all kinds require FDA certification. Unlike the FAA, which implements its comprehensive certification program on the basis of a single, all-inclusive law, FDA is reponsible for enforcing a variety of individual programs defined by Congress in a half dozen laws.

Interrelationships and International Developments

The specialized responsibilities of Federal agencies and the mandates of Congress may confuse those who are not familiar with Federal certification programs. An importer of television sets, for example, requires not only Federal Communications Commission certification, but FDA certification that viewers' eyes will not be exposed to harmful radiation from the cathode ray tube. A wholesaler of seafood products needs to be aware of grading programs of the Department of Commerce's National Marine Fisheries Service, the special requirements of FDA's Shellfish Sanitation Branch, and the general requirements for sanitation, labelling and plant identification set by FDA's Bureau of Foods. This directory is intended to assist in identifying pertinent and related certification programs.

Most Federal certification programs have in the past been established to meet domestic needs. Recently, however, the U.S. has originated certification programs in response to international initiatives. International organizations established by treaties to which the United States is signatory set product standards and regulations to alleviate specific problems, usually affecting safety or health, encountered in international trade. Certification is a common technique to assure compliance. The establishment of a U.S. Government certification program enables U.S. companies to comply and continue to engage in international trade.

As a result of the International Convention for Safe Containers, the U.S. Coast Guard has been designated this nation's Certifying Authority. A certification program has been established complying with requirements of the Convention for design approval, testing and certification, including affixing a safety approval plate to each Without this plate, a container cannot be entered into international traffic. If the container is refrigerated, or if it is a refrigerated trailer, another certification program applies. United Nations Economic Commission for Europe has set requirements for transporting perishable food which include design approval, testing, inspection and certification. To enable U.S. exporters to continue to use U.S.-made refrigerated containers and vehicles, the Department of Agriculture's Office of Transportation has been designated the U.S. certifying authority and has established a certification program in accordance with United Nations criteria. The U.S. Department of Labor certifies maritime cargo handling equipment as complying with the International Labor Organization Convention for cranes, derricks, wire rope and other equipment used to load and unload ships. Standards and certification requirements set by the United Nations for packing hazardous materials resulted in the of Department of Transportation's Materials Transportation Bureau being designated the "National Competent Authority" to evaluate and issue approval and conformance certificates for a wide variety of tanks and other types of packaging.

Few (if any) new Federal Certification programs are expected in the foreseeable future except those mandated by international requirements. In these cases, the Federal Government probably will participate only at the urging of industrial sectors which would be adversely affected if the certification process were not available to them.

Certification and the National Bureau of Standards

The U.S. Trade Agreements Act of 1979 implemented U.S. acceptance of the Agreement on Technical Barriers to Trade (also known as the "Standards Code") of the General Agreement on Tariffs and Trade (GATT). The Act assigned to the Department of Commerce responsibility to maintain an information center for standards and standards-related subjects, such as certification. The National Bureau of Standards Office of Product Standards Policy carries out this departmental responsibility through its National Center for Standards and Certification Information (NCSCI), which maintains a reference collection consisting of data on 240,000 standards, specifications, and related materials. NCSCI exchanges standards information with similar national centers in other countries and responds to requests for information from governmental and private sector organizations, as well as Besides specifications and standards, NCSCI seeks, individuals. maintains, and disseminates information on certification programs and activities as they relate to the application and use of specifications and standards.

In the area of certification, the Office of Product Standards Policy aims to improve the accessibility, understanding, and acceptability of certification programs. Specific objectives include help for interested parties in acquiring information on certification activities and facilitating the acceptance of U.S. based certification data by both domestic and foreign jurisdictions.

This directory is the result of one phase of the efforts initiated by NBS's Office of Product Standards Policy to accomplish its certification-related objectives. It is a companion volume to NBS SP 703 which lists private sector certification programs, and a third volume on state programs, currently under development. It will aid in recognizing the diversity and therefore the complexity of U.S. certification activities, and will serve as a useful reference for finding out about specific programs orperated by U.S. Government agencies.

Organization of the Directory

Sixty-one certification programs are arranged in alphabetic order by department or agency name and, where there is more than one certification program, in alphabetic order by name of the product or service. The index provides the quickest route to identify responsible agencies. Numerous synonyms and cross-references are provided. Each entry includes a block of keywords. These synopsize the scope of each certification program and, as such, assist the directory user to find pertinent information. These keywords provide the capability for simple computer search at some time in the future, and for that reason are separated by semicolons - the convention that is utilized in most search software.

Considerable effort was made to be comprehensive. More than 100 U.S. Government organizations were invited to provide information and documentation relevant to their certification programs. Information for the entries was voluntarily provided by the respondents. Other Federal organizations concerned with certification activities that are not included in this directory are invited to send pertinent information to:

National Center for Standards and Certification Information (NCSCI) Office of Product Standards Policy National Bureau of Standards Administration Building, Room A629 Gaithersburg, MD 20899

U.S. Government agencies are also encouraged to keep NBS informed of changes in name or address, or in the nature of their programs. In addition to this directory, NCSCI maintains a publicly accessible reference collection of current materials on U.S. Government certification programs.

Other NCSCI Documents of Possible Interest

In addition to this directory, NCSCI has published three related directories:

- NBS SP 649 <u>Directory of International and Regional</u>
 Organizations Conducting Standards-Related Activities,
 April, 1983,
- NBS SP 681 Standards Activities of Organizations in the United States, August 1984, and
- NBS SP 703 Private Sector Product Certification Programs in the United States, August, 1985.

A new microfiche revision of

- NBS SP 329 Index of U.S. Voluntary Engineering Standards, May, 1975

lists U.S. Voluntary Standards by key words in the titles.

NCSCI is also preparing a directory of State certification programs. Further information on these publications and activities can be obtained from NCSCI at the address listed above.

ALPHABETIC LISTING OF GOVERNMENT DEPARTMENTS AND AGENCIES

Products or Services

Dairy Products

Department/Agency

U.S. Department of Agriculture Agricultural Marketing Service Dairy Division, Room 2750-S Washington, D.C. 20250

(202) 382-9382

Initiated

1925

Compliance

Voluntary

Authority

CFR Title 7 Part 58 and Agricultural

Marketing Act of 1946

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; available from 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

Agency prepares all criteria documents

Keywords

grading; dairy products; butter; cheese; food

quality;

Products or Services

Fresh Fruits, Vegetables, Nuts, and

Related Products

Department/Agency

U.S. Department of Agriculture Agricultural Marketing Service

Fruits and Vegetables Division, Room 2056-S

Washington, D.C. 20250

(202) 447-5697

Initiated

1917

Compliance

Voluntary

Authority

Agricultural Marketing Act of 1946

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

Both certifier and program administrator

Type of Program

Voluntary premarketing evaluation Voluntary post marketing assessment Assessment prior to government purchase

Methodology

Third party certification

Inspection

Federal Government inspection Inspection by State government inspectors

trained by the USDA

Conformity Identification Certificate of Inspection

Availability of Documentation

There are no lists of participating

producers.

Obligations of Manufacturer/Vendor Must have a financial interest in the product. Pay assessed fee for service

rendered.

Enforcement

Although nearly all aspects of this program are voluntary, a full range of enforcement options apply to shippers who practice fraud.

Term

Certification made on lot by lot basis.

Standards, Codes, or Regulations

Grading criteria are established by Agricultural Marketing Service.
USDA grade marking is recognized nation-wide and world-wide in both private and public sectors.

Keywords

grading; fruits; vegetable; nuts; food
quality;

Products or Services

Meats, Prepared Meats, and Meat Products (beef, lamb, veal, calf, and pork)

Department Agency

U.S. Department of Agriculture Agricultural Marketing Service Livestock Seed Division

Meat Grading and Certification Branch, Room 2638-S

Washington, DC 20250

(202) 382-1246 Telex: 89491

Initiated

1946

Compliance

Voluntary

Authority

Agricultural Marketing Act of 1946

(as amended).

Aim

To facilitate the marketing of livestock and meat.

Benefits

In FY 1982, the Meat Grading and Certification (MGC) Branch graded an estimated 11.9 billion pounds of beef, 271.5 million pounds of lamb, and 38.3 million pounds of veal and calf. represents approximately 53 percent of the commercial beef slaughter or two-thirds of the steers and heifers slaughtered under Federal inspection. These figures also represent 76 percent of the commercial lamb slaughter and 10 percent of the commercial veal and calf slaughter. Additionally, the MGC Branch certified approximately 2.0 billion pounds of meat and meat products in FY 1982 for buyers such as Department of Defense, Livestock Industry Promotion Corporation, and the Federal School Lunch Program.

Agency Function

The MGC Branch provides onsite 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 performed in Government laboratories.

13

Inspection MGC Branch personnel.

Conformity Approved U.S. Department of Agriculture (USDA)
Identification 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 speci-

fications.

Term Continuous inspection on a voluntary basis

Reciprocity None

Standards, Codes, The agency develops and maintains its own or Regulations USDA approved standards and specifications

for the various meat items.

Keywords meat; meat products; grading;

Products or Services

Parts, Materials and Equipment for Rural Electric and Telephone Systems

Department/Agency

U.S. Department of Agriculture Rural Electrification Administration (REA) 14th and Independence Avenue, NW. Washington, DC 20250 (202) 382-9082, Electric (202) 382-8663, Telephone

Initiated

About 1938

Authority

7 CFR 1701

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.

Benefits

The standardization and product evaluation program yields many economies in the construction, operation, and maintenance of rural electric and telephone systems thus assuring dependable service at affordable rates.

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 lab 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 1985 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

Bulletin 43-5 and 344-2 are available on a subscription basis from the Superintendent of Documents, Government Printing Office, Washington, DC 20402

Enforcement

Delisting

Term

Indefinite; Bulletin 43-5 is published yearly and supplements are issued quarterly. Bulletin 344-2 is printed on a two-year basis followed by eleven supplements.

Standards, Codes, or Regulations

REA prepares product standards which define performance and design requirements together with acceptance criteria.

Keywords

approved products lists; acceptable materials; components; electric systems; distribution; transmission; telephone; electronic; microwave; telecommunications; radiotelephone; central office equipment; private branch exchanges;

Products or Services

Poultry, Shell Eggs, Egg Products, and Rabbits

Department/Agency

U.S. Department of Agriculture Agricultural Marketing Service Poultry Division Grading Branch, Room 3938-S Washington, DC 20250 (202) 447-3271 Telex: 89-491 TWX; 710-822-9424 and 710-822-1104

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; U.S.C. 1621-1627)
Egg Products Inspection Act (84 Stat.
1620-1635; 21 U.S.C. 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
Inspection
Audits

Certification by third party certifiers

Testing

Government laboratories Approved State laboratories Third party laboratories Manufacturer's laboratories

Inspection

Government Approved State government 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. Govern-

ment Printing Office.

Obligations of Manufacturer/Vendor

Operate in 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 certification of
ingredients by other Government agencies
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; grading; grading branch; poultry; grading; grading branch; poultry; rabbits; shell; eggs; USDA;

Products or Services

Processed Fruits and Vegetables

Department/Agency

U.S. Department of Agriculture Agricultural Marketing Service Fruit and Vegetable Division Processed Products Branch, Room 0709-S Washington, D.C. 20250

(202) 447-4693

Initiated

1931

Compliance

Voluntary except for products covered by Federal or State marketing orders.

