Significant Standards Related to MR Safety

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Disclosures
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Objectives
- An introduction to the "alphabet soup" of standards
- Understand how MR vendors use standards
- Awareness of how standards are developed

- This talk mentions 13 standards (2 ISO, 1 IEC, 6 ASTM, 4 NEMA/MITA).
  - Unless you plan testing, I don't think you need ANY of these
  - Labels derived from these stds should explain enough (if not, call them)

- Note: unless otherwise specifically noted, descriptions of processes are typically IEC/ISO methods
A Brief Introduction

➢ Member of IEC 60601-2-33 MT40 committee for 15 years
➢ Convenor of IEC 62464 (MT52) 4 years
➢ NEMA/MITA MR technical committee chair for 6 years, member of tech committee for 18+ (?) yrs
➢ Co-convenor of ISO 1510974 JWG for 9 years (active implants in MRI)

Alphabet Soup

➢ Some standards development organizations (SDOs)
  ▶ International:
    ➢ IEC: International Electrotechnical Commission
    ➢ ISO: International Standards Organization
    ➢ ASTM International (formerly American Society for Testing and Materials)
  ▶ National:
    ➢ NEMA/MITA: National Electrical Manufacturers Association / Medical Imaging and Technology Alliance
  ▶ Other key terms:
    ➢ JWG: Joint Working Group (in this context, ISO and IEC working together)
    ➢ IFU: Instructions For Use (manuals, documents etc that come with scanner)
    ➢ MT: Maintenance Team

Can you define “Safety”?

➢ ISO 14971 – Medical devices – Application of risk management to medical devices
  ➢ Safety: freedom from unacceptable risk,
  ➢ Risk: combination of the probability of occurrence of harm and the severity of that harm,
  ➢ Harm: physical injury or damage to the health of people, or damage to property or the environment.
  ➢ You cannot be perfectly safe. ISO 14971 helps determine acceptable probability levels
  ➢ FDA holds medical device vendors to certain safety levels
  ➢ FDA does not regulate the practice of medicine. MDs practice risk/benefit management with patients, can use devices “off-label” at higher risk level
Do we understand the word "standards"?

➢ Two types of standards:
  ➢ Measurement
    ➢ The science of metrology. The recently retired “kilogram” block “Le Grand K”
  ➢ Documentary (definition from NIST)
    ➢ “written agreements containing technical specifications or other precise criteria that may contain rules, guidelines, or definitions of characteristics. Standards ensure that materials, products, personnel qualifications, processes, and services are: adequate for their purpose, compatible and/or interchangeable, if necessary; ensure public health and safety; protect the environment; and/or improve economic performance.” (NISTIR 7614, The ABC’s of Standards Activities).

➢ This presentation about documentary standards
  ➢ But any measurements done on calibrated equipment, traced to references

How Vendors use Standards

➢ Vendors develop safe products based on codified rules experts (and experience) have shown to be appropriate
➢ Vendors make claims to regulators (e.g. FDA) about products based on known requirements, test methods
➢ Regulators familiar with the standards (usually), simplifies their work
  ➢ e.g. FDA maintains a website of “recognized” consensus standards, but will consider other stds (and different editions) but more questions, scrutiny
  ➢ The vendor documentation burden lower because methods known
➢ Note: Regulators authorize marketing etc product claims. Anything on our “label”, e.g. manual, other documents, stickers, markings etc.
  ➢ Working for a vendor I MUST NOT support “off-label” use of medical devices. But I can talk about the science.

A few remarks about standards usage (MR+implants)

➢ We are ALL learning workflows, usage. Early tests, labels not optimal
➢ Interpretation may vary between vendors, including those who wrote
➢ With regards to labeling, I have seen:
  ➢ Technically accurate, but impossible for MRI user to practically follow
  ➢ Unclear, too long, complex
  ➢ Incomplete
  ➢ We are making all-out efforts to fix standards, improve labeling clarity
➢ A caveat about labels, in defense of regulators
  ➢ Not all regulators approving MRI labeling are MRI experts
  ➢ There may exist a clinical need so they may permit “special” labels
  ➢ Once a label approved, other vendors may attempt to copy
  ➢ Regulators stop further approvals once issues realized

FDA = Friendly Device Agency ☺
How Standards are Developed?

