Healthcare Improvement Scotland | Inspections and reviews
To drive improvement

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

Service: Royal Infirmary of Edinburgh Hospital, Edinburgh

Service Provider: NHS Lothian

11 June – 12 June 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 Royal Infirmary of Edinburgh Hospital, Little France site on Tuesday 11 and Wednesday 12 of June 2024. This was our first inspection to this service.

We spoke with the following staff: associate medical director for acute services, director of imaging, head of nuclear medicine physics, lead medical physics expert, medical physics, principal technologist, consultant oncologist, consultant endocrinologist, consultant breast surgeon and nuclear medicine radiographers.

NHS Lothian have 5 sites with a nuclear medicine service or department however the inspection was focused on the Little France site. Nuclear medicine consists of diagnostic imaging of patients using radioactive materials (radiopharmaceuticals), therapeutic procedures and surgical sentinel lymph node biopsies.

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

What action we expect NHS Lothian to take after our inspection

The actions that Healthcare Improvement Scotland expects NHS Lothian 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 no requirements and no recommendations. The requirements are linked to compliance with IR(ME)R 2017.

Requirements	
	None.
Recommendations	
	None.

We would like to thank all staff who participated in the inspection for their assistance during the inspection.

2 What we found during our inspection

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 inspected at the Royal Infirmary of Edinburgh, Little France site and the Royal Hospital for Children and Young People. This included a positive culture, with motivated staff and safety values. All staff are issued with individual letters of entitlement and are familiar with their scope of practice.

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. This safety culture is demonstrated by the measures in place to ensure the appropriate competence of staff, employer's procedures (EPs), audit and governance arrangements in place.

NHS Lothian have a clear structure in place for the governance of the implementation of the ionising radiation medical exposure regulations. The NHS Lothian radiology IR(ME)R committee (LRIC) meets three to four times a year and reports to the NHS Lothian IR(ME)R board. All modalities and services are represented at one or both groups. Nuclear medicine has a representative covering diagnostic, therapy and sentinel lymph nodes. Information from the IR(ME)R board links into the NHS Lothian radiation safety committee and the medical director as chair.

There are a variety of forums where IR(ME)R related issues can be discussed, such as radiology management meetings and departmental 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.

It was highlighted that once a year there is a service review meeting between the endocrinologist, medical physics representative and the Administration of Radioactive Substances Advisory Committee (ARSAC) licence holders, where they discuss learning from the previous year and reflect on current practices in relation to medical exposure to ionising radiation.

Entitlement

NHS Lothian EPs on entitlement clearly outline the process of entitlement, stating the accountability and delegation of tasks across the NHS 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. Managers who entitle staff are required to undertake an IR(ME)R for managers training session with an MPE. This is conducted over a MS Teams live session, allowing discussion while a PowerPoint presentation is given. Senior managers will entitle responsible managers who can cascade the responsibility for entitlement thereafter in line with the EPs. For example, the lead radiographer will entitle the principal radiographers who then entitle their radiographers. This system is well understood by those involved and appropriate entitlement documents are in place. The entitlement is clearly linked to training, skills, and knowledge. All staff are issued with individual letters of entitlement and are familiar with their scope of practice.

Clinical directors or a responsible manager acting under the authorisation of the clinical director will entitle medical practitioners. We found the appropriate entitlement record in place for the oncologists, endocrinologists and breast surgeons.

NHS Lothian have five site licences and multiple practitioner ARSAC licences. The organisation has a system in place for the management of employer's and practitioner licences. The current procedures, which were recently updated, ensure practitioner licences are up to date and align to the employer's licence for each site. In addition, every nuclear medicine procedure is linked to an ARSAC licence. All ARSAC licences are available on the document management system. NHS Lothian are currently updating their employer's and practitioner's ARSAC licences.

Optimisation

Optimisation involves the implementing of procedures and techniques to reduce exposures as low as reasonably practicable. NHS Lothian 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.

Nuclear medicine is a part of the image optimisation team. Optimisation work has been undertaken on the CT scanner component of the SPECT and PET-CT scanners to improve image quality. The results of the work are reported at the image optimisation team. All therapeutic and diagnostic doses are in line with the ARSAC guidance notes.

