QuADRANT

QuADRANT Workshop

Monday 14th December 14:30-17:00 CET

Webinar 1: QuADRANT, Clinical Audit and Radiation Protection- An overview with with Emphasis on key WHO/IAEA Initiatives

Clinical audit as Defined in the European-Basic Safety Standards Directive

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HERCA is a voluntary association

- HERCA, the Heads of European Radiological protection Competent Authorities, was founded in 2007
- It is a voluntary association in which the heads of the Radiation Protection Authorities work together in order to identify and discuss common interests in significant regulatory issues.

32 countries (EU MS + IS, NO, CH, RS)
56 organisations (RPA + TSO),
310 nominations
Observers
EC, IAEA, OECD/NEA, WHO, US FDA

Introduction

- In 1997, the UK's National Institute for Health and Clinical Excellence (NICE) published the paper "**Principles for best practice in clinical audit**" and defined clinical audit as:
- *"a quality improvement process that seeks to improve patient care and outcomes through systematic review of care against explicit criteria and the implementation of change. Aspects of the structure, process and outcomes of care are selected and systematically evaluated against explicit criteria. Where indicated, changes are implemented at an individual, team, or service level and further monitoring is used to confirm improvement in healthcare delivery"*

Medical Exposure Directive in 97/43/Euratom:

The Medical Exposure Directive of 1997 introduced clinical audit for the first time, including it within the article relating to procedures.

“The Directive defined clinical audit as

> *“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”*

Medical Exposure Directive in 97/43/Euratom:

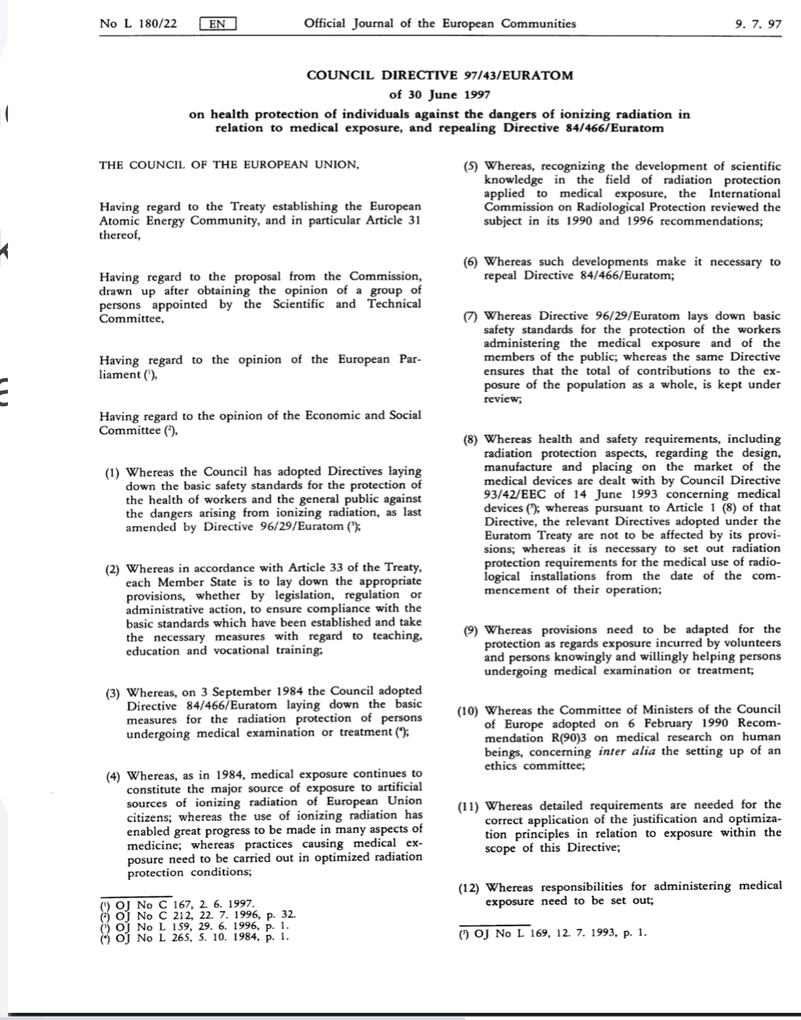
The definition is consistent in its approach with other definitions of clinical audit, but recognises the context of the Directive and is **therefore specific to medical radiological procedures**

The Directive included requirements for clinical audit under Article 6, relating to Procedures, and stated

“clinical audits shall be carried out in accordance with national procedures”

Introduction of requirements for clinical audit in 97/43/Euratom:

The requirement is not prescriptive in itself, but its inclusion in th Directive, which had to be be transposed through a legal framework implied that Member States should include some requirement for clinica audit in their legislation and regulations relating to radiation protection.



