Inspection Report of Compliance with the Ionising Radiation (Medical Exposure) Regulations (Northern Ireland) 2018

14 March 2019

South West Acute Hospital, Department of Radiology

Address: 124 Irvinestown Road, Enniskillen, BT74 6DN
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Public Health England (PHE) Advisor: Yvonne Sullivan

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Assurance, Challenge and Improvement in Health and Social Care

It should be noted that this inspection report should not be regarded as a comprehensive review of all strengths and areas for improvement that exist in the service. The findings reported on are those which came to the attention of RQIA during the course of this inspection. The findings contained within this report do not exempt the service from their responsibility for maintaining compliance with legislation, standards and best practice.

1.0 What we look for

The Ionising Radiation (Medical Exposure) Regulations (Northern Ireland) 2000 were revoked and new regulations The Ionising Radiation (Medical Exposure) Regulations (Northern Ireland) 2018, known as the IR(ME)R regulations, came into force on 6 February 2018. RQIA has employed a refreshed inspection methodology in relation to compliance of radiology services with the new regulations.

The inspection had a particular focus on the key changes to the regulations including:

- communication of benefits and risks
- diagnostic reference levels (DRL's)
- accidental and unintended exposures
- equipment
- carers and comforters
- medical physics expert
- non-medical imaging using medical radiological equipment

IR(ME)R is intended to protect individuals undergoing exposure to ionising radiation as:

- patients as part of their own medical diagnosis or treatment
- individuals as part of health screening programmes
- patients or other persons voluntarily participating in medical or biomedical, diagnostic or therapeutic research programmes
- to carers and comforters
- to asymptomatic individuals
- non-medical exposures using medical radiological equipment

2.0 Service details

Name of Establishment: South West Acute Hospital	**Department Inspected:** Diagnostic radiology services
Name of Employer: Dr Dermot Hughes, Medical Director, Western Health and Social Care Trust (WHSCT)	**Radiology Services Manager:** Mr Dan McLaughlin
Assistant Director of Acute Services(Operations and Service Improvement): Ms Fiona Beattie	**Lead Medical Physics Expert:** Mr Philip Doyle

4.0 Profile of services

The self-assessment form submitted prior to the inspection confirmed that each year, South West Acute Hospital diagnostic radiology department carries out approximately:

44,157	General radiology (plain film)
464	General fluoroscopy
10,148	Computed tomography (CT) scanning
50	CT interventional
1,693	DXA
391	Dental
6279	Magnetic resonance (MR)
12,072	Ultrasound scan (US)

MR and US services were not inspected, as these services do not involve the use of ionising radiation and therefore are not subject to the IR(ME)R regulations.

South West Acute Hospital department of radiology employs:

6.0	Consultant Radiologists (1.2wte vacant posts)
7	Reporting radiographers
25.2	Radiographers
3.6	Radiographer helpers
1	Diagnostic Radiology Lead Medical Physics Expert (MPE) under contract from Belfast Health and Social Care Trust)

5.0 Methodology

On 14 March 2019, warranted IR(ME)R inspectors from RQIA, with advice being provided by Public Health England (PHE) staff, visited the South West Acute Hospital, radiology department, as part of RQIA's IR(ME)R inspection programme.

Prior to the inspection, the service was requested to complete a self-assessment form (SAF) and provide RQIA with all relevant policies and procedures. This information was shared with PHE prior to the inspection visit, and was used to direct discussions with key members of staff working within the radiology department, and provide guidance for the inspection process.

The following Western Health and Social Care Trust (WHSCT) staff and MPE staff were in attendance for part or all of the inspection:

Ms Elizabeth England	Assistant Director of Nursing/Acute Services
Mr Marek Andrassak	Consultant Radiologist
Mr Glen Clarke	Radiologist
Mr Dan McLaughlin	Radiology Services Manager
Ms Hazel Grant	Department Manager
Ms Aisling Howell	Quality Co-Ordinator
Ms Adele Phair	DXA Lead Radiographer
Ms Martina Melanophy	CT Clinical Specialist
Mr Philip Doyle	Lead MPE

The inspection team reviewed relevant documentation and patient records. A tour of some areas of the radiology department was undertaken and the inspectors took the opportunity to speak with one plain film radiographer, one CT radiographer, one locum radiologist and one consultant radiologist.

