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ESPERANTO

4th Edition

Guide to Clinical Audit in Radiology

EUROPEAN SOCIETY OF RADIOLOGY

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Esperanto - Guide to Clinical Audit in Radiology

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CLAUD·IT

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1 / Esperanto – Purpose and Scope

This fourth iteration of the Guide to Clinical Audit in Radiology offers an enhanced clinical audit guide and an expanded section of audit templates. The purpose of this document is to further increase awareness and understanding of clinical audit within radiology departments across Europe and to support departments in developing effective clinical audit practice and processes. The guide has been developed based on *ESPERANTO - ESR Guide to Clinical Audit in Radiology and the ESR Clinical Audit Tool, 3rd Edition*, and as a part of the EU co-funded project CLAUD-IT.

This version of Esperanto maintains a broad selection of regulatory audit templates, as implementation of the mandatory requirements remains a high priority for radiology departments. The clinical audits have been updated, with 33 new templates addressing areas such as radiation protection, AI, justification, magnetic resonance imaging (MRI) safety and value-based radiology, among others, to enhance support for radiation protection and compliance with the Basic Safety Standards Directive (BSSD; see section 3)." Clinical audit as part of BSSD compliance is mandatory and subject to inspection, and a key aim of AUDITRAD: ESPERANTO for Radiology, 4th Edition, is to support radiology departments in this area.

This clinical audit guide outlines and defines various types of clinical audits, including self-assessment/internal audits, external audits, and internal audits conducted with external guidance. It emphasizes the critical role of clinical audits as required by the BSSD and their connection to inspections conducted by the relevant national radiation protection authority.

The guide and accompanying tool are designed to assist radiology departments in embedding clinical audit processes into routine practice. Emphasis is placed on meeting regulatory requirements and supporting the prioritization of clinical audit processes. Furthermore, the guide underscores the value of participation in clinical audits as a means of enhancing patient care and outcomes, encouraging active involvement to drive continuous improvement.

2 / Clinical Audit and Clinical Governance – an Introduction

Clinical audit in modern healthcare emerged as a concept in the late 1990s as part of the process of clinical governance. Clinical audit is an important tool within clinical governance and can be used to improve patient care, safety, experience and outcomes. Clinical audit is defined later in this document.

Clinical governance is defined as a framework through which healthcare organisations are accountable for continuously improving the quality of their services and safeguarding high standards of care by creating an environment in which excellence in clinical care can flourish. There are seven "pillars" of clinical governance:

- ★★ Service user, carer, public involvement
- ★★ Risk management
- ★★ Clinical audit
- ★★ Staffing/staff management
- ★★ Education and training
- ★★ Clinical effectiveness
- ★★ Clinical information

These structures and processes are fully integrated with other aspects of healthcare governance, including:

- ★★ Financial governance
- ★★ Information/information technology governance
- ★★ Research governance

3 / Clinical Audit – the ESR and the European Legal Perspective

The ESR works collaboratively with other organisations, including the European Commission and the Heads of the European Radiation Protection Competent Authorities (HERCA) to improve patient safety and quality of care throughout Europe.

Clinical audit is particularly important to radiologists and all professionals within the multi-professional imaging team, not only because it is an established and useful tool in healthcare which should be part of medical services across Europe, but also because of its incorporation into the Medical Exposure Directive 97/43/Euratom, which was subsequently replaced by the BSSD (Council Directive 2013/59/Euratom [1]), which comprehensively addresses the use of ionising radiation.

Recognizing that clinical audit was already a component of good practice in healthcare delivery established by national procedures, the text in both Directives was intentionally non-prescriptive. Member States involved in negotiating these Directives along with European Commission officials and the Council of the European Union acknowledged the significance of clinical audit within the broader healthcare context. They deliberately avoided imposing unhelpful or unnecessary conditions through the legal framework of the European Commission Directive.

Following adoption by the Council of the European Union, Member States had 4 years (i.e., until 6 February 2018) to bring into force the laws, regulations and administrative provisions necessary to transpose the Directive. According to the BSSD, carrying out clinical audit "in accordance with national procedures" is mandatory and a legal requirement within the European Union.

The BSSD has brought about major implications for European radiological practice in several areas within the field of radiation protection, including:

- ★★ Laying down basic safety standards for protection against the dangers of ionising radiation
- ★★ Emphasising the need for justification of medical exposure
- ★★ Introducing patient information requirements
- ★★ Strengthening requirements for recording and reporting doses from radiological procedures

Directives are addressed to Member States, and the European Commission generally favours fulfilling requirements through legislation rather than administrative measures. However, it is ultimately the responsibility of each Member State to determine how these requirements are implemented within its national legislation. In this process, Member States are encouraged to utilize the open wording of the Directive to align with existing legislation and administrative practices, ensuring consistency and coherence.

As the responsibility for transposition and implementation of the BSSD lies with the Member State, clinical audit cannot be delegated entirely to professional bodies. Nonetheless, many European Commission officials acknowledge the significant role clinical audit plays in influencing healthcare standards on a daily basis. While inspection remains a crucial aspect of regulatory compliance, it is not sufficient on its own to drive improvements in patient safety and care. Officials emphasize the importance of understanding the role of local clinical audits and encouraging active participation by local practitioners in audit activities. This approach is seen as fundamental to fostering a culture of regular quality assurance and continuous improvement in patient services.

The Directive does not make specific reference to internal audit (including self-assessment), external audit or internal audit with external direction. They are included within the European Commission document RP No. 159 – European Guidelines on Clinical Audit for Medical Radiological Practices (Diagnostic Radiology, Nuclear Medicine and Radiotherapy) [2]. (See section 11).

Clinical audit must be conducted by Member States in response to the requirements of Article 58(e) of the BSSD. These audits can be performed through various methods aligned with other established clinical audit procedures within Member States. However, regardless of the approach taken, greater awareness and understanding among imaging professionals and licence holders is needed regarding the clinical audit requirements within the legislative framework for radiation protection.

When the Member State's regulatory authority conducts inspections under national legislation, it is likely to engage in discussions about clinical audit processes with representatives of the licence holder. These discussions may also involve the institution's radiology and radiation protection professionals. In healthcare, and specifically in radiology, the licence holder typically refers to the legal entity ("the undertaking," as defined in the BSSD) responsible for the practices or activities conducted at a facility, including within the radiology department.

The licence, issued by a national authority, provides regulatory control through specific restrictions or conditions tied to the licensed activities. The organisation will provide the framework for clinical activities, while radiology professionals are responsible for specific operational aspects such as justification and optimisation.

Recognising its unique and key position in this process, the ESR is working with stakeholders to facilitate the implementation of the BSSD and support processes of clinical audit:

- ★★ To increase awareness amongst health professionals within radiology of the importance, principles and practice of clinical audit both as a key component of effective clinical governance and as mandated by the BSSD [3].
- ★★ To promote understanding and uptake of the concepts outlined within the BSSD, and the important role of clinical audit as referred to within the Directive.
- ★★ To provide health professionals and radiology departments with an audit guide and toolkit to support effective clinical audit

4 / What is Clinical Audit

Clinical audit as defined within the BSSD:

"A systematic examination or review of medical radiological procedures that 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." [1]

Or another definition:

"Audit involves improving the quality of patient care by looking at current practice and modifying where necessary" [4].

Clinical audit involves three core components: – [4]

a) Recognisably high standards of care
b) Transparent responsibility and accountability for those standards
c) A constant dynamic of improvement

The ALPINE principle is a guiding framework for most clinical audits, particularly those conducted at the individual or departmental level. It emphasizes that clinical audits should be Achievable, Local, Practical, Inexpensive, Non-threatening and Easy, ensuring accessibility and feasibility in everyday practice.

While a comprehensive discussion of quality improvement is beyond the scope of this document, clinical audit can be viewed as a quality improvement cycle that involves measuring the effectiveness of care against agreed/ proven standards. High-quality healthcare should adhere to the following principles: it must be safe, effective, patient-centred, timely, efficient and equitable.

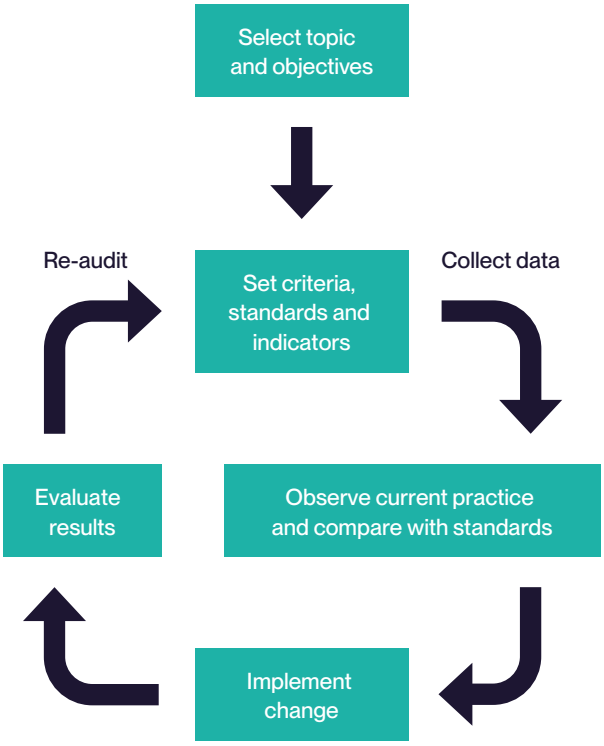
5 / Clinical Audit – Importance and Scope

High-quality clinical audit offers significant benefits to patients, radiology departments, and clinical services by:

- ★★ Promoting and facilitating high-quality medical care
- ★★ Providing opportunities for education, teaching, and interdisciplinary collaboration
- ★★ Driving improvements in the quality of care
- ★★ Demonstrating a commitment to patient and staff safety as well as compliance with the requirements outlined in the BSSD

6 / The Audit Cycle – Methodology

A complete audit involves a series of steps, the "audit cycle" – see the figure below.



As recommended, clinical audit has a wide potential scope [3], covering all components of the patient care pathway under the categories of structure, process and outcome.

- ★★ Structure – includes lines of authority, professional roles and radiation protection responsibilities, premises, equipment and information systems
- ★★ Process – justification and referral processes, protocols, optimisation procedures, patient dose assessment, image quality, emergency incident procedures and reliability of patient image/data transfer
- ★★ Outcome – includes methods for follow-up of the outcome of examinations/procedures, over both short and longer term. Outcome audits tend to be most labour intensive but can provide powerful data.

If a clinical audit reveals a failure to meet the established audit standard, confirming the need for service improvement, then a key component of the audit cycle is conducting a re-audit after implementing practice change(s). This process ensures that the service has improved, effectively "closing the audit loop" or "completing the audit cycle."

For specific aspects of radiological services and care, particularly those related to radiation protection as outlined in the BSSD — such as the review and use of diagnostic reference levels (DRLs) for radiodiagnostic examinations — service audits must be repeated periodically. The timing of these audits should align with local or national protocols. These periodic audits are required regardless of whether the target is met or not. Continued compliance requires that dose targets, for example, are met by DRL measurement and, when targets are not met, practice changes are documented.

7 / Clinical Audit vs Research

Clinical audit, like research projects, should be undertaken within an ethical framework that protects patient and staff identity/confidentiality, but some core differences between clinical audit and research may be observed [4]. Fundamentally, clinical audit, whether relating to clinical practice/service provision or in support of BSSD requirements, is based around compliance with targets/standards. In BSSD-related clinical audit, the standards are fixed and mandatory as set out within the BSSD [1].

Aspect	Clinical Audit	Research
Purpose	To ensure that current practice meets established standards and guidelines.	To generate new knowledge or validate existing knowledge.
Focus	Focused on measuring and improving quality of care.	Focused on answering specific research questions or testing hypotheses.
Standards	Compares current practice against existing standards or benchmarks.	No predefined standards; aims to discover or test principles.
Outcome	Identifies areas for improvement and confirms adherence to standards.	Produces generalizable results that can influence future practice or policy.
Process	Evaluates existing practices and makes changes to meet established criteria.	Conducts experiments, observations, or surveys to explore new concepts.
Methodology	Data collection focuses on compliance with specific standards (e.g., clinical guidelines).	Employs rigorous methodologies, including control groups and statistical analysis.
Participants	Typically involves staff and patients within a specific service or department.	May involve wider participant groups, including control groups, to test broader hypotheses.
Ethical approval	Usually does not require formal ethical approval if no new interventions are introduced.	Requires ethical approval, particularly if it involves new interventions or impacts patient care.
Application	Results are specific to the service or institution audited.	Results aim for general application across similar settings or disciplines.

8 / Clinical Audit and Value-Based Radiology

Clinical audit plays a pivotal role in the context of value-based radiology, which emphasizes delivering care that improves patient outcomes while optimizing resource utilization. By systematically evaluating radiological practices and outcomes against established standards, clinical audits help ensure that imaging services are not only clinically effective but also aligned with patient-centred goals. They enable the identification of inefficiencies, unnecessary procedures or areas where patient care can be enhanced.

Clinical audits support the principles of value-based care in:

- ★★ **Ensures Patient-Centred Care**: Clinical audits assess whether radiology services align with patient outcomes and prioritize patient needs, a cornerstone of value-based radiology.
- ★★ **Supports Justification and Optimization**: Audits help validate that imaging procedures are necessary and performed with optimized protocols, ensuring the best outcomes with minimal risks.
- ★★ **Promotes Resource Efficiency**: By identifying unnecessary imaging practices, audits contribute to the efficient use of healthcare resources, a key goal of value-based care.
- ★★ **Enhances Quality of Care**: Regular audits drive continuous improvement in imaging practices, ensuring high standards of clinical effectiveness and safety.
- ★★ **Improves Multidisciplinary Collaboration**: Audits foster communication and teamwork among radiologists, clinicians, and healthcare professionals to enhance decision-making and patient management.
- ★★ **Informs Cost-Effectiveness**: By identifying inefficiencies, audits contribute to balancing quality care with cost management in radiology services.
- ★★ **Strengthens Patient Safety**: Clinical audits help minimize unnecessary exposures and optimize imaging protocols, safeguarding patient well-being.

9 / Clinical Audit and AI

Artificial Intelligence (AI) is poised to transform radiology, potentially advancing diagnostic accuracy, workflow efficiency and personalised patient care. When implementing AI in radiology practice, clinical audits play a crucial role in ensuring that AI systems are performing safely, effectively and ethically. Auditing AI applications in radiology involves evaluating their performance against clinical standards (where available), monitoring their impact on diagnostic workflows and assessing their integration into patient-centred care pathways.

Clinical audits in AI should form part of a wider practice of post-market surveillance and is vital to help verify that algorithms perform consistently across diverse patient populations, identifying potential biases or areas where AI might underperform. Regular audits ensure that AI applications align with evidence-based practices, contributing to the quality and reliability of imaging interpretations.

Furthermore, AI-assisted clinical audits could enhance traditional auditing processes by automating data collection, identifying trends and offering actionable insights, thereby improving the efficiency and scope of quality assurance efforts. However, such AI itself would also need auditing to ensure its reliability in collecting relevant data.

With the adoption of AI in radiology practice, clinical audits become essential in balancing technological innovation and patient safety. They ensure that AI not only is applied in compliance with regulatory standards but also aligns with the principles of value-based care, including diagnostic effectiveness, resource optimization and equitable access. Combining AI and clinical audits potentially strengthens the culture of continuous quality improvement, fostering trust and value in imaging services.

Table: AI and Clinical Audit Considerations in Radiology

Aspect	Role of AI within Context	AI's Contribution
Performance monitoring	Identifies instances in which AI algorithms failed compared to established diagnostic standards	Automates performance tracking and identifies discrepancies or areas for improvement
Bias detection	Identifies instances of potential biases in AI performance across diverse patient populations or imaging modalities	Analysing local instances of AI failure to uncover patterns of variability or inequity in outcomes across different patient groups
Workflow integration	Ensures AI systems are seamlessly incorporated into existing radiology workflows	Optimises workflows by automating repetitive tasks and prioritising critical cases
Regulatory compliance	Confirms that AI applications are used in compliance with local, national, and international regulatory requirements	Provides documentation and traceability for compliance with standards (e.g., DRLs, GDPR)
Quality improvement	Monitors AI's impact on diagnostic quality and patient outcomes such as image quality, triage for specialist reviews, time efficiency savings	Generates insights for continuous improvement by identifying inefficiencies and errors in real-time, as well as staff/patient feedback
Patient safety	Evaluates the safety of AI-driven decisions to avoid misdiagnosis or missed diagnoses	Enhances radiation protection through dose optimization and error reduction

This table highlights how clinical audits and AI complement each other to ensure safe, effective and patient-centred radiology practices. It underscores the need for regular auditing to harness AI's benefits responsibly while maintaining high standards of care.

/ Setting Standards

Setting standards for expected performance or improvement in the workflow currently may be challenging for AI audits, as it is unlikely there is any national standard of quality. It will therefore be important for each audit evaluation of the specific AI to understand the core outcome in the care pathway intended to be monitored (e.g., is there a minimum turnaround time for reporting of certain studies, such as those for cancer imaging or emergency cases within the individual's healthcare system).

If there is no set standard available, then a few considerations may be warranted.

- Setting an expected level of improvement from prior status quo (pre-AI introduction), which would involve review of a prior audit where AI was not implemented and performing the audit again after the introduction of AI (e.g., percentage improvement expected for time efficiency, accuracy)
- Determining whether the AI performance matches those set by the vendor (e.g., false positive and false negative rates or the technical failure rates)
- For studies addressing differences in bias or performance across subgroups, determining what a significant difference would entail, as the prior standard and what subgroups are of interest in the population would be important.
- For work on patient safety, it the standard may be set to "never events" or significant adverse incidents occurring after introduction of AI rather than an evaluation of every possible pathology the AI could detect or minor errors

10 / Undertaking a Clinical Audit

A number of stages must be completed in the successful undertaking of a clinical audit. A draft, blank example audit template document is included in appendix 1.

Examples of clinical audit templates are included in appendix 2 (both clinical practice and also BSSD related), with regulatory audit topics found in appendix 3.

Below you will find an explanation of the process involved in undertaking a clinical audit. The points in this section can also be used to help complete additional suggested clinical audit templates.

STEPS WITHIN THE AUDIT CYCLE

1. Choose a Topic, Decide Objectives and an Audit Title

The audit topics:

- ★★ Should be of high priority
- ★★ May be compulsory (BSSD related)
- ★★ Or may be important on clinical grounds,

e.g., high risk or high-cost procedure

Objectives of the audit should be:

- ★★ Specific
- ★★ Measurable
- ★★ Achievable

2. Identify Resources

Identify the lead for the audit and other staff/time resources needed for data collection and analysis.

3. Define the Audit Standards

- ★★ Usually expressed as a target %
- ★★ May be a minimum standard, or an optimum (aspirational) standard depending on the topic
- ★★ Standards are usually derived following consultation with published literature, national/international or local guidelines and may be agreed following a consensus discussion amongst interested parties
- ★★ For some topics there is leeway for local auditing teams to decide on appropriate standards –

for other areas and in particular the radiation protection standards within the BSSD, the standards are fixed (and compulsory)

4. Confirm Item/Variable(s) to be Audited

5. Data Collection

- ★★ Identify source(s) of data, manual or computerised collection
- ★★ Decide on retrospective/prospective data collection

Sample details:

- ★★ Establish time period for data collection
- ★★ Establish sample size for each sample category e.g., number of patients, number of examinations
- ★★ Sample sizes will depend on the area under evaluation, the amount of information

being collected, ease of collection of data and resources available

6. Analyse Data

- ★★ Compare actual performance with the set standard
- ★★ Review if standard(s) (target) met
- ★★ Document reasons, possibilities for failure to meet a standard

7. Action Plan, Making Improvements

- ★★ Present audit results to local clinical/departmental teams
- ★★ Develop an action plan identifying changes to be made, by whom and over what time period
- ★★ Agree a time for re-audit to evaluate the effect of changes, as needed, or to evidence maintained compliance with best practice target(s), thereby completing the audit cycle

11

/ Internal vs. External Clinical Audit, Regulatory Audit and the Relationship with Inspection

Internal radiology departmental audit (including personal self-assessment) is recommended as a systematic and continuing activity. Audits should be of topics of high clinical priority, involving multi-professional working and collaboration. Clinical audit is a mandatory activity at departmental level as defined within the BSSD, with an intended focus on key areas of radiological practice involving radiation. Clinical audit in radiology departments should be able to provide evidence of compliance with national legislation intended to transpose the BSSD.

Regulatory audit, though it entails mandated absolute standards, will form a significant part of departmental audit programmes. When they are undertaken locally, they can be used to complement the process of inspection by the relevant national radiation protection competent authority. Regulatory audit is a type of audit that verifies compliance with regulations and standards and has become increasingly recognised since the requirement for BSSD transposition in 2018, with recent publications covering this topic [5]. Regulatory audits are helpful for radiology departments and employers to know that compliance with national regulations is maintained, but they will not replace the need for inspection. Inspection as a process is significantly different from clinical audit [5]. Inspection is performed as part of regulation under relevant legislation by inspectors on behalf of the competent authority with the ability to enforce requirements.

Clinical audit, outside of what is required by the BSSD, is not mandatory or a legal obligation. However, the Directive presumes and indirectly supports its implementation by referencing national arrangements. Active and ongoing participation in clinical audit is widely regarded as a marker of good practice. Furthermore, external regulators often consider evidence of such participation as an indicator of regulatory compliance and adherence to high standards of care. Clinical audits might also demonstrate (indirectly) appropriate optimization or justification. For example, an audit of the impact of exposure settings on image quality and subsequent patient management has clear value relating to optimisation of the medical exposure. An audit of the impact of contrast concentration might be intended to consider organ toxicity, but as a by-product may also include comments on exposure factors and again be helpful in demonstrating a specific example of optimisation. Just as importantly, it demonstrates a well-developed approach to optimisation within the institution.

A region or group of departments may initiate national processes of external audit, and a multidisciplinary external auditing team working in collaboration with local radiology departments to carry them out can be an important component. Setting up an external audit system will depend upon local/national resources and requirements and should be accredited by a suitable professional or scientific national body independent of the regulatory authority. This may have significant costs. External audits can provide broader perspectives with auditors better placed to judge the consistency, efficacy and outcomes of procedures from one health care setting to another. External audits do require well-trained and independent auditors (ideally healthcare professionals), avoidance of conflicts of interests and adequate funding.

A service provision/evaluation seeks to evaluate how well a service is performing but does not measure against a standard, although results may help derive future standards for use in clinical audit. An alternative approach is departmental or hospital internal audit with external direction, usually provided by a professional body or society. This can be extended to a coordinated initiative, which might provide information on a national situation as well as having value at the local level.

The Table below summarizes the key differences between clinical and regulatory audit and also between these two types of audits and inspection. The Table is reproduced with the kind permission of the HERCA Working Group on Medical Applications and is contained in its original form in the Addendum to the HERCA Position Paper Clinical Audit in Medical Radiological Practices [5].

	Clinical audit	Regulatory audit	Inspection
Defined criteria	Good practice or standard	Regulations	Regulations
Expected level of achievement	Locally/nationally defined	100% compliance against self-assessment of the regulatory requirements	100%
Aim	Promotes and develops clinical outcomes and quality of care	Demonstrates and may improve regulatory compliance	Checks the compliance with regulations and implement enforcement
Outcome and follow up	Recommendations to be considered by the audited party	Recommendations to be considered by the audited party	Decision made by the competent authority
Organization	Undertaking/peer review system	Undertaking/peer review system	Competent authority
BSSD	Mandatory	Not applicable	Mandatory

12 / QuADRANT – A European Initiative with an Emphasis on Clinical Audit

In 2019 the European Commission announced a proposal for tender, ENER/D3/2019-231-2, entitled "Constant Improvement in Quality and Safety of Radiology, Radiotherapy and Nuclear Medicine Through Clinical Audit." The project had the following key specific objectives.

