MR SAFETY POLICIES AND PROCEDURES

Triad Radiology Associates (TRA) has developed this MR Safety Manual to educate all MR personnel regarding safety in the MR environment at the facilities it serves. In addition to the TRA Manual, each MR facility may have unique policies that reflect its specific department or MR environment. It is the responsibility of the MR personnel to familiarize themselves with and abide by any such policies.

Questions and comments related to the TRA MR Safety Manual are welcome at any time. For additional or more specific information, MR personnel should read the *ACR Guidance Document on MR Safe Practices: 2013* (Kanal 2013) as it serves as the basis for the TRA Manual. Furthermore, MR personnel are encouraged to browse periodically the US Food and Drug Administration (FDA) Manufacturer and User Facility Device Experience (MAUDE) (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/search.cfm). This on-line database houses reports on medical devices that may have malfunctioned or caused a death or serious injury

PERIODIC REVIEW OF TRA MR SAFETY MANUAL

A continuous "works in progress," this Manual is updated as needed to reflect changes in technology or our practices. However, the MR Medical Director, the MR physicist, and the MR personnel who perform safety screenings must review it annually. While the MR physicist may document his/her review of the Manual in his/her report summarizing the annual MR equipment evaluation, each MR facility is responsible for documenting the annual review by its MR personnel.

Warnings or precautions are highlighted like this in the Manual.

Guidelines and reminders are emphasized and highlighted like this in the Manual.

TRA MR MEDICAL DIRECTOR

The TRA MR Medical Director oversees the MR Safety Program. Accordingly, he/she shall try and ensure that safe MR practice guidelines are established and maintained. At each facility that offers MR imaging services, Radiology Administration (i.e., the Director, Manager, MR Supervisor and/or Lead MR Technologist) shall use their best efforts to ensure that all policies and procedures resulting from the safe practice guidelines are adhered to at all times by facility personnel.

REPORTING OF MR SAFETY NEAR MISSES, INCIDENTS, AND ADVERSE EVENTS

MR Medical Director, Radiology Administration, and Facility Risk Management

Any and all safety-related near misses, incidents, or adverse events that occur in MR must be reported to the Medical Director and Radiology Administration within 24 hours or one business day of the occurrence. Such incidents should also be reported to

the facility Risk Management and should be considered for continuous quality improvement efforts. Such events help TRA and Radiology Administration learn about how to prevent recurrence and better avoid MR safety related issues in the future.

FDA MedWatch

TRA strongly recommends that any MR-related accident be reported to the FDA via MedWatch, the FDA Safety Information and Adverse Event Reporting Program (https://www.fda.gov/Safety/MedWatch/default.htm).

PRIMARY MR HAZARDS

Magnetic resonance (MR) utilizes three variants of magnetic fields to generate images:

- a strong static magnetic field (B_o),
- radiofrequency (RF) magnetic fields (B_1), and
- time varying magnetic field gradients (dB/dt).

Each of these components presents its own set of unique safety hazards – hence the MR safety program is designed to mitigate the risks of each. MR personnel are tasked with preventing or limiting the mechanical effects, heating effects, and electromagnetic effects that are inherent to the MR environment that may harm patients, visitors, ancillary team members, and equipment.

Static Magnetic Field (B_o)

Safety issues related to the strong static magnetic field include potential biological effects and various mechanical effects resulting from various forces that may ultimately cause patient discomfort or injury or may damage medical devices. Table 1 specifies the static magnetic field strengths above which the FDA considers "significant risk."

Biological Effects

When an electrical conducting fluid (such as blood) flows in an applied magnetic field, a transverse electromotive force (EMF) is developed that is proportional to the flow velocity and the field strength. This EMF induces small currents in tissues that in turn leads to small electric voltages on the body surface that can be detected by the use of metal electrodes on the skin. It actually produces a large signal during the T-wave phase of the cardiac cycle – hence this magneto-hemodynamic effect contributes to the difficulty in obtaining acceptable ECGs during MR procedures.

Bulk physical movement (like rapid head turning or rapid movement into or out of the magnet) also induces electrical currents throughout tissue – and these weak currents activate highly sensitive sensory tissues. For example, individuals who move their eyes rapidly while in the magnetic field in a darkened room may experience sensations of brief flashing lights called "magnetophosphenes."