Healthcare Improvement Scotland | Inspections and reviews
To drive improvement

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

Service: Gartnavel Hospital, Glasgow

Service Provider: NHS Greater Glasgow and Clyde

26 – 27 March 2024

NHS SCOTLAND

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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 allow 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 services are led, managed, and delivered.

About our inspection

We carried out an announced inspection to Gartnavel General Hospital on Tuesday 26 and Wednesday 27 of March 2024. We spoke with the following staff: Nuclear Medicine Physicians, IR(ME)R Lead, Head of Nuclear Medicine, Lead for Molecular Radiotherapy, Lead for PET-CT, Lead Technologists, Breast Surgeon, Endocrinologist and Clinical Scientists. This was our first inspection to this service.

The nuclear medicine department consists of diagnostic imaging of patients using radioactive materials (radiopharmaceuticals) and radiotherapy. There were 8600 procedures carried out, using a variety of diagnostic and therapeutic procedures. The Gartnavel General Hospital has 2x PET-CT,1xSPECT-CT, and a SPECT. NHC GGC also provide regional and national specialist services such as Selective Internal radiation therapy. The inspection team was made up of one inspector.

What action we expect NHS Greater Glasgow & Clyde to take after our inspection

The actions that Healthcare Improvement Scotland expects NHS Greater Glasgow & Clyde to take, are described as 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 two requirements and two recommendations. The requirements are linked to compliance with IR(ME)R 2017.

Direction	
Requirements	
1	NHS Greater Glasgow and Clyde must ensure that all staff who act as a referrer, operator or practitioner are provided with confirmation of their entitlement to confirm what duties they can perform. An individual entitlement letter or equivalent requires to be provided to staff who act in these roles. (see page 7). *Regulation 6(1)(a)* *Ionising Radiation (Medical Exposure) Regulations 2017*

Implementation and delivery	
Requirements	
2	NHS Greater Glasgow and Clyde must ensure all Directorates that undertake nuclear medicine activities provide information to the IR(M)ER lead to demonstrate compliance with the Ionising Radiation (Medical Exposure) Regulations 2017 in line with the Employer's EP-Guidance-006. (see page 9). *Regulation 6(2)* *Ionising Radiation (Medical Exposure) Regulations 2017*
Recommendations	
a	NHS Greater Glasgow and Clyde should continually monitor the medical physics expert workforce, consider the potential impact on the service provision, and mitigate any risk to service provision that are identified. (see page 13).
b	It is recommended that the results of clinical audits are shared with the IR(ME)R lead through the IR(ME)R governance groups to provide further assurance on the implementation of IR(ME)R. (see page 14)

An improvement action plan has been developed by NHS Greater Glasgow and Clyde and is available on the Healthcare Improvement Scotland website. https://www.healthcareimprovementscotland.scot/inspections-reviews-and-regulation/ionising-radiation-medical-exposure-regulations-irmer/

NHS Greater Glasgow and Clyde must address the requirements and make the necessary improvements as a matter of priority. We would like to thank all staff at Gartnavel General Hospital for their assistance during the inspection.

2 What we found during our inspection

Direction

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

Our findings

During the inspection staff demonstrated a strong understanding, and implementation of IR(ME)R in the nuclear medicine services at Gartnavel Hospital. This included a positive culture, with motivated staff and safety values.

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, employers' procedures, audit and governance arrangements in place.

NHS Greater and Glasgow and Clyde (NHS GGC) have a clear governance structure in place for the management of IR(ME)R and medical exposure to ionising radiation. The IR(ME)R lead chairs the radiation safety committee and the IR(ME)R working party. These committees provide the governance for the implementation of IR(ME)R and can escalate matters of concern to acute clinical governance groups and onto the Chief Executive as required. NHS GGC have operational groups for nuclear medicine that interface with the radiation safety committee and IR(ME)R working party. In addition, each nuclear medicine radiology sector undertakes an annual audit, EP NM-GGC-PROC-008, of employer's procedure compliance as a mechanism to demonstrate regulatory compliance and highlight any areas of improvement.

There are a variety of forums where IR(ME)R related issues can be discussed, such as weekly leads group and medical physics meetings. All staff we spoke with told us about a supportive and positive safety culture in place. This included an open culture for reporting incidents, and a focus on learning from errors and sharing learning across the team.

Entitlement

NHS GGC employer's procedure on entitlement clearly outline the process of entitlement, showing lines of accountability and delegation of tasks across the Board.

Documentation is in place that identifies who is a referrer, practitioner, and operator. There is clear documentation to demonstrate the scope of practice of all staff working in nuclear medicine. There are documents that demonstrate competence in the different activities undertaken by all staff in nuclear medicine. For example, a register that details on who can act as a practitioner or operator for renal, cardiac and brain imaging. The entitlement is clearly linked to training, skills, and knowledge.