6.0 Inspection outcome

	Regulations
Total number of areas for improvement	9

Details of the quality improvement plan (QIP) were discussed with senior management as part of the inspection process. The timescales for completion commence from the date of inspection. Ms Fiona Beattie, Assistant Director Acute Services (Operations and Service Improvement) joined the management team via teleconference for feedback on the inspection findings at the conclusion of the inspection.

7.0 The inspection - key findings

7.1 Duties of the employer

Employer's Procedures

The South West Acute Hospital, WHSCT, had the required Employer's Procedures in place which had been reviewed and updated in accordance with IR(ME)R 2018; ratified in January 2019. Employer's Procedures are reviewed every three years or more frequently if change is necessary.

The Radiation Safety Policy had been updated during March 2018 and review of this policy confirmed that the Employer has been clearly identified in line with IR(ME)R legislation. It was established that the overall responsibility for IR(ME)R lies with Dr Dermot Hughes, Medical Director, WHSCT, and his subsequent responsibilities are clearly set out. Flow charts were included in the Radiation Safety Policy which outlined governance and reporting structures in relation to the use of ionising radiation. These structures were discussed with senior management together with roles and responsibilities. Inspectors noted that the Medical Director, has nominated the Chair of the Radiation Protection Working Group (RPWG) to co-ordinate compliance with the requirements set out in the Radiation Safety Policy.

Review of the submitted documentation and discussion with the management team outlined that systems are in place to ensure that Employer's Procedures are complied with by practitioners and operators, through audit, induction and training. It was confirmed that the Employer, the Medical Director, WHSCT, receives reports on the level of compliance. The RPWG reports to the Risk Management Sub-Committee which in turn reports to the Governance Assurance Committee.

Document and version control are clearly noted on the Employer's Procedures and inspectors were informed that all relevant policies and procedures can be found on WHSCT intranet.

Quality Assurance programme for written policies and procedures

The Trust's radiology services have embarked on the journey of attaining accreditation from Imaging Services Accreditation Scheme (ISAS). A lead ISAS Radiographer has been appointed to move forward on the initiative in a co-ordinated fashion.

Review of the documentation provided to the inspection team, confirmed that a quality assurance system of documentation is in place and that the South West Acute Hospital is currently updating and uploading all documentation onto Q Pulse. Once this is completed the system will alert staff when review dates are due.

Some documentation was found to have a review date that had passed and other protocols without an author or version control. It was confirmed the implementation of quality management system (QMS) will address these anomalies and all hard copies will also be removed or replaced with updated versions when Q pulse is fully operational.

'Employer's Procedure I', outlines the quality assurance programmes in respect of written procedures, written protocols, and equipment. It was suggested adding equipment to the title of 'Employer's Procedure I' for clarity.

Diagnostic Reference Levels (DRLs)

The process for establishing, reviewing, and checking compliance with DRLs has been established with the collaboration with the MPEs and is set out in 'Employers Procedure K'. Dose audits are both site specific and compared across sites. RPWG had the responsibility to ensure DRL's are audited. The inspectors were informed that the Imaging Optimization Team (IOT) going forward will be responsible for reviewing DRL audits and ensuring any changes that are needed are actioned. Dose monitoring software is being considered to improve this process.

IOTs will look at establishing coding and equipment types to assess commonality across sites. It will help to identify those staff that can make changes to protocols. To get a base line the IOTs will look at any changes that have been made on the equipment since installation and compare this with the original settings.

The work of the IOT will provide information and assurances to the RPWG in line with governance systems. Reports will be made available on Q Pulse.

