Health Information and Quality Authority

An tÚdarás Um Fhaisnéis agus Cáilíocht Sláinte

Monitoring and Regulation of Healthcare Services

# National procedures for clinical audit of radiological procedures involving medical exposure to ionising radiation

19 June 2023

Safer Better Care

## *About the Health Information and Quality Authority*

The Health Information and Quality Authority (HIQA) is an independent statutory authority established to promote safety and quality in the provision of health and social care services for the benefit of the health and welfare of the public.

HIQA's mandate to date extends across a wide range of public, private and voluntary sector services. Reporting to the Minister for Health and engaging with the Minister for Children, Equality, Disability, Integration and Youth, HIQA has responsibility for the following:

- **Setting standards for health and social care services** — Developing person-centred standards and guidance, based on evidence and international best practice, for health and social care services in Ireland.
- **Regulating social care services** — The Chief Inspector within HIQA is responsible for registering and inspecting residential services for older people and people with a disability, and children's special care units.
- **Regulating health services** — Regulating medical exposure to ionising radiation.
- **Monitoring services** — Monitoring the safety and quality of health services and children's social services, and investigating as necessary serious concerns about the health and welfare of people who use these services.
- **Health technology assessment** — Evaluating the clinical and cost-effectiveness of health programmes, policies, medicines, medical equipment, diagnostic and surgical techniques, health promotion and protection activities, and providing advice to enable the best use of resources and the best outcomes for people who use our health service.
- **Health information** — Advising on the efficient and secure collection and sharing of health information, setting standards, evaluating information resources and publishing information on the delivery and performance of Ireland's health and social care services.
- **National Care Experience Programme** — Carrying out national service-user experience surveys across a range of health services, in conjunction with the Department of Health and the HSE.

# Table of Contents

# 1.0 Introduction

Clinical audit is a quality improvement tool central to providing good care and service to patients and people who use the services.* The purpose of clinical audit is to systematically review care and or services against agreed standards to ensure that the standards are being met. Where standards are not fully met the necessary actions should be taken. Clinical audit is an important tool to assure providers that their services are safe, reliable and of a high quality. Active participation in clinical audit is key to fostering a culture of regular quality assurance and continual improvement in services.[1]

Clinical audit is different from other improvement methods, such as research, regulatory audit or inspection,[2] certification or accreditation†. However, due to some similarities with other review systems and improvement methods, clinical audits should be developed in a way which minimises unnecessary overlap with other systems, and reduces duplication of efforts. Each audit is therefore designed for a specific purpose and differs in its scope, method, impact and use.

Clinical audit was introduced specifically for medical radiological procedures‡ through the European Commission Medical Exposure Directive 97/43/Euratom and updated more recently through the European Commission Basic Safety Standards Directive (BSSD) 2013/59/Euratom.[3] According to the BSSD article 58(e), carrying out clinical audit "in accordance with national procedures" is mandatory and a legal requirement within the European Union.

This national procedures document sets out the principles and essential criteria that undertakings must follow to ensure compliance with the requirements of European Union (Basic Safety Standards for Protection against Dangers Arising from Medical Exposure to Ionising Radiation) Regulations 2018 (S.I. No. 256 of 2018) as amended.[4] This document includes the details about the practical implementation of clinical audit and lists some topics that may be considered by undertakings.



* In addition to patients, people who use the service include clients, comforters and carers.
† The HSE's glossary of terms for clinical audit is available at https://www.hse.ie/eng/about/who/nqpsd/ncca/nomenclature-a-glossary-of-terms-for-clinical-audit.pdf
‡ Radiological procedures refers to diagnostic radiology, nuclear medicine and radiotherapy.

This 2013 EU Council Directive defines clinical audit as:

"a systematic examination or review of medical radiological procedures which seeks to improve the quality and outcome of patient care through structured review, whereby medical radiological practices, procedures and results are examined against agreed standards for good medical radiological procedures, with modification of practices, where appropriate, and the application of new standards if necessary."

In October 2022, through S.I. 528 of 2022,[5] an amendment to the European Union (Basic Safety Standards for Protection Against Dangers Arising from Medical Exposure to Ionising Radiation) Regulations 2018 (S.I. No. 256 of 2018) as amended, transferred responsibility for establishing 'national procedures' for clinical audit from the 'Minister' to the 'Authority' (HIQA). This legislation, and subsequent amendments, will be referred to as 'the regulations' from this point on in this document.

It is the responsibility of an undertaking to ensure that clinical audit is carried out in line with national procedures.

When undertakings§ are considering clinical audit, the definition of clinical audit included in the Patient Safety (Notifiable Incidents and Open Disclosure) Act 2023[6] should also be considered. In the Act this is defined as a clinically-led quality improvement process in healthcare:

> (a) for the purpose of improving patient care and outcomes through systematic review of care against explicit specific clinical standards or clinical guidelines and taking action to improve care when clinical standards or clinical guidelines are not met, and
>
> (b) which selects aspects of the structure, processes and outcomes of care for systematic evaluation against explicit specific clinical standards or clinical guidelines;...

§ An undertaking is defined in the regulations as 'a person or body who, in the course of a trade, business or other undertaking (other than as an employee), carries out, or engages others to carry out, a medical radiological procedure or the practical aspects of a medical radiological procedure'.

## 1.1. How the national procedures were developed

To develop the national procedures in clinical audit, a scoping exercise was carried out to gather existing information on clinical audit available for professionals working in the area of medical ionising radiation. An extensive review of the existing scientific literature was also carried out.

Following this, a stakeholder[**] engagement campaign was carried out with relevant stakeholders, details of the bodies included in this campaign are contained in Appendix 1. This engagement campaign initially included a scoping consultation with professional bodies and regulatory bodies. The information gathered from this scoping consultation and the literature was then collated, analysed and used to establish the draft national procedures.

A targeted focussed consultation was then carried out with stakeholders. Feedback from the targeted consultation has been incorporated into this draft document which is available for a six week public consultation starting in June 2023. Feedback from the public consultation will be implemented before finalising the *National procedures for clinical audit of radiological procedures involving medical exposure to ionising radiation.*

HIQA will review and update these national procedures, as required in line with best practice and legislative change.

## 1.2. Purpose, scope and use of this document

**Purpose —** the purpose of this document is to provide undertakings with the principles that need to be in place within their service to ensure compliance with the regulations.

**Scope —** this document includes information on the essential criteria for clinical audit of medical radiological procedures (diagnostic radiology, including dental, nuclear medicine and radiotherapy), along with information on implementing clinical audit and examples for each type of setting.

**Using this document —** this document has been developed with hyperlinked sections to facilitate easy navigation. Clicking on each link (in blue underlined font) will bring you directly to this part of the document.

Templates and checklists which undertakings may find useful are provided in the appendices:

- Appendix 3 – Clinical audit strategy template

[**] A stakeholder is either an individual, group or organisation who can affect or is affected by a project, initiative, policy or organisation.

- Appendix 4 – Clinical audit checklist
- Appendix 5 – Audit report template.

Examples of clinical audit topic in each medical radiological setting are also included in the appendices:

- Appendix 6 – Dental setting
- Appendix 7 – Radiology - diagnostic and interventional settings
- Appendix 8 – Nuclear Medicine - diagnostic and therapy settings
- Appendix 9 – Radiotherapy setting.

## 1.3. Who this document applies to

Although ensuring the implementation of clinical audit of medical radiological procedures is the responsibility of undertakings, this document applies to all professionals involved in medical radiological procedures in both dental and medical settings. Those impacted by these national procedures include the medical and dental professions carrying out radiological procedures and people using these services.

This document can also be used by other bodies. These include scientific societies, professional bodies, regulators of professions and national health bodies, all of whom play an important role in supporting clinical audit in public and private health and dental services provided nationally.

**What does clinical audit mean for patients and people who use the service?**

Patients and people who use the service can expect a service that:

- is focused on continually improving its safety and quality
- ensures the most appropriate procedures and treatments involving medical exposures are delivered safely to each person using the service.

**What does clinical audit mean for staff?**

Staff can expect that the service in which they work:

- helps them to understand the role of local clinical audit
- encourages them to actively participate in audit activity and foster a culture of regular quality assurance and continual improvement
- encourages them to implement recommendations from clinical audit findings to improve quality and safety in the services they provide.

**What does clinical audit mean for professional bodies and societies?**

Professional bodies and societies nationally and internationally can:

- play an important role in developing clinical audit templates and standards for radiological practices due to the knowledge and expertise of their members
- set out good practice especially in relation to the auditing of specific examinations and treatments, by providing guidance and recommendations to their members
- provide practical advice and support and promote collaboration and shared learning in relation to clinical audit of radiological practices
- facilitate education and training in clinical audit for their members.

**What does clinical audit mean for undertakings?**

Undertakings:

- should have a clinical audit strategy in place
- can use clinical audit to improve the quality and safety of patient care and services
- can use the findings of clinical audit to provide assurances of the quality and safety of patient care and services they provide
- can make this document available to all staff involved in medical radiological procedures so that they are aware of their role in relation to clinical audit.

## 1.4. Benefits of clinical audit

As illustrated in Figure 1, high-quality clinical audit can improve the quality of care, enhance the provision and organisation of services and promote the effective use of resources. It also provides learning opportunities for the team involved, the wider organisation and other service providers.[7] Any gaps and deficiencies identified through clinical audit can subsequently be addressed through recommendations, which are actioned through a quality improvement plan.[8]

Clinical audit can also facilitate collaboration[9] between professionals within a service and with other services and is a way for services to demonstrate a commitment to the quality and safety of the services they provide.

