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:	BreastCheck Group - Eccles Unit
Undertaking Name:	Health Service Executive
Address of Ionising Radiation Installation:	36 Eccles Street, Dublin 7
Type of inspection:	Announced
Date of inspection:	29 October 2025
Medical Radiological Installation Service ID:	OSV-0007346
Fieldwork ID:	MON-0044726

About the medical radiological installation (the following information was provided by the undertaking):

BreastCheck, the National Breast Screening Programme, was established regionally in 1998 and became a national service in 2007. The service has performed 2.6 million mammograms and detected over 18,000 cancers. BreastCheck Eccles Unit is one of four regional static units – with 3 others: 1 in Merrion, Dublin, 1 in Cork and 1 in Galway. The four static units provide screening, assessment/radiology clinics, result clinics, multidisciplinary meetings and nursing review clinics. Additionally, the service operates 24 mobile units which move between 54 locations across the country. The length of time the service operates at a mobile location is dependent on the size of the population required to be screened at that location.

The primary aim of the screening programme is to reduce the number of deaths from breast cancer in Ireland within the eligible population. Screening is provided to women aged 50 to 69 years, who have no symptoms of breast cancer. Through the provision of regular screening mammograms and subsequent assessment and treatment where required, BreastCheck works to reduce mortality by detecting breast cancer at the earliest stage, when a woman has more treatment options available, and treatment is likely to be less extensive and more successful.

In May 2024, BreastCheck launched a new clinical information management system, called AIRE, which acts as a primary call/recall register as well as an electronic screening record.

BreastCheck employs all staff involved in the breast cancer screening, diagnosis and initial treatment pathway, as follows: Radiographers, Radiologists, HCAs ,Nurses, Pathologists, Medical Scientists, Surgeons, Anaesthetists, Physics, Registrars, Administration, Scheduling, Secretaries, Programme Management, Quality Assurance.

Women who participate in BreastCheck will receive low doses of radiation per mammogram and this information is recorded on AIRE. The established quality assurance systems aim to optimise image quality and cancer detection, while maintaining client radiation dose as low as possible consistent with this.

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, as amended. 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] 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.

1. Governance and management arrangements for medical exposures:

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 October 2025	10:00hrs to 15:30hrs	Lee O'Hora	Lead
Wednesday 29 October 2025	10:00hrs to 15:30hrs	Agnella Craig	Support

Governance and management arrangements for medical exposures

As part of this inspection, inspectors reviewed documentation and visited the mammography screening department and spoke with staff and management. On this inspection, inspectors found effective governance, leadership and management arrangements which provided the necessary oversight for the protection of service users undergoing medical exposures.

BreastCheck Group – Eccles Unit operated as part of the National Screening Service (NSS) and the Health Service Executive (HSE) was the undertaking with overall responsibility for the radiation protection of service users. Local responsibility for the radiation protection of service users lay with the local Clinical Director who communicated upwards via multiple pathways to the HSE as required.

BreastCheck Group – Eccles Unit used a Radiation Safety Committee (RSC) and a Quality Assurance (QA) Imaging Group within the governance structure to ensure that radiation safety related issues could be considered and escalated appropriately.

Following a review of documents and records, and speaking with staff, inspectors were assured that systems and processes were in place to ensure that referrals were only accepted from those entitled to refer an individual for medical radiological procedures. Similarly, inspectors were satisfied that clinical responsibility for medical exposures was only taken by personnel entitled to act as practitioners as per the regulations. However, some work was required to improve the documentation of the clear allocation of responsibility for the radiation protection of service users.

The inspectors reviewed documentation and spoke with medical physics staff and management regarding medical physics expert (MPE) involvement in the safe delivery of medical exposures. From the documentation reviewed and following staff communication, the inspectors were assured that MPEs took responsibility for dosimetry, gave advice on medical radiological equipment and contributed to all aspects of the service required by the regulations.

Overall, notwithstanding the area for improvement in relation to update the documented allocation of responsibility, inspectors were assured that the undertaking had systems in place to ensure appropriate governance and oversight of the delivery of medical exposures at BreastCheck Group – Eccles Unit.

Regulation 4: Referrers

Inspectors were informed that BreastCheck has a legislative remit to acquire its population register information under the Health (Provision of Information) Act, 1997 and that people meeting certain criteria were issued a letter of invitation to

partake in the screening programme. From discussions with staff, the inspectors were satisfied that this letter met the requirements of a referral for medical exposure. Each letter was from the Clinical Director and satisfied the requirements of Regulation 4.

