

# Health Information and Quality Authority

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

| Name of Medical          | Tallaght University Hospital |
|--------------------------|------------------------------|
| Radiological             |                              |
| Installation:            |                              |
| Undertaking Name:        | Tallaght University Hospital |
| Address of Ionising      | Tallaght,                    |
| Radiation Installation:  | Dublin 24                    |
|                          |                              |
|                          |                              |
| Type of inspection:      | Announced                    |
| Date of inspection:      | 04 August 2020               |
| Medical Radiological     | OSV-0007409                  |
| Installation Service ID: |                              |
| Fieldwork ID:            | MON-0028532                  |

# About the medical radiological installation:

Tallaght University Hospital is a 600 bed teaching hospital affiliated to Trinity College Dublin. Located in south-west Dublin, the hospital is a provider of local, regional, supra-regional and national medical and surgical speciality departments catering for a direct catchment area of 110,000 and broader catchment area of 697,000. Tallaght University Hospital has both an Adult and Children's Emergency Department and is a National Urology Centre, a Regional Dialysis Centre and a Regional Orthopaedic Trauma Centre. The clinical referral base includes General Surgery, Colorectal Surgery, Hepatobiliary and Pancreatic Surgery, Vascular Surgery, Urology, Orthopaedics, Gynaecology, Ear Nose and Throat (ENT), Gastroenterology, Hepatology, Neurology, Endocrinology, Rheumatology, Medical Oncology and Haematology, Radiation Oncology, Cardiology, Respiratory Medicine and Emergency Department. Diagnostic facilities include two magnetic resonance imaging (MRI) scanners, two computed tomography (CT) scanners, two single photon emission computed tomography (SPECT) CT gamma cameras, three ultrasound (US) rooms, a fluoroscopy suite, and an interventional radiology (IR) suite. Other subspecialties include musculoskeletal US and interventions, cardiac CT and MRI, neuroradiology, gastrointestinal (GI) and genitourinary (GU) including women's imaging and prostate imaging with fused MRI/US transrectal biopsy and CT colonography. Approximately 160,000 radiology procedures are conducted annually within the department.

## 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 inspector¹ reviewed all information about this medical radiological installation². This includes any previous inspection findings, information submitted by the undertaking, undertaking representative or designated manager to HIQA³ and any unsolicited information since the last inspection.

As part of our inspection, where possible, we:

- talk with staff and management to find out how they plan, deliver and monitor the services that are provided to service users
- speak with service users<sup>4</sup> to find out their experience of the service
- observe practice to see if it reflects what people tell us
- review documents to see if appropriate records are kept and that they reflect practice and what people tell us.

## About the inspection report

In order to summarise our inspection findings and to describe how well a service is complying with regulations, we group and report on the regulations under two dimensions:

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

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

<sup>&</sup>lt;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>&</sup>lt;sup>4</sup> Service users include patients, asymptomatic individuals, carers and comforters and volunteers in medical or biomedical research.

This section describes HIQA's findings on compliance with regulations relating to the oversight and management of the medical radiological installation and how effective it is in ensuring the quality and safe conduct of medical exposures. It outlines how the undertaking ensures that people who work in the medical radiological installation have appropriate education and training and carry out medical exposures safely and whether there are appropriate systems and processes in place to underpin the safe delivery and oversight of the service.

#### 2. Safe delivery of medical exposures:

This section describes the technical arrangements in place to ensure that medical exposures to ionising radiation are carried out safely. It examines how the undertaking provides the systems and processes so service users only undergo medical exposures to ionising radiation where the potential benefits outweigh any potential risks and such exposures are kept as low as reasonably possible in order to meet the objectives of the medical exposure. It includes information about the care and supports available to service users and the maintenance of equipment used when performing medical radiological procedures.

A full list of all regulations and the dimension they are reported under can be seen in Appendix 1.

#### This inspection was carried out during the following times:

| Date                     | Times of Inspection     | Inspector     | Role    |
|--------------------------|-------------------------|---------------|---------|
| Tuesday 4 August<br>2020 | 09:30hrs to<br>14:30hrs | Lee O'Hora    | Lead    |
| Tuesday 4 August<br>2020 | 09:30hrs to<br>14:30hrs | Agnella Craig | Support |

# Governance and management arrangements for medical exposures

Inspectors found effective governance, leadership and management arrangements with a clear allocation of responsibility for the protection of service users undergoing medical exposures at Tallaght University Hospital (TUH). Reporting structures were well defined and clearly articulated to inspectors on the day of inspection. A radiation safety committee (RSC) was incorporated into the governance system and reported directly to the designated manager who in turn reported directly to the executive management team. Recent COVID-19 related physical restrictions prevented the RSC from meeting in 2020 but TUH had appropriate pathways to escalate radiation safety concerns to the undertaking directly through radiology management, the designated manager and the executive management team.

