IMDRF International Medical Device Regulators Forum

IMDRF STANDARDS WORKING GROUP (SWG)

[insert name, credentials, date and conference details]

IMDRF Mission

To strategically accelerate international medical device regulatory convergence to promote an efficient and effective regulatory model for medical devices that is responsive to emerging challenges in the sector while protecting and maximizing public health and safety.

Standards Working Group Membership

- Scott Colburn/FDA/USA, Chair
- Ying Huang/TGA/Australia
- Fabio Quintino/ANVISA/Brazil
- Kevin Day/Health Canada
- Jia Zheng/SDA/China
- Maurizio Andreano/DITTA/Siemens
- Peter Linders/DITTA/Philips
- Naoki Marooka/DITTA/Shimadzu
- Erik Hansson/European Commission
- Matthias Neumann/European Union
- Jeff Eggleston/GMTA/Medtronic
- Hideki Asai/GMTA/Hitachi
- Hiroshi Ishikawa/PMDA/Japan
- Madoka Murakami/PMDA/Japan
- Takeshi Endo/PMDA/Japan
- Vladimir Antonov/Roszdravnadzor/Russia
- Christopher Lam/HSA/Singapore
- Kookhan Kim/MFDS/Korea
- Heungil Ryu/MFDS/Korea
- Kyunghyun Kim/MFDS/Korea
- Gail Rodriguez/FDA/USA

WHY SUPPORT STANDARDS?

- Promote international trade
- Expeditious to rely upon consensus-driven standards rather than lengthy legal or rule-making approaches
- Encourages innovation and competition among product developers
- Reduces burdens on device companies by harmonizing expectations across international jurisdictions
- Speeds the pre-marketing review process
  - Standardized conformance assessments and test reporting
  - Less time needed for 'one-off' evaluations and requests for additional information
- Promotes regulatory science at national and international levels
- Ensures that patients have access to safe, effective and innovative devices
- Optimizes 'bench to bedside' time

STANDARDS WORKING GROUP (SWG)

- **Goal:** Enhance the use of standards to harmonize regional and national regulatory approaches
- **Objectives**
  1. Publish recommendations for developing 'regulatory-ready' standards (guidance)
  2. Enhance Regulatory Authority (RA) participation in standards development processes
  3. Advance IMDRF relationships with ISO and IEC as Category A Liaisons
  4. Analyze RAs' approaches to the use of standards in regulatory review

Objective One

Publish recommendations for developing 'regulatory-ready' standards

- 2017 Report: *Improving the Quality of International Medical Device Standards for Regulatory Use*
  - Evaluate regulatory readiness of standards
  - Investigate participation in Standards Developing Organizations (SDOs)
- 2018 Guidance: *Optimizing Standards for Regulatory Use*
  - How to improve standards and standards developing processes for use in device review
  - Encourage regulator participation in standards development

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Final Document

Title: Optimizing Standards for Regulatory Use

Authoring Group: IMDRF Standards Working Group

Date: 25 September 2018

Yuan Lin, IMDRF Chair

OPTIMIZING STANDARDS FOR REGULATORY USE

- Two elements
  - Improving standards' content to enhance utility for regulatory purposes
  - Encouraging regulatory authority participation in standards development
- Public consultation
- Publication October 2018

