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:	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:	07 July 2022
Medical Radiological Installation Service ID:	OSV-0007392
Fieldwork ID:	MON-0036811

About the medical radiological installation:

National Orthopaedic Hospital Cappagh is Ireland's major centre for elective orthopaedic surgery. The Hospital is one of twelve hospitals in the Ireland East Hospital Group. The Hospital has been the pioneer of orthopaedic surgery in Ireland and is now the biggest dedicated orthopaedic hospital in the country. National Orthopaedic Hospital Cappagh (NOHC) is a Voluntary Hospital founded in 1908 and is an elective hospital with 142 beds, catering for public and private 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 also 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 Specialist Rehabilitation Unit.

The Radiology Department is an integral part of the Hospital with over 24,000 radiological examinations performed in 2021. 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 newly installed computed tomography (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 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 7 July 2022	09:30hrs to 14:25hrs	Noelle Neville	Lead
Thursday 7 July 2022	09:30hrs to 14:25hrs	Kirsten O'Brien	Support
Thursday 7 July 2022	09:30hrs to 14:25hrs	Sheena Galvin	Support

Governance and management arrangements for medical exposures

An inspection was carried out at National Orthopaedic Hospital Cappagh on 7 July 2022 by inspectors to assess the hospital's compliance with the regulations. As part of this inspection, inspectors spoke with staff and management, reviewed documentation and visited several clinical areas within the radiology department including CT, dual-energy x-ray absorptiometry (DXA) and general X-ray.

Inspectors found that there was a clear allocation of responsibilities for the protection of service users from medical exposure to ionising radiation as required by Regulation 6(3). National Orthopaedic Hospital Cappagh was the undertaking for the hospital which had a local Radiation Safety Committee (RSC). Inspectors reviewed the terms of reference for this committee and noted that it had multi-disciplinary membership including the hospital's chief executive officer who was also the designated manager and undertaking representative. Membership also included the radiation safety officer, radiology services manager, radiologist**,** director of nursing, quality manager, risk and safety manager, facilities manager, medical physics expert (MPE) and representatives from other areas within the hospital including theatre and occupational health. This committee met twice a year and reported to the hospital's clinical governance and clinical risk committee which in turn reported to the board of directors of National Orthopaedic Hospital Cappagh. Inspectors were also informed that the hospital had recently set up a Radiation Protection Unit which reported to the RSC. This unit discussed operational matters in relation to radiation protection such as incident reporting, protocols, equipment and training and its membership included the radiology services manager, radiation safety officer, MPE and radiation protection adviser.

Inspectors were satisfied from reviewing a sample of referrals and speaking with staff that referrals for medical radiological exposures were only accepted at National Orthopaedic Hospital Cappagh from individuals entitled to refer as per Regulation 4 and that only those entitled to act as practitioner as per Regulation 5 took clinical responsibility for medical exposures at the hospital. In addition, all medical exposures for ionising radiation at the hospital were carried out under the clinical responsibility of an individual entitled to act as a practitioner as required by Regulation 10.

In relation to Regulations 19, 20 and 21, inspectors were satisfied that adequate processes were in place at National Orthopaedic Hospital Cappagh to ensure the continuity of medical physics expertise at the hospital. Inspectors noted MPE involvement in radiation protection across a range of responsibilities including dosimetry, strict surveillance of medical radiological equipment, optimisation, incident management and training of staff.

Overall, inspectors were satisfied that National Orthopaedic Hospital Cappagh had clear and effective governance and management structures to ensure the radiation

protection of service users.

Regulation 4: Referrers

National Orthopaedic Hospital Cappagh had a policy titled *Policy on the Justification of Medical Radiological Procedures* which was approved in December 2020. This policy outlined who can refer for medical radiological procedures at the hospital and included medical practitioners and registered nurses in limited circumstances. Inspectors were satisfied from reviewing a sample of referrals and speaking with staff that referrals for medical radiological exposures were only accepted at National Orthopaedic Hospital Cappagh from individuals entitled to refer as per Regulation 4.

Judgment: Compliant

Regulation 5: Practitioners

Inspectors were satisfied from a review of documentation and speaking with staff that only individuals entitled to act as practitioner as per Regulation 5 took clinical responsibility for medical exposures at National Orthopaedic Hospital Cappagh. Inspectors noted that further clarity should be included in documentation in relation to who specifically can act as practitioner at the hospital, for example radiographers and radiologists.