No L 180/22 EN Official Journal of the European Communities 9. 7. 97

COUNCIL DIRECTIVE 97/43/EURATOM

of 30 June 1997

on health protection of individuals against the dangers of ionizing radiation in relation to medical exposure, and repealing Directive 84/466/Euratom

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Atomic Energy Community, and in particular Article 31 thereof,

Having regard to the proposal from the Commission, drawn up after obtaining the opinion of a group of persons appointed by the Scientific and Technical Committee,

Having regard to the opinion of the European Parliament (1),

Having regard to the opinion of the Economic and Social Committee (2),

(1) Whereas the Council has adopted Directives laying down the basic safety standards for the protection of the health of workers and the general public against the dangers arising from ionizing radiation, as last amended by Directive 96/29/Euratom (3);

(2) Whereas in accordance with Article 33 of the Treaty, each Member State is to lay down the appropriate provisions, whether by legislation, regulation or administrative action, to ensure compliance with the basic standards which have been established and take the necessary measures with regard to teaching, education and vocational training;

(3) Whereas, on 3 September 1984 the Council adopted Directive 84/466/Euratom laying down the basic measures for the radiation protection of persons undergoing medical examination or treatment (4);

(4) Whereas, as in 1984, medical exposure continues to constitute the major source of exposure to artificial sources of ionizing radiation of European Union citizens; whereas the use of ionizing radiation has enabled great progress to be made in many aspects of medicine; whereas practices causing medical exposure need to be carried out in optimized radiation protection conditions;

(1) OJ No C 167, 2. 6. 1997.
(2) OJ No C 212, 22. 7. 1996, p. 32.
(3) OJ No L 159, 29. 6. 1996, p. 1.
(4) OJ No L 265, 5. 10. 1984, p. 1.

(5) Whereas, recognizing the development of scientific knowledge in the field of radiation protection applied to medical exposure, the International Commission on Radiological Protection reviewed the subject in its 1990 and 1996 recommendations;

(6) Whereas such developments make it necessary to repeal Directive 84/466/Euratom;

(7) Whereas Directive 96/29/Euratom lays down basic safety standards for the protection of the workers administering the medical exposure and of the members of the public; whereas the same Directive ensures that the total of contributions to the exposure of the population as a whole, is kept under review;

(8) Whereas health and safety requirements, including radiation protection aspects, regarding the design, manufacture and placing on the market of the medical devices are dealt with by Council Directive 93/42/EEC of 14 June 1993 concerning medical devices (1); whereas pursuant to Article 1 (8) of that Directive, the relevant Directives adopted under the Euratom Treaty are not to be affected by its provisions; whereas it is necessary to set out radiation protection requirements for the medical use of radiological installations from the date of the commencement of their operation;

(9) Whereas provisions need to be adapted for the protection as regards exposure incurred by volunteers and persons knowingly and willingly helping persons undergoing medical examination or treatment;

(10) Whereas the Committee of Ministers of the Council of Europe adopted on 6 February 1990 Recommendation R(90)3 on medical research on human beings, concerning *inter alia* the setting up of an ethics committee;

(11) Whereas detailed requirements are needed for the correct application of the justification and optimization principles in relation to exposure within the scope of this Directive;