Optimizing Standards for Regulatory Use

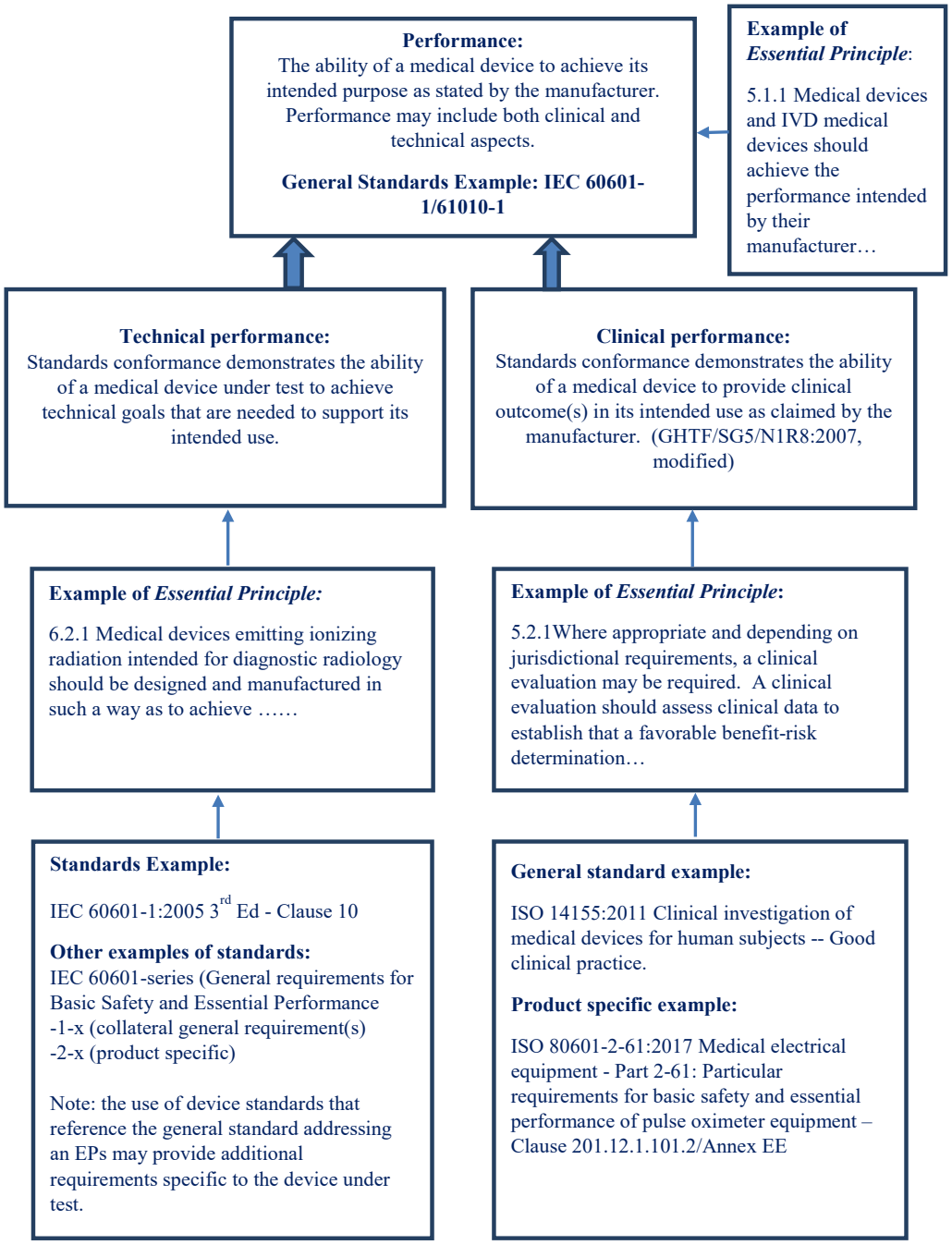
- **Audience**
  - Regulators
  - SDOs
  - Medical device community
- **Scope**
  - Resource for standards writers and regulators
  - All medical devices, including IVD

General Principles

1. Standards should map to *IMDRF Essential Principles of Safety and Performance of Medical Devices and IVD Medical Devices (2018)*
2. Performance versus design stipulations
3. Consensus standards preferred

1. MAP TO IMDRF *ESSENTIAL PRINCIPLES*

- Standards should reflect:
  - A close relationship between the standard's scope and one or more of the IMDRF EPs
  - The clarity and completeness of the requirements contained in the standard as it relates to a specific EP
  - Test methods for determining compliance with each of the requirements in the standard, and clear acceptance criteria for determining that each technical requirement is met


