

## Health Information and Quality Authority

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

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|-----------------------------------------------|---------------------------------------|
| Name of Medical Radiological Installation:    | National Orthopaedic Hospital Cappagh |
| Undertaking Name:                             | National Orthopaedic Hospital Cappagh |
| Address of Ionising Radiation Installation:   | Cappagh Road, Finglas, Dublin 11      |
| Type of inspection:                           | Announced                             |
| Date of inspection:                           | 04 March 2026                         |
| Medical Radiological Installation Service ID: | OSV-0007392                           |
| Fieldwork ID:                                 | MON-0049646                           |

About the medical radiological installation (the following information was provided by the undertaking):

National Orthopaedic Hospital Cappagh (NOHC) is Ireland's major centre for elective orthopaedic surgery. The hospital has been the pioneer of orthopaedic surgery in Ireland and is now the largest dedicated orthopaedic hospital in the country. The hospital has ambitious plans for the future development and expansion of its services.

National Orthopaedic Hospital Cappagh is a Voluntary Hospital founded in 1908 and is an elective hospital with 130 beds, catering mainly for public patients. It is a training hospital affiliated in equal volume to UCD and RCSI for surgical training, whilst also linked to RCPI for medical training. The hospital hosts the National Casting Certificate Programme which was established in 2016.

The hospital provides the full range of orthopaedic services including major joint replacement (ankle, hip, knee, shoulder, elbow and wrist), spinal surgery, primary bone tumour service, paediatric orthopaedics and sports injuries. The National Bone Bank is located in NOHC. In addition to being a surgical site, the hospital is home to a Centre for Rehabilitation.

The Radiology Department is an integral part of the hospital with over 22,700 radiological examinations performed in 2025. The Radiology Department uses imaging equipment to identify, diagnose and treat musculoskeletal conditions and sports-related injuries. The Radiology Department provides a diagnostic imaging service for both adults and paediatric patients. The range of medical ionising equipment includes two digital general radiographic rooms, one interventional fluoroscopy suite, a mobile x-ray machine, a CT scanner and three mobile fluoroscopy C-arms which are used in the operating theatres. There is a busy MRI department on site with two MRI scanners (1.5T and 3T).

## 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, as amended. 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:

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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.

## **1. Governance and management arrangements for medical exposures:**

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 4 March 2026 | 09:30hrs to 14:05hrs | Kay Sugrue      | Lead    |
| Wednesday 4 March 2026 | 09:30hrs to 14:05hrs | Kirsten O'Brien | Support |

## Governance and management arrangements for medical exposures

An inspection was carried out at the National Orthopaedic Hospital Cappagh (NOHC) on 4 March 2026. Inspectors visited the radiology department and met and spoke with staff involved in carrying out medical radiological procedures there. The computed tomography (CT) services, DXA, general X-ray and department interventional fluoroscopy suite were visited and a sample of records of completed medical radiological procedures in each clinical area were reviewed during this inspection. In addition, hospital documentation relevant to the radiation protection of service users and radiology governance arrangements were also reviewed.

From the review of referrals and local policies and procedures, inspectors were assured 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 a practitioner, as per the regulations. The hospital had ensured that a medical physics expert (MPE) was involved in medical radiological practices, which was evident in documentation reviewed and in discussions with staff. The arrangements to ensure the continuity of medical physics expertise were viewed and met regulatory requirements. The evidence gathered during the inspection satisfied the inspectors that MPE involvement was proportionate to the radiological risk posed by medical radiological practices at this facility.

Overall, inspectors found that radiology governance structures in place at the National Orthopaedic Hospital Cappagh, reviewed as part of this inspection, showed clear lines of communication within corporate and clinical governance structures. Despite some gaps in compliance identified and discussed in this report, inspectors noted that there was a strong staff commitment to the radiation protection of service users attending for medical radiological procedures at the hospital.

### Regulation 4: Referrers

Inspectors were satisfied that referrals were only accepted from those entitled to refer an individual for a medical radiological procedure. As per recent regulatory amendments, the hospital was making plans to expand the role of the referrer to physiotherapists who have completed the necessary training required by their professional body. Inspectors noted that staff at the hospital had taken a proactive approach towards ensuring that the necessary processes and oversight arrangements are in place before allocating referral rights to physiotherapists, to ensure regulatory compliance and alignment with the scope of practice by the relevant professional body.

