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:	Sports Surgery Clinic
Undertaking Name:	Sports Surgery Clinic
Address of Ionising Radiation Installation:	Northwood Avenue, Northwood, Santry, Dublin 9
Type of inspection:	Announced
Date of inspection:	29 March 2022
Medical Radiological Installation Service ID:	OSV-0005966
Fieldwork ID:	MON-0036379

About the medical radiological installation:

Sports Surgery Clinic is a private hospital specialising in orthopaedics, spine and sports medicine. The radiology department, located on the ground floor at SSC, is a multi-modality general radiology department with a particular focus on musculoskeletal and spine imaging. The multi-disciplinary diagnostic imaging team includes radiographers and radiologists with sub-speciality expertise. The majority of the workload involves out-patients.

Diagnostic imaging procedures available at SSC include:-

- a 64-slice computed tomography (CT) scanner,
- two digital radiography rooms,
- two magnetic resonance imaging (MRI) scanners,
- ultrasound,
- departmental fluoroscopy (image guided injections using mobile C-arms),
- dual-energy X-ray absorptiometry (DXA) scanner and
- seven theatres with 4 Mobile C-arms.

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
Tuesday 29 March 2022	10:00hrs to 16:00hrs	Agnella Craig	Lead
Tuesday 29 March 2022	10:00hrs to 16:00hrs	Lee O'Hora	Support

Governance and management arrangements for medical exposures

From the documentation reviewed in advance of this inspection and the information gathered on the day of inspection, inspectors were assured that the leadership, governance and management arrangements in place provided effective oversight of Sports Surgery Clinic (SSC). The chief executive officer, acting as the undertaking representative was the chairperson of the Radiation Safety Committee (RSC). The lines of reporting up to both this committee and the Health and Safety Committee were well defined and similarly the lines of communication from these committees to the undertaking were also clearly documented and articulated to inspectors on the day of inspection.

Over the course of this inspection, appropriate measures were found to be in place to ensure that all referrals were from those entitled to act as referrer as defined by the regulations. In addition, the reviewed documentation clearly detailed the specific circumstances when radiographers can act as referrers and staff were able to explain this allocation of responsibility to inspectors.

Similarly, inspectors were assured that clinical responsibility for medical exposures was taken by personnel entitled to act as practitioners as per the regulations and SSC had retained the presence of radiographers and or radiologists for all medical radiological procedures carried out at this facility.

The roles and responsibilities of the medical physics expert (MPE) were also clearly identified in the documentation and from speaking with staff, inspectors were satisfied that the MPE was involved in all aspects of radiation protection, as per the regulations. The level of involvement of the MPE was also found to be proportionate to the level of risk posed in this facility.

Overall, inspectors were assured of the governance and management arrangements in place to ensure that the undertaking has appropriate oversight of this facility.

Regulation 4: Referrers

The document titled *'Radiation Safety Procedures'* comprehensively specified the referral process in Sports Surgery Clinic. Referrals for medical radiological procedures were accepted from registered medical practitioners. In addition, the specific situations when radiographers could act as referrers was detailed in the documentation reviewed in advance of this inspection and included examples of when radiographers could amend referrals or complete a secondary referral. Staff who spoke with inspectors demonstrated a good understanding of the referral process which was consistent with the local policy.

Inspectors reviewed a sample of referrals and were satisfied that all referrals reviewed were from persons, as defined in Regulation 4.

Judgment: Compliant

Regulation 5: Practitioners

The personnel who can act as practitioner was detailed in the document titled *'Radiation Safety Procedures'*, and inspectors noted this was as per the regulations. On the day of inspection, a sample of records and other documentation was reviewed and inspectors were assured that only persons entitled to act as a practitioner were found to take clinical responsibility for medical exposures.

