

Clinical audit in terms of Directive 97/43/EURATOM

Georgi Simeonov
Directorate H. Nuclear Energy
Unit H4. Radiation Protection

Contents

- EU legislation on radiation protection
- Introduction to Directive 97/43/EURATOM
- Clinical audit in MED Directive
- Legal requirements for CA
- Other related requirements
- Expectations from the project

EU legislation on radiation protection

- EURATOM Treaty from 1957
 - Article 2: “ ... the Community shall ... establish uniform standards to protect the health of workers and of the general public”
- Basic Safety Standards
 - first directive from 1959
 - latest directive – 96/29/EURATOM
- Other EURATOM legislation

Directive 97/43/EURATOM

- Scope: “medical exposure” and carers and comforters
- Medical exposure
 - ›› patients – diagnosis and treatment
 - ›› occupational health surveillance
 - ›› health screening
 - ›› medical and biomedical research
 - ›› medico-legal



Directive 97/43/EURATOM (2)

- Justification
 - ›› medical use of ionizing radiation is in principle justified
 - ›› new types of practices shall be justified in advance before being generally adopted
 - ›› all individual medical exposures shall be justified in advance
 - ›› special attention if no direct health benefit to the exposed person (e.g. medico-legal)

Directive 97/43/EURATOM (3)

- Optimization
 - » consistent with obtaining the required diagnostic information or intended therapeutic purpose
 - » establishment and use of DRL
 - » optimization process shall include ... the consistent production of adequate diagnostic information or therapeutic outcome, ... quality assurance ...

Directive 97/43/EURATOM (4)

- Main provisions
 - Responsibilities: holder, prescriber, practitioner
 - Procedures: written protocols, referral criteria, MPE, CA, use of DRL
 - Training: practitioner and MPE
 - Equipment: ... QA, incl. dose assessment ...
 - Special practices
 - Potential exposure

Clinical audit in MED Directive

“A *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.”

Directorate-General
for Energy
and Transport



EUROPEAN
COMMISSION

Clinical audit in MED Directive (2)

Article 6.4.

Clinical audits shall be carried out in accordance with national procedures.

Directorate-General
for Energy
and Transport



EUROPEAN
COMMISSION

International Workshop on Practical Implementation of Clinical Audit for Medical Exposure to Ionizing Radiation, Tampere, Finland, 7-10 September 2008

Other provisions relevant to CA

- QA requirements
 - » Article 8.2. Member States shall ensure that:
 - ... appropriate quality assurance programmes including quality control measures and patient dose or administered activity assessments are implemented by the holder of the radiological installation.

Other provisions relevant to CA (2)

- DRL requirements
 - » Article 6.5. Member States shall ensure that appropriate local reviews are undertaken whenever diagnostic reference levels are consistently exceeded and that corrective actions are taken where appropriate.

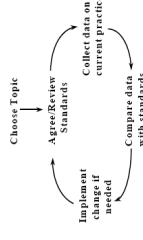
Other provisions relevant to CA (3)

- Areas of CA
 - » Justification: general and individual, involvement of prescriber and practitioner, etc.
 - » Optimization: DRL, dose constraints, guidance, elements of optimization process
 - » Responsibilities: prescriber/practitioner/MPE, delegation of practical aspects, medico-legal
 - » Procedures: written protocols, referral criteria
 - » Training: initial and continuing
 - » Equipment: surveillance, inventory, acceptance and performance testing
 - » Special practices: children, pregnant women

Expectations from the Guidance on CA

“A *systematic examination* ... through *structured review* ...”

>> System and structure of the CA



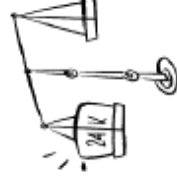
“...radiological *practices, procedures and results* are examined...”

>> Selection of topic of CA



“...practices, procedures and results are examined against *agreed standards*...”

>> Selection of standards



Expectations from the Guidance on CA (2)

“...review of *medical radiological procedures*...”

