



# Clinical audit vs inspection

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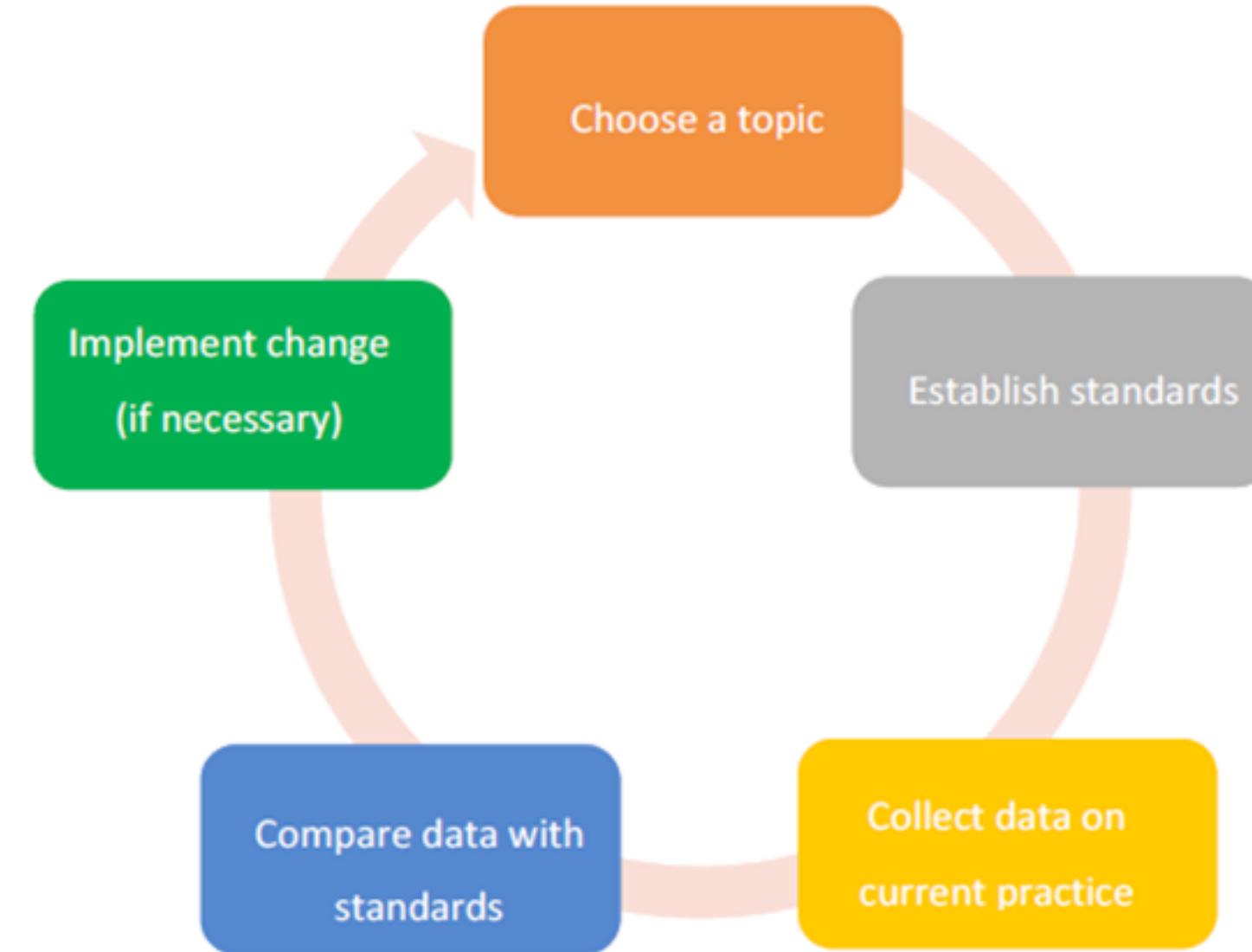
