Health Information and Quality Authority

An tÚdarás Um Fhaisnéis agus Cáilíocht Sláinte

Health Information and Quality Authority

Report of the assessment of compliance with medical exposure to ionising radiation regulations

Name of Medical Radiological Installation:	Portiuncula University Hospital
Undertaking Name:	Health Service Executive
Address of Ionising Radiation Installation:	Dunlo, Ballinasloe, Galway
Type of inspection:	Announced
Date of inspection:	04 February 2020
Medical Radiological Installation Service ID:	OSV-0007371
Fieldwork ID:	MON-0028549

About the medical radiological installation:

Portiuncula University Hospital, Ballinasloe, Co. Galway is part of the Saolta University Healthcare Group in the west of Ireland. Portiuncula University Hospital (PUH) is a 194 bed - Model 3 hospital providing acute surgery, acute medicine and critical care, emergency department, paediatric and maternity services. The hospital offers day surgery in addition to their role in providing for acute medical and surgical adult and paediatric patients. The hospital is part of the HSE National Integrated Medical Imaging System (NIMIS) Radiology Information System/Picture Archiving and Communication System (RIS/PACS) programme. The Radiology Department is multidisciplinary and provides services including:

-general X-ray

-mobile radiography

-fluoroscopy procedures

-radiology services in theatre

-computerised tomography (CT).

Radiology services are provided for inpatients; outpatient clinics; GPs and other hospital referrals with approximately 57,370 examinations undertaken per year. An evening and weekend on- call service is in operation in the hospital.

How we inspect

This inspection was carried out to assess compliance with the European Union (Basic Safety Standards for Protection against Dangers Arising from Medical Exposure to Ionising Radiation) Regulations 2018 and 2019. The regulations set the minimum standards for the protection of service users exposed to ionising radiation for clinical or research purposes. These regulations must be met by each undertaking carrying out such practices. To prepare for this inspection, the inspector[1] reviewed all information about this medical radiological installation[2]. This includes any previous inspection findings, information submitted by the undertaking, undertaking representative or designated manager to HIQA[3] and any unsolicited information since the last inspection.

As part of our inspection, where possible, we:

- talk with staff and management to find out how they plan, deliver and monitor the services that are provided to service users
- speak with service users[4] to find out their experience of the service
- observe practice to see if it reflects what people tell us
- review documents to see if appropriate records are kept and that they reflect practice and what people tell us.

About the inspection report

In order to summarise our inspection findings and to describe how well a service is complying with regulations, we group and report on the regulations under two dimensions:

1. Governance and management arrangements for medical exposures:

[1] Inspector refers to an Authorised Person appointed by HIQA under Regulation 24 of S.I. No. 256 of 2018 for the purpose of ensuring compliance with the regulations.
[2] A medical radiological installation means a facility where medical radiological procedures are performed.
[3] HIQA refers to the Health Information and Quality Authority as defined in Section 2 of S.I. No. 256 of 2018.
[4] Service users include patients, asymptomatic individuals, carers and comforters and volunteers in medical or biomedical research.

This section describes HIQA's findings on compliance with regulations relating to the oversight and management of the medical radiological installation and how effective it is in ensuring the quality and safe conduct of medical exposures. It outlines how the undertaking ensures that people who work in the medical radiological installation have appropriate education and training and carry out medical exposures safely and whether there are appropriate systems and processes in place to underpin the safe delivery and oversight of the service.

2. Safe delivery of medical exposures:

This section describes the technical arrangements in place to ensure that medical exposures to ionising radiation are carried out safely. It examines how the undertaking provides the systems and processes so service users only undergo medical exposures to ionising radiation where the potential benefits outweigh any potential risks and such exposures are kept as low as reasonably possible in order to meet the objectives of the medical exposure. It includes information about the care and supports available to service users and the maintenance of equipment used when performing medical radiological procedures.

A full list of all regulations and the dimension they are reported under can be seen in Appendix 1.