- To review the status of implementation of clinical audits in the Member States
- To identify good practices in Member States and available guidance and resources for clinical audits at national, European and international level
- To provide further guidance and recommendations on improving the implementation and integration of clinical audits into national healthcare systems
- To identify potential for further coordinated EU action on quality and safety of radiology, radiotherapy and nuclear medicine

The ESR, as lead of the consortium also involving the European Society of Radiotherapy and Oncology (ESTRO) and European Association of Nuclear Medicine (EANM) was successful in the tender application with the acronym QuADRANT [6] (Quality Improvement through Clinical Audit in Diagnostic (including Interventional) Radiology, Radiotherapy and Nuclear Medicine, including Therapies).

The project commenced in January 2020, with a planned duration of 30 months and comprised five work packages, including two conferences and a pan-European survey to establish current clinical audit status, challenges and barriers. QuADRANT concluded in July 2022, and the findings were published in January 2023 by the European Commission as part of their Radiation Protection Series.

According to the results from the study conducted under QuADRANT, establishing a national framework for clinical audits, including regulatory oversight and supportive infrastructure, is essential to ensure consistent quality in healthcare, particularly in areas involving ionising radiation and compliance with the BSSD. National professional societies play a critical role in developing guidance, providing leadership and fostering collaboration between stakeholders, while addressing barriers such as limited funding, prioritisation and expertise. Key enablers like improved remuneration, hospital accreditation and academic recognition can significantly enhance participation and effectiveness in clinical audits. Education and cultural shifts towards a multidisciplinary, "no blame" approach, alongside active patient involvement, are critical to embedding clinical audits into healthcare practices. Lastly, adapting good practice resources, like those from the QuADRANT project, can harmonise efforts and improve clinical audit processes across Europe.

QuADRANT is an important piece of work and has proven to be fundamental in providing a European roadmap for enhancing clinical audit uptake across Europe and improving experiences and outcomes for patients. In April 2024 the European Commission adopted recommendations on clinical audits of medical radiological practices, which were the outcome of collaborative work among the QuADRANT project, HERCA, SAMIRA Steering Group on Quality and Safety and European Commission [13].

13

/ EU-JUST-CT – European Co-Ordinated Action on Improving Justification of Computed Tomography

In April 2021 a 36-month project, EU-JUST-CT, was launched. The action was coordinated by ESR and funded by the European Union. The main objective was to improve the justification of computed tomography (CT) in the European Union through the development and implementation of a common approach, methodology and co-ordinated action in this area among the Member States.

Specifically, the project aimed to:

- Collect up-to-date information about CT examinations in Europe
- Develop a common methodology for auditing justification of CT examinations
- Carry out co-ordinated pilot audits of justification of CT examinations in different European countries
- Discuss the status of justification of CT examinations with the Member States and identify opportunities for further action

During the project's duration, pilot audits on CT examination justification were carried out in seven Member States using the ESR iGuide clinical decision support as a benchmark. The undertaking was part of the SAMIRA Action Plan and closely related to the QuADRANT study.

The EU-JUST-CT project has provided valuable insights into the current state of CT justification in Europe, showing that further action such as education on justification and clinical audit is needed. It also offers an audit methodology and guidance for imaging departments with the aim to advance the appropriate use of CT imaging, thereby further advancing patient safety and quality of care. The results and recommendations of the EU-JUST-CT project were published in September 2024 as Radiation Protection Series No. 205, European Co-Ordinated Action on Improving Justification of Computed Tomography [9].

14

/ CLAUD-IT – Clinical Audit Implementation in Europe - a Practical and Multidisciplinary Approach

CLAUD-IT is a 36-month project (September 2024 – August 2027) co-funded by the European Union under the EU4Health programme 2021–2027 (EU4H-2023-PJ-05 Action grants for a project on implementation of the agenda for medical ionising radiation applications (SAMIRA action plan) – organisation of clinical audit campaigns as a tool to improve quality and safety of medical applications of ionising). The project is supported by ESR and EANM and brings together 14 partners from 10 Member States.

CLAUD-IT builds on the results of the QuADRANT and EU-JUST-CT projects as well as resources developed by the ESR and EANM with the goal to further improve justification and optimization and hence the overall quality and safety of radiology and nuclear medicine procedures.

CLAUD-IT developed guidelines for clinical audit in nuclear medicine and expanded the 3rd edition of ESPERANTO - ESR Guide to Clinical Audit in Radiology to a version named **AUDITRAD: Esperanto – Guide to Clinical Audit in Radiology.** All materials developed under the project will be made available through an online repository, providing an open-access, one-stop shop for clinical audit resources in radiology and nuclear medicine. In the next stages, the project will use a phased approach to train over 250 professionals through a train-the-trainer model to ensure further implementation of clinical audit in Europe [14].

15 / The ESR Clinical Audit Tool

To support BSSD transposition and facilitate wider national participation in clinical audit, the ESR Audit and Standards Subcommittee, supported by the ESR office, has developed the ESR Clinical Audit Tool to supplement the Guide to Clinical Audit. The ESR Clinical Audit Tool is designed to increase awareness of the importance of clinical audit amongst radiologists and other healthcare professionals within radiology departments and help them incorporate clinical audit into their departmental work and processes. In addition, by engaging with clinical audits and the Clinical Audit Tool, departments will be able to demonstrate to external bodies/inspectors that their department is committed to well-documented and safe clinical care. Departmental regulatory audit will demonstrate regulatory compliance to the employer, but it will not replace inspection by the relevant national radiation protection competent authority.

The tool contains a series of templates.

- ★★ **Appendix 1** – a blank draft template that can be adapted according to local or national audit topics
- ★★ **Appendix 2** – an expanded area containing a series of audit templates. Templates are further subdivided into quality, safety, justification radiation protection, AI, and value-based-patient centred topics.

There is a free, open-access, extensive resource of audit templates covering many clinical topics available via the Royal College of Radiologists, London, UK – Auditlive [7]. This is well worth a look and contains a wide range of potential audit templates covering all specialty areas.

It is important to appreciate that the standards/targets for an audit may not be met. This is to be expected in many cases. It is important then to act and be seen to act on these audit findings and to implement necessary changes. A piece of imaging equipment may be too old and sub-standard. This can then be an opportunity for a department to raise this problem with relevant fund holders or regulatory bodies. Clinical audit should operate within an open and non-discriminatory operational culture where any observed non-compliance with standards is managed at a systematic rather than an individual level. Clinical audit should be seen as a positive experience, improving the standards of care, reinforcing good practice and acting as a driver for change when needed.

16 / Summary

The updated ESPERANTO Clinical Audit Guide provides a comprehensive framework for radiology departments across Europe to enhance the quality and safety of their services while ensuring compliance with the BSSD. This new version expands on previous editions by offering a broader selection of customizable audit templates, tools and methodologies specifically tailored to support both clinical and regulatory audits. It emphasizes the integration of clinical audits into routine practice, highlighting their role in improving patient outcomes, ensuring compliance with radiation safety standards and fostering a culture of continuous quality improvement. By detailing the audit cycle of setting objectives, benchmarking against standards, analysing data, implementing changes and re-auditing the guide underscores the importance of closing the audit loop to maintain high standards. The guide aligns with European initiatives such as QuADRANT, EU-JUST-CT and CLAUD-IT, incorporating their insights and best practices to strengthen audit implementation and encourage multidisciplinary collaboration. Additionally, it promotes education, resource sharing and a "no-blame" culture, empowering departments to identify and address deficiencies constructively. As an essential resource, this guide ensures radiology professionals are well-equipped to meet regulatory expectations, optimize patient care and advance quality assurance in medical imaging.

17 / References

[1] Council Directive 2013/59/Euratom on basic safety standards for protection against the dangers arising from exposure to ionising radiation and repealing Directives 89/618/Euratom, 90/641/Euratom, 96/29/Euratom, 97/43/Euratom, and 2003/122/Euratom. *Official Journal of the European Union*. L13;57:1–73 (2014). DOI: 10.2833/552398 Publications Office of the EU

[2] European Commission. Guidelines on Clinical Audit for Medical Radiological Practice (Diagnostic Radiology, Nuclear Medicine, and Radiotherapy). Radiation Protection Series No. 159; 2010. ISSN: 1681-6803. DOI: 10.2833/552398 Publications Office of the EU

[3] European Commission. Guidelines on Clinical Audit. Statement by the European Society of Radiology. *Insights into Imaging*. 2011;2(2):97–98. DOI: 10.1007/s13244-011-0065-8 PMC

[4] Healthcare Quality Improvement Partnership. *Clinical Audit – A Manual for the Clinical Audit Team*. 2012; pp. 1–25.

[5] Heads of the European Radiological Protection Competent Authorities (HERCA). *HERCA Position Paper: Clinical Audit in Medical Radiological Practices* (2019); pp. 1–18, including Addendum published in June 2021.

[6] European Society of Radiology (ESR). *Eurosafe Imaging, QuADRANT* [online]. Available at: http://www.eurosafeimaging.org/clinical-audit/quadrant.

[7] Royal College of Radiologists (RCR). *AuditLive*. London, UK. Available at: https://www.rcr.ac.uk/clinical-radiology/audit-and-qi/auditlive.

[8] European Commission: Directorate-General for Energy, Howlett D., Giammarile F., Jornet N., Hierath M., Clark J. *Current Status and Recommendations for Improving Uptake and Implementation of Clinical Audit of Medical Radiological Procedures: QuADRANT, a European Study on Clinical Audit of Medical Radiological Procedures*. 2022. DOI: 10.2833/468186 Publications Office of the EU

[9] European Commission: Directorate-General for Energy, Brkljačić B., Karoussou-Schreiner A., Sosna J., Foley S., et al. *European Co-ordinated Action on Improving Justification of Computed Tomography – Results and Recommendations from a Multi-National Study on CT Justification in the EU*. 2024. DOI 10.2833/80267 Publications Office of the EU

[10] European Society of Radiology (ESR). *ESR Concept Paper on Value-Based Radiology. Insights into Imaging*. 2017;8(5):447–454. DOI: 10.1007/s13244-017-0566-1

[11] Brady AP, Bello JA, Derchi LE, Fuchsjäger M, Goergen S, Krestin GP, Lee EJY, Levin DC, Pressacco J, Rao VM, Slavotinek J, Visser JJ, Walker REA, Brink JA. *Radiology in the Era of Value-Based Healthcare: A Multi-Society Expert Statement from the ACR, CAR, ESR, IS3R, RANZCR, and RSNA. Insights into Imaging*. 2020;11(1):136. DOI: 10.1148/radiol.2020209027

[12] Kemper EHM, Erenstein H, Boverhof BJ, Redekop K, Andreychenko AE, Dietzel M, Groot Lipman KBW, Huisman M, Klontzas ME, Vos F, IJzerman M, Starmans MPA, Visser JJ. *ESR Essentials: How to Get to Valuable Radiology AI: The Role of Early Health Technology Assessment—Practice Recommendations by the European Society of Medical Imaging Informatics. European Radiology*. 2024 (Dec 5). DOI: 10.1007/s00330-024-11188-3

[13] European Commission. Recommendation 2024/1112/Euratom of 18 April 2024 on clinical audits of medical radiological practices carried out pursuant to Council Directive 2013/59/Euratom. Official Journal of the European Union. L1112;112:1–12 (2024). Available at: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=OJ:L_202401112

[14] European Institute for Biomedical Imaging Research (EIBIR). CLAUD-IT: Clinical Audit Implementation in Europe – A Practical and Multidisciplinary Approach [online]. Available at: https://www.eibir.org/projects/claud-it/

18 / Acknowledgements

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19 / Appendices

- Appendix 1 – draft blank template
- Appendix 2 – clinical audit templates

APPENDIX 1

/ Audit template document (Blank)

1) Audit Title

2) Standard against which the audit topic is to be compared

3) Source of standard (or reference document)

4) Target / compliance percentage to be achieved

5) Item or variable to be audited

6) Method: Retrospective / Prospective / Other

7) Data or information to be collected

8) Sample details (categories, number of patients, collection time period)

9) Target achieved

Yes No Not applicable

10) Actions to be taken if the target is not met.

11) Timing for re-audit

APPENDIX 2

/ Clinical Audit Templates

This section contains a wide selection of example topics, please note the earlier reference to the Royal College of Radiologists Auditlive, an open access, reference site containing a wide range of audit templates [7].

1) Complication rates and diagnostic adequacy rates for percutaneous CT guided lung biopsy
2) Record of safety checklist and patient consent prior to interventional procedures
3) Adequate discussion of treatment proposals of oncological patients in a multi-disciplinary meeting (MDM)/tumour board
4) Improving referral process and guidelines – specific target: implementation of referral guidelines through iGuide – integrated directly into hospital ordering systems
5) Protocols around radiological procedures, information in reports
6) The practice of 'routine' preoperative chest X-rays
7) Audit appropriateness of inpatient chest X-rays or abdominal X-rays
8) What percentage of non-ionising imaging studies (MR/ultrasound) are consistent with referral guidelines
9) Pain sensation during image-guided interventions
10) Image quality in radiography
11) Image quality in CT
12) Justification of head CT
13) Incidence of contrast extravasation during CT injection and impact on patients
14) Impact of patient mis-identification errors and subsequent error rates of this type
15) Reject analysis of radiological images
16) Impact of a local training programme on first line reporting accuracy by junior doctors
17) Auditing the Appropriateness of CT referrals
18) Adequate completion of radiology request forms for X-ray and CT
19) Impact of departmental CT dose reducing protocol on image quality and diagnostic confidence
20) Impact of variation in volume of injected contrast in CT on image quality, diagnostic confidence and dose
21) Impact of adjusting frame/pulse rate in fluoroscopy on image quality, diagnostic confidence and dose
22) Adequacy of CT colonography (insufflation/bowel preparation)
23) Adequacy of irradiation beam size (collimation) in projection radiography
24) Radiographic image labelling – use of anatomical side markers for projection radiography
25) Reject rate for projection radiographs
26) Existence of predetermined CT technical protocols for each specific indication
27) How dose information should be transmitted to the patient
28) Follow-up of patient with high skin dose as a result of an interventional procedure
29) Multidisciplinary Team Roles in Managing Patient Radiation Protection
30) Waiting time for outpatient ultrasound appointments
31) Does the radiology department record statistics about patient satisfaction?
32) Paediatric abdominal CT without prior abdominal ultrasound
33) Quality control of X-ray diagnosis equipment
34) Typical doses and comparison with DRLs
35) MR Safety education
36) MR-safety "near misses" of projectiles
37) MR-safety "near misses": unknown foreign objects
38) MR quality: MR protocol audit for artifact minimization
39) Time taken for imaging report to become available to the referring clinician (and directly to the patient where appropriate)
40) Time between receiving referral and imaging for non-acute MRI and CT imaging (excluding scheduled follow-up surveillance)
41) Application security in MRI
42) Peer review

43) AI governance structure
44) Feedback mechanism radiology-pathology
45) Standardisation of CT/MRI reports for staging of cervical cancer
46) The Use of Chest Radiographs in Confirming Safe Nasogastric Tube (NG) Placement
47) The Clinical Radiologist and Multidisciplinary Team Meetings (MDM)
48) Evaluation of Minor and Major Complications Following Image-Guided Percutaneous Liver Biopsy
49) Evaluation of Adequacy of Thyroid Fine Needle Aspiration Cytology (FNAC) in the Diagnosis of Thyroid Nodules
50) Evaluation of Liver Biopsies Performed Using Imaging Guidance - Procedural Aspects, Diagnostic Adequacy and Accuracy
51) Radiology Departmental Staff Knowledge on the Management of Allergic Reactions to Contrast Media
52) Adequacy of Referrals for Ultrasound Assessment of Suspected Deep Venous Thrombosis (DVT)
53) Post-Procedural Documentation Following an In-patient Interventional Radiological Procedure.
54) The Use of Magnetic Resonance Imaging in the Investigation of Suspected Vestibular Schwannoma
55) Inappropriate Repeating of In-Patient Chest Radiographs at Short Intervals
56) Assessment of NTG placement with AI on chest radiography
57) Appropriate training for individuals with responsibility in using AI output for clinical decision making
58) Image quality in AI-based reconstruction
59) Appropriate use of AI solutions according to intended use statement / MDR CE class
60) MR Quality & Safety
61) Is there a departmental mechanism for providing patients (or their representative) with information relating to the risks/benefits associated with radiation dose from the medical exposure?
62) Is there an established mechanism within the department to register and analyse accidental /unintended exposures?
63) Is there a departmental policy for informing patients, or their representative, that they have undergone an accidental exposure?
64) Is there a mechanism for record keeping and retrospective analysis of accidental or unintended medical exposures?
65) Is there a mechanism for referring accidental exposure events to the medical physics expert (MPE) and informing the competent authority of significant events?
66) Does the department utilise criteria, provided by the relevant radiation protection competent authority, for what constitutes an accidental or unintended significant exposure?
67) Evaluation of Training and Competence in Radiation Protection for Non-Radiologists Responsible for Justification of Medical Exposures
68) Is there a departmental mechanism to confirm as necessary with the patient or patient representative and document the non-pregnancy status of individuals undergoing medical exposures?
69) Written protocol for the identification of who is responsible for the justification process
70) For radiation exposure related to health screening by invitation on asymptomatic individuals, is there a local policy affirming justification by a competent authority?
71) What percentage of examinations involving ionising radiation are justified in advance of being performed?
72) What mechanism exists on the request form for contacting referrers to permit pre-exposure justification discussions to occur if necessary?
73) Is there a written protocol for who may be responsible for justification of X-ray /fluoroscopic /ionising interventional radiological / CT-Scan procedures?
74) Is there a written protocol for who may be responsible for justification of CT examinations?
75) What mechanism is used to evaluate patient dose in high-dose procedures?
76) What percentage of radiodiagnostic procedures have established diagnostic reference levels (DRL)?
77) Specific technical requirements for equipment in use for medical exposures.
78) Eye lens dose limits for occupational exposure.
79) Initial education and training in radiation protection
80) Audit of education plus training in radiation protection, doses and side effects.
81) Assessment of Clinical Information Provision to Support Justification in Radiological Procedures
82) Staff dosimetry audit – this includes a draft adapted questionnaire.
83) Evaluation of the role and responsibilities of the medical physics expert
84) Radiation protection instruction
85) Implementation and Effectiveness of Dose Monitoring Software in Radiological Practice
86) Compliance and Optimization in Cone Beam Computed Tomography (CBCT)
87) Integration of Advanced Technologies for minimizing radiation exposure in high doses domains

Audit 1

/ Category: Value Based, Quality

1) **Audit Title**
Complication rates and diagnostic adequacy rates for percutaneous CT guided lung biopsy

2) **Standard against which the audit topic is to be compared**
National targets laid out in British Thoracic Society guidelines published in Thorax in 2003.

3) **Source of standard (or reference document)**
Manhire A, Charig M, Clelland C, *et al* Guidelines for radiologically guided lung biopsy *Thorax 2003*;58:920-936.

4) **Target / compliance percentage to be achieved**
Complications:
- ★ Pneumothorax <90%
- ★ Large pneumothorax requiring chest drain insertion <3%
- ★ Haemothorax <5%
- ★ Death <0.15%

Diagnostic accuracy: >90%

5) **Item or variable to be audited**
Diagnostic yield
Complications listed above

6) **Method: Retrospective / Prospective / Other**
Retrospective or prospective

7) **Data or information to be collected**
Type of lesion (solid, part solid, pure ground glass, cavitating, cystic components)
Size of lesion
Pleural depth
Number of passes
Fissure crossed (Y/N)
Needle gauge
Number of cases per site

8) **Sample details (categories, number of patients, collection time period)**
Data to be collected over 1 calendar year

9) **Target achieved**
Yes – No – Not applicable

10) **Actions to be taken if the target is not met.**
Further training. Possibly at a centre with higher volumes +/- specialisation in complex biopsies / additional CT guided thoracic intervention or a centre.

11) **Timing for re-audit**
3-year cycle (potentially sooner if concerns in relation to complication rates/diagnostic yield at first audit round)

Audit 2

/ Category: Safety

1) **Audit Title**

Record of safety checklist and patient consent prior to interventional procedures

2) **Standard against which the audit topic is to be compared**

Implementation of a surgical safety checklist significantly reduced patient morbidity and mortality [NEJM, 2009]. A modified WHO checklist is available for use in interventional radiology (Royal College of Radiologists, RCR – UK National Health Service, NHS – Cardiovascular and Interventional Society of Europe, CIRSE). Using a checklist is proposed for all interventional procedures [dependent on penetration of the skin, including biopsies or other tissue sampling]. There should be departmentally agreed safety processes including peri-procedural safety checks around any invasive procedure. These checks may be locally modified to be appropriate for different modalities and procedures. The use of safety checklists and patient consent should be recorded in the radiology record (report or radiology information system, RIS entry).

This audit relates to peri-procedural safety checks and patient consent.

3) **Source of standard (or reference document)**

https://www.cirse.org/education/standards-of-practice/ir-patient-safety-checklist/

Cardiovasc Intervent Radiol (2012) 35:244–246; DOI 10.1007/s00270-011-0289-5

Haynes AB, Weiser TG, Berry WR et al. A surgical safety checklist to reduce morbidity and mortality in a global population. New Engl J Med 2009; 360: 491- 99. http://www.nejm.org/doi/full/10.1056/NEJMsa0810119#t=article

National Patient Safety Agency, The Royal College of Radiologists. WHO Surgical Safety Checklist: for radiological interventions only. https://www.rcr.ac.uk/publication/standards-npsa-and-rcr-safety-checklist-radiological-interventions

NHS England Patient Safety Domain. National Safety Standards for Invasive Procedures (NatSSIPs) 2015.

4) **Target / compliance percentage to be achieved**

100%

5) **Item or variable to be audited**

A. Availability of locally agreed departmental interventional safety checklists for each interventional radiological procedure.
B. Documentation of completion of the safety checklist on radiology report of all radiological interventional procedures.
C. Documentation of patient consent in the radiology report.

6) **Method: Retrospective / Prospective / Other**

Retrospective or prospective

7) **Data or information to be collected**

A. Type of interventional procedure:
    a. Needle cytology or aspiration
    b. Biopsy
    c. Injection, such as steroid
    d. Major interventional procedure (e.g., angiographic, hepato-biliary)
B. Documentation of completion of interventional safety checklist in the radiology report.
C. Documentation of patient consent in the radiology report

8) **Sample details (categories, number of patients, collection time period)**

Categories to be collected:

- Type of interventional procedure
- Minor e.g., needle cytology
- Major procedure such as interventional vascular procedure

Suggested data to be collected/or use of CIRSE template:

- Correct patient
- Has patient read information sheet and had opportunity to ask questions?
- Correct site and side
- Allergy information
- Clotting and platelets checked
- Relevant imaging reviewed
- Verbal/written consent
- Complications recorded

9) **Target achieved**

Yes – No – Not applicable

10) **Actions to be taken if the target is not met.**

Presentation of audit findings at departmental meeting with all involved in any interventional radiological procedures.

Departmental education programme concerning the need for and importance of having safety checklists for interventional procedures and for documentation of consent and safety checklist to be included in the radiology report.

Establish roles and responsibilities for checklist within the team – to include all team members (different team members may lead on different checks and complete individual parts of the form. radiographers / nurses / assistants / radiologists).

Re-audit after department planning.

11) **Timing for re-audit**

Re-audit in 3-6 months following completion of initial audit with periodic re-audit to ensure maintained compliance.

Audit 3

/ Category: Value Based, Quality

1) **Audit Title**

Adequate discussion of treatment proposals of oncological patients in a multi-disciplinary meeting (MDM)/tumour board

2) **Standard against which the audit topic is to be compared.**

Established guidelines or institutional policies for the functioning of multidisciplinary meetings and different tumours.
Some commonly referenced standards include those from organizations like the National Institute for Health and Care Excellence (NICE), European Society for Medical Oncology (ESMO), or American Society of Clinical Oncology (ASCO).
The specific standards will vary based on the healthcare system or institution.

3) **Source of standard (or reference document)**

Majority of international guidelines for oncological treatment emphasize the importance of interdisciplinary discussions for treatment planning.

The Royal College of Radiologists Multidisciplinary team meetings: standards for clinical radiologists London: The Royal College of Radiologists, 2023.

4) **Target / compliance percentage to be achieved**

To be discussed and agreed locally, compliance with targets should be encouraged and a 100% figure for compliance with agreed targets could be considered.