Authority

CFR Title 7 Part 52 and Agricultural Marketing Act of 1946

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. As of 1984, over 300 plants participated with more than 10.5 million tons of commodities in 150 categories subject to inspection.

Agency Function

Certifier

Type of Program

Pre-marketing evaluation
Post-marketing assessment
Assessment prior to Government procurement

Methodology

Government, testing, inspection, audit, site approval, compliance with good manufacturing practices.

Testing

Government's lab
Manufacturer's lab used under view of
Government inspection
State labs if state is cooperating
in program
Third party labs may be used by
manufacturer for quality control

Inspection

Inspection by Government personnel, or cooperating State representatives.

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; available from the above address.

Obligations of Manufacturer

Manufacturer must submit to plant inspection and provision of samples at request of agency.

Enforcement

Since bulk of program is voluntary, means of enforcement is withdrawal of labelling 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

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

Products or Services

Refrigerated Vehicles

Department/Agency

U.S. Department of Agriculture Office of Transportation

Office of Transportation 1405 Auditor's Building

14th Street and Constitution Avenue, NW.

Washington, DC 20250

(202) 447-3963

Initiated

Being established

Compliance

Mandatory for manufacturers of refrigerated containers intended to be used in Europe.

Authority

International Carriage of Foodstuffs Act of

1982.

Aim

The program is responsive to an international agreement on the transport of perishable food which aims to promote public health and consumer values by assuring that transport equipment is initially capable of performing in a safe and effective manner.

Benefits

Technical requirements are based on transport refrigeration practices in countries which have successful records in commercial transport of perishable food.

Agency Function

Certifier

Type of Program

Pre-market evaluation

Methodology

Government design approval, testing, in-

spection.

Testing

Government lab

Government accredited lab

Inspection

Government

Conformity Identification

Lists of approved suppliers and certified

products

An internationally-recognized mark may be instituted at some time in the future.

Availability of Documentation

Lists available from Office of Transportation, the Department of Agriculture Obligations of Manufacturer

Subject a sample container to specified tests

Enforcement

Delisting

Term

Indefinite

Reciprocity

Recognition by foreign government agencies and international organizations (For the present, U.S. participation will be limited to certification for U.S. exporters).

Standards, Codes, or Regulations

U.S Department of Agriculture adopts test requirements agreed to in the international program sponsored by the United Nations Economic Commission for Europe.

Keywords

refrigerated trucks; refrigerated rail cars; perishable foodstuffs; international agreement; frozen food;

Products or Services

Tobacco, and Naval Stores

Department/Agency

U.S. Department of Agriculture Agricultural Marketing Service Tobacco Division Room 502 Annex Building 300 12th Street, SW.

Washington, DC 20250

(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 United States.

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-marketing 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:

Government

Naval Stores:

Licensed company inspectors Federal accepted appointees

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 *

Tobacco:

Reduction of sales opportunity or

withdrawal of inspection.

Naval Stores:

Withdrawal of inspection.

Term

Continuous inspection

Reciprocity

Recognition of certification by other Federal agencies and international

organizations.

Standards, Codes, or Regulations

7 CFR Part 29, Subpart C - Standards

7 CFR Part 160, Regulations and

Standards for Naval Stores

American Society for Testing and

Materials, Designation D 233, Sampling

and Testing Turpentine

Keywords

tobacco; naval stores; turpentine; rosin;

Products or Services Evaluation of Measuring Instruments

Department/Agency

U.S. Department of Commerce National Bureau of Standards (NBS) Office of Weights and Measures Gaithersburg, MD 20899

(301) 921-2401

Initiated

1984

Compliance

Voluntary

Authority

Resolution of the National Conference on Weights and Measures (NCWM) and NBS Organic Act (PL 81-619)

Aim

Provide an evaluation service for producers of specified kinds of measuring instruments used in commercial trade prior to acceptance for sale or use within the U.S.

Benefits

Provides a uniform means of recognizing the measurement quality of specific models of measuring instrument and the ability of their producers to manufacture instruments of consistent quality.

Agency Function

Certifier and program administrator

Type of Program

Pre-market evaluation

Methodology

NBS provides design approval, testing, inspection, auditing, and site approval either directly or jointly with an authorized laboratory.

Testing

Government approved laboratory (Authorized laboratory indicated above is most likely to be a certified State measurement laboratory).

Inspection

State government

Conformity
Identification

Certificates of conformance issued to manufacturer.
List of qualified manufacturers

Availability of Documentation

List published by NBS.

Obligations of Manufacturer/Vendor

Manufacturer 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

NBS prepares acceptance criteria, taking advice from NCWM, device manufacturers and participating laboratories and international organizations. The NCWM adopts these criteria by consensus vote.

Keywords

commercial measuring devices; measurement instruments; state laboratories; legal metrology; type evaluation; prototype; production control;

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
System Components Division
Gaithersburg, MD 20899

(301) 921-3723

Initiated

1979

Compliance

Mandatory for applicable information processing equipment to be purchased by Federal agencies.

Authority

Title 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

Methodology

NBS verification of compliance to specified standards by review of documentation, or demonstrated use with verified equipment.

Type of Program

Verification of compliance prior to consideration for purchase by Government.

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 deviations 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 agency. Applicable standards are available through the National Technical information Service, Springfield VA, 22161.

Obligations of 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 costs incurred.

Enforcement

Delisting

Term

Indefinite

Reciprocity

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

Standards, Codes, Regulations

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

Keywords

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

Measurement Calibration Services

Department/Agency

U.S. Department of Commerce National Bureau of Standards (NBS) Office of Weights and Measures Gaithersburg, MD 20899

(301) 921-2401

Initiated

1965

Compliance

Voluntary

Authority

PL 81-619 (NBS Organic Act).

Aim

Provide certification of state measurement laboratory capabilities to calibrate standards and equipment for measuring mass, length, volume, temperature, and frequency-based devices.

Benefits

Provides basis for consistent results in calibration and tolerance testing among States and between States and NBS. Provides measurement equivalency in regulation of interstate commerce.

Agency Function

Program administrator

Type of Program

A joint on-going activity between Federal and State Governments to evaluate, up-grade, and train measurement technicians in official State weights and measures laboratories.

Methodology

Government inspection and site approval. Installation and maintenance of measurement control programs. Program Requirements in NBS Handbook 143.

Testing

All delivery of services within this program is performed by state laboratories accredited by a Federal agency.

Inspection

Government

Conformity Identification

States receive certificates of accreditation and are identified in a list, NBS SP686. Instruments and standards certified by State laboratories may be identified by a governmentapplied mark.

Availability of Documentation

NBS SP686 is available from NBS.

Obligations of 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. Certificates of accreditation are valid for up to 3 years.

Reciprocity

NBS certification of a State laboratory carries recognition within that State and among the states and by private organizations.

Standards, Codes, or Regulations

Criteria documents are developed by NBS. See NBS Handbook 143 available from NBS.

Keywords

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

Processed Fish and Shellfish

Department/Agency

U.S. Department of Commerce
National Oceanic
and Atmospheric Administration
National Marine Fisheries Service
National Seafood Inspection Program
Washington, DC 20235
(202) 634-7058

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 the grading of major types of seafood sold for human consumption. The program also helps processors prepare processing specifications for nonstandard 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 product, testing, and certification.

Testing

Testing in government labs, recognized state labs, and 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. Lists 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 Manufacturer/Vendor

Producers must comply with sanitary, quality control, and inspection requirements in addition to providing office, laundry, and temporary lab space.

Enforcement

Delistina

Term

Indefinite term

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 any other country.

Standards, Codes, or regulations

Agency prepares all criteria documents including the Fishery Products Inspection Manual.

Keywords

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

Weather Observation

Department/Agency

U.S. Department of Commerce National Oceanic and Atmospheric Administration National Weather Service Basic Observations Branch 8060 13th Street, NW. Silver Spring, MD 20910 (301) 427-7792

Initiated

May 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 Manufacturer/Vendor

Certificate holder is required to maintain experience and participate in

annual training.

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

weather observation; eyesight examination; vision standards; snellen test; laeger test; radar observation; aviation weather; radiosonde observation; computer data entry; self-study; personnel;

Products or

Consumer Products

Services

(personal use devices intended for household, school, or recreational use)

Department/Agency

Consumer Product Safety Commission (CPSC)

Office of the General Counsel

1111 18th Street, NW. Washington, DC 20207

(202) 492-6980

Initiated

October 1972

Compliance

Mandatory

Authority

Public Law 92-573 as amended by PL 94-284,

95-319, 95-631-, 96373, 97-35

Aim

Reduce the number of consumer products which

present unreasonable risks.

Benefits

Specific products covered by CPSC Standards are now certified by manufacturers to con-

form 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 manu-

facturer 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 Commission 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

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

Fabrics Used in Wearing Apparel and Interior

Furnishings

Department/Agency

Consumer Product Safety Commission (CPSC)

Office of the General Counsel

1111 18th Street, NW. Washington, DC 20207

(202) 492-6980

Initiated

June 1953

Compliance

Mandatory

Authority

Public Law 83-88 as amended

Aim

Reduce risk of fire and injury or death related to fire, in or on fabric articles.

Benefits

Compliance with applicable standards and associated labelling 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 Manufacturers' labs

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/Vendor

Manufacturer may comply with the Act by guaranteeing conformance with applicable

standards based on test data.

Enforcement Product condemnation and destruction

Term Periodic audit testing/inspection is required to maintain certification.

required to maintain certification.

Reciprocity Conformity is recognized by other Federal

agencies, State governments, and private

organizations.

Standards, Codes, Criteria for standards are cited in the Act; or Regulations Commission recognizes the use of voluntary standards to accomplish the purpose of the

Act.

Keywords fabrics; wearing apparel; interior furnish-

ings; voluntary standards; flammability;

product testing;

Products or

Hazardous Substances

Services (chemicals which are toxic, corrosive, flammable, irrating, radioactive or pressuregenerating, and devices including these chemicals, or which may injure intended

users)

Department/Agency

Consumer Product Safety Commission (CPSC)

Office of the General Counsel

1111 18th Street, NW. Washington, DC 20207

(202) 492-6980

Initiated

July 1960

Compliance

Mandatory

Authority

Public Law 86-613 as amended by the Poison

Prevention Packaging Act P.L. 91-601

Aim

Reduce risk of injury to all intended users

of designated substances and devices.

Benefits

Informative labelling is now in effect and

selected products have been banned.

Agency Function

Program administrator

Type of Program

Pre-market evaluation

Methodology

Government approval of labelling information

to be provided with designated hazardous substances.

Testing

Manufacturers' labs

Government labs

Inspection

Government

Conformity Identification

Authorized label by manufacturer

Availability of Documentation

List of banned hazardous substances may be

obtained from CPSC.

Obligations of Manufacturer/Vendor

Carriers must keep records of interstate shipment of designated hazardous substances.