It was suggested to review 'Employers Procedure K' to include the role of the IOT in respect of DRLs.

Local DRL's are available for standard CT examinations. National and local DRLs were noted to be displayed in diagnostic radiology rooms. Staff spoken with demonstrated a clear understanding on the use of DRLs and what action to take in the event of DRLs being consistently exceeded.

Clinical audit

It was evident the imaging service has an underpinning culture of quality improvement. Management and staff demonstrated an inclusive, enthusiastic and proactive approach to patient centred service improvement.

There are systems in place to undertake clinical audits. Audit is managed via the radiology QMS and as previously discussed, the service is working towards ISAS accreditation which will require the establishment of a formal agreed audit schedule. The system will be programmed to create alerts to inform the responsible staff when the required audits are preformed and documented as per schedule.

A planned audit programme is in place and evidence of audits was provided. These were found to be multi-professional and included areas of compliance under IR(ME)R. Some clarification was sought on the role of the Office Manager, in respect of clinical audit, as outlined in submitted documentation. Assurances were given that the Office Manager was not directly involved in carrying out clinical audit as stated in the SAF. Inspectors were informed and staff confirmed that audit findings are shared with staff through monthly meetings and also through team briefings in their departments. However, there was no clear action plan post audit. There was a lack of evidence of how the audits influenced practice or when the audit was to be reviewed again.

An area of improvement was identified in relation to ensuring that an audit action plan is developed and implemented as necessary, formalising the re-audit process and the sharing of audit findings with the relevant stakeholders.

Accidental and unintended exposures

Following examination of procedures and discussion with staff it was clear that there are good systems in place to identify, report, record, manage, and learn from incidents and near misses.

Management and staff explained the clear process for reporting internally and then to the appropriate enforcing authority.

Suspected radiation incidents are reported to radiation protection supervisor (RPS) and the Clinical Specialist immediately. The RPS carries out a preliminary investigation of the incident as per Employers Procedure's appendix 9. The RPS informs the Clinical Lead, the Department Manager and the Radiation Services Manager if a radiation incident is found to have occurred.

The lead MPE is notified and undertakes a dose assessment to establish if the incident is notifiable to RQIA. All incidents are reported on DATIX. The Department Manager is responsible for ensuring the process is correctly followed and writing the report. Incidents are discussed at monthly governance meetings. The inspectors reviewed radiation incidents for May-November 2018. There was evidence of incident and near miss trends analysis having been undertaken. It was noted that there is no current action plan after the analysis of trends. It was confirmed that this will be developed going forward. The Radiation Service Manager is responsible for reviewing the analysis of trends and sharing this information within the governance structures.

‘Employer’s Procedure R’, which relates to communication with relevant stakeholders in relation to clinically significant unintended or accidental exposures, is in place. Whilst it is a detailed procedure it did not outline information on how the decision not to inform the patient is recorded. The self-assessment documentation submitted to RQIA did outline this process clearly and should be included in ‘Employers Procedure R’.

It was noted ‘Employers Procedure Q’, for the investigation and reporting of radiation and near miss incidents, was comprehensive however made reference to notifying Health and Safety Executive (HSE) of equipment failure which management were aware was not in keeping with the changes to IR(ME)R 2018.

An area of improvement has been identified to amend ‘Employer’s Procedure R’ (clinically significant incidents) to include information as to how the decision not to inform the patient is recorded and amend ‘Employers Procedure Q’ (investigating and reporting incidents) in relation to notifying the correct enforcing authority of equipment failure.

There were no reported incidents to RQIA in the past two years.

Training, competence and entitlement

There was evidence of induction, competency based assessments and continuing professional development for most grades of staff. Systems are in place to check the professional qualifications and registration of all employees with their appropriate professional bodies.

It was confirmed there are comprehensive systems in place to provide annual appraisals for all grades of staff. It was further confirmed that training and development needs are identified for individual staff as part of the appraisal process. Consultant radiologists have their appraisals undertaken by an approved medical appraiser.

