



Criteria for Clinical Audit

**Prepared by:
Faculty of Radiologists, Royal College of Surgeons in Ireland**

**Submitted to Council by:
Medical Ionising Radiation Committee on 7 October 2004**

Adopted by Council on 11 October 2004

Available from:
Office of Education and Training
Medical Council of Ireland
Lynn House
Portobello Court
Lower Rathmines Road
Dublin 6

Criteria for Clinical Audit

SI 478 of 2002 European Communities (Medical Ionising Radiation) Regulations states:

15.1. *The Medical and Dental Councils shall, within two years of the making of these regulations and in consultation with the Faculty of Radiologists of the Royal College of Surgeons of Ireland (RCSI), adopt criteria for clinical audit.*

Clinical Audit is a quality improvement process that seeks to improve patient care and outcome through systematic review of care and comparison with explicit criteria followed by the implementation of change. Aspects of the structure, processes and outcomes of care are selected and systematically evaluated against explicit criteria. Improvements are then instituted and the process re-evaluated, thus completing the audit cycle.

This paper explains and sets out the criteria for clinical audit in relation to statutory instrument number SI 478 of 2002. This SI transposes the European Union Council Directive 1997/43/Euroatom of the 30th June 1997, on the health protection of individuals against the dangers of ionising radiation in relation to medical exposure and repealing directive 84/466/Euratom.

The specific section of SI 478 dealt with in this paper is Article 15.

This process of audit is instituted to ensure that all installations and the professionals who work in them conform to the EU Directive. In interpreting the regulations, accepted clinical practice is considered to be that course of action or opinion that the general body of the speciality of diagnostic radiology, and radiation oncology in Ireland would consider proper. The basic criterion of Clinical Audit is that the standard of practice in the installation under scrutiny should equate to what is regarded as reasonable practice by the general body of practitioners (as defined in the SI 478) in the country.

While conducting audit activities at an installation, due regard would be paid to the quantity and quality of the equipment, resources and staff which is available. Assessment of the clinical practice of radiology will be led by clinical radiologists, nuclear medicine physicians and radiation oncologists who are engaged in full time or nearly full time clinical practice, similar to the installations been audited. The advice of a radiography service manager, the medical physicist/radiation protection adviser or the radiation safety officer may be appropriate.

Clinical Audit shall be conducted, firstly to confirm conformity to the various sections of SI 478, as follows

7:1 Justification of each individual medical exposure is a clinical decision to be made by the practitioner. Published guidelines of indications for various examinations from UK, Europe and North America are not criteria and do not override the responsibility of the radiologist to make this decision.

7.3. High risk or high dose procedures in diagnostic radiology require particular attention, including interventional procedures, CT scanning, pregnancy and Paediatric Radiology

7.6. "Health screening programmes shall be undertaken only with a prior consent of the Minister, which he may refuse to give, and in accordance with such criteria as he or such persons that he might nominate may specify".

As of this date, the only programme meeting these criteria is the Breast Check Programme.

7.7 New medical practices involving radiation exposure must have professional acceptance by the speciality or sub-specialty body within whose province they lie.

7.11. Requests for radiological exposure require a formal authorisation and appropriate clinical information, with previous records as appropriate.

8,9, Examinations shall conform to these regulations concerning medico legal

10 practice, occupational health and research.

13 Individuals performing medical radiological procedures shall be appropriately trained and qualified under the regulations. Certification of continuing medical education will be sought when the national regulations have so provided.

An Audit Committee within the Radiological installation is essential. This must be sponsored by the holder and should be led by a senior clinical radiologist, nuclear medicine physician or radiation oncologist, and should be broadly based with participation by all sectors of the departmental staff, management representatives and representatives of the department's "customers" i.e. referring physicians and patients. Does the committee meet on a regular basis with minutes of meeting? Have audit projects been conceived and carried through to conclusion with application of results to improve practice?

The emphasis should be on leadership, teamwork and support. The services of a permanent secretary are essential. Access to statistical, technical and information technology assistance may be required.

The auditors will give due notice of intention to audit the installation and will arrange to meet the practitioner in charge and members of the audit committee.

Audit activities are grouped as follows.

1. Structures - equipment and staffing levels
2. Processes, including quality assurance - how well do departmental processes work?
3. Outcomes - clinical outcomes are the best standard but are difficult to measure
4. Audit of doses and compliance with dose reference levels

There are very many specific criteria that may be evaluated and some are listed below:

A. Key indicators in radiological installations

1. Work Load
2. Access-waiting times and cancellations
3. Time from attendance for procedure to delivery of report to prescriber.
4. Time from dictation of report to delivery of report to prescriber.
5. Justification for prescribing procedures
6. Records – Delay or failure to obtain records

B. Critical events in diagnostic radiology

1. Films per examination, film reject rate.
2. Lost films, reports
3. Unplanned repeat films
4. Diagnostic accuracy
5. Complications of invasive procedures
6. Reactions to contrast media

C. Criterion based audit.

A specific topic may be selected in a particular installation. Items here are any areas of local concerns, areas of variation from usual practice, areas of perceived high risk.

Information provided for audit purposes should be confidential and used only for the purposes of audit.

Perhaps the most important resource required for audit is **time**. Workloads continue to rise inexorably and administration, teaching and research compete for audit time. In the UK the equivalent of one half session per week (around one and a half hours) was suggested as an appropriate amount of protected time for audit.

One of the causes of failure of the audit process is the absence of a clear standard against which to audit. Standard may be based on local agreement, consensus statements, results of research and recommendations from learned societies.

The role of the Faculty of Radiologists in audit is the promotion of standards eg referral criteria, training guidelines, quality and management guidelines against which audit projects can be measured. In addition the Faculty promotes audit by supporting the provision of adequate resources and as a requirement for training and for CME/CPD. Ultimately the aim is to improve Irish radiological services by comparing actual practice with generally agreed standards and to bring the two as close together as possible.

The process of Clinical Audit under current regulations is developing and the Medical Ionising Radiation Committee with the Faculty of Radiologists is willing to revisit this document when criteria for clinical audit are adopted.