Enforcement Marketing ban Product recall

Term Indefinite term

Reciprocity Approved labelling is recognized by other Federal agencies, State governments, and

private organizations.

Standards, Codes, Criteria for designating substances as or Regulations hazardous are prepared by CPSC.

Keywords hazardous substances; flammability; corrosi-

ve; toxicity; irritant; radioactivity; banned products; misbranded substances;

Parts, Materials and Components Used in Military Systems

Department/Agency

U.S. Department of Defense Director of Standardization and Acquisition Support The Pentagon, Room 2A-318 Washington, DC 20301

Initiated

1949

Compliance

Mandatory for those products defined by specifications having qualification 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, advance assessment of supplier capability. At the end of 1984 1300 QPL's existed listing more than 3000 manufacturers. Approximately 50 percent of these are U.S. small business manufacturers.

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 requirements for either in-process or other inspection by the manufacturer, or receiving inspection by the buyer.

Conformity Identification

Listing on Qualified Products Lists (QPL's) Authorized designation (JAN Mark) applied by manufacturer/distributor to qualified semiconductors, microelectronic, and established reliability products.

Availability of Documentation

DOD specifications and QPLs are distributed by:

Naval Publications and Forms Center 5801 Tabor Avenue Philadelphia, PA 19120

Obligations of 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

Indefinite for most products; 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. Ministries of Defense

Standards, Codes or Regulations

Program is based on qualification requirements specified in Military Specifications.

Keywords

quality control; procurement; qualification; testing; military; QPL;

Air and Water Treatment Facilities

Department/Agency

Environmental Protection Agency (EPA)
Office of Air Quality Programs, and
Office of Water Quality Programs

401 M Street, SW. Washington, DC 20460 (202) 382-5575, Air (202) 382-5400, Water

Initiated

1976

Compliance

Voluntary

Authority

40 CFR 20

Aim

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.

Availability of Documentation

Lists available from States and EPA.

Obligations of Manufacturer/
Vendor

Facilities must submit plans for review

whenever modifications are made.

Enforcement

Delisting

Term

Indefinite

Reciprocity

No reciprocity

Standards, Codes,

EPA defines acceptance criteria.

Keywords

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

pollution control;

Automotive Aftermarket Parts

Department/Agency

Environmental Protection Agency (EPA)
Manufacturers Operations Division (EN-340F)

401 M Street, SW. Washington, DC 20460

(202) 382-2515

Initiated

1980 (Modifications to current procedures are expected to be proposed in late 1985)

Compliance

Voluntary

Authority

Section 207 (a) of the Clean Air Act, 42 U.S.C. 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 emissions applies.

Agency Function

Program administrator

Type of Program

Self-certification by supplier

Methodology

Testing and self-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.

Obligation of Manufacturer/ Vendor Suppliers are required to establish and maintain records containing descriptions and results 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

automotive parts; vehicle emissions; air
pollution; replacement; aftermarket; warranty;
environment;

Drinking Water

Department Agency

Environmental Protection Agency (EPA) Office of Drinking Water (WH550)

401 M Street, SW. Washington, DC 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 141 and 142)

Aim

Broaden the base of testing facilities competent to analyze drinking water in disciplines of chemistry, microbiology, and radio-

chemistry.

Benefits

Easier access to competent testing facilities for all regulated and interested parties.

Agency Function

Certifier (in nonprimacy states, territories,

and Indian reservations)
Program administrator elsewhere.

Type of Program

Premarket 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 government

Conformity

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

Availability of Documentation

Lists are available from certifying authorities and EPA Regional Office.

Obligations of Manufacturer/Vendor

Certified labs must complete periodic performance evaluations satisfactorily, maintain competency in approved method, notify certifier of changes in staff or equipment and submit to periodic onsite 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 on expected to develop procedures for recognizing certifications among themselves.

Standards, Codes, or Regulations

EPA develops standard methods.
Agency recognizes methods prepared by others.

Keywords

drinking water; chemistry; microbiology; radiochemistry; quality assurance; performance evaluation; onsite evaluation;

Motor Vehicle Engines, Gasoline and Diesel

Agency Function

Environmental Protection Agency (EPA)
Office of Mobile Sources

2565 Plymouth Road Ann Arbor, MI 48105 (313) 668-4200

Initiated

1972

Compliance

Mandatory for producers and distributors of motor vehicle engines, automobiles, light duty trucks, and motorcycles.

Authority

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 though 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

Premarket evaluation; regulations provide for design evaluation, pre-production testing, and production auditing.

Methodology

Governmental design approval, testing, and audit in conjunction with manufacturer self-certification.

Testing

Government lab

Government accredited labs

Manufacturers' 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/ Vendor

Manufacturer must qualify new engine designs, new emission control system designs, and existing engine and emission control system designs when emission

regulations change.

Enforcement

Marketing ban Product recall

Term

Annual with audit testing

Reciprocity

Federal certification is recognized in all

States except California.

Standards, Codes of Regulations

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

Keywords

motor vehicles; light duty trucks; motorcycles; exhaust emissions; hydrocarbons; oxides of nitrogen; carbon monoxide; diesel engines;

evaporative emissions;

Private and Commercial Applicators of

Restricted Use Pesticides

Department/Agency

Environmental Protection Agency (EPA)

Office of Pesticide Programs

401 M Street, SW. Washington, DC 20460

(703) 557-7096

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

Federal Fungicide, Insecticide, and

Rodenticide Act (FIFRA) PL 94140 and PL 95

396

40 CFR 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 hazards associated with pesticide misuse.

Agency Function

Certifier in Colorado and Nebraska program. Administrator in all other States and territories in which the local program is

approved.

Type of Program

Premarket 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 EPA. Lists of certified applicators in Colorado and Nebraska are available directly from 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 years for commercial applicators.

Reciprocity

Reciprocity among States is based on State agreements which are on file with EPA. No formal list of reciprocal relations is available.

Standards, Codes, or Regulations

Certifications standards are promulgated by States and must be as stringent as required by FIFRA.

Keywords

pesticides, fungicides, rodenticides; insecticides; registered chemicals; restricted use; environmental hazards; personnel;

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 CFR 47 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 increase 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 compulsory installed marine safety-of-life equipment, and to some nonlicensed devices, including certain industrial, scientific, and medical 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 transmitting equipment used under a radio station license issued by the FCC in many of the radio services.
- -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 nonlicensed devices, mostly low power radio frequency devices and, in addition, to certain categories of receivers which tune anywhere in the band 30 to 890 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 writte 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

-A newly established procedure. (Report and Order - Docket No. 82-242 - released January 21, 1983.)

- -Applicability to particular categories of equipment has been established in the Report and Order Docket No. 83-10, released Jan. 26, 1984.
- -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 at its option, 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.
- -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 device, 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 of Part 2, and Part 68 of FCC Rules provides further information on this procedure.

Methodology

Program uses:

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

Testing

Testing may be performed by:

- FCC lab
- manufacturer's lab
- third-party lab.

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 Manufacturer/
Vendor

Maintain design of approved equipment. State maintenance requirements to users.

Enforcement

Marketing ban and product recall

Term

Indefinite term

Reciprocity

None. Test data from counterpart agencies is taken into consideration but no

reduction of test requirements is provided.

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

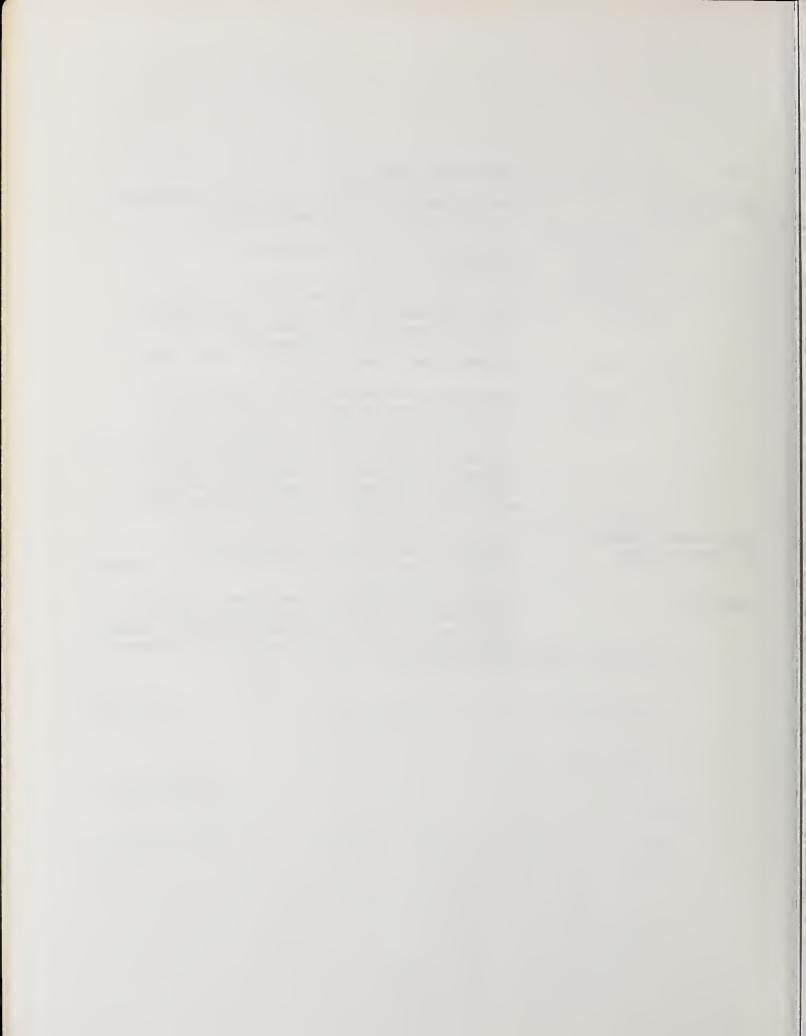
There are some specified exceptions to this requirement as given in Part 2 of the FCC rules, Sections 2.806, 2.809, 2.811 and 2.813. Also, there are a few categories of devices which are not subject to technical standards in the FCC rules. These devices must meet the applicable standards before importation.

Standards, Codes, or Regulations

Criteria promulgated by FCC; private sector standards are considered in preparing rules.

Keywords

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



Parts, Materials, and Equipment

Department/Agency

General Services Administration (GSA)
Office of Federal Supply Services
Commodity Management Division (FCM)
Washington, DC 20406
(703) 557-1001

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.

Authority

Armed Services Property Regulations of 1944 Federal Property Management Regulations, (FPMR) 101-29

Aim

As a means of expediting contract awards and deliveries of designated products, manufacturers are required to have these products pretested 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 inspection of each lot.

Benefits

The availability of products known to be qualified reduces the costs and time to select products for inclusion in equipment and systems that must perform reliably. Ready availability of qualified products reduces purchase lead times and increases quality of the equipment using these products. At the end of 1984, approximately 80 Federal Qualified Products Lists (QPL's) existed listing more than 450 manufacturers. 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 General Services Administration (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 Qualified Products Lists (QPL's)

Availability of Documentation

Federal QPL's and specifications are distributed by:

General Services Administration Specification Unit (WFSIS) 7th and D Streets, SW. Washington, DC 20406

Obligations of Manufacturer/Vendor

Manufacturers and distributors must supply test samples, ordinarily bear the cost of testing, maintain quality and notify of design changes. Reference may be made to listing on QPL's in advertising and 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.

