



Healthcare
Improvement
Scotland

Inspections
and reviews
To drive improvement

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

Victoria Hospital, Kirkcaldy
NHS Fife

28–29 January 2020

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About our IR(ME)R 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 of care approach and the quality framework together allows us to provide external assurance of the quality of healthcare provided in Scotland.

- **The quality of care approach** 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 framework.
- **Our quality 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. 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 2017 to the quality framework.

How we inspect services that use ionising radiation for medical exposure

The focus of our inspections is to ensure each service is implementing the Ionising Radiation (Medical Exposure) Regulations 2017 (IR(ME)R). 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 address the radiation protection of persons undergoing medical exposures.
- 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 of care framework.

More information about the quality framework and quality of care approach can be found on our website:

www.healthcareimprovementscotland.org/our_work/governance_and_assurance/quality_of_care_approach.aspx

Summary of inspection

About our inspection

We carried out an announced inspection from Tuesday 28 to Wednesday 29 January 2020. We spoke with a number of staff including the chief executive, medical director, radiology and diagnostic imaging services manager, lead consultant radiologist and radiographers. The inspection team was made up of two inspectors.

Victoria Hospital, Kirkcaldy offers plain film, computerised tomography (CT) and nuclear medicine. The focus of this inspection is the imaging department.

What we found

What the service did well

- All staff were fully aware of their roles and responsibilities in relation to radiation protection of persons undergoing medical exposure.
- The NHS board clinical audit provides a good overview of the implementation of IR(ME)R.

What the service needs to improve

- Clinical audit of outsourced radiologist services.

Detailed findings from our inspection can be found on page 8.

What action we expect NHS Fife to take after our inspection

This inspection resulted in four requirements and four recommendations. Requirements are linked to compliance with IR(ME)R. See Appendix 1 for a full list of the requirements and recommendations.

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

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

We would like to thank all staff at the radiology department, Victoria Hospital, for their assistance during the inspection.

What we found during our inspection

Outcomes and impact

This section is where we report on what key outcomes the service has achieved and how well the service meets people's needs.

Domain 1 – Key organisational outcomes

High performing healthcare organisations identify and monitor key measures that help determine the quality of service delivery and the impact on those who use the service or work with the service.

IR(ME)R requires that those who refer for a patient to be exposed to medical radiation, those who operate equipment and those healthcare professionals (medical and non-medical) who justify that the procedure is necessary, must be adequately trained and entitled to do so. Entitlement is given to each person involved in the process by the employer.

What we found - fulfilment of statutory duties and adherence to national guidelines

Entitlement

Entitlement is a process required by the regulations. The medical director entitles all medical staff in NHS Fife and general practitioners in the NHS board area. This process sets out the scope of practice that an individual can undertake, such as to the type of referrals and clinical evaluations that can be undertaken. An individual's scope of practice is set out in a formal letter from the employer and an individual is required to work within this scope of practice. The scope of practice depends on the qualifications, role, training and experience of an individual. An individual's scope of practice can change over time, such as following additional training or moving to a new role.

We looked at the radiographer spreadsheet that provides an overview of all the practitioners and operators with details of their scope of entitlement.

All radiologists who are Fellows of the Royal College of Radiologists are entitled as a practitioner, to carry out justifications, authorise exposures and undertake clinical evaluations. A radiologist is a doctor who is specially trained to interpret diagnostic images such as X-rays and CT scans and offer an opinion on the most appropriate type of scan, both ionising radiation and non-ionising radiation.

A practitioner assesses a request for exposure against the clinical data supplied by the referrer. The practitioner must have adequate training and be competent to consider the potential detriment of the exposure against the potential benefits for that individual.

Radiographers are entitled, depending on their training, to:

- act as operators
- carry out certain types of justifications as a practitioner of plain film x-rays, and
- undertake clinical evaluations.

CT radiographers act as a practitioner for some exposures and are authorised under protocol for other exposures. A staff member who is entitled under protocol will authorise an exposure following guidelines with the radiologist remaining responsible for the justification.