Performance:
The ability of a medical device to achieve its intended purpose as stated by the manufacturer. Performance may include both clinical and technical aspects.
General Standards Example: IEC 60601-1/61010-1
Example of Essential Principle:
5.1.1 Medical devices and IVD medical devices should achieve the performance intended by their manufacturer…
Technical performance:
Standards conformance demonstrates the ability of a medical device under test to achieve technical goals that are needed to support its intended use.
Clinical performance:
Standards conformance demonstrates the ability of a medical device to provide clinical outcome(s) in its intended use as claimed by the manufacturer. (GHTF/SG5/N1R8:2007, modified)
Example of Essential Principle:
6.2.1 Medical devices emitting ionizing radiation intended for diagnostic radiology should be designed and manufactured in such a way as to achieve ……
Example of Essential Principle:
5.2.1Where appropriate and depending on jurisdictional requirements, a clinical evaluation may be required. A clinical evaluation should assess clinical data to establish that a favorable benefit-risk determination…
Standards Example:
IEC 60601-1:2005 3rd Ed - Clause 10
Other examples of standards:
IEC 60601-series (General requirements for Basic Safety and Essential Performance
-1-x (collateral general requirement(s)
-2-x (product specific)
Note: the use of device standards that reference the general standard addressing an EPs may provide additional requirements specific to the device under test.
General standard example:
ISO 14155:2011 Clinical investigation of medical devices for human subjects -- Good clinical practice.
Product specific example:
ISO 80601-2-61:2017 Medical electrical equipment - Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment – Clause 201.12.1.101.2/Annex EE

2. Performance versus Design Stipulations

- Express a standard's requirements with references to performance, rather than to specific device features
- Fosters innovation and healthy marketplace dynamics
- An example from the *ISO/IEC Directives Part 2* illustrates this principle:

> *Different approaches are possible in the specification of requirements concerning a table:*
>
> *Design requirements: The table shall have four wooden legs.*
>
> *Performance requirements: The table shall be constructed such that [the table top remains level and at its original height] when subjected to … [stability and strength criteria].*

3. Consensus Standards

- **Fairness:** the needs of all stakeholders, including regulators, are considered in standards development.
- **Compatibility:** standards are compatible with the internationally accepted principles of safety and performance of medical devices.
- **State of the art:** standards represent the state of art in a technological field.
- **Efficiency:** they should also promote economic benefits, e.g., reducing redundant reporting requirements, streamlining regulatory activities and harmonizing expectations across different countries and regions.

3. Consensus Standards (cont'd)

- **Completeness:** within its scope, a standard address all predictable elements related to Essential Principles of device safety and/or performance.
- **Verifiability:** requirements include verifiable objective measurements.
- **Repeatability**: testing methods in standards will yield consistent results across different certified test houses.
- **Consistency:** terms and symbols across standards are as consistent as possible.
- **Clarity:** standards are clear, unambiguous, and easily understood.
- **Accessibility:** standards and associated documents should be reasonably available to relevant stakeholders.

Optimizing Standards Content

- Standards should be crafted so that conformity to them can reduce regulatory burden, demonstrate conformance to IMDRF's EPs, and feature:
  - A strong rationale that:
    - Explains the general requirements and identifying test methods and/or other means of demonstrating compliance
    - Demonstrates how conformance to the standard achieves its goal of satisfying the associated EPs
  - Summary of the type of stakeholder groups involved in the drafting and editing of the standard
  - Identification of risk and direction on how to address
  - A clear scope
  - Terms and definitions established and accepted in other standards
  - Means to assess clinical performance if applicable as part of the normative requirements

OPTIMIZING STANDARDS CONTENTS

- Standards should feature (cont'd):
  - Clear and quantitative acceptance criteria that can adequately support IMDRF EPs
  - Explanation of how conformance can be met if no acceptance criteria are included
  - If acceptance criteria not mandatory, justification for why, and how to demonstrate conformance to the standard
  - Well accepted and verified test methods (including for new or unfamiliar methods)
  - Transparent and clear (e.g., 'track changes') revisions
  - An annex or table that cross references the standard's clauses to the Essential Principles

Best Practices

- Consider regulatory requirements at every step
- Write a strong Business Plan
  - Robust needs analysis: market, safety, regulatory
  - Expectations for regulatory utility
  - Emphasize conformity assessment
- Encourage and solicit a wide variety of expertise
- Get involved – early!