This inspection was carried out during the following times:

Date	Times of Inspection	Inspector	Role
Tuesday 4 February 2020	09:00hrs to 16:00hrs	Agnella Craig	Lead
Tuesday 4 February 2020	09:00hrs to 16:00hrs	Lee O'Hora	Support

Governance and management arrangements for medical exposures

Inspectors found that there was effective leadership, governance and management arrangements in place locally. There were also clear systems and processes in place detailing a clear allocation of responsibility for the radiation protection of service users within Portiuncula University Hospital. The general manager (GM) was the designated person responsible for radiation protection for the hospital and was a member of the governance committees, including the Radiation Safety Committee (RSC) and the Radiology Directorate Quality and Safety Committee. Based on the terms of reference of the RSC reviewed by inspectors, this committee provides oversight and is an effective mechanism for ensuring the quality and safe conduct of medical exposures in this facility.

From the documents and records reviewed, inspectors were assured that systems and processes were in place to ensure that referrals were only accepted from those entitled to refer an individual for medical radiological procedures. Furthermore, all procedures involving medical exposure to ionising radiation were conducted under the clinical responsibility of those recognised in the regulations as practitioners.

While a medical physics expert (MPE) was available to give advice to this facility, the level of involvement was limited and this was acknowledged by staff on the day of inspection. This deficit has been raised by the MPE and inspectors were informed by management that the issue has been escalated at hospital group level and was under review. Although the level of involvement of the MPE was limited, inspectors were assured by the mechanisms in place which relied on available radiography staff, including the radiography services manager and the radiation safety officer.

The hospital currently reports to the Saolta University Health Care Group; however, any issues relating to medical exposure to ionising radiation should also be communicated to the Health Service Executive (HSE) as the HSE is the undertaking with overall responsibility for this facility. The specific reporting mechanism for this was not made available to inspectors on the day of inspection. Furthermore, although local processes for reporting radiation incidents were clearly known, some staff members reported a lack of clarity in relation to the reporting process to the HSE National Radiation Protection Office. To ensure the undertaking has full oversight of the local facility, it is important that responsibilities and lines of accountability are clearly delineated and understood at local level as well as hospital group and national HSE level.

Regulation 4: Referrers

Portiuncula University Hospital receives referrals in electronic format from referrers within the hospital. Only those entitled to refer have access to the Radiology

Information System (RIS), and specific ordering rights are customised relating to scope of practice. For example, referrals are received from Advanced Nurse Practitioners for specific procedures.

Referrals from sources external to the hospital, including referrals from general practitioners (GPs) and dentists are received in hard copy format and uploaded to the RIS. Referrals for medical radiological procedures reviewed on the day of inspection were only accepted from registered medical practitioners. Staff that spoke with inspectors demonstrated a comprehensive understanding of the referral process and this was consistent with local policy.

Judgment: Compliant

Regulation 5: Practitioners

Those entitled to act as practitioners were clearly identified in hospital policies reviewed by inspectors. Staff also communicated that only radiographers and radiologists were entitled to act as practitioners at this hospital. From the records of medical exposures reviewed on the day of inspection, inspectors were satisfied that only those entitled to act as practitioners had taken clinical responsibility for individual medical exposures.

Judgment: Compliant

Regulation 6: Undertaking

The governance structures in place facilitated the allocation of responsibilities with respect to radiation protection within the hospital and at the Saolta University Health Care Group level. At a hospital level, a Radiology Directorate Quality and Safety Committee and a Radiation Safety Committee (RSC) were in place to discuss aspects relating to medical exposure to ionising radiation. The general manager was a member of these committees, with the deputy general manager representing the general manager when necessary. From the documentation provided, it was unclear how frequently these committees met. Staff clarified that the intention is to meet once a month, with the RSC meeting three times a year and the overarching Radiology Directorate Quality and Safety Committee meeting eight to nine times a year. A Radiation Incident Review group also met monthly with the risk manager and outcomes from these meetings were directed to the RSC and or the Radiology Directorate Quality and Safety Committee, as necessary.