Judgment: Compliant

Regulation 5: Practitioners

Inspectors were informed that BreastCheck Group - Eccles Unit considered radiographers and radiologists as practitioners. Inspectors reviewed a sample of referrals and records of clinical evaluation of the outcome for a range of medical radiological procedures on the day of inspection and were satisfied that only appropriately qualified individuals were considered practitioners by BreastCheck Group - Eccles Unit.

Judgment: Compliant

Regulation 6: Undertaking

The HSE was identified to inspectors as the undertaking and the Clinical Director was the individual responsible for the radiation protection of service users at BreastCheck Group - Eccles Unit. Inspectors were informed that the BreastCheck Group reported via the NSS Chief Executive Officer (CEO) to the Chief Clinical Officer (CCO) of the HSE. BreastCheck Group - Eccles Unit was one of four services overseen by the BreastCheck Group, each service established as a BreastCheck Group Unit with associated BreastCheck Mobile Units. The Clinical Director of each service took clinical responsibility for the implementation of radiation protection procedures locally.

Inspectors noted that the BreastCheck Group used a RSC with responsibility for recommending radiation protection measures within the NSS to comply with all statutory requirements for all facilities where radiation is used. The RSC was chaired by the Lead Clinical Director and met twice yearly at six month intervals.

Inspectors also noted that the BreastCheck Group used a BreastCheck QA Imaging Group which was a subgroup of BreastCheck's QA Committee. Inspectors were informed that this QA Imaging Group monitored technical image quality for the screening and assessment processes, particularly performance, physics quality assurance, equipment management, fault reporting and review of adverse incidents. This group met quarterly, was chaired by the Radiography Services Manager (RSM) and reported to the BreastCheck QA Committee.

While inspectors were assured that governance arrangements and communication pathways were well established, articulated and documented, some work was required to improve the documentation of the clear allocation of responsibility; namely the referral process, who were considered practitioners, the practitioner's record of justification and the documentation of responsibility and associated processes used by BreastCheck Group - Eccles Unit to ensure that clinical audits are carried out in accordance with national procedures established by HIQA. These areas noted for improvement and clarity in documentation are discussed further under Regulation 8 and 13(4).

Notwithstanding the above, inspectors were satisfied that effective governance, leadership and management arrangements for the protection of service users undergoing medical exposures were in place.

Judgment: Substantially Compliant

Regulation 19: Recognition of medical physics experts

The mechanisms in place to provide continuity of medical physics expertise were described to inspectors by staff and management. All evidence supplied satisfied inspectors that the undertaking had the necessary arrangements in place to ensure continuity of MPE expertise at BreastCheck Group - Eccles Unit.

Judgment: Compliant

Regulation 20: Responsibilities of medical physics experts

The professional registration certificates from the Irish College of Physicists in Medicine for the medical physicists were reviewed by inspectors and were up-to-date.

From reviewing the documentation and speaking with staff at the facility, inspectors were satisfied that arrangements were in place to ensure that MPEs took responsibility for dosimetry, gave advice on radiological equipment and contributed to the application and use of diagnostic reference levels (DRLs), the definition of QA programmes, the delivery of radiology equipment acceptance testing, the analysis of accidental or unintended exposures and the training of practitioners. Inspectors were assured that the involvement and contribution of MPEs at BreastCheck Group - Eccles Unit was in line with the requirements of Regulation 20.

Judgment: Compliant

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

From speaking with the relevant staff members and following a radiation safety document review, inspectors established that the involvement of the MPE was both appropriate for the service and commensurate with the risk associated with the service provided at BreastCheck Group - Eccles Unit.

Judgment: Compliant

Safe Delivery of Medical Exposures

Inspectors reviewed the systems and processes in place to ensure the safety of service users undergoing medical exposures at this service and many areas of good practice were noted.

However, an area of improvement noted by inspectors related to Regulation 13(4), namely some work was required to ensure that clinical audits were carried out in accordance with HIQA's national procedures. Similarly, although inspectors were assured that all procedures were justified in advance by a practitioner, further work was required to ensure that the record of justification satisfied the requirements of Regulation 8.

Inspectors were satisfied that DRLs were established, used and reviewed and BreastCheck's approach to the systematic review of service user dose and utilisation of DRLs was considered an area of good practice by the inspectors.

