Key themes and concerns in 2021 to 2022

Key themes in diagnostic imaging

Through our work in diagnostic imaging over 2021/22, we have identified some significant 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.

Registering novel or high-dose diagnostic services

When a new provider applies to register with CQC to carry on a regulated activity, our Registration teams assess the application and supporting evidence to make sure the provider will be able to meet regulations.

We assisted with assessing 4 registration applications from providers that were all intending to provide novel or high-dose diagnostic services. The assessments involved 2 site visits.

Two of the applicants were independent providers intending to deliver services in patients' own homes using a domiciliary X-ray machine. Our reviews found poor quality documentation, including both IR(ME)R-related and other documents that we need to see to be assured about safety, such as safeguarding and infection control policies. Although contracted medical physics experts had provided templates to the service, the employer had not adapted them to the service. For example, one service referenced CT scanners in its employer's procedures even though it was not using them, and the other service included inappropriate examinations in its protocols such as whole spine X-rays.

It was clear in our interviews with both these employers that they were unaware of the significance of these documents and had not received appropriate advice from the contracted medical physics service.

Dental inspections

Our team of dental inspectors carries out inspections of primary care dental services (10% of all dental services registered with CQC). This includes the arrangements for dental radiography. Our IR(ME)R team has rarely carried out inspection visits of individual dental radiography services as there is a lower level of risk associated with the low doses to patients.

However, in 2021/22 we carried out 2 dental inspections as part of a sampling exercise to assess compliance with IR(ME)R and a further 2 in the first quarter of 2022/23. We inspected 2 traditional dental services led by dental surgeons registered with the General Dental Council and 2 imaging services providing cone beam CT, orthopantomogram and cephalometry X-rays, carried out by radiographers and trained/qualified dental nurses.

What we found

- Each service had a contract with a medical physics expert to support with all relevant aspects of the regulations.
- The majority of Schedule 2 employer's procedures were in place, although we found these did not always reflect local practice.

- Programmes of quality assurance for local equipment were not always carried out in line with established professional guidance, with some only comprising visual checks, with no further exposure checks.
- There were only minimal records of training, although the records we did see were generally good.

Key themes in nuclear medicine

Through our work in nuclear medicine over 2021/22, 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.

Factors affecting therapy administrations

We received 13 notifications relating to radionuclide therapies. In 12 of these, the patient received a dose that was more than 10% higher or 10% lower than that prescribed for them (for example, over 110% or under 90% of the prescribed dose). A number of root causes contributed to these:

- 5 involved high residual activity or incorrect set-up of administration equipment, such as different tubing sets, leaking connections or air bubbles in the line.
- 4 notifications related to delivery issues for iodine-131, due either to supply interruptions or incorrect reference dates.
- 1 related to a SIRT (selective internal radiation therapy) administration where an occluded hepatic artery led to a blocked catheter that had to be discarded.
- 1 case involved an extravasation of radium-223.
- In another case, 2 operators failed to notice that the activity of an I-131 capsule was 11% higher than intended.

Actions for employers

- Make sure you have the correct equipment available for administering radionuclide therapies. Where you need to use different tubing, consider testing levels of residual activity in them before clinical use.
- When ordering therapeutic radiopharmaceuticals, make sure you use the latest advice from the manufacturer on lead times.
- Operators must check the reference date, time and activity of delivered radiopharmaceuticals carefully. You should check that this is embedded in their processes and that more than one operator makes these checks.

Gas used for ventilation during lung scans

An incident was reported where multiple patients received sub-optimal lung ventilation-perfusion (VQ) scans. Usually, the process uses argon gas as a carrier to suspend and transport technetium-99m particles to the patient's lungs. However, a cylinder that was used to supply the Technegas generator contained an air-like gas composition rather than argon. This had a negative impact on the image quality and increased background counts.

In this instance, hospital porters were responsible for delivering new canisters when needed. They had inadvertently replaced the argon cylinder with another containing an air-like gas, and this mistake was not detected by departmental staff for a week. During this time, six patients had undergone VQ scans.

When the error was detected, the department asked for advice from pharmacy and anaesthesia colleagues, as well as the manufacturers of the gas and generator. All agreed that there would be no detriment to the patients' health. A radiologist reviewed all six scans and identified two that needed to be repeated. The portering management team were notified and a new process was implemented where a member of staff checked the gas cylinder at delivery and the scanning operator made a check before administering Technegas. This was reinforced through updating procedures, sharing learning with all relevant members of staff and updating competency checks for operators.

Actions for employers

- Consider implementing checks of gas cylinders before starting VQ scans, to ensure operators are using the correct gas.