Judgment: Compliant

Regulation 6: Undertaking

From reviewing documents in advance of this inspection, inspectors were informed of the governance structures in place for the radiation protection of service users within this facility. The terms of reference for the RSC were provided to inspectors along with minutes of the last three meetings. The radiology services manager was the designated manager in this facility and was a member of this committee. The RSC was chaired by the chief executive officer who is currently the undertaking representative. This committee also reported to the Health and Safety Committee and a *'Radiation Safety Annual Report'* is produced by the designated manager and presented to the Health and Safety committee. Inspectors were provided with a copy of this report for 2021 and noted that the purpose of this report was to provide a summary of radiation safety activities with information and updates on radiation protection training, incidents, quality assurance (QA) testing and audits included in this report. The agenda items and minutes from recent meetings of the Health and Safety committee were also reviewed by inspectors and inspectors were satisfied that issues relevant to the radiation protection of service users were discussed at this committee's meetings.

A clear allocation of responsibilities was included in the *'Radiation Safety Procedures'* document and this allocation was known by staff who spoke with inspectors on the day of inspection. In addition, staff explained the specific circumstances where radiographers can act as referrers or adapt a referral and this was in line with the documented allocation of responsibilities. The specific role and responsibilities of other personnel involved in radiation protection including the MPE was also clearly documented and again this was known by staff who spoke with inspectors.

Based on the evidence gathered as part of this inspection, inspectors were assured

from the governance arrangements in place that the undertaking had strict oversight ensuring radiation protection of service users.

Judgment: 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. Similarly, practitioners and the MPE were found to be involved in the optimisation process for medical exposure to ionising radiation. Inspectors were also satisfied that referrers and practitioners were involved in the justification process for individual medical exposures.

Additionally, the practical aspects of medical radiological procedures were only carried out at this facility by individuals entitled to act as practitioners as per the regulations. As an additional assurance SSC had retained the presence of radiographers and or radiologists for all medical radiological procedures carried out at this facility. In the absence of nationally defined training requirements on aspects of radiation protection for non-radiology doctors, as per Regulation 22, this is viewed as good practice in SSC to ensure the protection of service users from medical exposure to ionising radiation.

Judgment: Compliant

Regulation 19: Recognition of medical physics experts

Inspectors viewed the service level agreement in place with the MPE and found this detailed the arrangements in place with the MPE. Staff who spoke with inspectors reported that they had adequate access to medical physics expertise and inspectors were satisfied that SSC had adequate processes in place to ensure the continuity of medical physics expertise at this facility.

Judgment: Compliant

Regulation 20: Responsibilities of medical physics experts

From reviewing the documentation and speaking with staff, inspectors were satisfied with the MPE's level of involvement and contribution at SSC. An MPE was found to take responsibility for dosimetry and contributed to quality assurance and

acceptance testing at this facility. The MPE had also contributed to establishing, reviewing and advising on DRLs and was also involved in and provided training in the area of radiation protection. The evidence reviewed also demonstrated that an MPE was involved in optimising medical exposures and in analysing events involving, or potentially involving, accidental or unintended medical exposures.

Inspectors were assured by the arrangements that the MPE had acted and given specialist advice as appropriate on matters relating to the radiation protection of service users at SSC.

Judgment: Compliant

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

On the day of inspection, inspectors were assured of the mechanisms in place to ensure that an MPE was involved in medical radiological procedures at this facility and that this level of involvement was in line with the level of radiological risk.

Judgment: Compliant

Safe Delivery of Medical Exposures

Inspectors reviewed the systems and processes in place to ensure the safety of service users undergoing medical exposures at this facility. Sports Surgery Clinic demonstrated a high level of compliance with the regulations assessed and staff demonstrated a strong awareness on matters relating to radiation protection. This included having written protocols for each type of procedure and information for service users regarding the risks associated with medical exposures including multilingual pregnancy posters. An up-to-date inventory of equipment and quality assurance reports were provided to inspectors which showed that an appropriate quality assurance programme was in place and the equipment was kept under strict surveillance. Diagnostic reference levels (DRLs) were also in use in the clinical areas and evidence that these were regularly reviewed was also available.