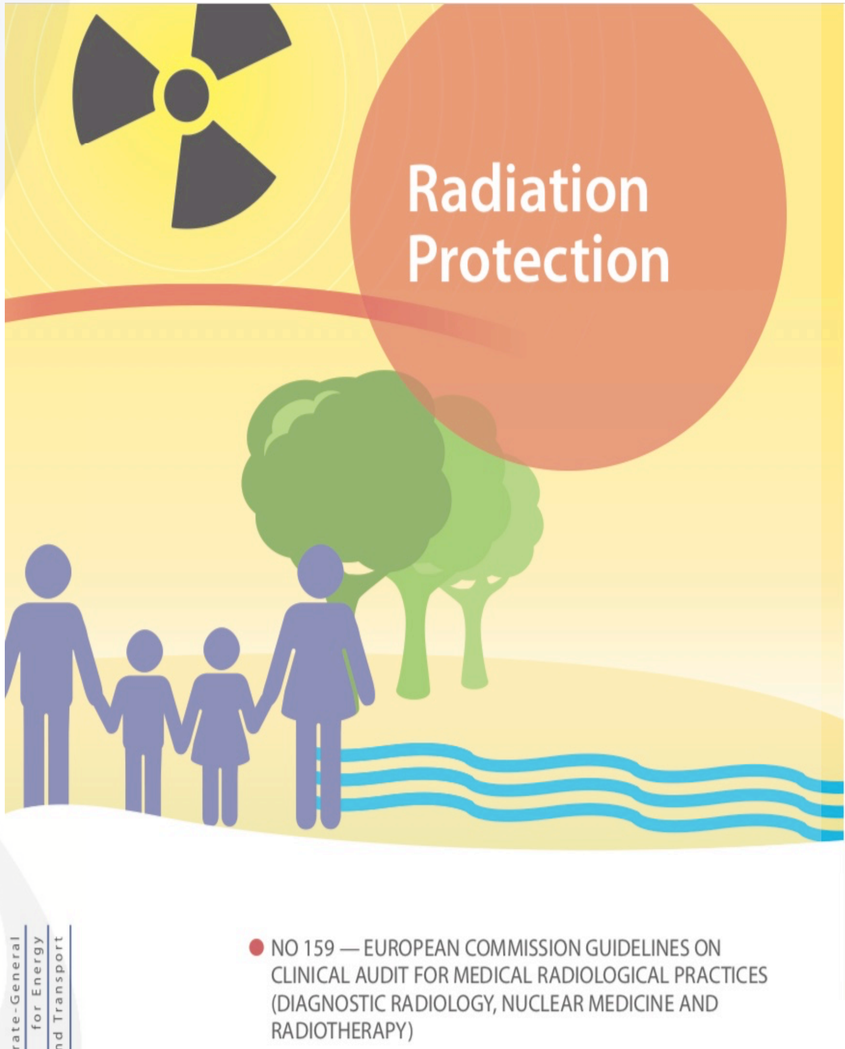
(12) Whereas responsibilities for administering medical exposure need to be set out;

(1) OJ No L 169, 12. 7. 1993, p. 1.

European guidelines on clinical audit for medical radiological practice *(RP No.159)*

Lack of understanding within the radiological community on how regulatory requirements for clinical audit should be met lead the European Commission's Working party of Medical Exposure under the Article 31 Group of Experts to advise that European guidance should be developed on implementation of clinical audit of medical radiological procedures

The guidance was published in 2009



European guidelines on clinical audit for medical radiological practice *(RP No.159)*

The report describes:

- The basic principles and prerequisites of clinical audit
- The interrelation of clinical audit with other audit systems
- The Interrelation with regulatory control
- The practical implementation of clinical audit
- Generic criteria of good practice
- Specific audit criteria

European guidelines on clinical audit for medical radiological practice *(RP No.159)*

The general objectives of clinical audit should be to:

1. Improve the quality of patient care
2. Promote the effective use of resources
3. Enhance the provision and organisation of clinical services
4. Further education and training

Requirements for clinical audit in the EC Basic Safety Standards

Directive(BSSD) 2013/59/Euratom

- Article 58(e), relating to Procedures, of the BSSD repeats previous requirements for clinical audit, making clear that Member States shall ensure the requirements are met

- The definition of clinical audit is largely unchanged from 1997, with only “where appropriate” replacing “where indicated” in relation to the modification of practices

COUNCIL DIRECTIVE 2013/59/EURATOM

of 5 December 2013

laying down basic safety standards for protection against the dangers arising from exposure to ionising radiation, and repealing Directives 89/618/Euratom, 90/641/Euratom, 96/29/Euratom, 97/43/Euratom and 2003/122/Euratom

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Atomic Energy Community, and in particular Articles 31 and 32 thereof,

Having regard to the proposal from the European Commission, drawn up after having obtained the opinion of a group of persons appointed by the Scientific and Technical Committee from among scientific experts in the Member States, and after having consulted the European Economic and Social Committee,

Having regard to the opinion of the European Parliament,

Having regard to the opinion of the European Economic and Social Committee,

Whereas:

(1) Point (b) of Article 2 of the Euratom Treaty provides for the establishment of uniform safety standards to protect the health of workers and of the general public. Article 30 of the Euratom Treaty defines "basic standards" for the protection of the health of workers and the general public against the dangers arising from ionising radiations.

