Role of Standards and Relation to Essential Principles for Medical Devices and IVDs

IMDRF Training:

Essential Principles of Safety and Performance of Medical Devices and IVD Medical Devices (IMDRF/GRRP WG/N47)

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Chair ISO/TC 210 [2023 – 2025]
Quality Management & Corresponding General Aspects for Products with a Health Purpose Including Medical Devices

Agenda

- History of Standards
- FDA's Division of Standards and Conformity Assessment Program (DSCA)
- Standards Recognition/Use/Development
- Optimizing standards for regulatory purposes and their role with the Essential Principles
- Question/Answer Period

What is important?

What do we hope to achieve from today?

Where do we go from there?

History of Standards & Strategic Use:

- **1821 – President John Quincy Adams:** Weights and measures may be ranked among the necessaries of life to every individual of human society. ….They are necessary to every occupation of human industry; to the distribution and security of every species of property; to every transaction of trade and commerce; ….The knowledge of them, as in established use, is among the first elements of education, ….. This knowledge is riveted in the memory by the habitual application of it to the employments …throughout life.

- **2020: Director of NIST:** Standards are the infrastructure for innovation, a critical component in bringing technologies from the lab to the market. Standards create a common language for trade and improve quality of life by enhancing safety, security, interoperability and the environment.

- **2000:** Cauldron thickness "*We're trying to standardise cauldron thickness. Some of these foreign imports are just a shade too thin — leakages have been increasing at a rate of almost three percent a year*"

  —Percy Weasley's explanation - ***Harry Potter 4: The Goblet of Fire***

US GOV. USE OF STANDARDS

1976

Medical Device Amendments of 1976

USC 514 – Performance Standards

1990

Safe Medical Device Act of 1990

Promulgation of mandatory standards development at the Agency's discretion

1995-1998

FDA Modernization Act (Sec 514(c))

Added ability to formally recognize a standard

Added the ability to accept a formal Declaration of Conformity **[1997]**

National Technology & Transfer Advancement Act (NTTAA) [1995] &

OMB A-119 Circular [1998 updated 2016]

2016

21st Century Cures Act: added to 514(c):

Transparency of regulatory decisions on use of standards

Training to employees

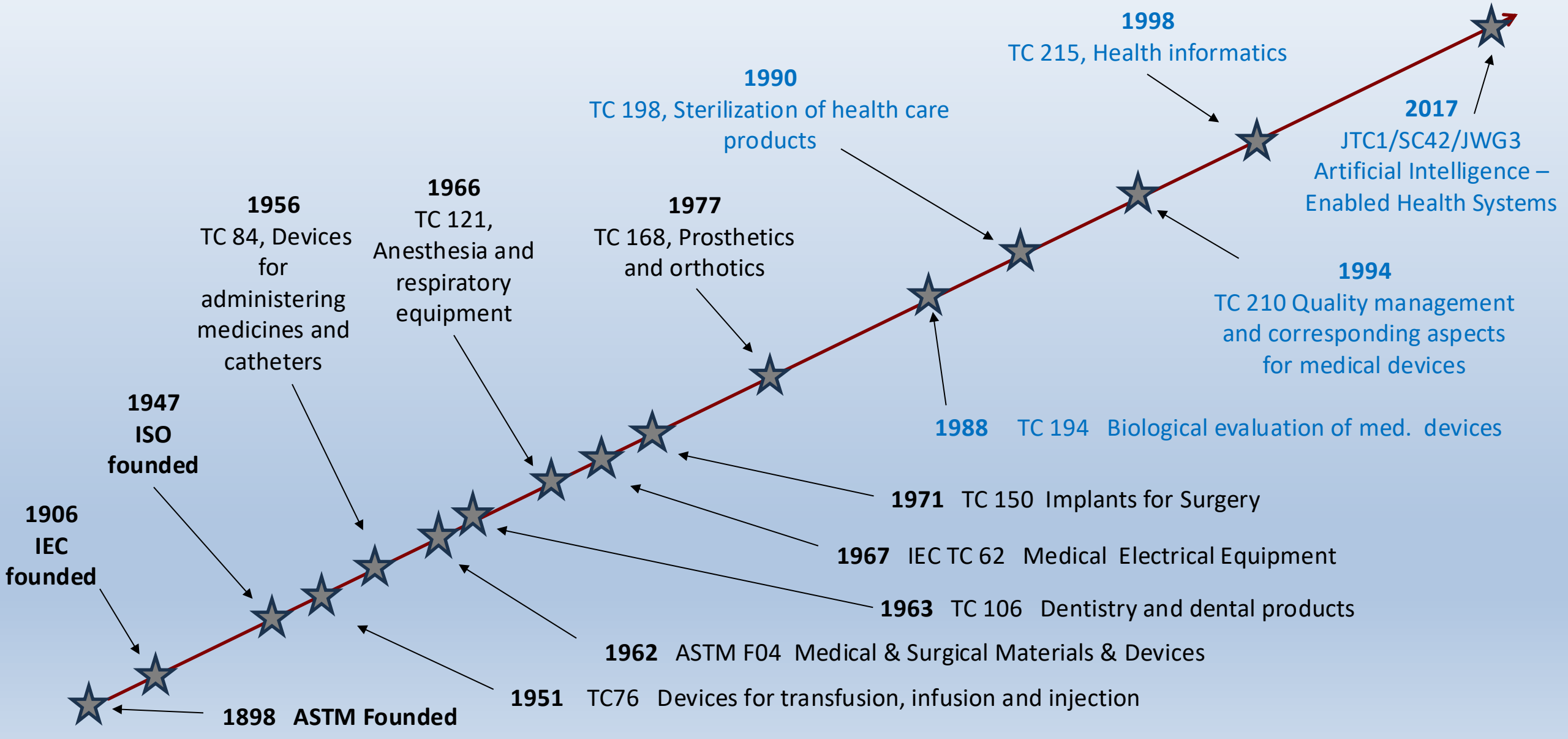
Focus on global harmonization

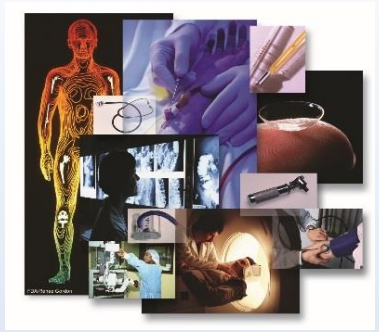
2018

Accreditation Scheme for Conformity Assessment [ASCA] Program – Sec 514(d)

