IEC Subcommittee 62B (Diagnostic Imaging Equipment): Recent and Active Projects

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Disclosures

- Research Grant Siemens AG
- Speaker and Scientific Advisory Board Member, Bayer Healthcare

IEC Diagnostic Imaging Equipment

- **Opportunity for clinical physicist involvement in writing and revising standards for performance**
- Standards dictate machine performance and sometimes testing requirements
- More involvement from physicists involved in day to day practice will benefit all
- Revisions of standards or new standards shared with AAPM subcommittees for comments to be relayed through USNC

IEC 62B Active Teams and Projects

- WG 45: Items within the controlled access area of Magnetic resonance equipment for human application
- WG 46: Medical electrical equipment - Particular requirements for basic safety and essential performance of dental X-ray equipment
- PT 62985: Methods for calculating Size Specific Dose Estimate (SSDE) on Computed Tomography
- JWG 1: Requirements for the safety and compatibility of magnetic resonance imaging for patients with an active implantable medical device linked to ISO/TC 150/SC 6

IEC 62B Active Teams and Projects

- MT 30: Computed Tomography
- MT 31: Mammographic X-ray Equipment
- MT 32: Requirements for X-ray source assemblies
- MT 34: Revision of 60601-2-37: Medical electrical equipment - Part 2-37: Particular requirements for the safety of ultrasonic medical diagnostic and monitoring equipment
- MT 37: Diagnostic X-ray equipment - general requirements for radiation protection and particular requirements for radiography and radioscopy

IEC 62B Active Teams and Projects

- MT 39: Dental Imaging Equipment
- MT 40: Magnetic Resonance Equipment for Medical Diagnosis
- MY 41: Revision of IEC 60601-2-43
- MT 44: Characteristics of Digital X-ray Imaging Devices
- MT 47: Protective Devices Against Diagnostic Medical X-radiation

IEC 62B Active Teams and Projects

- MT 50: Diagnostic X-ray Imaging Equipment – Characteristics of General Purpose and Mammographic Anti-Scatter Grids
- MT 51: Medical Electrical Equipment – Medical Image Display System – Part 1: Evaluation Methods
- MT 52: Maintenance of the IEC 62464 Series, Magnetic Resonance Equipment for Medical Imaging

IEC 62B and AAPM

- Experts are put forward by national committees for MT/PT/QG membership
- Experts typically come from regulatory agencies (FDA), manufacturers or clinical/academic personnel
- MTs and WGs without experts from clinical or academic setting are identified throughout
- IEC work items can be influenced by organizations such as AAPM or EFOMP

IEC 62B and AAPM

- Example initiative of AAPM and IEC involvement/coordination
- **Development of IEC 62494-1 which defined Exposure Index and Deviation Index as parameters for radiographic technique assessment**

Equipment testing issues: role of IEC standards and AAPM

- FDA contact:
- J. Nick Walker
- CDRH/OIR/Division of Radiological Health
- James.Walker@fda.hhs.gov

- Information courtesy Nick Walker

Motivation

- FDA diagnostic x-ray performance standards, which are largely mirrored by the states, are difficult to revise to keep up with evolving technology.
- Standards Development Organizations exist whose standards are often more up to date while assuring equivalent or improved patient & operator safety and performance.
- Standards need to be accompanied by testing procedures for use by physicists and regulators.

Concept: proposal made at 2015 CRCPD Annual Meeting

- Propose formation of a new WG to develop performance testing procedures
- FDA aids in development/delivery of testing procedures & related training
- Manufacturers include procedures in labeling (user manuals, etc.)
- Testing methods incorporated into IEC standards as appropriate
- WG continually improves testing methods