(2) In order to perform its task, the Community laid down basic standards for the first time in 1959 by means of Directives of 2 February 1959 laying down the basic standards for the protection of the health of workers and the general public against the dangers arising from ionising radiation ([1]). The Directives have been revised several times, most recently by Council Directive 96/29/Euratom ([2]) which repealed the earlier Directives.

(3) Directive 96/29/Euratom establishes the basic safety standards. The provisions of that Directive apply to normal and emergency situations and have been supplemented by more specific legislation.

(4) Council Directive 97/43/Euratom ([3]), Council Directive 89/618/Euratom ([4]), Council Directive 90/641/Euratom ([5]) and Council Directive 2003/122/Euratom ([6]) cover different specific aspects complementary to Directive 96/29/Euratom.

(5) As recognised by the Court of Justice of the European Union in its case-law, the tasks imposed on the Community by point (b) of Article 2 of the Euratom Treaty to lay down uniform safety standards to protect the health of workers and the general public does not preclude, unless explicitly stated in the standards, a Member State from providing for more stringent measures of protection. As this Directive provides for minimum rules, Member States should be free to adopt or maintain more stringent measures in the subject-matter covered by this Directive, without prejudice to the free movement of goods and services in the internal market as defined by the case-law of the Court of Justice.

(6) The Group of Experts appointed by the Scientific and Technical Committee has advised that the basic safety standards, established according to Articles 30 and 31 of the Euratom Treaty, should take into account the new recommendations of the International Commission on Radiological Protection (ICRP), in particular those in ICRP Publication 103 ([7]), and should be revised in the light of new scientific evidence and operational experience.

HERCA WGMA initiatives regarding clinical audits

Nov 2016

Action week

European action on the inspection of justification in radiology

- 17 European countries participated
- 148 inspections were carried out
- All inspections were performed according to a common inspection template.


HERCA
HEADS OF THE EUROPEAN RADIOLOGICAL PROTECTION COMPETENT AUTHORITIES

7 NOVEMBER 2016

PRESS RELEASE

HERCA launches a European inspection campaign to assess patient radiation protection in diagnostic radiology

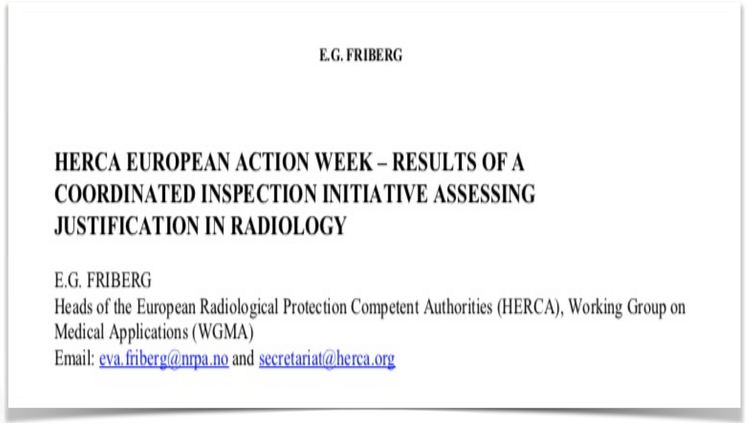
Main weaknesses identified concerning clinical audit were:

