

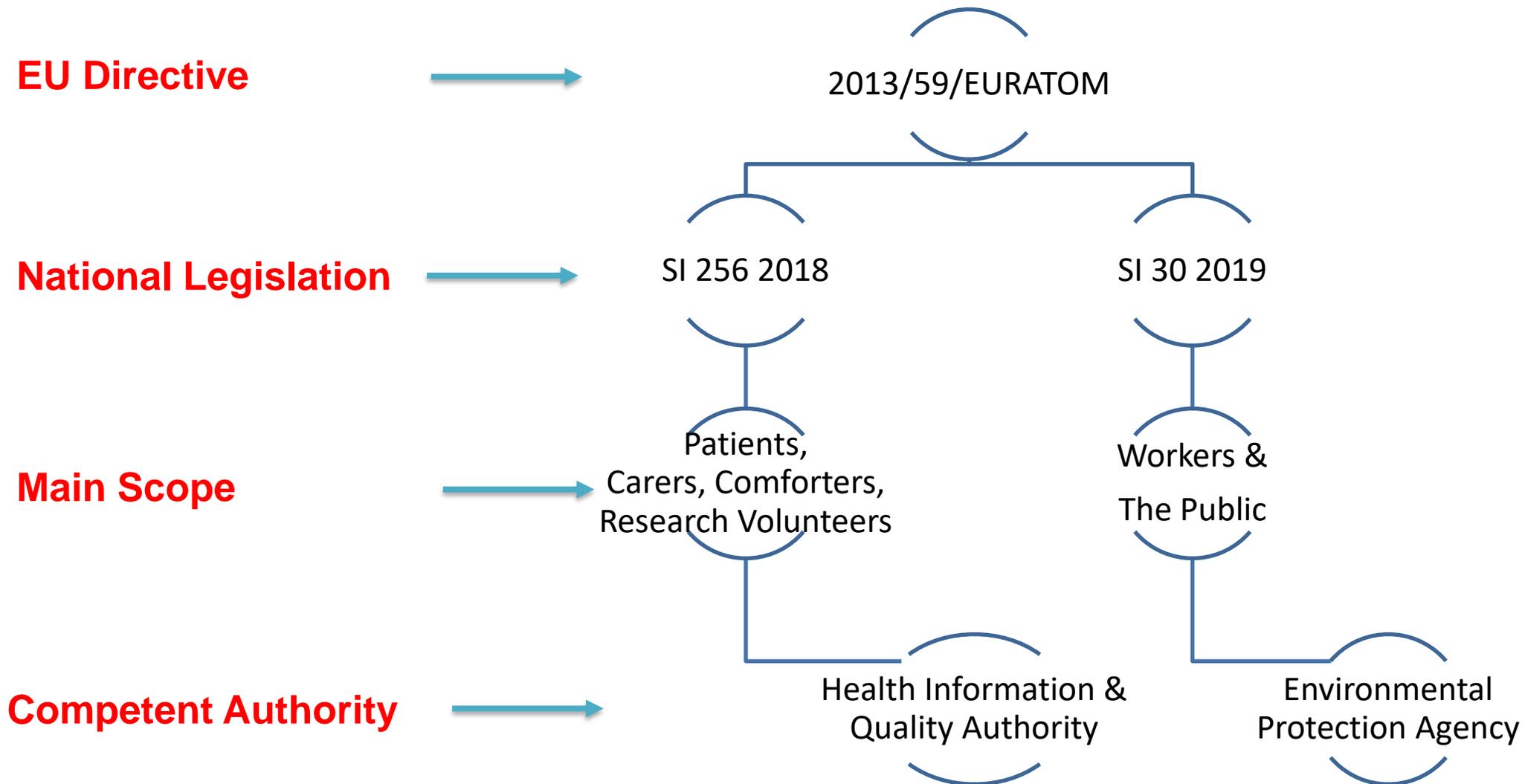


National Procedures for Clinical Audit of Medical Radiological Procedures

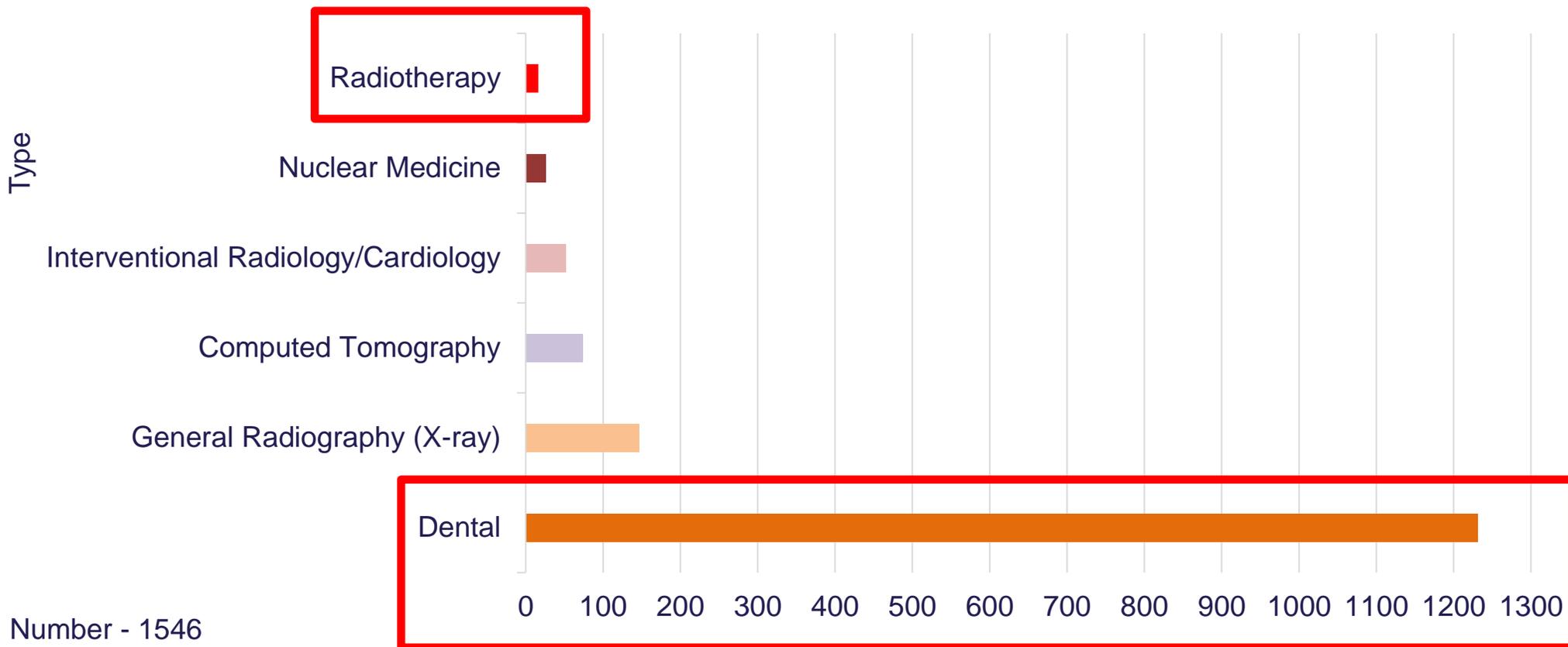
Dr. Agnella Craig,
Regional Manager,
Medical Exposures to Ionising Radiation,
Healthcare Regulation Directorate
Health Information and Quality Authority

Danielle Bracken,
Inspector of Healthcare Services,
Healthcare Regulation Directorate
Health Information and Quality Authority

