Healthcare Improvement Scotland | Inspections and reviews
To drive improvement

Ionising Radiation (Medical Exposure) Regulation

Inspection methodology

March 2023

NHS SCOTLAND

Healthcare Improvement Scotland is committed to equality. We have assessed the inspection function for likely impact on equality protected characteristics as defined by age, disability, gender reassignment, marriage and civil partnership, pregnancy and maternity, race, religion or belief, sex, and sexual orientation (Equality Act 2010). You can request a copy of the equality impact assessment report from the Healthcare Improvement Scotland Equality and Diversity Advisor on 0141 225 6999 or email **contactpublicinvolvement.his@nhs.net**

Published March 2023

www.healthcareimprovementscotland.org

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Introduction

Healthcare Improvement Scotland (HIS) regulates medical exposure to ionising radiation in Scotland on behalf of Scottish Ministers. We inspect services to ensure that they comply with the Ionising Radiation (Medical Exposure) Regulations 2017. Services include:

- NHS hospitals
- private hospitals
- dentists, and
- any other area involving patient medical exposure of ionising radiation.

(In the context of this document services will be used as the collective term for all of the above)

Protection of patients, individuals and carers and comforters for medical and nonmedical exposures are covered by the Ionising Radiation (Medical Exposure) Regulations 2017 (IR(ME)R) in Great Britain. The regulations aim to ensure that ionising radiation is used safely and protect patients from the risk of harm during exposure. They set out the responsibilities of employers for radiation protection and the basic safety standards that employers must meet. The regulations apply to both the independent and public sectors (the NHS). Responsibilities include:

- minimising unintended, or accidental medical exposures
- justifying each exposure to ensure the benefits outweigh the risks, and
- optimising diagnostic doses to keep them 'as low as reasonably practicable' for their intended use.

About this document

This document sets out the methodology that Healthcare Improvement Scotland will use to carry out IR(ME)R inspections. The purpose of this document is to inform the public and employers providing facilities and activities to which the regulations apply of the process we will use to carry out our inspections; to measure compliance against the Regulations.

We benchmark compliance against the regulations with guidance provided by:

- Department of Health and Social Care (DHSC)
- Guidance written and established by all regulatory bodies for health for statutory notifications of significant accidental and unintended exposures (SAUE).
- Royal College of Radiologists has produced guidance relating to radiology and radiotherapy. UK Health Security Agency and the medical societies have provided IR(ME)R guidance for diagnostic and radiotherapy exposures
- Ionising Radiation (Medical Exposure) Regulations: Implications for clinical practice in radiotherapy
- Ionising Radiation (Medical Exposure) Regulations: Implications for clinical practice in diagnostic imaging, interventional radiology and diagnostic nuclear medicine explain how regulations should be interpreted in clinical practice.
- Any other relevant professional standards and guidance where applicable

This methodology document offers guidance on the inspection process informed by:

- Ionising Radiation (Medical Exposure) Regulations 2017
- Health and Safety at Work etc Act 1974,
- IAEA Safety Standards Series No. GSR Part 1 (Rev. 1) General Safety Requirements, governmental, legal and regulatory framework for safety and
- Healthcare Improvement Scotland's Quality Assurance Framework domains and quality indicators.

This methodology document also sets out important principles to guide the inspection process and ensure that people who use services do so safely and the risks from ionising radiation are minimised.

Feedback and consistency.

We also seek feedback from NHS staff, International Atomic Energy Agency (IAEA) peer review missions, other UK IR(ME)R regulators and the Scottish Government, as a means of reviewing our methodology and ensuring our work is improving safe standards of care

To provide effective co-ordination of radiation safety across a diverse range of stakeholders, the UK's government departments, devolved administrations and regulators routinely collaborate and share information and issues through the Radiological Safety Group (RSG) and other key co-ordination groups. Healthcare Improvement Scotland is part of this group which supports the consistent enforcement of I(RME)R.

