MAGNET SAFETY IN MAGNETIC RESONANCE IMAGING SUITE CONSTRUCTION

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This paper examines whether the parties concerned with the design and construction of Magnetic Resonance Imaging (MRI) suites adequately address the risks to construction staff from the presence of the static magnetic field of the magnet during the construction phase, and whether this hinders effective health and safety management on site. Concerns are raised about which party to the works is actually responsible for site access controls once the magnet has been energised and to where these controls should extend. Screening of operatives, the need for its documentation and the desirability of health surveillance for those operatives exposed to the static magnetic field of 0.5 mT and above is discussed. Evidence is presented of conflicting advice from the NHS regarding the designed position of the 0.5 mT footprint of the static magnetic field being retained within the MRI scanner room or allowed to pass to the technical room. There appears to be a contrast between operational MRI suite procedures and those at construction stage. This results in there being in a gap in knowledge needed for the efficient management of health and safety on site covering the period within the construction phase between magnet energisation and handover of the MRI suite to the Client for operational use.

Keywords: design management, health and safety, project management.

INTRODUCTION

Although MRI suite projects are specifically the subject of this Paper, the findings themselves could just as equally apply to any construction project where specialist suppliers also contribute to the design process, thus demonstrating the need for them to be brought into the decision making process as early as possible at initial design stage as, "each designer needs to discuss the types and format of supporting information with the CDM-Co-ordinator who has to identify and provide information to those who need it". (The Association for Project Safety 2007 (a) p. 90)

Magnetic resonance imaging as a modality has seen a gradual rise in the rate of installations since the middle 1990s, when the full benefits of superconducting magnet technology became available. Some of these earlier magnets are still installed in their original locations, but generally and as technology has evolved further, they have been replaced on a regular basis. In a study of MRI installations in NHS hospitals in Scotland, Wales and England, it was determined that the oldest magnet still in use was installed in 1992. (Price, T. *et al.* (a) in press)

Prior to the middle 1990s, NHS hospitals regularly used their project management teams to manage both ionising and non-ionising radiation producing installations, with this system working well. For political and economic reasons, and coupled with a rapid rise in installations for both MRI and X-ray, specialist pre-installation

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companies evolved. These companies, having specialist knowledge of the particular construction requirements of each modality, each magnet vendor and often even of each equipment model were usually appointed as sub-contractors to magnet vendors in order to carry out the necessary construction work to enable installation of the required imaging equipment to take place. However, one disadvantage of this change in methodology appears to have been a fragmentation of the design and construction processes, resulting in a possible misunderstanding by CDM duty holders of their responsibilities to each other and to their charges. This is most evident in relation to the design function, where CDM 2007 makes it clear that measures should be taken in order to 'avoid foreseeable risks' of any design. (The Approved Code of Practice (ACoP) to The Construction (Design and Management) Regulations [CDM 2007] Paragraph 125) One of the control measures outlined in CDM 2007 is the requirement that "Risk Management proposals/methods that the Designers have assumed or decided will be appropriate", (The Association for Project Safety 2007 (b) Para 11.2.5) and made available for development of the Construction Phase Plan by the principal contractor. These are measures that should also be identified, if they are not eliminated during the construction phase, for adoption by those using, de-commissioning or demolishing any structure(s) on completion of the project and to be included in the health and safety file at the end of the project. Nevertheless, it is quite feasible that the Principal Contractor would have the opportunity, by utilising his technical and managerial expertise, to eliminate many residual design hazards during the construction phase - but this requires him to have knowledge of them.

MRI magnets are installed within a Faraday (RF) cage (the scanner room). Faraday cages are constructed of conductive material, usually of copper or aluminium, and are essential in ensuring that external static electrical fields are prevented from distorting the RF signal being utilised to create the image. This RF cage will be normally have been designed and constructed by a specialist RF cage supplier either through the Client, the magnet vendor or the pre-installation contractor. Faraday cages do not protect the magnet from the influence of magnetic fields external to the MRI magnet, or in reverse, protect persons or objects outside the Faraday cage from reach of the magnetic fields supported by the MRI.

