
RCSI

Feidhmeannacht na Seirbhíse Sláinte
Health Service Executive


# Requirements for Clinical Audit in Medical Radiological Practices (Diagnostic Radiology, Radiotherapy and Nuclear Medicine)

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**Health Service Executive**

**Faculty of Radiologists**

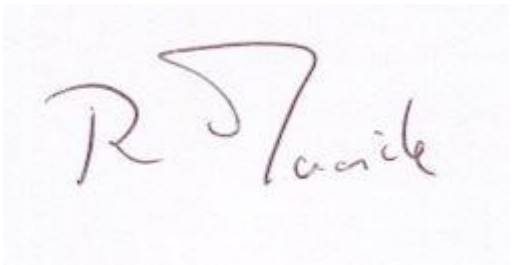
**January 2011**

# Foreword

All health service providers and employees have a responsibility regularly to audit the clinical quality of the service they provide. A significant number of publications and requirements have been introduced, some specific to radiological practices. Providers and employees have requested guidelines on practical and effective ways of meeting this requirement. The HSE and the Faculty of Radiologists consulted with stakeholders to develop this guide which provides a summary of the relevant requirements, guidance on local structures and governance to enable providers. We, the undersigned, hope that its publication will serve to focus attention on what is a critical element in the safe and effective governance of any radiological health service.

This guide is the first in what its authors anticipate will be an iterative process. The more widely the guide is used, the more we will all learn about the most effective ways of conducting audits of this kind, and the better subsequent versions of the guide and related documents will be.

We would like to thank the team of the Medical Exposures Radiation Unit, HSE and the Faculty of Radiologists for the production of this publication and the National Radiation Safety Committee for their guidance. We are convinced that rigorous and effective clinical audit represents one of the most powerful tools at our disposal to improve the quality of the service we provide to patients, and we would urge all those who provide radiological health services to implement the recommendations within.



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**Quality Safety and Risk, HSE**

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## Contents:



## Appendices

# 1. Introduction

This document outlines a summary of the requirements for Clinical Audit in Radiological Practice and a guide to the implementation of structures and processes for an effective audit cycle (appendix 4).

Clinical audit is “a systematic examination or review of medical Radiological procedures. It 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. Modifications of the practices are implemented where indicated and new standards applied if necessary.” (EC Directive 97/43 EURATOM (MED)

By comparing the practice of the service against the standards of good practice, clinical audits can inform the staff of the health care service and all other stakeholders about the essential elements of quality and the weak points of the overall clinical service. The audits will indicate areas for improvement and provide reassurance on issues such as safety and efficacy, all of which are essential to creating an environment of continuous development. In a blame-free environment, this can lead to an improved and more content situation for patients, staff and referring physicians.

The report of the Commission (2008) on Patient Safety and Quality Assurance “Building a Culture of Patient Safety” recognised the importance of Clinical Audit. “Clinical Audit arguably constitutes the single most important method which any healthcare organisation can use to understand and ensure the quality of the service it provides.”

# 2. Clinical Audit Requirements and Guidelines for Ireland

Clinical Audit is a professional and organisational responsibility. E.U. Member States are required to implement Clinical Audit in Radiology "in accordance with national procedures" (EC Directive 97/43 Euratom (MED). Statutory Instrument 478 (2002) and its amendments transposed the EU Directive in to Irish law. This currently places a requirement on organisations to engage an external auditor, appointed by the HSE, to audit radiological practice every five years. The next audit is due to be completed by 2012.

As part of the enactment of Section 11 of the Medical Practitioner Act 2007, participation in clinical audit is now required for all registered medical practitioners. By May 2011, medical practitioners must enrol in a professional competence scheme and engage in professional competence activities. It is proposed in the Act that all Doctors should engage in clinical audit, and at a minimum participate in one audit exercise annually. The Act recommends that doctors spend a minimum one hour per month in audit activity.

The Medical Council published the "Criteria for Clinical Audit" in 2004 as required in Statutory Instrument 478 (2002) (Appendix 2). The Dental Council published their "Criteria for Clinical Audit" in 2008, available on their website.