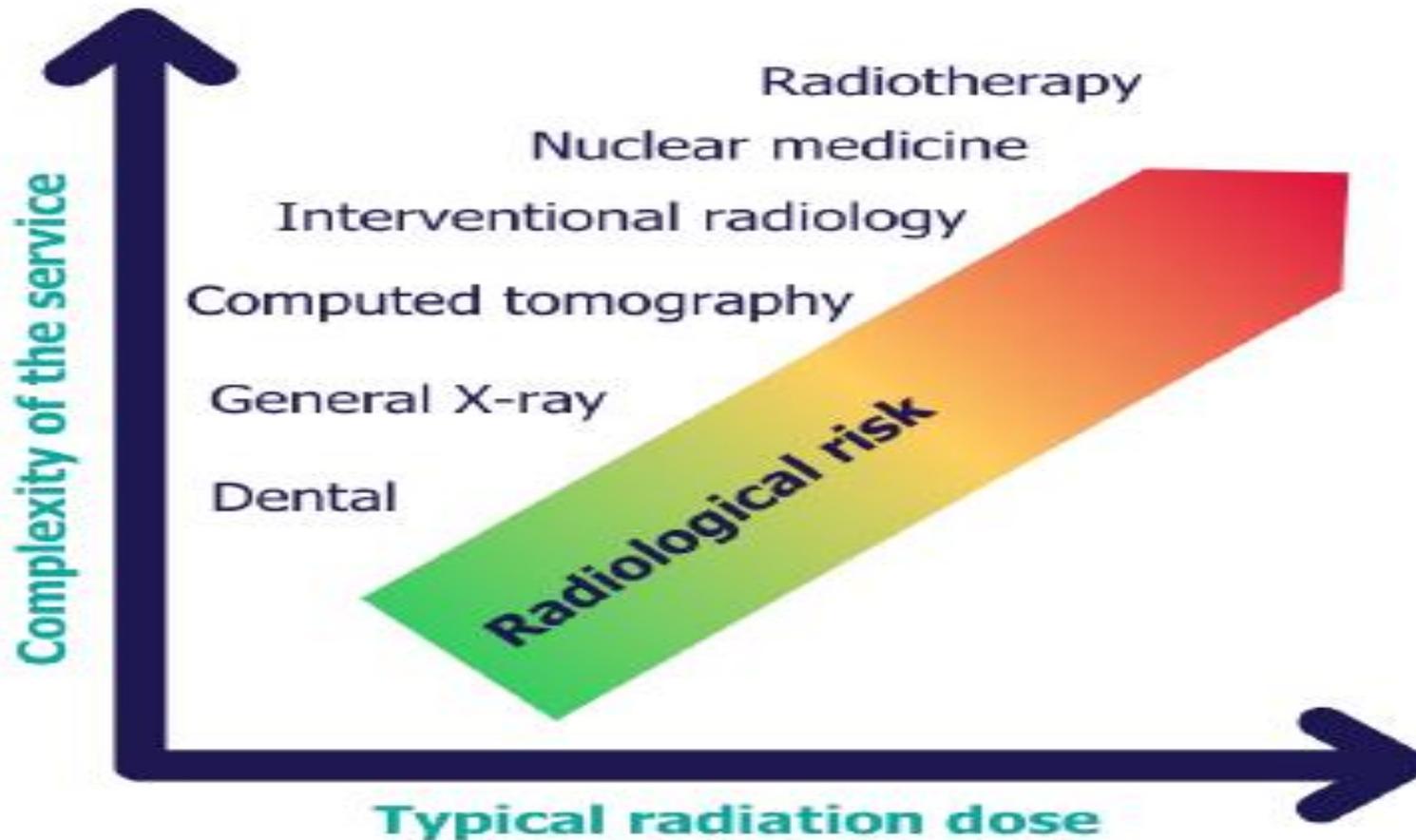
Legislative basis



Regulatory function



Service Type, complexity and type of radiological risk

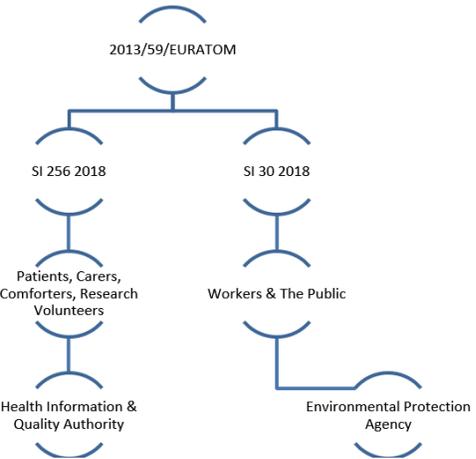


Competent authority functions

- Dose constraints for carers and comforters
- Criteria for acceptability of equipment
- Establishment and review of national DRLs
- Population dose estimation from medical exposures
- Receipt and risk rating of all accidental or unintended exposures
- Report on lessons learned from significant accidental or unintended exposures



Legislative basis



European Union (Basic Safety Standards for Protection Against Dangers Arising from Medical Exposure to Ionising Radiation)

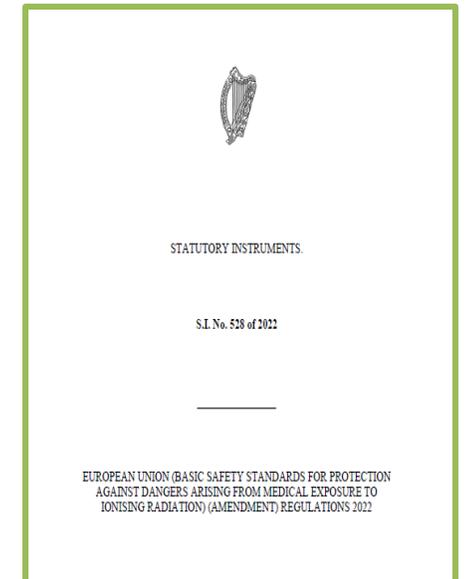
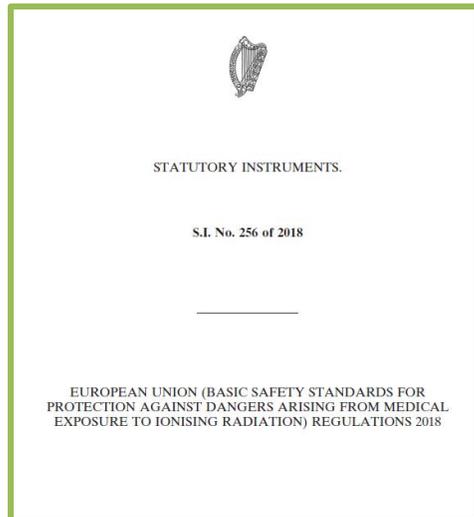
Regulation 13(4) of the principal regulations

*An undertaking shall ensure that clinical audits are carried out in accordance with national procedures established by the **Minister**.*

S.I. No. 528 of 2022



*An undertaking shall ensure that clinical audits are carried out in accordance with national procedures established by the **Authority**.*

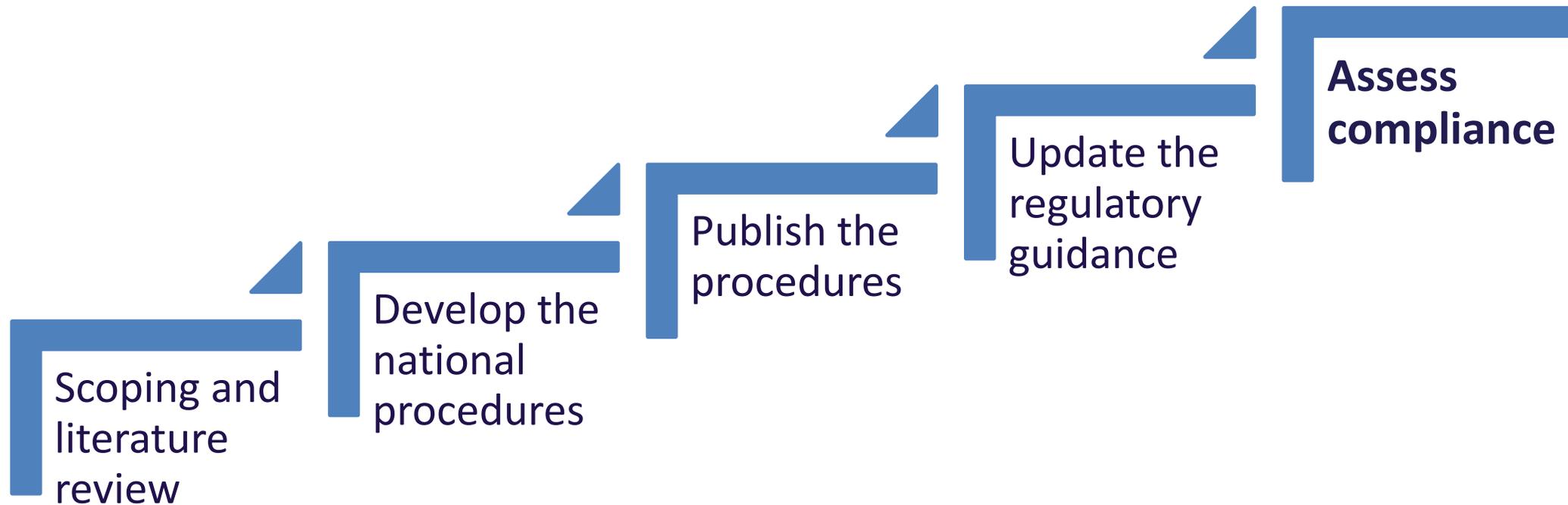


Clinical Audit

Definition- EU Council Directive 2013/59/Euratom

"clinical audit" means
a systematic examination or review of medical radiological procedures
which seeks to improve the quality and outcome of patient care
through structured review, whereby
medical radiological practices, procedures and results
are examined against **agreed standards** for good medical radiological
procedures,
with **modification of practices**, where appropriate,
and **the application of new standards** if necessary.

