NISTIR 8118r1

A Guide to United States Electrical and Electronic Equipment Compliance Requirements

Lisa M. Benson
Karen Reczek

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https://doi.org/10.6028/NIST.IR.8118r1

National Institute of Standards and Technology
U.S. Department of Commerce

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A Guide to United States Electrical and Electronic Equipment Compliance Requirements

Lisa M. Benson*
Karen Reczek
Standards Coordination Office

* *Dakota Consulting*

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Revised February 2017
October 2016

National Institute of Standards and Technology
Kent Rochford, Acting NIST Director and Under Secretary of Commerce for Standards and Technology

Acknowledgements

The lead author for this document is Lisa M. Benson, Dakota Consulting, under contract to the Standards Coordination Office of NIST. Additional guidance, initial research, and review of the document were provided by the staff of the Standards Coordination Office of NIST including: Mary Donaldson, Gordon Gillerman, Erik Puskar, and Ramona Saar. Invaluable support was also received from the knowledgeable experts of the Consumer Product Safety Commission (CPSC), the Department of Energy; Environmental Protection Agency (EPA), Food and Drug Administration (FDA), Federal Communications Commission (FCC), and the Occupational Safety and Health Administration (OSHA), who provided input into the document and also conducted a thorough review. From the CPSC: Andrew Trotta; From DOE: Bryan Berringer and Michael Kido; From the EPA: Eamon Monahan; From the FDA: Scott Colburn and Jianchao Zeng; From the FCC: George Tannahill; From the OSHA: Kevin Robinson.

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A Guide to United States

Electrical and Electronic Equipment Compliance Requirements

How To Use This Guide

- Regulations are mandatory
- Standards are voluntary (unless "Incorporated by Reference", or prescribed as performance standards, in a regulation)
- Guidelines may be voluntary (but are often *de facto* industry standards)
- "**Red**" text highlights mandatory requirements
- "**Blue**" text indicates a hyperlink to a website, page, or document on the web

Scope

This guide addresses electrical and electronic consumer products including those that will come into contact with food. In addition, it includes electrical and electronic products used in the workplace as well as electrical and electronic medical devices. The scope does not include vehicles or components of vehicles, electric or electronic toys, or recycling requirements.

Overview of U.S. Federal Regulatory Framework

Once a law has been enacted by Congress, the appropriate federal agency (e.g., the Consumer Product Safety Commission, the Federal Trade Commission, the Food and Drug Administration, *et al*.) may create regulations to implement the law. Before such regulations can be adopted, the appropriate federal agency ordinarily will issue a notice of proposed rulemaking (NPRM) to solicit public comments on the proposed rules. To provide opportunity for public comment, the appropriate federal agency must issue draft regulations or "Proposed Rules" that are published in the *Federal Register* and as a World Trade Organization Technical Barriers to Trade (WTO TBT) notification. The agency reviews the comments and can then issue a "Final Rule" that also is published in the *Federal Register*, and later, published annually in the *Code of Federal Regulations (CFR)*. Together, the enabling acts/laws (published in the *United States Code (USC)* once passed) and the final regulations (published in the *Code of Federal Regulations*) provide a framework for the implementation and enforcement of most federal laws in the United States.

Federal Regulatory Authorities and Technical Regulations (Mandatory)

Several U.S. federal agencies are responsible for regulations pertaining to electrical and electronic products.

Agency	Scope
Consumer Product Safety Commission (CPSC)	Children's products, hazardous substances, labeling of hazardous products, consumer product safety
Customs and Border Protection (CBP)	Country of origin for most imported products
Department of Energy (DOE)	Energy efficiency
Environmental Protection Agency (EPA)	Toxic substances, Energy Star
Federal Communication Commission (FCC)	Radio frequency and digital devices
Food and Drug Administration (FDA)	Food contact substances, medical products and devices
Federal Trade Commission (FTC)	Labeling, EnergyGuide standards, environmental claims
Occupational Safety and Health Administration (OSHA)	Occupational safety, nationally recognized testing program

Consumer Product Safety Commission (CPSC)

Consumer Product Safety Act

Title 15, United States Code, Chapter 47, Sections 2051-2089

The Consumer Product Safety Act, entered into law on October 27, 1972, was enacted to establish the Consumer Product Safety Commission and define its authority with the purpose of protecting the public against unreasonable risks of injury associated with consumer products; assisting consumers in evaluating the comparative safety of consumer products, developing uniform safety standards for consumer products; and promoting research and investigation into the causes and prevention of product-related deaths, illnesses, and injuries.

Consumer Product Safety Improvement Act of 2008 (CPSIA)

Public Law 110–314, August 14, 2008

On August 14, 2008, the President signed into law Public Law 110-314 (Consumer Product Safety Improvement Act of 2008). On August 12, 2011, amendments to the Act were signed, Public Law 112–28, August 12, 2011. This landmark consumer product safety law provided CPSC with significant new regulatory and enforcement tools as part of amending and enhancing several CPSC statutes, including the Consumer Product Safety Act.

Children's Products Only

The Consumer Product Safety Improvement Act (CPSIA) enacted in 2008 regulates specific substances in children's products. The CPSIA sets limits for lead content and phthalates in

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children's products. A children's product is defined as a consumer product designed or intended primarily for children age 12 years or younger.

With respect to children's electrical and electronic products, Section 101(a) on page 3 of the CPSIA **restricts children's products and components of children's products to a lead content limit of 100 parts per million (ppm) with limited exceptions.** In addition, the use of paint or surface coating on children's electrical and electronic products **must not exceed 90 ppm.**

Certain children's electronic products for which it is not technically feasible to remove lead may allow a higher lead limit exemption. These include:

- Lead blended into the glass of cathode ray tubes, electronic components, and fluorescent tubes.
- Lead used as an alloying element in steel. **The maximum amount of lead shall be less than 0.35% by weight (3,500 ppm).**
- Lead used in the manufacture of aluminum. **The maximum amount of lead shall be less than 0.4% by weight (4,000 ppm).**
- Lead used in copper-based alloys. **The maximum amount of lead shall be less than 4% by weight (40,000 ppm).**
- Lead used in lead-bronze bearing shells and bushings.
- Lead used in compliant pin connector systems.
- Lead used in optical and filter glass.
- Lead oxide in plasma display panels (PDP) and surface conduction electron emitter displays (SED) used in structural elements; notably in the front and rear glass dielectric layer, the bus electrode, the black stripe, the address electrode, the barrier ribs, the seal frit and frit ring, as well as in print pastes.
- Lead oxide in the glass envelope of Black Light Blue (BLB) lamps.

In addition, components of electronic devices that are removable or replaceable, such as battery packs and light bulbs, and that are inaccessible when the product is fully assembled, are not subject to the total lead limits.

Certificates and Mandatory Third-Party Testing

Section 102 on page 8 of the CPSIA **requires every manufacturer or importer of all consumer products that are subject to a consumer product safety rule enforced by the CPSC to issue a general certificate of conformity based on testing of the product** and stating that the product complies with the applicable standard, regulation, or ban. The certificate must accompany the product and be furnished to the retailer or distributor. Section 102 also **requires the manufacturers or importers of children's products (products designed and intended primarily for children age 12 years or younger) to certify that the products comply with all relevant product safety rules by issuing a children's product certificate** supported by tests performed by a CPSC-accepted third-party testing laboratory that has been accredited. CPSC also has regulations pertaining to certificates; they can be found at 16 CFR 1110.

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For more detailed information, see CPSC's:
Testing and Certification and
FAQs - Certification and Third-Party Testing

Specific Products Regulated under the Consumer Product Safety Act (CPSA)

Seasonal and Decorative Lighting
16 CFR 1120 lists products that have characteristics whose existence or absence present a substantial product hazard. This list includes seasonal and decorative lighting products that lack certain readily observable safety characteristics. Seasonal and decorative lighting is defined as portable, plug-connected, temporary-use lighting that is factory-assembled with push-in, midget- or miniature-screw base lampholders connected in series or with candelabra- or intermediate-screw base lampholders connected in parallel, directly across the 120 volt input.

All seasonal and decorative lighting must meet the following requirements:

- **Minimum wire size**
- **Sufficient strain relief**
- **Overcurrent protection**

These characteristics are addressed in the voluntary standard UL 588 S*tandard for Safety for Seasonal and Holiday Decorative Products.*

Hand Supported Hair Dryers
16 CFR 1120 lists products that have characteristics whose existence or absence present a substantial product hazard, including hand supported hair dryers. **Hand supported hair dryers must provide integral immersion protection** as specified in this regulation, or will be considered a hazardous product.

Extension Cords
16 CFR 1120 lists products that have characteristics whose existence or absence present a substantial product hazard, including extension cords. Extension cords that do not contain one or more of five applicable readily observable characteristics set forth in the rule, as addressed in a voluntary standard, are deemed a substantial product hazard under the Consumer Product Safety Act. **All general-use extension cords (indoor and outdoor extension cords, including indoor seasonal extension cords) must have the following characteristics** as described in the regulation:

- **Minimum wire size**
- **Sufficient strain relief**
- **Proper polarity**
- **Proper continuity**
- **Outlet covers for 2-wire indoor extension cords or jacketed cord for outdoor extension cords**

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Omnidirectional CB Base Station Antennas

Omni Directional CB base station antennas **must comply with the specified requirements for field joints, feed cables, electrical protection, manufacturer's instructions and warnings, and certificates of compliance as per** 16 CFR 1204 *Safety Standard for Omnidirectional Base Station Antennas*. This regulation describes two performance tests to determine if the means chosen by the manufacturer to protect against the shock hazard will provide adequate protection. One is an insulating material effectiveness test in which a high voltage electrode or test rod is brought into contact with the antenna at any point within the protection zone established by the regulation to ensure that the insulation can withstand the voltage for 5 minutes without transmitting more than 5 milliamperes (mA) root-mean-square (rms) of electric current. The other test is the antenna mast system test which is intended to determine whether the means provided to protect against electrocution will withstand the stress imposed when an antenna-mast system falls onto a power line.

Walk Behind Lawn Mowers

16 CFR 1205 *Safety Standard for Walk Behind Power Lawn Mowers* **outlines mandatory safety, labeling, and performance requirements for walk behind lawnmowers.** The standard is intended to reduce the risk of injury to consumers caused by contact, primarily of the foot and hand, with the rotating blade of the mower. Walk behind mowers are **subject to certification of compliance and labeling requirements.**

Residential Garage Door Operators

16 CFR 1211 *Safety Standard for Automatic Residential Garage Door Operators* includes entrapment protection requirements as well as certification and recordkeeping requirements. **All residential garage door openers must comply with the entrapment protection of UL 325 as well as additional protections as outlined in this regulation,** including having an external entrapment protection (e.g., electric eye or door edge sensor) or constant contact control button. Additionally, **a sticker must be placed on the wall mounted control button warning consumers of the potential for entrapment.**

Infant Swings

16 CFR 1223 *Safety Standard for Infant Swings* **requires that all infant swings comply with all applicable provisions of ASTM F2088-13, Standard Consumer Safety Specification for Infant Swings**, which has been incorporated by reference into this regulation. From an electrical perspective, the standard requires that all AC adapters meet all national safety standards. Infant swings are also subject to third-party testing and certification.

Citizens Band (CB) Base Station Antennas, TV Antennas, and Supporting Structures

16 CFR 1402 *CB Base Station Antennas, TV Antennas, and Supporting Structures* **requires manufacturers and importers of CB base station antennas, outdoor television antennas, and their supporting structures, to provide notification of ways to avoid hazard of electrocution** that exists when these products are allowed to come near powerlines during installation and removal. In addition, ***performance and safety data must also be provided***.