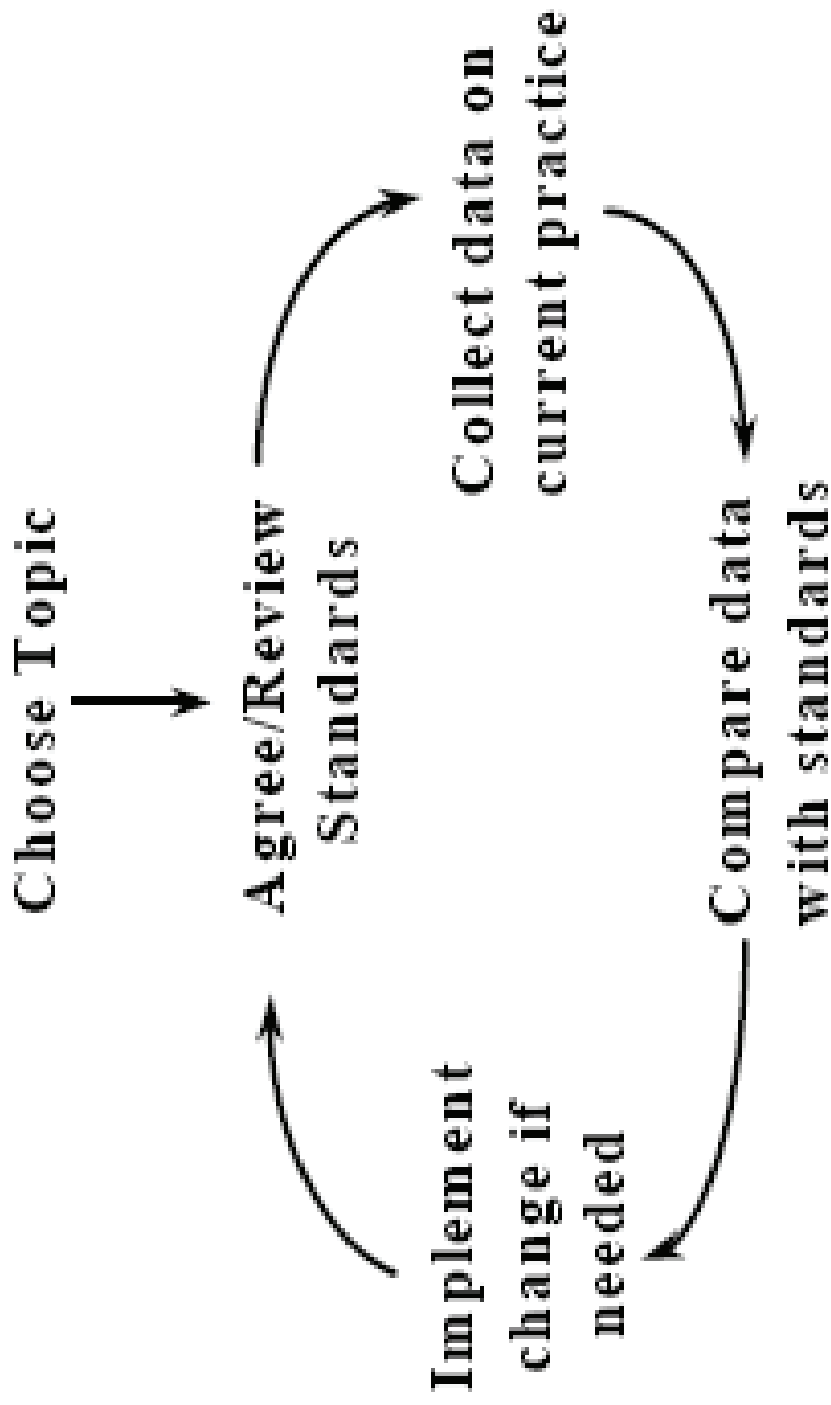
- » Collection and evaluation of data
- » Practical aspects of implementation to diagnostic radiology, NM and radiotherapy



“...*modification of practices* where indicated...”

- » Definition and implementation of corrective actions





THANK YOU