The European Commission subsequently published Guidelines on Clinical Audit for Medical Radiological Practices (Diagnostic Radiology, Nuclear Medicine and Radiotherapy) in 2009 **(RP 159)** and these have been accepted by the Medical Council, the Faculty of Radiologists, the National Radiation Safety Committee and the HSE as best practice and are recommended for use in all Radiology departments. It is recognised that time and resources will need to be managed to ensure that performing clinical audit is part of normal daily activity in a radiology patient service. Clinical audit will highlight if the service provided is actually safe and effective and which issues need to be addressed at the Radiation Safety Committee meetings.

These guidelines state that clinical audit should be conducted in all aspects of Radiological services covering structure, process and outcomes. It should be a systematic and continuing activity with multidisciplinary involvement. EU Commission guidelines should guide all clinical audits within radiology departments. A document is attached which aims to summarise the European Commission Guidelines on Clinical Audit for Medical Radiological Practices (Diagnostic Radiology, Nuclear Medicine and Radiotherapy), 2009 (Appendix 1).

Guidelines on clinical audit for Radiologists have recently been issued by the Faculty of Radiologists as part of its Quality Assurance Programme. An excerpt from these guidelines is listed in Appendix 3.

The introduction of the proposed Health Information Bill and other national developments in clinical audit will further influence the requirement for audit. The HSE with the Faculty of Radiologists has set a date of review for this document for December 2012, or earlier if required.

# 3. Clinical Audit Structures, Processes and Accountability

The Clinical Audit Criteria of the Medical Council (2004) states that:

'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.'

Since the publication of the Clinical Audit Criteria in 2004, there have been a number of developments in the implementation of clinical audit nationally. The first ***HSE National Baseline Audit of Radiological Practices (2008)*** made a set of recommendations concerning the structures and governance necessary to support a process of effective audit in this area. The ***EU Commission Guidelines on Clinical Audit for Medical Radiological Practices (Diagnostic Radiology, Nuclear Medicine and Radiotherapy), 2009,*** have been accepted for use in Ireland. In addition, the HSE has produced the document ***Excellence in Clinical Governance (2010).*** Specific recommendations on clinical audit have been made in the ***Building a Culture of Patient Safety - Report of the Commission on Patient Safety and Quality Assurance, 2008.***

These documents, recommendations and implementations have been reviewed and the National Radiation Safety Committee (NRSC) has produced the following recommendations:

## 3.1 Roles and Responsibilities for Clinical Audit

An effective programme for clinical audit at a location requires a supporting governance structure with clear accountabilities assigned to individuals to facilitate and mandate the practice of clinical audit. For example, locations should have a multidisciplinary hospital/organisation Committee, such as a Patient Safety Committee, Risk Management Committee, Clinical Audit Committee, chaired by the CEO or Hospital Manager, that has the authority to make decisions and implement changes based on clinical audits that have taken place. A sample local governance structure is portrayed in Appendix 5.

The CEO/Hospital Manager has responsibility in all facilities (and through the Clinical Director in HSE locations) to ensure structures and effective processes are in place for radiological clinical audit and integrated in to existing and planned clinical governance and clinical audit arrangements for the location.

The Radiologist/Radiation Oncologist appointed as the Practitioner in Charge has the lead responsibility for radiological clinical audit activity in the facility, monitoring and ensuring that changes are implemented as a result.

The Practitioner in Charge will ensure audit plans are delivered on and that the audit results are reported to the hospital CEO and Board (where applicable) on an annual basis, or appoint another Radiologist/Radiation Oncologist with this responsibility.

The role of the Radiographic Services Manager in clinical audit is to ensure that agreed standards and protocols are in place and adhered to. The Radiation Safety Officer may be assigned specific responsibility to monitor and ensure clinical audit takes place.

Although audit is mainly a multidisciplinary activity, clinical audit carried out by individual clinicians can be a valuable foundation on which departments can build audit plans, particularly annual plans. Each individual, both professionals and administrators, also has a responsibility for regularly auditing their own activity.