Activity scaling for paediatric studies

We received an enquiry from an employer concerning scaling activities for paediatric administration of radiopharmaceuticals, based on the values set out in the Administration of Radioactive Substances Advisory Committee's ARSAC Notes for Guidance. This gives fractions of adult administered activity based on approximately 2kg intervals, which means that activities for children whose weight falls between these values is open to some interpretation. Some departments use interpolation to calculate an activity fraction based on the individual child's weight; others round up the child's weight to the nearest value instead.

Actions for employers

- Agree an appropriate method for scaling paediatric activities with the practitioner(s) and state this in departmental procedures. Use ongoing audit activities to ensure that staff adhere to this chosen method.

Key themes in radiotherapy

Through our work in radiotherapy over 2021/22, 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.

Authorising additional imaging

To ensure the optimal treatment for patients, there is a need for additional imaging – either pre-treatment scans or on-treatment verification. All exposures, including concomitant doses that arise when using imaging to guide the treatment itself, need to be authorised by practitioners. However, in practice this is not always achievable, and the task is often delegated to operators in accordance with protocols defined by the practitioner. These protocols usually have a defined number of additional images that can be taken before involving a clinician and can only be approved by specific individuals, for example a pre-treatment superintendent radiographer or an imaging specialist.

During inspections we found poor training and associated records relating to who can authorise additional imaging. Often, the ability to authorise further images is linked to a job role or band, for example superintendent radiographer or any Band 7 radiographer. However, there is no specific training or competency that demonstrates that the individual can perform that task initially or how that competency is maintained. We did see some examples of good practice, which include defined competencies and enhanced IR(ME)R training for individuals who are authorising additional imaging, but this is the exception.

Actions for employers

- Document the process to authorise additional imaging and ensure that the training for any person entitled to do this is properly trained through a clear associated training package.

Commissioning new equipment

Commissioning new equipment, specifically new linacs (linear accelerators) or superficial treatment machines, is a complicated process so this is not a routine event. As such, it is unlikely that centres will have defined procedures or processes for installing and commissioning equipment and therefore will take more of a project management approach. As part of this process, the delivered dose of ionising radiation to the patient must be measured and assessed, not just the output of the machine.

Example: Incorrectly calculating the dose output on a new machine

We received a notification relating to the installation of a superficial treatment machine. An error in calculating applicator factors resulted in multiple patients receiving an average underdose of 21% over an 11-month period. A member of staff who was calibrating a new chamber holder for the equipment noticed the error as they were checking a new version of the planning dataset. They spotted a difference that they couldn't explain and raised it with the medical physics experts, who conducted 3 independent calculations and concluded that the original planning dataset was incorrectly calculated.

The centre suspended treatments and carried out dose assessments for all affected patients, who were contacted according to the employer's duty of candour policy.

The error resulted from a failure to update a spreadsheet that was used to calculate the planning dataset, which reflected the change in the length of the applicator. This meant the new machine gave a lower dose rate. The second person checking this new planning dataset did not go back to first principles and used the same dataset, which meant that the error was not noticed.

As the output measurements from the machine were correct, the initial commissioning process and subsequent daily quality assurance checks also did not raise any concerns.

During the 11-month period when patients were being incorrectly treated, the treatment radiographers noted that the times to deliver standard doses were different to the original machine. Although the treatment radiographers raised this with the medical physics team, their response was that longer times were to be expected based on the physical differences of the machine (having longer applicators) and the measured dose rates. In this case, incorrectly calculating the dose output meant that patients were incorrectly treated.

Most centres do not carry out patient-specific quality assurance of treatment as most systems are not capable of performing in-vivo measurements on a kV beam without degrading the treatment. This makes it even more vital to assess the dose of ionising radiation to the patient during commissioning – not just the output of the machine.

Actions for employers

- Make sure the commissioning process for new equipment is adequately documented and covers the entire end-to-end process. The process to assess the dose delivered to the patient for all treatment modalities must also be documented, even ones that are not easily assessed.

Clinically significant accidental or unintended exposure

Regulation 8(1) requires that when there is a clinically significant accidental or unintended exposure (CSAUE), the employer's procedures referenced in schedule 2 must set out the process for:

- informing the referrer, practitioner and individual involved
- providing information on the outcome of the investigation of the incident.
- reporting the incident if it is deemed a CSAUE.

We have found that employers' procedures in radiotherapy have not routinely defined 'clinically significant'. Services were not always able to provide examples of what would constitute as a clinically significant incident. We saw minimal reference of procedures to inform the referrer, practitioner and patient if a clinically significant unintended or accidental exposure occurred, and the outcome of the investigation was not always clearly outlined in incident policies.

Actions for employers

- Make sure your employer's procedures refer clearly to clinically significant exposures (CSAUEs). Procedures should clearly outline the process to inform the referrer, practitioner and patient and this should be adequately referenced in radiotherapy incident policies. Make all staff aware of the type of incidents that fall within the clinically significant category.