Esperanto ESR Guide to Clinical Audit in Radiology

3rd Edition

EUROPEAN SOCIETY OF RADIOLOGY

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CONTENTS

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Esperanto Purpose and Scope

This third iteration of Esperanto 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. QuADRANT – an ESR led clinical audit related initiative on behalf of the European Commission is also reviewed and its implications discussed.

This version of Esperanto maintains a broad selection of regulatory audit templates as implementation of these mandatory requirements remains a high priority for radiology departments. There has been a significant expansion of clinical audit templates and in particular clinical audit in support of radiation protection and BSSD compliance (BSSD – Basic Safety Standards Directive, see section 3). Clinical audit as part of BSSD compliance is mandatory and subject to inspection and a key aim of Esperanto is to support radiology departments in this area.

This clinical audit guide also discusses and defines different types of clinical audit – namely self-assessment/internal audit, external audit and internal audit with external direction. The importance of clinical audit as mandated within the BSSD and its relationship to inspection (by the relevant national radiation protection competent authority) is highlighted.

It is anticipated that this audit guide and tool will support radiology departments in the process of incorporating clinical audit into everyday working practice, with prioritisation given to implementing regulatory requirements and supporting processes of clinical audit. The importance of participation in clinical audit in improving patient care and outcomes is recognised and encouraged.

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Clinical Audit and Clinical Governance – an Introduction

Clinical audit in modern healthcare emerged as a concept in the late 1990's 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/IT governance
- Research governance

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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 comprehensive Basic Safety Standards Directive (Council Directive 2013/59/Euratom [1], BSSD), addressing the use of ionising radiation.

Recognising that clinical audit was already a feature of good practice in healthcare delivery, with national procedures in place, the text in both Directives was deliberately not prescriptive. The Member States negotiating these Directives, European Commission officials and ultimately the Council of the EU all recognised the importance of clinical audit in the wider healthcare context and did not wish to impose unhelpful or unnecessary conditions through a legal instrument (the European Commission Directive).

Following adoption by the Council of the European Union, Member States had 4 years (ie. 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 much prefers that requirements are met in legislation rather than through administrative means. It is however the Member State that determines exactly how these requirements are met in its national legislation. In doing so, it should use the open wording of the Directive to ensure consistency with existing legislation and administrative processes.

Because the onus for transposition and implementation of the BSSD is on the Member State, clinical audit cannot be left entirely to professional bodies. Nevertheless, many European Commission officials are of the view that clinical audit can influence standards in healthcare on a day-to-day basis. They recognise that inspection, while an essential part of regulatory compliance, cannot alone make Improvements in patient safety and patient care and that understanding of the role of local clinical audit, and active participation by local practitioners in audit activity are key to fostering a culture of regular quality assurance and continual 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. This is 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 (9).

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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 3 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 applies to the majority of clinical audit, particularly at individual/departmental level – clinical audit should be **A**chievable, **L**ocal, **P**ractical, **I**nexpensive, **N**on-threatening and **E**asy.

A detailed discussion of quality improvement (QI) is beyond the scope of this document, clinical audit however can be considered a QI cycle involving measurement of effectiveness of care against agreed/proven standards. Good quality healthcare should be: safe, effective, patient centred, timely, efficient and equitable.

Clinical audit needs to be carried out by Member States, in response to the requirements of the BSSD article 58(e). These audits may be carried out in a number of ways, consistent with other specified procedures for clinical audit within the Member State, but whatever these may be, there is a need for better understanding by imaging professionals and licence holders of clinical audit requirements within a legislative structure relating to radiation protection. When the Member State's Regulatory Authority carries out its inspections under its national legislation, it is likely it will discuss clinical audit processes with the representatives of the licence holder as well as discussing the details with the institution's radiology and radiation protection professionals. In healthcare, and specifically in radiology, the licence holder will usually be the legal organisation ("the undertaking" as referred to in the BSSD) responsible for the practices (or activities) carried out in a facility, including the radiology department. The licence will be issued by a national authority and provides a level of regulatory control through restrictions or conditions relating to the licenced activity. The organisation will provide the framework under which clinical activities will take place, while the radiology professionals will be responsible for specific actions 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 supporting 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 within 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.

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Clinical Audit Importance and Scope

High quality clinical audit can benefit patients, radiology departments and clinical services in several ways:

- Promotes and facilitates high quality medical care
- Provides educational, teaching and interdisciplinary collaborative opportunities
- Can be used to drive improvements in quality of care
- Allows departments to demonstrate a commitment to patient/staff safety and compliance, according to the requirements outlined within the BSSD.

Clinical audit has a wide recommended 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.

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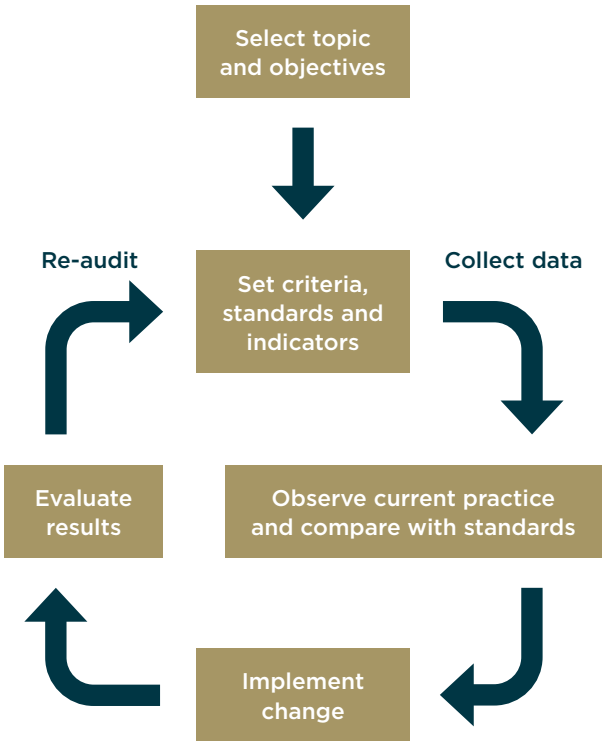
The Audit Cycle Methodology

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



If a clinical audit reveals a failure to meet the audit standard confirming the need for service improvement, then a key component of the audit cycle is a re-audit following the implementation of practice change(s) to confirm the service is improved and “closing the audit loop” or “completing the audit cycle”. For certain aspects of radiological service/care (particularly around radiation protection and as outlined in the BSSD) e. g. review and use of diagnostic reference levels (DRLs) for radio-diagnostic examinations, these service audits will need to be repeated periodically (timing to be established according to local/national protocols) and they will need to be repeated regardless of whether the target is met or not met – continued compliance with dose targets is required for example with DRL measurement, with documented practice changes made if the target is not met.

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Clinical Audit vs Research

Clinical audit, like research projects, should be under taken within an ethical framework, protecting patient and staff identity/confidentiality. There are some core differences between clinical audit and research [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 Directive [1].