Judgment: Compliant

Regulation 6: Undertaking

Inspectors found that there was a clear allocation of responsibilities for the protection of service users from medical exposure to ionising radiation as required by Regulation 6(3). Inspectors reviewed documentation including governance structure organograms and spoke with staff and management in relation to the governance arrangements at National Orthopaedic Hospital Cappagh.

National Orthopaedic Hospital Cappagh was the undertaking for the hospital which had a local RSC. Inspectors reviewed the terms of reference for this committee and noted that it had multi-disciplinary membership including the hospital's chief executive officer who was also the designated manager and undertaking representative. Membership also included the radiation safety officer, radiology services manager, radiologist, director of nursing, quality manager, risk and safety manager, facilities manager, MPE and representatives from other areas within the hospital including theatre and occupational health. This committee met twice a year

and reported to the hospital's clinical governance and clinical risk committee which in turn reported to the board of directors of National Orthopaedic Hospital Cappagh. Inspectors were also informed that the hospital had recently set up a Radiation Protection Unit which reported to the RSC. This unit discussed operational matters in relation to radiation protection such as incident reporting, protocols, equipment and training and its membership included the radiology services manager, radiation safety officer, MPE and radiation protection adviser.

Overall, inspectors were satisfied that clear and effective governance and management structures were in place at National Orthopaedic Hospital Cappagh to ensure the radiation protection of service users at the hospital.

Judgment: Compliant

Regulation 10: Responsibilities

Inspectors were satisfied that all medical exposures for ionising radiation at National Orthopaedic Hospital Cappagh were carried out under the clinical responsibility of an individual entitled to act as a practitioner as per Regulation 5. Inspectors were also satisfied from a review of a sample of referrals, documentation and speaking with staff that both the referrer and practitioner were appropriately involved in the justification of individual medical radiological exposures.

The practical aspects of medical exposures were only carried out by persons entitled to act as practitioner. Inspectors also noted that practitioners and MPEs were involved in the optimisation process for medical exposures.

In addition, National Orthopaedic Hospital Cappagh had retained the presence of radiographers together with other non-radiology specialities in areas such as theatre, where medical exposures were conducted. In the absence of new training requirements being implemented, as per Regulation 22, this is viewed as good practice to ensure the protection of service users from medical exposure to ionising radiation.

Judgment: Compliant

Regulation 19: Recognition of medical physics experts

Inspectors were satisfied from speaking with staff and management and reviewing documentation that adequate processes were in place to ensure the continuity of medical physics expertise at the hospital. Inspectors were informed by staff and management that a service level agreement was in place within the Ireland East Hospital Group which ensured appropriate access to medical physics expertise at the

hospital. This access included the on-site presence of an MPE for one day every week.

Judgment: Compliant

Regulation 20: Responsibilities of medical physics experts

Inspectors reviewed the professional registration certificates of MPEs at National Orthopaedic Hospital Cappagh and were satisfied that MPEs gave specialist advice, as appropriate, on matters relating to radiation physics as required by Regulation 20(1).

Inspectors noted involvement in radiation protection by MPEs across a range of responsibilities as outlined in Regulation 20(2) at the hospital. MPEs took responsibility for dosimetry, gave advice on medical radiological equipment and contributed to the definition and performance of a quality assurance programme and acceptance testing of this equipment. MPEs were involved in optimisation including the application and use of DRLs. In addition, MPEs at the hospital carried out dose calculations for any incidents relating to ionising radiation and contributed to the training of staff in relation to radiation protection. Inspectors noted an area of good practice in relation to training and education where a periodic newsletter which focused on topics relating to the radiation protection of service users was available to staff at the hospital.

Inspectors noted that MPEs also liaised with the hospital's radiation protection adviser as required by Regulation 20(3).

Judgment: Compliant

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

Inspectors were satisfied that MPEs were appropriately involved at National Orthopaedic Hospital Cappagh, with the level of involvement commensurate with the radiological risk posed by the hospital.

Judgment: Compliant

Safe Delivery of Medical Exposures

Inspectors spoke with staff and management, reviewed documentation and visited

several clinical areas within the radiology department including CT, DXA and general X-ray at National Orthopaedic Hospital Cappagh.

