



Healthcare  
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Scotland

Inspections  
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To drive improvement

# Announced Inspection Report: Ionising Radiation (Medical Exposure) Regulations 2017

**Service:** Raigmore Hospital, Inverness

**Service Provider:** NHS Highland

30 April – 1 May 2024

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First published July 2024

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# 1 A summary of our inspection

## Background

Healthcare Improvement Scotland has a statutory responsibility to provide public assurance about the quality and safety of healthcare through its inspection activity.

The quality assurance system and the quality assurance framework allows us to provide external assurance of the quality of healthcare provided in Scotland. We have aligned the Ionising Radiation (Medical Exposure) Regulations (IR(ME)R) 2017 to the framework.

## Our focus

The focus of our inspections is to ensure each service is implementing IR(ME)R 2017. Therefore, we only evaluate the service against quality indicators that align to the regulations. We want to find out how the service complies with its legal obligations under IR(ME)R 2017 and how well services are led, managed and delivered.

## About our inspection

We carried out an announced inspection to Raigmore Hospital on Tuesday 30 April and Wednesday 1 May 2024. We spoke with the following staff: Head of Medical Physics (Radiation Police Lead / IR(ME)R Lead), nuclear medicine consultant, Head of Nuclear Medicine Section, Medical Physics Expert, Technical Manager, clinical technologists, breast surgeon, endocrinologist, Chair of the Radiation Safety Committee and two members of the executive team. This was our first inspection to this service.

The nuclear medicine section consists of diagnostic studies and outpatient therapies using radioactive materials (radiopharmaceuticals). The department operates two SPECT-CT cameras. Over 2000 patients attend each year and over 30 different diagnostic and therapeutic procedures are currently offered. Examples of Nuclear Medicine procedures provided by the section include iodine therapy, myocardial perfusion imaging, brain imaging (for investigation of dementia and movement disorders), lung scanning (for pulmonary embolism) and bone scintigraphy. A paediatric imaging service is also provided.

The inspection team was made up of one senior inspector and two inspectors as observers.

## What action we expect NHS Highland to take after our inspection

The actions that Healthcare Improvement Scotland expects NHS Highland to take are called requirements and recommendations.

- **Requirement:** A requirement is a statement which sets out what is required of a service to comply with the Regulations. Requirements are enforceable at the discretion of Healthcare Improvement Scotland.
- **Recommendation:** A recommendation is a statement that sets out actions the service should take to improve or develop the quality of the service but where failure to do so will not directly result in enforcement.

This inspection resulted in 2 requirements and 6 recommendations.  
Requirements are linked to compliance with IR(ME)R.

Direction	
Requirements	
1	<p>NHS Highland must ensure that the doses arising from the computed tomography exposure are kept as low as reasonably practicable consistent with the intended clinical outcomes (see page 9)</p> <p><i>Regulation 12 (1)</i> <i>Ionising Radiation (Medical Exposure) Regulations 2017</i></p>
Recommendations	
a	NHS Highland should provide clarity on the roles and responsibilities of the IR(ME)R lead (radiation policy lead) for all nuclear medicine services and how the role relates to all the professional groups that provide elements of IR(ME)R assurance (see page 8).
b	NHS Highland should have a governance system that co-ordinates and links the delivery of assurance information in relation to the implementation of IR(ME)R in nuclear medicine (see page 8).
c	NHS Highland should consider the establishment of multidisciplinary radiation imaging optimisation teams for nuclear medicine to consolidate expertise to consistently optimise all examinations using ionising radiation, including CT scans. Taking into consideration dose, image quality and clinical outcomes (see page 9).

Implementation and delivery	
Requirements	
2	NHS Highland must include the Medical Physics Expert in the analysis of events involving, or potentially involving, accidental or unintended exposures (see page 16).  <i>Regulation 14(3)(f)</i> <i>Ionising Radiation (Medical Exposure) Regulations 2017</i>
Recommendations	
d	It is recommended that NHS Highland define the process by which medical physics and clinical scientist staff are deemed competent to justify under protocol including how this process is documented (see page 12)
e	It is recommended that the results of clinical audits are shared with the IR(ME)R lead or alternative governance groups to provide further assurance on the implementation of IR(ME)R (see page 16)

Results	
Recommendations	
f	NHS Highland should use inclusive language in the employer's procedures and practice when enquiring of individuals of childbearing potential to reduce the possibility of an unintentional exposure to a fetus (see page 18).