The National Radiation Safety Committee recommends the following to assist in delivering on audit responsibilities;

It is recommended that ***the Radiation Safety Committee should oversee the hospital's responsibility and extend its terms of reference to include clinical audit, as follows:***

- The annual clinical audit plan of the Radiological Clinical Audit Working Group should be presented to the Radiation Safety Committee who recommends it to the CEO/Hospital Manager / Hospital Board through local structures, such as a Hospital Clinical Audit Committee.
- Approve the annual progress report of the Radiological Clinical Audit Working Group and present it to the CEO/Hospital Manager / Hospital Board through local structures.
- Review the work of the Radiological Clinical Audit Working Group at each meeting and provide advice on priorities and risks.
- The membership of the Radiation Safety Committee should include the chair of the Radiological Clinical Audit Working Group and the Radiation Safety Officer.
- Have formal links to the clinical governance committee and other related hospital committees and be integrated within the hospital, safety, risk and clinical governance frameworks.

### 3.2 Radiological Clinical Audit Working Group

A working group, chaired by the Radiologist/Radiation Oncologist with lead responsibility for Clinical Audit, should be established and meet frequently, at minimum four times per year.

#### 3.2.1 Recommended Terms of Reference for Radiological Clinical Audit Working Group.

- Produce an annual clinical audit plan, based on a risk assessment to identify high dose, high risk or high volume procedures, to be recommended to the Radiation Safety Committee.
- The agreed plan for audit should include consideration of relevant hospital priorities and of guidance which may be issued by the NRSC, Faculty of Radiologists or HSE from time to time.
- Conduct audits as agreed in workplan and ensure work programme is assigned as appropriate.
- Monitor the audit process to ensure that it is effective and provides a clear record of adherence to the audit cycle (appendix 4) and that recommendations are implemented.

- Monitor and deliver staff education and training in audit as required.
- Produce an annual progress report for approval by the Radiation Safety Committee. This report will detail types of audit, numbers of audits completed, recommended actions, changes implemented and review dates set.

### 3.2.2 Recommended membership of Radiological Clinical Audit Working Group

As recommended in ***"Criteria for Clinical Audit" (Medical Council)***;

'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.'

It is recommended that the following members are included on the working group:

- Radiologist/Radiation Oncologist with lead responsibility for Clinical Audit, chair.
- Radiographer with lead responsibility for Clinical Audit / Radiation Safety Officer.
- Clinical Audit Facilitator, where applicable or representative of the Clinical Director (HSE locations), or equivalent.
- Radiation Protection Adviser / Medical Physics Expert.

Additional members can be added when additional expertise is required for specific audits, for example, dental or nurse prescribing audits.

## 3.3 Audit of Dental Practices

Dental practitioners and holders should audit their practice in accordance with the Clinical Audit Criteria produced by the Dental Council. Where dental clinical audit committees exist in the public sector, it is recommended that their terms of reference are extended to include radiation issues. Their membership will differ to the above but should be reviewed and modified, where appropriate, in accordance with clinical governance criteria as established by the HSE.

In all other cases, Practitioners and Holder should implement a regular process of clinical audit in accordance with the criteria and guidelines set down by their Professions' guidelines. Reference can be made to the European Commission Guidelines on Clinical Audit for Medical Radiological Practices (Diagnostic Radiology, Nuclear Medicine and Radiotherapy), 2009.

## 3.4 Audit of Small Radiological Practices

It is recommended that small radiological practices link in with a local Radiation Safety Committee where possible. Where a practice does not have access to a Radiation Safety Committee or a Clinical Audit Committee, a process of regular clinical audit should be implemented, following the criteria and guidelines as approved by professional guidelines. The clinical audits will be available for review, as requested, by the HSE, as outlined in guidance to holders issued in March 2010.

# 4. Audit Required by Statutory Instrument 478 (2002)

In addition to the ongoing programme for clinical audit, the CEO/Hospital Manager is required, in Statutory Instrument 478 (2002), to ensure that the clinical practice is audited by the HSE at least once every five years in accordance with the Clinical Audit Criteria published by the Medical and Dental Councils.