5) **Item or variable to be audited**

- Documented treatment recommendations discussed in MDM in medical records.
- Clear treatment plant (e.g., surgery, chemotherapy, radiotherapy, or palliation) and next steps.

6) **Method: Retrospective / Prospective / Other**

Due to electronic documentation of a tumour board, such events can be recorded prospectively; retrospective post-hoc analysis can also be considered

7) **Data or information to be collected**

Registration of recommended treatment after MDM.

Verification of recommended treatment and follow up

8) **Sample details (categories, number of patients, collection time period)**

Typical time periods are one year for the audit. Revision of 50 patients/year. Could be different oncologic MDT teams (Brain, Liver breast etc.)

9) **Target achieved (yes / no / not applicable)**

10) **Actions to be taken if the target is not met**

Internal guideline. Change of workflow. Improve communication. Review staff training. Educational sessions.

11) **Timing for re-audit**

The audit should be repeated periodically to confirm compliance with standards.

Audit 4

/ Category: Justification

1) **Audit Title**

   Improving referral process and guidelines – specific target: implementation of referral guidelines

2) **Standard against which the audit topic is to be compared.**

   Application of referral guidelines in conformance with certain established reference – iGuide as a specific European reference as appropriate, but other society or national and international guidelines should also be considered

3) **Source of standard (or reference document)**

   Updated (2025) version of iGuide Guidelines, agreed and signed by the subspeciality expert committees, local guidelines[1], accepted by iGuide

4) **Target / compliance percentage to be achieved**

   80% of referrals conforming to iGuide (or other utilised and established reference) then increase to 90% on re-audit

5) **Item or variable to be audited**

   Sample of referrals (10 referrals for 5 selected examinations, + 10 referrals for 5 selected indications (different concepts in iGuide) compared to guideline criteria. All types of radiological exams (ionising and non-ionising) can be included, with variable numbers and time periods.

6) **Method: Retrospective / Prospective / Other**

   Retrospective (registry evaluation from hospital HIS/RIS) or prospective

7) **Data or information to be collected**

   Sample of referrals (e.g., 10 referrals from 5 selected examinations/indications)

8) **Sample details (categories, number of patients, collection time period)**

   10 referrals from 5 selected examinations, 10 referrals from 5 selected indications during the past one month

9) **Target achieved (yes / no / not applicable)**

10) **Actions to be taken if the target is not met**

    Convene with radiologists, radiographers, and referring clinicians to identify root causes. Update local guidelines if necessary. Enhance workflow processes (e.g., electronic alerts for non-conforming referrals). Implement or improve guideline integration within HIS/RIS. Conduct targeted training sessions for referrers, including clinicians, nurses, and administrative personnel authorized to submit referrals. Introduce periodic feedback mechanisms to referrers.

11) **Timing for re-audit**

    Yes, re-audit in 6 months focused on outcome of remedial actions (in case target not achieved or significant deviations observed during audit), periodic re-audit to ensure maintained compliance

1 when a hospital has passed the pilot test, can define local guidelines, based on local practise. If the Hospital does not use iGuide, can also have local guidelines.

Audit 5

/ Category: Quality, Safety

1) **Audit Title**

Assessment of Inclusion of Examination Protocols and Contrast Material Details in Radiology Reports

2) **Standard against which the audit topic is to be compared**

European Society of Radiology (ESR) Standards for Radiology Reporting. ACR Practice Parameter for Communication of Diagnostic Imaging Findings (American College of Radiology). Radiology department's agreed standard operating procedures (SOPs). Hospital policy for radiology reporting.

3) **Source of standard**

European Society of Radiology (ESR). Good practice for radiological reporting. Guidelines from the European Society of Radiology (ESR). Insights Imaging. 2011 Apr;2(2):93-96. Local / national agreed standard

4) **Target / compliance percentage to be achieved**

100 %

5) **Item or variable to be audited**

Selected procedure types: Ionising modalities (e.g., CT scans). Non-ionising modalities (e.g., ultrasound or MRI). Procedures involving intravenous contrast (e.g., CT, MRI).

Documentation of: Protocol details (e.g., CT phases, MRI sequences). Contrast material information (e.g., name, dose, injection details).

6) **Method: Retrospective / Prospective / Other**

Retrospective or prospective

7) **Data or information to be collected**

Presence of Protocol Details: Ensure the protocol is clearly documented in a dedicated section of the report (preferably at the beginning). Includes all phases for CT or sequences for MRI.

Contrast Material Information (if applicable): Name of the contrast material.

Dosage administered. Injection details (e.g., rate, volume, site).

8) **Sample details (number of patients, collection time period)**

100 consecutive reports

9) **Target achieved (yes /no)**

10) **Actions to be taken if the target is not met.**

Disseminate audit findings to radiologists and other reporters. Highlight the importance of documenting protocols and contrast details in reports. Develop actionable steps to address issues (e.g., training, workflow changes). Provide examples of well-structured reports.

11) **Timing for re-audit**

In one year

Audit 6

/ Category: Justification

1) **Audit Title**

The practice of 'routine' preoperative chest X-rays

2) **Standard against which the audit topic is to be compared**

Indications for pre-operative chest X-rays are limited, yet they are still widely requested, causing unnecessary radiation exposure for the patient and work /costs for departments. The standards against which requests for x-rays should be compared during audits should first be compared with European guidelines, then national ones, but it would also be necessary to refer to the strictly internal guidelines of the facility in which the clinical activity is directly practiced. Different facilities have different degrees of complexity and specialists (e.g. thoracic surgeons) may need additional tests to not directly harm the Patient, who remains the most important thing to pay attention to.

3) **Source of standard**

Local / national guidance on the indications for / performance of pre-operative chest X-rays

Suggest (attached PDF):

a. The Royal College of Radiologists: https://www.rcr.ac.uk/career-development/audit-quality-improvement/auditlive-radiology/pre-operative-chest-radiographs-cxr-for-elective-surgery/
b. Academy of Medical Royal Colleges: https://ebi.aomrc.org.uk/interventions/pre-operative-chest-x-ray/

4) **Target / compliance percentage to be achieved**

100 % – to be discussed within the department. It could also be suggested to be integrated into departmental evaluations in relation to individual performance to maintain an internal average standard within the department not below a certain level (for example not lower than 95%)

5) **Item or variable to be audited**

Consecutive pre-operative chest X-ray requests

6) **Method: Retrospective / Prospective / Other**

Retrospective/prospective

7) **Data or information to be collected**

List of elective operations over fixed period, e. g. 3 months and those patients who had a pre-operative chest X-ray

8) **Sample details (number of patients, collection time period)**

100 pre-operative chest X-ray requests.

9) **Target achieved**

(yes /no)

10) **Actions to be taken if the target is not met**

Educating referring clinicians and radiology department staff about the guidelines. It is also helpful to display a summary version of the guidelines on the department noticeboard to notify new hires and to remind everyone else. Where possible, the integration of a PDF that references the guidelines within the hospital RIH or HIS may also be suggested.

11) **Timing for re-audit**

1 year

Audit 7

/ Category: Justification

1) **Audit Title**

   Audit appropriateness of inpatient chest X-rays or abdominal X-rays

2) **Standard against which the audit topic is to be compared**

   Inpatient chest and abdominal X-rays are often overused, misinterpreted or repeated at inappropriate intervals.
   There is potential for harm to patients due to misdiagnosis, inappropriate ionising radiation exposure.

   Clinical Guidelines: Compare against established clinical guidelines such as those from the Royal College of Radiologists (RCR) and the National Institute for Health and Care Excellence (NICE).

3) **Source of standard (or reference document)**

   Local / national / international / referral guidelines

4) **Target / compliance percentage to be achieved**

   90 % – to be discussed and agreed

5) **Item or variable to be audited**

   Chest X-ray or abdominal X-ray

6) **Method: Retrospective / Prospective / Other**

   Retrospective or prospective

7) **Data or information to be collected**

   ★ list of inpatients in a time interval with clinical data and relevant diagnosis review clinical information / indication on request form
   ★ review notes documentation of findings
   ★ review timings /indication of repeat X-rays

8) **Sample details (categories, number of patients, collection time period)**

   100 patients

9) **Target achieved**

   Yes – No – Not applicable

10) **Actions to be taken if the target is not met.**

    Discuss with referrers /radiology department to reinforce and embed referral guidelines

11) **Timing for re-audit**

    1 year

Audit 8

/ Category: Justification

1) **Audit Title**

What percentage of non-ionising imaging studies (MR/ultrasound) are consistent with referral guidelines

2) **Standard against which the audit topic is to be compared**

Clinical referrers should be familiar with and use the referral guidelines, with or without a decision support system (e.g. ESR iGuide) to avoid inappropriate or incorrect investigation (radiation exposure). The BSSD and the justification process applies to practices involving ionising radiation. It is important that all imaging studies, ionising and non-ionising (MR, ultrasound) are undertaken according to (local / national) referral guidelines. This template applies to authorisation of non-ionising studies, but can readily be applied or adapted to justification of ionising studies.

3) **Source of standard**

ESR iGuide: ESR iGuide **/ Local or National Guidelines:** Examples: NICE (National Institute for Health and Care Excellence) Guidelines in the UK or ACR (American College of Radiology) Appropriateness Criteria in the US. Check specific local/national medical associations or radiology societies for referral standards.

4) **Target / compliance percentage to be achieved**

100 % (compulsory) is the aspirational standard, this audit involves non-ionising investigations, e. g. MR /US and as such is included in the clinical practice section but can readily be extended to ionising investigations (justification)

5) **Item or variable to be audited**

All or selected non-ionising (or ionising) radiological procedures

6) **Method**

Retrospective or prospective

7) **Data or information to be collected**

★★ Presence of a clinical question/diagnosis on the request form

★★ Request meets agreed referral guidelines

8) **Sample details (number of patients, collection time period)**

100 reports

9) **Target achieved**

(yes /no)

10) **Actions to be taken if the target is not met**

Education of clinical referrers around referral (and justification) processes

11) **Timing for re-audit**

1 year

Audit 9

/ Category: Value Based, Safety

1) **Audit Title**

Pain sensation during image-guided interventions

2) **Standard against which the audit topic is to be compared**

Managing pain sensation during interventional procedure is a key element to reduce patient discomfort.

- International guidelines: such as a) Cardiovascular and Interventional Radiological Society of Europe (CIRSE): CIRSE Guidelines on Percutaneous Needle Biopsy (PNB); b) Royal College of Radiologists (RCR): Sedation and pain management in interventional radiology; c) European Federation of Societies for Ultrasound in Medicine and Biology (EFSUMB): Guidelines on Interventional Ultrasound (INVUS), Part I General Aspects (long Version)
- National guidelines: in Italy the Italian Society of Medical Radiology (SIRM).

3) **Source of standard (or reference document)**

- CIRSE Guidelines on Percutaneous Needle Biopsy (PNB). Veltri A et al. Cardiovasc Intervent Radiol. 2017 Oct;40(10):1501-1513. doi: 10.1007/s00270-017-1658-5.
- EFSUMB Guidelines on Interventional Ultrasound (INVUS), Part I General Aspects (long Version)
- Sedation, Analgesia, and Local Anesthesia: A Review for General and Interventional Radiologists. Thea C et al. RadioGraphics 2013 33:2, E47-E60
- Anesthesia Practices for Interventional Radiology in Europe. A. Vari et al CardioVascular and Interventional Radiology (2017) 40: 803-813

4) **Target / compliance percentage to be achieved**

- Patients undergoing image-guided interventions in the radiology department are asked to indicate a value on the pain scale ranging from 1 – 10 before procedure and after procedure
- All values are prospectively registered
- Evaluation may be done in a detailed manner, taking into consideration the type of intervention, the different body regions, operators, etc.

5) **Item or variable to be audited**

Percentage reduction in pain sensation compared to baseline.

6) **Method: Retrospective / Prospective / Other**

This is an audit best performed prospectively.

7) **Data or information to be collected**

- Values of Pain scale ranging from 1 – 10 before and after procedure.
  Type of procedure
- Variable of patient (i.e. age, BMI, ASA score)

8) **Sample details (categories, number of patients, collection time period)**

To be discussed locally

9) **Target achieved (yes / no / not applicable)**

Improvements in management of pain sensation during interventional procedures

10) **Actions to be taken if the target is not met**

Review the specific interventional techniques of pain management.

11) **Timing for re-audit**

This audit should be repeated periodically every 6 months and in case of recruitment of new doctors in interventional radiology team.

Audit 10

/ Category: Quality

1) **Audit Title**

   Image quality in radiography

2) **Standard against which the audit topic is to be compared.**

   Radiographs should meet local, national, or international quality assurance standards. High-quality radiographs should provide adequate diagnostic information with minimal repeat rates, avoiding unnecessary radiation exposure to patients. Standards should align with radiology guidelines, such as ensuring proper positioning, collimation, exposure settings, and image sharpness.

3) **Source of standard (or reference document)**

   EU 16260 EN

   EU 16261 for paediatrics

   DIMOND III

   (National reference levels for dose comparison, for paediatrics EC RP 185 if no national DRLs)

   European Guidelines on Quality Criteria for Diagnostic Radiographic Images (EUR 16260 EN).

4) **Target / compliance percentage to be achieved**

   To be discussed locally.

5) **Item or variable to be audited**

   (Clinical) image quality: Percentage of radiographs meeting diagnostic quality standards, Repeat rate of radiographs and reasons for repeats (e.g., positioning error, exposure error) and Compliance with collimation and radiation dose guidelines.

6) **Method: Retrospective / Prospective / Other**

   Retrospective

   (Dose information included)

7) **Data or information to be collected**

   Radiographic images. Assess radiographs using a structured checklist evaluating key quality factors (e.g., positioning, contrast, sharpness)

8) **Sample details (categories, number of patients, collection time period)**

   Usually the most common examinations, or if new equipment/new or updated protocols. E.g., 20 consecutive chest/pelvis, hip X-rays

9) **Target achieved (yes / no / not applicable)**

10) **Actions to be taken if the target is not met**

    Conduct interviews with staff to assess their understanding of image quality evaluation criteria for different examination procedures.

    Examine records of image quality audits and analyses of rejected and repeated images.

    Assess the imaging process, including factors such as positioning, projection, collimation, noise, and others.

    Actions depend on the problem recognized in the evaluation.

    If the image quality is acceptable, but the DRLs are exceeded, look at the possibilities to decrease dose without losing diagnostic image quality, also record the true collimation.

11) **Timing for re-audit**

    Should be part of yearly QA.

Audit 11

/ Category: Quality

1) **Audit Title**
   Image quality in CT

2) **Standard against which the audit topic is to be compared**
   To be discussed locally and compared.
   See e.g., Zarb, Rainford, McEntee 2009.
   Preferably combined with patient dose evaluation.

3) **Source of standard (or reference document)**
   EUR 16262 EN (National reference levels for dose comparison, for paediatrics EC RP 185 if no national DRLs)

4) **Target / compliance percentage to be achieved**
   To be discussed locally.

5) **Item or variable to be audited**
   (Clinical) image quality

6) **Method: Retrospective / Prospective / Other**
   Retrospective

7) **Data or information to be collected**
   CT examinations (Dose information included)

8) **Sample details (categories, number of patients, collection time period)**
   To be decided locally.
   Usually the most common CT examinations, or if new scanner, new or recently updated protocols E.g., 20 consecutive head CTs, routine abdomen CTs or routine chest CT, etc.

9) **Target achieved (yes / no / not applicable)**

10) **Actions to be taken if the target is not met**
    If image quality is not sufficient, look at the technical possibilities of optimization together with the dose information.
    Discuss with medical physics expert.
    If the image quality is good, but the DRLs are exceeded, look at the possibilities to decrease dose without losing diagnostic image quality, also notice the scan lengths.

11) **Timing for re-audit**
    One year, or sooner if the target is not met

Audit 12

/ Category: Justification

1) **Audit Title**

   Assessing the Justification of Head CT

2) **Standard against which the audit topic is to be compared**

   Guidelines for appropriate imaging referrals, e.g., European Society of Radiology iGuide guidelines, Royal College of Radiologists iRefer guidelines, local appropriateness criteria standards for imaging justification based on clinical need.

3) **Source of standard (or reference document)**

   National and international imaging referral guidelines, such as ACR Appropriateness Criteria.

4) **Target / compliance percentage to be achieved**

   100% compliance with justification criteria.

5) **Item or variable to be audited**

   - Documentation of clinical justification for head CT.
   - Adherence to imaging referral guidelines.
   - Indication for referral.
   - Justification against referral criteria.
   - Completeness of clinical information provided by referrers.

6) **Method**

   Retrospective.

7) **Data or information to be collected**

   - Clinical indications provided.
   - Documentation of justification.
   - Adherence to justification (appropriateness) criteria.
   - Outcome of imaging (diagnostic yield).

8) **Sample details**

   50 consecutive head CT referrals over a three-month period.

9) **Target achieved**

   Yes / No.

10) **Actions to be taken if the target is not met**

    - Provide refresher training on justification criteria for radiologists and referring clinicians.
    - Enhance documentation processes for justification of head CT.
    - Develop a checklist to ensure compliance before imaging is conducted.

11) **Timing for re-audit**

    6 months.

Audit 13

/ Category: Value Based, Safety

1) **Audit Title**

   Incidence of Contrast Extravasation During CT Injection and Impact on Patients

2) **Standard against which the audit topic is to be compared**

   To be discussed and agreed locally. The incidence of contrast extravasation varies but tends to be <1%.
   <1% of affected patients have severe injury.

3) **Source of standard (or reference document)**

   Standards are derived by local reference data but should also be formatted according to national/international publications and guidelines.

4) **Target / compliance percentage to be achieved**

   To be discussed and agreed locally, compliance with targets should be encouraged and a 100% figure for compliance with agreed targets could be considered.

5) **Item or variable to be audited**

   The incidence of clinically apparent contrast extravasation.

   The incidence of complications/injury – mild/moderate/severe and their nature.

   The incidence of diagnostic failure of CT study and need for repeat.

6) **Method: Retrospective / Prospective / Other**

   Depending on how robustly such events are recorded retrospective or prospective analysis can be considered.

7) **Data or information to be collected**

   Evidence of contrast extravasation during CT injection. Evidence of serious injury (compartment syndrome, ulceration, skin necrosis) or less severe injury (pain, erythema, tenderness, swelling). Note also any diagnostic failure due to lack of contrast and if study needed to be repeated.

8) **Sample details (categories, number of patients, collection time period)**

   To be discussed and agreed locally, large cohort of patients and scans likely to be needed to give representative data.

9) **Target achieved**

   Yes – No – Not applicable

   A reasonable sample size needed to ensure representative data, agree locally.

10) **Actions to be taken if the target is not met.**

    Review staff training/injection technique. Educational sessions. New staff enrolled on IV training courses and renewal of skills for all staff involved.

11) **Timing for re-audit**

    The audit should be repeated periodically to ensure either ongoing compliance with targets or necessary improvements as required.

Audit 14

/ Category: Value Based, Safety

1) **Audit Title**

Impact of Patient Mis-identification Errors and Subsequent Error Rates of This Type.

2) **Standard against which the audit topic is to be compared**

Patient mis-identification incidents is an error or near miss that has the potential to cause, an accidental or unintended exposure to ionizing radiation or wrong diagnosis.

A patient mis-identification error can be defined as when:

a. an individual receives a procedure where none was intended,
b. the wrong individual is referred for diagnostic imaging,
c. an individual receives the wrong diagnostic imaging,
d. an individual receives the right diagnostic imaging, at the wrong time due to misidentification.
e. A patient misidentification near miss can be defined an error is identified before the examination or procedure begins.
f. Before imaging exam/procedure a checklist form could be completed by radiology staff.

3) **Source of standard (or reference document)**

Standards can in part be derived from historical/local data but should also be formulated in light of national/international publications and guidelines:

- Sheehan SE, Safdar N, Singh H, Sittig DF, Bruno MA, Keller K, Kinnard S, Brunner MC. Detection and Remediation of Misidentification Errors in Radiology Examination Ordering. Appl Clin Inform. 2020 Jan;11(1):79-87. doi: 10.1055/s-0039-3402730.
- Preventing Patient Identification Incidents in Diagnostic Imaging, Nuclear Medicine and Radiotherapy – guiding principles for safe practice in the United Kingdom, Ionising Radiation (Medical Exposure) Regulations.
- Sadigh G, et al. S. JOURNAL CLUB: Evaluation of Near-Miss Wrong-Patient Events in Radiology Reports. AJR Am J Roentgenol. 2015 Aug;205(2):337-43. doi: 10.2214/AJR.14.13339.

4) **Target / compliance percentage to be achieved**

To be agreed locally and considering relevant guidelines.

5) **Item or variable to be audited**

The frequency of patient mis-identification errors.

6) **Method: Retrospective / Prospective / Other**

Retrospective or prospective.

7) **Data or information to be collected**

Patient mis-identification errors occurring within the period of the audit; any effect on clinical outcome; other adverse effects (i.e. unnecessary radiation exposure); reasons for error; timing of error recognition, remedial actions.

8) **Sample details (categories, number of patients, collection time period)**

To be agreed locally, including time period for the audit.

9) **Target achieved (yes / no / not applicable)**

Compliance with standards yes/no.

10) **Actions to be taken if the target is not met**

Review causes for misidentification, remedial actions (these may include education programmes, the introduction of a checklist form), re-audit.

11) **Timing for re-audit**

This audit should be repeated periodically to confirm either compliance with standards or, if needed, that necessary improvements have been made. All departmental staff should be involved proactively in training and educational initiatives to reduce the likelihood of this type of error.

Audit 15

/ Category: Justification, Quality

1) **Audit Title**

   Reject Analysis of Radiological Images

2) **Standard against which the audit topic is to be compared**

   The percentage of rejected images should be within acceptable limits according to local, national, or international quality assurance guidelines. The common reasons for rejection (e.g., positioning errors, motion artifacts, or exposure issues) should be identified and addressed to improve departmental processes and reduce repeat rates.

3) **Source of standard (or reference document)**

   These are derived from existing published literature and available guidelines at local, national and international level. Recommendations from radiology societies (e.g., European Society of Radiology (ESR) or American College of Radiology (ACR)).

   References: European Guidelines on Quality Criteria for Diagnostic Radiographic Images (EUR 16260 EN).

4) **Target / compliance percentage to be achieved**

   To be agreed locally and considering relevant guidelines.

5) **Item or variable to be audited**

   The image rejection rate, type of examination, reason for image rejection.

6) **Method: Retrospective / Prospective / Other**

   This audit can be performed retrospectively or prospectively.

7) **Data or information to be collected**

   Number and type of images rejected, documented reasons for image rejection (e.g., patient positioning, improper patient preparation, equipment malfunctioning).

8) **Sample details (categories, number of patients, collection time period)**

   To be agreed locally, including areas of radiographic practice to be included, number of patients, period of collection.

9) **Target achieved (yes / no / not applicable)**

10) **Actions to be taken if the target is not met**

    Share audit findings with radiographers and radiologists.

    Develop targeted interventions, such as training programs to address common errors, reviewing protocols, or calibrating equipment.

    Set realistic goals for reducing the rejection rate within a defined timeframe.

11) **Timing for re-audit**

    This audit should be repeated periodically to confirm continuing compliance with standards or if needed, that necessary improvements have occurred. All/replacement staff must be proactively involved in training and education around the importance of high-quality techniques in reducing reject analysis rates.

Audit 16

/ Category: Quality

1) **Audit Title**

Impact of a Local Training Programme on First Line Reporting Accuracy by Junior (Trainees) Radiologist Doctors.

2) **Standard against which the audit topic is to be compared**

This topic can have different levels of comparison:

1. International guidelines: such as
    a. Royal College of Radiologists (RCR): Standards of accuracy for diagnostic reporting, specifically for doctors in training.
    b. European Society of Radiology (ESR): Guidelines on reporting accuracy and good practices in training.
2. National guidelines: for example, in Italy the References on diagnostic skills and reporting protocols – Italian Society of Medical Radiology (SIRM).
3. Scientific literature: Using as a comparison published studies that evaluate similar training interventions on medical residents and the related improvements in diagnostic accuracy. Not less than 5 years.