An improvement action plan has been developed by NHS Highland and is available on the Healthcare Improvement Scotland website.  
<https://www.healthcareimprovementscotland.scot/publications/category/inspection-reports/>

NHS Highland must address the requirements and make the necessary improvements as a matter of priority.

We would like to thank all staff at Raigmore Hospital for their assistance during the inspection.

## 2 What we found during our inspection

### Direction

<b>Domain 1: Clear vision and purpose</b>	<b>Domain 2: Leadership and culture</b>
<b>Key questions we ask:</b> <i>How clear is the service's vision and purpose?</i> <i>How supportive is the culture and leadership of the service?</i>	

### Our findings

#### Entitlement

NHS Highland has a clear policy for entitlement of medical and clinical technologist, clinical scientist, radiopharmacy, nursing, non-medical referrers, administration, and clerical staff). All the staff working in nuclear medicine have up to date entitlement records and clearly defined scopes of practice which align to their training records and competency.

Employers and practitioners who administer radioactive substances require an appropriate license from the Administration of Radioactive Substances Advisory Committee (ARSAC). The licensed practitioner is then entitled by the employer. This includes the entitlement for the administration of all radiopharmaceuticals in clinical use matched by the Employers License. We saw evidence of regular reviews of the ARSAC license holders to ensure they are performing the tasks that they are entitled to carry out.

The breast surgeons undertaking (Sentinel Lymph Node Biopsy) SLNB are entitled by NHS Highland as operators and referrers and have the appropriate entitlement certificates. The surgeons are using authorisation guidelines from the practitioner who is the ARSAC license holder.

NHS Highland also have in place entitlement arrangements for consultants that routinely refer to NHS Highland from other health boards.

#### Safety culture

A radiation safety culture can help to strengthen safety in the use of radiation technology, preventing injuries and reducing unnecessary or unintended radiation dose to patients. The safety culture was demonstrated through the measures in place to ensure the appropriate competence of staff, employer's procedures (EPs), audit, and governance arrangements in place.

All staff we spoke with told us about a supportive and positive safety environment. This included an open culture for reporting incidents, and a focus on learning from errors and sharing learning across the team.

The radiation safety committee is chaired by a consultant radiologist. The radiation policy lead, who also acts as the IR(ME)R lead, is a member of the group. A service lead report from the nuclear medicine section, which includes information on IR(ME)R compliance and assurance is submitted to the radiation safety committee. The committee reports to NHS Highland's health and safety group, which reports to the board committees' groups (clinical governance committee and staff governance committee). We were also advised that the radiation policy lead links directly to the chief officer of acute services. The chief officer confirmed that any concerns would be escalated to them by the radiation policy lead, such as incidents involving Nuclear Medicine services.

### **What needs to improve**

There is uncertainty on some of the roles within the Nuclear Medicine Section team at Raigmore Hospital. This is the IR(ME)R lead and how it relates to the professional groups that provide elements of IR(ME)R assurance in the nuclear medicine department. The other role is the Chair of the Radiation Safety Committee and how it relates to the IR(ME)R assurance.

There is an absence of operational awareness of the governance arrangements in relation to IR(M)ER governance structures and how this corresponds to services using nuclear medicine. In comparison, diagnostic radiology (plain film x-ray/CT) there are groups on IR(ME)R compliance and optimisation.

### **Recommendation a**

- NHS Highland should provide clarity on the roles and responsibilities of the IRMER lead (Radiation policy lead) for all nuclear medicine services and how the role relates to all of the professional groups that provide elements of IR(ME)R assurance.

### **Recommendation b**

- NHS Highland should have a governance system that co-ordinates the delivery of assurance information in relation to the implementation of IR(ME)R in nuclear medicine.

### **Optimisation**

Dose optimisation and the production of a local diagnostic reference level (LDRL) has been undertaken for the administration of diagnostic



radiopharmaceuticals. NHS Highland have undertaken dose audits to support their optimisation work. The ARSAC license holder has undertaken several evaluations to demonstrate that the LDRL which is below the ARSAC guidance note suggested national diagnostic reference level (NDRL) is effective in maintaining suitable clinical outcomes. A spreadsheet has been developed with the LDRLs in comparison to the NDRL with the reason for the LDRL. All diagnostic administrations are to be within +/- 10% of the agreed LDRLs. Radiopharmaceuticals administered intravenously for therapeutic purposes are to be within +/- 5% of the prescribed activity. Oral administrations of Iodine<sup>131</sup> are to be within +/- 10% of the prescribed activity.