The next external audits will commence in 2011 and are to be completed by 2012. A schedule of audits and chosen topics will be issued to all locations in advance of commencement of audit. Audits will be conducted by a multidisciplinary team appointed by the HSE, led by a Radiologist / Radiation Oncologist or Dentist.

The external audit topic chosen will be in accordance with the Clinical Audit Criteria. The team will also take in to account priority areas such as:

- high dose/high risk/high volume procedures
- potential for benefit to practice and patient
- economic and efficient use of resources
- evidence of variation in current treatment approaches
- outcomes and feasibility of implementation

The external audit will check for evidence that there is an ongoing, effective cycle of clinical audit in place in the radiological facility (appendix 4).

# 5. How to Audit

The Royal College of Radiologists (UK) has an extensive list of audit recipes which could assist radiology departments in the selection of audits, "Clinical Audit in Radiology: 100 + Recipes" (1996) and Audit Live is available on its website www.rcr.ac.uk.

**The following is a bibliography of documents providing guidance on clinical audit:**


Godwin, R., de Lacey, G. and Maguire, A. (1996) Clinical Audit in Radiology: 100 + Recipes. London: Royal College of Radiologists.

Health Information and Quality Authority (2010) Draft *National Standards for Safer Better Healthcare.* Dublin. Available: http://www.hiqa.ie/media/pdfs/Safer_better_care_draft_standards_A4.pdf.

Health Service Executive (2009) *An Introduction to Audit Compliance with SI 478 (2002), Audit Subcommittee of the Dental Radiation Safety Committee (Dublin North East and Dublin Mid Leinster).* Dublin. Available: http://www.hse.ie/eng/about/Who/HSE_An_Introduction_to_Clinical_Audit_in_Dentistry.pdf.

Health Service Executive (2010) *'Clinical Audit e-learning module'*. Available https://www.hseland.ie/ekp/servlet/ekp?CID=CA&TX=FORMAT1&TEACHREVIEW=N&PX=N.

Health Service Executive (2008) '*Healthcare Audit Criteria and Guidance'*. Available http://www.hse.ie/eng/About/Who/OQR014_2_20080806_v1_Healthcare_Audit_Criteria_and_Guidance.pdf.

International Atomic Energy Agency (2010) '*Comprehensive Clinical Audits of Diagnostic Radiology Practices: A Tool for Quality Improvement'. Available:* http://www-pub.iaea.org/MTCD/publications/PDF/Pub1425_web.pdf.

International Atomic Energy Agency (2003) '*Comprehensive Clinical Audits of Radiotherapy Practices: A Tool for Quality Improvement'. Available:* http://www-pub.iaea.org/MTCD/publications/PDF/Pub1297_web.pdf.

Irish Dental Association (2009) *'Clinical Audit in Dental Radiology'*. Dublin Available: www.dentist.ie, members' section.

Royal College of Radiologists (2010) *RCR Audit Live.* Available: https://www.rcr.ac.uk/audittemplate.aspx?PageID=1016.

## 5.1 Useful References


Dental Council (2008) *'Criteria for Clinical Audit'*. Dublin.

Department of Health and Children (2008) *'Building a Culture of Patient Safety - Report of the Commission on Patient Safety and Quality Assurance'.* Dublin.

European Commission (1997) *'Council Directive 97/43 Euratom'*. Luxembourg: Office for Official Publications of European Communities.

European Commission (2009) *'Guidelines on Clinical Audit for Medical Radiological Practices (Diagnostic Radiology, Nuclear Medicine and Radiotherapy)'.* Luxembourg: Office for Official Publications of European Communities.

Faculty of Radiologists (2010) '*Guidelines for the Implementation of a National Quality Assurance Programme in Radiology - Version 1.0*'. http://www.radiology.ie/news/docs/National%20Radiology%20QA%20Guidelines%20v1%200.pdf.

Health Service Executive (2010) *'Achieving Excellence in Clinical Governance: Towards a Culture of Accountability'.* Dublin.

Medical Council (2004) *'Criteria for Clinical Audit'.* Dublin.