Existing testing standards for x-ray equipment

- CT:
  - IEC 61223-3-5 Ed 1.0 (2004-08) Evaluation and routine testing in medical imaging departments–Part 3-5: Acceptance tests–Imaging performance of computed tomography X-ray equipment; Corrigendum 1 (2006-03)
  - IEC 61223-2-6 Ed 2.0 (2006-11) Evaluation and routine testing in medical imaging departments – Part 2-6: Constancy tests –Imaging performance of computed tomography X-ray equipment
- Dental:
  - IEC 61223-3-4 Ed 1.0 (2000-03) Evaluation and routine testing in medical imaging departments - Part 3-4: Acceptance tests - Imaging performance of dental X-ray equipment
- Withdrawn radiography/fluoroscopy:
  - IEC 61223-3-1 Evaluation and routine testing in medical imaging departments – Part 3-1: Acceptance tests – Imaging performance of X-ray equipment for radiographic and radioscopic systems

Current Status

- Need for new and updated testing standards, particularly for rad/fluoro.
- FDA made proposal to IEC MT37 and MT41 in June 2015 to include QC procedures for the end user in radiography and fluoroscopy standards.
- IEC team also discussed incorporating user quality control features into IEC standards for radiographic and fluoroscopic systems (e.g., modeled after NEMA XR-27 for interventional equipment)

Related Efforts on QC/QA

- AAPM developing recommendations for testing procedures for rad/fluoro that could inform IEC testing standards development.
  - AAPM TG150 Task Group No. 150 Acceptance Testing and Quality Control of Digital Radiographic Imaging Systems
  - AAPM TG 272: Comprehensive Acceptance Testing and Evaluation of Fluoroscopy Imaging Systems (New)

Proposed requirements for testing

- QC instructions should cover all available operating modes.
- QC should cover annual physics testing, as well as testing to be done at more regular intervals (e.g., by a technologist).
- Tests should cover image quality and dosimetry evaluation, as well as other aspects of device performance that could degrade over time.

Proposed requirements for testing (cont.)

- Manufacturers expected to include quantitative acceptance criteria which are determined by the manufacturers and not based on relative performance when compared to previous QC testing.
- Manufacturers could deviate from the standard's testing procedures only where necessary based on device configuration/features.

In Summary

- Increased reliance on IEC standards will require adjustments on the part of FDA, states, and imaging professionals.
- Availability of standard testing methods could make the transition easier.
- Physicist involvement key to assure good testing methods.
  - Strong participation by U.S. physics community in IEC CT standards development
  - AAPM community not represented in IEC groups for other modalities (e.g. dental).

IEC standard 62494-1 defines which parameter as a vendor-neutral parameter for radiographic image quality:

20%	1. Relative X-ray Exposure
13%	2. Tube Current Time Product
44%	3. Deviation Index
13%	4. Automatic Exposure Control
9%	5. Enter answer text here...

Correct Answer:

- 3: Deviation Index

Seibert JA, Morin RL. The standardized exposure index for digital radiography: an opportunity for optimization of radiation dose to the pediatric population. *Pediatric Radiology*. 2011;41(5):573-581.

Summary of MTs/WG activity and scope

- Description of current activities and responsibilities of maintenance teams and working groups in medical imaging equipment subcommittee in following slides
- MTs without current membership of AAPM member who is not affiliated with the FDA or a manufacturer are noted

CT Maintenance Team (MT30)

- Technical committee 62
- Subcommittee 62B
- Convenor: John Jaeckle

- Information provided by Cynthia McCollough


PHILIPS
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Existing standards overseen by MT 30

- 60601-2-44 Ed. 3: Particular requirements for the basic safety and essential performance of X-ray equipment for computed tomography
- 61223-3-5: Acceptance tests – Imaging performance of computed tomography X-ray equipment
- 61223-2-6: Constancy tests – Imaging performance of computed tomography X-ray equipment

Current work items

- Updating and combining of Acceptance Testing and Constancy Testing standards
- Development of a new standard for SSDE

Meetings

- Semi-annual meetings, rotating between Asia, Europe and US locations
- Web conference calls as needed

Activities of interest

- CTDIvol is not patient dose
- AAPM Report 204 describes the concept and methodology related to determining Size Specific Dose Estimates (SSDE)
- Adoption of SSDE by the ACR Dose Index Registry and others requires a standard implementation by the vendors
- The US initiated a “work item” to develop such a standard, which was approved. The first meeting of the project team was in March 2015.