**Figure 1. Benefits of clinical audit**

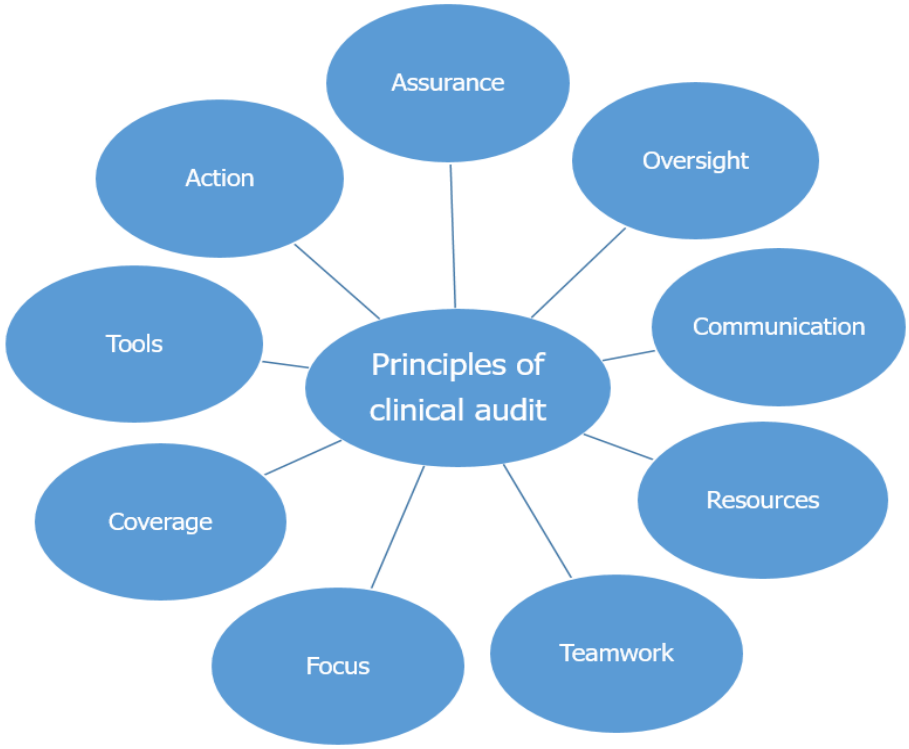
## 2.0 Framework for clinical audit

The framework for clinical audit includes the principles and essential criteria that undertakings must have in place to ensure compliance with these national procedures. More detail on how HIQA inspects services providing medical exposure to ionising radiation can be found in the guide for medical services[10] and the guide for dental services,[11] which are available on www.hiqa.ie.

The *Assessment-judgment framework for undertakings providing medical exposure to ionising radiation,*[12] sets out the lines of enquiry (questions) to be explored by inspectors in order to assess compliance with the regulations being monitored or assessed. *Guidance on the assessment of compliance in undertakings providing medical exposure to ionising radiation* is also available on the HIQA website and provides information to undertakings about how the regulations are assessed and how compliance is measured.

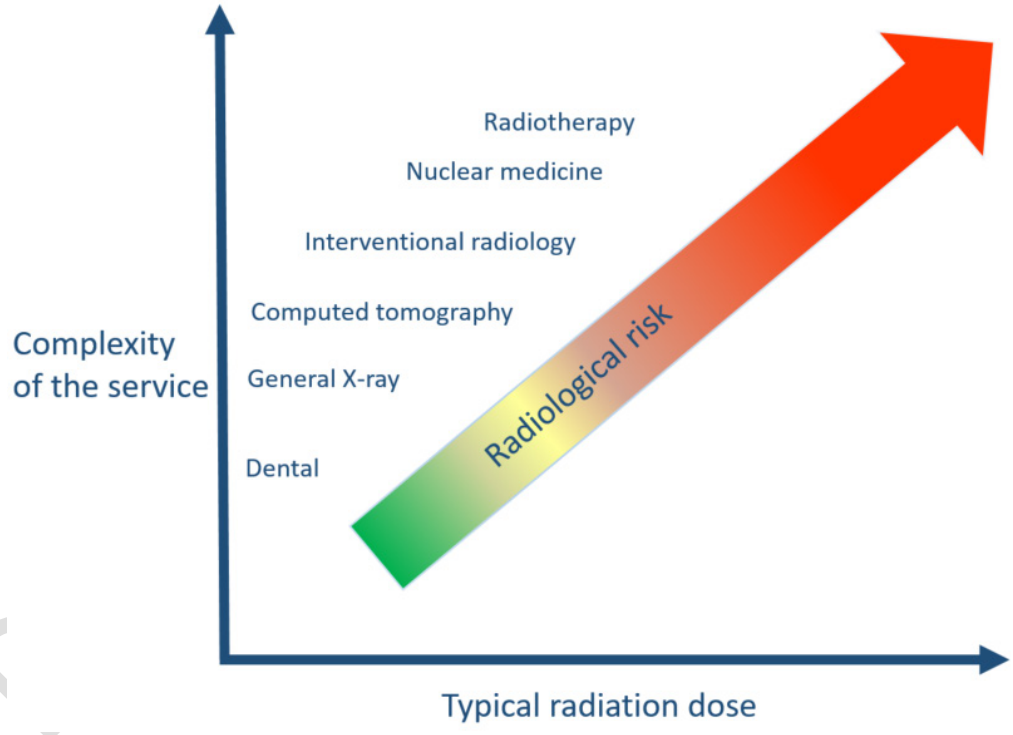
The principles and essential criteria that undertakings must have in place to ensure compliance with these national procedures have been established from engagement with affected parties and stakeholders. These principles are shown in Figure 2.

**Figure 2. Principles for clinical audit**



The extent to which an undertaking engages with or uses these principles depends on the size, scale and complexity of the organisation and this should be considered when designing a clinical audit strategy. Additionally, the degree to which undertakings apply these principles must be proportionate to the level of radiological risk within the service. For example, the clinical audit strategy for a large organisation such as a hospital may differ from that of smaller organisations such as a stand-alone dental facility. A larger organisation should also consider how the clinical audit strategy for medical radiological procedures relates to the organisation's overall clinical audit strategy.[13] For clinical audit to be meaningful, sustainable and achievable, it should be integrated into the service's overall audit programme to improve the quality of the service provided. Figure 3 shows the service types using ionising radiation for medical radiological procedures and the level of radiological risk within these services. A template for a clinical audit strategy is included in Appendix 2. However, undertakings can develop their own template appropriate to the level of complexity within their organisation.

**Figure 3- Service type, complexity and typical level of radiological risk**




The framework for clinical audit in Table 1 details the **principles and essential criteria** that an undertaking must implement to:

- support clinical audit within the areas conducting medical radiological procedures and
- ensure compliance with the regulations.

**Table 1. Framework for clinical audit**

| | **Principle** | **Essential criteria** |
|---|---|---|
| 1 | Assurance | An undertaking must be assured that *the national procedures* have been implemented and maintained in line with the level of radiological risk within its service. |
| 2 | Oversight | An undertaking must have a mechanism in place which identifies the oversight of clinical audit in the service. |
| | | An undertaking must have an identified clinical audit strategy that is aligned with the level of radiological risk in the service. |
| | | The clinical audit strategy must be aligned with up-to-date evidence and national priorities. |
| | | The clinical audit strategy must be implemented throughout the service. |
| 3 | Communication | An undertaking must ensure appropriate communication pathways are in place for all interested parties and stakeholders. |
| 4 | Resources | An undertaking must be aware of, and provide, the resources that are required to implement the clinical audit strategy. |
| 5 | Teamwork | An undertaking must ensure that the approach to clinical audit includes a multidisciplinary team.* |
| 6 | Focus | An undertaking must ensure that clinical audit is prioritised based on risk and service needs in order to improve practice and the quality and outcome of patient care. |
| 7 | Coverage | An undertaking must ensure that the scope and depth of the clinical audit strategy is appropriate and transparent. |
| 8 | Tools | An undertaking must have identified and made available the appropriate resources and tools to facilitate clinical audit. |
| 9 | Action | An undertaking must have a mechanism in place to ensure results and recommendations from clinical audit are addressed, re-evaluated and that quality improvement plans are implemented and sustained. |

* For a sole trader dentist this may include the other personnel working within the service such as the medical physics expert, dental nurse, administrative staff.

More detailed information in relation to criteria for clinical audit can be found in the European Commission's *Radiation Protection No. 159 – European Commission Guidelines on Clinical Audit for Medical radiological practices (Diagnostic Radiology, Nuclear Medicine and Radiotherapy*).[7]

Information on enablers to maximise the impact and implementation of clinical audit are described in the European Commission's *Radiation Protection: No 198: Current Status and Recommendations for Improving Uptake and Implementation of Clinical Audit of Medical Radiological Procedures* [14] and in the HSE's National Review of Clinical Audit (2019).[15]

A description and further details on the principles and essential criteria is available in Appendix 2. Information on the practical implementation of clinical audit follows in the next section.

## 3.0 Practical implementation of clinical audit

The purpose of clinical audit is to continually improve practices. Before implementing clinical audit, a clinical audit strategy which aligns with the principles of clinical audit, as detailed the previous section, should be developed. An example template for a clinical audit strategy is provided in Appendix 3.

A clinical audit schedule can also be developed which details which topics are to be audited, when they are to be audited and by whom. Figure 4 shows the relationship between the clinical audit strategy, schedule and audit topics.

**Figure 4: Clinical audit strategy, schedule and topic relationship**

## 3.1. Clinical audit strategy

To develop a clinical audit strategy, undertakings should consider good practice guidelines from national and international recommendations. Guidelines and consensus statements developed by national and or international scientific societies and professional bodies can also be considered.

Undertakings should ensure all relevant interested parties and stakeholders especially those delivering care are involved at every stage of the audit. Audits should be carried out in line with the service's overall audit strategy and should be prioritised based on:

- a high risk area
- areas within a service requiring specific attention, which may be identified by the undertaking, or other individuals that support clinical audit within a service.

Information to support this strategy can come from:

- incidents or near misses
- the initiation of a new type of practice
- inconsistent practice
- feedback from patients or people using the service
- non-compliances.

Audit topics can also be prioritised based on a specific national or international focus. The clinical audit topics can be detailed in a clinical audit schedule.

### *Determining the audit topics*

Good practice in clinical audit should cover the whole clinical pathway in line with the definition of clinical audit in Section 1.0 of this document. To ensure oversight across the full clinical pathway, undertakings should consider the following three main elements: structure, process, and outcome, which are defined in Table 2.

**Table 2. Three main elements for oversight across the full clinical pathway**

| | |
|---|---|
| **Structure** | Structure demonstrates the attributes of the settings in which care occurs. This includes the material resources (such as facilities and equipment), human resources, and organisational structure. |
| **Process** | Process demonstrates what is actually done in giving and receiving care. It includes the practitioner's activities in making a diagnosis and recommending or implementing treatment. |
| **Outcome** | Outcome demonstrates the effects of care on the health status of patients and populations. It is appreciated that auditing the clinical outcome may be very difficult. In radiological procedures, outcome refers to the results of the examination or treatment as they apply to the patient. |

Undertakings can consider the topics listed in Table 3 when planning clinical audit. This list is not exhaustive and more detail on possible topics is provided in Appendix 6 to 9. Criteria for specific exams or treatment are not further discussed in this document but links to some useful published literature can also be found in these appendices.

