Essential Principles of Safety and Performance of Medical Devices and IVD
Scene Setting

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Key Points to Remember

- IMDRF Essential Principles (EPs) are our **blueprint** to provide safe and effective product, no matter the jurisdiction
- EPs combined with International Consensus Standards (“Standards”) are our **recipe for success**
- Application of the EPs and Standards should be **flexible**
- **Manufacturers** are generally responsible for demonstrating conformity
- Implementation of EPs and Standards help regulators operationalize **reliance**

What are Essential Principles?

- Essential Principles (EPs) are fundamental design and manufacturing requirements for medical devices that, when met, provide assurance the device is **safe** and **performs as intended**, offers significant benefits to, among others, manufacturers, users, patients/consumers, and to Regulatory Authorities. [1]

1 https://www.imdrf.org/sites/default/files/docs/imdrf/final/technical/imdrf-tech-181031-grrp-essential-principles-n47.pdf

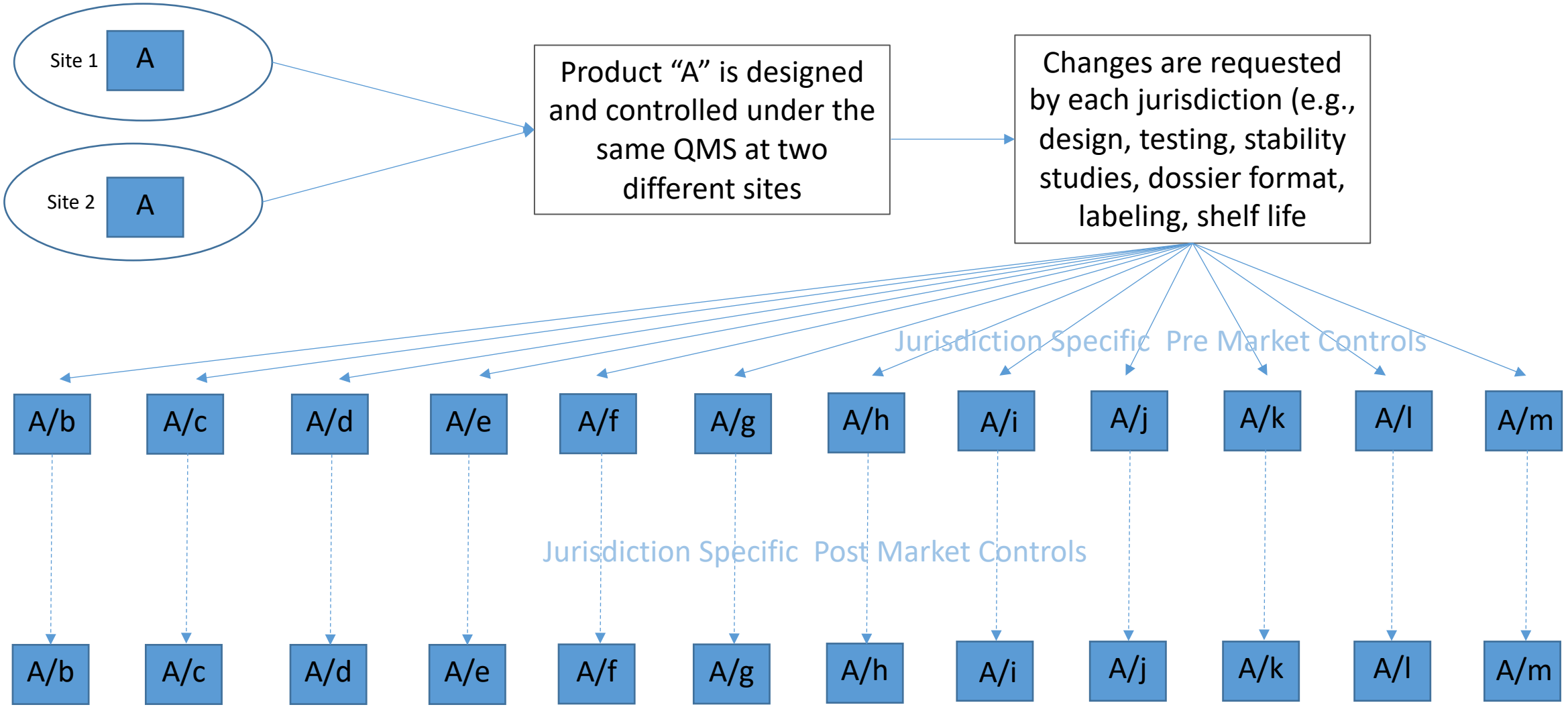
EPs are our Blueprint for Safe and Effective Product

Imagine trying to use these LEGO bricks …

to build this complex skyscraper …

… without any guidance or detailed blueprint.