➢ Slowly...
  ➢ by committee (an international group speaking many languages),
  ➢ by significant consensus,
  ➢ a “patchwork quilt” developed over many editions,
  ➢ by a rotating committee membership,
  ➢ Reviewed on a multi-year cycle (e.g. MITA; 5 years)

➢ New stds started by “NWIP” (New Work Item Proposal)
  ➢ All key development stages have international votes
  ➢ Voted on by national technical advisory groups (e.g. I am an accredited member of the US delegation)

The most important MR safety std IEC 60601-2-33

➢ Title: Particular requirements for the basic safety and essential performance of magnetic resonance equipment for medical diagnosis
  ➢ Substantially a diagnostic imaging safety doc
  ➢ “Basic safety and essential performance” is a key and complicated expression that defines the focus of std. Out of scope for this presentation

➢ It covers (partial list):
  ➢ B0, SAR, Gradient exposure requirements
  ➢ Acoustic noise outputs
  ➢ The list of required information to release (e.g. gauss line plots)

➢ I believe all MR vendors follow the standard
  ➢ The NEMA/MITA safety stds document how various measurements done

NEMA/MITA Safety Standards (1)

➢ Three (fourth “in press”) standards related to safety:
  ➢ MS-4 Acoustic Noise Measurement Procedure for Diagnostic Magnetic Resonance Imaging Devices
    ➢ MGAN (max gradient noise), MCAN (max clinical seq noise)
    ➢ Undergoing major revision to consider MR worker safety (e.g. at bore opening), latest generation of big gradients
  ➢ MS-8 Characterization of the Specific Absorption Rate for Magnetic Resonance Imaging Systems (whole body)
    ➢ Completed major revision a couple of years ago for 3T, large bore systems
NEMA/MITA Safety Standards (2)

➢ MS-10 Determination of Local Specific Absorption Rate (SAR) in Diagnostic Magnetic Resonance Imaging
  ➢ Not considered useful today. Scheduled for total rewrite after MS-4
➢ MS-14 Characterization of RF Coil Heating in Magnetic Resonance Imaging Systems
  ➢ New, to publish later this summer
  ➢ Motivated by FDA request to improve clarity of IEC general standard on regular practices to ensure RF coils do not over-heat, injure patient

ASTM International Standards (1)

➢ Gratefully acknowledge input from Terry Woods, PhD (FDA) on status
➢ Five standards, an additional new one in progress:
  ➢ F2052 Standard Test Method for Measurement of Magnetically Induced Displacement Force on Medical Devices in the Magnetic Resonance Environment
    ➢ Status: Interlaboratory study to determine precision and bias statement that is a required part of ASTM stds

ASTM International Standards (2)

  ➢ Status: Major revision to include 3T, excluding calorimetry over entire phantom, focus on local SAR. Complete 2019
➢ F2213 Standard Test Method for Measurement of Magnetically Induced Torque on Medical Devices in the Magnetic Resonance Environment
  ➢ Status: Additional methods added in 2017. Interlab study being designed, prep work for next revision
➢ F2503 Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment
  ➢ Status: Update with optional list of parameters that could be included. Regularize and unify the presentation of information. Pub 2019
ASTM International Standards (3)

➢ WK58852 Standard Guide for Assessing the Safety of non-implanted Medical Equipment in the MR Environment
  ➢ Assessment of medical equipment (passive and active) that does not go in the bore of the scanner.
  ➢ A guide, not a test method.
  ➢ How to address projectile hazard, functioning of the device and device interference with MR images.
  ➢ Likely a very simple first edition. Pub 2020

ISO/IEC TS 10974 (1)

➢ Title: Assessment of the safety of magnetic resonance imaging for patients with an active implantable medical device
➢ A joint initiative (JWG) between active implant (ISO), MR vendors (IEC)
➢ Develop tests to confirm implant characteristics in MRI
➢ Tests support correct MR Conditional labels/instructions
➢ Almost NO tests occur in an MR scanner. Bench tests more accurate, test one field at a time. Supports claims across all MR vendor systems
➢ “TS” Technical Specification, not a std (yet). A way to develop, test ideas. Based on two editions of TS, standard now in development
➢ Do NOT confuse with new CMS payment for scanning MR Unsafe pacemakers, based on extensive literature reporting successful scanning WHEN BACKED UP WITH IMMEDIATELY AVAILABLE EMERGENCY RESPONSE STAFF

ISO/IEC TS 10974 (2)

Figure 2 — Relationship between MR scanner output fields (RF, gradient, B0) and hazards (test method clause numbers in parentheses)
Where do I get these standards?

- $0
  - [https://www.nema.org/](https://www.nema.org/)
    - MRI stds free for pdf download, after you create a free account

- $$
  - [https://www.astm.org/](https://www.astm.org/)

- $$$$$
  - [https://www.iso.org/store.html](https://www.iso.org/store.html)
  - [https://webstore.iec.ch/](https://webstore.iec.ch/)
  - Shop other national stds organizations. May be a lower price
  - Many different “versions” (e.g. redline etc) price different
  - NOTE: some stds exist in special national variants

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