Several areas of good practice were noted by inspectors at the hospital. Inspectors were informed by staff and management that justification in advance was carried out by a practitioner and inspectors found from a sample of records reviewed that a record of justification in advance was retained for all imaging modalities at the hospital as required by Regulations 8(8) and 8(15). Inspectors reviewed a range of local DRLs in place at National Orthopaedic Hospital Cappagh for a variety of modalities, including fluoroscopy, theatre, general X-ray and DXA. Inspectors were satisfied that the hospital had established, regularly reviewed and used DRLs as required by Regulation 11. In addition, inspectors were satisfied that equipment was kept under strict surveillance at National Orthopaedic Hospital Cappagh as required by Regulation 14(1).

In relation to Regulation 13, written protocols were in place at National Orthopaedic Hospital Cappagh for standard medical radiological procedures and the hospital had adopted referral guidelines which were available to staff and referrers. In addition, inspectors reviewed several audits ongoing and completed at the hospital. Regulation 13(2) states that an undertaking shall ensure information relating to patient exposure forms part of the report of the medical radiological procedure. Inspectors were informed that while measures had been provided by the Health Service Executive (HSE) through the National Integrated Medical Imaging System (NIMIS) to facilitate compliance with this regulation, these measures had not been implemented by practitioners at the hospital. National Orthopaedic Hospital Cappagh, the undertaking for the hospital, is responsible for ensuring compliance with this requirement of the regulations and must ensure that compliance measures are implemented at the hospital in relation to Regulation 13(2).

Inspectors noted from discussions with staff and management that there had been a particular focus on increasing the number of incidents and near misses reported at the hospital through staff information sessions and meetings. It is important that National Orthopaedic Hospital Cappagh build on the work completed to date and continue to promote a culture of incident reporting at the hospital. An increase in the reported numbers of incidents and near misses would allow for proactive trending and analysis which would assist in identifying and taking appropriate measures to minimise the probability and magnitude of actual incidents at the hospital as required by Regulation 17.

Overall, inspectors were satisfied that National Orthopaedic Hospital Cappagh demonstrated that systems and processes were in place to ensure the safe delivery of medical radiological exposures to service users.

Regulation 8: Justification of medical exposures

National Orthopaedic Hospital Cappagh had a policy titled *Policy on the Justification of Medical Radiological Procedures* which was approved in December 2020. This

policy clearly outlined the justification process and who was responsible for carrying out this process at the hospital. Inspectors were informed by staff and management that justification in advance was carried out by a practitioner and inspectors found from a sample of records reviewed that a record of justification in advance was retained for all imaging modalities at the hospital as required by Regulations 8(8) and 8(15).

Inspectors were satisfied from reviewing a sample of records that referrals were in writing and stated the reason for the medical radiological procedure. In addition, National Orthopaedic Hospital Cappagh provided risk and benefit information to service users in relation to medical radiological procedures and information was also available on posters which were displayed in the waiting areas of the hospital.

Judgment: Compliant

Regulation 11: Diagnostic reference levels

National Orthopaedic Hospital Cappagh had a *Diagnostic Reference Level Policy* which was approved in November 2020. This policy set out the procedure for establishing local DRLs for adult and paediatric service users and also the requirement to review these periodically as required. Inspectors reviewed a range of local DRLs in place at National Orthopaedic Hospital Cappagh for a variety of imaging modalities, including fluoroscopy, theatre, general X-ray and DXA. Inspectors were satisfied that the hospital had established, regularly reviewed and used DRLs as required by Regulation 11.

Judgment: Compliant

Regulation 13: Procedures

Written protocols were in place at National Orthopaedic Hospital Cappagh for standard medical radiological procedures as required by Regulation 13(1). The hospital had adopted referral guidelines which were available to staff and referrers as required by Regulation 13(3).

Inspectors reviewed several clinical audits ongoing and completed during 2021 and 2022 at the hospital. National Orthopaedic Hospital Cappagh demonstrated that a range of clinical audit was taking place across various imaging modalities including general X-ray, fluoroscopy and CT. These included audits of triple identification checks, justification in advance, patient dose and screening time and pregnancy status declaration forms. Inspectors noted that the hospital viewed clinical audit as an important tool and used it to identify areas of good practice together with areas for improvement in order to ensure the safe delivery of medical exposures to service

users.

