HERCA

HEADS OF THE EUROPEAN RADIOLOGICAL PROTECTION COMPETENT AUTHORITIES

HERCA Working group on Medical Applications

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Addendum to the HERCA clinical audit position paper

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Title: **Addendum to the HERCA clinical audit position paper by the HERCA WGMA**

Summary: Definition of clinical audit under the BSSD and how this differs from regulatory audit and inspection

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HERCA Board of Heads

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Addendum to the HERCA clinical audit position paper

1. Aim

There is still confusion among the medical professions and regulators regarding differing types of 'audit' and how these apply to the Council Directive 2013/59/Euratom. Following on from our previous paper 'HERCA Position Paper Clinical Audit in Medical Radiological practices'[i] and QuADRANT working party survey and workshop (December 20), this supplement has been designed to further differentiate 'clinical audit' from 'regulatory audit'. It also aims to strengthen the understanding of the expectations during inspection by the competent authority and enforcement decisions around regulation of clinical audit.

2. Background

Clinical audit is an important tool within clinical governance which ensures continuous quality improvement of a healthcare service. There is a specific requirement to undertake clinical audit of medical radiological practices under the BSSD article 58(e).

In contrast, the aim of a **regulatory audit** is to verify that practice is compliant with regulations and to ensure that clinical practice correctly reflects employers' procedures and policies. These are not a requirement under the BSSD and should be considered separately due to the differences in their outcomes and criterium.

IAEA documents on audits, QUAADRIL, QUANUM and QUATRO documents, contain valuable descriptions and examples of clinical audit, but also include many elements of other types of audits, e.g., regulatory audit.

Regulatory audits will not replace inspection but are viewed as an important tool for employers to assess compliance with radiation regulations and radiation protection governance and frameworks.

Historically many countries did not have a robust and routine clinical audit programme and therefore adoption of regulatory audits were established in order to effectively role out an audit programme. Whilst we need to understand the difference between what constitutes a clinical audit compared to a regulatory audit HERCA recognises that many countries still use regulatory audits in parallel with clinical audits during transposition to the new BSSD requirements.

Numerous countries have put too much emphasis on the use of checklists checking compliance with regulations. Although this was a good first step making people familiar with the audit process and radiation protection regulations, compliance with regulations is not part of clinical audits but may be considered as good practice.

Many member states participate in accreditation programmes and in some countries, accreditation is a mandatory requirement. HERCA are in agreement that accreditation and the processes that exist as part of being an accredited department does not necessarily ensure the compliance with the BSSD to undertake clinical audit. Accreditation does not automatically replace clinical audit.

To reiterate this paper is to try and improve consistency in Europe's approach to clinical audit requirements, "do we do the right things, do we do them the right way, how can we improve on clinical outcomes"

The table below summarises the differences between the two types of audits as well as the 'inspection' elements:

	Clinical audit	**Regulatory audit**	**Inspection**
Defined criteria	Good practice or standard	Regulations	Regulations
Expected level of achievement	Locally/nationally defined	100% compliance against self-assessment of the regulatory requirements	100%
Aim	Promotes and develops clinical outcomes and quality of care	Demonstrates and may improve regulatory compliance	Checks the compliance with regulations and implement enforcement
Outcome and follow up	Recommendations to be considered by the audited party	Recommendations to be considered by the audited party	Decision made by the competent authority
Organization	Undertaking/peer review system	Undertaking/peer review system	Competent authority
BSSD	Mandatory	Not applicable	Mandatory

3. Clinical audit

There are numerous approaches to radiological clinical audit but all with the same goal of improving patient care and clinical outcomes within practices that utilise ionising radiations. A clinical audit will aim to establish a quality improvement process in healthcare and lets providers and patients know where their services are doing well and where there can be improvements to clinical care and outcomes.

Clinical audit consists of assessing a clinical outcome or a process, against well-defined standards set on the principles of evidence-based medicine in order to identify the changes needed to improve the quality of care.

Clinical audit can be described as a cycle. Within the cycle there are stages that follow the systematic process of: establishing best practice; measuring against criteria; taking action to improve care; and monitoring to sustain improvement.

