



Regulation of medical exposure to ionising radiation

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Nurse Midwife Referrers of Radiological Procedures CPD Study Day
8 June 2023

Outline of presentation

- Introduction to HIQA's role as the competent authority for medical exposures
- Assessment of compliance
 - What to expect during an inspection
 - Regulatory requirements and
 - Overview of inspection findings
- Summary

MEDICAL EXPOSURE TO IONISING RADIATION

PATIENTS AND SERVICE USERS

The European basic safety standards for protection arising from medical exposure to ionising radiation were transposed into Irish law in 2019 (S.I. No. 256 of 2018). The regulations designate HIQA as the independent competent authority for medical exposures in Ireland.

HIQA's role in ionising radiation is to promote better, safer practice across all public and private facilities in Ireland providing medical and dental radiological services. HIQA achieves this through its regulatory programme and health technology assessment programme.



Developing Guidelines and
Establishing Guidance



Regulating and
Assessing Compliance



Evidence-based
justification of practices

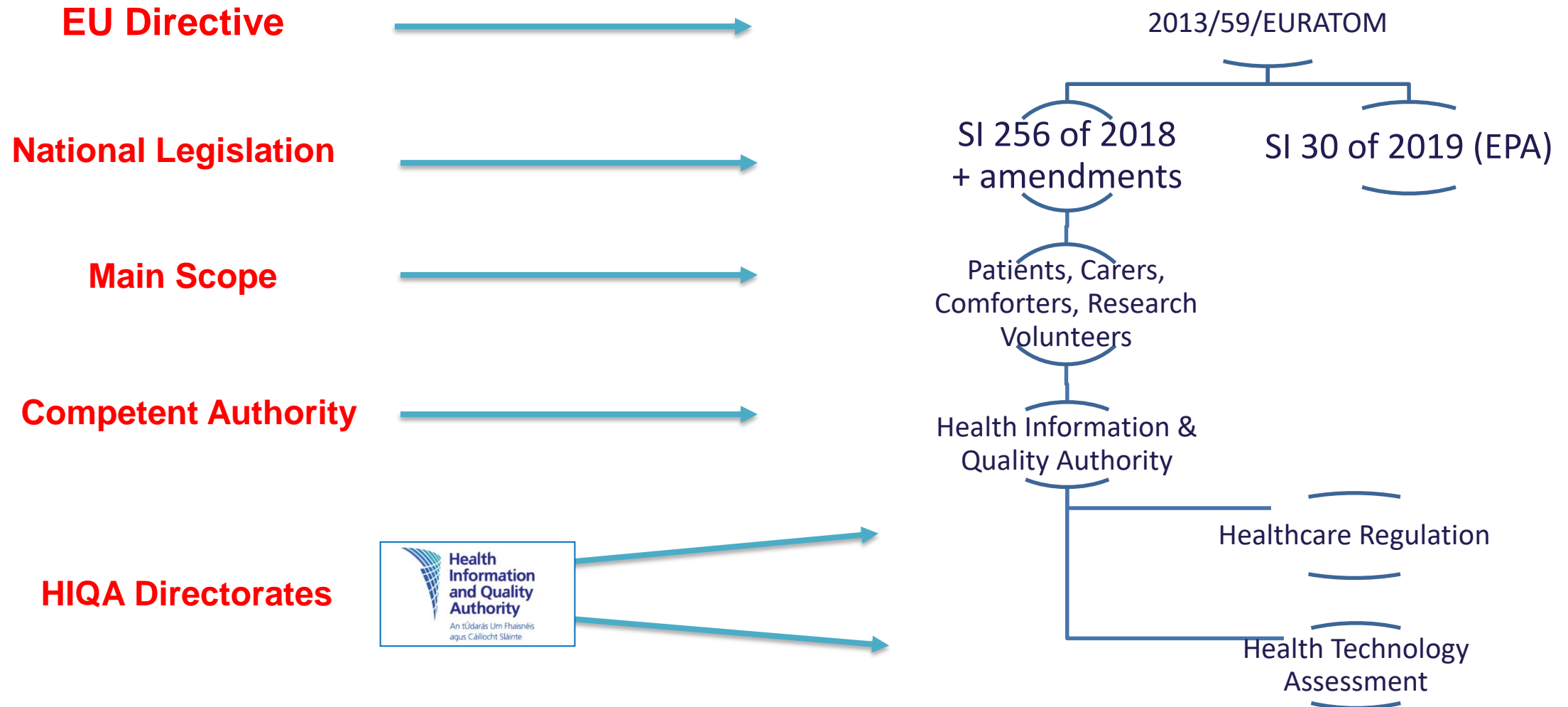
More information about our work is available online at:

<https://www.hiqa.ie/areas-we-work/ionising-radiation>

Introduction to HIQA's role as the competent authority for medical exposures



HIQA's legislative basis



Healthcare Regulation Directorate

- Inspection

- HIQA's role as regulator of medical exposure to ionising radiation is to assess compliance with European Union (Basic safety standards for protection against dangers arising from medical exposure to ionising radiation) Regulations 2018, as amended.
- Role in regulating **public** and **private** facilities which provide medical exposures to ionising radiation
- HIQA take a risk-based and graded approach to regulation across a range of medical radiological services.