To enable radiographers and others to act as practitioners, NHS Fife has a set of criteria that staff must meet. One part of the criteria is to have an assessment of competence conducted, as detailed in their employer's procedure EP2-2, EP2-3 and EP3-A20. Healthcare Improvement Scotland will be undertaking a further review of the assessment process at a future date.

Radiographers are entitled to act as operators and work with a variety of different diagnostic equipment. Each radiographer is trained to work with each specific machine and training records are kept to demonstrate that the training was completed. All the records we reviewed detailed the training provided. Training is monitored through the routine staff appraisal system.

All staff we spoke with were very clear on their roles and responsibilities in relation to their own entitlement. Staff were clear that they would only undertake tasks they were entitled to do so. Radiography staff work across the different hospitals in NHS Fife to ensure that all staff gain the appropriate experience to support their scope of entitlement.

Referral

A referral can only be made by a person who is entitled to do so. Referrals will come into the radiology department from a variety of sources, both within the hospital and from the community. Community referrals are made by dentists, GP's and non-medical referrers. Referrals from hospital staff are made internally to the radiology information system. External referrals are made through an electronic referral system or on cards. The information from card referrals are scanned into the radiology information system.

Medical staff registered with the General Medical Council or dentists registered with the General Dental Council can make referrals. Hospital medical staff can refer for diagnostic examinations including nuclear medicine and interventional examinations. GP's can refer for general radiography and dental practitioners can refer for dental specific examinations. Medical staff in training can make referrals as per referral protocols during the day, but not out of hours.

Non-medical referrers have a specific scope of practice that depends on their qualifications and where they work. A staff member would be nominated by the clinical manager and must meet the criteria in EP2-1. To become a non-medical referrer, it must be demonstrated that there is a clinical need for the staff member to undertake that role. Prior to being entitled as a non-medical referrer, we were told staff have to attend a course run by NHS Fife.

Once a staff member has been entitled as a non-medical referrer they will be sent confirmation in writing with their scope of practice. Their details are added to a spreadsheet which radiographers can access to check their scope of practice. The staff member will then be added to the IT system to allow them to make referrals. The system does not restrict what a non-medical referrer can refer for, except for low and high dose. The role of the radiographer is to check that referrals made by non-medical referrers are within the appropriate scope of practice as part of their pre exposure checks. All radiographers we spoke to could describe the procedure to check non-medical referrers and we were shown the spreadsheet.

The radiographers we spoke with all confirmed that they check referral information as part of their routine checks. We were shown how this would be undertaken. This acts as a control to identify discrepancies with patient identification, duplicate scans, correct part of the body and that there is sufficient clinical information in plain film to justify an exposure.

What needs to improve

We discussed non-medical referrers, including advanced nurse practitioners based in community healthcare. It was not clear if non-medical referrers in the community were NHS Fife staff with full access to the IR(ME)R policies, training and controls as detailed in the employer's procedures or if they were employed by a different health provider, such as a GP practice, and did not have full access to the employer's procedure, training and controls. NHS Fife must be assured that all non-medical referrers based in the community have controls in place, access to policies and training to comply NHS Fife employer's procedures and with IR(ME)R.

Justification

Radiologists review all referrals, other than standard plain film, to ensure that there is sufficient information to be able to justify the referral. Radiographers review all the standards plain film referrals. A rheumatologist and dental practitioner can also justify exposure within their scope of practice. Both the radiologist and radiographer will review the clinical information and decide if the procedure can be justified. Where there is insufficient clinical information, the radiographer and radiologist may contact the referrer to clarify the referral. If required, a new referral will be requested with more detailed information. They would also select the correct protocol for the medical exposure of ionising radiation. The radiologist or radiographer may also decide that another type of procedure with a lower dose or a non-ionising radiation option would be more appropriate.

When the referral is inappropriate and justification cannot be approved, the referrer will be contacted and informed of the decision.

