Medical Equipment Standards

- What are standards?
- Types of technical specifications covered in standards. Why are they important?
- Examples of standards

17.4.1 Application of Standards to management and maintenance of medical equipment.

17.4.2 The purpose and importance of medical equipment standards.

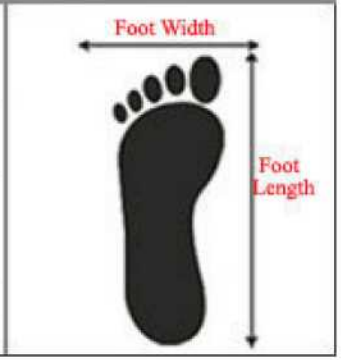
Unit C 17.4 Global Medical Equipment Regulations

Module 279-17-C Regulations, Standards and Ethics

Standard shoe sizes

In most countries we can order shoes (or clothes) simply by referring to a size.
This is only possible because manufacturers follow some **industrial standards** in making shoes and clothes.

Adult Mens Shoes Size Table							
Europe	38	39	40	41	42	43	44
Standard	240	245	250	255	260	265	270
Foot Length (cm)	23.6-24	24.1-24.5	24.6-25	25.1-25.5	25.6-26	26.1-26.5	26.6-27
Foot Width (cm)	9-9.5	9.5	9.5-10	10	10-10.5	10.5	10.5-11



There are **no regulations** covering shoe sizes !

System	Size										System
Europe	39	40	41	42	43	44	45	46	Europe
China	39	40	41	42	43	44	45	46	China
UK	6	6.5	7.5	8	9	9.5	10.5		UK
USA/Canada	6.5	7	8	8.5	9.5	10	11	12	USA/Canada
Japan	24.5	25		26	27	27.5	29	30	Japan
Australia	6	6.5	7.5	8	9	9.5			Australia
Foot Length(mm)	245	250	255	260	265	270	275	280	

International Standardization is more difficult to achieve……

Standards are not primarily about safety, but about convenience and efficiency ….

Non-standard electrical plugs

Incompatibility between electrical plugs and receptacles is a good example where different countries follow different standards.

For users/customers,
this hampers international travel

For manufacturers of products, this increases the cost of production, without adding value for customers.

Standardization

Name 10 things that are standardized across the world

Name 10 things that are not standardized, but that you would like to be standardized…..

Standardization

10 things that are **standardized across the world**

- the internet / websites
- e-mail
- lightbulbs
- USB sticks
- car tire air connections
- air traffic control
- printer ink cartridges within one brand
- phone call handling
- SIM cards
- paper sizes (A4, etc.)
- freight container sizes
- credit cards
- Barcodes

10 things that are **not standardized**, but that users / travellers would probably like to be standardized…..

- traffic: driving left of right side of the road
- cars: steering wheel left or right in the car
- traffic priority rules (on roundabouts)
- electric power: voltage and frequency
- financial currencies
- sizes of shoes and clothes
- printer ink cartridges between brands
- …

Medical Equipment standardization is limited….

Standardized (examples only)

Medical gas / regulators, flow meters, ….

X-ray dose measurement

digital image data formats (DICOM)

Patient Information (HL7)

Not Standardized (examples only)

Consumables

Spare parts

User Interfaces

Performance (Image Quality, …)

….

Limiting competition ….

Equipment Inventory List Zambia(?), Form for Maintenance in Zambia(?), Preventive Maintenance protocols…

Standards in Medical Devices are important

Health care workers are well aware **of incompatible consumables** or **replacement parts** in medical devices of similar function that are made by different manufacturers (e.g. IV set, X-ray cassettes).

The lack of available consumables and repair parts is an important cause of medical equipment problems that are constantly encountered in developing countries.

Most medical devices are used globally. The safety, performance and consistent quality of medical devices is, therefore, an international public health interest. Thus, **global harmonization** of **medical device standards** (and regulations) is critical.

End of Intro …

What is a standard ?

Standards are **documented agreements**

- containing **technical specifications** or other precise criteria
- to be used consistently as **rules, guidelines** or definitions of characteristics,
- to ensure that materials, products, process and services are **fit for their purpose**.