Healthcare Regulation Directorate - Competent Authority Functions

- **Regulation 11:** Establishment and review of national DRLs
- **Regulation 12:** Dose constraints for carers and comforters
- **Regulation 14:** Criteria for acceptability of equipment
- **Regulation 17:** Annual report on lessons learned from significant accidental or unintended exposure events
- **Regulation 13:** Establishing national procedures for clinical audit for medical exposures - *on-going work*

Public consultation for the *National procedures for clinical audit of medical exposures* will commence in the coming weeks

Update: Public consultation commenced 19 June 2023 and closes **31 July 2023**



Lessons learned from notifications of medical exposure to ionising radiation in 2020

76 incidents in 2020
65 incidents occurred in diagnostic imaging, mainly in CT services.
11 incidents occurred in radiotherapy services.

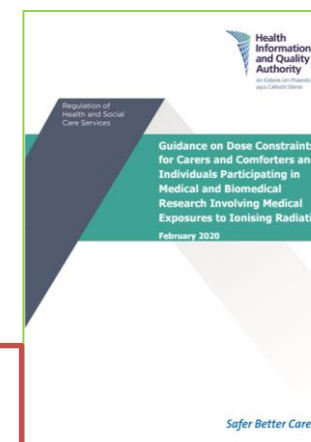
What we found

- Increased reporting:** 11% increase since 2019 in number of incidents reported. Half reports received from only 20% of hospitals.
- 1st time:** We received reports from diagnostic imaging, interventional cardiology.
- The wrong person:** 34% of incidents involved the wrong person.

What needs to improve ?

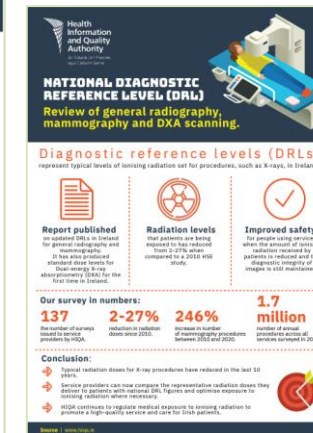
Empowerment	Justification	Communication	Correction
Empower staff to report Empower patients to be included in the identification process Empower staff and patients to share relevant information	Justify procedures at every stage Seek previous imaging	Communicate within the service and with patients Communication with other providers and to HQIA	Review all incidents Look for trends in similar incidents Take corrective actions appropriate for the incidents

Source | www.hiqa.ie



Guidance on Dose Constraints for Carers and Comforters and Individuals Participating in Medical and Biomedical Research Involving Medical Exposures to Ionising Radiation
February 2020

Health Information and Quality Authority
Safer Better Care



NATIONAL DIAGNOSTIC REFERENCE LEVEL (DRL)
Review of general radiography, mammography and DXA scanning.

Diagnostic reference levels (DRLs)
represent typical levels of ionising radiation set for procedures, such as X-rays, in Ireland.

- Report published:** An updated DRLs in Ireland for general radiography and mammography. Standardised dose levels for diagnostic procedures (DRLs) for the first time in Ireland.
- Radiation levels:** Radiation levels are being compared to the national DRLs to see if they are being exceeded.
- Improved safety:** For major areas of practice, when the amount of ionising radiation received is less than the DRL, the diagnostic integrity of images is still maintained.

Our survey in numbers:
137 DRLs in 2019
2-27% increase in number of notifications received between 2019 and 2020
246% increase in number of notifications received between 2019 and 2020
1.7 million number of annual procedures across all services surveyed in 2019.

Conclusion:
Typical radiation doses for X-ray procedures have reduced in the last 10 years.
Service providers can now compare the representative radiation doses they deliver to patients with national DRLs, figure out exposure to ionising radiation where necessary.
HIQA continues to regulate medical exposure to ionising radiation to promote a high-quality service and care for Irish patients.

Source | www.hiqa.ie



Diagnostic Reference Levels
Guidance on the establishment, use and review of diagnostic reference levels for medical exposure to ionising radiation.
Updated July 2021

Health Information and Quality Authority
Safer Better Care



HIQA'S 2019 OVERVIEW REPORT ON ACCIDENTAL OR UNINTENDED MEDICAL EXPOSURES TO IONISING RADIATION

In 2019, we received 68 notifications
But zero notifications from some relatively high dose services from Interventional Radiology and Cardiology.

Patient safety culture
To prevent errors, you need to implement robust and efficient measures. These measures should review systems and process as a whole, human error being only one part of a system.

Why should I report near-misses locally?

- To be compliant
- To improve patient safety
- To minimise the probability of preventable events

Diagnostic Imaging
In 2019, the majority of the notifications came from CT and related to the incorrect service user being imaged.
The key learnings were to have strong patient identification systems in place to correctly establish the right patient at all stages of the patient journey for X-ray.

Radiotherapy
HIQA received 13 notifications from radiotherapy services in 2019.
Overall, there was a positive culture of reporting across radiation oncology services.