All grades of staff are responsible for maintaining their own portfolio of evidence to maintain their individual professional accreditation.

The inspectors reviewed a range of radiographer’s records of induction, mandatory training, sign off records for Employers Procedures and entitlement forms. Inspectors were informed that equipment training had been provided on all equipment by the manufacturer’s application specialist when the hospital initially opened. However, there was no documented evidence of this training available as it is a number of years ago.

It was noted that radiographers were entitled as referrers when additional views were required to complete an examination. Discussion took place on this matter and management agreed to review this position and consider additional views as part of the procedures covered by the authorisation guidelines. Staff confirmed that they had received update training from the MPE on the new IR(ME)R regulations. Entitlement records were noted not to contain clear staff competency frameworks to underpin each duty holder’s scope of practice. The inspectors were informed that the department is developing a training log book with a statement of competency which will be incorporated into the entitlement process. This will certainly strengthen the current entitlement process. There is a practice educator employed to oversee the training of radiography staff which is commendable.

In contrast, there were no training records or entitlement documentation for radiologists. Discussion with radiologists demonstrated varying levels of understanding of their roles and responsibilities under IR(ME)R. An area of improvement has been identified to ensure radiologists have evidence of compliance with IR(ME)R in relation to induction, training and entitlement.

The senior team reported that radiographers had been appropriately entitled according to their training, competencies and individual scope of practice. Entitlement is reviewed at annual appraisal and adjusted accordingly if a staff member's scope of practice had changed.

It was confirmed that there was a robust initial process of entitlement for non-medical referrers. They complete an application form including evidence of appropriate training and competency which has been confirmed by a consultant or professional manager. Having completed all the necessary training and gained competency, the non-medical referrer is then entitled in accordance to their specific scope of practice by the Clinical Lead and Radiology Services Manager. A letter of entitlement is sent to the referrer and to the RPS for department records. The name of the non-medical referrer is added to the WHSCT authorised referrers list on Q Pulse. On discussion, it was apparent that non-medical referrers are not subject to formal periodic review of their entitlement.

An area of improvement has been identified to ensure non-medical referrers have formal written review of their entitlement and the register of named non-medical referrers is updated accordingly.

Currently only non-medical referrers are audited to check justification rates of referrals, it was suggested that this could be rolled out to other groups.

The arrangements for the Republic of Ireland (ROI) referral requests (medics only) were discussed and it was confirmed that they are infrequent but when received that they are hand written. The Department Manager checks the referral. The process for ROI referrals needs to be more robust with a clear process for accepting and checking the referral.

An area of improvement has been identified in relation to establishing a formal process for entitlement for ROI referrers and the acceptance of ROI referrals.

The MPE confirmed that the Medical Director entitles the MPEs as an Operator and that entitlement of MPEs was currently under a regional review to ensure complete and clear Employer lines of accountability in the process.

Advice was provided on the entitlement process in relation to ensuring there is evidence of robust adherence to the trust's procedures and legislation, management were receptive to this advice.

Referrals

The referral guidelines currently being used are the Royal College of Radiologists i-Refer Guidelines Making the Best Use of Clinical Radiology 8th edition.

Referral guidelines are available on the WHSCT intranet.

Staff described how diagnostic referrals are made to the department, including prioritising referrals and specifically timed future examinations.

A clear process was evidenced for returning/rejecting referrals which are incomplete, inappropriate or unjustified. Cancelling referrals was discussed including how referrers are made aware of the process to cancel a referral they have made.

7.2 Justification and Authorisation of individual medical exposures

Justification and authorisation was discussed with staff, who demonstrated an understanding of the process and described how justification and authorisation is recorded electronically on the radiology information system (RIS). This was evidenced in a randomly selected number of patient records.

