



Health Information and Quality Authority

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

Name of Medical Radiological Installation:	Naas General Hospital
Undertaking Name:	Health Service Executive
Address of Ionising Radiation Installation:	Craddockstown Road, Naas East, Naas, Kildare
Type of inspection:	Announced
Date of inspection:	18 December 2019
Medical Radiological Installation Service ID:	OSV-0007367
Fieldwork ID:	MON-0028230

About the medical radiological installation:

Naas General Hospital (NGH) is a statutory hospital owned and managed by the Health Service Executive (HSE). NGH is a 243 bed acute general hospital that is part of the Dublin Midlands Hospital Group. The Radiology Department at NGH provides diagnostic imaging services to inpatients, outpatients, Emergency Department and Medical Assessment Unit patients, and patients referred from Primary Care in the Kildare/West Wicklow region and the surrounding counties. It provides general X-ray, DXA scanning, fluoroscopy, mobile X-ray, ultrasound, computed tomography (CT) and magnetic resonance imaging.

Routine services are provided from 9am to 5pm, Monday-Friday, with full out-of-hours on-call cover provided for the Emergency Department and Inpatient X-ray. Full out-of-hours on-call cover for CT is also provided. Radiation protection and medical physics services are provided by staff from a major teaching hospital within the Dublin Midlands Hospital Group. There is on-site presence of the Medical Physics Expert in NGH one day per week with additional visits for the purposes of Quality Assurance and equipment commissioning, as required. Approximately 33,500 ionising radiation procedures are performed annually within the Radiology Department. A further 23,100 ionising radiation procedures are conducted on an annual basis outside the Radiology Department. NGH is part of the HSE National Integrated Medical Imaging System (NIMIS) Radiology Information System/Picture Archiving and Communication System (RIS/PACS) programme.

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 inspector¹ reviewed all information about this medical radiological installation². This includes any previous inspection findings, information submitted by the undertaking, undertaking representative or designated manager to HIQA³ 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 users⁴ 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
Wednesday 18 December 2019	09:00hrs to 16:00hrs	Agnella Craig	Lead
Wednesday 18 December 2019	09:00hrs to 16:00hrs	Kirsten O'Brien	Support
Wednesday 18 December 2019	09:00hrs to 16:00hrs	Noelle Neville	Support

Governance and management arrangements for medical exposures

Inspectors found that there was effective leadership, governance and management arrangements in place locally with systems and processes detailing a clear allocation of responsibility for the radiation protection of service users within Naas General Hospital. The General Manager (GM) was the designated person responsible for radiation protection for the hospital and the chair of the hospital's Radiation Safety Committee (RSC). This committee was incorporated into local governance structures, reporting to the Quality and Patient Safety Committee and the Executive Management Committee. The RSC provides oversight and is an effective mechanism for ensuring the quality and safe conduct of medical exposures.

Along with reporting to the Dublin Midlands Hospital group, the hospital also report to the undertaking through the HSE's National Radiation Protection Office. 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 was 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. The scheme of delegation sent from the National Radiation Protection Office to the hospital was only received on the day before inspection and this may help in clarifying the mechanism of communicating with the undertaking.

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.

Inspectors were informed of the process in place to ensure involvement and continuity of medical physics expertise. A recent service level agreement with a hospital in the same hospital group resulted in an increase in the presence of medical physics expertise onsite. This agreement resulted in a medical physics expert having dedicated time to attend the department on a weekly basis, and maintain continuity of services. From the documentation reviewed, inspectors were assured that the level of involvement of the medical physics expert was proportionate to the level of risk in the service.

From speaking with staff and the documents reviewed, inspectors were assured that medical exposures took place under the clinical responsibility of a practitioner and that both the practitioner and the medical physics expert were involved in the optimisation process. For clarity, policies and procedures relating to the delegation of the practical aspects of medical radiological procedures to individuals should be updated to fully reflect current practice at the hospital.