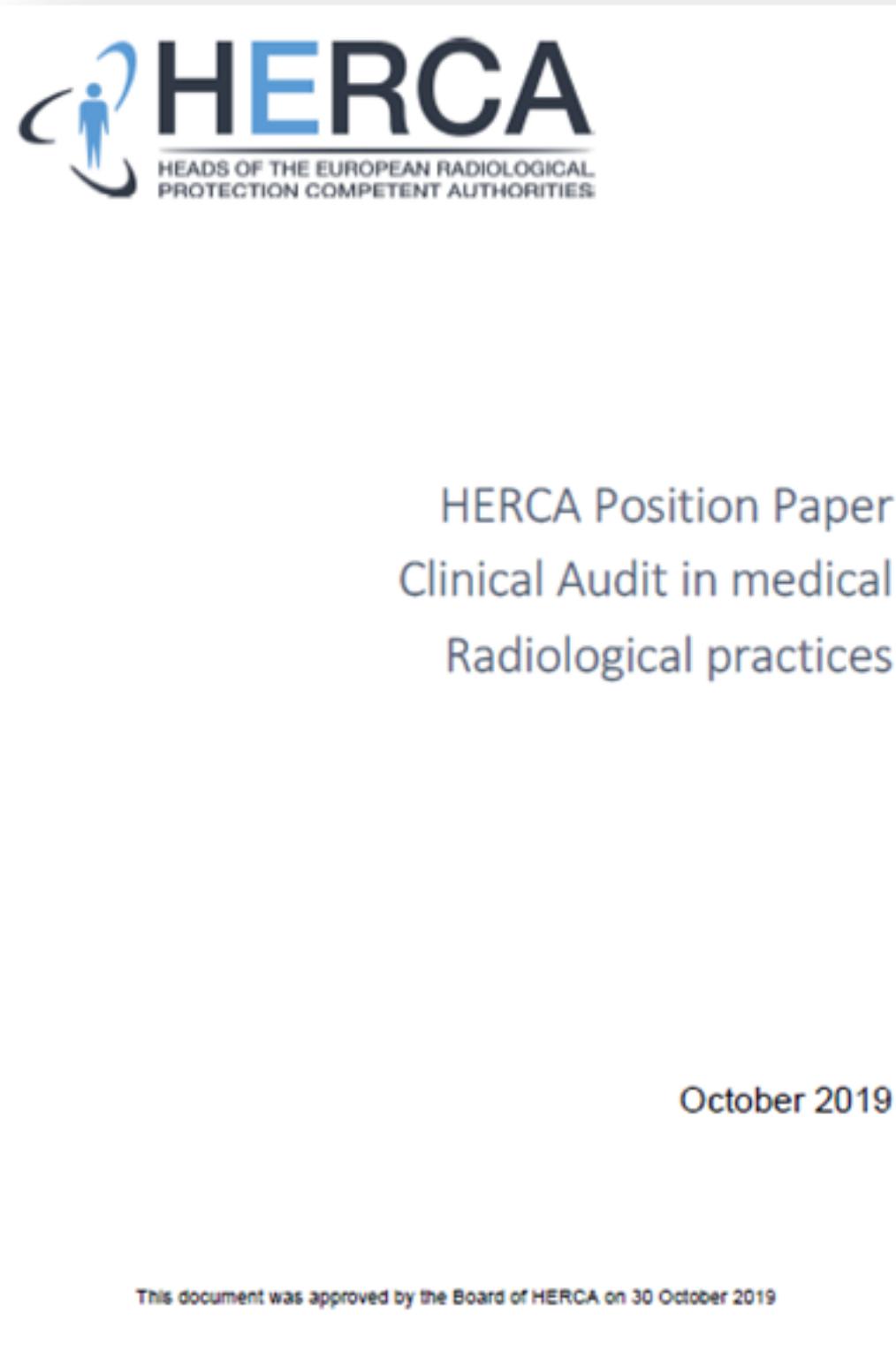
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# Learning objectives