**Table 3. Sample of clinical audit topics**

| Type | Topic |
|---|---|
| **Audits of structure** | Organisation and management structure |
| | Allocation of responsibilities |
| | Personnel, education and training |
| | Premises and equipment |
| **Audits of process** | Referral process |
| | Justification process |
| | Diagnostic and treatment procedures |
| | Optimisation |
| | Imaging process |
| | Radiopharmacy procedures (applicable in nuclear medicine) |
| | Treatment process (applicable in radiotherapy and nuclear medicine) |
| | Diagnostic report |
| | Records |
| | Quality management |
| | Incident reporting and management |
| **Audits of Outcome** | Outcome of procedure (diagnostic) |
| | Clinical outcome (therapy) |

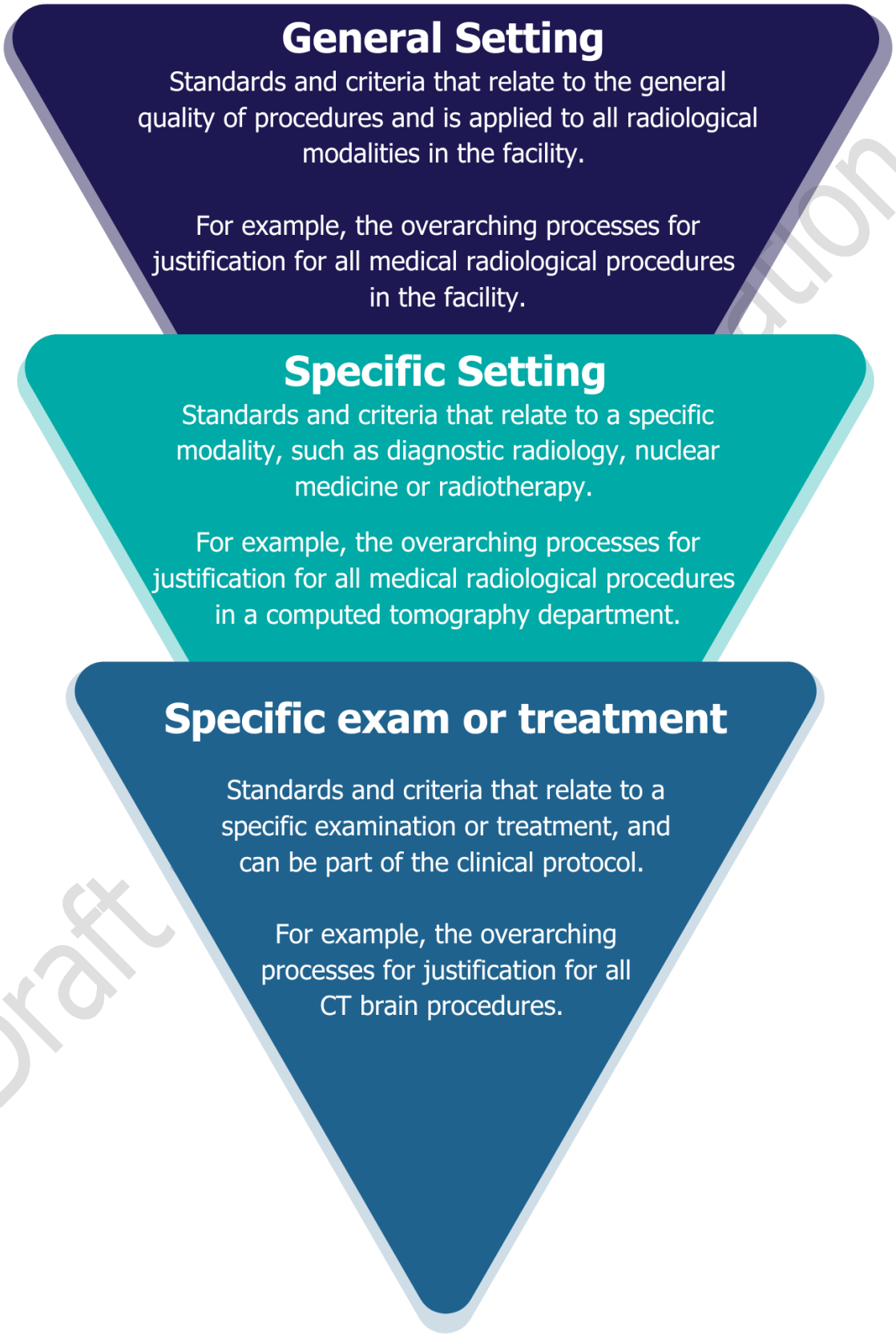
Undertakings should also consider clinical audit coverage. Clinical audit coverage will vary in relation to audit scope, depth and frequency.

**Scope** — a single clinical audit can assess either the whole clinical pathway from referral to follow-up (comprehensive audit), or can be limited to specific critical parts of the pathway (partial audit). The aim should be to audit the whole clinical pathway, while partial audits can be used to focus in detail on the parts of the process that are of significant interest.

**Depth** — clinical audits can assess the general parts of the service, general either to all radiological procedures or specific specialities, or can go deeper to a selected individual examination or treatment. A quality clinical audit strategy should address all three levels of activities as shown in Figure 5.

**Frequency** — clinical audits should be a continual activity and the frequency of each audit activity can be detailed in the clinical audit schedule.

**Figure 5. Example of coverage, levels and depth of clinical audit**



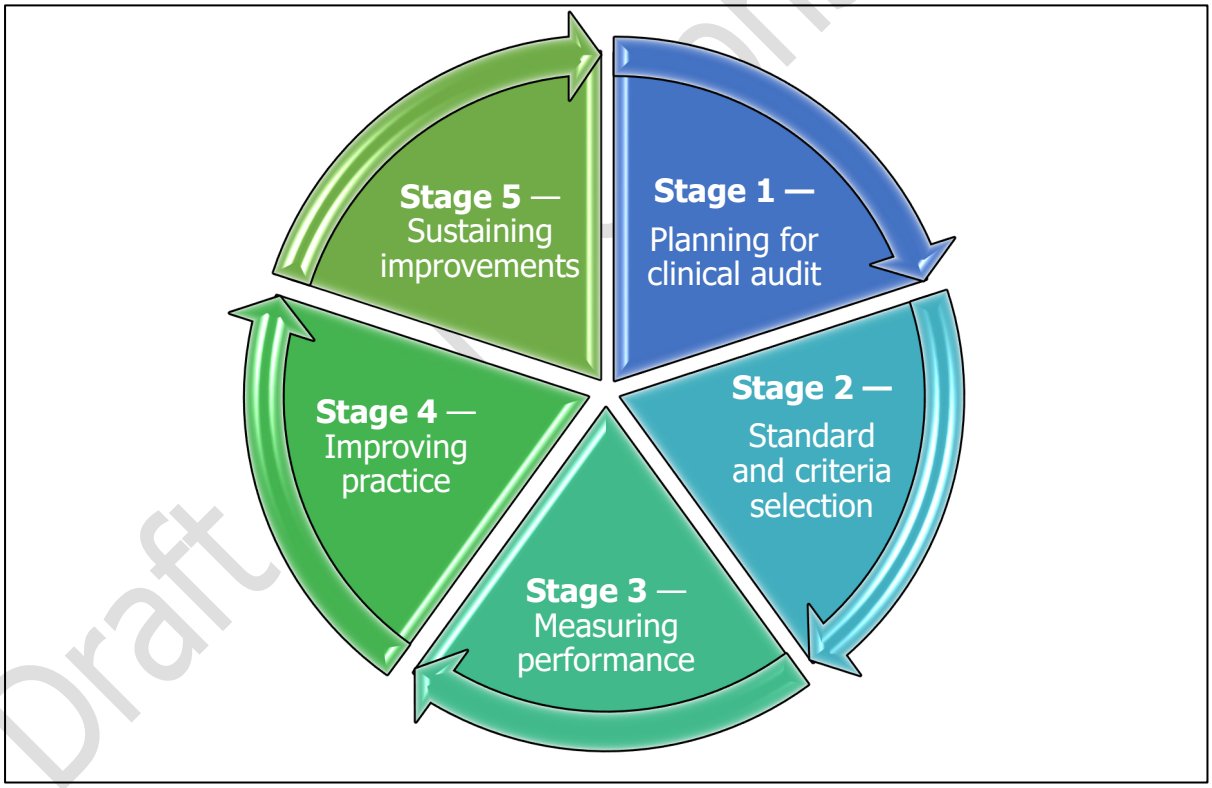
## 3.2. The clinical audit cycle

Each audit topic should be conducted in line with the clinical audit cycle. Numerous sources[1,8,13,16,17,18] refer to the clinical audit cycle in stages and provide practical resources to help support and facilitate clinical audit. The clinical audit cycle in Figure 6 has been adapted from these sources.

The clinical audit cycle consists of:

- planning the use of audit resources and selecting clinical audit topics
- selecting the relevant standards of good practice
- measuring performance by assessing the local practice and comparing it with the standard
- improving by implementing change when necessary, and
- checking that improvements have been sustained by re-auditing after a certain time.

**Figure 6. Overview of the clinical audit cycle**




The clinical audit cycle should be applied to each audit topic by following the five key stages as outlined below. An audit checklist can be used to ensure that all aspects of the clinical audit cycle are covered for the audit topic and ensure a consistent approach for all audits. Appendix 4 contains an example of an audit checklist.

## *Stage 1 — planning a clinical audit*

**Choosing a topic —** the specific audit topic chosen should be based on the audit strategy and the audit schedule. Audit topics should be selected based on their importance or relevance to the service. Audits should be useful and contribute to quality improvement and also span across different aspects of the service. While repeat audits can be very valuable, it is important that the range of audits aligns with the scope of service and desired outcomes.

**Involving interested parties and stakeholders —** the resources required, such as time and staff needed for data collection and analysis, should be identified and provided. All people taking part in the audit should understand the aim of the audit and their role in it. Responsibilities should be clear, including who will lead the audit and who will have oversight for ensuring audit recommendations are being put in place. Auditing teams should consider how the views of patients and people who use the service can inform the audit, for example, views contained in complaints, feedback and patient satisfaction surveys.