Enforcement

Delisting

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

quality control; procurement; testing; Federal; QPL;

Color Additives

Department/Agency

U.S. Department of Health and Human Services Food and Drug Administration (FDA) Center for Food Safety and Nutrition Division of Color Technology (HFF-430)

200 C Street, SW. Washington, DC 20204

(202) 245-1141

Initiated

1977 (latest authority)

Compliance

Mandatory

Authority

P.L. 94-295, 21 CFR 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

As an ongoing program, color additive certification monitors conformance of additives to existing requirements and identifies need for new limitations.

Agency Function

Certifier

Type of Program

Pre-marketing evaluation

Methodology

Government testing

Testing

Government labs

Inspection

Government

Conformity
Identification

List of approved colors and certified

products

Availability of Documentation

Lists available from FDA.

Obligations of Manufacturer/

Vendor

Manufacturers must conform with Good Manufacturing Practices (GMP) and report any known ill effects associated with certified addi-

tives.

Enforcement

Marketing ban Product recall Delisting

Certification is provided on a batch basis. Term

Reciprocity Certification is recognized by other Federal agencies, State agencies, and private sector

organizations.

Agency prepares criteria for certification. Standards, Codes, or Regulations

Agency adopts test methods prepared by others such as the Association of Official Analytic

Chemists.

Keywords color additives; foods; drugs; cosmetics;

certification; adulteration; misbranding;

carcinogens;

Electronic Products

Department/Agency

U.S. Department of Health and Human Services

Food and Drug Administration (FDA)

Center for Devices and Radiological Health

5600 Fishers Lane Rockville, MD 20857 (301) 443-4690

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 nonionizing 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 Manufacturer/

Manufacturer must keep production and distribution records; notify buyers of nonconforming equipment and recall such equipment for

repair.

Enforcement Marketing ban

Certification applies for the life of each Term

distinctive model.

Reciprocity No effective reciprocity

Agency sets criteria and publishes performance Standards, Codes,

or Regulations standards.

electronic radiation; microwave ovens; lasers; Keywords

sunlamps; ultrasonic therapy equipment; x-ray

equipment; mercury vapor lamps; television receivers; product labelling;

Drugs Containing Insulin

Department/Agency

U.S. Department of Health and Human Services

Food and Drug Administration (FDA)

Center for Drugs and Biologics

5600 Fishers Lane Rockville, MD 20857 (301) 443-1016

Initiated

1969

Compliance

Voluntary

Authority

21 CFR Part 429

Aim

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-market evaluation

Methodology

Compliance with Good Manufacturing Practices

Government inspection

Testing

Government lab
Manufacturer's lab

Inspection

Government

Conformity Identification

Lists of qualified suppliers and certified

products

Availability of Documentation

Lists available from FDA.

Obligations of Manufacturer/Vendor

Producer must keep production records for two

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 recognized by other Federal agencies, State agencies, and private sector

organizations.

Standards, Codes, Agency prepares certification criteria. or Regulations Agency adopts test methods of the

United States Pharmacopeial Convention and the

National Formulary.

Keywords insulin; packaging; labelling; color coding;

distribution; records;

Drugs for Human Use

Department/Agency

U.S. Department of Health and Human Services Food and Drug Administration (FDA) Center for Drugs and Biologics 5600 Fishers Lane Rockville, MD 20857 (301) 443-1016

Compliance

Mandatory

Authority

Food, Drug, and Cosmetic Act, 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-market 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 the Drug Listing Branch (HFN-315) of the FDA.

Obligations of Manufacturer/Vendor

Producers are required to register establishments, maintain sanitary conditions, provide substantial clinical evidence of safety and effectiveness, prepare adequate labelling and instructions for use, submit advertising for approval, comply with Good Manufacturing Practices, use approved packaging, and advise FDA of known adverse reactions.

Enforcement

Marketing ban and product recall

Term

No specific term; retesting is based on changes in product characteristics, composition, or intended use. A major consideration is any misbrading or adulteration.

Reciprocity

Certification is recognized widely in 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., U.S. Pharmacopeia, Homeopathic Pharmacopeia, or National Formulary.

Keywords

drugs; antibiotics; registration; labelling;
good manufacturing practices; sanitation;
misbranding; adulteration; recall; packaging;
premarket evaluation;

Food and Drugs for Animals

Department/Agency

U.S. Department of Health and Human Services Food and Drug Administration (FDA) Center for Veterinary Medicine (HFV-1) Rockville, MD 20857 (301) 443-3450

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-market 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 Third-party lab

Inspection

Government

Conformity Identification Lists of approved products and qualified producers are maintained by FDA.

Availability of Documentation

Official lists may be obtained from the FDA Center for Veterinary Medicine.

Obligations of Manufacturer/Vendor

For all products, producers are required to register establishments annually, maintain sanitary conditions, provide adequate labelling, and comply with Good Manufacturing Practices. For NDA 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; testing is based on changes in product characteristics composition or intended use. A major consideration is any misbranding or adulteration.

Reciprocity

Certification 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

FDA prepares the regulatory requirements including the GMP, but draws some technical input from the National Academy of Sciences.

Keywords

animal feed; pet food; food additives; veterinary medicines; animal drugs; mis-branding; adulteration; good manufacturing practices; registration;

Food for Humans

Department/Agency

U.S. Department of Health and Human Services

Food and Drug Administration (FDA)

Bureau of Foods 5600 Fishers Lane Rockville, MD 20857

(301) 443-1544

Initiated

1938

Compliance

Mandatory

Authority

Food, Drug and Cosmetic Act of 1938, as

amended

Aim

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-market evaluation

Methodology

Government inspection

Testing

Government labs
Manufacturers' labs
Third party labs

State/local government labs

Inspection

Government

State/local government

Conformity
Identification

Proper informative labelling; 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 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

Other Federal agencies

State agencies

Private sector organizations

Standards, Codes, or Regulations

Agency prepares all criteria document.

Keywords

adulterated product; misbranded product; dietary foods; infant foods; nutrition labelling; good manufacturing practices; standard of quality; sanitation; standard of

identity; fill of container standard;

Food Inspection Personnel

Department/Agency

U.S. Department of Health and Human Services

Food and Drug Administration (FDA)

5600 Fishers Lane Rockville, MD 20857

(301) 443-1544

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 inspec-

tion 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 Governments

Conformity Identification

Lists of certified inspectors are kept by participating State health departments.

Availability of Documentation

Lists must be obtained at the State level.

Term

Retesting every three years.

Reciprocity

Recognition by:

other Federal agencies,

State agencies,

private organizations.

Standards, Codes, or Regulations

Agency prepares criteria documents.

Keywords

food; retail sales; sanitation; program
evaluation; model ordinance; training; personnel certification;

Fresh and Frozen Molluscan Bivalves (oysters, clams and mussels)

Department/Agency

U.S. Department of Health and Human Services Food and Drug Administration (FDA) Shellfish Sanitation Branch, HFF-344 200 C Street, SW. Washington, DC 20204 (202) 485-0149

Initiated

1925

Compliance

Voluntary/cooperative

Authority

Federal Food, Drug and Cosmetic Act (Secs. 402, 403, 701(a) as amended Public Health Service Act (Secs. 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 main tain sanitary conditions during the handling and processing of shellfish.

Benefits

Shellfish products marketed in interstate commerce are safe for human consumption.

Agency Functions

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 conduct 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 ICSS is provided free to all States, shellfish industry, and other interested individuals upon request.

Obligations of Manufacturer/Vendor

Shellfish industry is required to meet state shellfish sanitary requirements for harvesting, handling and processing operations, 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 APHA. FDA develops and revises manual of operations. Manual revisions are approved by state shellfish control agencies.

Keywords

oysters; clams; mussels; shellfish;
National Shellfish Sanitation Program; NSSP;
interstate; seafood;

Infant Formula

Department/Agency

U.S. Department of Health and Human Services

Food and Drug Administration (FDA)

Center for Food Safety and Applied Nutrition Division of Regulatory Guidance (HFF-310)

200 C Street, SW. Washington, DC 20204

(202) 245-3117

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).

Testina

Manufacturers lab

Inspection

Government

Conformity

Identification

Lists of approved suppliers and certified

products

Availability of Documentation

Lists available from FDA.

Obligations of

Manufacturer/

Quarterly recertification by each producer. Prompt notification to FDA of any suspected

batch noncompliance, adulteration, or

misbranding.

Enforcement

Vendor

Maketing ban

Product recall by agency or producer

Term Audit testing/inspection to assure conformance

with quality control requirements prescribed

by agency.

Reciprocity Certification recognized by other Federal

agencies, State agencies, and private sector

organizations.

Standards, Codes, or Regulations

Technical requirements specified in the Act.

Keywords infant formula; nutrition requirements; good

manufacturing practices; quality control; adulteration; misbranding; product recall;

Medical Devices

Department/Agency

U.S. Department of Health and Human Services Food and Drug Administration (FDA)

Center for Devices and Radiological Health

(HFZ-1)

5600 Fishers Lane Rockville, MD 20857

(301) 443-4690

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 efficaceous in their intended use.

Benefits

For Class III devices, the program provides a more thorough design review.

For Classes I and II devices, the program

provides clear public expectations.

Agency Function

For Class III devices, certifier.

For Classes I and II devices, program adminis-

trator.

Type of Program

Pre-market evaluation

Methodology

For Class III, Government design approval, audit inspection, and site approval; manu-

facturers supply test data.

For Classes I and II, manufacturer self-certification and compliance with Good Manu-

facturing 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 maintained by FDA. For Classes I and II, manufacturer self-certification is evi-

denced through information required in

product labelling.

Availability of Documentation

Official lists are available from FDA Center for Devices and Radiologic Health.

Obligations of 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 non-compliances 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 recognized widely in U.S., but no foreign reciprocity.

Standards, Codes, or Regulations

FDA prepares requirements for Class III; standards for Class II may be from private sector; FDA develops and maintains GMP rules.

Keywords

medical devices; classification; misbranding; adulteration; good manufacturing practices; investigation use; recall; premarket notification;

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 Certification Branch 944 Chestnut Ridge Road Morgantown, WV 26505-2888 (304) 291-4331

Initiated

1972

Compliance

Voluntary

Authority

CFR Title 30 Part 11 CFR Title 30 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

There are 21 domestic manufacturers and five importers. The certifying laboratory evaluates approximately 2000 samples of respiratory protective devices. 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 postmarketing assessment, in the form of defect investigation.

Methodology

Federal agency design approval and testing

Testing

Government laboratory and manufacturers

labs

Inspection

Federal agency representatives only

Conformity Identification

Approved products lists and governmentapproved labels applied by manufacturer.

Availability of Documentation

Approved products lists available to equipment users at above address.

Obligations of Manufacturer

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 labelling if approval is suspended.

Enforcement

Delisting

Product recall (voluntary by manufacturer)

Notification to users

Term

Indefinite term

Reciprocity

Other Federal agencies (e.g. NRC)

State agencies

Government of Canada (counterpart agencies)

Standards, Codes, or Regulations

Agency prepares criteria documents.