Once the superconducting magnet has been energised, which usually takes place whilst still within, but towards the end of the construction phase of the project; a static magnetic field is produced. The strength of this static magnetic field is measured in Gauss (G) or millitesla (mT).

An operational MRI suite would normally contain of a minimum of two controlled areas - an outer and an inner one, with the outer controlled area being an area "totally enclosed, and of such a size to contain the 0.5 mT (5 Gauss) magnetic field contour" (Device Bulletin, December 2007 Section 4.5.1)) and an inner controlled area, "within the confines of the MRI Controlled Area containing the 3 mT (30 Gauss) magnetic field contour." (Device Bulletin, December 2007 Section 4.6.1)

The static magnetic field is the subject of this Paper because during the construction phase (and throughout the life of the installation) there may be potential hazards and risks to construction employees and third parties because of a gap in information transfer between all those disciplines involved with an MRI construction project because;

- Unlike other medical imaging equipment, MRI superconducting magnets to which this Paper is restricted, once energised, are always ‘on’ and producing a static magnetic field.
- Large static magnetic fields extend in three dimensions around the magnet and generic positions of the static magnetic field will necessarily change with each individual project. For ‘open’ format ‘hamburger bun’ type magnets the larger component of the static magnetic field is vertical, resulting in slightly diminished hazards on the same level as the magnet (as compared to bore format magnets) but greater hazards above and below. (Price. T *et al.* 2009 a)
- Magnetic fields are invisible and it is impossible to know if they are on or off, or to be aware of them unless told. There are referenced documents (The American College of Radiology Guidance Document for Safe MR Practices 2007) discussing patient and staff exposure to electro-magnetic fields (EMF’s) and maximum exposure limits (ICNIRP 2004 pp 267-311). Despite this advice, these controls do not appear to be considered until the MRI suite reaches the operational stage and is handed over to the Client even though, once the magnet has been energised, the same hazards exist during the construction phase.
- 5 gauss is the threshold for exposure to the static magnetic field of all individuals that have not been successfully screened for contra-indications. UK government advice is that “A person fitted with a heart pacemaker must not enter the MR Controlled area”. (Device Bulletin 2007 Section 4.11.1.1) However, it should be appreciated that this hazard is not a direct biological one to the individual, but a risk of magnetic field electro-mechanical interference with the medical device. One description of the effect of the static magnetic field on pacemakers (Young R. 2000) is that “the magnetic reed switch that varies the heart rate can be inadvertently switched by the static field and revert to its default setting.” This could lead to irregular heart rhythm of the bearer of the pacemaker and eventually to his/her serious handicap or death.
- Within the published NHS Estates literature there is ambiguity as to the area(s) within the MRI suite to which the 5 Gauss footprint should be contained.

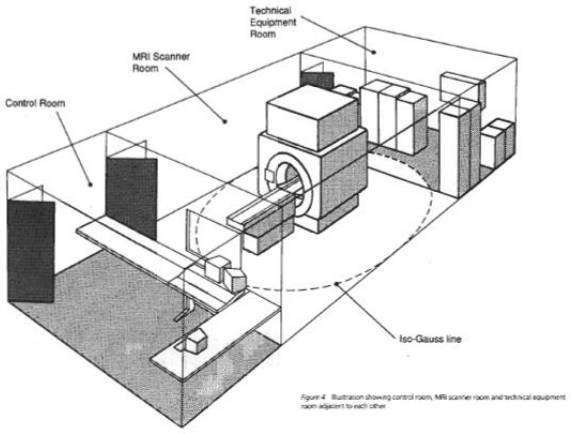

Figure 1: NHS Estates advice regarding the retention of the 5 gauss footprint within the magnet (scanner) room and technical (equipment) room, but without mentioning the y axis (Image Courtesy of NHS Estates)

Although it is recommended that the 5 gauss line of the static magnetic field should be restricted to the magnet (examination) room and the technical room, this published advice shows an illustration (reproduced in Figure 1 above) of a generic footprint of

the x (lateral) and z (horizontal) axes of the static magnetic field to a magnet, whilst ignoring that of the y (vertical) axis. (Health Building Note 6 - Supplement 1. p 16 Fig: 4). Conflicting advice is that the 5 gauss line is ideally "constrained within the confines of the MRI scanner room" (NHS Estates. Magnetic Resonance Imaging - Health Guidance Note 1997 p 6).