NHS GGC have the appropriate employers and practitioners Administration of Radioactive Substances Advisory Committee (ARSAC) licences in place. There are procedures to ensure practitioner licences are up to date and align to the employer's licence for each site and there is a spreadsheet that matches both licenses. In addition, all ARSAC licences are available on the document management system and every nuclear medicine procedure is linked to an ARSAC licence.

What needs to improve

Individual entitlement documentation is available for non-medical staff in the nuclear medicine department. Clinician entitlement as an operator is detailed in the EP NM-GGC-FORM- 20. However, clinicians acting as either a referrer, operator or practitioner have not been provided with an individual entitlement letter or equivalent. NHS GGC need to have a system in place to appropriately entitle those who act as a referrer, operator, or practitioner. (requirement 1)

Requirement 1

- NHS Greater Glasgow and Clyde must ensure that all staff who act as a referrer, operator or practitioner are provided with confirmation of their entitled to confirm what duties they can perform. An individual entitlement letter or equivalent requires to be provided to staff who act in those roles. Regulation 6(1)(a).

Optimisation

Optimisation involves the implementing of procedures and techniques to reduce exposures as low as reasonably practicable. NHS GGC have written protocols in place for all standard procedures which are specific to each type of equipment. Protocols include exposure factors for each routine examination.

NHS GGC has a multidisciplinary optimisation group for nuclear medicine and positron emission tomography. All therapeutic and diagnostic doses are in line with the ARSAC guidance notes. There is a working group to review and optimise the acquisition protocols which include other factors such as patient set up. An example is the CT scanner component of the PET-CT has been optimised to produce a lower dose than a standalone CT that is used for diagnostic imaging.

Oncology services have previously undertaken a clinical outcome audit and as a result, have managed to reduce the therapy dose required in some procedures.

As part of the planning process for selective internal radiotherapy, patients undergo a procedure using a lower dose of Tc-99m to review where potentially the radioactive material could spread. Using this information the interventional radiologist will undertake a procedure to ensure that delivery of the high dose Y^{90} is limited to the area to be treated. Selective internal radiotherapy treatment is optimised for the patient and personalised dosimetry is carried out for each treatment, reducing the dose to organs at risk.

Implementation and delivery

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

Our findings

NHS GGC has a clear and comprehensive set of employer's procedures (EP's) accessible to all staff to support the safe delivery of nuclear medicine services. NHS GGC clearly demonstrated the implementation of the employer procedures for the delivery of nuclear medicine services. Staff have a clear understanding of their roles and responsibilities and scope of practice.

Employer's procedures

NHS GGC have level 1 employer's procedures (EPs) that cover all modalities and a comprehensive set of level 2 and 3 EPs for nuclear medicine, these are stored on a document management system and is accessible to all staff. There are clear guidelines on who can update and amend EPs, which are reviewed at a minimum of every 3 years.

The radiology departments across NHS GGC undertake an annual audit of employer's procedure compliance as a mechanism to demonstrate regulatory compliance and identify areas of improvement.

What needs to improve

Currently only departments within the Diagnostics directorate undertake an annual audit of employer's procedure compliance as a mechanism to demonstrate regulatory compliance. It has been identified that this needs to include all Directorates that use nuclear medicine.

Requirement 2

- NHS Greater Glasgow and Clyde must ensure all Directorates that undertake nuclear medicine activities provide information to the IR(M)ER lead are able to demonstrate compliance with the employer's procedure Ionising Radiation (Medical Exposure) Regulations 2017 in line with the employer's procedure EP-Guidance-006. (Reg 6(2)

Training

NHS GGC have a clear system for training, development, and assessment of competencies for staff working in nuclear medicine. We observed up-to-date training records in place which includes equipment specific training, the use of calibrators and quality assurance procedures. Staff who had been deemed competent to train others had training records in place which reflect this. Training also includes equipment operated by medical staff in the surgical teams.

The technologists training records were comprehensive and demonstrated up-to-date competence in line with their scope of practice. Medical staff training and competence is a part of their annual appraisal and annual job planning meeting. In addition, all medics undertake medical revalidation every 5 years.

The staff training, qualifications and knowledge are linked to their entitlement and scope of practice.

Referral

NHS GGC have clear and comprehensive referral criteria for nuclear medicine and have in place referral guidelines in the employer's procedures, which have been developed with relevant clinical specialists. In addition, all staff have access to I-Refer.