National Institute for Clinical Excellence (2002). *'Principles for Best Practice in Clinical Audit'.* Oxford: Radcliffe Medical Press.

Stationery Office (2007) *'Medical Practitioners Act, 2007'*. Dublin.

Stationery Office (2002) '*Statutory Instrument No. 478 European Communities (Medical ionising Radiation) Regulations (2002), 303 (2007) and 459 (2010)'.* Dublin.


## 5.2 Websites

www.dentalcouncil.ie
www.dentist.ie
www.hqip.org.uk
www.hse.ie/eng/about/Who/clinicalaudit.html
www.hiqa.ie
www.iaea.org
www.medicalcouncil.ie
www.myesr.org
www.nice.org.uk
www.patientsafetyfirst.ie
www.radiology.ie

# Appendix 1

## European Commission Guidelines on Clinical Audit

European Society of Radiologists' summary:

### Background

In October 2009, the European Commission published guidelines relating to clinical audit for radiological practice, including all investigations and therapies involving ionising radiation.

http://ec.europa.eu/energy/nuclear/radiation_protection/publications_en.htm

This is in line with the European Atomic Energy Community's remit to establish uniform safety standards to protect workers and the general public from the dangers of ionising radiation. The relevant pre-existing Council Directives are 96/29 Euratom and 97/43/Euratom. The latter introduced the requirement for clinical audit of diagnostic radiology, nuclear medicine and radiotherapy. Article 6 .4 in the section on ***procedures*** states that ***'Clinical audits shall be carried out in accordance with national procedures'***. Clinical audit of procedures is therefore mandatory. The guideline gives recommendations and suggestions for the implementation of clinical audit in member states, taking a wide interpretation of the procedures/processes which should be audited. MRI and ultrasound imaging are not included, as the guideline covers only ionising radiation, although the same principles can be applied to these modalities.

This ESR document aims to summarise the guideline, but the EC document is 110 pages long, and the interested reader is referred to the original publication.

### Definitions

Clinical audit in the document is defined as a 'systematic examination or review of medical radiological procedures. It seeks to improve the quality and outcome of patient care through structured review whereby radiological practices, procedures and results are examined against agreed standards for good medical radiological procedures. Modifications of practices are implemented where indicated and new standards applied if necessary.'

It emphasises that clinical audit is not research, quality system audit, accreditation or a regulatory activity but a multi-professional activity which is both scheduled and systematic, carried out by auditors with knowledge of the procedures, combine internal assessment of performance with external review, and identify areas for future improvement. All those involved in audit should respect the confidentiality of patient data, staff discussions, audit reports and other performance data. Much emphasis is placed on the difference between clinical audit and other quality systems and regulatory inspections, there being clear differences in the purpose, focus, scope, methods and the consequences of the results of the observations,

their impact and use. Regulatory bodies should neither carry out clinical audits directly nor exclusively set up the criteria for the audits.

**Scope of clinical audit**

The document recommends that the whole patient pathway should be subject to clinical audit, under the categories of structure, process and outcome and that it should address both radiation protection for the patient and key components of the overall quality system, which are enumerated in the guidance. Under structure; lines of authority, radiation safety responsibilities, staff issues, premises and equipment are included. In process, justification and referral processes, protocol and process availability, optimisation procedures, patient dose, image quality, emergency incident procedures, and reliability of information transfer are key themes. Outcome audit includes methods for follow up of the outcome of examinations both short and longer term. This is acknowledged as providing the greatest challenge, particularly in relation to diagnostic accuracy.

The process is one of sampling of performance and comparing the results with a pre-selected standard of good practice. If the standard is not met, reasons for this are sought, changes implemented and a re-audit carried out to ensure improvement.

Standards may come from various sources, which are enumerated in the document.

**Internal vs. external audit**

Internal assessment within units or departments, which should employ standard audit methodology, is recommended as a systematic and continuing activity with a significant annual output of departmental audit data.