Radiographers can also authorise exposures under protocol with a named consultant identified as the practitioner. We saw clinical guidelines to support staff who authorise under protocol that clearly explain the parameters under which the radiographer will authorise an exposure. These clinical guidelines identify the lead radiologist as the consultant.

What needs to improve

The radiology information system does not provide an option to record exposures authorised under protocol and therefore a compromise is being made on where to record an authorisation under protocol. NHS Fife must provide clarity on how it will record authorisations under protocol and ensure that the employer's procedure reflects the chosen method. There should be consideration on how staff clearly record an individual's role and modify the radiology information system to allow the recording of authorisations under protocol to be recorded in a separate box.

Records

During our inspection, we looked at the radiography information system and found staff were recording information appropriately, including:

- the correct patient information
- referral information
- details of the entitled referrer, operator and person justifying the exposure
- justification record
- pregnancy checks,
- exposure type and dose, and

- clinical evaluation.

The radiographers we spoke with could confidently explain and demonstrate:

- pre-exposure checks
- non-medical referrers checks
- patient ID checks
- pregnancy status checks
- recording of dose and number of images
- dose reference levels (DRLs)
- the quality assurance records and
- use of the handover form.

Requirement 1

- NHS Fife must be able to demonstrate that the non-medical referrers based in community healthcare have suitable controls in place, access to policies and training to comply with NHS Fife employer's procedures.

Recommendation 1

- It is recommended that the NHS Fife radiology information system is modified to allow the recording of authorising under protocol in a separate box on the radiology information system or equivalent.

Service delivery

This section is where we report on how well the service is delivered and managed.

Domain 5 – Safe, effective and person-centred care delivery

High performing healthcare organisations are focused on safety and learning to take forward improvements, and put in place appropriate controls to manage risks. They provide care that is respectful and responsive to people’s individual needs, preferences and values delivered through appropriate clinical and operational planning, processes and procedures.

What we found - safe delivery of care

NHS Fife has a duty under IR(ME)R to develop written procedures commonly referred to as employer’s procedures. These are intended to provide a framework under which professionals can practice. NHS Fife has adopted a level 1, 2 and 3 approach to employer’s procedures. Level 1 procedures apply to whole of NHS Fife, level 2 refer to modality and level 3 are specific to departments. NHS Fife has developed procedure in line with schedule 2 of IR(ME)R. As part of the visit we reviewed the level 1 and 2 employer’s procedures.

What needs to improve

It was noted that the policy on updating and reviewing employer’s procedures did not provide details on the involvement of the medical physics expert and their contribution to radiological practice.

Safety Culture

We spoke to the chief executive, medical director, radiology and diagnostic service manager, radiographers and the lead consultant radiologist, about the culture within the radiology department. Everybody we spoke with was positive about the safety culture within the department. The medical director told us that the organisation has worked hard on the culture and wanted to promote a spirit of learning

Staff told us:

- there is an open culture
- there were good working relationships between consultants
- the radiology team support each other and support learning, and
- there was a learning culture.

Throughout the radiology department we saw patient information posters in place. The posters provide general information on the exposure to ionising radiation and were prominently displayed and accessible in waiting areas and in patient cubicles.

The Society of Radiographers' 'PAUSE' poster was displayed throughout the radiology department. The poster encourages staff to stop and take the time to get everything in place before undertaking an exposure. Staff confirmed that they are supported to take the time needed to complete all the appropriate checks.

Staff also told us how information was communicated through emails, notice boards, communication tools and meetings. The communication would cover a variety of subjects including feedback from audits, learning from events, reported equipment faults and changes to employer's procedures.

Employer's Procedures

We discussed the governance arrangements for the updating and reviewing of employer's procedures, whereby:

- level 1 is authorised by the IR(ME)R lead
- level 2 is authorised by the responsible manager, and
- level 3 is authorised by the departmental managers. The process is detailed in the policy titled IR(ME)R-01.

Making enquiries of individuals who could be pregnant

Radiography staff told us they would ask anyone of child bearing capacity, aged between 12 and 55, the pregnancy status questions for exposures where the lower abdomen and pelvis are directly in the primary beam. They would modify the questions based on the age of the person. A form is used to record that the questions have been asked and the patient signs the form confirming the discussion. The form is then scanned into the patient record. We saw examples of these completed forms.