**Audit template —** once the audit topic is known, the specific aims and objectives of that audit should be documented in the audit template. Please see Appendix 5 for a sample audit template. However undertakings can consider more specific audit templates within their individual settings, some of which are referenced here.[1,19,20]

**Aims —** the aim describes the reasons for carrying out the audit which is to assess the level or quality of the current practice. The aim should be agreed by the team working on the audit.

**Objectives —** the aim of the audit should be broken down into measurable parts – the objectives. These objectives should be SMART[21] objectives, as described in Table 4.

**Table 4. Overview of SMART objectives for clinical audit**

| | | |
|---|---|---|
| **S** | **S**pecific | What are you trying to do? Why? By when? Who will be involved and who will it affect? |
| **M** | **M**easurable | How will you measure what you are doing? |
| **A** | **A**chievable | With the tools you have, can you reach your goal? Is it achievable? |
| **R** | **R**ealistic | The objective should be realistic, relevant and aligned with the organisation's overall aims and objectives |
| **T** | **T**ime-bound | The attainment of objectives should be timely and time-bound. |

## *Stage 2 — standard and criteria selection*

**Identify standards —** once the aims and objectives have been defined the standards and relevant criteria to be used in the audit should be defined by the team. This includes identifying best practice in the area under audit. Best practice is usually that which is outlined in published literature, and national or international guidelines, and can take the form of quality indicators. A quality indicator should be reliable, accurate, sensitive to changes, specific in terms of the quality expected, relevant, easily understood and able to influence decisions.[22] Where published recommendations and guidance do not exist, standards can be set through local agreement.

**Identify criteria —** the standard set should be a measurable value. Criteria are measurable statements about what should be happening.

**Set target —** the target or expected performance level can be the minimum expected standard or the optimum standard, usually expressed as a target percentage or threshold.

## *Stage 3 — measuring performance*

Once the audit aims, objectives and standards have been agreed, data collection can begin. Performance is measured by comparing the data collected (actual performance) against the expected standard (expected performance).

**Collecting data —** data collection should be made as straightforward as possible, built into day-to-day work and use electronic data where available in order to reduce the need to manually search for data. Tools for collecting data should be easy to use, and ready-made tools and templates can be adapted for local use.

Data can be collected from existing information or a plan can be developed to collect future or anticipated information. It is important to collect only the data required to satisfy the aim of the audit. No unnecessary data should be collected. **Undertakings should ensure that collected data complies with data security principles and best practice on information governance, such as data protection and the General Data Protection Regulation (GDPR) and any other relevant legislation pertaining to clinical audit.**[††]

The sample size should be agreed in line with best practice, while an adequate sample size (such as the number of examinations, number of patients or people who use the service) can be reached by auditing small numbers regularly. Details on the collection methods should be recorded in the audit documentation in order to facilitate repeat data collection and re-audit.

**Analysing data —** collected data is compared to the agreed target or threshold to measure compliance with standards. Where standards are not met, the extent of the deviation should be quantified to determine the level of action needed. Deviations can be deemed:

- not significant
- significant but resolvable with current resources or
- significant and requiring additional resources to be resolved.

**Presenting data —** simple statistics, such as percentages and basic graphs can be used to provide the clearest possible picture of performance. To facilitate discussion of audit findings, a brief audit report should be produced for each audit. The report should describe the aims and objectives of the audit, the data collection and analysis methods uses, and present the findings and recommendations from the audit team.

## *Stage 4 — improving practice*

**Agree actions —** recommendations and the action plan for improvement should be discussed between the audit team, management of the service or practice and those affected by the recommendations. This is to ensure that the recommendations are implementable and that priorities and timescales for action are agreed.

**Agree responsibilities for action —** recommendations from the action plan should be assigned to whoever has accountability for overseeing their implementation. However, all of those involved in and affected by the required action should be aware of their role and responsibility in bringing about the necessary changes.

[††] Chapter 4 of the HSE's Clinical Audit: A Practical Guide (2023) provides detail on 'Data Protection, General Data Protection Regulation (GDPR) and Ethical Issues for Clinical Audit'.

## *Stage 5 — sustaining improvements*

**Encourage learning —** the audit findings, recommendations and action plan should be shared widely with all staff who are affected. This will help keep everyone engaged and aware of what needs to improve and to motivate them to implement the necessary change or improvement in practice. Learning may be used to inform clinical audit in other areas and learning may also be shared with people using the service if appropriate.

**Monitor progress of the recommendations —** those with responsibility for overseeing the implementation of recommendations should report on progress to the undertaking at regular intervals as required and in the agreed format.

**Monitoring improvements —** once you have completed the objectives a period of time should be allowed in order for changes to take effect. After an agreed set period, a re-audit may take place to measure the level of improvement and complete the audit cycle. Methods other than re-audit can also be considered, for example, monitoring of key performance indicators.[‡‡]

The method used to monitor improvements should continue until the results provide assurance to the undertaking that the agreed standards are being met consistently.

**Implications for the audit strategy and schedule —** learning from individual audits may be used to inform and update the clinical audit strategy and the clinical audit schedule.



[‡‡] Key performance indicator is a quantifiable measure of performance over time for a specific objective.

# 4.0 Conclusion

Clinical audit is a quality improvement process central to good care and service provision to patients. This document aims to support undertakings to implement clinical audit as a quality improvement tool. The purpose of clinical audit is to systematically review care and services against agreed standards and determine if these standards are being met. When standards are not fully met, undertakings must take the necessary action to address these gaps and bring about improvement. Clinical audit can also be used to make services more efficient.

To meet the requirements of the regulations, undertakings should:

- consider the principles of clinical audit identified in this document and apply these to their service
- develop a clinical audit strategy based on the level of complexity and radiological risk in the service
- conduct clinical audits according to identified priorities
- apply the clinical audit cycle for each audit
- use findings from clinical audit to improve practice.

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[§§] If not already cited, all online references were accessed at the time of preparing this guidance. Please note that online addresses may change over time.

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# Glossary of terms

**clinical audit** — a systematic examination or review of medical radiological procedures which seeks to improve the quality and outcome of patient care through structured review, whereby medical radiological procedures, procedures and results are examined against agreed standards for good medical radiological procedures, with modification of practices, where appropriate, and the application of new standards if necessary.

**criteria** — a standard by which something may be judged or decided.

**CT** — stands for Computed Tomography, an imaging technique used to visualise both the soft tissue and bone inside your body.

**diagnostic reference levels (DRLs)** — dose levels in medical radiodiagnostic or interventional radiology practices, or, in the case of radio-pharmaceuticals, levels of activity, for typical examinations for groups of standard-sized patients or standard phantoms for broadly defined types of equipment.

**dose constraint** — a constraint set as a prospective upper bound of individual doses, used to define the range of options considered in the process of optimisation for a given radiation source in a planned exposure situation.

**framework —** a basic structure underlying a system, concept or text.

**interventional radiology** — the use of X-ray imaging techniques to facilitate the use of devices in the body for diagnostic or treatment purposes.

**ionising radiation** — energy transferred in the form of particles or electromagnetic waves of a wavelength of 100 nanometres or less (a frequency of $3 \times 10^{15}$ hertz or more) capable of producing ions directly or indirectly.

**medical exposure** — exposure incurred by patients or asymptomatic individuals as part of their own medical or dental diagnosis or treatment, and intended to benefit their health, as well as exposure incurred by carers and comforters and by volunteers in medical or biomedical research.

**medical radiological** — pertaining to radiodiagnostic and radiotherapeutic procedures, and interventional radiology or other medical uses of ionising radiation for planning, guiding and verification purposes.

**medical radiological procedure** — any procedure giving rise to medical exposure.

**quality assurance** — all those planned and systematic actions necessary to provide adequate assurance that a structure, system, component or procedure will perform

satisfactorily in compliance with agreed standards. Quality control is a part of quality assurance.

**quality control** — the set of operations (programming, coordinating, implementing) intended to maintain or to improve quality. It includes monitoring, evaluation and maintenance at required levels of all characteristics of performance of equipment that can be defined, measured, and controlled.

**standard** — a level of quality or attainment.

# List of appendices

# Appendix 1 – Engagement with key affected parties and stakeholders

As part of the consultation process to develop these guidelines, engagement with the following key stakeholders and affected parties took place:

| **Key affected parties and stakeholders** |
| --- |
| ▪ CORU<br>▪ Dental Council of Ireland<br>▪ Department of Health<br>▪ European regulators of medical ionising radiation<br>▪ European Society of Radiology (ESR) - President<br>▪ Irish Association of Physicists in Medicine (IAPM)<br>▪ Irish College of Physicists in Medicine (ICPM)<br>▪ Irish Dental Association (IDA)<br>▪ Irish Institution of Radiographers and Radiation Therapists (IIRRT)<br>▪ Irish Medical Council<br>▪ National Radiation Protection Committee<br>▪ Nursing and Midwifery Board of Ireland (NMBI)<br>▪ Private Hospitals Association (PHA)<br>▪ RCSI Faculty of Radiologists and Radiation Oncologists<br>▪ Voluntary Hospitals Forum<br>▪ National Radiation Protection Committee<br>▪ National Radiation Protection Committee – Co-chair |

# Appendix 2 – Framework for clinical audit: principles and essential criteria

This table provides some further detail on the essential criteria. Some examples of documentation that undertakings may have in place to show how these are considered is also included. Undertakings should consider the size, scale and level of complexity of their service, along with the level of radiological risk in the service.

