

International Workshop on Practical Implementation of
Clinical Audit for Medical Exposure to Ionizing Radiation
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CLINICAL AUDIT

Conclusions: Major feedback on the draft EC Guidelines

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Conclusions on the Draft EC Guideline



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Feedback

Major issues/Internal audit

- **Make clear that clinical audit should be both internal and external, supplementing each other, while in the document put more weight on internal audits and self-assessments; internal audits may be easier to achieve in short term and better promotes internal culture change, less threatening, less risk of overlap with other assessments, little cost**

Data analysis can be made by independent way

Conclusions on the Draft EC Guideline



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Feedback

Major issues

- **Quality system** should be considered as general criteria for good practices in health care organizations.
- **Engourage scientific societies to make their role stronger**
- **Frequency of audits in accordance with the complexity of the procedure (dental practices<---->radiotherapy); case-specific re-audits sooner than regular**

Desirable frequency of external audits: 2-5 years

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Feedback

Major issues

- **Engourage professional initiation, ownership and active participation in auditing**

Support by professional and administrative management essential

- **Improved consideration needed:**

Focus on whole organization and not individuals

Setting of objectives (by auditing or audited organization?)

Confidentiality (informing the authorities?)

Conclusions on the Draft EC Guideline

Feedback



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Major issues

- Auditing clinical outcome should be the main goal and the document should encourage to develop strategies to cover this

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Feedback

Explain better or clarify:

- **Clinical audit must supplement/fit to other quality assessments and regulatory inspections (stress in executive summary)**
- **Stress more justification and optimization**
- **Comprehensiveness in external and internal audits**

On-line systems could be used for assessments

Express limitation of an audit in terms of statistical reliability (--- sampling), softer evidence in clinical audits is acceptable

- **Taking into account the complexity of the practices**

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Feedback

Explain better or clarify:

- Auditor selection procedure --how to handle disagreements, how to ensure independence and impartiality
- General: when something cannot be assessed in external audits, the external audit should focus on the way of assessments in internal audits
- The concept of audit - make use of ISO 17000
- Description of accreditation and certification, differences

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Feedback



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Proposed additions/Audit coverage :

- **Image quality assessment should be included for diagnostic radiology and NM as a part of the process**

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Proposed additions/ Auditing organization:

- **Competence requirements for the external auditing organization**
- **Presence of a medical physics expert in the audit team is always essential**

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Feedback

Comments on acceptability

- **Realistic and flexible enough to be applied in all EU countries (EFOMP)**
- **Acceptable and broad enough, general framework sufficient enough (EFRS)**
- **Acceptable and useful basis for developing clinical audits, with proposed modifications (ESR, ESTRO, EANM, Authorities, quality/competence assessment organizations)**

Thank you!