Areas of good practice were identified by inspectors including the conduct of clinical audit at this facility and inspectors noted improvements in compliance rates in the audits reviewed on the day of inspection. Staff explained to inspectors that an initiative to include all staff in clinical audit had helped to increase compliance rates.

Inspectors reviewed the *'Radiation Safety Policy'* which clearly outlined the process for the management of accidental and unintended exposures and significant events and staff demonstrated a good understanding of this process. Incidents and potential incidents were tracked, analysed and categorised and inspectors noted a

low number of incidents in this facility. However after discussing this with staff and reviewing the mechanisms in place to learn from incidents, such as having visible reminders located in key areas in each room, inspectors were assured that the recorded number was an accurate representation of the number of incidents.

One area of improvement noted by inspectors related to Regulation 13(2), namely that the information relating to the medical exposure did not form part of all patients' reports as required. However, some methods had been devised to manually record this information in the absence of an automated process and staff informed inspectors that a project was underway to ensure compliance with the requirements of Regulation 13(2) in the near future.

Overall, inspectors were satisfied that, at the time of inspection, the Sports Surgery Clinic had effective systems and processes in place to ensure the safe delivery of medical exposures.

Regulation 8: Justification of medical exposures

The *'Radiation Safety Procedures'* document was reviewed in advance of this inspection and inspectors noted the comprehensive approach to justification. This included details on the personnel with responsibility for justification, guidance for referrers on what should be considered when requesting and justifying a procedure and the radiographers' role as practitioners in justifying procedures.

On the day of inspection, inspectors spoke with practitioners who explained how medical exposures are justified in advance of the medical exposure. 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. The record of justification of medical radiological procedures that was recorded by a practitioner in advance of the procedure was also available for all medical radiological procedures reviewed on the day of inspection.

Results of a clinical audit titled *'Justification of X-ray Referrals Audit 2021'* reviewed by inspectors as part of this inspection demonstrated that the information included on X-ray referrals was aligned with local referral criteria and with the requirements of the regulations. The number of referrals deemed to have sufficient medical data present to enable the justification of the exam had increase from 51% in 2020 to 98% in 2021.

Information about the benefits and risks associated with the radiation dose from medical exposures in radiology was available to patients in the form of leaflets and in posters in the waiting areas at SSC.

Judgment: Compliant

Regulation 11: Diagnostic reference levels

As per the requirements of the regulations, DRLs have been established for radiodiagnostic examinations. DRLs relevant to the medical exposures carried out in each X-ray room were visible in each room and staff demonstrated an awareness of the use of DRLs in this facility. Inspectors were informed of the processes used firstly to review DRLs and secondly to investigate when local DRLs were found to exceed national levels. Although national DRLs are currently not available for the therapeutic procedures carried out at this facility, the department had created local DRLs for these procedures and these were audited on an annual basis. This was viewed as an example of good practice and showed the undertaking's commitment to closely monitor service users' radiation doses for all medical radiological procedures carried out at SSC.

Judgment: Compliant

Regulation 13: Procedures

On the day of inspection, inspectors found that written protocols were established for standard medical radiological procedures and these protocols were available in each area where medical exposures were conducted. Both hard and soft copy formats were available to staff and inspectors noted the easily accessible flip-folder which displayed the protocols in the control area. The process to ensure printed documentation is kept up to date was also explained to inspectors and provided assurance to inspectors of alignment of hard and soft copy versions.

Referral guidelines for medical imaging were available for referrers on the clinic's computers and the programme and process of clinical audit was explained to inspectors. Inspectors reviewed a sample of clinical audits conducted at this clinic and noted increases in the rates of compliance in these reports in recent years. When discussing the significant increase in compliance seen in clinical audits, for example, in the audit of justification as described earlier, inspectors were informed of an initiative introduced at this facility. This initiative included involving all staff in clinical audit and was viewed as an example of good practice based on the increase in compliance recorded in recent years.

