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

Medical Device Regulatory Convergence Project (MDRC)

Good Regulatory Practices & Technical Competencies

South Africa Health Products Regulatory Authority (SAPHRA) & Regulated Sector

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Essential Principles of Safety and Performance

Participation of Anvisa in the IMDRF Working Groups since its foundation

IMDRF Good Regulatory Review Practices Working Group


IMDRF/GRRP WG/N47 FINAL:2018
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Brazilian Regulation for the Essential Principles of Safety and Performance

RDC 56/2001

Harmonized Regulation in Mercosur

Same requirements applied among the Mercosur member states

Argentina, Brazil, Paraguay and Uruguay

Total population - 268.5 M
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Considering the need to update the regulations, Brazil proposed the adoption of the IMDRF technical document to the other member states of Mercosur.

Final text approved by the Mercosur Sub-Commission of Medical Devices in May 2023, after internal Public Consultations.

Internalization in progress. Expected to be published by Anvisa until November 2023.
Why update these essential principles?

1) Patient Safety
2) Rapid Technological Advancements
3) Equitable Access
4) Market Confidence
5) Global Harmonization
6) Data Privacy and Security
7) Adapting to Novel Risks
8) Clinical Efficacy
9) Innovation and Industry Growth
10) Ethical and Social Considerations
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Another important IMDRF document is directly linked to Safety and Performance Principles

IMDRF/GRRP WG/N52 FINAL:2019
Principles of Labelling for Medical Devices and IVD Medical Devices
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Fundamental design and manufacturing requirements that provide assurance that a medical device or IVD is safe and performs as intended by the manufacturer.
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Safety and Performance

General and specific risk considerations specific to medical devices, IVDs, or both
Includes list of relevant standards/guidance documents

Examples:
- Material characterization
- Clinical evaluation
- Conditions of use
- Diagnostic functions
- Software aspects
- General labeling principles
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Labeling

Labeling elements and information specific to medical devices, IVDs, or both

Examples:
- Label
- Instructions for use
- Software as a medical device
- Lay users
- Information intended for the patient
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The adoption of these common principles worldwide offers benefits to:

• Manufacturers
• Users
• Patients
• Regulatory authorities

Reducing regulatory compliance costs and enabling faster access to new medical technologies
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Emphasizes a balance between safeguarding public health and not burdening the industry unnecessarily

**Compliance to Essential Principles throughout product life-cycle**

- Design
- Production
- Postproduction
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“Should” indicates that among several possibilities, one is recommended as particularly suitable, without mentioning or excluding others, or that a certain course of action is preferred but not necessarily required, or that (in the negative form) a certain possibility or course of action should be avoided but is not prohibited.

“May” is used to indicate that a course of action is permissible within the limits of the standard.

“Can” is used as a statement of possibility and capability.

“Must” is used only to describe “unavoidable” situations, including those mandated by government regulation.
A manufacturer of a medical device or IVD medical device is expected to design and manufacture a product that is safe and performs as intended throughout its life cycle.

Essential Principles Applicable to all Medical Devices and IVD Medical Devices

Essential Principles Applicable to Medical Devices other than IVD Medical Devices

Essential Principles Applicable to IVD Medical Devices
• Develop a risk management plan for each device
• Identify and analyze known and foreseeable hazards associated with each device
• Evaluate the risks associated with intended use and foreseeable misuse
• Control or eliminate risks based on specific requirements
• Evaluate the impact of production and post-production information on overall risk
• Adjust control measures if necessary
Clinical Evaluation

- This evaluation involves analyzing clinical data to confirm a positive balance between benefits and risks for the device.
- This data can include reports from clinical investigations or performance evaluations, published scientific literature, and clinical experiences.
EP’s Applicable to all Medical Devices and IVD Medical Devices

Chemical, Physical, and Biological Properties

• Material Selection
• Process Impact
• Research Validation
• Mechanical Properties
• Surface Properties
• Chemical and Physical Specifications
• Contaminants and Residues
• Substance Egress
• Unintentional Substance Ingress
• Infection Risk
Sterilization and Microbial Contamination

- Facilitate safe cleaning, disinfection, sterilization, and re-sterilization by the user
- Maintain microbial state during transportation and storage
- Validated methods for products labeled as sterile
- Packaging should minimize contamination when devices are provided non-sterile
Considerations of Environment and Conditions of Use

• Devices intended for use alongside other medical devices
  • The entire combination, including connection systems, must ensure safety and not compromise the specified performance

• Consider the intended environment and usage conditions to minimize various risks
  • Risks to users or others caused by physical features, user interface design, and foreseeable external influences like magnetic fields, humidity, temperature, and pressure

• Software interactions, maintenance and calibration mechanisms, unauthorized access risks, ergonomic usability, and safe disposal/recycling
Devices that Incorporate Software or are Software as a Medical Device

- Ensure accuracy, reliability, safety, and performance
- In case of a single fault, measures should be taken to eliminate or reduce resulting risks
- Software should be developed, manufactured, and maintained using up-to-date practices, considering development cycles, risk management, verification, and validation
- When software is intended for use with mobile platforms, the platform's characteristics and usage environment should be considered
- Cybersecurity measures are also essential
EP’s Applicable to all Medical Devices and IVD Medical Devices

Protection against the Risks posed by Devices intended for use by Lay Users

- Consider the capabilities and limitations of lay users
- IFU should be easy to comprehend
- Additional training might be required when risks remain
- Result interpretation
- Verification of the correct function of the device
- Alert to the user when the device fails to operate
EP’s Applicable to all Medical Devices and IVD Medical Devices

Labeling

• Refer to IMDRF/GRRP WG/N52
• Information needed to distinctively identify the medical device or IVD medical device and its manufacturer
• Accompanied by, or direct the user to any safety and performance information relevant to the user, or any other person, as appropriate
• Information may appear on the device itself, on the packaging or in the instructions for use, or be readily accessible through electronic means, and should be easily understood by the intended user
Other important topics discussed in this section
• Protection against Electrical, Mechanical, and Thermal Risks
• Active Medical Devices and Devices Connected to Them
• Devices with a Diagnostic or Measuring Function
• Protection against Radiation
• Devices Incorporating Materials of Biological Origin
EP’s Applicable to Medical Devices other than IVD MD

Additional EP’s to the previously listed
• Chemical, Physical and Biological Properties
• Protection against Radiation
• Particular Requirements for Implantable Medical Devices
• Protection against the Risks Posed to the Patient or User by Medical Devices Supplying Energy or Substances
• Medical Devices Incorporating a Substance Considered to be a Medicinal Product/Drug
EP’s Applicable to IVD Medical Devices

Additional EP’s to the previously listed

- Chemical, Physical and Biological Properties
- Performance Characteristics
  - Analytical performance
  - Clinical performance
  - Validated control procedures
- Traceability of Calibrators and Controls
- Standardized Units
- Performance Evaluation
Conclusion

Essential Principles of Safety and Performance for MD and IVD MD
• Trust and reliability in the technologies
• Innovation with responsibility
• Maximize patient well-being while minimizing risks
• High standards
• Contribute to the advancement of medical science
THANK YOU!

OBRIGADO!

MEDICAL DEVICES OFFICE

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