READ OUR FULL REPORT AT WWW.HIQA.IE

HTA Directorate

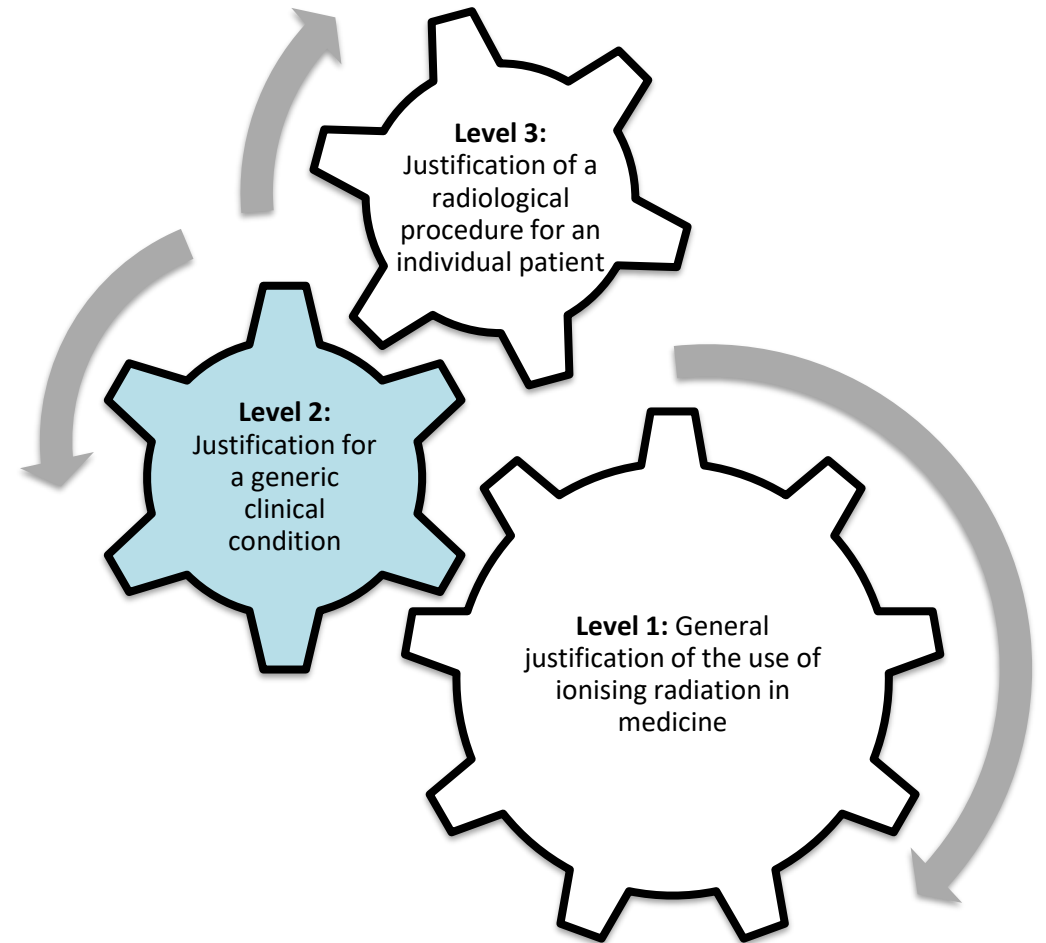
HTA medical exposure to ionising radiation team began carrying out generic justification of new practices in 2023 – outcomes published on website

Regulation 7 Justification of practices

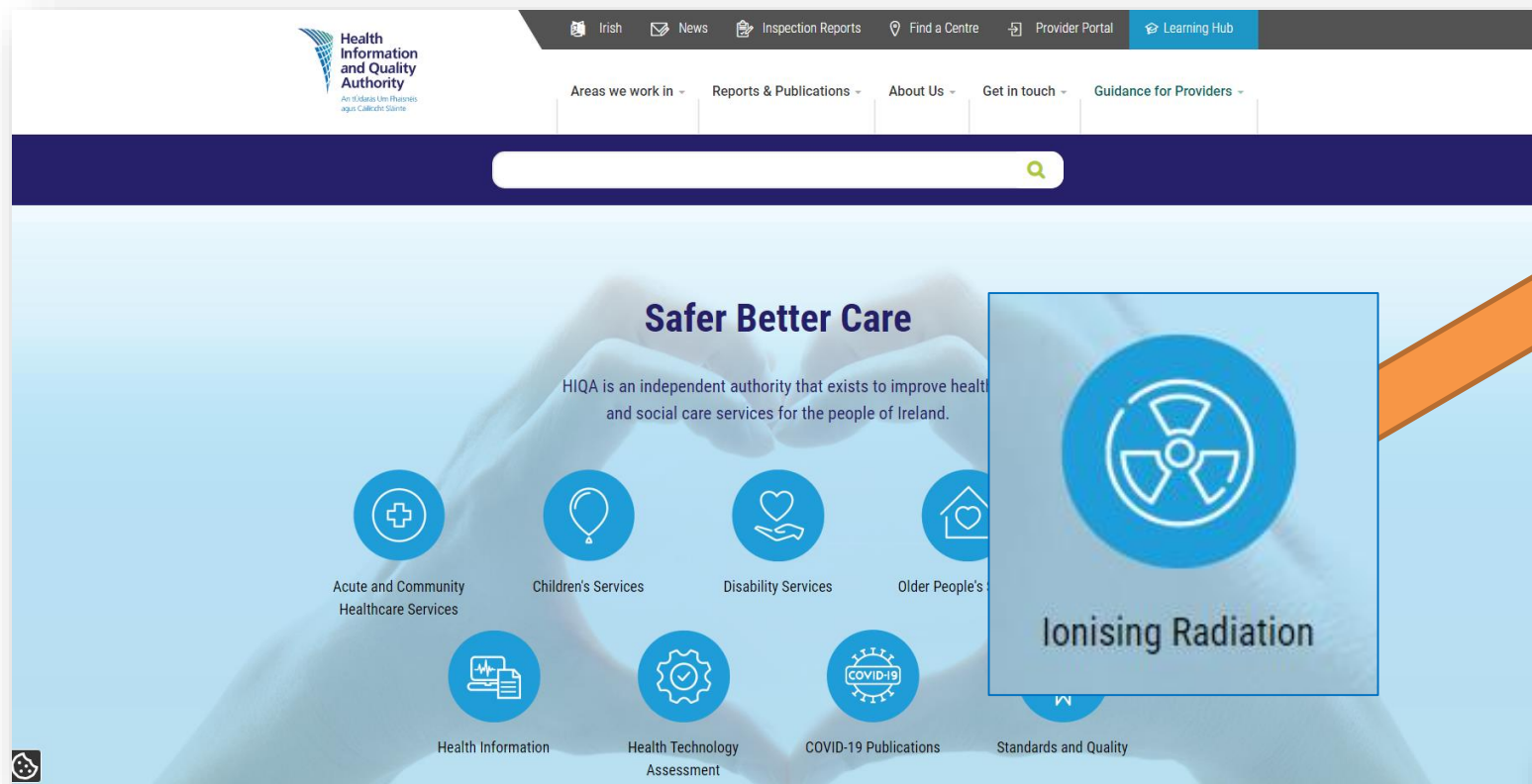
- requires that new types of practices involving medical exposure are justified by HIQA in advance of them being generally adopted.

