



CLINICAL AUDIT

# **Clinical auditing and quality assurance as tools in the implementation of ALARA in the medical sector**

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# ALARA for **patient** protection?



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## ....Reasonably Achievable....

### X-ray imaging and nuclear medicine

**Limit dose  
to patient**



**Provide image  
quality sufficient for  
reliable diagnosis**

### Radiotherapy

**Eradicate  
tumor**



**Avoid complications  
of healthy tissues**

# ALARA for **patient** protection?



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**....Reasonably Achievable....**

**Management of the radiation dose  
to patient must be **consumerate**  
with the medical purpose**

# Increased attention to QA



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- **Proper justification, optimization and quality assurance (QA) procedures are important to ensure the high quality and safety of RADIOLOGICAL (x-ray diagnostics, nuclear medicine and radiotherapy) procedures**
- **A worldwide tendency to establish quality systems and introduce appropriate quality audits**
- **In Europe, Council Directive 97/43/EURATOM (the MED directive) introduced the concept of clinical audit for medical RADIOLOGICAL procedures.**

**Poor understanding and  
implementation of Clinical audit →  
Special EC project 2007-2008**



## **European Commission Guidelines on Clinical Audit**

**for Medical Radiological Practices (Diagnostic radiology,  
nuclear medicine and radiotherapy)**

**Radiation Protection 159**

**Available from:**

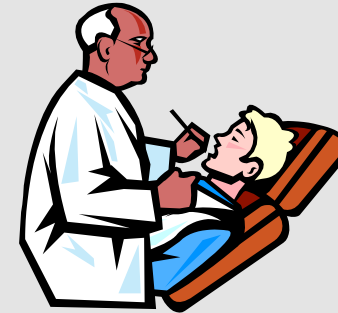
**[http://ec.europa.eu/energy/nuclear/  
radiation\\_protection/  
publications\\_en.htm](http://ec.europa.eu/energy/nuclear/radiation_protection/publications_en.htm)**

# Clinical Audit ?

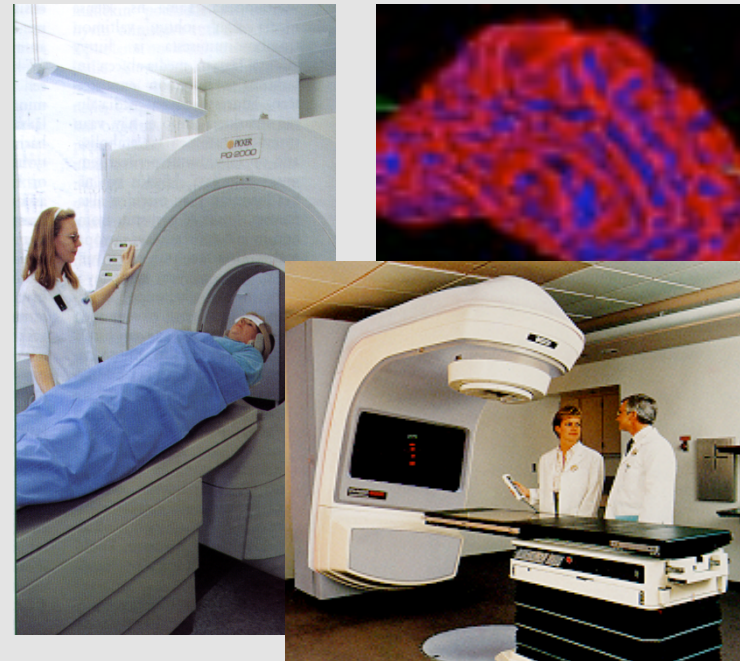


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**A general term applicable  
to any medical practice**



**MED-directive  
(97/43/EURATOM)  
introduced to  
medical  
*radiological*  
practices**



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# **Clinical Audit definition**

## **EC Directive 97/43/Euratom (MED)**



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**Systematic examination or review  
of medical radiological procedures  
which seeks to improve  
the quality and the outcome of patient care  
through structured review whereby  
radiological practices, procedures and results  
are examined against agreed standards  
for good medical radiological procedures,  
with modification of practices where indicated  
and the application of new standards if  
necessary**

# **Clinical audit = Tool for the implementation of ALARA**



CLINICAL AUDIT

## **In clinical audit**

**...radiological practices, procedures and results  
are examined against agreed standards  
for good medical radiological procedures...**

