



## Health Information and Quality Authority

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

Name of Medical Radiological Installation:	Bon Secours Hospital Dublin
Undertaking Name:	Bon Secours Health System
Address of Ionising Radiation Installation:	Glasnevin, Dublin 9
Type of inspection:	Announced
Date of inspection:	31 August 2021
Medical Radiological Installation Service ID:	OSV-0007388
Fieldwork ID:	MON-0033538

## About the medical radiological installation:

The Bon Secours Private Hospital in Dublin (BSD) is an independent acute care hospital located in Glasnevin in North Dublin providing medical care to patients from Dublin and across Ireland since 1951. BSD is part of the Bon Secours Health System healthcare group and includes hospitals in Cork, Dublin, Galway, Limerick, Tralee, a care village in Cork and an outreach Clinic in Cavan. Today BSD continues to be a very much embedded in the local community of Glasnevin and North Dublin. In 2002, the hospital was the first internationally accredited hospital in Ireland when it achieved JCI Accreditation. The hospital provides a range of tests, examinations, surgical procedures and medical services on an inpatient, day case and outpatient basis. The hospital has 98 Inpatient beds, 76 Daycare beds, Consulting Suites, Operating Theatres for major and minor surgery, Endoscopy, Cardiology and Diagnostic Imaging facilities. The main Diagnostic Imaging facilities are located on the first floor in the hospital and provide imaging services to diagnose and treat a wide range of medical conditions to all patients attending the hospital. Diagnostic Imaging typically operates Monday to Friday from 8am-5.30pm. An emergency out-of-hours service is available outside of these times. BSD is a busy multidisciplinary department and performs approximately 33,000 studies a year. Services provided by the Diagnostic Imaging department include: General Radiography, Computed Tomography (CT), DXA scanning, Interventional Radiology and Cardiology, Fluoroscopy including mobile Fluoroscopy and mobile radiography. The multidisciplinary Diagnostic Imaging team is made up of: Consultant Radiologists, Diagnostic Imaging Services Manager, Radiographers, Radiation Protection Advisor & Medical Physics Expert, Medical Physics Expert, Radiation Protection Officer, Nursing staff, Clerical Administration and Diagnostic Imaging Assistants.

## 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<sup>1</sup> reviewed all information about this medical radiological installation<sup>2</sup>. This includes any previous inspection findings, information submitted by the undertaking, undertaking representative or designated manager to HIQA<sup>3</sup> 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<sup>4</sup> 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:**

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<sup>1</sup> 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.

<sup>2</sup> A medical radiological installation means a facility where medical radiological procedures are performed.

<sup>3</sup> HIQA refers to the Health Information and Quality Authority as defined in Section 2 of S.I. No. 256 of 2018.

<sup>4</sup> 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 31 August 2021	10:00hrs to 15:30hrs	Lee O'Hora	Lead
Tuesday 31 August 2021	10:00hrs to 15:30hrs	Agnella Craig	Support

## Governance and management arrangements for medical exposures

On this inspection, inspectors found effective governance, leadership and management arrangements with a clear allocation of responsibility for the protection of service users undergoing medical exposures at the Bon Secours Hospital Dublin. As part of this inspection, inspectors reviewed documentation and visited the interventional cardiology suite, CT and general radiography department and spoke with staff and management.

Overall responsibility for the radiation protection of service users lay with the Bon Secours Health System which operated a wider hospital group. Reporting structures were well defined and clearly articulated to inspectors on the day of inspection. The Bon Secours Hospital Dublin incorporated a radiation safety committee (RSC) into the governance system which reported directly to the undertaking via the hospital manager. The wider hospital group also used a radiation safety forum in which the Bon Secours Hospital Dublin was represented by the radiography services manager (RSM) and the radiation protection officer (RPO) and inspectors were satisfied that both committees provided an effective mechanism to ensure appropriate oversight of medical radiological procedures at this installation. RSC minutes reviewed detailed the undertakings ability to use these committees to highlight potential regulatory non-compliances, formulate actions and subsequently monitor ongoing compliance levels. Some examples of this seen on inspection related to the record of practitioner justification, the inclusion of information relating to patient dose on the report and the implementation of formal arrangements to ensure continuity of MPE expertise. This ability to review practice and address potential regulatory shortcomings was seen as an effective use of these governance structures by the Bon Secours Hospital Dublin.