Regulation 8(6)

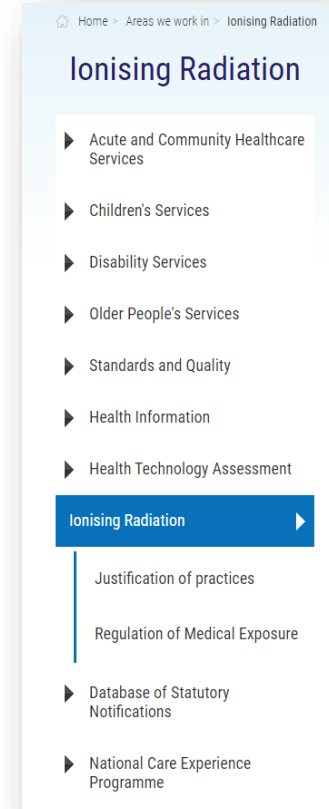
- Publishing guidance on the specific justification of medical radiological procedure on an asymptomatic individual, performed for the early detection of disease that is not part of a health screening programme – **on-going work**



HIQA website (www.hiqa.ie)



The screenshot shows the HIQA website homepage. At the top, there is a navigation bar with links for Irish, News, Inspection Reports, Find a Centre, Provider Portal, and Learning Hub. Below this is a search bar and a menu with categories like 'Areas we work in', 'Reports & Publications', 'About Us', 'Get in touch', and 'Guidance for Providers'. The main content area features a large banner with the text 'Safer Better Care' and a description of HIQA's mission. Below the banner are several circular icons representing different service areas: Acute and Community Healthcare Services, Children's Services, Disability Services, Older People's Services, Health Information, Health Technology Assessment, COVID-19 Publications, and Standards and Quality. A blue box with a radiation symbol and the text 'Ionising Radiation' is overlaid on the page, with an orange arrow pointing from the right towards it.



This screenshot shows a navigation menu for the 'Ionising Radiation' section. The menu is titled 'Ionising Radiation' and includes a list of sub-sections: Acute and Community Healthcare Services, Children's Services, Disability Services, Older People's Services, Standards and Quality, Health Information, Health Technology Assessment, and Ionising Radiation (which is highlighted with a blue bar and a right-pointing arrow). Below the highlighted section, there are two sub-items: 'Justification of practices' and 'Regulation of Medical Exposure'. At the bottom of the menu, there are two more sub-sections: 'Database of Statutory Notifications' and 'National Care Experience Programme'.

Regulation of Medical Exposure to Ionising Radiation >

Justification of practices >

HIQA website



Home > Areas we work in > Ionising Radiation > Regulation of Medical Exposure to Ionising Radia...

Regulation of Medical Exposure to Ionising Radiation

Reader View: Off

- ▶ Acute and Community Healthcare Services
- ▶ Children's Services
- ▶ Disability Services
- ▶ Older People's Services
- ▶ Standards and Quality
- ▶ Health Information
- ▶ Health Technology Assessment
- ▶ Ionising Radiation**
 - Justification of practices
 - Regulation of Medical Exposure**
- ▶ Database of Statutory Notifications
- ▶ National Care Experience Programme

The European Union (Basic Safety Standards for Protection Against Dangers Arising from Medical Exposure to Ionising Radiation) Regulations 2018 and 2019 provide a framework for regulating medical exposure to ionising radiation in Ireland. HIQA is the competent authority in Ireland with responsibility for inspecting against and enforcing these regulations. This means that we regulate all service providers (undertakings) of medical exposures in Ireland against these regulations. Through monitoring and regulatory programmes, we aim to provide assurances to the public that undertakings are implementing and meeting relevant medical exposures regulations and are making quality and safety improvements that safeguard all service users.

