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| **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:**  Occupational exposure to electromagnetic fields (EMF) | | |
| **Area affected:**  MRI | | |
| **Source of Risk (Background):**  Three types of electromagnetic field are employed in MRI, and each is associated with physiological effects.   * Exposure to strong static magnetic fields, particularly when there is rapid motion of the head, is associated with transient sensory effects such as vertigo, nausea, and a metallic taste. These effects resolve once the movement stops or the affected person is removed from the field. There are no known longer-term health consequences. These effects can only occur if an individual is very close to the magnet. * Exposure to the switched magnetic field gradients used in MRI can result in peripheral nerve stimulation, which at sufficiently high levels of exposure can result in intolerable pain. This can only occur if an individual is inside the scanner or very close to the bore of the magnet (wthin 0.5-1 m) while imaging is taking place * Exposure to RF magnetic fields can result in excessive tissue heating. In practical terms, this can only occur if an individual is inside the scanner during imaging.   Additionally, all three types of electromagnetic fields may cause malfunction of implanted medical devices.  The Control of Electromagnetic Fields at Work Regulations 2016 [1] place an obligation on employers to assess occupational EMF exposure, perform risk assessments, put appropriate control measures in place, and provide workers with appropriate information and training.  The Regulations contain exposure limit values (ELVs) for occupational exposure to EMFs, but the development, testing, installation, use and maintenance of, or research related to, MRI equipment for patients in the health sector is exempted from these ELVs, subject to certain conditions. The HSE has also exempted certain MRI activities that do not fall within this definition.  The conditions that apply to the exemptions are as follows.   * The exposure of employees is reduced to the lowest level reasonably practicable\*; and * Employees are protected against the health effects and safety risks arising from their exposure to electromagnetic fields.   There is copious evidence (e.g. Capstick et al 2008) [2] to show that MR workers can exceed the ELVs for time varying magnetic fields when they move around in the vicinity of the MR scanner and if they are close to the scanner (within 0.5-1.0 m) while images are being acquired. There may be exceptional circumstances in which the limits for exposure to RF fields may be exceeded.  \*Since the transient physiological effects encountered in MRI only occur above a particular exposure threshold (although this threshold may vary somewhat between individuals), there is no need for further reduction of exposure below that level. Thus ALARP effectively only applies at exposure levels at which effects may occur, which only arise within approximately 0.5-1 m from the scanner.  Additionally, the Regulations contain an action level (AL) for a static magnetic field of 0.5 mT, above which employers in the UK are required to make a suitable and sufficient assessment of the risks to employees arising from their exposure to electromagnetic fields and subsequently eliminate or reduce to a minimum, so far as is reasonably practicable, the risks identified in the most recent risk assessment. This risk assessment must include consideration of Action Levels as well as multiple other factors, including other health and safety related information.  This 0.5 mT static magnetic field limit comes from the EU Physical Agents Directive (2013) which in turn comes from ICNIRP guidance (2009) which in turn references IEC 60601-2-33 (2002). More recently, the 4th edition of IEC 60601-2-33 (2023) has relaxed the limit from 0.5 mT to 0.9 mT, more closely aligning it with the limit in other medical device standards (esp. that for pacemakers, ISO 14117). However, the UK committee has concerns about the lack of evidence presented in the standard to demonstrate that a relaxation from 0.5 mT to 0.9 mT is appropriate for all medical implants, since the only international standards prescribing medical devices to be unaffected by static magnetic fields of flux density of up to 1 mT (± 0.1 mT) are for cardiac pacemakers and ICDs (e.g. ISO 14117).  There are no known reported incidents of medical devices malfunctioning when exposed to magnetic fields up to 1.0 mT. | | |
| **Supporting Evidence:**  Published data on hazards and EMF exposure (e.g. [2]) in MRI. MHRA guidelines on safe use of MRI [3].  HSE guidance on The Control of Electromagnetic Fields at Work Regulations 2016. | | |
| **Factors the risk contains:** *(if for COSHH include route of exposure, length of exposure time and exposure limits)*  Electromagnetic fields. | | |
| **Potential Consequence if risk is realised:**   * Transient physiological effects. * Malfunction of implanted medical devices | | |
| **Section 3: Current Control Measures** | | |
| These risks are well understood by the MRI community and have been managed on a daily basis since the first clinical MRI scanners in the mid 1980s.  MR staff only remain in the scanner room during imaging if it is necessary, e.g. to care for a patient or perform clinical procedures.  MR staff only approach within 1 m of the magnet if it is necessary e.g. for cleaning, testing set-up or operation of the scanner or to perform clinical procedures.  Sensory effects are reduced to the lowest level reasonably practicable by avoiding, where practicable, rapid head movements in close proximity to the scanner and/or being inside or in close proximity to the MRI machine bore during scanning when the gradient and RF fields are applied.  Staff are protected against the health effects and safety risks posed, by inclusion of information about these risks and how to avoid them in MRI safety training.  All staff are screened for anything that might put them at higher risk from exposure to EMFs and are further restricted from exposure if appropriate, for example:   * pregnant staff are not allowed in the MR Environment during scanning (while the gradient magnetic fields are in operation) because of the risk of excessive acoustic noise exposure to the fetus; for this reason workers are encouraged to advise their line manager in writing if they become pregnant; * staff with implanted medical devices are not given unrestricted access to areas where their device is exposed to a static magnetic field strength great than [enter locally defined threshold here].   Where an employee reports experiencing a health effect and that employee is believed to have been exposed to EMFs exceeding any ELV, health surveillance and medical examinations are provided as appropriate. | | |
| **Section 4: Risk Rating**  *Use the consequence, likelihood and risk score tables in the accompanying guidance to identify the scores below.* | | |
| **Consequence Score:** | | |
| **Likelihood Score:** | | |
| **Risk Score:** | | |
| **Initial Risk Grading:** | | |

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| **Section 5: Risk Reduction Options** | | | | | | |
| **Options** | | Revised Risk Score | | Cost | | |
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| **Section 6: Directorate/Divisional Agreed Actions** | | | | | | |
| **Actions** | | Lead | | Target Date | | |
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| **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] The Control of Electromagnetic Fields at Work Regulations 2016.  [2] Capstick M, McRobbie D, Hand J, Christ A, Kühn S, Hansson Mild K, Cabot E, Li Y, Melzer A, Papadaki A, Prüssmann K, Quest R, Rea M, Ryf S, Oberle M, Kuster N. An investigation into occupational exposure to electromagnetic fields for personnel working with and around medical magnetic resonance imaging equipment. Employment, Social Affairs and Equal Opportunities DG, European Commission, 2008. Available at: <http://www.itis.ethz.ch/assets/Downloads/PapersReports/Reports/VT2007017FinalReportv04.pdf>.  [3] D. Grainger, “Safety Guidelines for Magnetic Resonance Imaging Equipment in Clinical Use,” Medicines and Healthcare Products Regulatory Agency. Available at https://www.gov.uk/government/publications/safety-guidelines-for-magnetic-resonance-imaging-equipment-in-clinical-use | | | | | | |