There is an ongoing review of protocols for the administration of I<sup>131</sup> therapy lead by the nuclear medicine physician, ARSAC license holder. They have undertaken studies that can be used to modify the therapy dose based on thyroid uptake. Allowing for more specific dose optimisation in for I<sup>131</sup> therapy patients.

### **What needs to improve**

There are two SPECT-CTs in the nuclear medicine section, one installed in 2013 and the other installed in 2021. There had been no dose optimisation on either CT. It was highlighted that support from the diagnostic optimisation group had been requested previously. It is essential dose optimisation of the CT is undertaken as it is highlighted that image quality has the potential to be sub optimal in a small number of cases.

Nuclear medicine should have a forum to discuss optimisation, such as an image optimisation team. The team should be responsible for oversights of dose management, evaluating their impact and communicating outcomes widely. The dose optimisation team should monitor the review of adult and paediatric protocols for optimisation considering evolving technology and local factors.

### **Requirement 1**

- NHS Highland must ensure that the doses arising from the computed tomography exposure are kept as low as reasonably practicable consistent with the intended clinical outcomes.

### **Recommendation c**

- NHS Highland should consider the establishment of multidisciplinary radiation imaging optimisation teams for nuclear medicine to consolidate expertise to consistently optimise all examinations using ionising radiation, including CT scans. Taking into consideration dose, image quality and clinical outcomes.

## Implementation and delivery

Domain 3: Co-design, co-production	Domain 4: Quality improvement	Domain 5: Planning for quality
<b>Key questions we ask:</b> <i>How well does the service engage its stakeholders?</i> <i>How well does the service manage and improve performance?</i>		

### Our findings

NHS Highland have clear mechanisms for referrals to nuclear medicine, including for non-medical referrers. Justification protocols are in place which have been reviewed and approved by the ARSAC license holder. Additionally, NHS Highland have good training records which clearly identify an individual's competencies and those who can deliver training.

#### Employer's procedures

NHS Highland have a comprehensive set of EPs which cover all modalities including nuclear medicine. These include level 2 procedures which relate to nuclear medicine, and they are reviewed every 2 years by a multidisciplinary team, which includes the MPE, ARSAC license holder and clinical technologist.

#### Training

All staff must complete the Departmental IR(ME)R training. We observed that all technologists have up-to-date training records. There is a comprehensive collection of training documentation which includes competency assessment in the level 3 EPs, NM-3 training and education. The completion of these documents is linked to a person's scope of entitlement. This includes training on all the equipment they will use, including the calibrators and quality control checks. Training on cannulation and the signs of extravasation has also been undertaken. As each person is deemed competent, their training record is signed by a senior member of staff before they can use the equipment independently. Training was provided to all operators to provide advice to carers and comforters and authorise any potential exposures.

#### Referral

NHS Highland have clear and comprehensive referral criteria for nuclear medicine. Furthermore, the referral criteria is provided to those entitled to refer from outside NHS Highland. There is no electronic referral system and referrals are made using a standard referral form. Referrals received from

non-medical referrers are clearly identifiable. All staff are clear about accessing the Level 3 document listing the entitled referrers to check whether the referral is within the referrers scope of entitlement. When a referral is received it is scanned and uploaded to the Radiology Information System (RIS).

The practitioner or operator authorised under protocol review the referral and clinical information. They have access to the patients' clinical history and review any additional information as required, such as previous imaging, relevant test results, for example antibody or thyroid function test as appropriate. If sufficient information has been provided the examination or test can be justified, this is then recorded on RIS.

Staff described depending on the circumstance how they would seek additional information or reject a referral if it does not have sufficient clinical information to justify the exposure.

#### Justification

NHS Highland undertake a variety of diagnostic and therapy exposures and use a range of radioisotopes and routinely use, Thallium201, Iodine123, Iodine131, Radium223, Technetium99 and Iodine125.