It was confirmed that radiographers act as operators and authorise under guidelines for plain film x-ray. All CT examinations are justified by the Consultant Radiologist covering CT on that day. An initial Radiologist justifies the referral to allow the patient to receive an appointment. If there are no changes to the examination the initial radiologist acts as the practitioner, if changes are required the radiologist making those changes is then listed on RIS as the practitioner.

It was noted there are three documents in CT that are being used as authorisation guidelines. An area of improvement was identified in relation to providing complete clarity in the use of these documents and ensuring that authorisation guidelines are clearly identified as such and have an author outlined who acts as the practitioner.

The International Society of Radiographers and Radiological Technologists (ISRRT) Justification and Authorisation Flow chart was in place and its use was discussed. It was suggested that it should be used with a clear understanding of each process and the duty holder's role when undertaking each task; and that it is reflective of practice and the jurisdiction.

There is no formal process for the justification of carers and comforters in place. An area of improvement was identified in relation to establishing a justification process for the exposure of carers and comforters and developing a form to capture this process.

The MPE has established dose constraints for carers and comforters which are outlined in 'Employer's Procedure V'. Staff confirmed that information on carers and comforters is recorded on RIS under patient examination entry.

Non- medical exposures using medical radiology equipment

The 'Employer's Procedure N', which outlines the arrangements in place for non-medical imaging, was reviewed and found to be satisfactory. Staff confirmed that non-medical imaging is clearly identified on the request form and must be justified by an entitled practitioner.

7.3 Optimisation

There are good arrangements in place to ensure that exposures are kept as low as reasonably practicable. 'Employer's Procedure P' outlines the arrangements in place, these include:

- applications training
- radiographic protocols
- standard operating protocols
- routine equipment maintenance
- DRLs displayed in the imaging room
- appropriate exposure charts
- incident management
- management of near misses
- patient dose surveys
- daily quality assurance of equipment

As stated previously Image Optimisation Teams (IOTs) are being established and terms of reference were provided to the inspection team. Staff were aware of the IOTs and displayed an understanding of their role in the optimisation of exposures.

The MPE described their involvement on the IOT and confirmed that they are involved in dose audits; the establishment of local DRLs; setting up of protocols and risk assessment.

Communication of benefits and risks of having an exposure to ionising radiation

Staff displayed various levels of understanding in relation to the process of providing the individual (or their representative) to be exposed with adequate information on the benefits of having the exposure and the risks associated with the radiation dose. It was suggested staff training be provided to support staff with this task.

It was good to note information posters prominently displayed in the waiting areas for outpatients of the imaging department.

There were no posters displayed in relation to in-patients and the emergency department waiting areas. An area of improvement was identified with regards to displaying posters in these in-patient and the emergency department waiting areas.

Inspectors reviewed written patient information and preparation leaflets which had been developed and found them to be well written.

Paediatrics

Paediatric imaging is provided by the radiology department. It was noted that special attention is paid to optimisation when undertaking exposures of children. This includes:

- paediatric exposure charts (see comment below)
- modified views
- alternative techniques not involving ionising radiation where appropriate
- use of established paediatric DRLs

Review of the exposure charts in use noted that the paediatric section specified a size or age range for children. Staff confirmed that there are a range of settings for children which they can select depending on the age and size of the child. Specific paediatric imaging protocols have been developed.

Clinical Evaluation

An 'Employer's Procedure G' is in place for the clinical evaluation for medical exposures and it outlines that a documented clinical evaluation is produced for all medical exposures.

There is an audit trail in the RIS which identifies which exposures have not been reported on.

Evidence was gathered on a sample of patient records on the RIS to ensure a clinical evaluation has taken place.

7.4 Expert Advice

The WHSCT retains the services of a MPE on a contractual basis. The MPE was present for the duration of the inspection. It was confirmed the appointed MPEs are currently recognised by Department of Health and are entitled as operators who are competent and appropriately trained for their scope of practice.