1. Distinguish clinical audit from inspection and ISO certification audits.
2. Understand the purpose, structure, and outcomes of clinical audits.
3. Identify the core principles of effective clinical audit (e.g., ALPINE).
4. Compare audit methodologies: QUATRO vs CLAUDIT.
5. Recognize the strategic value of external clinical audits in radiological practice.

# A clinical audit is not an inspection



# Clinical audit: what do they aim to?



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**

Council Directive 2013/59/EURATOM

# A clinical audit is not an inspection



	AUDIT	INSPECTION
Basis	Standards and good practices	Standards and good practices Legislation and regulation
Outcome	Recommendations and suggestions	Requirements and enforcement
Organisation	Undertaking/peer review systems	Competent authority
Teams	Professionals (multidisciplinair team)	Inspectors and advisors
Scope	Comprehensive	Constrained
Benefit for the institution	Ensure improvements in the quality and outcome of patient care	Cerfication/recertification
Benefit for the region/country when conducted at a national level	<ul style="list-style-type: none"><li>• transfer best practice between institutions</li><li>• Setting of higher more appropriate standards</li></ul>	

# Clinical audits aim



- Improve the quality of patient care
- Promote the effective use of resources
- Improve the delivery and organization of clinical services
- Contribute to professional education and training

# In practice a clinical audit should



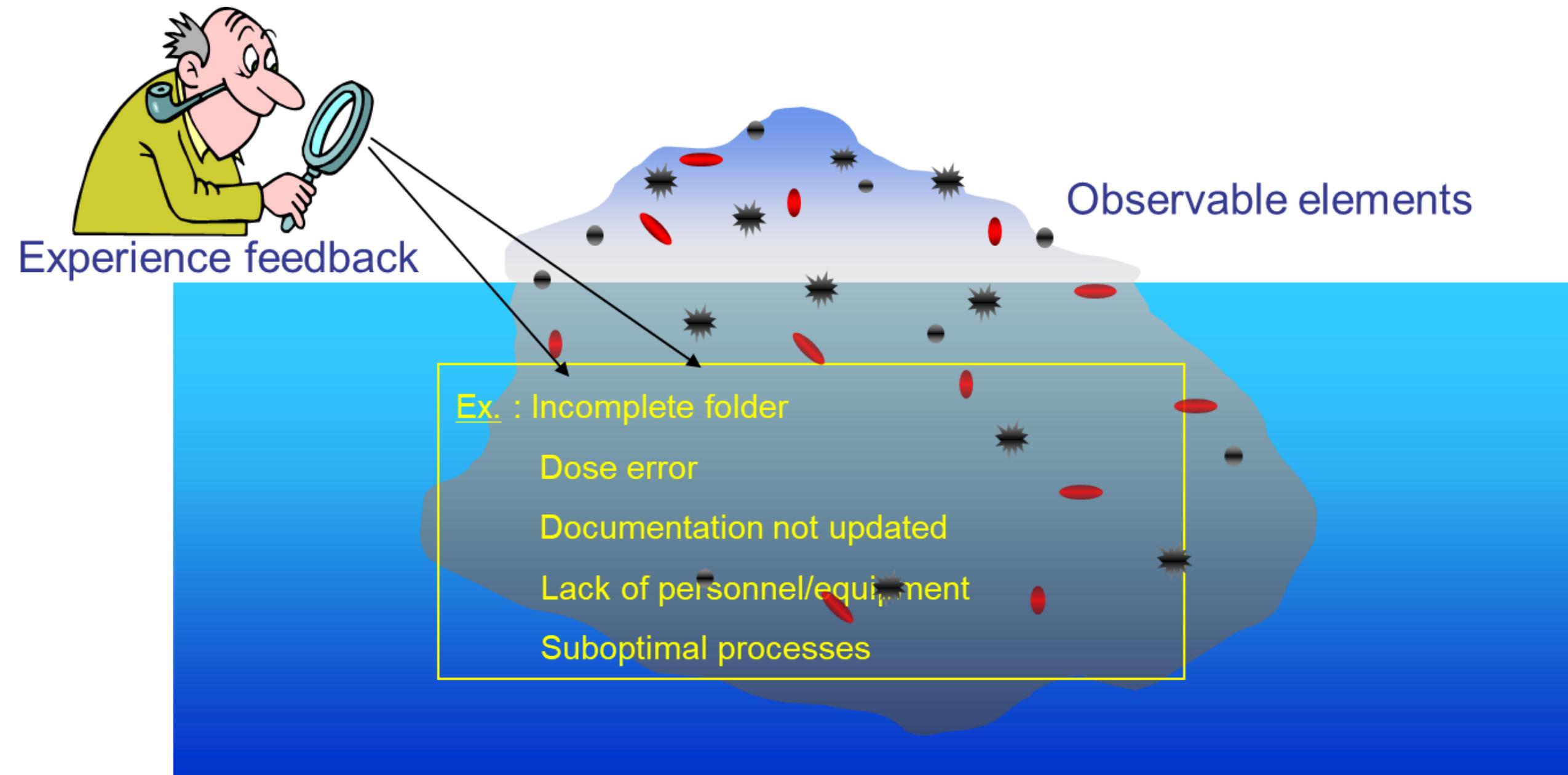
- Be ALPINE (Achievable, Local, Practical, Inexpensive, Non-Threatening and Easy)
- Multi-disciplinary, multi-professional activity
- Follow accepted rules and standards
- Be systematic and continuous activity
- Be carried out by auditors with extensive clinical knowledge and experience
- Combine internal and external assessments
- Evaluate current status and propose areas for future improvement
- Not be research, quality system or regulatory activity
- Address practical clinical work by different professionals
- Assess local practice against defined good practice (taking into consideration local circumstances)