Now imagine you had to build thousands of these. Let's look at an example.



The result is multiple iterations of a QMS for the same product, tailored to meet jurisdiction specific requirements

Which journey would you be more able to navigate?

***NOTE: It is key to acknowledge that jurisdictional difference are better tolerated when there is a scientifically valid reason for them, they add to patient safety, and they are established through the Good Regulatory Practices process.

*JUDGE HARRY PREGERSON INTERCHANGE: L.A., Calif.

Overview of IMDRF Essential Principles

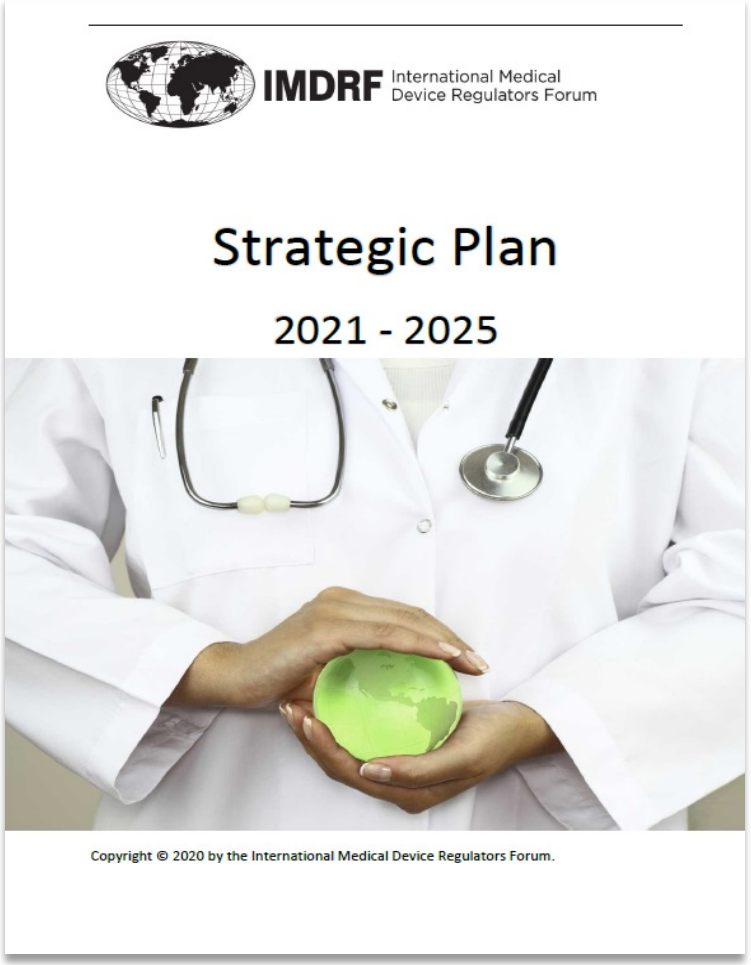
IMDRF Good Regulatory Review Practices Working Group

- Mission: Develop guidance that establishes good regulatory review practices for regulatory authorities and/or their conformity assessment bodies