Regulation 4: Referrers

Naas General Hospital receives referrals in electronic and hard copy format from sources both internal and external to the hospital. Referrals for medical radiological procedures, reviewed on the day of inspection, were only accepted from registered medical practitioners in Ireland and registered Advanced Nurse Practitioners (ANP's). Staff that spoke with inspectors demonstrated a comprehensive understanding of the referral process and this was consistent with local policy.

Inspectors were informed that referrals received in hard copy format are typically from local General Practitioners (GPs). Electronic referrals could only be made by users with appropriate ordering rights on the hospital's Radiology Information System (RIS). ANP referral was audited routinely and a 94% level of compliance for appropriateness of referrals was recorded in the records reviewed. Additional referral audits from different categories of referrer would provide the undertaking with further assurance of compliance with the policies in place ensuring that all referrals are only accepted from those entitled to act as referrers.

Judgment: Compliant

Regulation 5: Practitioners

Those entitled to act as practitioners were clearly identified in hospital policies reviewed by inspectors. 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. Staff also communicated that only radiographers and medical doctors working in the Radiology Department were entitled to act as practitioners at Naas General Hospital and this was consistent with local policy.

Judgment: Compliant

Regulation 6: Undertaking

From a review of documentation and discussion with senior management, systems and processes were in place with a clear allocation of responsibility for the protection of service users within Naas General Hospital. The general manager of the hospital was the chair of the Radiation Safety Committee and this committee

reported to the Quality and Patient Safety Committee, the Health and Safety Committee, and the hospital's Executive Management Committee. The Executive Management Committee reported to the Dublin Midland Hospital Group.

Inspectors were informed that the hospital also reported to the HSE National Radiation Protection Office. The specific processes associated with this dual reporting structure were not available on the day of inspection and inspectors were informed that the process was evolving. Furthermore, a lack of clarity in relation to the reporting process to the HSE National Radiation Protection Office was expressed by some staff members who met with inspectors. To ensure appropriate management and governance arrangements for the radiation protection of service users within the HSE, it is important that the lines of responsibility and accountability are clearly understood within this dual reporting system.

Inspectors were informed that management had just recently received the scheme of delegation from the HSE National Radiation Protection Office. Within this dual reporting system, this scheme may provide clarity on the reporting process within the HSE and assure the undertaking of the protection of service users and compliance with the regulations.

Judgment: Substantially Compliant

Regulation 10: Responsibilities

Naas General Hospital had systems and processes in place to ensure that all medical exposures took place under the clinical responsibility of a practitioner. From the documents reviewed and speaking with staff, inspectors were assured that the practitioner and the medical physics experts were involved in the optimisation process.

Only practitioners were involved in the practical aspects of a medical exposure and further delegation of the practical aspects of a medical exposure was not required in Naas General Hospital. Documentation should be updated to fully reflect this current practice at the hospital.

Judgment: Compliant

Regulation 19: Recognition of medical physics experts

Inspectors were informed that a service level agreement was in place to supply Medical Physics Expert (MPE) services to Naas General Hospital. The service level agreement resulted in the on-site presence of an MPE at least one day per week at the hospital, with additional cover for quality assurance testing and commissioning

of new equipment, as required.

The service level agreement, drawn up with a major teaching hospital in the same hospital group, allowed the hospital to benefit from shared resources across hospitals within the same group which assured inspectors of the continuity of MPE services.

Judgment: Compliant

Regulation 20: Responsibilities of medical physics experts

Naas General Hospital had systems in place to ensure that medical physics experts (MPE) met the requirements of Regulation 20. From documents reviewed on the day of inspection, and from speaking with a MPE, it was evident that the MPE takes responsibility for dosimetry and is involved in quality assurance and acceptance testing, clinical audits, optimisation of procedures and establishing and reviewing DRLs.

The MPE also gives advice on medical radiological equipment and is involved in documentation development and the training and education of staff. Although a judgment of compliance was determined in respect of Regulation 20, full documentation of the role and responsibilities of the MPE would provide further assurance of compliance with this regulation.