Endocrinologists have reduced the administered dose for benign thyroid conditions by 50% where clinically indicated and appropriate to do so. This has been the result of clinical audits undertaken with the support of medical physics that have demonstrated the success of the treatment

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 Lothian has a clear and comprehensive set of EP's accessible to all staff to support the safe delivery of nuclear medicine services. NHS Lothian clearly demonstrated the implementation of the EPs 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 Lothian have level 1 EPs that cover all modalities and a comprehensive set of level 2 and 3 EPs for nuclear medicine. The EPs are stored on an electronic document control system. Level 1 and 2 EPs are available on the NHS Lothian intranet where staff can access them. Level 3 EPs are available to all relevant departmental staff. All EPs have a minimum review period of every two years. Any member of staff can highlight areas of change and request the EPs to be reviewed at any time.

The radiology departments across NHS Lothian undertake an annual audit of the EPs compliance as a mechanism to demonstrate regulatory compliance and identify areas of improvement.

Training

NHS Lothian have a clear system for training, development and assessment of competencies for staff working in nuclear medicine. NHS Lothian have comprehensive training records in place for all staff groups. Training and entitlement records define the competency description and how it will be assessed and evaluated. Training records are held by line managers which aligns to the staff's scope of practice.

We observed up-to-date training records in place which includes equipment specific training, the use of calibrators and quality assurance procedures. Staff who are deemed competent to train others have training records in place which reflect this.

An entitlement spreadsheet records the information on entitlement and scope of practices. It includes details on staff who will are able to supervise and train other staff based on their level of experience and training.

Medical staff training and competence is a part of their annual appraisal and annual job planning meeting. In addition, all medical staff undertake medical revalidation every five years. Training records also included equipment operated by medical staff in the surgical teams.

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

Referral

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

Referrals are predominantly electronic but can also be on paper and email. Referrals are only be accepted from staff groups who are entitled to refer. Referrals clearly identify an individual as a clinician or non-medical referrer. A referral can be made by medical and dental practitioners. Medical referrers are entitled to refer for all diagnostic nuclear medicine procedures and PET-CT investigations. Non-medical referrers can refer on behalf of a consultant for example, PET-CT imaging or as part of their role if entitled to do so.

NHS Lothian EP2 RAD 01 details the mechanism to approve a non-medical referrer. There is a register available that provides information on approved non-medical referrers, their scope of practice and referral protocols. Referrals are required to include the appropriate level of clinical information to be able to justify a request. To support referrals NHS Lothian have detailed imaging protocols in place.

For Ra-223 therapy, a paper booking form is completed as part of the referral. The booking form must contain the appropriate clinical information and consent details. NHS Lothian oncology consultants will also see patients at facilities in NHS Fife and follow the same process.

There is also a standard I-131 therapy referral form, which includes key information to support consistency. This ensures that the referral includes the clinical indicators for the treatment to support the justification process.

Within breast surgery for sentinel lymph nodes the breast surgeon will be the referrer, using the patient administration log.

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

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

There is a clear referral process for Iodine I-131 treatment. A standard document is 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 Lothian are part of regional services and will see patients from other NHS boards. For example, in oncology for thyroid cancer, I-131 therapy treatment NHS Lothian consultants review patients at their Multi-disciplinary Team (MDT) that have been referred by NHS Fife and NHS Borders. There are clear referral criteria and consent processes in place.

Justification

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

All therapy justifications are undertaken by ARSAC licence holders. Justification of diagnostic procedures are undertaken by an ARSAC licence holder or by entitled operators working under a protocol who may be a radiologist or surgeon. NHS Lothian have comprehensive justification protocols in place. 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 also 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. For example, for Ra-223 metastatic castration resistant prostate cancer (mCRPC) the guidelines developed by the oncologist (ARSAC licence holder) provides parameters on the procedures,

clinical indications, exclusions, who can justify the exposure and information on the administered activity.

The consultant radiologists ARSAC licence holder will justify diagnostic examination either electronically or on a printed referral. The ARSAC licence holder will indicate the examination to be undertaken, however the paper form is often not signed. When an ARSAC license holder justifies an examination on paper, this information is then manually entered into the electronic system and the paper referral is securely disposed. NHS Lothian should consider if the primary document used for justifying an examination should be retained and if it should include a signature.