While inspectors were informed that the general manager reports information to the Saolta University Health Care Group through the Group Executive Council, the specific relationship between the hospital and the HSE as the undertaking with

overall responsibility for this installation was not made clear to inspectors. The specific mechanisms to communicate with the HSE through the National Radiation Protection Office was also not known by staff or documented in the documentation reviewed by inspectors. Furthermore, in relation to the dental unit within the hospital (consisting of two intra-oral dental machines), inspectors were informed that this unit was under the remit of the designated manager at Portiuncula University Hospital and this unit was governed by the same policies and processes as in the radiology department. However, this did not align with notification information provided to HIQA regarding the allocation of governance and responsibility for this unit. Clarity from the undertaking on the allocation of responsibility as noted above by inspectors would provide an assurance of the radiation protection of service users.

Judgment: Substantially Compliant

Regulation 10: Responsibilities

Inspectors were assured that all medical exposures took place under the clinical responsibility of a practitioner. From the documentation reviewed and discussions with staff, medical exposures were only performed by radiographers and or radiologists. Inspectors were assured that the optimisation process included the practitioner and the medical physics expert.

Judgment: Compliant

Regulation 19: Recognition of medical physics experts

Inspectors were informed that MPE services were provided by University Hospital Galway, through an informal arrangement. This arrangement meant that services were provided but the MPE did not have a regular onsite presence. The MPE was supported by a physicist to carry out quality assurance of equipment at the hospital. Inspectors were informed that if the MPE is not available, the physicist from University Hospital Galway could provide continuity of services. While inspectors were assured that the MPE had an oversight role for this installation, a formal arrangement should be in place to ensure the continuity of medical physics expertise.

Judgment: Substantially Compliant

Regulation 20: Responsibilities of medical physics experts

Specific documentation outlining the roles and responsibilities of an MPE was not available to inspectors. From documents reviewed on the day of inspection and from speaking with staff, it was evident that the MPE takes responsibility for doses delivered to service users, reviewing diagnostic reference levels (DRLs), quality assurance and acceptance testing. The MPE also gives advice on medical radiological equipment and is involved in training and education of staff. Inspectors were informed that the MPE's involvement in the optimisation process is limited to equipment and quality assurance testing rather than having a role in protocol design, development and review, which is an opportunity for improvement.

Judgment: Compliant

Regulation 21: Involvement of medical physics experts in medical radiological practices

From the documentation reviewed, inspectors were assured that the MPE was involved in medical radiological practices. However, inspectors identified scope for more involvement of the MPE in line with the radiological risk posed by the service. Staff who spoke with inspectors acknowledged that the involvement of the MPE was limited; for example, involvement in optimisation did not include protocol design or review.

Inspectors were informed that the MPE had raised the level of MPE involvement as an issue to management who acknowledged that the level of involvement of MPEs was limited. Inspectors were informed that this issue was subsequently raised at a general managers' forum and the issue was being considered. A formal agreement with documentation detailing the role and responsibilities of the MPE in line with the level of radiological risk in this service, would provide assurance of the undertaking's compliance with this regulation.

Judgment: Substantially Compliant

Safe Delivery of Medical Exposures

Inspectors found evidence that Portiuncula University Hospital had appropriate systems and processes in place to ensure that safe and effective medical exposures are provided to service users. This included evidence of appropriate processes to ensure optimisation of procedures, the use of diagnostic reference levels (DRLs), appropriate quality assurance programmes, written protocols for each type of procedure carried out and posters relating to pregnancy and the risks associated with radiation exposure available in the Radiology Department. The proactive approach taken by staff to diagnostic reference levels demonstrates the benefit of

establishing and reviewing DRLs without affecting the diagnostic outcome of the exposure.

Although the personnel with specific responsibility for justification was detailed in the documentation reviewed and was in line with the regulations, a record that justification had been conducted was not evident in all records reviewed. Identifying a specific process to ensure documented evidence of justification of all procedures will facilitate the undertaking to come into compliance with Regulation 8(8) and 8(15).

Inspectors also found that this facility was not in compliance with Regulation 13(2) as information relating to patient exposure was not included on the report of the medical exposure, and this was acknowledged by staff.