1 The concept of clinical audit is not fully understood

2 Lack of national or local procedures for performing clinical audits

3 Clinical audits are rarely performed in medical imaging

4 Review of national regulatory frameworks indicated that clinical audits were not fully implemented at a national level


E.G. FRIBERG

HERCA EUROPEAN ACTION WEEK – RESULTS OF A COORDINATED INSPECTION INITIATIVE ASSESSING JUSTIFICATION IN RADIOLOGY

E.G. FRIBERG
Heads of the European Radiological Protection Competent Authorities (HERCA), Working Group on Medical Applications (WGMA)
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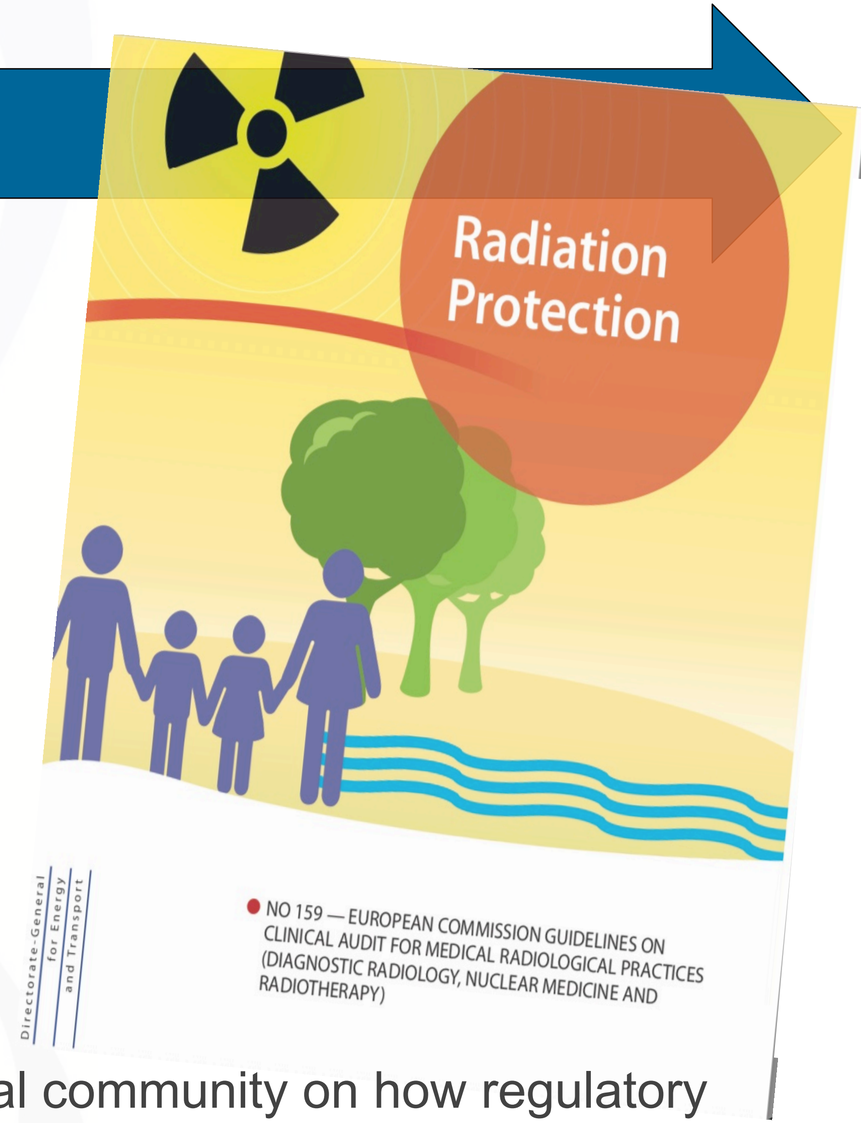
HERCA WGMA initiatives regarding clinical audits