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Portable Generators

16 CFR 1407 *Portable Generators: Requirements to Provide Performance and Technical Data by Labeling* **requires manufactures to provide consumers with a specified notification concerning the carbon monoxide poisoning hazard associated with use of portable generators**.

Pools and Spas

16 CFR 1450 *Virginia Graeme Baker Pool and Spa Safety Act (VGB Act)* **requires that each swimming pool or spa drain cover that is manufactured, distributed, or entered into commerce in the United States conform to the entrapment protection requirements of the performance standard ANSI/APSP-16 2011, *Suction Fittings for Use in Swimming Pools, Wading Pools, Spas, and Hot Tubs.***

Federal Hazardous Substances Act (FHSA)

Title 15, United States Code, Chapter 30, Sections 1261-1278

16 CFR 1500 *Federal Hazardous Substances Act (FHSA) Regulations*

FHSA regulations set forth requirements for hazardous household products ("hazardous substances".) The FHSA **requires** household substances that meet the definition of hazardous (as defined in the Act) **to bear cautionary labeling to warn the consumer of the hazard(s) associated with the use of the product, that would enable the consumer to safely use and store the product, first aid instructions where applicable, and the statement "keep out of the reach of children."** Whether a product must be labeled depends on its formulation and the likelihood that consumers will be exposed to any hazards it presents in reasonable and foreseeable customary use which includes ingestion by children. The FHSA also defines as "banned hazardous substances" those products that are intended for use by children that present an electrical, mechanical, or thermal hazard, with some exceptions. The Act also allows the Consumer Product Safety Commission to ban through rulemaking certain products that are so dangerous or the nature of the hazard is such that the cautionary labeling requirements are not adequate to protect consumers.

Sharp Points and Edges on Children's Products

16 CFR 1500.48 "Technical requirements for determining a sharp point in toys and other articles intended for use by children under 8 years of age" sets forth the test method for determining if a sharp point, exposed in normal use or through reasonably foreseeable damage or abuse, on toys and other articles intended for use by children under 8 years of age, presents a potential risk of injury by puncture or laceration under section 2(s) of the Federal Hazardous Substances Act, and codified in 15 U.S.C. 1261 (s).

Likewise, 16 CFR 1500.49 "Technical requirements for determining a sharp metal or glass edge in toys and other articles intended for use by children under 8 years of age" provides the sharp edge test method used to make a determination if metal or glass edges, exposed in normal use or as a result of reasonably foreseeable damage or abuse, on toys and other articles intended

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for use by children under 8 years of age, present a potential risk of injury by laceration or avulsion under section 2(s) of the Federal Hazardous Substances Act, codified in 15 U.S.C. 1261 (s). **Children's electrical and electronic products may not contain sharp points and edges.**

For more detailed information, see CPSC's:
Federal Hazardous Substances Act (FHSA) Requirements

Household Refrigerators
16 CFR 1750 *Standard For Devices To Permit The Opening Of Household Refrigerator Doors From The Inside* **requires that household refrigerators be equipped with a device enabling its doors to be opened easily from the inside,** either by the application of an outwardly directed force to the inside of the door or by the rotation of a knob similar to a conventional doorknob. The device must not interfere with the refrigerator's ability to preserve food under normal conditions of use.

Pending Regulations of Note
The CPSC has published the following notices in the *Federal Register Notices of Proposed Rulemaking* (NPRM). See:

Notice of Proposed Rulemaking: Table Saw Blade Contact Injuries (February, 15 2012)
Notice of Proposed Rulemaking: Prohibition of Children's Toys and Child Care Articles Containing Specified Phthalates (December 30, 2014)
Notice of Proposed Rulemaking: Certificates of Compliance (May 13, 2013)
Notice of Proposed Rulemaking: Safety Standard for Automatic Residential Garage Door Operators (September 2, 2015)
Notice of Proposed Rulemaking: Safety Standard for Infant Bouncer Seats (October 19, 2015)

Customs and Border Protection (CBP)

Marking of Imported Articles and Containers
Title 19, United States Code, Chapter 4, Section 1304
All products imported into the U.S. **must conform** to 19 CFR 134, Country of Origin Marking regulations. These regulations require that every article of foreign origin (or its container) imported into the U.S. be marked in a conspicuous place as legibly, indelibly, and permanently as the nature of the article (or its container) will permit, in such a manner as to indicate to an ultimate purchaser in the U.S., the English name of the country of origin of the article at the time of importation.

For more detailed information, see CBP's:
Terminology and Methods for Marking of Country of Origin on U.S. Imports

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Department of Energy (DOE)

Energy Policy and Conservation Act (EPCA)
Title 42, United States Code, Chapter 77, Energy Conservation was enacted for the promotion of energy conservation. With respect to electrical and electronic products, the Act prescribes test procedures to measure energy efficiency, energy use, water use, or estimated annual operating cost of a covered product during a representative annual use cycle or period of use as well as charging the Federal Trade Commission with the responsibility of establishing labeling requirements.

Under the Act, **it is unlawful for a manufacturer or private labeler to:**

- **Distribute into commerce any new product covered under the Act, unless the product is labeled in accordance with the rules and it conforms to a specified applicable energy conservation standard, except to the extent that the product is covered by a regional standard that is more stringent than the base national standard.**
- **Remove or make required labeling illegible.**
- **Knowingly sell a product that violates regional standards.**
- **Distribute in commerce an adapter that is designed to allow an incandescent lamp that does not have a medium screw base to be installed into a fixture or lampholder with a medium screw base socket, and is capable of being operated at a voltage range at least partially within 110 and 130 volts.**

See EnergyGuide Standards and Labeling for Home Appliances in the FTC section for labeling requirements.

Energy Efficiency Standards, Testing, and Certification for Residential Consumer Products
10 CFR 430 *Energy Conservation Program for Consumer Products* establishes the testing requirements for products specified under the Energy Policy and Conservation Act. **Covered products must meet the requirements of the standard specified for that product.**

10 CFR 429 Subpart B sets forth the procedures for manufactures to certify that covered products and equipment comply with the applicable conservation standards. These regulations describe how manufacturers **must establish certified ratings based on conducting DOE test procedures on a sample of units of a given basic model** and subsequently apply DOE's statistical sampling plans. The regulations also describe how manufacturers **must submit certification reports to DOE, and how manufacturers must maintain records underlying the certification**. Finally, the regulations describe processes for DOE-initiated testing and enforcing compliance with the certification provisions and the energy and water conservation standards.

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The electrical and electronic consumer products covered under this Act include:

- Battery Chargers
- Boilers
- Ceiling Fans
- Central Air Conditioners and Heat Pumps
- Clothes Dryers
- Clothes Washers
- Computer and Battery Backup Systems
- External Power Supplies
- Dehumidifiers
- Direct Heating Equipment
- Dishwashers
- Furnace Fans
- Furnaces
- Hearth Products
- Kitchen Ranges and Ovens
- Microwave Ovens
- Miscellaneous Refrigeration
- Pool Heaters
- Portable Air Conditioners
- Refrigerators and Freezers
- Room Air Conditioners
- Set-Top Boxes
- Televisions
- Water Heaters
- Ceiling Fan Light Kits
- Certain Lamps
- Compact Fluorescent Lamps
- Fluorescent Lamp Ballasts
- General Service Fluorescent Lamps
- General Service Incandescent Lamps
- General Service Lamps
- High-Intensity Discharge Lamps
- Incandescent Reflector Lamps
- Light Emitting Diode Lamps
- Luminaires
- Metal Halide Lamp Fixtures
- Torchieres

For more detailed information, see DOE's Appliance and Equipment Standards Program

Environmental Protection Agency (EPA)

ENERGY STAR Program

42 U.S.C § 6294a establishes the voluntary ENERGY STAR Program. ENERGY STAR is a joint program of the Department of Energy and Environmental Protection Agency that sets voluntary energy efficiency specifications in over 70 product categories. To earn the ENERGY STAR label, products must be certified by an EPA-recognized third party certification body, based on testing in an EPA-recognized laboratory. In addition, manufacturers of the products must participate in verification testing programs run by recognized certification bodies. Covered products include:

- Appliances
- Building Products
- Commercial Food Service Equipment
- Electronics
- Heating & Cooling
- Lighting
- Office Equipment
- Water Heaters
- Other

For more detailed information, see EPA's About Energy Star

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Non-Essential Products Containing Chlorofluorocarbons (CFCs) and Hydrochlorofluorocarbons (HCFCs)

In the United States, ozone-depleting substances are regulated as Class I or Class II controlled substances.

- Class I substances, including Chlorofluorocarbons (CFC's), have a higher ozone-depleting potential and have been completely phased out in the U.S., except for exemptions allowed under the Montreal Protocol.
- Class II substances are hydrochlorofluorocarbons (HCFCs), which were transitional substitutes for many Class I substances and are being phased out now.

As a Party to the Montreal protocol, the U.S. must phase out the use of HCFCs completely by 2030. The Clean Air Act schedules for the phase out of HCFC production and consumption, and for the restriction of HCFC use, appear in section 605.

40 CFR 82 Subpart I *Ban on Refrigeration and Air-Conditioning Appliances Containing HCFCs* **prohibits the sale or distribution in interstate commerce any pre-charged appliance or any pre-charged appliance component for air-conditioning or refrigeration appliances containing HCFC-22, HCFC-142b or a blend containing one or both of these controlled substances.**

40 CFR 82 Subpart E sets forth specific labeling requirements, including a warning statement for products that contain Class I or Class II substances. **Each product containing a Class I or Class II substance must bear the following warning statement, meeting the requirements for placement and form:**

> **WARNING: Contains [or Manufactured with, if applicable] [*insert name of substance*], a substance which harms public health and environment by destroying ozone in the upper atmosphere.**
>
> ***For more detailed information, see EPAs***
> Phaseout of HCFCs (Class II Ozone-Depleting Substances)

Toxic Substance Control Act (TCSA)

The Toxic Substances Control Act of 1976 (15 USC 2601-2692) provides EPA with authority to require reporting, record-keeping and testing requirements, and restrictions relating to chemical substances and/or mixtures. Certain substances are generally excluded from TSCA, including, among others, food, drugs, cosmetics, and pesticides.

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Mercury-Containing and Rechargeable Battery Management Act
Title 42, United States Code, Chapter 137, Sections 14301-14336
The purpose of the Act is to phase out the use of mercury in batteries and facilitate the collection and recycling of nickel-cadmium rechargeable, small sealed lead-acid rechargeable, and other regulated batteries. Regulated batteries include those containing cadmium and/or lead electrodes or other batteries subject to a determination by the Administrator of the EPA. The Act requires that regulated batteries are easily removable from rechargeable consumer products or sold separately. In addition, the Act establishes labeling requirements for regulated batteries and rechargeable products without easily removable batteries, including a three chasing arrows or comparable recycling symbol, as well as statements dependent on the battery and product type.

The Act prohibits the sale of

- **Alkaline-manganese batteries to which mercury has been intentionally introduced, except for alkaline-manganese button cells, which are limited to 25 milligrams of mercury per button cell;**
- **Zinc-carbon batteries containing intentionally introduced mercury; and**
- **Button cell mercuric-oxide batteries.**

For more detailed information, see EPA's
Implementation of the Mercury Containing and Rechargeable Battery Management Act

Federal Communications Commission (FCC)

Radio Frequency Devices
The FCC's mandate is to regulate private sector telecommunications in the public interest. They do this by establishing technical regulations for transmitters and other devices that generate or use radio frequency (RF) energy to minimize their potential for causing interference.

