

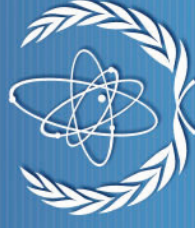
International Workshop on Practical Implementation of  
**Clinical Audit for Medical Exposure to Ionizing Radiation**  
8–10 September 2008, Tampere, Finland



# IAEA activities in comprehensive audit for radiation medicine

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**IAEA**  
International Atomic Energy Agency

# Major activities of IAEA in human health

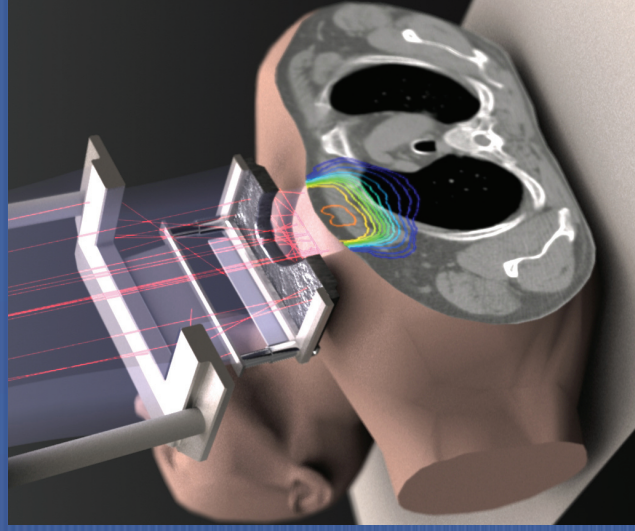
Quality Assurance

International Conference  
on  
Quality Assurance and  
New Techniques in  
Radiation Medicine



Vienna, Austria  
13-15 November 2006

Therapy



Cancer

Diagnosis



Infection  
cancer  
heart

Prevention



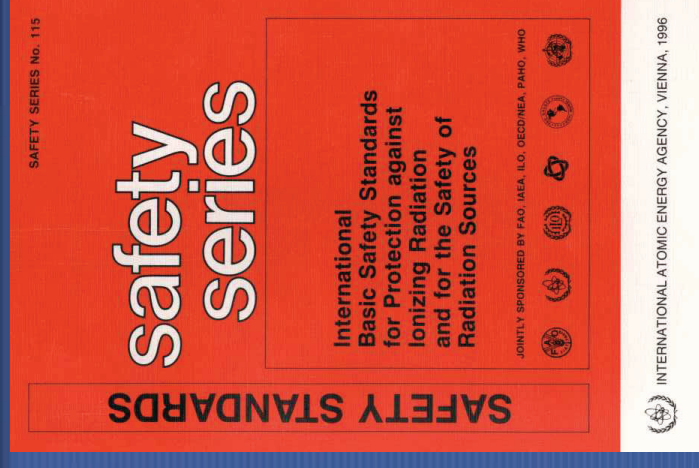
Nutrition

TLD & Lab  
Networks



# Introduction of comprehensive audit

- The IAEA has recognized the need to audit medical radiation technology (diagnostics & therapy)
- International Basic Safety Standards (BSS) is a foundation
- EC Directive 97/43/Euratom: EU countries are in the process of devising a methodology for clinical audit



*Revised BSS: 11.23 Registrants and licensees shall ensure that quality assurance programmes for medical exposures include, as appropriate to the medical radiation facility:*

*.....  
(e) periodic radiological clinical audits, by the radiological medical practitioners, of the radiological procedures performed at the facility*

# Focus on comprehensive audit

- IAEA methodology for comprehensive audit has been developed for radiotherapy, nuclear medicine and diagnostic radiology
- Common approach was adopted for the preparation and organization of audit, its implementation and reporting
- Audit methodology reflects diversity of services in NM and diagnostic radiology.