## Different phases

Different phases			
	Self-assessment	Internal clinical audit	External clinical audit
Level	Department	Hospital	Nationwide
Who carries out?	Personnel of the department	Auditors from other departments within the hospital/institution	Auditors from other hospitals/institutions
Result	Self-assessment report	Internal audit report	External audit report

**Identify areas for improvement → Actions for improvement**

# External clinical audits



# 8 reasons for external clinical audits



1. Ensure the quality and safety of the techniques and technologies used in radiotherapy (RT)
2. Establish, maintain, and improve quality standards
3. Identify problems that could cause harm to patients
4. Harmonize clinical practice and promote equity
5. Support the implementation of complex techniques
6. Facilitate awareness and understanding of existing problems through benchmarking between centers with similar equipment
7. Obtain an external/independent opinion of Radiation Oncology and Medical Physics services (structure/process/outcomes)
8. Structure/review the quality management system

# Differences between clinical audits and audits for ISO certification



Aspect	Clinical audit	ISO certification audit
Main objective	To improve clinical quality, patient outcomes, and service effectiveness by evaluating current practice against explicit, evidence-based standards.	Certify compliance with international quality standards (ISO 9001).
Scope of evaluation	Focused on specific clinical topics or pathways (e.g., cancer care, antibiotic prescribing), driven by local or national health priorities.	Organization-wide scope (administrative, operational, etc.).
Approach and Methodology	Systematic, cyclical process: identify standard → measure performance → analyze gap → implement change → re-audit. May include internal and external peer review.	Audit by ISO-certified auditor. Based on ISO quality system requirements.
Structure and procedure	Uses defined audit tools or protocols (e.g., audit templates, indicators, patient records). Focus on data collection, stakeholder engagement, and multidisciplinary team input.	Review of procedures, documentation and regulatory compliance

# Differences between clinical audits and audits for ISO certification



Aspect	Clinical audit	ISO certification audit
Results and impact	Leads to targeted quality improvement plans, professional development, service redesign, and accountability. Emphasis on closing the audit loop.	Results in a pass/fail determination, possibly with non-conformance reports and improvement recommendations. Certification awarded if compliant.
Stakeholder involvement	High involvement: clinicians, nurses, managers, sometimes patients. Encourages co-design and feedback from those delivering and receiving care.	Limited to process owners and quality managers; minimal direct involvement from frontline clinicians or patients.
Frequency and follow-up	One-off or periodic, based on needs	Annual follow-up audit and full reassessment every 3 years

# Different approaches for clinical audits



Aspect	QUATRO and BQUATRO (IAEA Radiotherapy Audit)	CLAUD-IT (EU Radiology/Nuclear Medicine Audits)
Clinical Domain	Specialized focus: external beam radiotherapy departments.	Broader scope: radiology and nuclear medicine across hospital settings.
Audit Structure	Comprehensive external audits by international experts.	Two-phase: pilot audits + national implementation using templates and expert guidance.
Methodology Tools	QUATRO manual with technical checklists and forms.	EsPERANTO guide (4th ed.), audit templates, aligned with national/EU guidelines.
Audit Team	External multidisciplinary team (MPE, RO, RTTs).	Local and national blended teams trained and supported externally.
Implementation	Centralized, one-off or periodic external audits.	Embedded national roll-out with EU-wide coordination and sustainability model.
Capacity Building	Limited to audit visit; capacity building not core focus.	Includes training programs, repositories, and resources for long-term development.
Audit Focus Areas	Technical quality, safety, equipment, procedures, protocols.	Emphasis on quality improvement, professional engagement, standardization, and reproducibility.