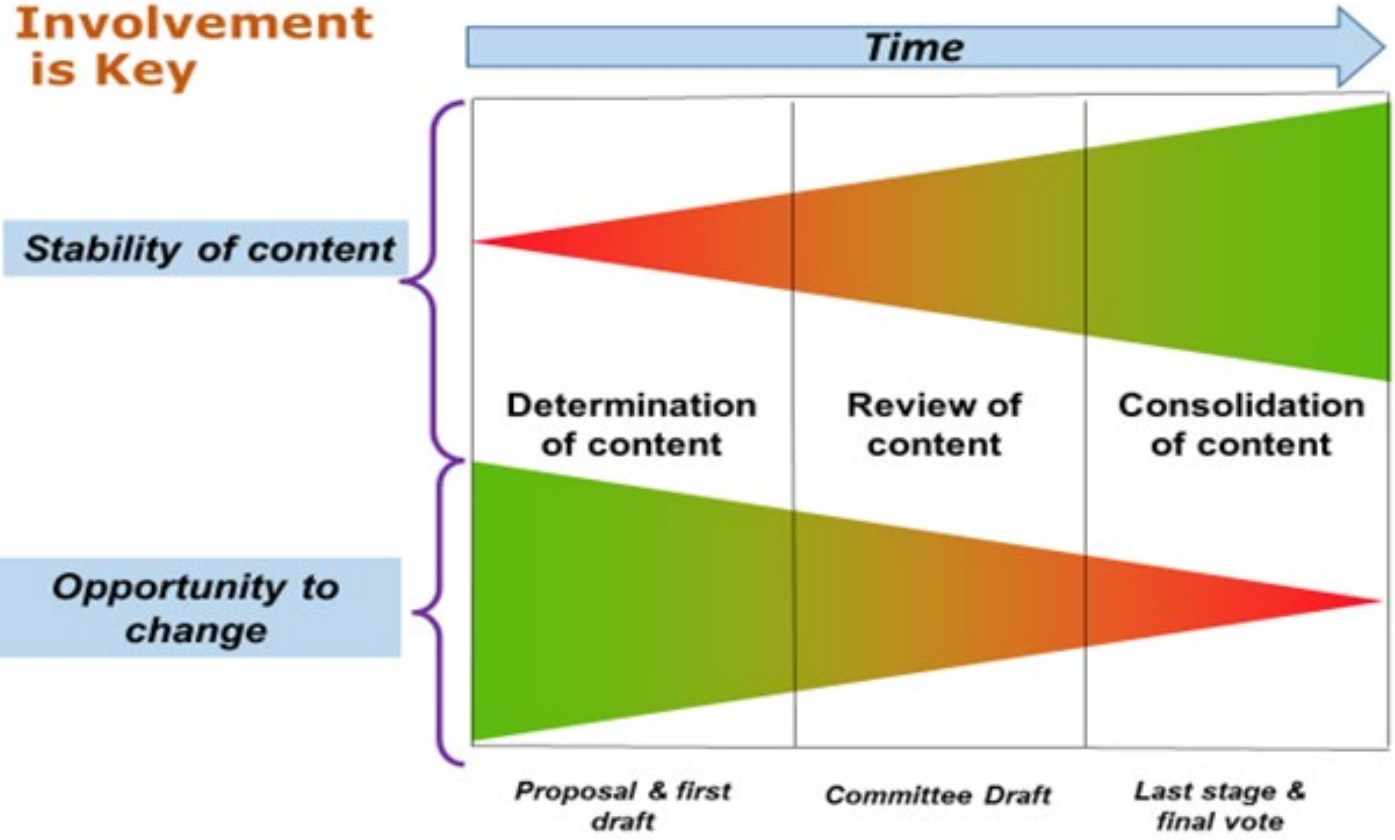
ENHANCING PARTICIPATION

- Regulators should build a strong standards program that encourages contributions to standards development
- Engagement with SDOs is essential
  - Through National Bodies and Mirror Committees
  - On SDO Technical Committees
- Contribute regulatory perspective
- Consider leadership roles

Effective Commenting

- Get involved early (at NWIP stage) and remain engaged throughout the entire process
- Become familiar with the draft
- Listen to others, consult regulatory colleagues
- Consider impact on regulatory processes, especially conformity assessment, testing methods and audit requirements
- Articulate your position clearly and concisely
- Use SDO's approach and templates
- Offer alternative language

Early Involvement is Key



RESOURCES

- Asian Harmonization Working Group Playbook (see in particular Chapter 7) http://www.ahwp.info/sites/default/files/ahwp-files/4_Technical_Committee/AHWP%20Playbook%20for%20Implementation%20of%20MD%20Reg%20Framework.pdf
- IMDRF Essential Principles of Safety and Performance of Medical Devices and IVD Medical Devices: 2018 (IMDRF GRRP WG/N47 forthcoming)
- 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
- Society for Standards Professionals https://www.ses-standards.org/page/A2?
- 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