- What we do**
We use regulations to monitor and inspect services which use medical exposure to ionising radiation.
- The legislation**
The primary regulations.
- Inspections**
Inspections are carried out to seek assurance that undertakings are in compliance with the regulations.
- Radiation incident notifications and forms**
Notify HIQA of a significant event.
- Information events**

Home > Areas we work in > Ionising Radiation > Justification of practices

Justification of practices

Reader View: C

- ▶ Acute and Community Healthcare Services
- ▶ Children's Services
- ▶ Disability Services
- ▶ Older People's Services
- ▶ Standards and Quality
- ▶ Health Information
- ▶ Health Technology Assessment
- ▶ Ionising Radiation**
 - Justification of practices**
 - Regulation of Medical Exposure
- ▶ Database of Statutory Notifications
- ▶ National Care Experience Programme

According to the legislation (Statutory Instrument 256 of 2018), HIQA must justify:

- any new practices that involve exposing patients to ionising radiation before they are generally adopted*
- existing practices that involve exposing patients to ionising radiation, if new and significant information becomes available about the efficacy or safety of the practice itself or about any alternative practice that could replace it

*generally adopted means the practice is used for broad categories of patients, rather than individual patients. The process whereby HIQA approves a practice for a broad category of patients is also known as 'generic justification'.

- How to apply for generic justification**
To apply for the generic justification please see information below
- Medical Exposure to Ionising Radiation (MEIR) Expert Advisory Group**
See information on HIQA's EAG which advises on medical exposure to ionising radiation functions
- Applications in progress**
See list of applications for generic justification currently in progress
- Generic justification decisions**
Published reports on the justification of practices involving medical exposure to

What to expect during an inspection



The inspection announcement



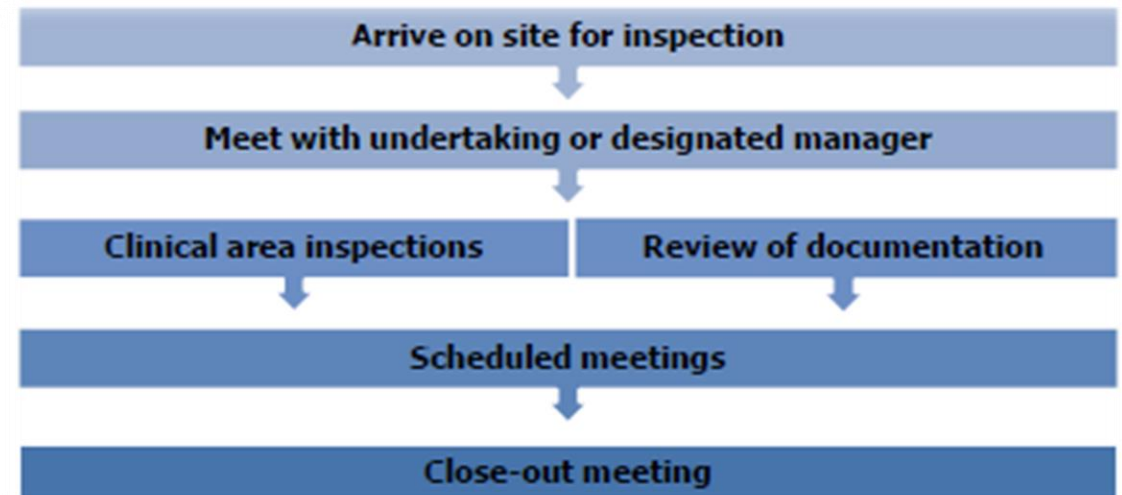
- Inspections can be **announced, short-notice announced** or **unannounced**
- If announced or short-notice announced, documentation will be requested in advance of the on-site inspection
- Inspections are specific to an individual facility and undertaking
- Duration on-site will be dependent on the size and scale of the activities conducted and findings throughout the inspection
- Guidance on what to expect and the inspection process has been published and is available at www.hiqa.ie

The inspection day

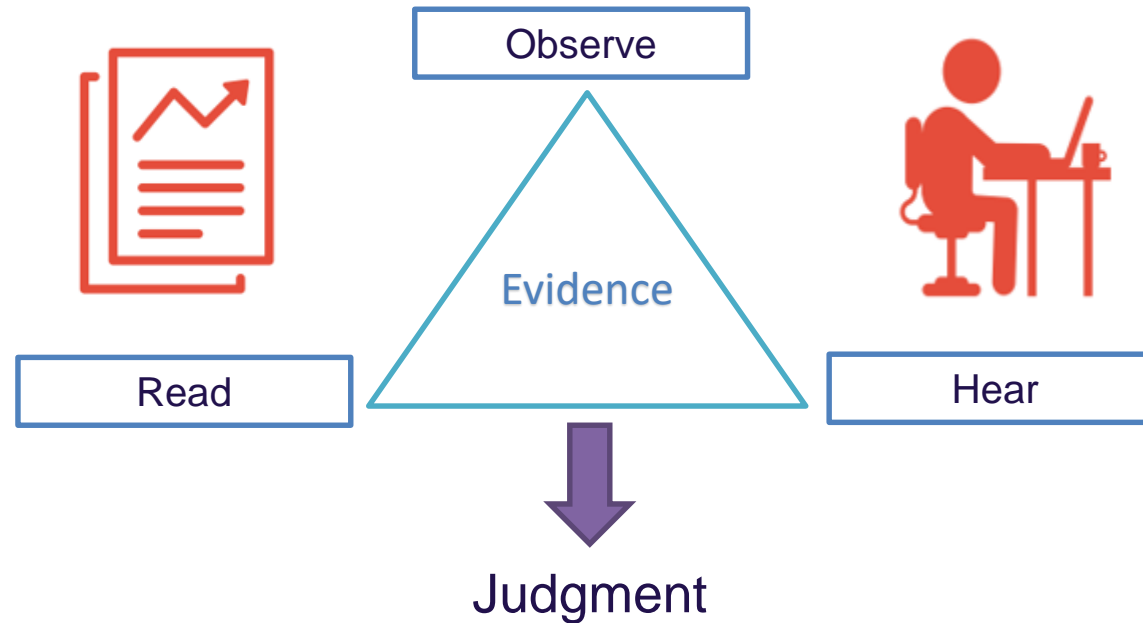
During the inspection, inspectors will gather information relating to:

- the systems and processes in place for:
 - the safe delivery of ionising radiation
 - risk management and incident reporting
 - communicating with clinical staff about radiation protection arrangements
- access to and use of policies, procedures and guidelines to support the safe use of medical exposure to ionising radiation
- monitoring arrangements in place for ionising radiation
- staff training and sharing of learning relevant to ionising radiation delivery.