A manufacturer can declare to be compatible with a specific standard. This will inform his customers on many underlying specifications & will assure the customer that his product will function well…..

Types of technical specifications covered in standards

Standards can establish a wide range of specifications for products, processes and services

1. **Prescriptive** specifications obligate **product characteristics**, e.g. device dimensions, biomaterials, test or calibration procedures
2. **Design** specifications set out the specific **design characteristics** of a product, e.g. operating room facilities or medical gas systems.

3. **Performance** specifications ensure that a product meets a **prescribed test**, e.g. strength requirements, measurement accuracy, battery capacity, or maximum defibrillator energy.
4. **Management** specifications set out requirements for the **processes and procedures** companies put in place, e.g. quality systems for manufacturing or environmental management systems.

A standard may contain a combination of specifications.

Why are Standards important ?

Standards can serve different purposes. They can:

1. Provide **reference criteria** that a product, process or service must meet.
2. Provide **information that enhances safety, reliability and performance** of products, processes and services.
3. **Assure consumers** about reliability or other characteristics of goods or services provided in the marketplace.
4. **Give consumers more choice** by allowing one firm's products to be substituted for, or combined with, those of another.

Generic Management Standards

Recent years have seen the development and application of what are known as “generic management system standards”, where “**generic**” means that the standards’ requirements can be applied to any organization, regardless of the product it makes or the service it delivers, and “**management system**” refers to what the organization does to manage its processes.

With management standards standardize the methods of management, rather than the products (outcomes) of the company. This is based on the relation that if you have high quality management (if you are ‘**a quality organization**’), you will also have high quality products.

Two of the most widely known series of generic management system standards are:

- the **ISO 9000** series for **managing quality systems**, and
- the **ISO 14000** series for environmental management systems.

More about **ISO 9000** series later in this course…..

Result oriented Standards

Next to generic Management standards, you will also find reference to terms such as:

- **outcome-oriented standards**,
- **objectives standards**,
- **result-oriented standards**

all with roughly the same meaning/intention.

These terms indicate that the standards specify **the objectives (ends)** to be achieved while leaving the **methods (means)** to the implementers.

In other words: standards on what you will achieve, not how you will achieve it…..

This can minimize possible ***constrictive*** effects of standards.

Examples of Standards

ISO13485 and **ISO13488** are specific ISO quality systems standards for **medical device manufacturing**.

Table 3. Quality system standards used by different authorities

COUNTRY/REGION	STANDARDS/REGULATIONS	CONFORMITY ASSESSMENT
Australia	ISO13485 or EN46001* ISO13488 or EN46002*	Government and Third party
Canada	ISO13485, ISO13488	Third party
European Union	EN46001* or ISO13485 EN46002* or ISO13488	Third party
Japan	GMP #40 ordinance GMPI #63 ordinance QS Standard for medical devices #1128 notice	Government
United States	QS (21 CFR part 820)	Government

with international 'harmonization', differences can be reduced

Examples of Standards (continued)

ISO 13485:2003 is applicable to **all providers and manufacturers of medical devices, components, contract services and distributors of medical devices**. The standard is the basis for regulatory compliance in local markets, and most export markets.

ISO 9001:2008 signifies that a company engages in the **creation of new products**. It requires that the development of manufactured products have an approval process and a set of rigorous quality standards and development records before the product is distributed.

IEC 60601-1, for **electrical medical devices**, both mains-powered and battery powered. See separate lecture on this standard, later in this series of lectures)

IEC 62304 for **medical software**.

Conformity assessment with Standards

There are four common industrial methods for assessing conformity to a standard.

1. A **product**'s conformity to standards is commonly assessed by **direct testing**.
2. A **process** can be assessed by **audit**. Certification organizations or regulatory authorities attest that products or processes conform to a standard by authorizing the display of their certification mark.
3. The conformity to management standard by an organization is known as **management systems registration**. Formally established **audit procedures** are followed by certified auditors who are supported by technical experts of the domain under audit. Management System **Registration bodies** (Registrars) issue registration certificates to companies that meet a management standard such as ISO9000, or to medical device manufacturers that meet the ISO13485/ISO9001 standards.
4. **Accreditation** is used by an authoritative body to give formal recognition that an organization or a person is competent to carry out a specific task. For example, in Europe, **Notified Bodies** are notified or accredited by the relevant State Competent Authority to carry out conformity assessment of medical devices.