Agency adopts standards prepared by others for

quality plans and respirator maintenance.

Keywords

respirators; air samplers; gas masks; breathing apparatus; face pieces; coal mine dust; pesticides; design

approval;

Building Products for Construction

Department/Agency

U.S. Department of Housing and Urban Development (HUD) Office of Manufactured Housing and Construction Standards

451 Seventh Street SW. Washington, DC 20410 (202) 755-5929

Initiated

1965

Compliance

Voluntary

Authority

CFR Title 24 Part 200.935

Aim

Prevent product failures and misrepresentations of products. 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 standard.

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 labs

State/local government labs

Agency-accredited labs

Inspection

Third party

Conformity Identification

Authorized mark or label by manufacturer or third-party validator. More than seventy third-party validators participate in the HUD Building Products Certification Program for approximately twenty products ranging from carpeting to plywood.

Availability of Documentation

All documentation is published in the Federal Register.

Obligations of Manufacturer/Vendor

Manufacturers are obligated to cease marking products 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 in 24 CFR Part 24.

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 organizations. 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 200.935.

Keywords

building products; certification; thirdparty validation; mortgage insurance; housing; administrators; acceptance criteria;

Manufactured Housing

Department/Agency

U.S. Department of Housing and Urban Development (HUD)

Manufactured Housing Standards Division

451 Seventh Street, SW. Washington, DC 20410

(202) 755-6590

Initiated

1976

Compliance

Mandatory

Authority

National Manufactured Housing Construction and Safety Standards Act, PL 93-382, 42 U.S.C 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 nationwide certification program has accomplished the stated purposes of the Act as well as improved interstate commerce in manufactured housing.

Agency Function

Program administrator

Type of Program

Pre-emptive, mandatory, national regulation

Methodology

Third-party certification of building plans and in-factory enforcement for compliance.

Testing

Third-party labs
Manufacturer's lab

Inspection

Third-party

State government

Conformity Identification

Authorized label by manufacturer Lists of approved manufacturers

Availability of Documentation

Lists are maintained by the agency and the State Approved Administrators.

Obligations of Manufacturer/Vendor

Manufacturers must keep sufficiently accurate component data by finished unit serial number so that purchasers can be notified if an imminent safety hazard is

alleged.

Enforcement

Marketing ban on unlabelled homes; product recall on defective units; removal of third-party inspection agencies for repeated inadequate performance.

Term

Indefinite term

Reciprocity

Other Federal agencies

State agencies

Standards, Codes, or Regulations

Agency adopts standards prepared by others and provides necessary integrating requirements.

Keywords

inspection; product safety; design approval;

Surface and Subsurface Safety Valves

Department/Agency

U.S. Department of the Interior Minerals Management Service 12203 Sunrise Valley Drive, Reston, VA 22091 (703) 860-7506

Initiated

1980

Compliance

Mandatory

Authority

CFR Title 30, Part 250.11 Outer Continental Shelf (OCS) Orders

Aim

Prevention of 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 certification

Testing

Third-party accredited laboratories

Inspection

Third-party

Conformity

Identification

Authorized mark or label by manufacturer

Availability of Documentation

Available from ASME at 345 E. 47th Street, New York, New York 10017.

Obligations of Manufacturer/Vendor

Traceability.

Enforcement

Delisting.

Term

3 years.

Reciprocity

None.

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

safety valves; oil; gas; petroleum;
pollution-prevention; offshore; OCS;

Diesel-Powered Equipment for Gassy Mines

Department/Agency

U.S. Department of Labor Mine Safety and Health Administration 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 gas may be present.

Authority

PL 91-173; 30 U.S.C. 957

PL 95-164; 30 U.S.C. 961, 951; 30 CFR 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 dieselpowered mine machinery have been minimized.

Agency Function

Certifier

Type of Program

Pre-market evaluation

Methodology

Government design approval, testing,

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 Manufacturer/

Manufacturer must maintain production

Vendor

according to type-approved drawings, including modifications to design required for approval, and employ acceptable quality control plan.

Enforcement Marketing ban; removal from mine use of non-

conforming equipment; legal action.

Term Indefinite

Reciprocity Other international, Federal and State agencies

Private organizations

Standards, Codes, Agency prepares criteria documents. or Regulations

Keywords non-coal mines; diesel-powered equipment; mining machines; transporters; exhaust gases;

flammable atmospheres; dust collectors; electrical components; ventilators; safety;

Electrical Equipment for Mines

Department/Agency

U.S. Department of Labor Mine Safety and Health Administration Approval and Certification center, Box 251 Triadelphia, WV 26059

(304) 547-0400

Initiated

1977

Compliance

Mandatory

Authority

PL 95-164; 30 U.S.C. 961, 951; 30 CFR 18

PL 91-173; 30 U.S.C. 957

Aim

To provide uniform means for evaluating electrical equipment used in gassy mines for mining, illuminating, and measuring in order

to reduce workplace hazards.

Benefits

Accidents and deaths related to electricallypowered 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 Manufacturer/

Vendor

Manufacturer must maintain production according to type-approved drawings, including modifications to design required for approval and employ acceptable quality control plan.

Enforcement

Marketing ban; removal, from mine use, of nonconforming equipment; legal action.

Term Indefinite

Reciprocity Other international, Federal and State agencies,

private organizations

Standards, Codes, Agency prepares criteria documents. or Regulations

Keywords coal mines; electrical equipment; illumination;

intrinsically-safe equipment; signalling
devices; pumps; fans; compressors; battery
powered equipment; instruments; shuttle cars;

safety;

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 Avenue, NW.
Washington, DC 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 & Health Standards for General industry;
29 CFR, Part 1915 -- Occupational Safety & Health Standards for Shipyard Employments;
29 CFR, Part 1917-1918 -- Occupational Safety and Health Standards for Marine Terminals;
Longshoring;
29 CFR, Part 1926 -- Construction Safety & Health Standards;
29 CFR, Part 1928 -- Occupational Safety & Health Standards for Agricultural Employments.

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 is required to be listed, labelled, or approved by third-party laboratories.

Benefits

The Occupational Safety and Health Administration (OSHA) certification program enables employers to install equipment which has demonstrated compliance with applicable standards and regulations. OSHA workplace inspections can 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 Federal Register Notice of March 6, 1984.

Inspection

OSHA inspectors can inspect equipment in the

workplace.

Obligations of 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 or more stringent than the 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 American National Standards Institute, American Society of Mechanical Engineers, National Fire Protection Association, Underwriters Laboratories and others.

Keywords

safety; health; job safety; machinery; equipment; construction; agriculture; diving; fire protection; medical services; ventilation; hazardous materials; personal protective equipment; material handling; tools; welding; electrical;

Maritime Cargo Handling Equipment

Department/Agency

U.S. Department of Labor

Occupational Safety and Health Administration (OSHA)

Division of Maritime Compliance Assistance

200 Constitution Avenue, NW.

Washington, DC 20210

(202) 523-8133

Initiated

1971

Compliance

Mandatory

Authority

29 CFR 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

United States Coast Guard.

Benefits

Safety of longshoremen, seamen, and dock workers has been improved by this program which fullfills U.S. responsibilities for International Labor Organization (ILO)

Convention No. 32.

Agency Function

Program Administrator

Type of Program

Post-marketing assessment

Methodology

Third party certification

Testing

Government accredited lab

Inspection

Third party

Conformity

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 publi-

cize a list of their clients.

Obligations of Manufacturer/ Vendor

Cooperate with a specific third-party certifier regarding design, fabrication, and installation data and maintenance require-

ments.

Enforcement

Delisting or ban on usage.

Term

Annual retesting

Reciprocity

Other Federal and State agencies

Standards, Codes, or Regulations

Agency adopts standards prepared by others.

Keywords

accreditation; cranes; derricks; materials handling equipment; wire rope; safe working

loads;

Packages and Containers for Radioactive

Material

Department/Agency

Identification

Nuclear Regulatory Commission
Office of Nuclear Material Safety

and Safeguards
Washington, DC 20555
(301) 427-4122

Initiated 1974

Compliance Mandatory

Authority Title 10, Code of Federal Regulations,

Part 71

Aim/Benefits Protection of public health and safety

and the environment.

Agency Function Program administrator or 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 Approved packages are assigned an indent-

ification number.

Availability of Part 71 Docket Files

Documentation United States Nuclear Regulatory Commission

Public Document Room Washington, DC 20555

(202) 634-3273

Obligations of Report defects or noncompliance.

Manufacturer/Vendor Report significant reduction of effective-

ness 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)

Keywords

packaging, radioactive material; nuclear; safety; environment;

Breath Alcohol Testers and Their Calibration Units

Department/Agency

U.S. Department of Transportation (DoT)
National Highway Traffic Safety Administration
Office of Alcohol Countermeasures, NTS-21,
400 Seventh Street, SW.
Washington, DC 20590
(202) 426-9581

Initiated

1984

Compliance

Voluntarily adopted by States and local jurisdictions. Manufacturers voluntarily submit testers for evaluation and listing.

Authority

23 U.S.C. 402 and 49 CFR 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 National Highway Traffic Safety Administration (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 Department of Transportation 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 Manufacturer/Vendor

Manufacturer must submit a unit for test.

Term

Indefinite

Standards, Codes, or Regulations

Acceptance criteria have been developed by NHTSA in collaboration with NBS.

Keywords

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

Cylinders for Transportation of Hazardous Materials

Department/Agency

U.S. Department of Transportation (DoT)
Research and Special Programs Administration
Office of Hazardous Materials Regulation

400 7th St., NW.

Washington, DC 20590

(202) 426-2075

Initiated

1964

Compliance

Mandatory

Authority

49 CFR 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

Inspection

Third-party

Conformity

Identification

Authorized identity by manufacturer

Availability of Documentation

No central registry of manufacturers; all cylinders legal for service are marked.

Obligations of Manufacturer/Vendor

Manufacturers must maintain quality control.

Vendors must cycle inventory.

Users must not use out-of-date cylinders.

Enforcement

Product recall

Term

15-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 U.S.A.

Standards, Codes, or Regulations

Agency has integrated product requirements based on industry test methods.

Keywords

cylinders; hazardous materials; hydrotest; quality control; inspection; maintenance; safety;

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 engineering representatives, and designated manufacturing inspection representatives.

Department/Agency

U.S. Department of Transportation (DoT) Federal Aviation Administration (FAA) Office of the Associate Administrator for Aviation Standards 800 Independence Avenue, SW. Washington, DC 20591 (202) 426-3131

Initiated

1926

Compliance

Mandatory

Authority

Federal Aviation Act of 1958 (49 U.S.C.), CFR 14, Parts 1 to 199

Aim

Promote, regulate, and encourage the development of civil aviation in such a manner as to promote its development and provide for the safe and efficient use of the airspace.

Benefits

The FAA certification system has helped 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 miles traveled.

Agency Function

Program administrator and certifier.

Type of Program

The comprehensive FAA product certification program includes assessment of the initial design; evaluation of the initial products; compliance with demonstrated 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 Production Certificate is issued to holders of type certificates upon demonstration that their quality control system assures that products conform to the type certificate.

