

Announced Inspection Report: Ionising Radiation (Medical Exposure) Regulations

Service: Aberdeen Royal Infirmary, Aberdeen

Service provider: NHS Grampian

29-30 November 2023

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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 quality assurance 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 Aberdeen Royal Infirmary, Aberdeen, on Wednesday November 29 and Thursday 30. We spoke with staff, including the medical physics experts, radiologists, endocrinologist and technologists. Aberdeen Royal Infirmary provides iodine therapy and diagnostic nuclear medicine.

The inspection team was made up of two inspectors.

What action we expect NHS Grampian to take after our inspection

The actions we expect the NHS board 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 and where failure to do so will not directly result in enforcement.

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

Direction	
Requirements	
1	NHS Grampian must ensure that there is an assurance that referrals from other NHS Boards are done so by appropriately entitled, registered healthcare providers, working within their scope of practice. (see page 8). <i>Regulation 17 Ionising Radiation (Medical Exposure) Regulations 2017</i>
Recommendation	
a	NHS Grampian should consider accessing specialist NM REALM meetings in a neighbouring board (page 8).
b	NHS Grampian should consider auditing the radiopharmaceutical activity level at the time of SLNB surgery (page 9).

Implementation and delivery	
Requirement	
2	NHS Grampian should ensure that the medical physics experts who authorise under protocol have clear justification criteria that they are using to authorise, including the specific referral specialism (see page 12). <i>Regulation 17 Ionising Radiation (Medical Exposure) Regulations 2017</i>
Recommendation	
c	NHS Grampian should update the employer's procedures to clearly document the quality assurance programme and the frequency and purpose of clinical audit (see page 10).
d	NHS Grampian should consider workforce planning to ensure an adequate provision of specialist advice from a Medical Physics Expert (MPE) to safely deliver nuclear medicine (see page 14).

An improvement action plan has been developed by the NHS board and is available on the Healthcare Improvement Scotland website.
https://www.healthcareimprovementscotland.org/our_work/inspecting_and_regulating_care/ionising_radiation_regulation.aspx

NHS Grampian must address the 2 requirements and 3 recommendations and make the necessary improvements as a matter of priority.

We would like to thank all staff at Aberdeen Royal Infirmary for their assistance during the inspection.

2 What we found during our inspection

Direction

This is where we report on how clear the service's vision and purpose are and how supportive its leadership and culture is.

Domain 1: Clear vision and purpose	Domain 2: Leadership and culture
Key questions we ask: <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

We saw excellent demonstration of skills and knowledge in nuclear medicine and a good culture, with motivated staff and good safety culture. NHS Grampian has a positive approach to optimisation, and has delivered tangible improvements in dose reduction in CT.

Entitlement

NHS Grampian's Employer's procedure N1 (Entitlement) outlines the process for entitlement across the NHS board. The policy cross refers to the grids NHS Grampian use to list competencies against which duty holders will be assessed. These are comprehensive documents which demonstrate competence in the activities undertaken by all staff in NM.

The policy also clearly outlines who will entitle staff to act as a referrer, practitioner or operator. They are all issued a written record of their scope of practice.

The Administration of Radioactive Substances Advisory Committee (ARSAC) licence holders ensure they are regularly performing the tasks as detailed on their licence and entitled to perform. They also have access to ongoing continuing professional development to maintain their skills.

What needs to improve

NHS Grampian accept referrals from multi-disciplinary team meetings in neighbouring NHS Boards and the Islands. The level 1 procedure details that NHS consultants employed by other boards within Scotland can refer according to the referral entitlement within their board. Referral are made by the consultant who will complete a NHS Grampian referral template. There is an assumption that the referrer is registered healthcare providers appropriately entitled by their NHS Board and is working within their scope of practice.

(requirement 1).

The ARSAC licence holders would benefit from access to specialist radiology events and learning meeting (REALM) meetings for NM to ensure that they can reflect on practice and share learning.