| | **Principle** | **Essential criteria** | *Appropriate to the type of service* | |
|---|---|---|---|---|
| | | | **Description and detail** | **Example of documentation** |
| 1 | Assurance | An undertaking must be assured that *the national procedures* (this document) have been implemented and maintained in line with the level of radiological risk within its service. | ▪ The clinical audit strategy is established, regularly reviewed and updated as required<br>▪ The service undergoes regular monitoring to ensure all improvements are sustained | Clinical audit strategy for the service<br>Clinical audit strategy for the organisation<br>Minutes of meetings<br>Audit records<br>Quality indicator records |
| 2 | Oversight | An undertaking must have a mechanism in place which identifies the oversight of clinical audit in the service. | ▪ A steering committee or other formal group for clinical audit is in place and meets quarterly/regularly<br>▪ Appropriate communication channels to the undertaking have been identified | Organogram<br>Terms of reference<br>Minutes of meetings |
| | | An undertaking must have an identified clinical audit strategy that is aligned with the level of radiological risk in the service. | There is a clinical audit strategy in place that:<br>▪ has been approved by the steering committee and clinical governance committee<br>▪ is implemented in all relevant areas has resulted in service improvement | Clinical audit strategy<br>Minutes of meetings<br>Examples of implementation, for example staff newsletters, education sessions, information resources on the intranet |
| | | The clinical audit strategy must be aligned with up-to-date evidence | | |

| | Principle | Essential criteria | *Appropriate to the type of service* | |
|---|---|---|---|---|
| | | | **Description and detail** | **Example of documentation** |
| | | and any national priorities identified relevant to the setting. | | |
| | | The clinical audit strategy must be implemented throughout the service. | | |
| 3 | Communication | An undertaking should ensure appropriate communication pathways are in place for all stakeholders | ▪ All stakeholders have been informed of the clinical audit strategy<br>▪ Communication has taken place across all stages of the clinical audit cycle<br>▪ Audits involve people who use the service<br>▪ Results and recommendations have been shared with all stakeholders within the organisation and externally as appropriate | Minutes of meetings<br>Audit records<br>Communications with people who use the service |
| 4 | Resources | An undertaking should consider the resources that are required to implement the clinical audit strategy | The service has:<br>▪ an identified lead (or co-ordinator) for clinical audit<br>▪ suitably qualified staff in post to support clinical audit<br>▪ clinical audit is supported in the organisation from a resource perspective | Training records<br>Audit records |

| | Principle | Essential criteria | *Appropriate to the type of service* | |
|---|---|---|---|---|
| | | | **Description and detail** | **Example of documentation** |
| | | | ▪ incorporated clinical audit into daily practice and has mechanisms in place t*o manage the time implications (knock on effect on services)*<br>▪ Clinical audit training is available to all staff to include training on tools and available techniques | |
| 5 | Teamwork | An undertaking has ensured that the approach to clinical audit includes the multidisciplinary team at all stages | There is evidence of:<br>▪ multidisciplinary audit throughout the service<br>▪ multi-service audit throughout the organisation<br>▪ audit with other external organisations where appropriate | Audit records<br>Minutes of meetings<br>Individual department records |
| 6 | Focus | An undertaking has ensured that clinical audit is prioritised based on risk and service needs to improve the quality and outcome of patient care | ▪ Clinical audit activity is focused with clearly-stated quality improvement aims and SMART objectives<br>▪ Evidence of audits that were initiated by other clinical governance areas e.g. risk, complaints | Minutes of meetings<br>Audit records |
| 7 | Coverage | An undertaking should ensure that the scope and depth of the clinical audit strategy is transparent | ▪ Within the scope and depth of clinical audit both comprehensive and partial audit have been considered (See Section 4) | Minutes of meetings<br>Audit templates<br>Audit records |

| | Principle | Essential criteria | *Appropriate to the type of service* | |
|---|---|---|---|---|
| | | | **Description and detail** | **Example of documentation** |
| | | | ▪ The frequency of clinical audit has been considered and is appropriate to the level of risk in the service<br>▪ Unnecessary, wasteful or inappropriate audits are not initiated with the reasons documented | |
| 8 | Tools | An undertaking should have identified and made available the appropriate resources and tools to facilitate clinical audit | ▪ Multidisciplinary discussions on appropriate tools, techniques and the standards that will be used<br>▪ Tools and techniques such as PDSA cycles, lean six sigma, decision trees, process mapping | Minutes of meetings<br>Audit templates<br>Audit records |
| 9 | Action | An undertaking should have a mechanism in place to ensure results and recommendations from clinical audit are addressed, re-evaluated and quality improvement plans are implemented and sustained | ▪ Action plans have been generated as a result of audits<br>▪ All audits which have generated an action plan are re-audited.<br>▪ Audits feed into other clinical governance areas, where appropriate | Audit records |

# Appendix 3 – Clinical audit strategy template

Each service should have a strategy for clinical audit in place which identifies how the undertaking ensures the essential criteria for clinical audit are managed in that service. This clinical audit strategy may be a simple document or very detailed depending on the scale of the organisation and the level of radiological risk in the service. An example of a template which may be used is provided here.

| |
|---|
| **Management and responsibilities - who is responsible?**<br><br>This section should outline the service's commitment to the delivery of safe and effective services, how it supports clinical audit as a tool through which the quality and safety of services can be improved and assured. This section should detail who has oversight for clinical audit, the resources in place for clinical audit and the time period the strategy applies to, for example, the next three years. |
| **Personnel -who does it?**<br><br>This section should detail the staff with direct responsibility for clinical audit to ensure the quality and safety of services they provide. This strategy should also identify that all staff working in the service have responsibility for clinical audit and it should detail how communication around clinical audit takes place. |
| **Prioritisation and schedule -what should be done and when?**<br><br>This section should detail to what extent clinical audit is carried out, including what is audited, how audits are prioritised, planned and agreed, and how often audits are conducted |
| **Method - how will it be done?**<br><br>This section should outline how the service will implement clinical audit, what the agreed approach to clinical audit is and what methods and tools will be used. How progress with audit recommendations is ensured should also be included. |

# Appendix 4 – Clinical audit checklist

This is an example of an audit checklist that can be used to ensure that all aspects of the clinical audit cycle are covered for the audit topic.

| **Stage 1: Plan for audit** | **Complete?** |
|---|---|
| Choose a topic | |
| Involve interested parties and stakeholders | |
| Audit template | |
| **Stage 2: Select standard and criteria** | **Complete?** |
| Identify standard | |
| Identify criteria | |
| Set targets | |
| **Stage 3: Measure performance** | **Complete?** |
| Collect data | |
| Analyse data | |
| Present data | |
| **Stage 4: Make Improvements** | **Complete?** |
| Agree actions | |
| Agree responsibilities for action | |
| **Stage 5: Sustain Improvements** | **Complete?** |
| Encourage learning | |
| Monitor progress (of recommendations and actions) | |
| Monitor improvement (for example, re-audit) | |

# Appendix 5 – Audit report template

This is an example of an audit report template that can be used to ensure that all the necessary information relating to the audit are documented in the audit report.

| | |
|---|---|
| **Audit topic and title:** | |
| **Department or speciality:** | |
| **Date of report:** | **Date topic was last audited (if applicable):** |
| **Audit lead (co-ordinator):** | |
| **Key interested parties and stakeholders:** | |
| **Aim and objectives:**<br>Reason for the audit | |
| **Standard and target:**<br>Standard for comparison, include reference document, target or compliance percentage to be achieved. | |
| **Methodology:**<br>Data or information to be collected e.g. population, sample size, time period, tool used | |
| **Results:**<br>Measured data. | |
| **Findings and conclusion:**<br>Was the target achieved?<br>Services may wish to risk rate findings to help prioritise actions. | |
| **Recommendation(s):**<br>Actions to be taken if target not met | **Timing for re-audit:** |

# Appendix 6 – Dental setting audit topics

Examples of topics in the dental practice setting are provided here. These topics have been adapted from the European Commission's Radiation Protection series no. 159 – Guidelines on Clinical Audit for Medical radiological procedures (Diagnostic Radiology, Nuclear Medicine and Radiotherapy). These examples are not an exhaustive list. Undertakings should develop their topics based on the national procedures in line with the complexity of the service and the level of radiological risk within the service. At the end of this table please find additional resources.

| Type | Topic | Description |
|---|---|---|
| **Structure** | Organisation and management structure | ▪ Assessing how lines of accountability and reporting structures operate in practice against documented lines of accountability and reporting structures can provide assurances that they are clear and are functioning. |
| | Allocation of responsibilities | ▪ Assessing practice against local policies that describe the allocation and delegation of responsibilities including shared responsibilities. This can provide assurances that delegation is working as intended and not leading to any issues such as lack of clarity of responsibilities or miscommunications.<br>▪ Assessing the continuity of appropriate personnel throughout the patient journey can provide assurance that the most appropriate personnel are involved in the patient's care at the right point in their care journey. |
| | Personnel, education and training | ▪ Assessing up-to-date training records, supervision, observation of practice and confirming professional registration as appropriate and adherence to guidance from regulators of professions. This can provide assurance that all staff have adequate training for their responsibilities and the duties and tasks they carry out as part of their work. |

| Type | Topic | Description |
|---|---|---|
| | Premises and equipment | ▪ The infrastructure should be assessed to ensure that it meets the required specifications to ensure the safety of the environment in which care is provided.<br>▪ Inventories of medical radiological equipment for each medical radiological installation should be up to date and reviewed regularly to provide assurances that oversight is in place of potential issues such as equipment nearing the end of its useful life.<br>▪ Review of records of all medical radiological equipment should be kept under strict surveillance, for example, acceptance testing, performance testing, equipment maintenance, fault and error logs, records of any corrective actions to provide assurances of quality and functionality of equipment. |
| | | |
| **Process** | Referral process | ▪ Practice should be assessed for compliance with written policies, procedures and guidelines defining who is entitled to refer for a medical exposure and the process for accepting referrals to ensure the process is being adhered to. This can be achieved by reviewing a sample of records and or observing the process in practice several times. |
| | Justification process | ▪ Practice should be assessed for compliance with written policies, procedures, protocols and guidelines for justification of individual exposures that include those involved and responsible for justification to ensure the process is being adhered to. This can be achieved by reviewing a sample of records and or observing the process in practice several times. |
| | Diagnostic and treatment procedures | ▪ Practice should be assessed for compliance with written policies, procedures, protocols and guidelines for all processes in place for example: |

| Type | Topic | Description |
|---|---|---|
| | | ▪ patient identification process<br>▪ that the provision of information on risks and benefits of exposure as appropriate, in advance of exposure.<br>To ensure the process is being adhered to. This can be achieved by reviewing a sample of records and or observing the process in practice several times. |
| | Optimisation | ▪ Practice should be assessed for compliance with written policies, procedures, protocols and guidelines relevant to optimisation, including consistency of dose and the practical aspects of medical exposures to ensure the process is being adhered to. This can be achieved by reviewing a sample of records and or observing the process in practice several times. |
| | Imaging process | ▪ Practice should be assessed for compliance with written, evidence based, approved, protocols for every type of standard medical exposure, for each type of equipment, and for relevant categories of patients to ensure they are being adhered to. This should include evidence that there are processes in place to assess the quality of images. |
| | Diagnostic Report | ▪ A sample of examinations should be assessed to ensure that a documented image report has been produced and meets the agreed standard. The image report should include the examination type and information about the dose received by the patient. |
| | Records | ▪ The system in place to manage records (including back-up systems) should be assessed to ensure that the management of biographical, clinical and imaging data is meeting the required standard and managed in line with GDPR and legal requirements. |