The MPE provides ongoing advice and support to the management team on a range of issues including dosimetry and evaluation of dose, quality assurance (QA) matters relating to radiation protection, and radiological equipment.

The MPE is involved in high dose CT services. The MPE contributes to the radiation protection of patients and others; establishment of local DRLs; QA of the equipment; acceptance testing of equipment; installation design and technical specification of equipment; analysis of accidental or unintended exposures; selection of equipment for radiation protection measurements; training of practitioners and other staff on radiation protection and compliance with regulations. It was confirmed the MPE had provided training on IR(ME)R regulations 2018.

7.5 Equipment

An inventory of radiological equipment was supplied which contained most of the legislative information. An area of improvement was identified in relation to including the year of manufacture; the year of installation of radiological equipment; and details of ancillary equipment such as the CT injector pump on the inventory of radiological equipment.

There is an appropriate amount of equipment available for the workload of the radiology department.

It was confirmed that annual equipment quality assurance (QA) is carried out by the regional medical physics team and training has been provided to radiographers carrying out routine equipment QA testing. Equipment QA results are sent to the clinical site leads and actioned. A sample of QA test reports was reviewed.

All QA forms and procedures are under review as part of the ISAS process. Management outlined the robust procedure for equipment handover and when to report a fault. A working group has been set up to produce generic procedures that are then tailored to specific site needs.

7.6 Patient identification

'Employer's Procedure A' is in place to correctly identify individuals to be exposed to ionising radiation. The procedure references the three point patient identification process, and it clearly outlines that it is the responsibility of the operator who carries out the medical exposure, to ensure that the correct patient receives the correct medical exposure, according to the referral.

Staff confirmed that the operator responsible must sign their name beside the identity (ID) check on the request form or input this electronically in RIS as appropriate. Review of a sample of patient records confirmed an ID check had been recorded.

7.7 Pregnancy Enquiries

'Employer's Procedure D' for making enquiries of individuals of childbearing potential to establish whether the individual is or may be pregnant or breast feeding was in place and found to be adequate.

Staff interviewed demonstrated a very good understanding of making pregnancy enquiries, describing clearly what they would do in a range of situations and where to record details of these enquiries.

It was noted that the RIS system indicated the age range for making pregnancy enquires to be 11-55, the flow chart 12-55 and the 'Employer's Procedure D' did not specify any age range.

An area of improvement was identified in relation to ensuring consistency in the age range outlined for making pregnancy enquiries.

"Inform the radiographer if you are pregnant" posters were displayed in the changing areas in the department.

7.8 Research

The management team confirmed that no research is currently being conducted in the South West Acute Hospital radiology department.

'Employer's Procedure O' is in place for research exposures carried out in the trust.

7.9 Review of environment

The inspection team reviewed the facilities available in relation to diagnostic imaging. The department was found to be clean, tidy and well organised. There were posters to provide patients with information regarding benefit and risk of the exposure and pregnancy posters were also displayed. There was a well-appointed waiting area for inpatients and changing cubicles for outpatients.

7.12 Staff discussion, review of patient records

The inspection team met with radiographers and discussed: the application of the Employer's Procedures; the role and function of duty holders; patient identification; the use of authorisation guidelines; induction; continued professional development; the use of DRLs as a reference tool; and the action to be taken if they thought a patient had received an accidental or unintended exposure. Staff demonstrated a good working knowledge of Employer's Procedures and the other areas discussed. As stated previously the inspection team also spoke to radiologists in relation to their role and responsibilities under the IR(ME)R regulations and an area of improvement has been made in relation to ensuring there is evidence of training, competency and entitlement. Review of patient records indicated that the correct procedures are being followed.

7.13 Conclusion

Radiological practice in South West Acute Hospital radiology department was found to be safe, effective and in line with the principles of IR(ME)R and good practice guidelines.