Judgment: Compliant

## Regulation 5: Practitioners

Inspectors were satisfied that only practitioners, as defined in the regulations, took clinical responsibility for individual medical exposures.

Judgment: Compliant

## Regulation 6: Undertaking

Inspectors reviewed the radiology governance arrangements in place in relation to the radiation protection of service users and found that overall, the established committees and forums within the governance framework provided effective communication pathways up to the Board of Directors, at undertaking level. There were clear lines of reporting from staff involved in delivering medical exposures via the radiation protection unit (RPU) and the radiation safety committee (RSC) and from there, to the clinical governance and clinical risk committee to the undertaking. The CEO, who also fulfilled the role of the undertaking representative and designated manager for this facility, chaired the RSC. Minutes from each of these forums, reviewed by inspectors, showed there was multidisciplinary representation and appropriate oversight by senior management at the hospital.

As discussed under Regulations 4 and 8, inspectors noted that the undertaking was proactively reviewing processes and practices to ensure compliance with recent regulatory amendments, which is considered good practice. However, not all regulatory amendments had been considered. For example, while a research project involving medical exposures had been approved locally by the hospital research ethics committee, this approval had not been sought by a research ethics committee recognised in line with Statutory Instrument (S.I.) No. 256 of 2018, as amended through S.I. No. 29 of 2023. Also, the allocation of responsibility and the process for approving the submission of an application for generic justification of a new type of practice to HIQA was not evident in documentation reviewed, therefore, these gaps should be addressed to ensure compliance with Regulation 6(3).

A small number of inconsistencies were observed in local policies where in some cases processes did not fully align with day-to-day practices. For example, the process applied at the hospital for establishing paediatric facility diagnostic reference levels differed to what was documented and described to inspectors. Additionally, the allocation of responsibility for justifying medical exposures did not include the radiologist's role in justifying fluoroscopy guided imaging procedures, therefore, relevant documents should be revised and updated.

Notwithstanding the gaps in compliance identified above, inspectors were satisfied from discussions with management and staff, that the leadership and management in place underpinned and supported staff commitment to the radiation protection of service users and ensuring compliance with the regulations.

Judgment: Substantially Compliant

### Regulation 10: Responsibilities

On the day of inspection, all medical exposures were found to have taken place under the clinical responsibility of a practitioner, as defined in the regulations. Inspectors were satisfied that referrers and practitioners were involved in the justification process for individual medical exposures. There was also evidence to show that practitioners and the MPE were involved in the optimisation process as per the requirements of this regulation.

Judgment: Compliant

### Regulation 19: Recognition of medical physics experts

Formal processes were evident for the provision of MPE advice and services at the hospital. While noting the continuity arrangements in place which met regulatory requirements, inspectors were informed that the radiology service provided by the hospital was expanding with a new paediatric unit under development. Inspectors noted in the RSC minutes from 4 December 2025 that additional MPE input would be required for this service. Inspectors were informed that the undertaking was actively seeking to increase levels of resources and these efforts should be continued to ensure ongoing regulatory compliance.

Judgment: Compliant

### Regulation 20: Responsibilities of medical physics experts

Inspectors reviewed the up-to-date professional registration certificates from the Irish College of Physicists in Medicine for medical physicists and were satisfied that an MPE gave specialist advice, as appropriate, on matters relating to radiation physics as required by Regulation 20(1). There was also evidence to show that the requirements of Regulation 20(3) were met as one of the MPEs providing specialist

advice cover at the hospital was also the radiation protection adviser (RPA) at the hospital.

In relation to Regulation 20(2), inspectors found that MPE responsibilities set out under this regulation were met in this facility. Documentation such as local policies, minutes from the RPU and RSC meetings, communication and staff discussions demonstrated that the MPE gave advice on medical radiological equipment and contributed to the radiation protection of services users subject to medical exposure at this facility. Staff informed inspectors of the MPE's on-site presence and how the MPE contributed to optimisation including the application and use of diagnostic reference levels (DRLs) and associated DRL audits. A quality assurance (QA) programme for all medical radiological equipment in use at the hospital was established and annual QA of equipment was completed by the MPE. Other inputs by the MPE included dose calculations for any incidents and training of staff in relevant aspects of radiation protection.

Judgment: Compliant

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

As described under Regulation 20, inspectors were satisfied that MPE responsibilities were met and MPE involvement and contribution was appropriate and proportionate to the radiological risk posed by medical radiological practices at NOHC. This was in line with regulatory requirements.