A separate undertaking was co located at TUH. Inspectors saw a service level agreement between undertakings, which was reviewed and updated annually. This document clearly defined the roles of each undertaking and gave good assurances that the appropriate responsibilities were clearly defined. The arrangement between undertakings and their respective responsibilities was well articulated by senior hospital management to inspectors. Inspectors were satisfied that shared structures and reporting pathways ensured good communication and oversight across both undertakings and strengthened radiation safety practice at TUH.

Inspectors reviewed documentation and spoke with senior management regarding medical physics expert (MPE) involvement in the safe delivery of medical exposures. Inspectors noted some outstanding annual MPE quality assurance (QA). Senior management and staff indicated that this was due to on-site restrictions of MPE staff as well as current MPE staffing levels. Senior management acknowledged the possible shortcomings with the existing arrangement and inspectors were informed that the issue has been escalated and was currently on the hospital risk register. Despite this, inspectors were satisfied that the existing arrangement did not present a current safety risk and the temporary issues with continuity of expertise were currently being addressed.

## Regulation 4: Referrers

Documentation reviewed by inspectors defined referrers as per the regulations. All referrals for medical exposures reviewed by inspectors were from the relevant professions. Nurse referrers, their specialities and individual scope of practice was well defined in documentation seen by inspectors and staff articulated a good knowledge of the referral process and locally defined referrers.

Judgment: Compliant

## Regulation 5: Practitioners

Documentation reviewed by inspectors defined practitioners as per the regulations and clearly identified radiographers as practitioners and comprehensively detailed their role in the justification of medical exposures. However, dental nurses were also listed as practitioners. Both hospital and radiology management acknowledged this as an error in documentation and assured inspectors that this was not reflective of the practice at TUH. Inspectors verified this in the clinical area through staff interaction and while reviewing a sample of radiology referrals. Inspectors were satisfied that dental nurses were not acting as practitioners at TUH at the time of inspection. Inspectors suggested documentation is changed to reflect practice.

Judgment: Compliant

## Regulation 6: Undertaking

Clear organograms of the TUH organisation structure as well as radiation safety specific structures were reviewed by inspectors. These structures and reporting pathways were well articulated by senior hospital management to inspectors.

The RSC played an important role in the overall radiation safety structure and governance in TUH. Inspectors were satisfied that escalation pathways still existed in the absence of meetings in 2020 due to ongoing COVID-19 restrictions. Alternate hospital structures ensured good communication between the radiology clinical director and the executive management team.

A separate undertaking operated on site. A service level agreement was supplied to inspectors. This documentation clearly defined the roles of each undertaking and gave good assurances that the appropriate responsibilities were clearly defined. This was well articulated by senior hospital management. Shared structures ensured good communication and oversight across both undertakings.

Judgment: Compliant

#### Regulation 19: Recognition of medical physics experts

Inspectors spoke with registered medical physics experts (MPEs) and reviewed professional registrations of the MPE who provided services to TUH assisted by supporting medical physicists. However, at the time of inspection TUH was operating

with half its complement of medical physics staff and only one medical physics expert.

Inspectors were informed that no formal arrangement existed for continuity of expertise, but unofficial arrangements provided continuity of MPE expertise. The current shortage of MPEs and medical physics support was acknowledged by senior hospital management and was on the hospital risk register. Although there were no regulatory deficiencies seen in practice, management at TUH should review the continuity and contingency arrangements for medical physics experts and address any current MPE risks on the hospital risk register.

Judgment: Substantially Compliant

#### Regulation 20: Responsibilities of medical physics experts

Documentation reviewed clearly defined the roles of the medical physics expert in relation to equipment QA and incident reporting.

The MPE's role in relation to acceptance testing, performance testing and definition of technical specifications was clearly articulated to inspectors on the day of inspection. Inspectors were informed that the MPE also played an important role in the initial communication of accidental and unintended exposures and significant events as well as their associated investigation reports to HIQA.