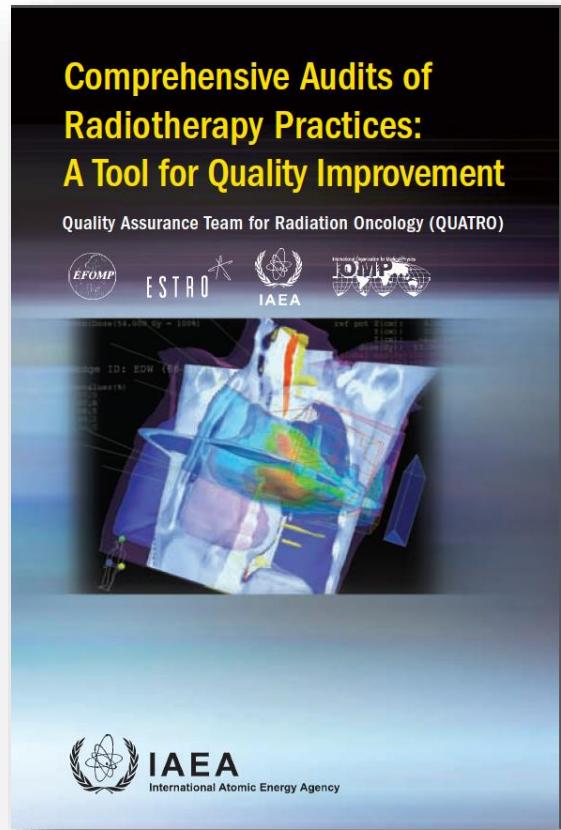
# Comprehensive clinical audits:

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## QUATRO clinical audits

Aspect	Description
 Main Objective	Evaluate and improve RT practice through peer review and a comprehensive assessment of clinical components.
 Scope	Clinical focus: infrastructure, procedures, radiation protection, staffing, and training.
 Methodology	Conducted by a multidisciplinary team (ROs, MPEs, RTTs) using the QUATRO methodology.
 Approach	Detailed review of clinical practice to identify improvement areas and promote patient care excellence.
 Outcomes	Report with specific recommendations – no direct regulatory consequences.
 Frequency	Based on the centre's needs or in response to quality improvement requests.



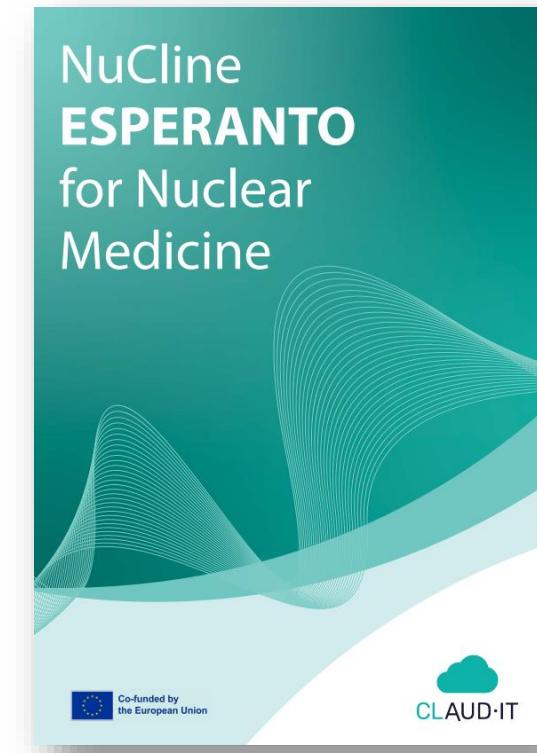
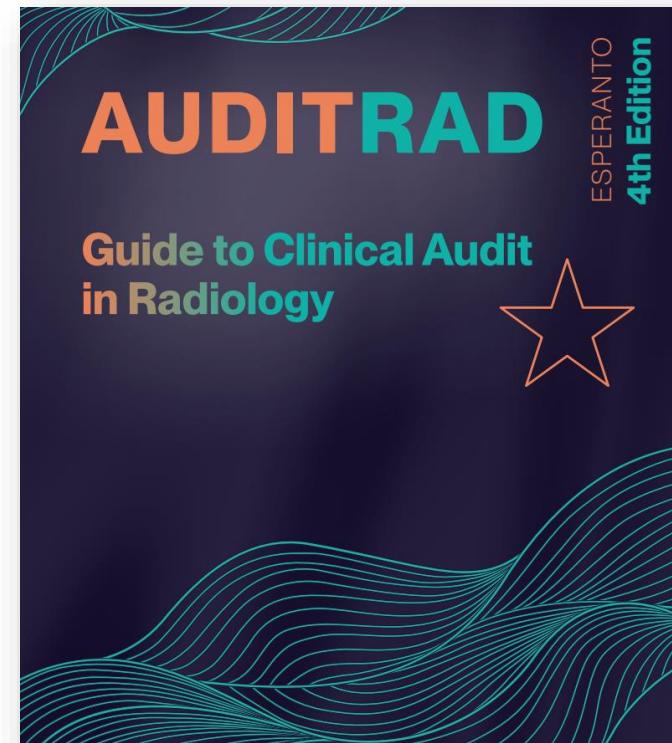
# Focused clinical audits