CLINICAL AUDIT (NON-REGULATORY)	RESEARCH
Standards based – Standards may be flexible, based around good practice guidelines for example	Aims to establish best practice
Evaluates whether clinical practice or service provision meets standards	Often a one-off study, testing a new theory
Specific and local (practice based) findings may not be transferable to other settings	Designed so findings can be replicated and transferable
Aims to improve services	Aims to generate new knowledge

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Undertaking a Clinical Audit

There are a number of stages 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, 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

6) **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

7) **Analyse Data**

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

8) **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

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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 will form a significant part of departmental audit programmes, these regulatory audits have mandated absolute standards – 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 audit is helpful for radiology departments and employers to know that there is compliance with national regulations, but this 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 of 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 requirement, although the Directive assumes and indirectly requires it to be carried out by its reference to national arrangements. Evidence of active and ongoing participation in clinical audit is considered a marker of good practice and would be taken into account as such by an external regulator, as a marker of regulatory compliance. Clinical audits might also demonstrate (indirectly) appropriate optimisation 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 and just as importantly, a well-developed approach to optimisation within the institution.

There is a drive to set up national processes of external audit – a multidisciplinary external auditing team working in collaboration with local radiology departments to carry out external audits, possibly across a region or many departments. 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, occurring separately from 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, it 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 audit 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 on clinical audit [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

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QuADRANT – A European Initiative With An Emphasis On Clinical Audit

In 2019 the European Commission put a project out to tender, ENER/D3/2019-231-2, entitled "Constant Improvement in Quality and Safety of Radiology, Radiotherapy and Nuclear Medicine Through Clinical Audit." The project has key specific objectives: -.

a) To review the status of implementation of clinical audits in the Member States.

b) To identify good practices in Member States and available guidance and resources for clinical audits at national, European and international level.

c) To provide further guidance and recommendations on improving the implementation and integration of clinical audits into national healthcare systems.

d) To identify potential for further coordinated EU action on quality and safety of radiology, radiotherapy and nuclear medicine.

The ESR, as lead of a consortium also involving ESTRO (European Society of Radiotherapy and Oncology) and EANM (European Association of Nuclear Medicine) 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 duration of 30 months and comprises 5 work packages (WPs), including two conferences and a pan-European survey to establish current clinical audit status, challenges and barriers. The final project report for the European Commission will provide a collection of best practices (suitable for wider implementation) and guidance and recommendations on improving the implementation and integration of clinical audit into European Member State healthcare systems.

QuADRANT is an important piece of work and is likely to be fundamental in providing a European roadmap for enhancing clinical audit uptake across Europe and improving experiences and outcomes for patients.

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The ESR Clinical Audit Tool

To support BSSD transposition and to 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 to help them incorporate clinical audit into their departmental work and processes. In addition, by engaging with clinical audits/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 to the employer that there is regulatory compliance, 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 which can be adapted according to local or national audit topics.
- Appendix 2 – this area has been expanded and contains a series of clinical audit topics. These relate to clinical practice – service provision examples, although not strictly clinical audit, are included in this section. Templates covering clinical audits in support of BSSD requirements are now also included, namely audits that are clinical but also allow demonstration of regulatory compliance. Templates are further subdivided into areas of departmental practice where appropriate e.g., examination requesting, patient or staff focused, workflow related, examination reporting.
- Appendix 3 – a series of suggested regulatory audit topics, initially developed via a piloting project amongst EuroSafe Imaging Star radiology departments.

The regulatory audit templates in Appendix 3 are aligned to topics defined by the BSSD; these audits have a compulsory 100% compliance target and it is essential departments embed these key requirements as a priority, supporting processes of clinical audit can then be developed as mandated within the BSSD.

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 to be seen to act on these audit findings and to implement necessary changes. It may be that a piece of imaging equipment is too old and substandard; 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.

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Summary

Engagement with clinical audit is an indicator of good clinical practice and is now a requirement within the BSSD. The ESR has produced this Guide to Clinical Audit and an accompanying Audit Tool/Templates to support radiology departments across Europe in complying with the requirements of the BSSD and to enhance the quality of the clinical care they provide.

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References

[1] Council Directive 2013/59/Euratom on basic safe ty 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. OJ of the EU. L13;57:1-73(2014).

[2] European Commission Guidelines on Clinical Audit for Medical Radiological Practice (Diagnostic Radiology, Nuclear Medicine and Radiotherapy). Radiation Protection Directive No. 159; 2010.ISSN 1681-6803.

[3] European Commission Guidelines on Clinical Audit. Statement by the European Society of Radiology. Insights Imaging 2011: 2(2); 97-98.

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

[5] HERCA. HERCA Position Paper: Clinical Audit in Medical Radiological Practices. 2019; 1-18; and Addendum to the HERCA clinical audit position paper published in June 2021

[6] ESR. Eurosafe imaging, QuADRANT (online). Available from; http://www.eurosafeimaging.org/clinical-audit/quadrant

[7] Auditlive. Royal College of Radiologists, London, UK. [https://www.rcr.ac.uk/clinical-radiology/audit-and-qi/auditlive]

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Acknowledgements

Prof. David C. Howlett, Chair ESR Audit and Standards Subcommittee and Clinical Lead QuADRANT project, Dr. Núria Bargalló Alabart, Chair ESR Quality, Safety and Standards Committee, Mr. Steve Ebdon-Jackson, ESR Audit and Standards Subcommittee, Alexandra Karoussou-Schreiner, Chairman HERCA WGMA (Working Group Medical Applications) and member ESR Audit and Standards Subcommittee, Dr. Adrian P. Brady, ESR 1st Vice-President and QuADRANT Co-Lead, Prof. Andrea G. Rockall, Chair ESR National Societies Committee, Mr. Vasilis Syrgiamiotis, Dr. Marta Sans Merce, Dr. Roman Klöckner and Dr. Raija Seuri as members of the ESR Audit and Standards Subcommittee, all members of the ESR Audit and Standards Subcommittee, Ms. Susi Arjomand and the ESR Office.

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Appendices

Appendix 1 – draft blank template

Appendix 2 – clinical audit templates

Appendix 3 – regulatory audit templates

Appendices

Appendix 1 – draft blank template

Appendix 2 – regulatory audit topics (relating to regulation of medical exposures using ionising radiation)

Appendix 3 – clinical audit topics (relating to service provision and clinical practice)

APPENDIX 1

Audit Template Document (Blank)

Audit Title

Standard against which the audit topic is to be compared

Source of standard (or reference document)

Type of audit – clinical regulatory or clinical non-regulatory

Target / compliance percentage to be achieved

Item or variable to be audited

Method: Retrospective / Prospective / Other

Data or information to be collected

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

Target achieved

☐ yes ☐ no ☐ not applicable

Actions to be taken if the target is not met.