3) **Source of standard (or reference document)**

The source of the standard will be derived from existing published literature, in particular meta-analysis and systematic reviews of specific training techniques issued by national or supranational institutions and available guidelines at local, national and international levels.

4) **Target / compliance percentage to be achieved**

To be agreed locally and considering relevant guidelines.

5) **Item or variable to be audited**

A wide variety of reporting situations can be included.

The ability to detect emergency findings such as pneumothorax or massive effusion on X-ray, cerebral haemorrhage or stroke on CT, hemoperitoneum, etc., should be added to the audit objectives.

6) **Method: Retrospective / Prospective / Other**

This is an audit best performed prospectively.

7) **Data or information to be collected**

An initial assessment of junior doctor reporting performed at start of rotation. Intervention made e.g., seminar/ series of sessions/online tutorials covering the reporting area in question and then a repeat assessment.

8) **Sample details (categories, number of patients, collection time period)**

To be discussed locally, results of reporting assessments pre and post teaching intervention

9) **Target achieved (yes / no / not applicable)**

Improvements in junior doctor reporting accuracy anticipated.

10) **Actions to be taken if the target is not met**

Review the topic taught, mechanism/timing/frequency of delivery. Discuss with junior doctors the preferred form of teaching delivery, including practical cases, review attendance at teaching sessions, also feedback on results.

11) **Timing for re-audit**

This audit should be repeated periodically with new rotations of junior doctors – consider also repeating the teaching with a particular cohort if desired reporting improvements following teaching are not apparent.

Audit 17

/ Category: Justification

1) **Audit Title**

   Assessing the Appropriateness of CT Referrals

2) **Standard against which the audit topic is to be compared**

   Guidelines for appropriate imaging referrals, e.g., European Society of Radiology iGuide guidelines, Royal College of Radiologists iRefer guidelines or local appropriateness criteria.

3) **Source of standard (or reference document)**

   National and international imaging referral guidelines, such as ACR Appropriateness Criteria.

4) **Target / compliance percentage to be achieved**

   95% compliance with appropriateness guidelines.

5) **Item or variable to be audited**

   - Indication for referral.
   - Justification against referral criteria.
   - Completeness of clinical information provided by referrers.

6) **Method**

   Retrospective.

7) **Data or information to be collected**

   - Clinical indication for referral.
   - Appropriateness according to guidelines.
   - Outcome of imaging (diagnostic yield).

8) **Sample details**

   50 consecutive CT referrals over a three-month period.

9) **Target achieved**

   Yes / No.

10) **Actions to be taken if the target is not met**

    - Provide targeted training for referring clinicians.
    - Distribute referral guidelines.
    - Develop a checklist to ensure compliance before imaging is conducted.

11) **Timing for re-audit**

    6 months.

Audit 18

/ Category: Justification, Quality

1) **Audit Title**

   Adequate Completion of Radiology Request Forms for X-Ray and CT.

2) **Standard against which the audit topic is to be compared**

   This audit can include a wide variety of radiology procedures which involve exposure to ionising radiation e.g., x-ray, CT, screening, it can also be extended to non-ionising studies e.g., ultrasound/MRI. Radiology request forms should be fully completed, including all essential details such as patient demographics, clinical history, reason for the examination, and referrer information. Forms must comply with local and national standards for imaging referrals to facilitate appropriate justification and reporting.

3) **Source of standard (or reference document)**

   The source of standards would be establishing published literature and local/national guidelines for radiology referral and justification. Basic Safety Standards Directive (BSSD), Council Directive 2013/59/Euratom. Institutional radiology referral policies.

   References: ESR iGuide (European Society of Radiology). National Institute for Health and Care Excellence (NICE) imaging referral guidelines.

4) **Target / compliance percentage to be achieved**

   To be agreed locally, but 100% compliance could be the recommended best practice standard.

5) **Item or variable to be audited**

   To evaluate adequate completion of all required variables on the request form (including patient identifiers, clinical information, study requested, identity of requester and full contact details for requester).

6) **Method: Retrospective / Prospective / Other**

   This audit is best performed prospectively, but retrospective analysis is also possible.

7) **Data or information to be collected**

   Collect and evaluate radiology request forms from the department's archive or electronic system.

   Use a structured checklist to assess the presence and completeness of key information.

8) **Sample details (categories, number of patients, collection time period)**

   To be decided locally, including types of procedure request to be audited, number of patients and time period.

9) **Target achieved (yes / no / not applicable)**

10) **Actions to be taken if the target is not met**

    Discussion with referrers, education of referring medical staff, discussion within radiology department around rejections of incomplete request forms.

11) **Timing for re-audit**

    This audit should be periodically repeated to ensure continuing compliance or to demonstrate required changes in referral practice have been achieved. A continuing process of education for referrers is also desirable.

Audit 19

/ Category: Safety, Quality

1) **Audit Title**

Impact of Departmental CT Dose Reducing Protocol on Image Quality and Diagnostic Confidence

2) **Standard against which the audit topic is to be compared.**

CT imaging protocols should achieve a balance between minimizing radiation dose (adhering to ALARA principles) and maintaining diagnostic image quality sufficient for clinical decision-making. A wide variety of CT procedures/protocols can be included; amendment of existing CT scanning protocol and the effect on image quality and diagnostic confidence are to be assessed.

3) **Source of standard (or reference document)**

Existing published literature and national/international imaging standards and guidelines. European Commission Diagnostic Reference Levels (DRLs). European Guidelines on Quality Criteria for Computed Tomography (EUR 16262 EN). ACR Appropriateness Criteria.

4) **Target/compliance percentage to be achieved**

To be discussed locally, Improving or maintaining the diagnostic yield of CT across a range of procedures whilst introducing new/dose reducing protocols

5) **Item or variable to be audited**

The percentage reduction in radiation dose compared to baseline.

Percentage of CT images meeting diagnostic quality standards.

Clinician-reported diagnostic confidence levels (using a Likert scale or similar).

6) **Method: Retrospective / Prospective / Other**

Prospective

7) **Data or information to be collected**

CT examinations 50-100 (Dose information and protocol included)

8) **Sample details (categories, number of patients, collection time period)**

To be agreed upon locally; to adapt according to each CT machine and the diagnostic imaging.

9) **Target achieved (yes/no/not applicable)**

Image quality/diagnostic confidence maintained/improved by the effect of a new protocol with documented reduction in dose.

10) **Actions to be taken if the target is not met.**

Present findings to the radiology team, including examples of images with high and low quality. Develop recommendations to refine dose-reducing protocols if needed, balancing dose and diagnostic utility. Provide additional training to radiographers on protocol implementation, if required.

11) **Timing for re-audit**

Periodic re-auditing is recommended; 6 months.

Audit 20

/ Category: Safety, Quality

1) **Audit Title**

Impact of Variation in Volume of Injected Contrast in CT on Image Quality, Diagnostic Confidence and Dose.

2) **Standard against which the audit topic is to be compared**

This audit examines whether varying the volume of injected contrast (working within agreed parameters on volume/concentration) can reduce radiation dose whilst maintaining image quality and diagnostic confidence.

3) **Source of standard (or reference document)**

Generally, the volume and concentration of IV contrast injected will depend on a variety of factors e.g., renal function, type of scan, patient weight – these factors will be determined according to local, national, international guidelines and protocols.

References: Optimizing the Use of Iodinated Contrast Media for CT: Managing Shortages and Planning for a Sustainable and Secure Supply

CADTH Health Technology Review, Contrast Media Guidelines (European Society of Urogenital Radiology (ESUR)).

4) **Target / compliance percentage to be achieved**

Maintaining image quality and diagnostic confidence whilst reducing required radiation dose by variation in injected contrast during CT. Defined locally.

5) **Item or variable to be audited**

A variety of CT procedures/studies can be evaluated which require intravenous contrast injection. The survey could be extended to include oral contrast where applicable.

6) **Method: Retrospective / Prospective / Other**

This audit is best performed prospectively.

7) **Data or information to be collected**

Volume of contrast media administered per CT protocol.

Image quality score (using a standardized grading system).

Diagnostic confidence rating (from reporting radiologists).

Correlation between contrast volume, image quality, and radiation dose.

8) **Sample details (categories, number of patients, collection time period)**

To be decided locally, including type of CT procedures evaluated

9) **Target achieved (yes / no / not applicable)**

Maintaining image quality/diagnostic confidence, monitoring the effect on radiation dose at the lowest possible radiation dose.

10) **Actions to be taken if the target is not met**

CT contrast volume will need to be adjusted (within agreed parameters) if there is reduction in image quality/diagnostic confidence and/or increased radiation doses required.

11) **Timing for re-audit**

Periodic re-auditing is recommended to ensure image quality/diagnostic confidence is maintained and procedural dose remains acceptable with injected CT contrast variation.

Audit 21

/ Category: Quality, Safety

1) **Audit Title**

Impact of Adjusting Frame/Pulse Rate in Fluoroscopy on Image Quality, Diagnostic Confidence and Dose.

2) **Standard against which the audit topic is to be compared**

Fluoroscopy screening devices usually have parameters pre-set, but these can be changed usually by service engineers. Image quality, diagnostic confidence, dose standards created using sources below. Fluoroscopy frame/pulse rates should balance minimized radiation exposure (adhering to ALARA principles) with maintaining sufficient image quality to support diagnostic confidence.

3) **Source of standard (or reference document)**

Generally, the source of the standard would be published literature and guidelines at local, national, international level. References ICRP Publication 117: Radiation Protection in Fluoroscopy. European Guidelines on Optimizing Fluoroscopy Settings (EUR 16261).

4) **Target / compliance percentage to be achieved**

Maintaining image quality and diagnostic confidence whilst minimising dose is the desired outcome/target.

5) **Item or variable to be audited**

Dose reduction whilst maintaining diagnostic confidence and image quality. A variety of fluoroscopic procedures can be included in the audit (e.g., upper and lower GI contrast studies).

Frame/pulse rate settings used during fluoroscopy procedures.

Image quality scores (using standardized assessment criteria).

Diagnostic confidence ratings from interpreting radiologists or clinicians.

Radiation dose metrics (e.g., dose-area product (DAP), fluoroscopy time).

6) **Method: Retrospective / Prospective / Other**

This audit is best performed prospectively.

7) **Data or information to be collected**

Retrieve data on fluoroscopy settings, dose metrics, and clinical outcomes from PACS or equipment logs. Use standardized tools to assess image quality (e.g., contrast resolution, motion artifacts). Collect diagnostic confidence ratings via surveys or structured interviews with clinicians.

8) **Sample details (categories, number of patients, collection time period)**

To be decided locally, including which imaging procedures are to be evaluated. Example: review a sample of 50-100 fluoroscopy procedures with varying frame/pulse rate settings over a specified period.

9) **Target achieved (yes / no / not applicable)**

As demonstrated by maintaining image quality and diagnostic confidence at the lowest reasonable dose.

10) **Actions to be taken if the target is not met**

The dose will need to be adjusted (raised) if audit and review indicates an unacceptable loss of image quality and reduction in diagnostic confidence. Share findings with radiology and fluoroscopy teams, highlighting cases with suboptimal settings.

Update fluoroscopy protocols to incorporate optimized frame/pulse rates for specific procedures.

11) **Timing for re-audit**

Periodic re-auditing is recommended to ensure image quality/diagnostic confidence is maintained and procedural dose is acceptable.

Audit 22

/ Category: Quality, Safety

1) **Audit Title**

Adequacy of CT colonography (insufflation/bowel preparation)

2) **Standard against which the audit topic is to be compared**

To be discussed and agreed locally with managerial and radiographic teams

3) **Source of standard (or reference document)**

Standards of practice for computed tomography colonography (CTC) Joint guidance from the British Society of Gastrointestinal and Abdominal Radiology and The Royal College of Radiologists" (2021).
Available at https://www.rcr.ac.uk/publication/standards-practice-computed-tomography-colonography-ctc-joint-guidance-britishsociety

4) **Target / compliance percentage to be achieved**

100% (aspirational), to be agreed locally

5) **Item or variable to be audited**

Use of pre-procedure protocol for bowel preparation and faecal tagging. Use of rectal catheter with balloon deflated on at least one series. Insufflation of colon with carbon dioxide to produce sufficient colonic distension. Administration of hyoscine butyl bromide to optimise colonic distension, unless contraindicated.

6) **Method: Retrospective / Prospective / Other**

Retrospective or prospective

7) **Data or information to be collected**

Patient demographics Did patient follow bowel prep instructions? [Y/N]

Hyoscine N-butyl bromide (Buscopan) administered? [Y/N]

If no, was reason recorded? [Y/N]

Both scan series reviewed for: Adequacy of faecal tagging - graded as follows:

- ★ Good (tagged faeces appears white on soft tissue windows)
- ★ Suboptimal (tagged faeces appears hyperdense to soft tissue but not white, or incomplete tagging i.e., tagging agent has not reached the distal colon)
- ★ Poor (tagged faeces isodense / hypodense to soft tissue) Rectal tube position - correctly positioned on both series? [Y/N] Balloon deflated on one series [Y/N] Gas insufflation using carbon dioxide via automated insufflator [Y/N] Colonic distension, graded as follows:
- ★ Complete on both series
- ★ Complete between the two series (some areas of inadequate distention but adequately distended on the other series)
- ★ Incomplete (inadequate distension of certain areas of colon on both series) If Incomplete, was reason recorded e.g., frailty? [Y/N]

8) **Sample details (categories, number of patients, collection time period)**

To be agreed locally, minimum 100 consecutive patients

9) **Target achieved**

Yes / No (with percentages for each category to inform quality improvement)

10) **Actions to be taken if the target is not met.**

- ★ If faecal tagging is insufficient, the pre-procedure protocol may be reviewed.
- ★ Deliver training to radiographers performing CTC to educate on accurate recording of hyoscine butyl bromide administration, rectal tube positioning and insufflation pressures.
- ★ Encourage radiographers to seek advice from CTC reporters at time of scan if there is uncertainty over the adequacy of a scan.
- ★ If colonic distention is poor on one or both scans, rectal tube balloon inflation can be reviewed.
- ★ If there is a significant difference in practice or results between two or more CT sites, consider a standardised protocol.

11) **Timing for re-audit**

Periodically. If changes are implemented, re-audit in 6-12 months to assess for improvement

Audit 23

/ Category: Quality, Safety

1) **Audit Title**

   Adequacy of irradiation beam size (collimation) in projection radiography

2) **Standard against which the audit topic is to be compared.**

   To be discussed and agreed locally with managerial and radiographic teams, noting variations in patient presentation and size of both anatomy and receptors. Ideally four collimation marks per extremity projection and two for all trunk radiographs.

3) **Source of standard (or reference document)**

   Existing published literature and local / national guidance

   References: European Guidelines on Quality Criteria for Diagnostic Radiographic Images (EUR 16260 EN).
   International Atomic Energy Agency (IAEA) standards on radiographic quality and safety.

4) **Target / compliance percentage to be achieved**

   For local agreement in line with published literature

5) **Item or variable to be audited**

   Number of collimation marks evident on each pre-processed radiograph

6) **Method: Retrospective / Prospective / Other**

   Retrospective

7) **Data or information to be collected**

   Number of collimation marks evident on each pre-processed radiograph. Types of radiographic examinations.
   Potential barriers to appropriate collimation (patient size / pathology etc). Optional additional measurement of excess field size.

   Typical KAP values compared with DRLs. Non-compliance may indicate excessive collimation if the image quality is adequate.

8) **Sample details (categories, number of patients, collection time period)**

   To be agreed locally, including radiograph types for inclusion, number of patients or period of collection to ensure representativeness of sample. Recommend consecutive radiographs (minimum 30 per body part: e.g., 30 extremity, 30 chest, 30 pelvis)

9) **Target achieved (yes / no / not applicable)**

   Compliance with local / national / published standards

10) **Actions to be taken if the target is not met.**

    Sharing of results with staff to allow for staff education and training. Follow up re-audit to evaluate impact of education and training with staff

11) **Timing for re-audit**

    Repeated periodically, with more frequent audits appropriate when compliance levels are low

Audit 24

/ Category: Quality

1) **Audit Title**

Radiographic image labelling – use of anatomical side markers for projection radiography

2) **Standard against which the audit topic is to be compared**

To be discussed and agreed locally. All projection radiographs should include a legible anatomical side marker, placed prior to exposure. It should be specified that the anatomical marker should be textual or, better yet, iconographic, even better if in colour, in any case strongly contrasted with the radiological image under examination and, in any case, unequivocal.

3) **Source of standard (or reference document)**

Existing published literature and local/national guidance

International Guidelines:
- IAEA: Recommends proper use of anatomical markers to ensure safety and minimize errors.
- ESR: Provides standards for labelling and documentation in radiographic imaging.

European Directives:
- BSSD: European Basic Safety Standards mandate proper labelling for traceability and radiation safety.

National Guidelines:
- Local or national regulations (e.g., Italy's ISS recommendations or NHS protocols in the UK).

Best Practices:
- SoR: Advocates for pre-exposure physical side markers to ensure image integrity.
- ACR: Emphasizes labelling and traceability in medical imaging.

Scientific Literature:
- Studies in journals like European Radiology highlight the importance of pre-exposure markers.

These references ensure compliance with international standards and enhance the quality and safety of radiographic practices. PDFs of the guidelines listed can be easily found online, where they are updated, as well as recent literature. Internal company guidelines should always be considered.

4) **Target / compliance percentage to be achieved**

100%

5) **Item or variable to be audited**

Percentage of projection radiographs which have a visible side marker.

6) **Method: Retrospective / Prospective / Other**

Prospective, retrospective or periodic

7) **Data or information to be collected**

Percentage of images which have a side marker. Percentage of images where a side marker is in the primary beam and placed pre-exposure. Percentage of images where side marker was placed at time of post-processing, but pre-exposure marker is visible in secondary beam. Percentage of images where a side marker was only placed at post processing.

8) **Sample details (categories, number of patients, collection time period)**

For local agreement to ensure representativeness of sample to include range of staff and examination types.

9) **Target achieved (yes / no / not applicable)**

Yes/No

10) **Actions to be taken if the target is not met.**

Identify the failures and the reasons for failures. Discuss the results at radiographer audit meetings. Potential further actions might include:
- Training on correct use of PACS,
- Using radiographer identifiable clip-on markers,
- Reminder notices on the X-ray units.

Individual result sharing may be appropriate for persistent failures.

11) **Timing for re-audit (yes / no / not applicable)**

Repeated periodically, with more frequent audits appropriate when compliance levels are low

Audit 25

/ Category: Quality

1) **Audit Title**

   Reject rate for projection radiographs

2) **Standard against which the audit topic is to be compared**

   To be discussed and agreed locally with local managerial and radiographic teams, noting variations in published reject analysis rates and between imaging technologies (film-screen, CR, DR).

3) **Source of standard (or reference document)**

   Existing published literature and local/national guidance

4) **Target / compliance percentage to be achieved**

   For local agreement in line with published literature/national guidance

5) **Item or variable to be audited**

   Image rejection rate for projection radiography examinations of differing types. Also, to include reason for rejection

6) **Method: Retrospective / Prospective / Other**

   Retrospective or prospective

7) **Data or information to be collected**

   Number and type of images rejected documented reasons for rejection

8) **Sample details (categories, number of patients, collection time period)**

   To be agreed locally, including areas of radiographic practice to be included, number of patients or period of collection to ensure representativeness of sample.

9) **Target achieved**

   Yes – No – Not applicable

   Compliance with local/national/published standards for the technology (film-screen, CR, DR)

10) **Actions to be taken if the target is not met.**

    Root cause analysis to consider areas for future improvement (for example reasons for rejection, reject rates per examination type, common errors) to allow for staff education. Follow up re-audit to evaluate impact of education and training with staff.

11) **Timing for re-audit**

    Repeated periodically, with more frequent audits appropriate when compliance levels are low

Audit 26

/ Category: Quality

1) **Audit Title**

Existence of predetermined CT technical protocols for each specific indication

2) **Standard against which the audit topic is to be compared**

Due to the rapid evolution of CT technology and the greatly increased number of examinations performed for different indications, the techniques for performing an optimal examination have also increased. The CT examination can be more effectively adapted to the presumed diagnosis by using a suitable technical protocol.

- Germany: Qualitätssicherungsleitlinie CT der Bundesärztekammer
- Standardized metrics of quality for varying specifications.
- Implicitly addresses dose settings for a varying patient collective by means of constitution

3) **Source of standard (or reference document)**

in Germany: https://www.bundesaerztekammer.de/fileadmin/user_upload/BAEK/Themen/Qualitaetssicherung/_Bek_BAEK_Leitlinie_Computertomographie_ONLINE_KORR_Vers_25_05_2023.pdf

4) **Target / compliance percentage to be achieved**

The most common clinical protocols (50% of patients examined using these protocols) should have a corresponding technical protocol available.
Every 6 Month. Benchmark each protocol with respect to dose reference levels. Analyse for handling errors and image quality.

5) **Item or variable to be audited**

Protocol Development and evaluation process. Dose management? Dose Reference Levels? Documentation of changes and physician feedback?

6) **Method: Retrospective / Prospective / Other**

Prospective: development of CT Scan parameters and reconstruction settings to address the medical question. Done by medical physics expert with regards to QA-Guidelines. Afterwards evaluation of the proposal to the responsible physician. If everything is okay, implementation of the protocol.
Retrospective: Analysation of the protocols' performance regarding AEC-performance, handling, image quality (with physicians) and exposure (median over a study collective of the same used protocol to obtain an exposure value (CTDI) for comparison with dose reference levels should be exceeded.

7) **Data or information to be collected**

- Are the protocols useful/ Are they not created individually to fit the demands of different physicians?
- Has the overview been maintained? Is a defined structure given? Is it clear which protocol addresses which medical indication?

8) **Sample details (categories, number of patients, collection time period)**

- Are CT-protocols periodically analysed by means of performance (image quality, exposure, functionality of the AEC) and error potential (complicated protocols with a demand for special introduction to the personal)?
- Do SOPs (Standard operation procedures) exist for each implemented protocol in a way that personnel have easy access?
  - Are those SOPs easy to understand and can be easily applied in reality
  - What workflow addresses changes in already implemented protocols to reduce error potential due to habits?
  - How robust are the implemented CT protocols against highly variant patient constitutions?
  - Functionality of the AEC (Performance-Plateaus should be avoided)
  - Image quality should be ensured
  - Overexposure should be avoided (very thin patients)
  - Underexposure should be avoided (very big patients)
- Is there a workflow for imaging of extreme patients (adipositas permagna/ anorexia)?
- If it is necessary: Are there protocols to ensure image quality by maintaining the ALARA-Principle intact for imaging certain BMI intervals?
- Each used protocol should result in images with a quality such that the medical question can be answered. Extreme situations should be carried out in presence of a medical physics expert.

9) **Target achieved**

Yes – No – Not applicable

10) **Actions to be taken if the target is not met.**

Refer to available technical protocols to start developing the own protocols.

- ▶ Check the protocol parameters whether some of the QA-requirements are not yet met and adjust respectively. Then check after the first 200 Patients or at least after 2 months if a trend can be seen whether the optimisation yield the targeted improvement or not.
- ▶ If not try to further improve with regards to QA-requirements until the target is reached

11) **Timing for re-audit**

One year, or sooner if the target is not met

Audit 27

/ Category: Value Based, Quality

1) **Audit Title**

How dose information should be transmitted to the patient

2) **Standard against which the audit topic is to be compared**

"A major goal of radiation risk communication in medicine is to ensure that patients, parents and/or caregivers receive the information they need in a way that the can understand. They need sufficient and straightforward information to understand the imaging care being performed" (from WHO leaflet, see below)

3) **Source of standard (or reference document)**

- WHO leaflet intitled: "COMMUNICATING RADIATION RISKS IN PAEDIATRIC IMAGING Information to support healthcare discussions about benefit and risk". https://www.who.int/ionizing_radiation/pub_meet/radiation-risks-paediatric-imaging/en/
- Dauer et al., Fears, Feelings, and Facts: Interactively Communicating Benefits and Risks of Medical Radiation with Patients; AJR:196, April 2011
- McCollough et al., Answers to Common Questions About the Use and Safety of CT scans; Mayo Clin Proc. 2015;90(10):1380-1392
- Radiation Dose: Communicating With Patients Management Matrix 2014, Volume 14 - Issue 4
- Quality Initiatives- Radiation Risk: What You Should Know to Tell Your Patient, Francis R. Verdun, François Bochud, François Gudinchet, Abbas Aroua, Pierre Schnyder, Reto Meuli. Radiographics, Volume 28 • Number 7, November-December 2008
- Communicating Radiation Risk to Patients: Experiences Among Radiographers in Norway, Anita F. Reitan and Audun Sanderud. Journal of Medical Imaging and Radiation Sciences 51 (2020) S84-S89

4) **Target / compliance percentage to be achieved**

100%

5) **Item or variable to be audited**

How, when and which dosimetric information is transmitted to the patient

6) **Method: Retrospective / Prospective / Other**

Retrospective or Prospective

7) **Data or information to be collected**

Document with the information transmitted

The dose report from the performed examination

8) **Sample details (categories, number of patients, collection time period)**

For the first 100 patients all categories the documentation transmitted concerning their dosimetry as per protocol/guideline.