If a patient knows they are pregnant, or thinks they might be, then consideration is given to postponing the exposure if possible. If the exposure requires to go ahead when pregnancy cannot be excluded, employer's procedure EP3-A28 provides guidance on what information needs to be provided to the patient, who needs to be consulted and what information recorded. The employer's procedure states that a radiologist should be contacted to justify an exposure where pregnancy is possible. The decision to proceed should be documented in the radiology information system by the

consultant radiologist. If the exposure has been justified, staff will provide a patient information sheet explaining the risk-benefit of the exposure. The information sheet used is taken from the Royal College of Radiologists.

What needs to improve

The Royal College of Radiologists' risk-benefit information sheet is not written in plain English and does not provide an opportunity for the patient to discuss the procedure in more depth with the referrer. NHS Fife should review how the risk and benefit information is provided to the patient. In addition, the Royal College of Radiologist information provided for patients should be reviewed to ensure the patient can easily understand it.

Employer's procedure EP 3-A28 states that many of the steps of the process should be undertaken. From the discussion sessions with the senior managers, it is clear that the process is not optional. Therefore, it is recommended that the wording in the employer's procedure is changed to reflect that staff must undertake the process for pregnancy checks and documentation.

Carers and comforters procedures

NHS Fife have a policy on carers and comforters that details the operator's responsibilities and the dose constraints. All staff we spoke to were aware of the policy and procedures to follow.

General duties in relation to equipment

We were shown the equipment inventory for radiological equipment. An employer's procedure is in place for an equipment inventory and quality assurance. As part of the procedure, an assessment will be made on the continued use of any equipment and unintended radiation exposure. This may result in equipment being withdrawn from use. Any equipment identified as a high priority for replacement will be replaced as soon as practicable. The chief executive discussed the process of financing replacement equipment and that process is discussed by the appropriate corporate groups. The radiology and diagnostic imaging manager is a member of the capital replacement and asset management group. This group uses a risk-based approach when discussing the financing of replacing radiology equipment.

As part of our visit we focused on the reporting of faults and procedures for quality assuring equipment. All staff could describe the fault reporting procedure and the procedure for taking equipment out of use, if required. Before an engineer undertakes repairs, there is a formal process of handing over the equipment to the engineer. When repairs are completed, the engineer returns the responsibility of the equipment to the radiology department. The engineer will indicate if any of the work they have undertaken will potentially

affect the dose output. All staff told us that a quality assurance check would be undertaken prior to a machine being used. We saw the handover form used as well as separate quality assurance checks. Routine quality assurance was also undertaken and the appropriate records were in place.

What needs to improve

When we visited the radiology department, the handover records did not indicate if any additional quality control had been undertaken prior to the equipment being put back in use. However, it could be cross-referenced to the quality control records for the machine, which were located in a different location. Consideration should be given to including quality checks that have been completed in the engineer handover record.

Optimisation

Dose optimisation is the balance between the lowest dose and the image quality that is clinically suitable. A dose reference level (DRL) can be set which provides an indicator on the expected dose from an exposure.

DRLs are set following dose surveys and can differ depending on the type of image required and the age of the machine. Dose surveys can be set nationally or locally.

- National DRLs are a result of data being submitted from a variety of NHS boards across the UK. For example, NHS Fife is providing data to support the development of a national paediatric CT head DRL.
- Local dose surveys look at the information gathered in NHS Fife and NHS Lothian.

Following local surveys, local DRLs are set. These levels provide a reference point on what the expected dose from an exposure should be. Any new local DRL will be submitted to the IR(ME)R Board to be authorised. If a dose given is above the DRL, the operator can review the factors that affect the dose, which may account for a different dose, such as the patient's height and weight. If the difference cannot be explained, the radiographer can discuss with their manager and medical physics expert what further checks are needed. Where local DRL's are not available, the Scottish or UK DRLs are adopted, if available. In the radiology department we saw DLR charts for radiography staff to use as a quick reference.

