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:	Human Body Composition Laboratory
Undertaking Name:	University of Limerick
Address of Ionising Radiation Installation:	PG052c, PESS Building, University of Limerick, Limerick
Type of inspection:	Announced
Date of inspection:	19 July 2021
Medical Radiological Installation Service ID:	OSV-0007171
Fieldwork ID:	MON-0030758

About the medical radiological installation:

University of Limerick established a research-based facility to investigate human body composition in 2008. Whole body and segment body composition analysis is carried out using dual-energy X-ray absorptiometry (DXA) equipment as part of the research carried out at the Human Body Composition Laboratory.

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
Monday 19 July 2021	11:00hrs to 14:30hrs	Kirsten O'Brien	Lead
Monday 19 July 2021	11:00hrs to 14:30hrs	Kay Sugrue	Support

Governance and management arrangements for medical exposures

This on-site inspection was prompted following the review of a self-assessment questionnaire submitted to HIQA by the University of Limerick Human Body Composition Laboratory and subsequent lack of assurance provided by the undertaking to demonstrate that appropriate actions had been taken to come into compliance in an undertaking assurance report returned to HIQA in June 2021.

The University of Limerick is overseen by a governing authority that has overall responsibility for the affairs of the university. The Radiation Safety Plan outlines management, governance and oversight arrangements at the University of Limerick. The President of the University reports directly to the governing authority and is the chair of the Executive Committee of the University. The terms of reference of the Executive Committee outline a number of functions, for example, to provide advice to the President on matters of strategic and operational significance.

A medical physics expert (MPE) was found to act or give specialist advice at the Human Body Composition Laboratory. Inspectors reviewed records and found that the MPE evaluated the dose delivered to volunteers undergoing medical exposures as part of medical or biomedical research and contributed to optimisation, including the use of diagnostic reference levels. The MPE attended the annual Radiation Safety Committee (RSC) meeting and gave advice on medical radiological equipment at the university.

The University of Limerick has a RSC to advise on radiation safety policy which the heads of departments are responsible for implementing. The head of department appoints a departmental radiological protection supervisor for each area that uses ionising radiation. However, inspectors found that the University of Limerick had not ensured that the allocation of responsibilities for the radiation protection of volunteers in medical or biomedical research from medical exposures to ionising radiation was aligned to the regulations. For example, a referrer or a practitioner was not involved in the justification of individual medical exposures. Similarly, a practitioner was not involved in all aspects of the optimisation process for DXA procedures at the Human Body Composition Laboratory. Furthermore, persons not entitled to carry out the practical aspects of medical radiological procedures had been delegated this role at the Human Body Composition Laboratory. From a review of DXA procedures carried out, inspectors found that individuals not entitled to conduct medical exposures had carried out medical radiological procedures.

Following this inspection the undertaking was required to submit an urgent compliance plan to address urgent risks relating to the governance and management arrangements for medical exposures. The undertaking's response did provide assurance that the risks identified on the day were adequately addressed.

Regulation 4: Referrers

Inspectors reviewed a sample of medical exposures that had been performed at the Human Body Composition Laboratory and spoke to staff who had conducted the medical exposures. From the information obtained by inspectors on the day of inspection, medical radiological procedures were found to have been carried out in the absence of a referral from a person entitled to refer as per the regulations.

Under this regulation the undertaking was required to submit an urgent compliance plan to address an urgent risk. The undertaking's response did provide assurance that the risk was adequately addressed.

Judgment: Not Compliant

Regulation 5: Practitioners

On the day of inspection, following a review of records, documentation and speaking with staff at the university, inspectors found that clinical responsibility for individual medical exposures had not been allocated to a person entitled to act as a practitioner as per the regulations. Clinical responsibility for volunteers in medical or biomedical research undergoing medical exposure must only be taken by a person entitled to act as a practitioner and includes referral, justification, optimisation, the practical conduct of the exposure and evaluation of the outcome.

Under this regulation the undertaking was required to submit an urgent compliance plan to address an urgent risk. The undertaking's response did provide assurance that the risk was adequately addressed.

Judgment: Not Compliant

Regulation 6: Undertaking

Inspectors reviewed documentation provided in advance and on the day of inspection and spoke with the designated manager and other members of staff at the university. The University of Limerick is overseen by a Governing Authority that has overall responsibility for the affairs of the university. The President of the University reports directly to the Governing Authority and is the chair of the Executive Committee of the University. The Executive Committee terms of reference outline a number of functions, for example, to provide advice to the President on matters of strategic and operational significance. The Chief Operating Officer is the undertaking representative for the University of Limerick and is also a member of

the executive committee.