Referrals are received electronically through an online portal which links to the radiology information systems. Referrals will only be accepted from staff groups who are entitled to refer. The referral system clearly identifies who has made the referral, allowing checks to be made that the referrer is entitled to refer. Breast surgeons use hard copy referral forms so they can annotate the injection site for Tc-99m. These referrals are scanned onto the radiology information system (RIS). Medical referrers are entitled to refer for all diagnostic nuclear medicine procedures and PET-CT investigations.

The ARSAC licence holder advised that if a referral does not have sufficient clinical information to justify the exposure, they would contact the referrer for further information. If sufficient information is subsequently provided the ARSAC licence holder or radiologist (under protocol) would update the events comment box on RIS and the referral would be approved.

If the clinical information does not warrant a referral the request would be rejected, and the referrer notified by email with the reason why.

There is a clear referral process for Iodine 131 (I131) treatment. A standard document in place for the endocrinologist to make a referral, this includes the need for clear clinical indicators for treatment such as relapsing Graves' disease.

NHS GGC are part of national (Scotland) and regional services for example, in oncology for thyroid cancer, I^{131} treatment and neuroendocrine tumours for Lu^{177}treatment. There are clear referral criteria in place for the treatment of patients. The referral from the national and regional groups is discussed by a multidisciplinary team which has access to all the relevant clinical information and imaging from patients to support a referral. The referral will be undertaken by a consultant who entitled to refer to NHS GGC. NHS GGC is also a part of a UK Multidisciplinary Team (MDT) for paediatric services for neuroblastoma. This national MDT operates in the same way as other the Scottish based national and regional MDT groups.

NHS GGC operates a national service for selective internal radiation therapy. A national MDT has access to all the relevant clinical information and imaging from patients to support a referral based on the clinical indicators. This is a highly specialist service, that currently carries out 3 procedures a year and has clear specialist referral criteria. The referral is made by a consultant entitled by NHS GGC.

Justification

NHS GGC undertake a variety of diagnostic and therapy exposures and uses a range of radioisotopes and routinely use, $Gallium^{68}$, $Yttrium^{90}$, $Iodine^{123}$, $Iodine^{131}$, $Radium^{223}$, Fluorine-18, $Lutetium^{177}$ and $Technetium^{99}$.

All therapy justifications are undertaken by ARSAC licence holders. Justification of diagnostic procedures are undertaken by an ARSAC licence holder or by operators who may be a radiologist, physicist or technologist who authorise under protocol. NHS GGC has comprehensive justification protocols. These 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. Authorisation protocols have all been issued by a named ARSAC licence holder. The protocol guidelines provide clear guidance for the radiologist to enable them to authorise exposures which meet the required criteria. Justification of exposures to carers and comforters, and for the CT component of SPECT-CT and PET-CT may be undertaken by appropriately entitled clinical scientists.

Justification for therapy treatments is undertaken by the specialists, consultant nuclear medicine physicians 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 all the relevant clinical history as part of the justification process. When proceeding with I^{131} therapy the endocrinologist will see that measures are taken to ensure that the patient stops any thyroid blockers to ensure the I^{131} 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^{131} treatment will not be effective.

Imaging and treatment

The day before a patient attends the department, their referral information is reviewed. This acts as a secondary check on the information in the referral and reviews the protocol selected for the procedure.

NHS GGC have a guidance document on the acquisition protocols for each type of examination. NHS GGC order individual vials of radiopharmaceuticals required for the patients attending the next day. Some of the radiopharmaceuticals are manufactured in the in-house radiopharmacy and delivered to the department in individual vials or a multi vial for FDG^{18}. Procedures are in place for the storage and dispensing of radiopharmaceuticals and dose reference levels (DRLs) are displayed in the dispensing room.

Staff demonstrated a good understanding of the EPs and the procedures for ensuring that the correct radiopharmaceutical and activity were linked to individual patients.

Operators must follow local guidelines on administration, which requires recording pre-administration activity in the syringe and residual syringe activity which provides the administered activity which is recorded in the RIS. Staff are confident on how to undertake calibration and review activity tolerance levels of each radiopharmaceutical. When administering a radiopharmaceutical there are two staff members present in the department.

The administration of radiopharmaceutical is weight based for all paediatric patients. 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 were 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 that the 'hot spot' would be clearly marked on the patients notes to ensure this would not affect the clinical evaluation.

NHS GGC use an auto injector for the administration of fluorodeoxyglucose (FDG) used in PET-CT scans. The FDG is manufactured on site in a multi dose vial. The auto injector is linked to the RIS and will administer the required dose based on the patient information, which includes their weight and height. The correct volume is then calculated based on the activity level at the time of administration.

