An update from the HIQA inspection team on activities in 2025

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14 May 2026

Health Information and Quality Authority
An tÚdarás Um Fhaisnéis agus Cáilíocht Sláinte

Summary

- Competent Authority functions and responsibilities of HIQA
- IAEA
- Inspections
- What's new, new-ish and not new
- Other involvement

A quick recap….

- Medical exposure '…*means exposure incurred by patients or asymptomatic individuals as part of their own medical or dental diagnosis or treatment, and intended to benefit their health, as well as exposure incurred by carers and comforters and by volunteers in medical or biomedical research*.'

- HIQA assesses compliance with **S.I. No. 256 of 2018** and its **6** amendments:
  1. S.I. No. 332 of 2019,
  2. S.I. No. 413 of 2019,
  3. S.I. No. 528 of 2022,
  4. S.I. No. 29 of 2023,
  5. S.I. No. 245 of 2025 and
  6. S.I. No. 280 of 2025.

- HIQA's functions are delivered by:
  - Healthcare Regulation Directorate (Healthcare Services MEIR Team) (HC) and
  - Health Technology Assessment Directorate (HTA).

HIQA Pillars

- **Regulation 11:** Establishment and review of national DRLs
- **Regulation 12**: Dose constraints for carers and comforters
- **Regulation 13:** Establishing national procedures for clinical audit for undertakings (2023)
- **Regulation 14:** Criteria for acceptability of equipment
- **Regulation 17:** Receipt and risk rating of all accidental or unintended exposure events / Annual report on lessons learned from significant accidental or unintended exposure events
- **Regulation 18:** Population dose estimation from medical exposures (2024)

- **Regulation 7:** Justification – Types of practices (February 2023)
- **Regulation 8 (5):** Asymptomatic Guidelines (November 2025)

Assessment of compliance

The Regulations require HIQA, the Authority, to perform a number of functions.

HIQA satisfies these functions largely by developing and publishing relevant information on our website for undertakings and their staff

The undertaking should incorporate all HIQA publications into its policies, procedures and guidelines (PPGs) and use the available information to ensure systems and processes are in place to achieve regulatory compliance, in particular, the assessment-judgement framework (AJF) and associated guidance

HIQA assess compliance through inspection and other monitoring tools

The Healthcare Regulation MEIR team

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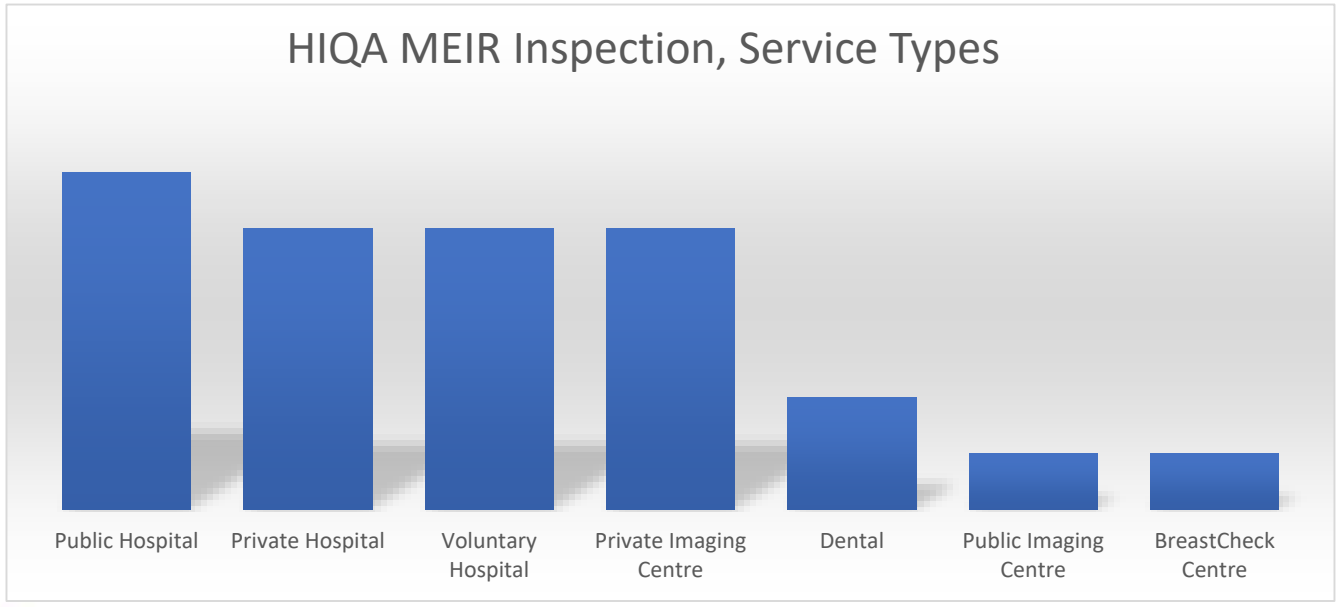
IAEA's Integrated Regulatory Review Service (IRRS) Mission to Ireland 2026