An Airworthiness Certificate 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 Parts Manufacturer Approval are marked "FAA-PMA". Those manufactured in accordance with a TSO authorization are marked with applicable TSO number.

Availability of Documentation

No lists of approved or qualified products or suppliers are published for general distribution by the FAA.

Obligations of Manufacturer/Vendor

Each manufacturer or user of certified products, including TSO items, shall report any accident, failure, mal-function, or defect that could result in fire, engine failure, primary structural defect, loss of 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 tests, 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. it is determined that the public interest and safety requires it, the FAA may issue an order amending, suspending or revoking, all or part of any Type Certificate, Production Certificate, Airworthiness Certificate, 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 United States. 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 the ICAO guidelines in the United States. The U.S. Department 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 United States 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 United States, 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 CFR Part 14, Parts 1 to 199. Approximately 60 nongovernment standards are incorporated in TSO's. These are primarily standards developed by the Society of Automotive Engineers, Radio Technical Commission for Aeronautics, and Aerospace Industries Association.

Keywords

type certificate; production certificate; airworthiness; PMA; TSO; aircraft; engines; propellers; avionics; parts; materials; processes; bilateral agreements; safety; quality; performance;



Lifesaving, Engineering, Fire Protection, and Pollution Prevention Equipment for Recreational Boats and Commercial Vessels

Department/Agency

U.S. Department of Transportation (DoT) Coast Guard Washington, DC 20593 Telex: 892427

For electrical, pneumatic, and hydraulic equipment:

Engineering Branch, G-MTH-2 (202)426-2160

All other equipment:
Survival Systems Branch, G-MVI-3

(202)426-1444

Initiated

1946

Compliance

Mandatory for equipment required to be used on recreational boats and commercial vessels.

Authority

33 CFR 159; 46 CFR 2, 159-164

Aim

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-marketing evaluation, inspection, and

testing

Methodology

Government design approval, and audit of 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 testing 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 COMDTINST M16714.3A) available for sale through Government Printing Office, order number 050-012-00212-6.

Obligations of Manufacturer/Vendor

Manufacturer is required to produce approved item exactly as described in approved plans. Some recordkeeping required.

Enforcement

Delisting. Civil and criminal penalties are also available in certain cases.

Term

Five years. Renewal generally available on request.

Reciprocity

None

Standards, Codes, or Regulations

33 CFR 159.15 and 46CFR 160-164 define applicable requirements and criteria.

Keywords

marine safety; marine pollution prevention; recreational boats; commercial vessels; equipment;

Motor Vehicle Safety

Department/Agency

U.S. Department of Transportation (DOT)

National Highway Traffic Safety Administration 400 Seventh St. SW.,

Washington, D.C. 20590

(202) 426-2829

Initiated

1966

Compliance

Mandatory

Authority

National Traffic and Motor Vehicle Safety Act

of 1966 as amended

Aim

Regulate design, construction, and performance of motor vehicles to protect the public

against unreasonable risk of injury in

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

The agency maintains lists of vehicle and equipment manufacturers who have undertaken product recalls for the purpose of achieving compliance with Federal Motor Vehicle Safety

Standards.

Obligations of Manufacturer/ Vendor

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

Term

Marketing ban

Enforcement

Reciprocity

Product recall

Indefinite

Other Federal agencies

State agencies

Private sector organizations may be paid contractors to the agency for detection of

of defects or compliance research

Standards, Codes, or Regulations

Agency prepares criteria documents.

Keywords

automobiles; trucks; shoolbuses; motor vehicle equipment; used vehicles; compliance;

safety; product recall; labelling;

Packaging of Hazardous Materials for Export

Department/Agency

U.S. Department of Transportation (DoT) Research and Special Programs Administration Office of Hazardous Materials Regulation

Materials Transportation Bureau

Washington, DC 20590

(202) 426-2075

Initiated

March 13, 1985

Compliance

Voluntary

Authority

49 U.S.C. 1804, 1805, 1808; 49 CFR 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

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-marketing 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

certificates 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, Standards set forth in the U.N. Recommenor Regulations dations (Transport of Dangerous Goods), and Department of Transportation requirements

listed as 49 CFR, Part 171, Subchapter C.

Keywords transportation; hazardous materials; packaging;

containers; export; international; approval agencies;

United Nations; National Competent Authority;

Packaging of Radioactive Materials for Transport

Department/Agency

U.S. Department of Transportation (DoT)
Research and Special Programs Administration
Office of Hazardous Materials Regulation
400 7th St., NW.

Washington, DC 20590 (202) 436-2311

Initiated

1975

Compliance

49 U.S.C. 1803, 1808 as amended

49 CFR 173.465-.469

Authority

Mandatory

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 acceptance

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/

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) 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; packaging; radioactive material; package approval; quality assurance; transportation; domestic; international; IAEA; safety;

Pipelines for Hazardous Fluids

Department/Agency

U.S. Department of Transportation (DoT)
Research and Special Programs Administration
Office of Hazardous Materials Regulation
400 7th Street, NW.
Washington, DC 20590

(202) 426-2392

Initiated

1968

Compliance

Mandatory

Authority

49 U.S.C. 1803-1809

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 United

States meets expectations.

Agency Function

Program administrator

Type of Program

Pre-installation review with periodic test on safety equipment throughout the useful life of

the pipeline.

Methodology

Third-party certification: welder and plastic pipe assemblers. Manufacturer self-certification: valves, pressure-limiting devices, and overall

installation to specified standards.

Testing

Manufacturer or third-party

Inspection

Third-party

Conformity Identification

Lists of qualified welders/installers and approved installations are published.

Availability of Documentation

Certification of Welders by American Welding Society; comparable program by 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 an approximate annual cycle, not to exceed 17 month intervals.

Reciprocity

Approved pipelines are not regulated by any other Federal or State agency or private organization.

Standards, Codes, or Regulations

Agency mainly adopts standards of other organizations.

Keywords

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

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 Office of Hazardous Materials Regulation

400 Seventh Street, SW.

Washington, DC 20590

(202) 426-2075

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 lab

Inspection

Third-party

Conformity Identification Direct marking on tanks

Certificates of construction issued by

Agency.

Availability of Documentation Certificates of construction are kept by

Agency and AAR.

Obligations of Manufacturer/ Vendor

Manufacturer is obligated to use approved

welders during construction.

Enforcement Delisting or product recall if defects

can be repaired.

Term Certification is essentially indefinite.

Reciprocity Other Federal agencies

State agencies

Private sector organizations

Canadian government

Standards, Codes, Agency adopts standards of other

or Regulations organizations and provides integrating

requirements.

Keywords railroads; hazardous materials; design

approval; witness testing; welder certifi-

cation; railway car couplers;

Rear End Marking Devices for Passenger, Commuter and Freight Trains

Department/Agency

U.S. Department of Transportation (DOT) Federal Railroad Administration (FRA) Office of Standards and Procedures 400 Seventh Street, SW. Washington, DC 20590 (202) 426-0897

Initiated

1978

Compliance

Mandatory

Authority

Sec. 202, 84 Stat. 971, 45 U.S.C. 431 and 49 CFR 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. Currently twenty devices produced by six manufacturers are listed.

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 list of approved devices

Availability of

49 CFR, Part 221, Appendix B

Obligation of Manufacturer

Produce devices that are the same as samples tested for 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

lights; reflectors; strobe; photometric; colorimetric; qualified laboratory; railroad; railway; transportation; safety;

Shipboard Navigational Aides

Department/Agency

U.S. Department of Transportation (DOT)

Coast Guard

Waterways Safety Branch (G-WWM-1)

Washington, D.C. 20593

(202) 426-1940

Initiated

January 1985

Compliance

Mandatory

Authority

CFR Title 33 Chapter 164

Port and Tanker Safety Act of 1978

Aim

To improve the standard 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

Authorized label by manufacturer

Availability of Documentation

No lists of conforming products are published.

Obligations of Manufacturer/

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

automatic radar plotting aids; speed indicators; gyro compasses; bearing encoders; collision avoidance systems; steering gear; alarms; loran receivers; depth sounding devices;

Shipping Containers

Department/Agency

U.S. Department of Transportation (DoT) Coast Guard Merchant Vessel Inspection Division Office of Merchant Marine Safety Washington, DC 20593

(202) 426-4431

Initiated

1977

Compliance

Mandatory

Authority

International Safe Container Act

Aim

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 identify

Certifying Authorities.

Obligations of Manufacturer/ Vendor

Owner and lessees are responsible for maintaining each container in a safe condition.

Enforcement

Detention of unsafe and noncomplying containers.

Term

Individual containers and vehicles are subject to re-inspection every 30 months.

Reciprocity

Certification is recognized by foreign governments and international organizations.

Standards, Codes, or Regulations

Standards are included in the International Convention for Safe Containers, regulations in 49 CFR Parts 450-453.

Keywords

cargo container; design approval; international; Convention for Safe Containers; CSC; Approved Continuous Examination; ACEP;

Special Tanks for Transportation of Hazardous Materials

Department/Agency

U.S. Department of Transportation (DoT)
Research and Special Programs Administration
Office of Hazardous Materials Regulation
400 7th Street NW

400 7th Street, NW. Washington, DC 20590

(202) 426-2075

Initiated

1964

Compliance

Mandatory

Authority

49 CFR 178.270-272

(special category reauthorized by PL 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/

Manufacturer must maintain integrity of design, quality control, and cooperate in

Vendor

investigation of suspected faults.

Enforcement Product recall Delisting

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 and State agencies, private

organizations; Canadian government.

Standards, Codes, Agency integrates standards from other sources or Regulations into program.

Keywords tanks; hazardous materials; transportation;

hydrotesting; quality control; safety;

Tanks for Transport of Hazardous Materials

Department/Agency

U.S. Department of Transportation (DoT)
Research and Special Programs Administration
Office of Hazardous Materials Regulation
400 Seventh St., NW.
Washington, DC 20590

(202) 755-2075

Initiated

1964

Compliance

Mandatory

Authority

49 U.S.C. 1803-1809 49 CFR 173.32-34

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 the 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

Manufacturer or third-party lab

Inspection

Periodic inspection is performed by owner.

Conformity Identification

Certified tanks are identified by marking as

specified in the regulation.

Availability of Documentation

Agency maintains lists of manufacturers of

certified tanks by type.

Obligations of Manufacturer/

Manufacturer must maintain design control and submit design changes for approval.

Vendor

Enforcement Marketing ban (also extends to distributors).

Term

Tanks must be hydrotested every five years and documented inspection performed every 2 1/2 years; safety relief valves must be tested at 2

1/2-year intervals to maintain certification.

Reciprocity Other Federal agencies and State agencies,

private organizations and Canada.

Standards, Codes, Agency adopts standards from other or Regulations organizations and provides integrating

material.

Keywords portable tanks; hazardous materials; design

approval; hydrotesting; witness testing;

Electronic Fund Transfer Authentication Devices

Department/Agency

U.S. Department of the Treasury

Assistant Secretary for Electronic Systems

and Information Technology

15th Street and Pennsylvania Avenue NW.