9) **Target achieved (yes / no / not applicable)**

10) **Actions to be taken if the target is not met**

Define a way on how to transmit the dosimetric information to your patient and establish guidelines for the process.

11) **Timing for re-audit**

One year

Audit 28

/ Category: Safety

1) **Audit Title**

Follow-up of patient with high skin dose as a result of an interventional procedure

2) **Standard against which the audit topic is to be compared**

Monitoring the patient, identifying the complications quickly and if necessary, organizing a follow-up are key elements to manage the complications appropriately in Germany: "Strahlenschutzverordnung Anlage 14 2) Interventionen".

- Any occurrence of a deterministic effect that was not expected for the defined intervention.
- Any excess of the total dose area product of 50,000 centi-gray times square centimetre if a deterministic skin defect of second or higher degree occurs acutely or within 21 days after the interventional examination.
- Joint Commission Peak Skin Dose greater 4 Gy in the following 6 Month
- i.e. Follow-up PSD greater 1 Gy
- Follow-up check of the patients Skin 21 days after excessing the PSD threshold.

3) **Source of standard (or reference document)**

Eliseo Vano, Javier Escaned, Sergio Vano-Galvan, Jose M. Fernandez, Carmen Galvan; Importance of a Patient Dosimetry and Clinical Follow-up Program in the Detection of Radiodermatitis After Long Percutaneous Coronary Interventions; Cardiovasc Intervent Radiol (2013) 36:330–337

Guidelines for Patient Radiation Dose Management, Stecker et al, J Vasc Interv Radiol 2009

Fluoroscopically Guided Interventional Procedures: A Review of Radiation Effects on Patient`s Skin and Hair, Balter et al, Radiology 2010

Haute Autorité de Santé (HAS) (https://has-sante.fr/jcms/c_1754223/fr/ameliorer-le-suivi-des-patients-en-radiologie-interventionnelle-et-actes-radioguides): Improve patient follow-up in interventional radiology and radio guided procedures for reducing the risk of deterministic effects.

4) **Target / compliance percentage to be achieved**

100% fulfilment of the requirements

5) **Item or variable to be audited**

How skin dose to the patient is evaluated, existence of criteria for patient follow-up and implementation of the follow-up. Appropriate notifications other agencies as per guidance.

- Workflow? From the discovery to the notification of the responsible institutes/doctors to the notification and examination of the patients
- Are Patients notified about possible skin reaction due to possible high radiation exposure pre-interventional via education

6) **Method: Retrospective / Prospective / Other**

retrospective and prospective

7) **Data or information to be collected**

Patient skin dose after interventional procedures, criteria for patient follow-up

- Reference Point Dose
- Calculation/Determination PSD
- Joint commission PSD
- Dose Area Product

8) **Sample details (categories, number of patients, collection time period)**

For one year of treated patients

9) **Target achieved**

Yes – No – Not applicable

10) **Actions to be taken if the target is not met.**

Evaluate the feasibility of introducing a correct skin dose evaluation or at least trigger values to trigger a patient follow-up.

Implementation of the follow-up workflow via SOP such that each necessary institution is involved in the development process of the workflow

11) **Timing for re-audit**

One year, or sooner if the target is not met

Audit 29

/ Category: Safety

1) **Audit Title**

   Multidisciplinary Team Roles in Managing Patient Radiation Protection

2) **Standard against which the audit topic is to be compared**

   The key standard is ensuring the presence of a multidisciplinary team with the correct expertise. This team should include at least one radiologist, one radiographer, and one medical physicist, each contributing their essential roles in managing patient radiation protection effectively.

3) **Source of standard (or reference document)**

   IAEA web page: https://www.iaea.org/resources/rpop/health-professionals/radiology/responsibilities-of-health-professionals

4) **Target / compliance percentage to be achieved**

   100%

5) **Item or variable to be audited**

   Presence of at least one representative from each profession (radiologist, radiographer, medical physicist) actively involved in patient radiation protection.

6) **Method: Retrospective / Prospective / Other**

   Retrospective or Prospective

7) **Data or information to be collected**

   Number of staff responsible for patient radiation protection, categorized by profession (radiologist, radiographer, medical physicist).

   Number and types of radiological procedures performed over a one-year period.

8) **Sample details (categories, number of patients, collection time period)**

   Collect information about the number of procedures per year and staff implicated in radiation protection

9) **Target achieved (yes / no / not applicable)**

   Yes

10) **Actions to be taken if the target is not met**

    Prepare a report highlighting gaps in the team composition for patient radiation protection. Present findings to clinical and administrative teams. Emphasize the importance of including all key professionals in radiation protection to ensure compliance with standards and enhance patient safety. Develop an action plan to recruit or assign necessary team members.

11) **Timing for re-audit**

    One year (or sooner if key components missing)

Audit 30

/ Category: Value based, Quality

1) **Audit Title**

   Assessing Waiting Time for Outpatient Ultrasound Appointments

2) **Standard against which the audit topic is to be compared**

   National or local standards for acceptable waiting times for outpatient ultrasound appointments. These standards can be set by government health agencies, professional organizations, or patient advocacy groups. Moreover, data from similar healthcare institutions or regional averages can be used as benchmarks to compare waiting times.

3) **Source of standard (or reference document)**

   Local policies on waiting times or national guidelines on patient access to diagnostic services.

4) **Target / compliance percentage to be achieved**

   100% compliance with national or locally set targets for waiting times.

   Note: Waiting time targets may vary depending on the type of ultrasound examination (e.g., abdominal, cardiac, musculoskeletal) and the clinical urgency of the case.

5) **Item or variable to be audited**

   - Time from referral to appointment scheduling.
   - Time from referral to completed ultrasound examination.

6) **Method**

   Retrospective.

7) **Data or information to be collected**

   - Date of referral.
   - Date of appointment scheduling.
   - Date of completed examination.
   - Referral type (urgent, routine).

8) **Sample details**

   100 consecutive referrals over a three-month period.

9) **Target achieved**

   Yes / No.

10) **Actions to be taken if the target is not met**

    - Review staffing levels and appointment scheduling practices.
    - Consider additional ultrasound sessions or resources.
    - Identify bottlenecks in the scheduling process and implement solutions.

11) **Timing for re-audit**

    6 months after implementing changes.

Audit 31

/ Category: Value Based

1) **Audit Title**

Does the radiology department record statistics about patient satisfaction?

2) **Standard against which the audit topic to be compared**

The radiology department should have a structured process for collecting, recording, and analysing patient satisfaction data to identify areas for improvement and enhance the overall patient experience.

3) **Source of standard**

Guidelines on patient-centred care from professional bodies such as the European Society of Radiology (ESR) or American College of Radiology (ACR).

Institutional policies on patient satisfaction and service evaluation.

PO Alderson AJR 2000;175:319-323

CD Johnson Radiographics 2009;29:951-959

4) **Target /compliance percentage to be achieved**

100%

5) **Item or variable to be audited**

Presence of a system for collecting patient satisfaction data (e.g., surveys, feedback forms).

Frequency of data collection (e.g., monthly, quarterly).

Analysis and use of collected data to implement service improvements.

6) **Method: Retrospective / prospective / Other**

Retrospective or prospective

7) **Data or information to be collected**

Data around patient satisfaction – using locally /nationally agreed questionnaire, data items.

8) **Sample details**

As above – for local agreement, example 50 – 100 consecutive patients

9) **Target achieved**

Yes / No

10) **Action to be taken if target is not met**

Review all aspects of the questionnaire where target(s) not met, multidisciplinary departmental discussion and implement necessary practice changes

11) **Timing for re-audit**

One year

An example of a patient radiology departmental satisfaction survey is included overleaf, this can be used locally or adapted for use according to local requirements. The ESR Patient Advisory Group's patient satisfaction survey is also available, this is a more detailed document but again can be adapted as necessary for local use.

/ Patient Satisfaction Questionnaire – part 1

Department of Clinical Radiology

There is a scoring system in place

1	2	3	4	5	6	7	8	9	10
Very unsatisfied				Neutral (not satisfied or unsatisfied)					Very satisfied

Additional information

Are you?

Male Female

What age group are you?

Under 18 years 18 – 30 years 31 – 65 years 66 and over

1) What type of radiology examination did you attend for today?

X-ray CT scan MRI scan Ultrasound Mammogram

2) Did you receive information about your X-ray/scan before your appointment?

Yes – informed by GP or hospital specialist

Yes – written information sheet from radiology department

Yes – phone call or text message from radiology department

Yes – email from radiology department

No – no information received

3) How satisfied were you with the information provided, did it help you understand the X-ray/scan?

1	2	3	4	5	6	7	8	9	10
Very unsatisfied									Very satisfied

/ Patient Satisfaction Questionnaire – part 2

4 a) How satisfied were you with the waiting time for the provided X-ray/scan appointment?

1	2	3	4	5	6	7	8	9	10
Very unsatisfied									Very satisfied

4 b) How satisfied were you with the convenience of the provided X-ray/scan appointment?

1	2	3	4	5	6	7	8	9	10
Very unsatisfied									Very satisfied

5) How satisfied were you with the directions provided for finding the radiology department (information letter, website, signs in hospital)?

1	2	3	4	5	6	7	8	9	10
Very unsatisfied									Very satisfied

6 a) How satisfied were you with the radiology department reception staff, were they friendly?

1	2	3	4	5	6	7	8	9	10
Very unsatisfied									Very satisfied

6 b) Were they helpful?

1	2	3	4	5	6	7	8	9	10
Very unsatisfied									Very satisfied

7) How did you find the following aspects of the radiology department waiting area?

Cleanliness (including toilets)	Excellent	Good	Neutral	Poor
Layout (including facilities for children)	Excellent	Good	Neutral	Poor
Comfort	Excellent	Good	Neutral	Poor
Changing facilities	Excellent	Good	Neutral	Poor
Overall impression	Excellent	Good	Neutral	Poor

/ Patient Satisfaction Questionnaire – part 3

8) Was your X-ray/scan appointment performed on time?

Yes

No issues

No – minor delay

No – major delay

9) Did the member of staff involved in your X-ray/scan introduce themselves clearly?

Yes

No

10) Were you given a clear explanation of the X-ray/scan and what was involved?

Yes – clearly

Yes – to some extent

No

11 a) Did the radiology member of staff take time to answer your questions?

Yes – full and clear

Yes – to some extent

No

11 b) Did the radiology member of staff give you a clear explanation as to how you would receive your test results?

Yes – full and clear

Yes – to some extent

No

12) What was your overall impression of the service provided by our radiology department?

Excellent

Good

Neutral

Poor

Audit 32

/ Category: Justification, Quality

1) **Audit Title**
   Paediatric abdominal CT without prior abdominal ultrasound examination

2) **Standard against which the audit topic is to be compared.**
   To be discussed and agreed locally with local managerial, referring physicians, radiologists.

3) **Source of standard (or reference document)**
   Existing published literature and local / national guidance

4) **Target / compliance percentage to be achieved**
   To be determined based on local agreements in line with published literature/national guidance.

5) **Item or variable to be audited**
   All abdominal CT examinations of patients under 18 years.

6) **Method: Retrospective / Prospective / Other**
   Retrospective or prospective

7) **Data or information to be collected**
   Number of abdominal CT procedures performed on paediatric patients without prior abdominal ultrasound examination.

8) **Sample details (categories, number of patients, collection time period)**
   To be agreed locally. The number of patients and the time period for data collection should ensure a representative sample.

9) **Target achieved (yes / no / not applicable)**
   Compliance with local / national / published standards

10) **Actions to be taken if the target is not met.**
    Root cause analysis to consider areas for future improvement.
    Present findings at departmental meetings with all stakeholders involved in paediatric abdominal CT imaging.
    Develop and implement an educational program emphasizing the importance of performing abdominal ultrasound prior to abdominal CT in the paediatric population.

11) **Timing for re-audit**
    Develop and implement an educational program emphasizing the importance of performing abdominal ultrasound prior to abdominal CT in the paediatric population.
    Repeated periodically, with more frequent audits appropriate when compliance levels are low.

Audit 33

/ Category: Safety

1) **Audit Title**

Quality control of X-ray diagnosis equipment

2) **Standard against which the audit topic is to be compared.**

To be discussed and agreed locally.

3) **Source of standard (or reference document)**

National guidance.
If national guidance is not available, suggested publications:
RP 162
IAEA HUMAN HEALTH SERIES No. 19 (2012)
IAEA HUMAN HEALTH SERIES No. 47 (2023)
EFOMP Mammo Protocol (2017)
EFOMP Quality control in digital breast tomosynthesis (DBT) (2023)
EFOMP Quality control of dynamic X-ray imaging systems (2024)
IPEM Report 32
IPEM Report 91
AAPM Report No. 270

4) **Target / compliance percentage to be achieved**

All X-ray diagnosis equipment, including interventional X-ray devices and displays, is subject to regular quality control in accordance with national/published standards. Local protocols for the quality control describe in detail the procedures, the distribution of responsibilities, frequencies, performance criteria (ideally with remedial and suspension levels) and the procedure in case of non-compliance.

5) **Item or variable to be audited**

Local protocols for the quality control of X-ray diagnosis equipment (including interventional X-ray devices and displays) and reports on the performed quality control checks

6) **Method: Retrospective / Prospective / Other**

Retrospective

7) **Data or information to be collected**

Local protocols for the quality control of X-ray diagnosis equipment (including interventional X-ray devices and displays) and reports on the performed quality control checks

8) **Sample details (categories, number of patients, collection time period)**

Collect local protocols for the quality control of X-ray diagnosis equipment (including interventional X-ray devices and displays) and reports on the performed quality control checks available for the last year, for all X-ray diagnosis equipment. Collect all reports of non-compliances and reports on corrective actions.

9) **Target achieved (yes / no / not applicable)**

Yes/No

10) **Actions to be taken if the target is not met.**

Development and/or upgrade of local quality control protocols, education of all involved (medical physicists and radiographers).

11) **Timing for re-audit**

One year

Audit 34

/ Category: Safety, Quality

1) **Audit Title**

   Typical doses and comparison with DRLs

2) **Standard against which the audit topic is to be compared.**

   To be discussed and agreed locally.
   Preferably combined with image quality evaluation.

3) **Source of standard (or reference document)**

   National guidance.
   If national guidance is not available, suggested publications:
   ICRP 135, RP180, RP185, RP195, scientific publications

4) **Target / compliance percentage to be achieved**

   For each modality, typical doses are periodically calculated for the most common procedures and compared with local, national, regional or EU DRLs. Wherever applicable, typical doses are calculated for indications and compared with indication-based DRLs. Adequate image quality assured.

5) **Item or variable to be audited**

   Local reports containing calculations of typical doses and their comparison with local, national, regional or EU DRLs, as well as recommendations on corrective action if needed (in cases when typical doses are significantly lower or significantly lower than DRLs).

6) **Method: Retrospective / Prospective / Other**

   Retrospective

7) **Data or information to be collected**

   Local reports containing calculations of typical doses and their comparison with local, national, regional or EU DRLs, as well as recommendations on corrective action if needed (in cases when typical doses are significantly lower or significantly lower than DRLs).

8) **Sample details (categories, number of patients, collection time period)**

   Collect local reports containing calculations of typical doses and their comparison with local, national, regional or EU DRLs, as well as recommendations on corrective action if needed available for the last year.

9) **Target achieved (yes / no / not applicable)**

   Yes/no

10) **Actions to be taken if the target is not met.**

    Raise staff awareness of the need to record and track patient doses. Sharing results with staff to allow for corrective actions and staff education and training. Medical physics expert should be involved in process. Follow up re-audit to evaluate impact of education and training with staff.

11) **Timing for re-audit**

    One year

Audit 35

/ Category: Safety

1) **Audit Title**

MR Safety education

2) **Standard against which the audit topic is to be compared**

All professionals with access to the MR suite should meet the recommended level of initial education and training in MR safety. All education and training provided for the different professions (radiologists, radiographers, nurses, clinicians, medical physicists, researchers, other staff etc.) shall be documented.

3) **Source of standard**

Local guidelines on MR Safety; ESR publication "The European MR Safety Landscape" (https://doi.org/10.1186/s13244-024-01813-6), ACR Manual on MR Safety.

4) **Target/compliance percentage to be achieved**

All personnel with access to the MR Room should have basic MR safety training for personal protection from static magnetic fields, including in the presence of implants on their own person; all personnel involved in patient scanning should have advanced MR safety training that, additionally, covers risks from exposure to time-varying magnetic fields (gradients and radiofrequency), including in the presence of implants.

5) **Item or variable to be audited**

Local and national protocol and documentation on relevant initial theory and training in MR safety

6) **Method**

Prospective/Retrospective

7) **Data or information to be collected**

Data from staff records

8) **Sample details**

List of all relevant staff involved in:

- Accessing the MR scanner room for any reason (including cleaning, maintenance, etc.)
- Operating the MR scanner for patient examination
- Performing ancillary operations to MR scanning (e.g. anaesthesia, resuscitation)
- Referring patients for an MR scan

Document the date and nature of the last MR-safety-specific training

9) **Target achieved**

Yes/No

10) **Action to be taken if the target is not met**

If the target is not met the cause must be identified. Review content/provision of staff relevant curricula at local/national level. Create internal training programs or gain access to external courses on MR safety.

11) **Timing for re-audit**

If the target is not met a re-audit should be done within two years, after an appropriate course offering for personnel is instituted. If the target is met, the re-audit could be done every four years.

Audit 36

/ Category: Safety

1) **Audit Title**

MR-safety "near misses": unknown foreign objects

2) **Standard against which the audit topic is to be compared**

All foreign objects in and on a patient's body should be identified prior to a MR scan. If a foreign object is seen in a routine MR examination without prior knowledge, it can be considered a "near-miss" as it could have potentially had hazardous consequences for the patient.

3) **Source of standard**

Local guidelines on MR Safety; ACR Manual on MR Safety.

4) **Target/compliance percentage to be achieved**

Patients with unexpected foreign objects visible in an MR scan: 0-1/year

5) **Item or variable to be audited**

Adequacy of MR safety screening procedures.

6) **Method**

Prospective/Retrospective

7) **Data or information to be collected**

Number of MR examinations in the considered period showing an unexpected foreign object or artifact indicating the presence of a foreign object (implant or otherwise) that was not present in the MR safety questionnaire and/or patient records.

8) **Sample details**

All MR examinations within a 12-month period

9) **Target achieved**

Yes/No

10) **Action to be taken if target not met**

If the target is not met, a review of the MR safety screening protocol needs to be performed.
Possible causes can be (but not necessarily limited to): MR safety questionnaire, patient workflow, availability of patient records.

11) **Timing for re-audit**

If the target is not met a re-audit should be done within one year, after appropriate modifications to the patient's workflow are instituted.
If the target is met, the re-audit could be done every three years.

Audit 37

/ Category: Safety

1) **Audit Title**

MR-safety "near misses": projectile accidents

2) **Standard against which the audit topic is to be compared**

Any ferromagnetic object brought in the vicinity of an MR scanner will be attracted to it, endangering patients and personnel that find themselves in the trajectory. While proper projectile-related accidents should already be reported in the internal accident reporting system, "near misses" are overlooked, but need to be minimized. In some cases, personnel or visitors present hazardous behaviour by bringing ferromagnetic objects in the vicinity of the scanner, but either are stopped by trained personnel before they can approach the magnet, or the ferromagnetic object becomes indeed a projectile, but no injury happens.

3) **Source of standard**

Local guidelines on MR Safety; ACR Manual on MR Safety.

4) **Target/compliance percentage to be achieved**

Projectile "near misses": 0-1/considered period

5) **Item or variable to be audited**

Adequacy of MR safety awareness procedures, compliance with standards of access to the MR suite.

6) **Method**

Prospective

7) **Data or information to be collected**

When an MR-safety-trained staff stops a person from entering the scanner room with a ferromagnetic object, or a projectile event is witnessed, without health consequences, a report form must be completed, indicating at minimum:

- Date and time of the incident
- Actual projectile or risk of projectile
- Type of person involved (patient, visitor, staff, including staff category e.g. radiology medical personnel, non-radiology medical personnel, non-medical personnel)
- Type of object involved

8) **Sample details**

The reports are collected within a 6-month period

9) **Target achieved**

Yes/No

10) **Action to be taken if target is not met**

If the target is not met, a review of the MR safety access protocol needs to be performed, according to which category of people was responsible for the accidents. Possible causes can be (but not necessarily limited to): Architecture of the MR Suite (zoning, access control), MR safety education, patient workflow.

11) **Timing for re-audit**

A re-audit should be carried out every two years.

Audit 38

/ Category: Quality

1) **Audit Title**

MR-quality: MR protocol audit for artifact minimization

2) **Standard against which the audit topic is to be compared**

All MR images that are sent for reading need to have sufficient diagnostic quality, and the images made available for reading should properly reflect the protocol requested by the radiologist (without omissions). In some cases, some sequences cannot achieve diagnostic quality due to implants or other inevitable sources of artifacts. In these cases, it is acceptable to have omissions in the protocol, but this eventuality should be considered beforehand.

3) **Source of standard**

Local clinical protocols, global/local gold standard for radiology examinations.

4) **Target/compliance percentage to be achieved**

- Non-diagnostic-quality image series: <2%.
- Omitted image series: <2%

5) **Item or variable to be audited**

Adequacy of MR protocols to the patient population, adequacy of MR scanning procedures.

6) **Method**

Prospective

7) **Data or information to be collected**

Over the period considered, radiologists should collect the following data for each patient exam:

- Total number of series submitted for reading
- Total amount of series in the standard scanning protocol for the medical question
- Number of series discarded from diagnosis because of artifacts
- For any series discarded:
  - Type of sequence acquired
  - Artifact type (e.g. motion, susceptibility...)
- For any series omitted:
  - Type of sequence that was to be acquired

8) **Sample details**

Reports are collected from 500 MR Examinations

9) **Target achieved**

Yes/No

10) **Action to be taken if the target is not met**

If the target is not met, a review of the criticalities needs to be performed, identifying whether the primary sources are:

- Personnel training/experience (i.e. personnel is not able to properly execute the scan or not able to recognize critical artifacts)
- Protocol inadequacy.

For example, if a sequence frequently fails in a specific type of examination, alternatives should be considered (e.g. by implementing sequences more robust to artifacts: e.g. radial acquisitions in case of frequent motion artifacts)

11) **Timing for re-audit**

A re-audit should be performed every three years.

