



Health Information and Quality Authority

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

Name of Medical Radiological Installation:	Alliance Medical at Bon Secours Hospital Tralee
Undertaking Name:	Alliance Medical Diagnostic Imaging Ltd
Address of Ionising Radiation Installation:	Bon Secours Hospital, Strand Street, Tralee, Kerry
Type of inspection:	Announced
Date of inspection:	29 September 2021
Medical Radiological Installation Service ID:	OSV-0005993
Fieldwork ID:	MON-0030677

About the medical radiological installation:

Alliance Medical Diagnostic Imaging provide computed tomography (CT) imaging services within the Bon Secours Hospital Tralee. A 128 slice CT machine is employed to provide the service.

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 users⁴ 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
Wednesday 29 September 2021	09:45hrs to 12:50hrs	Noelle Neville	Lead
Wednesday 29 September 2021	09:45hrs to 12:50hrs	Kay Sugrue	Support

Governance and management arrangements for medical exposures

Alliance Medical Diagnostic Imaging Ltd (Alliance Medical) is co-located on the grounds of a private hospital and provides a CT imaging service to this hospital. On the day of inspection, inspectors found that there was effective leadership, governance and management arrangements in place at Alliance Medical with systems and processes detailing a clear allocation of responsibility for the protection of service users. The governance structures of Alliance Medical showed that local oversight for radiation protection was provided by a Radiation Safety Committee (RSC). This committee in turn reported to quality and governance which reported to Alliance Medical senior management. A good example of radiation protection governance arrangements described to inspectors and seen in documents reviewed was the established links between the host hospital and the undertaking. Inspectors were informed that these links helped to provide oversight and greater assurances to both organisations on the radiation protection of service users referred from the host hospital to the Alliance Medical facility.

Of note, inspectors saw the application of learning gained from previous regulatory inspections disseminated across facilities within the Alliance Medical undertaking. This was evident in documentation revision and document development and demonstrated strong organisational commitment and oversight of radiation protection.

From the records reviewed and discussions with staff, inspectors were assured that referrals were only accepted from those entitled to refer service users for medical exposures. In addition, inspectors were assured that medical exposures took place under the clinical responsibility of a practitioner and the practitioner and medical physics expert (MPE) were involved in the optimisation process. MPE involvement in the facility was evident, with the level of involvement in line with the CT services provided at Alliance Medical. There were also contingency arrangements in place for the continuity of MPE expertise should the need arise.

Overall, inspectors were assured of the governance and management arrangements in place at Alliance Medical to oversee radiation protection for service users.

Regulation 4: Referrers

Inspectors were satisfied that referrals reviewed were from referrers as defined in the regulations. Referrers were clearly identifiable in each of the referrals reviewed and professional registration numbers could be checked and verified by staff if needed.

Judgment: Compliant

Regulation 5: Practitioners

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

Judgment: Compliant

Regulation 6: Undertaking

Inspectors were satisfied that the facility had clearly defined the allocation of responsibility for the radiation protection of services users. Documentation provided showed clear lines of communication within corporate and clinical governance structures. The governance structures of Alliance Medical Diagnostic Imaging Ltd showed that local oversight for radiation protection was provided by a Radiation Safety Committee (RSC). This committee in turn reported to quality and governance which reported to Alliance Medical senior management.

Alliance Medical was co-located on the grounds of a private hospital and provided a CT imaging service to this hospital. A good example of radiation protection governance arrangements described to inspectors and seen in documents was the established links between the host hospital and the undertaking. For example, dual governance of radiation protection was facilitated through shared representation on the RSC from both co-located facilities. Inspectors were informed that these links helped to provide oversight and greater assurances to both organisations on the radiation protection of service users referred from the host hospital to the Alliance Medical facility.

Of note, inspectors saw the application of learning gained from previous regulatory inspections disseminated across facilities within the Alliance Medical undertaking. This was evident in documentation revision and development and demonstrated strong organisational commitment and oversight of radiation protection.

Overall, inspectors were assured of the governance and management arrangements in place at Alliance Medical to oversee radiation protection for service users.

Judgment: Compliant

Regulation 10: Responsibilities

Inspectors were satisfied that there were systems and processes in place to ensure that all medical exposures took place under the clinical responsibility of a practitioner. At this facility, radiologists were recognised as practitioners and had clinical responsibility for service users undergoing medical exposures. The radiation safety policy clearly set out the delegation of practical aspects to radiographers, including dose optimisation and pregnancy status enquiry and recording.

Judgment: Compliant

Regulation 19: Recognition of medical physics experts

Inspectors were satisfied that a recognised medical physics expert (MPE) supported this service and arrangements were in place to ensure continuity of MPE expertise. The MPE's up-to-date professional registration certificate was reviewed by inspectors on the day of inspection.

Judgment: Compliant

Regulation 20: Responsibilities of medical physics experts

Inspectors were satisfied that the MPE met the requirements of the regulations. The MPE was involved in quality assurance of medical radiological equipment, patient dosimetry, review and sign off of facility DRLs and advice and dose calculation for radiation incidents. While the MPE was not involved in staff training, inspectors were informed that this was provided centrally by Alliance Medical.

Judgment: Compliant

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

Inspectors were satisfied with the documentation reviewed and information provided by staff, including the MPE, that the undertaking had arrangements in place to ensure that the level of involvement of the MPE was in line with the level of risk posed at this facility providing a CT imaging service.