We work collaboratively with other IR(ME)R regulators to support the consistent interpretation of IR(ME)R and any associated guidance. We will highlight any regional variations to the interpretation of the regulations at the time of inspection and through stakeholder engagement opportunities.

Inspection methodology

UK policy is consistent with the International Atomic Energy Agency (IAEA) Fundamental Safety Objective and Fundamental Safety Principles. These set out the basis for requirements and measures for the protection of people and the environment against radiation risks and for the safety of facilities and activities that give rise to those risks. How we regulate radiological and civil nuclear safety in the UK

UK regulations set out broad regulatory requirements, supported by relevant codes of practice and guidance, and it is for the employer to determine and justify how best to achieve them. This approach allows an employer to be innovative and to achieve the required high levels of radiological protection by adopting practices that meet its circumstances. It also encourages continuous improvement and the adoption of relevant good practices rather than simply meeting a prescribed standard

Our inspection activity supports NHS boards and independent healthcare services to comply with the regulations, national and international guidance documents that supports patient safety, highlight areas of good practice and identify areas for improvement and adopt responsive enforcement action when necessary.

Our inspections are announced to allow us to work with services to ensure that key personnel are available to reduce the impact on the service delivery. We may carry out targeted unannounced inspection if required. This approach aligns to the Organisation for Economic Co-operation and Development (OECD) regulatory Enforcement and Inspections guidance which states: ‘‘Except in specific circumstances experience has shown that advance notification of visit can help both regulated subjects and inspectors.’’

Approach to inspection

We follow the HIS Quality Assurance System and Scottish regulators strategic code of practice in the exercising of our regulatory function and in addition we have incorporated the principles of better regulation, namely

- Transparent
- accountable,
- consistent,
- proportionate and

- targeted only where needed.

These link with the core guiding principles of the HIS Quality Assurance System, which are

- User focussed
- Transparent & supportive, yet independent
- Integrated and co-ordinated
- Improvement focussed
- Intelligence-led and risk-based

We will tailor our approach depending on the nature of the facilities and activities we are regulating and the desired outcomes. This includes a commitment to advice and support for those who seek to comply, allied with robust and effective enforcement when justified. Adopting a positive enabling approach in pursuing outcomes.

We will deliver baseline inspections to a modality, (facilities and activities) delivered by each NHS board or registered independent healthcare service by March 2025. Once completed we will adopt a risk-based approach to regulation, which includes our graded approach to inspection. This will determine the frequency and location of our inspections.

This enables the targeting of inspection resources and contributes to a national drive for a risk based, proportionate and intelligence-led approach to scrutiny and assurance across all healthcare.

How our graded approach will work

Our approach to a graded approach to inspection aligns to IAEA General Safety Requirements, Part 1 (Rev 1) Requirement 29 “The regulatory body shall develop and implement a programme of inspection of facilities and activities, to confirm compliance with regulatory requirements and with any conditions specified in the authorization. In this programme, it shall specify the types of regulatory inspection (including scheduled inspections and unannounced inspections) and shall stipulate the frequency of inspections and the areas and programmes to be inspected”

Our inspection prioritisation will be proportionate to the radiation risks associated with facilities and activities in line with IAEA General Safety requirements and guided by Application of a Graded Approach in Regulating the Safety of Radiation Sources. The application of the IAEA guidance suggests inspections to each site/facility and would result in approximately 70 inspections every year. Based on our approach to drive improvement through stakeholder engagement, actively work with stakeholders to support improvements, sharing learning and a willingness of services to seek compliance with IR(ME)R, a more targeted approach to inspection has been taken. Our approach

will deliver inspections based on the employer, modality and associated radiation risk not on the site/facility/activity alone. The inspection frequency will be greater for facilities and activities with a high overall relative risk as detailed in IAEA TECDOC 1974 and a lower frequency of inspections for services that fall into the moderate and low overall relative risk categories. Low risk dental radiography (intra oral and orthopantomography (OPG) xrays) will not be part of the proactive inspections process and not subject to a defined frequency of inspection. Alternative methods of driving improvements through collaboration with key stakeholders and education will be utilised. Reactive inspections where required will be risk based, proportionate and intelligence led.