With respect to Regulation 17, the specific processes for reporting incidents and near misses was detailed in documentation and known by staff but a process to facilitate the analysis of incidents for trending purposes was currently not in place in this hospital. The mechanism to inform the undertaking of incidents was also not clear to staff. Implementing a system for analysis of potential incidents will aid the undertaking to come in to compliance with Regulation 17.

Although some areas require attention in order to reach full compliance, overall, inspectors were assured by the arrangements in place that this service was providing safe medical exposures to ionising radiation.

Regulation 8: Justification of medical exposures

Inspectors reviewed information available for patients, and this outlined the benefits and risks associated with radiation for standard procedures carried out at this hospital.

Inspectors were informed that justification in advance of medical exposures is conducted by appropriate individuals as defined in Regulation 5, and these individuals outlined the process they use to justify all exposures. Referral guidelines were available to staff and staff explained that they would either consult these guidelines or discuss issues with a colleague should they have concerns about a referral.

All referrals reviewed on the day of inspection were available in writing, stated the reason for the request and were accompanied by medical data which allowed the benefits versus the risk of exposures to be considered by the practitioner.

Inspectors noted that a record of justification was not documented for all procedures carried out at this hospital. This was evident in the sample of records reviewed on the day of inspection and from speaking with staff responsible for the justification of medical exposures. As a result, the hospital was not in full compliance with this regulation and this finding was acknowledged by staff. Further utilisation of

the current Radiology Information System to record the process of justification may assure the undertaking that all medical exposures are justified in advance and aid the undertaking to reach compliance with Regulations 8(8) and 8(15).

Judgment: Substantially Compliant

Regulation 9: Optimisation

A recent guideline developed by the radiology services manager and the radiation safety officer outlined justification and optimisation. This document included details of staff responsibilities in relation to optimisation and the specific processes that facilitate optimisation. This guideline highlighted a number of aspects that can be considered for optimisation, including quality assurance, patient positioning, protocol use, clinical audits and review of diagnostic reference levels. This guideline also referenced the policy on carers and comforters which was made available to inspectors on the day of inspection.

Judgment: Compliant

Regulation 11: Diagnostic reference levels

DRLs have been established for radiological procedures in this hospital and were compared to local and national levels. A comparison of DRLs from 2018 to 2019 with respect to one particular procedure had shown a significant drop in dose. This was as a result of modifying the specific technique. Staff also informed inspectors of processes that were followed previously with respect to DRLs, which were found to be below the national average but which impacted on image quality. This proactive approach taken by staff in this hospital demonstrates the benefit of establishing and reviewing DRLs without affecting the diagnostic outcome of the exposure.

In addition to DRLs being available in electronic format, inspectors noted that relevant DRLs were available in hard copy format in the CT area. Staff informed inspectors that visibility of DRLs in the clinical area helped increase awareness.

Expanding the current documentation about DRLs to include a formal structure on DRL review and subsequent actions and responsibilities would increase the undertaking's assurance of compliance with this regulation.

Judgment: Compliant

Regulation 13: Procedures

Written protocols were established for standard medical radiological procedures carried out at this hospital and these were available in both electronic and hard copy format. Staff demonstrated an awareness of and an ability to access these protocols.

A list of clinical audits proposed for 2019–2020 was provided to inspectors. Inspectors were informed that although a programme of clinical audit is devised, some proposed audits were not conducted or analysed due to resource issues. A quality improvement plan following audit was also lacking. Inspectors were informed that clinical audit has been added as a standing item on the governance committees. This may aid in prioritising clinical audit and quality improvement if staff are available to conduct, analyse and act on findings from clinical audits.

To ensure compliance with Regulation 13(2), an undertaking should ensure that information relating to patient exposure forms part of the report of the medical radiological procedure. Inspectors were informed by staff that information relating to the patient exposure is not recorded on the report. As a result, the hospital was not fully compliant with this regulation and this finding was acknowledged by staff.