The University of Limerick has a RSC to advise on radiation safety policy which the heads of departments are responsible for implementing. The head of department appoints a departmental radiological protection supervisor for each area that uses ionising radiation. The designated manager is the departmental radiological protection supervisor for the Human Body Composition Laboratory who is a member of the RSC.

The Radiation Safety Plan outlines management, governance and oversight arrangements at the University of Limerick and provides overarching information on individuals that may use medical radiological equipment for medical or research exposures. However, from a review of local documentation relating specifically to the Human Body Composition Laboratory Body, in particular, the Standard Operating Procedure for PESS Department, inspectors found that the University of Limerick had allocated responsibility for the radiation protection to persons not recognised in the regulations to act in that regard. In particular, the university had delegated the practical aspects of medical exposures to persons not recognised in the regulations. Similarly, a referrer or practitioner was not involved in the justification of individual medical exposures.

Notwithstanding that inspectors were informed that a practitioner was initially involved conducting a risk assessment of doses for DXA procedures for consideration by an ethics committee, inspectors were not satisfied that a practitioner had been clearly allocated responsibility for optimisation of medical exposures at the Human Body Composition Laboratory and consequently was not involved in the optimisation process as required.

In order to achieve compliance with this regulation, the University of Limerick must clearly allocate all aspects of radiation protection for volunteers undergoing medical exposure to ionising radiation as part of medial or biomedical research to appropriately recognised individuals as per the regulations.

Under this regulation the undertaking was required to submit an urgent compliance plan to address an urgent risk. The undertaking's response did provide assurance that the risk was adequately addressed.

Judgment: Not Compliant

Regulation 10: Responsibilities

Records, documentation and policies relating to medical exposures of volunteers in medical or biomedical research at University of Limerick were reviewed by inspectors. Additionally, inspectors spoke with staff, including management at the Human Body Composition Laboratory and persons who carried out the DXA procedures. On the day of inspection, University of Limerick had not ensured that all medical exposures took place under the clinical responsibility of a practitioner. The

university should ensure that systems are put in place to ensure that clinical responsibility for medical exposures is allocated to an appropriate person entitled to act as practitioner as required by the regulations. Clinical responsibility for service users undergoing medical exposure includes referral, justification, optimisation, the practical conduct of the exposure and evaluation of the outcome.

Over the course of the inspection, inspectors found that the justification process of individual medical exposures did not involve a referrer or a practitioner. Inspectors also reviewed documentation which outlined the individuals that were delegated the practical aspects of the DXA procedures at the Human Body Composition Laboratory. Inspectors also reviewed records of previous DXA procedures and spoke with the staff who had performed these procedures at the university. Inspectors found that University of Limerick had delegated the practical aspects to persons that were not entitled to carry out the practical aspects of a medical radiological procedure. Management at the Human Body Composition Laboratory had identified this as part of a self-assessment questionnaire issued by HIQA which was submitted in October 2019. Further assurance was not provided by the undertaking to demonstrate that appropriate actions had been taken to come into compliance in an undertaking assurance report returned to HIQA in June 2021 prompting this on-site inspection. Inspectors found that the status of non-compliance with respect of Regulation 10(4) had remained unchanged from 2019 and this was acknowledged by management at the Human Body Composition Laboratory on the day of inspection.

Additionally, while inspectors found that while an MPE was involved in the optimisation process, University of Limerick had not ensured that a practitioner and or a person entitled to carry out the practical aspects of the medical radiological procedures were involved in the optimisation process as required by the regulations. Inspectors were informed that a practitioner was initially involved in the conduct of a risk assessment of doses for DXA procedures for consideration by an ethics committee. A practitioner should take clinical responsibility for each medical exposure including involvement in the optimisation process to ensure that each volunteer in medical and biomedical research receives a dose that is as low as reasonably achievable. For example, a practitioner should be involved in an on-going basis in the assessment and evaluation of the radiation doses received by volunteers in medical or biomedical research at the Human Body Composition Laboratory to ensure the optimisation of protection and safety is appropriate. This should also include overall responsibility for the practical aspects including ensuring the consistent production of adequate diagnostic information through evaluation of the outcome of the DXA procedure.