All justifications are undertaken by ARSAC licence holders or by an operator, who authorise under protocol. The protocols include steps to reduce the risk of radiation and ensure that lower dose options are considered or undertaken before the use of nuclear medicine is justified. There are clear authorisation protocol guidelines in place and have all been issued by a named ARSAC licence holder. The protocol guidelines provide clear guidance for the operator to enable them to authorise exposures which meet the required criteria.

Justification for therapy treatments is undertaken by the consultant nuclear medicine physician and consultant endocrinologists within their area of expertise. The clinical information and history are considered to support the decision to refer a patient. Consultants have access to the relevant clinical history as part of the justification process. When proceeding with I<sup>131</sup> therapy the endocrinologist will see that measures have been taken to ensure that the patient stops any thyroid blockers to ensure the I<sup>131</sup> treatment will be predominantly taken up in the thyroid. Should the thyroid blocker not be stopped in time there is an increased potential that the I<sup>131</sup> treatment will not be effective.

One clinical scientist and one oncologist are trained and entitled to justify (authorise) under protocol. The training is mentored by the consultant in nuclear medicine. (ARSAC license holder) who will identify when staff have

attained the correct level of competence. Training for two members of nuclear medicine staff is ongoing.

### **What needs to improve**

There was limited documentation to demonstrate that medical physics staff had attained competency to justify under protocol within their scope of practice.

### **Recommendation d**

- It is recommended the NHS Highland define the process by which medical physics and clinical scientist staff are deemed competent to justify under protocol including how this process is documented.

### **Imaging and treatments**

A review of the patient information on RIS which includes the referral and justification and indicates protocol is carried out the day before studies are undertaken by the department staff. If there are any anomalies this can be raised prior to the patient arriving to the department.

Staff demonstrated a good understanding of the EPs and the procedures for ensuring that the correct radiopharmaceutical and activity are linked to individual patients, which are included in the level 3 EPs. NHS Highland have a clear administration checklist that is used to record all relevant procedures for delivering nuclear medicine diagnostic imaging. On completion, the checklist is scanned onto the patients record in RIS.

Staff are confident on how to measure and review activity tolerance levels of each radiopharmaceutical. When administering a radiopharmaceutical there are two staff members present.

The administration of radiopharmaceutical is weight based for all paediatric patients and for myocardial perfusion studies. The department has calibrated scales to ensure that they have the most up to date weight prior to calculating the volume to be administered.

Staff are clear about the risks of extravasation (the leakage of radioactive material at the injection site). We were informed that the diagnostic test would only proceed if adequate activity had been successfully injected, and if there was potentially a 'hot spot' this would be clearly marked on the patients notes to ensure this would not affect the clinical evaluation.

In the event of any image anomalies, all staff confirmed that they will stop the process and seek advice from the MPE.

### Clinical evaluations

For diagnostic imaging clinical evaluations are undertaken by Consultant in Nuclear medicine who is the ARSAC license holder and clinical scientists depending on the type of examination and reports are uploaded to the RIS. The Breast surgeons will record the clinical outcomes in the patients notes and link them to the pathology results. In the case of radionuclide therapy ( $I^{131}$  and Radium-223), the report records the administered activity, date of administration and route of administration.

### Records

The radiology information system is used to record the referral through to the clinical evaluation.

We observed information recorded on the RIS, including:

- scanned referral documents.
- administration checklists.
- details of the referrer and operator.
- identification checks.
- pregnancy checks.
- the recorded dose.
- the radiopharmaceutical.
- justification, and clinical evaluation.

The RIS allows staff to record information specific to nuclear medicine, including the activity level of the radiopharmaceutical as it's dispensed.

### Patient identification

All staff we spoke with told us patient identification checks are always carried out. This includes name, date of birth, address, who made the referral and the reason for the procedure.

We were advised if a patient could not identify themselves and were not accompanied by a person who could do so for them, the exposure would not proceed. All staff were aware of communication aids, such as LanguageLine, to support any barriers to communication.

### Expert advice

NHS Highland have a dedicated medical physics team and as part of this team they have dedicated MPEs in place to support nuclear medicine. All MPEs are on the RPA2000 register. NHS Highland recently conducted a calculation of the MPE for Nuclear Medicine using the calculator published by the Institute of Physics and Engineering in Medicine (IPEM). The result of the calculation

indicated that the current provision was appropriate. The medical physics team work closely with staff across nuclear medicine.