- In addition to this electro-mechanical interference, there are also two other physical forces, being (a) torque and (b) translational attraction (the projectile effect) which can be exerted by magnetic fields upon ferromagnetic objects. When subjected to magnetic fields, a heart pacemaker or other medical device or implant could twist (torque) within the individual so as to align itself with the magnetic field to which it is exposed, or be pulled towards the magnet by translational attraction whilst embedded in the individual's body. "One of the most vulnerable parts of the body is the eye. The adequate screening of patients or others with **suspected** intra-ocular ferromagnetic metallic objects is most important before they are allowed to enter the MR controlled area of the MRI suite." (Device Bulletin 2007 Section 4.11.5.1)
- Exposure of unscreened plant and tools also risks causing the 'projectile effect', thus giving rise to the possibility of workers being injured whilst in the path of the projectile. Additionally, there is the potential of the cost of damage to the magnet bore, or those of a quench of the magnet in order to remove the object.
- Although the ACoP to CDM 2007 is clear, it is difficult to ascertain the hierarchy and perception of accountability of the parties during the pre-handover (construction phase) period of an MRI project.

RESEARCH AIMS AND OBJECTIVES

The aim of this work is to identify the potential safety issues of the exposure of construction workers to the static magnetic field of the magnet, with the objective that the information obtained will help to assist clients and their duty-holders appointed under CDM 2007 in managing health and safety during the construction phase of an MRI project.

RESEARCH METHOD

It was necessary to discover the relationship between the Client, his architect/designer, the magnet supplier, the RF cage supplier and the pre-installation or Principal Contractor to determine if there was sufficient acceptance of safety responsibilities of each of the parties, as well as to establish the hierarchy of health and safety management from site start-up until completion and handover of the MRI suite to the Client. Safety management hierarchy is of particular interest to HSE Safety Inspectors, and legal notices can be issued if the hierarchy is not clearly documented. It was necessary to determine how, during the construction process, access to the immediate area of the magnet was controlled, and by whom. It was also necessary to establish if operatives working on the construction of the MRI Suite were made aware of any residual risks notified by designers and of the control measures put in place on site by the Principal Contractor in order to manage those risks. It was necessary to enquire if information on these hazards and contained in magnet suppliers' Site Planning Guides was being made available to operatives in the form of site specific risk assessments and method statements and how this was being managed.

So as to validate the hypotheses and in order to form a valid conclusion and submit recommendations, questionnaires were sent to pre-installation contractors, RF cage and magnet suppliers before assembling the information gathered in order to extract a snap-shot of current practice. Additional material supplied by architects from a parallel questionnaire was included in the research. The study was limited because only one magnet vendor was forthcoming in allowing his project managers to answer the questionnaire, but the results obtained highlight the need for clear lines of responsibility in any construction project to be clearly determined and understood.

Interview and data collection process

The most important element of the research was to find the opinions and perceptions of the people and companies with hands-on experience of what was actually happening on site, rather than what was supposed to be happening. Magnet vendor Project Managers, pre-installation company Contracts Managers and RF cage owner/managers were interviewed, as they were the persons who had actually experienced conditions on site whilst an MRI suite was being constructed. Architects involved with current MRI projects were also interviewed, as were two PFI Contractor Design Managers.

The Questionnaire

A questionnaire for each of the parties involved in the study was compiled, that is to say; architect, RF cage supplier, magnet vendor and pre-installation contractor. Each questionnaire had the same questions, but was orientated from their own position in the supply chain so as to identify differences in each player's perception of what they or others should be doing on site. Some persons to whom the questionnaire was sent felt that some of the information was commercially sensitive and refused to reply.