All the operators we spoke with could describe how they would select the correct protocol for the intended purpose. The radiologists we spoke with described how they consider image quality with as low as dose as was

reasonably practical when justifying an exposure. They also told us they would always consider if there was an alternative to ionising radiation.

The equipment used to expose patients to ionising radiation have a variety of protocols that help deliver standardised exposures. Exposures can be modified for adults and children and take account of different body sizes.

NHS Fife and NHS Lothian share an image optimisation group. This beneficial arrangement supports alignment of protocols and reduction of doses from exposures across the two NHS board areas.

Accidental or unintended exposure

When staff members identify an incident or near miss, they are required to report it on DATIX (risk management system). If the incident was due to operator error, they would undertake a reflective practice statement. If it was a referrer error, this would be passed to the clinical team of the referrer to investigate. Reflective practice would be used if the referrer was a doctor in training. It is recommended that reflective practice be used by all referrers and not just the medical staff in training and radiographers. All staff we spoke with could explain the incident reporting process. All DATIX incidents go to the medical physics expert, who provides information on dose and whether the incident needs to be notified to the regulator.

Monthly reports on incidents are sent to the directorate meeting for discussion. We were told monthly reviews are done for incidents and near misses and this is reported at the clinical governance group every 3 months. If a pattern of incidents is attributed to an individual, this will result in further discussions with the individual, such as further training.

Requirement 2

- NHS Fife must revise their employer's procedure regarding the provision of risk and benefit information to a pregnant patient, other than by use of an information sheet. The procedure must detail where this information is recorded, and by whom.

Recommendation 2

- It is recommended that NHS Fife review the wording in the employer's procedure EP3-A28 to clearly state what staff must undertake as part of the process for pregnancy checks and documentation.

Recommendation 3

- It is recommended that NHS Fife review the information sheet provided to patients who are possibly or definitely pregnant to ensure it is easily understood and patients can understand the risk and benefit of the exposure.

Domain 6 – Policies, planning and governance

High performing healthcare organisations translate strategy into operational delivery through development and reliable implementation of plans and policies, and have effective accountability, governance and performance management systems in place.

What we found - policies and procedures

NHS Fife's IR(ME)R-01 policy clearly sets out how the organisation manages the implementation of IR(ME)R. The chief executive has overall responsibility for the compliance with IR(ME)R. The chief executive described the governance arrangements to provide them with assurance that IR(ME)R was being implemented. The IR(ME)R policy, IRMER-01, clearly defines the medical director as IR(ME)R policy lead for NHS Fife. The medical director then authorises clinical directors and general managers to support the implementation of the regulations.

The IR(ME)R Board for NHS Fife meets once each year and provides strategic governance for the implementation of IR(ME)R in NHS Fife. The IR(ME)R Board looks at compliance with the regulations and establishes effective management controls. It provides assurance to the medical director that IR(ME)R is being implemented. The IR(ME)R Board has representation from different professions including the medical physics experts, the radiology and diagnostic imaging service manager and lead radiologist. The IR(ME)R Board links into the annual board radiation protection committee. Both of these groups link to the NHS Fife clinical governance committee, chaired by a non-executive board member. Minutes of the clinical governance committee are shared at the NHS Fife Board meeting. This structure provides a clear route of communication of IR(ME)R issues from the IR(ME)R committee to the NHS Fife Board and chief executive.

What we found - risk management, audit and governance

Outsourced services: governance arrangements

NHS Fife uses a private company to provide radiologist services for the justification process and clinical evaluations for CTs. The medical director, provides oversight of the private company.

As part of the inspection, we reviewed the governance arrangements for the outsourced service and discussed the service with the medical director, lead radiologist and radiographers. All radiologists provided by the private company have to be registered with the General Medical Council. The company undertakes its own quality assurance and clinical audits and provides this information to NHS Fife. This is the only established mechanism of clinical audit of the services provided by the private company. The medical director stated that they received a good service from the private company.