Under this regulation the undertaking was required to submit an urgent compliance plan to address an urgent risk. The undertaking's response did provide assurance that the risk was adequately addressed.

Judgment: Not Compliant

Regulation 19: Recognition of medical physics experts

Inspectors were satisfied that University of Limerick had appropriate arrangements in place to insure the continuity of medical physics expertise at the Human Body Composition Laboratory.

Judgment: Compliant

Regulation 20: Responsibilities of medical physics experts

On the day of inspection, an MPE was found to act or give specialist advise at the Human Body Composition Laboratory. Inspectors reviewed records and found that the MPE carried out quality assurance (QA) testing which included the evaluation of the doses delivered to volunteers undergoing medical exposures as part of medical or biomedical research and contributed to optimisation, including the establishment of diagnostic reference levels. The MPE also attended the annual RSC meeting and gave advice on medical radiological equipment at the university.

Judgment: Compliant

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

On the day of inspection an MPE was involved as appropriate for consultation and advice on matters relating to radiation protection concerning medical exposure.

Judgment: Compliant

Safe Delivery of Medical Exposures

Inspectors viewed a sample of DXA procedures conducted at the Human Body Composition Laboratory and requested the written referrals for these procedures. Inspectors were informed that volunteers in medical and biomedical research undergoing medical exposures were not referred by a referrer in writing to a practitioner. Additionally, individual medical exposures carried out at the Human Body Composition Laboratory were not justified in advance, taking into account the specific objectives of the exposures and the characteristics of the individual involved by a practitioner.

While inspectors were satisfied that the dose constraints used as part of the proposal for medical or biomedical research were largely consistent with the dose constraints established by HIQA as per Regulation 12(1), the University of Limerick should review their documentation to ensure that all policies, procedures and guidelines reflect up-to-date published guidance as required by the regulations. Similarly, the written protocols for DXA procedures conducted at the Human Body Composition Laboratory should also be updated to ensure that they also are consistent with the regulations.

The University of Limerick had an appropriate system in place to record any accidental or unintended exposures or significant events at the Human Body Composition Laboratory. Additionally, inspectors were satisfied that an appropriate QA programme had been implemented and maintained at the Human Body Composition Laboratory. However, inspectors noted that annual QA performed by an MPE is currently overdue and the university should ensure that measures are in place to ensure that QA is carried out within appropriate time frames.

Following this inspection the undertaking was required to submit an urgent compliance plan to address urgent risks relating to the safe delivery of medical exposures to ionising radiation. The undertaking's response did provide assurance that the risks identified on the day were adequately addressed.

Regulation 8: Justification of medical exposures

Inspectors spoke with staff, including management at the Human Body Composition Laboratory and persons who carried out the DXA procedures on the day of inspection. Additionally, inspectors reviewed records, documentation and policies relating to medical exposures of volunteers in medical or biomedical research at University of Limerick.

Inspectors viewed a sample of DXA procedures conducted at the Human Body Composition Laboratory and requested the written referrals for these procedures. However, written referrals for these medical exposures were not available and inspectors were informed that volunteers participating in medical and biomedical research were not referred by a referrer in writing to the individual performing the medical exposure. Additionally, individual medical exposures carried out at the Human Body Composition Laboratory were not justified in advance, taking into account the specific objectives of the exposures and the characteristics of the individual involved by a practitioner.

Under this regulation the undertaking was required to submit an urgent compliance plan to address an urgent risk. The undertaking's response did provide assurance that the risk was adequately addressed.

Judgment: Not Compliant

Regulation 12: Dose constraints for medical exposures

Inspectors reviewed documentation relating to the use of relevant dose constraints in the optimisation of protection and safety for persons subject to medical exposure as part of medical or biomedical research. While inspectors were satisfied that the dose constraints used as part of proposals for medical or biomedical research were largely consistent with the dose constraints established by HIQA as per Regulation 12(1), the University of Limerick should review their documentation to ensure that it reflects up-to-date published guidance as required by the regulations.

Judgment: Substantially Compliant

Regulation 13: Procedures

Inspectors reviewed documentation, including the Standard Operating Procedure for PESS Department, and spoke with staff at the Human Body Composition Laboratory and found that while written protocols were available, these did not fully align with the regulations. For example, the appendices of this document should be updated to ensure that they reflect who is entitled to carry out the practical aspects of DXA procedures at the university.

Following a review of a sample of DXA procedures, inspectors found that information relating to exposure was included on the report of the medical radiological procedure.

