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:	Children's Health Ireland at Crumlin
Undertaking Name:	Children's Health Ireland
Address of Ionising Radiation Installation:	Crumlin, Dublin 12
Type of inspection:	Announced
Date of inspection:	06 February 2020
Medical Radiological Installation Service ID:	OSV-0006026
Fieldwork ID:	MON-0028237

About the medical radiological installation:

Children's Health Ireland at Crumlin, previously known as Our Lady's Children's Hospital Crumlin, is an acute paediatric hospital. The hospital is also a national referral centre for a range of specialities including children's childhood cancers and blood disorders, cardiac diseases, major burns, cystic fibrosis, and rheumatology.

Children's Health Ireland at Crumlin is a part of Children's Health Ireland, a single statutory entity, established following the publication of the Children's Health Bill 2018, to provide paediatric services and take over the services currently provided by the existing three Dublin children's hospitals; Our Lady's Children's Hospital, Crumlin, Temple Street Children's University Hospital, and the National Children's Hospital at Tallaght University Hospital.

The radiology department at Children's Health Ireland at Crumlin (CHIC) provide imaging services for a paediatric patient population referred from a variety of disciplines including cardiology and oncology.

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
Thursday 6 February 2020	09:00hrs to 16:05hrs	Maeve McGarry	Lead
Thursday 6 February 2020	09:00hrs to 16:05hrs	Kirsten O'Brien	Support

Governance and management arrangements for medical exposures

Children's Health Ireland (CHI) is the undertaking for CHI at Crumlin. The site Chief Executive Officer (CEO) was the designated manager for the hospital and was a member of the governance committee at undertaking level and the corporate management team at facility level. Undertaking responsibilities as per regulations were delegated to the designated manager by the undertaking.

Overall, inspectors found effective leadership, governance and management arrangements in place with systems and processes detailing the allocation of responsibility for the radiation protection of service users. The designated manager had a good awareness of issues relating to radiation protection and was a member of the local Radiation Safety Committee (RSC).

The medical physics expert (MPE) was found to have a pivotal role in radiation protection at the hospital and was closely involved in relevant aspects of the clinical service. Inspectors were informed that there was an informal arrangement in place to ensure the continuity of medical physics expertise through MPEs employed by the undertaking at other locations.

The hospital's radiation safety procedures were found to be aligned to current legislation. A pragmatic approach had been adopted by the hospital to address legislative changes and to align local practices accordingly. The hospital had clearly outlined the role of the radiographer as a referrer and practitioner and had set out a clinical governance framework document to support this role development. The roles and responsibilities outlined in policies were reflective of the day-to-day practices seen by inspectors and were clearly articulated by staff.

Overall, inspectors found formalised local governance arrangements and organisational structures with clear lines of accountability in place for the radiation protection of service users. Several proactive initiatives referenced in this report demonstrate strong local governance and an understanding of the radiation protection needs of the paediatric population that receive care at CHI at Crumlin.

Regulation 4: Referrers

The local radiation safety procedures stated that a person shall not refer an individual to a practitioner for a medical radiological procedure unless they are one of the referrers outlined in Regulation 4. On the day of inspection, a sample of referrals reviewed were accepted from registered medical practitioners and appropriately trained nurse prescribers.

Good practice was evident as the radiation safety policy specified circumstances where the radiographer could act as referrer. These specific circumstances were in relation to adapted and secondary referrals. Adapted referrals applied to correcting laterality or correcting where an incorrect area had been referred. Secondary referrals involved imaging required to further assist diagnosis, for example, the use of orbital imaging in advance of magnetic resonance imaging. Such secondary referrals could only be made by the clinical specialist radiographer within their own modality. The circumstances where a radiographer could refer or adapt a referral was clearly articulated by the clinical staff who spoke to inspectors.

Judgment: Compliant

Regulation 5: Practitioners

The practitioners outlined in the radiation safety procedures who were assigned clinical responsibility were dental surgeons, medical practitioners and radiographers. Inspectors reviewed a sample of records in relation to medical exposures and found that those taking clinical responsibility were in line with these regulations and local policies.