Washington, DC 20220

(202) 566-2200

Initiated

1984

Compliance

Mandatory for all Government bureaus that receive or send funds or securities electroni-

cally through the U.S. Treasury.

Authority

U.S. Treasury Directive 81-80

Aim

Assure that equipment which authenticates electronic fund transfers complies with designated standards to minimize exploitation of Electron-

ic 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: Treasury Standard compliance: National Bureau of Standards (NBS), Institute for Computer Sciences and Technology.

Security evaluation guidance: National Security

Agency (NSA).

Type of Program

Pre-market evaluation

Assessment prior to government purchase

Methodology

Testing by NBS and NSA

Testing

NBS Institute for Computer Sciences and

Technology and NSA

Inspection

Treasury

Conformity Identification A list of certified equipment and software is maintained by Department of the Treasury.

Availability of Documentation List and other technical documentation available from Department of Treasury Assistant Secretary, Electronic Systems and Information Technology.

Obligations of Manufacturer/ Vendor

Comply with criteria.

Enforcement

Delisting

Term

Indefinite term

Reciprocity

None

Standards, Codes, or Regulations

Federal Information Processing Standard (FIPS) 46, Fed Std 1027, ANSI X9.9 and X9.17. Criteria documents are coordinated by Treasury.

Keywords

communications security; electronic fund transfer; EFT; encryption standard; validation; interface requirements; computer security; cryptography; authentication devices; financial;

Products

Automotive Driving Aids and Automatic Wheelchair Lifts

Department/Agency

Veterans Administration Prosthetic & Sensory Aids Service (121) 810 Vermont Avenue, NW. Washington, DC 20420 (202) 389-2011

Initiated

Driving aids, March 27, 1975; wheelchair lifts May 10, 1978.

Compliance

Mandatory only for purchases funded by the Veterans Administration (VA).

Authority

Public Law 91-666

Aim

Provide quality equipment and assure 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, 27 out of 36 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 10-84-214. Currently, 15 wheelchair lift companies and 12 hand control suppliers are certified.

Availability of Documentation

The VA Quality Products List, DM&S Circular 10-84-214, dated December 17, 1984 lists certified suppliers of wheelchair lift sytems. Hand control suppliers are included in the January 1985 compliance list.

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 aides.

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

Keywords

adaptive equipment; hand controls; prosthetic aids, driving aids; automotive; wheelchair lifts; safety; quality;

Products

Self Propelled and Motorized Wheelchairs

Department/Agency

Veterans Administration
Prosthetic & Sensorv Aids Service (121)

810 Vermont Avenue, NW. Washington, DC 20420

(202) 389-2011

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 when made 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

Ten VA propelled wheelchair suppliers and two motorized wheelchair suppliers are currently listed.

Availability of Documentation

The General Services Administration's (GSA) Federal Supply Schedule for wheel-chairs 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

Federal Register, Vol. 42, No. 239 - December 13, 1977, defines standards for self propelled wheelchairs. Requirements for motorized wheelchairs are specified in Federal Register, Vol. 46, No. 240 - December 15, 1981.

Keywords

prosthetic aids; wheelchairs; safety;
quality;

Products or Services

Tests and Procedures Performed

by Veterans Administration Medical Center

Laboratories

Department/Agency

Veterans Administration

Pathology Service, Department of Medicine

and Surgery

810 Vermont Avenue, NW. Washington, D.C. 20240

(202) 389-2348

Initiated

1970

Compliance

Voluntary

Aim

Standardization and uniformity in laboratory test performance throughout the 204 clinical laboratories, 44 nuclear medicine laboratories, 144 special purpose laboratories of the Veterans Administration

system.

Benefits

Improved quality of care for patients.

Peer-reviewed process provides crosseducational 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 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

or Regulations Laboratory Accreditation Program (CAPLAP).

Keywords pathology; clinical laboratories; nuclear

medicine;

INDEX BY PRODUCT OR SERVICE CERTIFIED

| PRODUCT | | | | | | | | | | | | | | | | | | | | | | PA | GE |
|--------------|--------|------|------|-----|----|-----|----|----|-----|---|-----|----|----|-----|----|----|----|---|---|-----|----|-----|----|
| ADDITIVES, | COLOR | ₹ | • | • | • | • | • | • | • | • | • | • | • | • | • | • | • | • | • | • | | • | 63 |
| ADHESIVES . | | | • | • | • | • | • | • | • | • | • | • | • | • | • | • | • | • | • | • | ٠ | | 61 |
| AFTERMARKET | PART | s. | • | • | • | • | • | • | • | • | • | • | • | • | • | • | • | • | • | • | • | • | 47 |
| AGRICULTURA | AL SAF | ETY | . • | • | • | • | • | • | • | • | • | • | • | • | • | • | • | • | • | • | • | • | 95 |
| AIR SAMPLE | RS | | • | • | • | • | • | • | • | • | • | • | • | • | • | • | • | • | • | | • | • | 83 |
| AIR TREATME | ENT F | ACII | ITI | ES | | • | • | • | • | • | • | • | • | • | • | • | • | • | • | • | • | • | 45 |
| AIRCRAFT. | | | • | • | | • | • | • | • | • | • | • | | • | • | • | • | • | • | • | | .1 | 05 |
| AIRCRAFT EN | NGINES | 3 | • | • | • | • | • | • | • | • | • | • | • | • | • | • | • | • | • | • | • | .1 | 05 |
| ALCOHOL TES | STERS, | BF | REAT | Ή | • | • | • | • | • | • | • | • | • | • . | • | • | • | • | • | • | • | .1 | 01 |
| ANIMAL FEEL | · · | | • | • | • | • | • | • | • | • | • | • | • | • | • | • | • | • | • | • | • | • | 71 |
| ANTIBIOTICS | · · | | • | • | • | • | • | • | • | • | • | • | • | • | • | • | • | • | • | • | • | • | 69 |
| APPLICATORS | OF E | PEST | CICI | DE | | • | • | • | • | • | • | • | • | • | • | • | • | • | • | • | • | • | 53 |
| AUTHENT ICAT | ON I |)EVI | CES | 5, | EL | EC | TF | ON | IIC | F | מטי | ID | ТR | AN | SF | ER | ١. | • | • | • | • | .1 | 33 |
| AUTOMOBILE | EMISS | SION | ıs. | • | • | • | • | • | • | • | • | • | • | • | • | • | • | • | • | • | 47 | , | 51 |
| AUTOMOBILE | ENGIN | NES. | • | • | • | • | • | • | • | • | • | • | • | • | • | • | • | • | • | • | • | • | 51 |
| AUTOMOBILE | PARTS | S & | EQU | JIP | ME | INT | 1 | • | • | • | • | • | • | • | • | • | • | • | • | . 4 | 7, | 1 | 13 |
| AUTOMOBILES | 3 | | • | • | • | • | • | • | • | • | • | • | • | • | • | • | • | • | • | • | • | . 1 | 13 |
| AUTOMOTIVE | DRIV | ING | AID | ES | | • | • | • | • | • | • | • | • | • | • | • | • | • | • | • | • | . 1 | 35 |
| AUTOMOTIVE | SAFET | Y. | • | • | • | • | • | • | • | • | • | • | • | • | • | • | • | • | • | • | • | .1 | 13 |
| AVIATION WE | EATHER | R OE | BSEF | RVE | RS | 3. | • | • | • | • | • | • | • | • | • | • | • | • | • | • | • | • | 35 |
| AVIONICS. | | | • | • | • | • | • | • | • | • | • | • | • | • | • | • | • | • | • | • | • | .1 | 05 |
| BEEF | | | | | | | | | | | | | | | | | | | | | | | 13 |

| PRODUCT | | | | | | | | | | | | | | | | | | | | | | PA | GE |
|--------------|----------|------|-----|-----|-----|----|----|---|---|---|---|---|---|---|---|---|---|---|---|-----|----|-----|-----|
| BOATS, RECRE | AT IONAL | | • | | • | • | • | | | • | | | • | | | • | | | | | • | . 1 | 11 |
| BREATH ALCOH | OL TEST | ERS | • | • | • | • | | | | • | • | | • | | | • | | | | • | • | . 1 | 01. |
| BREATHING AP | PARATUS | S . | • | • | • | • | | | • | • | | • | • | | • | • | | | | | | • | 83 |
| BROADCAST EQ | UIPMENT | | • | • | • | • | • | | | • | • | • | | • | • | | | | | • | • | • | 55 |
| BUILDING PRO | DUCTS | | • | | • | • | | | | | | | | | | | | • | | • | | | 85 |
| BUTTER | | | | • | • | | | | | | | | | | | • | | | | | | | .9 |
| CABINETS, FI | LING . | | | | • | | | | | • | | | | | • | • | | | | • | | | 61 |
| CALIBRATION, | INSTRU | MENT | 1 . | • | • | | | | | | • | • | • | | • | • | • | • | | . 3 | ι, | 1 | 01 |
| CARGO HANDLI | NG EQUI | PME | VT, | N | 1AR | TI | IM | Œ | | | | | | • | | | • | | | • | 95 | , | 97 |
| CARPET | | | • | • | • | • | • | • | • | • | • | • | • | • | • | | • | | • | | | • | 85 |
| CHEESE | | | • | • | • | • | • | • | • | • | • | • | • | • | • | • | • | | • | • | • | • | .9 |
| CHEMICALS | | | ٠ | | • | • | • | • | • | • | • | • | | • | • | • | • | • | • | • | 41 | , | 53 |
| CHICKENS | • • • | | • | • | • | • | • | • | • | • | • | • | • | • | • | • | • | • | | • | • | • | 17 |
| CLAMS | | | | • | • | • | | • | • | • | • | • | • | • | | • | • | • | • | • | 33 | , | 77 |
| CLINICAL LAB | ORATORY | TES | STS | S . | | • | • | | • | • | • | | • | • | • | • | | | • | • | | .1 | 39 |
| CLOTHING | • • • | | • | • | • | • | • | | • | • | | • | • | • | • | • | • | | | | • | • | 39 |
| COAL DUST SA | MPLERS | | • | • | • | • | • | • | • | • | • | • | • | • | • | • | • | | • | | • | | 83 |
| COLOR ADDITI | VES | • • | • | | | • | | • | • | • | • | | • | • | • | • | | | | • | | | 63 |
| COMMUNICATIO | NS EQUI | PME | T | • | • | • | • | • | • | • | • | • | | • | • | • | • | • | | | 15 | , · | 55 |
| COMPUTER INT | ERFACES | S | • | | | • | • | • | • | • | | | • | • | • | | • | | • | • | | • | 29 |
| COMPUTERS | • • • | | • | | • | • | • | • | • | | • | | | • | • | | | | • | | | | 55 |
| CONSTRUCTION | SAFETY | 7 | • | • | • | • | | | • | | | | • | • | • | • | • | • | • | • | | | 95 |
| CONSUMER PRO | DUCTS. | | • | • | • | • | • | • | • | • | • | • | • | • | | • | • | • | | • | • | • | 37 |
| CONTAINERS | CARGO | | | | | | | | | | | | | | | | | | | 11 | 5 | 1 | 27 |