Mammographic X-ray equipment (MT31)

- Technical committee 62
- Subcommittee 62B
- Convenor: Steven Kachelmeyer

- No AAPM member who is non-FDA or Manufacturer involved as expert

Standards Overseen

- IEC 60601-2-45, Ed. 1: Medical electrical equipment - Part 2-45: Particular requirements for the safety of mammographic X-ray equipment and mammographic stereotactic devices.
- IEC 61223-3-2, Ed. 1: Evaluation and routine testing in medical imaging departments - Part 3-2: Acceptance tests - Imaging performance of mammographic X-ray equipment.

X-ray Tube Assembly Maintenance Team (MT32)

- Technical committee 62
- Subcommittee 62B
- Convener: Tomas Bengtsson

- No AAPM member who is non-FDA or Manufacturer involved as expert

- Information courtesy Brian Lounsberry


TOSHIBA
Taro Toshiba
TOSHIBA

Existing standards maintained by MT 32

- 60601-2-28 ed.2: Particular requirements for the basic safety and essential performance of X-ray tube assemblies for medical diagnosis
- 60336 ed.4: X-ray tube assemblies for medical diagnosis – Characteristics of focal spots
- 60522 ed.2: Determination of the permanent filtration of X-ray tube assemblies
- 60526 ed.2: High voltage plug and socket connections for medical X-ray equipment
- 60613 ed.3: Electrical and loading characteristics of X-ray tube assemblies for medical diagnosis
- 60806 ed.1: Determination of the maximum symmetrical radiation field from a rotating anode X-ray tube for medical diagnosis

Current MT 32 work items

- 60601-2-28 ed.3:
  - Updating for correspondence to edition 3.1 of the 60601-1 General Standard (main purpose of update… currently tied to ed. 3.0)
  - Adding technical improvements along the way
- 60336 ed. 5:
  - Updating mainly to eliminate the use of film for recording slit images; replacing with digital image acquisitions
- 60522 ed. 3:
  - Rewording and reorganizing document for clarity
  - Expanding to cover methods to determine filter QEFs in general (i.e., not limiting to permanent filtration only)

Meetings

- Spring/Fall annual meetings, rotating between Asia, Europe and US locations
- “Homework assignments” and email communications between face-to-face meetings (phone conferences very rare)

Ultrasound safety standards (MT34)

- Technical committee 62
- Subcommittee 62B
- Convenor: John Abbot
- Revision of 60601-2-37: Medical electrical equipment - Part 2-37: Particular requirements for the safety of ultrasonic medical diagnostic and monitoring equipment
- No AAPM member who is non-FDA or Manufacturer involved as expert

Radiation Protection for Radiography(MT37)

- Technical committee 62
- Subcommittee 62B
- Convenor: Ursula Kniesberg

- Maintenances of standards related to radiation protection for Radiography

MRI Safety Maintenance Team (MT40)

- Technical committee 62
- Subcommittee 62B
- Convenor: Georg Frese

- No AAPM member who is non-FDA or Manufacturer involved as expert

- Information courtesy of Michael Steckner

Existing standards overseen by MT 40

- 60601-2-33 Ed. 3.1: Particular requirements for the safety of magnetic resonance equipment for medical diagnosis
  - Amendment #2 has just successfully completed the FDIS vote and anticipated to publish before AAPM annual meeting

Current work items

- Amendment #2:
  - Increasing static magnetic field limit from 4T to 8T to align with other standards
  - The release of FPO:B (Fixed Parameter Option:Basic) to enable the scanning of appropriately labeled active implants using field level output constrained limits (vs patient physiologic safety limits)
  - Limited release of transmit coil technology definitions
- 4th edition major plan: convert from a SAR based RF limit safety approach to a thermal model

Meetings

- Semi-annual meetings, rotating typically between Europe and Washington DC
- Web conference calls as needed