RESULTS

To whom were the questionnaires sent?

Pre-installation Contractors: In cases where the contract is turnkey to the magnet vendor, the pre-installation contractor will normally carry out the role of Principal Contractor. Where the contract is a PFI, the Principal Contractor will normally sub-contract the works, but not always to specialist sub-contractors. In the following, read Principal Contractor (under CDM 2007) for Pre-installation Contractor (PIC) and vice versa, but not as him being the Site Waste Management Plans Regulations 2008 (SWMP 2008) Principal Contractor, although there may be cases where this could be the same duty holder position under both sets of Regulations, but with each having different responsibilities. (Price, T. *et al.* 2009b pp 12-17)

RF cage Suppliers: Questionnaires were sent to five cage suppliers, with two not responding, thus giving a return rate of 60%.

Architects: Questionnaires were sent to three Architects and two PFI Contractor Design Managers whose speciality was hospital design. Replies were received from all five, giving a return rate of 100%.

Magnet Vendor: Following telephone conversations to ascertain their susceptibility to participating in the study by completing the questionnaires and by having a one hour meeting with their Health and Safety Manager, the questionnaires were sent by e-mail to the National Project Manager of a magnet vendor, where four of his eight Project Managers supplied separate responses to the questionnaire, a return rate of 50%.

DISCUSSION

What became apparent is that the responses to the questionnaires by the pre-installation contractors and the magnet vendors were sufficiently conflicting to justify concentration of the research on these groups, but with peripheral input of architects and RF cage suppliers.

Siting of the magnet

The siting of the magnet (examination) room within an MRI suite is important because if the static magnetic field produced by the magnet is allowed to pass to areas outside the RF cage, then third parties may be affected if the footprint is not identified and controlled areas set up to manage the risk of persons coming into contact with high magnetic fields.

The magnet vendor was the party who believed the most that he was involved in the design process early enough to be able to make a contribution to the siting of the MRI suite. The PIC felt he himself was not. Architects broadly thought that they were involved early enough, but the RF cage supplier stated that magnet vendors fitted magnets into cages supplied by others even when they had not been involved in the cage procurement process. As the cage supplier would normally be the party designing any necessary magnetic shielding, it casts doubt on who is actually specifying the design of the RF cage and any required magnetic shielding to the magnet room, as architects would not normally have such specific knowledge.

It was confirmed that the magnet vendor was not faced with a fait accompli regarding the overall suitability of siting of the magnet, a fact also borne out to some extent by architects' replies, indicating that in cases where the magnet vendor was not specified at the early design stage, architects had nevertheless taken magnet vendors general siting requirements into consideration. From discussions with architects, this was found to be manifested by the Client instructing the architect to 'take the worst case scenario' when considering the effects of the static magnetic field when deciding on any given MRI suite location.

Which of the players considered themselves to be designers?

Questions were posed to determine if the parties felt they were part of the design process. The magnet vendor was the most positive party, with the PIC 'to some extent'. It was discovered that even when supply of the cage was not in the magnet vendor's package, the magnet vendor still felt he was part of the design process, whereas the PIC did consider himself to be, but not to the same extent. Clearly there is no proof of design co-ordination by the Client's CDM Co-ordinator.

Further questions were developed to determine if the parties were involved in any magnetic shielding requirements, so as to establish if they were able to influence the management of health and safety on site. Responses showed that the PIC, magnet vendors and cage suppliers as well as architects were involved in magnetic shielding discussions if it affected the safety of site operatives, but where it did not affect the operation of the magnet the PIC was consulted less, which appears logical. Where magnetic shielding (or the lack of it) was discussed then all parties were consulted, including the PIC 'to some extent', except that where the operation of the magnet was not affected, the PIC was not consulted. This leads to the impression that the design emphasis is solely on the effect of the environment on the magnet rather than to include the effect of the magnet on the environment, which by implication includes the health and safety of the construction operatives (and eventually users of the

completed magnet installation). 'The general rule for NMR installations can be summed up one simple phrase: protect the magnet from the environment and the environment from the magnet'. (Einstein S.G. and Hilal S.K. 1985 pp 267-311)