Regulation 13(2) states that an undertaking shall ensure information relating to patient exposure forms part of the report of the medical radiological procedure. Inspectors were informed that while measures had been provided by the Health Service Executive (HSE) through the National Integrated Medical Imaging System (NIMIS) to facilitate compliance with this regulation, these measures had not been implemented by practitioners at the hospital. National Orthopaedic Hospital Cappagh, the undertaking for the hospital, is responsible for ensuring compliance with this requirement of the regulations and must ensure that compliance measures are implemented at the hospital in relation to Regulation 13(2).

Judgment: Not Compliant

Regulation 14: Equipment

Inspectors were satisfied that equipment was kept under strict surveillance at National Orthopaedic Hospital Cappagh as required by Regulation 14(1). The hospital had a protocol which outlined the quality assurance programme in place for equipment. Inspectors received an up-to-date inventory of medical radiological equipment in advance of the inspection and noted that appropriate quality assurance programmes were in place for each unit of equipment as required by Regulation 14(2). Inspectors reviewed records of performance testing and were satisfied that testing was carried out on a regular basis as required by Regulation 14(3) and there was a process in place to report any equipment faults or issues arising if needed. In addition, inspectors were satisfied that acceptance testing was carried out on equipment before the first use for clinical purposes as required by Regulation 14(3).

Inspectors noted that some medical radiological equipment at the hospital was identified as being past nominal replacement dates. However, the hospital had a system to track this and escalate equipment needing replacement. Inspectors reviewed an assessment form which is completed for equipment in use past the suggested nominal replacement date. Following an assessment of equipment, a team including an MPE, radiology services manager, radiologist and CEO of the hospital declare if the equipment is suitable for continued use and this form is then discussed at the RSC. Management assured inspectors that this equipment was routinely monitored and meeting all quality assurance and performance tests.

Judgment: Compliant

Regulation 16: Special protection during pregnancy and breastfeeding

National Orthopaedic Hospital Cappagh had a policy titled *Protection of the Unborn Child Arising from Ionising Radiation Received during Medical Diagnostic or Therapeutic Procedures* which was approved in December 2020. This policy included specific staff responsibilities, for example, the practitioner and referrer role in ensuring that all reasonable measures are taken to minimise the risks associated with potential fetal irradiation during medical exposure of female patients of childbearing age.

Inspectors were satisfied that a referrer and practitioner inquired as to the pregnancy status of service users and recorded the answer to this inquiry in writing. In addition, inspectors noted multiple notices in waiting areas to raise awareness of the special protection required during pregnancy in advance of medical exposures.

Judgment: Compliant

Regulation 17: Accidental and unintended exposures and significant events

Inspectors were satisfied from discussions with staff and management and a review of documents, that National Orthopaedic Hospital Cappagh had implemented an appropriate system for the recording and analysis of events involving or potentially involving accidental or unintended medical exposures.

National Orthopaedic Hospital Cappagh had a policy titled *Incident Management* which was approved in September 2021. Inspectors found that this policy clearly outlined the process for incident reporting at the hospital including HIQA's three day timeline for reporting significant events of accidental or unintended exposures. Inspectors noted that the hospital had submitted one notification to HIQA since the commencement of the regulations in 2019. This notification was reported following the identification of multiple non-notifiable incidents of a similar nature and demonstrated trending, oversight and management of incidents.

Inspectors noted from discussions with staff and management that there had been a particular focus on increasing the number of incidents and near misses reported at the hospital through staff information sessions and meetings. It is important that National Orthopaedic Hospital Cappagh build on the work completed to date and continue to promote a culture of incident reporting at the hospital. An increase in the reported numbers of incidents and near misses would allow for proactive trending and analysis which would assist in identifying and taking appropriate measures to minimise the probability and magnitude of actual incidents at the hospital.

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	Compliant
Regulation 11: Diagnostic reference levels	Compliant
Regulation 13: Procedures	Not 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-0036811

Date of inspection: 07/07/2022

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	Not Compliant
Outline how you are going to come into compliance with Regulation 13: Procedures: The hospital plans to look at all available options for complying with Regulation 13 (2). • This issue will be discussed at the next Clinical Governance & Clinical Risk Committee Meeting (September 2022) and next Radiation Safety Committee meeting (planned October 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.	Not Compliant	Orange	28/02/2023