Several steps may be taken prior to initiating a clinical audit. A team of people may identify the topic for example:

- areas where problems have been encountered in radiological practice.
- what patients, public or staff have recommended that an issue or concern be looked at. For example: *renal impairment due to administration of contrast during CT scans identified by clinicians prompted a clinical audit to reduce the bolus dose of contrast from 100mls to 50mls, the aim of the audit was to identify if this would reduce the burden on the kidneys but with no adverse effect on image quality*
- where there is a potential for improving service delivery.
- areas of high volume, risk or cost, where improvements could be made. For example: *An audit to determine whether the number of images acquired during a skeletal survey of a child sustaining non-accidental injuries could be reduced the aim of the audit was to demonstrate whether the reduction in dose is merited by a potential loss of diagnostic information*

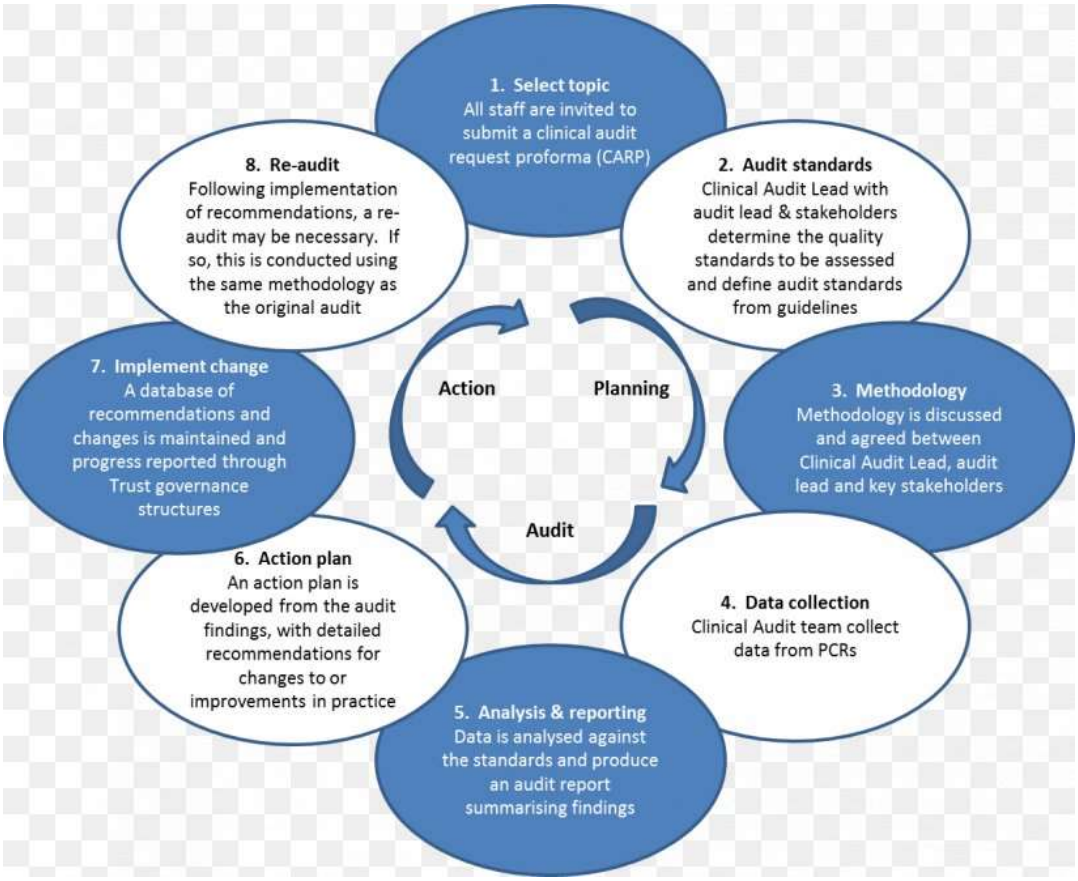
Once agreement has been made a locally defined and detailed methodology needs to be developed taking into consideration:

1. An objective for the audit
2. Key stakeholders required
3. Sample sizes

- Data capture and analysis
- Ethical and information governance factors
- Inclusion/exclusion criteria
- How data recording and analysis will be done

The methodology should be carried out in a repeatable and clear format.

There should always be some form of re-audit to ensure any changes to practice are appropriate and continue to work in the best interests of the patient. The diagram below shows the typical cycle of clinical audit[ii].



Clinical audit is not carried out by the competent authority but by a means of internal practice or external peer review

Examples of clinical audits:

Professional and advisory bodies throughout Europe publish a range of clinical audit topics[iii,iv,v]. These cover a wide variety of subjects. These audits seek to improve patient care and outcomes using a systematic review against a standard or benchmark.

- An audit to assess the adequacy of clinical information on CT major trauma imaging requests from the Emergency Department[vi] (Appendix 1)
- Unjustified CT examinations in young patients[vii]
- National Survey on Justification of CT-examinations in Sweden[viii]

4. Regulatory audit

Regulatory audit enables an employer to assure themselves of their compliance against legislation and regulation across the whole of their radiation protection framework and governance arrangements. This can include both occupational and patient elements.

Types of regulatory audit will depend on the regulations used in each individual country.