The undertaking had developed a bespoke method to ensure that information relating to patient exposure consistently formed part of the medical radiological procedure report and records reviewed demonstrated a comprehensive approach to the investigation and mitigation of risk from accidental and unintended exposures and significant events.

Records of multidisciplinary acceptance and performance testing for all radiological equipment at the facility satisfied the inspectors that the undertaking had implemented and maintained a robust QA programme.

Overall, inspectors were assured that BreastCheck Group – Eccles Unit had a commitment to patient dose optimisation and ensured appropriate systems were in place to support the consistent, safe delivery of medical exposures.

Regulation 8: Justification of medical exposures

Inspectors spoke with staff and reviewed a sample of referral records on the day of inspection. BreastCheck used a bespoke radiology information system (RIS) which used three main pages to input and retain service user X-ray information, namely a check in page, a radiographer's page and a final screening reading data sheet.

Inspectors were informed that the record of justification was found on the check in page and this page was used as the formal record of justification in advance at the time of inspection. However, in some cases reviewed, this record of justification was completed by a non-practitioner staff member. While inspectors were assured that all medical exposures were individually reviewed by a practitioner using the radiographer's page, inspectors noted that the formal process for recording justification by a practitioner needed to be clearly documented to ensure that such records are attributable to a practitioner.

Judgment: Substantially Compliant

Regulation 9: Optimisation

Over the course of the inspection, inspectors were assured that the BreastCheck Group operated a rigorous QA programme, and were informed that this programme was externally accredited by the European Reference Organisation for Quality Assured Breast Screening and Diagnostic Services in March 2025.

The extensive QA programme included all radiology equipment and also focused special attention on image review monitors. The radiology equipment QA programme is discussed further under Regulation 14. All screening images were noted to be double-read, meaning that they were reviewed by 2 consultant specialist radiologists who agreed on the outcome.

Inspectors were also informed that the BreastCheck Group employed four QA radiographers established at the clinical specialist level. Inspectors were informed that all QA radiographers played an important role in the QA Imaging Group and acted as an extra layer of assurance maintaining patient dose optimisation through the monitoring of technical image quality, equipment performance and QA, fault reporting and review of adverse incidents. Bespoke dose management software helped BreastCheck to systematically analyse and optimise service user radiation dose as discussed under Regulation 11. All of these individual measures were considered areas of good practice, strengthening service user dose optimisation at BreastCheck Group – Eccles Unit.

Staff who spoke to inspectors on the day demonstrated a commitment to ongoing education and training in the area of radiation protection, legal requirements and optimisation of service user dose. Similarly, records reviewed and staff communication satisfied the inspectors that the undertaking facilitated and supported this commitment via access to various educational platforms including

HSEland and Moodle. Many training resources were developed in-house by medical physics staff. This was seen as an area of good practice provided by the undertaking to support and assist in the radiation safety training of all relevant staff. Inspectors were also informed that BreastCheck provided annual training days for both radiologists and radiographers.

Overall, inspectors were satisfied that BreastCheck Group's commitment to multiple QA processes and radiation safety training ensured that all doses due to medical exposure for radiodiagnostic mammography procedures were kept as low as reasonably achievable consistent with obtaining the required medical information.

Judgment: Compliant

Regulation 11: Diagnostic reference levels

Following a review of DRL documentation and records, inspectors were satisfied that DRLs have been established, were compared to national levels, and were used in the optimisation of medical radiological procedures at this facility. Inspectors visited the clinical area and observed multiple examples of local facility DRLs displayed in the screening rooms.

BreastCheck Group also used a bespoke dose monitoring system to establish equipment, service unit and BreastCheck Group (local) DRLs. This system facilitated DRLs to be established based on all procedures completed by the BreastCheck Group resulting in a robust data set representative of the doses received by the entire screening population. Subsequent DRL and service user dose data was readily available and could be delineated based on equipment and service user differences, allowing in-depth dose analysis and subsequent opportunities for optimisation. Established BreastCheck DRLs were regularly reviewed and discussed and BreastCheck's approach to the use of DRLs was considered an area of good practice in the optimisation of service user dose.

Judgment: Compliant

Regulation 13: Procedures

On the day of inspection, inspectors found that written protocols were established for standard medical radiological procedures. A sample of these were reviewed in the clinical areas visited by inspectors. Staff in the clinical areas clearly articulated how these protocols were made available to them.

Inspectors spoke with staff and reviewed a sample of imaging reports in the final screening reading data sheet of the RIS system. For all records reviewed information

relating to patient exposure formed part of the report satisfying the requirements of Regulation 13(2).

