

Voluntary and mandatory standards

- o Difference between voluntary and mandatory standards
- o Agencies that mandate standards
- o Role of government in legislating mandatory standards



17.5.3 Contrast voluntary and mandatory standards and provide examples of each

Unit C 17.5 Global Medical Equipment Regulations

Module 279-17-C Regulations, Standards and Ethics

Voluntary vs Mandatory standards

Most standards are **Voluntary**

Examples of
Voluntary Standards
(USA)



Carbon Monoxide

CO Alarms
Generators, Portable
Gas Appliances (CO Sensors)

Chemical

Air Cleaners
Child-Resistant Packaging
Gasoline Containers, Child-Resist.
Phthalates

Children's Products

Bassinets/Cradles
Beds

- Bunk
- Toddler

Bedside Sleepers
Booster Seats
Chairs

- High
- Youth

Changing Tables
Cribs

- Commercial
- Full Size
- Non Full Size & Play Yards

Infant Bedding & Accessories
Infant Bouncers

Infant Carriers

- Frame
- Handheld
- Soft

Infant Gates

Infant Slings
Infant Swings
Infant Walkers
Jewelry

Playground Equipment

- Age < 2
- Home
- Public

Stationary Activity Centers
Strollers
Toys

Child Drowning

Bath Seats
Infant Tubs
Pools/Hot Tubs/Spas

- Portable Pools
- Pool Alarms
- Pools and Spas
- Suction Release Devices

Electrical/Fire

Batteries
Clothes Dryers

Electric Heaters
National Electrical Code
Smoke Alarms

Fire

Cabinet Heaters/Cylinders
Candles
Lighters
Mattresses
Sprinklers
Gas Ranges

Household/Recreation (Mechanical)

Off-Road Vehicles

- All-Terrain Vehicles
- Recreational Off-Highway Vehicles

Amusement Rides, Portable
Bicycles
Fuel Tanks
Garage Doors/ Gate Operators
Helmets, Recreational
Ladders
Mowers
Ranges
Shopping Carts
Soccer Goals
Scooters, Motorized
Table Saws
Tree Stands, Hunting
Window Blind Cords

Standards can be mandated (become Mandatory) by a

- Company:** 'All our medical equipment should have be painted in our Brand colours'
- Professional society:** 'BMET's in Zambia should keep an inventory in their hospital'
- Industry:** 'Medical Devices should be electrically safe through following IEC 60601'
- Government:** 'All hospitals in Zambia should maintain an inventory'
- Trade Agreement:** 'Import of Chinese equipment should come with an English language user manual'

with each Mandatory Standard it must be specified what the **sanction** is for 'non-compliance'.

A **Standard** may be called a **Regulation** when it becomes mandated by a government or an international trade agreement.

Examples of Mandatory Standards (USA)

and there are many, many more

<http://www.cpsc.gov/en/Regulations-Laws-Standards/Regulations-Mandatory-Standards-Bans>

Chemistry sets	FHSA	1500.83(a)(23) 1500.85(a)(1)	Guide to Federal Hazardous Substances Act (FHSA) Requirements
Children's Products containing lead or lead paint	FHSA CPSIA	1500.87 1500.88 1500.89 1500.90 1500.91 15 U.S. Code § 1278a	Guide to Federal Hazardous Substances Act (FHSA) Requirements Total Lead Content FAQ Lead in Paint FAQ
Chlorofluorocarbons, self pressurized products containing	CPSA	1401	
Choking hazard warnings (small parts, balloons, marbles, balls)	FHSA	1500.19	Guide to Federal Hazardous Substances Act (FHSA) Requirements Small Parts Regulation Business Guidance
Cholestyramine, anhydrous	PPPA	1700.14(a)(10)v	Guide to Child Resistant and Senior-Friendly Packages
Cigarette lighters	CPSA	1210	Cigarette Lighters Business Guidance
Cigarette Lighters containing petroleum distillate	FHSA	1500.83(a)(20)	Guide to Federal Hazardous Substances Act (FHSA) Requirements
Clacker balls	FHSA	1500.18(a)(7) 1500.86(a)(5)	Guide to Federal Hazardous Substances Act (FHSA) Requirements
Cleaning products	FHSA PPPA	1500.83(a)(11) 1700.14(a)	Guide to Federal Hazardous Substances Act (FHSA) Requirements Guide to Child Resistant and Senior-Friendly Packages
Clothing Textiles	FFA	1610	

Examples of Mandatory Standards (USA)

Final and Proposed Rules

High Chairs, Infant Bouncer Seats, Children's Folding Chairs and Stools, Infant Bath Tubs, Portable Hook-On Chairs, Frame Child Carriers, Substantial Product Hazard List: Extension Cords, Corded Window Coverings, Prohibition of Children's Toys and Child Care Articles Containing Specified Phthalates, Recreational Off-Highway Vehicles, Seasonal and Decorative Lighting Products, Magnet Sets, Sling Carriers, All-Terrain Vehicles (ATVs), Soft Infant and Toddler Carriers, Hand-Held Infant Carriers, Strollers and Carriages, Bedside Sleepers, Bath Seats, Toddler Beds, Full-Size Cribs, Bassinets and Cradles, Cigarette Lighters Certificates of Compliance,

Role of government in legislating mandatory standards

When a standard is mandated by a government or an international trade agreement, it may be called a Regulation and it normally becomes **Legally Obligatory**.

Countries that are considering making standards mandatory should take into account the potential consequences under **international agreements on technical barriers to trade**.

A **barrier to trade** is a government-imposed restraint on the flow of international goods or services.

The most common barrier to trade is a **tariff—a tax on imports**. Tariffs raise the price of imported goods relative to domestic goods (goods produced at home)



In other words: make sure that you do not make certain standards mandatory for import products in your country if these are in conflict with international regulations, unless you want to pick a fight...

END

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