Clinical evaluations

Clinical evaluations are undertaken by ARSAC licence holders, radiologists, clinical physicists and clinical technologists depending on the type of examination and reports are uploaded to the RIS. Double reporting is routinely undertaken for all paediatric and epilepsy patients. Double reporting is also undertaken for complex cases in PET-CT and for a variety of cancer patients.

Records

The RIS is used to record the referral through to the clinical evaluation.

We viewed information recorded on the RIS and it included the following:

- the correct patient information
- 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 GGC have a medical physics team in place for nuclear medicine. The medical physics expert role is to provide 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.

The medical physics expert also provides advice on whether an incident requires to be reported to Healthcare Improvement Scotland.

What needs to improve

NHS GGC have conducted a calculation of the medical physics expert requirement using the calculator published by the Institute of Physics and Engineering in Medicine

(IPEM). The result of the calculation indicated that the current provision of 16.5 WTE medical physics experts was below the recommended levels of 24 WTE from IPEM. NHS GGC believe that based on the type and scope of work undertaken by the medical physics team, a more realistic number would be 20.5 WTE. The information on the MPE staffing numbers have been escalated by the IR(ME)R lead, to the executive team.

Recommendation a

- NHS Greater Glasgow and Clyde should continually monitor the medical physics expert workforce, consider the potential impact on the service provision and mitigate any risk to service provision that are identified.

General duties in relation to equipment

NHS GGC have an equipment register that includes all equipment that could affect the dose. There is a protocol in place for updating the register so that it is kept up to date. The register also includes 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 (taking into account the function, workload and age of equipment). All staff who conduct quality assurance have been trained to do so. There is guidance on the quality assurance required for each piece of equipment.

The results of quality assurance checks are recorded against the activity 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 Medical Physics Expert (MPE) is informed. All staff we spoke with advised that they undertake quality assurance checks following a visit from an engineer. Staff use a Co-57 plate as part of their quality assurance checks.

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

Clinical audit

Clinical audit is 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. NHS GGC undertake clinical audits across different specialisms. Audits have been undertaken in the follow areas:

- PSMA PET-CT scans
- GP referral for bone scans and the impact on waiting times
- In endocrinology services to monitor the clinical effectives of the therapy treatment
- Oncology services to reduce the therapy dose
- Sentinel lymph noted biopsy node visualisation rates.

What needs to improve

NHS GGC undertake a variety of clinical audits across different Directorates, however outcomes or a summary of audit results are not being shared with the IR(ME)R working party. The results should be shared with the IR(M)ER working part of alternative governance to provide additional assurance on the implementation of IR(ME)R.

Recommendation b

- It is recommended that the results of clinical audits are shared with the IR(ME)R lead through the IR(ME)R 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. All staff we spoke to, confirmed they felt 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 MPE's 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.

Results

Domain 6: Relationships	Domain 7: Quality Control
Key questions we ask: *What difference has the service made?* *What has the service learned?*	

Our findings

Risk benefit conversations

NHS GGC have a comprehensive employer's procedure outlining the risk and benefit information to be shared with the patient. Risk and benefit information for carers and relatives is included in the information shared with patients.

Oncology services have a patient information booklet that provides details on the risks and benefits of the treatments. Patients also have access to an informational DVD from the Butterfly Trust and a nurse specialist is available to offer advice to patients.

What needs to improve

It may be useful to use comparisons to natural background radiations as part of how the information on risk and benefit is communicated to individuals.

Making enquiries of individuals who could be pregnant and breast feeding

All staff we spoke with advised that all patients of childbearing age will be asked to confirm their pregnancy status and if they are breast feeding. Those who are not pregnant are asked to sign a form to confirm and this is then scanned on to the RIS. If a patient is unsure about their pregnancy status, they are 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 this will be clearly indicated on the referral. The ARSAC licence holder can also justify an exposure in the event of false positive results.

If a patient is breastfeeding, they are provided with written confirmation to interrupt or discontinue breastfeeding following administration of the radiopharmaceutical. NHS GGC follow the feeding interruption times for the various radiopharmaceuticals as outlined in the ARSAC notes for guidance.

Carers and comforters procedures

Clear guidelines for staff are in place if a carer or comforter is required to ensure they understand the risk and can provide informed consent. The appointment letter includes the risks to carers and comforters and advice on reducing the risk during an exposure. Local policies provide guidance on the dose a carer or comforter can be exposed to. This is defined for both diagnostic and therapeutic exposures. NHS GGC monitor the doses received by comforters and carers of patients undergoing therapy treatments.

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 allow 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 quality assurance framework.

Further information about the Quality Assurance Framework can also be found on our website at: The Quality Assurance System (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.
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