

Significance of standards in the regulations on medical devices in the US and the EU

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Definition of standard

document, established by consensus and approved by a recognized body, that provides, for common and repeated use, rules, guidelines or characteristics for activities or their results, aimed at the achievement of the optimum degree of order in a given context

NOTE Standards should be based on the consolidated results of science, technology and experience, and aimed at the promotion of optimum community benefits.

[ISO/IEC Guide 2:1996, definition 3.2]

Standard development organizations (1)

various different public and private bodies who work on the basis of

- geographical/political units (global, regional, national), or
- professional competence (informatics, electrotechnology, health care)

and who have established various means of co-operation:

- direct reporting, contractual agreements, memoranda of understanding.

Standard development organizations (2)

standards bodies have one feature in common:

- non-profit associations who work on the basis of
 - participation of interested parties
 - consensus
 - transparency

Legal function of standards

- in contractual law
specification of products and services under contract
- in civil liability
compliance with requirements for safety
- in product regulation
compliance with requirements for safety and appropriate performance

Standards specify

- essential principles for safety and performance:
 - product specific (vertical) performance/properties
 - device class (horizontal) performance/properties
 - operation procedures
- quality management system:
 - general quality management
 - sector specific quality management
 - risk management
 - verification, validation and evaluation

US use of standards

Medical devices regulations are defined in detail in the Code of Federal Regulations.

The use of standards follows the principle of the “Least Burdensome Approach” laid down in the “FDA Modernization Act” of 1997:

- standards are viewed as a reasonable possibility to comply with certain specific and well defined requirements,
- suitable standards receive the status of a “recognized standard”

A “recognized standard”

- may be any national or international standard
- must be issued by a standards body that satisfies certain conditions (e.g. consensus, transparency, no conflict with regulations)
- must correspond to regulations and devices defined in the Code of Federal Regulations
- is evaluated by FDA
- is recognized by publishing it and the devices/regulations it is valid for in the Federal Register

Process of standard recognition

FDA or public



CDRH Project Team (PT)

standard



CDRH Standards Task

Group (STG)

assessment,

for

proposes standard

assesses

identifies needs, reviews

proposals, coordinates

recommends

publication

Group Standards Program
Coordination Staff



*manages PTs and STGs,
reviews recommend.,
coordinates publication*

CDRH Branches



*prepare for use of
recognized standard*

Federal Register

*recognition through
publication of
standard, target*

regulation, target

devices

Recognized standards in FDA processes

- FDA accepts compliance with recognized standards as indication of compliance with regulations;
- the use of recognized standards must be documented in “certificate of conformance”;
- compliance with a standard replaces detailed examination of the relevant data and/or processes
- in justified cases FDA may still examine the corresponding data/processes in detail

Characteristics of recognized standards:

- are national or international standards from various sources;
- correspond to specific regulations, cover specific devices;
- are evaluated by FDA;
- are published in the Federal Register (including target regulations and devices);
- are not mandatory.

EU/EFTA use of standards

follows the principles of “New and Global Approach Directives” which lay down

- very general essential requirements for safety and effectiveness of the devices
- and very general requirements for quality management systems;
- precise specification of requirements are delegated to harmonized standards and common technical specifications

Harmonised standards

for each new and global approach directive

- the European Commission mandates and finances the development of certain standards by CEN/CENELEC to specify certain essential requirements or processes,
- decides about their acceptability, and
- publishes their reference in the Official Journal of the European Communities

= harmonised standards

Harmonised standards development procedure

EU Commission

mandates standard

Working Group (WG)

develops draft

Technical Committee (TC)

accepts draft

CEN/CENELEC circulates
for inquiry

*national standards
bodies comment on
draft*



EU Commission and
Com. Stand.+Tech. Reg.



CEN/CENELEC circulates
for vote



EU Commission

*approves (or disapproves)
draft*

*national standards bodies
adopt standard*

*publishes reference of in
Official Journal of the
European Community*

Harmonised standards in the CE marking process

- give the preferred definition for compliance with essential / quality system requirements
- play key role in composing the technical documentation
- are a basis for the certification process of notified bodies
- are references for competent authorities in dealing with incident reports

Characteristics of harmonised standards:

- are mandated and financed by the EU Commission
- are approved by the EU Committee on Standards and Technical Regulations
- they list their reference to specific requirement(s) of a given directive in Annex Z
- their reference is published in the Official Journal of the European Community
- are not mandatory

Common Technical Specifications development procedure

EU Commission

mandates CTS



CTS-Committee

develops draft



EU Expert Group

accepts draft



EU Commission and
Com. Stand.+Tech. Reg.



EU Commission

*approves (or
disapproves) draft*

*publishes full text in
Official Journal of the
European Community*

CTS in the CE-marking process

- compliance in essence mandatory to satisfy the essential requirements,
- compliance proven in the technical documentation,
- compliance always confirmed by conformity assessment body, for certain devices down to the level of lot release.

Characteristics of common technical specifications (CTS)

- are mandated and financed by the EU Commission
- are developed by a committee nominated by the EU Commission
- are approved by the EU Committee on Standards and Technical Regulations
- the full text is published in the Official Journal of the European Community
- are required for the determination of reference methods and materials, for performance evaluation, design and lot release
- essentially mandatory

Conclusion

the basic approach to medical devices regulations is different in the US and the EU:

- the US Code of Federal Regulations lays down detailed performance, property and process requirements
- EU directives give very general essential and quality management requirements.

Standards are used accordingly:

- in the US to facilitate compliance with the regulations,
- in the EU to specify the regulations in detail and then to facilitate compliance.

In spite of these differences in approach technical and quality management standards

- are successfully utilized in both systems,
- and both systems have have very similar if not identical demands on standards.

A mutual recognition of “harmonized” and “recognized” standards may benefit manufacturers and competent authorities.