## **ALARA:**

**”working in compliance with the standards  
for good medical radiological procedures  
(justification, optimization, ... etc)”**



# Objectives of Clinical Audit (RP 159)

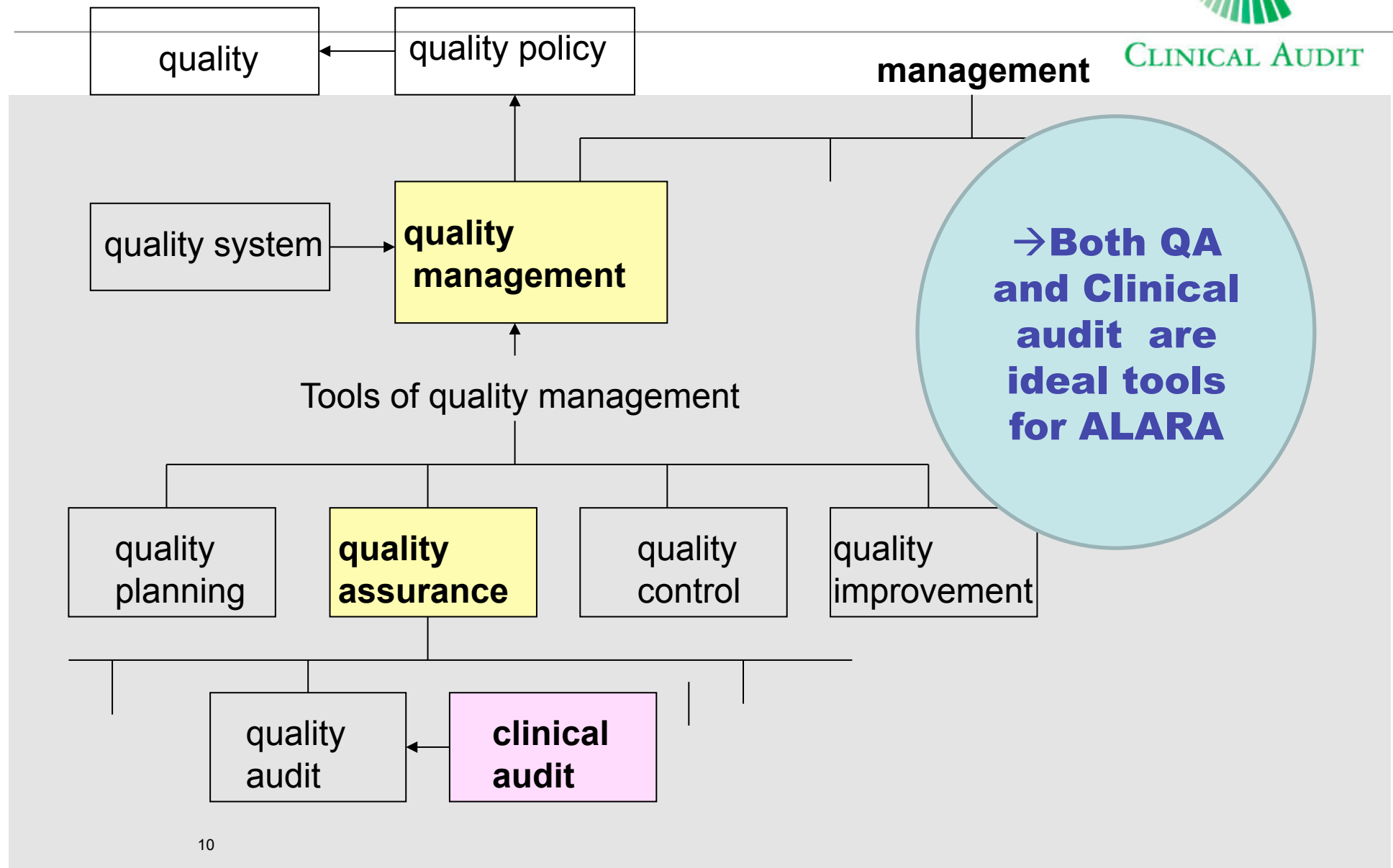


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***The **general purpose** of any clinical audit is to***