Overall staff were found to be knowledgeable and professional. It is acknowledged the work that has been undertaken to ensure compliance with the IR(ME)R 2018 including; updating the radiation safety policy and the Employers Procedures; the MPE providing training on the new regulations to management and staff and developing posters and information leaflets for the communication of the benefits and risks of medical exposures to patients (and/or their representative).

As stated previously, it was evident the radiology department has an underpinning culture of quality improvement. Management and staff demonstrated an inclusive, enthusiastic and proactive approach to patient centred service improvement. The staff feedback provided on the day of inspection confirmed this approach.

Inspectors concluded that there were no identified serious concerns regarding the actual delivery of the service.

There were nine areas of improvement identified as a result of this inspection. These are fully outlined in the appended Quality Improvement Plan (QIP).

The management team and staff are to be commended for their commitment and enthusiasm to ensuring that the department is striving to operate within the legislative framework and maintaining optimal standards of practice for patients.

The inspectors would like to extend their gratitude to the management team and staff for their hospitality and contribution to the inspection process.

8.0 Quality improvement plan

Areas for improvement identified during this inspection are detailed in the Quality Improvement Plan (QIP). Details of the QIP were discussed with senior management as part of the inspection process. The timescales commence from the date of inspection.

It is the responsibility of the Employer to ensure that all areas for improvement identified within the QIP are addressed within the specified timescales.

8.1 Areas for improvement

Areas for improvement have been identified where action is required to ensure compliance with The Ionising Radiation (Medical Exposure) Regulations (Northern Ireland) 2018 known as IR(ME)R and other published standards which promote current best practice to improve the quality of service experienced by patients.

8.2 Actions to be taken by the service

The QIP should be completed and detail the actions taken to address the areas for improvement identified. The employer should confirm that these actions have been completed and return the completed QIP via independent.healthcare@rqia.org.uk for assessment by the inspector.

<table>
<tr><th colspan="2">Quality Improvement Plan</th></tr>
<tr><td colspan="2">Action required to ensure compliance with The Ionising Radiation (Medical Exposure) Regulations (Northern Ireland) 2018 and other published standards which promote current best practice to improve the quality of service experienced by patients.</td></tr>
<tr><td>Area for improvement 1

Regulation: 7

Stated: First time

To be completed by:
14 June 2019</td><td>The Employer shall ensure that an audit action plan is developed and implemented as necessary; and formalise the re-audit process and the sharing of audit findings with the relevant stakeholders.

Ref: 7.1</td></tr>
<tr><td></td><td>Response by the Employer detailing the actions taken:
The audit list provided to the inspector has been updated to include dates and the name of the responsible officer for the audit. (See atached). A standardised report format is available and will be completed by the responsible officer and the results presented at the Radiation Protection Subgroup and sooner to the governance group if non compliant. The scheduling of the audits will be managed though Q-Pulse and a schedule clearlly identified (audit schedule attached).</td></tr>
</table>

Area for improvement 2 **Regulation:** 8 (1) Schedule 2 (l) **Stated:** First time **To be completed by:** 14 June 2019	The Employer shall amend 'Employer's Procedure R' (clinically significant incidents) to include information as to how the decision not to inform the patient is recorded and amend 'Employers Procedure Q' (investigating and reporting incidents) in relation to notifying the correct enforcing authority of equipment failure. Ref: 7.1
	Response by the Employer detailing the actions taken: This process was acknowledged during the inspection and the written response amended and added as Procedure R to the Employer's Procedures. (Copy of updated Employer's Procedures attached) Ref Procedure Q. The reference to the Health and Safety Executive has been removed This revised Employer's procedures is currently progressing through the trust's internal governance mechanism for sign off by the new Medical Director.
Area for improvement 3 **Regulation:** 6(2), 6(3), 17 Schedule 2 (b) **Stated:** First time **To be completed by:** 14 July 2019	The Employer shall ensure radiologists have evidence of compliance with IR(ME)R in relation to induction, training and entitlement. Ref: 7.1
	Response by the Employer detailing the actions taken: An induction pack has been redrafted. It includes the required reading list for new employees e.g.Employer's Procedures, Local Rules, signficant findings process, training as operator for specific equipment. The entitlement form has been redesigned to include relevant IRMER training and use of equipment. The role of the practitioner has been detailed. Training records for individual pieces of equipment have been redesigned to include radiologist sign off as operators where required, e.g. CT flurosocopy or conventional fluoroscopy. New staff (including locums) will be required to sign off on completion of training/demonstration of new kit. Exisitng staff will be required to sign off for any new software or equipment upgrades. Entitlement will be reviewed annually and documented during appraisal. Revised radiologist entiltlement form attached.
Area for improvement 4 **Regulation**: 6(1)(a) Schedule 2(b) **Stated:** First time **To be completed by:** 14 June 2019	The Employer shall ensure non-medical referrers have formal written review of their entitlement and the register of named non-medical referrers is updated accordingly. Ref: 7.1
	Response by the Employer detailing the actions taken: The non medical referrers list has been reviewed. Any referrers who are no longer entitled to refer have been removed. All remaining referrers have been sent an updated letter to include the referrers' resposnisbility leaflet.