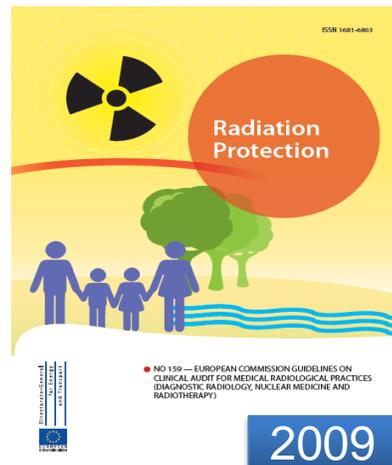
Project overview



Scoping and Literature Review

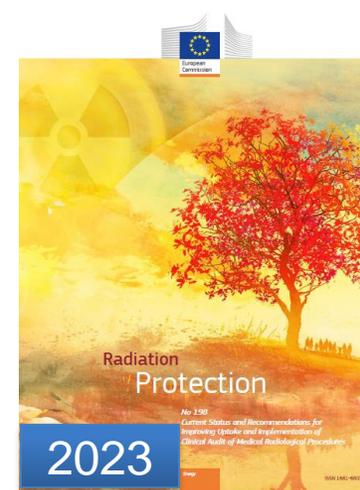
EU commission guidance No. 159

Guideline on Clinical Audit
for Medical Radiological Practices
Diagnostic radiology,
Nuclear medicine and
Radiotherapy



EU commission guidance No. 198

Current Status and
Recommendations for Improving
Uptake and Implementation of
Clinical Audit of Medical
Radiological Procedures



Scoping and Literature Review

Recent Guidance

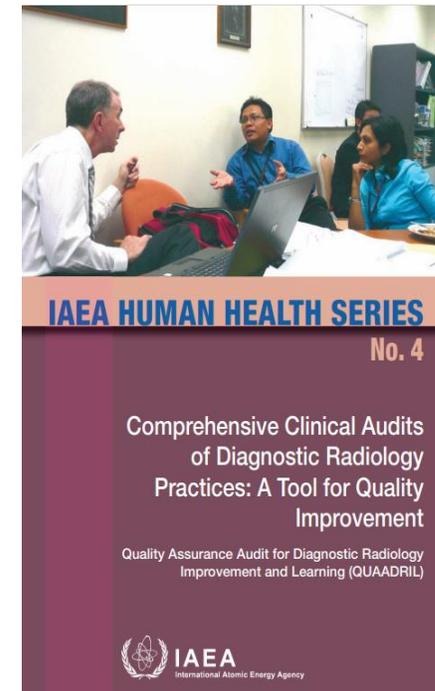
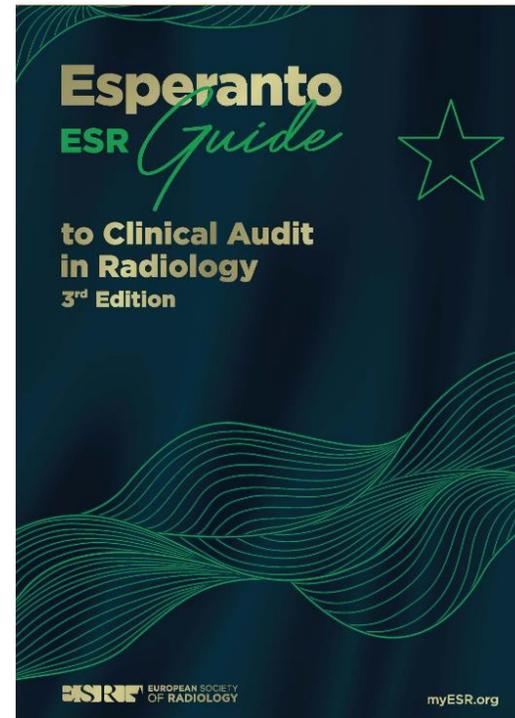
- **Dentistry**
- Radiology
- Nuclear Medicine
- Radiotherapy
- Nursing and Midwifery



Scoping and Literature Review

Recent Guidance

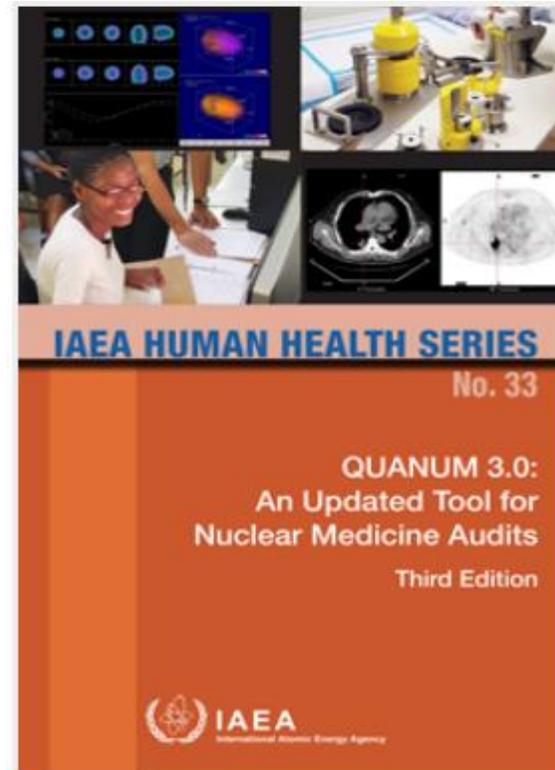
- Dentistry
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Scoping and Literature Review

Recent Guidance

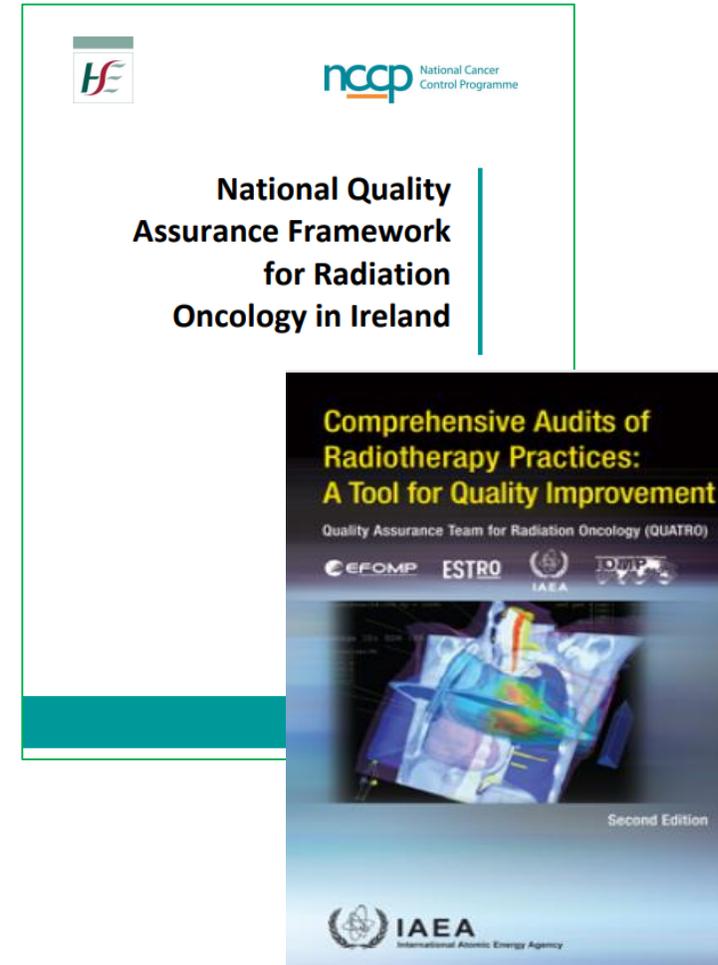
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Scoping and Literature Review

Recent Guidance

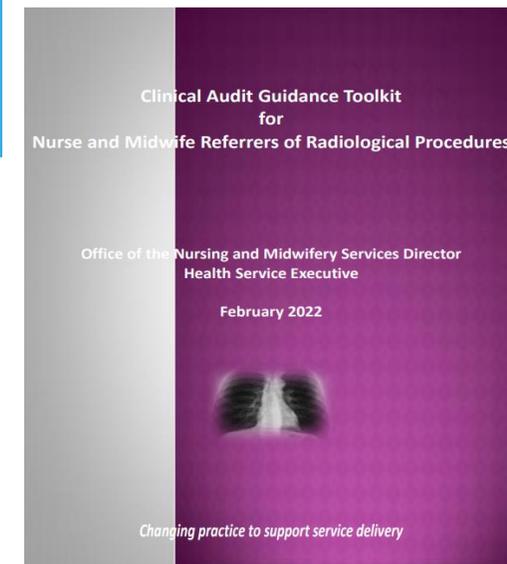
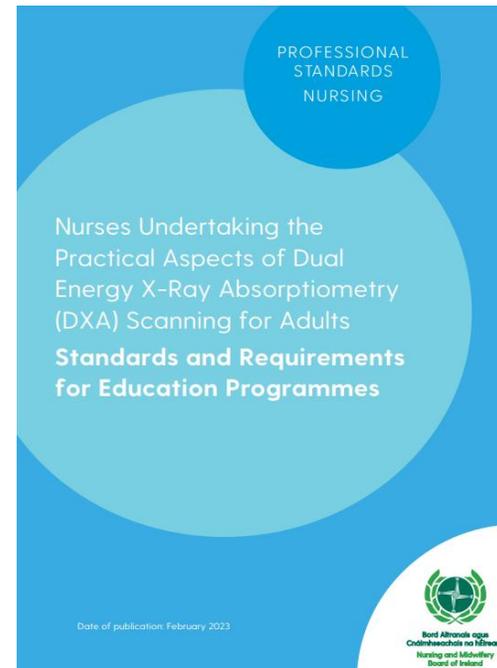
- Dentistry
- Radiology
- Nuclear Medicine
- **Radiotherapy**
- Nursing and Midwifery