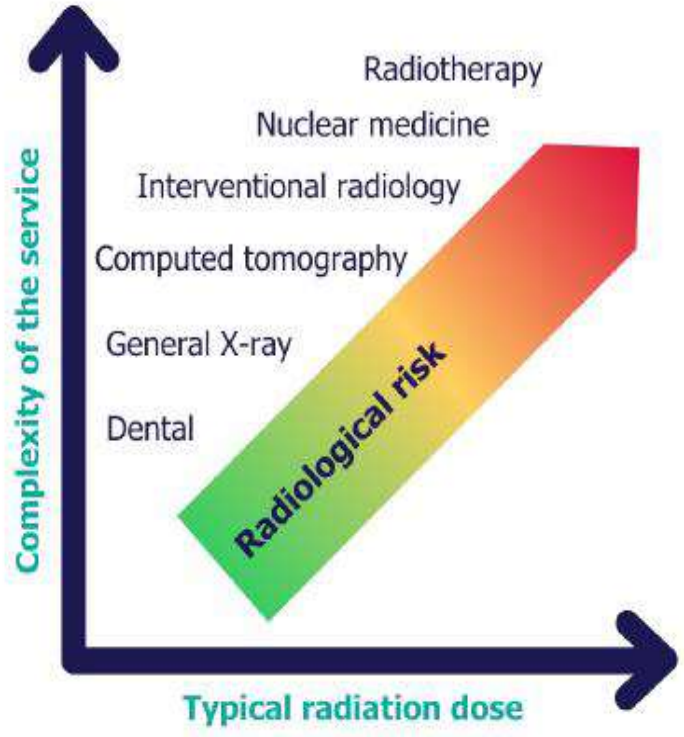
- Objective of mission was to review of Ireland's compliance with IAEA safety standards
- Onsite component conducted from 19 to 28 January 2026,conducted by an international team of senior safety experts.
- A self-assessment exercise and associated preparatory work was completed and submitted in 2025.
- Key parties involved included representatives from the Department of Climate, Energy and the Environment (DCEE), the Department of Health (DOH), the Environmental Protection Agency (EPA) and the Health Information and Quality Authority (HIQA).
- Overall very positive outcome with the press release from the IAEA stated
- Final report which will include recommendations and suggestions is expected to be published on the IAEA website after July 2026.

https://www.iaea.org/newscenter/pressreleases/iaea-mission-finds-comprehensive-regulatory-framework-for-nuclear-and-radiation-safety-in-ireland