Timing for re-audit

☐ yes ☐ no ☐ not applicable

APPENDIX 2

Clinical Audit Topics (Relating to Clinical Practice, to Clinical Audit in Support of BSSD Compliance and also Incorporating Service Provision)

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) Key points on how to manage patient radiation protection
30) Waiting time for outpatient ultrasound appointments
31) Does the radiology department record statistics about patient satisfaction?

Patient satisfaction questionnaire

Audit 1

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) **Type of audit – clinical, patient focussed**

5) **Target / compliance percentage to be achieved**
Complications:

- ★ Pneumothorax <20%
- ★ Large pneumothorax requiring chest drain insertion <3%
- ★ Haemothorax <5%
- ★ Death <0.15%

Diagnostic accuracy: >90%

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

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

8) **Additional 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

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

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

11) **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.

12) **Timing for re-audit (yes / no / not applicable)**
3-year cycle (potentially sooner if concerns in relation to complication rates/diagnostic yield at first audit round)

Audit 2

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) **Type of audit – clinical, patient focussed, reporting**
Compulsory: legal requirement

5) **Target / compliance percentage to be achieved**
100 %

6) **Item or variable to be audited**
A. Availability of locally agreed departmental interventional safety check-lists for each interventional radiological procedures
B. Documentation of completion of the safety check-list on radiology report of all radiological interventional procedures.
C. Documentation of patient consent in the radiology report.

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

8) **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

Suggest 100 interventional procedures to be reviewed.

9) **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

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

11) **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 and importance of having safety check-lists for interventional procedures and for documentation of consent and safety check-list 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

12) **Timing for re-audit (yes / no / not applicable).**
Yes: re-audit in 3-6 months following completion of initial audit with periodic re-audit to ensure maintained compliance.

Audit 3

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.**
This audit can include various treatment indications. The best use cases can be found in oncology because the patients have to undergo interdisciplinary discussion in a tumor board repeatedly (sometimes for several years). If the audit should be focused on radiology only, typical indications in interventional radiology would be appropriate. For other disciplines typical high-volume treatments (e.g., liver resection, start of chemotherapy etc.) can also be included

3) **Source of standard (or reference document)**
An interdisciplinary discussion is requested in the majority of guidelines for most treatments; in addition, several societies are requesting a similar approach for certifications.

4) **Type of audit – clinical, patient focussed, workflow related**
This is a clinical audit – incorrect or suboptimal treatment decisions might increase the risk of treatment failure, potentially therefore also EU-BSS related.

5) **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.

6) **Item or variable to be audited**
Completion rate of an interdisciplinary discussion of oncological patients in a tumour board prior to initiating treatment

7) **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

8) **Data or information to be collected**
Presentation / discussion of a particular patient in an interdisciplinary tumour board.

9) **Sample details (categories, number of patients, collection time period)**
Typical time periods are one year for the audit.

10) **Target achieved (yes / no / not applicable)**
Compliance with standards (completion rate >95%): yes/no.

11) **Actions to be taken if the target is not met**
Internal guideline. Change of workflow. Improve communication. Review staff training. Educational sessions.

12) **Timing for re-audit (yes / no / not applicable)**
The audit should be repeated periodically to confirm compliance with standards.

Audit 4

1) **Audit Title**
Improving referral process and guidelines – specific target: implementation of referral guidelines through ESR iGuide – integrated directly into hospital ordering systems

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

3) **Source of standard (or reference document)**
iGuide / ESR (or alternative system)

4) **Type of audit – clinical, workflow, requesting**
Compulsory. Legal requirement.

5) **Target / compliance percentage to be achieved**
90% of referrals conforming to iGuide (or other utilised and established reference)

6) **Item or variable to be audited**
Sample of referrals (e.g., 10 referrals from 5 selected examinations/indications) compared to guideline criteria. A wide variety of investigations, both ionising and non-ionising can be included, with variable numbers and time periods.

7) **Method: Retrospective / Prospective / Other**
Retrospective (registry evaluation from hospital HIS/RIS) or prospective

8) **Data or information to be collected**
Sample of referrals (e.g., 10 referrals from 5 selected examinations/indications)

9) **Sample details (categories, number of patients, collection time period)**
10 referrals from 5 selected examinations/indications during the past one month

10) **Target achieved (yes / no / not applicable)**
90% level = target achieved

11) **Actions to be taken if the target is not met**
Appropriate remedial actions and their time-frame discussed within department including radiologists and radiographers and referring clinicians

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

Audit 5

1) **Audit Title**
Protocols around radiological procedures, information in reports

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. Inclusion of this information is important and can have a role reporting follow up studies and subsequent protocol planning (change of parameters, increasing contrast material dose etc.)

3) **Source of standard**
Local / national agreed standard

4) **Type of audit – clinical, reporting**
Compulsory: legal requirement

5) **Target / compliance percentage to be achieved**
100 %

6) **Item or variable to be audited**
All radiological procedures – selected procedure types, e. g. ionising (CT) or non-ionising (ultrasound) or involving intravenous contrast (CT or MR) can be selected

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

8) **Data or information to be collected**
Presence of the examination protocol in a separated part of the report (suggest at the beginning)

- ★ correct details of protocols (phases in CT, sequences in MR etc.)
- ★ contrast material application details if used

9) **Sample details (number of patients, collection time period)**
100 consecutive reports

10) **Target achieved**
Yes / no

11) **Actions to be taken if the target is not met.**
Disseminate results to reporters, meet/discuss with radiologists and emphasise importance

12) **Timing for re-audit (yes / no /not applicable)**
In one year

Audit 6

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

3) **Source of standard**
Local / national guidance on the indications for / performance of pre-operative chest X-rays

4) **Type of audit – clinical practice, requesting, also BSSD related**
Compulsory. Legal requirement

5) **Target / compliance percentage to be achieved**
100 % – to be discussed within the department

6) **Item or variable to be audited**
Consecutive pre-operative chest X-ray requests

7) **Method: Retrospective / Prospective / Other**
Retrospective/prospective

8) **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

9) **Sample details (number of patients, collection time period)**
100 pre-operative chest X-ray requests

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

11) **Actions to be taken if the target is not met**
Educating referring clinicians and radiology department staff about the guidelines

12) **Timing for re-audit (yes / no / not applicable)**
1 year

Audit 7

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

3) **Source of standard**
Local / national referral guidelines

4) **Type of audit – clinical, requesting, also BSSD-related**

5) **Target / compliance percentage to be achieved**
90 % – to be discussed and agreed

6) **Item or variable to be audited**
Chest X-ray or abdominal X-ray

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

8) **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

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

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

11) **Actions to be taken if the target is not met**
Discuss with referrers /radiology department to reinforce and embed referral guidelines

12) **Timing for re-audit (yes / no / not applicable)**
1 year

Audit 8

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 (eg. 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**
Local /national referral guidelines (e. g. for ultrasound /MRI)

4) **Type of audit – clinical, requesting**

5) **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)

6) **Item or variable to be audited**
All or selected non-ionising (or ionising) radiological procedures

7) **Method**
Retrospective or prospective

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

- ★ Presence of a clinical question/diagnosis on the request form
- ★ Request meets agreed referral guidelines

9) **Sample details (number of patients, collection time period)**
100 reports

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

11) **Actions to be taken if the target is not met**
Education of clinical referrers around referral (and justification) processes

12) **Timing for re-audit (yes / no / not applicable)**
1 year

Audit 9

1) **Pain sensation during image-guided interventions**
This document provides suggestions and outline guidance for an audit/QI project and can be used with addition- al/local guidance to develop a formal template with locally agreed targets and solutions.