The frequency of inspections shall be in accordance with the following graded approach:

Modality	**Diagnostic modality (including interventional and fluoroscopy**	**Nuclear medicine (therapy and diagnostic)**	**Radiotherapy**
Risk	Low	Medium	High
Inspection frequency	Every 5 years	Every 3 years	Every 2-3 years
Priority areas	Interventional services	Nuclear medicine therapy High dose rate (Brachytherapy) SIRT High activity diagnosis	All accelerators

Our focus

All inspections will reflect the existing context of operating environments and service pressures within NHSScotland hospitals and other independent healthcare settings.

We will adopt, where possible, a persuasive approach to regulation. Seeking to secure co-operation, promote compliance and build long-term improvements. However, where this is not possible, we will adopt a more compliance-based inspection model and use enforcement powers where required.

The focus of inspections is to:

- ensure patients who are exposed ionising radiation as part of a medical exposure is done so in line with current standards and best practice
- report our findings during our inspection and ensure the NHS board and providers of independent healthcare services produce an improvement action plan to address any areas for improvement identified, and

- engage with staff and management if there is evidence, they are not implementing the principles and requirements of the regulations.

We will inspect using the IR(ME)R 2017, professional guidance and standards both national and international that provide guidance on how to interpret the regulations and our Quality Assurance Framework (2022). In addition, any other standards that become relevant during the course of the inspection.

Onsite inspection

The inspection team will comprise of:

- inspectors, and
- as required, staff from the medical exposures group UK Health Security Agency (UKHSA) to support the inspection team either on site or remotely.

All inspectors will carry a photo identification card warrant to carry out an IR(ME)R inspection. All members of the inspection team are enrolled in the Protecting Vulnerable Groups (PVG) scheme. The different types of inspections are detailed in appendix 1.

Inspection team roles and responsibilities

The onsite inspection is expected to take place over 2 days (depending on the size of the site). Off-site discussion with representatives of the facilities inspected, using Microsoft Teams may also form part of the inspection. When inspectors are onsite, this will generally be between 8.00am – 6.00pm. We will try to ensure minimal disruption to the provision of care to patients.

Inspectors will try to minimise the burden on staff delivering care when we visit departments. However, where necessary, we will speak with members of staff to discuss their role, knowledge and awareness of employer's procedures to implement IR(ME)R requirements.

The inspection programme will be agreed and shared in advance with the IR(ME)R lead or nominated contact. We will also request any information that will be required to carry out the inspection, including a template for the collation of necessary staffing information.

During our inspection, the inspectors will:

- use inspection aide memoires and document findings in contemporaneous notes
- access information held in relation to IR(ME)R
- carry out group discussions with staff, in a small group or one-to-one discussions (face to face and using Microsoft Teams) at an agreed time
- access radiology information systems, policies and employer’s procedures, where appropriate

- ask the service to provide relevant information as required,
- visit departments and view equipment, calibration, records, documentation and talk to staff
- observe practices in the nuclear medicine department

Inspectors will be escorted when visiting departments and informed of any control measures to protect their health and safety.

Verbal high-level feedback will be available during the inspection. In the event of serious concerns or where enforcement is being considered the IR(ME)R lead or their representative will be informed as soon as practicably possible.

Should the service require clarification of any points made in the high-level feedback, they should contact the senior inspector.

The stages of the inspection are set out in appendix 2.

Use of experts on inspection

We will always use experts that do not have the potential for a conflict of interest in line with IAEA guidance. We may be supported on inspection by staff from the Medical Exposures Group (MEG) at UKHSA – a multi-disciplinary group of clinically trained and experienced staff, including clinical scientists and radiographers from each of the radiological modalities: diagnostic imaging, nuclear medicine and radiotherapy. This group of staff have experience supporting IR(M)ER inspections in the UK.