Judgment: Compliant

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

Involvement of the medical physics experts in medical radiological procedures was clearly evidenced through discussions with staff and from reviewing the documentation relating to medical radiological procedures. From the documentation reviewed, inspectors were assured that the level of involvement was in line with the radiological risk posed by the service.

Judgment: Compliant

Safe Delivery of Medical Exposures

Overall, inspectors found that Naas General Hospital had promoted the safe delivery of medical exposures to protect service users from potential risks associated with

medical exposures carried out in the hospital. Full compliance was found in relation to three of the six regulations investigated within this section. Evidence of the safe delivery of medical exposures included; diagnostic reference levels (DRLs) being established, reviewed and compared to national and European levels and available to staff; equipment having appropriate quality assurance and maintenance testing programmes in place for all equipment; special protection of service users during pregnancy with policies and procedures in place to protect service users during pregnancy, with adequate posters highlighting the risks associated with radiation exposure available throughout the department.

The remaining three regulations, investigated within this section, require some improvements in order to become fully compliant.

From the records reviewed on the day of inspection, justification was not documented on some general radiology procedures, although justification in advance was documented for high risk procedures. A uniform process to document that justification, in advance of medical exposures, has taken place by the practitioner may facilitate compliance with Regulation 8.

Information related to patient exposure was not available on the sample of reports reviewed by inspectors. Inspectors were informed that this information is not routinely included in the report. To ensure compliance with Regulation 13(2), information relating to the patient exposure must form part of all reports of medical radiological procedures.

Although processes were in place to report radiation incidents and potential incidents and local management had full oversight of events associated with ionising radiation medical exposures, systems and processes to analyse near misses were not in place. Trending the radiation incidents and near misses may provide an opportunity to evaluate the processes in place and identify potential gaps and areas for improvement. Additionally, it would provide full oversight to the undertaking of actual or potential radiation incidents.

Regulation 8: Justification of medical exposures

All referrals reviewed on the day of inspection were available in writing, stated the reason for the request and were accompanied by sufficient medical data which was consistent with hospital policy.

Inspectors noted a hospital policy which identified that all referrals must be justified in accordance with local protocols. Inspectors were informed that these protocols have been developed with specific reference to the Royal College of Radiologists iRefer guidelines. Up-to-date copies of these protocols were available in soft copy format in the examination rooms.

Information relating to the benefits and risks associated with radiation was available for patients on posters in the waiting areas in the Radiology Department. Staff

demonstrated that they could access information relating to the dose level associated with a procedure, should patients ask about this. These levels were compared with background radiation dose as a tool to help patients' understanding of the level of dose associated with specific procedures.

Inspectors were informed that radiographers justified all general X-Ray procedures carried out at the hospital. For higher dose modalities, such as Computed Tomography, inspectors observed that justification in advance by consultant radiologists was conducted and recorded using the vetting module of the Radiology Information System (RIS). Inspectors reviewed records and policies and spoke with staff and found that justification in advance was not recorded for all procedures carried out at the hospital. While justification in advance occurred and was documented for some general radiographic procedures using the vetting module on the RIS, this was not consistent across all general radiographic procedures. A uniform process to record practitioner justification of medical exposures may facilitate compliance with Regulation 8.

Judgment: Substantially Compliant

Regulation 11: Diagnostic reference levels

From the documents reviewed on the day of inspection, Diagnostic Reference Levels (DRLs) for radiodiagnostic examinations were established and reviewed regularly, in line with the local policy. DRLs were displayed in the Radiology Department and staff demonstrated awareness of their availability and use.

Regulation 11 states that local DRLs should be compared with national and European DRLs, and inspectors were informed that this is in place in the hospital. DRLs were also sent to the Radiation Safety Committee for review. Inspectors were informed that findings from a dose audit had been used to identify procedures that resulted in doses consistently higher than expected. The specific piece of equipment used in this procedure was subsequently replaced. This highlights the value of setting and reviewing DRLs and conducting dose audits to ensure the safe delivery of medical exposures.