Inspectors gather this evidence by **talking with staff, visiting the clinical areas and reviewing documentation**. They may also talk with service users.



Assessment of compliance



Compliant: a judgment of compliant means the undertaking or other person is in **full compliance** with the relevant regulation.

Substantially compliant: a judgment of substantially compliant means that the undertaking or other person has **generally met the requirements of the regulation** but some action is required to be fully compliant. This finding will have a risk rating of yellow, which is low risk.

Not compliant: a judgment of not compliant means the undertaking or other person has **not complied with a regulation** and that considerable action is required to come into compliance.

Assessment of compliance



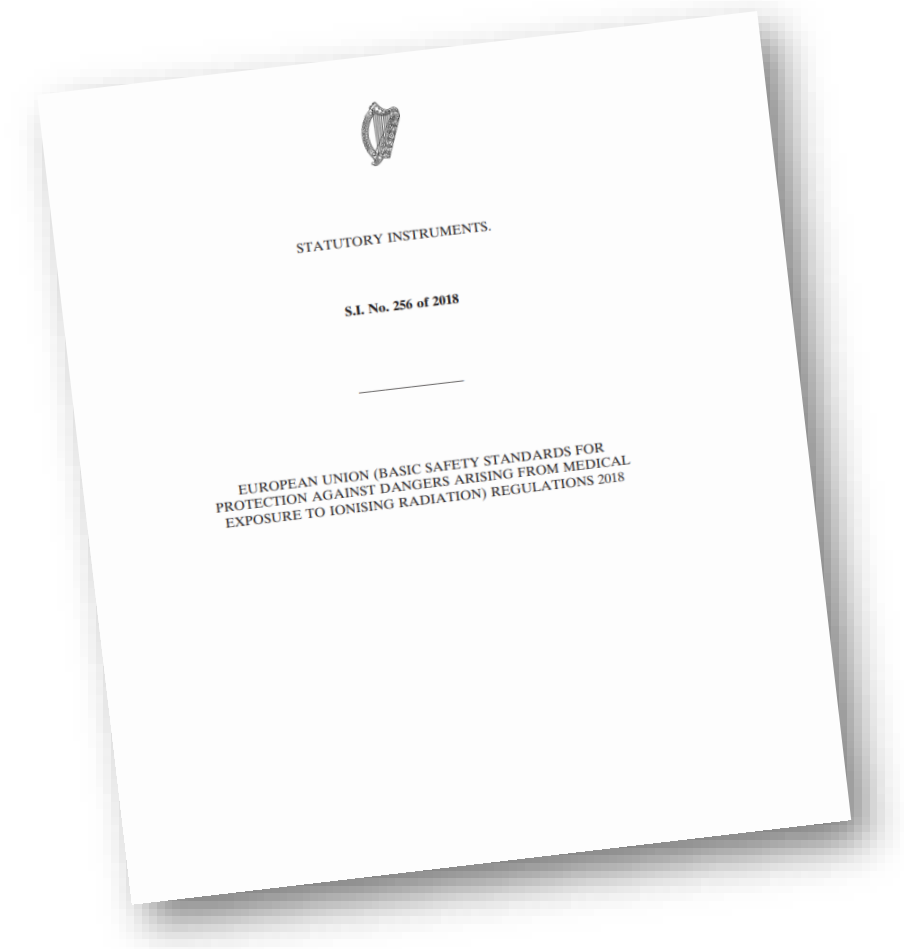
Referrers: Regulatory requirements and assessment of compliance with the regulations



Assessment of compliance - Overview

Referrers are mentioned in the following regulations:

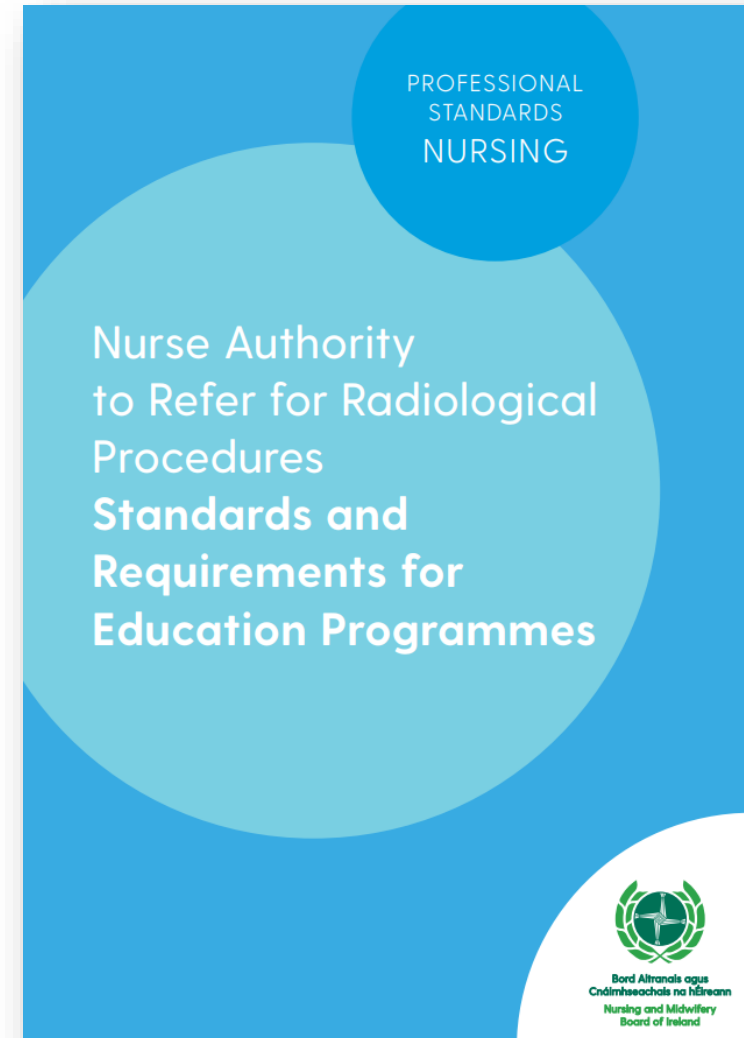
- Regulation 4: Referrers
- Regulation 8: Justification of medical exposures
- Regulation 10: Responsibilities
- Regulation 13: Procedures
- Regulation 16: Special protection during pregnancy and breastfeeding
- Regulation 17: Accidental and unintended exposures and significant events



Regulation 4: Referrers

Regulation 4: Referrers

- Sets out what professions can refer a patient to a practitioner for a medical radiological procedure
- 14(1)(a)...a registered nurse or registered midwife within the meaning of the Nurses and Midwives Act 2011 (No. 41 of 2011) **who meets the standards and requirements set down from time to time by the nursing and midwifery Board of Ireland** in relation to the prescribing of medical ionising radiation by nurses or midwives...

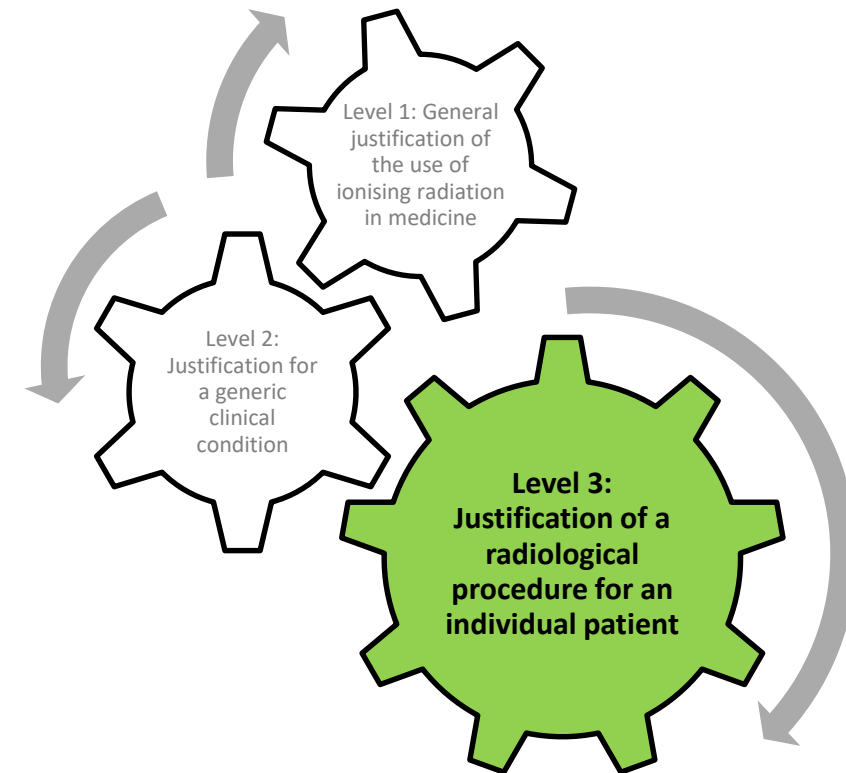


Regulation 8 and 10: Justification

Regulation 8: Justification of medical exposures and Regulation 10: Responsibilities

Regulation 8(1): Justification – *sufficient net benefit...and...taking into account the efficacy, benefits and risks of available alternative techniques having the same objective but involving no or less exposure to ionising radiation.*

- Regulation 10(3): Justification process of individual medical exposures involves the referrer **and** a practitioner
- Regulation 8(10): Referrals must be **in writing, state the reason for requesting the particular procedure** and **accompanied by sufficient medical data** to enable the practitioner to carry out a justification assessment
- Regulation 8(12): The referrer **and** the practitioner should **obtain previous diagnostic information or medical records** relevant to the planned exposure and consider their data to avoid unnecessary exposure
- Regulation 8(13): Referrer or the practitioner shall ensure that the patient* is **provided with adequate information** relating to the benefits and risks associated with the radiation dose from the medical exposure



Regulation 17

Regulation 17: Accidental and unintended exposures and significant events

Ability to identify, record, analyse and minimise the occurrence of an accidental and unintended exposure to ionising radiation

- Notification to HIQA within the specified timelines once specific thresholds are met – currently 17 categories of significant events
- Arrangements in place to identify incidents involving or potentially involving accidental or unintended exposure to ionising radiation including, record-keeping and analysis of incidents involving or potentially involving accidental or unintended exposure to ionising radiation
- Undertakings shall have arrangements in place to inform **the referrer** ... about clinically significant unintended or accidental exposures and the results of the analysis

Lessons learned from medical exposure to ionising radiation incidents in 2021



86 incidents in 2021

66 incidents occurred in diagnostic imaging, mainly in CT services.