Scoping and Literature Review

Recent Guidance

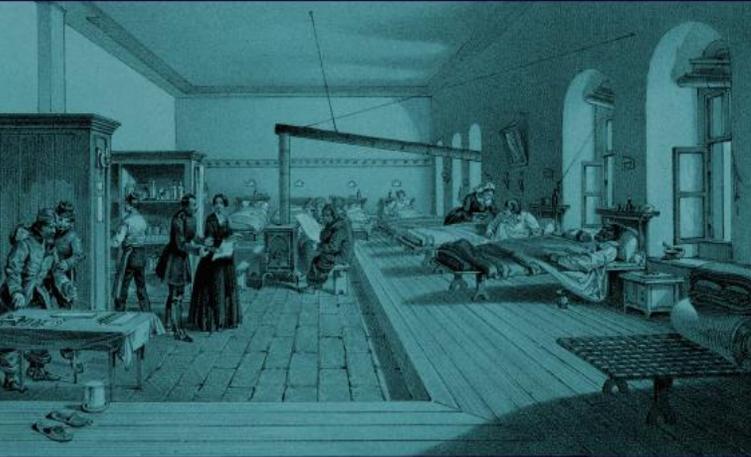
- Dentistry
- Radiology
- Nuclear Medicine
- Radiotherapy
- **Nursing and Midwifery**



Scoping and Literature Review



Healthcare Quality
Improvement Partnership



Clinical Audit
A Manual for Lay Members
of the Clinical Audit Team

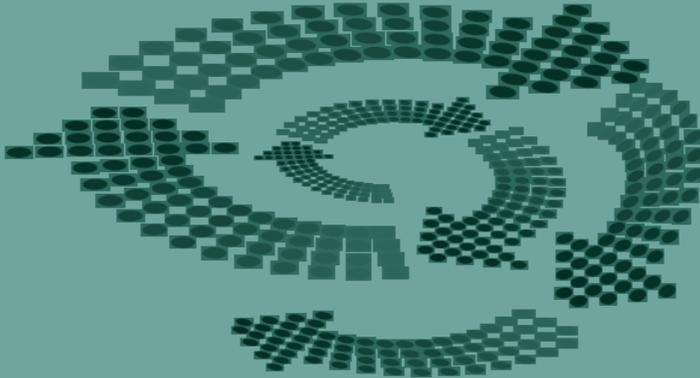


Ionad Náisiúnta
d'Iniúchadh Clínicíúil
An Stiúirthóireacht um Ardchaighdeán
agus Sábháilteacht Othar

National Centre
for Clinical Audit
National Quality and Patient
Safety Directorate

HSE National Centre for Clinical Audit

Clinical Audit
A Practical Guide 2023



HSE National Centre for Clinical Audit

Scan for National
Centre for Clinical
Audit website

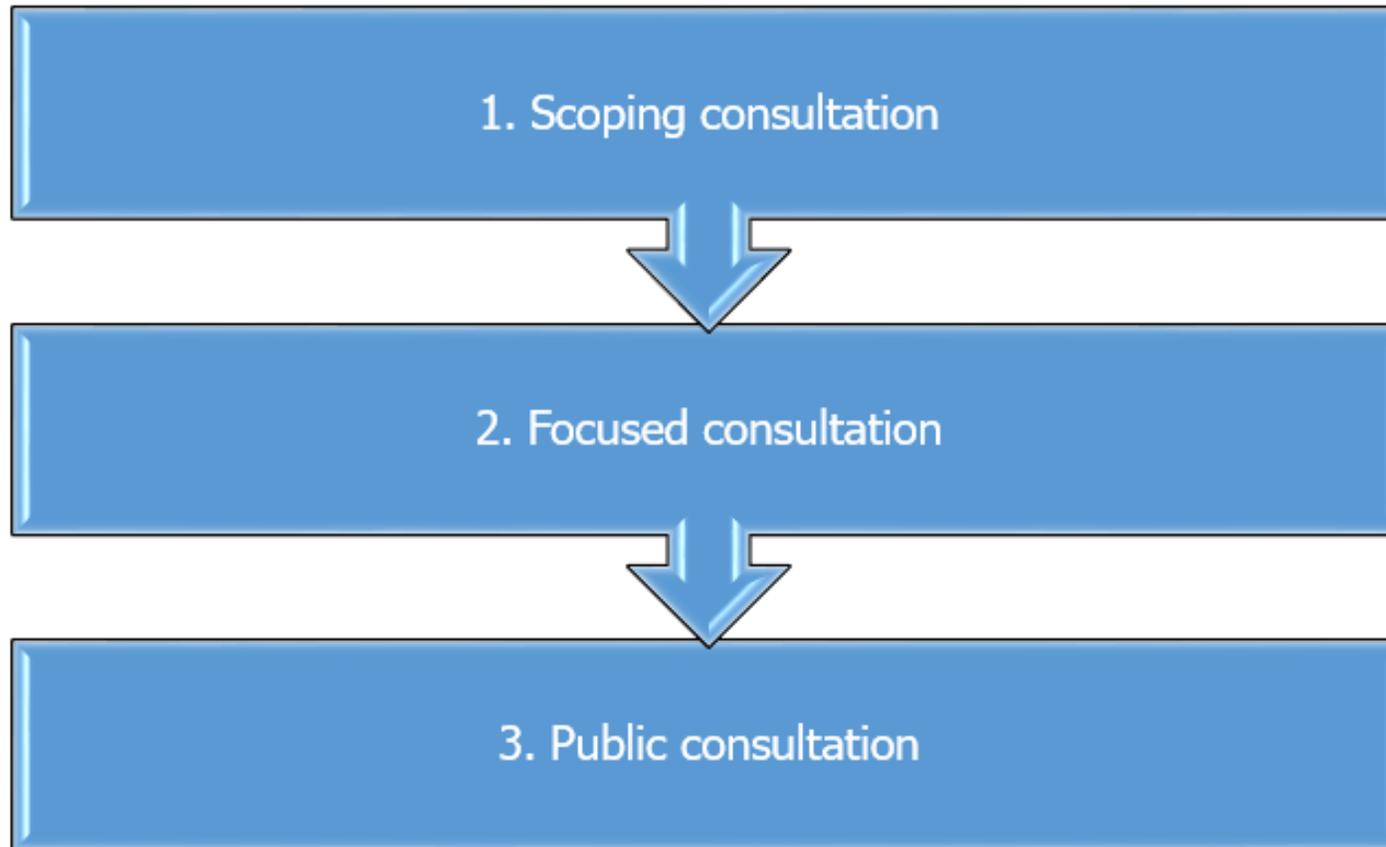


Healthcare Quality
Improvement Partnership

Best practice in clinical audit



Stages of stakeholder engagement



Scoping consultation

Regulatory bodies and professional bodies

- Interpretation of Clinical audit relating to medical radiological procedures
- Types of clinical audit activity currently in place
- How clinical audit affects the professions/members

Principles for clinical audit



Focused consultation

- Are the principles and essential criteria for clinical audit clear?
- Are the sample templates useful?
- Are appendices clear?
- Are there additional resources that would be useful to add?
- Is it clear what undertakings need to have in place to be in compliance?

Public consultation

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

**Public consultation on
national procedures for clinical audit of
radiological procedures involving
medical exposure to ionising radiation**


HIQA is responsible for regulating
medical exposure to ionising radiation in Ireland
in services including hospitals, medical imaging centres and dental practices.

Medical exposure to ionising radiation is when radiation is used...

			
for assessment, such as at your dentist.	in the diagnosis process, such as an X-ray.	as a treatment such as radiotherapy for cancer	for medical research

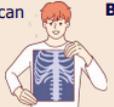
HIQA's function has increased to establish national procedures for clinical audit of medical radiological procedures.

This means that undertakings (providers of the services) must ensure compliance with the national procedures for clinical audit.