Reporting

We publish inspection reports for patients, public and services, based on what we find during inspections. Services can use our reports to find out what other facilities and activities do well and use this information to help make improvements. Our reports are available on our website at www.healthcareimprovementscotland.org

The NHS board chief executive or the registered service manager in the case of independent healthcare services, the IR(ME)R lead and key contacts will receive a draft version of the inspection report following the onsite inspection within 6 weeks. However, this timeframe may be adjusted dependent on inspection findings and time required to review additional evidence. The service provider (facilities and activities) will then have 10 working days from receipt of the draft report to agree the factual accuracy of the report and to draft an improvement action plan. Following finalisation of the report, an embargoed report will go to Scottish Government approximately 1 week before publication.

The final inspection report and improvement action plan will be published on our website approximately 10 weeks after the inspection. More detail can be found on Appendix 2: Stages of inspection.

Areas of good practice

When the inspection team gather strong evidence that a service is delivering areas of good practice, good ways of working or good outcomes for patients, this is reported in the inspection report. This can then be used to share learning across NHSScotland and to give recognition to the NHS boards involved.

Requirements and recommendations

A requirement sets out what action is required from an NHS Board or IHC service provider (who delivers the facilities and activities) to comply with IR(ME)R. A requirement means the employer has not met the required statutory standard in the opinion of the inspector. All requirements must be addressed and the necessary improvements implemented. A recommendation relates to best practice which we believe the service should follow to improve standards of care.

Improvement action plans

The NHS Board or IHC service provider is asked to produce an improvement action plan and is responsible for making the necessary improvements to meet the requirements. The inspection team will review the content and timeframes of the actions outlined in the improvement action plan and may provide comments back to the employer with suggested amendments.

The inspection team may also request to meet with colleagues from the service or carry out another onsite visit to discuss and assess their implementation of improvement actions or to request evidence of completion.

We will follow-up on the progress made by the service in relation to the actions outlined in the improvement action plan. This will take place at approximately 18 weeks after the publication of the inspection report.

Our approach to following up on requirements will depend on the associated risk of those who use the facilities and activities and our assessment of the providers capacity to improve.

We may need to follow up with a further inspection to confirm the facilities and activities has met the requirements. If the areas for improvement present a significant breach in the legislation or potential enforcement action is being considered, then we will conduct follow-up activity before requesting the 18-week update of the improvement action plan.

Improvement action plans will remain published on our website with the inspection report. In the instance where a follow up inspection has been carried out because of concerns, the improvement

action plan will remain in addition to any further improvement action plans after the follow up inspection.

During future inspections to services, we may review progress against previous improvement action plans to seek assurance that all actions were completed or have been progressed

Additional follow-up inspections

The nature of any additional follow-up activity will be determined by the level of compliance and the risk gap identified. It may involve one or more of the following additional elements:

- a future announced inspection
- a future targeted announced or unannounced inspection looking at specific areas of concern
- a meeting with key members of staff from the facilities or activities
- a written submission by the employer (of the facilities and activities) outlining progress made, along with supporting evidence, or
- formal enforcement action initiated. This process may continue until the inspection team is satisfied the necessary improvement actions have been completed.

Enforcement

Our enforcement approach supports transparency, accountability, proportionality and consistent enforcement. We commit to early dialogue with those we regulate to resolve issues or address non-compliance. Our enforcement will be based on responsive regulation principles; that is inspection enforcement actions will be modulated depending on risk factors and behaviour of the facilities and activities we inspect. Differentiating between facilities and activities that are generally compliant or actively working to improve and those who deliberately choose not to comply. These considerations will help inform the choice of intervention and whether to take early formal enforcement action.

Our enforcement approach follows the enforcement management model developed by the Health and Safety Executive as amended for radiation safety. The enforcement management model provides inspectors with a framework for making consistent enforcement decisions and helps managers monitor enforcement decisions, in line with health and safety legislation and Healthcare Improvement Scotland policy.