Records of acceptance testing, and regular medical physics quality assurance testing were reviewed by inspectors. Although all existing records were reviewed were signed off by an MPE, some annual MPE quality assurance was outstanding. This was acknowledged by staff as result of COVID-19 on-site working restrictions and current medical physicist staffing levels. A time bound plan to address the outstanding QA was provided on request and this assured inspectors that outstanding QA testing would be completed within the given time frame.

Judgment: Compliant

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

Regulators focused on specific regulations when assessing the involvement of the medical physics expert. After documentation review and speaking to senior management and staff, inspectors were satisfied that TUH involved MPEs appropriately and commensurately with the regulatory specific risks reviewed.

Judgment: Compliant

## Safe Delivery of Medical Exposures

Inspectors found that radiation protection processes implemented by TUH ensured the safe delivery of medical exposures.

Inspectors were satisfied that TUH has processes in place to ensure that all medical procedure referrals are accompanied by the relevant information and justified in advance by a practitioner. Information on the risks associated with medical exposure to ionising radiation are available throughout the radiology department and this resource was well articulated by staff in the clinical area to inspectors. However, two areas for potential improvement in the justification of individual medical exposures were noted by inspectors to include the documentation of radiographer justification in hospital policy and the recording of justification in a more consistent fashion to ensure records can be retrospectively reviewed and audited in line with time frames specified in legislation.

Inspectors found that TUH had a comprehensive list of protocols for medical radiological procedures and these were readily available to staff in the clinical area. Referral criteria were also readily available to the appropriate staff and were well articulated to inspectors on the day. Inspectors saw examples of a wide variety of radiation safety related clinical audits that were carried out within the radiology department. Inspectors noted that a more comprehensive, multidisciplinary approach by TUH to support and promote the audit process may improve and formalise the radiology department's ability to implement necessary changes essential for the safe delivery of medical exposures.

Inspectors were informed, and subsequently observed, that information relating to exposure did not form part of the report of the medical radiological procedure. This was acknowledged by senior hospital and radiology management as an area for improvement to ensure regulatory compliance.

Inspectors were satisfied that TUH had implemented an extensive radiology equipment quality assurance programme and noted a plan to address outstanding quality assurance testing mentioned in the governance and management section of this report.

After review of accidental and unintended exposure notifications submitted by TUH and discussion with senior hospital and radiology management, inspectors were satisfied that all reasonable measures were taken to minimise the probability and magnitude of accidental or unintended exposures. Despite this, areas for potential improvement were highlighted to senior management and staff by inspectors. These included the consistent reporting of incidents and supply of investigation reports within the time frames specified by the Authority, the consistent communication to those affected by incidents in line with legislative requirements, and the consistent inclusion of corrective measures to avoid such events in the investigation report for

each accidental and unintended exposure and significant event reported to HIQA.

Overall there were areas noted for improvement on inspection, these did not pose current risks to the safety, health or welfare of service users.

## Regulation 8: Justification of medical exposures

Through documentation review, referral review and staff communication inspectors were satisfied that the required data set of referral information is consistently requested from referrers and medical exposures are not considered unless this information is supplied.

Inspectors were satisfied that previous diagnostic information was considered for all referrals reviewed during the inspection. Inspectors also observed that information relating to the risks and benefits of medical exposure was available to service users. Risk benefit information in poster format was displayed throughout patient waiting areas visited and was also available in pamphlet format. Staff in the clinical area were well versed on this literature and articulated this to inspectors.

In relation to justification for X-rays, Inspectors were informed of a system where radiographers signed the procedure triple identification form which served as a record of justification. Documentation reviewed by inspectors clearly outlined the radiographers role as a practitioner and their responsibilities in relation to the justification of medical procedures but did not outline how this is done and should be updated to reflect local practice. Although documentation reviewed by inspectors stated the requirement for justification in advance of all medical radiological procedures, inspectors noted that a record of practitioner justification of medical exposures was not consistently recorded to the record of examination. Hospital and radiology senior management acknowledged this as an area for improvement, to ensure full regulatory compliance.

Judgment: Substantially Compliant

#### Regulation 13: Procedures

Inspectors were satisfied that protocols were well documented. Staff in the clinical area demonstrated knowledge of and were able to access these on request. Procedure protocols were available to staff in the clinical areas in soft and hard copy.