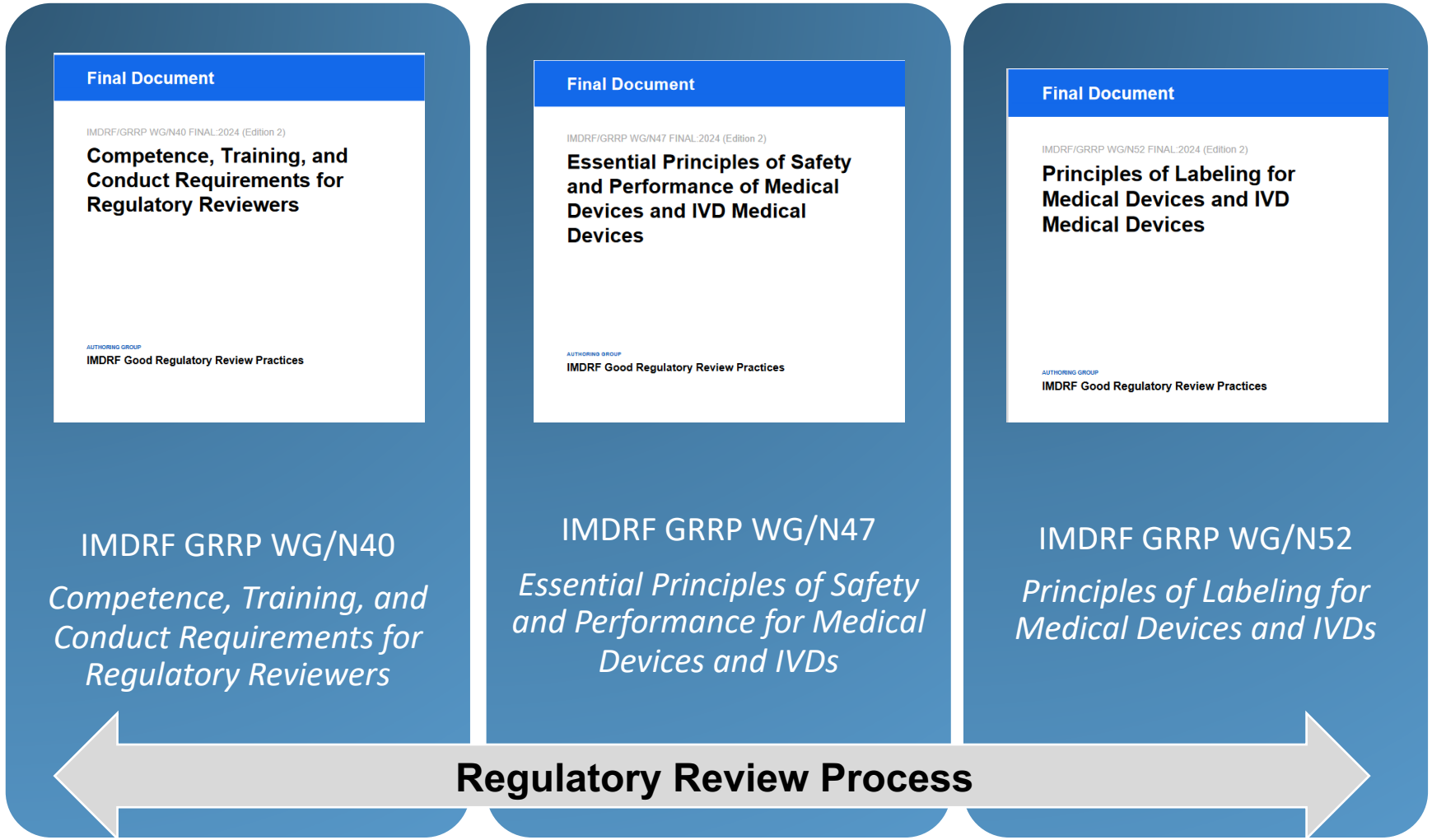
- Goals:
  - Promote consistency, predictability, quality, and transparency in regulatory marketing review programs
  - Increase efficiency and competency of review process
  - Provide opportunities for convergence of regulatory review requirements
  - Provide benefit to all regulators, even those in the early stages of developing a regulatory system for medical devices

GRRP WG Areas of Focus

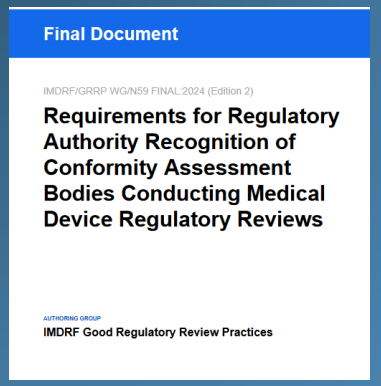
- **Technical requirements** for conducting regulatory reviews
- **Competency requirements** for regulatory reviewers
- **Requirements for organizations** performing regulatory reviews