Judgment: Compliant

Regulation 6: Undertaking

Inspectors found that the undertaking provided a clear allocation of responsibilities for the radiation protection of service users. Staff who spoke to inspectors clearly understood their roles and responsibilities which was consistent with documentation reviewed by inspectors.

The designated manager was the site CEO and was a member of the Radiation Safety Committee (RSC) which met twice per year. The minutes of the local RSC were provided to an undertaking level radiation safety committee which was chaired by the undertaking representative and attended by the MPE. This group level RSC provided oversight of radiation protection issues at undertaking level. Inspectors were informed that this committee primarily provided a forum for strategic planning for future developments within CHI.

The designated manager was a member of the hospital's corporate management team and the CHI governance committee. Issues in relation to radiation protection could be communicated to the undertaking via the radiation safety committee and the governance committee.

Judgment: Compliant

Regulation 10: Responsibilities

Local policy stated that clinical responsibility for individual medical exposures was the responsibility of a practitioner and included justification, optimisation and clinical evaluation of the outcome. Clinical responsibility was clearly allocated particularly by distinguishing how clinical responsibility applied to radiographers as practitioners. The local policy stated that appropriately trained radiographers with postgraduate qualifications could perform aspects of clinical evaluation of the outcome under agreed local governance structures. For example, radiographers in the emergency department participated in a red dot system to highlight abnormal results on X-ray images. Staff who spoke to inspectors could clearly articulate their role and responsibility in line with the local policy.

There was evidence that the MPE, practitioner and those involved in the practical aspects were involved in optimisation. Also, there was evidence seen by inspectors that the justification process involved both the practitioner and referrer.

The practical aspects of medical exposure were delegated only to practitioners at the hospital. Furthermore, the local policy identified the current gap in national radiation protection training for practitioners in order to meet the requirements of these regulations. Inspectors noted that practitioner status has been assigned to certain non-radiologist consultants. In the absence of nationally defined training requirements for non-radiologist consultants, local management had safety assurances in place by ensuring a radiographer was involved in the practical aspects of all procedures including in theatre and interventional cardiology.

Judgment: Compliant

Regulation 19: Recognition of medical physics experts

The hospital was resourced with one whole time equivalent medical physics expert. Inspectors were informed that continuity of medical physics expertise was available within the CHI group when the resident MPE was absent. However, the MPE noted that while continuity of Radiation Protection Advisor (RPA) services was formalised through a service level agreement, the MPE cover was not formalised in such a manner. Although inspectors were satisfied that there was anecdotal evidence of MPE service continuity, there may be opportunity for the undertaking to formalise the existing arrangements.

Judgment: Compliant

Regulation 20: Responsibilities of medical physics experts

The medical physics expert worked closely with the full time radiation safety officer (RSO) at the hospital and had delegated certain tasks to the RSO including quality control checks. The MPE was found to be responsible for dosimetry and closely involved in the clinical service. This involvement included optimisation, the establishment and approval of diagnostic reference levels (DRLs) and dose monitoring for procedures conducted at the facility. The MPE was also involved in the selection of equipment, an example of which included the selection of an X-ray system which provided low dose paediatric orthopaedic imaging.

Staff informed inspectors that the process for reporting an incident included notifying the MPE at the time of discovery. There was evidence that the MPE was involved in the analysis of events involving accidental or unintended exposures.

The MPE, supported by the RSO, provided training to staff including undergraduate nurses and anaesthetists under a locally developed radiation safety lecture programme. As part of induction, all new clinical staff in radiology, including practitioners, were provided with a lecture on the hospital's radiation safety procedures.

Judgment: Compliant

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

Inspectors were satisfied with the involvement of the MPE at CHI at Crumlin. It was clear from discussions with staff and documentation reviewed that the MPE was closely involved with the clinical service and had a pivotal role in leading radiation safety at the hospital.

Judgment: Compliant

Safe Delivery of Medical Exposures

Overall, inspectors found that the hospital had implemented measures to ensure the safe delivery of medical exposures to ionising radiation. Radiation protection practices demonstrated several examples of good practice, particularly evident in relation to optimisation of the special practices conducted at this paediatric hospital. Inspectors found that the selection of equipment, practical techniques used, quality assurance programmes in place and the assessment of dose were

all considerate of the patient cohort.