Formal engagement in conformity assessment - ISO/IEC 17025

Standards: From a Product to a Systems Focus





CDRH In Perspective

- CDRH oversees
  - 175,000 medical devices on US market
  - 18,000 medical device manufacturers
  - 25,000 medical device facilities worldwide
- Each year we receive
  - 22,000 premarket submissions (includes supplements and amendments)
  - 1.4 million reports on medical device adverse events and malfunctions

CDRH Standards Engagement By the Numbers

400

CDRH staff engaged in standards development

1500+

Recognized standards

303

Years of standards experience in DSCA

36

Standards development organizations we work with

2

Lists of recognized standards we update yearly

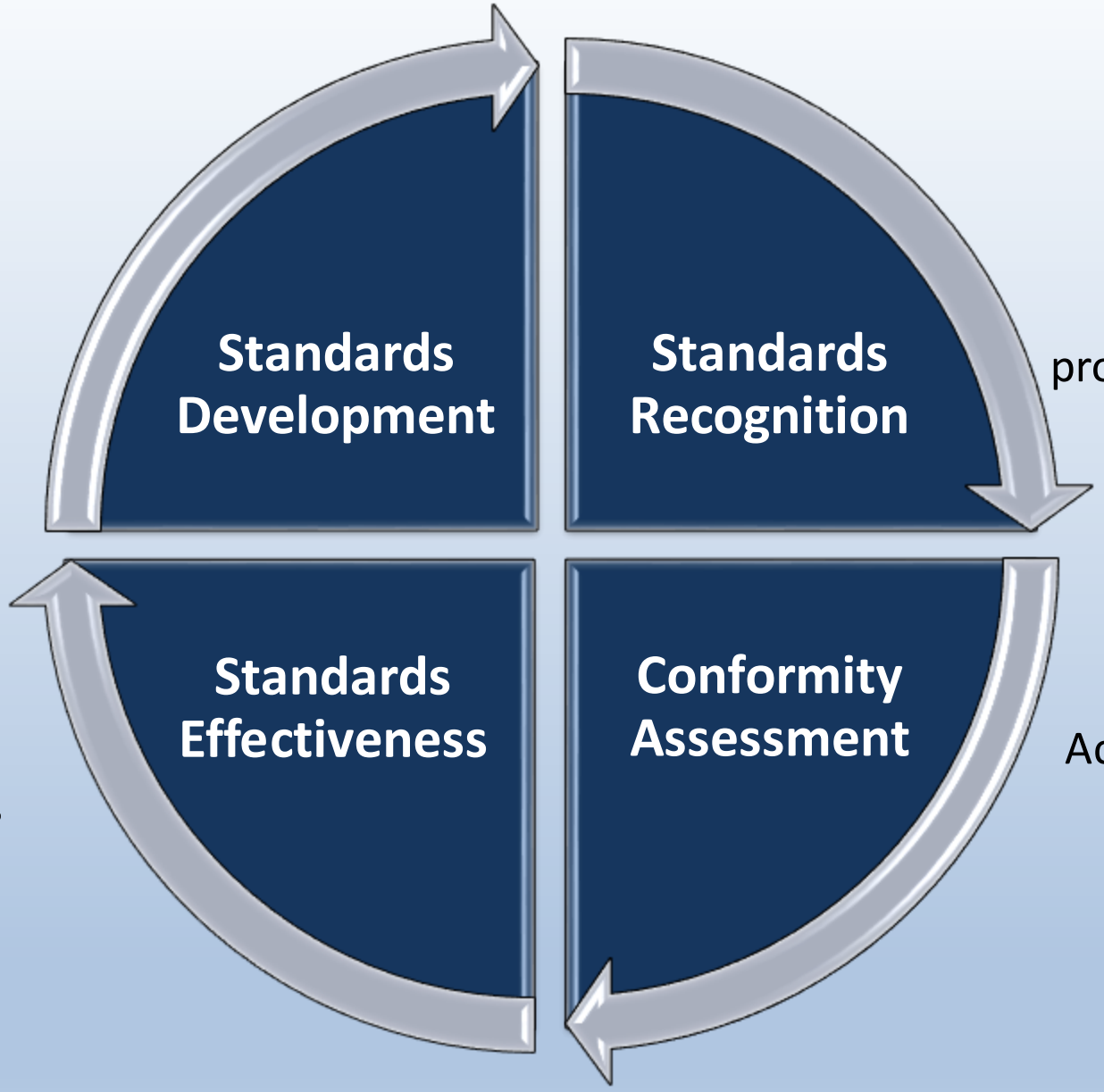
7

Number of standards cited in an average 510(k)

600

Standards development organization technical committees we contribute expertise to

Standards Development: leadership and participation to optimize standards for regulatory use



***Standards Recognition*:** robust formal program to advance use of standards

***Standards Effectiveness*:** ongoing evaluation of current standards to meet regulatory and public health needs

Conformity Assessment: Accreditation Scheme for Conformity Assessment (ASCA) Declarations of Conformity (DoC)

Division of Standards & Conformity Assessment [DSCA]

Standards Recognition Section 514(c)

- 514(c)(1)(A) In addition to establishing a performance standard under this section, the Secretary shall, by publication in the Federal Register, **recognize all or part of an appropriate standard established by a nationally or internationally recognized standard development organization for which a person may submit a declaration of conformity** in order to meet a premarket submission requirement or other requirement under this Act to which such standard is applicable.