Clinical audit is a tool used for quality improvement and is an essential part of making sure you receive good care and service.


Link to consultation 

Clinical audit means that people can expect a service which has safe procedures and treatment and is focused on improvement.


Benefits of clinical audit include:

- improved care and services
- better use of resources
- promote learning.



HIQA wants to hear the views of the Irish public.

Please provide feedback by Monday, 31 July 2023 at www.hiqa.ie.

Is it clear in this document what undertakings (providers) need to have in place to be compliant with the requirements for clinical audit in the regulations?

Is the framework (principles and essential criteria) understandable and clear?

Publication



National procedures for clinical audit of radiological procedures involving medical exposure to ionising radiation
November 2023

 In Ireland, HIQA is responsible for regulating medical exposure to ionising radiation in services including hospitals, medical imaging centres and dental practices.

HIQA's function has increased to establish national procedures for clinical audit of medical radiological procedures and will monitor compliance with these procedures.



The national procedures provides:

1. essential criteria for audit
2. examples of audit topics for each setting
3. links to literature and resources
4. templates and checklists.

This means that undertakings (providers of the services) are responsible for ensuring compliance with the national procedures for clinical audit.



Clinical audit is a tool used for quality improvement and is an essential part of making sure you receive good care and service.

Medical exposure to ionising radiation is when radiation is used...

-  for assessment, such as at your dentist.
-  in the diagnosis process, such as an X-ray.
-  as a treatment such as radiotherapy for cancer
-  for medical research

HIQA.ie



Monitoring and Regulation of Healthcare Services

National procedures for clinical audit of radiological procedures involving medical exposure to ionising radiation

November 2023

Safer Better Care

Benefits of clinical audit



Principles of clinical audit



Clinical audit – patients and people using the service

What does clinical audit mean for patients and people who use the service?

Patients and people who use the service can expect a service that:

- is focused on continually improving its safety and quality
- ensures the most appropriate procedures and treatments involving medical exposures are delivered safely to each person using the service.

Clinical audit - staff

What does clinical audit mean for staff?

Staff can expect that the service in which they work:

- helps them to understand the role of local clinical audit
- encourages them to actively participate in clinical audit and foster a culture of regular quality assurance and continual improvement
- encourages them to implement recommendations from clinical audit findings to improve quality and safety in the services they provide.

Clinical audit - undertakings

What does clinical audit mean for undertakings?

Undertakings:

- should have a clinical audit strategy in place
- can use clinical audit to improve the quality and safety of patient care and services
- can use the findings of clinical audit to provide assurances of the quality and safety of patient care and services they provide
- can make this document available to all staff involved in medical radiological procedures so that they are aware of their role in relation to clinical audit.