Referral guidelines were available to all staff on the TUH intranet and staff in the clinical area were able to access these on request.

Inspectors found on review of referrals and subsequent radiology reports that

information relating to exposure was not available on the report. This was also articulated to inspectors by senior radiology management and staff in the clinical area. Furthermore, the radiology department undertook a wide array of audits, two of which were reviewed by inspectors. Despite one audit demonstrating actionable findings no evidence of any related changes were available. Senior management acknowledged the need for a more comprehensive and hospital wide approach to close out of audit related issues. These two areas were identified as areas for improvement and should be addressed by management at TUH.

Judgment: Substantially Compliant

# Regulation 14: Equipment

Policy documents reviewed by inspectors detailed extensive QA testing by medical physics staff and radiographers.

Inspectors reviewed records of equipment commissioning, MPE quality assurance and radiographer quality assurance. Documentation reviewed by inspectors detailed the roles and responsibilities of the MPE in relation to radiology equipment. Documentation seen by inspectors also defined responsibilities for access, close out of corrective actions required, the process for the return of equipment to clinical use after QA and or remedial interventions to the radiography services manager (RSM). Inspectors were satisfied that good communication between the healthcare professionals involved in the process gave assurances that equipment related issues were dealt with in a timely manner.

Inspectors were supplied with a full equipment inventory which detailed the most recent MPE testing dates, nominal replacement dates and record of decision to use beyond nominal replacement date. When equipment had passed its nominal replacement dates, the MPE had re-assessed the performance of the equipment and recorded a decision to keep the equipment in service. Some MPE regular performance testing was overdue, this was acknowledged by staff on the day and inspectors were informed it was due to COVID-19 related on-site working restrictions. Inspectors were supplied with a plan and a time frame to address the outstanding QA testing by senior hospital management and were assured that this would be progressed and completed as described.

Judgment: Compliant

# Regulation 17: Accidental and unintended exposures and significant events

Inspectors reviewed documentation detailing the system of record keeping and analysis of events involving or potentially involving accidental or unintended medical

exposures. A clear allocation of responsibility at all stages of this process was detailed in the documents reviewed. This process was well articulated to inspectors by staff in the clinical area and inspectors observed staff information posters relating to the process throughout the clinical areas visited on the day of inspection.

Inspectors reviewed accidental and unintended exposures and significant events reported to HIQA by TUH. Inspectors found that both initial notification of the accidental and unintended exposures and significant events and the subsequent investigation reports were not all reported to HIQA within the time frames suggested by the Authority in guidance material. Furthermore, although TUH deemed some accidental and unintended exposures and significant events to be clinically significant, the information supplied to HIQA did not indicate that the referrer, the practitioner and the patient or their representative were informed of the incident in all cases. Finally, full details concerning the corrective measures taken to avoid such events was not present for all investigation reports received. Despite these regulatory issues, further communications with the undertaking and their representatives as well as information gained through the inspection process assured inspectors that these issues did not represent a current safety issue. There is, however, a need to ensure consistent regulatory compliance in the future reporting and investigation of all accidental and unintended exposures and significant events under Regulation 17 and this was brought to the attention of senior hospital management.

Judgment: Substantially 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 19: Recognition of medical physics experts                                   | Substantially<br>Compliant |
| Regulation 20: Responsibilities of medical physics experts                              | Compliant                  |
| Regulation 21: Involvement of medical physics experts in medical radiological practices | Compliant                  |
| Safe Delivery of Medical Exposures  |                            |
| Regulation 8: Justification of medical exposures  | Substantially<br>Compliant |
| Regulation 13: Procedures   | Substantially              |
|   | Compliant                  |
| Regulation 14: Equipment  | Compliant                  |
| Regulation 17: Accidental and unintended exposures and                                  | Substantially              |
| significant events  | Compliant                  |

# Compliance Plan for Tallaght University Hospital OSV-0007409

Inspection ID: MON-0028532

Date of inspection: 04/08/2020

#### **Introduction and instruction**

This document sets out the regulations where it has been assessed that the undertaking is not compliant with the European Union (Basic Safety Standards for Protection against Dangers Arising from Medical Exposure to Ionising Radiation) Regulations 2018 and 2019.