Judgment: Substantially Compliant

Regulation 14: Equipment

Following a review of documentation submitted to HIQA, inspectors were satisfied that an appropriate QA programme had been implemented and maintained at the Human Body Composition Laboratory. Routine performance testing was carried out daily before use as per manufacturer requirements and regular servicing for preventative and maintenance purposes was conducted by the manufacturer.

An MPE was found to perform QA which included an assessment of dose. However, from communicating with individuals on the day of inspection and reviewing QA records, inspectors noted that MPE QA had not been completed this year to date and was now overdue. The university should ensure that measures are in place to ensure that QA is carried out annually within the time frames as required.

Judgment: Substantially Compliant

Regulation 17: Accidental and unintended exposures and significant events

University of Limerick had an appropriate system in place to record any accidental or unintended exposures or significant events at the Human Body Composition Laboratory. Inspectors reviewed documentation, including the Radiation Safety Plan, and spoke with staff who communicated the process for reporting any incidents that may occur at the university, both internally through normal health & safety procedures to the Safety Officer and externally to HIQA as required. Any incidents that may occur are also discussed as part of the standing agenda at the RSC.

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	Not Compliant
Regulation 5: Practitioners	Not Compliant
Regulation 6: Undertaking	Not Compliant
Regulation 10: Responsibilities	Not 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	Not Compliant
Regulation 12: Dose constraints for medical exposures	Substantially Compliant
Regulation 13: Procedures	Substantially Compliant
Regulation 14: Equipment	Substantially Compliant
Regulation 17: Accidental and unintended exposures and significant events	Compliant

Compliance Plan for Human Body Composition Laboratory OSV-0007171

Inspection ID: MON-0030758

Date of inspection: 19/07/2021

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 4: Referrers	Not Compliant
Outline how you are going to come into compliance with Regulation 4: Referrers: S: A XXX Consultant Radiologist will act as Referrer. If unavailable, the Professor of Radiology at UL will dovetail in their absence. M: The Referrer (as defined in S above) will provide a request for the Medical Exposure to Ionising Radiation for each subject participant in writing. The format of the request will be by electronic medium with digital signature. Requests will be archived in electronic format to monitor progress and subsequent audit. A: Consultant Radiologists have had oversight of the Medical Exposure to Ionising Radiation conducted at the Human Body Composition Laboratory since its inception in 2008. Consultant Radiologist as defined in S and M above have consented to act as stated in S and M above. R: As per M above, this is realistic and achievable with immediate effect. T: As per S,M,A,R above, with immediate effect.	
Regulation 5: Practitioners	Not Compliant
Outline how you are going to come into compliance with Regulation 5: Practitioners: S: A XXX Consultant Radiologist will act as Practitioner. If unavailable, the Professor of Radiology at UL will dovetail in their absence. M: The Practitioner (as defined in S above) will take clinical responsibility for the Medical Exposure to Ionising Radiation for each subject participant and confirm this in writing. The format of the request will be by electronic medium with digital signature. Requests will be archived in electronic format to monitor progress and subsequent audit. A: Consultant Radiologists have had oversight of the Medical Exposure to Ionising Radiation conducted at the Human Body Composition Laboratory since its inception in 2008. Consultant Radiologist as defined in S and M above have consented to act as	

stated in S and M above.
R: As per M above, this is realistic and achievable with immediate effect.
T: As per S,M,A,R above, with immediate effect.

Regulation 6: Undertaking	Not Compliant

Outline how you are going to come into compliance with Regulation 6: Undertaking:
S: Research using Medical Exposure to Ionising Radiation to determine a participant's body composition will continue to be justified by approval by the University's Research Ethics Committee. Following approval, the pathway for authorisation of the use of Medical Exposure to Ionising Radiation will proceed from the Referrer and Practitioner (as defined in response to Regulation 4 and 5 above) to a Radiographer to undertake the practical aspects. The Radiographer will be one/or more of the panel of radiographers employed at the XXX Radiology Department, or specialist registrars from the Radiology Department seeking professional development through the conduct of research in human body composition.
M: As per the response to Regulation 4 and 5 above, the scan will be requested by the Practitoner. The request will be by electronic medium with digital signature. Requests will be archived in electronic format to monitor progress and subsequent audit. Individual participant's Medical Exposure to Ionising Radiation will be recorded, archived in electronic format, and provide adequate information of the outcome for review. As noted in the report, quantification of participant's Medical Exposure to Ionising Radiation is recorded and summative exposure reviewed by the Radiographer, Radiologist (Practitioner) and Medical Physics Expert (MPE).
A: As defined in S and M above this is achievable within the staffing resources available to XXX/UL.
R: As per S,M and A above, this is realistic and achievable.
T: As per S,M,A,R above, can be enacted upon the recruitment/assignment of the radiographer.