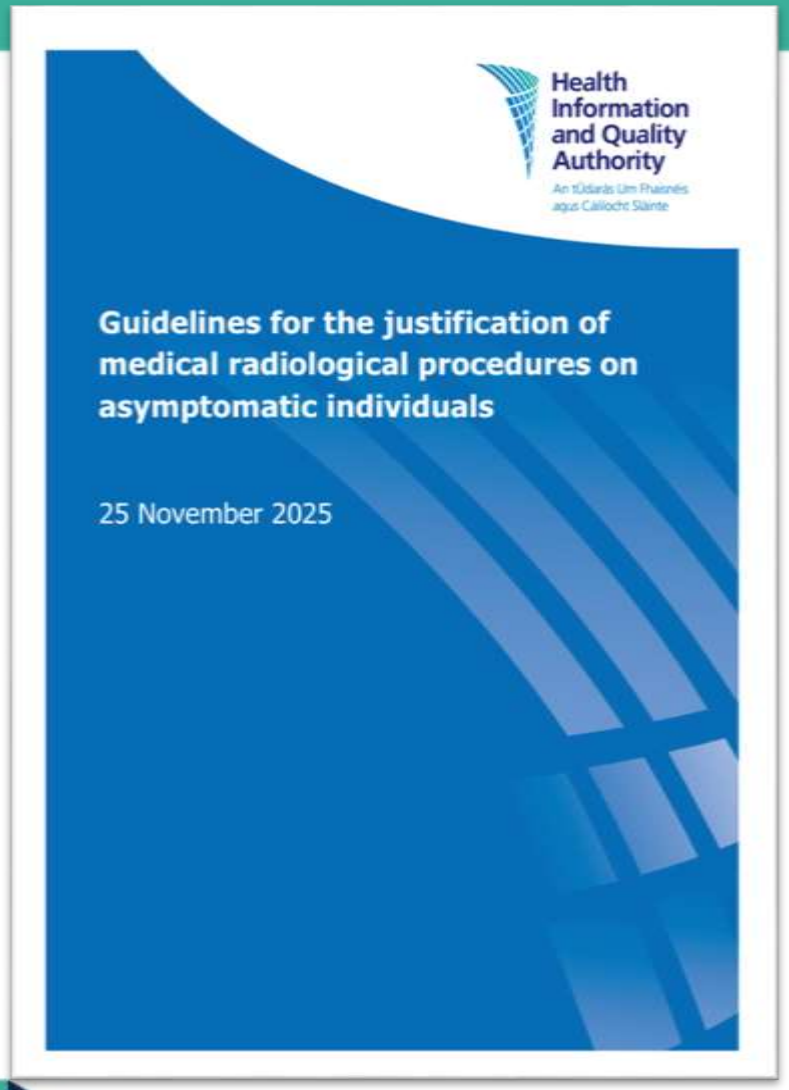
Regulation through inspection

- HIQA's role as regulator of medical exposure to ionising radiation is to assess compliance with the Regulations (2018) including all subsequent amendments.
- In 2025, HIQA conducted a range of inspections in a number of different service types.



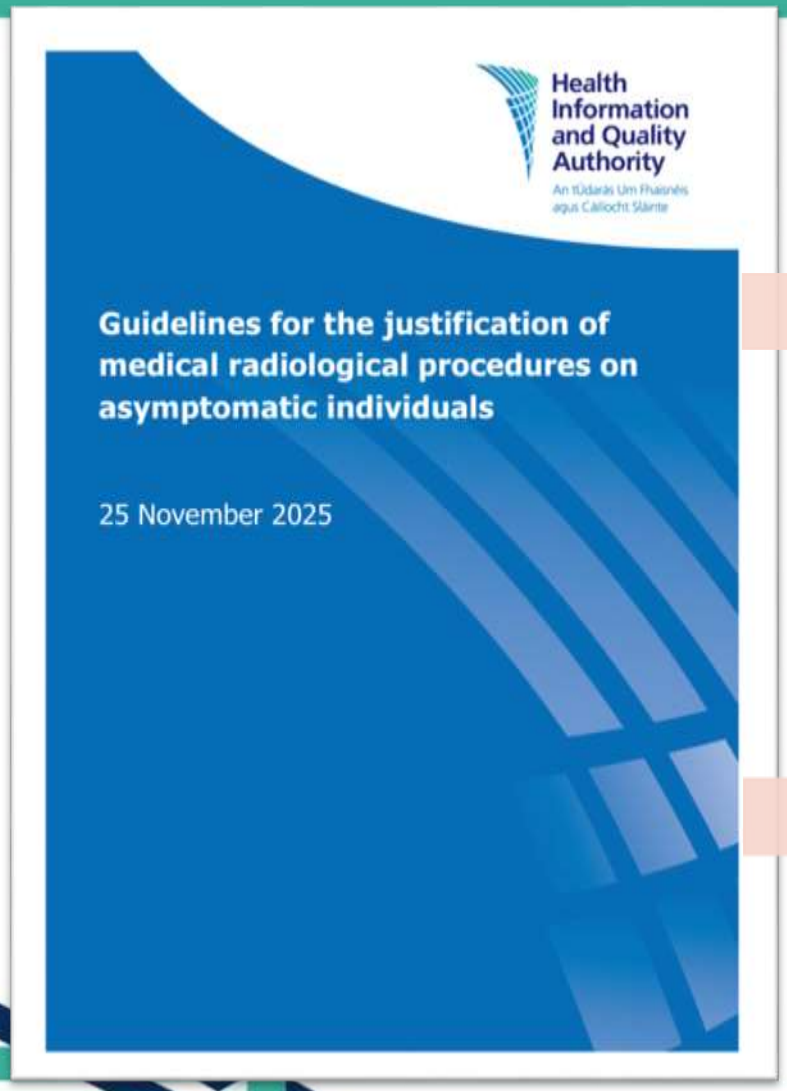


What's new ?