Judgment: Compliant

Regulation 13: Procedures

Written protocols were in place for standard medical exposures for each type of equipment. These were available both in hard copy and electronic format in the examination rooms. Inspectors were informed that some protocols were being

updated to reflect the legislative changes introduced at the beginning of 2019.

The hospital utilised the iRefer guidelines and inspectors observed that access to these guidelines was available in examination rooms. Staff demonstrated a knowledge of and awareness about when to access these guidelines. Staff were able to demonstrate how to access these guidelines in soft copy format in the examination rooms. Details of referral guidelines was also available in policy and procedure documents.

A number of clinical audits were conducted regularly and inspectors viewed the list of audits conducted since January 2019. These included a Patient Identification Check, Pregnancy Status Check, Plain Film Radiography Image Quality Check, and a Carers and Comforters Audit. Inspectors heard from staff that in addition to the standard audits conducted to date, additional clinical audits will be developed and implemented in 2020. The expansion of the range of clinical audits would be beneficial in providing NGH with additional assurances of their compliance with the regulations.

Inspectors reviewed a sample of reports of medical radiological procedures and found that information related to the patient exposure was not included as part of the report of medical radiological procedures at Naas General Hospital. This finding was consistent with information reported by staff. To ensure compliance with Regulation 13(2), information relating to patient exposure must form part of all reports of medical radiological procedures.

Judgment: Substantially Compliant

Regulation 14: Equipment

Naas General Hospital provided inspectors with an up-to-date inventory of all medical radiological equipment.

Review of equipment is listed as a standing item in the Terms of Reference of the Radiation Safety Committee. This review consists of reviewing the quality assurance and maintenance in addition to replacement of equipment. From reviewing the minutes of recent meetings, inspectors confirmed that medical radiological equipment is a matter of discussion at the RSC meetings.

Records reviewed by inspectors showed that appropriate quality assurance programmes, including regular performance testing, had been implemented and maintained. There was documented evidence to show that acceptance testing was carried out on new medical radiological equipment.

Judgment: Compliant

Regulation 16: Special protection during pregnancy and breastfeeding

The hospital's medical exposures procedures and pregnancy policy outlined the process for determining pregnancy status and the process to be followed if pregnancy cannot be ruled out. The pregnancy policy was part of an older radiation safety document which was being updated at the time of the inspection. Inspectors were informed that the new radiation safety document, currently in draft format, is due to be implemented early in 2020.

From the records reviewed on the day of inspection, pregnancy checks were routinely performed and documented by radiographers prior to carrying out the medical exposures. This was in line with the local pregnancy policy. Inspectors spoke with staff who demonstrated a knowledge and understanding of the pregnancy policy. Inspectors observed that clinical audits to assess compliance with the pregnancy policy were carried out.

Posters alerting patients to inform staff of their pregnancy status were observed in all waiting areas and examination rooms.

Judgment: Compliant

Regulation 17: Accidental and unintended exposures and significant events

The terms of reference of the Radiation Safety Committee (RSC) reviewed by inspectors clearly outlined the roles, responsibilities and lines of accountability of the committee with respect to accidental and unintended exposures and significant events. Incidents were a standing agenda item at the RSC meetings. The minutes of previous RSC meetings viewed by inspectors confirmed that the terms of reference were followed by the RSC. This assured inspectors that reasonable measures are taken to minimise the probability and magnitude of accidental or unintended exposures and significant events.

A paper-based system was in place for recording radiation incidents. Near misses were also recorded in the paper-based system. Staff who spoke with inspectors on the day of inspection demonstrated a knowledge and understanding of the incident reporting processes within the hospital.

Inspectors were informed that learning from incidents and potential incidents was fed back to staff through regular staff meetings.

Although incidents and near misses are recorded, inspectors were informed that near misses are not analysed locally for trending purposes. In addition, although the local processes for reporting incidents was 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, the undertakings should have full

oversight of each facility. Developing clear processes for reporting incidents will increase this oversight and assure the undertaking of their compliance ensuring safe delivery of medical exposures.