Recommendation a

- NHS Grampian should consider accessing specialist NM REALM meetings in a neighbouring board.

Requirement 1

- NHS Grampian must ensure that there is an assurance that referrals from other NHS Boards are done so by appropriately entitled, registered healthcare providers, working within their scope of practice.

Safety culture

We saw a highly motivated and enthusiastic team who spoke of a supportive and positive safety culture. All staff told us that although incidents have been very rare the culture is open, and the focus would be on learning from errors and sharing learning across the team. We saw evidence that near misses and incidents are clearly recorded and investigated to promote learning.

NHS Grampian order individual vials of the radiopharmaceuticals required for the patients attending the next day. Some of the radiopharmaceuticals are manufactured in the in house pharmacy. Comprehensive procedures are in place for the storage and dispensing of radiopharmaceuticals. Each individual vial is labelled for each patient. Accompanying each vial is a document, Form N7.1, that details the radio pharmaceutical, activity at the time of production, dispensing and at use, who administered the radiopharmaceutical and the amount. Staff were confident with how to do the calibration, and about the activity tolerance levels of each radiopharmaceutical before administration. Staff were clear on when to use the copper shielding when measuring the activity of different radiopharmaceuticals. When calculating the amount to be administered staff calculate volume based on the prescription and rate of decay. They told us they would not proceed if the activity tolerance level had fallen out with these.

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

Optimisation

NHS Grampian's multidisciplinary dose optimisation group has delivered

tangible improvements in nuclear medicine. The dose reference level (DRL) DRL for the CT aspect of NM has been reduced below the national average. Furthermore, changes have been made which resulted in an improvement in the quality of images in brain scans, and therefore improved confidence in reporting.

What needs to improve

The administration of the radiopharmaceutical prior to Sentinel Lymph Node Biopsy (SLNB) is based on time. NHS Grampian do not carry out an audit to check the actual activity at the time of surgery is correct. There is a reliance on the surgeon sharing highlighting any issues identifying the node.

Recommendation b

- NHS Grampian should consider auditing the radiopharmaceutical activity level at the time of SLNB surgery.

Implementation and delivery

This is where we report on how well the service engages its stakeholders and also how it manages and improves performance.

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

Our findings

NHS Grampian has clear referral guidelines and audited referral criteria to ensure compliance with the guidelines. NHS Grampian has a comprehensive set of protocols accessible to all nuclear medicine staff.

Employer's procedures

NHS Grampian has a comprehensive set of employer's procedures (EPs) for nuclear medicine. The radiation safety committee reviews the level 1 EPs and the departmental responsible person reviews the level 2 EPs. Changes to the EPs are communicated to the staff at meetings and by email.

What needs to improve

The EPs do not capture all of the work undertaken in NHS Grampian. We saw evidence that a Quality Assurance programme is embedded and complied with, however, this is not reflected in the procedure. Similarly, a clinical audit is regularly conducted, but the frequency and focus of the audits is not reflected in the procedure. Finally, the employer's procedures do not clearly advise that staff who are authorising under protocol should use the justification function on the radiology information system (RIS) to demonstrate that the ARSAC license holder is accountable and note that they justified under protocol.

Recommendation c

- NHS Grampian should update the employer's procedures to record the Quality Assurance programme, the frequency and purpose of clinical audit and the accountability of the ARSAC licence holder in justification under protocol.

Training

We saw up-to-date training records in place. These included training on all the equipment they use, including the calibrators. Staff who had been deemed experts and competent to train others had training records in place which

reflected this.

The technologists training records were very comprehensive and demonstrated up to date competence in line with their scope of practice. The training records for radiologists is an e-portfolio that provides assurance of competency to the lead for NM.

In NHS Grampian a training record for the relevant aspects of the breast surgeons role in SNLB is easily accessible in the nuclear medicine department. This ensures the head of department has assurance about competence of all relevant operators and practitioners.

