The Role of Standards

An Industry Perspective

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- International Standards provide instructions, guidelines, rules or definitions that are then used to design, manufacture, install, test & certify, maintain and repair electrical and electronic devices and systems.
- They reflect the global consensus and distilled wisdom of experts who have been delegated by their countries to participate in standards activities.
- Medical device companies consider international standards essential for quality and risk management because they allow them to design and manufacture products of consistent quality and performance.
- International standards also form the basis for conformity testing and certification.

Standards developing organizations (SDO)

AAMI Product & sterility standards [aami.org]

ASME Dimensioning and fastener standards [asme.org]

ASTM Materials specifications & testing [astm.org]

CISPR Electromagnetic compatibility & testing standards [iec.ch]

IEC International electrical standards [iec.ch]

IEEE Standards in electrical engineering & software [ieee.org]

IPC Printed circuit boards & components [ipc.org]

ISO International non-electrical standards [iso.org]

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IEC

IEC 60601-1

Edition 3.2 2020-08
CONSOLIDATED VERSION

INTERNATIONAL STANDARD

colour inside

Medical electrical equipment –
Part 1: General requirements for basic safety and essential performance

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INTERNATIONAL STANDARD **ISO 13485**

Third edition
2016-03-01

Medical devices — Quality management systems — Requirements for regulatory purposes

Dispositifs médicaux — Systèmes de management de la qualité — Exigences à des fins réglementaires

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INTERNATIONAL STANDARD **ISO 80601-2-90**

First edition
2021-08

Medical electrical equipment —

Part 2-90:
Particular requirements for basic safety and essential performance of respiratory high-flow therapy equipment

Appareils électromédicaux —

Partie 2-90: Exigences particulières pour la sécurité de base et les performances essentielles des équipements de thérapie respiratoire à haut débit

ISO IEC

Reference number
ISO 80601-2-90:2021(E)

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Designation: F3014 – 14

Standard Test Method for Penetration Testing of Needles Used in Surgical Sutures[1]

This standard is issued under the fixed designation F3014; the number immediately following the designation indicates the year of original adoption or, in the case of revision, the year of last revision. A number in parentheses indicates the year of last reapproval. A superscript epsilon (ε) indicates an editorial change since the last revision or reapproval.

INTRODUCTION

The purpose of this test method is to provide a common method for fixturing and measuring the penetration force of a surgical needle. Most surgical needles are coated to facilitate passage through tissue. This coating needs to be both lubricious and durable. The lubricity of the coating acts to lower the penetration force, while the durability of the coating maintains the needle's ability to pass through tissue multiple times with minimum increase in penetration force. It has been observed that, when a coating is found to be more lubricious, that coating is often less durable. Likewise, when a coating is found to be more durable, that coating is often less lubricious. Comparative measurements of lubricity and durability can provide an expectation of how the coated needle may perform during actual use. This standard does not presently address the testing medium. Test medium will be addressed in the next phase of this test method development. However, this test method does require certain medium characteristics to be identified.

American National Standard

ANSI/AAMI SW96:2023

Standard for medical device security—Security risk management for device manufacturers

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THE LIFE OF A STANDARD

- Standards are periodically reviewed to determine if they need to be revised, reaffirmed or withdrawn.
- This is done every 5 years or so depending on the SDO that published it.
- The process is consensus based among the countries having a vote in the area of concern
- If a standard is being used but does not need any technical changes, it is reaffirmed.
- Reaffirmation is designated by (R) or (R:YYYY)

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A standard may have

Amendment

- It may be published by itself (A1:2006 to ISO 10993-4:2002) or as a combined edition (IEC 60601-1:2005 + A1:2012 + A2:2020 = Ed. 3.2)
- Only 2 amendments are allowed, then a new edition is required

Corrigendum

- Corrects technical or editorial mistakes. (ISO 10993-1:2009 CORR1:2010)
- Usually issued soon after publication of a new edition or an amendment.

1 or more informative annexes

Why manufacturers use standards

- International consensus on contents
- A starting point for what is safe (products & processes)
- Consistency in interpretation & use
- 1 design, 1 set of test reports, 1 technical file for use world-wide
- Regulatory submissions are more uniform, faster and cost effective
- Reduces regulatory submission review and approval times
- Decreases the time to deliver life saving therapies to patients

- Although not *required*, customers & regulators expect their use

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How are standards used by manufacturers?