Note that in North America, the term "registration" is used for an organization while "certification" is reserved for products. Many other countries use "certification" for both a product and an organization.

National standards systems

A country may have many voluntary standards bodies. However, normally there is **one official national organization that coordinates and accredits the standards development bodies in the country**.

This official national organization would have the authority **to endorse a document as a national standard** in accordance with official criteria, and it also represents the country in the various international standards organizations.

In the United States, the **American National Standards Institute (ANSI)**, a private, non-profit organization, is an official national organization.

ANSI
American National Standards Institute

In Europe there is a committee composed of **CEN (Comité Européen de Normalisation), CENELEC** (the European Committee for Electrotechnical Standardization) and **ETSI** (the European Telecommunication Standards Institute).

cen
European Committee for Standardization
Comité Européen de Normalisation
Europäisches Komitee für Normung

For developing countries, reference to a standards system not only helps medical device administration, it is also important for other industrial and economic developments. International development agencies increasingly realize that **a standardized infrastructure is a basic requirement** for the success of economic policies that will improve productivity, market competitiveness and export capability.

International standards systems

The three major **international** standardization organizations are:

- the International Electro technical Commission **(IEC),** covering **electrical and electronic engineering**,
- the International Telecommunication Union (ITU) for telecommunications
- the International Organization for Standardization **(ISO),** covering **the remainder**.

For information technology, risk management, quality systems and many other areas, **joint ISO/IEC** technical committees manage standardization.

Other organizations also produce documents on international standardization. Their documents are usually **adopted by ISO/IEC/ITU** as international standards if they have been developed in accordance with international consensus criteria. Any grouping of five member countries can also propose a standard to be considered by ISO for adoption as an international standard.

Identification of Standards

Standards are generally designated by an **alphabetical prefix** and a **number**. The letters (e.g. ISO, IEC) indicate the body that has approved them, while the numbers identify the specific standard and the year in which it was finalized.

The standard reference code often gives an indication of adoption where standards are equivalent. For example:

the standard

ANSI/AAMI/ISO 15223:2000 means the international standard ISO 15223 (established in 2000) adopted by the Association for the Advancement of Medical Instrumentations in the United States, which in turn is designated by the American National Standards Institute (ANSI) as an American national standard.

Accreditation

UNI EN ISO 9001 indicates an Italian national standard (UNI) which is an adoption of a European standard (EN), which is itself an adoption of the International Standard ISO9001.

Names of Standards are indicated by prefixes

EN denotes a Standard which is adopted by the European community and is controlled by the European Committee for Standardisation (CEN).

ISO denotes a worldwide standard issued by the International Organisation for Standardisation.

National standards specify the requirements for application in the particular country.

BS denotes Britain's National Standards which are controlled by the British Standards Institute (BSI).

When a national standard is equal to the international standard, prefixes can be combined, as in e.g.
"**BS EN ISO/IEC** 17020: 2004 General criteria for the operation of various types of bodies performing inspection".

The '2004' in this name indicates the year that a version of the standard was agreed upon. It helps to distinguish different versions of a standard that has evolved over time.

Voluntary standards rather than Regulations for medical devices

Although a standard can be set and mandated by an authority, the current trend is for the **adoption of voluntary standards** established by consensus from all interested parties.

The use of voluntary standards originated from the realization that while **regulations** generally address the **essential safety and performance principles**, manufacturers and users still need to know more, detailed specifications pertaining to specific products. This is better implemented by voluntary standards than by regulations.

The use of voluntary/consensus standards has many advantages including the following:

- They are normally developed by experts with access to the **vast resources** available in the professional communities. By taking advantage of such existing resources, the government can overcome its own **limited resources** for providing product specific technical requirements and characteristics.
- Conformity to standards can also be assessed by an **accredited third party** (such as a notified body in Europe), which is a well-established industrial practice around the world.
- As technology advances, it is much easier to **update standards** than to change regulations. Timely development and periodic revision by expert groups make medical device standards effective and efficient tools for supporting health care.

END

The creation of this presentation was supported by a grant from THET:
see https://www.thet.org/