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
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Introduction

Healthcare Improvement Scotland is the regulator of 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. Services include:

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

The regulations set out the responsibilities of duty holders – the employer, referrer, IR(ME)R practitioner and operator – for radiation protection and the basic safety standards that duty holders must meet.

About this document

This document sets out our methodology for the inspection of services. The document offers guidance on the inspection process informed by:

- compliance with regulations, and
- Healthcare Improvement Scotland’s Quality Framework domains and quality indicators.

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

The Quality of Care Approach

Our quality of care approach is how we design our inspection methodologies and provide external assurance of the quality of healthcare provided in Scotland. There are three components:

- **the approach** itself – the methodology and the principles that underpin it, that we use for all of our quality assurance work
- **the framework** – outlines the quality indicators used for external quality assurance, and
- the standard operating procedure – a set of standardised tools, templates and processes that can be used across our quality assurance work, wherever possible.

The following principles underpin how we carry out our quality assurance function and are embedded into the design of all our programmes of work. All of our inspections and reviews are:

- user-focused – we put people who use services at the heart of our approach
- transparent and mutually supportive, yet independent – we promote and support a complementary approach to self-evaluation for improvement, challenge and intervention as required
- intelligence-led and risk-based – we take a proportionate approach to inspection and review that is informed by intelligence
- integrated and co-ordinated – we draw on the collective participation of relevant scrutiny bodies and other partners to share intelligence and minimise duplication of effort, and
- improvement-focused – we support continuous and sustained quality improvement through our quality assurance work.

The principles of the quality of care approach and framework together, provide the key point of reference to inform our inspections. For the quality assurance work that we lead on the Quality Framework (supplemented as required by any relevant service-specific standards, indicators or legislation) forms the basis of inspections.

The Quality Framework

The Quality Framework follows the Health Foundation recommendations that Government regulators and national agencies should design their systems for oversight and regulation in a way that allows organisations to demonstrate their safety, rather than their compliance with prescriptive centrally mandated measures. It provides guidance to services, and to those externally

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quality assuring them, about what good quality care looks like and how this can be evaluated. It is arranged in nine broad areas of focus referred to as ‘domains’ that cover all aspects of a healthcare providers work. Each domain includes quality indicators designed to help with self-evaluation and improving the quality of care provided for all users of services. These are neither exhaustive nor prescriptive. The nine domains in the framework can broadly be grouped under three headings related to:

- outcomes and impact
- service delivery, and
- vision and leadership.
The foundations of inspection

We use an open and transparent method for inspecting and reporting on our findings, using standardised processes. Our inspection process:

- uses our Quality Framework as the basis for inspection
- asks services to evaluate themselves against the regulatory requirements, tell us how they think they are performing, and identify what action they will take to make those improvements
- make sure we take a risk based and proportionate approach to inspection by using service risk, previous inspection and notifications, and
- helps us produce inspection reports, with clear information about the implementation of the regulations, which are published on our website.

This is useful for:

- people who use the services
- organisations themselves to drive improvement and assess compliance with statutory duties, and
- Scottish Ministers.

The three stages of inspection

The inspection process is in three stages.

**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
- review requirements and recommendations made at previous inspections, if available
- review any notifications received about the service, and
- develop an inspection plan.

**Stage 2 - Inspection**

During the inspection we will:
• Meet with the IR(ME)R lead (or equivalent), the operational management team including medical physics experts (MPEs), lead radiologist, radiographers and visit the relevant departments.

• Evaluate and sample evidence against the Ionising Radiation (Medical Exposure) Regulations 2017.

• 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.

• Provide verbal feedback to the management team and, where possible, the IR(ME)R lead. See Appendix 2 for the three types of inspection.

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 (EMM).

• Issue the inspection report in draft format and ask the provider to make comments on factual accuracy.

• Send the final version of the inspection report to the service provider (see below for more information about our publication timescales).

• Request and review an action plan from the provider with responses to any requirements or recommendations that we make including appropriate timescales.

Finalising the report

Inspection reports will be made final:

• when the service provider agrees with the draft report without amendment

• when factual errors have been corrected following the service returning the factual accuracy error response form, or

• the provider 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, we give providers 10 working days to check their draft report for factual accuracy.

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<th>Publication timescales</th>
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<td>6 weeks after inspection</td>
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<td>10 weeks after inspection</td>
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**Following up**

Our approach to following up on requirements will depend on the associated risk of those who use the service and our assessment of the provider’s capacity to improve.

We request a further updated action plan 18 weeks after inspection if appropriate. However, this updated action plan may not be enough evidence. We may need to follow up with a further inspection to confirm the provider has met the requirements. In addition, if the areas for improvement present a risk to those using the service then we will conduct follow-up activity before requesting the 18 week update of the improvement action plan.

**Following-up 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**

The effect of the prohibition notice is to 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.
Appendix 1: Structure of the Quality Framework
Appendix 2: 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.

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.