GRRP Documents

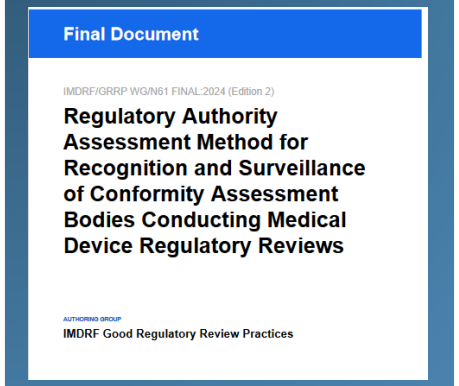


GRRP Documents



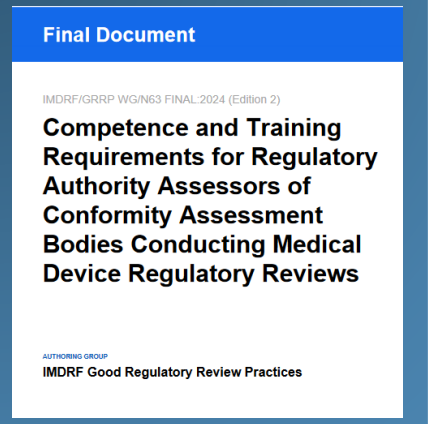
IMDRF GRRP WG/ N59

Requirements for Regulatory Authority Recognition of CABs



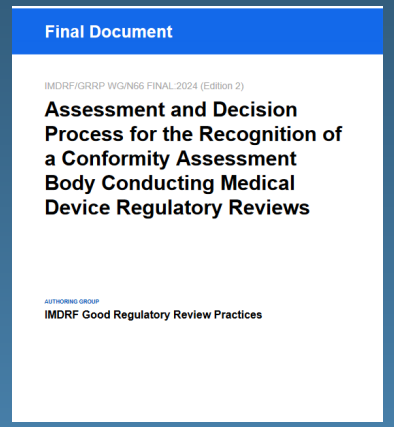
IMDRF GRRP WG/ N61

Assessment Methods for Recognition of CABs



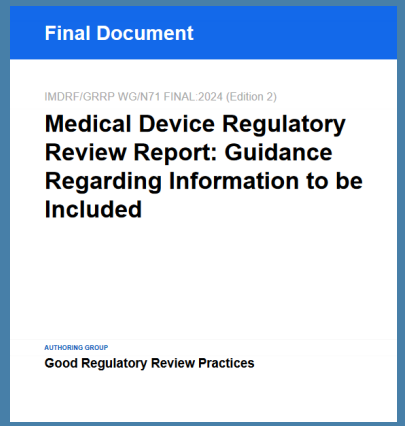
IMDRF GRRP WG/N63

Competence and Training Requirements for Assessors of CABs



IMDRF GRRP WG/N66

Assessment and Decision Process for the Recognition of CABs Conducting Medical Device Regulatory Reviews



IMDRF GRRP WG/N71

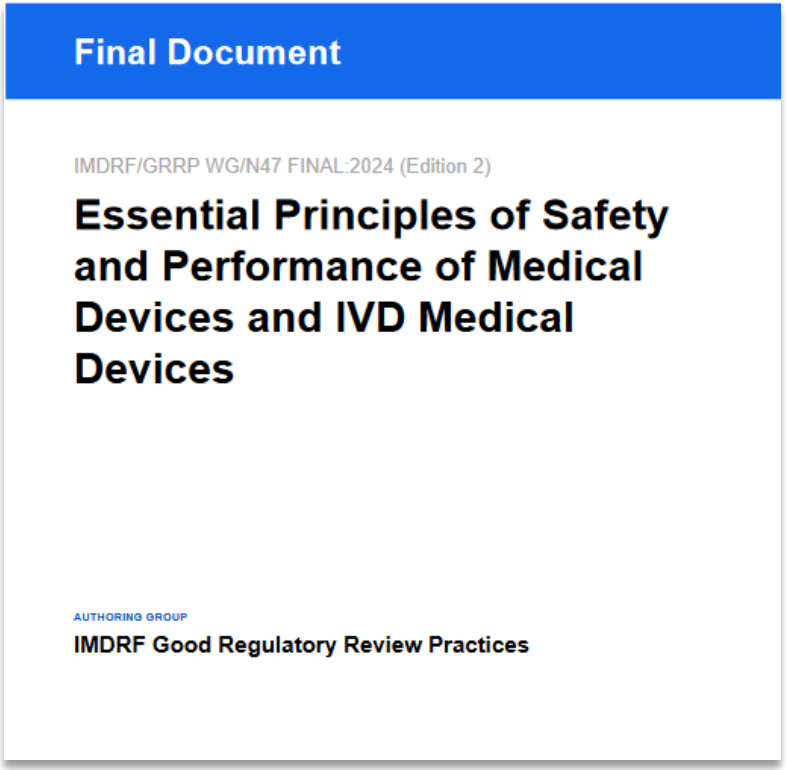
Medical Device Regulatory Review Report: Guidance Regarding Information to be Included