Standards Recognition Section 514(c)

- (B) **If a person elects to use a standard recognized** by the Secretary under subparagraph (A) to meet the requirements described in such subparagraph, **the person shall provide a declaration of conformity** to the Secretary that certifies that the device is in conformity with such standard. **A person may elect to use data, or information, other than data required by a standard recognized under subparagraph (A) to meet any requirement regarding devices under this Act.**

Standards Recognition Section 514(c)

- GUIDANCE.—The Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, **shall review and update**, if necessary, previously **published guidance and standard operating procedures identifying the principles for recognizing standards, and for withdrawing the recognition of standards**, under section 514(c) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360d(c)), **taking into account the experience with and reliance on a standard by foreign regulatory authorities and the device industry,** and whether recognition of a standard will promote harmonization among regulatory authorities in the regulation of devices.

Why Consensus Standards?

- Participation by all stakeholders in standards development including - *especially* - regulators
  - Chance to influence standards during development
- Reduce burdens on manufacturers by harmonizing expectations across jurisdictions
- Streamline conformity assessment
- Promote regulatory science at national and international levels
- Speeds Patient access to safe, effective devices

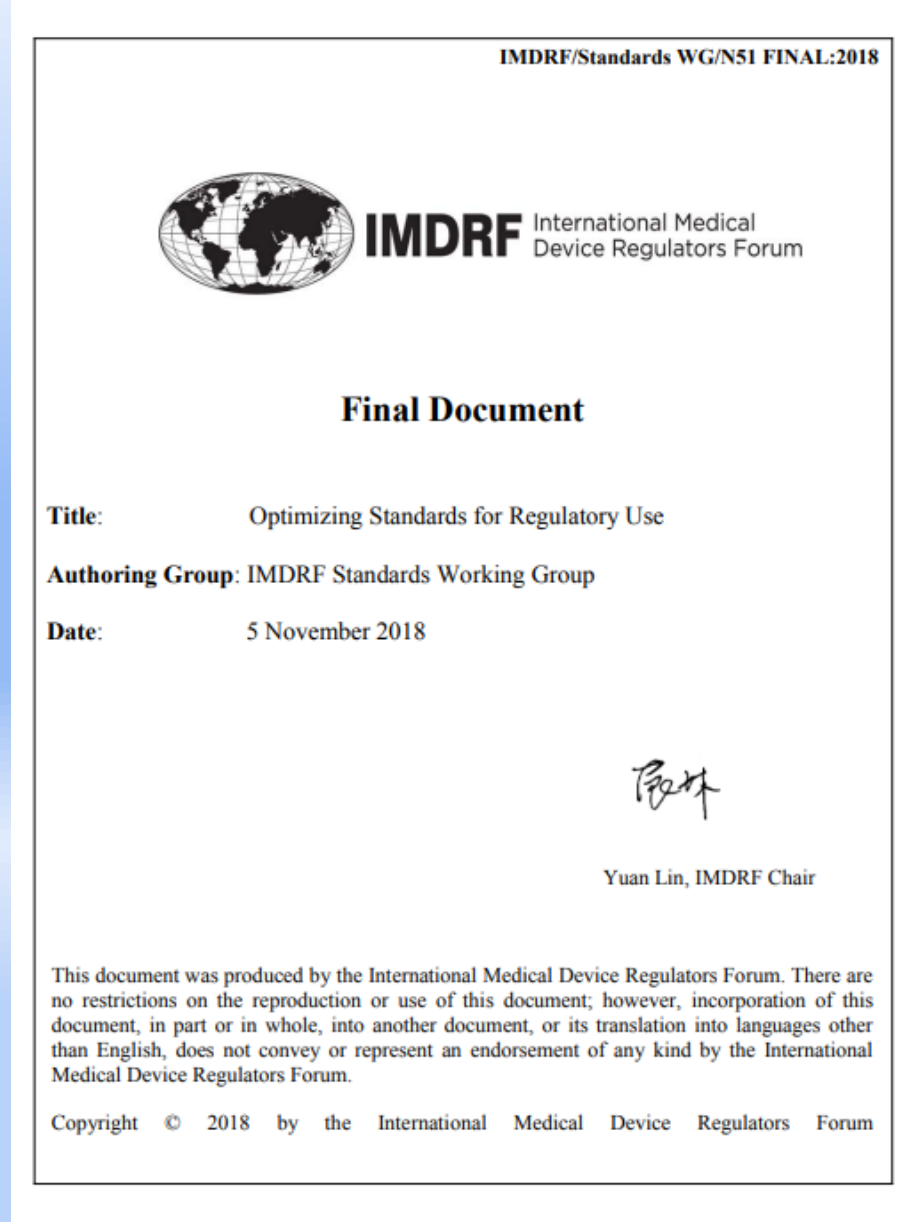
Using Consensus Standards

- Voluntary
  - Only mandatory if cited in regulation ('incorporated by reference')
- In any type of premarket submission
- With a DOC (recognized standards only) or 'General Use' (any standards, recognized or not)

IMDRF International Medical Device Regulators Forum

Optimizing Standards for Regulatory Use

- Standards must be improved for regulatory use
- IMDRF members should participate as early as possible in standards development