2017 - 2018

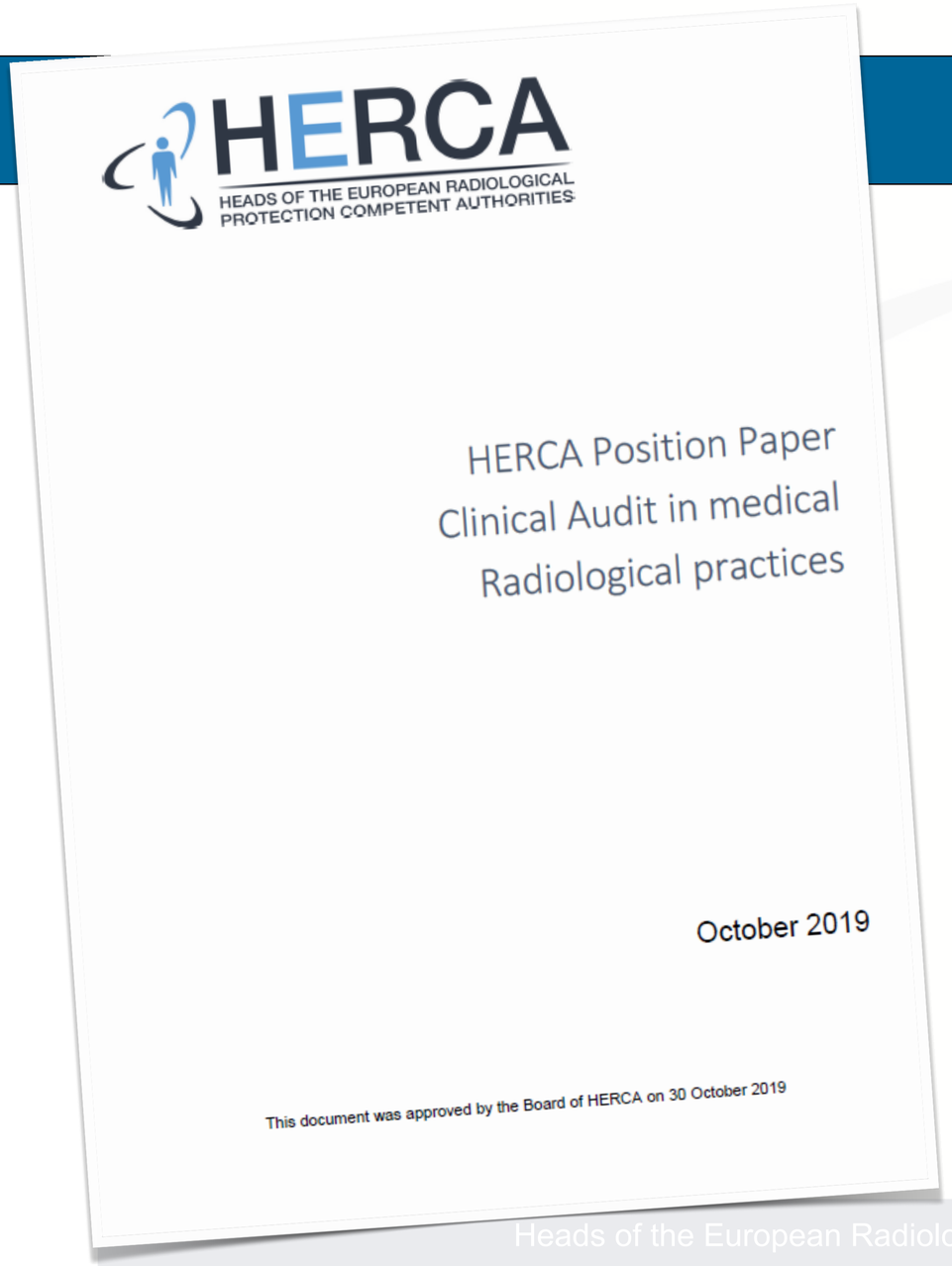
Meetings with ESR, EANM and ESTRO

Discussions on their activities regarding clinical audit and their understanding of the differences between audit and inspection



HERCA became aware of some lack of understanding within the radiological community on how regulatory requirements for clinical audit should be met and what the differences are between clinical audit and inspection.

HERCA WGMA initiatives regarding clinical audits



Oct 2019

HERCA position paper

« Clinical audit in medical radiological practices »

Diagnostic radiology, image-guided interventional procedures, nuclear medicine and radiotherapy

https://www.herca.org/highlight_item.asp?itemID=16

HERCA position paper on clinical audit

- Executive Summary
- Key messages
- Introduction and background
- Definitions of clinical audit and the clinical audit cycle
- Clinical audit relating to Euratom
- Clinical audits, other audits and inspections of radiological practices

HERCA position paper on clinical audit

- Expectations of radiation protection competent authorities regarding clinical audit
- Challenges for implementing clinical audit
- Conclusions
- References
- Appendix : National and International initiatives relating to Clinical audit