| Type | Topic | Description |
|---|---|---|
| | Quality Management | ▪ The quality management system should be assessed to ensure that there is documented evidence that:<br>▪ policies and procedures are regularly audited and peer reviewed<br>▪ records of patients or people using the service are maintained in line with GDPR<br>▪ the quality assurance programme for equipment is implemented, maintained and aligned with the requirements of the regulations<br>▪ an appropriate programme of assessment of dose is in place and functioning well. |
| | Incident reporting and management | ▪ Practice should be assessed for compliance with written policies, procedures, protocols and guidelines on the identification, reporting and management of accidental and unintended exposures and significant events to ensure the process is being adhered to. This can be achieved by reviewing a sample of records and or observing the process in practice several times. |
| | | |
| **Outcome** | Outcome of procedure | ▪ Outcome of radiological procedures should be assessed to ensure there is documented evidence of observations and recording of results for example, does the medical ionising procedure facilitate the diagnosis of the presenting complaint, and the subsequent management of the complaint? |

| **Literature and resources for Dental services**<br>This list may be useful in informing clinical audit but is not an exhaustive list. | | |
|---|---|---|
| **Resource** | **Description** | **Reference** |
| European Commission's Radiation Protection series no. 198 – Current Status and Recommendations for Improving Uptake and Implementation of Clinical Audit of Medical Radiological Procedures | This resource provides information on enablers to maximise the impact and implementation of clinical audit. It contains a literature review outlining general principles of clinical audit and principles specific to diagnostic radiology settings. | https://op.europa.eu/o/opportal-service/download-handler?identifier=94c09d1b-9230-11ed-b508-01aa75ed71a1&format=PDF&language=en&productionSystem=cellar |
| HSE Midwest Oral Health Services Ionising Radiation Protection Policy | This resource contains guidance and audit templates in relation to medical exposures to ionising radiation. | https://www.hse.ie/eng/services/publications/primary/hse-mid-west-community-healthcare-oral-health-services-ionising-radiation-protection-policy-part-a1.pdf |
| IDA website | In the members only area, this resource contains guidance and audit templates in relation to medical exposures to ionising radiation. | https://www.dentist.ie/ |

| | | |
|---|---|---|
| Esperanto ESR guide to clinical audit | This resource from the European Society of Radiologists provides a wide range of audit templates that could be adopted or adapted for local use | https://www.myesr.org/media/4136 |
| Auditlive UK | This resource from the Royal College of Radiologists provides a wide range of audit templates that could be adopted or adapted for local use Search audit templates by key word such as 'justification' | https://www.rcr.ac.uk/clinical-radiology/audit-and-qi/auditlive |

# Appendix 7 – Radiology - diagnostic and interventional settings audit topics

Examples of topics in both the diagnostic and interventional radiology setting are provided. These topics have been adapted from the European Commission's Radiation Protection series no. 159 – Guidelines on Clinical Audit for Medical radiological procedures (Diagnostic Radiology, Nuclear Medicine and Radiotherapy). These examples are not an exhaustive list. Undertakings should develop their topics based on the national procedures in line with the complexity of the service and the level of radiological risk within the service. At the end of this table please find additional resources.

**For smaller practices using plain X-ray and DXA, Appendix 6 might be more appropriate to follow.**

| Type | Topic | Description |
|---|---|---|
| **Structure** | Organisation and management structure | ▪ Assessing how lines of accountability and reporting structures operate in practice against documented lines of accountability and reporting structures can provide assurances that they are clear and are functioning.<br>▪ Assessing that the unit/department staffing levels and required resources are proportionate with service demand can provide assurances of safe staffing and resource levels. |
| | Allocation of responsibilities | ▪ Assessing practice against local policies that describe the allocation and delegation of responsibilities including shared responsibilities. This can provide assurances that delegation is working as intended and not leading to any issues such as lack of clarity of responsibilities or miscommunications.<br>▪ Assessing the continuity of appropriate personnel throughout the patient journey can provide assurance that the most appropriate personnel are involved in the patient's care at the right point in their care journey. |

| Type | Topic | Description |
|---|---|---|
| | Personnel, education and training | ▪ Assessing up-to-date training records, supervision and observation of practice can provide assurance that all staff have adequate training for their responsibilities and the duties and tasks they carry out as part of their work. |
| | Premises and equipment | ▪ The infrastructure should be assessed to ensure that it meets the required specifications to ensure the safety of the environment in which care is provided.<br>▪ Inventories of medical radiological equipment for each medical radiological installation should be up to date and reviewed regularly to provide assurances that oversight is in place of potential issues such as equipment nearing the end of its useful life.<br>▪ Review of records of all medical radiological equipment should be kept under strict surveillance, for example, acceptance testing, performance testing, equipment maintenance, fault and error logs, records of any corrective actions to provide assurances of quality and functionality of equipment. |
| | | |
| **Process** | Referral process | ▪ Practice should be assessed for compliance with written policies, procedures and guidelines which define:<br>▪ who is entitled to refer to a practitioner for a medical exposure,<br>▪ the processes and procedures in place for accepting referrals,<br>▪ how the undertaking is assured each referral is from a referrer.<br>This is to ensure the process is being adhered to. This can be achieved by reviewing a sample of records and or observing the process in practice several times. |
| | Justification process | ▪ Practice should be assessed for compliance with written policies, procedures, protocols and guidelines for justification of individual |

| Type | Topic | Description |
|---|---|---|
| | | exposures that include those involved and responsible for justification to ensure the process is being adhered to. This can be achieved by reviewing a sample of records and or observing the process in practice several times. |
| | Diagnostic and treatment procedures | ▪ Practice should be assessed for compliance with written policies, procedures, protocols and guidelines for all processes in place for example:<br>▪ patient identification process<br>▪ pregnancy determination and breastfeeding status process<br>▪ that the provision of information on risks and benefits of exposure as appropriate, in advance of exposure.<br>▪ To ensure the process is being adhered to. This can be achieved by reviewing a sample of records and or observing the process in practice several times. |
| | Optimisation | ▪ Practice should be assessed for compliance with written policies, procedures, protocols and guidelines relevant to optimisation, for example:<br>▪ optimisation policy<br>▪ quality assurance<br>▪ dose management systems<br>▪ diagnostic reference levels<br>This is to ensure the process is being adhered to. This can be achieved by reviewing a sample of records and or observing the process in practice several times. |
| | Imaging process | ▪ Practice should be assessed for compliance with written, evidence based, approved, protocols for every type of standard medical exposure, for each type of equipment, and for relevant categories of patients to |

| Type | Topic | Description |
|---|---|---|
| | | ensure they are being adhered to. This should include evidence that there are processes in place to assess the quality of images. |
| | Diagnostic Report | ▪ A sample of examinations should be assessed to ensure that a documented image report has been produced and meets the agreed standard. The image report should include the examination type and information about the dose received by the patient. |
| | Records | ▪ The system in place to manage records should be assessed to ensure that the management of biographical, clinical and imaging data is meeting the required standard and managed in line with GDPR and legal requirements. |
| | Quality Management | ▪ The quality management system should be assessed to ensure that there is documented evidence that:<br>▪ policies and procedures are regularly audited and peer reviewed<br>▪ records of patients or people using the service are maintained in line with GDPR<br>▪ the quality assurance programme for equipment is implemented, maintained and aligned with the requirements of the regulations<br>▪ an appropriate programme of assessment of dose is in place and functioning well. |
| | Incident reporting and management | ▪ Practice should be assessed for compliance with written policies, procedures, protocols and guidelines on the identification, reporting and management of accidental and unintended exposures and significant events to ensure the process is being adhered to. This can be achieved by reviewing a sample of records and or observing the process in practice several times. |

| Type | Topic | Description |
|---|---|---|
| **Outcome** | Outcome of procedure | ▪ The system in place to monitor the outcome of radiological procedures should be assessed to ensure that documented evidence of observations and recording of short term results, for example success of diagnosis, acute side effects are in place. |

| **Literature and resources diagnostic and interventional radiology**<br>This list may be useful in informing clinical audit but is not an exhaustive list. | | |
|---|---|---|
| **Resource** | **Description** | **Reference** |
| European Commission's Radiation Protection series no. 198 – Current Status and Recommendations for Improving Uptake and Implementation of Clinical Audit of Medical Radiological Procedures | This resource provides information on enablers to maximise the impact and implementation of clinical audit. It contains a literature review outlining general principles of clinical audit and principles specific to diagnostic radiology settings. | https://op.europa.eu/o/opportal-service/download-handler?identifier=94c09d1b-9230-11ed-b508-01aa75ed71a1&format=PDF&language=en&productionSystem=cellar |
| Esperanto ESR guide to clinical audit | This resource from the European Society of Radiologists provides a wide range of audit templates | https://www.myesr.org/media/4136 |

| | | |
|---|---|---|
| | that could be adopted or adapted for local use | |
| Auditlive, Royal College of Radiologists, London, UK. | This resource from the Royal College of Radiologists provides a wide range of audit templates that could be adopted or adapted for local use | https://www.rcr.ac.uk/clinical-radiology/audit-and-qi/auditlive |
| The Royal College of Radiologists iRefer guide | This resource from the Royal College of Radiologists provides detailed referral guidelines for medical radiological procedures. | https://www.irefer.org.uk/ |
| ACR Appropriateness Criteria® \| American College of Radiology | The ACR Appropriateness Criteria® (AC) are evidence-based guidelines to assist referring physicians and other providers in making the most appropriate imaging or treatment decision for a specific clinical condition. | https://www.acr.org/Clinical-Resources/ACR-Appropriateness-Criteria |