47 CFR 2 Subpart J *Equipment Authorization Procedures* establishes procedures for products that use or emit radio frequency energy. The processes are Verification, Declaration of Conformity, and Certification. Verification is a self-approval process where any capable testing facility can test a device to ensure the product complies with appropriate requirements. Declaration of Conformity requires a product be tested by an accredited, FCC recognized laboratory to ensure that the product complies with the requirements. Certification is an equipment authorization issued by an independent entity recognized by the FCC to approve products within their scope of recognition. These entities, known as Telecommunication Certification Bodies (TCBs), approve products to the FCC requirements. Products approved under the Certification process are identified by FCC ID number.

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It is unlawful to sell, lease, import for sale or lease, or advertise for sale or lease a radiofrequency device unless it complies with all applicable technical, labeling, identification, and administrative requirements applicable to that device.

RF devices include, but are not limited to,

- incidental, unintentional, and intentional radiators defined in 47 CFR 15,
- industrial, scientific, and medical equipment described in 47 CFR 18, and
- transmitters operating under FCC licensed radio services (examples of other licensed radio services include the Commercial Radio Services described in 47 CFR 22 and 24).

47 CFR 15, *Radio Frequency Devices* sets forth the requirements for testing and equipment authorization for intentional, unintentional, and incidental radiators. The regulation classifies devices as

- unintentional (equipment that is not intended to transmit information over the air, e.g., clocks, radios, TVs), 47 CFR 15 Subpart B;
- intentional (equipment that transmits information over the air, e.g., remote controls, cordless telephones), 47 CFR 15 Subparts C through H; and
- incidental (generates RF energy during course of its operation, though not designed to intentionally emit it, e.g., dc motors, mechanical light switches), 47 CFR 15.13.

The regulation classifies unintentional radiator radio frequency devices as

- Class A – used exclusively in industrial, business, and commercial applications, and
- Class B – used in residential environment (e.g., personal computers, calculators, and similar devices).

47 CFR 15 also establishes specific labeling requirements for intentional, unintentional, or incidental radiators depending on the approval process required (i.e. Certification, Verification, or Declaration of Conformity)**. All products must meet the applicable labeling requirements.**

47 CFR 18, *Industrial, Scientific, and Medical Equipment* sets forth the requirements for testing and equipment authorization for industrial, scientific, and medical equipment (ISM) which includes equipment used by consumers (e.g., microwave ovens, jewelry cleaners for home use and ultrasonic humidifers.) ISM equipment is equipment that uses RF energy to do work as opposed to using RF energy to convey information. **ISM equipment must be designed and constructed in accordance with good engineering practice with sufficient shielding and filtering to provide adequate suppression of emissions on frequencies outside the specified frequency bands. The Regulation also requires that consumer ISM equipment, unless otherwise specified, must be authorized under either the Declaration of Conformity or certification procedure prior to use or marketing.**

Equipment operated under Emergency Alert System (47 CFR 11), Commercial Mobile (47 CFR 20), Public Mobile (47 CFR 22), Personal Communications (47 CFR 24), Satellite Communications (47 CFR 25), Miscellaneous Wireless Communications (47 CFR 27), Telephone Terminal

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Equipment (47 CFR 68), Radio Broadcast Services (47 CFR 73), Auxiliary Broadcast Services (47 CFR 74), Cable Television Relay (47 CFR 78), Maritime Services (47 CFR 80), Aviation Services (47 CFR 87), Private Land Mobile Services (47 CFR 90), Personal Radio Services (47 CFR 95), Amateur Radio Service (47 CFR 97), and Fixed Microwave Services (47 CFR 101) are also **subject to equipment authorization as specified in the rule part they operate under**.

The following Equipment Class and Rule Part combinations are to be used to complete the Equipment Authorization Form.

Equip. Class	**Equipment Class Description**	CFR **Title 47 Part Number**
8CC	Part 18 Consumer Device	18
AIS	Automatic Identification Systems	80
AMP	Amplifier	101, 22, 22H, 24, 24D, 24E, 25, 27, 73, 74, 80, 87, 90, 95, 97
B2I	Part 20 Industrial Booster (CMRS)	22H, 24D, 24E, 27, 90S
B2P	Part 20 Provider-Specific Consumer Booster (CMRS)	22H, 24E, 27, 90S
B2W	Part 20 Wideband Consumer Booster (CMRS)	22H, 24E, 27, 90S
B9A	Part 90 Class A Industrial Booster (non-SMR)	90
B9B	Part 90 Class B Industrial Booster (non-SMR)	90
BOS	All other signal boosters other than 20.21/90.219	101, 22, 25, 90, 97
BPL	Access Broadband Over Powerline System	15G
CRD	Part 15 Radar Detector	15B
CRR	Superregenerative Receiver	15B
CSR	Scanning Receiver	15B
CXX	Communications Rcvr for use w/ licensed Tx and CBs	15B
CYY	Communications Receiver used w/Pt 15 Transmitter	15B
DCD	Part 15 Low Power Transmitter Below 1705 kHz	15C
DSC	Part 15 Security/Remote Control Transmitter	15.231, 15.231(e)
DSR	Part 15 Remote Control/Security Device Transceiver	15.231
DSR	Part 15 Remote Control/Security Device Transceiver	15.231(e)
DSS	Part 15 Spread Spectrum Transmitter	15C

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Equip. Class	Equipment Class Description	CFR Title 47 Part Number
DTS	Digital Transmission System	15C
DWM	Part 15 Wireless Microphone	15C
DXT	Part 15 Low Power Transceiver, Rx Verified	15C
DXX	Part 15 Low Power Communication Device Transmitter	15C
EAD	Part 11 Emergency Alert Devices	11
EAV	Part 15 Automatic Vehicle Identification System	15.251
ETB	Part 15 Cordless Telephone Base Transceiver	15C
ETR	Part 15 Cordless Telephone Remote Transceiver	15C
ETS	Part 15 Cordless Telephone System	15C
FAP	Part 15 Anti-Pilferage Device	15C
FDS	Part 15 Field Disturbance Sensor	15.245, 15.253
FRB	Part 95 Family Radio Base Transmitter	95A
FRB	Part 95 Family Radio Base Transmitter	95B
FRE	Part 95 Family Radio Ear Held Transmitter	95A, 95B
FRF	Part 95 Family Radio Face Held Transmitter	80, 95A, 95B
FRT	Part 95 Family Radio Body Worn Transmitter	95A, 95B
GAT	Part 15 Auditory Assistance Device (Transmitter)	15.237
GEP	406 MHz EPIRB	80.1101(c)(5)
GHF	Part 80 HF Transmitter (GMDSS)	80.1101(c)(4)
GHH	Part 80 VHF Hand Held Transmitter (GMDSS)	80.1101(c)(7)
GMF	Part 80 MF Transmitter (GMDSS)	80.1101(c)(3)
GVH	Part 80 VHF Transmitter (GMDSS)	80.1101(c)(4)
HID	Part 15 TV Interface Device	15B
JBC	Part 15 Class B Computing Device/Personal Computer	15B
JBP	Part 15 Class B Computing Device Peripheral	15B
LMS	Part 90 Location & Monitoring Transmitter	90.353, 90.355
LPR	Level Probing Radar	15.209, 15.256
MRD	Marine Radar	80, 90
MWR	Part 80 Marine Watch Receiver	80.269
NII	Unlicensed National Information Infrastructure TX	15E
PCB	PCS Licensed Transmitter	101C, 22, 22H, 24.232(b), 24D, 24E, 27, 90, 95G
PCE	PCS Licensed Transmitter held to ear	22, 22H, 24D, 24E, 27, 90

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Equip. Class	Equipment Class Description	CFR Title 47 Part Number
PCF	PCS Licensed Transmitter held to face	22H, 24, 24D, 24E, 90
PCT	PCS Licensed Transmitter worn on body	22, 22H, 24D, 24E, 27, 90, 95I
PLB	Personal Locator Beacons	95K
PUB	Part 15 Unlicensed PCS Base Station	15D
PUE	Part 15 Unlicensed PCS portable Tx held to ear	15D
PUF	Part 15 Unlicensed PCS portable Tx held to face	15D
PUT	Part 15 Unlicensed PCS portable Tx worn on body	15D
RNV	Part 80 NAVTEX Receiver	80.1101(c)(1)
SRT	Radar Transponder	80.1101(c)(6)
SSA	Ship Security Alert Systems (SSAS)	80
TBC	Licensed Broadcast Station Transmitter	27, 73, 74
TBF	Licensed Broadcast Transmitter Held to Face	74.861
TBT	Licensed Broadcast Transmitter Worn on Body	74.861
TDC	Part 80 DSC Controller	80.1101(c)(2)
TDC	Part 80 DSC Controller	80.1101(c)(3)
TDC	Part 80 DSC Controller	80.1101(c)(4)
TLD	Licensed LPAS Devices	74.832
TNB	Licensed Non-Broadcast Station Transmitter	101, 22, 22G, 22H, 25, 27, 74, 78, 80, 87, 90, 90.203(j)(4), 90.203(j)(5), 90.203(j)(7), 90.203(j)(8), 90.210, 90.210(e) 90.217, 90.217(b), 90.217(c), 90.221, 90.259, 90.265, 90.265(b), 90, 90Y, 95A, 95C 95D, 95F, 95G, 95H, 95I, 95J, 95L
TNE	Licensed Non-Broadcast Transmitter Held to Ear	101, 22, 22G, 22H, 25, 27, 74, 80, 87, 90, 90.203(j)(4), 90.203(j)(5), 90.203(j)(7), 90.203(j)(8), 90.210, 90.210(e), 90.217,

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Equip. Class	Equipment Class Description	CFR Title 47 Part Number
		90.217(b), 90.217(c), 90.259, 90.265, 90.265(b), 90Y, 95A, 95C, 95F, 95G, 95H, 95J, 95L
TNF	Licensed Non-Broadcast Transmitter Held to Face	101, 22, 22G, 22H, 25, 27, 74, 80, 87, 90, 90.203(j)(4), 90.203(j)(5), 90.203(j)(7), 90.203(j)(8), 90.210, 90.210(e), 90.217, 90.217(b), 90.217(c), 90.259, 90.265 90.265(b), 90R, 90S, 90Y, 95A, 95C, 95D, 95F, 95G, 95H, 95J, 95L
TNT	Licensed Non-Broadcast Transmitter Worn on Body	101, 22, 22G, 22H, 25, 27, 74, 80, 87, 90, 90.203(j)(4), 90.203(j)(5), 90.203(j)(7), 90.203(j)(8), 90.217, 90.217(b), 90.217(c), 90.259, 90.265, 90.265(b), 90Y, 95A, 95C, 95D, 95F, 95G, 95H, 95I, 95J, 95L
UWB	Ultra Wideband Transmitter	15F
WBT	Wideband Transmitter	15.250, 15.252
WG1	White Space Device with Geo-location- Mode 1	15H
WG2	White Space Device with Geo-location- Mode 2	15H
WGF	White Space Device with Geo-location- Fixed	15H
WS1	White Space Device with Sensing-Mode 1	15H
WS2	White Space Device with Sensing-Mode 2	15H
WSF	White Space Device with Sensing-Fixed	15H

For more detailed information, see FCC's:
Equipment Authorization Approval Guide

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Mobile and Portable Devices

Portable and mobile devices that operate in the Cellular Radiotelephone Service (47 CFR 22 Subpart H), the Personal Communications Service (PCS) (47 CFR 24), the Satellite Communications Service (47 CFR 25), the Wireless Communications Service (47 CFR 27), the Maritime Service (ship earth stations only) (47 CFR 80), and Specialized Mobile Radio Service (47 CFR 24, 25, 27, 80 (ship earth stations devices only) and 90) at frequencies of 1.5 GHz or below and their effective radiated power (ERP) is 1.5 watts or more, or if they operate at frequencies above 1.5 GHz and their ERP is 3 watts or more, **are subject to RF emissions requirements as specified in the rule part that they operate under. All of these portable and mobile devices are also subject to the routine environmental evaluation for RF exposure requirement of 47 CFR 2.1091 (bottom of page 706) (mobile devices) and/or 47 CFR 2.1093 (page 708) (portable devices) prior to equipment authorization or use.**

Portable devices operating in the Wireless Medical Telemetry Service (WMTS) (47 CFR Part 95 Subpart H) and the Medical Device Radio communications Service (MEDRADIO) (47 CFR 95 Subpart I) **are subject to RF emissions limits as specified in the rule part they operate under and also to routine environmental evaluation for RF exposure prior to equipment authorization or use.** Unlicensed PCS (47 CFR Part 15 Subpart D), Unlicensed National Information Infrastructure (U-NII) (47 CFR Part 15 Subpart E), and millimeter wave devices (47 CFR Part 15 Subpart C) are subject to **RF emission requirements specified in the rule section they operate in and are also subject to routine environmental evaluation for RF exposure prior to equipment authorization or use** if their ERP is 3 watts or more or if they meet the definition of a portable device**.** All other mobile and portable devices are categorically excluded from routine environmental evaluation for RF exposure.