Radiographers and medical staff can contact the company for advice. All justifications are attributed to an individual and their details are recorded on the radiology information system. We saw examples of justifications and clinical evaluations provided by the private company.

What needs to improve

NHS Fife must develop an employer's procedure that includes the scope of clinical audit for the private company providing the radiologist services.

Clinical audit

NHS Fife employer's procedure EP1-9 details the arrangements for clinical audits. All sites throughout NHS Fife using ionising radiation will undertake the same clinical audits. The service manager for diagnostic and imaging manages the delivery of these audits. EP1-9 provides a list of the type of audits that will be undertaken. We were shown a spreadsheet with the audit programme. The scope of audits included:

- staff qualifications
- equipment inventory
- review of DRLs
- staff competency records, and
- review of radiation incidents.

The audit policy states 'results from audits and the corrective action are to be shared with the staff to ensure improvements are introduced and sustained'.

To support the scope of clinical audit, NHS Fife should review the audits published on the Royal College of Radiologists' website. The published audits may provide options for different audits that NHS Fife may want to undertake.

An annex to the employer's procedure EP1-9 provided a good example of a clinical audit that provided an overview on the implementation of IR(ME)R. This audit is completed annually and responsible managers submit the results as part

of an annual report to the IR(ME)R board. The annual audit includes wide ranging checks on the implementation of employer's procedures and includes reviews of a random selection of patient requests and patient records.

We were shown an informative audit report on near misses. This is where the intervention of the radiographer prevented a patient from being exposed to unnecessary ionising radiation. It concluded that the radiographers have stopped more incidents than they had missed, demonstrating that the radiographers are well trained and knowledgeable in identifying potential issues.

What needs to improve

The employer's procedure EP1-9 contained a table of clinical audits. There was no detail on the frequency of the audits. We were shown a separate audit spreadsheet as evidence of the audits and their frequency, however, this spreadsheet was not included in the employer's procedure.

Requirement 3

- NHS Fife must develop an employer's procedure that includes the role of clinical audit for outsourced radiologist services. The policy should include what is to be audited and the frequency.

Recommendation 4

- It is recommended that NHS Fife align the employer's procedure EP1-9 clinical audits with the programme of clinical audits that are being undertaken.

Domain 7 – Workforce management and support

High performing healthcare organisations have a proactive approach to workforce planning and management, and value their people supporting them to deliver safe and high quality care.

What we found - staff recruitment, training and development

Expert advice

NHS Fife contracts medical physics experts from NHS Lothian. The medical physics experts are appointed by letter by the IR(ME)R lead. We were shown the appointment letter. The medical physics experts provide advice to NHS Fife in relation to compliance with IR(ME)R. Their role includes:

- commissioning of new equipment
- quality assurance of equipment
- dose monitoring, training and analysis of events
- providing advice on whether or not an incident requires to be reported to Healthcare Improvement Scotland, and
- creation of an annual report on IRMER compliance.

The medical physics expert told us they were involved in discussions on image quality with radiologists and setting up protocols for the different machines. This ensures consistency amongst radiologists and their adoption of the protocols.

Staff told us the medical physics experts were easily contactable and available for advice and support. The medical physics expert told us that they were on site at least every 2 weeks and attend various groups and that their role complies with the requirements under IR(ME)R.

Training

We found that there were comprehensive training records in place for staff involved in delivering medical exposure to ionising radiation. Once a radiographer qualifies, NHS Fife provides induction and ongoing training. We saw records that demonstrated the training had been provided. There were clear training records for operators of equipment in the department and this included CT and plain film equipment. Student radiographers can only work under the supervision of a qualified radiographer. A radiographer's training record is closely linked to their entitlement. We reviewed a sample of records and the entitlement records corresponded to the training records.

Operators must be trained to use the different types of machines. We were told that anyone operating a machine must be trained on the specific equipment. All the radiographers we spoke with said they had received appropriate training and all training records inspected were up to date. It is the responsibility of the radiographer to maintain their own continual professional development as part of their professional registration.