IMDRF Standards Recognition Survey

IMDRF Standards Recognition Survey

Dear Colleague,

This survey is Part One of an IMDRF research project **investigating how Regulatory Authorities (RAs) use consensus standards in their regulatory review of medical devices.** The analysis from this survey (and from Part Two, the IMDRF Standards Checklist, included in this correspondence) will advance IMDRF efforts to harmonize medical device review processes around the world.

Note: your identity will not be shared outside IMDRF; however, the name of your agency will be recorded and used for internal IMDRF analysis. Confidentiality is assured; however, anonymity is not.

Instructions: The survey should take **no more than 20 minutes** to complete. Each RA should submit **one response only**. Please use free text fields liberally, as not every element of an RA's system will clearly fit into the response choices given, and your descriptions will be critical to the quality of the data being gathered. Please become familiar with the definitions below so that responses are consistent.

Please complete this survey (and the IMDRF Standards Checklist), save and email to gail.rodriguez@fda.hhs.gov **no later than 23 November 2018**.

Thank you in advance for your contribution to regulatory science.

DEFINITIONS

DIRECT/FORMAL RECOGNITION PROGRAM

INFORMAL RECOGNITION PROGRAM

FULLY RECOGNIZED STANDARD

PARTIALLY RECOGNIZED STANDARD

USE/ALLOW/ACCEPT

MANDATORY STANDARD

VOLUNTARY STANDARD

CONFORMITY ASSESSMENT

SURVEY QUESTIONS

What is the name of the Regulatory Authority (RA) you represent?
Click or tap here to enter text.

Does your RA have a formal standards function or department?
☐Yes
☐No

Does your RA have a formal standards recognition program?
☐Yes, please describe, then go to question 5
Click or tap here to enter text.
☐No

Is there an informal program or set of procedures in place that allows or encourages the use of standards?

☐Yes - please describe

Click or tap here to enter text.

☐No – thank you for your time, go to the end of the survey.

What is the legal basis or authority for your standards recognition program? In other words, does your RA rely upon specific medical device regulations/directives/directorate/law stating that a medical device standard can/should/must be used by manufacturers to demonstrate compliance with a regulatory requirement?

Please describe

Click or tap here to enter text.

Do you involve your national standards body in the process of recognition?