Area for improvement 5 **Regulation:** 6(1)(a) Schedule 2(b) **Stated:** First time **To be completed by:** 14 June 2019	The Employer shall establish a formal process for entitlement for ROI referrers and the acceptance of ROI referrals. Ref: 7.1
	Response by Employer detailing the actions taken: A new Procedure (Procedure Y) has been added to the Employer's Procedures. Currently known ROI GPs are identified in NIPACS. On receipt of request from an unknown ROI GP the request will be reviewed and IMC regstration checked. If the referrer is confirmed to be on the IMC register a consolidated log in will be issued by the NIPACS manager. A letter of entitlement and a copy of the "Referrer's Responsibilty" leaflet will be sent from the department Manager as per example attached.
Area for improvement 6 **Regulation:** 11(3)(b) Schedule 2 (n) **Stated:** First time **To be completed by:** 14 May 2019	The Employer shall establish a justification process for the exposure of carers and comforters and develop a form to record this process. Ref: 7.2
	Response by the Employer detailing the actions taken: Standard Operating procedure has been drafted. See attached. Risk Benefit has been more fully explained. Procedure V updated Instruction to include relvant information on RIS i.e. tick the comforter and care box in the "local defintions" section of the confirmation page of the RIS. The operator is then to add the dose record and details of the examination and alterations to any standard protocol
Area for improvement 7 **Regulation:** 6(1) Schedule 2 (i) **Stated:** First time **To be completed by:** 14 May 2019	The Employer shall ensure that information posters outlining the benefits of having the exposure and the risks associated with the radiation dose are displayed in the in-patient and the emergency department waiting areas. Ref: 7.3
	Response by the Employer detailing the actions taken: The Radiology department Managers have reviewed the number and location of radiation does posters and installed more in those areas identified by the inspectors
Area for improvement 8 **Regulation:** 15 (2) **Stated:** First time **To be completed by:** 14 May 2019	The Employer shall ensure that the year of manufacture, the year of installation of radiological equipment and details of any ancillary equipment such as the CT injector pump are included on the equipment inventory record. Ref: 7.5
	Response by the Employer detailing the actions taken: Asset register has been updated in Q-Pulse. Year of Manufacturer now recorded. Screen shot from Q Pulse attached showing updated asset data sheets

Area for improvement 9 **Regulation:** 11(1) (f) Schedule 2 (c) **Stated:** First time **To be completed by:** 14 May 2019	The Employer shall ensure consistency in the age range outlined for making pregnancy enquiries within relevant documentation. Ref: 7.7
	Response by the Employer detailing the actions taken: Procedure D updated and amended. Flowcharts in radiology rooms updated and replaced

Please ensure this document is completed in full and returned via independent.healthcare@rqia.org.uk

The Regulation and Quality Improvement Authority

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