The FCC differentiates mobile and portable devices by the proximity to the user during use. Mobile devices, covered under 47 CFR 2.1091 (page 706), are defined as a transmitting device designed to be used in other than fixed locations and generally used in a manner that the radiating structure is at least 20 cm from the body of the user or nearby persons. Examples of mobile and portable devices include cellular and PCS mobile telephones with vehicle mounted antennas and other radio devices that use vehicle mounted antennas. **These devices must be evaluated for exposure potential with respect to Maximum Permissible Exposure (MPE) limits for field strength or power density or with respect to specific absorption rate (SAR) limits, whichever is most appropriate for the specific use and operating configuration of the device.**

Portable devices, covered under 47 CFR 2.1093 (page 708), are defined as a transmitting device designed to be used so the radiating structure is within 20 cm of the body of the user. These devices include handheld cellular phones and PCS mobile phones that incorporate the radiating antenna into the hand-piece and wireless transmitters carried close to the body. **RF evaluation must be based on specific absorption rate (SAR) limits.**

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Compliance limits are set for both occupational/controlled exposure and general population/uncontrolled exposure based on a person's awareness and ability to exercise control over his/her exposure.
Mobile or portable devices may not be imported and/or marketed until they have shown compliance with the technical standards that have been specified by the Federal Communications Commission.

For more detailed Information, see FCC's
Equipment Authorization Approval Guide
Radio Frequency Safety - Office of Engineering and Technology
RF Exposure Procedures and Equipment Authorization Policies for Mobile and Portable Devices
RF Exposure Compliance Reporting and Documentation Considerations
Equipment Authorization System Test Firm Search
Radio Frequency Wireless Technology in Medical Devices - Guidance for Industry and Food and Drug Administration Staff

External Radio Frequency Power Amplifiers
Per 47 CFR 2.815, it is illegal to manufacture, sell, lease, or import external radio frequency power amplifiers capable of operation on any frequency or frequencies below 144 MHz unless the amplifier has received a grant of certification. These amplifiers shall comply with the following:

- The external radio frequency power amplifier shall not be capable of amplification in the frequency band 26-28 MHz.
- The amplifier shall not be capable of easy modification to permit its use as an amplifier in the frequency band 26-28 MHz.
- No more than 10 external radio frequency power amplifiers may be constructed for evaluation purposes in preparation for the submission of an application for a grant of certification.
- If the external radio frequency power amplifier is intended for operation in the Amateur Radio Service (47 CFR 97), the requirements of 47 CFR 97.315 and 47 CFR 97.317 must be met.

Emergency Alert System Equipment
Requirements for equipment used as part of the Emergency Alert System (EAS) can be found at 47 CFR 11 subpart B. **EAS encoders and decoders must be certified** in accordance with 47 CFR 2 subpart J and must also meet the requirements of 47 CFR 15. In addition, **manufacturers must include instructions and information on how to install, operate, and program an EAS Encoder, EAS Decoder, or combined unit and a list of all state and county ANSI numbers with each unit sold or marketed in the U.S.**

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Public Mobile Services
Transmitters operating under Public Mobile Services (47 CFR 22) are **subject to certification requirements** of 47 CFR 2. In addition, equipment under this part **is subject to RF emission requirements.**

Amateur Radio
Equipment operated under Amateur Radio Services (47 CFR Part 97) **are subject to RF emissions requirements.** In addition, **amplifiers are subject to certification.**

Fixed Microwave Services
Transmitters used in the private operational fixed and common carrier fixed point-to-point microwave and point-to-multipoint services under 47 CFR 101, Fixed Microwave Services, must be a type that has been verified for compliance. Manufacturers of transmitters used under this section may request certification or obtain verification by following the applicable procedures set forth in 47 CFR 2. In addition, certification for an individual transmitter may also be requested by an applicant for a station authorization.

A transmitter presently shown on an instrument of authorization, which operates on an assigned frequency in the 890-940 MHz band and has not been certificated, may continue to be used by the licensee without certification provided such transmitter continues otherwise to comply with the applicable rules and regulations. Certification or verification is not required for portable transmitters operating with peak output power not greater than 250 mW. If operation of such equipment causes harmful interference, the FCC may require the licensee to take such corrective action as is necessary to eliminate the interference.

The regulations also set forth minimum payload capacity requirements for equipment employing digital modulation techniques and requirements for bit rate.

Equipment for People with Disabilities
The Communications Act of 1934 requires that **telecommunication manufacturers make, when feasible, devices that are accessible to people with disabilities**. If not feasible, the manufacturer must make its devices compatible with peripheral devices that are commonly used by people with disabilities. Devices include telephones, wireless handsets, fax machines, answering machines and pagers.
Manufacturers of equipment operating under Commercial Mobile Services (16 CFR 20) that offer to service providers four or more hearing aid compatible handset models for use in (or imported for use in) the United States **must ensure that it offers a minimum number of the handsets.** The number of handsets offered must be the greater of the following:

- at least two handset models in that air interface or
- at least one-third of its handset models in that air interface.

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For More Information, see FCC's
Telecommunications Access For People with Disabilities

Telephone Terminal Equipment
47 CFR 68, *Connection of Terminal Equipment to the Telephone Network* governs the connection of Terminal Equipment (TE) to the Public Switched Telephone Network (PSTN) as well as TE that is connected to wireline facilities owned by wireline telecommunications providers and used to provide private line services. The Regulations establish processes to identify, publish, and update technical criteria for TE and also to approve TE for attachment to the network. The rules also provide for the development and maintenance of a publicly accessible database of approved TE and for labeling TE that have been shown to comply with the technical criteria. All approved TE are required to be listed in the database and to be properly labeled.

47 CFR 68 also contains rules concerning Hearing Aid Compatibility and Volume Control (HAC/VC) for telephones, dialing frequency for automated dialing machines, source identification for fax transmissions, and technical criteria for inside wiring.
TE suppliers can obtain TE approval in two ways. Suppliers can obtain certification from private Telecommunications Certification Bodies (TCBs). A list of TCBs that have notified the FCC of their capability to test TE is available in FCC KDB publication 784838. Alternatively, suppliers may declare their own TE to conform to applicable technical criteria using the Suppliers Declaration of Conformity (SDoC). In either case, the TE must first be tested or undergo other engineering analysis to ensure compliance with applicable technical criteria, and a report must be created documenting the results. Once compliance with technical criteria has been demonstrated, the supplier must apply to the Administrative Council for Terminal Attachments (ACTA) to have its approved TE listed in the ACTA database.

The regulation also specifies mandatory labeling requirements for approved TE.

For more detailed information, see
Administrative Council for Terminal Attachments

Federal Trade Commission (FTC)

Federal Trade Commission Act (FTC Act)
15 United States Code, Chapter 2, Subchapter I, Sections 41-58
The FTC Act broadly prohibits unfair or deceptive acts or practices in or affecting commerce. The commission will find deception if, either by the inclusion or exclusion of information, it is likely to:

- Mislead consumers acting reasonably under the circumstances, or
- Affect the consumer's choice or conduct, thereby leading to injury.

The FTC Act allowed the FTC to enact several Acts and Regulations intended to prohibit unfair or deceptive acts or practices.

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EnergyGuide Standards and Labeling for Home Appliances

16 CFR 305, *Energy and Water Use Labeling for Consumer Products Under the Energy Policy and Conservation Act ("Energy" Labeling Rule)* establishes **requirements for specific labeling and/or marking of certain consumer appliances** with information indicating the product's operating cost (or different useful measure of energy consumption) and related information, disclosing its water use rate and related information, or stating its compliance with applicable standards. Appliances covered under this act include:

- Refrigerators
- Dishwashers
- Water heaters
- Room air conditioners
- Clothes washers
- Clothes dryers
- Central air conditioners and central air conditioning heat pumps
- Furnaces
- Direct heating equipment
- Pool heaters
- Kitchen ranges and ovens
- Television sets
- Fluorescent lamp ballasts
- General service fluorescent lamps
- Medium base compact fluorescent lamps
- General service incandescent lamps, including incandescent reflector lamps
- Metal halide lamp fixtures
- Ceiling fans
- Freezers
- Boilers (electrical)

Environmental Claims

16 CFR 260, *Guides for the Use of Environmental Marketing Claims*

These guides apply to environmental claims included in labeling, advertising, promotional materials and all other forms of marketing, whether asserted directly or by implication, through words, symbols, emblems, logos, depictions, product brand names, or through any other means, including marketing through digital or electronic means such as the Internet or electronic mail. The guides apply to any claim about the environmental attributes of a product, package, or service in connection with the sale, offering for sale, or marketing of such product, package or service for personal, family or household use, or for commercial, institutional, or industrial use.

In 2012, an update by the FTC modified the existing guide sections on general environmental benefit, compostable, degradable, ozone, recyclable, and recycled content claims. It also added new sections on carbon offsets, certifications and seals of approval, free-of claims, non-toxic claims, made with renewable energy claims, and made with renewable materials claims.

For more detailed information, see FTC's:

Environmental Claims: Summary of the Green Guides

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Food and Drug Administration (FDA)

Food Contact Substances

Some electrical products and/or appliances are used in food preparation. In 1997, Congress passed the Food and Drug Administration Modernization Act, which amended the Food Drug and Cosmetic Act. The major purpose behind this legislation was to streamline FDA's regulatory practices, and one of the procedures it introduced was a notification process for food contact substances.

Once known as indirect food additives, a food contact substance (FCS) is defined as "any substance intended for use as a component of materials used in manufacturing, packing, packaging, transporting, or holding food if such use is not intended to have a technical effect in such food." Common types of food contact substances include coatings, plastics, paper, adhesives, as well as colorants, antimicrobials, and antioxidants found in packaging.

The term "safe," as it refers to food additives and ingredients (including food contact substances), is defined in 21 CFR 170.3(i) as a "reasonable certainty in the minds of competent scientists that a substance is not harmful under the intended conditions of use."