Inspectors found that information relating to patient exposure formed part of the report of some medical radiological procedures as required by Regulation 13(2). However this information was not automatically transferred to records for procedures on all pieces of equipment. This facility had devised some methods to facilitate manually collecting the data and recording it on the patients' records, however, on the day of inspection information about patient dose was not included on a number of records reviewed by inspectors. Inspectors were informed that a plan was being progressed with management in order to come into compliance with

Regulation 13(2).

Judgment: Substantially Compliant

Regulation 14: Equipment

Inspectors were satisfied that all medical radiological equipment was kept under strict surveillance by the undertaking based on the comprehensive quality assurance and performance testing programme that was implemented and maintained. From the inventory of equipment provided to inspectors and further documentation reviewed on-site, inspectors were assured that all QA was up-to-date at the time of inspection. Evidence was also available to show that any issues identified as part of the equipment services had been followed up in a timely manner.

Equipment and QA were discussed at the RSC meetings and inspectors noted that equipment approaching or at its nominal replacement date was discussed at the RSC meetings before deciding on its continued use. Inspectors were also informed of the business plan for replacing older equipment.

Inspectors were satisfied that the equipment had passed the quality assurance testing and based on the evidence detailed above, the undertaking had appropriate processes in place to ensure oversight.

Judgment: Compliant

Regulation 16: Special protection during pregnancy and breastfeeding

On the day of inspection, posters and leaflets in multiple languages were displayed in changing rooms and waiting areas to raise awareness of the special protection required during pregnancy and breastfeeding in advance of medical exposures. Inspectors were informed by staff of the process in place to inquire about pregnancy status and this aligned with the process described in the policy documents reviewed in advance of the inspection.

From the records reviewed on the day of inspection, inspectors were assured that the referrer or the practitioner had inquired about and recorded the pregnancy status, as per the regulations.

Judgment: Compliant

Regulation 17: Accidental and unintended exposures and significant events

From reviewing documents in advance of this inspection, including the document titled *'Radiation Incident Reporting Policy'* inspectors were assured that the undertaking had implemented measures to minimise the likelihood of incidents for patients undergoing medical exposures in this facility. Evidence was available to show that incidents were a standing agenda item discussed at the RSC meetings, and also at the quarterly Health and Safety Committee meetings. Staff informed inspectors of the process used to record accidental or unintended exposures and near-miss events, which are then reviewed to determine if the incident is deemed reportable to relevant agencies, including HIQA.

A system of record-keeping and analysis of events involving or potentially involving accidental or unintended medical exposures had been implemented and maintained and an annual summary report was provided to inspectors. The specific corrective actions carried out after incidents was detailed in this report, along with the subsequent audits conducted to establish if the implemented corrective actions had reduced the likelihood of incidents and near-misses. Based on the systems and processes in place and the actions taken in relation to incidents, inspectors were satisfied that the number of incidents in this facility was an accurate reflection of the low numbers of incidents in this facility.

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	Substantially 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 Sports Surgery Clinic OSV-0005966

Inspection ID: MON-0036379

Date of inspection: 29/03/2022

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	Substantially Compliant

Outline how you are going to come into compliance with Regulation 13: Procedures:
Currently the patient exposure for a procedure is not available automatically in the Radiology report for CT and DEXA. Unfortunately both of these modalities operate on software platforms that do not allow the automation required and are not upgradeable. Our RIS (Radiology Information System) currently doesn't allow the free text patient dose field to translate to the Radiology report, therefore we have to implement a manual workaround for CT and DEXA.

1. Solutions

a. We will continue to engage and work with our RIS vendor to develop the system to be more flexible in transposing free text dose fields into radiology reports. A RIS upgrade is expected in Q4 2022 during which we hope to progress this
b. When we replace modalities, especially those concerned, as they become end of life/unfit for purpose a particular consideration will be made to ensuring dose transfer compatibility

2. In the meantime

a. CT – Improve Radiologists compliance in dictating the dose into the report. E.g. apply a template report for Radiologists that includes 'Radiation dose' as a heading.
b. DEXA – since inspection a change has been made to our DEXA structured reports to include the patient dose

Compliance will be audited for both of these over the coming months.

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	31/12/2022