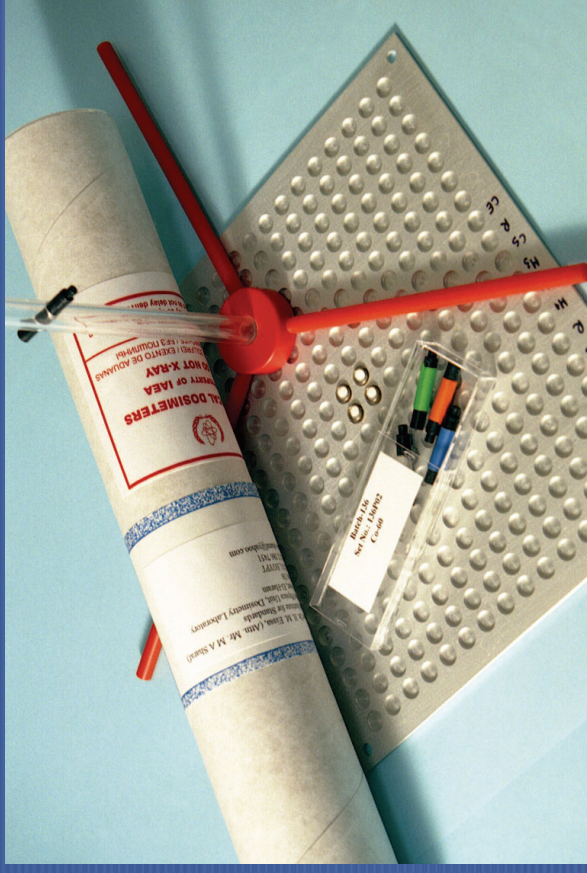
# IAEA audits in radiotherapy

- **ONGOING:** IAEA/WHO TLD postal dose audits of radiotherapy beam calibration (39 years, ~7000 beams checked in ~1600 hospitals in 119 countries)



- **NEWLY IMPLEMENTED:**

- Quality Assurance  
Team for Radiation  
Oncology (**QUATRO**)
- radiation oncologist
  - medical physicist
  - RTT



# QUATRO modality

REACTIVE AUDIT

PROACTIVE AUDIT

IAEA-TECDOC-1543

## On-site Visits to Radiotherapy Centres: Medical Physics Procedures

Quality Assurance Team for Radiation Oncology  
(QUATRO)

*Problems in dosimetry,  
treatment planning, etc.*


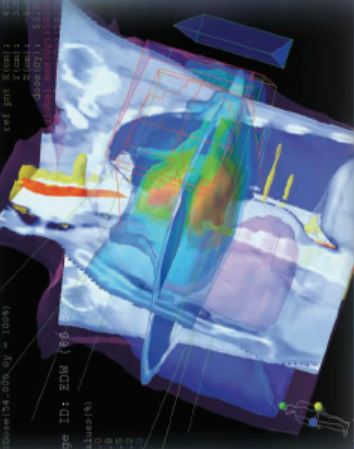


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March 2007

## Comprehensive Audits of Radiotherapy Practices: a Tool for Quality Improvement

Quality Assurance Team for Radiation Oncology (QUATRO)



# Comprehensive audit in RT

## Proactive audit

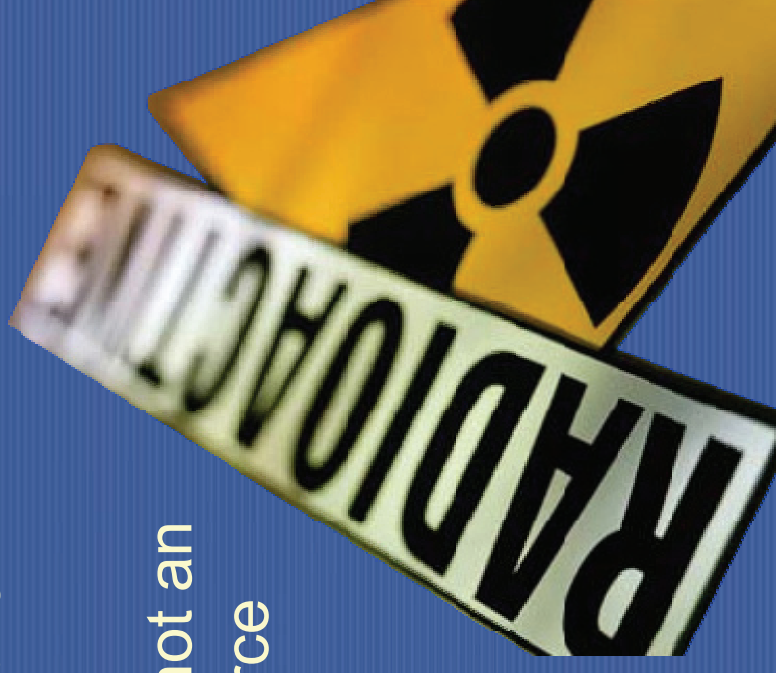
- Peer review and evaluation of the quality of all elements involved in radiation therapy processes (staff, equipment and procedures, patient protection and safety, overall performance)
- Any areas for improvement will be identified with a view to bring the radiotherapy services to the internationally accepted level.