☐Yes

☐No

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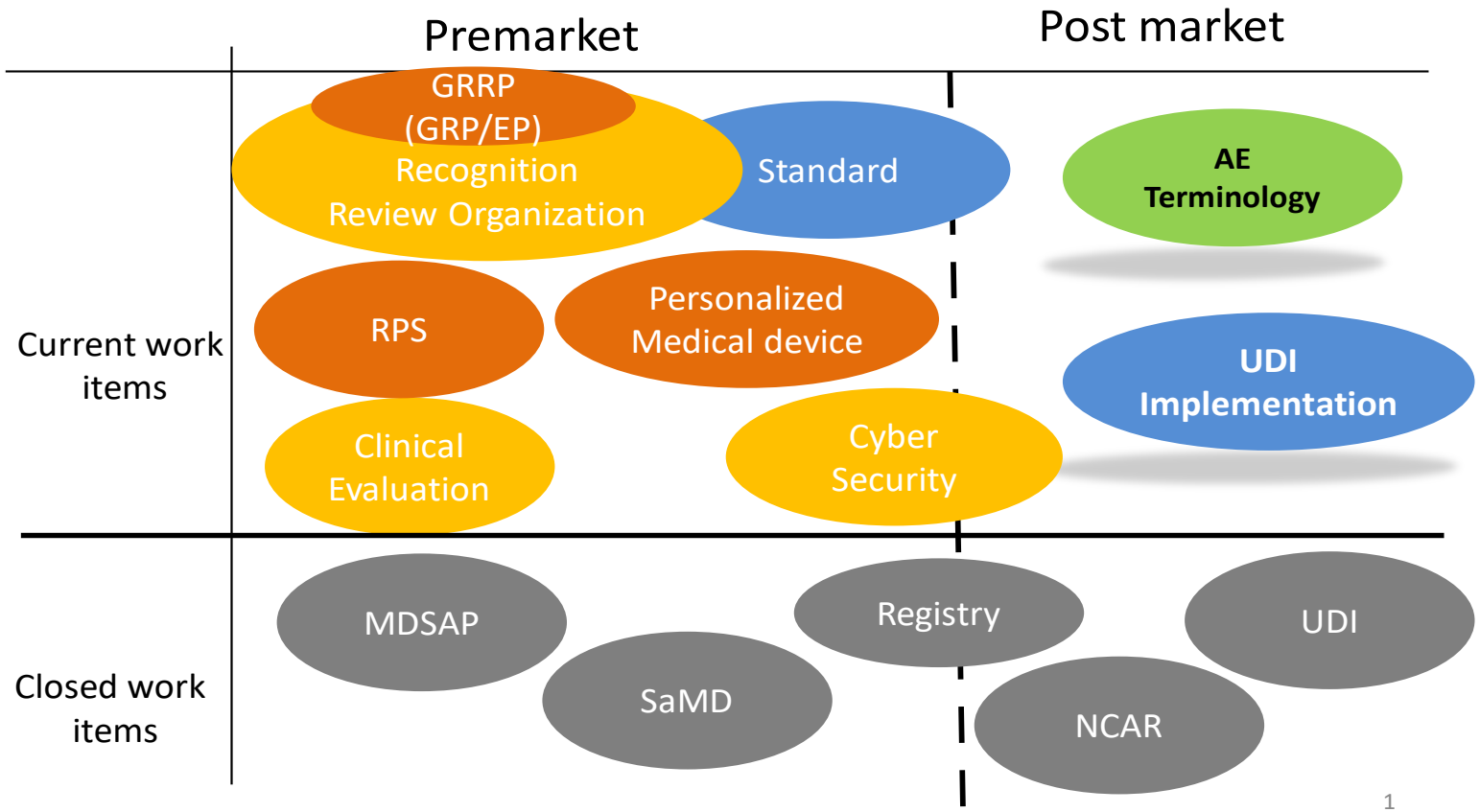
1. This checklist (see this document's second sheet 'Standards Checklist') features 1,126 standards used in medical device review. We ask that you provide complete answers for all. If you are unable to answer all of them because of time constraints, please at least answer rows 2-293.
2. The TC/SC (column B) lists the SDOs TC/SC based upon the ISO/IEC Document referenced (column A) as the lead SDO. For example, ISO 80369-1 is [ISO] TC210; IEC 80369-5 is [IEC] SC62D.
3. The Latest Publication listed may not account for relevant Amendments or Technical Corrigendum published; however, it is assumed that the use of standards includes the most recent such publications. If appropriate, please note this in Column M 'Comments.
4. Please feel free to add other, non-ISO and IEC standards that are used/recognized by your Regulatory Authority after row 1,127.
5. Please see definitions for key terms below these instructions.
6. When you have completed this document, please save it as 'Standards Checklist [your regulatory authority name]' and email it to gail.rodriguez@fda.hhs.gov, along with your completed 'Standards Survey' document, **no later than 23 November 2018**.
Thank you.

Not recognized but its use is allowed?	Please choose 'yes' or 'no' from the drop-down menu, or type in a response (yes, no, Y or N)
Use not allowed ?	Please choose 'yes' or 'no' from the drop-down menu, or type in a response (yes, no, Y or N)
Which version is recognized/allowed?	Please type the version/year of the standard your Regulatory Authority recognizes or allows the use of
Is its use mandatory?	Please choose 'yes' or 'no, voluntary' from the drop-down menu, or type in a response (yes, no, or vountary)
Recognized /allowed in full ?	Please choose 'yes' 'no, in part' or 'no, modified by RA' from the drop-down menu
Which part(s) are not recognized or allowed ?	Please type in the part or parts of the standard that your Regulatory Authority does not recognize
Is this non-recognized or not allowed part modified?	Please choose 'yes' or 'no' from the drop-down menu, or type in a response (yes, no, Y or N)
What is the reason for non-recognition or modification?	Please choose a reason from the drop-down menu, or type in the reason for the non-recognition

IMDRF Documents

Working Group Activities



THANK YOU