Following review of documents and records, and speaking with staff, 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. Similarly, inspectors were satisfied that clinical responsibility for medical exposures was only taken by personnel entitled to act as practitioners as per the regulations.

Inspectors reviewed documentation and spoke with staff regarding medical physics expert (MPE) involvement in the safe delivery of medical exposures. Evidence of professional registration and arrangements to ensure continuity of MPE expertise was also supplied to inspectors. From the documentation reviewed, inspectors were assured that the level of involvement of MPE was proportionate to the level of radiological risk at the installation and that the MPE took responsibility for, and contributed to, all aspects of medical exposures as required by the regulations.

Overall, inspectors were satisfied that a clear and effective allocation of responsibility for the protection of service users ensured the safe conduct of medical

exposures at the Bon Secours Hospital Dublin.

#### Regulation 4: Referrers

Following review of referral documentation, a sample of referrals for medical radiological procedures and by speaking with staff, inspectors were satisfied that the Bon Secours Hospital Dublin only accepted referrals from appropriately recognised referrers. In line with the regulations, radiographers were also considered referrers in this facility and the specific circumstances in which radiographers could act as referrers were clearly outlined in local policies and articulated to inspectors by staff.

Judgment: Compliant

#### Regulation 5: Practitioners

Following review of radiation safety procedure documentation, a sample of referrals for medical radiological procedures and by speaking with staff and management, inspectors were satisfied that Bon Secours Hospital Dublin had systems in place to ensure that only appropriately qualified individuals took clinical responsibility for all individual medical exposures.

Judgment: Compliant

#### Regulation 6: Undertaking

Documentation reviewed by the inspectors outlined a clear allocation of responsibility for the protection of service users by Bon Secours Health System operating at the Bon Secours Hospital Dublin. The Bon Secours Hospital Dublin were supported by a radiation safety committee, which met twice yearly and reported to the undertaking representative and hospital group board via the hospital manager. Inspectors were informed that this committee was responsible for monitoring and overseeing radiation protection to ensure compliance with regulatory and licensing conditions.

The undertaking also established a hospital group radiation protection forum, which met every three months, and Bon Secours Hospital Dublin was represented on this by the Radiation Protection Officer (RPO) and the Radiography Services Manager (RSM). This forum provided a mechanism to discuss radiation safety issues at a group level and provided a further pathway of communication to the undertaking representative and Board.

Terms of reference and minutes from the last three meetings of both committees were provided to inspectors. From reviewing the documents associated with these committees, speaking with staff and visiting clinical areas, inspectors were satisfied that a clear and effective allocation of responsibility for the protection of service users ensured the safe conduct of medical exposures at the Bon Secours Hospital Dublin. Minutes reviewed also supplied evidence of the undertaking's ability to use these committees to identify, discuss, address and monitor regulatory non-compliances, for example, the record of practitioner justification. Minutes from the group radiation safety forum dated November 2020 highlighted the issue as identified in HIQA inspection reports. Evidence of minutes from RSC meeting was reviewed and noted that auditory compliance had moved from 50% compliance in February 2021 to 76% compliance by June 2021.

Overall, systems, processes and audit mechanisms seen by inspectors demonstrated the ability of Bons Secours Hospital Dublin to effectively manage and oversee radiation protection.

Judgment: Compliant

### Regulation 10: Responsibilities

Following review of radiation safety procedure documentation, a sample of referrals for medical radiological procedures and by speaking with staff and management, inspectors were satisfied that Bon Secours Health System ensured that all medical exposures took place under the clinical responsibility of a practitioner at the Bon Secours Hospital Dublin.

Inspectors were assured that the optimisation process involved the practitioner and the medical physics expert (MPE) in all aspects of optimisation as highlighted in the document *Radiation Safety Procedures For The Use Of X-Ray In All Areas Of The Hospital*. Further information in relation to this is detailed under Regulation 9.

Similarly, inspectors were satisfied that the justification process for individual medical exposures involved the practitioner and the referrer at the Bon Secours Hospital Dublin following the review of documentation, assessing a sample of referrals for medical radiological procedures and by speaking with staff.

Judgment: Compliant

### Regulation 19: Recognition of medical physics experts

The mechanisms in place to provide continuity of medical physics expertise at the hospital were described to inspectors and the details were available in documents

and service level agreements (SLAs) reviewed as part of this inspection. In addition, evidence that this regulation had been discussed at the RSC meeting and had been acted on to ensure the appropriate mechanisms to ensure continuity of MPE expertise were formally established was also available to inspectors.