Inspectors reviewed the *Radiography Audit Strategy* document provided which outlined that BreastCheck's approach to audit focused on imaging technical repeats and technical recall rates, auditing radiation incidents and dose audit. Although inspectors were satisfied that clinical audits were carried out by BreastCheck Group – Eccles Unit, more work is required to ensure that clinical audits are carried out in accordance with HIQA's national procedures.

Judgment: Substantially Compliant

Regulation 14: Equipment

From the evidence available, inspectors were satisfied that all medical radiological equipment was kept under strict surveillance by the undertaking. This had included the implementation and maintenance of a comprehensive QA programme. This QA programme included appropriate MPE acceptance and regular performance testing, manufacturer testing and regular radiographer testing. Evidence was also available to show that any issues identified as part of the equipment quality assurance programme had been followed up in a timely manner.

Inspectors were provided with an up-to-date inventory which was verified on site.

Judgment: Compliant

Regulation 17: Accidental and unintended exposures and significant events

From reviewing documents, speaking with staff and reviewing local incident records, inspectors were assured that the undertaking had implemented measures to minimise the likelihood of incidents for patients undergoing medical exposures at BreastCheck Group - Eccles Unit. Evidence was available to show that incidents were discussed at the appropriate committee levels and inspectors were assured that all incidents and near miss events were used to prevent similar occurrences.

Inspectors were also satisfied that a system of record-keeping and analysis of events involving or potentially involving accidental or unintended medical exposures had been implemented and maintained by the undertaking at BreastCheck Group - Eccles Unit.

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, as amended. 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	Substantially 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	Substantially Compliant
Regulation 9: Optimisation	Compliant
Regulation 11: Diagnostic reference levels	Compliant
Regulation 13: Procedures	Substantially Compliant
Regulation 14: Equipment	Compliant
Regulation 17: Accidental and unintended exposures and significant events	Compliant

Compliance Plan for BreastCheck Group - Eccles Unit OSV-0007346

Inspection ID: MON-0044726

Date of inspection: 29/10/2025

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, as amended.

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 6: Undertaking	Substantially Compliant

Outline how you are going to come into compliance with Regulation 6: Undertaking:
To ensure that the undertaking provides 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 that evidence of such allocation can be provided to the Authority in such form and manner as may be prescribed. BreastCheck will undertake the following.

1. Revision of BC/HS-020 Radiation Safety Procedures
Actions:
• Review and update the BC/HS-020 Radiation Safety Procedures to set out the allocation of responsibilities for all relevant staff and document will be approved by the Radiation Safety Committee.
- Incorporate language consistent with the requirement, ensuring clarity on how the undertaking discharges its duties and delegation with regard to justification, optimisation, and protection.

Outcome: Updated approved document clearly demonstrating responsibility allocation across all relevant roles.

2. Update BC/QP 002 Overview of BreastCheck
Actions:
• Revise BC/QP 002 Overview of BreastCheck to explicitly define and call out in detail the responsibilities and duties of all staff involved in medical exposures.
- Clearly state within the document that a radiographer is a healthcare practitioner and delegated responsibility for the purposes of medical exposures to ionising radiation, consistent with the regulatory definition.
• Specify responsibilities for each role, including:
o Healthcare Practitioners (Radiographers): Justification of medical exposures where authorised, ensuring clinical oversight, and contributing to the protection of patients and other individuals.
o Medical Physics Experts: Provision of scientific and technical advice on optimisation,

equipment performance, and dose assessment.
o Referrers: Provision of adequate clinical information to support justification.
• Ensure the revised document demonstrates a clear description of responsibilities across all roles as required by the regulation.
• This document will be approved at BreastCheck Executive Management Team meeting.

Outcome: BC/QP 002 Overview of BreastCheck reflects regulatory terminology and explicitly outlines the roles and responsibility for relevant Staff.

3. Use of QPulse (NSS Quality management Information System) for Document Control and Acknowledgement
Actions:
• Initiate the change control and approval workflow to ensure the updated documents are authorised in the form and manner prescribed by internal NSs/BreastCheck governance.
• Both revised BC/HS-020 Radiation Safety Procedures and BC/QP 002 Overview of BreastCheck will be
- Approved by appropriate committee
- Uploaded to QPulse in accordance with NSS Document management procedures.
- Distributed electronically to the relevant staff to ensure mandatory electronic notifications are sent to these staff requesting staff read and electronically acknowledge reading of the updated documents.
- implemented with briefing and training (as required)

Outcome: Controlled and fully auditable documentation demonstrating compliance and responsibility allocation.