Referral

Referrals are received electronically through an online portal or by email. For all diagnostic nuclear medicine procedures and PET investigations, medical referrers are entitled in an NHS Grampian level 1 procedure (EP2) which is available on the Radiation Protection intranet page.

NHS Grampian has clear and comprehensive referral criteria for nuclear medicine. These have been developed with relevant clinical specialists. In addition to the referrals that meet the strict criteria NHS Grampian accept referrals for 'problem solving cases' where the use of NM diagnostic scans aims to provide clinical information to support a diagnosis. These referrals are subject to an audit, which is supervised by the radiologist to explore whether all such referrals that were accepted had therapeutic value.

The radiology staff told us that if a referral does not have sufficient clinical information to justify the exposure, it would be rejected. If there was a need for a small amount of additional information then the radiologist contacts the referrer, seeks the additional information and documents this on RIS in the justification box. Emails relating to these referrals are also kept for auditing.

There is a clear referral process for Iodine 131 (¹³¹I) treatment. A standard document is in place for endocrinologist to make a referral that includes the need for clear clinical indicators for treatment. The document supports consistency of referrals for ¹³¹I treatment. The patient pathway to ¹³¹I therapy can be the result of up to 18 months of treatment before a patient receives ¹³¹I which is a definitive treatment. The clinical information and history are considered to support the decision to refer a patient.

Justification

NHS Grampian undertake a wide variety of diagnostic Nuclear Medicine and PET/CT exposures, including sentinel node localisation. ¹³¹I and Ra-223 therapies are also performed.

NHS Grampian has comprehensive justification protocols, which are regularly

reviewed and updated. We heard that this includes steps to reduce the risk of radiation and ensure that lower dose options are considered/completed before nuclear medicine. NHS Grampian have a comprehensive flow chart to support the justification process, and clearly identifies the steps to be taken if a referral cannot be justified.

What needs to improve

NHS Grampian accept referrals for PET CT from a multi-disciplinary meeting. The PET radiologist is part of this review meeting. Referrals received from these reviews can be justified by the physicist however, the guidelines did not document the criteria they use to authorise a referral. The physicists performing this authorisation has to use the justification box on RIS as there is no authorisation function or alternative method.

Requirement 2

NHS Grampian should ensure that the medical physics experts who authorise under protocol have clear justification criteria that they are using to authorise, including the specific referral specialism.

Records

We looked at the information recorded on the radiography information system and noted that staff had documented:

- the correct patient information
- details of the referrer and operator
- identification checks
- pregnancy checks
- the recorded dose
- the radiopharmaceutical
- justification, and
- clinical evaluation.

The radiology information system (RIS) allows staff to record information specific to nuclear medicine, including the activity level of the radiopharmaceutical as its 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. Consistent with the employers procedure N5 Patient Identification, we were told 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 to support any barriers to communication.

Expert advice

NHS Grampian has an appointment letter for the medical physics experts and they are registered on RPA2000.

The medical physics experts provide:

- input into the development of protocols and employer's procedures
- scientific support
- advice for carers and comforters
- support with clinical audit
- local dose reference levels
- investigations of quality assurance is out with tolerance levels
- supporting software solutions
- optimisation and dose optimisation groups, and
- commissioning and acceptance testing of new equipment

They also provide support on the analysis of incidents and advice on whether an incident requires to be reported to Healthcare Improvement Scotland.

What needs to improve

NHS Grampian has conducted a calculation of the medical physics expert requirement using the calculator published in the British Journal of Radiology. The result of the calculation indicated that the current provision of 2 WTE medical physics experts is not adequate. 2.5 WTE is required for the current service, and this will increase to 3 WTE with the planned introduction of complex therapy services, such as Lutetium-177 Dotatate (recommendation d).

Recommendation d

- NHS Grampian should consider workforce planning to ensure an adequate provision of specialist advice from medical physics experts to safely deliver nuclear medicine.

