Inspections and enforcement activity in 2021 to 2022

Using a graded approach to regulatory activity

In response to findings from the International Atomic Energy Agency's peer review in 2019, we have reviewed our approach to scheduling inspections. Along with the IR(ME)R enforcement authorities in Wales, Northern Ireland and Scotland, we take a graded approach to our work.

This means that the levels of analysis, frequency of inspection and actions we are required to take are proportionate to the extent of the radiological hazards posed by the modality or practice. This means that we focus more resources on those areas that pose a greater potential radiological risk to patients, such as radiotherapy and nuclear medicine therapies, and less on those such as dental and plain film X-ray.

Diagnostic imaging

During the year, we carried out:

- 14 inspections
- 2 dental inspections.

In some cases, our inspections involved multiple visits to assess compliance at different locations operating under one employer, or to investigate compliance following enforcement action. We found 21 cases of non-compliance with the regulations in diagnostic imaging and made 47 recommendations following inspection activity. Most recommendations are similar to those from previous years. We discuss some examples in more detail under the key themes in diagnostic imaging.

Regulations 6(1), 6(2) and 6(5)(b): As in previous years, the most common recommendations related to the employer's procedures. We made 14 recommendations to ensure that employers have a full set of procedures that clearly set out their intended purpose of supporting staff when delivering care, and that reflect clinical practice.

Regulation 8: 8 recommendations related to incident management, where we asked employers to improve processes for investigating incidents, monitoring themes and making statutory notifications to CQC as the enforcing authority.

Regulation 15: We cited equipment in 9 recommendations, 5 of which related to the need for audit trails to include information on quality assurance records, faults and associated actions. A further 4 recommendations related to updating equipment inventories to ensure they include all mandatory fields.

Other recommendations related to establishing diagnostic reference levels and monitoring the risks posed by a shortage of medical physics experts.

As a result of our work, we also issued 7 Improvement Notices. See further information on these in our enforcement register.

Alongside our usual IR(ME)R compliance inspections we worked with colleagues under the Health and Social Care Act and supported 2 inspections.

Nuclear medicine

During the year, we carried out 6 inspections and made 19 recommendations as a result, relating to:

- **Regulation 6(1):** required written procedures, particularly those set out in Schedule 2 (4 recommendations)
- **Regulation 6(5)(c):** the frequency of review of dose data to inform diagnostic reference levels (1 recommendation)
- **Regulation 7:** insufficient clinical audit arrangements (2 recommendations)
- **Regulation 8:** arrangements for unintended or accidental exposures, including the study of risk for radiotherapeutic exposures (3 recommendations)
- **Regulation 12:** shortfalls around optimisation, including the exposures of carers and comforters (3 recommendations)
- **Regulation 15:** quality assurance of equipment and the content of the equipment inventory (3 recommendations)
- **Regulation 17:** arrangements for training and keeping training records (3 recommendations)

There was no enforcement activity in nuclear medicine during 2021/22.

Radiotherapy

During the year, we carried out:

- 13 inspections
- 3 additional compliance visits to follow up.

From these inspections, we issued 7 Improvement Notices and made 22 recommendations. These included:

- **Regulations 6 and 6(1):** reviewing the employer's procedures to ensure they reflect clinical practice, with an appropriate quality assurance process (5 recommendations)
- **Regulations 17, 17(2) and 17(4):** training records for duty holders, with particular focus on practitioners (6 recommendations).

Other recommendations related to arrangements for clinical audit, accidental or unintended exposures, involvement of the medical physics expert and the performance of equipment.

One Improvement Notice followed an inspection under the Health and Social Care Act, where we noted non-compliance relating to quality assurance of protocols and procedures.