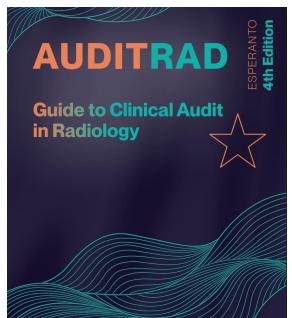
**Scope:** Target specific processes, procedures, or areas within a department.

**Objective:** Address particular concerns or high-risk areas to implement immediate improvements.

**Example:** The  project aims to enhance clinical audit practices in EU Member States by organizing targeted audit campaigns in radiology and nuclear medicine, focusing on specific aspects to improve quality and safety.



# Focused clinical audits



## Clinical audit templates

### Category Justification

Written protocol for the identification of who is responsible for the justification process

For radiation exposure related to health screening by invitation on asymptomatic individuals, is there a local policy affirming justification by a competent authority?

What percentage of studies involving ionizing radiation are justified in advance of being performed?

What mechanism exists on the request form for contacting referrers to permit pre-exposure justification discussions to occur if necessary?

Is there a written protocol for who may be responsible for justification of X-ray/fluoroscopy/ionizing interventional radiological CT-Scan procedures?

Is there a written protocol for who may be responsible for justification of CT studies

### Audit title

Standard against the audit topic is to be compared

### Source of standard

Target/Compliance percentage to be achieved

### Item of variable to be audited

### Method

Data or information to be collected

### Sample details

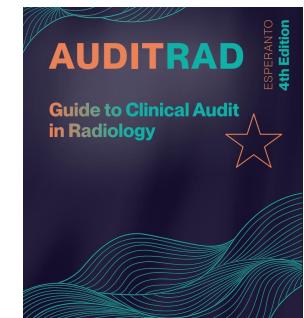
### Target details

Action to be taken if the target is not met

### Timing for re-audit

[https://www.eibir.org/app/uploads/2025\\_Esperanto-ESR-Guide-to-Clinical-Audit-in-Radiology-4th-Edition\\_20-02.pdf](https://www.eibir.org/app/uploads/2025_Esperanto-ESR-Guide-to-Clinical-Audit-in-Radiology-4th-Edition_20-02.pdf)

# Focused clinical audits



## Clinical audit templates

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Audit 74

/ Category: Justification

1) Audit Title

Is there a written protocol for who may be responsible for justification of CT studies?

2) Standard against which the audit topic is to be compared

BSSD

3) Source of standard

National legislation intended to transpose and implement requirements included within the Council Directive 2013/59/Euratom, Article 57

4) Target / compliance percentage to be achieved

100 %

5) Item or variable to be audited

Local rules: written protocol for identification of those with responsibility for the justification of CT studies

- Mechanism for unlocking self-reliant justifications in the RIS after achieving the specialist knowledge in radiology?
- Is there a process for assistant physicians such that they can gain experience under the supervision of senior physicians for CT justifications?

6) Method

prospective/retrospective

7) Data or information to be collected

- Written protocol for identification of those with responsibility for the justification of CT studies
- Criteria for inclusion
- Correlation with request forms /order comms
- Percentage correctly completed, signed, dated

8) Sample details

One month as above

9) Target achieved

Yes / no

10) Action to be taken if the target is not met

Establishment of a written protocol for responsibility for the justification of CT studies

Education of staff, staff training

11) Timing for re-audit

One year, or sooner if target not met

# Summary



- Clinical audits are structured tools to improve patient care quality, not regulatory inspections.
- Comprehensive external audits like **QUATRO** provide full-spectrum evaluation of clinical and technical processes.
- CLAUDIT introduces flexible, focused audit campaigns across EU radiology services.
- ISO certification ensures procedural quality; clinical audits ensure clinical relevance.
- Integration of clinical audits in hospital systems boosts transparency, education, and continuous improvement.