2) **Methodology**

- Pain during image – guided interventions may be monitored quantitatively by using the pain scale ranging from 1 – 10 after each intervention
- Patients undergoing interventions in the radiology department are asked to indicate a value on the pain scale
- All values are prospectively registered in the RIS
- Evaluation may be done in a detailed manner, taking into consideration the type of intervention, the different body regions, operators, etc

3) **Impact on improvement**

- The results for each procedure can be evaluated periodically, thus allowing monitoring of specific procedures in the department
- Conclusions may result in specific measures, (e. g., improving patient information, specific interventional techniques, local anaesthesia, i. v. (pre-)medication, hypnosis, etc.)

4) **Possible questions**
Are you aware of the patient's pain sensation in your department? Do you monitor pain sensation? Which are the procedures leading to an average pain sensation greater than 4? What are the proposed measures to improve the results?

Audit 10

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

2) **Standard against which the audit topic is to be compared**
To be discussed and agreed locally.
Preferably combined with patient dose evaluation.

3) **Source of standard (or reference document)**
EU 16260 EN
EU 16261 for pediatrics
(National reference levels for dose comparison, for pediatrics EC RP 185 if no national DRLs)

4) **Type of audit – clinical audit, BSSD related, patient focussed**

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

6) **Item or variable to be audited**
Image quality

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

8) **Data or information to be collected**
Radiographic images.

9) **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

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

11) **Actions to be taken if the target is not met**
Actions depend on the problem recognized in the evaluation (positioning, projection, collimation, noise etc.)
If the image quality is good, but the DRLs are exceeded, look at the possibilites to decrease dose without losing diagnostic image quality, also record the true collimation.

12) **Timing for re-audit (yes / no / not applicable)**
Should be part of yearly QA.

Audit 11

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

2) **Standard against which the audit topic is to be compared**
To be discussed locally.
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 pediatrics EC RP 185 if no national DRLs)

4) **Type of audit – clinical, BSSD related, patient focussed**

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

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

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

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

9) **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 CTs.

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

11) **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.

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

Audit 12

1) **Audit Title**
Justification of head CT

2) **Standard against which the audit topic is to be compared**
Discussed and agreed locally.

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

- Referral guidelines (iRefer, ACC)
- e.g., Quality of Referral, Pitman 2017
- (Should a head-injured child receive a head CT scan? A review. Maguire, Boutis et al, 2011)

4) **Type of audit – clinical audit, BSSD related, requesting**

5) **Target / compliance percentage to be achieved**
Discussed and agreed locally.

6) **Item or variable to be audited**
Referral quality (Possible to allow justification).
Justification of the examination according to standards/guidelines.

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

8) **Data or information to be collected**
Referrals for *emergency head CT/pediatric head CT for example*

9) **Sample details (categories, number of patients, collection time period)**
Discussed and agreed locally. (e.g., 20-30 consecutive patients/3months/6months)

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

11) **Actions to be taken if the target is not met**
Review of the justification process: availability of referral guidelines, institutional instructions for good referral or standardised referral form, roles of professionals in the justification process (referring physician, radiographer/technician/radiologist)

12) **Timing for re-audit (yes / no / not applicable)**
Re-audit necessary after above actions/practice changes/education.

Audit 13

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) **Type of audit**
Clinical audit – loss of diagnostic information due to lack of contrast opacification may also cause diagnostic failure and a need to repeat an ionising study, also BSSD related, reporting/patient focussed.

5) **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.

6) **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.

7) **Method: Retrospective / Prospective / Other**
Depending on how robustly such events are recorded retrospective or prospective analysis can be considered.

8) **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.

9) **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.

10) **Target achieved (yes / no / not applicable)**
A reasonable sample size needed to ensure representative data, agree locally.

11) **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.

12) **Timing for re-audit (yes / no / not applicable)**
The audit should be repeated periodically to ensure either ongoing compliance with targets or necessary improvements as required.

Audit 14

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**
To be discussed and agreed locally.

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.

4) **Type of audit – clinical audit, BSSD related (incident reporting), workflow/patient related**

5) **Target / compliance percentage to be achieved**
To be agreed locally and in light of relevant guidelines.

6) **Item or variable to be audited**
The frequency of patient mis-identification errors.

7) **Method: Retrospective / Prospective / Other**
Retrospective or prospective.

8) **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 e.g., unnecessary radiation exposure; reasons for error; remedial actions.

9) **Sample details (categories, number of patients, collection time period)**
To be agreed locally, including time period for the audit.

10) **Target achieved (yes / no / not applicable)**
Compliance with standards yes/no.

11) **Actions to be taken if the target is not met**
Review causes for misidentification, remedial actions (these may include education programmes), re-audit.

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

1) **Audit Title**
Reject Analysis of Radiological Images.

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.

3) **Source of standard (or reference document)**
These are derived from existing published literature and available guidances at local, national and international level.

4) **Type of audit – clinical audit, BSSD related, workflow**

5) **Target / compliance percentage to be achieved**
To be agreed locally and in light of relevant guidelines.

6) **Item or variable to be audited**
The image rejection rate, type of examination, reason for image rejection.

7) **Method: Retrospective / Prospective / Other**
This audit can be performed retrospectively or prospectively.

8) **Data or information to be collected**
Number and type of images rejected, documented reasons for image rejection (e.g., patient positioning, improper patient preparation).

9) **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.

10) **Target achieved (yes / no / not applicable)**
Is there compliance with agreed standards

11) **Actions to be taken if the target is not met**
This needs to be managed sensitively, review of reasons for rejection, review of local radiographic practices where necessary, education of relevant staff around key principles.

12) **Timing for re-audit (yes / no / not applicable)**
This audit should be repeated periodically to confirm either continuing compliance with standards or, if needed, that necessary improvements have occurred. It is important all/replacement staff are involved proactively in training and education around the importance of high-quality technique in reducing reject analysis rates.

Audit 16

1) **Audit Title**
Impact of a Local Training Programme on First Line Reporting Accuracy by Junior Doctors.

2) **Standard against which the audit topic is to be compared**
To be discussed and agreed locally, results of initial evaluations may be of help in deriving local standards.

3) **Source of standard (or reference document)**
The source of the standard will be derived from existing published literature and available guidances at local, national and international level.