IMDRF/Standards WG/N51 FINAL:2018

IMDRF International Medical Device Regulators Forum

Final Document

Title: Optimizing Standards for Regulatory Use

Authoring Group: IMDRF Standards Working Group

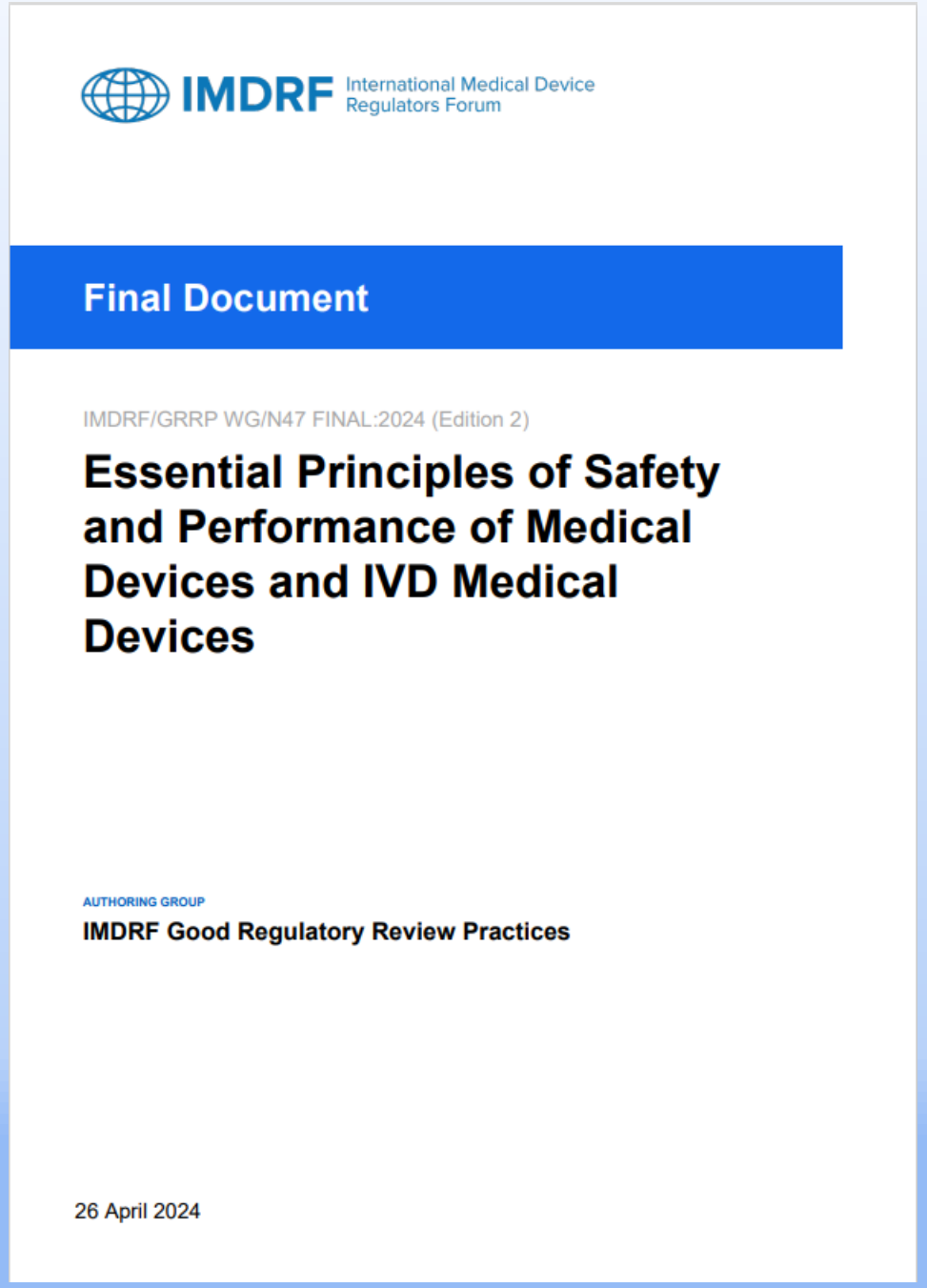
Date: 5 November 2018

Yuan Lin, IMDRF Chair

IMDRF International Medical Device Regulators Forum

Standards Roles in Compliance with IMDRF Essential Principles

- Appendix A: Use of Standards in Meeting Essential Principles
- Appendix B: Guidance on Essential Principles



Appendix A:

Use of Standards in Meeting Essential Principles

- Consensus standards provide a greater level of detail and specificity than can be expressed in the essential principles

- The essential principles of safety and performance and their related standards can be useful in the fulfilment of regulatory requirements throughout the lifecycle of medical devices and IVDs

- Does not replace additional requirements from RAs

Appendix A:
A. General Approach to Using Standards

- The essential principles of safety and performance are the general, high-level criteria that when met play a major role in the determination that a device is safe and effective.
- It is not possible to assure an acceptable level of safety and performance in the lifecycle by simply being compliant with standards at one time. The requirements in a single standard typically do not meet all the specific parts of a given EP. A process for continuous compliance is required and the expectation is that this is achieved through the use of a robust quality management system and a risk management process.

Appendix A:

B. Use of Standards by Regulatory Authorities

Standards suitable to address the essential principles should be based on:

a) close relationship of the scope of the standard to one or more of the EPs

b) the clarity, effectiveness, and completeness of the technical requirements contained in the standard as it relates to a specific EPs

c) the existence of test methods for determining compliance with each of the technical requirements in the standard, and

d) the definition of clear acceptance criterion for determining that each technical requirement is met.

In the absence of international standards, it may be appropriate for Regulatory Authorities having jurisdiction to accept the use of regional or national consensus standards or industry standards.

Appendix A:

C. Assessing the Conformity of a Medical Device and IVD Medical Device

- In assessing the conformity of a medical device with the EPs, standards or parts of several standards may be utilized and combined in a way that is appropriate for the specific medical device or IVD medical device. In some cases, the use of parts of standards and/or combinations of standards should be acceptable for conformity assessment purposes.

- If the combination of standards does not cover all the necessary EPs of safety and performance for a specific medical device or IVD medical device, other means of demonstrating conformance to the essential principles should be used.

Appendix A:

D. Risk Management within Consensus Standards

- Risk management is increasingly becoming a key principle within standards. For example, many medical device consensus standards include risk management principles in the application of these standards during the medical device and IVD medical device lifecycle.

