

Key themes and concerns in 2022/23

When we identify significant concerns and recurring themes in our work, we share the learning to provide actions that can help employers to improve in these areas.

Key themes in diagnostic imaging

Referral errors

We received 99 notifications relating to errors by referrers. Of these, 60 related to the wrong patient, 16 were due to the scan not being cancelled in time, and a further 15 were due to not checking previous imaging.

In many cases, the error could have been prevented by having more robust systems or making additional checks. For example, in many cases opportunities were missed by not checking the clinical indications against the person having the procedure.

Some providers have considered additional steps and equipment to try to reduce manual errors, such as using barcode scanners instead of having to type in the patient's ID number.

Actions for employers

- Think about how the referral pathway works in practice, such as when cancellations are needed.
- Think of different methods to cut down on potential input errors, such as using barcode scanners.
- Make sure staff are trained and understand the importance of following additional steps beyond the patient ID check.

Fluoroscopy training for radiologists

We received multiple notifications regarding unintended doses in fluoroscopic procedures where the radiologist was operating the equipment. The primary cause of the notifications was a lack of training in using the equipment, leading to errors such as:

- using acquisition instead of fluoroscopy
- switching to inappropriate clinical protocols
- performing incorrect acquisition runs when fluoroscopy was more suitable because of a misunderstanding in terminology.

Actions for employers

- Make sure radiologists are trained on equipment specific features and have adequate in-person supervision where appropriate.
- Clarify any terminology that staff may misunderstand, especially for new members of staff or those who work at multiple sites.

Dental over-exposures

We received notifications where multiple patients had received over-exposures as part of a dental examination. The cause of the errors was a result of altering either protocol settings or equipment features (such as collimation attachments) and not subsequently correcting them.

For these notifications, there were several notable contributing factors:

- Some members of staff were not always adequately trained on the site-specific equipment features, and therefore did not recognise the implications of making changes.
- In some cases, staff were not aware that settings had been changed and subsequently did not notice.
- Spot checks or audits were not carried out following maintenance visits, which may have picked up the alterations.

Actions for employers

- Train staff sufficiently on equipment features and their potential dose implications.
- Make sure staff know when to escalate queries or concerns around changing equipment settings.
- Carry out spot audits following visits from external contractors to ensure that the equipment settings and set-up remain optimised.

Key themes in nuclear medicine

Through our work in nuclear medicine over 2022/23, we have identified some concerns and themes in specific areas. We've taken the learning from these to provide some actions that employers can take to help encourage improvement in these areas.

Incorrect radiopharmaceuticals and operator errors

In April 2023, we published the latest version of the guidance on significant accidental and unintended exposures (SAUEs), which added a new category. This addition makes all instances reportable where a patient received the incorrect radiopharmaceutical – regardless of activity or dose. We added this to address the upwards trend of operator errors in preparation or administration of radiopharmaceuticals.

Unsafe staffing levels are often contributing factors for these incidents, with operators being forced to rush due to high workloads and therefore missing key checks. Often, another operator had not carried out a second check, or this second operator did not check all elements, for example, vial label, calibrator setting, or syringe volume.

Actions for employers

- Review the staffing levels to ensure that operators can carry out critical safety checks.
- Review and adapt patient lists when staffing levels are reduced.
- Have a clear procedure to make second checks of radiopharmaceuticals at both preparation and administration stages, detailing the factors that should be checked.
- Make sure the process involves confirming in writing that the first and second checks have taken place and by whom.
- Ensure that both operators are adequately trained to detect any errors.

Coordinating sentinel lymph node biopsy procedures

We received 4 notifications relating to sentinel lymph node biopsy (SLNB) procedures in 2022/23. In all 4 incidents, inadequate communication between surgical and nuclear medicine departments was the root cause. In 3 instances, failure to notify the nuclear medicine department of cancelled surgeries meant patients received an unnecessary administration of a radiopharmaceutical. In the other case, not enough injections were requested for the list, which meant the patient could not receive the full number.

Although the radiation exposure from these administrations is very low, it indicates a theme of poor communication between hospital departments, which has a negative effect on patients.

Actions for employers

- Review the co-ordination and communication processes between departments and improve where necessary.
- Establish clear processes to communicate when there are changes and cancellations of surgical lists.