4) **Type of audit – clinical audit, BSSD related, reporting/patient related**

5) **Target / compliance percentage to be achieved**
To be agreed locally and in light of relevant guidelines.

6) **Item or variable to be audited**
A wide variety of reporting situations can be included – a good example would include junior doctor assessment of nasogastric tube placement on chest radiograph.

7) **Method: Retrospective / Prospective / Other**
This is an audit best performed prospectively.

8) **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.

9) **Sample details (categories, number of patients, collection time period)**
To be discussed locally, results of reporting assessments pre and post teaching intervention.

10) **Target achieved (yes / no / not applicable)**
Improvements in junior doctor reporting accuracy anticipated.

11) **Actions to be taken if the target is not met**
Review the topic taught, mechanism/timing/frequency of delivery. Discuss with junior doctors preferred form of teaching delivery, review attendance at teaching sessions, also feedback on results.

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

1) **Audit Title**
Auditing the Appropriateness of CT Referrals.

2) **Standard against which the audit topic is to be compared**
This audit can cover a wide variety of CT procedures and can be extended to other forms of imaging (ultrasound/MRI). Standard for compliance to be set and agreed locally.

3) **Source of standard (or reference document)**
The source of standards will generally be existing published literature and guidances at local, national and international level e.g., the use of CT in head injury.

4) **Type of audit – clinical audit, BSSD related, workflow / requesting**

5) **Target / compliance percentage to be achieved**
To be agreed locally and in light of relevant guidelines.

6) **Item or variable to be audited**
The appropriateness of referrals for CT procedures, do they align with best practice guidance and recommendations.

7) **Method: Retrospective / Prospective / Other**
Retrospective or prospective.

8) **Data or information to be collected**
See above – review of clinical information provided in support of CT request and assessment of appropriateness.

9) **Sample details (categories, number of patients, collection time period)**
To be decided locally, including type of CT procedure to be audited, number of patients, time period.

10) **Target achieved (yes / no / not applicable))**
Review results and compliance with standard.

11) **Actions to be taken if the target is not met**
A process of education of referrers, review of local referral practices and guidelines and education of radiology staff around rejection of inappropriate imaging requests.

12) **Timing for re-audit (yes / no / not applicable)**
This audit should be repeated periodically to ensure continuing compliance or to demonstrate required changes in referral practice have been achieved and maintained. A continuing process of education for referrers is also desirable.

Audit 18

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. Standards to be set locally but an aspirational standard of 100% completion could be considered.

3) **Source of standard (or reference document)**
The source of standards would be establishing published literature and guidances at local, national and international level.

4) **Type of audit – clinical audit, BSSD related, requesting / workflow**

5) **Target / compliance percentage to be achieved**
To be agreed locally, but 100% compliance could be the recommended best practice standard.

6) **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).

7) **Method: Retrospective / Prospective / Other**
This audit is best performed prospectively, but retrospective analysis is also possible.

8) **Data or information to be collected**
See above – the requested variables for completion on the request form to be completed.

9) **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

10) **Target achieved (yes / no / not applicable)**
Review results and compliance with standard documented.

11) **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.

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

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**
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)**
The source of standards would be published literature and guidances at local, national and international level.

4) **Type of audit – clinical audit, BSSD related (optimisation), reporting**

5) **Target / compliance percentage to be achieved**
Improving or maintaining the diagnostic yield of CT across a range of procedures whilst introducing new/dose reducing protocols (e.g., lower dose protocols lung, orbits etc).

6) **Item or variable to be audited**
Image quality and diagnostic confidence as affected by new, lower dose CT protocols, a wide spectrum of CT techniques evaluated. Alternatively, the effect of differing non-dose reducing CT protocols on diagnostic performance could also be assessed.

7) **Method: Retrospective / Prospective / Other**
This audit is best performed prospectively.

8) **Data or information to be collected**
Effect on image quality/diagnostic confidence of introduction of a new CT protocol, close reducing protocols to be prioritised for this audit, but alternative CT protocols without dose reduction could also be considered.

9) **Sample details (categories, number of patients, collection time period)**
To be decided locally, including types of CT procedure included and protocols used.

10) **Target achieved (yes / no / not applicable)**
Image quality/diagnostic confidence maintained/improved by the effect of a new protocol with documented reduction in dose.

11) **Actions to be taken if the target is not met**
Protocols will need to be adjusted and dose optimised as appropriate to allow image quality and diagnostic confidence to be maintained.

12) **Timing for re-audit (yes / no / not applicable)**
Periodic re-auditing is recommended to ensure image quality/diagnostic quality are maintained in line with new protocols. Newer/upgraded CT protocols may also become available.

Audit 20

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 guidances and protocols.

4) **Type of audit – clinical, BSSD related (optimisation), reporting / patient focussed**

5) **Target / compliance percentage to be achieved**
Maintaining image quality and diagnostic confidence whilst reducing required radiation dose by variation in injected contrast during CT.

6) **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.

7) **Method: Retrospective / Prospective / Other**
This audit is best performed prospectively.

8) **Data or information to be collected**
Effect on image quality/diagnostic confidence and required radiation dose according to variation in IV contrast volume/concentration used in CT procedures.

9) **Sample details (categories, number of patients, collection time period)**
To be decided locally, including type of CT procedures evaluated.

10) **Target achieved (yes / no / not applicable)**
Maintaining image quality/diagnostic confidence, monitoring the effect on radiation dose at the lowest possible radiation dose.

11) **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.

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

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.

3) **Source of standard (or reference document)**
Generally, the source of the standard would be published literature and guidances at local, national, international level.

4) **Type of audit – clinical audit, BSSD related, reporting**

5) **Target / compliance percentage to be achieved**
Maintaining image quality and diagnostic confidence whilst minimising dose is the desired outcome/target.

6) **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).

7) **Method: Retrospective / Prospective / Other**
This audit is best performed prospectively.

8) **Data or information to be collected**
Variations in dose according to adjustment of frame/pulse rate with recording of image quality and diagnostic confidence.

9) **Sample details (categories, number of patients, collection time period)**
To be decided locally, including which imaging procedures are to be evaluated.

10) **Target achieved (yes / no / not applicable)**
As demonstrated by maintaining image quality and diagnostic confidence at the lowest reasonable dose.

11) **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.

12) **Timing for re-audit (yes / no / not applicable)**
Periodic re-auditing is recommended to ensure image quality/diagnostic confidence is maintained and procedural dose is acceptable.

Audit 22

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-british-society

4) **Type of audit – clinical audit, clinical practice and BSSD related, reporting**

5) **Target / compliance percentage to be achieved**
100% (aspirational), to be agreed locally

6) **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.

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

8) **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]

9) **Sample details (categories, number of patients, collection time period)**
To be agreed locally, minimum 100 consecutive patients

10) **Target achieved (yes / no / not applicable)**
Yes / No (with percentages for each category to inform quality improvement)

11) **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.