There is a clear referral process for Iodine 131 (I131) treatment. A standard document is in place for the endocrinologist to make a referral that includes the need for clear clinical indicators for treatment. The document supports consistency of referrals for I131 treatment. Thyroid cancer patients requiring I131 are reviewed as part of a multidisciplinary surgical pathway which includes an endocrinologist where the relevant clinical information is shared, and justification can be assessed. The patient pathway to I131 therapy can be the result of up to 18 months of treatment before a patient receives I131 which is a definitive treatment. As part of the justification of I131 therapy treatments for thyrotoxicosis the endocrinologist confirmed they review the clinical history of the patient to ensure that it is the most appropriate treatment option.

Breast surgeons carrying out sentinel lymph node biopsy and will justify their own referrals as they have been authorised under protocol by the ARSAC licence holder.

Imaging and treatment

The in-house radiopharmacy or supplier will provide the radiopharmaceuticals on the day required in single vials or a multi dose vial for PET scans. There are scanning protocols in place for all nuclear medicine. The day before a patient attends the department, their referral information is reviewed. This is a secondary check on the information in the referral and reviews the protocol selected for the procedure.

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

Operators must follow local guidelines on administration. Quality control is carried out on the calibrator each day before drawing up and administration of radioisotopes. Dispensed doses are measured in the dose calibrator and the

activity level of the dose drawn up will be within plus or minus 10% of the (LDRL).

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.

NHS Lothian use a multi vial of fluorodeoxyglucose (FDG) used in PET-CT scans. The required dose is 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.

The timing of patient injections is managed to optimise image acquisition. When administering a radiopharmaceutical there are two staff members present in the department.

Ra-223 administration is delivered over six visits. The administered dose is weight based which NHS Lothian have calibrated scales to weigh the patient at each visit. The administered dose will be modified if the patient weight changes by 10%. We were advised that additional health checks would be undertaken to ensure that the Ra-233 can be safely delivered.

Staff will at times require to cannulate adult patients to administer a radioisotope. 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 that the 'hot spot' would be clearly marked on the patients notes to ensure this does not affect the clinical evaluation. NHS Lothian review their incident rate of extravasation against the national average. They reported their rate was below the national average.

Tc-99m is administered to patients who undergo a sentinel lymph biopsy. A patient administration log is used to record the relevant patient information and confirmation such as the administration of Tcm-99 has been authorised, injected dose, site and time of injection. The activity at the time of surgery is calculated based on the decay calculation taken from the time of production of the radiopharmaceutical and the time of surgery. The surgeon using the gamma probe identifies the hot nodes for removal and records the number of nodes removed on the patient administration log.

Clinical evaluations

For diagnostic imaging clinical evaluations are undertaken by consultant radiologists, ARSAC license holder other entitled staff. All diagnostic imaging are reported by the ARSAC licence holders and reports made available to the referrer. The breast surgeons

will record the clinical outcomes in the patients notes and link them to the pathology results.

In the case of I131 and Radium-223 therapies, the report records the administered activity, date of administration and route of administration. For patients undergoing Ra-223 treatment it was confirmed that patients will be monitored over the course of their treatment and their progress is recorded and evaluated.

Records

TRAK is used to record the referral through to the clinical evaluation.

We viewed information recorded that included the following:

- the correct patient information.
- details of the referrer and operator.
- identification checks.
- the recorded dose.
- the radiopharmaceutical.
- justification (including those transcribed into the system by the nuclear medicine radiographer), and
- clinical evaluation.

The system does not facilitate the scanning of documents and therefore paper copies of the pregnancy checks are kept in the department.

Patient identification

All staff we spoke with advised us that 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 are aware of communication aids, such as LanguageLine, to support any barriers to communication.

Expert advice

NHS Lothian have a dedicated nuclear medicine medical physics team to support nuclear medicine. All MPEs are on the RPA2000 register. NHS Lothian recently conducted a calculation of the MPE for Nuclear Medicine using the calculator published by the Institute of Physics and Engineering in Medicine (IPEM) and The European Federation of Organisations for Medical Physics. Policy Statement No. 7.1. The result of the calculation indicated that the current

provision is appropriate. The medical physics team work closely with staff across nuclear medicine.