The Principal Contractor under the Construction (Design and Management) Regulations 2007 (CDM 2007)

Further questions were intended to determine which of the players usually held the Duty Holder position of Principal Contractor and were therefore responsible for the management of health and safety on site. As expected, the PIC showed greater acceptance of the role of Principal Contractor. In two cases, the magnet vendor had replied that he 'to a small extent' or 'to some extent' accepted this CDM Duty Holder position. The magnet vendor replies showed them to be unanimous in that they produced risk assessments and method statements before energisation of the magnet, as was broadly the case with the cage supplier. The score of the PIC was very low and may be because he was relying on the magnet vendor to manage the whole magnet energisation process and in isolation from the other site controls. It would make sense for the PIC to be appointed Principal Contractor during the first part of the process and until he had finished construction works and left site. At this stage, the magnet vendor could become the Principal Contractor and manage site health and safety. It would be unrealistic to expect any PIC who had become Principal Contractor at the commencement of the works to continue in this role once he had finished the pre-installation works and left site. If he remained Principal Contractor, he would be unable to manage health and safety in this period up until final handover of the MRI suite to the Client, particularly as this period could include instruction and training of hospital staff in the use of the imaging equipment.

The Principal Contractor and the management of safety relating to the static magnetic field

Questions were set so as to determine if there was site-specific information on the position of the 5 gauss footprint and measures advised by the magnet vendor that should be used to control residual risks as a result of magnet energisation. The study was trying to establish if the site-specific physical position of the 5 gauss footprint had been identified to the Principal Contractor. The magnet vendor believed that he did supply site-specific information regarding the position of the 5 gauss footprint, but the PIC did not agree. In further questions, it was the PIC who did not attach so much importance to annotated site specific drawings with the magnet vendor scoring highest, then the PIC, with the cage supplier scoring lowest in believing that site specific information was included so as to control the magnet's residual risk to site operatives once the magnet had been energised. There was absence of evidence showing a clear process. This situation is complicated further in that there are no clear guidelines as to where the 5 gauss footprint of the static magnetic field should be allowed to extend, inasmuch that in discussing the fringe (or 'stray') field and the implications for safety, the NHS state that 'The controlled area is normally defined from the boundary of the 5 gauss fringe field contour. Ideally, this is constrained within the confines of the MRI scanner room', but later goes on to say in paragraph 5.15 that 'the 0.5 mT contour should be entirely contained within the boundaries of the MRI scanner and technical room'. (NHS Health Guidance Note 1997. *Magnetic Resonance Imaging:* Para 2.13)

Who sets up a controlled area around the magnet?

A question asked who set up the controlled area around the magnet, with another enquiring who set up any controlled area for areas contiguous to the RF cage. The magnet vendor advocated setting up a controlled area around the magnet, with 40% of the PIC's replying 'to some extent' and 40% 'not at all'. Later, this response was mirrored in that the magnet vendor was the party most likely to set up a controlled area where the 5 gauss footprint was not retained within the cage. Surprisingly and as they were supposed to be in control of the site, 20% of the PIC's replied 'not at all' or 'to a small extent' on the desirability of setting up a controlled area.

Who polices access to the controlled area?

From questions to ascertain who was felt to be responsible for policing access to the controlled area and to other areas to where the 5 gauss footprint may extend, responses from the magnet vendor scored the highest, with the PIC scoring the lowest. Again and under CDM, the PIC is supposed to be in control of the site, as well as being responsible and accountable for the management of health and safety on the site. The PIC appeared (wrongly) to relinquish this task to the magnet vendor.

Screening of operatives

Questions asked about screening to operatives generally and then specifically for the presence of implants, followed by questions relating to the screening of tools and equipment for ferromagnetic properties.

