

RISK ASSESSMENT RECORD FORM

Please refer to the accompanying guidance when completing this form

Section 1: Administrative Details

Name of Assessor: Job Title: Date of Assessment:

Section 2: Activity/Task

Activity /Task

Provision of an MRI service

Risk:

Heating/burns to patient tissue due either to direct heating by RF radiation or to heating of objects in contact with patient's skin

Area affected:

MRI

Source of Risk (Background):

Induction of currents in conducting objects in contact with a patient's skin due to RF magnetic fields can lead to extreme heating resulting in burns. Such objects can include ECG leads, pulse oximeter and other monitoring probes, some types of make-up and some piercings and tattoos. Furthermore if the patient is poorly positioned in the scanner (e.g. in contact with the bore, arms/legs touching to form current loops), direct heating of tissue can also result in burns.

Supporting Evidence:

Published data on hazards in MRI. MHRA guidelines on safe use of MRI [1].

Factors the risk contains: (if for COSHH include route of exposure, length of exposure time and exposure limits)
RF heating.

Potential Consequence if risk is realised:

- Serious injury due to RF burns.

Section 3: Current Control Measures

The scanner is CE marked and meets the requirements of IEC 60601-2-33 [2]. This standard limits the RF power deposited into the patient's body using three operating modes: normal, first level controlled, second level controlled. In the absence of medical devices or other conducting objects implanted in or in contact with the patient's body, the scanner is safe if operated in accordance with the manufacturer's Instructions for Use.

When ECG monitoring is used within the scanner, high impedance / carbon fibre ECG leads and electrodes are used, or wireless monitoring is used.

Pulse oximeter leads used within the scanner are fibre optic to prevent current induction.

Comment [SK1]: Sites may wish to add other devices to this list in accordance with local needs.

Staff are trained in correct placement of MRI coils, cables and patients to minimise risk of direct thermal or RF burns.

Patients are given a 'panic button' and asked to press it if they feel heating, e.g. around tattoos

Leads are regularly inspected by staff for signs of damage.
Section 4: Risk Rating <i>Use the consequence, likelihood and risk score tables in the accompanying guidance to identify the scores below.</i>
Consequence Score:
Likelihood Score:
Risk Score:
Initial Risk Grading:

Section 5: Risk Reduction Options		
Options	Revised Risk Score	Cost
No further reduction required.		

Section 6: Directorate/Divisional Agreed Actions		
Actions	Lead	Target Date

Section 7: Risk Grading				
	Consequence	Likelihood	Score	Grade
Initial:				
Current (will be the same as initial to begin with):				
Residual:				

Section 8: Review
Risk Owner:
Planned Review Date:

Reference
[1] D. Grainger, "Safety Guidelines for Magnetic Resonance Imaging Equipment in Clinical Use," Medicines and Healthcare Products Regulatory Agency, Mar. 2015.
[2] IEC (2015) standard 60601-2-33, ed 3 am 2