Judgment: Substantially Compliant

Regulation 14: Equipment

Prior to inspection, inspectors were provided with an up-to-date inventory of medical radiological equipment and noted the equipment was kept under strict surveillance regarding radiation protection. Documentation reviewed by inspectors showed that appropriate quality assurance programmes, including regular performance testing had been implemented and maintained for each piece of medical radiological equipment on the inventory. Although some of the equipment had passed the nominal replacement date, inspectors noted that they had passed all necessary quality assurance tests and had been approved for clinical use. Equipment was an item discussed at the Radiation Safety Committee and the Radiology Directorate Quality and Safety Committee and replacement of end-of-life equipment has been escalated to hospital group level.

Judgment: Compliant

Regulation 16: Special protection during pregnancy and breastfeeding

Inspectors were informed by staff of the process in place to inquire about pregnancy status. The policy in place since August 2019 and the clinical audit conducted on recording date of last menstrual period (LMP) were also reviewed by inspectors. Although the LMP date was not recorded in some records viewed on the day of

inspection, a record of pregnancy status was documented on all records viewed by inspectors and therefore the undertaking was found to be compliant with the regulations.

An additional document — 'Local rules for radiation safety procedures and standard operating procedures for mobile radiography and fluoroscopy' — reviewed by inspectors contained a procedure for checking the date of the LMP, and some variance was found between this document and the new policy. Staff recognised the importance of removing out-of-date policies and procedures to aid in awareness and compliance with local policies.

Judgment: Compliant

Regulation 17: Accidental and unintended exposures and significant events

An electronic system (Qpulse) was in place for recording radiation incidents. Near misses were also recorded in this system. Staff who spoke with inspectors on the day of inspection demonstrated a knowledge and understanding of the incident reporting processes within the hospital. In addition to recording the incident in the system, staff were aware of the process of reporting the incident to the radiation safety officer and the radiology services manager and the subsequent steps taken in investigating incidents and near misses. Inspectors were informed that learning from incidents and potential incidents was fed back to staff through monthly radiographer meetings. Radiation incidents was also an agenda item on the RSC and the Radiology Directorate Quality and Safety Committee.

However, a process to analyse incidents for trending purposes was currently not in place in this hospital. Additionally, although the local processes for reporting incidents were clearly known, staff reported a lack of clarity in relation to the reporting process to the HSE National Radiation Protection Office. For compliance with the regulations, an undertaking should have full oversight of each facility. Developing clear processes for reporting incidents to the undertaking will increase oversight and assure the undertaking of compliance with this regulation.

Judgment: Substantially Compliant

Appendix 1 – Summary table of regulations considered in this report

This inspection was carried out to assess compliance with the European Union (Basic Safety Standards for Protection against Dangers Arising from Medical Exposure to Ionising Radiation) Regulations 2018 and 2019. The regulations considered on this inspection were:

Regulation Title	Judgment
Governance and management arrangements for medical exposures	
Regulation 4: Referrers	Compliant
Regulation 5: Practitioners	Compliant
Regulation 6: Undertaking	Substantially Compliant
Regulation 10: Responsibilities	Compliant
Regulation 19: Recognition of medical physics experts	Substantially Compliant
Regulation 20: Responsibilities of medical physics experts	Compliant
Regulation 21: Involvement of medical physics experts in medical radiological practices	Substantially Compliant
Safe Delivery of Medical Exposures	
Regulation 8: Justification of medical exposures	Substantially Compliant
Regulation 9: Optimisation	Compliant
Regulation 11: Diagnostic reference levels	Compliant
Regulation 13: Procedures	Substantially Compliant
Regulation 14: Equipment	Compliant
Regulation 16: Special protection during pregnancy and breastfeeding	Compliant
Regulation 17: Accidental and unintended exposures and significant events	Substantially Compliant

Compliance Plan for Portiuncula University Hospital OSV-0007371

Inspection ID: MON-0028549

Date of inspection: 04/02/2020

Introduction and instruction
This document sets out the regulations where it has been assessed that the undertaking is not compliant with the European Union (Basic Safety Standards for Protection against Dangers Arising from Medical Exposure to Ionising Radiation) Regulations 2018 and 2019.