Clinical audit

- The intention of Clinical Audit is to improve the outcome of patient care
- Clinical audit should be systematic and on going
- There is a role for both internal and external clinical audit
- Clinical audits should be carried out by individuals with a comprehensive understanding of audit technique

Internal Clinical audit

- Internal clinical audit is to be carried out by the establishment itself at a local level (individual, departmental, hospital) on its own initiative and consistent with national requirements

- The objectives of internal clinical audits should be set by the management of the department, hospital

Internal Clinical audit

- Internal clinical audit can also take place with external direction – a system whereby guidance or direction is provided from an external body, e.g. national professional society

- Internal clinical audits can be implemented by nominating auditors from another department of the establishment

- Should this not be possible, the internal audit can be carried out by auditors from the audited department in the form of a self-assessment

External Clinical audit

- External clinical audit is carried out by auditors who are external to the establishment to be audited. These can be carried out by international, national or regional audit organisations

- For external audits, the objectives should be agreed between the auditing organisation and establishment to be audited

- Auditors performing external clinical audits should be independent to the audited establishment in order to evaluate the practice of their peers without any bias

Other types of audits

- Dose audits, of staff and patient doses are conducted regularly in most departments
- Healthcare audits are important in improving aspects of clinical services
- Regulatory audit verifies compliance with regulations and standards
- Regulatory audit is helpful to the employer but does not replace the need for inspection

Inspection

- Defined as “an investigation by or on behalf of any competent authority to verify compliance with national legal requirements”
- Significant differences between clinical audit and inspections
- Both are required
- An inspection will result in a pass/failed, mesures need to be taken, outcome
- Clinical audit will result in recommendations and suggestions for improvement

Differences between inspection and clinical audit

	Inspection	Audit
Basis	legislation and regulation	standards and good practice
Outcome	requirements and enforcement	recommendations and suggestions
Organisation	Competent Authority	Undertaking/ peer review systems
Teams	inspectors and advisors	professionals
Scope	constrained	comprehensive

Expectations of competent authorities regarding clinical audit

- Inspection must address whether clinical audit is being carried out or not
- Clinical audit provides an on-going assessment of clinical practice in a way inspection cannot
- Clinical audit is a continuous process and can demonstrate whether quality and safety are embedded within a service
- Inspection takes place periodically, has a short duration and only focuses on legal compliance

Expectations of competent authorities regarding clinical audit

- For example, an inspection of justification would include discussions concerning the process itself and responsibilities, while an audit relating to justification might focus on the impact of a procedure on patients' healthcare management and outcome

- Similarly, inspection of optimisation might include verification that QA programmes, protocols and diagnostic reference levels are in place, while an audit might address the impact of reducing exposure factors on resulting diagnostic accuracy and subsequent patient management

Expectations of competent authorities regarding clinical audit

- Clinical audits are not meant to replace inspections as a means of demonstrating regulatory compliance.

- HERCA is of the opinion that the two processes, clinical audit and inspection, are complementary and that whatever form of clinical audit is in place, its primary role is to ensure improvements in the quality and outcome of patient care

Expectations of competent authorities regarding clinical audit

- When conducted on a national scale clinical audit may provide a mechanism for transfer of best practice between institutions, as well as the setting of higher and more appropriate standards

- Clinical audit can demonstrate cooperation between professional groups which is a key element of optimisation and therefore of interest to the regulator

Expectations of competent authorities regarding clinical audit

- HERCA is of the opinion that it is the responsibility of those who carry out clinical audit to bring non-compliance with radiation protection principles and specific regulatory requirements to the attention of the audited organisation/undertaking.

- It is the undertaking’s responsibility to carry out corrective measures.

Challenges for implementing clinical audit

- HERCA is of the opinion that for clinical audit to be implemented financial and human resources need to be made available and particularly education and training of auditors needs to be put in place.

- The establishment of a national auditing organisation that will coordinate and develop clinical audit could be a good solution for clinical audit implementation

Conclusion

Clinical audit is a requirement of the BSSD 2013/59/Euratom and has to be transposed into national legislation and implemented in the European Union. It is an excellent tool for improving the quality of healthcare and has to be undertaken by the undertaking or a peer review system

Thank you for your attention

For further information see

www.herca.org