Judgment: Compliant

### Safe Delivery of Medical Exposures

Inspectors reviewed the systems and processes in place to support the safe delivery of medical exposures in NOHC and were satisfied that the radiation protection of adults and children subject to examinations involving ionising radiation was a central focus for staff involved in the service provision. This was evident in the approach taken towards clinical audit practices which were carried out in accordance with the national procedures. This approach provided assurance that justification in advance of each medical exposure and optimisation were prioritised while also maintaining image quality for reporting purposes. It was also clear from the review of documentation and records that medical radiological equipment was strictly maintained to ensure it was fit for continued clinical use. Records viewed from completed medical radiological procedures showed that pregnancy queries were

made for relevant service users and information relating to the exposure was also included in each report.

Despite the good practices in many areas described under this domain, inspectors identified some areas for improvement, specifically, in relation to the approval of research projects involving ionising radiation by a recognised research ethics committee and in relation to gaps in the referral process discussed under Regulation 8. There was also scope to increase reporting levels for near misses or good catches as described under Regulation 17.

Overall, inspectors were satisfied that staff exhibited a focused commitment to the radiation protection of services users which was underpinned by the monitoring and oversight provided by the management staff in this facility.

## Regulation 8: Justification of medical exposures

Inspectors were informed that a research project involving medical exposures to ionising radiation had been approved by the hospital research ethics committee prior to commencing at the hospital. In addition, inspectors were informed that input in relation to the justification and optimisation of medical exposures and patient doses from a medical physics expert was not requested as part of this local approval process. While taking these steps to approve this project, inspectors noted from relevant documents reviewed that approval had not been sought by a research ethics committee recognised in line with Statutory Instrument (S.I.) No. 256 of 2018, as amended through S.I. No. 29 of 2023. During further discussions with management, inspectors were informed that this research project no longer involved medical exposures, however, this did not negate the requirement to ensure that the provisions of the regulations were met during the initial examination and approval of this research project which at that time did involve medical exposures. Inspectors therefore concluded that staff awareness in relation to the regulatory requirements for the approval of medical or biomedical research projects involving medical exposure must be strengthened and relevant hospital policy and processes updated.

In relation to Regulation 8(5), inspectors were informed that staff were in the process of reviewing practices at the hospital regarding medical exposures on asymptomatic individuals to provide assurance that where, and if relevant, these procedures are carried out in accordance with HIQA's recently published *Guidelines for the justification of medical radiological procedures on asymptomatic individuals*.

From a review of records, inspectors found that a written referral was not clearly evident for a small sample of fluoroscopy guided imaging procedures. Inspectors also observed that the clinical details included in the referrals for a small sample of procedures carried out in theatre needed to be expanded upon, to adequately inform the justification of a medical exposure by a practitioner. Therefore, these gaps should be reviewed to ensure compliance with Regulation 8(10) and 8(15) which should then provide evidence of overall compliance with Regulation 8.

Judgment: Substantially Compliant

### Regulation 9: Optimisation

A hospital policy document *Optimisation of Medical Radiological Procedures* was issued in May 2024, the purpose of which, was to ensure that optimisation of medical exposures is undertaken in line with best practice. On review of this document, inspectors noted that the roles and responsibilities for optimisation were clearly documented in addition to the procedures to be followed by staff that covered a range of topics relevant to optimisation of medical exposures.

Good practices were noted in the area of clinical audit involving optimisation. For example, an audit was conducted from September to October 2025 to investigate inconsistencies identified in some protocols for similar procedures applied between the two general X-ray rooms. These discrepancies were identified following the introduction of evidence based additional beam filtration to further optimise the dose to from these examinations in September 2024. Relevant protocol adjustments were made to standardise the protocol used in both X-ray rooms with the assistance of the equipment's applications specialist. A further audit was necessary to reinstate a protocol from one of the X-ray rooms which had been deleted accidentally following a service visit. In another audit focused on lowering the dose to sensitive organs during CT brain examinations, refresher staff training on optimal patient positioning techniques led to significant dose reductions to these organs without impacting the image quality of the studies.

These examples of audit reports highlighted the close monitoring of practices and image quality review from a multidisciplinary perspective, while also demonstrating staff consideration of best practice and evidence towards the review of protocols and optimisation of doses to patients when carrying out general and CT examinations.

