European guideline on clinical audit: How to implement in nuclear medicine in Bulgaria
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Directive 97/43/EURATOM (MED-directive)

Article 2. Definitions
Clinical audit: a systematic examination or review on 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 application of new standards if necessary.

Article 6. Procedures
Clinical audits shall be carried out in accordance with national procedures.

There has been a high variation in the implementation of clinical audit in legislation of different EU countries.

Implementation in Finnish legislation
Radiation Act 592/1991
Section 39 c (amendment 1142/23.12.1998)
The responsible party (= the licensee) shall arrange a systematic assessment of the medical use of radiation (clinical audit), in which:
1. a review is made of examination and treatment procedures followed, of radiation exposures and of the results of examination and treatment,
2. these are compared with known good examination and treatment procedures, and
3. measures considered necessary are proposed for improving practices and preventing unwarranted exposure to radiation.

Decree of the Ministry of Social Affairs and Health on the medical use of radiation, 423/2000
Section 20, Obligation to audit
• The clinical audits prescribed in section 39 c of the Radiation Act shall be arranged so that they complement self-assessment of activities in an appropriate manner. The objective shall be for the practice of a responsible party involving exposure to radiation to be audited in all essential respects at intervals not exceeding five years.
• Clinical audits may cover the whole of the medical use of radiation for which the responsible party is responsible or a specified part thereof. Clinical audits shall be performed by qualified and experienced experts who are independent of the responsible party.

Decree of the MSAH on the medical use of radiation, 423/2000
Section 21, Performance of audits
The subjects of clinical audits shall include the following:
1) specification of powers and responsibilities;
2) referrals and recommendations guiding the issuing thereof;
3) the practice and information flow observed in assessing justifications;
4) instructions and practices pertaining to the performance of procedures involving exposure to radiation;
5) equipment for examinations and treatment;
6) radiation doses arising from procedures and the examination and treatment results achieved;
7) the quality, recording and flow of information pertaining to procedures;
8) staff training;
9) the definition and application of quality assurance activities; and
10) self-assessments of activities, assessment of results and the use of results.

Decree of the MSAH on the medical use of radiation, 423/2000
Section 22, Audit report
• The audit report shall be addressed to the responsible party. The report shall present the essential observations made in the audit, the assessments and conclusions drawn on their basis, and the recommendations of the party performing the audit for development measures.
The Advisory Committee for Clinical Audit

- In 2004, a national steering group, or an Advisory Committee for Clinical Audit, for the development and follow-up of the clinical audits in Finland was established by the Ministry of Social Affairs and Health.
- The Advisory Committee is a multidisciplinary group of clinical experts, independent of any auditing organizations.
- Its tasks include, among other things:
  - evaluation of the suitability and coverage of the criteria used in clinical audits for different sub-areas (diagnostic radiology, nuclear medicine and radiotherapy),
  - evaluation of the importance of other quality audits in medical practice (such as audits for accreditation),
  - making proposals and promoting the use of special practice-specific criteria in clinical audits, and
  - collecting summaries and review of the results, including analysis of the impact of audits on radiation protection of the patient.

The first clinical audit of NM departments in Finland 1/3

- Auditors in the first audit round: 1 physicist, 1 or 2 technicians (and 1 radiochemist/2 departments)
- Auditing company: only one auditing company
- Duration of the audits: 1d (21 dept.) - 2 d (2 dept.)
- Dead line: The first audit had to be done until 12.5.2005
- Number of NM departments audited: 23

Clinical audit of NM departments in Finland 2/3

Number of questions (the 10 different areas)

- specification of powers and responsibilities 8
- referrals and recommendations guiding the issuing thereof 3
- the practice and information flow observed in assessing justifications 5
- instructions and practices pertaining to the performance of procedures involving exposure to radiation 21
- equipment for examinations and treatment 7
- radiation doses arising from procedures and the examination and treatment results achieved 7
- the quality, recording and flow of information pertaining to procedures 2
- staff training 4
- the definition and application of quality assurance activities 4
- self-assessments of activities, assessment results and the use of results 5

Clinical audit of NM departments in Finland 3/3

Recommendations given, total 139 (23 departments)

Subjects to be considered before the next audit round 1/2

- The difference between inspections made by the competent authority (STUK) and clinical audits has to be clarified.
- To avoid overlapping with regulatory inspections, the criteria used should be more "clinical".
- The content of the audit reports should be improved.
- The duration of the audit – benefit to the department to be audited
- The competence/qualification of the auditors – there was no nuclear medicine physician in the auditing group on the first audit round (!)