- HTA presentation
- Webinar recording and slides available on HIQA's website
- Undertakings should utilise the guidelines and ensure that they are currently taking steps to demonstrate how they are in compliance with this regulatory requirement

What’s new ?



1. Has the undertaking ensured that, in the case of a medical radiological procedure on an asymptomatic individual, performed for the early detection of disease:
   a. the procedure, -
      i) is part of a health screening programme, or
      ii) has specific documented justification for that individual by a practitioner, in consultation with the referrer, in accordance with guidelines published by HIQA under Regulation 8(6), and
   b. special attention is given to the provision of adequate information to the individual, relating to the benefits and risks associated with the radiation dose from the medical exposure in line with Regulation 8(13)?

part of a national health screening programme, inspectors may review:

- evidence that medical radiological procedures are conducted in accordance with HIQA guidelines, to include:
  - reviews that ensure that the undertaking has adequate oversight that these types of medical radiological procedures are justified and conducted in accordance with HIQA guidelines
  - records of justification for these types of medical radiological procedures
  - policies, procedures and guidelines relevant to these types of medical radiological procedures
  - risk profiles that are completed based on the most up-to-date evidence
  - information provided to asymptomatic service users about the potential benefit and harm of the medical radiological procedure, including the implications of possible findings
  - the processes in place for integrating results of examinations into integrated care pathways for managing a clinical condition identified during asymptomatic screening
  - Appropriate quality assurance in line with available evidence.

What’s new ?

Considerations for compliance

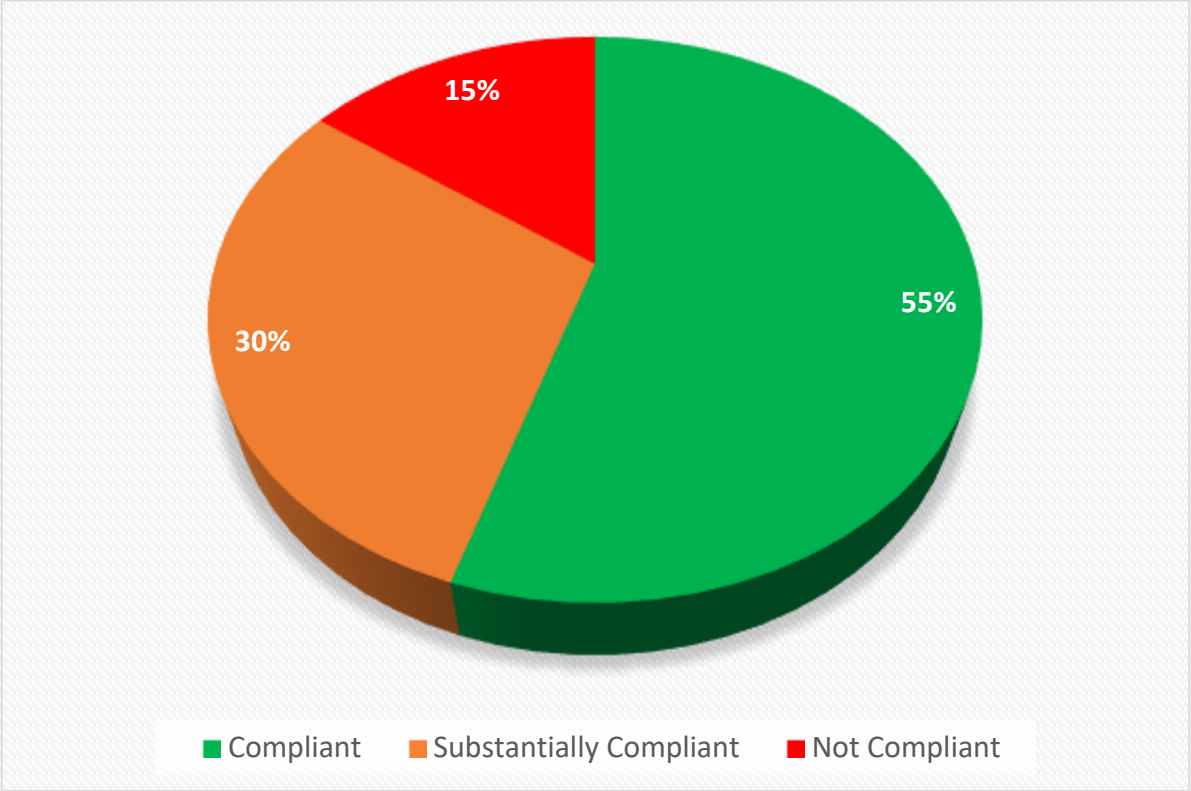
- Is there a documented process in place, are the governance and associated responsibilities defined?
- Has the undertaking reviewed its service and identified all procedures done on asymptomatic individuals which are NOT part of an **approved national health screening programme**?
- Has the above been documented formally?
- If so have all guideline statements been satisfied?
- Is this clearly documented and understood by all staff, service users and referrers?