The medical physics expert (MPE) 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 outwith tolerance levels.
- optimisation.
- dose reference levels.
- staff training.
- development of EPs, and
- analysis and reporting of incidents.

The MPEs have also been active in delivering IR(ME)R training for managers across different staff groups and supporting improvement projects.

General duties in relation to equipment

NHS Lothian has an equipment register in place for all radiological equipment that could affect the dose. There is a protocol for updating the register to ensure that it is kept up to date. There are clear procedures for the quality assurance of radiology equipment detailed in EP2/RAD/11. All staff have been trained to undertake quality assurance and are familiar with the frequency and types of quality assurance undertaken. There is guidance on the quality assurance required for each piece of equipment. Daily and monthly spreadsheets are readily available to view the quality assurance undertaken. 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. Staff demonstrated the daily quality assurance and use of flood sources. There is also a programme of quality assurance undertaken by the medical physics team. The MPEs who carry out the quality assurance on the diagnostic CT scanners also undertake quality assurance on the CTs used in nuclear medicine. The quality assurance programme is based on manufacturer guidance and guidance from the Institute of Physics and Engineering in Medicine (IPEM). Quality assurance in also in place for the gamma probes used by breast and other surgeons undertaking sentinel lymph node biopsies.

The EP includes a process for 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.

Audits are undertaken by each directorate/department as detailed in EP14 to provide regulatory compliance. These standard audits review the practices and procedures in place and are undertaken annually with the results presented at the IR(ME)R Board.

In addition, to the standard audit each directorate is responsible for their own clinical audit programmes as part of ongoing quality improvement.

There is a wide variety of clinical audit activity undertaken by NHS Lothian, within nuclear medicine.

Examples of clinical audits include:

- Within Ra-223 therapy the clinical scientist has audited the patient weight based activity protocol, reviewing the appropriate weight based activities are administered on the day of treatment. It was found that there was "excellent agreement" between the administered activity and the calculated on the day activity.
- The endocrinology consultants have undertaken audits of thyrotoxicosis treatment reviewing the prescribed dose against the actual dose. In addition, they are part of a national reviews into the treatment of thyroid cancer and the use of I131. As a result of audits the number of patients requiring radical I131 has reduced since 2010.
- The ARSAC guidance notes indicates an activity of 800MBq for Multi-Gated Acquisition (MuGa) scans. As a result of an audit reviewing image, it was identified that an activity of 500MBq provided images that were clinical effective. As a result, routine MuGa scans are now undertaken at the lower activity.

The outcomes from clinical audits undertaken are included in the IR(ME)R regulatory compliance audit.

Accidental or unintended exposure

NHS Lothian EPs detail the measures that it takes to reduce the probability and magnitude of an accidental or unintended dose to patients from medical exposures. Implementation of the EPs and local rules, and learning from incidents are part of the overall control measures.

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 are confident to report any instances. Incidents are investigated by the departmental staff with support from the MPE. Staff confirmed learning from incidents is shared through a variety of forums. The MPEs are familiar with the need to report incidents that meet the statutory notification guidance.

Oncologists, endocrinologists and the breast surgeon all confirmed that there is a positive culture for the reporting of incidents.

NHS Lothian medical physics team record incidents in a data base and monitor this data for trends. They review the trends based on a variety of criteria such as by equipment, location and procedure. The medical physics team have a dashboard on the core categories and locations. Medical physics provide a report to the LRIC to share the experience and learning form incidents.

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 Lothian have comprehensive EPs 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.

As part of the therapy pathway, patients are informed of the risks and benefits as part of the consent process. Patients are provided with an information leaflet relevant to their pathway. Information is also provided for carers and comforters as required. The 'Booking form' for Ra-233 and I131 treatments require information confirming that patient consent has been undertaken and patient information provided.

Making enquiries of individuals who could be pregnant and breast feeding

All staff we spoke with advised that all patients of childbearing age are 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 a record of this is stored in the department. 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 Lothian follow the feeding interruption times for the various radiopharmaceuticals as outlined in the ARSAC notes for guidance.

Carers and comforters procedures

NHS Lothian have the appropriate EPs in place for carers and comforters for both diagnostic and therapeutic exposures.

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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