- Documentation of these risk management activities can provide a justification that manufacturers design and manufacturing decisions meet a Regulatory Authority's requirements

Appendix B:
Guidance on Essential Principles

- The table in this annex is intended to provide general guidance for meeting the EPs of safety and performance.
- Standards and guidances listed are not intended to encompass all of the requirements to meet a particular essential principle.
- Additional standards, guidance may be applicable and better suited for demonstration of meeting relevant EPs

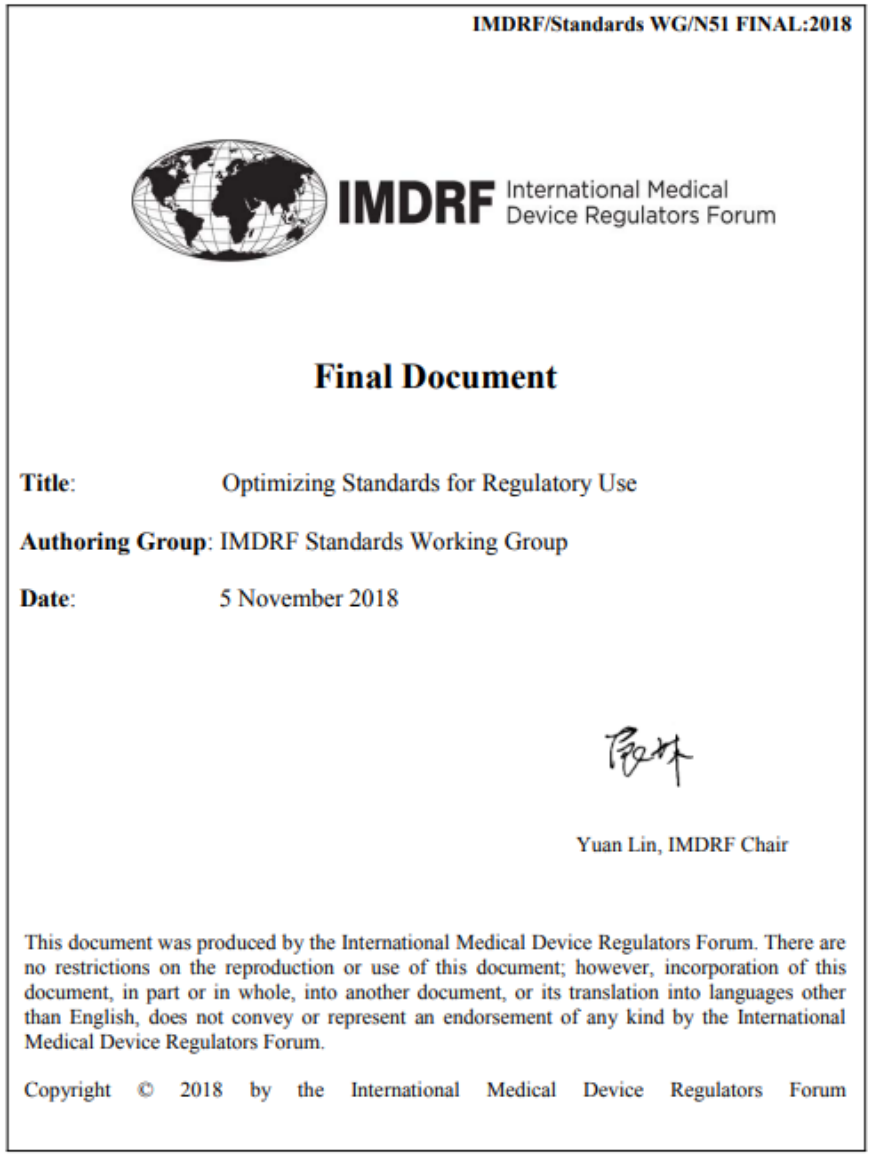
Appendix B:
Guidance on Essential Principles

Example of IMDRF EPs N47 with Standards

Essential Principle	Guidances	Relevant Standards
5.5		IEC 60601 IEC 61010 IEC 62366-1 IEC/TR 62366-2 IEC 80001 ISO 80369 IEC 62304

Optimizing Standards for Regulatory Use

- Standards must be improved for regulatory use
- IMDRF members should participate as early as possible in standards development
- Standards can demonstrate how to meet relevant EPs for a product



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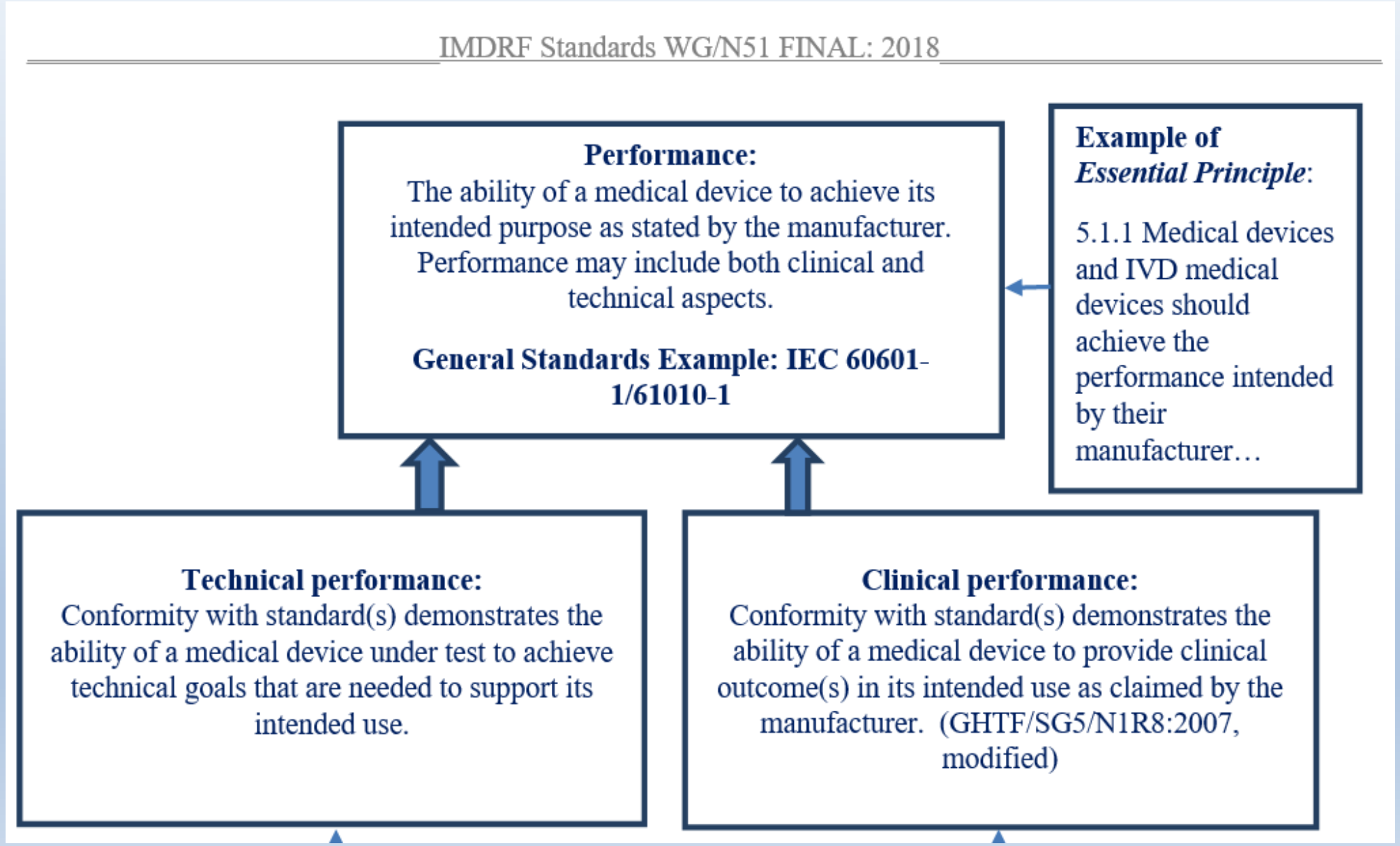
Use of Standards in Neeting IMDRF *Essential Principles*