The hospital had several strategies in place to optimise dose and to provide assurance around the dose administered to service users. Details of how optimisation was achieved per modality was prospectively outlined in documentation. This included the extensive use of dose tracking systems which inspectors were informed provided assurance that optimisation was consistently achieved. Automated dose tracking systems were in place for most equipment and where an automated system was unavailable, dose was monitored through manual mechanisms.

Inspectors found there was a comprehensive approach to DRLs at the hospital. Local DRLs were up-to-date, available in the clinical areas inspected and were integrated into the dose tracking systems where possible. Situations where the DRLs were exceeded were investigated and signed off by the MPE or RSO.

Inspectors found that there was a strong culture of auditing within the hospital, which provided assurance around the quality of practices. The array of audits conducted was comprehensive and included aspects of image quality and the consistent production of X-rays. There was evidence that audit cycles were well delineated and that staff periodically received re-education and training based on findings. In addition, staff received feedback on audit findings and incidents through a Radiation Safety Newsletter, which was found to be an example of good practice.

The allocation of responsibility for justification was well outlined for each modality. There was evidence that justification processes were considerate of previous diagnostic information and that practitioners actively sought to use alternative non-ionising techniques. However, there were areas for improvement in relation to the documentation of justification of medical radiological procedures. Inspectors found that the hospital did not have a uniform process to record justification for all medical exposures. Furthermore, there was no documentary evidence that information relating to patient exposure consistently formed part of the reports of the medical radiological procedures.

Overall, inspectors found that many patient safety initiatives demonstrated a strong culture of radiation protection for paediatric patients at the hospital and any areas noted for improvement did not demonstrate a patient safety concern.

Regulation 8: Justification of medical exposures

All referrals reviewed by inspectors on the day of inspection were available in writing, stated the reason for the request and were accompanied by sufficient medical data. Staff were able to demonstrate that previous diagnostic information acquired locally and at other hospitals was available through a national imaging system. There was also evidence that cases discussed at multidisciplinary meetings included consideration to previous diagnostic imaging and interventions to inform

future clinical decision-making for those service users.

Inspectors were satisfied that the justification process took non ionising radiation imaging alternatives into account such as MRI and ultrasound. For example, staff informed inspectors that justification of exposures involving children under three months old considered the potential use of ultrasound. A further example was given to inspectors where an external referral for CT brain and orbits may be changed by the radiologist to a CT of the brain and an ultrasound scan of the orbits to reduce dose to the patient.

According to local policy, justification involved both referrers and practitioners. The allocation of responsibility for justification was clearly outlined for each modality. For example, justification could be performed by radiographers for general X-ray procedures and by consultant radiologists for CT. Samples of records of justification reviewed by inspectors were in line with this policy.

Inspectors found that justification of CT and nuclear medicine for each procedure was documented in advance. However, for general radiography and interventional cardiology procedures, justification was not documented. This finding was accepted by the management and staff. To ensure compliance with Regulations 8(8) and 8(15), the hospital should ensure that medical exposures are justified in advance and records evidencing compliance with this regulation are kept.

Information relating to risks and benefits of medical exposure was provided on the hospital website and on a locally developed poster. This poster included frequently asked questions and a section on the risk associated with your child's X-ray exam. Staff informed inspectors that if a service user, parent or guardian had specific queries about risks the medical physics expert would provide an explanation. Overall inspectors found that given the paediatric patient population the provision of information on the risks and benefits of medical exposure could be considered by the undertaking as a potential area of improvement.

Judgment: Substantially Compliant

Regulation 9: Optimisation

There were examples of good practice in relation to optimisation evident throughout the inspection. The radiation safety procedures described the approach to optimisation as collaborative and outlined how optimisation was achieved for each modality. This included the dose monitoring system used for that modality, relevant audits conducted and the associated ongoing education provided to staff.

The MPE was found to be closely involved in optimisation particularly in relation to the use of dose monitoring systems, which were used on all medical radiological equipment either through automated or manual systems.