Relationship between the clinical audit strategy, the schedule and the topics



Structure

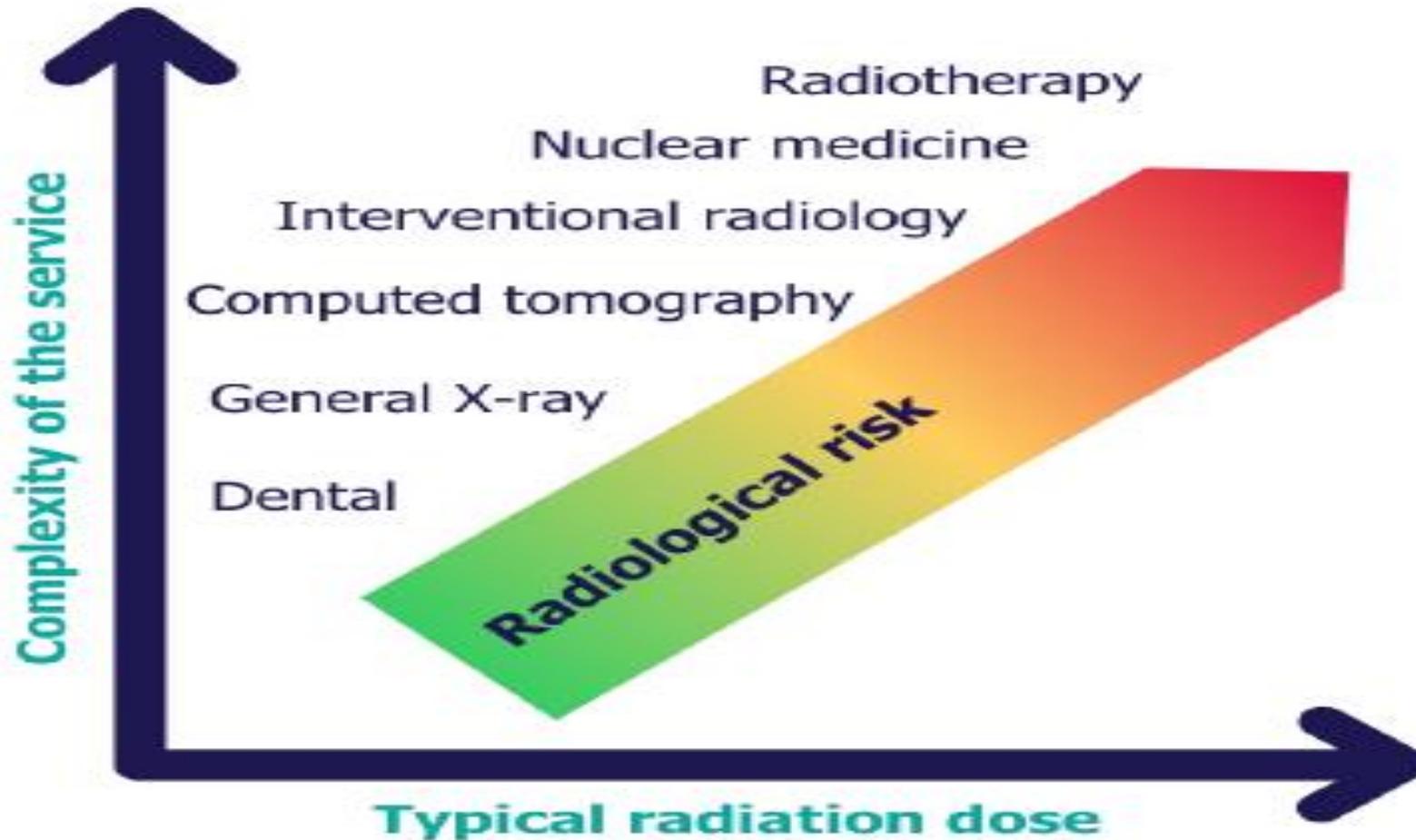
Process

Outcome

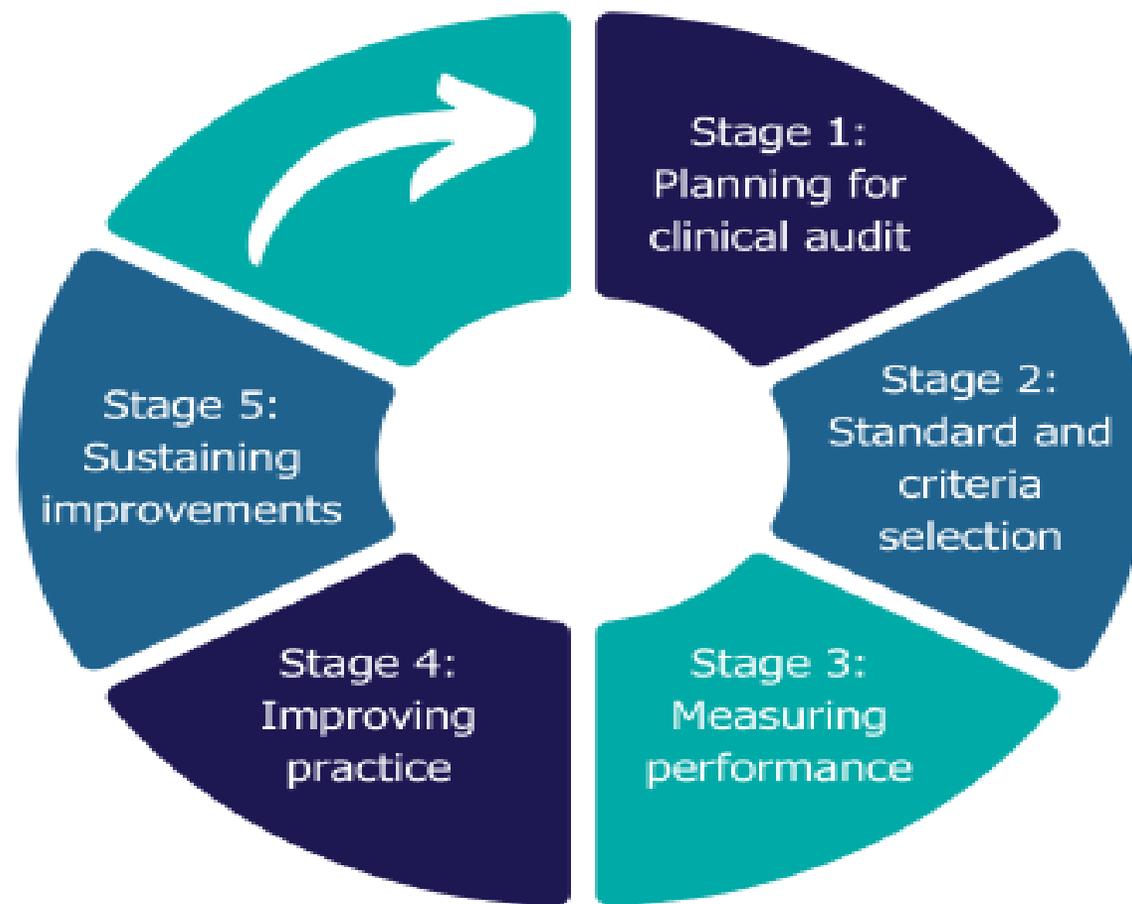
Clinical audit Strategy

Principles	What does this mean?
Assurance, Oversight, Resources	Who is responsible?
Communication, Teamwork	Who does it?
Focus, coverage	What should be done? When should it be done?
Tools, action	How will it be done?

Clinical audit Strategy

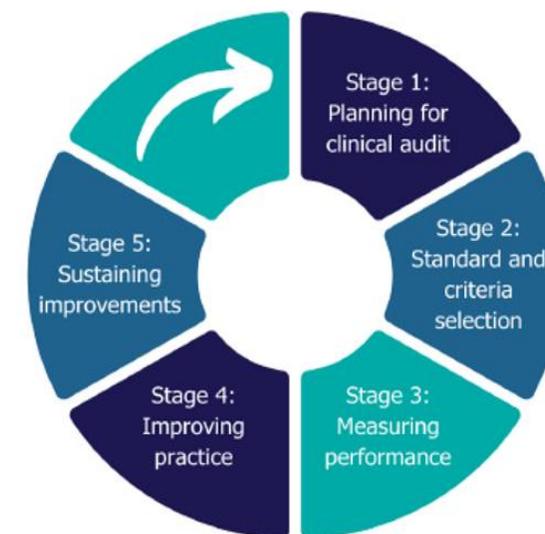


Overview of the clinical audit cycle

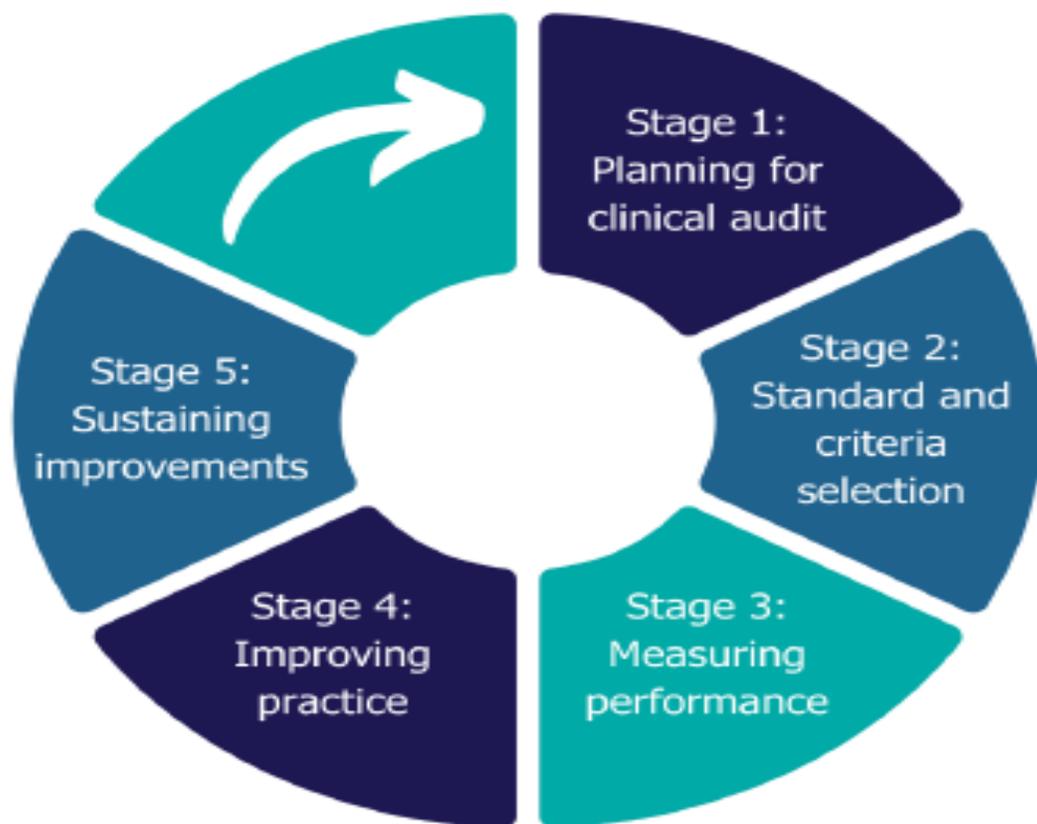


Clinical audit checklist

Stage 1: Plan for audit	Complete?
Choose a topic	
Involve interested parties and stakeholders	
Audit template	
Stage 2: Select standard and criteria	Complete?
Identify standard	
Identify criteria	
Set targets	
Stage 3: Measure performance	Complete?
Collect data	
Analyse data	
Present data	
Stage 4: Make Improvements	Complete?
Agree actions	
Agree responsibilities for action	
Stage 5: Sustain Improvements	Complete?
Encourage learning	
Monitor progress (of recommendations and actions)	
Monitor improvement (for example, re-audit)	



Documenting the clinical audit cycle – audit report form



Audit topic and title:	
Department or speciality:	
Date of report:	Date topic was last audited (if applicable):
Audit lead (co-ordinator):	
Key interested parties and stakeholders:	
Aim and objectives: Reason for the audit.	
Standard and target: Standard for comparison, include reference document, target or compliance percentage to be achieved.	
Methodology: Data or information to be collected e.g. population, sample size, time period, tool used.	
Results: Measured data.	
Findings and conclusion: Was the target achieved? Services may wish to risk rate findings to help prioritise actions.	
Recommendation(s): Actions to be taken if target not met	Timing for re-audit:

Documenting the clinical audit cycle

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Results:	
Measured data.	
Findings and conclusion:	
Was the target achieved?	
Services may wish to risk rate findings to help prioritise actions.	
Recommendation(s):	Timing for re-audit:
Actions to be taken if target not met	



Documenting the clinical audit cycle

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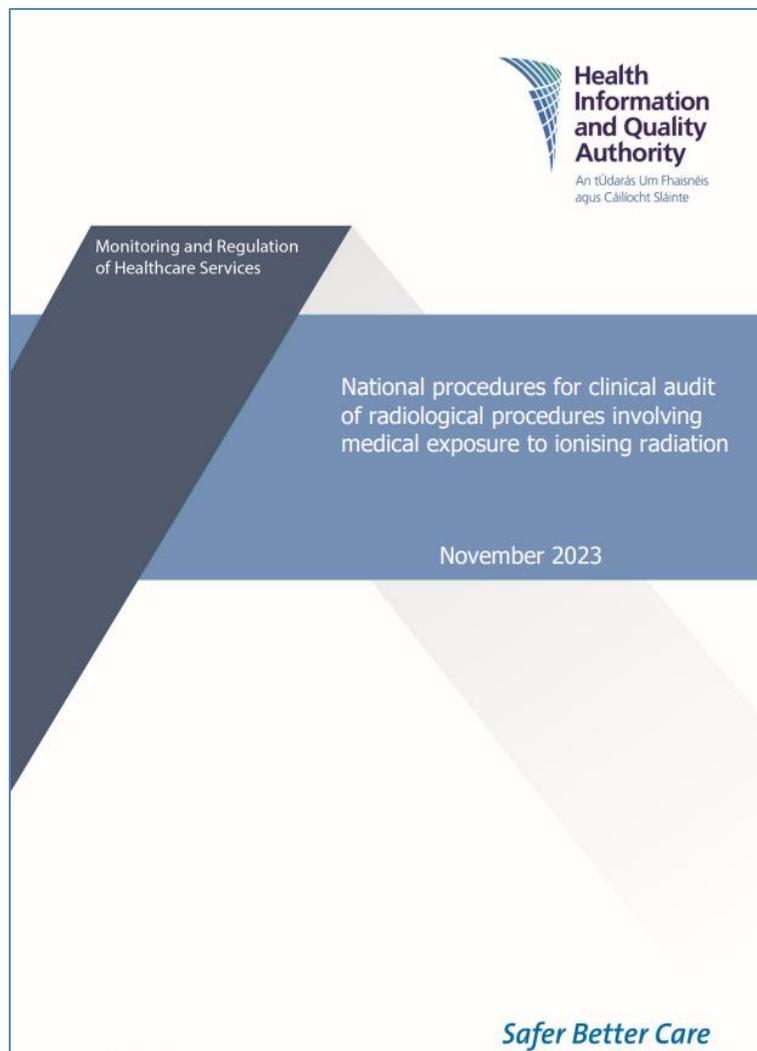


Documenting the clinical audit cycle

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Resources - appendices



Appendix Number	Setting
Appendix 6	Dental
Appendix 7	Radiology (diagnostic and interventional)
Appendix 8	Nuclear Medicine (diagnostic and therapy)
Appendix 9	Radiotherapy

Assessing Compliance



How do inspectors assess compliance?