- They are the basis for our quality, documentation & design systems
- They are part of a product's specification before design starts
- Material, component & process selection use pertinent standards
- Design & prototyping follows pertinent standards
- Verification and compliance testing follows pertinent standards
- Production facilities are certified to applicable standards
- Certification testing to pertinent standards by test labs
- Safety related standards are listed in regulatory filings

How are standards used by regulators?

- Laws, regulations and guidances determine a countries requirements & expectations
- The use of standards to show (partial) compliance is generally accepted
- Some regulators maintain a list of the standards that may be used or preferred and how they may be used
- Some regulators require testing to standards be duplicated in their own laboratories
- Some regulators require periodic audits to confirm compliance to quality system and manufacturing facility expectations
- The MDSAP (Medical Device Single Audit Program) has a group of regulators accepting the result of a single audit

Partial compliance to a standard

- Sometimes there are portions of a standard that do not apply to a manufacturer's product
  - Example: IEC 60601-1 *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance* has a clause on Protection against unwanted and excessive radiation hazards yet not every medical electrical device emits or uses radiation
- Sometimes a regulator does not recognize a portion of a standard due to a conflict with a law, regulation or guidance
- In general, partial compliance with a standard is allowed if sufficient rationale is provided

Other benefits of using standards & EPs

- Consistent & uniform defined terms
- Stability and a well-defined process for revision
- International, consensus based documents
- Flexibility in choosing which ones apply and to what degree
- Well established source organizations where you can go with questions and requests for additional information
- Well established base of existing users willing to share their expertise & experiences

Standards ⇦ ? ⇨ Essential Principles

- Standards define the minimum requirements for safety of the device or process
- Standards writers strive to cover any hazards that are unique to the product or process
- Standards are written in a way to define what is safe and a method of testing to show a requirement is met
- This leaves the how a requirement is met up to the manufacturer (design flexibility)

- Essential Principles of Safety and Performance provide broad, high-level, criteria for design, production, and postproduction throughout the life-cycle of all medical devices
- Compliance with the Essential Principles of Safety and Performance, via the use of applicable standards throughout a product's lifecycle, is an acceptable approach for applying controls relative to a device's safety and performance by the RAs with Jurisdiction
- The Essential Principles do not include testing or design recommendations
- The Essential Principles are a good starting point at the beginning of a product design or a draft standard

Example of a standard referring to EPs

INTERNATIONAL STANDARD

ISO 20417

First edition
2021-04

Medical devices — Information to be supplied by the manufacturer

Dispositifs médicaux — Informations à fournir par le fabricant

Annex E
(informative)

Reference to the IMDRF *essential principles* and labelling guidances

This document has been prepared to support the *essential principles* and labelling requirements of *information to be provided by the manufacturer* as part of a *medical device* according to the International Medical Device Regulators Forum (IMDRF). This document is intended to be acceptable for conformity assessment purposes.

Conformance with this document provides one means of demonstrating conformance with the specific *essential principles* of IMDRF/GRRP WG/N47:2018[3] and labelling principles IMDRF/GRRP WG/N52:2019.[4] Other means are possible. Table E.1 maps the clauses and subclauses of this document with the *essential principles* of IMDRF/GRRP WG/ N47:2018. Table E.2 maps the clauses and subclauses of this document with the labelling principles of IMDRF/GRRP WG/N52:2019.

Table E.1 — Correspondence between this document and the *essential principles*

Essential principle of IMDRF/GRRP WG/N47:2018[3]	Corresponding clause(s)/ sub-clause(s) of this document	Qualifying remarks/Notes
5.1.3 c)	6.6.2 a) 3)	The requirement for training is not addressed.
5.1.4	6.1.6, 6.6.2 a) 6)	
5.1.5 b)	4 e)	The requirement is only covered for the content of the *information supplied by the manufacturer.*
5.1.6	6.4	The requirement is only covered for the durability of the *marking* for the *expected lifetime.*
5.4.7	5.12 a), 5.12 c)	
5.5.1	6.6.2 e) 2)	Only the requirement to disclose restrictions in the *IFU* is covered.
5.5.8	6.6.2 a) 10)	Only the requirement to disclose safe disposal or recycling *procedures* and measures is covered.