**GOAL: QUALITY IMPROVEMENT**

# Comprehensive RT audit is **NOT** designed for

- Investigation of incidents or reportable medical events (misadministration)  
👉 specialised audit (QUATRO reactive)
- Assessment for entry into cooperative clinical research studies
- Regulatory purposes, i.e. audit is not an enforcing tool but an impartial source of advice on quality improvement





# Request for a comprehensive audit in RT



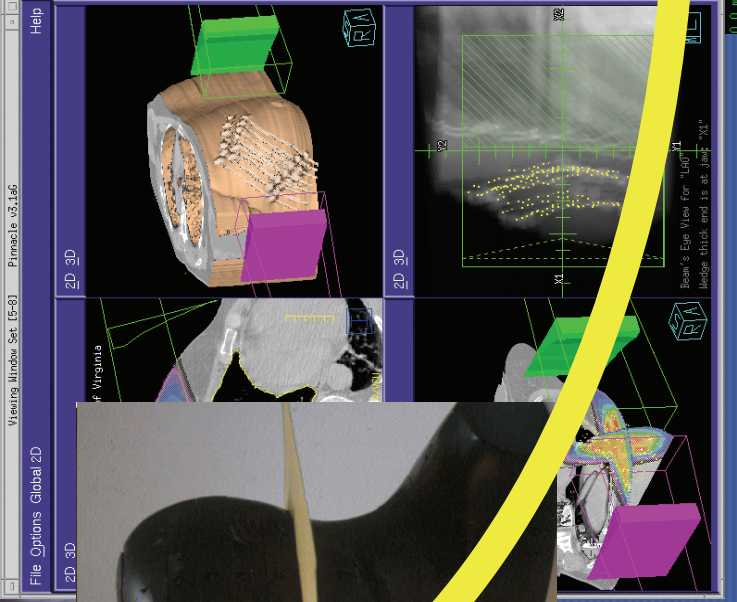
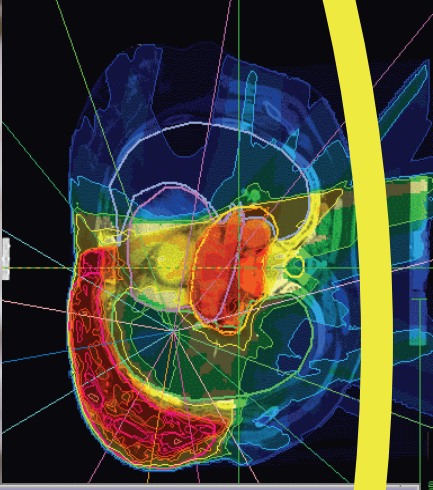
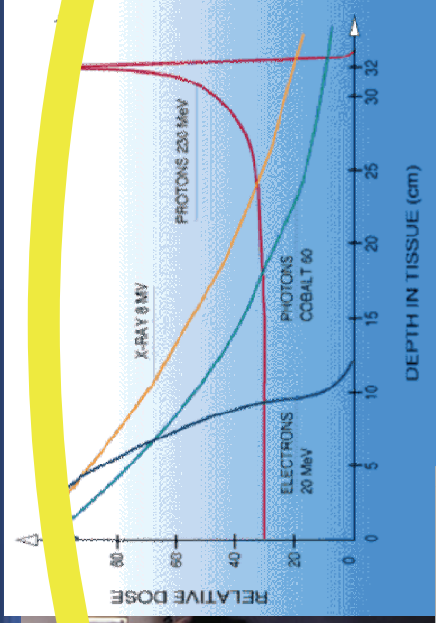
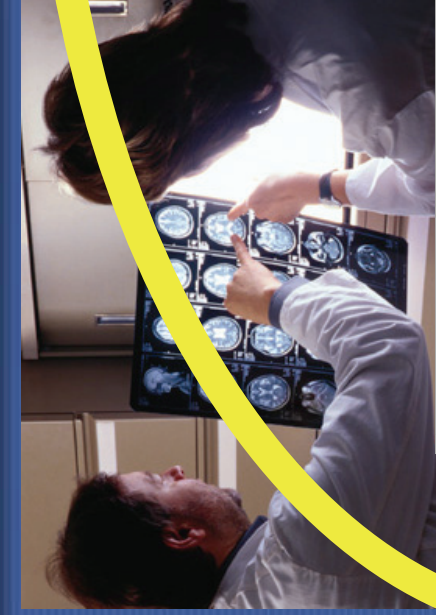
## Proactive audit