Conformity Assessment Body (CAB) Recognition and Operations

Role of IMDRF Essential Principles

- Conformity ensures that the medical device or IVD is safe and performs as intended through its lifecycle, under the control of the manufacturer's Quality Management System
  - Development
  - Marketing
  - Post-market

- IMDRF EP use facilities global alignment in state-of-the-art safety and performance expectations
  - Built on earlier EPs developed under GHTF
  - ISO 16142 EP standards withdrawn in 2023



IMDRF/GRRP/N47 Overview

- General and specific risk considerations that pertain to medical devices, IVDs, or both, that should be addressed in order to demonstrate conformant safety and performance
  - Not all EPs apply to every product

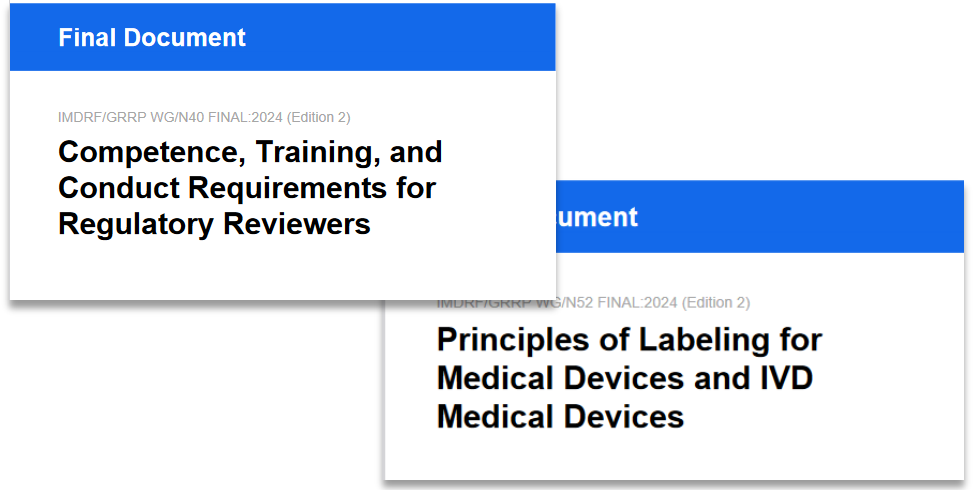
- Also includes supplementary information:
  - How standards can be optimally used to meet EPs
  - List of standards and guidance that may be helpful in demonstrating conformity

5.6 **Protection against Electrical, Mechanical, and Thermal Risks**

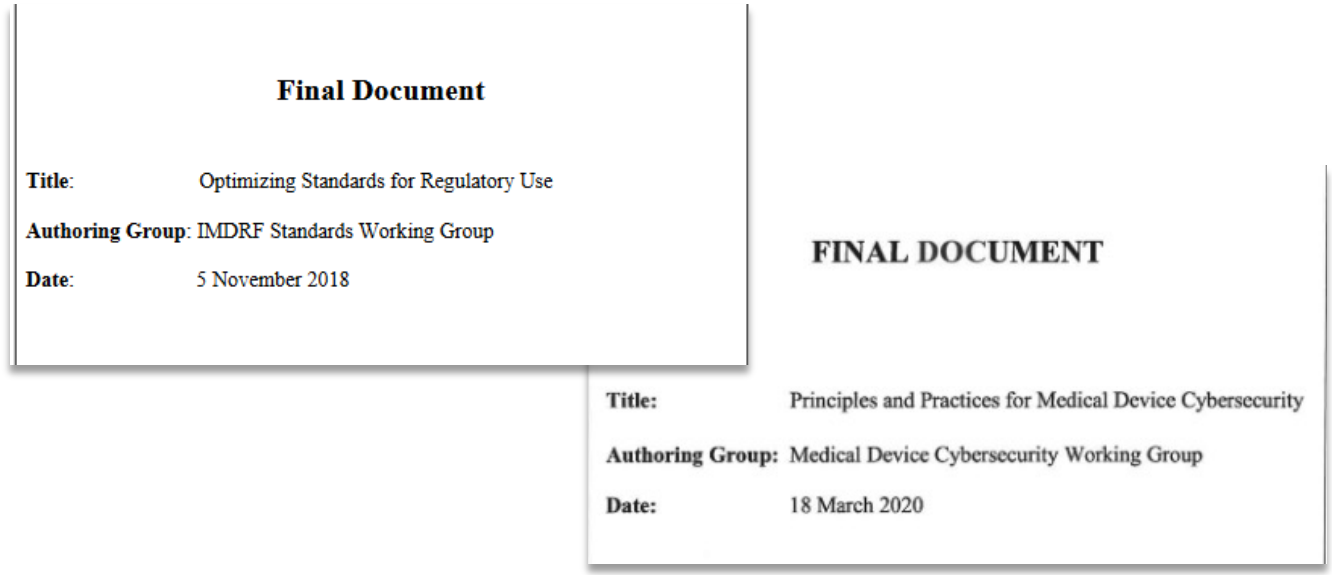
5.6.1 Medical devices and IVD medical devices should be designed and manufactured in such a way as to protect users against mechanical risks connected with, for example, resistance to movement, instability, and moving parts.