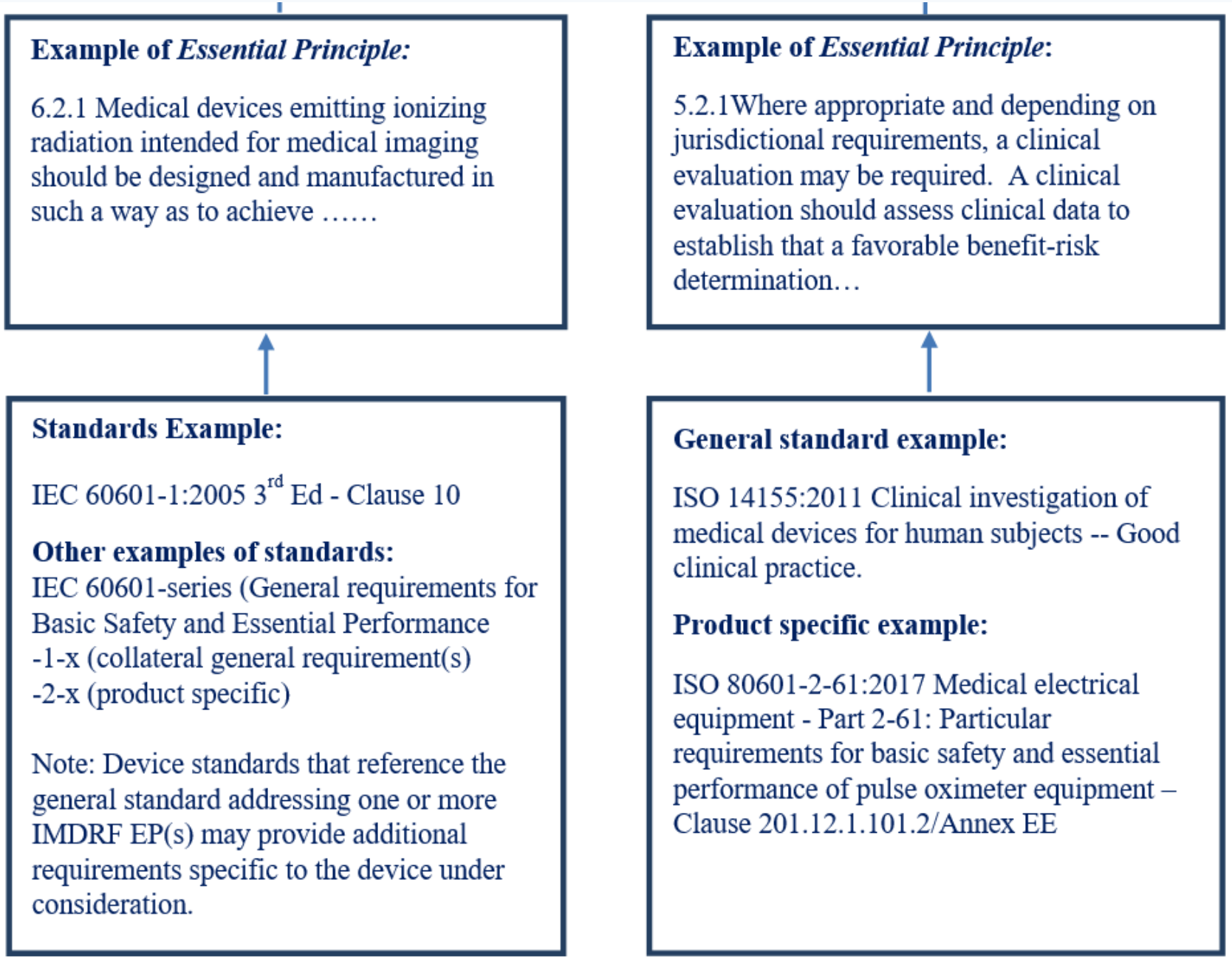


Figure 1: Example of standards addressing Safety and Performance of the IMDRF *Essential Principles*

Standards Mapping to EPs Example cont.

Table H.1 lists the clauses and subclauses of this document corresponding to the essential principles of IMDRF/GRRP WG/N47:2018[9].

NOTE When an essential principle does not appear in Table H.1, it means that it is not addressed by this document.