What's new-ish ?

We published the *National procedures for clinical audit of radiological procedures involving medical exposure to ionising radiation* in November 2023 and began to assess compliance mid 2024.

In 2025, Regulation 13(4) was assessed in the majority of services inspected

Has the undertaking ensured that clinical audits are carried out in line with national procedures established by HIQA?



What's new-ish ?

Has the undertaking ensured that clinical audits are carried out in line with national procedures established by HIQA?

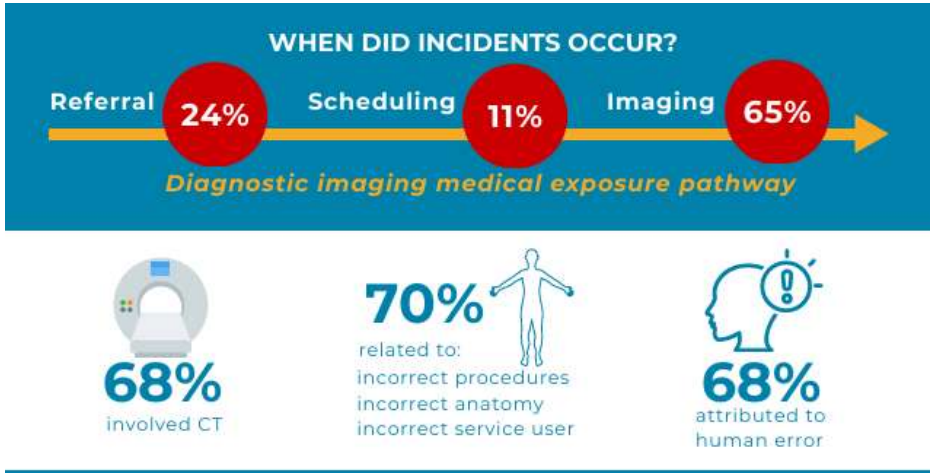
Considerations for compliance

- In facilities with existing corporate audit strategies, how is HIQA's national procedures incorporated or addressed?
- Is there a documented clinical audit strategy (Does it align with the principles of clinical audit), is the governance of radiology audit clearly defined and aligned with the national procedures?
- Is there a schedule?
- Do audit topics cover the three main elements for oversight across the full clinical pathway (structure, process, outcome)

What's new…..but not new ?

In 2025 HIQA published its 6th *'lessons learned from significant events'* as required by Regulation 17(2).

The findings are consistent from 2019



What's new…..but not new ?

The Authority shall ensure that mechanisms are in place for the timely dissemination of information, relevant to radiation protection in medical exposure, regarding lessons learned from significant events.

Human error – Are contributing factors considered?

Corrective actions – Consider the efficacy……

Consider bottlenecks and gatekeeper staff – Consider resource allocation

Other Involvement

European Commission
Directorate-General for Energy

Engaged in the promotion of national and inte
radiation protection through:

CA

Steering Group on Qua

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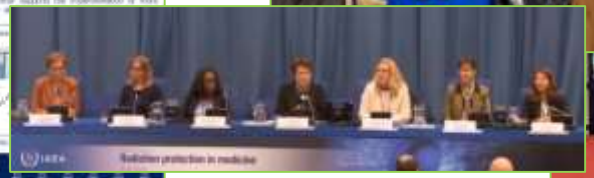
Radiation Applications (SAMIRA) initiatives

FANC
FEDERAL AGENCY FOR NUCLEAR CONTROL



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Summary

- Well established regulator, now familiar to the stakeholders.
- Transparent approach to regulation.
- New and additional competent authority functions are changing elements and aspects of this.
- However, we strive to ensure that we make all information available before compliance judgements are made on inspection.
- Please take some time to visit our website – we are always open to direct communication on any regulatory issues (**radiationprotection@hiqa.ie**).

Visit HIQA's website

All documentation and information can be found at **www.hiqa.ie**

Thank you

Contact us: **radiationprotection@hiqa.ie**

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