- Request by radiation oncology department, hospital or Ministry of Health (endorsed by the department)
- Entry level:
  - infrastructure & equipment
  - qualified staff & training programmes
  - QA programme
  - cancer registry

# QUATRO audit timescale

- Typical duration 5 days per department
- Entrance briefing
- Days 1-3: team activities (tour, interviews, review of documentation, procedures, observation of practical work)
- Days 4-5:
  - Preparation of a preliminary report and recommendations
  - Physics measurements (dosimetry for tele- and brachytherapy, TPS check, benchmark cases, verification of data consistency)
- Exit briefing

# Comprehensive RT audit





# Conclusion of QUATRO audit

- A. The institution is suitable to perform the radiotherapy services at the internationally accepted level
- B. The audit team has identified areas for improvement, resolvable by the institution
- C. There are underlying major problems that cannot be resolved by the institution or without significant resources

**B, C** 🖱️

**follow-up audits**



# Dissemination of the audit report

- **Full audit report** – confidential
  - The requestor (typically DIR or Head Dept.)
  - Individuals named by the institution
- **Summary report** – national authorities
  - National Liaison Officer for Technical Cooperation with IAEA
  - Ministry of Health



# The IAEA approach to QUATRO

QUATRO guidelines drafted	2003 – 2004
Publication	2007
Audit teams trained	2005 & 2006 - ongoing
Requests received from Member States	2004 - ongoing
Preparation of the audit logistics	2004
Implementation of QUATRO audits (incl. lessons learnt meetings)	2005 - ongoing

# QUATRO in various regions

## **Africa**

- 2 QUATRO workshops in 2006
- QUATRO guide used for internal audits
- 1st mission in 2006

## **Asia**

- Training of auditors in 2005, upcoming regional workshops
- 8 missions conducted to-date, further missions planned