Audit 39

/ Category: Quality, VB

1) **Audit Title**
   Time taken for imaging report to become available to the referring clinician (and directly to the patient where appropriate)

2) **Standard against which the audit topic is to be compared**
   Nationally or locally agreed standard

3) **Source of standard (or reference document)**
   National policy documents on targets or locally agreed performance targets

4) **Target / compliance percentage to be achieved**
   100% compliance with national or local target

5) **Item or variable to be audited**
   Time period between imaging taking place and report being available to the referrer, patient (as applicable)

6) **Method: Retrospective / Prospective / Other**
   retrospective

7) **Data or information to be collected**
   Waiting times for imaging reports to be completed and time taken to make these available to referrer, patient (as applicable)

8) **Sample details (categories, number of patients, collection time period)**
   Referrer type (family doctor, hospital doctor), Anatomical site, Suspected pathology (cancer-non-cancer), Initial diagnosis or follow up.
   50-100 patients

9) **Target achieved**
   Yes - no - not applicable

10) **Actions to be taken if the target is not met.**
    Review staffing levels and scheduling process and reporting processes (prioritisation - acute, chronic, initial diagnosis, follow-up)

11) **Timing for re-audit**
    6 - 12 - 18 - 24 months

Audit 40

/ Category: Quality, VB

1) **Audit Title**
   Time between receiving referral and imaging for non-acute MRI and CT imaging (excluding scheduled follow-up surveillance)

2) **Standard against which the audit topic is to be compared**
   Nationally or locally agreed standard

3) **Source of standard (or reference document)**
   National policy documents on targets or locally agreed performance targets

4) **Target / compliance percentage to be achieved**
   100% compliance with national or local target

5) **Item or variable to be audited**
   Time period between receipt of referral for non-acute MRI or CT imaging and imaging taking place (excluding schedules follow-up surveillance)

6) **Method: Retrospective / Prospective / Other**
   retrospective

7) **Data or information to be collected**
   Waiting times for scanning of completed referrals for non-acute MRI and CT imaging requests (excluding scheduled follow-up sessions)

8) **Sample details (categories, number of patients, collection time period)**
   Referrer type (family doctor, hospital doctor), Anatomical site, Suspected pathology (cancer-non-cancer), Initial diagnosis or follow up. 50-100 con

9) **Target achieved**
   Yes - no - not applicable

10) **Actions to be taken if the target is not met.**
    Review staffing levels and scheduling process
    Review equipment availability (scanner numbers, scanner uptime (equipment functioning))

11) **Timing for re-audit**
    6 - 12 - 18 - 24 months

Audit 41

/ Category: Safety

1) **Audit Title**

Application security in MRT

2) **Standard against which the audit topic is to be compared**

Respective local regulation; In Germany: Technical Rules for the Occupational Health and Safety Ordinance on Electromagnetic Fields (TREMF) - Federal Institute for Occupational Safety and Health

3) **Source of standard (or reference document)**

Respective local standard; In Germany: https://www.baua.de/DE/Home

4) **Target / compliance percentage to be achieved**

100% fulfilment of the requirements

5) **Item or variable to be audited**

- Structural safety aspects (warning signs/danger areas)
- Personal safety aspects (training, awareness talks, etc.)
- Systemic safety aspects (SOPs, safety instructions)

6) **Method: Retrospective / Prospective / Other**

Retrospective

7) **Data or information to be collected**

e.g. child protocols, (digital) device manual / initial instruction, instruction protocols, list of authorized personnel, MR-compatible materials, implants: manufacturer specifications or implant passport (country-dependent), education

8) **Sample details (categories, number of patients, collection time period)**

e.g. how many applications, how many processes described, evidence of instruction and training, evidence of daily safety and functional checks before use on patients, number of incorrect applications

9) **Target achieved**

Yes – No – Not applicable

10) **Actions to be taken if the target is not met.**

Formulate measures, e.g. retraining, structural changes, revision of processes

11) **Timing for re-audit**

One year, or sooner if the target is not met

Audit 42

/ Category: Quality

1) **Audit Title**
   Peer review

2) **Standard against which the audit topic is to be compared**
   National or locally agreed standard

3) **Source of standard (or reference document)**
   https://insightsimaging.springeropen.com/articles/10.1186/s13244-021-01056-9

4) **Target / compliance percentage to be achieved**
   Depending on local policy

5) **Item or variable to be audited**
   Proportion of radiological studies that underwent peer review

6) **Method: Retrospective / Prospective / Other**
   Retrospective

7) **Data or information to be collected**
   Proportion of radiological studies that underwent peer review

8) **Sample details (categories, number of patients, collection time period)**
   Proportion of radiological studies that underwent peer review

9) **Target achieved**
   Yes – No – Not applicable

10) **Actions to be taken if the target is not met.**
    Implement peer review or enhance participation

11) **Timing for re-audit**
    One year, or sooner if the target is not met

Audit 43

/ Category: Quality, AI

1) **Audit Title**
   AI governance structure

2) **Standard against which the audit topic is to be compared**
   Locally agreed standard

3) **Source of standard (or reference document)**
   https://pmc.ncbi.nlm.nih.gov/articles/PMC9713445/

4) **Target / compliance percentage to be achieved**
   Depending on local policy

5) **Item or variable to be audited**
   AI governance structure

6) **Method: Retrospective / Prospective / Other**
   Retrospective

7) **Data or information to be collected**
   Information about AI governance structure

8) **Sample details (categories, number of patients, collection time period)**
   N/A

9) **Target achieved**
   Yes – No – Not applicable

10) **Actions to be taken if the target is not met.**
    Implement AI governance structure

11) **Timing for re-audit**
    One year, or sooner if the target is not met

Audit 44

/ Category: Quality

1) **Audit Title**
   Feedback mechanism radiology-pathology

2) **Standard against which the audit topic is to be compared**
   Locally agreed standard

3) **Source of standard (or reference document)**
   https://www.sciencedirect.com/science/article/pii/S1546144019303047?via%3Dihub

4) **Target / compliance percentage to be achieved**
   Depending on local policy

5) **Item or variable to be audited**
   Proportion of radiological studies that received pathology feedback

6) **Method: Retrospective / Prospective / Other**
   Retrospective

7) **Data or information to be collected**
   Proportion of radiological studies that received pathology feedback

8) **Sample details (categories, number of patients, collection time period)**
   Proportion of radiological studies that received pathology feedback

9) **Target achieved**
   Yes – No – Not applicable

10) **Actions to be taken if the target is not met.**
    Implement or improve proportion of radiological studies that received pathology feedback

11) **Timing for re-audit**
    One year, or sooner if the target is not met

Audit 45

/ Category: Quality

1) **Audit Title**
   Standardisation of CT/MRI reports for staging of cervical cancer

2) **Standard against which the audit topic is to be compared.**
   Standardise the Imaging reports with using a common reporting template (to facilitate communication between radiologists and clinical team and for the keys points).

3) **Source of standard (or reference document)**
   Existing published literature and international guidance.

4) **Target / compliance percentage to be achieved**
   100% (aspirational), to be agreed locally

5) **Item or variable to be audited**
   All radiological procedures (CT, MRI) – using standard protocols

6) **Method: Retrospective / Prospective / Other**
   Prospective

7) **Data or information to be collected**
   All imaging examinations (Dose information, protocol included and contrast material details if used)

8) **Sample details (categories, number of patients, collection time period)**
   20 reports CT and 20 reports MRI

9) **Target achieved (yes / no / not applicable)**
   Yes

10) **Actions to be taken if the target is not met.**
    Using a standardised protocol.
    In case of artefacts in images scans, repeat exams should be considered (especially in MRI) without any risk to the patient

11) **Timing for re-audit**
    Periodically. If changes are implemented, re-audit in 6 months to assess for improvement.

Audit 46

/ Category: Justification

1) **Audit Title**

The Use of Chest Radiographs in Confirming Safe Nasogastric Tube (NG) Placement

2) **Standard against which the audit topic is to be compared**

National Patient Safety Standard Alert, UK.

3) **Source of standard (or reference document)**

National Patient Safety Agency, UK, Safety Alert 2016. - Nasogastric Tube Placement, Continuing Risk of Death and Severe Harm

4) **Target / compliance percentage to be achieved**

To be agreed locally, 100% compliance is the recommended standard.

5) **Item or variable to be audited**

- Chest radiograph (CXR) only to be used if pH indicators of nasogastric aspirate are non-contributory.
- The CXR should clearly show the NG tube and clarify its position in relation to bronchi/carina, oesophagus and left hemidiaphragm
- NG tube position assessed by someone competent to do so, decision recorded, no feeding until safe assessment confirmed.
- Formal report by radiologist, this can be obtained urgently as required in difficult cases.

6) **Method: Retrospective / Prospective / Other**

Retrospective or prospective

7) **Data or information to be collected**

Chest X-rays reviewed with patient records.

8) **Sample details (categories, number of patients, collection time period)**

50 consecutive patients with history of NG tube insertion.
To be discussed locally.

9) **Target achieved**

Yes – No – Not applicable

10) **Actions to be taken if the target is not met.**

Review of the clinical pathway, involve ward and radiographic staff and clinical teams and clarify diagnostic pathway.

11) **Timing for re-audit**

Periodic re-audit, if failing to achieve standards, short period re-audit following appropriate meetings and clarification of pathway.

Audit 47

/ Category: Value Based

1) **Audit Title**
   The Clinical Radiologist and Multidisciplinary Team Meetings (MDM)

2) **Standard against which the audit topic is to be compared**
   Published document from the Royal College of Radiologists, UK.

3) **Source of standard (or reference document)**
   Clinical Radiology - Multidisciplinary Team Meetings - Standards for Clinical Radiologists. Royal College of Radiologists. London 2023.

4) **Target / compliance percentage to be achieved**
   To be agreed locally.

5) **Item or variable to be audited**
   - Ensure attendance and image review pre-meeting by a radiologist with sufficient expertise in the meeting.
   - Identify required time for meeting, meeting preparation and post-meeting actions.
   - Assess triage of cases and ensure only suitable cases, with relevant clinical information and previous imaging are included.
   - Check image storage, retrieval and display systems confirm to local/national requirements.
   - Capture and review summary of discussions occurs in all cases.
   - Record major discrepancies and identify process for onwards communication.

6) **Method: Retrospective / Prospective / Other**
   Retrospective or prospective

7) **Data or information to be collected**
   Collect/review data as above

8) **Sample details (categories, number of patients, collection time period)**
   Collection time period to be agreed (3-6 months)

9) **Target achieved**
   Yes – No – Not applicable

10) **Actions to be taken if the target is not met.**
    Review with colleagues. Ensure efficient time is available for radiologist participation, assess job plans and MDM room facilities and support processes.

11) **Timing for re-audit**
    Periodic, short period of re-audit if standards not achieved.

Audit 48

/ Category: Safety, Quality

1) **Audit Title**
   Evaluation of Minor and Major Complications Following Image-Guided Percutaneous Liver Biopsy

2) **Standard against which the audit topic is to be compared**
   Set of standards set out as part of a previous UK national audit.
   Guidelines in the Use of Liver Biopsy in Clinical Practice, published in Gut in 2020.

3) **Source of standard (or reference document)**
   Howlett D C et al. Findings of the UK National Audit Evaluating Image-Guided or Assisted Liver Biopsy - Part 2. Minor and Major Complications and Procedure - Related Mortality. Radiology 2013; 266(1); 226-235.

4) **Target / compliance percentage to be achieved**
   Minor pain <30%
   Severe pain <3%
   Vasovagal hypotension <3%
   Significant haemorrhage <0.5%
   Haemobilia <0.1%
   Puncture of another organ <0.1%
   Death <0.1%

5) **Item or variable to be audited**
   Compliance with above parameters

6) **Method: Retrospective / Prospective / Other**
   Retrospective or prospective

7) **Data or information to be collected**
   Details of post-procedural complications. Review of imaging, patient records.

8) **Sample details (categories, number of patients, collection time period)**
   To be discussed, to consider 50-100 consecutive patients undergoing image guided percutaneous liver biopsy.

9) **Target achieved**
   Yes – No – Not applicable

10) **Actions to be taken if the target is not met.**

11) **Timing for re-audit**
    One year, or sooner if the target is not met

Audit 49

/ Category: Safety, Quality

1) **Audit Title**
   Evaluation of Adequacy of Thyroid Fine Needle Aspiration Cytology (FNAC) in the Diagnosis of Thyroid Nodules

2) **Standard against which the audit topic is to be compared**
   NICE (National Institute of Clinical Excellence) Guidelines, UK

3) **Source of standard (or reference document)**
   Thyroid Cancer - Assessment and Management. NICE Guidance NG230 - Published 2022.

4) **Target / compliance percentage to be achieved**
   Adequacy of cytological aspirate for analysis ≥85%
   Thy1 (inadequate) rate (excluding Thy1C) <15%.

5) **Item or variable to be audited**
   Adequacy of thyroid cytology sampling

6) **Method: Retrospective / Prospective / Other**
   Retrospective or prospective

7) **Data or information to be collected**
   Cytology findings following FNAC (fine needle aspiration cytology).
   Follow-up imaging data, repeat FNAC, use of core biopsy, patient record, subsequent thyroid surgery.

8) **Sample details (categories, number of patients, collection time period)**
   Patient data to be collected, sample size 50-100 consecutive patients.

9) **Target achieved**
   Yes – No – Not applicable

10) **Actions to be taken if the target is not met.**
    Review FNAC technique (consider rapid onsite evaluation ROSE). Discuss with onsite pathology.
    Ensure sampling uses ultrasound guidance, consider cytology technician or cytologist present at time of sampling if staffing allows, consider core biopsy if appropriate cases.

11) **Timing for re-audit**
    Yearly re-audit cycle, sooner if target not met (and practice changes instigated).

Audit 50

/ Category: Safety, Quality

1) **Audit Title**

Evaluation of Liver Biopsies Performed Using Imaging Guidance - Procedural Aspects, Diagnostic Adequacy and Accuracy

2) **Standard against which the audit topic is to be compared**

Set of standards set out as part of a previous US National Audit. Also, Guidelines in the Use of Liver Biopsy in Clinical Practice, published in Gut in 2020.

3) **Source of standard (or reference document)**

Howlett DC et al. Findings of a UK National Audit Evaluating Image Guided or Image-Assisted Liver Biopsy Procedural Aspects, Diagnostic Adequacy and Accuracy. Radiology 2012; vol 265, no 3.

4) **Target / compliance percentage to be achieved**

- Completed consent form in patient record - 100%
- Evidence post-procedural instructions documented in notes - 100%
- Sample sufficient for histological assessment - >98%
- Diagnostic accuracy for liver lesion >90%

5) **Item or variable to be audited**

Compliance with above parameters

6) **Method: Retrospective / Prospective / Other**

Retrospective or prospective

7) **Data or information to be collected**

Details of consent form completion, review patient records. Review of imaging findings and pathology data.

8) **Sample details (categories, number of patients, collection time period)**

To be discussed, to consider 50-100 consecutive patients undergoing image-guided percutaneous liver biopsy.

9) **Target achieved**

Yes – No – Not applicable

10) **Actions to be taken if the target is not met.**

Review with clinical and pathology colleagues. Discuss biopsy technique, needle size, number of passes. Review case mix and type of biopsy needle.

11) **Timing for re-audit**

Regular process of re-audit, minimum 3 yearly if targets met, sooner (1 year) if targets not met and practice changes instigated.

Audit 51

/ Category: Safety

1) **Audit Title**

Radiology Departmental Staff Knowledge on the Management of Allergic Reactions to Contrast Media

2) **Standard against which the audit topic is to be compared**

Local/national guidance. RANZCR Guidelines.

3) **Source of standard (or reference document)**

RANZCR Iodinated Contrast Guidelines V.2.3 (2018)

4) **Target / compliance percentage to be achieved**

100%

5) **Item or variable to be audited**

Correct staff responses to key questions on management of contrast reactions. Include staff involved in patient care, anyone who may potentially be exposed to a contrast reaction; all those who administer IV contrast.

6) **Method: Retrospective / Prospective / Other**

Retrospective

7) **Data or information to be collected**

Questionnaire distributed to key staff members, e.g. radiologists, radiographers, nursing staff, nursing assistants. Questionnaire should cover aspects of allergy to include:

- urticaria
- bronchospasm
- hypotension
- bradycardia
- cardiac arrest.

A sample questionnaire is included on the Royal College of Radiologists, UK, Auditlive website (please access the audit template on this topic). This can be adjusted according to local policy/protocols.

8) **Sample details (categories, number of patients, collection time period)**

Staff members sampled, 100% completion.

9) **Target achieved**

Yes – No – Not applicable

10) **Actions to be taken if the target is not met.**

All findings anonymised. Review and present results, reinforce protocols.

11) **Timing for re-audit**

Periodic re-audit if targets not met. Shorter interval if non-compliance, suggest 6 months (once practice changes instigated).

Audit 52

/ Category: Justification

1) **Audit Title**
   Adequacy of Referrals for Ultrasound Assessment of Suspected Deep Venous Thrombosis (DVT)

2) **Standard against which the audit topic is to be compared**
   Local guidelines if available
   NICE (National Institute of Clinical Excellence, UK)

3) **Source of standard (or reference document)**
   NICE - CG 158. Venous Thromboembolic Diseases: Diagnosis, Management and Thrombophilia Testing. 2023.

4) **Target / compliance percentage to be achieved**
   100% compliance

5) **Item or variable to be audited**
   - Specific clinical question (? DVT) on request form
   - Sufficient clinical information provided
   - D-Dimer status
   - Wells score (or equivalent)

6) **Method: Retrospective / Prospective / Other**
   Retrospective or prospective

7) **Data or information to be collected**
   Compliance with audited variables

8) **Sample details (categories, number of patients, collection time period)**
   50 - 100 patients

9) **Target achieved**
   Yes – No – Not applicable

10) **Actions to be taken if the target is not met.**
    If automated requesting, ensure appropriate questions are included as mandatory fields. Review requesting process with clinical teams.

11) **Timing for re-audit**
    Re-audit in 1 year if targets met, shorter period for re-audit if non-compliance with targets (once practice changes instigated).

Audit 53

/ Category: Safety, Quality

1) **Audit Title**
Post-Procedural Documentation Following an In-patient Interventional Radiological Procedure.

2) **Standard against which the audit topic is to be compared**
CIRSE Clinical Practice Manual

3) **Source of standard (or reference document)**
Guidance published Cardiovascular and Interventional Radiology; 2021; 44(9); 1498.

4) **Target / compliance percentage to be achieved**
To be agreed locally, 100% is the recommended standard.

5) **Item or variable to be audited**
Post-procedural documentation either electronically or written in the patient notes.
This should be legible if handwritten, signed and dated. It should include information for the clinical team covering:
- type of procedure
- type/amount of anaesthesia
- procedural related details, any complications, post procedural recommendations
- contact number if concerns
- use of antibiotics/analgesia
- length of stay recommendation.

6) **Method: Retrospective / Prospective / Other**
Retrospective or prospective

7) **Data or information to be collected**
Details of post-procedural interventional radiology documentation (in-patients)

8) **Sample details (categories, number of patients, collection time period)**
To be agreed locally
Sample size 50-100 patients

9) **Target achieved**
Yes – No – Not applicable

10) **Actions to be taken if the target is not met.**
Review practice and processes with all members of the interventional radiology and clinical teams, including ward nursing staff.

11) **Timing for re-audit**
Rolling audit, shortened period of re-audit if standards not achieved (e.g. 6 months) following interventions.

Audit 54

/ Category: Justification

1) **Audit Title**
   The Use of Magnetic Resonance Imaging in the Investigation of Suspected Vestibular Schwannoma

2) **Standard against which the audit topic is to be compared**
   National Institute of Clinical Excellence, UK (NICE)

3) **Source of standard (or reference document)**
   Guideline NG98 - Hearing loss in Adults - Assessment and Management, October 2023

4) **Target / compliance percentage to be achieved**
   Do referrals meet one of the recommended criteria - agree local targets.

5) **Item or variable to be audited**
   MR is recommended in:
   - adults with hearing loss and localising symptoms or signs (e.g. facial weakness)
   - adults with sensorineural hearing loss and no localising signs if there is asymmetry or pure-tone audiometry of 15dB or more at any 2 adjacent test frequencies (see local guidelines)

6) **Method: Retrospective / Prospective / Other**
   Retrospective or prospective

7) **Data or information to be collected**
   Clinical referral information and correlation with suggested criteria

8) **Sample details (categories, number of patients, collection time period)**
   100 consecutive patients (to be agreed locally)

9) **Target achieved**
   Yes – No – Not applicable

10) **Actions to be taken if the target is not met.**
    Review referral criteria with local referrers and agree referral parameters.

11) **Timing for re-audit**
    Periodic re-audit, earlier resample (e.g. 6 months) if target not met.

Audit 55

/ Category: Justification

1) **Audit Title**
   Inappropriate Repeating of In-Patient Chest Radiographs at Short Intervals

2) **Standard against which the audit topic is to be compared**
   Local/national guidance

3) **Source of standard (or reference document)**
   Council Directive 2013 59 Euratom, BSSD (Basic Safety Standards Directive).
   Relevant national guidance documents on appropriate use of imaging.

4) **Target / compliance percentage to be achieved**
   90%

5) **Item or variable to be audited**
   All chest radiographs should only have been performed where clinically indicated and where a clinical question is to be answered.

6) **Method: Retrospective / Prospective / Other**
   Retrospective or prospective

7) **Data or information to be collected**
   Serial chest radiographs, often several times a day/daily are a particular issue in some areas, e.g. intensive care (ICU/CCU).
   The audit requires review of chest X-rays performed over a set time period, assessment of prior radiographs, clinical information provided, radiograph findings and documentation, processes of justification.

8) **Sample details (categories, number of patients, collection time period)**
   100 chest radiographs, in-patients and in scenarios where multiple radiographs performed (ICU/CCU), but audit can be extended to all in-patients.

9) **Target achieved**
   Yes – No – Not applicable

10) **Actions to be taken if the target is not met.**
    Education of staff performing radiographs, clinical teams, BSSD requirements around justification.

11) **Timing for re-audit**
    Periodic re-audit, e.g. yearly, earlier re-audit if target not met.

Audit 56

/ Category: AI

1) **Audit Title**

Assessment of NGT placement with AI on chest radiography

2) **Standard against which the audit topic is to be compared**

NHS Patient Safety Alert

3) **Source of standard (or reference document)**

NHS England Patient Safety Alert: Nasogastric tube misplacement: continuing risk of death and severe harm, https://www.england.nhs.uk/publication/patient-safety-alert-nasogastric-tube-misplacement-continuing-risk-of-death-and-severe-harm/

4) **Target / compliance percentage to be achieved**

100% accuracy for detection of NGT placement

5) **Item or variable to be audited**

Number of adverse incidents reported from misplaced NGT

Diagnostic accuracy of AI for inappropriate NGT detection

6) **Method: Retrospective / Prospective / Other**

Prospective (ideally) but can be retrospective if AI already implemented without any audit already conducted

7) **Data or information to be collected**

Number of radiographs requested for NGT placement as indication

Number of radiographs with indwelling NGT placement

AI output in these radiographs for NGT placement (FP, FN, TP, TN)

Comparison of AI output with radiologist report

Cases where AI output is inaccurate

Documentation of any incidents relating to malposition leading to patient harm in the hospital over the audit time frame.

8) **Sample details (categories, number of patients, collection time period)**

6 months

9) **Target achieved**

Yes – No – Not applicable

10) **Actions to be taken if the target is not met.**

Present results at local audit meeting to raise awareness.

Review of false positive (most importantly) and false negative cases to understand pitfalls for AI analysis.

Improved education for NGT siting and evaluation on CXR for hospital staff involved in reviewing NGT (e.g. resident doctors, nursing staff etc on the ward)

Evaluate internally within radiology department and hospital patient safety team whether to remove the AI if this is causing false reassurance to staff with false outputs

11) **Timing for re-audit**

One year, or sooner if the target is not met

Audit 57

/ Category: AI

1) **Audit Title**

Appropriate training for individuals with responsibility in using AI output for clinical decision making

2) **Standard against which the audit topic is to be compared**

EU AI Act

3) **Source of standard (or reference document)**

EU AI Act Article 4 (AI Literacy) - https://artificialintelligenceact.eu/article/4/

"Providers and deployers of AI systems shall take measures to ensure, to their best extent, a sufficient level of AI literacy of their staff and other persons dealing with the operation and use of AI systems on their behalf, taking into account their technical knowledge, experience, education and training and the context the AI systems are to be used in, and considering the persons or groups of persons on whom the AI systems are to be used."

4) **Target / compliance percentage to be achieved**

100% compliance for training for any staff intending to use the AI output to guide clinical decisions

5) **Item or variable to be audited**

Completion of local training session on interpretation of AI outputs and common pitfalls

If the local training involves an informal assessment of understanding, then passing this assessment could be another measure.