Example of a standard referring to EPs

Table E.1 — Correspondence between this document and the *essential principles*

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5.5.1	6.6.2 e) 2)	Only the requirement to disclose restrictions in the *IFU* is covered.
5.5.8	6.6.2 a) 10)	Only the requirement to disclose safe disposal or recycling *procedures* and measures is covered.

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Annex G
(informative)

Reference to the general safety and performance requirements for *medical devices*

This document has been prepared to support the general safety and performance requirements of regulation (EU) 2017/745.[5] This document is intended to be acceptable for conformity assessment purposes.

Conformance with this document provides one means of demonstrating conformance with the specific indicated general safety and performance requirements of regulation (EU) 2017/745[5]. Other means are possible. Table G.1 maps the clauses and subclauses of this document with the general safety and performance requirements of regulation (EU) 2017/745.

NOTE When a general safety and performance requirement does not appear in Table G.1, it means that it is not addressed by this document.

Table G.1 — Correspondence between this document and the general safety and performance requirements for *medical devices*

General safety and performance requirements of regulation (EU) 2017/745, Annex I[5]	Corresponding clause(s)/ sub-clause(s) of this document	Qualifying remarks/Notes
4	—	
(c)	4 a), 6.6.2 a) 3), 6.6.2 a) 6)	The requirement for training is not addressed.
Last sentence	6.6.2 a) 6) ii)	
5	—	
(b)	4 e)	This requirement is covered as it relates to the *information supplied by the manufacturer.*
10.4.5	6.1.3 c), 6.6.2 j) 3) iv)	

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Annex ZA
(informative)

Relationship between this European standard and the General Safety and Performance Requirements of Regulation (EU) 2017/745 aimed to be covered

This European standard has been prepared under a Commission's standardisation request M/575 to provide one voluntary means of conforming to the General Safety and Performance Requirements of Regulation (EU) 2017/745 of 5 April 2017 concerning medical devices [OJ L 117].

Once this standard is cited in the Official Journal of the European Union under that Regulation, compliance with the normative clauses of this standard given in Table ZA.1 confers, within the limits of the scope of this standard, a presumption of conformity with the corresponding General Safety and Performance Requirements of that Regulation, and associated EFTA regulations.

For application of this European standard under Regulation (EU) 2017/745,

1. the scope is limited to medical devices and accessories for a medical device as defined in that Regulation and to products regulated as a device under that Regulation;

2. in case of differences between terms defined in this European standard and terms defined in that Regulation, the terms defined in the Regulation shall prevail;

3. the manufacturer's policy for establishing criteria for risk acceptability (see 4.2 of this European standard) shall ensure that the criteria comply with the General Safety and Performance Requirements of that Regulation.

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Table ZA.1 – Correspondence between this European standard and Annex I of Regulation (EU) 2017/745 [OJ L 117]

General Safety and Performance Requirements of Regulation (EU) 2017/745	Clause(s) / subclause(s) of this EN	Remarks / Notes
3, first paragraph	4.1 to 4.5	Covered.
3, second paragraph	4.1, 4.2	Covered.
3, item (a)	4.4	Covered in respect of the process requirements.
3, item (b)	5	Covered in respect of the process requirements. Device-specific execution of the process is not covered.
3, item (c)	5.5, 6	Covered in respect of the process requirements. Device-specific execution of the process is not covered.
3, item (d)	7	Covered in respect of the process requirements. Device-specific execution of the process is not covered.
3, item (e)	10	Covered in respect of the process requirements. Device-specific execution of the process is not covered.

When something doesn't apply

- Standards and the Essential Principles are written to cover the broad base of a topic
- This means there will be sections/portions that may not apply to:
  - A manufacturers product or process
  - A regulation, law or guidance (e.g.: FDA partial recognition of a standard, or the conditional application language shown a few slides ago)
- If something doesn't apply, most regulators allow a statement that a certain section does not apply if there is a clear rationale for the exception

The future of Essential Principals according to Jeff

- Standards developing organizations are currently allowing informative annexes that map the standard to the EPs
- If it becomes clear that regulators “favor” submissions that use EPs, manufacturers will expend more effort documenting their use
- At that point, standards writers will include the creation of the informative annexes in their planning
- More use of EPs in standards and in submissions will expedite reviews and the timely access to life-saving devices


Questions?