Emphasis is however placed on external clinical audit whereby an external auditing body or auditors carry out the audit. A cycle of external audit, carried out every 5 years is recommended. The guideline recommends the development of special auditing organisations to carry this out. These should preferably be non-profit organisations, if possible, supported by professional and/or scientific societies. These auditing organisations should be accredited by a national accreditation body. International audit services may be exploited where no national systems exist. Auditors would require a suitable professional background and would comprise a multidisciplinary team which could include radiologists, radiographers and medical physicists. They should have received specific training in audit and should be independent of the process/unit being audited.

The costs of the external audit process should be borne directly by the radiological unit unless the organisation of audits is carried out through a directly funded government body. The unit to be audited should foster an open and constructive atmosphere amongst its staff towards the process. Emphasis should be placed on avoiding misunderstanding, or confusion with other quality assessment activities.

The guideline suggests that a special national or regional advisory group, or steering committee of clinical experts, independent of the auditing organisations,

may prove useful in the overall coordination and development of clinical audit implementation, criteria and procedures. The group should preferably be established by the Health Ministry or other government organisation, in order to ensure appropriate authority and financing. The role of professional/scientific societies, it is suggested, can be of great value in developing standards of good practice and in providing practical advice, stimulus and support for the establishment of appropriate clinical audit organisations.

**Conclusions**

For many, clinical audit will be a relatively new concept. This guideline reinforces EC support for the concept, and suggests how it may be developed nationally within member states.

**Appendix 2**


# 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

**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 and staff 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 being 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, 10 Examinations shall conform to these regulations concerning medico legal 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.

NB Important to reflect this in the earlier sections 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 e.g. 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.***

## Appendix 3

## Faculty of Radiologists (2010)

## 'Guidelines for the Implementation of a National Quality Assurance Programme in Radiology - Version 1.0'

# Extract on Clinical Audit:

**Clinical Audit**
As part of the enactment of Section 11 of the Medical Practitioner Act 2007, participation in clinical audit is now required for all registered medical practitioners. By May 2011, medical practitioners must enrol in a professional competence scheme and engage in professional competence activities. It is proposed in the Act that all Doctors should engage in clinical audit, and at a minimum participate in one audit exercise annually. The Act recommends that doctors spend a minimum one hour per month in audit activity.

The Faculty of Radiologists, RCSI, will facilitate the formalisation of audit activities for Radiology by:
a) Including regular audit activity as part of the Radiology Registrar Training Programme
b) Encouraging health service providers to resource the audit process with both personnel and time
c) Encouraging Radiology departments to undertake standard radiology audit cycle menus annually (e.g. Royal College of Radiologists Audit Live) and
d) Organising national audits as necessary

Clinical audit is a quality improvement process and this document recommends a number of clinical audit activities in which a Radiology Department should be engaged.

**1.5 Focused Audit**
Currently ad hoc audit is a frequent activity in many Radiology Departments but may not be recorded in a formalised manner or credit given for participation. As part of the enactment of Section 11 of the Medical Practitioner Act 2007, participation in clinical audit is now required for all registered medical practitioners. Clinical audit should be conducted in all aspects of Radiology services covering structure, process and outcomes. Routine focused audit of report turnaround time and report completeness should be conducted. Local protocol will determine what other audit(s) to conduct, frequency of audit(s) and number of cases to be considered. As far as possible the audit cycle should be completed through the implementation of change and the assessment of improvements made.

The Royal College of Radiologists (UK) has an extensive list of audit recipes which could assist radiology departments in the selection of audits.

**Key Quality Indicators**

- Number of Audits
- Audit Type

Individual can be divided into the following categories:

- Structure
- Process
- Outcome

- % of Audits with Audit Cycle complete

### 2.4 Focused Audit, Interventional Radiology

Audit should be used by all practitioners of radiology be it basic biopsy and drainage work or more complex embolisation work. For interventional Radiologists these audits should be steered towards patient outcome, procedure success, complication rate and patient experience.