Judgment: Compliant

### Regulation 11: Diagnostic reference levels

In line with the requirements of this regulation, inspectors found that adult and paediatric facility DRLs were regularly established and reviewed and where relevant, compared with national DRLs. Local DRLs were reviewed each year by the RSC and the 2025 local DRLs were displayed in control rooms of the areas visited by inspectors. Inspectors reviewed DRL audits carried out to establish local DRLs for common procedures conducted in this facility which demonstrated multidisciplinary involvement and noted that appropriate investigations took place for DRLs found to

exceed national DRLs. Follow up actions were also taken to address any image quality issues identified during these audits.

Inspectors noted that the hospital had a version controlled local policy in place titled *Diagnostic Reference Levels Policy*, which was approved for use in December 2024, with a three year review date. While compliance was met with respect of this regulation, gaps in information provided in this document, previously referred to under Regulation 6, should be addressed to provide more detail and greater alignment between what is documented and day-to-day practices.

Judgment: Compliant

### Regulation 13: Procedures

Inspectors were satisfied that the undertaking complied with all the sub-regulations under Regulation 13. Written protocols for standard adult and paediatric procedures were evident, as per Regulation 13(1). A sample of reports for medical radiological procedures carried out across the range of modalities at the hospital were viewed by inspectors and demonstrated that information relating to the patient exposure was included in line with Regulation 13(2). In relation to Regulation 13(3), referral guidelines were available to staff and referrers as required.

With respect to Regulation 13(4), good practices were observed regarding clinical audits which were carried out in accordance with HIQA's national procedures. For example, staff had utilised the clinical audit strategy template in the national procedures when developing the hospital clinical audit strategy and had referenced all the principles and essential criteria within this strategy. A programme for audit was approved by the RSC for 2026 audits with strong oversight evident. From audit reports reviewed, inspectors noted that recommendations and corrective actions were assigned to individuals to complete within defined timelines and, where necessary, re-audit was undertaken when less than expected compliance was achieved. For example, an audit carried out by staff in the general X-ray department between 1 to 12 December 2025 that looked to estimate referral errors for plain film requests and identify the reasons for these referral errors. This was a follow-up to a similar audit also completed in 2025. The audit report viewed by inspectors identified that the corrective actions implemented following the earlier audit had significantly reduced referral errors from 9% to 3%. This reduction was achieved through targeted training of new referrers to the hospital on established referral processes and referral systems in place and was noted as a good example of how audit can be used to drive improvement in referral practices.

Judgment: Compliant

### Regulation 14: Equipment

Good practices were observed in relation to the strict surveillance of medical radiological equipment required under Regulation 14(1). An up-to-date inventory of medical radiological equipment was verified during the inspection and a QA programme was in place and implemented in line with set timelines. Adherence to the QA programme was monitored by the RSC. Inspectors observed from records that acceptance testing had been completed by an MPE and regular performance testing was carried out in line with expected frequencies. Any issues identified with equipment were promptly addressed.

Judgment: Compliant

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

From a sample of records reviewed and discussions with staff, inspectors were satisfied that a referrer and practitioner were involved in establishing the pregnancy status of service users which was evident in referrals reviewed and pregnancy declaration forms used to record the answers to the query. These completed forms were saved onto the radiology information system under the service user record for the relevant medical exposure. Awareness on the special protection to be considered during pregnancy before undergoing a medical exposure was promoted on notices displayed in service user waiting areas throughout the radiology department. Compliance with the requirements of this regulation was monitored by audit and demonstrated good compliance.

Judgment: Compliant

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

The undertaking had an electronic system in place for the recording and review of any incidents and near misses, involving accidental or unintended exposures to ionising radiation, in the service. The processes implemented were underpinned by an overarching incident management policy which outlined significant events of accidental or unintended exposures notifiable to HIQA in appendix 9.5. The document *Radiation Safety Procedures (Local Rules)* also provided additional information and a process chart outlining what a staff member should do if a radiation incident is identified. These documented processes were consistently articulated by staff to inspectors. Staff identified to inspectors that there was potential to increase reporting levels, particularly in relation to referral issues picked up and modified by radiographers before proceeding with a medical exposure. From these discussions and the review of the summary analysis of 2025 incidents, inspectors concluded that given the overall activity levels within this facility and the associated levels of reporting, there was potential to improve the reporting of near

misses and good catches. Although found to be compliant with this regulation during this inspection, management should continue to seek ways to promote the reporting of near misses and good catches to identify trends and potential areas for improvement.