EP Synergies With Other IMDRF Work

- Other GRRP WG activities



- Additional IMDRF WGs



Use of IMDRF EPs in Device Assessment

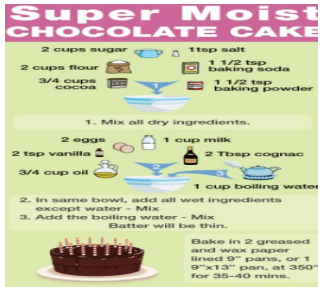
EPs combined with International Standards are our recipe for success

Goal: A chocolate cake

In our analogy, IMDRF **Essential Principles** are the goal. They are what we are aiming for S&E product per established standards.

Directions: The recipe

International Standards are the recipe or instructions to collect the right kind and right amount of evidence to demonstrate the Essential Principles have been met.



The Action: Actually baking the cake

Conformity Assessment is the actual activity of verifying that the standard or another valid method was applied in the design, manufacturing, installation, maintenance or repair of a MD or IVD.

Just like a recipe ensures a cake turns out as intended, EP and standards ensure that MD/IVDs are safe and perform as intended

Application of the EPs and Standards should be flexible

- International Standards should be **applied with adequate flexibility** to allow appropriate alternative methods to prove conformity.
- **Standards should not be mandatory** and it should be recognized that it is normal for only part of a standard to be used. It is even acceptable for the manufacturer to submit their own protocol used to test the product.
- In an industry that is constantly evolving, with new technologies emerging, adapting is important. Therefore, manufacturers need the **option to comply with the EPs through alternative methods** and **be able to justify why an EP does not apply to their device**.

Example: A new type of implantable device may use a novel material not covered by existing consensus standards. The manufacturer can provide alternative evidence to demonstrate safety and performance, ensuring the device meets EPs.

Use common sense and scientific judgment for how the EPs are met – could be the standard or a protocol from the manufacturer. Multiple ways you can meet conformity – or, the EP may not apply at all

IMDRF Essential Principles

Roles and Responsibilities

Manufacturers are responsible to implement EPs in design, development, and manufacturing processes, demonstrate conformity to the EPs* and monitor performance postmarket/report issues per regulatory requirements.

Regulators and their accredited conformity assessment bodies (CABs) are responsible to indicate which standards they recognize and also review and approve the technical documentation to ensure all relevant EPs have been met.

Distributors are obligated by the manufacturer or legal representative, typically through contract, to help the manufacturer meet their QM obligations after launch and ensure EPs continue to be met.

Standards Developing Organizations develop and update standards acceptable for international use, and can indicate which EPs can be met with each standard.

NOTE: Manufacturer can contract with a recognized 3rd party to do the testing.

Implementation of EPs and Standards help regulators operationalize Reliance

- When a product is manufactured to meet a common set of Essential Principles, using the same applicable international standards, **consistent evidence is generated** to demonstrate the product is safe and effective.
- Common requirements, common standards, and common evidence facilitate application of reliance because regulators know and trust what testing has been done; what evidence has been gathered; and that the **Essential Principles according to the international standards have been met**.
- Strength in creating a **safe and effective product comes from the stability and repeatability** of the process based on consistent requirements. Complexity introduces more opportunity for error.
- Unnecessary **complexity can act as a barrier** for some manufacturers (especially small to medium organizations) wanting to introduce innovation.

Recalling Key Points

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