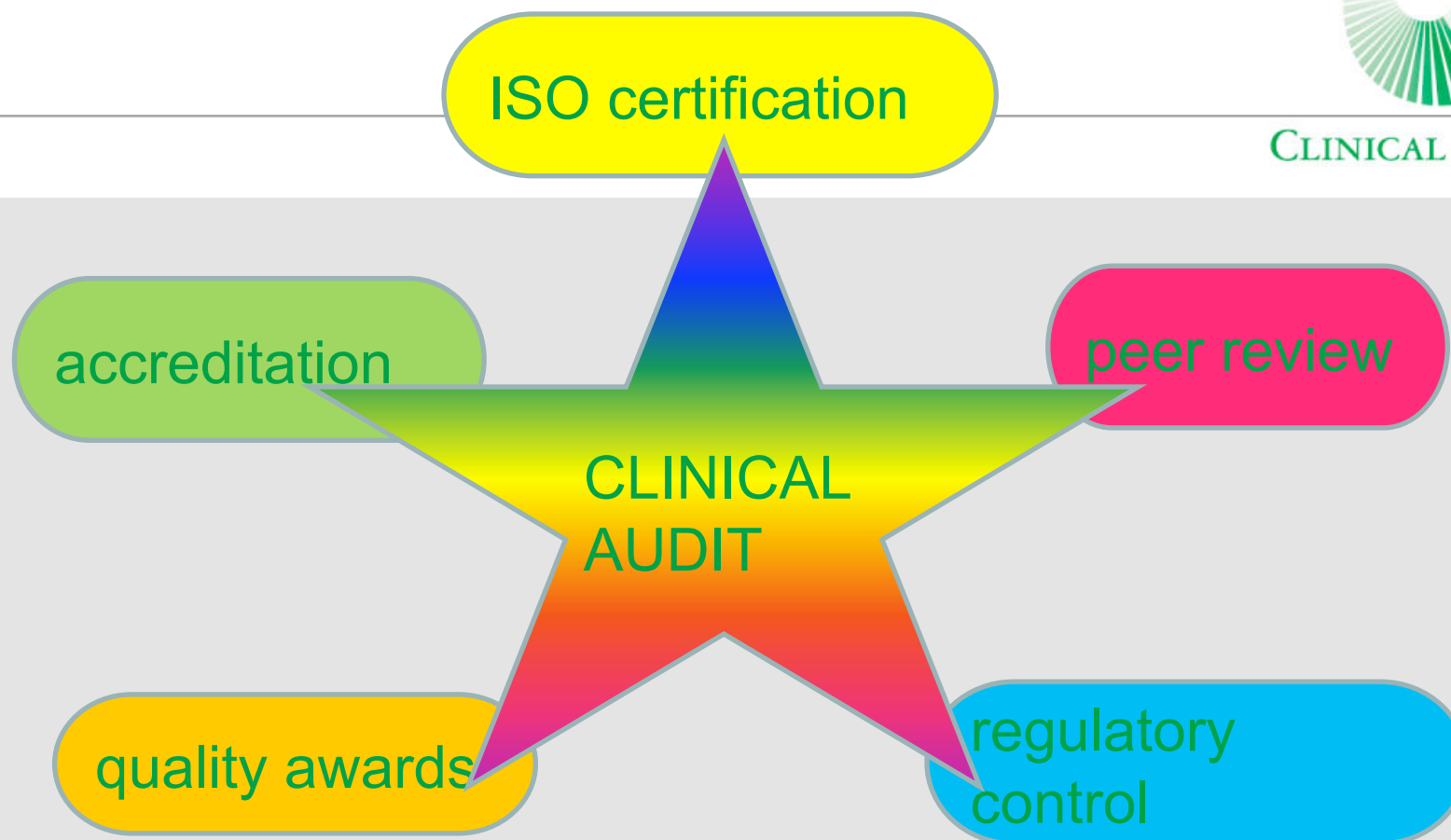
- ***improve the quality of **patients' care*****
- ***improve the effective **use of resources*****
- ***enhance the provision and organization of **clinical services*****
- ***further professional **education and training*****

***With these objectives, clinical audit is an integral part of the overall quality improvement process and should be considered as **an integral part of quality management and clinical governance.*****





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**While Clinical audit is an important part of the overall QA activities, it should **not be confused with** other audit and control systems**

# EC Guideline on Clinical Audit (RP 159)

## Purpose



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**To provide guidance on clinical auditing for an improved implementation of Article 6.4 of MED (97/43/ EURATOM)**

**To enable the member States *to adopt the model of clinical audit with respect to their national legislation and administrative provisions.***



# EC Guideline on Clinical Audit (RP 159)

## Purpose



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- *It is important to recognize that this guideline is **NOT** a legal requirement.*
- *According to the MED directive, clinical audits should be carried out “in accordance with national procedures”.*
- *The purpose of this guideline is to give **recommendations** and highlight some possible “national procedures”.*