The MPE role provides support with:

- commissioning of new equipment.
- acceptance testing of new equipment.
- establishing baselines for quality assurance.
- calibration of equipment.
- investigation if quality assurance is out with tolerance levels.
- optimisation.
- dose reference levels.
- staff training.
- development of employer's procedures, and
- analysis of incidents.

### **What needs to improve**

The MPEs in nuclear medicine are not a part of the process to decide if an incident requires to be reported to Healthcare Improvement Scotland. See accidental or unintended exposure section for further information (see page 16).

### **Contracted services**

NHS Highland use external contracted services to provide clinical evaluations. The IR(ME)R Lead approves and entitles operators provided by the contracted services. This includes a check that radiologists are registered with the General Medical Council on the specialist register.

The quality of the clinical evaluations provided by the contracted services is monitored through a system of audits carried out by a nuclear medicine consultant.

### **General duties in relation to equipment**

NHS Highland have a register that includes all equipment that could affect the dose. The register also records the planned replacement date for all equipment.

There is a quality assurance programme in place with testing schedules for all equipment involved in Nuclear Medicine and is based upon manufacturer recommendations, national guidelines and MPE advice (considering the function, workload, and age of equipment). All staff who conduct quality assurance have been trained to do so. There is clear guidance on the quality assurance required for each piece of equipment in the employer's procedures. The guidance is very clear and detailed. It includes the frequency and types of

checks, the parameters and calibration equipment to be used. For example, Co57 plate as part of the flood test.

The results of quality assurance checks are recorded against the tolerance levels. All staff indicated that if the quality assurance is out-with tolerance levels, the quality assurance check is repeated. If it continues to be out-with tolerance, the equipment is removed from use and the MPE is informed. All staff we spoke with advised that they undertake quality assurance checks following a visit from an engineer.

The employer's procedure also includes the process when handing over the equipment to a maintenance contractor and the action to be taken before equipment is put back into use.

### **Clinical audit**

An IR(ME)R compliance audit is conducted annually of 100 randomly selected referral cards and administration checklists from scans which took place over a 12-month period. The purpose of the audit was to determine compliance with IR(ME)R 17. Referrals for most types of nuclear medicine test were included in the 2023 audit. This audit considered two aspects, the information on the accepted referral cards, completed by the referrer, and the administration checklists filled out by operators in Nuclear Medicine. The audit provided key findings and identified areas of improvement.

The clinical audit is also a quality improvement process that is central to patient care and involves the review of the delivery of healthcare to ensure that best practice is being carried out. Lead by the head of nuclear medicine and the nuclear medicine consultant, NHS Highland undertake clinical audits across different specialisms. There is evidence that the breast surgeons review the use of Tc99m- and the identification of hot nodes and the link to clinical outcomes.

### **What needs to improve**

NHS Highland undertake a variety of clinical audits across different directorates. However, outcomes or a summary of audit results from outside the Nuclear Medicine Section are not being shared more widely. The results should be shared with the IR(ME)R lead or alternative governance to provide additional assurance on the implementation of IR(ME)R throughout NHS Highland.

## Recommendation e

- It is recommended that the results of clinical audits outside the Nuclear Medicine Section are shared with the IR(ME)R lead or alternative governance groups to provide further assurance on the implementation of IR(ME)R.

### Accidental or unintended exposure

All staff we spoke with are fully aware of the local protocols for recording and reporting any near misses or incidents. The staff confirmed they are confident to report any instances. Incidents are investigated by the departmental staff with support from the MPE. Staff confirmed learning from incidents was cascaded at a variety of forums. The MPEs are familiar with the need to report incidents that meet the statutory notification guidance. At the nuclear medicine service meetings, incidents are a standing agenda item. If an incident occurs, the patient is informed at the time of the incident or by the referrer at a later date.

### What needs to improve

Following the recording of an incident on DATIX which IR(ME)R applies, the first stage of an investigation of a radiation incident is undertaken by a radiation protection advisor. The MPE will be involved in making the radiation dose assessment. The final decision on reporting will be undertaken in line with the EPs by a radiation protection advisor. As the incident relates to IR(ME)R the nuclear medicine MPE is required to be involved in all stages of the investigation. The MPE is central to the review of incidents and the subsequent investigations both at the initial and longer investigation stages as they contribute to the incident analysis.