Observe



Evidence

Read

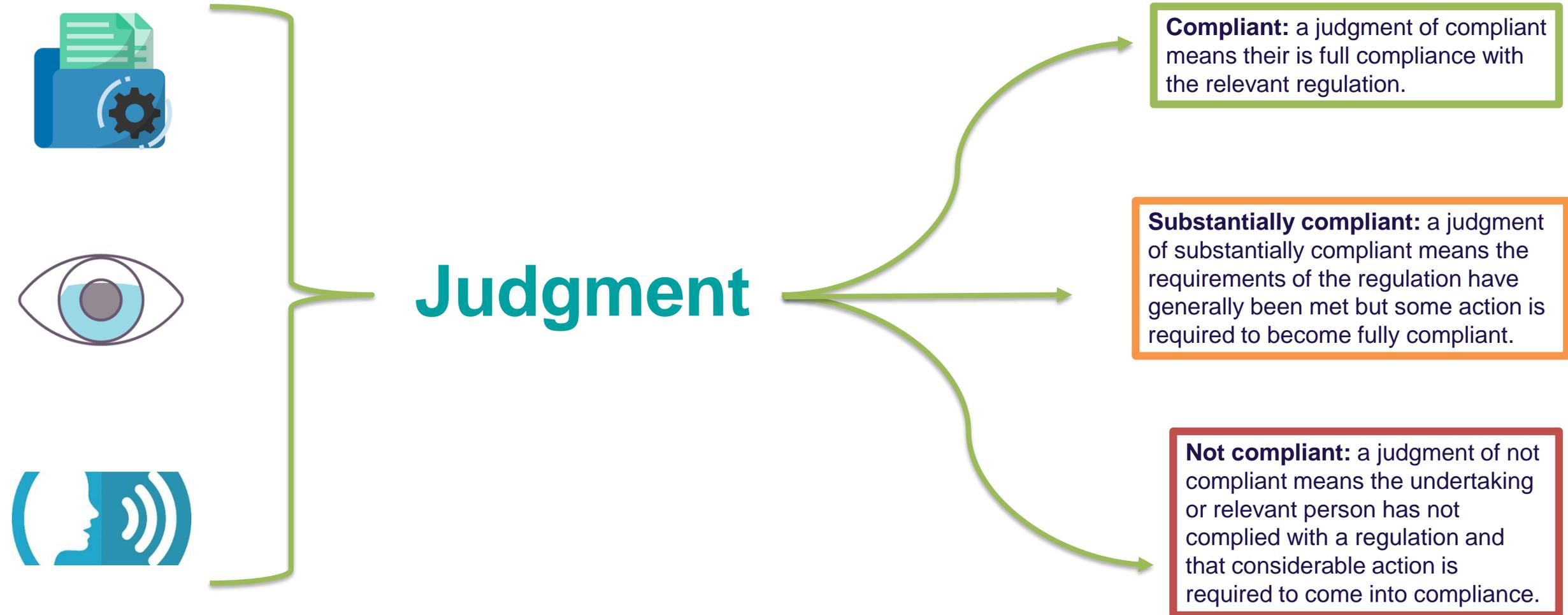
Hear



Judgment



Judgment descriptors



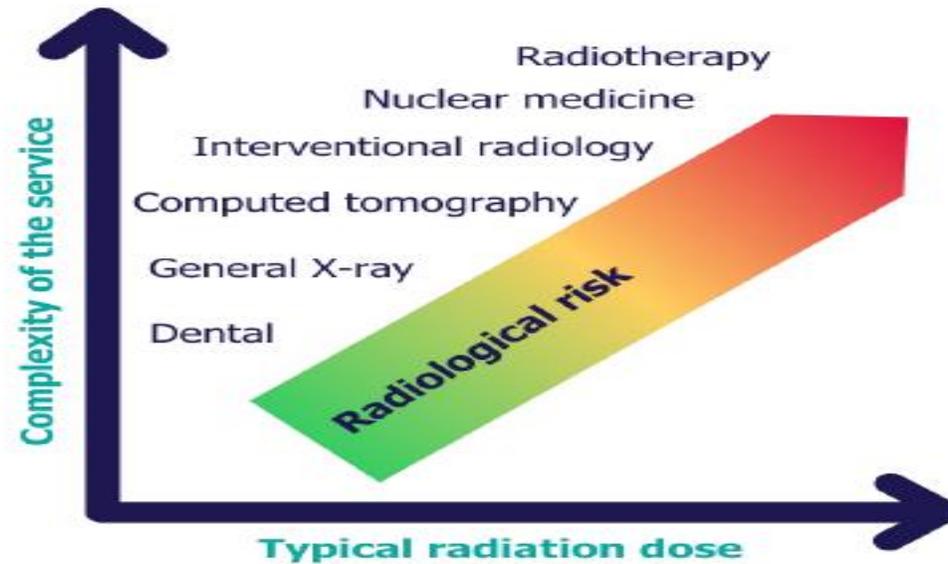
Judgments



Monitoring and Regulation of Healthcare Services

Guidance on the assessment of compliance in undertakings providing medical exposure to ionising radiation
Updated November 2023

Safer Better Care



Monitoring and Regulation of Healthcare Services

Assessment-judgment framework for undertakings providing medical exposure to ionising radiation
Updated November 2023

Safer Better Care

Assessing compliance

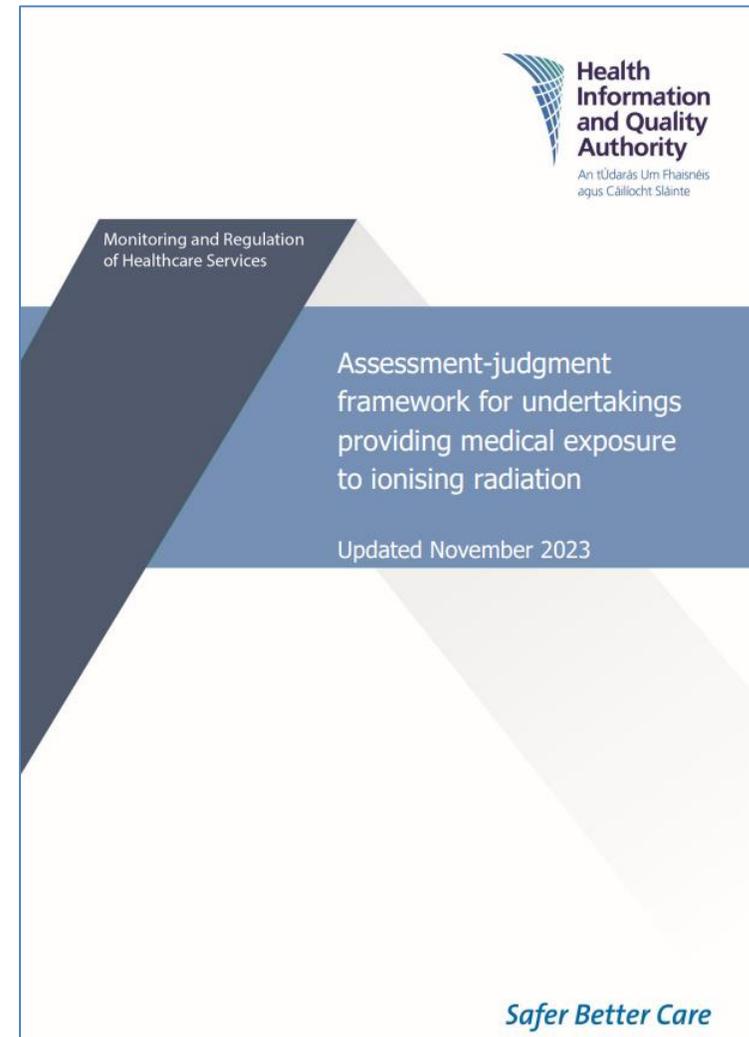
Regulation 13 (4)

*An undertaking shall ensure that
clinical audits
are carried out in accordance with
national procedures established by the Authority.*

Assessing compliance

Assessment-judgment framework for undertakings providing medical exposure to ionising radiation
Health Information and Quality Authority

Dimension: Safe delivery of medical exposures	
Regulation 13	Procedures
Line of enquiry	<ol style="list-style-type: none">1. Has the undertaking established written protocols for every type of standard medical radiological procedure for each type of equipment for relevant categories of patients?2. Has the undertaking ensured that information relating to patient exposure forms part of the report of the medical radiological procedure?3. Has the undertaking ensured that referral guidelines for medical imaging, taking into account the radiation doses, are available to referrers?4. Has the undertaking ensured that clinical audits are carried out in line with national procedures established by HIQA?