# EC Guideline on Clinical Audit (RP 159)

## Contents



- **Basic principles of clinical audit (objectives, coverage etc)**
- **Topics to be covered**
- **Criteria of good practice on generic levels**
- **Interrelation of clinical audit with other audit systems and with regulatory control.**
- **General advice for practical implementation**

# EC Guideline on Clinical Audit (RP 159)

## General principles



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- It is obvious from the definition that all grades of staff (all professionals) of medical care must be involved
- It is a truly multi-disciplinary, multi-professional activity.



**No-blame environment, confidentiality**

**→ IDEAL TOOL FOR ALARA**

# EC Guideline on Clinical Audit (RP 159)

## General principles



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- It should be carried out by competent experts with good experience in clinical practices
- Auditors must be independent from the unit to be audited
- Auditors need specific training on audit techniques and criteria



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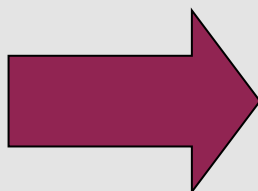
# EC Guideline on Clinical Audit (RP 159)

## Internal and external audits



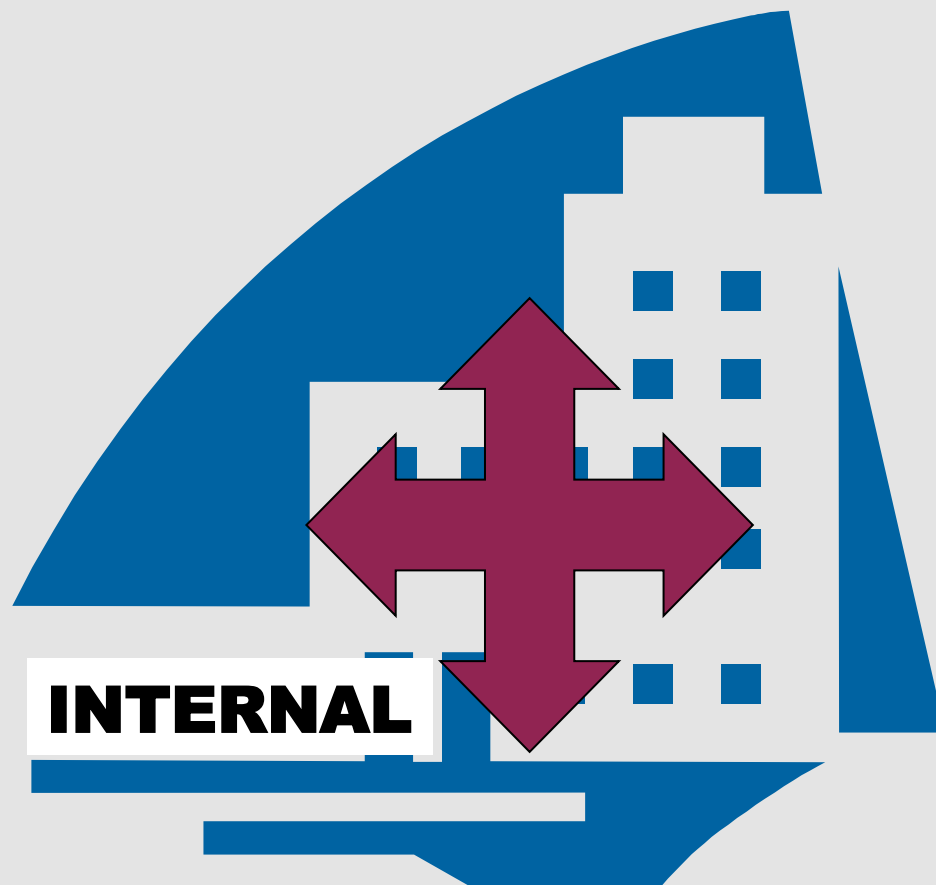
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**EXTERNAL**