The overall regulatory status of a food contact material is dictated by the regulatory status of each individual substance that comprises the article. **The individual substance that is reasonably expected to migrate to food because of its intended use in the food contact material must be covered by one of the following:**

- A regulation listed in Title 21 Code of Federal Regulations. Consult 21 CFR 174-179 to see if the use of the component is an appropriately regulated indirect additive.
    - Components of a food packaging material used in compliance with a regulation in 21 CFR (174-179) need no further FDA review. Most of the regulated indirect food additives can be found in CFSAN's "Indirect Additive" Database.
        - General Indirect Food Additives (21 CFR 174)
        - Adhesives and Components of Coatings (21 CFR 175)
        - Paper and Paperboard Components (21 CFR 176)
        - Polymers (21 CFR 177)
        - Adjuvants, Production Aids, and Sanitizers (21 CFR 178)
        - Irradiation in the Production, Processing and Handling of Food (21 CFR 179)
- Meeting the criteria for GRAS status (including but not limited to a GRAS regulation or GRAS notice). Consult 21 CFR 182-186 and the list of GRAS Notices to see if the use of the component is listed as Generally Recognized As Safe (GRAS).
    - Substances GRAS in food (21 CFR 182)
    - Substances affirmed as GRAS in food (21 CFR 184)
    - Substances affirmed as GRAS for use in food packaging (21 CFR 186)
    - Summary of all GRAS Notices
- A prior sanctioned letter. Consult 21 CFR 181 to see if the use of the component is listed as Prior Sanctioned. Prior Sanctioned substances are those substances whose use in contact

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with food is the subject of a letter issued by FDA or USDA before 1958 offering no objection to a specific use of a specific substance.

- A Threshold of Regulation (TOR) exemption request. Consult the listing of Threshold of Regulation Exemptions to check if the component is exempted from a petition or an FCN (Food Contact Notification) as a food additive because it becomes a component of food at levels that are below the threshold of regulation. A substance used in a food contact article may be exempted by FDA from the need of an FCN or a petition (regulation) as a food additive if the use in question has been shown to result in a very low concentration (0.5 ppb). For details see, "Submitting Requests Under 21 CFR 170.39 Threshold of Regulation for Substances Used in Food Contact Articles."
- An effective Food Contact Substance Notification (FCN). Consult the listing of Effective Food Contact Substance Notifications. The listing of effective food contact substance notifications, the regulation, guidance documents, and additional information regarding the notification program are listed on the Food Contact Substance web page. However, you should be aware that FCNs are proprietary and users must be able to trace the substance they use back to the manufacturer for which the notification is effective.

Manufacturers wishing to determine if FDA has a regulation for a specific food additive can view a list of food additives online, via the Food Additives Status List (formerly called Appendix A of the Investigations Operations Manual (IOM)). This list organizes additives found in many parts of 21 CFR into one alphabetized list. Additives included are those specified in the regulations promulgated under the Federal Food Drug & Cosmetics Act (FD&C Act), under Sections 401 (Food Standards), and 409 (Food Additives). The Food Additives Status List includes short notations on use limitations for each additive. For complete information on its use limitations, refer to the specific regulation for each substance. For example, the EAFUS list (Everything Added to Food in the United States), is a helpful reference within the limitations described at the beginning of the database.

Medical Products

Electrical and electronic medical devices are subject to medical device regulations. Medical devices are classified into three categories – Class I, II, III – with regulatory control increasing with each class. Class I generally does not require Premarket Notification (510(k)), Class II devices generally do require Premarket Notification (510(k)), and Class III generally require Premarket Approval.

Manufacturers of medical devices for sale in the U.S. **must comply with basic regulatory requirements** including:

- Establishment registration (21 CFR 807),
- Medical Device Listing (21 CFR 807),
- Premarket Notification 510(k) (21 CFR 807 Subpart E), unless exempt, or Premarket Approval (21 CFR 814),
- Investigational Device Exemption (IDE) for clinical studies (21 CFR 812),
- Quality System regulation (21 CFR 820),

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- Labeling requirements (21 CFR 801), and
- Medical Device Reporting (21 CFR 803) (For current Rule see *Final Rule - Medical Device Reporting: Electronic Submission Requirements* and *Final Rule - Medical Device Reporting: Electronic Submission Requirements; Correcting Amendments*

Federal Food, Drug, and Cosmetic Act (FD&C Act) Section 514 [21 U.S.C. 360d] authorizes FDA to establish (and periodically evaluate) performance standards that are necessary to provide reasonable assurance of safety and effectiveness of medical devices. In addition to establishing performance standards, Section 514(c) [21 U.S.C. 360d (c)] also authorizes the FDA to recognize appropriate (voluntary consensus) standards established by nationally or internationally recognized standard development organizations. To streamline the regulatory review process, applicants may utilize (or make a declaration of conformity with respect to) applicable FDA recognized standards in order to meet a premarket submission requirement or other requirement. FDA requires that certain medical devices meet mandatory performance standards. FDA has recognized over 1190 standards which can be searched on the Recognized Consensus Standards page.

Classification, as well as, in some cases, other requirements for electric and electronic medical devices, can be found within the following Regulations:

- 21 CFR 862 Subpart C – *Clinical Laboratory Instruments* provides identification, classification, and other requirements for various clinical laboratory Instruments.
- 21 CFR 864 Subpart F – *Automated and Semi Automated Hematology Devices* provides, identification, and classification requirements for various automated and semi-automated devices used in hematology.
- 21 CFR 866 Subpart A – *General Provisions*, Subpart B – *Diagnostic Devices*, Subpart C *Microbiology Devices*, Subpart E – *Immunology Laboratory Equipment and Reagents*, Subpart F – *Immunological Test Systems*, and Subpart G – *Tumor Associated Antigen Immunological Test Systems* provide general provisions, identification, and classification for devices used for immunology and microbiology.
- 21 CFR 868 Subpart A – *General Provisions*, Subpart B – *Diagnostic Devices*, Subpart C – *Monitoring Devices*, Subpart F – *Therapeutic Devices*, and Subpart G – *Miscellaneous* provide general provisions, identification, and classification for Anesthesiology Devices.
- 21 CFR 870 Subpart A - *General Provisions*, Subpart B - *Cardiovascular Diagnostic Devices*, Subpart C - *Cardiovascular Monitoring Devices*, Subpart D - *Cardiovascular Prosthetic Devices*, Subpart E - *Cardiovascular Surgical Devices*, and Subpart F - *Cardiovascular Therapeutic Devices* provide general provisions, identification, classification, and other requirements for devices used in cardiovascular procedures.
- 21 CFR 872 Subpart A - *General Provisions*, Subpart B - *Diagnostic Devices*, Subpart E - *Surgical Devices*, Subpart F - *Therapeutic Devices*, and Subpart G - *Miscellaneous Devices* provide general provisions, identification, classification, and other requirements for dental devices.
- 21 CFR 874 Subpart A - *General Provisions*, Subpart B - *Diagnostic Devices*, Subpart D - *Prosthetic Devices*, Subpart E - *Surgical Devices*, and Subpart F - *Therapeutic Devices*

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provide general provisions, identification, classification, and other requirements for ear, nose, and throat devices.

- 21 CFR 876 Subpart A - *General Provisions*, Subpart B - *Diagnostic Devices*, Subpart C - *Monitoring Devices*, Subpart E - *Surgical Devices*, and Subpart F - *Therapeutic Devices* provide general provisions, identification, classification, and other requirements for gastroenterology-urology devices.
- 21 CFR 878 Subpart A - *General Provisions*, Subpart B - *Diagnostic Devices*, Subpart E - *Surgical Devices*, and Subpart F - *Therapeutic Devices* provide general provisions, identification, classification and other requirements for general and plastic surgery devices.
- 21 CFR 880 Subpart A - *General Provisions*, Subpart C - *General Hospital and Personal Use Monitoring Devices*, Subpart F - *General Hospital and Personal Use Therapeutic Devices*, and Subpart G - *General Hospital and Personal Use Miscellaneous Devices* provide general provisions, identification, classification and other requirements for general hospital and personal use devices.
- 21 CFR 882 Subpart A - *General Provisions*, Subpart B - *Neurological Diagnostic Devices*, Subpart E - *Neurological Surgical Devices*, and Subpart F - *Neurological Therapeutic Devices* provide general provisions, identification, classification, and other requirements for neurological devices.
- 21 CFR 884 Subpart A - *General Provisions*, Subpart B - *Obstetrical and Gynecological Diagnostic Devices*, Subpart C - *Obstetrical and Gynecological Monitoring Devices*, Subpart E - *Obstetrical and Gynecological Surgical Devices*, Subpart F - *Obstetrical and Gynecological Therapeutic Devices*, and Subpart G - *Assisted Reproduction Devices* provide general provisions, identification, classification, and other requirements for obstetrical and gynecological devices.
- 21 CFR 886 Subpart A - *General Provisions*, Subpart B - *Diagnostic Devices*, Subpart E - *Surgical Devices*, and Subpart F - *Therapeutic Devices* provide general provisions, identification, classification, and other requirements for ophthalmic devices.
- 21 CFR 888 Subpart A - *General Provisions*, Subpart B - *Diagnostic Devices*, and Subpart E - *Surgical Devices* provide general provisions, identification, classification, and other requirements for orthopedic devices.
- 21 CFR 890 Subpart A - *General Provisions*, Subpart B - *Physical Medicine Diagnostic Devices*, Subpart D - *Physical Medicine Prosthetic Devices*, and Subpart F - *Physical Medicine Therapeutic Devices* provide identification, classification, and other requirements for physical medicine devices.
- 21 CFR 892 Subpart A - *General Provisions*, Subpart B - *Diagnostic Devices*, and Subpart F - *Therapeutic Devices* provide general provisions, identification, classification, and other requirements for radiology devices.
- 21 CFR 898 *Performance Standards for Electrode Lead Wires and Patient Cables* requires that any connector in a cable or electrode lead wire having a conductive connection to a patient shall be constructed in such a manner as to comply with certain provisions of standard IEC 601–1: Medical Electrical Equipment.

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Mammography Equipment

In addition to Radiation Emitting Products requirements below, **mammography equipment must be specifically designed for the purpose of mammography**. The prohibition of using non-mammography equipment includes systems that have been modified or equipped with special attachments for mammography. Specific requirements for mammography equipment are outlined in 21 CFR 900.12(b) Quality Standards, including motion of tube-image receptor assembly, image receptor sizes, light fields, magnification, focal spot selection, compression, automatic exposure control, x-ray film, intensifying screens, film processing solutions, lighting, and film masking devices. **Mammography equipment is also subject to FDA Medical Device Requirements.**

Radiation Emitting Products

The Radiation Control provisions, as required by 21 CFR Subchapter J – Radiological Health, apply to all electronic products, which are defined as any manufactured or assembled product (or component, part, or accessory of such product) which, when in operation contains or acts as part of an electronic circuit and emits (or in the absence of effective shielding or other controls would emit) electronic product radiation. Examples include diagnostic x-ray or ultrasound devices, sunlamps, microwave ovens, television receivers and monitors (cathode ray tube only), CD players, and laser welders.

All radiation emitting products must be designed to comply with applicable performance standards and must not permit unnecessary exposure to radiation during use. Before introduction into U.S. commerce, **each unit must be certified that it complies with performance standards.** A product report must be submitted to the FDA demonstrating compliance to the applicable standard. Additional reporting and record keeping requirements are also specified in the Regulation. Specific reporting requirements can be found in 21 CFR 1002. **Medical devices are additionally subject to FDA Medical Device Requirements.**

Performance Standards

21 CFR 1010, Performance Standards for Electronic Products: General
21 CFR 1020, Performance Standards for Ionizing Radiation Emitting Products
21 CFR 1030, Performance Standards for Microwave and Radio Frequency Emitting Products
21 CFR 1040, Performance Standards for Light-Emitting Products
21 CFR 1050, Performance Standards for Sonic, Infrasonic, and Ultrasonic Radiation-Emitting Products

In addition to specific labeling requirements found in the above standards, general labeling requirements of 21 CFR 801 apply. The following information must be provided on a tag or permanently affixed label that is visible when the product is fully assembled:

- a statement that the product complies with the applicable performance standard;
- full name and address of the manufacturer of the product; and
- the place and month and year of manufacture.