6) **Method: Retrospective / Prospective / Other**

Prospective (prior to AI usage by healthcare professional)

7) **Data or information to be collected**

Number of healthcare professionals likely to encounter or use the AI output (include clinical staff - nurses, doctors, radiologists, radiographers for the particular AI application)

Attendance at local training session prior to AI usage (and pass mark for any informal assessments set)

8) **Sample details (categories, number of patients, collection time period)**

Annually (every year)

9) **Target achieved**

Yes – No – Not applicable

10) **Actions to be taken if the target is not met.**

Raise awareness of educational assessment required

Make it a mandatory training module for all staff at induction

Collect feedback from staff on reasons for not attending the training

11) **Timing for re-audit**

One year, or sooner if the target is not met

Audit 58

/ Category: AI

1) **Audit Title**
   Image quality in AI-based reconstruction

2) **Standard against which the audit topic is to be compared**
   To be discussed and agreed locally, preferably accounting for dose evaluation where appropriate.

3) **Source of standard (or reference document)**
   EU 16260 and EU 16261 (paediatrics) for X-ray; EU 16262 for CT; DRLs.
   To be established locally for other modalities.

4) **Target / compliance percentage to be achieved**
   To be discussed locally

5) **Item or variable to be audited**
   Diagnostic image quality

6) **Method: Retrospective / Prospective / Other**
   Retrospective

7) **Data or information to be collected**
   To be detailed locally. Should include a representative sample of consecutive examinations employing AI-based image reconstruction.

8) **Sample details (categories, number of patients, collection time period)**
   Consecutive imaging exams, as routinely acquired in clinical practice. Appropriate sample size and time period to be established based on local practice.

9) **Target achieved**
   Yes – No – Not applicable

10) **Actions to be taken if the target is not met.**
    Actionable items may include use of alternative AI image reconstruction model or use of non-AI image reconstruction techniques.

11) **Timing for re-audit**
    One year, or sooner if the target is not met

Audit 59

/ Category: AI

1) **Audit Title**
   Appropriate use of AI solutions according to intended use statement / MDR CE class

2) **Standard against which the audit topic is to be compared**
   EU MDR / EU AI Act

3) **Source of standard (or reference document)**
   EU AI Act Article 6 (Classification Rules for High-Risk AI Systems) - https://artificialintelligenceact.eu/article/6
   MDCG 2021-24 - Guidance on classification of medical device (https://health.ec.europa.eu/system/files/2021-10/mdcg_2021-24_en_0.pdf)

4) **Target / compliance percentage to be achieved**
   100% compliance of MDR CE intended use statement and usage of AI systems

5) **Item or variable to be audited**
   Alignment of actual AI usage with intended use statement

6) **Method: Retrospective / Prospective / Other**
   Prospective (before AI usage make sure users are aware of intended use statement)
   Retrospective (after AI usage review if usage was in accordance with intended use statement)

7) **Data or information to be collected**
   AI usage information (either electronically or by discussing with staff)

8) **Sample details (categories, number of patients, collection time period)**
   Annually (every year)

9) **Target achieved**
   Yes – No – Not applicable

10) **Actions to be taken if the target is not met.**
    Raise awareness of intended use statement for AI systems use and education on regulatory frameworks

11) **Timing for re-audit**
    One year, or sooner if the target is not met

Audit 60

/ Category: Quality, Safety

1) **Audit Title**
   MR Quality & Safety

2) **Standard against which the audit topic is to be compared.**
   The examination /procedure protocol of each radiological procedure should be included in the report as well as contrast material name and injection data.

3) **Source of standard (or reference document)**
   Existing published literature and national/international guidelines.

4) **Target / compliance percentage to be achieved**
   To be discussed locally.

5) **Item or variable to be audited**
   Image quality and safety in MRI

6) **Method: Retrospective / Prospective / Other**
   Prospective

7) **Data or information to be collected**
   All MRI imaging examinations (protocol included and contrast material details if used)

8) **Sample details (categories, number of patients, collection time period)**
   50 reports

9) **Target achieved (yes / no / not applicable)**
   Yes

10) **Actions to be taken if the target is not met.**
    Actions depend on the problem recognized in the evaluation (positioning, artefacts, noise etc.)
    Relates to the risk assessments and MRI checklist.
    Checks whether recommended implant safety protocols are known and followed.
    Equipment management (MRI recommendations, emergency procedures, anaesthesia, special issues etc.)

11) **Timing for re-audit (yes / no / not applicable)**
    Periodically. 6-12 months

Audit 61

/ Category: Safety, Value Based

1) **Audit Title**

   Is there a departmental mechanism for providing patients (or their representative) with information relating to the risks/benefits associated with radiation dose from the medical exposure?

2) **Standard against which the audit topic is to be compared**

   BSSD

3) **Source of standard**

   National legislation intended to transpose and implement requirements included within the Council Directive 2013/59/Euratom, Article 57

4) **Target / compliance percentage to be achieved**

   100 %

5) **Item or variable to be audited**

   Local rules. Pathway for identification of risks/benefits available widely for patients and/or their representatives and implemented

   For example:

   - Departmental procedure, including identified responsible person
   - Information sheets with appointment letters
   - Information provided within the department for patients/patient representatives
   - Explicitly for Interventions where deterministic skin effects can occur when exceeding 2 Gy Peak Skin Dose

6) **Method: Retrospective /Prospective**

7) **Data or information to be collected**

   Confirmation of written risk/benefit pathway in the local rules

8) **Sample details**

   - Dose thresholds and accompanied possible skin reaction should be mentioned.
   - Relations towards why radiation protection is not recommended anymore should be named.

9) **Target achieved**

   Yes / no

10) **Action to be taken if the target is not met**

    The establishment of a written risk/benefit pathway in the local rules

11) **Timing for re-audit**

    One-year review if target met. Repeat audit 3 months if target not met/incomplete

Audit 62

/ Category: Safety

1) **Audit Title**

Is there an established mechanism within the department to register and analyse accidental/unintended exposures?

2) **Standard against which the audit topic is to be compared**

BSSD

3) **Source of standard**

National legislation intended to transpose and implement requirements included within the Council Directive 2013/59/Euratom, Article 63

4) **Target /compliance percentage to be achieved**

100 %

5) **Item or variable to be audited**

The existence of a department repository for this information, with agreed mechanisms in place for record keeping and analysis of accidental or unintended exposures: Ticket systems, Dose Management System?

6) **Method**

Retrospective / Prospective

7) **Data or information to be collected**

The existence of a department repository for this information

The number of cases / years, case outcomes in terms of registration and root cause analysis

8) **Sample details**

- Naming the process which acts after accidental/ unintended exposure occurred.
- Confirmation of appropriate resources
- Retrospective calculation of the number of cases per year
- Circumstances of the exposure in each case, analysis of causes, appropriate policy adjustments made
- Process to inform the authorities since this counteracts the necessary justifying indication

9) **Target achieved**

Yes / no

10) **Action to be taken if the target is not met.**

Creation of appropriate resource, review department policies on recording and analysing accidental or unintended exposures of this nature

11) **Timing for re-audit**

One year, or sooner if target is not met

Audit 63

/ Category: Safety, Value Based

1) **Audit Title**
   Is there departmental policy for informing patients or their representative that they have undergone an accidental exposure?

2) **Standard against which the audit topic is to be compared**
   BSSD

3) **Source of standard (or reference document)**
   National legislation intended to transpose and implement requirements included within the Council Directive 2013/59/Euratom, Article 63

4) **Target / compliance percentage to be achieved**
   100 %

5) **Item or variable to be audited**
   Local policy rules. Pathway for follow up of accidental exposure. Arrangements also to be in place to inform the referrer and the practitioner

6) **Method: Retrospective / Prospective / Other**
   Retrospective/prospective

7) **Data or information to be collected**
   Confirmation of existence of local rules pathway for accidental exposure follow up number of cases/year Date/Time/Reason for accidental exposure together with dose consequences, if any, of the exposure

8) **Sample details (categories, number of patients, collection time period)**
   One year analysis of the above

9) **Target achieved**
   Yes – No – Not applicable

10) **Actions to be taken if the target is not met.**
    Implementation of clear pathway in the local rules

11) **Timing for re-audit**
    One year, or sooner if target not met

Audit 64

/ Category: Safety

1) **Audit Title**
   Is there a mechanism for record keeping and retrospective analysis of accidental or unintended medical exposures?

2) **Standard against which the audit topic is to be compared**
   BSSD

3) **Source of standard**
   National legislation intended to transpose and implement requirements included within the Council Directive 2013/59/Euratom, Article 63

4) **Target / compliance percentage to be achieved**
   100 % (Such a resource must exist)

5) **Item or variable to be audited**
   Formal record of accidental or unintended exposures

6) **Method**
   Retrospective / prospective

7) **Data or information to be collected**
   - Review of components of formal record of accidental or unintended medical exposures Number of incidents
   - Patient demographics
   - Date, time and nature of incidents
   - Corrective measures taken and timings, dissemination of learning points
   - protocols of M&M conferences with corrective measure

8) **Sample details**
   One year review of formal record of accidental or unintended medical exposures

9) **Target achieved**
   Yes / no

10) **Action to be taken if the target is not met**
    Creation of a detailed formal record of accidental or unintended medical exposures
    Are mechanisms in place to disseminate learning information from accidental or unintended exposures to relevant parties

11) **Timing for re-audit**
    One year, or sooner if target is not met

Audit 65

/ Category: Safety

1) **Audit Title**
   Is there a mechanism for referring accidental exposure events to the medical physics expert (MPE) and informing the competent authority of significant events?

2) **Standard against which the audit topic is to be compared**
   BSSD

3) **Source of standard (or reference document)**
   National legislation intended to transpose and implement requirements included within the Council Directive 2013/59/Euratom, Article 63

4) **Target / compliance percentage to be achieved**
   100%

5) **Item or variable to be audited**
   Local rules. Identification of an appropriate information pathway

6) **Method: Retrospective / Prospective / Other**
   Retrospective/prospective

7) **Data or information to be collected**
   Identification of an appropriate information pathway Contact details for the MPE and the competent authority official date/time/reason/ consequences of the exposure, actions taken

8) **Sample details (categories, number of patients, collection time period)**
   Review of one-year accidental exposures

9) **Target achieved**
   Yes / No

10) **Actions to be taken if the target is not met.**
    Implementation of an appropriate information pathway Review contact details and route of communication with MPE

11) **Timing for re-audit**
    One year, or sooner if target not met

Audit 66

/ Category: Safety

1) **Audit Title**

Does the department utilise criteria, provided by the relevant radiation protection competent authority, for what constitutes an accidental or unintended significant exposure?

2) **Standard against which the audit topic is to be compared**

BSSD

3) **Source of standard**

National legislation intended to transpose and implement requirements included within the Council Directive 2013/59/Euratom, Article 63

4) **Target / compliance percentage to be achieved**

100 %

5) **Item or variable to be audited**

Local rules. Criteria defining significant accidental or unintended exposures, as provided by the relevant radiation protection competent authority. SOPs

6) **Method**

Retrospective/prospective

7) **Data or information to be collected**

Criteria defining accidental or unintended exposures of significance Date / time / cause / consequences of each exposure

Documentation and instructions to staff

8) **Sample details**

One year review of above

9) **Target achieved**

Yes / no

10) **Action to be taken if the target is not met.**

Implementation of such a resource, liaison with radiation protection competent authority for guidance.

Integration of resources and content to be communicated during the yearly radiation protection instruction.

11) **Timing for re-audit**

One year, or sooner if target is not met

Audit 67

/ Category: Justification

1) **Audit Title**

Evaluation of Training and Competence in Radiation Protection for Non-Radiologists Responsible for Justification of Medical Exposures

2) **Standard against which the audit topic is to be compared**

BSSD

3) **Source of standard**

National legislation intended to transpose and implement requirements included within the Council Directive 2013/59/Euratom, Article 59.

Torresin, A., Evans, S., Lizio, D. et al. Practical recommendations for the application of DE 59/2013. Radiol med 124, 721–727 (2019). https://doi.org/10.1007/s11547-019-01031-x

4) **Target /compliance percentage to be achieved**

To be determined through consensus with all stakeholders before commencing the audit. Aspirational Target: 100% compliance

5) **Item or variable to be audited**

Training Requirements: Verification of local rules specifying the training requirements for non-radiologists authorized to justify procedures.

Delegated Procedures: Review of the types of radiological procedures deemed suitable for delegation to non-radiologists.

Training Programme: Availability, content, and components of the training programme for delegated non-radiologists.

Participant Assessment: Methods used to evaluate participants' readiness and competence to justify procedures safely.

6) **Method**

Retrospective / Prospective / Other

7) **Data or information to be collected**

- Identification of procedures that are delegated for justification
- Identification for a training programme for delegated non-radiologists
- Components of the programme
- Method by which participant is shown to be safe
- Number of participants
- Percentage of participants who complete the course successfully, reasons for failure

8) **Sample details**

One-year review of the above

9) **Target achieved**

Yes / no

10) **Action to be taken if the target is not met**

Creation of a training programme for non-radiologists to whom justification is delegated

Review of processes and selection around types of procedure suitable for non-radiologist justification

11) **Timing for re-audit**

One year-if the target is not met, re-audit within six months after implementing corrective actions.

Audit 68

/ Category: Value Based, Safety

1) **Audit Title**

Is there a departmental mechanism to confirm as necessary with the patient or patient representative and document the non-pregnancy status of individuals undergoing medical exposures?

2) **Standard against which the audit topic is to be compared**

BSSD

3) **Source of standard**

National legislation intended to transpose and implement requirements included within the Council Directive 2013/59/Euratom, Article 62

4) **Target / compliance percentage to be achieved**

100 %

5) **Item or variable to be audited**

Request form /Order comms

- In life threatening cases medical exposure can become necessary, even if the patient is pregnant. Therefore: Is there a mechanism to estimate the fatal dose depending on the imaging procedure and how can this be minimized (Involving Medical physicists)?
- Is there a mechanism to calculate the fatal dose retrospectively?
- Is the pregnant patient informed about this via an official document?

6) **Method**

Retrospective / prospective

7) **Data or information to be collected**

Identification of a place on the request form /order comms for the practitioner or operator to record the patient's date of (first day of) the last menstrual period.

Ensure that the data is entered, signed, dated

8) **Sample details**

One-month review of request forms / order comms

9) **Target achieved**

Yes / no

10) **Action to be taken if the target is not met**

Amendment to include place for this data on the request form

Appropriate staff training to ensure that the data is always recorded

11) **Timing for re-audit**

One year, or sooner if target is not met

Audit 69

/ Category: Justification

1) **Audit Title**

Written protocol for the identification of who is responsible for the justification process

2) **Standard against which the audit topic is to be compared**

BSSD

3) **Source of standard**

National legislation intended to transpose and implement requirements included within the Council Directive 2013/59/Euratom, Article 57

Torresin, A., Evans, S., Lizio, D. et al. Practical recommendations for the application of DE 59/2013. Radiol med 124, 721–727 (2019). https://doi.org/10.1007/s11547-019-01031-x

4) **Target / compliance percentage to be achieved**

100 %

5) **Item or variable to be audited**

Presence of a designated area on the request form or order communication system for the justification process.

Confirmation that the justification has been completed by the appropriate practitioner.

Validation of proper authorization, including signature and date.

6) **Method**

Retrospective / Prospective / Other

7) **Data or information to be collected**

- Presence of a field for justification in the request form or order communication system.
- Documentation verifying that justification was completed, signed, and dated by an authorized practitioner.
- Instances where the justification field was left incomplete or completed by an unauthorized individual.

8) **Sample details**

One-month request form / order comms

9) **Target achieved**

Yes / no

10) **Action to be taken if the target is not met**

- Redesign of Documentation: Revise the request form or order communication system to clearly indicate the requirement for justification.
- Staff Education and Training: Provide targeted training for relevant staff on the importance of proper documentation and authorization in the justification process.
- Authorization Validation: Ensure that only practitioners authorized to justify specific procedures are identified and their roles documented.

11) **Timing for re-audit**

One year, or sooner if target is not met

Audit 70

/ Category: Justification

1) **Audit Title**

   For radiation exposure related to health screening by invitation on asymptomatic individuals, is there a local policy affirming justification by a competent authority?

2) **Standard against which the audit topic is to be compared**

   BSSD

3) **Source of standard**

   National legislation intended to transpose and implement requirements included within the Council Directive 2013/59/Euratom, Article 55.2.h

4) **Target / compliance percentage to be achieved**

   100 %

5) **Item or variable to be audited**

   Confirmation of a certified programme on health screening, or specific documented justification for that individual by the practitioner, in consultation with the referrers following guidelines from the relevant medical society and the competent authority

6) **Method**

   Retrospective / Prospective / Other

7) **Data or information to be collected**

   - Policy on health screening or individual justification by a competent authority (see above)
   - Relevant criteria
   - Patient numbers

8) **Sample details**

   Three-month review of above

9) **Target achieved**

   Yes /no

10) **Action to be taken if the target is not met**

    Implementation of a policy on health screening or justification process involving practitioner/referrer and a competent authority

11) **Timing for re-audit**

    One year, or sooner if target not met

Audit 71

/ Category: Justification

1) **Audit Title**
   What percentage of studies involving ionising radiation are justified in advance of being performed?

2) **Standard against which the audit topic is to be compared**
   BSSD

3) **Source of standard**
   National legislation intended to transpose and implement requirements included within the Council Directive 2013/59/Euratom, Article 55

4) **Target / compliance percentage to be achieved**
   100 %

5) **Item or variable to be audited**
   Request forms / order comms: justification practitioner identification

6) **Method**
   Retrospective/prospective

7) **Data or information to be collected**
   Request forms / order comms:
   - Justification practitioner identification
   - Percentage correctly completed and verified
   - Availability of a process to view the patient's radiological history

8) **Sample details**
   One-month review of the above

9) **Target achieved**
   Yes / no

10) **Action to be taken if the target is not met**
    Amendment of request forms / order comms
    Education of individuals involved in justification, review of justification practitioners' identity / qualifications
    Suggest a radiological history monitoring system

11) **Timing for re-audit**
    One year, or sooner if target not met

Audit 72

/ Category: Justification, Value Based

1) **Audit Title**

   What mechanism exists on the request form for contacting referrers to permit pre-exposure justification discussions to occur if necessary?

2) **Standard against which the audit topic is to be compared**

   BSSD

3) **Source of standard**

   National legislation intended to transpose and implement requirements included within the Council Directive 2013/59/Euratom, Article 55

4) **Target / compliance percentage to be achieved**

   100 %

5) **Item or variable to be audited**

   Request form / order comms Relevant communication data pathway documented clearly

6) **Method**

   Retrospective / Prospective / Other

7) **Data or information to be collected**

   Request form / order comms Relevant communication data pathway Referrer name / location / phone / email information, all clearly legible, Percentage of each correctly completed, Percentage of exams performed without a request form complete with communication data

8) **Sample details**

   One-month review of the above

9) **Target achieved**

   Yes / no

10) **Action to be taken if the target is not met.**

    Revision of request form / order comms to include pertinent contact information for referrer Education of referrers around importance (and legal requirement) of provision of contact details

11) **Timing for re-audit**

    One year, or sooner if target not met

Audit 73

/ Category: Justification

1) **Audit Title**
   Is there a written protocol for who may be responsible for justification of X-ray /fluoroscopic /ionising interventional radiological / CT-Scan procedures?

2) **Standard against which the audit topic is to be compared**
   BSSD

3) **Source of standard**
   National legislation intended to transpose and implement requirements included within the Council Directive 2013/59/Euratom, Article 57

4) **Target / compliance percentage to be achieved**
   100 %

5) **Item or variable to be audited**
   Local rules: written protocol for delegated responsibility for the justification of fluoroscopic / ionising interventional radiological procedures

6) **Method**
   Retrospective /Prospective /Other

7) **Data or information to be collected**
   Written protocol for responsibility for the justification of fluoroscopic / ionising interventional radiological procedures
   Criteria for inclusion
   Correlation with request forms / order comms Percentage correctly completed, signed, dated

8) **Sample details**
   One month as above

9) **Target achieved**
   Yes / no

10) **Action to be taken if the target is not met**
    Establishment of a written protocol for responsibility for the justification of fluoroscopic / ionising interventional radiological procedures
    Review staff training, education

11) **Timing for re-audit**
    One year, or sooner if target is not met

Audit 74

/ Category: Justification

1) **Audit Title**

   Is there a written protocol for who may be responsible for justification of CT studies?

2) **Standard against which the audit topic is to be compared**

   BSSD

3) **Source of standard**

   National legislation intended to transpose and implement requirements included within the Council Directive 2013/59/Euratom, Article 57

4) **Target / compliance percentage to be achieved**

   100 %

5) **Item or variable to be audited**

   Local rules: written protocol for identification of those with responsibility for the justification of CT studies

   - Mechanism for unlocking self-reliant justifications in the RIS after achieving the specialist knowledge in radiology?
   - Is there a process for assistant physicians such that they can gain experience under the supervision of senior physicians for CT justifications?

6) **Method**

   prospective/retrospective

7) **Data or information to be collected**

   - Written protocol for identification of those with responsibility for the justification of CT studies
   - Criteria for inclusion
   - Correlation with request forms /order comms
   - Percentage correctly completed, signed, dated

8) **Sample details**

   One month as above

9) **Target achieved**

   Yes / no

10) **Action to be taken if the target is not met**

    Establishment of a written protocol for responsibility for the justification of CT studies

    Education of staff, staff training

11) **Timing for re-audit**

    One year, or sooner if target not me

Audit 75

/ Category: Quality

1) **Audit Title**
   What mechanism is used to evaluate patient dose in high dose procedures?

2) **Standard against which the audit topic is to be compared**
   BSSD

3) **Source of standard**
   National legislation intended to transpose and implement requirements included within the Council Directive 2013/59/Euratom, Article 60

4) **Target / compliance percentage to be achieved**
   100 %

5) **Item or variable to be audited**
   Calibrated, approved dose calculation systems in all high dose equipment
   - Differentiate between legal and own DRL. How are own DRL established?
   - Is there an optimisation process paired with DRL checks?
   - How are the legal quality controls of the DRL of CT, interventions and X-rays handled?

6) **Method**
   Retrospective/prospective

7) **Data or information to be collected**
   Dose calculation and recording systems in CT/IR/NM systems
   Patient exposure results in each of these

8) **Sample details**
   One-month review of above

9) **Target achieved**
   Yes / no

10) **Action to be taken if the target is not met.**
    Equipment modification or replacement to install appropriate measurement systems in all high dose equipment
    Consultation with medical physics experts and Competent Authority

11) **Timing for re-audit**
    One year, or sooner if the target is not met

Audit 76

/ Category: Safety

1) **Audit Title**
   What percentage of radiodiagnostic procedures have established diagnostic reference levels (DRL)?

2) **Standard against which the audit topic is to be compared**
   BSSD
   Please note also recent European Commission published guidelines on paediatric DRLs – this would be another suitable subject for audit
   European Guidelines on Diagnostic Reference Levels for Paediatric Imaging

3) **Source of standard**
   National legislation intended to transpose and implement requirements included within the Council Directive 2013/59/Euratom, Article 56

4) **Target / compliance percentage to be achieved**
   100 %

5) **Item or variable to be audited**
   Establishment and regular review of DRLs for all radiodiagnostic examinations
   - Differentiate between legal and own DRL. How are own DRL established?
   - Is there an optimisation process paired with DRL checks?
   - How are the legal quality controls of the DRL of CT, interventions and X-rays handled?