Safety of Image Guided Intervention Equipment (MT 41)

- Technical committee 62
- Subcommittee 62B
- Convenor: Lionel Desponds

- Information courtesy Andrew Kuhls-Gilcrist

Existing standards overseen

- IEC 60601-2-43: Particular requirements for basic safety and essential performance of X ray equipment for interventional procedures

Current work items

- Revision of IEC 60601-2-43

Meetings

- 1/2015: Paris
- 6/2015: Shenyang
- 6/2016: Vienna

Activities of interest

- Alignment with IEC 60601-1 edition 3.1
- Update to reference first amendment of IEC 60601-2-54: Particular requirements for the basic safety and essential performance of X-Ray equipment for radiography and radioscopy
- Update to include aspects from IEC 61910-1: Radiation Dose Documentation – Part 1: Radiation dose structured reports for radiography and radioscopy
- Recommendation to have mapping of estimated skin dose or streaming RDSR
- 10 min recovery for emergency fluoro
- Consideration of touchscreen controls
- Patient support testing for protection against ingress of water

Characteristics of Digital X-ray Imaging Devices (MT 44)

- Technical committee 62
- Subcommittee 62B
- Convenor: Raoul Bastiaens

- Maintenances of standards related to digital x-ray devices

- No active clinical physicist member

Protective devices against diagnostic medical X-radiation(MT 47)

- Technical committee 62
- Subcommittee 62B
- Convenor: Ludwig Buermann

- Maintenances of standards related to protective devices

- No active clinical physicist member

Characteristics of radiographic anti-scatter grids (MT 50)

- Technical committee 62
- Subcommittee 62B
- Convenor: Jos Van Vroonhoven

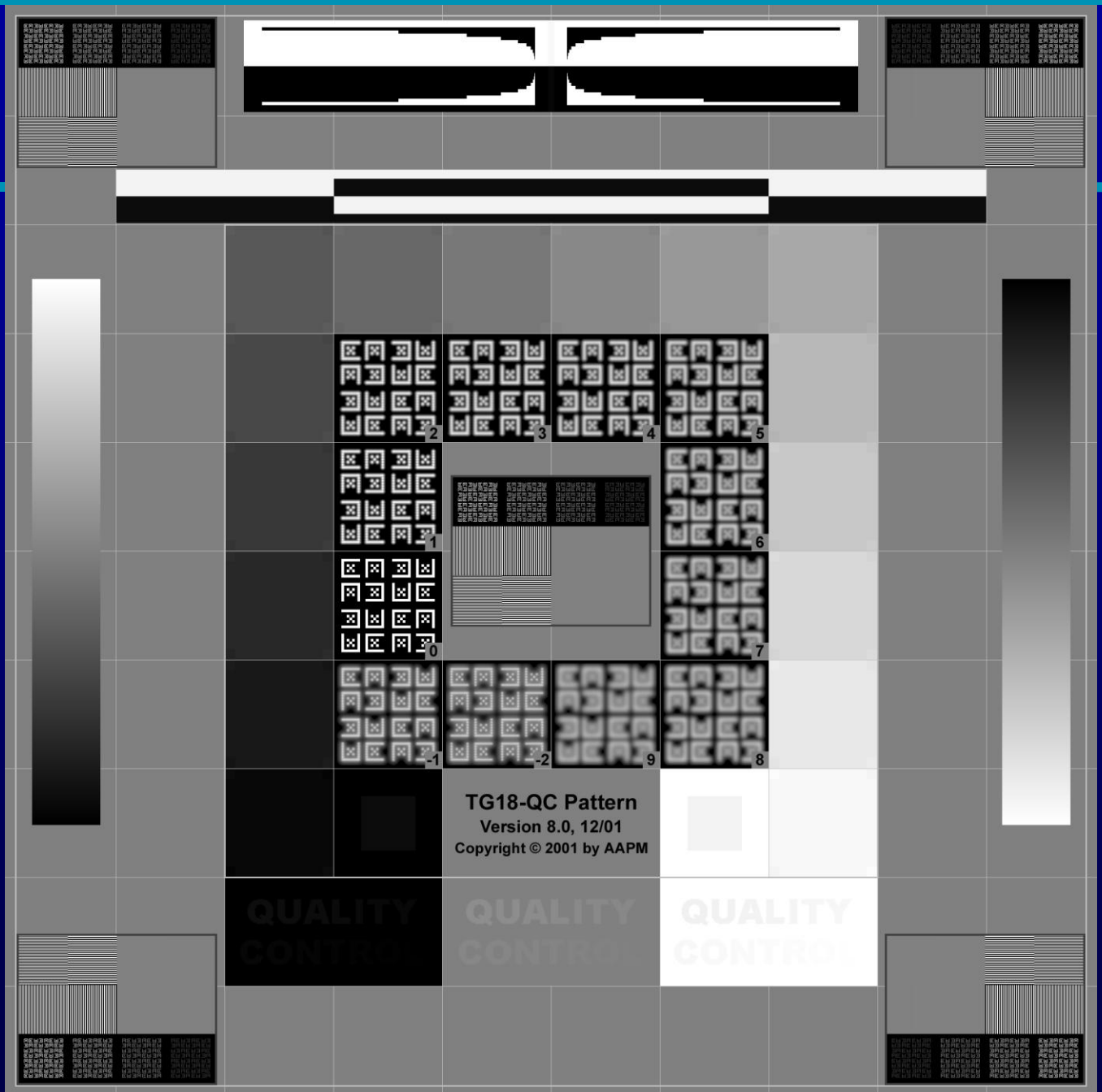
- Maintenances of standards related to anti-scatter grids