Monitoring and Regulation of Healthcare Services

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

Assessment-judgment framework for undertakings providing medical exposure to ionising radiation

Updated November 2023

Safer Better Care

Assessing compliance

Examples of information and evidence for Regulation 13

Through review of documents pre-inspection or during on-site inspection activity

Inspectors may review:

- local policies, procedures and guidelines for carrying out clinical audits which are in line with national procedures
- results and reports of clinical audits relevant to medical exposures.

Through communication

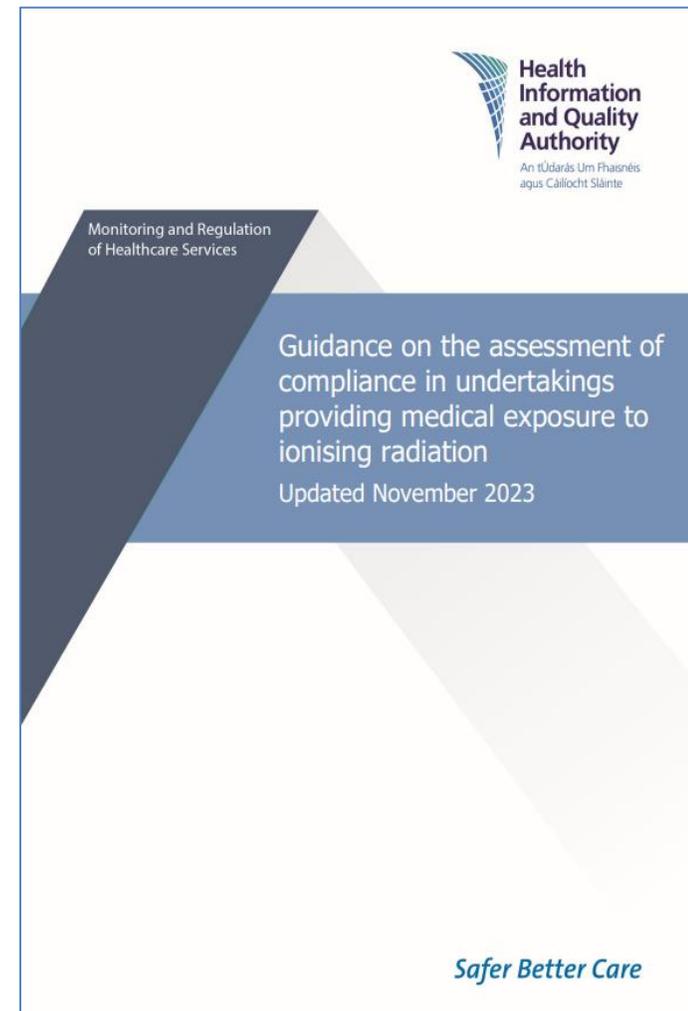
Inspectors may communicate with the undertaking and or staff in the facility:

- to establish the systems in place to complete clinical audits
- regarding the procedures used to carry out clinical audits.

Through observation

Inspectors will observe:

- if clinical audit results and learning are available to staff.



**Health
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and Quality
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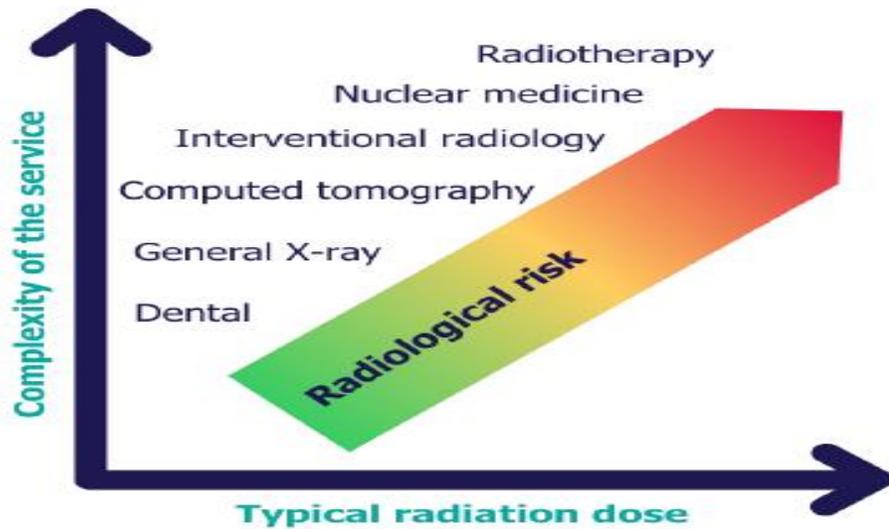
Monitoring and Regulation
of Healthcare Services

Guidance on the assessment of
compliance in undertakings
providing medical exposure to
ionising radiation
Updated November 2023

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Assessing compliance

Is there a Clinical Audit Strategy?



In summary

- European Union (Basic safety standards for protection against dangers arising from medical exposure to ionising radiation) Regulations 2018 and associated amendments
- HIQA's remit across a range of regulatory and competent authority functions
- Remit expanded in October 2022
- Responsibility for establishing national procedures in clinical audit
- Developed national procedures in consultation with key stakeholders
- Supporting guidance documentation
- Assess undertakings level of compliance

Guidance on the assessment of
compliance in undertakings
providing medical exposure to
ionising radiation
Updated November 2023

Safer Better Care

Assessment-judgment
framework for undertakings
providing medical exposure
to ionising radiation
Updated November 2023

Safer Better Care

National procedures for clinical audit
of radiological procedures involving
medical exposure to ionising radiation

November 2023

Safer Better Care

A guide to the inspection of medical
services providing medical exposure
to ionising radiation

Updated September 2023

Safer Better Care

A guide to the inspection of dental
services providing medical exposure
to ionising radiation

Updated September 2023

Safer Better Care

HIQA is an independent authority that exists to improve health and social care services for the people of Ireland.



Acute and Community Healthcare Services



Children's Services



Disability Services



Older People's Services



Ionising Radiation



Health Information



Health Technology Assessment



COVID-19 Publications



Standards and Quality


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[Reports & Publications](#)
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Home > Areas we work in > Ionising Radiation

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
- ▶ Find a Centre

From 8 January 2019, the EU Council Directive 2013/59/Euratom, which sets basic safety standards for protection arising from exposure to ionising radiation, has been transposed into Irish law. This legislation has designated HIQA as the independent competent authority for medical exposures.

What is ionising radiation?



Watch on  YouTube

Every day, people are exposed to both natural and artificial sources of radiation and radioactivity. Natural sources include radon and cosmic radiation, while artificial or man-made sources include medical ionising radiation and residual nuclear contamination. Radiation exposure from natural sources is difficult to eliminate; however, appropriate controls and regulation of the use of ionising radiation can help reduce or prevent inappropriate medical exposures.

From 8 January 2019, the EU Council Directive 2013/59/Euratom, which sets basic safety standards for protection arising from exposure to ionising radiation, has been transposed into Irish law. This legislation has designated HIQA as the independent competent authority for medical exposures. The purpose of HIQA's ionising radiation (medical exposures) regulatory and health technology assessment programmes is to promote better, safer practice across all service providers using medical exposures in Ireland.

References

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3. European Union (Basic Safety Standards for Protection Against Dangers Arising from Medical Exposure to Ionising Radiation) Regulations 2018 (S.I. No. 256 of 2018) <https://www.irishstatutebook.ie/eli/2018/si/256/>
4. European Union (Basic Safety Standards for Protection Against Dangers Arising from Medical Exposure to Ionising Radiation) Regulations 2022 as amended (S.I. No. 528 of 2022) <https://www.irishstatutebook.ie/eli/2022/si/528/made/en/print>
5. Patient Safety (Notifiable Incidents and Open Disclosure) Bill 2019 <https://www.oireachtas.ie/en/bills/bill/2019/100/>
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7. A Practical Guide to Clinical Audit, Pre-Hospital Emergency Care Council 2013 <https://www.phecit.ie/Images/PHECC/Clinical%20Practice%20Guidelines/CPG%20Approved%20Orgs/STN019%20Practical%20Guide%20to%20Clinical%20Audit.pdf>
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