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For more detailed information, see FDA's
How to Get Your Electronic Product on the US market (Video)
How to Study and Market Your Medical Device
Radiation-Emitting Products Industry Assistance: Walk-through
Labeling Requirements for Radiation Emitting Devices and Products
FDA Recognized Consensus Standards

Occupational Safety and Health Administration (OSHA)

Occupational Safety and Health Act of 1970 (OSH Act)
United States Code Title 29, Chapter 15
The OSH Act, codified in 29 USC 15, was established to ensure safe and healthful working conditions for every working man and woman in the nation and to preserve human resources. Among many other provisions, the Act provides for the development and promulgation of occupational safety and health standards.

Nationally Recognized Testing Laboratories (NRTL) Program
The requirements for NRTL approval of equipment used in the workplace are found in the Agency's general industry standards, 29 CFR part 1910. For example, 29 CFR 1910.303(a) and 29 CFR 1910.307(c) (read together with the definitions of "approved" and "acceptable" in 29 CFR 1910.399) generally require electrical equipment or products used in the workplace to be approved by NRTLs. A comprehensive list of products requiring NRTL approval can be found on OSHA's *Type of Products Requiring NRTL Approval* website page.

OSHA recognizes an NRTL for testing and certifying specific products. The scope of recognition specifies:

- the product-testing standards which an NRTL can use to test and certify products,
- the types of test results that an NRTL may accept from other organizations (including manufacturers), and
- which of the NRTL's testing facilities are covered by OSHA's recognition.

OSHA's recognition of an organization as an NRTL assures that it is:

(1) independent of the product's manufacturer, supplier and vendor,
(2) capable of testing and certifying the product using specified product-testing standards, and
(3) regularly evaluated by OSHA for compliance with OSHA's requirements and policies regarding the NRTL Program.

OSHA evaluates an NRTL's capability by reviewing its testing and certification procedures as well as its quality assurance program.

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An NRTL's approval of a product generally consists of testing, inspection, and certification. Testing involves determining whether a sample or prototype of the product meets the applicable requirements of one or more specific consensus-based, U.S. product safety test standards. If the product meets the test standard requirements, the NRTL performs an inspection of the manufacturing facility to verify that the product resulting from a production run is or will be in conformance with the test standard's requirements. Following a satisfactory initial inspection, the NRTL issues its certification which provides assurance that the product conforms to the specific test standard(s). The NRTL also authorizes the manufacturer to apply the NRTL's certification mark to each unit of the manufactured product. After issuing its certification, the NRTL conducts periodic follow-up (i.e., quality-assurance and compliance) inspections of each manufacturing facility to provide assurance that the product currently manufactured at the facility and bearing the NRTL's mark is identical to the product that the NRTL tested and certified.

For more detailed information, see OSHA's:
OSHA Law & Regulations (refer to Subpart S for electrical equipment)
Current list of NRTLs
OSHA's Nationally Recognized Testing laboratory (NRTL) Program
Frequently Asked Questions

Overview of U.S. State Regulatory Frameworks

A growing number of areas are covered by both state and federal statutes, including consumer protection, employment, and food and drug regulation. (State laws give way to stricter federal laws that address the same issue.) When a state's Governor signs the bill, it becomes a state law. Once a law has been enacted by a state, it is the responsibility of the appropriate state agency to create the regulations necessary to implement the law.

State Regulatory Authorities and Technical Regulations (Mandatory)

In the U.S., some state laws and regulations are enacted which are more stringent than the federal laws. These laws include regulations for product labeling, packaging, chemical restrictions, etc. California is heavily regulated for many consumer products.

Agency/Organizations	Scope
State Authorities Responsible for Weights and Measures	Labeling
Toxics in Packaging Clearinghouse (TPCH)	Packaging
California Air Resource Board	Air cleaners

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California Energy Commission	Appliance labeling, battery charging systems
California Office of Environmental Health Hazard Assessment (OEHHA)	Toxic chemicals and substances
California Business & Professions Code	Made in the USA claims and smart televisions
California Department of Toxic Substances Control	Chemicals of concern in consumer products
Illinois Department of Public Health	Lead labeling
Minnesota Department of Commerce	Formaldehyde in children's products
Vermont Agency of Natural Resources	Batteries
Washington Department of Ecology	Lead, cadmium, and phthalates in children's products
Several States	Appliance energy efficiency, button cell batteries, BPA in food contact substances, chemicals of concern, ROHS, electronic waste, flame retardants, mercury, and National Electric Code.

Appliance Energy Efficiency

Several States, including, but not limited to, Arizona, California, Connecticut, Maryland, Massachusetts, Missouri, New Hampshire, New Jersey, New York, Oregon, Washington, Vermont, and Rhode Island have established energy efficiency standards for appliances not covered under federal law. Covered products must meet minimum energy efficiency requirements to be sold in that state. Under certain conditions, states may petition to have a stricter standard than the federal standards for a federally covered product.

> **For information on state energy efficiency policies, see:** National Conference of State Legislatures State Efficiency Policies.

Button Cell Batteries

Several states including Connecticut, Louisiana, Maine, and Rhode Island **prohibit the sale of mercury-containing button cell batteries and products that contain mercury-containing button cell batteries.**

Bisphenol A (BPA) in Food Contact Products

Connecticut, Illinois, New York, Vermont and Washington ban the use of food contact products containing BPA. **Connecticut and Vermont ban BPA in reusable food and beverage containers. Illinois and Washington ban BPA in children's food or beverage containers. New York bans BPA from children's products**, but allows for BPA-free products to be labeled as such.

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Chemicals of Concern

Several states, including Oregon, Washington, Vermont, and Maine, **require manufacturers selling children's products that contain a chemical that is included on the state's chemicals of concern list to provide notice to the state prior to sale in that state**. In some cases, the manufacturer must remove or make a substitution for the chemical.

Restriction of Hazardous Substances (ROHS)

Several US States, including California, Connecticut, Florida, Hawaii, Iowa, Illinois, Maryland, Maine, Michigan, Minnesota, New Hampshire, New Mexico, New York, Oregon, Rhode Island, Virginia, Vermont, and Washington, have regulations modeled after the European Union's RoHS directive.

For many of the states listed above, **an electronic device that is prohibited for sale in the European Union under the RoHS directive, due to the concentration of one or more heavy metals exceeding a specific concentration value, is prohibited from being sold in that state**.

The heavy metal limits are

- Cadmium: 0.01%
- Hexavalent Chromium: 0.1%
- Lead: 0.1%
- Mercury: 0.1%
- Polybrominateddiphenyls (PBBs): 0.1%
- Polybrominateddiphenyl ethers (PBDEs): 0.1%

Electronic Waste

Several states, including California, Connecticut, Hawaii, Illinois, Maine, Maryland, Michigan, Minnesota, New Jersey, Oklahoma, Rhode Island, and Wisconsin, have implemented laws that establish a mechanism for disposing of electronic waste through a registration and recycling waste fee. In general, devices cannot be sold unless they are visibly labeled with the manufacturers name or brand. Manufacturers must also register with each respective state. Additionally, some of the states listed require a statement as to whether or not the electronic device complies with the heavy metal concentrations of the European Union's RoHS Directive. There may also be reporting requirements for each state.

> **For additional information, see Electronics Recycling Coordination Clearinghouse's** Map of States with Legislation

Flame Retardants

Twelve states regulate the use of polybrominated diphenyl ethers (PBDE), pentabromodiphenyl ether (pentaBDE) and/or octabromodiphenyl ether (octaBDE). Eight of these states also have regulations restricting decabromodiphenyl ether (decaBDE). Illinois, Indiana, Minnesota, New

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York, and Rhode Island require manufacturers of certain electronic products to notify the state if their products exceed the European Union's maximum concentration values for PBDEs.

Mercury Containing Electronic Products

Several states have enacted mercury reduction or elimination laws. Connecticut, Louisiana, Maine, Massachusetts, Minnesota, New York, Rhode Island, Vermont, and Washington have labeling requirements. Connecticut, Louisiana, Maine, Massachusetts, New Hampshire, New York, North Carolina, Rhode Island, and Vermont have product notification requirements. Connecticut, Louisiana, Maine, Massachusetts, Minnesota, New Hampshire, New Jersey, New York, North Carolina, Rhode Island, Vermont, and Washington have instituted product bans or phase outs for products such as mercury-added fever thermometers and other types of thermometers, thermostats, automotive switches, manometers, switches and relays, various instruments and measuring devices, and mercury-added novelties.

> **For more information, see:**
> *Interstate Mercury Education and Reduction Clearinghouse (IMERC) Compliance Guidance*

National Electrical Code (NEC)

The NEC is a consensus code published by the National Fire Protection Association. The NEC is published every three years. It covers the installation of electrical products for public or private use and requires that certain electrical products meet the requirements of specific standards. This is not a national standard but has been **adopted as law by state governments and local authorities**. Check with the local authority having jurisdiction (AHJ) to see if there are amendments that modify parts of the codes or standards. It is important to remember that AHJs enforce the codes adopted in their jurisdiction, which can be different codes or different editions of the NEC.

The code requires that all electrical components be listed or labeled (typically by a Nationally Recognized Testing Laboratory (NRTL)) or be approved for installation by the AHJ on an installation by installation basis. See OSHA Nationally Recognized Testing Program for more information.

Packaging and Labeling

UPLR

The Uniform Packaging and Labeling Regulations (UPLR) contained in *NIST Handbook 130, Uniform Laws and Regulations in the Areas of Legal Metrology and Engine Fuel Quality*, have been adopted into law in 45 of the 50 U.S. states (Louisiana, Minnesota, Rhode Island, Wyoming and North Dakota have not adopted it). The purpose of these regulations is to provide accurate and adequate information as to the identity and quantity of contents of packages so that purchasers can make price and quantity comparisons.

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UPLR requires that consumer packaging bear a label specifying the identity of the commodity; the name and place of business of the manufacturer, packer, or distributor; and the net quantity of contents in terms of weight or mass measure, or numerical count in a uniform location upon the principal display panel.

Toxics in Packaging Legislation

This legislation was originally drafted by the Source Reduction Council of the Coalition of Northeastern Governors (CONEG) in 1989. It was developed in an effort to reduce the amount of heavy metals in packaging and packaging components that are sold or distributed throughout the United States. The law is designed to phase out the use and presence of mercury, lead, cadmium, and hexavalent chromium in packaging. The legislation has been successfully adopted by nineteen states.

> ***For more detailed information, see Toxics in Packaging Clearinghouse white paper:***
> Toxics in Packaging Fact Sheet

State of California

Air Cleaner Regulation

This Regulation limits the amount of ozone produced from indoor air cleaning devices. All air cleaner models marketed or sold in California **must first be tested by the California Air Resource Board (ARB) and certified that the product does not produce an ozone emission concentration exceeding 0.050 ppm** as required by the regulation. This includes air cleaners sold via the Internet. In addition, **all packaging must show the required label printed on the package.**

> **For more information, see California Air Resource Board's webpage:**
> AB 2276 Air Cleaner Regulation

Appliance Labeling Regulation

No manufacturer or distributor may sell an appliance in California unless it is permanently marked with a serial number unique to that appliance. In addition, the **manufacturer must provide, on the first page of the warranty or instruction manual, or on a separate card, a description of the appliance along with a space for recording the model number and serial number, the description of the location of such numbers on the appliance, and instructions to the final purchaser to record and retain the numbers.**

Battery Charging Systems

California regulates the energy efficiency of battery charging systems beyond that of the federal government. The standard limits the energy consumption in active charge, maintenance mode,

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and standby. Battery charging systems **must be tested for energy efficiency at a California Energy Commission (CEC) approved laboratory. The product is then submitted to the CEC and upon approval the model is listed in the appliance database. When approved, each product must be labeled with a "BC" inside a circle.** This regulation applies to all products containing battery charging systems. Examples of products with battery charging systems include notebook computers, tablets, power tools, electric toothbrushes, shavers, phones, mobile workstations, and Uninterruptible Power Supplies (UPS).
Note: Federal battery charger standards [10 CFR 429] will go into effect in 2018 preempting California's requirements.