Radiologist training and continual professional development is managed through their annual appraisals and medical revalidation process.

Locum staff follow the same induction process and follow the same competencies as other staff. They are issued with their letter of entitlement in the same way as other NHS Fife staff.

What needs to improve

There was evidence of continual education for radiologists and radiographers, however, it was not always possible to identify the training that related specifically to IR(ME)R. The policy on continual IR(ME)R education was unclear for those non-radiology staff who still have obligations under IR(ME)R. NHS Fife must develop a procedure that details the continual education requirements for all who work within the scope of IR(ME)R.

Requirement 4

- NHS Fife must develop a procedure that details the continued education requirements for all who work within the scope of IR(ME)R.

- No recommendations.

Appendix 1 – Requirements and recommendations

The actions that Healthcare Improvement Scotland expects the independent healthcare service 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.

Domain 1 – Key organisational outcomes	
Requirement	
1	NHS Fife must be able to demonstrate that the non-medical referrers based in community healthcare have suitable controls in place, access to policies and training to comply with NHS Fife employer’s procedures (see page 12). <i>Regulation 6(2) Ionising Radiation (Medical Exposure) Regulations 2017</i>
Recommendation	
1	It is recommended that the NHS Fife radiology information system is modified to allow the recording of authorising under protocol in a separate box on the radiology information system or equivalent (see page 12).

Domain 5 – Safe, effective and person-centred care delivery	
Requirement	
2	NHS Fife must revise their employer’s procedure regarding the provision of risk and benefit information to a pregnant patient, other than by use of an information sheet. The procedure must detail where this information is recorded, and by whom (see page 17). <i>Regulation 6(8) Ionising Radiation (Medical Exposure) Regulations 2017</i>
Recommendations	

2	It is recommended that NHS Fife review the wording in the employer's procedure EP3-A28 to clearly state what staff must undertake as part of the process for pregnancy checks and documentation (see page 17).
3	It is recommended that NHS Fife review the information provided to patients who are possibly or definitely pregnant to ensure it is easily understood and patients can understand the risk and benefit of the exposure (see page 17).

Domain 6 – Policies, planning and governance

Requirement	
3	NHS Fife must develop an employer's procedure that includes the role of clinical audit for outsourced radiologist services. The policy should include what is to be audited and the frequency (see page 20). <i>Regulation 7 Ionising Radiation (Medical Exposure) Regulations 2017</i>
Recommendation	
4	It is recommended that NHS Fife align the employer's procedure EP1-9 clinical audits with the programme of clinical audits that are being undertaken (see page 20).

Domain 7 – Workforce management and support

Requirement	
4	NHS Fife must develop a procedure that details the continued education requirements for all who work within the scope of IR(ME)R (see page 22). <i>Regulation 6(3)(b) Ionising Radiation (Medical Exposure) Regulations 2017</i>
Recommendations	
None	

Complaints/Concerns

If you would like to raise a concern or complaint regarding any aspect of the inspection then please discuss this with the lead inspector in the first instance.

If there is a concern or complaint about the conduct of an inspector please contact Kevin Freeman-Ferguson, Head of Service Review, kevin.freemanferguson@nhs.net in the first instance to discuss your concerns in more detail.

Alternatively, Healthcare Improvement Scotland has a complaint and feedback service that can be contacted directly. Details can be found on our webpage.

http://www.healthcareimprovementscotland.org/about_us/contact_healthcare_improvement/complaints.aspx

Our contact details are:

Healthcare Improvement Scotland

Gyle Square
1 South Gyle Crescent
Edinburgh
EH12 9EB

Telephone: 0131 623 4300

Email: comments.his@nhs.net

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or email contactpublicinvolvement.his@nhs.net

Healthcare Improvement Scotland

Edinburgh Office
Gyle Square
1 South Gyle Crescent
Edinburgh
EH12 9EB

Glasgow Office
Delta House
50 West Nile Street
Glasgow
G1 2NP

0131 623 4300

0141 225 6999

www.healthcareimprovementscotland.org