20 incidents occurred in radiotherapy services.

What we found



Increased reporting

26% increase in notifications submitted in 2021, when compared with that of 2019 when HIQA began receiving notifications



Our Portal

Increased use of HIQA's portal system for submission of notifications



The wrong person

26% of incidents involved the wrong person

What needs to improve ?

Corrective Actions

Consider system-focused measures rather than people-focused measures for increased effectiveness.

Low Reporting Rates

Review practices in place to ensure all incidents are being identified and reported, as required.

Timely Reporting of Incidents to HIQA

HIQA must be informed within three working days of discovery of an incident.

Use of Quality, Risk and Safety Resources

Use quality, risk and safety resources where available to enhance oversight, mitigate risk and increase learning.

Overview of findings 2022

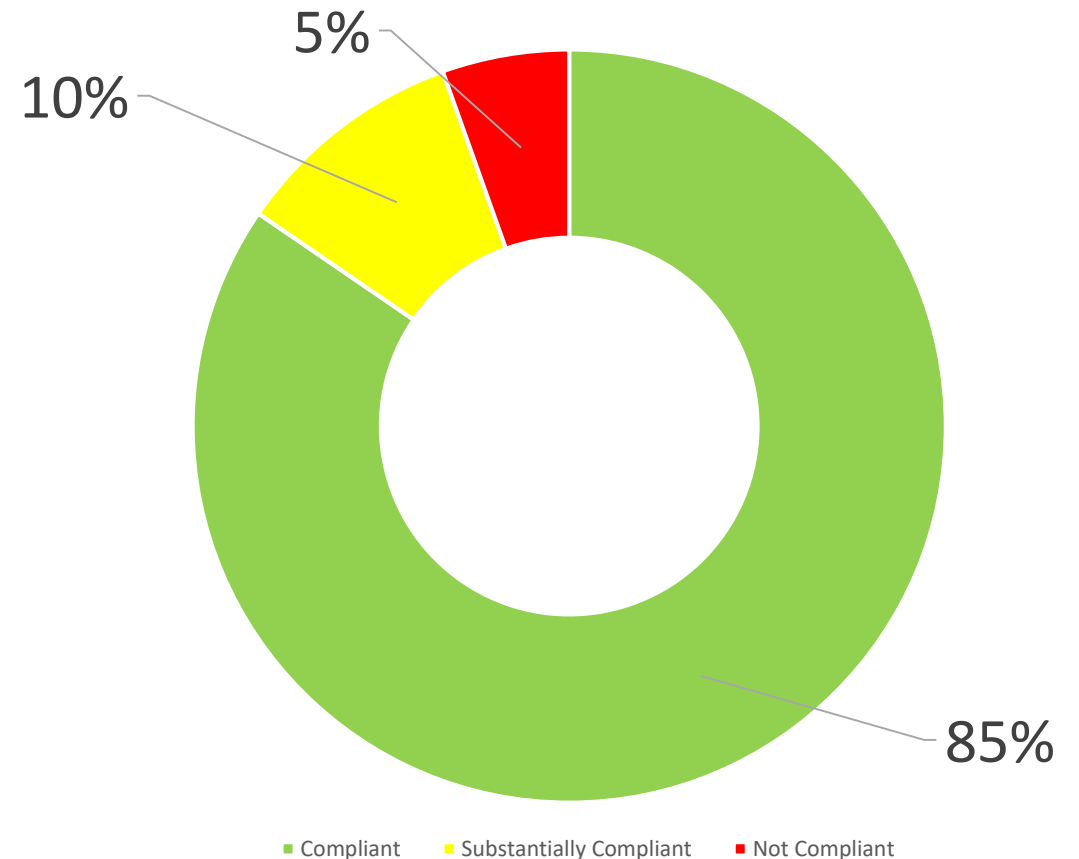


Ionising radiation regulation 2022

2022 inspection activity

- 63 inspections in total
- 24 inspections of dental practices
 - Mixture of follow up on self-assessment questionnaire findings and routine monitoring
- 39 were a mixture of public and private hospitals (including acute and community), private imaging centres and standalone DXA units

Levels of compliance with regulations assessed in non-dental facilities 2022



Summary



Summary


- Introduction to HIQA's role as the competent authority for medical exposures
 - Legislative basis
 - Competent authority functions including HTA Directorate
 - Where to find more information (www.hiqa.ie)
- Assessment of compliance
 - What to expect during an inspection
 - Documentation available
 - Overview of inspection
 - How compliance is assessed
 - Regulatory requirements
 - Key regulations relating to referrers
 - Overview of inspection findings 2022

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Developing Guidelines and Establishing Guidance Regulating and Assessing Compliance Evidence-based justification of practices

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Questions?

For ionising radiation regulation queries:
radiationprotection@hiqa.ie



**Health
Information
and Quality
Authority**

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Thank You

For ionising radiation regulation queries:
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