




MRI Risk Assessment - New Guidelines / Safety Requirements

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The Design of All New MRI Facilities Now Requires Consideration of Ferromagnetic Screening Technology

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February/2010

Dear Joseph,

This newsletter highlights some significant changes to the design requirements surrounding all new MRI facilities, namely the requirement for provisions addressing the incorporation of ferromagnetic detection technology. This modification is hardly surprising when one considers the growing consensus toward ferromagnetic detection technology shared by a multitude of accrediting bodies. While this requirement essentially applies to the design of new facilities, over time this would logically lay the ground work for an accreditation standard.

Additionally, the eight year legal battle surrounding the death of Michael Colombini in 2001 has been settled between the parents of Michael Colombini and Westchester County Medical Center for \$2.9M. While many things have changed since this tragic incident, the potential for equally tragic incidents remains as great as it was in 2001. A southern California hospital was recently fined for injuries suffered by a patient when a transfer gurney comprised of ferromagnetic material was brought into the MRI suite. While the facility subsequently implemented remedial measures as a direct result of this incident, they appear at first blush to be insufficient to dramatically reduce the potential for similar incidents.

The outcome of this growing movement of recommendation, design requirement, acknowledgement of liability and regulatory fines is a generally perceived standard of care within the MRI facility. A standard of care that requires adoption of the ACR Four Zone Principle and effective and enforced screening procedures utilizing properly implemented ferromagnetic detection technologies.

New MRI Design Requirements



The Guidelines for Design and Construction of Health Care Facilities were revised last month in accordance with their scheduled revision cycle and significant modifications specific to design configuration requirements for MRI suites were included.



One important addition is the requirement for design professionals to include provisions for the siting of ferromagnetic detection systems. Additionally, the American College of Radiology "Guidance Document for safe MR Practices" is also cited therein as a conformance document, in which ferromagnetic detection technology is specifically recommended. These important updates reflect the evolving standard of care within the

imaging suite and the proper integration of ferromagnetic detection technology as endorsed by the Joint Commission, the Department of Veterans Affairs, the American Society for Healthcare Engineering and the American College of Radiology.

The American Society for Healthcare Engineering and the American Hospital Association, in collaboration with the Facility Guidelines Institute, have released the 2010 revision Guidelines after extensive discussion, analysis and consensus from experts representing every aspect of healthcare facility design. The framework is shaped by the highest level of experience, present knowledge and current technologies. Consequently, these Guidelines form the reference base utilized by the Joint Commission as well as the vast majority of state health departments in the review of facility design.

2.2-3.4.4.2 Design configuration of the MRI suite

- (1) Suites for MRI equipment shall be planned to conform to the four-zone screening and access control protocols identified in the American College of Radiology's "Guidance Document for Safe MR Practices."
- (2) The layout shall include provisions for the following functions:
 - (a) Patient interviews and clinical screening
 - (b) Physical screening and changing areas (as indicated)
 - (c) Siting of ferromagnetic detection systems
 - (d) Access control
 - (e) Accommodation of site-specific clinical and operational requirements

Guidelines for Design and Construction of Health Care Facilities (2010 Edition) (excerpt) (Full guidelines available through the Facilities Guidelines Institute)

Litigation in Colombini Case Concludes

New York State Supreme Court

Settlement details released in \$2.9M Colombini MRI suit
By Wayne Forrest
AuntMinnie.com staff writer
February 5, 2010

A New York court has released the details of a \$2.9 million legal settlement received by the parents of a 6-year-old boy who was killed nine years ago when an oxygen canister was brought into the MRI suite where he was being scanned.

The parents of Michael Colombini reached the settlement with Westchester County Health Care of Valhalla, NY. Details of the settlement, which was formally agreed upon in October 2009, became official and made public on January 21 by the Supreme Court of the

State of New York for Westchester County.

In July 2001, the youngster was anesthetized and placed in an MRI scanner for follow-up after surgery to remove a benign brain tumor. When the boy began to suffer respiratory distress, the MRI staff tried to use the suite's built-in oxygen supply, but it did not work. When someone brought a portable steel oxygen tank into the room, the magnetic force of the MRI scanner pulled the tank toward the system. The tank struck the boy in the head, and he died two days later.

The parents initially brought a \$20 million lawsuit against Westchester Medical Center and its parent company, Westchester County Health Care; Dr. Terence Matalon, who was the center's chief of radiology at the time of the incident but was not present when the death occurred; two of the radiologic technologists who were present at the time of the accident; and GE Healthcare of Chalfont St. Giles, U.K., manufacturer of the MRI system.

GE was dismissed as a defendant in the case in a pretrial motion, and the settlement discontinues with prejudice any previous action against the company. The agreement also discontinues any actions with prejudice against Westchester County Health Care staff who were named in the lawsuit, including Matalon.

By Wayne Forrest
AuntMinnie.com staff writer
February 5, 2010

(Copy of Settlement -

http://www.newyorkinjurycasesblog.com/uploads/file/Colombini%20v_%20Westchester%20-%20Compromise%20Order.pdf)

Southern California Hospital Fined

Published: Jan. 22, 2010

Updated: 7:13 p.m.



By COURTNEY PERKES

THE ORANGE COUNTY REGISTER

Hoag Hospital has been fined \$50,000 by the state Department of Public Health after an MRI patient on a metal gurney was magnetically pulled into the imaging machine, the hospital said Friday. In a memo to staff, Dr. Richard Afable, chief executive officer of Hoag Memorial Hospital Presbyterian, described the scenario and policy changes to prevent future incidents. He was in Los Angeles on Friday and could not be reached for comment.

Afable said that last January a woman was taken into an MRI room on a metal gurney that was not compatible with the machine. The

powerful magnet in the MRI pulled the gurney into the machine and the patient's leg was trapped for about three minutes. She was taken to the

emergency room and spent three days in the hospital for treatment of fractures in her lower leg and foot. Hoag failed to follow its policy of not allowing gurneys that are not MRI safe in the hallways outside the testing room, Afable said. The hospital has adopted new procedures including a checklist that must be done before entering the MRI room and installation of a camera for monitoring.

"The fact is no system is infallible, but we have strengthened our system due to this event and feel strongly that we can prevent anything similar from happening again," Afable wrote. "We have shared what we have learned with the medical community in order to prevent similar events from occurring at other MRI facilities."

The fine is the hospital's third since 2007, when the state began penalizing hospitals for incidents likely to cause serious injury or death to patients. Last year, Hoag was fined \$25,000 for failing to follow physician's orders for continuous monitoring of a heart patient, which resulted in death, the state said. In 2008, Hoag received a \$25,000 penalty for leaving a sponge in a cancer patient's body during surgery. The state has since increased the penalties to \$50,000.

<http://www.ocregister.com/articles/mri-230615-hospital-hoag.html>

For more information on Metrasens, our Ferromagnetic Detection Technology or how we can assist you in raising the safety level of your facility, please visit our website at <http://www.metrasens.com>

Sincerely,

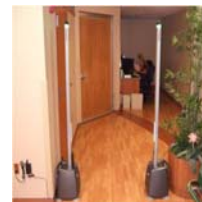


Joseph Barwick
Vice-President - North America
Metrasens

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