Table H.1 — Correspondence between this document and the IMDRF essential principles

Essential principle of IMDRF/GRRP WG/N47:2018[9]	Corresponding clause(s)/sub-clause(s) of this document	Qualifying remarks/Notes
5.3.3	Clause 4 Clause 5 Clause 6	This principle is only partially covered by this document since this document does not provide requirements on manufacture. This document addresses effectiveness of the intended connection; it does not leak when used as intended.
5.5.1	Clause 4 Clause 5 Clause 6	This principle is only partially covered by this document since it only addresses the effectiveness of the intended connection and mechanically prevents incorrect connections to other small-bore connectors that would be an unacceptable risk.
5.5.2 b)	Clause 4 Clause 5 Clause 6	This principle is only partially covered by this document since this document does not provide requirements on manufacture. This document mechanically prevents the use error of incorrectly connecting other small-bore connectors that would be an unacceptable risk.
5.5.5	Clause 4 Clause 5 Clause 6	This principle is only partially covered by this document since this document does not provide requirements on manufacture. This document addresses effectiveness of the intended connection and mechanically prevents incorrect connections to other small-bore connectors that would be an unacceptable risk.

Appendix B: Guidance on Essential Principles

Example from ISO 80369-2:2024

Annex H
(informative)

Reference to the IMDRF essential principles

This document has been prepared to support the essential principles for *medical device* or *accessories* incorporating respiratory *application small-bore connectors* according to the International Medical Device Regulators Forum (IMDRF).

Table H.1 lists the clauses and subclauses of this document corresponding to the essential principles of IMDRF/GRRP WG/N47:2018[9].

NOTE When an essential principle does not appear in Table H.1, it means that it is not addressed by this document.

IMDRF EPs from N47 and N52: EP Mapping Example from ISO 20417:2021

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.

Summary

Standards and standardization processes can be made more effective by developing a better understanding of the needs and requirements of those who use or who are affected by standards.

Improvements in standards will contribute to global harmonization efforts at all levels and allow for reliance.

Continuous innovation is the key to the advancement of medical device technology and improved public health. Ideally, standards supporting or referenced in regulatory requirements are developed and applied in such a way as to allow product innovation by industry while assuring safety and effectiveness [performance].

Voluntary standards and guides can assist manufacturers to comply with legal requirements. If the standards are accepted within a given regulatory system, compliance with such standards can be deemed to satisfy the legal requirements. The regulatory acceptance does not, of itself, imply that such standards are mandatory.

Summary Continued

Medical device standards represent a consensus on requirements that foster innovation while protecting public health.

Harmonized compliance with the regulations, a key element of timely market introduction of advance technology, can be facilitated by the appropriate use of relevant medical device standards. This is based on the premise that:

- standards are based on experience or, in other words, are retrospective,
- innovation can present unanticipated challenges to experience,
- rigid, mandatory, application of standards can deter innovation,
- operation of a quality management system, subject to assessment, has become widely acknowledged as a fundamental and effective tool for the protection of public health,
- quality management systems include provisions that address both innovation and experience,
- such provisions of quality management systems include field experience, risk analysis,
- management, phased reviews, documentation and record keeping, as well as the use of product and process standards.

U.S. FOOD & DRUG ADMINISTRATION + Devices

Questions???

US Standards Resources

- **Standards & Conformity Assessment Program**
  www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/standards-and-conformity-assessment-program#intro

- **FDA Recognized Consensus Standards Database**
  www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

- **Recognition and Withdrawal of Voluntary Consensus Standards guidance**
  www.fda.gov/regulatory-information/search-fda-guidance-documents/recognition-and-withdrawal-voluntary-consensus-standards

- **Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices**
  www.fda.gov/regulatory-information/search-fda-guidance-documents/appropriate-use-voluntary-consensus-standards-premarket-submissions-medical-devices

- **US Standards Strategy**
  https://share.ansi.org/Shared%20Documents/Standards%20Activities/NSSC/USSS-2020/USSS-2020-Edition.pdf

- **Contact S-CAP:** CDRHStandardsStaff@fda.hhs.gov

FDA Industry Updates and Education

1. CDRH New

- Sign up at: https://public.govdelivery.com/accounts/USFDA/subscribers/qualify

2. CDRH Learn: Multi-Media Industry Education

- Videos, audio recordings, power point presentations, software-based “how to” modules
- www.fda.gov/CDRHLearn

3. Device Advice: Text-Based Education

- Comprehensive regulatory information on premarket and postmarket topics
- www.fda.gov/DeviceAdvice

4. Division of Industry and Consumer Education (DICE)

- Email: DICE@fda.hhs.gov
- Phone: 1(800) 638-2041 or (301) 796-7100 (Hours: 9 am-12:30 pm; 1 pm-4:30pm EST)
- Web: www.fda.gov/DICE