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, as amended. 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                                                               | 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               |
| <b>Safe Delivery of Medical Exposures</b>                                               |                         |
| Regulation 8: Justification of medical exposures                                        | Substantially Compliant |
| Regulation 9: Optimisation                                                              | Compliant               |
| Regulation 11: Diagnostic reference levels                                              | Compliant               |
| Regulation 13: Procedures                                                               | Compliant               |
| Regulation 14: Equipment                                                                | Compliant               |
| Regulation 16: Special protection during pregnancy and breastfeeding                    | Compliant               |
| Regulation 17: Accidental and unintended exposures and significant events               | Compliant               |

# Compliance Plan for National Orthopaedic Hospital Cappagh OSV-0007392

Inspection ID: MON-0049646

Date of inspection: 04/03/2026

## 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, as amended.

This document is divided into two sections:

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

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

A finding of:

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

## Section 1

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

### Compliance plan undertaking response:

| Regulation Heading                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | Judgment                |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|
| Regulation 6: Undertaking                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | Substantially Compliant |
| Outline how you are going to come into compliance with Regulation 6: Undertaking: <ul style="list-style-type: none"><li>• NOHC is committed to ensuring S.I. No. 29 of 2023. PP-COR-18 Research Ethics Procedure is under review. The undertaking has sought clarification on how ethics approval for research studies involving medical exposure are dealt with for studies involving ionising radiation as part of routine treatment and where additional exposure is required as part of the research study. Any relevant research application approvals will be withheld pending this clarification.</li><li>• The PP-RAD-38 DRL Policy and PP-RAD-39 Justification Policy have been updated to reflect everyday practices and sent to the Radiation Safety Committee Members for approval. The document management system will be updated with revised policies.</li></ul> |                         |
| Regulation 8: Justification of medical exposures                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | Substantially Compliant |
| Outline how you are going to come into compliance with Regulation 8: Justification of medical exposures: <ul style="list-style-type: none"><li>• The NOHC ethics committee chairperson has been informed of the obligations of the committee under SI 256 of 2018 and SI 29 of 2023.</li><li>• PP-RAD-39 Justification Policy have been updated to reflect the role of radiologists in justification of medical exposures and sent to the Radiation Safety Committee Members for approval. The document management system will be updated with revised policies.</li></ul>                                                                                                                                                                                                                                                                                                      |                         |

- All Practitioners have been informed to use x-ray referral forms for patients where the radiologist is taking on the role of referrer.
- All referrers will be reminded of their obligation to provide clear clinical indications for each patient referral.

## 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      | 30/06/2026               |
| Regulation 8(2) | An undertaking shall ensure that each medical or biomedical research project involving medical exposure for which it is responsible                                                                                                                                                                                                                                                                                | Not Compliant           | Orange      | 30/06/2026               |

|                     |                                                                                                                                                                                                                                                                    |                         |        |            |
|---------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|--------|------------|
|                     | has been examined and approved by an ethics committee prior to the commencement of such project.                                                                                                                                                                   |                         |        |            |
| Regulation 8(10)(a) | A referrer shall not refer an individual to a practitioner for a medical radiological procedure unless the referral is in writing,                                                                                                                                 | Substantially Compliant | Yellow | 30/05/2026 |
| Regulation 8(10)(b) | A referrer shall not refer an individual to a practitioner for a medical radiological procedure unless the referral states the reason for requesting the particular procedure, and                                                                                 | Substantially Compliant | Yellow | 30/05/2026 |
| Regulation 8(10)(c) | A referrer shall not refer an individual to a practitioner for a medical radiological procedure unless the referral is accompanied by sufficient medical data to enable the practitioner to carry out a justification assessment in accordance with paragraph (1). | Substantially Compliant | Yellow | 30/06/2026 |
| Regulation 8(15)    | An undertaking shall retain records evidencing compliance with this Regulation for a period of five years from the                                                                                                                                                 | Substantially Compliant | Yellow | 30/05/2026 |

|  |                                                                                           |  |  |  |
|--|-------------------------------------------------------------------------------------------|--|--|--|
|  | date of the medical exposure, and shall provide such records to the Authority on request. |  |  |  |
|--|-------------------------------------------------------------------------------------------|--|--|--|