Types of formal enforcement action

Improvement notice

An improvement notice will require the employer, or other duty-holder, to take remedial action. This will usually be within a specified time frame consistent with the level of concern and the resources required to rectify the non-compliance(s). We will follow up improvement notices to seek assurances from the employer and check that they have completed the actions.

Prohibition notice

A prohibition notice will suspend the activity until remedial action has been implemented and inspectors are satisfied with the outcome. We will ask the employer for assurance about the remedial action it has taken. This would normally require a return visit to check that the actions were complete.

Where we have served an improvement or prohibition notice, the employer has a right of appeal against this decision to an employment tribunal.

Crown Office and Procurator Fiscal Service

We can report possible offences with our recommendations to the Crown Office and Procurator Fiscal Service (COPFS) for them to decide what action to take. The decision to notify the Procurator Fiscal is a significant one and will only be taken in the most serious of instances.

Further information

Further information about any of our inspections can be found on the 'Inspecting and regulating care' section of the Healthcare Improvement Scotland website.

Appendix 1: Inspection types

Full inspection

During this type of inspection, we will assess and report on the performance of services using the Ionising Radiation (Medical Exposure) Regulations 2017 that are aligned to the Quality Framework domains. The most appropriate domains or quality indicators will be selected for individual services. This may involve the use of experts to advise the inspection team.

Follow-up inspections

A follow-up inspection will focus on requirements and recommendations made at an inspection. We will evaluate how the provider has addressed these requirements and recommendations to improve outcomes for people using services and their families and carers. This may involve the use of experts to advise the inspection team.

Unannounced inspection

An unannounced inspection can be undertaken where there is a specific need. Such as to assess the provision of out of hours support or appropriate entitled staff of delivering services.

Notification inspection

In response to notifications, a focused inspection may result in an inspection of a particular issue. This may involve the use of experts to advise the inspection team.

Appendix 2: Stages of inspection

Stage 1 - Before the inspection

Before the inspection, we will:

- check the service has a licence for radiopharmaceuticals, if appropriate
- decide which type of inspection – full or follow-up, modality and key activities
- review requirements and recommendations made at previous inspections, if available
- review any notifications received about the service, and
- develop an inspection programme in collaboration with the service. Including arrangements for meeting with key staff and visiting the relevant department.

Stage 2 – During the inspection

During the inspection we will:

- meet with the IR(ME)R lead (or equivalent), the operational management team including medical physics experts, lead radiologist, radiographers and visit the relevant departments
- evaluate and sample evidence against the Regulations
- provide feedback on our evaluation including areas of good practice and areas for improvement
- if appropriate, decide the level of enforcement action and inform the service provider of any decision (a decision may not be possible on the day and the service provider will be informed that they will be informed with 2 working days of a decision following a review), and
- provide verbal feedback to the management team and, where possible, the IR(ME)R lead.

Stage 3 - After an inspection

After each inspection we:

- issue any notices within 5 working days of our inspection, including details of the services provider's right of appeal against the decision to an employment tribunal, following the enforcement management model
- issue a draft inspection report and ask the employer to make comments its factual accuracy (see finalising inspection report) and ask for an improvement action plan, with timescales to address requirements and recommendations made in the report
- send the final version of the inspection report to the employer
- publish the report

Finalising the report process

Inspection reports will be made final:

- if the employer agrees with the draft report without any amendments
- when factual errors have been corrected following the service returning the factual accuracy error response form, or
- if the service does not return the factual accuracy error response form within 10 working days of receipt of the draft report.

To ensure we publish our inspection reports no later than 10 weeks following inspection.

Publication timescales	
6 weeks after inspection	employer receives draft report to check for factual accuracy
8 weeks after inspection	employer returns any comments on factual accuracy, sign-off sheet and improvement action plan
9 weeks after inspection	Employer receives final report
10 weeks after inspection	Final report and improvement action plan published on the Healthcare Improvement Scotland website