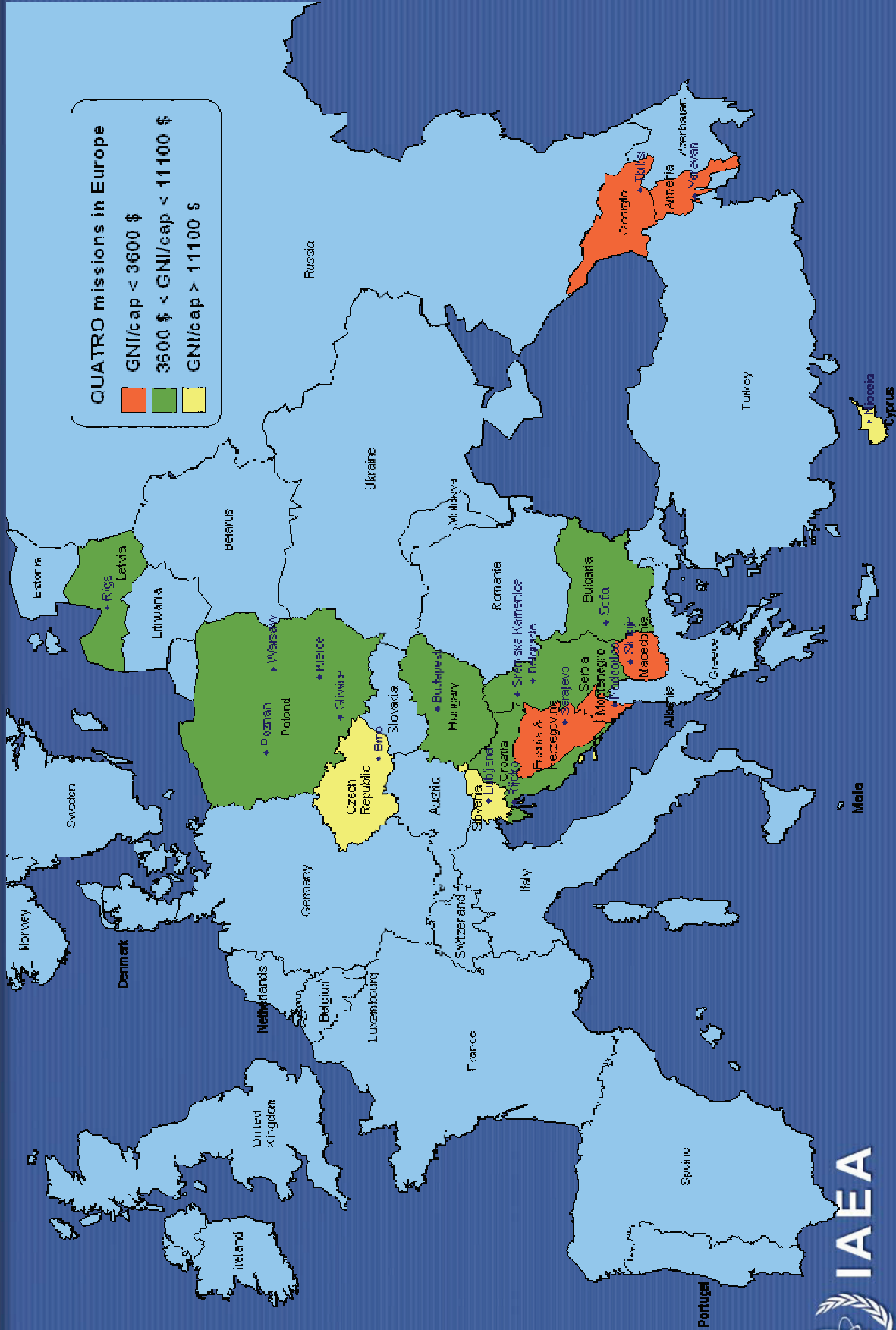
## **Europe**

- Training of auditors in 2005 and 2006 (7 audit teams)
- 18 missions conducted to-date, further missions planned

## **Latin America**

- 2 QUATRO regional workshops in 2005
- 8 QUATRO missions in 2008-2009

# QUATRO audits in Europe to-date





# IAEA audits of NM practices

- All-inclusive guidelines (QUANUM) for self-appraisal and external audit have been developed
- Comprehensive audit reviews:
  - Quality of services taking into account diversity of NM practices
  - Processes: patient investigations, reports, patient management and outcomes
  - Infrastructure: human resources incl. training, equipment (level, QC, maintenance)
  - Radiation protection and safety
  - Quality Management System
- QUANUM methodology is being tested in Africa, Asia, Europe and Latin America.



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# QUANUM audit process

- Audit request following self-appraisal
- Data input into NUMDAB
- Pre-visit questionnaire
- On-site review by an audit team
  - Observations
  - References
  - Non-conformances
- Audit conclusion and recommendations
- Remedial action
- Follow-up



# Clinical audit in diagnostic radiology

- Audit methodology drafted in 2007
- Two pilot missions in 2008:
  - Kuala Lumpur, Malaysia
  - Banja Luka, Bosnia & Herzegovina
- Documentation review to be finished end of 2008
- Audit format:
  - 3 auditors: radiologist, radiographer and medical physicist
  - physical measurements will be taken
- Audit document design intended to promote rapid completion of audit process after the visit

# Clinical audit in diagnostic radiology

Differences with therapy audit:

- Greater range of diverse activities making it difficult to cover any area in depth
- To be discovered.....





# Summary and Conclusion

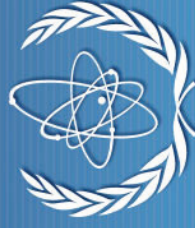
- QUATRO provides a useful tool for improvement of radiotherapy practices
- Audit procedures for nuclear medicine and diagnostic radiology have been developed and are under implementation
- IAEA is the first international organization who prepared the methodology, trained experts and started the implementation of the comprehensive audit in radiotherapy worldwide



## **Acknowledgement**

Numerous international experts who have contributed to the development of the IAEA guidelines for comprehensive audits in radiation medicine and conducted audit missions

**Thank you for your attention**



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