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COMP Canadian Organization of Medical Physicists
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Member of / Membre de IOMP

29 November, 2018

Richard Smith
Chief, Ionizing Radiation Physical Sciences Division
Consumer and Clinical Radiation Protection Bureau
Health Canada / Government of Canada
richard.smith3@canada.ca

Dear Mr Smith,

Safety Code 26 (1987), Guidelines on Exposure to Electromagnetic Fields from Magnetic Resonance Clinical Systems, was developed in the very early days of MRI. Since then the technology, applications and associated safety concerns have grown substantially and Safety Code 26 is now very much outdated. A new safety code for MR, or a substantially revised Safety Code 26, would become a significant cornerstone in the establishment of consistency for MR patient care and safety throughout the nation. A COMP position statement in 2014 advocated for the development of an MR safety code modeled after Safety Code 35. As active and significant stakeholders in this field, the COMP Imaging Committee is here to help Health Canada with such an endeavour.

It is our recommendation that a new MR Safety Code document should (at minimum): a) encompass all current and reasonably foreseeable MR technology, b) provide an updated and expanded safety discussion that includes siting (e.g. safety zones), staffing guidelines and operational considerations and c) include specific recommendations related to Quality Assurance. A further suggestion is to ensure that the safety code considers research facilities and pre-clinical scanners as appropriate so that the document does not inadvertently impede the activities of these important facilities.

More specifically, the MR Safety Code should include recommendations related to at least the following:

A. Technology:

   a. high magnetic field strength systems (Safety Code 26 considers only ≤ 2T)

   b. specialty MR scanners (e.g. PET/MR, extremity systems, MR-guided radiation therapy devices such as MR-FUS and MRgRT)

   c. MR systems with high gradient pulse amplitudes and switching rates

   d. systems with parallel transmit RF technology

B. Safety:

   a. Siting safety zones similar to those proposed by the American College of Radiology

b. Guidelines for patient screening

c. Medical devices (active, e.g. stimulators, and passive, e.g. stents), testing & labeling standards

d. Guidelines for who can operate an MR scanner and under which circumstance (for both clinical and pre-clinical scanners)

e. Safety training and credentials

f. Patient and health care worker exposure levels to:

   i. Radiofrequency energy

   ii. Static magnetic fields,

   iii. Magnetic field gradients – both static and time dependent,

   iv. Acoustic noise,

g. Pregnancy

h. Healthy volunteers

i. Cryogens and quenches

j. Gadolinium-based contrast agents

C. Quality Assurance:

a. Statement on the requirements for quality assurance for MR systems

b. Roles of personnel in carrying out a Quality Assurance program

c. Itemization of Acceptance Testing and Quality Control tests (like Safety Codes 35 and 36)

d. Adherence to good clinical practice guidelines

The expertise of imaging medical physicists from across the country that are members of our organization is a unique and valuable resource. If Health Canada decides to undertake the development of a new MR Safety Code document, we would be pleased to be invited to become involved.

Sincerely,

COMP Imaging Committee

References:

1) American College of Radiology Quality Control Manual for MRI. 2015.

2) Acceptance Testing and Quality Assurance Procedures for Magnetic Resonance Imaging Facilities, American Association of Physicists in Medicine report #100, 2010.

3) Canadian Organization of Medical Physicists. Position Statement: Imaging Medical Physics in Canada. InterActions. 2014;60(1):12-13). Available here.

4) Expert Panel on MR Safety, Kanal E, Barkovich JJ, Bell C, Borgstede JP, Bradley WG, et al. ACR guidance document on MR safe practices: 2013. Journal of Magnetic Resonance Imaging. 2013 Mar;37(3):501-530.

5) Tsai LL, Grant AK, Mortele KJ, Kung JW, Smith MP. A Practical Guide to MR Imaging Safety: What Radiologists Need to Know. Radiographics. 2015 Oct;35(6):1722-1737.