12) **Timing for re-audit (yes / no / not applicable)**
Periodically. If changes are implemented, re-audit in 6-12 months to assess for improvement.

Audit 23

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

4) **Type of audit – clinical audit, BSSD related, reporting / staff focussed**

5) **Target / compliance percentage to be achieved**
For local agreement in line with published literature

6) **Item or variable to be audited**
Number of collimation marks evident on each pre-processed radiograph

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

8) **Data or information to be collected**
Number of collimation marks evident on each pre-processed radiographs. Types of radiographic examinations. Potential barriers to appropriate collimation (patient size/pathology etc). Optional additional measurement of excess field size.

9) **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)

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

11) **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

12) **Timing for re-audit (yes / no / not applicable)**
Repeated periodically, with more frequent audits appropriate when compliance levels are low

Audit 24

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

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

4) **Type of audit – clinical audit, clinical practice and BSSD related, reporting**

5) **Target / compliance percentage to be achieved**
100%

6) **Item or variable to be audited**
Percentage of projection radiographs which have a visible side marker.

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

8) **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.

9) **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.

10) **Target achieved (yes / no / not applicable)**
Yes/No

11) **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.

12) **Timing for re-audit (yes / no / not applicable)**
Repeated periodically, with more frequent audits appropriate when compliance levels are low

Audit 25

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) **Type of audit – clinical audit, BSSD related, reporting / workflow**

5) **Target / compliance percentage to be achieved**
For local agreement in line with published literature/national guidance

6) **Item or variable to be audited**
Image rejection rate for projection radiography examinations of differing types. Also, to include reason for rejection

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

8) **Data or information to be collected**
Number and type of images rejected, documented reasons for rejection

9) **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.

10) **Target achieved (yes / no / not applicable)**
Compliance with local/national/published standards for the technology (film-screen, CR, DR)

11) **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

12) **Timing for re-audit (yes / no / not applicable)**
Repeated periodically, with more frequent audits appropriate when compliance levels are low

Audit 26

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.

3) **Source of standard (or reference document)**
https://www.aapm.org/pubs/CTProtocols/
https://www.imagewisely.org/Imaging-Modalities/Computed-Tomography/Protocol-Design

4) **Type of audit – clinical, BSSD related, reporting, workflow**

5) **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

6) **Item or variable to be audited**
Number and content of technical protocols available

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

8) **Data or information to be collected**
Number and content of technical protocols available

9) **Sample details (categories, number of patients, collection time period)**
Collect technical protocols available for the last year

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

11) **Actions to be taken if the target is not met.**
Refer to available technical protocols to start developing the own protocols.

12) **Timing for re-audit (yes / no / not applicable)**
One year

Audit 27

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 they 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 entitled: "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) **Type of audit – clinical, BSSD related, patient focussed**

5) **Target / compliance percentage to be achieved**
100%

6) **Item or variable to be audited**
How, when and which dosimetric information is transmitted to the patient

7) **Method: Retrospective / Prospective / Other**
Retrospective or Prospective

8) **Data or information to be collected**
Document with the information transmitted

9) **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

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

11) **Actions to be taken if the target is not met**
Define a way on how to transmit the dosimetric information to your patient

12) **Timing for re-audit (yes / no / not applicable)**
One year

Audit 28

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.

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

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) **Type of audit – clinical, BSSD related, patient focussed**

5) **Target / compliance percentage to be achieved**
100%

6) **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.

7) **Method: Retrospective / Prospective / Other**
Retrospective or Prospective

8) **Data or information to be collected**
Patient skin dose after interventional procedures, criteria for patient follow-up

9) **Sample details (categories, number of patients, collection time period)**
For one year of treated patients

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

11) **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.

12) **Timing for re-audit (yes / no / not applicable)**
One year

Audit 29

1) **Audit Title**
Key points on how to manage patient radiation protection

2) **Standard against which the audit topic is to be compared**
The key point is to have the right team with the correct expertise. A team composed of a radiologist, a radiographer and a medical physicist is essential to manage patient radiation protection. Each of them has an essential role with respect patient radiation protection.

3) **Source of standard (or reference document**
IAEA web page: http://www.iaea.org/resources/rpop/health-professionals/radiology/responsibilities-of-health-professionals

4) **Type of audit – clinical audit / service evaluation, BSSD related**

5) **Target / compliance percentage to be achieved**
100%

6) **Item or variable to be audited**
At least one representative of each profession (radiologist, radiographer, medical physicist) should be involved in radiation protection

7) **Method: Retrospective / Prospective / Other**
Retrospective or Prospective

8) **Data or information to be collected**
Number of responsible concerning patient radiation protection and from which profession and number and type of procedures performed within one year.

9) **Sample details (categories, number of patients, collection time period)**
Collect information about the number of procedures per year and staff implicated in radiation protection

10) **Target achieved (yes / no / not applicable)**
Yes

11) **Actions to be taken if the target is not met**
Report to clinical/administrative teams and discuss the importance of having appropriate core team members

12) **Timing for re-audit (yes / no / not applicable)**
One year (or sooner if key components missing)

The key point is to have the right team with the correct expertise.

Audit 30

1) **Audit Title**
Waiting Time for Outpatient Ultrasound Appointments
(why is this a priority – e. g., increased complaints from patients)

2) **Standard against which the audit topic is to be compared**
National or local accepted best practice, e. g., 30 minutes

3) **Source of standard**
Professional organisation e. g., Royal College of Radiologists (UK) or national professional society

4) **Type of audit – service evaluation, workflow, patient focussed**

5) **Target /compliance percentage to be achieved**
90 % – this can be amended following local discussion and agreement

6) **Item or variable to be audited**
Patient waiting time for outpatient ultrasound

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

8) **Data or information to be collected**
Time of ultrasound examination following patient booking into the department (review patient arrival time vs booked appointment time)

9) **Sample details (number of patients, collection time period)**
For example, 100 consecutive patients, or 1 week data collection period

10) **Target achieved (yes / no / not applicable)**
Y/N

11) **Actions to be taken if the target is not met**
If not met, review reasons for non-compliance

- ★ Insufficient radiologists, sonographers, ultrasound machines
- ★ Machine failure (review age of machines, service contract intervals)
- ★ Inefficient appointment or booking-in system
- ★ Patients late (parking problems, issues receiving appointments)
- ★ Insufficient allocated time for scans
- ★ Large number of urgent patients/inpatients
- ★ Discuss results in multidisciplinary format and implement necessary changes

12) **Timing for re-audit (yes /no /not applicable)**
3 months (for example)

Audit 31

1) **Audit Title**
Does the radiology department record statistics about patient satisfaction?