Professional body guidance in the UK[ix,x] also has given examples of regulatory audits which cover patient safety and occupational aspects

Questions may include:

- Are radioactive material and medical devices secured to prevent unauthorised access?
- Are the appropriate personnel supplied with dosimeters?
- Are pregnancy enquiries carried out and documented as per procedure?
- Is each medical exposure justified by a practitioner or authorised against protocol?
- Are local rules read and signed by all parties required to do so?

Another example is presented in Appendix 2

Regulatory audit is not a requirement under the BSSD and is not carried out by the competent authority

5. Inspection

Inspections do not replace clinical or regulatory audit and will be undertaken on a frequency defined by each competent authority against the graded approach to risk as laid out in the **BSSD article 38 (1).**

In relation to clinical audit, during inspection the competent authority will assess an employer's audit programme relating to medical radiological practices to ensure that the requirements of this regulation are being met however the results of the clinical audits are not assessed for efficacy, accuracy or clinical outcomes.

6. Appendices

6.1 Appendix 1 – Example of clinical audit from the Royal College of Radiologists (UK)

Indications for CT imaging in the severely injured patient [xi]

Descriptor:

An audit to assess the adequacy of clinical information on CT major trauma imaging requests from the Emergency Department (ED).

Background:

There is evidence to suggest correlation between inadequate clinical information and inaccurate radiology reports.

The RCR outline indications for polytrauma CT imaging in the document 'Standards of practice and guidance for trauma radiology in severely injured patients, 2nd edition'. Standard 7 in this guidance states that a CT request in the trauma setting should comply with the Ionising Radiation (Medical Exposure) Regulations justification regulations in the same way as any other request for imaging involving ionising radiation.

The guidance suggests that an annual audit of justification in trauma imaging should be carried out by the radiology department.

The Cycle:

The Standard:

Clinical information on the radiology requests should satisfy at least one criteria for polytrauma CT as recommended by the Royal College of Radiologists in 'Standards of practice and guidance for trauma radiology in severely injured patients, 2nd edition'.

The acceptable criteria are as follows:

- There is haemodynamic instability

- The mechanism of injury or presentation suggests that there may be occult severe injuries that cannot be excluded by clinical examination or plain films

- FAST (if used) has demonstrated intra-abdominal fluid

- Plain films suggest significant injury, such as pneumothorax or pelvic fractures

- There is obvious severe injury on clinical assessment.

Two essential pieces of information which should be included in the referral are mechanism of injury and visible and suspected injuries.

Target:

100% of radiology requests for polytrauma imaging should satisfy at least one criterion for polytrauma CT.

100% of referrals should include details of mechanism of injury, and visible and suspected injuries.

Assess local practice

Indicators:

Correct indications for polytrauma CT imaging on imaging requests by ED team.

Documentation of mechanism of injury, and visible and suspected injuries on the referral.

Data items to be collected:

Patient demographics, Clinical information from CT trauma request

Suggested number:

Retrospective collection of 100 (or 1 months' worth of) trauma CT requests from the Emergency Department.

Suggestions for change if target not met

Present audit findings to the Emergency Department team and discuss the benefits of clinical information at the time of CT trauma imaging referrals. Give immediate constructive feedback to the referrer after receiving unjustifiable radiology requests for polytrauma scans.

6.2 Appendix 2 – Example of regulatory audit performed by a Medical Physics Expert (UK)

[redacted] Medical Physics Quality System

	Question	Comments	Guidance ref
1.15	Any specific issues from RP committee meetings that need to be discussed today?	Nothing raised.	
2 Radiation Risk assessment, contingency plans and local rules			
2.1	Radiation risk assessment for all activities	Yes. However the latest version of the mobile radiography radiation risk assessment was not found on the shared drive. **Action** Mobile radiography radiation risk assessment to be saved on shared drive. If it cannot be located – contact [redacted] radiation safety for a copy	IRR17 reg 8
2.2	Records of review of risk assessment	Yes	ACOP guidance para 78
2.3	Contingency plans in place	**Action** CT contingency plan (within local rules) for responding to a person walking into the room during an exposure to be rephrased at next local rules update). [2]	IRR17reg 13
2.4	Contingency plans rehearsed	**Action** Awareness of contingency plans be raised through daily huddles [2]	IRR17 reg 13(2), ACOP guidance para 246
2.5	Local rules available	Yes. On shared drive and hard copies in shared areas.	IRR17 reg 18 ACOP guidance para 343
2.6	Local rules up to date	Yes	ACOP guidance para 340(e)
2.7	Local rules satisfactory	Yes. It was noted that [redacted] has taken on the role clinical director.	ACOP guidance para 336
2.8	Local rules read and signed by staff	Yes – ongoing	ACOP guidance para 345
3 Controlled and supervised areas			

Radiation Safety	General		Form
RS F.063	Revision: 1.1	Date of Issue: XX/12/2018	Page 4 of 10

7. References

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