The magnet vendor again scored the highest, whereas it was not confirmed by the PIC. The magnet vendor contradicts this statement in a later question where it was the PIC who gave a more positive response in feeling that operative and contractor screening for implants or metal objects in their bodies should be carried out. Again in another question, it was the magnet vendor who scored the highest for the controls on tools and plant to the controlled area, with both PIC and magnet vendor scoring high in that these controls were just to the RF cage.

Responsibility of highlighting any RF cage design failings that may cause workers to come into contact with the 5 gauss footprint of the static magnetic field

The purpose of another question was to establish if the Principal Contractor or Pre-installation Contractor understood he had a responsibility to give feedback to the designers if he felt the design was allowing his operatives to come into contact with the 5 gauss footprint. The replies were as expected, in that all parties felt they had a responsibility, with the magnet vendor scoring highest. However, the actual site position of the 5 gauss footprint needs to be identified in order for this to become effective.

Desirability of health monitoring of operatives' exposure to the static magnetic field

A question aimed to establish if the parties believed that health monitoring of operatives' exposure to the static magnetic field was desirable. Interestingly, 50% of the magnet vendors replied 'not at all'. Conversely, all the PIC's thought health monitoring to be desirable, indicating a lack of co-ordination between the magnet vendor and the PIC in the management of health and safety on site.

Control by contractors of operatives' exposure to the hazards of magnet installation

A question enquired if contractors should do more to control operatives' exposure to the hazards of magnet installation. All respondees felt that contractors should do more.

Confusion with RF and static magnetic fields

It was elucidated from both magnet vendor and PIC, albeit in varying degrees, that there was confusion between operatives of the effects of these EMF's, believing them to be adequately controlled within the RF cage. The responses of the PIC's to this question as the CDM Duty Holder responsible for the management of health and safety on site varied between 'to a small extent' through to' to a large extent'.

Is there a gap in health and safety information transfer between the magnet vendor and contractors?

All parties, albeit in varying degrees, felt that there was a gap in health and safety information transfer, with the PIC feeling more strongly than the magnet vendor.

Do survey participants believe there could be dangers to health from exposure to static magnetic fields?

80% of the PIC's felt there was a danger from static magnetic fields, but only 50% of the magnet vendors agreed**,** with the other 50% replying 'not at all'. This signals that inadequate information is used to carry out a risk assessment used to develop a method statement to take account of the risks from the static magnetic field.

CONCLUSIONS

The survey questionnaire highlighted the fact that there was no agreement on:

- whether exposure to the 5 gauss footprint of the static magnetic field was hazardous to health
- whether identification of the actual site specific position of the 5 gauss footprint of the static magnetic field was necessary and whether it should be confined to the RF cage
- whether site specific planning guides containing site specific information on methods of controlling residual risks of the energised magnet are issued by the magnet vendor.
- who should carry out operative screening and be responsible for its documentation, or even whether screening should be documented at all.
- who should police access to the controlled area - or even if there should be a controlled area either inside or to areas outside the RF cage where the 5 gauss footprint may be present

Evidence gleaned from the questionnaire on construction operative screening for implants, etc and its lack of documentation was worrying. Despite the hazard of a static magnetic field being forever present once the magnet had been energised during the construction phase, this is in stark contrast to the documentation requiring to be completed by an individual entering the controlled area of an operational MRI suite, even as a visitor, where he/she would be required to satisfactorily complete a questionnaire before being granted access. There was no agreement that the 5 gauss footprint should be retained within the RF cage or of whether its (installed) 5 gauss footprint should be mapped on site. There appears to be a contrast between operational MRI suite procedures and those at construction stage. The evidence produced shows

that there is a gap in knowledge transfer. This gap needs to be filled so as to ensure the efficient management of health and safety on site covering the period within the construction phase between magnet energisation and the handover of the completed MRI suite to the Client for operational use.

FURTHER WORK

This paper reports ongoing research at Edinburgh Napier University. The aim of this research is to develop guidelines to improve the nature and quality of information to be included in future Information Packs and Health and Safety Files prepared by CDM Co-ordinators, and by Construction Phase Plans prepared by Principal Contractors under CDM 2007.

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