### Requirement 2

- NHS Highland must include the medical physics expert in the analysis of events involving, or potentially involving, accidental or unintended exposures. (Reg 14(3)(f))



## Results

Domain 6: Relationships	Domain 7: Quality Control
<b>Key questions we ask:</b> <i>What difference has the service made?</i> <i>What has the service learned?</i>	

### Our findings

NHS Highland have produced a variety of information leaflets and an information mini poster (NM-PR3) for patients that have been referred to the nuclear medicine department.

#### Risk benefit conversations

Risk benefit information is given to patients in a leaflet, and this is sent to the patient before attending their appointment. The leaflet includes basic information about exposure to radiation and invites patients to contact the department if they have any concerns or queries.

Information is also available for staff to contextualize the radiation dose in comparison to the equivalent background radiation dose in years and months when talking to patients. There is also a specific information sheet for staff to support risk benefit conversations with patients attending for a lung ventilation and perfusion scan.

#### Making enquiries of individuals who could be pregnant

There are clear procedures and staff awareness for the checking of pregnancy status before exposure to nuclear medicine (establishing whether patients of childbearing potential are or may be pregnant or breast-feeding). Patients are provided with written information before the imaging is carried out. This includes the need to advise the department if the patient is or could be pregnant or is breast feeding. All staff we spoke with advised that all female patients of childbearing age are asked to confirm their pregnancy status. Those who are not pregnant will be asked to sign a form to confirm this. If a patient is pregnant, or there is potential that they are, then the IR(ME)R practitioner will decide if the exposure should proceed.

#### What needs to improve

The current practice of enquiring of individuals of childbearing potential to establish whether the individual is or may be pregnant or breastfeeding does not include a mechanism to include transgender, non-binary and intersex patients.

NHS Highland require to review the current practice for making enquiries of individuals of childbearing potential to establish whether the individual is or may be pregnant or breast feeding and use inclusive language in employer's policies and procedures reducing the potential for unintentional exposure of a fetus.

### **Recommendation f**

- NHS Highland should use inclusive language in the employer's procedures and practice when enquiring of individuals of childbearing potential to reduce the potential for unintentional exposure of a fetus.

### **Carers and comforters' procedures**

Staff are clear on the procedures for carers and comforters potentially affected by a patient's nuclear medicine exposure. Risk benefit information is provided to carers and comforters. This includes the risks to themselves and advice on reducing their risk of exposure. The appointment letter for patients undergoing therapy exposures also includes the risks to carers and comforters.

## Appendix 1 – About our inspections

### Our approach

Healthcare Improvement Scotland has a statutory responsibility to provide public assurance about the quality and safety of healthcare through its inspection activity.

The quality assurance system and the quality assurance framework together allows us to provide external assurance of the quality of healthcare provided in Scotland.

- **The quality assurance system** brings a consistency to our quality assurance activity by basing all our inspections and reviews on a set of fundamental principles and a common quality assurance framework.
- **Our quality assurance framework** has been aligned to the Scottish Government's *Health and Social Care Standards: My support, my life* (June 2017). These standards apply to the NHS, as well as independent services registered with Healthcare Improvement Scotland. They set out what anyone should expect when using health, social care or social work services.

We have aligned the Ionising Radiation (Medical Exposure) Regulations (IR(ME)R) 2017 to the quality assurance framework.

Further information about the framework can also be found on our website at: [The Quality Assurance System \(healthcareimprovementscotland.org\)](https://www.healthcareimprovementscotland.org)

### How we inspect services that use ionising radiation for medical exposure

The focus of our inspections is to ensure each service is implementing IR(ME)R 2017. Therefore, we only evaluate the service against quality indicators that align to the regulations.

### What we look at

- how the service complies with its legal obligations under IR(ME)R 2017 and addresses the radiation protection of persons undergoing medical exposures, and
- how well services are led, managed and delivered.

After our inspections, we publish a report on how well a service is complying with IR(ME)R and its performance against the Healthcare Improvement Scotland quality assurance framework.

You can read and download this document from our website.

We are happy to consider requests for other languages or formats. Please contact our Equality and Diversity Advisor on 0141 225 6999 or email [his.contactpublicinvolvement@nhs.scot](mailto:his.contactpublicinvolvement@nhs.scot)

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