Judgment: Compliant

### Regulation 20: Responsibilities of medical physics experts

MPE professional registration was reviewed by inspectors and was up to date. From reviewing the documentation and speaking with staff at the hospital, inspectors were satisfied that the Bon Secours Health System had arrangements in place to ensure the involvement and contribution of MPEs at the Bon Secours Hospital Dublin was in line with the requirements of Regulation 20.

Judgment: Compliant

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

From speaking with the relevant staff members and following radiation safety document review, inspectors established that the involvement of the MPE was both appropriate for the service and commensurate with the risk associated with the service provided at the Bon Secours Hospital Dublin.

Judgment: Compliant

## Safe Delivery of Medical Exposures

Inspectors found that radiation protection processes implemented by the Bon Secours Hospital Dublin ensured the safe and effective delivery of medical exposures.

Following review of a sample of referrals in the computed tomography (CT) and interventional cardiology departments, inspectors were assured that the Bon Secours Hospital Dublin had processes in place to ensure that all medical procedure referrals were accompanied by the relevant information, justified in advance by a practitioner and that practitioner justification was recorded. Bespoke service user information was available throughout the radiology department on the day of inspection. This information was specific to patient doses delivered by the facility as well as the different modalities and risk benefit information was available for the CT,



interventional cardiology, fluoroscopy and general X-ray departments on the day of inspection.

Inspectors reviewed documentation detailing a comprehensive approach to the concept of optimisation including equipment, protocols, image assessment, radiation dose monitoring, incident investigation and audit. Over the course of the inspection, evidence of the multidisciplinary approach to all aspects of optimisation was available and this was considered an example of a comprehensive, well defined, systematic approach to the optimisation of medical radiological procedures.

Diagnostic reference levels (DRLs) were established, used and reviewed. Inspectors noted that local facility DRL review in higher dose areas such as CT and interventional cardiology had led to a multidisciplinary review of imaging protocols which in turn delivered service user dose reductions in the interventional cardiology and CT departments. This use of local DRL review to closely monitor, and in certain cases, optimise service user radiation doses was seen as a positive use of regulatory required reviews to optimise service user outcomes.

Inspectors reviewed examples of a range of clinical audits used to monitor and improve compliance with regulatory requirements including pregnancy protocol compliance, justification and patient dose audits. Clinical audit is a key tool in providing assurances to the hospital that all medical exposures are carried out safely and in compliance with the regulations. Inspectors found that a culture of radiation safety focused clinical audit was embedded in the Bon Secours Hospital Dublin. Radiation safety audit results and learning outcomes were clearly displayed in the clinical area on the day of inspection.

One area noted for improvement on inspection was that information relating to patient exposure did not consistently form part of the medical radiological procedure report. However, inspectors were satisfied that this non-compliance had already been highlighted and escalated accordingly and that the undertaking was currently working with the radiology information system supplier to develop and implement a solution at a hospital group level.

Inspectors were satisfied that the Bons Secours Hospital Dublin kept equipment under strict surveillance regarding radiation protection. Inspectors noted that routine equipment testing was used to inform the overarching optimisation process. For example, some image quality variations noted during MPE quality assurance (QA) initiated further investigation by the equipment manufacturer. This was seen as an example of how the undertaking was using information gained through quality assessments and proactively optimising medical exposures to improve service user outcomes.

Overall, inspectors were assured that the the Bons Secours Health System had comprehensive systems in place to support the safe delivery of medical exposures at the Bon Secours Hospital Dublin.

## Regulation 8: Justification of medical exposures

Inspectors spoke to staff and reviewed a sample of referrals in a number of clinical areas on the day of inspection. Evidence reviewed demonstrated that processes were in place to ensure all individual medical exposures were justified in advance and that all individual justification by a practitioner was recorded. In addition, RSC minutes detailed how management had previously identified a possible regulatory non-compliance in the documentation of justification, and had addressed this and monitored subsequent performance using radiation safety audit. This was noted as an area of good practice at the Bon Secours Hospital Dublin.

In line with Regulation 8, all referrals reviewed by inspectors on the day of inspection were available in writing, stated the reason for the request and were accompanied by medical data which allowed the practitioner to consider the benefits and the risk of the medical exposure. Staff spoken to on the day consistently informed inspectors that previous diagnostic information was routinely sought to avoid unnecessary exposure.