| PRODUCT |
|---|
| CONTAINERS FOR RADIOACTIVE MATERIALS |
| COUPLERS, RAILWAY TANK CARS |
| CRANES |
| CYLINDERS FOR HAZARDOUS MATERIALS |
| DAIRY PRODUCTS |
| DATA PROCESSING INTERFACES |
| DERRICKS |
| DENTAL INSTRUMENTS & DEVICES |
| DEVICES, MARINE SANITATION |
| DIVING SAFETY |
| DOORS |
| DOORS, VAULT |
| DRIVING AIDS, AUTOMOTIVE |
| DRINKING WATER |
| DRUGS FOR ANIMALS |
| DRUGS FOR HUMANS |
| EGGS & EGG PRODUCTS |
| ELECTRICAL EQUIPMENT & COMPONENTS |
| ELECTRONIC EQUIPMENT & COMPONENTS 15, 43, 55, 65, 105 |
| ELECTRONIC FUND TRANSFER AUTHENTICATION DEVICES |
| ELECTRONIC RADIATION |
| EMISSIONS, AUTO |
| ENGINES AIRCRAFT |

| PRODUCT | 3E |
|--------------------------------------|-----|
| ENGINES, GASOLINE & DIESEL | 91 |
| EQUIPMENT, AIRCRAFT | .05 |
| EQUIPMENT, CARGO HANDLING | 97 |
| EQUIPMENT, ELECTRIC | 93 |
| EQUIPMENT, MOTOR VEHICLE | 113 |
| EQUIPMENT FOR MINES | 93 |
| EQUIPMENT, OFFICE | 61 |
| EQUIPMENT SAFETY | 11 |
| EQUIPMENT, TELEPHONE | 55 |
| EXHAUST EMISSIONS | 91 |
| FABRICS | 39 |
| FACTORY-BUILT HOUSING AND COMPONENTS | 87 |
| FILING CABINETS | 61 |
| FIRE PROTECTION | 95 |
| FISH, FRESH | 73 |
| FISH, PROCESSED | 33 |
| FISSILE MATERIAL PACKAGING | 117 |
| FLAMMABILITY | 41 |
| FOOD | 77 |
| FOOD FOR ANIMALS | 71 |
| FOOD FOR INFANTS | ,79 |
| FOOD, FROZEN | 23 |
| FOOD INSPECTION PERSONNEL | 75 |
| FOOD. PERISHABLE | 23 |

| PRODUC | <u> </u> | | | | | | | | | | | | | | | | | | | | | | | PA | GE |
|--------|----------|---------------|------|-----|------|-----|-----|-----|-----|----|----|-----|-----|-----|-----|----|----|-----|---|----|----|-----|-----|-----|----|
| FOOD, | TRANSP | ORTAT | ION | • | • | • | • | • | • | • | • | • | • | • | • | • | • | • | • | • | • | • | • | • | 23 |
| FRESH | FISH . | • • | | • | • | • | • | • | • | • | • | • | • | • | • | • | • | • | • | • | • | • | • | • | 73 |
| FRESH | FRUIT. | • • | | • | • | • | • | • | • | • | • | • | • | • | • | • | • | • | • | • | • | • | • | • | 11 |
| FRESH | SEAFOO | D | | • | • | • | • | • | • | • | • | • | • | • | • | • | • | • | • | • | • | • | 73 | 3, | 77 |
| FRESH | VEGETA | BLES | | • | • | • | • | • | • | • | • | • | • | • | • | • | • | • | • | • | • | • | • | • | 11 |
| FROZEN | N SHELL | FISH. | • | • • | • | • • | | • | • | • | | • | • | • | • | | • | • | • | | | | | | 77 |
| FRUIT | , FRESH | | | • | • | • | • | • | • | • | • | • | • | • | • | • | • | • | • | • | • | • | • | • | 11 |
| FRUIT | , PROCE | SSED | | • | • | • | • | • | • | • | • | • | • | • | • | • | • | • | • | • | • | • | • | • | 21 |
| FURNIS | SHINGS, | INTE | RIO | R. | • | • | • | • | • | • | • | • | • | • | • | • | • | • | • | • | • | • | | • | 37 |
| GAS MA | ASKS | | | • | • | • | • | • | • | • | • | • | • | • | • | • | • | • | • | • | • | • | • | • | 83 |
| HAZARI | DOUS MA | TERIA PACK | • | | ויאכ | 'A' | N | ERS | · | • | • | • | • | . 1 | .03 | 3, | 11 | .5, | 1 | 21 | L, | 12 | 29, | . 1 | 31 |
| HAZARI | oous su | BSTAN | ICES | • | • | • | • | • | • | •, | • | • | • | • | • | • | • | • | • | • | 41 | . , | 53 | 3, | 95 |
| HOUSE | HOLD PR | RODUCT | s. | • | • | • | • | • | • | • | • | • | | • | • | • | • | • | • | • | • | • | • | • | 37 |
| HOUSI | NG, MAN | UFACT | URE | D. | • | • | • | • | • | • | • | • | • | • | • | • | • | • | • | • | • | • | | | 87 |
| INDUST | rial s | AFETY | · · | • | • | • | • | • | • | • | • | • | • | • | • | • | • | • | | • | • | • | • | • | 95 |
| INFAM | r FORMU | JLA . | | • | • | • | • | • | • | • | • | • | • | • | • | | • | • | • | • | • | • | • | • | 79 |
| INPUT | OUT PUT | CHAN | INEL | 11 | TT I | ERI | PA(| CES | S . | • | • | • | • | • | • | • | • | • | • | • | • | • | • | • | 29 |
| INSECT | ricide | APPLI | CAT | ORS | 5. | • | • | • | • | • | • | • | • | • | • | • | • | • | • | • | • | • | • | | 53 |
| INSTR | UMENTS, | MEAS | URI | NG | • | • | • | • | • | • | • | • | • | • | • | • | • | | • | • | • | | 27 | 7, | 31 |
| INSUL | IN | | | • | • | • | • | • | • | • | • | • | • | • | • | • | • | • | • | • | • | • | • | • | 67 |
| INTER | FACES, | INFOF | TAMS | 101 | 1 1 | PRO | CI | ESS | SIN | 1G | ΕÇ | נטנ | [PN | 1EN | 1T | • | • | • | • | • | • | • | • | • | 29 |
| JOB S | AFETY . | | | • | • | • | • | • | • | • | • | • | • | • | • | • | • | • | • | • | • | • | | | 95 |
| LAMPS | . MERCU | JRY VA | POR | | | | | | | | | | | | | | | | | | | | | | 65 |

| PRODUCT | E |
|------------------------------------|---|
| LAMPS, SUN | 5 |
| LASERS | 5 |
| LEGAL METROLOGY | 7 |
| LIFE SAVING EQUIPMENT | 1 |
| LIFTS, WHEELCHAIR | 5 |
| LIGHTS, REAR END, RAILWAY TRAINS | 3 |
| LIVESTOCK | 3 |
| LONGSHORING SAFETY | 7 |
| MACHINERY SAFETY | 5 |
| MANUFACTURED HOUSING & COMPONENTS | 7 |
| MARINE POLLUTION EQUIPMENT | 1 |
| MARINE SAFETY EQUIPMENT | 1 |
| MARINE TERMINAL SAFETY | 7 |
| MARITIME CARGO HANDLING EQUIPMENT | 7 |
| MATERIALS | 5 |
| MEASURING INSTRUMENT CALIBRATION | 1 |
| MEASURING INSTRUMENT EVALUATION | 7 |
| MEDICAL DEVICES & EQUIPMENT | 1 |
| MEDICAL LABORATORY TESTS | 9 |
| MEDICAL SERVICES | 5 |
| MEDICINE | 9 |
| MICROWAVE COMMUNICATIONS EQUIPMENT | 5 |
| MICROWAVE OVENS | 5 |

| PRODUCT |
|------------------------------------|
| MILITARY COMPONENTS |
| MINING MACHINES |
| MOTOR VEHICLE ENGINES |
| MOTOR VEHICLES |
| MOTORIZED WHEELCHAIRS |
| MUSSELS |
| NAVAL STORES |
| NAVIGATION AIDES |
| NUCLEAR PACKAGES AND CONTAINERS |
| NUTS |
| OBSERVER, WEATHER |
| OYSTERS |
| PACKAGES FOR RADIOACTIVE MATERIALS |
| PACKAGING OF HAZARDOUS MATERIALS |
| PADLOCKS |
| PAINTS |
| PARTS |
| PATHOLOGY TESTS |
| PERISHABLE FOOD TRANSPORTATION |
| PESTICIDE APPLICATORS |
| PET FOOD |
| PIPE ASSEMBLERS |

| PRODUCT PAGE |
|--|
| PIPELINES |
| POLLUTION CONTROL |
| PORK |
| POULTRY |
| PROCESSED FISH |
| PROCESSED FRUIT |
| PROCESSED SEAFOOD |
| PROCESSED VEGETABLES |
| PROSTHETIC AIDS |
| PROTECTIVE EQUIPMENT 61, 83, 95 |
| QUALIFIED PRODUCTS LISTS |
| RABBITS |
| RADAR OBSERVATION |
| RADIO FREQUENCY GENERATORS |
| RADIOACTIVE MATERIAL PACKAGES & CONTAINERS |
| RADIOACTIVITY |
| RADIOS |
| RAILWAY CARS, REFRIGERATED |
| RAILWAY TANK CARS |
| RAILWAY TRAIN REAR END MARKING DEVICES |
| RECEIVERS, RADIO |
| RECEIVERS, TELEVISION |
| RECREATIONAL BOATS |

| PE | AGE |
|---------------------------|-----|
| ECREATIONAL PRODUCTS | 37 |
| EFLECTORS, RAILWAY TRAINS | 123 |
| EFRIGERATED RAILWAY CARS | 23 |
| EFRIGERATED VEHICLES | 23 |
| ESPIRATORS | 83 |
| osin | 25 |
| AFES | 61 |
| AFETY & RELIEF VALVES | 89 |
| AFETY EQUIPMENT | 11 |
| ANITATION DEVICES, MARINE | 111 |
| CHOOL PRODUCTS | 37 |
| CHOOLBUSES | 113 |
| EAFOOD, FRESH | 73 |
| EAFOOD, PROCESSED | 33 |
| ELF PROPELLED WHEELCHAIRS | 137 |
| HELLFISH, FRESH | 77 |
| HELLFISH, FROZEN | 77 |
| HELLFISH, PROCESSED | 33 |
| HIP SAFETY | .11 |
| HIPBOARD NAVIGATION AIDES | .25 |
| HIPPING CONTAINERS | .27 |
| HIPYARD SAFETY | 95 |
| INT.AMPS | 65 |

| PRODUCT | <u>E</u> |
|--|----------|
| ETERINARY MEDICINE | 71 |
| 71SION | 35 |
| NATER QUALITY | 49 |
| NATER TREATMENT FACILITIES | 45 |
| WEATHER OBSERVATION | 35 |
| WELDERS | 19 |
| HEELCHAIR LIFTS | 35 |
| HEELCHAIRS, MOTORIZED & SELF PROPELLED | 37 |
| VIRE ROPE | 97 |
| C-RAY EQUIPMENT | 65 |
| ACHTS | 11 |

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