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 TS10974 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
  - F2119 *Standard Test Method for Evaluation of MR Image Artifacts from Passive Implants*
    - Status: Major revision ongoing. More appropriate experimental sequences. Consideration of a computational method. Complete 2020?

ASTM International Standards (2)

- F2182 *Standard Test Method for Measurement of Radio Frequency Induced Heating Near Passive Implants During Magnetic Resonance Imaging*
  - 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)

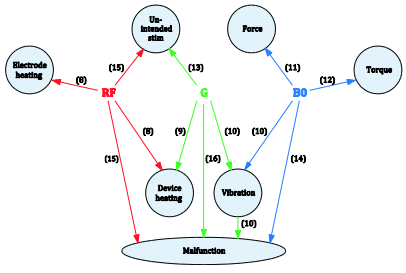

Figure 2 — Relationship between MR scanner output fields (RF, gradient, B_0) and hazards (test method clause numbers in parentheses)

Where do I get these standards?

- $0
  - https://www.nema.org/
    - MRI stds free for pdf download, after you create a free account
- $$
  - https://www.astm.org/
- $$$$$
  - https://www.iso.org/store.html
  - 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