Regulation 10: Responsibilities	Not Compliant

Outline how you are going to come into compliance with Regulation 10: Responsibilities:
S: The responsibilities for research using Medical Exposure to Ionising Radiation to determine a participant's body composition directed by a Referrer and Practitioner and undertaken by a Radiographer as per response to Regulation 4, 5, and 6 above.
M: As per the response to Regulation 4, 5 and 6 above, the responsibilities recorded and archived in electronic format, for subsequent review and audit.
A: As defined in S and M above this is achievable within the staffing resources available

to XXX/UL.
R: As per S,M and A above, this is realistic and achievable.
T: As per S,M,A,R above, can be enacted upon the recruitment/assignment of the radiographer.

Regulation 8: Justification of medical exposures	Not Compliant

Outline how you are going to come into compliance with Regulation 8: Justification of medical exposures:
S: Research using Medical Exposure to Ionising Radiation to determine a participant's body composition will continue to be justified by approval by the University's Research Ethics Committee. Application to Research Ethics includes a quantified radiation dose and risk assessment of that dose as a Medical Exposure to Ionising Radiation to an individual participant. As declared in response to Regulation 4 and 5 above, following approval, the pathway for authorisation of the use of Medical Exposure to Ionising Radiation will proceed from the Referrer and Practitioner to a Radiographer to undertake the practical aspects.
M: As per the response to S and to Regulation 4, 5 and 6 above this is manageable within the current expertise of the XXX/UL/MPE personnel.
A: As defined in S and M above this is achievable within the staffing resources available to XXX/UL.
R: As per S,M and A above, this is realistic and achievable.
T: As per S,M,A,R above, with immediate effect.

Regulation 12: Dose constraints for medical exposures	Substantially Compliant

Outline how you are going to come into compliance with Regulation 12: Dose constraints for medical exposures:
S: The current documentation that defines the dose constraints to refer the up-to-date published guidance.

M: Manageable without recourse to further expert guidance

A: As defined in S and M above this is achievable within the staffing resources available to XXX/UL/MPE.

R: As per S,M and A above, this is realistic and achievable.

T: As per S,M,A,R above, with immediate effect.

Regulation 13: Procedures	Substantially Compliant

Outline how you are going to come into compliance with Regulation 13: Procedures:
S: The current SOP documentation reviewed to align with the regulations. This will include an update of the appendices to record entitlement to carry out the practical aspects of Medical Exposure to Ionising Radiation at the ULBC laboratory.

M: Manageable without recourse to further expert guidance

A: As defined in S and M above this is achievable within the staffing resources available to XXX/UL/MPE.

R: As per S,M and A above, this is realistic and achievable.
T: As per S,M,A,R above, and as the personnel recruited/appointed to carry out the practical aspects of Medical Exposure to Ionising Radiation at the ULBC laboratory are known.

Regulation 14: Equipment	Substantially Compliant

Outline how you are going to come into compliance with Regulation 14: Equipment:
S: MPE QA not completed by date of inspection because of Covid-19 restrictions. The annual date of inspection is, normally, between March to May, deferred to September 15th for 2021 and communicated to the Inspectors on the day of inspection, i.e. July 19th 2021.

M: As per S above, manageable without recourse to further action.

A: As defined in S and M above this is achievable without recourse to further action.

R: As per S,M and A above, this is realistic and achievable.
T: As per S,M,A,R above on 15th September 2021.