General duties in relation to equipment

The quality assurance (QA) of all equipment is regularly conducted. All staff who conduct quality assurance have been trained to do so. There is also a quality control log to support the implementation of quality assurance of each piece of equipment detailing the list of equipment and frequency of QA checks.

The results of quality assurance checks are recorded along with the activity tolerance levels. All staff told us 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 Medical Physics Expert (MPE) is informed. All staff we spoke with advised that they undertake quality assurance checks following a visit from an engineer.

Dose reference levels (DRLs) are displayed in the dispensing room. Most are based on the ARSAC baseline levels. Local optimisation has led to local DRLs for some exposures. NHS Grampian use an auto injector for the administration of fluorodeoxyglucose (FDG) used in PET scans. The FDG is manufactured on site in a multi dose vial. The auto injector is linked to the RIS system and will administer the required dose based on the patient information, which includes their weight and height. The correct volume is then be calculated based on the activity level at the time of administration.

Clinical audit

NHS Grampian conduct regular clinical audits. A comprehensive audit of compliance with IR(ME)R is conducted and the results shared with the radiation safety committee. Additionally, audits are conducted which are based on operational or clinical need. There have been 6 audits completed this year. A recent example is that a significant increase in red cell mass studies was identified. An audit was conducted to explore this and ensure that all referrals were within the clinical guidelines.

NHS Grampian has recently introduced a PET REALM meeting that provides an opportunity for medical staff to review scans and clinical reporting and learn from their colleagues. As mentioned earlier in the report, NHS Grampian do not have a NM REALM meeting.

Accidental or unintended exposure

All staff we spoke with fully understood the significant accidental or unintended exposures (SAUE) guidance and the local protocols for recording and reporting any near misses or incidents. We saw evidence that NHS Grampian records all near misses and incidents. This is a useful approach to monitoring incidents and promoting learning from them.

Results

This is where we report on what difference the service has made and what it has learned.

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

Our findings

NHS Grampian has a robust approach to risk benefit. Comprehensive written information is shared with patients, carers and comforters.

Risk benefit conversations

NHS Grampian have a comprehensive employers procedure outlining the risk and benefit information to be shared with the patient (EP2 Patient Information). A copy of the Nuclear Medicine 'Your Test and You' poster is provided to all in-patients and written information is given to outpatients, which is specific to their appointment. We saw the letter sent to patients attending for radioiodine therapy. This is very detailed and comprehensive.

Risk and benefit information for carers and relatives is included in the comprehensive information shared with patients

Making enquiries of individuals who could be pregnant

All staff we spoke with told us that all patients of child bearing age will be asked to confirm their pregnancy status. Those who are not pregnant are asked to sign a form to confirm and this is then scanned on to the RIS system. If a patient is unsure about their pregnancy status they will be asked to complete a pregnancy test. All patients who are attending for iodine therapy are asked to take a pregnancy test to ensure iodine therapy is not provided to anyone who is pregnant.

If a patient is pregnant and the referrer has deemed the exposure essential – the technologist would query this and seek assurance prior to proceeding.

Carers and comforters procedures

EP21 (Carers and Comforters in Nuclear Medicine) provides clear guidance about the justification of exposure of carers and comforters. This includes clear dose limits - 1 mSv per annum as a result of diagnostic Nuclear Medicine procedures and 5 mSv per annum as a result of therapy Nuclear Medicine

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procedures. The employers procedure also states that the operator carrying out the exposure should direct the carer to the information on the “Your Test and You” posters within the Nuclear Medicine and PET departments.

- No requirements
- No recommendations.

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 of 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 framework.

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

We want to find out:

- 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.

Complaints

If you would like to raise a concern or complaint about an independent healthcare service, you can complain directly to us at any time. However, we do suggest you contact the service directly in the first instance.

Our contact details are:

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