Pregnancy procedures for nuclear medicine

Regulation 6 and Schedule 2 of IR(ME)R 17 require the employer to have procedures that include establishing whether a person is or may be pregnant or breastfeeding. The risk to patients who are pregnant or breastfeeding, and their children, is different in nuclear medicine, due to the systemic administration of radiopharmaceuticals. As such, pregnancy procedures must set out specific arrangements for nuclear medicine examinations and include information on when to test for pregnancy. For some therapeutic administrations, confirmation of menstrual history is not sufficient to exclude pregnancy, due to the risk to the foetus.

Actions for employers

- Ensure procedures to check for pregnancy include specific arrangements for procedures involving the administration of radiopharmaceuticals.
- Consider relevant publications, including the ARSAC Notes for Guidance, when writing and reviewing procedures.
- Review the current measures for excluding the possibility of pregnancy before carrying out therapeutic exposures, and include the process for pregnancy testing, where appropriate.

Key themes in radiotherapy

Through our work in radiotherapy over 2022/23, we have identified some concerns and themes in specific areas. We've taken the learning from these to provide some actions that employers can take to help encourage improvement in these areas.

Brachytherapy authorisation guidelines

IR(ME)R states that a medical exposure to ionising radiation cannot take place unless the referral has been justified and authorised (Regulation 11(1)(c)).

- **Justification** is the responsibility of the practitioner – in the case of brachytherapy treatments, the practitioner must hold a practitioner licence from the Administration of Radioactive Substances Advisory Committee (ARSAC) (IR(ME)R Reg 5).
- **Authorisation** is a separate process to justification and is the documentation confirming that justification has taken place.

Where it is not possible for the practitioner to authorise every exposure, they may issue written authorisation guidelines to allow appropriately trained and entitled operators to authorise these exposures (IR(ME)R Regulation 11(5)). Authorisation may be carried out by either a practitioner or an operator in accordance with the authorisation guidelines. Practitioners and operators should be entitled to authorise referrals following the employer's procedures. A letter from the practitioner permitting an operator to authorise under their practitioner licence is not sufficient to meet the requirements of IR(ME)R.

An ARSAC practitioner licence is not required for individuals who authorise exposures according to authorisation guidelines or who perform other practical aspects of the exposure such as treatment planning, insertion, and clinical evaluation. Authorisation guidelines should be written within the local protocols and available to the operator following the authorisation guidelines.

Actions for employers

- When using authorisation guidelines, make sure they are written and ratified by one named IR(ME)R practitioner. When medical staff are acting under the supervision of a licensed practitioner, this should be as part of their training and the practitioner should be involved in oversight and mentorship, with appropriate authorisation guidelines in place.
- Once appropriately qualified and trained, medical staff should obtain their own licence and be entitled as a practitioner. The practitioner should have oversight of the procedure for which they are responsible.

Employers' procedures

Regulation 6(1) requires the employer to have written procedures, as specified in Schedule 2, as a minimum – they may provide additional Schedule 2 procedures than the minimum required by IR(ME)R.

We have made recommendations against Regulation 6 where employers' procedures read more as a 'policy statement'. These described **why** a procedure was being carried out, rather than providing duty holders with specific procedural steps to follow.

Actions for employers

Make sure your employer's procedures are documented and that they define the responsibilities of the duty holders involved in the process. They should include clear instructions on how and when a process should be carried out and who is responsible.

SAUE threshold awareness

Regulation 8 requires the employer to have systems and procedures to reduce the likelihood of a SAUE occurring and to appropriately manage incidents that do happen.

Most centres use commercially available incident management systems that all duty holders can use to report incidents when they happen. In these systems, all incidents are logged on the system – ideally by the individual who was either involved with or discovered the occurrence, regardless of its severity. Incidents are then triaged and reviewed by either a dedicated individual or group, who grades them and escalates appropriately. Following an investigation or closure of the incident, the reporting individual is then informed of the outcome.

This approach means centres are confident that all exposures that meet the threshold for notification to the regulating authority are reported, as all incidents – regardless of severity – are captured.

However, during our inspections we have found that, because of this, duty holders and operators appear to have poor awareness of what constitutes a notifiable incident and there is significant confusion, especially in relation to verification imaging thresholds. The system also relies heavily on the triage process in identifying events that are notifiable.

We have issued multiple enforcement notices and recommendations against Regulation 8 relating to incidents not being reported to the regulating authority in line with the regulations. These resulted from an inadequate triage process that was exacerbated by lack of awareness by the reporting individual.

Actions for employers

- Make sure all duty holders are aware of the notification thresholds for reporting to the regulating authority.
- Check that the triage process for assessing incidents involves more than one person to ensure that the process is robust.