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 4(2)	A person shall not carry out a medical radiological procedure on the basis of a referral from a person other than a referrer.	Not Compliant	Red	20/08/2021
Regulation 5(a)	A person shall not take clinical responsibility for an individual medical exposure unless the person taking such responsibility ("the practitioner") is a registered dentist within the meaning of the Dentists Act 1985 (No. 9 of 1985),	Not Compliant	Red	20/08/2021
Regulation 5(b)	A person shall not take clinical responsibility for an individual medical exposure unless the person taking such responsibility ("the practitioner") is a registered medical practitioner within	Not Compliant	Red	20/08/2021

	the meaning of the Medical Practitioners Act 2007 (No. 25 of 2007), or			
Regulation 5(c)	A person shall not take clinical responsibility for an individual medical exposure unless the person taking such responsibility ("the practitioner") is a person whose name is entered in the register established and maintained by the Radiographers Registration Board pursuant to section 36 of the Health and Social Care Professionals Act 2005 (No. 27 of 2005).	Not Compliant	Red	20/08/2021
Regulation 6(3)	An undertaking shall provide for a clear allocation of responsibilities for the protection of patients, asymptomatic individuals, carers and comforters, and volunteers in medical or biomedical research from medical exposure to ionising radiation, and shall provide evidence of such allocation to the Authority on request, in such form and manner as may be	Not Compliant	Red	20/08/2021

	prescribed by the Authority from time to time.			
Regulation 8(8)	An undertaking shall ensure that all individual medical exposures carried out on its behalf are justified in advance, taking into account the specific objectives of the exposure and the characteristics of the individual involved.	Not Compliant	Red	20/08/2021
Regulation 8(10)(a)	A referrer shall not refer an individual to a practitioner for a medical radiological procedure unless the referral is in writing,	Not Compliant	Red	20/08/2021
Regulation 8(10)(b)	A referrer shall not refer an individual to a practitioner for a medical radiological procedure unless the referral states the reason for requesting the particular procedure, and	Not Compliant	Red	20/08/2021
Regulation 8(10)(c)	A referrer shall not refer an individual to a practitioner for a medical radiological procedure unless the referral is accompanied by sufficient medical data to enable the practitioner to carry out a justification	Not Compliant	Red	20/08/2021

	assessment in accordance with paragraph (1).			
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	Red	20/08/2021
Regulation 10(1)	An undertaking shall ensure that all medical exposures take place under the clinical responsibility of a practitioner.	Not Compliant	Red	20/08/2021
Regulation 10(2)(a)	An undertaking shall ensure that the optimisation process for all medical exposures involves the practitioner,	Not Compliant	Red	20/08/2021
Regulation 10(2)(c)	An undertaking shall ensure that the optimisation process for all medical exposures involves those entitled to carry out practical aspects of medical radiological procedures as specified by the undertaking or practitioner under paragraph (4).	Not Compliant	Red	20/08/2021
Regulation 10(3)(a)	An undertaking shall ensure that the justification	Not Compliant	Red	20/08/2021

	process of individual medical exposures involves the practitioner, and			
Regulation 10(3)(b)	An undertaking shall ensure that the justification process of individual medical exposures involves the referrer.	Not Compliant	Red	20/08/2021
Regulation 10(4)(a)	Practical aspects of a medical radiological procedure may be delegated by the undertaking, as appropriate, to one or more individuals, (i) registered by the Dental Council, (ii) registered by the Medical Council, (iii) registered by the Nursing and Midwifery Board of Ireland, (iv) whose name is entered in the register established and maintained by the Radiographers Registration Board pursuant to section 36 of the Health and Social Care Professionals Act 2005, or (v) recognised by the Minister under Regulation 19, as appropriate, provided that such person has completed training	Not Compliant	Red	20/08/2021

	in radiation safety prescribed or approved pursuant to Regulation 22(3) by the appropriate body.			
Regulation 10(6)	An undertaking or practitioner shall not delegate practical aspects of a medical radiological procedure to a person other than an individual referred to in paragraph (4).	Not Compliant	Red	20/08/2021
Regulation 10(7)	A person shall not carry out practical aspects of a medical radiological procedure unless he or she is a practitioner or a person delegated pursuant to paragraph (4).	Not Compliant	Red	20/08/2021
Regulation 12(5)	An undertaking shall ensure that relevant dose constraints established under paragraph (1), as specified or approved by an ethics committee on a case by case basis as part of a proposal for medical or biomedical research, are used in the optimisation of protection and safety for persons subject to medical exposure as part of medical or	Substantially Compliant	Yellow	20/08/2021

	biomedical research.			
Regulation 13(1)	An undertaking shall ensure that written protocols for every type of standard medical radiological procedure are established for each type of equipment for relevant categories of patients.	Substantially Compliant	Yellow	20/08/2021
Regulation 14(1)	An undertaking shall ensure that all medical radiological equipment in use by it is kept under strict surveillance regarding radiation protection.	Substantially Compliant	Yellow	20/08/2021