**Should be of equal  
importance  
and supplement  
each other**

**INTERNAL**



**→ IDEAL TOOL FOR ALARA**

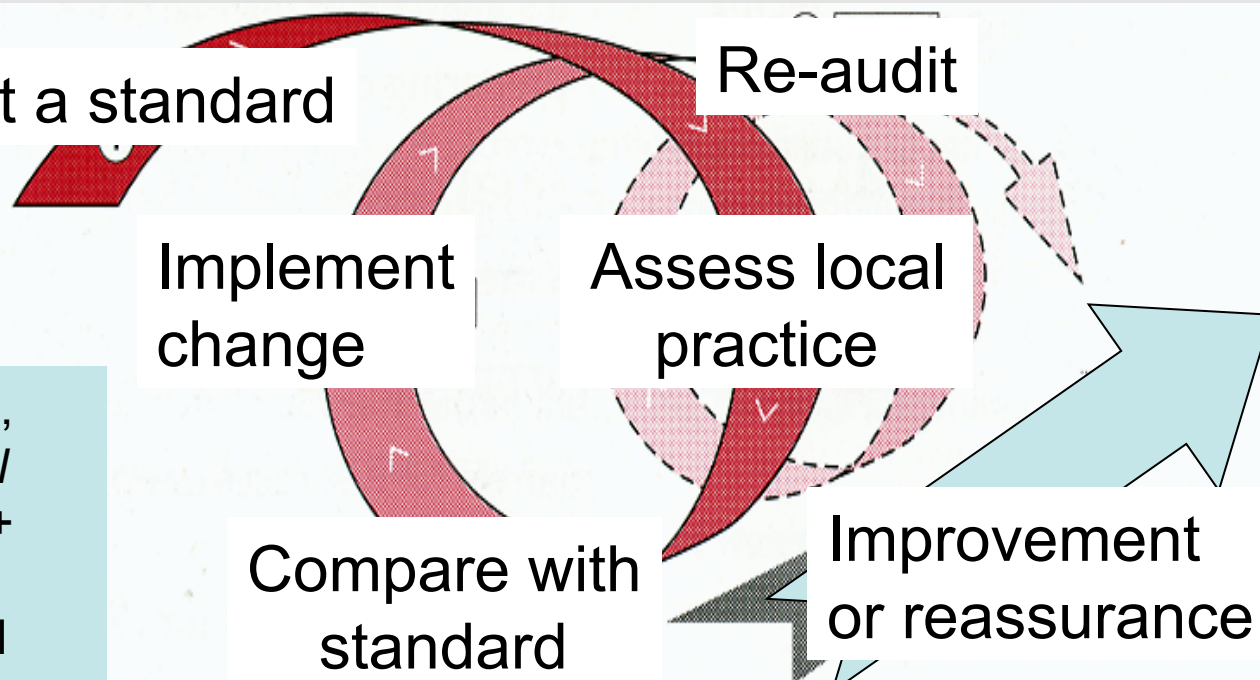
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## Clinical audit: **Continuous** activity for improvement

Figure 2 Preferred:  
the audit summarised as a spiral  
of repeating cycles.

Goodwin R, de Lacey G,  
Manhire A (eds). *Clinical  
Audit in Radiology: 100+  
Recipes*, 1996 by  
permission of The Royal  
College of Radiologists



→ **IDEAL TOOL FOR ALARA**

# EC Guideline on clinical audit (RP 159)

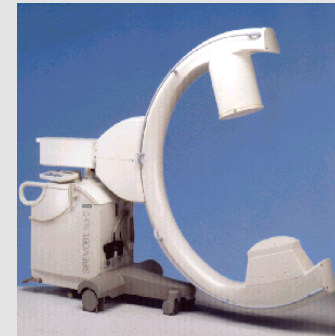
## Coverage of clinical audit



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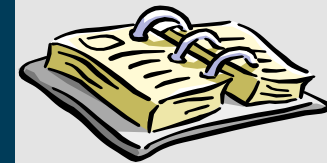
### Structure:

***The physical attributes such as buildings, facilities and staff.***



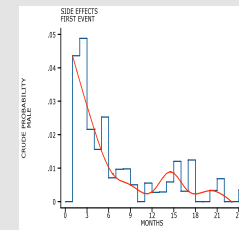
### Process:

***The care provided by staff i.e. what the staff actually do.***



### Outcome:

***The end result of examination or treatment for the health of patient***



# EC Guideline on clinical audit (RP 159)

## Coverage of clinical audit



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### Scope

- whole RADIOLOGICAL processes (**comprehensive** audit)
- limited to specific critical parts (**partial** audit)



# EC Guideline on clinical audit (RP 159)



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## Priorities for RADIOLOGICAL procedures process

- **Justification**, referral practices
- **quality of local guidelines/ optimization procedures**
- **dose and image quality**
- **dose delivery to patients (RT)**
- **quality assurance / control programs**
- **emergency procedures**
- **information transfers systems**