Judgment: Compliant

Safe Delivery of Medical Exposures

Inspectors reviewed the systems and processes in place to ensure that service users undergoing medical exposures delivered by Alliance Medical were safe. Alliance Medical demonstrated a high level of compliance with the regulations assessed and staff demonstrated strong local ownership and awareness on matters relating to radiation protection. This included evidence of the use of diagnostic reference levels (DRLs), 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 and quality assurance reports were provided to inspectors which showed that an appropriate quality assurance programme was in place and the CT unit was kept under strict surveillance.

Areas of good practice were identified by inspectors including the conduct of clinical audit at the facility including an annual radiation safety audit which assessed areas including legislative compliance, pregnancy status, CT justification and dose audit. Inspectors reviewed a sample of records and spoke with staff and found that justification in advance was conducted by the radiologist and records of same were available for review. 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 the report as required. However, management informed inspectors that a project was underway and due to be completed in the short term to ensure that the requirements of Regulation 13(2) were met.

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 for each month. Of note, inspectors were informed that a quality strategy for 2021 aimed to increase the number of potential incidents reported with a view to reducing the number that become actual patient incidents which was noted as a proactive approach to incident management.

Overall, inspectors were satisfied that Alliance Medical had effective systems and processes in place to ensure that service users undergoing medical exposures were safe.

Regulation 8: Justification of medical exposures

All referrals reviewed by inspectors on the day of inspection were available in writing, stated the reason for the request and were accompanied by sufficient medical data. Staff demonstrated to inspectors that previous diagnostic information from procedures which took place at the hospital was available for review on the hospital's radiology information system.

Information in relation to the benefits and risks associated with radiation was available to service users undergoing medical exposures, on posters in service user

waiting areas and on the Alliance Medical website. Inspectors noted a comprehensive patient information poster with useful dose comparisons and associated risk versus benefit for various CT procedures.

The radiation safety policy clearly set out the process for justification of medical exposures at the facility. Inspectors observed evidence that CT procedures were justified in advance by a radiologist as required by Regulation 8(8) and records of this were available for each medical exposure as required by Regulation 8(15).

Judgment: Compliant

Regulation 11: Diagnostic reference levels

Inspectors were satisfied that diagnostic reference levels (DRLs) were established, reviewed and compared to national DRLs for the CT unit at this facility and the process for same was detailed in the radiation safety policy. Documents reviewed in advance of the inspection indicated that one local facility DRL was slightly above the national DRL. However, inspectors were informed that a review established that this was due to limited data points due to low scan volumes for this procedure type which was confirmed by the MPE. Overall, all other local DRLs were below national DRLs at this facility.

Judgment: Compliant

Regulation 13: Procedures

Written protocols for every type of standard CT procedure were available to staff at this facility both in hard and soft copy. These protocols contribute to providing an assurance that CT procedures are carried out in a consistent and safe manner.

Inspectors were informed that information relating to the medical exposure did not form part of the report as required under Regulation 13(2). However, management informed inspectors that a project was underway and due to be completed in the short term to ensure that the requirements of Regulation 13(2) were met.

Referral guidelines, iRefer, were available to referrers and staff on desktop computers. Notices and access cards were also available with information on how to access electronic iRefer guidelines.

Inspectors found that there was a system of audit in place. A comprehensive radiation safety audit for 2021 was viewed demonstrating that regular audit was undertaken at the facility including legislative compliance, pregnancy status, CT justification and dose audit.

Judgment: Substantially Compliant

Regulation 14: Equipment

Inspectors were provided with an up-to-date inventory of medical radiological equipment and noted that equipment was kept under strict surveillance regarding radiation protection. Documentation reviewed by inspectors showed that appropriate quality assurance programmes, including regular performance testing had been implemented for the CT unit at the facility.

Inspectors were also shown an electronic fault log which was available on the equipment vendor's website. This log enabled easy access to the status of reported faults and ensured that issues were followed up on in a timely and transparent way.

Judgment: Compliant

Regulation 16: Special protection during pregnancy and breastfeeding

Inspectors were satisfied that there was an established process to determine the pregnancy status of service users and this process was documented in the radiation safety policy. Records reviewed showed that radiographers had responsibility for making enquiries as to pregnancy status and these records were uploaded to the radiology information system.

Inspectors observed posters in the service user waiting area, including multilingual posters, with the aim of increasing the awareness of women to whom this regulation applied.

Judgment: Compliant

Regulation 17: Accidental and unintended exposures and significant events

Inspectors reviewed the radiation safety policy which clearly outlined the process for the management of accidental and unintended exposures and significant events. Significant events were reported to HIQA within the required timelines and staff clearly articulated the process for reporting incidents and potential incidents to inspectors.

Incidents and potential incidents were tracked, analysed and categorised for each month. There was evidence of discussion following the tracking and analysis of incidents and potential incidents and recommendations made as a result of same. Of

note, inspectors were informed that a quality strategy for 2021 aimed to increase the number of potential incidents reported with a view to reducing the number of issues that translate to patient incidents which was noted as a proactive approach to incident management.

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 Alliance Medical at Bon Secours Hospital Tralee OSV-0005993

Inspection ID: MON-0030677

Date of inspection: 29/09/2021

Introduction and instruction

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

This document is divided into two sections:

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

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

A finding of:

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

Section 1

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

Compliance plan undertaking response:

Regulation Heading	Judgment
Regulation 13: Procedures	Substantially Compliant
Outline how you are going to come into compliance with Regulation 13: Procedures: : The Qaelum program has been recommended to the Bon Secours Group ,the controllers of the RIS PACS system for CT in the Bon Secours Hospital Tralee, by AMDI. They have stated that they will await feedback from Alliance Medicals experience before deciding on a final service provider to address regulation 13b. Alliance Medical have agreed to provide this feedback at the Radiology Forum in January 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	01/01/2023