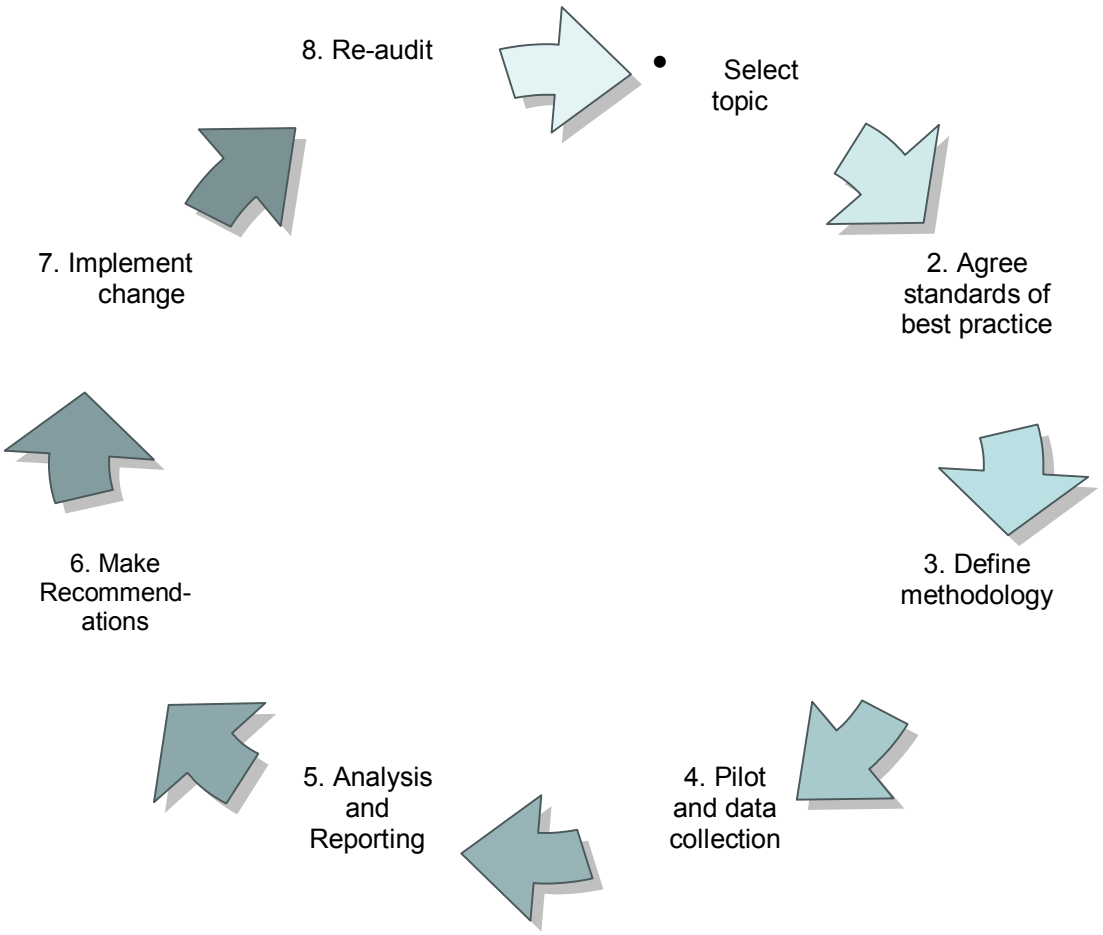
Within the Royal College of Radiologists" (UK) list of audit recipes there is a category for audits which are applicable to Interventional Radiology which could assist radiology departments in the selection of audits Link to RCR Audit Live - Intervention Audits

**Key Quality Indicators**

- Number of Audits performed
- Number of Audits where the audit cycle is completed
- Audit Type: audits can be based on any aspect of interventional practice including,
- Indications for procedures
- Patient (and procedure) outcomes
- Radiation exposure
- Equipment and disposable usage
- Procedure success
- Complication rate
- Peri-procedural care
- Patient experience

## Appendix 4

# Clinical Audit Cycle



## Appendix 5

# Sample Clinical Audit Structures and Responsibilities

The arrangements set out below are an example to indicate the accountability and governance arrangements for Radiological Clinical Audit. These will vary depending on location and committees and roles may vary in name. However, all Responsibilities should be imbedded in the hospital structure with accountability up to and including the CEO.

**Individual Responsibility** **Committee Responsibility**