For more information, see California Energy Commission's:
Frequently Asked Questions: Battery Charging Systems

Lead and Other Toxic Substances
California regulates lead and numerous other substances and chemicals, in both adult and children's products, through their Safe Drinking Water and Toxic Enforcement Act of 1986, more popularly known as **Proposition 65 or Prop 65** (California Health and Safety Code, Section 25249.5, et seq.). These settlements provide guidelines for suggested limits. Prop 65's List of Hazardous Substances is maintained and updated as new chemicals are identified.

The following warning language **is required on products sold in California if they contain chemicals on the Proposition 65 list** and the amount of exposure caused by the product is not within defined safety limits.

WARNING: This product contains chemicals known to the State of California to cause cancer and birth defects or other reproductive harm.

For more detailed California official information on Proposition 65, see:
Office of Environmental Health Hazard Assessment (OEHHA), Proposition 65 in Plain Language
Prop65 News

Made in the USA
A recent law relaxed California's strict "Made in USA" law. Under the revised law "Made in the USA", "Made in America", "U.S.A.", or similar labels are allowed even if a product has some foreign components. The labeling is permitted if any foreign component or part does not constitute more than 5% of the final wholesale value of the product or any foreign component or part does not constitute more than 10% of the final wholesale value of the product AND the manufacturer can show that those components cannot be obtained or produced domestically.

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Safer Consumer Products Regulations
The Safer Consumer Products Regulations applies to all consumer products placed in the stream of commerce in California. It requires manufacturers or other responsible entities to seek safer alternatives to harmful chemical ingredients in widely used products. The regulation requires the Department of Toxic Substances Control to adopt regulations that will establish a process for identifying and prioritizing chemicals in consumer products and to establish a process for evaluating chemicals of concern in consumer products and their potential alternatives.

For more detailed information, see
What are the Safer Consumer Products Regulations?

Smart Televisions
California law AB 1116, *Committee on Privacy and Consumer Protection. Connected Televisions* (Chapter 524) **requires that manufacturers of smart televisions with voice recognition features inform the user of the features during setup or installation.** The law also **prohibits conversations that are recorded from being used for advertising purposes**. In addition, the law states that manufacturers are only liable for functionality provided at the time of the original sale of a connected television and are not liable for functionality provided by applications that the user chooses to use in the cloud or are downloaded and installed by a user.

State of Illinois

Lead
Public Act 097-0612, The Lead Poisoning Prevention Act
The Act makes it illegal to sell, have, offer for sale, or transfer children's products that contain a total lead content in any component part of the item that is more than 0.004% (40 parts per million) but less than 0.06% (600 parts per million) by total weight (or a lower federal or State standard for lead content if applicable) **unless that item bears a warning statement that indicates that at least one component part of the item contains lead.** The warning statement must contain at least the following:

"WARNING: CONTAINS LEAD. MAY BE HARMFUL IF EATEN OR CHEWED. COMPLIES WITH FEDERAL STANDARDS."

The Act also makes it illegal to sell, or give away any lead-bearing substance that may be used by the general public, **unless it bears a warning statement as prescribed below, or as prescribed by any other federal regulation.** The statement shall be located in a prominent place on the item or package (16 CFR 1500.121).

If no regulation is prescribed, the warning statement shall be as follows when the lead-bearing substance is a lead-based paint or surface coating:

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"WARNING-CONTAINS LEAD. MAY BE HARMFUL IF EATEN OR CHEWED. See Other Cautions on (Side or Back) Panel. Do not apply on toys, or other children's articles, furniture, or interior or exterior exposed surfaces of any residential building or facility that may be occupied or used by children. KEEP OUT OF REACH OF CHILDREN."

If no federal regulation is prescribed, the warning statement shall be as follows when the lead-bearing substance contains lead-based paint or a form of lead other than lead-based paint:

"WARNING: CONTAINS LEAD. MAY BE HARMFUL IF EATEN OR CHEWED. MAY GENERATE DUST CONTAINING LEAD. KEEP OUT OF REACH OF CHILDREN."

The warning statements do not apply to any product for which federal law governs warning in a manner that preempts state authority.

State of Minnesota

Formaldehyde in Children's Products

Minnesota bans the sale of certain products intended for children aged 8 and under that contain intentionally added formaldehyde or ingredients that degrade into formaldehyde. Children's product is defined as a product primarily designed or intended by a manufacturer to be physically applied to or introduced into a child's body, including any article used as a component of such a product, excluding a food, beverage, dietary supplement, pharmaceutical product or biologic, child's toy (covered under ASTM F963), or a medical device.

State of Vermont

Stewardship Program for Batteries

Product Stewardship for Primary Batteries and Rechargeable Batteries **requires manufacturers that sell primary batteries in Vermont to implement an approved collection plan or be a member of an approved stewardship organization.**

State of Washington

Lead, Cadmium, and Phthalates in Children's Products

Washington's Children's Safe Products Act restricts the sale of children's products containing more than 0.009 percent by weight of lead; more than 0.004 percent by weight of cadmium; or 0.10 percent by weight of phthalates, individually or in combination.

The limits and scope of this law are more stringent than the current federal requirements. Products included under this Act include children's cosmetics, jewelry, toys, car seats, and childcare articles, including clothing and footwear.

See Washington Department of Ecology's:
Children's Safe Products Act Webpage

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Overview of the U.S. Voluntary Standards Framework

The U.S. system of standards development is driven by the private sector. The majority of U.S. standards are voluntary and developed through consensus methods that reflect the needs of producers and manufacturers, users and consumers, and the government. The American National Standards Institute (ANSI) (a non-governmental, not-for-profit organization) coordinates much of the private sector activities of the voluntary standards development community in the U.S. There are hundreds of voluntary standards developing organizations in the United States responsible for standardization in many different industries and business sectors. The National Institute of Standards and Technology (NIST), a part of the U.S. Department of Commerce, is the national metrology laboratory for the United States. NIST provides the technical measurement infrastructure to support global trade and the commercial measurement system. NIST, through its Standards Coordination Office, advises on and coordinates federal participation in standards settings.

Standards Developing Organizations (SDOs)

Association for The Advancement of Medical Instrumentation (AAMI)

4301 N. Fairfax Drive, Suite 301
Arlington, VA 22203-1633 USA
Telephone: +1.703.525.4890
Contact

The Association for the Advancement of Medical Instrumentation (AAMI) is a nonprofit organization founded in 1967 providing global leadership to support the healthcare community in the development, management, and use of safe and effective healthcare technology

AAMI is the primary source of consensus standards, both national and international, for the medical device industry, as well as practical information, support, and guidance for healthcare technology and sterilization professionals.

AAMI, under the auspices of the American National Standards Institute, ISO, and IEC, administers several international committees that develop global standards for electromedical equipment.

ASTM International

100 Barr Harbor Drive
P.O. Box C700
West Conshohocken, PA 19428-2959 USA
Telephone: + 1.610.832.9500
Staff Directory

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ASTM International develops and maintains consensus standards and test methods pertaining to protective electrical and electronic equipment. A number of the ASTM standards are *Incorporated By Reference* in the *CFR* (as cited above under OSHA) and are **mandatory**.

There are several ASTM Committees responsible for electrical and electronic products because the category is so broad. Electrical and/or product standards are under the jurisdiction of the following subcommittees:

- D09 Electrical and Electronic Insulating Materials
- F01 Electronics
- F05 Business Imaging Products
- F11 Vacuum Cleaners
- F15 Consumer Products
- F26 Cooking and Warming Equipment

A small sampling of ASTM voluntary electrical and electronic product standards includes, but is not limited to:

D149	Standard Test Method for Dielectric Breakdown Voltage and Dielectric Strength of Solid Electrical Insulating Materials at Commercial Power Frequencies
D150	Standard Test Methods for AC Loss Characteristics and Permittivity (Dielectric Constant) of Solid Electrical Insulation
D257	Standard Test Methods for DC Resistance or Conductance of Insulating Materials
D1932	Standard Test Method for Thermal Endurance of Flexible Electrical Insulating Varnishes
D5425	Standard Guide for Development of Fire Hazard Assessment Standards of Electrotechnical Products
F1944	Standard Practice for Determining the Quality of the Text, Line- and Solid-Fill Output Produced by Ink Jet Printers
F360	Standard Practice for Image Evaluation of Electrostatic Business Copies
F2729	Standard Consumer Safety Specification for Constant Air Inflatable Play Devices for Home Use
F2208	Standard Safety Specification for Residential Pool Alarms
F420	Standard Test Method for Access Depth Under Furniture of Vacuum Cleaners
F1409	Standard Test Method for Straight Line Movement of Vacuum Cleaners While Cleaning Carpets
F2771	Standard Test Method for Determining the Luminance Curve of an Electroluminescent Lamp at Ambient Conditions
F1596	Standard Test Method for Exposure of a Membrane Switch or Printed Electronic Device to Temperature and Relative Humidity
F1047	Standard Specification for Frying and Braising Pans, Tilting Type
F1217	Standard Specification for Cooker, Steam
F2202	Standard Specification for Slow Cook/Hold Ovens and Hot Food Holding Cabinets

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F2521	Standard Specification for Heavy-Duty Ranges, Gas and Electric
F2796	Standard Specification for Hot Food Holding Tables
F2834	Standard Specification for Induction Cooktops, Counter Top, Drop-in Mounted, or Floor Standing
F2835	Standard Specification for Underfired Broilers

American Society of Heating, Refrigerating and Air-Conditioning Engineers (ASHRAE)

1791 Tullie Circle, N.E.
Atlanta, GA 30329 USA
Telephone +1.404.636.8400
Email

ASHRAE is a global society advancing human well-being through sustainable technology for the built environment. With a focus on building systems, energy efficiency, indoor air quality, refrigeration, and sustainability, ASHRAE develops standards and conducts research for both its members and others professionally concerned with HVAC, refrigeration processes, and the design and maintenance of indoor environments. ASHRAE standards are voluntary unless referenced in a federal or state code. Some of ASHRAE's standards Include:

Guideline 11	Field Testing of HVAC Controls Components
Guideline 13	Specifying Building Automation Systems
Standard 15	Safety Code for Mechanical Refrigeration
Standard 16	Method of Testing for Rating Room Air Conditioners and Packaged Terminal Air Conditioners
Standard 29	Methods of Testing Automatic Ice Makers
Standard 32.1	Methods of Testing for Rating Vending Machines for Bottled, Canned and Other Sealed Beverages
Standard 37	Methods of Testing for Rating Electrically Driven Unitary Air Conditioning and Heat Pump Equipment
Standard 51	Laboratory Methods of Testing Fans for Aerodynamic Performance Rating
Standard 94.2	Method of Testing Thermal Storage Devices with Electrical Input and Thermal Output based on Thermal Performance
Standard 116	Methods of Testing for Rating Seasonal Efficiency of Unitary Air-Conditioners and Heat Pumps
Standard 118.1	Method of Testing for Rating Commercial Gas, Electric, and Oil Service Water Heating Equipment
Standard 128	Method of Rating Portable Air Conditioners
Standard 135	BACnet – A Data Communication Protocol for Building Automation and Control networks
Standard 135.1	Method of Test for conformance to BACnet
Standard 146	Method of Testing and Rating Pool Heaters