Subjects to be considered before the next audit round 2/2

- Assessment of the whole radiological process (radiation protection practices in general)
- A pilot
- In-depth assessment of selected examination(s) or treatment(s)
Recommendation of the Advisory Committee for Clinical Audit (No. 1, 2005)

Qualification of the auditors

- At least one person having qualification for "chief auditor"
- Different specialists as follows in clinical audits of nuclear medicine:
  - nuclear medicine physician
  - nuclear medicine physicist
  (hospital physicist specialised in NM)
  - nuclear medicine technician
- Other specialists if necessary (e.g. cardiologist, hospital engineer, radiochemist, radiopharmacist)

Examples of EANM guidelines

Cardiology
- EANM/ESC procedural guidelines for myocardial perfusion imaging in nuclear cardiology
- EANM/ESC guidelines for radionuclide imaging of cardiac function

Oncology - Procedure Guidelines For Tumour Imaging
- Bone Scintigraphy
- Breast Scintigraphy
- FDG-PET

Dosimetry
- EANM Dosimetry Committee series on standard operational procedures for pre-therapeutic dosimetry I: blood and bone marrow dosimetry in differentiated thyroid cancer therapy

Examples of literature for setting the standards of good practice in NM (EU Guideline) 1/2

- BNMS Nuclear Medicine Generic Quality Guidelines for the Provision of Radionuclide Diagnostic Services (http://www.bnmsonline.co.uk/index.php?option=com_content&task=view&id=103&Itemid=153)
- Other guidelines on BNMS website (Clinical, generic, other). (http://www.bnmsonline.co.uk/index.php?option=com_content&task=blogcategory&id=103&Itemid=151)

Examples of literature for setting the standards of good practice in NM (EU Guideline) 2/2

- Other guidelines on EANM website (https://www.eanm.org/scientific_info/guidelines/guidelines_intro.php?navid=54)

Recommendations of the Advisory Committee for Clinical Audit for the next audit round in NM in Finland

The subjects to be audited in nuclear medicine

- NM examinations for children
- Bone Imaging
- Radiolodine therapy of thyroid (131I) (hyperthyroidism)
- Use of CT in NM departments (PET-TT and SPET-TT)

Criteria for evaluation

- Recommendations given by EANM www.eanm.org
- Radiation protection publications of European Commission RP 118 Referral guidelines for imaging (updated 2008)
- RP 97 Radiation protection following I-131 therapy (exposures due to out-patients or discharged in-patients)

Energy: Publications - European commission

Examples of literature for setting the standards of good practice in NM (EU Guideline)

- Other guidelines on EANM website (https://www.eanm.org/scientific_info/guidelines/guidelines_intro.php?navid=54)

Inspection/clinical audit, what’s the difference?

Definitions, MED-directive

"Inspection: inspection is an investigation by any competent authority to verify compliance with national provisions on radiological protection for medical radiological procedures, equipment in use or radiological installations".

"Clinical audit: a systematic examination or review on 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 application of new standards if necessary."
### The priorities of clinical audit of RADIOLOGICAL practices (EC Guideline, draft)

| Structure | • The mission of the unit for RADIOLOGICAL practices  
• Lines of authorities and radiation safety responsibilities  
• Staffing levels, competence and continuous professional development of staff, in particular for radiation protection  
• Adequacy and quality of premises and equipment |
| Process | • Justification and referral practices, including referral criteria  
• Availability and quality of examination and treatment guidelines (protocols, procedures)  
• Optimization procedures  
• Patient dose and image quality in diagnostic radiology and nuclear medicine procedures, and comparison of patient dose with nationally accepted reference levels  
• Procedures for dose delivery to the patient in radiotherapy (beam calibrations, accuracy of dosimetry and treatment planning)  
• Quality assurance and quality control programmes  
• Emergency procedures for incidents in use of radiation  
• Reliability of information transfer systems |
| Outcome | • Methods for the follow-up of outcome of examinations and treatment (short term and long term) |

### What should be taken into consideration when starting clinical audits?  
#### General subjects
- What is the status of clinical audit in Bulgaria?  
- Implementation in legislation?  
- Internal audit/external audit?  
- Documented quality system in hospitals/NM departments?  
- Standards for good procedures for NM?  
- How to motivate the hospitals?  
- Training of the auditors?  
- Accreditation of NM departments/procedures?  

#### Who will perform the audits
- Who will perform the audits/audit organisation?  
- Financing of audits?  
- Peer group audits e.g. NM departments audit each others?  
- As a project (e.g. the first audit as a pilot project)?  
- An international organisation? (e.g. IAEA)  
- Selecting the auditors?  
- What to audit? The whole practice/an important field?