This document is divided into two sections:

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

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

#### A finding of:

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

#### Section 1

The undertaking is required to set out what action they have taken or intend to take to comply with the regulation in order to bring the medical radiological installation back into compliance. The plan should be **SMART** in nature. **Specific** 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 19: Recognition of medical physics experts | Substantially Compliant |

Outline how you are going to come into compliance with Regulation 19: Recognition of medical physics experts:

The Head of Medical Physics and Clinical Engineering at Tallaght University Hospital has put 4 specific measure in place to ensure the Hospitals is compliant with the regulation 19. Items 1 and 2 are in place (as of 12th October 2020).

- 1. The Principal Physicist at TUH (who is the Radiation Protection Adviser (PRA) & Medical Physics Expert (MPE) is agreeable to be contactable 24/7. This is in place from 12th October 2020.
- 2. The Senior Physicist (who is an MPE) and employed by TUH, is currently on a period of leave. Has confirmed to the Hospitals that she is agreeable to provide MPE support in the event that Principal Physicist is not available. This is in place as of 12th October 2020
- 3. A Senior Physicist, recently recruited to TUH, is training to be an MPE. This will provide access to a third MPE in TUH. Training should be completed by end 2021.
- 4. The Head of Medical Physics and Clinical Engineering will develop a pathway (by end November 2020) to make RPA (with MPE) Services to be contracted to TUH at short notice, if these services are required.

The Deputy CEO will monitor compliance with the above plan at the monthly radiology directorate meetings.

| Regulation 8: Justification of medical  | Substantially Compliant |  |  |
|---|-------------------------|--|--|
| exposures   |                         |  |  |
| '   |                         |  |  |
| Outline how you are going to come into compliance with Regulation 8: Justification of |                         |  |  |

medical exposures:

TUH radiographers we will continue with the practice of ticking the examination & initialling the form. This form will be scanned into the patient's record on NIMIS so that the information will be available for 5 years and auditable at any time.

This will be monitored by the Radiography Services Managers to ensure compliance. This will be implemented by 30th October 2020. We will review and audit on a monthly basis.

The Hospitals is waiting on a national solution (technical solution allowing justification to be recorded on NIMIS). The Chairperson of the Voluntary Hospitals Risk Management forum (VHARMF) Radiation Safety Advisory Group have written (on the 7th October 2020) to the Chair of NRPC (Acute Hospitals Operations), seeking assistance on progressing issues related to Regulation 8 at a national level. The Hospitals, through the Office of the deputy CEO, will week an update on the progress by 31st December 2020.

We aim to be fully compliant by 30th January 2021.

The Deputy CEO will monitor the progress with this plan at the monthly directorate meetings.

Regulation 13: Procedures

Substantially Compliant

Outline how you are going to come into compliance with Regulation 13: Procedures: At present the dose is reported in the final report for Nuclear Medicine Studies.

The Hospital (RSM and Deputy CEO) are working with the national NIMIS team to seek an automated solution. The issue has also been escalated to the HSE at a National Level by the end of October 2020 by the Deputy CEO, through the Hospitals group.

The Deputy CEO will keep this issue in constant review (at monthly directorate meetings and at monthly Performance meetings with Dublin Midlands Hospitals Group) and work with NIMIS National team.

The Hospitals will implement the automated solution when available to ensure compliance with HIQA regulations. This will be no later than 30th June 2021.

The Chairperson of the VHARMF Radiation Safety Advisory Group have written to the Chair of NRPC, seeking assistance on progressing issues related to Regulation 13 at a national level.

| Regulation 17: Accidental and        | Substantially Compliant |
|--------------------------------------|-------------------------|
| unintended exposures and significant |                         |
| events                               |                         |
|                                      |                         |

Outline how you are going to come into compliance with Regulation 17: Accidental and unintended exposures and significant events:

TUH duly note the feedback from HIQA, the Hospitals (The Principal Physicist at TUH) will ensure that in future only those incidents that are considered clinically significant are identified as such to HIQA.

A New dedicated Radiation Incident forms will be developed by the end of October 2020 by the Radiology Service manager. This will be submitted for approval to the Director of QSRM at TUH, with sign off by week 19th October 2020. This will ensure all relevant details are provided at the time of incident reporting allowing prompt reporting to the Authority.

The Principal Physicist at TUH will be responsible for reporting incidents to HIQA within the timeline as set out in the regulation. This process is now in place and agreed.

The Principal Physicist at TUH will also be responsible to report on the results of the investigation and corrective measures, this will be reported to HIQA within the timeline as set out in the regulation. This process is now in place and agreed.