The hospital had implemented an education programme around the consistent

production of adequate diagnostic information in general radiology. A number of retrospective cases are selected whereby the practical aspects of medical exposure could be improved. The RSO provided feedback to the radiographers in an education session on how these procedures could be further optimised.

Further assurances were in place around optimisation through audits conducted. One such audit was a reject analysis, which involved the assessment of images that were repeated. A staff education session was instigated, where the audit results exceeded a tolerance level. In addition, an assurance was in place around clinical evaluation of imaging through peer review conducted by radiologists. An example of good practice was evident as staff received feedback on audit findings through a Radiation Safety Newsletter.

In relation to the potential dose to carers and comforters, a risk assessment of procedures carried out at the hospital had been conducted. This risk assessment determined that one particular nuclear medicine procedure had the potential to result in a dose of 1mSv to a carer and comforter. Additional precautions had been put in place to monitor dose to relevant carers and comforters in relation to this procedure. To aid decision-making around the exposure to carers and comforters in nuclear medicine and in general radiography algorithms were available in local policy. These included helping staff make decisions around pregnant carers and comforters. Guidance was available to parents, guardians and hospital staff caring for service users following nuclear medicine procedures.

Judgment: Compliant

Regulation 11: Diagnostic reference levels

Local diagnostic reference levels (DRLs) had been established for all procedures at the hospital and these were up-to-date at the time of inspection. Inspectors were informed that to drive quality improvement the local DRLs used were cognisant of international paediatric DRLs. Inspectors noted from the radiation safety procedures that where national DRLs were not in place, the hospital sought to develop local DRLs such as in the case of dental radiography. For example, the hospital had extrapolated data from adult reference levels to develop a paediatric local DRL for intra-oral X-rays and orthopantomography (OPG).

The local DRLs were integrated into the dose monitoring systems where possible. Inspectors were informed that where a local DRL was exceeded, on CT for example, an alert was created which was reviewed by the MPE or RSO and the outcome was investigated and recorded.

For general radiography, a DRL audit was conducted monthly. A sample of procedures for one examination were taken and the dose compared to the local DRL. The results were investigated if found to be in excess of the local DRL.

Overall, inspectors found that there were effective mechanisms in place to monitor

and evaluate radiation doses received by patients in the service.

Judgment: Compliant

Regulation 13: Procedures

Hardcopy written protocols were available in the clinical areas for each type of medical radiological procedure and staff demonstrated an awareness of these to inspectors. The procedures in general and mobile radiography had exposure factors for seven different age categories of children.

Referral guidelines for medical imaging taking into account radiation doses were available through an online link accessible in clinical areas. In nuclear medicine, staff informed inspectors that international guidelines supplemented referral guidelines to aid decision-making.

Inspectors reviewed a sample of reports of medical radiological procedures and found that they did not consistently contain information relating to the patient exposure as required by regulations. This finding was acknowledged and accepted by management. To ensure compliance with Regulation 13(2), the hospital should ensure that information relating to patient exposure consistently forms part of the report of the procedure.

Inspectors reviewed a sample of clinical audits conducted at the facility. These included audits of pregnancy status determination, injected activity in nuclear medicine and the use of referral guidelines. In addition to such audits there was a periodic review of image quality and the consistent production of adequate diagnostic information. Based on these audit findings, staff in general X-ray frequently received re-education on the practical aspects of medical exposure. There was evidence that education and feedback to staff were key components of audit cycles at the hospital.

Judgment: Substantially Compliant

Regulation 14: Equipment

Inspectors found compliance with this regulation from the records reviewed. Equipment was kept under strict surveillance and quality assurance procedures were in place in line with regulatory requirements. The annual quality assurance was undertaken and approved by the MPE. The MPE was supported by the RSO in carrying out regular performance testing. Evidence of acceptance testing by the MPE was provided for equipment installed in 2019.

Judgment: Compliant

Regulation 15: Special practices

As a paediatric hospital, consideration to special practices in relation to the medical exposure of children was found to be a focus during this inspection. Inspectors noted that the selection of equipment, practical techniques used, quality assurance programmes and assessment of dose were all considerate of the patient population.