ASCA Resources

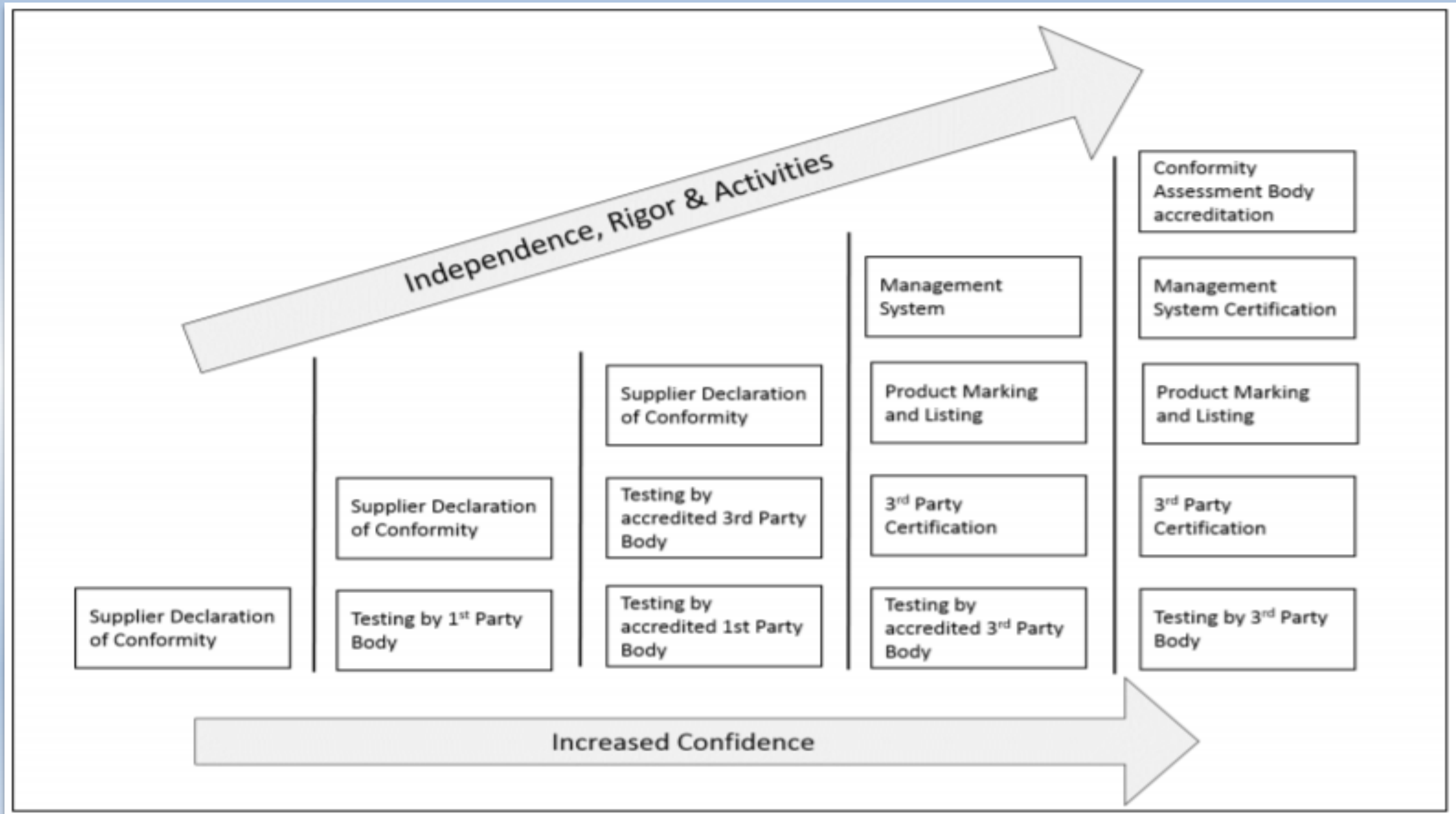
- **ASCA Pilot web page**
  www.fda.gov/medical-devices/standards-and-conformity-assessment-program/accreditation-scheme-conformity-assessment-asca
- **ASCA Pilot program guidance**

  https://www.fda.gov/regulatory-information/search-fda-guidance-documents/accreditation-scheme-conformity-assessment-asca-pilot-program
- **ASCA Standards-specific guidances**
  - **Basic Safety and Essential Performance standards-specific guidance:** https://www.fda.gov/regulatory-information/search-fda-guidance-documents/basic-safety-and-essential-performance-medical-electrical-equipment-medical-electrical-systems-and
  - **Biocompatibility standards-specific guidance:** https://www.fda.gov/regulatory-information/search-fda-guidance-documents/biocompatibility-testing-medical-devices-standards-specific-information-accreditation-scheme
- **Ask ASCA!** ASCA@FDA.HHS.GOV

Other Resources

- IMDRF Essential Principles of Safety and Performance of Medical Devices and IVD Medical Devices: 2018 WG/N47 https://www.imdrf.org/documents/essential-principles-safety-and-performance-medical-devices-and-ivd-medical-devices
- IMDRF Strategic Plan 2020: http://www.imdrf.org/docs/imdrf/final/procedural/imdrf-proc-151002-strategic-plan-2020.pdf
- International Electrotechnical Commission (IEC) http://www.iec.ch/about/activities/standards.htm?ref=home
- International Organization for Standardization (ISO) https://iso.ch/home.html
- ISO Conformity Assessment tools to support public policy: the CASCO Toolbox, accessed at https://www.iso.org/sites/cascoregulators/02_casco_toolbox.html
- ISO/IEC Directives Parts 1 (Ed. 13, 2017) and 2 (Ed. 7, 2016)
- ISO/IEC Guide 59, Code of good practice for standardization 1994
- ISO/IEC Guide 63:2012 Guide to the development and inclusion of safety aspects in International Standards for medical devices https://www.iso.org/standard/50729.html
- ISO/IEC 17007:2009, Conformity assessment – Guidance for drafting normative documents suitable for use for conformity assessment
- ISO/IEC 17050-1:2004 Conformity Assessment – Supplier's Declaration of Conformity – Part 1: General Requirements
- ISO/IEC 17050-2:2004 Conformity Assessment – Supplier's Declaration of Conformity – Part 2: Supplemental Information
- ISO 14971:2007 Medical devices – Application of risk management to medical devices
- World Health Organization WHO Global Model Regulatory Framework for Medical Devices including in vitro diagnostic medical devices 2017
- World Trade Organization Agreement on Technical Barriers to Trade 1994, accessed at https://www.wto.org/english/docs_e/legal_e/17-tbt_e.htm

Flexibility to Address Confidence



Scott's Bio

- Scott Colburn is the Director of the Office of Readiness and Response (ORR) at the Food and Drug Administration's Center for Devices and Radiological Health. In this role, Scott is responsible for the overall leadership and strategic direction on medical device cybersecurity, standards and conformity assessment while providing oversight and coordination related to public health emergency preparedness and response. He is a member to many standards developing organizations (SDO) policy and strategy committees and currently is the Chair of ISO TC210 - *Quality management and corresponding general aspects for products with a health purpose including medical devices.*

- After a span of 27 years serving in the US Army and US Public Health Service Commissioned Corps as a nurse, regulator and public health advocate, Scott continued his career as a civil servant through his role at FDA to drive his passion for standardization and global harmonizing engaging with organizations like the International Medical Device Regulators Forum [IMDRF], and his numerous affiliations across dozens of SDOs.