6) **Method**
   Retrospective/prospective

7) **Data or information to be collected**
   Exposure levels for all radiodiagnostic procedures compared to DRLs
   Percentage in each category above the DRL

8) **Sample details**
   One-month review of above

9) **Target achieved**
   Yes / no

10) **Action to be taken if the target is not met**
    Remedial action to reduce exposure dose levels Equipment implications / staffing training
    Protocols for scanning
    Appropriate local reviews instigated whenever DRLs are consistently exceeded, and corrective action taken without delay

11) **Timing for re-audit**
    Rolling audit programme, frequency to be agreed locally and with medical physics expert

Audit 77

/ Category: Safety

1) **Audit Title**

Specific technical requirements for equipment for use in medical exposures

2) **Standard against which the audit topic is to be compared**

BSSD

The BSSD article 60 has introduced specific requirements for new equipment, there are no current requirements for equipment replacement solely based on age (as opposed to performance, see article 60.2)

3) **Source of standard**

National legislation intended to transpose and implement requirements included within the Council Directive 2013/59/Euratom, Article 60

4) **Target / compliance percentage to be achieved**

100 % – mandatory and subject to inspection

5) **Item or variable to be audited**

A number of potential audit variables, including:

- Fluoroscopy equipment without a device to automatically control dose rate, or without an image intensifier, is prohibited
- IR equipment should have the facility to inform the practitioner of the quantity of radiation produced during the procedure
- IR/CT equipment should have the facility to inform the practitioner at the end of the procedure of relevant parameters for assessing patient dose
- IR/CT equipment has the capacity to transfer the above information to the record of the examination

Please note there are a number of exemptions detailed within the BSSD; these should be referred to prior to auditing

- Digital documentation of medical exposure and scan parameters like kV, mAs, collimation etc.
- Hardware based radiation reduction like gantry tilt and rolling collimators.
- Grid manually removable, Filter adjustable, easy to optimise scan protocols
- Modulation types like 3D, sectorial, EKG triggered, kV
- Multi-Topogram planning for CT?
- PSD on the fly calculation?

6) **Method**

Retrospective/Prospective/Other

Assessment of all existing / prospective equipment

7) **Data or information to be collected**

See above

8) **Sample details (number of patients, collection time period)**

See above

9) **Target achieved (yes / no / not applicable)**

Yes or No

10) **Actions to be taken if the target is not met**

If N, this is an important issue which needs urgent review and discussion with appropriate authorities/ regulatory bodies and likely investment in new, updated equipment

11) **Timing for re-audit**

One year, or sooner if the target is not met

Audit 78

/ Category: Safety

1) **Audit Title**

Eye lens dose limits for occupational exposure

2) **Standard against which the audit topic is to be compared**

The BSSD modifies the occupational dose limit for the eye lens to 20 mSv/year from the previous value of 150 mSv/year.
Special circumstances exist, allowing 100 mSv over 5 years, subject to a maximum dose of 50 mSv in a single year.
Please note new lens dose limits for apprentices and students also (Article 11)

3) **Source of standard**

National legislation intended to transpose and implement requirements included within the Council Directive 2013/59/Euratom, Article 9

4) **Type of audit - regulatory**

5) **Target / compliance percentage to be achieved**

100 %

6) **Item or variable to be audited**

Local protocols/procedures, implemented and updated Measurement of occupational dose exposure

- 20 Gy per year - How measured?
- Was radiation protection provided?
- After 15 Gy annual examination by company doctor for radiation damage.

7) **Method**

Retrospective or prospective

8) **Data or information to be collected**

Personal eye dosimetry measurements

9) **Sample details**

Eye dosimetry measurements for individuals/radiologists with potential high dose ionising lens exposure e. g. interventional radiology

10) **Target achieved**

yes / no

11) **Actions to be taken if the target is not met**

If target is not met the cause must be identified. Review protocols and procedures, involve medical physicist. Education/discussion and review local radiation protective practice with relevant radiologist/individual

12) **Timing for re-audit**

A continuous programme of rolling audit, with early and prompt intervention and re-audit if target is not met

Please see also audit template 62

Audit 79

/ Category: Safety

1) **Audit Title**

Initial education and training in radiation protection

2) **Standard against which the audit topic is to be compared**

All professionals involved in medical diagnostic imaging should meet the recommended level of initial education and training in radiation protection. All education and training provided for the different professions (radiologists, radiographers, nurses, clinicians, medical physicists etc) shall be documented.

3) **Source of standard**

National legislation intended to transpose and implement requirements included within the Council Directive 2013/59/Euratom, Article 18

4) **Target/compliance percentage to be achieved**

Radiation protection education and training starts at the entry level to the medical, dental and other healthcare professional schools. The Euratom BSS Directive [EC, 2000, RP 116] states that 'Member States shall encourage the introduction of a course on radiation protection in the basic curriculum of medical and dental schools.

Radiation protection courses should, however, have a different orientation and content for medical and dental students. Appropriate courses should be available to junior doctors, nurses, radiographers, etc.

100% of professionals must meet the criteria.

Professionals who did not take radiation protection courses in school can complete them at the beginning of their employment. These courses should be taught by entities approved by the national competent authority.

5) **Item or variable to be audited**

Local and national protocol and documentation on relevant initial theory and training in radiation protection

6) **Method**

Retrospective /prospective

7) **Data or information to be collected**

Data from staff records and/or national curricula

8) **Sample details**

List of all relevant staff with records on education and year of examination.

9) **Target achieved**

Yes/No

10) **Action to be taken if target not met**

If target is not met the cause must be identified. Review content/provision of staff relevant curricula at local/ national level

11) **Timing for re-audit**

If target is not met a re-audit should be done within one year. If met, the re-audit could be done every two years

Audit 80

/ Category: Safety

1) **Audit Title**

   Assessment of education plus training in radiation protection (including setting up national curricula, diplomas, formal qualifications), doses and side effects (including awareness of doses/risk by justifying staff)

2) **Standard against which the audit topic is to be compared**

   Each member state should arrange a program of continuous education in radiation protection for radiology departmental staff involved in any aspect of radiation protection (BSSD)

3) **Source of standard (or reference document)**

   National legislation intended to transpose and implement requirements included within the Council Directive 2013/59/Euratom. Local/national agreed process, Article 18

4) **Target / compliance percentage to be achieved**

   100 % (compulsory)

5) **Item or variable to be audited**

   Participation, education in local and/or national program, program of assessment / compliance as appropriate

6) **Method: Retrospective / Prospective / Other**

   Retrospective/Prospective/Other. Inspection of the education tool Levels of compliance/assessment amongst staff

7) **Data or information to be collected**

   Existence of an education programme, contents, review

8) **Sample details (categories, number of patients, collection time period)**

   All staff involved in radiation protection

9) **Target achieved**

   Yes – No

10) **Actions to be taken if the target is not met.**

    Establish, review local/national training programme

11) **Timing for re-audit**

    In one year

Audit 81

/ Category: Justification, Quality

1) **Audit Title**

Assessment of Clinical Information Provision to Support Justification in Radiological Procedures

2) **Standard against which the audit topic is to be compared**

Each imaging request involving ionising radiation should undergo a justification process.

For accurate justification radiologists/radiographers need to know the exam related clinical data including previous imaging findings. These are important in reporting as well as planning the most appropriate radiological examination and protocolling accordingly. BSSD.

3) **Source of standard**

National legislation intended to transpose and implement requirements included within the Council Directive 2013/59/Euratom, Article 55

4) **Target / compliance percentage to be achieved**

100 % (compulsory)

5) **Item or variable to be audited**

All ionising radiological procedures (non-ionising procedures can also be included, although these are not currently covered by the justification process)

6) **Method**

Retrospective or prospective

7) **Data or information to be collected**

Review consecutive clinical request forms, clinical information provided should be:

★★ Concise, pertinent

★★ With relevant, coherent information in logical structure

★★ With a clear clinical question and indication of clinical urgency

★★ Without irrelevant information, including relevant previous history (imaging, medical)

8) **Sample details (number of patients, collection time period)**

100 request forms

9) **Target achieved**

Yes / No

10) **Actions to be taken if the target is not met**

★★ **Education for Referrers:** Conduct targeted training sessions for referring clinicians on the importance of providing appropriate clinical information. Develop and disseminate guidelines or templates for completing request forms effectively.

★★ **Feedback Mechanisms:** Introduce regular feedback loops to referrers based on audit results.

11) **Timing for re-audit**

One year, or sooner if target is not met

Audit 82

/ Category: Safety

1) **Audit Title**

Staff Dosimetry Audit

Definitions (Council Directive 2013/59/Euratom, December 2013/BSSD)

★★ "occupational exposure" means exposure of workers, apprentices and students, incurred in the course of their work.

★★ "dose constraint" means 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.

★★ "dose limit" means the value of the effective dose (where applicable, committed effective dose) or the equivalent dose in a specified period which shall not be exceeded for an individual.

★★ category A: those exposed workers who are liable to receive an effective dose greater than 6 mSv per year or an equivalent dose greater than 15 mSv per year for the lens of the eye or greater than 150 mSv per year for skin and extremities.

★★ category B: those exposed workers who are not classified as category A workers.

	STAFF	STUDENTS AND APPRENTICES
Effective dose (mSv)	20 (*) (1)	6
Eye lens dose (mSv)	20 (2)	15
Skin/extremities (mSv)	500	150

(*) *in the case of pregnant workers, the maximum dose to the unborn child is set at 1mSv.*

(1) *a higher effective dose of up to 50 mSv may be authorised by the competent authority in a single year, provided that the average annual dose over any five consecutive years, including the years for which the limit has been exceeded, does not exceed 20 mSv.*

(2) *or 100 mSv in any five consecutive years subject to a maximum dose of 50 mSv in a single year.*

Member States shall require the undertaking or, in the case of outside workers, the employer, to decide on the categorisation of individual workers prior to their taking up work that may give rise to exposure, and to regularly review this categorisation based on working conditions and medical surveillance. The distinction shall also consider potential exposures.

2) **Standard against which the audit topic is to be compared**

Compliance with Council Directive 2013/59/Euratom and relevant national legislation regarding occupational exposure, dose limits, and categorisation of workers.

3) **Source of standard**

Council Directive 2013/59/Euratom and Member State-specific legislation.

4) Target / compliance percentage to be achieved

100% compliance with dose limits and categorisation requirements for staff and students/apprentices.

5) Item or variable to be audited

- Compliance with dose limits for Category A and B workers:
  - Effective dose (mSv/year)
  - Eye lens dose (mSv/year)
  - Skin/extremities dose (mSv/year)
- Worker categorisation based on exposure risk.
- Maintenance of accurate dosimetry records.
- Training provided to staff regarding radiation protection.

6) Method

- Retrospective and prospective data review.
- Review of dosimetry records and training logs.

7) Data or information to be collected

- Dose records for Category A and B workers.
- Training documentation and attendance records.
- Medical surveillance reports.
- Incident reports (if any).

8) Sample details

- List of all staff and students/apprentices exposed to occupational radiation.
- Dosimetry records over the past year.

9) Actions to be taken if the target is not met.

Root Cause Analysis, Immediate Corrective Measures, Enhanced Monitoring, Policy Review and Update, Stakeholder Communication, Schedule Re-audit:

10) Timing for re-audit

- If the target is not met - within 6 months.
- If the target is met - annual audits to ensure continued compliance.

Audit template questionnaire for staff dosimetry

		Comments
Are occupationally exposed staff monitored	Yes No Partially	
Are occupationally exposed staff classified in a specific category (A or B)	Yes No Partially	
Are outside workers also monitored as exposed workers employed on a permanent basis by the undertaking	Yes No Partially	
Are staff aware of how to correctly wear the different dosemeters	Yes No Partially	
Are dose constraint values (as optimisation tool) established for the occupationally exposed	Yes No Partially	
Are occupationally exposed staff aware of the dose limits	Yes No Partially	
Are occupationally exposed staff aware of the dose constraint values	Yes No Partially	
Are the results of individual monitoring communicated to the individuals	Yes No Partially	
Are the results of the dosimetry recorded in the medical records	Yes No Partially	
Medical follow up of exposed workers	Yes No Partially	
What are the actions undertaken when exceeding a dose constraint	Yes No Partially	
In the case of accidental exposure, is there a procedure for the readout of the dosemeter and dose results communication	Yes No Partially	
Number of high dose alerts per year		
Number of times dose limit exceeded per year		

PLEASE SPECIFY THE CATEGORY OF THE WORKER (A OR B) WHEN FILLING OUT THE FOLLOWING TABLE:

	Whole body dosemeter under apron	Whole body dosemeter over apron	Extremities dosemeter	Eye lens dosemeter	APD (electronic personal dosemeter)
Position					
Type / model (TLD, OSL, ...)					
Exchange					

Audit 83

/ Category: Quality

1) **Audit Title**

Evaluation of the role and responsibilities of the medical physics expert (MPE)

2) **Standard against which the audit topic is to be compared**

Definition of "medical physics expert" described as:
individual or, if provided for in national legislation, a group of individuals, having the knowledge, training and experience to act or give advice on matters relating to radiation physics applied to medical exposure, whose competence in this respect is recognized by the competent authority.

3) **Source of standard**

National legislation intended to transpose and implement requirements included within the Council Directive 2013/59/Euratom, December 2013, chapter 2, article 4, definition 49.

4) **Target / compliance percentage to be achieved**

100 %

5) **Item or variable to be audited**

A. Medical Physics expert duties and responsibilities:
B. Takes responsibility for dosimetry, including physical measurements for evaluation of the dose delivered to the patient and other individuals subject to medial exposure,
C. optimizes the radiation protection of patients and other individuals subject to medical exposure, including the application and use of diagnostic reference levels (DRLs),
D. Concerning medical radiological equipment:
   i. ☆ gives advice,
   ii. ☆ defines and performs quality assurance,
   iii. ☆ performs acceptance testing,
   iv. ☆ prepares technical specifications and installation design,
   v. ☆ performs surveillance,
   vi. ☆ analyses the events involving, or potentially involving, accidental or unintended medical exposures,
   vii. ☆ is involved in the selection of equipment required to perform radiation protection measurements,
E. performs training of practitioners and other staff in relevant aspects of radiation protection,
F. shall be involved:
   i. ☆ in radiotherapeutic procedures other than standardised therapeutic nuclear medicine procedures,
   ii. ☆ in standardised therapeutical nuclear medicine procedures as well as in radiodiagnostic and interventional radiology procedures, involving high doses,
   iii. ☆ for other medical radiological procedures for consultation and advice on matters relating to radiation protection concerning medical exposure,
   iv. ☆ in the development of new clinical protocols or research,
G. shall liaise with the radiation protection expert.

6) **Method**

Retrospective/prospective

7) **Data or information to be collected**

Role and responsibilities of the medical physics expert.

8) **Sample details**

Review of one-year quality assurance reports and other results from duties.

Documentation of patient's radiation protection optimization process.

9) **Target achieved**

Yes/no

10) **Action to be taken if the target is not met**

Proposing corrective actions depending on the identified deficiencies

11) **Timing for re-audit**

One year, or sooner if target not met

Audit 84

/ Category: Safety

1) **Audit Title**
   Radiation protection instruction

2) **Standard against which the audit topic is to be compared**
   Local / national agreed standard. European Council Directive 2013/59/Euratom on BSS. IAEA

3) **Source of standard**
   https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32013L0059
   https://www-pub.iaea.org/MTCD/Publications/PDF/PRTM-5_web.pdf

4) **Target / compliance percentage to be achieved**
   90 %

5) **Item or variable to be audited**
   Personnel yearly instruction, content and appropriateness. Attendance documentation.

6) **Method**
   Retrospective

7) **Data or information to be collected**
   Presentations, text and attendance documentation

8) **Sample details**
   The complete documentation as stated on the previous point

9) **Target achieved**
   Yes / no

10) **Action to be taken if the target is not met.**
    - Content: create a check list from your radiation protection authority and update the instruction contents accordingly
    - Documentation: make radiation protection instructions available centrally through your QMS
    - Attendance: Create a quarterly schedule for instructions to ensure maximum attendance

11) **Timing for re-audit**
    One year

Audit 85

/ Category: Safety, Quality

1) **Audit Title**

Implementation and Effectiveness of Dose Monitoring Software in Radiological Practice

2) **Standard against which the audit topic is to be compared**

Dose monitoring systems must be implemented and used effectively to track, analyse, and optimize patient radiation exposure in line with the Basic Safety Standards Directive (BSSD) and relevant national regulations to ensure patient safety, compliance with diagnostic reference levels (DRLs), and continuous improvement in radiation dose management.

3) **Source of standard (or reference document)**

National legislation and regulations derived from Council Directive 2013/59/Euratom, Articles 55 and 56, covering patient protection, dose optimization, and dose record management.

4) **Target / compliance percentage to be achieved**

Aspirational Target: 100% of eligible procedures should be monitored using the dose monitoring software, and reports should demonstrate effective use for optimization.

5) **Item or variable to be audited**

Availability of dose monitoring software for all modalities using ionizing radiation. Completeness and accuracy of dose data recorded for each procedure. Use of DRLs for benchmarking and optimization of radiation dose levels. Availability of routine reports analysing dose data by modality, procedure type, and patient demographics. Maintenance of patient dose records as part of their medical records. Communication of dose levels to patients, when required, particularly in high-dose procedures.

6) **Method: Retrospective / Prospective / Other**

Retrospective/prospective

7) **Data or information to be collected**

- Percentage of imaging equipment integrated with dose monitoring software.
- Number of procedures for which dose data was successfully recorded.
- Number and percentage of procedures exceeding DRLs.
- Frequency and comprehensiveness of dose reports.

8) **Sample details (categories, number of patients, collection time period)**

Review 100 dose reports or 3 months of software usage data, whichever is more comprehensive

9) **Target achieved**

Yes – No – Not applicable

10) **Actions to be taken if the target is not met.**

Technical Upgrades: Integrate missing modalities with the dose monitoring software. Provide additional training for staff on software use and interpreting dose data. Review and update DRLs based on the latest standards and benchmarks. Implement corrective actions for procedures frequently exceeding DRLs. Revise institutional policies to mandate the use of dose monitoring software for all ionizing radiation procedures.

11) **Timing for re-audit**

6 months

Audit 86

/ Category: Safety, Quality

1) **Audit Title**
Compliance and Optimization in Cone Beam Computed Tomography (CBCT)

2) **Standard against which the audit topic is to be compared**
Compliance with Council Directive 2013/59/Euratom (BSSD) Articles 54–56, focusing on justification, optimization, and dose limitation.

3) **Source of standard**
National legislation implementing the Euratom directive. Council Directive 2013/59/Euratom (BSSD) Articles 54–56, focusing on justification, optimization, and dose limitation.

4) **Target / compliance percentage to be achieved**
100 % (compulsory)

5) **Item or variable to be audited**
★★ Clinical indication documented for all procedures.
★★ Adherence to DRLs and patient-specific protocols.
★★ Operator certification and training in radiation safety.
★★ Regular maintenance and calibration.
★★ Proper use of safety measures and protocols.
★★ Accurate recording of patient doses.

6) **Method**
Retrospective or prospective

7) **Data or information to be collected**
Number and percentage of procedures with documented clinical indications. Adherence to referral guidelines.
Average radiation doses per CBCT examination compared to DRLs. Frequency of protocol adjustments based on patient-specific needs.
Number and percentage of operators with up-to-date training and certification. Maintenance and calibration logs.
Availability and proper use of protective measures. Documentation of radiation safety training for staff.

8) **Sample details (number of patients, collection time period)**
Sample Size: 50–100 consecutive CBCT procedures. Collection Period: 6 months to 1 year, depending on procedure volume.

9) **Target achieved**
(yes / no)

10) **Actions to be taken if the target is not met**
Update referral and justification guidelines. Optimize imaging protocols. Conduct staff training. Address equipment issues and improve maintenance schedules.

11) **Timing for re-audit**
One year, or sooner if target not met

Audit 87

/ Category: Safety

1) **Audit Title**

Integration of Advanced Technologies for minimizing radiation exposure in high doses domains

2) **Standard against which the audit topic is to be compared**

BSSD

3) **Source of standard**

National legislation intended to transpose and implement requirements included within the Council Directive 2013/59/Euratom, Article 56.4

4) **Target / compliance percentage to be achieved**

100 %

5) **Item or variable to be audited**

Assess whether the department is implementing tools and strategies to optimize radiation protection by minimizing exposure to ionising radiation while maintaining diagnostic quality

6) **Method**

Retrospective / Prospective / Other

7) **Data or information to be collected**

Documentation of advanced dose-reduction technologies integrated into the equipment or installed in the department

Written protocols for the use of dose-reduction technologies and strategies

Historical data trends showing dose reduction over time (if tracked).

8) **Sample details**

One month review of above

9) **Target achieved**

Yes /no

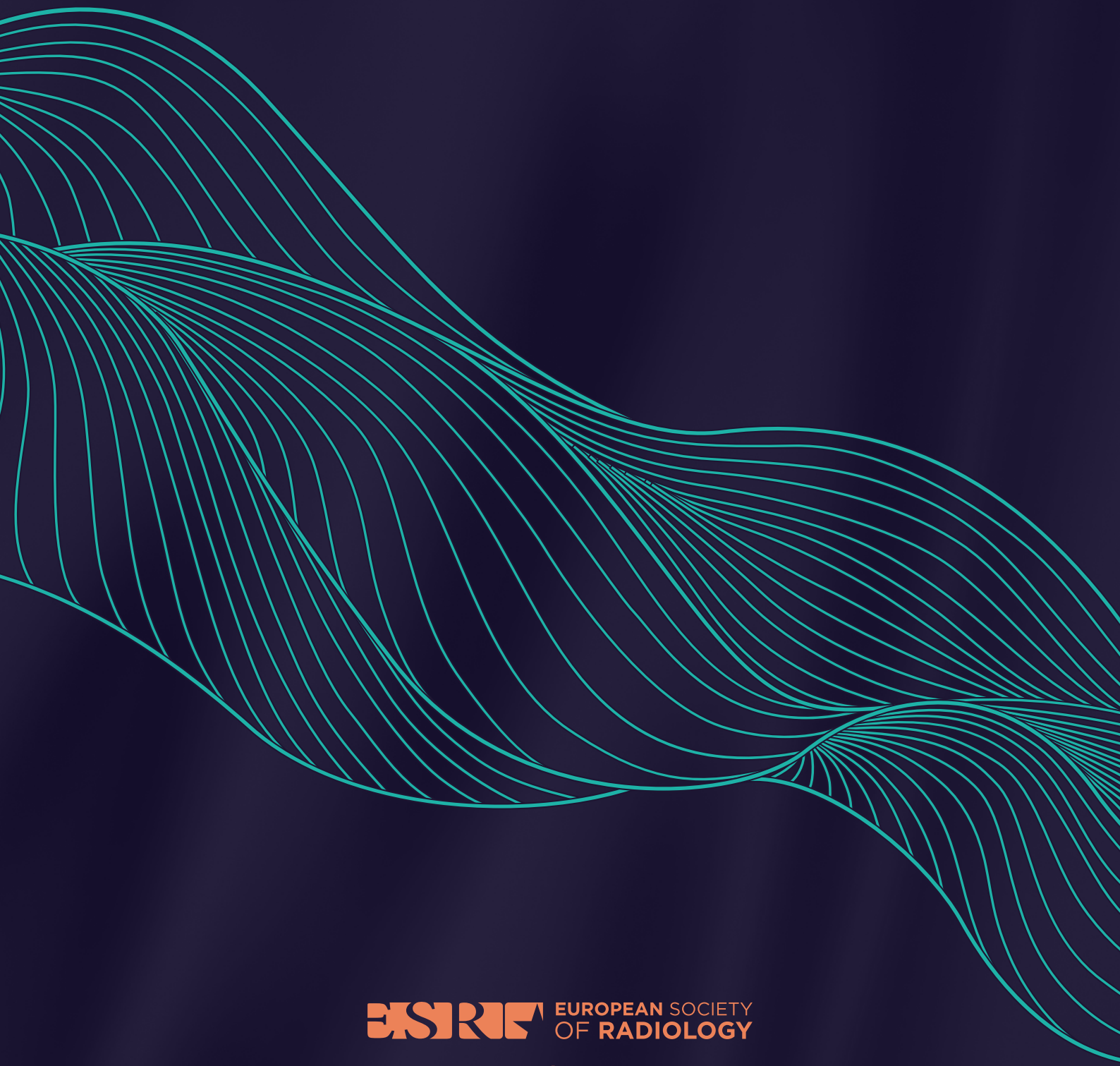
10) **Action to be taken if the target is not met**

If the target is not met, conduct a root cause analysis to identify gaps and implement corrective actions, such as staff training, protocol revision, or equipment upgrades. Regularly monitor progress and establish clear timelines to achieve compliance.

11) **Timing for re-audit**

One year, if target not met

/ Notes



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