In relation to the selection of equipment, the hospital had acquired a particular orthopaedic imaging system based on identified clinical requirements and dose reduction potential suited to paediatric patients. Inspectors were also informed that the interventional cardiology equipment was selected similarly, cognisant of the clinical workload for paediatric cardiology procedures.

Inspectors found that the practical techniques used in medical exposures were adapted to the patient cohort. Exposure factors for general radiology were provided for seven categories of age. Furthermore, exposure factors for mobile X-ray were adapted if the patient presented in an incubator or a bed. Inspectors were also informed that limited views were used where possible, for example, imaging to check vascular line positioning was limited to the area of interest only. Optimisation of dose in CT had regard for both image quality and processing techniques. In CT, all exposures considered weight and clinical indication and a lower dose protocol was used where possible, for example follow up cystic fibrosis chest imaging.

The assessment and verification of dose outside of nuclear medicine was evaluated through the two dose tracking systems used at the hospital. Inspectors were informed that these systems were closely monitored. In nuclear medicine, administered doses were in accordance with international guidelines for paediatric patients and practices were audited.

Judgment: Compliant

Regulation 16: Special protection during pregnancy and breastfeeding

Inspectors found that the requirements of this regulation were met from the evidence reviewed. The radiation safety procedures included a policy on establishing the pregnancy status of female patients of child-bearing age. The policy also outlined the process when pregnancy could not be ruled out. Ongoing audits were conducted in relation to adherence with this protocol. There was evidence that findings of such audits were communicated to staff via the Radiation Safety Newsletter. Inspectors were informed that the current policy was under review at undertaking level, with a view to developing a concerted approach to pregnancy

determination across all CHI sites in due course.

Judgment: Compliant

Regulation 17: Accidental and unintended exposures and significant events

The hospital had taken reasonable measures to minimise the probability and magnitude of accidental or unintended exposures through audit, quality assurance and risk assessments. A local policy was in place for the management of accidental and unintended exposures and significant events. Incidents were reported through an online system to the risk department and the relevant reports were sent to the MPE. Staff who spoke to inspectors were able to articulate the process in place in line with local policy.

Trending of actual and potential accidental and unintended exposures and significant events were provided to inspectors for 2019. While the volume of actual and potential events trended was low relative to activity levels, staff relayed that there was a good reporting culture. Staff informed inspectors that they received feedback from incidents through staff meetings and through a newsletter.

The hospital's radiation safety committee standing agenda included a review of incident reports. Inspectors found there was good oversight from governance about risk relating to medical exposures. The hospital had submitted one significant event to HIQA and management and staff demonstrated a good understanding of learning from this event.

Judgment: 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	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 9: Optimisation	Compliant
Regulation 11: Diagnostic reference levels	Compliant
Regulation 13: Procedures	Substantially Compliant
Regulation 14: Equipment	Compliant
Regulation 15: Special practices	Compliant
Regulation 16: Special protection during pregnancy and breastfeeding	Compliant
Regulation 17: Accidental and unintended exposures and significant events	Compliant

Compliance Plan for Children's Health Ireland at Crumlin OSV-0006026

Inspection ID: MON-0028237

Date of inspection: 06/02/2020

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 8: Justification of medical exposures	Substantially Compliant
Outline how you are going to come into compliance with Regulation 8: Justification of medical exposures: In relation to interventional cardiology, these procedures are now vetted via the vetting module on the Radiology Information System (RIS). It has been agreed that the general radiography exams will be moved to the vetting module of the RIS (the same as CT and HCCL).	
Regulation 13: Procedures	Substantially Compliant
Outline how you are going to come into compliance with Regulation 13: Procedures: All radiology reports shall now contain the following statement – "Where relevant, statutory information relating to the patient radiation dose is available in the image header or hard-coded onto the image itself."	

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 8(8)	An undertaking shall ensure that all individual medical exposures carried out on its behalf are justified in advance, taking into account the specific objectives of the exposure and the characteristics of the individual involved.	Substantially Compliant	Yellow	03/04/2020
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	03/04/2020
Regulation 13(2)	An undertaking shall ensure that information relating to patient exposure forms part of the report	Substantially Compliant	Yellow	20/03/2020

	of the medical radiological procedure.			