→ **IDEAL TOOL FOR ALARA**

# Audit of justification



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- **Justification is a cornerstone ("Gate keeper") of radiation protection and must be among the priorities of clinical audit**
- **Audit of compliance with guidelines can be a simple and effective tool for improving referral patterns**

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# EC Guideline on clinical audit (RP 159)

## Practical procedures



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### Interviews Reviews of documents and data

**A sufficient  
Quality Manual must  
be available**



### Physical measurements or tests

**Some indicators of quality  
are best assessed by  
comparative  
measurements or physical  
tests**



**→ IDEAL TOOL FOR ALARA**

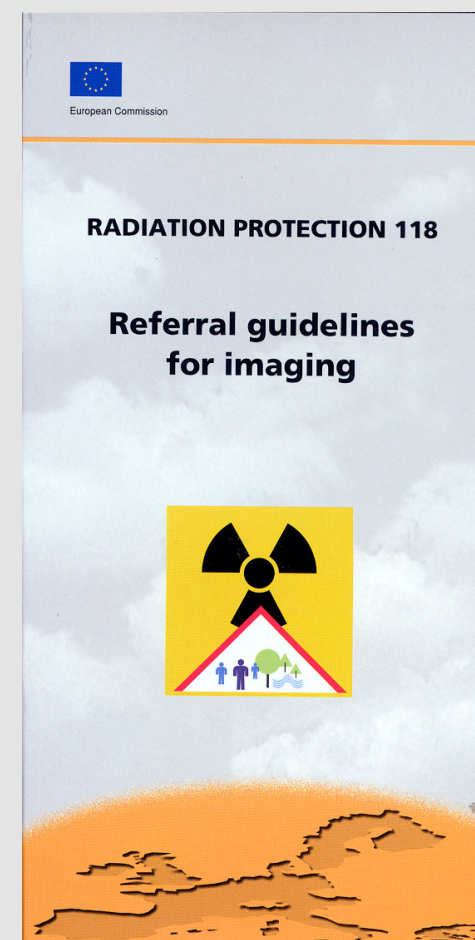
# EC Guideline on clinical audit (RP 159)



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## Standards of good practice

- **Good practice should be based on the most recent considerations of evidence based data, long term experience and knowledge gained.**
- **Possible sources:**
  - **Legal requirements**
  - **Results of research**
  - **Consensus statements**
  - **Recommendations by learned societies**
  - **Local agreement**



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# Clinical audit as a benchmarking tool

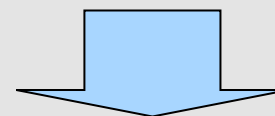


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**A group of experts proposes criteria of good practice for a selected examination/treatment problem or specified sub-procedure of the examination/treatment**

**Results of audit to be compared and used as a benchmarking tool to achieve improved evidence and to adjust the chosen criteria.**



**Preliminary  
criteria applied in  
clinical audits**



**→ IDEAL TOOL FOR ALARA**

# Conclusions



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- **Clinical audit is part of the overall QA activities and a systematic review of the procedures in order to improve the quality and the outcome of patient care**
- **Clinical audit can have a major impact on developing the medical RADIOLOGICAL practices in compliance with the most recent data on good practices → AN IDEAL TOOL FOR ALARA**
- **QA is a necessary tool for ALARA, and clinical audit an ideal tool for QA**

# **ALARA for **patient** protection? Clarification needed!**



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**....Reasonably Achievable....**

**Management of the radiation dose  
to patient must be **consumerate**  
with the medical purpose**



# Guidance for clinical audit



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**EC Guidelines: RP 159**  
**General Framework**  
**for sustainable national systems**  
**Basic principles, Basic criteria**

**IAEA Guides**  
**(QUATRO-Radiotherapy,**  
**QUADRIL-Diagnostic radiology,**  
**NM)**  
**Practical guidance for**  
**comprehensive**  
**external audits**

**Other existing**  
**guides**  
**Practical guidance for**  
**internal audits/**  
**partial external audits**  
**(selected topics)**  
**e.g. Audit Live in UK**







A serene sunset scene over a calm lake. The sky is a mix of soft pinks, purples, and blues. The water reflects the colors of the sky. On the left, there are dark silhouettes of trees and a wooden dock. A small boat is moored near the dock. The overall mood is peaceful and quiet.

*Thank you!*