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	Compliant
Regulation 20: Responsibilities of medical physics experts	Compliant
Regulation 21: Involvement of medical physics experts in medical radiological practices	Compliant
Safe Delivery of Medical Exposures	
Regulation 8: Justification of medical exposures	Substantially 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 Naas General Hospital OSV-0007367

Inspection ID: MON-0028230

Date of inspection: 18/12/2019

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
<p>Outline how you are going to come into compliance with Regulation 6: Undertaking:</p> <p>General Manager to liaise with the Hospital Group and the HSE National Radiation Protection Office to ensure lines of responsibility and accountability are understood by all staff within this dual reporting system.</p>	
Regulation 8: Justification of medical exposures	Substantially Compliant
<p>Outline how you are going to come into compliance with Regulation 8: Justification of medical exposures:</p> <p>It is not considered practical or efficient to use the current NIMIS vetting module for recording justification in advance for all plain X-ray procedures. The General Manager will liaise with the Hospital Group to engage with the NIMIS RIS/PACS provider with the aim of introducing a technological solution which will allow for timely and efficient justification for all medical exposures (appropriate to the level of risk).</p>	

Regulation 13: Procedures	Substantially Compliant
<p>Outline how you are going to come into compliance with Regulation 13: Procedures:</p> <p>The General Manager will liaise with the Hospital Group to engage with the NIMIS RIS/PACS provider through HSE management to seek a technological solution which will allow the automatic transfer of medical exposure information into the Radiology report.</p> <p>This is a substantial project and our first step will be to define a scope for our request. As the wording in Regulations 13 and 14 is different, a normal legal interpretation would suggest that "information relating to patient exposure" is not the same as "relevant parameters for assessing the patient dose". Therefore, the latter cannot be used for compliance with both regulations. The most meaningful quantity, and the only one that can be used to combine the dose from different types of medical exposure, would be effective dose. We can see at least three, increasingly-complex, approaches:</p> <ol style="list-style-type: none"> 1. The inclusion of a field with the effective dose calculated from the local DRL for the specific examination. 2. Tables of conversion coefficients to calculate effective dose from the relevant parameters for individual exposures. 3. Automatic calculation of effective dose (or size-specific dose estimate) based on computer interpretation of the acquired images and radiation dose structured report. <p>We would appreciate any guidance that HIQA could provide as to their interpretation of the meaning of "information related to patient exposure", including whether a numerical quantity is required for compliance and, if so, the nature and accuracy of that numerical quantity.</p> <p>The Radiology department has prepared a Radiation safety audit plan for 2020 and this will be overseen by the Radiation Safety Committee.</p>	
Regulation 17: Accidental and unintended exposures and significant events	Substantially Compliant
<p>Outline how you are going to come into compliance with Regulation 17: Accidental and unintended exposures and significant events:</p> <p>There is an established practice of incident reporting in Naas General Hospital (NGH) based on the number of clinical incidents reported. Patient safety incidents are reported on the National Incident Management System (NIMS) in line with national guidelines. These incidents are reviewed at the Hospital's Quality and Safety Committee meeting that is well attended by members of management and clinical staff at the Hospital. The Hospital holds Serious Incident Management Team (SIMT) meetings to review serious incidents and reportable events.</p>	

A system has been established to track and trend all radiology-related and all radiation-related clinical incidents including near misses in NGH. From 2020, quarterly reports on all reported incident/near misses are sent, from the NIMS system, by the Quality, Risk and Patient Safety Department to the Radiology Services Manager and are reviewed by the multi-disciplinary team at the Radiology Users Group Meeting. This report includes the categorisation of the incidents. The multi-disciplinary Radiology Users Group will have oversight of specific learning's or actions A number of activities will be undertaken during the year to educate radiography staff on different types of incidents in radiology (not just those involving accidental and unintended exposures) to ensure that a culture of recognising and learning from incidents and near-misses is thoroughly embedded in the culture of the Radiology Department.

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	30/04/2020
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	31/01/2021

	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	31/01/2021
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	Orange	31/01/2021
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	29/02/2020