NHS Greater Glasgow and Clyde

ID: DR-GGC-RISK-050

Risk Assessment Form

Use this form for any detailed risk assessment unless a specific form is provided. Refer to your Summary of Hazards/Risks and complete forms as required, including those that are adequately controlled but could be serious in the absence of active management. The Action Plan and reply section is to help you pursue those requiring action.

Name of Initial Assessor/Reviewer:	John McLean	**Post Held:**	MR Safety Expert
Department:	**Imaging**	**Date (Initial Review):**	**2/4/2015**

Subject of Assessment: E.g.: hazard, task, equipment, location, people

Scanning pregnant patients in MRI using First Level Controlled Mode

Hazards (Describe the harmful agent(s) and the adverse consequences they could cause)

The hazards of concern in this risk assessment are the RF field and imaging gradients and their impact on the foetus when using 1st Level Mode (also known as Controlled Mode).

Scanning pregnant patients in Normal Mode or use of GBCA's during pregnancy have been addressed in separate risk assessments. Similarly, noise considerations in pregnant patients undergoing MRI have also been addressed elsewhere.

Description of Risk

Whilst there has been concern about the effects of MRI on the foetus in the past, to date, there have been no demonstrated adverse effects to mother or foetus as a result of the mother having had an MRI scan during pregnancy. The MHRA guidelines state that "pregnant patients be scanned in Normal Mode wherever possible".

However, it may be the case that it is necessary to go to 1st Level Mode (also known as Controlled Mode) to complete the patient scanning, depending on the nature of the patient request. There is similarly no evidence to suggest that 1st Level Mode has caused any adverse event to mother or foetus, but this mode does allow greater heating of the patient as well as increasing the likelihood of peripheral nerve stimulation. The MHRA guidelines go on to further state that if a scan needs to be conducted in 1st Level Mode the decision to do so should be based on a risk-benefit analysis and should be discussed between the referring clinician, an MR Radiologist and the patient.

Implementing such a policy is not easily done in practice; a Radiographer might be half way through an MRI examination protocol when it is apparent that the scan will need to continue in 1st Level Mode. To start to consider the risks and benefits at this stage and to try and contact the referrer and Radiologist let alone discuss with the patient the implications of this is simply not practicable. Given that there is no evidence to suggest a clear risk of running the scan in 1st Level Mode on a pregnant patient our recommendation is that 1st Level Mode should be used if it is necessary in order to complete the clinical scanning protocol.

It is important to remember that the MRI scan has been vetted and thus that there is a clear clinical indication and therefore benefit to the patient from the scan being conducted. If the pregnancy was unknown at the time of referral, a Radiologist must be made aware and asked to justify the examination with this additional information, as described in the pregnancy pathway.

Existing Precautions	**Describe how they might fail to prevent adverse outcomes.**
If a scan protocol is likely to require First Level Mode, the Radiologist must justify this in advance. Prior to beginning the scan on a pregnant patient, the Radiographer should	

explain to the patient that scanning will begin in Normal Mode but that it might be necessary to scan in 1st Level Mode. They should explain the implications of this to the patient i.e. that this might result in slightly more heating but that there have been no known adverse effects to the mother or child as a result of pregnant patients having had MRI scans. If the patient is unhappy that any scanning be done in 1st Level Mode, then scanning can only proceed in Normal Mode. This may mean certain sequences may need altered or may not be able to be acquired. If the patient is happy that 1st Level Mode may need to be used then scanning should begin in Normal Mode with 1st Level Mode only being used if it is necessary for the clinical scans to be completed.	

Level of Risk - Is the control of this risk adequate?
Give more than one risk level if the assessment covers a range of circumstances. You can use the 'matrix' to show how 'likelihood' and 'consequences' combine to give a conclusion. Also, be critical of existing measures: if you can think how they might fail, or how they could be improved, these are indications of a red or orange risk.

Risk Matrix

Likelihood	**Impact/Consequences**				
	Negligible	**Minor**	**Moderate**	**Major**	**Extreme**
Almost Certain	Medium	High	High	V High	V High
Likely	Medium	Medium	High	High	V High
Possible	Low	Medium	Medium	High	High
Unlikely	Low	Medium	Medium	Medium	High
Rare	Low	**Low**	Low	Medium	Medium

Very High **High** **Medium** **Low**

Current risk level

Given the current precautions, and how effective and reliable they are, what is the current level of risk? **Green** is the target – you have thought it through critically and you have no serious worries. Devise ways of making the risk green wherever you can. **Yellow** is acceptable but with some reservations. You can achieve these levels by reducing the inherent risk and or by effective and reliable precautions.
High (Orange) or Very High (Red) risks are unacceptable and must be acted on: use the Action Plan section to summarise and communicate the problems and actions required.

Action Plan (if risk level is **High (Orange) or Very High (Red)**

Use this part of the form for risks that require action. Use it to communicate, with your Line Manager or Risk Coordinator or others if required. If using a copy of this form to notify others, they should reply on the form and return to you. Check that you do receive replies.

Describe the measures required to make the work safe. Include hardware – engineering controls, and procedures. Say what you intend to change. If proposed actions are out with your remit, identify them on the plan below but do not say who or by when; leave this to the manager with the authority to decide this and allocate the resources required.

Proposed actions to control the problem List the actions required. If action by others is required, you must send them a copy	By Whom	Start date	Action due date

Action by Others Required - Complete as appropriate: (please tick or enter YES, name and date where appropriate)

Report up management chain for action	
Report to Estates for action	
Contact advisers/specialists	
Alert your staff to problem, new working practice, interim solutions, etc	

Reply

If you receive this form as a manager from someone in your department, you must decide how the risk is to be managed. Update the action plan and reply with a copy to others who need to know. If appropriate, you should note additions to the Directorate / Service Risk Register.

If you receive this as an adviser or other specialist, reply to the sender and investigate further as required.

Date of last review As per QPulse record **Next review date:** As per QPulse record