This document is divided into two sections:

Section 1 is the compliance plan. It outlines which regulations the undertaking must take action on to comply. In this section the undertaking must consider the overall regulation when responding and not just the individual non compliances as listed in section 2.

Section 2 is the list of all regulations where it has been assessed the undertaking is not compliant. Each regulation is risk assessed as to the impact of the non-compliance on the safety, health and welfare of service users.

A finding of:

- **Substantially compliant -** A judgment of substantially compliant means that the undertaking or other person has generally met the requirements of the regulation but some action is required to be fully compliant. This finding will have a risk rating of yellow which is low risk.

- **Not compliant -** A judgment of not compliant means the undertaking or other person has not complied with a regulation and considerable action is required to come into compliance. Continued non-compliance — or where the non-compliance poses a significant risk to the safety, health and welfare of service users — will be risk rated red (high risk) and the inspector will identify the date by which the undertaking must comply. Where the non-compliance does not pose a risk to the safety, health and welfare of service users, it is risk rated orange (moderate risk) and the undertaking must take action *within a reasonable timeframe to* come into compliance.

Section 1

The undertaking is required to set out what action they have taken or intend to take to comply with the regulation in order to bring the medical radiological installation back into compliance. The plan should be **SMART** in nature. **S**pecific to that regulation, **M**easurable so that they can monitor progress, **A**chievable and **R**ealistic, and **T**ime bound. The response must consider the details and risk rating of each regulation set out in section 2 when making the response. It is the undertaking's responsibility to ensure they implement the actions within the timeframe.

Compliance plan undertaking response:

Regulation Heading	**Judgment**
Regulation 6: Undertaking	Substantially Compliant

Outline how you are going to come into compliance with Regulation 6: Undertaking:
Action
Standard Operational Procedure to clearly delineate lines of responsibility and accountability which will include:

• HSE Governance structure and organogram for medical incident reporting
• governance of radiation protection in hospitals and community healthcare organisations
• Process for notification of medical radiation incidents to the HSE

Timeframe: 31.05.2020

Action by:
1. General Manager,
2. Radiography Services Manager,
3. Radiation Protection Officer,
4. Radiation Protection Adviser,
5. Quality and Risk Manager

Dental Unit

Action by:
• Radiation Protection Officer
• General Manager

Action completed:

• Dental unit in dental clinic has been confirmed to be under the auspices of the General Manager CHO2 Primary Community Care and the Principal Dentist CHO2 Primary community Care.

• Reply from National radiation Protection Office 28/04/2020 stated that the office has correct delegation mangers on file as above.

Regulation 19: Recognition of medical physics experts	Substantially Compliant

Outline how you are going to come into compliance with Regulation 19: Recognition of medical physics experts:
Action:
• Written formal arrangement between Portiuncula University Hospital and medical Physics in Galway University Hospital with regards to oversight of installation and level of on-site presence

Action by:
• General Manager
• Radiation Protection Adviser

Timeframe: 6 months – December 2020

Regulation 21: Involvement of medical physics experts in medical radiological practices	Substantially Compliant

Outline how you are going to come into compliance with Regulation 21: Involvement of medical physics experts in medical radiological practices:
Action
• Formal agreement with documentation to include detailed roles and responsibilities of Medical Physics expert in line with radiological risk in the service

Action by
• General Manager
• Radiation Protection Adviser/MPE

Timeframe: 6 months – December 2020

Regulation 8: Justification of medical exposures	Substantially Compliant

Outline how you are going to come into compliance with Regulation 8: Justification of medical exposures:
Action: to extend the vetting process to all radiological examinations in order to comply with justification of requests and as an audit tool for quality improvement process

Process:
• Vetting structure modified on NIMIS
• Business cases for Clinical Specialist Radiographer in general radiography, DEXA and Interventional/fluoroscopy Radiography required
• Appointment of clinical specialist radiographer in general radiography, DEXA and Interventional/fluoroscopy Radiography required

To date:
• Acting CSR appointed in general radiography 13.04.2020 to vet (justify)