| | | |
|---|---|---|
| International Atomic Energy Agency (IAEA) Human Health Series No.4 Comprehensive Clinical Audits of Diagnostic Radiology Practices: A Tool for Quality Improvement 2010 | This resource sets out principles and criteria for good practice in relation to organisation and management structure and radiological procedures – designed as an external audit tool | https://www.iaea.org/publications/8187/comprehensive-clinical-audits-of-diagnostic-radiology-practices-a-tool-for-quality-improvement |
| European Society of Radiology iGuide | This resource from the European Society of Radiology ESR, provides guidance for appropriate imaging | https://www.myesr.org/esriguide |
| European Society of Radiology eGuide | This resource from the European Society of Radiology ESR is an educational guide which utilises the ESR iGuide as a learning tool | http://www.eurosafeimaging.org/esr-eguide |
| EuroSafe Imaging Together - for patient safety | These resources and guidance relate to what patients should know about radiological procedures | http://www.eurosafeimaging.org/information-for-patients/what-patients-should-know |

| | | |
|---|---|---|
| ESR Eurosafe Imaging Paper | This resource outlines how the EuroSafe Imaging initiative has impacted on the promotion of radiation protection within services using medical ionising radiation | Frija, G., Hoeschen, C., Granata, C. et al. ESR EuroSafe Imaging and its role in promoting radiation protection – 6 years of success. Insights Imaging 12, 3 (2021). https://doi.org/10.1186/s13244-020-00949-5 |
| European Society of Radiology (ESR) (2020) Performance indicators for radiation protection management—suggestions from the European society of radiology. Insights Imaging. | This resource provides suggestions from the European Society of Radiology for measuring performance in relation to radiation protection within healthcare services | https://doi.org/10.1186/s13244-020-00923-1 |
| Diagnostic Reference Levels – Health Information and Quality Authority HIQA | This resource provides guidance on the establishment, use and review of diagnostic reference levels for medical exposure to ionising radiation | https://www.hiqa.ie/sites/default/files/2021-07/Diagnostic-Reference-Levels_Undertaking-guidance.pdf |
| ESR Eurosafe Imaging Paper | This resource provides requirements and recommendations from the EuroSafe imaging initiative | Loose RW, Vano E, Mildenberger P et al (2020) Radiation dose management systems—requirements and recommendations for users |

| | | |
|---|---|---|
| | in relation to radiation dose management systems | from the ESR EuroSafe Imaging initiative. Eur Radiol. https://doi.org/10.1007/s00330-020-07290-x |
| ESR Eurosafe Imaging Paper | This resource provides practical advice and guidance from the EuroSafe imaging initiative in relation to harmonisation of imaging dosimetry in clinical practice | Vano E, Frija G, Stiller W et al (2020) Harmonisation of imaging dosimetry in clinical practice: practical approaches and guidance from the ESR EuroSafe Imaging initiative. Insights Imaging 11:54. https://doi.org/10.1186/s13244-020-00859-6 |

# Appendix 8 – Nuclear Medicine - diagnostic and therapy settings audit topics

Examples of topics in both the diagnostic nuclear medicine and radiotherapeutic nuclear medicine setting are provided. These topics have been adapted from the European Commission's Radiation Protection series no. 159 – Guidelines on Clinical Audit for Medical radiological procedures (Diagnostic Radiology, Nuclear Medicine and Radiotherapy). These examples are not an exhaustive list. Undertakings should develop their topics based on the national procedures in line with the complexity of the service and the level of radiological risk within the service. At the end of this table please find additional resources. The topics that apply to radiotherapeutic nuclear medicine only are identified.

| Type | Topic | Description |
|---|---|---|
| **Structure** | Organisation and management structure | ▪ Assessing how lines of accountability and reporting structures operate in practice against documented lines of accountability and reporting structures can provide assurances that they are clear and are functioning.<br>▪ Assessing that the unit/department staffing levels and required resources are proportionate with service demand can provide assurances of safe staffing and resource levels. |
| | Allocation of responsibilities | ▪ Assessing practice against local policies that describe the allocation and delegation of responsibilities including shared responsibilities. This can provide assurances that delegation is working as intended and not leading to any issues such as lack of clarity of responsibilities or miscommunications.<br>▪ Assessing the continuity of appropriate personnel throughout the patient journey can provide assurance that the most appropriate personnel are involved in the patient's care at the right point in their care journey. |

| Type | Topic | Description |
|---|---|---|
| | Personnel, education and training | ▪ Assessing up-to-date training records, supervision and observation of practice can provide assurance that all staff have adequate training for their responsibilities and the duties and tasks they carry out as part of their work. |
| | Premises and equipment | ▪ The infrastructure should be assessed to ensure that it meets the required specifications to ensure the safety of the environment in which care is provided.<br>▪ Inventories of medical radiological equipment for each medical radiological installation should be up to date and reviewed regularly to provide assurances that oversight is in place of potential issues such as equipment nearing the end of its useful life.<br>▪ Review of records of all medical radiological equipment should be kept under strict surveillance, for example, acceptance testing, performance testing, equipment maintenance, fault and error logs, records of any corrective actions to provide assurances of quality and functionality of equipment. |
| | | |
| **Process** | Referral process | ▪ Practice should be assessed for compliance with written policies, procedures and guidelines which define:<br>▪ who is entitled to refer to a practitioner for a medical exposure,<br>▪ the processes and procedures in place for accepting referrals,<br>▪ how the undertaking is assured each referral is from a referrer.<br>This is to ensure the process is being adhered to. This can be achieved by reviewing a sample of records and or observing the process in practice several times. |

| Type | Topic | Description |
|---|---|---|
| | | Radiotherapeutic nuclear medicine:<br>▪ Practice should be assessed for compliance with written policies, procedures and guidelines defining referral criteria and the process to access treatment to ensure the process is being adhered to. This can be achieved by reviewing a sample of records and or observing the process in practice several times. |
| | Justification process | ▪ Practice should be assessed for compliance with written policies, procedures, protocols and guidelines for justification of individual exposures that include those involved and responsible for justification to ensure the process is being adhered to. This can be achieved by reviewing a sample of records and or observing the process in practice several times. |
| | | Radiotherapeutic nuclear medicine:<br>▪ Practice should be assessed for compliance with written policies, procedures, protocols and guidelines relating to treatment decision to ensure that decisions have been made by a full multidisciplinary team in accordance with evidence based guidelines and using the required minimum dataset for treatment decisions. |
| | Diagnostic and treatment procedures | ▪ Practice should be assessed for compliance with written policies, procedures, protocols and guidelines for all processes in place for example:<br>▪ patient identification process<br>▪ pregnancy determination and breastfeeding status process<br>▪ that the provision of information on risks and benefits of exposure as appropriate, in advance of exposure. |

| Type | Topic | Description |
|---|---|---|
| | | This is to ensure the process is being adhered to. This can be achieved by reviewing a sample of records and or observing the process in practice several times. |
| | Optimisation | ▪ Practice should be assessed for compliance with written policies, procedures, protocols and guidelines relevant to optimisation, for example:<br>▪ optimisation policy<br>▪ quality assurance<br>▪ dose management systems<br>▪ diagnostic reference levels<br>This is to ensure the process is being adhered to. This can be achieved by reviewing a sample of records and or observing the process in practice several times. |
| | Imaging process | ▪ Practice should be assessed for compliance with written, evidence based, approved, protocols for every type of standard medical exposure, for each type of equipment, and for relevant categories of patients to ensure they are being adhered to. This should include evidence that there are processes in place to assess the quality of images. |
| | Treatment process | Radiotherapeutic nuclear medicine:<br>▪ A sample of treatment plans should be assessed to ensure that treatment planning has been performed according to the relevant internationally accepted system and a dosimetric analysis of optimal administered activity has been performed.<br>▪ Practice should be assessed for compliance with written policies, procedures, protocols and guidelines relevant to treatment delivery, for example:<br>▪ actions in relation to significant deviation from outcomes |

| Type | Topic | Description |
|---|---|---|
| | | ▪ management of side effects<br>This is to ensure the process is being adhered to. This can be achieved by reviewing a sample of records and or observing the process in practice several times. |
| | Diagnostic Report | ▪ A sample of examinations should be assessed to ensure that a documented image report has been produced and meets the agreed standard. The image report should include the examination type and information about the dose received by the patient. |
| | Records | ▪ The system in place to manage records should be assessed to ensure that the management of biographical, clinical and imaging data is meeting the required standard and managed in line with GDPR and legal requirements. |
| | | Radiotherapeutic nuclear medicine:<br>▪ A sample of treatment records should be assessed to ensure that the agreed minimum dataset has been recorded and is accurate so that the treatment delivered to the patient can be recalculated based on the recorded information if required. |
| | Quality Management | ▪ The quality management system should be assessed to ensure that there is documented evidence that:<br>▪ policies and procedures are regularly audited and peer reviewed<br>▪ records of patients or people using the service are maintained in line with GDPR<br>▪ the quality assurance programme for equipment is implemented, maintained and aligned with the requirements of the regulations<br>▪ an appropriate programme of assessment of dose is in place and functioning well. |

| Type | Topic | Description |
|---|---|---|
| | Incident reporting and management | ▪ Practice should be assessed for compliance with written policies, procedures, protocols and guidelines on the identification, reporting and management of accidental and unintended exposures and significant events to ensure the process is being adhered to. This can be achieved by reviewing a sample of records and or observing the process in practice several times. |
| | | |
| **Outcome** | Outcome of procedure | ▪ The system in place to monitor the outcome of radiological procedures should be assessed to ensure that documented evidence of observations and recording of short term results for example success of diagnosis, acute side effects are in place. |
| | Clinical outcome | Radiotherapeutic nuclear medicine:<br>▪ There are systems in place to monitor clinical outcomes including inefficacy, side effects, morbidity and survival should be assessed to ensure that outcome data is routinely recorded. |

| **Literature and resources – diagnostic nuclear medicine and radiotherapeutic nuclear medicine**<br>The following resources may be useful in informing clinical audit, this is not an exhaustive list. | | |
|---|---|---|
| **Resource** | **Description** | **Reference** |
| European Commission's Radiation Protection series no. 198 – Current Status and Recommendations for Improving Uptake and Implementation of Clinical Audit of Medical Radiological Procedures | This resource provides information on enablers to maximise the impact and implementation of clinical audit. It contains a literature review outlining general principles of clinical audit and principles specific to nuclear medicine settings. | https://op.europa.eu/o/opportal-service/download-handler?identifier=94c09d1b-9230-11ed-b508-01aa75ed71a1&format=PDF&language=en&productionSystem=cellar |
| QUANUM 3.0: An Updated Tool for Nuclear Medicine Audits. Third Edition. 2021 | This resource provides a detailed description of the quality management systems that should be in place in nuclear medicine services covering both diagnostic and nuclear medicine therapy.<br>Clinical audit checklists are provided – these are designed for use by external auditors, however, they can | https://www.iaea.org/publications/13619/quanum-30-an-updated-tool-for-nuclear-medicine-audits |