The Deputy CEO will ensure this revised incident forms are developed and monitored at monthly directorate meetings. Also the reporting to HIQA will be monitored at the directorate meetings.

All aspects of regulation 17 will be in place by the 30th October 2020. With monthly reviews by deputy CEO

#### Section 2:

#### Regulations to be complied with

The undertaking and designated manager must consider the details and risk rating of the following regulations when completing the compliance plan in section 1. Where a regulation has been risk rated red (high risk) the inspector has set out the date by which the undertaking and designated manager must comply. Where a regulation has been risk rated yellow (low risk) or orange (moderate risk) the undertaking must include a date (DD Month YY) of when they will be compliant.

The undertaking has failed to comply with the following regulation(s).

| Regulation             | Regulatory requirement   | Judgment                   | Risk rating | Date to be complied with |
|------------------------|--|----------------------------|-------------|--------------------------|
| Regulation 8(15)       | An undertaking shall retain records evidencing compliance with this Regulation for a period of five years from the date of the medical exposure, and shall provide such records to the Authority on request. | Not Compliant              | Yellow      | 30/01/2021               |
| 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              | Yellow      | 30/06/2021               |
| Regulation<br>17(1)(d) | An undertaking shall ensure that arrangements are made to inform the referrer and the practitioner, and the patient, or their representative, about clinically significant                                   | Substantially<br>Compliant | Yellow      | 30/10/2020               |

|                  | T                                  | T             | 1                                     | 1          |
|------------------|------------------------------------|---------------|---------------------------------------|------------|
|                  | unintended or accidental           |               |                                       |            |
|                  | exposures and the                  |               |                                       |            |
|                  | results of the                     |               |                                       |            |
|                  | analysis,                          |               |                                       |            |
| Regulation       | An undertaking                     | Substantially | Yellow                                | 30/10/2020 |
| 17(1)(e)         | shall ensure that                  | Compliant     |                                       |            |
|                  | the Authority is                   |               |                                       |            |
|                  | notified, promptly                 |               |                                       |            |
|                  | and as soon as                     |               |                                       |            |
|                  | possible, of the                   |               |                                       |            |
|                  | occurrence of any                  |               |                                       |            |
|                  | significant event,                 |               |                                       |            |
|                  | as defined by the                  |               |                                       |            |
|                  | Authority in                       |               |                                       |            |
|                  | guidelines issued                  |               |                                       |            |
|                  | for that purpose,                  |               |                                       |            |
| <u> </u>         | and                                | 0 1 1         | \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ | 00/40/2022 |
| Regulation       | An undertaking                     | Substantially | Yellow                                | 30/10/2020 |
| 17(1)(f)         | shall ensure that                  | Compliant     |                                       |            |
|                  | the results of the                 |               |                                       |            |
|                  | investigation into any significant |               |                                       |            |
|                  | event notified                     |               |                                       |            |
|                  | under                              |               |                                       |            |
|                  | subparagraph (e)                   |               |                                       |            |
|                  | and the corrective                 |               |                                       |            |
|                  | measures to avoid                  |               |                                       |            |
|                  | such events, are                   |               |                                       |            |
|                  | reported to the                    |               |                                       |            |
|                  | Authority within                   |               |                                       |            |
|                  | the time period                    |               |                                       |            |
|                  | specified for such                 |               |                                       |            |
|                  | events by the                      |               |                                       |            |
|                  | Authority in                       |               |                                       |            |
|                  | guidelines issued                  |               |                                       |            |
|                  | by it for that                     |               |                                       |            |
|                  | purpose.                           |               |                                       |            |
| Regulation 19(9) | An undertaking                     | Substantially | Yellow                                | 30/10/2020 |
|                  | shall put in place                 | Compliant     |                                       |            |
|                  | the necessary                      |               |                                       |            |
|                  | arrangements to ensure the         |               |                                       |            |
|                  |                                    |               |                                       |            |
|                  | continuity of expertise of         |               |                                       |            |
|                  | persons for whom                   |               |                                       |            |
|                  | it is responsible                  |               |                                       |            |
|                  | who have been                      |               |                                       |            |
|                  | recognised as a                    |               |                                       |            |
|                  | Trecognisca as a                   | I .           | L                                     | 1          |

| med | ical physics   |  |  |
|-----|----------------|--|--|
| exp | ert under this |  |  |
| Reg | ulation.       |  |  |