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

3) **Source of standard**
PO Alderson AJR 2000;175:319-323
CD Johnson Radiographics 2009;29:951-959

4) **Type of audit – service evaluation, patient focussed**

5) **Target /compliance percentage to be achieved**
100%

6) **Item or variable to be audited**
All aspects of the patient experience

7) **Method: Retrospective / prospective / Other**
Retrospective or prospective

8) **Data or information to be collected**
Data around patient satisfaction – using locally/nationally agreed questionnaire, data items

9) **Sample details**
As above – for local agreement, example 50 – 100 consecutive patients

10) **Target achieved**
Yes/No

11) **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

12) **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

○	○	○	○	○	○	○	○	○	○	○
0	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?

○	○	○	○	○	○	○	○	○	○	○
0	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?

0	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?

0	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)?

0	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?

0	1	2	3	4	5	6	7	8	9	10
very unsatisfied										very satisfied

6 b) Were they helpful?

0	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 explanation
- ☐ 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 explanation
- ☐ Yes – to some extent
- ☐ No

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

- ☐ Excellent
- ☐ Good
- ☐ Neutral
- ☐ Poor

APPENDIX 3

Regulatory Audit Topics (Relating to Regulation of Medical Exposures Using Ionising Radiation)

For all the regulatory audit topics in this section the Basic Safety Standards Directive (Council Directive 2013/59/Euratom [1], BSSD) is the quoted source of the standard. For each audit, however, specific reference to local regulatory requirements is required, as derived from the Directive. These regulatory audits can verify compliance with regulations and standards and can provide reassurances to departments and employers – they do not replace the need for inspection.

1) 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) Is there an established mechanism within the department to register and analyse accidental /unintended exposures?
3) Is there a departmental policy for informing patients, or their representative, that they have undergone an accidental exposure?
4) Is there a mechanism for record keeping and retrospective analysis of accidental or unintended medical exposures?
5) Is there a mechanism for referring accidental exposure events to the medical physics expert (MPE) and informing the competent authority of significant events?
6) Does the department utilise criteria, provided by the relevant radiation protection competent authority, for what constitutes an accidental or unintended significant exposure?
7) Is there evidence of appropriate training for individuals (particularly non-radiologists) with responsibility for justification?
8) 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?
9) Is there a written protocol for the identification of who is responsible for the justification process?
10) For radiation exposure related to health screening by invitation on asymptomatic individuals, is there a local policy affirming justification by a competent authority?
11) What percentage of examinations involving ionising radiation are justified in advance of being performed?
12) What mechanism exists on the request form for contacting referrers to permit pre-exposure justification discussions to occur if necessary?
13) Is there a written protocol for who may be responsible for justification of X-ray/fluoroscopic/ interventional ionising radiological procedures?
14) Is there a written protocol for who may be responsible for justification of CT examinations?
15) What mechanism is used to evaluate patient dose in high-dose procedures?
16) What percentage of radiodiagnostic procedures have established diagnostic reference levels (DRL)?
17) Specific technical requirements for equipment in use for medical exposures.
18) Eye lens dose limits for occupational exposure.
19) Initial education and training in radiation protection.
20) Audit of education plus training in radiation protection, doses and side effects.
21) Provision of clinical information to support justification.
22) Staff dosimetry audit – this includes a draft adapted questionnaire.
23) Evaluation of the role and responsibilities of the medical physics expert.

Audit 1

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) **Type of audit – regulatory**

5) **Target / compliance percentage to be achieved**
100 %

6) **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

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

8) **Data or information to be collected**
Confirmation of written risk/benefit pathway in the local rules

9) **Sample details**
N/A

10) **Target achieved**
Yes /no

11) **Action to be taken if the target is not met**
The establishment of a written risk/benefit pathway in the local rules

12) **Timing for re-audit**
One-year review if target met. Repeat audit 3 months if target not met/incomplete

Audit 2

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) **Type of Audit – regulatory**

5) **Target / compliance percentage to be achieved**
100 %

6) **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

7) **Method**
Retrospective / Prospective / Other

8) **Data or information to be collected**
The existence of a department repository for this information
The number of cases/year, case outcomes in terms of registration and root cause analysis

9) **Sample details**
Confirmation of appropriate resource
Retrospective calculation of the number of cases per year
Circumstances of the exposure in each case, analysis of causes, appropriate policy adjustments made

10) **Target achieved**
Yes/no

11) **Actions 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

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

Audit 3

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**
National legislation intended to transpose and implement requirements included within the Council Directive 2013/59/Euratom, Article 63

4) **Type of Audit – regulatory**

5) **Target / compliance percentage to be achieved**
100 %

6) **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

7) **Method**
Retrospective/prospective

8) **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

9) **Sample details**
One year analysis of the above

10) **Target achieved**
Yes/no

11) **Action to be taken if the target is not met**
Implementation of clear pathway in the local rules

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

Audit 4

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) **Type of Audit – regulatory**

5) **Target / compliance percentage to be achieved**
100 % (Such a resource must exist)

6) **Item or variable to be audited**
Formal record of accidental or unintended exposures

7) **Method**
Retrospective/prospective

8) **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

9) **Sample details**
One year review of formal record of accidental or unintended medical exposures

10) **Target achieved**
Yes/no

11) **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

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

Audit 5

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**
National legislation intended to transpose and implement requirements included within the Council Directive 2013/59/Euratom, Article 63

4) **Type of Audit – regulatory**

5) **Target / compliance percentage to be achieved**
100 %

6) **Item or variable to be audited**
Local rules. Identification of an appropriate information pathway

7) **Method**
Retrospective/prospective

8) **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

9) **Sample details**
Review of one-year accidental exposures

10) **Target achieved**
Yes/no

11) **Action to be taken if the target is not met**
Implementation of an appropriate information pathway Review contact details and route of communication with MPE

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

Audit 6

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) **Type of Audit – regulatory**

5) **Target / compliance percentage to be achieved**
100 %

6) **Item or variable to be audited**
Local rules. Criteria defining significant accidental or unintended exposures, as provided by the relevant radiation protection competent authority

7) **Method**
Retrospective/prospectiv

8) **Data or information to be collected**
Criteria defining accidental or unintended exposures of significance date/time/cause/consequences of each exposure

9) **Sample details**
One year review of above

10) **Target achieved**
Yes/no

11) **Action to be taken if the target is not met**
Implementation of such a resource, liaison with radiation protection competent authority for guidance

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

Audit 7

1) **Audit Title**
Is there evidence of appropriate training for individuals (particularly non-radiologists) with responsibility for justification?