- No active clinical physicist member

Medical Displays Maintenance Team (MT51)

- Technical committee 62
- Subcommittee 62B
- Convenor: Aldo Badano

- Information courtesy Aldo Badano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Existing standards overseen by MT51

- 62563-1: Medical image display systems – Part 1: Evaluation methods

Current work items

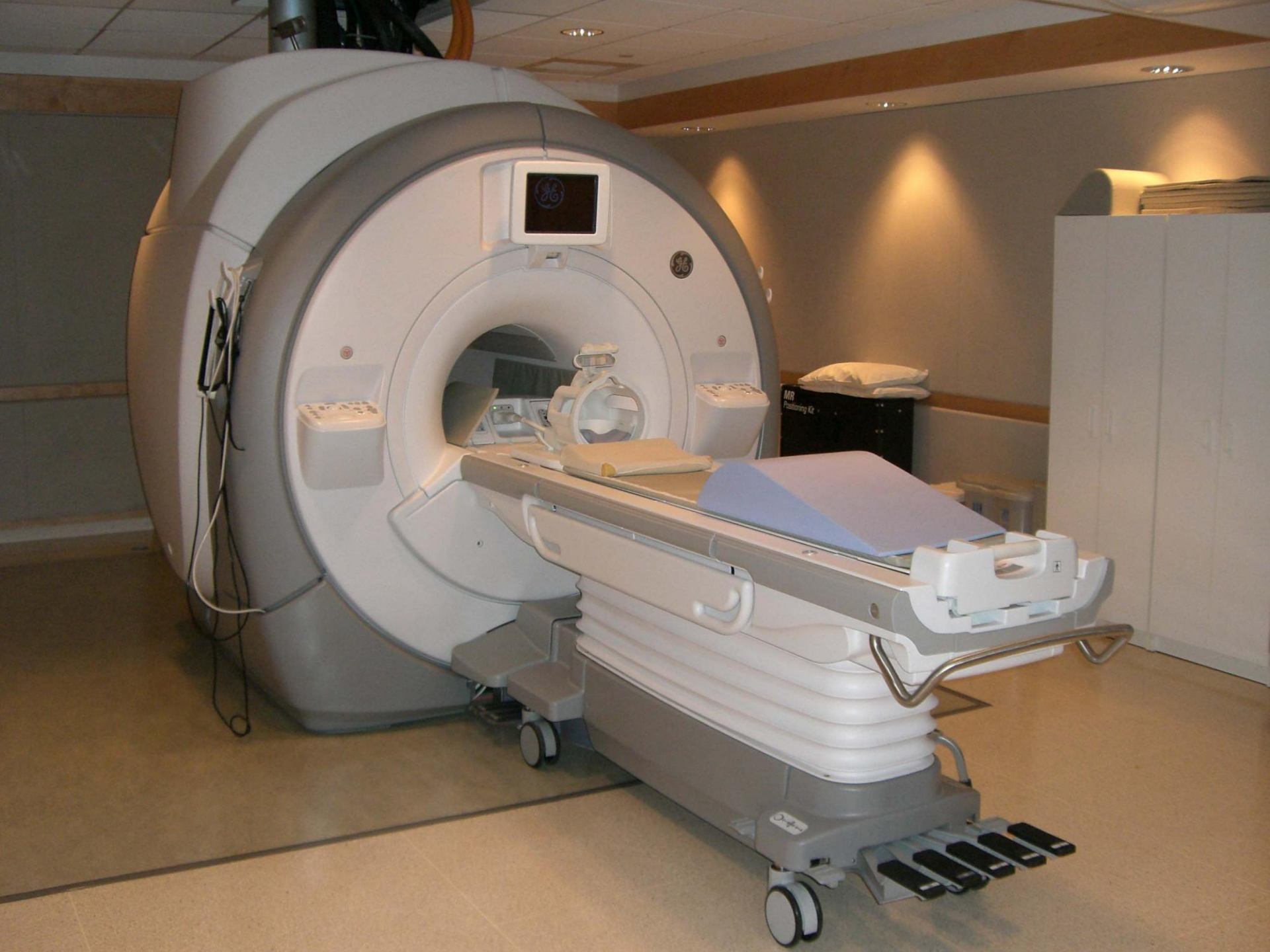
- 62563-1-1: Grayscale tracking methods (out for vote)
- Updating 62563-1 for handheld image viewers
- Updating 62563-1 for volumetric displays

Meetings

- Semi-annual meetings, rotating between Asia, Europe and US locations
- Web conference calls at least twice a year

MRI System Performance Maintenance Team (MT52)

- Technical committee 62
- Subcommittee 62B
- Convenor: Michael Steckner (USA)
- Committee just formed


MR
Positioning Kit

Existing standards overseen by MT 52

- 62464-1 Ed. 1.0: Determination of essential image quality parameters
- 62464-2 Ed. 1.0: Classification criteria for pulse sequences.

Current work items

- 62464-1
  - 62464-1 is beyond its “stability date”
  - First goal: renew, update. Heavily based on old versions of selected NEMA/MITA MS series standards
  - Otherwise: correction of errors. Additionally perhaps new tests, methods?
- 62464-2
  - Will address at future date

Meetings

- MT52 just formed
- Anticipate significant use of web conference calls

*Safety of Active Implants in MRI (*JWG1*)*

- JWG: Joint Working Group between ISO and IEC
- Co-Convenor: Curt Sponberg (USA - ISO)
  - ISO TC150/SC6/JWG2
- Co-Convenor: Michael Steckner (USA – IEC)
  - IEC SC62B/JWG1

Existing standards overseen by JWG1

- ISO/IEC TS 10974 Ed. 1.0: Assessment of the safety of magnetic resonance imaging for patients with an active implantable medical device
  - TS (Technical Specification)
  - Its not a standard yet. This is first stage towards a full international standard

Current work items

- TS 10974 Ed. 2: Nearing final draft completion. Focus on further development of testing methodology, clarity, necessary prescriptive details
  - Publication anticipated early 2016
- Work on a further TR (Technical Report) to provide uncertainty assessment details related to RF exposures
- Intent to start work on the next edition (international standard) in 2016