Inspectors visited the clinical area and observed multiple posters, both general and procedure specific, which provided service users with information relating to the benefits and risks associated with the radiation dose from a range of medical exposures. Pamphlet versions of these posters were also available to service users in the X-ray department.

Judgment: Compliant

## Regulation 9: Optimisation

Inspectors reviewed the document *Radiation Safety Procedures For The Use Of X-Ray In All Areas Of The Hospital*. This document outlined the Bon Secours Hospital Dublin's approach to optimisation which included: equipment, protocols, image assessment, radiation dose monitoring, incident investigation and audit.

Inspectors reviewed evidence of multidisciplinary approaches to both CT and interventional cardiology procedure protocol review. These reviews were led by the clinical specialist radiographers and involved the equipment manufacturer, the MPE, radiologists and cardiologists. These protocol reviews were considered positive radiation safety processes, involving all relevant personnel and resulted in patient dose reductions in a range of CT and interventional cardiology procedures. Some aspects of this multifaceted approach to optimisation are also considered in other Regulations, for example, Regulations 8, 11, 13 and 14.

Judgment: Compliant

## Regulation 11: Diagnostic reference levels

Following review of documentation pertaining to DRLs, inspectors were satisfied that DRLs have been established, were compared to national levels, and were used in the optimisation of medical radiological procedures at this facility. Inspectors visited the clinical area and observed multiple examples of local facility DRLs displayed in the clinical areas.

Inspectors were provided with evidence that an extensive multi disciplinary protocol analysis was used following comparison with national levels. This approach was used to ensure protocol and dose optimisation in CT and the interventional cardiology suite, acknowledging that the local facility doses were already below the national DRLs. This was seen as a proactive use of local facility dose information to optimise procedure protocols and subsequently reduce patient dose.

For the single procedure where a local facility DRL exceeded the national DRL, inspectors were provided with records of the investigation and corrective actions. Inspectors were satisfied that the Bon Secours Hospital Dublin satisfied all regulatory requirements in relation to Regulation 11.

Judgment: Compliant

## Regulation 13: Procedures

Written protocols for every type of standard radiological procedure carried out at the Bon Secours Hospital Dublin were available to inspectors on the day of inspection. A sample of these were reviewed in the clinical areas visited by inspectors. Staff spoken to in the clinical areas clearly articulated how these protocols were made available to them. Inspectors were satisfied that multidisciplinary protocol review in CT and interventional cardiology had led to patient dose optimisation at the Bon Secours Hospital Dublin as detailed previously.

Inspectors spoke to staff and reviewed a sample of imaging reports in a number of clinical areas on the day of inspection. Inspectors saw evidence that information relating to patient exposure formed part of the report for all CT reports reviewed. However, patient exposure information for other reports reviewed was not seen, for example in interventional cardiology. Hospital staff spoken to on the day informed inspectors that this non-compliance with the regulations had been discussed locally and at a hospital group level and that the undertaking was currently working with the radiology information system supplier to develop and implement a solution at a hospital group level.

The specific referral guidelines used in this facility were documented in the *Radiation Safety Procedures For The Use Of X-Ray In All Areas Of The Hospital* policy. In addition, the personnel with overall responsibility for selecting referral guidelines

was also documented in this policy and inspectors were informed that these referral guidelines were made available digitally for the relevant staff on the associated digital platforms.

Inspectors reviewed the document *Radiation Safety Procedures For The Use Of X-Ray In All Areas Of The Hospital, Part 4: Audit*. This document clearly outlined the Bon Secours Hospital Dublin's systematic approach to radiation safety audit and provided a list of audits included in the audit program. Examples of clinical audits listed in the audit program included; reject analysis, pregnancy protocol compliance, justification and patient dose audits. All of these audits were available to inspectors for review. In the clinical area, results and learning from audits were available to all staff. Inspectors saw that information relating to educational sessions initiated by the audit process were also available for staff on the audit board. Audit was a standing agenda point of the local radiation safety committee and evidence that relevant issues relating to audit were discussed by this committee was reviewed by inspectors.

As outlined in Regulation 6 and 8, RSC minutes and audit records reviewed by inspectors detailed the hospital's ability to identify a regulatory non-compliance in the documentation of justification. This was subsequently addressed by developing a process where practitioners recorded the justification of all individual medical exposures using the hospital radiology information system. The RSC subsequently monitored compliance and improvements using a '*justification in advance audit*'. This was noted as an area of good practice at the Bon Secours Hospital Dublin, by which the RSC proactively considered regulatory non-compliances, implemented solutions and monitored improvements using the existing well defined audit structures and associated communication pathways.