Action by:
• Radiography Services Manager
• Associate Clinical Director Radiology
• General Manager
• Clinical Support Services Director
• HR Manager

Timeframe: 1 year. May 2021

Regulation 13: Procedures	Substantially Compliant

Outline how you are going to come into compliance with Regulation 13: Procedures:
Audit:

Action: set up Radiology departmental Audit group, and plan implementation and audit cycle which will report to the Radiology Directorate Quality and Safety Committee and the PUH Quality and Safety Group

Action by:
• Associate Clinical Director Radiology
• Radiography Services Manager
• Radiation Protection Officer
• Clinical Specialist Radiographers

Timeframe: 6 months – November 2020
Dose report:

Action: Patient exposure forms a part of medical report. This is a national issue for all installations on the NIMIS system

• 17/04/2020 – RPO reported issue regarding patient exposure on medical report to NIMIS national lead.

Action by;
• RPO
• NIMIS National Team

Timeframe: awaiting timeframe from NIMIS National Team

Regulation 17: Accidental and unintended exposures and significant events	Substantially Compliant

Outline how you are going to come into compliance with Regulation 17: Accidental and unintended exposures and significant events:
Action

Standard Operational Procedure to clearly delineate lines of responsibility and accountability which will include:

• HSE Governance structure and organogram for medical incident reporting
• Governance of radiation protection in hospitals and community healthcare organisations
• Process for notification of medical radiation incidents to the HSE National Radiation Protection Office
• Process to analysis incidents for trending purposes required through Qpulse system – National Incident Management System (NIMS)

Action by:
• General Manager
• Radiography Services Manager
• Radiation Protection Officer
• Radiation Protection Adviser
• Quality and Risk Manager
• Associate Clinical Director

Timeframe: 3 months - August 2020

Section 2:

Regulations to be complied with

The undertaking and designated manager must consider the details and risk rating of the following regulations when completing the compliance plan in section 1. Where a regulation has been risk rated red (high risk) the inspector has set out the date by which the undertaking and designated manager must comply. Where a regulation has been risk rated yellow (low risk) or orange (moderate risk) the undertaking must include a date (DD Month YY) of when they will be compliant.

The undertaking has failed to comply with the following regulation(s).

Regulation	Regulatory requirement	Judgment	Risk rating	Date to be complied with
Regulation 6(3)	An undertaking shall provide for a clear allocation of responsibilities for the protection of patients, asymptomatic individuals, carers and comforters, and volunteers in medical or biomedical research from medical exposure to ionising radiation, and shall provide evidence of such allocation to the Authority on request, in such form and manner as may be prescribed by the Authority from time to time.	Substantially Compliant	Yellow	31/05/2020
Regulation 8(8)	An undertaking shall ensure that all individual medical exposures carried out on its behalf are justified in advance, taking into account the	Substantially Compliant	Yellow	01/05/2021

	specific objectives of the exposure and the characteristics of the individual involved.			
Regulation 8(15)	An undertaking shall retain records evidencing compliance with this Regulation for a period of five years from the date of the medical exposure, and shall provide such records to the Authority on request.	Substantially Compliant	Yellow	01/05/2021
Regulation 13(2)	An undertaking shall ensure that information relating to patient exposure forms part of the report of the medical radiological procedure.	Not Compliant	Yellow	01/05/2021
Regulation 17(1)(c)	An undertaking shall ensure that for all medical exposures, an appropriate system is implemented for the record keeping and analysis of events involving or potentially involving accidental or unintended medical exposures, commensurate with the radiological risk posed by the practice,	Substantially Compliant	Yellow	01/12/2020
Regulation 19(9)	An undertaking shall put in place	Substantially Compliant	Yellow	01/12/2020

	the necessary arrangements to ensure the continuity of expertise of persons for whom it is responsible who have been recognised as a medical physics expert under this Regulation.			
Regulation 21(1)	An undertaking shall ensure that, in medical radiological practices, a medical physics expert is appropriately involved, the level of involvement being commensurate with the radiological risk posed by the practice.	Substantially Compliant	Yellow	01/12/2020