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Standard 164.2	Method of Test for Self-Contained Residential Humidifiers
Standard 185.1	Method of Testing UVC Lights for Use in HVAC&R Units or Air Ducts to Inactivate Microorganisms on Irradiated Surfaces
Standard 185.2	Method of Testing Ultraviolet Lamps for Use in HVAC&R Units or Air Ducts to Inactivate Airborne Microorganisms
Standard 190	Method of Testing for Rating Indoor Pool Dehumidifiers
Standard 195	Method of Test for Rating Air Terminal Unit Controls
Standard 206	Method of Testing for Rating of Multi-Purpose Heat Pumps for Residential Space Conditioning and Water Heating

Association of Home Appliance Manufacturers (AHAM)

1111 19th Street NW, Suite 402
Washington DC 20036 USA
Telephone +1.202.872.5955
Email

AHAM is the trade association of the home appliance manufacturing industry. Its members include the manufacturers of major, portable, and floor care home appliances and the companies who supply and service these manufacturers. AHAM develops voluntary technical standards that relate primarily to the measurement of specific product performance characteristics for major and portable appliances. An AHAM standard is mandatory if incorporated by reference in a federal code. AHAM standards include:

AHAM HLD-1	Clothes Dryers
AHAM HLW-1	Clothes Washers
ANSI/AHAM DH-1	Dehumidifiers
ANSI/AHAM DW-1	Dishwashers
ANSI/AHAM ER-1	Electric Ranges
AHAM FWD-1	Food Waste Disposers
AHAM OV-1	Oven Volume
AHAM HRF-1	Refrigerators/Freezers
ANSI/AHAM RAC-1	Room Air Conditioners
AHAM TC-1	Trash Compactors
AHAM CM-1	Coffee Makers
ANSI/AHAM HU-1	Humidifiers
ANSI/AHAM I-1	Irons
ANSI/AHAM AC-1	Room Air Cleaners – CADR
ANSI/AHAM AC-2	Room Air Cleaners – Sound
AHAM AC-3	Room Air Cleaners – Accelerated Loading
AHAM SC-1	Slow Cookers

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IEEE Standards Association

IEEE Operations Center
445 Hoes Lane
Piscataway, NJ 08854-4141 USA
Phone: +1.732.981.0060

The IEEE-SA is a leading consensus building organization that nurtures, develops and advances global technologies. Applicable standards include:

IEEE 1625-2008	IEEE Standard for Rechargeable Batteries for Multi-Cell Mobile Computing Devices
IEEE 1725-2011	IEEE Standard for Rechargeable Batteries for Cellular Telephones

National Electrical Manufacturers Association (NEMA)

1300 North 17th Street
Suite 900
Arlington, Virginia 22209 USA
Telephone +1.703.841.3200
Contact

NEMA is the association of electrical equipment and medical imaging manufacturers. Its members manufacture a diverse set of products including power transmission and distribution equipment, lighting systems, factory automation and control systems, and medical diagnostic imaging systems. NEMA publishes over 600 standards. NEMA standards are voluntary unless incorporated by reference into a federal or state regulation or code.

National Fire Protection Association (NFPA)

1 Batterymarch Park
Quincy, Massachusetts 02169-7471 USA
Telephone +1.617.770.3000

NFPA is a global non-profit organization dedicated to fire and electrical safety. NFPA delivers information and knowledge through more than 300 consensus codes and standards, research, training, education, outreach, and advocacy.

National Fire protection codes and standards include, but are not limited to:

NFPA 70	National Electrical Code®
NFPA 70A	National Electrical Code® Requirements for One- and Two-Family Dwellings
NFPA 70B	Recommended Practice for Electrical Equipment Maintenance

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NFPA 70E	Standard for Electrical Safety in the Workplace®
NFPA 72	National Fire Alarm and Signaling Code
NFPA 73	Standard for Electrical Inspections for Existing Dwellings
NFPA 75	Standard for the Fire Protection of Information Technology Equipment
NFPA 76	Standard for the Fire Protection of Telecommunications Facilities
NFPA 77	Recommended Practice on Static Electricity
NFPA 79	Electrical Standard for Industrial Machinery

UL Standards

UL Standards are used to assess products; test components, materials, systems, and performance; and evaluate environmentally sustainable products, renewable energies, food and water products, recycling systems, and other innovative technologies. UL standards, which are primarily safety standards, are voluntary unless incorporated by reference into a federal or state regulation or code.

Testing and Certification Bodies

Testing

Consumer Product Safety Commission (CPSC) accepted third-party testing facilities for children's products can be found at the CPSC Third-Party Testing Laboratory Accreditation page.

Test facilities that are recognized by the FCC to perform radio frequency equipment authorization testing can be found at the Federal Communications Commission (FCC) Equipment Authorization Test Firm Search page.

Certification

Products Subject to Consumer Product Safety Rules

Section 102 of the CPSIA (page 8) **requires every manufacturer or importer of all consumer products that are subject to a consumer product safety rule enforced by the CPSC to issue a certificate** stating that the product complies with the applicable standard, regulation, or ban. The certificate must accompany the product and be furnished to the retailer or distributor. Section 102 also **requires the manufacturers or importers of children's products for age 12 years or younger to certify that the products comply with all relevant product safety standards by issuing a children's product certificate** supported by tests performed by a CPSC-accepted third-party testing laboratory.

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Products Subject to Energy Conservation Standards

10 CFR 429 **requires every manufacturer of certain consumer, commercial and industrial appliances subject to energy conservation standards to submit a certification report to the DOE certifying that each basic model meets the applicable energy conservation standard(s).** This must be done before distributing the product in commerce and annually thereafter.

Products Subject to FCC Rules that Emit Radio Frequency (RF) Energy

47 CFR 15, *Radio Frequency Devices* and 47 CFR 18, *Industrial, Scientific, and Medical Equipment* require that certain products be authorized under a certification procedure prior to use or marketing along with proper labeling. Examples of devices subject to certification which must be submitted to a Telecommunications Certification Body (TCB) are mobile phones, RF lights, microwave ovens, RC transmitters, family radio transmitters, telemetry transmitters, cordless phones, walkie-talkies, ultra-wideband transmitters, and software defined radio transmitters. Computers and computer peripherals may be authorized under the certification procedures or the Declaration of Conformity procedures. Most transmitters operating under other FCC radio service rule parts are also required to be authorized under the certification procedure.

To view a listing of TCBs, click TCB Search under Reports at OET Telecommunications Certification Bodies (TCB) System. As of July 12, 2015, all new grants of certification are issued by TCBs and the FCC is no longer accepting applications for the FCC to issue the grant of certification.

Questions related to the FCC's equipment authorization program should be directed to the FCC Office of Engineering and Technology's (OET) Knowledge Database (KDB) inquiry system using the link for *Submit an Inquiry*.

NOTE: After July 12, 2016, all products that are to be certified by a TCB **must be tested in a testing lab that the FCC has recognized as accredited.** A search for recognized testing labs is located on the FCC's Equipment Authorization System Test Firm Search page.

Products Used in the Workplace

A number of OSHA standards require product testing and certification by a Nationally Recognized Testing Laboratory (NRTL). An NRTL is a third-party organization recognized by OSHA as having the technical capability to perform safety testing and certification of particular types of products. After certifying that a product meets specific safety standards, the NRTL authorizes the manufacturer to place the NRTL's registered certification mark on the product.

Organizations can be found at OSHA's Current List of NRTLs.

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RELEVANT U.S. GOVERNMENT AGENCIES

U.S. Customs and Border Protection (CBP)

1300 Pennsylvania Avenue, NW
Washington, DC 20229 USA
Telephone: +1.703.526.4200 and (toll-free) +1.877.227.5511
Email via online form

For more detailed information, see the U.S. International Trade Commission's:
Harmonized Tariff Schedule of the United States – Chapter 84 and Chapter 85 on Electrical and Electronic Equipment

U.S. Consumer Product Safety Commission (CPSC)

4330 East West Highway, Bethesda, MD 20814 USA
Telephone: +1.301.504.7923
Email via online form

CPSC Office	Telephone
Office of International Programs and Intergovernmental Affairs	+1.301.504.7071
Office of Compliance and Field Operations	+1.301.504.7915
Deputy Director	+1.301.504.7520
Office of Import Surveillance	+1.301.504.7677

Department of Energy

Office of the Assistant General Counsel for Enforcement
1000 Independence Ave., SW, Washington, DC, 20585
Telephone: +1.202.586.5281
List of Contacts

Environmental Protection Agency (EPA)

Imports Program
2000 Traverwood Drive, Ann Arbor, MI 48105 USA
Telephone: +1.734.214.4100
Fax: +1.734.214.4676
List of Contacts

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Federal Communications Commission (FCC)

Federal Communications Commission
445 12th Street SW, Washington, DC 20554
Telephone: +1.888.225.5322
Contact FCC

Federal Trade Commission (FTC)

600 Pennsylvania Avenue, NW, Washington, DC 20580 USA
Telephone: +1.202.326.2222
List of Contacts

U.S. Food and Drug Administration (FDA)

10903 New Hampshire Ave, Silver Spring, MD 20993
Telephone: +1.888.463.6332
Contact FDA

Occupational Safety and Health Administration (OSHA)

Directorate of Standards and Guidance
200 Constitution Avenue, NW, Washington, DC 20210 USA
Office of Physical Hazards
Telephone: +1.202.693.2092

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U.S. Electrical and Electronic Industry and Market Data

Industry Trade Associations

Advanced Medical Technology Association (AdvaMed)
701 Pennsylvania Ave, N.W., Suite 800, Washington, D.C. 20004-2654 USA
Telephone +1.202.783.8700
info@advamed.org

Air Conditioning, Heating and Refrigeration Institute (AHRI)
2111 Wilson Blvd, Suite 500, Arlington, VA 22201
Telephone +1.703.524.8800 USA
General questions: mcardenas@ahrinet.org

National Electrical Manufacturers Association (NEMA)
1300 North 17th Street, Suite 900, Arlington, Virginia 22209 USA
Telephone +1.701.841.3200
Contact Form

Association of Home Appliance Manufacturers (AHAM)
1111 19th Street, NW, Suite 402, Washington, DC 20036 USA
Telephone: +1.202.872.5955
info@aham.org

Consumer Technology Association
1919 S. Eads Street, Arlington, VA 22202 USA
Telephone +1.866.858.1555 or +1.703.907.7600
Email: cea@CE.org

Medical Device Manufacturers Association (MDMA)
1333 H Street NW, Suite 400 West, Washington, DC 20005 USA
Telephone +1.202.354.7171

Telecommunications Industry Association (TIA)
1320 North Courthouse Road, Suite 200, Arlington, VA 22201 USA
Telephone +1.703.907.7700

Electrical and Electronic Products Market Data

E-Stats 2014: Measuring the Electronic Economy
Economy-Wide Statistics Briefs, U.S. Census Bureau. Released June 6, 2016.

This publication is available free of charge from: https://doi.org/10.6028/NIST.IR.8118r1

ADDENDUM/CORRIGENDUM

The following changes has been made to this document since the initial publication in October 2016.

Page(s)	**Items Changed**	**Other Details**
13-16	FCC Equipment Class table	Complete revision of the table.
41	Removed introductory paragraph in the **Testing** section.	
44	Added FCC to the listing of **Relevant Government Agencies**.	Inadvertently omitted upon initial publication.

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Revised February 2017
October 2016
Prepared by the Standards Information Center
Standards Coordination Office (SCO)
National Institute of Standards and Technology (NIST)
standardsinfo@nist.gov
http://www.standards.gov