Judgment: Substantially Compliant

## Regulation 14: Equipment

From the evidence available, inspectors were satisfied that all medical radiological equipment was kept under strict surveillance by the undertaking. Inspectors reviewed records of acceptance and performance testing for all radiological equipment at the facility and were assured that the undertaking had implemented and maintained an extensive quality assurance program.

Inspectors were provided with an up-to-date inventory which was verified on site. Records of decisions to use radiology equipment beyond nominal replacement dates were reviewed. Staff spoken with clearly articulated the undertaking's capital investment strategies and how these incorporated radiology equipment when deemed necessary by the RSC. Inspectors were assured following record review and by speaking with staff that the Bon Secours Hospital Dublin and the undertaking had comprehensive equipment monitoring and replacement strategies in place for

equipment that had exceeded pre determined nominal replacement dates.

Inspectors reviewed documentation detailing the undertaking's approach to the optimisation process and, in particular, image quality assessment. Records of MPE testing on a particular piece of equipment detailed a slight drop in image quality as defined by predetermined metrics used for that particular system. Although the slight decrease in image quality was within acceptable limits of performance, inspectors were supplied with evidence of a planned manufacturer site visit to review and optimise equipment image quality. This was seen as an example by the undertaking to proactively optimise equipment performance even in cases where pre defined limits of acceptability were not exceeded.

Judgment: Compliant

### Regulation 15: Special practices

The Bon Secours Hospital Dublin had mechanisms in place to ensure special attention was given to optimising medical exposures involving high doses to the patient. For example, inspectors reviewed policies and procedures utilised in the interventional cardiology department to identify potential high skin doses in patients undergoing cardiac interventional procedures. Inspectors were assured that systems were in place to monitor, identify and follow up patients who may be exposed to relatively high skin doses. Staff spoken to in the interventional cardiology department clearly articulated the practical application of these policies in clinical practice.

Judgment: Compliant

### Regulation 16: Special protection during pregnancy and breastfeeding

Documentation reviewed satisfied inspectors that the Bon Secours Hospital Dublin had processes in place to ensure that all appropriate service users were asked about pregnancy status by a practitioner and the answer was recorded. Staff articulated the process clearly to inspectors on the day of inspection and sample referrals reviewed by inspectors verified the consistent recording of the relevant information in line with local policies and procedures.

Multilingual posters were observed throughout the department with bespoke information relating to the patient dose for a range of diagnostic procedures. Inspectors were assured that measures had been taken to increase awareness of individuals to whom Regulation 16 applies.

Judgment: Compliant

### Regulation 17: Accidental and unintended exposures and significant events

From reviewing documents in advance of this inspection, inspectors were assured that the undertaking had implemented measures to minimise the likelihood of incidents for patients undergoing medical exposures in this facility. Inspectors were satisfied that the Bon Secours Hospital Dublin had a system of record-keeping and analysis of events involving or potentially involving accidental or unintended medical exposures and that this system had been implemented and maintained. Minutes of the RSC were reviewed by inspectors and detailed that accidental and unintended exposures and significant events were a standing agenda point.

Staff spoken to on the day consistently demonstrated a clear knowledge of the process by which the Bon Secours Hospital Dublin records and escalates all accidental and unintended exposures and significant events.

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
<b>Governance and management arrangements for medical exposures</b>	
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
<b>Safe Delivery of Medical Exposures</b>	
Regulation 8: Justification of medical exposures	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 Bon Secours Hospital Dublin OSV-0007388

Inspection ID: MON-0033538

Date of inspection: 31/08/2021

## 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 13: Procedures	Substantially Compliant
Outline how you are going to come into compliance with Regulation 13: Procedures: The Bon Secours Hospital System is currently assessing two dose management systems for use in all centres. Both systems have the ability to input the dose onto the report. The Bon Secours Procurement Dept. is currently organising evaluations and quotations. We hope to make the decision on the preferred system before the end of the year, and have the system installed by 30.06.2022.	

## 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 13(2)	An undertaking shall ensure that information relating to patient exposure forms part of the report of the medical radiological procedure.	Substantially Compliant	Yellow	30/06/2022