Meetings

- Tri-annual meetings, rotating between Europe and Washington DC
- Comprised of multiple sub-groups focused on the specific clauses (each clause details a specific risk to patient) within TS. Sub-groups start/end when clause work finish, committee reforms next set of sub-groups as members available
- Numerous web conference calls per sub-group

Activities of interest

- The development of test methods that can be used to ascertain appropriate MR conditional scanning limits.
- Implant standards historically under ISO.
  - ISO standards: implant related patient safety
  - IEC 60601-2-33: MRI patient safety
  - JWG1 (TS10974): the safety interface between implants/MR scanners

NEMA/MITA MRI PERFORMANCE STANDARDS (MR Tech Committee)

- NEMA (National Electrical Manufacturers Association)
- MITA (Medical Imaging & Technology Alliance)
- NEMA “MS1-12” series of standards
- Chair: Michael Steckner

Existing standards overseen MITA

- MS 1-2008 Determination of Signal-to-Noise Ratio (SNR) in Diagnostic Magnetic Resonance Imaging
- MS 2-2008 Determination of 2D Geometric Distortion in Diagnostic Magnetic Resonance Images
- MS 3-2008 Determination of Image Uniformity in Diagnostic Magnetic Resonance Images
- MS 4-2010 Acoustic Noise Measurement Procedure for Diagnostic Magnetic Resonance Imaging (MRI) Devices
- MS 5-2009 Determination of Slice Thickness in Diagnostic Magnetic Resonance Imaging

Existing standards overseen MITA (cont.)

- MS 6-2008 Determination of Signal-to-Noise Ratio and Image Uniformity for Single-Channel, Non-Volume Coils in Diagnostic Magnetic Resonance Imaging (MRI)
- MS 7-1993 Measurement Procedure for Time Varying Gradient Fields (dB/dt) for Magnetic Resonance Imaging Systems (rescinded: now in IEC 60601-2-33)
- MS 8-2008 Characterization of the Specific Absorption Rate (SAR) for Magnetic Resonance Imaging Systems
- MS 9-2008 Characterization of Phased Array Coils for Diagnostic Magnetic Resonance Images (MRI)

Existing standards overseen MITA (cont.)

- MS 10-2010 Determination of Local Specific Absorption Rate (SAR) in Diagnostic Magnetic Resonance Imaging
- MS 11-2010 Determination of Gradient-Induced Electric Fields in Diagnostic Magnetic Resonance Imaging
- MS 12-2010 Quantification and Mapping of Geometric Distortion for Special Applications

Current work items

- MS-8 SAR Determination: Major overhaul considers higher fields, larger patient apertures, emergence of multi-channel birdcage transmit coils
- All standards are on a 5 year “review, revise, rescind” schedule
- Other technical work items as NEMA/MITA MR vendor membership deems necessary
  - e.g. Request from FDA to develop a consistent set of transmit technology definitions to be used in regulatory submissions (e.g. implant industry). First developed by NEMA/MITA, transferred to MT40, to release in A#2

Meetings

- Various as needed, occasionally in conjunction with NEMA MR Section committee (regulatory issues) typically at NEMA/MITA headquarters in Washington DC (Rosslyn, VA)
- Frequent web conference calls

Activities of interest

- The Technical committee devoted to issues of mutual concern among member MR vendors (Alltech, GE, Hitachi, IMRIS, Philips, Siemens, Toshiba). This supports the work of the MR Section committee which discusses regulatory issues.

IEC standard 62464-1 focused on MRI defines parameters for the evaluation of:

58%	1. Image Quality
6%	2. dB Levels
30%	3. Stray Magnetic Fields
3%	4. Scan Speed
3%	5. Reconstruction Algorithms

Correct Answer:

- 1: Image Quality

MRI quality assurance using the ACR phantom in a multi-unit imaging center, Toni M. Ihalainen , Nadja T. Lönnroth , Juha I. Peltonen , Jouni K. Uusi-Simola, Marjut H. Timonen , Linda J. Kuusela , Sauli E. Savolainen , Outi E. Sipilä. Acta Oncologica 2011 50:6 , 966-972

Thank You