| | | |
|---|---|---|
| | be used for internal audit purposes also. | |
| International Atomic Energy Agency Quality Management Audits in Nuclear Medicine (QUANUM) papers | These resources provide information on the practical implementation of the Quality Management Audits in Nuclear Medicine - QUANUM programme. | Dondi M, Torres L, Marengo M, Massardo T, Mishani E, Van Zyl Ellmann A, et al. Comprehensive Auditing in Nuclear Medicine Through the International Atomic Energy Agency Quality Management Audits in Nuclear Medicine (QUANUM) Program. Part 1: the QUANUM Program and Methodology. Semin Nucl Med. 2017;47(6):680-6.<br><br>https://pubmed.ncbi.nlm.nih.gov/28969766/ |
| | Part 1 details the QUANUM programme and methodology<br><br>Part 2 provides and analysis of results<br><br>Part 3 provides outcome analysis | Dondi M, Torres L, Marengo M, Massardo T, Mishani E, Van Zyl Ellmann A, et al. Comprehensive Auditing in Nuclear Medicine Through the International Atomic Energy Agency Quality Management Audits in Nuclear Medicine Program. Part 2: Analysis of Results. Semin Nucl Med. 2017;47(6):687-93.<br><br>https://pubmed.ncbi.nlm.nih.gov/28969767/ |
| | | Dondi M, Paez D, Torres L, Marengo M, Delaloye AB, Solanki K, et al. Implementation of Quality Systems in Nuclear Medicine: Why It Matters. An Outcome Analysis (Quality Management Audits in Nuclear Medicine Part III). Semin Nucl Med. 2018;48(3):299-306.<br><br>https://pubmed.ncbi.nlm.nih.gov/29626946/ |

# Appendix 9 – Radiotherapy setting audit topics

Examples of topics in the radiotherapy setting are provided. These topics have been adapted from the European Commission's Radiation Protection series no. 159 – Guidelines on Clinical Audit for Medical radiological procedures (Diagnostic Radiology, Nuclear Medicine and Radiotherapy). These examples are not an exhaustive list. Undertakings should develop their topics based on the national procedures in line with the complexity of the service and the level of radiological risk within the service. At the end of this table please find additional resources.

| Type | Topic | Description |
|---|---|---|
| **Structure** | Organisation and management structure | ▪ Assessing how lines of accountability and reporting structures operate in practice against documented lines of accountability and reporting structures can provide assurances that they are clear and are functioning. |
| | Allocation of responsibilities | ▪ Assessing practice against local policies that describe the allocation and delegation of responsibilities including shared responsibilities. This can provide assurances that delegation is working as intended and not leading to any issues such as lack of clarity of responsibilities or miscommunications.<br>▪ Assessing the continuity of appropriate personnel throughout the patient journey can provide assurance that the most appropriate personnel are involved in the patient's care at the right point in their care journey. |
| | Personnel, education and training | ▪ Assessing up-to-date training records, supervision and observation of practice can provide assurance that all staff have adequate training for their responsibilities and the duties and tasks they carry out as part of their work. |

| Type | Topic | Description |
|---|---|---|
| | Premises and equipment | ▪ The infrastructure should be assessed to ensure that it meets the required specifications to ensure the safety of the environment in which care is provided.<br>▪ Inventories of medical radiological equipment for each medical radiological installation should be up to date and reviewed regularly to provide assurances that oversight is in place of potential issues such as equipment nearing the end of its useful life.<br>▪ Review of records of all medical radiological equipment should be kept under strict surveillance, for example, acceptance testing, performance testing, equipment maintenance, fault and error logs, records of any corrective actions to provide assurances of quality and functionality of equipment. |
| | | |
| **Process** | Referral process | ▪ Practice should be assessed for compliance with written policies, procedures and guidelines defining referral criteria and the process to access radiotherapy treatment to ensure the process is being adhered to. This can be achieved by reviewing a sample of records and or observing the process in practice several times. |
| | Justification process | ▪ Practice should be assessed for compliance with written policies, procedures, protocols and guidelines relating to treatment decision to ensure that decisions have been made by a full multidisciplinary team in accordance with evidence based guidelines and using the required minimum dataset for treatment decisions.<br>▪ Practice should be assessed for compliance with written policies, procedures, protocols and guidelines for justification of individual exposures that include those involved and responsible for justification to ensure the process is being adhered to. This can be achieved by |

| Type | Topic | Description |
|---|---|---|
| | | reviewing a sample of records and or observing the process in practice several times. |
| | Diagnostic and treatment procedures | ▪ Practice should be assessed for compliance with written policies, procedures, protocols and guidelines for all processes in place for example:<br>▪ patient identification process<br>▪ pregnancy determination and breastfeeding status process<br>▪ that the provision of information on risks and benefits of exposure as appropriate, in advance of exposure.<br>This is to ensure the process is being adhered to. This can be achieved by reviewing a sample of records and or observing the process in practice several times. |
| | Optimisation | ▪ Practice should be assessed for compliance with written policies, procedures, protocols and guidelines relevant to optimisation, for example:<br>▪ Contouring target volumes and organs at risk<br>▪ Optimised and evaluated treatment plans<br>▪ quality assurance<br>▪ dose management systems<br>This is to ensure the process is being adhered to. This can be achieved by reviewing a sample of records and or observing the process in practice several times. |
| | Imaging process | ▪ Practice should be assessed for compliance with written, evidence based, approved, protocols for every type of standard medical exposure, for each type of equipment, and for relevant categories of patients to |

| Type | Topic | Description |
|---|---|---|
| | | ensure they are being adhered to. This should include evidence that there are processes in place to assess the quality of images. |
| | Treatment process | ▪ A sample of treatment plans should be assessed to ensure that treatment planning has been performed according to the relevant internationally accepted system and in accordance with protocols where treatment have been combined for example the combination of brachytherapy and external beam therapy.<br>▪ Practice should be assessed for compliance with written policies, procedures, protocols and guidelines relevant to treatment delivery, for example:<br>▪ patient immobilisation<br>▪ treatment imaging technique<br>▪ verification of treatment parameters<br>▪ actions in relation to significant deviation from outcomes<br>▪ management of side effects<br>This is to ensure the process is being adhered to. This can be achieved by reviewing a sample of records and or observing the process in practice several times. |
| | Records | ▪ A sample of treatment records should be assessed to ensure that the agreed minimum dataset has been recorded and is accurate so that the treatment delivered to the patient can be recalculated based on the recorded information if required.<br>▪ The system in place to manage records should be assessed to ensure that the management of biographical, clinical and imaging data is meeting the required standard and managed in line with GDPR and legal requirements. |

| Type | Topic | Description |
|---|---|---|
| | Quality Management | ▪ The quality management system should be assessed to ensure that there is documented evidence that:<br>▪ policies and procedures are regularly audited and peer reviewed<br>▪ records of patients or people using the service are maintained in line with GDPR<br>▪ the quality assurance programme for equipment is implemented, maintained and aligned with the requirements of the regulations<br>▪ an appropriate programme of assessment of dose is in place and functioning well. |
| | Incident reporting and management | ▪ Practice should be assessed for compliance with written policies, procedures, protocols and guidelines on the identification, reporting and management of accidental and unintended exposures and significant events to ensure the process is being adhered to. This can be achieved by reviewing a sample of records and or observing the process in practice several times. |
| | | |
| **Outcome** | Clinical outcome | ▪ There are systems in place to monitor clinical outcomes including inefficacy, side effects, morbidity and survival should be assessed to ensure that outcome data is routinely recorded. |

| **Literature and resources – radiotherapy**<br>The following resources may be useful in informing clinical audit, this is not an exhaustive list. | | |
|---|---|---|
| **Resource** | **Description** | **Reference** |
| European Commission's Radiation Protection series no. 198 – Current Status and Recommendations for Improving Uptake and Implementation of Clinical Audit of Medical Radiological Procedures | This resource provides information on enablers to maximise the impact and implementation of clinical audit. It contains a literature review outlining general principles of clinical audit and principles specific to radiotherapy settings. | https://op.europa.eu/o/opportal-service/download-handler?identifier=94c09d1b-9230-11ed-b508-01aa75ed71a1&format=PDF&language=en&productionSystem=cellar |
| Comprehensive Audits of Radiotherapy Practices: A Tool for Quality Improvement. Quality Assurance Team for Radiation Oncology (QUATRO), Second Edition. International Atomic Energy Agency (IAEA), 2022. | QUATRO audits have been carried out by the IAEA external QUATRO auditor teams in radiotherapy departments for over 20 years. This resource sets out a number of comprehensive audits of radiotherapy practices including infrastructure, equipment and procedure audits. | https://www.iaea.org/publications/14754/comprehensive-audits-of-radiotherapy-practices-a-tool-for-quality-improvement |

| | | |
|---|---|---|
| National Quality Assurance Framework for Radiation Oncology in Ireland. National Cancer Control Programme, Health Service Executive. 2021. | This resource provides guidance on quality indicators for radiation oncology services.<br><br>Appendices include a local facility self-assessment tool and EC recommendations of standards for radiotherapy audit. | https://www.hse.ie/eng/services/list/5/cancer/profinfo/radonc/radiation-oncology-quality-assurance-framework.pdf |
| IAEA survey paper | This resource provides results of a survey of radiotherapy departments' current practice in relation to quality assurance activities. | Healy BJ, Budanec M, Ourdane B, Peace T, Petrovic B, Sanz DE, et al. An IAEA survey of radiotherapy practice including quality assurance extent and depth. Acta Oncol. 2020;59(5):503-10.<br><br>https://pubmed.ncbi.nlm.nih.gov/31973620/ |
| American Association of Physicists in Medicine | This resource describes methodology for improving quality and safety of services by focussing on weaknesses and variability in radiotherapy processes. | Huq MS, Fraass BA, Dunscombe PB, et al. The report of Task Group 100 of the AAPM: application of risk analysis methods to radiation therapy quality management. Med Phys. 2016;43(7):4209–4262.<br><br>https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4985013/ |

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