Action owners:
BreastCheck Programme Manager
Chief Physicist

Completion by:
End of Q1 2026

Regulation 8: Justification of medical exposures	Substantially Compliant

Outline how you are going to come into compliance with Regulation 8: Justification of medical exposures:
Regulation 8 (11)

To ensure that a practitioner carrying out a medical radiological procedure on foot of a referral shall, having taken into account any medical data provided by the referrer, satisfy himself or herself that the procedure as prescribed in the referral is justified, and

that organisational systems and documentation fully support this requirement.

1. Update AIRE (BreastCheck Clinical Information system) – Move the justification section to the Radiographer Questionnaire Page
Actions:
• Update the Radiographer questionnaire Page of AIRE to ensure terminology and functionality align with the requirement that the practitioner must satisfy himself or herself of the justification of the procedure, ensuring that justification is recorded at the point of care and where the medical radiological procedure is performed.
• Removal of the justification section from the check-in questionnaire page in AIRE to the radiographer page

Outcome: AIRE system that documents delegated health practitioner responsibility for justification.

2. Update BC/QP 002 Overview of BreastCheck and BC RAD 020 to Highlight Radiographers as Healthcare Practitioners role in justification
Actions:
• Amend BC/QP 002 Overview of BreastCheck and BC RAD 020 Radiation Safety document to state that a radiographer is considered a healthcare practitioner for the purposes of justification, where authorised.
• Clearly outline that, in line with the requirement, a radiographer acting as a practitioner must:
o Review and consider any medical data provided;
o Satisfy themselves that the procedure is justified prior to carrying it out;
o Document justification in radiographer questionnaire page on AIRE.
• Ensure responsibilities are aligned with the regulatory language on referrals and practitioner decision-making.
• Ensure the documents distribution list includes the relevant staff to ensure mandatory electronic notifications are sent to these staff requesting staff read and electronically acknowledge reading of the updated documents
• In line with implementation of the updated documents ensure the relevant briefing and training (if required) are held

Outcome: Documents explicitly documents radiographers as Healthcare Practitioners s and set out their role in justification and documentation of same.

Action owners:
BreastCheck Programme Manager
Chief Physicist

Completion by:
End of Q1 2026

Regulation 8 (15)
Regulation 8(15) requires that an undertaking (must retain records evidencing compliance with Regulation 8 for a period of five years from the date of the medical exposure.

Retaining justification records for 5 years Actions:
• Outcome: AIRE interface already in place to ensure justification records are captured, retained, and retrievable in accordance with the Regulation and HSE Record Retention policy.

Status completed

Regulation 13: Procedures	Substantially Compliant

Outline how you are going to come into compliance with Regulation 13: Procedures:
1. Develop a Clinical Audit strategy document for ionising radiation in line with the HIQA Clinical audit strategy template to ensure that clinical audits for ionising radiation are conducted in accordance with national procedures established by HIQA and follow the audit cycle.

• Define governance including reporting, assurance and oversight and escalation if required
• Roles and responsibilities
• Criteria for selecting & prioritising audits
• Monitoring and review processes of recommendation and Quality improvement plans
• Clinical Audit Strategy will be approved by BreastCheck Executive management Team

2. Adapt the use of HIQA clinical audit templates that align with HIQA National procedures for clinical audit of radiological procedures involving medical exposure to ionising radiation to use within our setting.

These templates (Clinical Audit checklist, Clinical Audit report, Clinical audit topics) will be used to ensure clinical audits for ionising radiation are conducted in accordance with national procedures established by HIQA and follow the audit cycle.

Action owners:
Lead Clinical Director of BreastCheck
National Radiography Service manager
BreastCheck Quality Assurance Coordinator

Completion by:
End of Q1 2026

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 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 prescribed by the Authority from time to time.	Substantially Compliant	Yellow	31/03/2026
Regulation 8(11)	A practitioner carrying out a medical radiological procedure on foot of a referral shall, having taken into account any	Substantially Compliant	Yellow	31/03/2026

	medical data provided by the referrer under paragraph (10)(c), satisfy himself or herself that the procedure as prescribed in the referral is justified.			
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.	Substantially Compliant	Yellow	16/12/2025
Regulation 13(4)	An undertaking shall ensure that clinical audits are carried out in accordance with national procedures established by the Authority.	Substantially Compliant	Yellow	31/03/2026