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

4) **Type of Audit – regulatory**

5) **Target /compliance percentage to be achieved**
100 % here would be an aspirational standard, a local standard here can be arrived at by prior agreement with all involved parties

6) **Item or variable to be audited**
Local rules: training requirements for delegated non-radiologists; types of procedures suitable for justification

7) **Method**
Retrospective/Prospective/Other

8) **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

9) **Sample details**
One-year review of the above

10) **Target achieved**
Yes/no

11) **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

12) **Timing for re-audit**
One year, or sooner if target not me

Audit 8

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) **Type of Audit – regulatory**

5) **Target / compliance percentage to be achieved**
100 %

6) **Item or variable to be audited**
Request form/Order comms

7) **Method**
Retrospective/Prospective/Other

8) **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

9) **Sample details**
One-month review of request forms/order comms

10) **Target achieved**
Yes/no

11) **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

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

Audit 9

1) **Audit Title**
Is there a 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

4) **Type of Audit – regulatory**

5) **Target / compliance percentage to be achieved**
100 %

6) **Item or variable to be audited**
Request form/order comms

7) **Method**
Retrospective/Prospective/Other

8) **Data or information to be collected**
Confirmation of appropriate place on the request form for justification by practitioner. Confirmation that this has been completed by appropriate person, signed, dated

9) **Sample details**
One-month request form/order comms

10) **Target achieved**
Yes/no

11) **Action to be taken if the target is not met**
Redesign of the request form/order comms, education relevant staff
Ensure that the justification practitioner has authorised the procedure
Confirm those practitioners authorised to justify specific procedure

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

Audit 10

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) **Type of Audit – regulatory**

5) **Target / compliance percentage to be achieved**
100 %

6) **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

7) **Method**
Retrospective/Prospective/Other

8) **Data or information to be collected**
Policy on health screening or individual justification by a competent authority (see above)
Relevant criteria
Patient numbers

9) **Sample details**
Three-month review of above

10) **Target achieved**
Yes/no

11) **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

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

Audit 11

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) **Type of Audit – regulatory**

5) **Target / compliance percentage to be achieved**
100 %

6) **Item or variable to be audited**
Request forms/order comms: justification practitioner identification

7) **Method**
Retrospective/prospective

8) **Data or information to be collected**
Request forms/order comms: Justification practitioner identification Percentage correctly completed and verified

9) **Sample details**
One-month review of the above

10) **Target achieved**
Yes/no

11) **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

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

Audit 12

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) **Type of Audit – regulatory**

5) **Target / compliance percentage to be achieved**
100 %

6) **Item or variable to be audited**
Request form/order comms Relevant communication data pathway documented clearly

7) **Method**
Retrospective/Prospective/Other

8) **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

9) **Sample details**
One-month review of the above

10) **Target achieved**
Yes/no

11) **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

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

Audit 13

1) **Audit Title**
Is there a written protocol for who may be responsible for justification of X-ray/fluoroscopic /ionising interventional radiological 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) **Type of Audit – regulatory**

5) **Target / compliance percentage to be achieved**
100 %

6) **Item or variable to be audited**
Local rules: written protocol for delegated responsibility for the justification of fluoroscopic/ionising interventional radiological procedures

7) **Method**
Retrospective/Prospective/Other

8) **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

9) **Sample details**
One month as above

10) **Target achieved**
Yes/no

11) **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

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

Audit 14

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) **Type of Audit – regulatory**

5) **Target / compliance percentage to be achieved**
100 %

6) **Item or variable to be audited**
Local rules: written protocol for identification of those with responsibility for the justification of CT studies

7) **Method**
prospective/retrospective

8) **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

9) **Sample details**
One month as above

10) **Target achieved**
Yes/no

11) **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

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

Audit 15

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) **Type of Audit – regulatory**

5) **Target / compliance percentage to be achieved**
100 %

6) **Item or variable to be audited**
Calibrated, approved dose calculation systems in all high dose equipment

7) **Method**
Retrospective/prospective

8) **Data or information to be collected**
Dose calculation and recording systems in CT/IR/NM systems
Patient exposure results in each of these

9) **Sample details**
One-month review of above

10) **Target achieved**
Yes/no

11) **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

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

Audit 16

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) **Type of Audit – regulatory**

5) **Target / compliance percentage to be achieved**
100 %

6) **Item or variable to be audited**
Establishment and regular review of DRLs for all radiodiagnostic examinations

7) **Method**
Retrospective/prospective

8) **Data or information to be collected**
Exposure levels for all radiodiagnostic procedures compared to DRLs
Percentage in each category above the DRL

9) **Sample details**
One-month review of above

10) **Target achieved**
Yes/no

11) **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

12) **Timing for re-audit**
Rolling audit programme, frequency to be agreed locally and with medical physics expert

Audit 17

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) **Type of audit - regulatory**

5) **Target / compliance percentage to be achieve**
100 % – mandatory and subject to inspection

6) **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

7) **Method**
Retrospective/Prospective/Other
Assessment of all existing/prospective equipment

8) **Data or information to be collected**
See above

9) **Sample details (number of patients, collection time period)**
See above

10) **Target achieved (yes / no / not applicable)**
Y/N

11) **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

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

Audit 18

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

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 22

Audit 19

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) **Type of audit - regulatory**

5) **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.

6) **Item or variable to be audited**
Local and national protocol and documentation on relevant initial theory and training in radiation protection

7) **Method**
Retrospective/prospective

8) **Data or information to be collected**
Data from staff records and/or national curricula

9) **Sample details**
List of all relevant staff with records on education and year of examination

10) **Target achieved**
Yes/No

11) **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

12) **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 20

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**
National legislation intended to transpose and implement requirements included within the Council Directive 2013/59/Euratom. Local/national agreed process, Article 18

4) **Type of audit – regulatory**

5) **Target / compliance percentage to be achieved**
100 % (compulsory)

6) **Item or variable to be audited**
Participation, education in local and/or national program, program of assessment/compliance as appropriate

7) **Method**
Retrospective/Prospective/Other. Inspection of the education tool
Levels of compliance/assessment amongst staff

8) **Data or information to be collected**
Existence of an education programme, contents, review

9) **Sample details**
All staff involved in radiation protection

10) **Target achieved**
Yes/No

11) **Actions to be taken if the target is not met**
Establish, review local/national training programme

12) **Timing for re-audit**
(yes / no / not applicable) In one year

Audit 21

1) **Audit Title**
Provision of clinical information to support justification

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) **Type of audit – regulatory**

5) **Target / compliance percentage to be achieved**
100 % (compulsory)

6) **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)

7) **Method**
Retrospective or prospective

8) **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)

9) **Sample details (number of patients, collection time period)**
100 request forms

10) **Target achieved**
Yes/No

11) **Actions to be taken if the target is not met**
Education for referrers

12) **Timing for re-audit**
(yes / no / not applicable)
One year, or sooner if target not met

Audit 22

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 on the basis of working conditions and medical surveillance. The distinction shall also take into account potential exposures.

Targets are to be locally derived and agreed as directed by the Council Directive.

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	
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		
Medical follow up of exposed workers	☐ Yes ☐ No ☐ Partially	

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 23

Evaluation of the role and responsibilities of the medical physics expert

Definitions (Council Directive 2013/59/Euratom, December 2013/BSSD)

- "medical physics expert" means an 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 recognised by the competent authority;

This template itemises the expected roles and responsibilities of the medical physics expert and can be used to develop a dedicated audit questionnaire, targets to be locally derived and agreed.

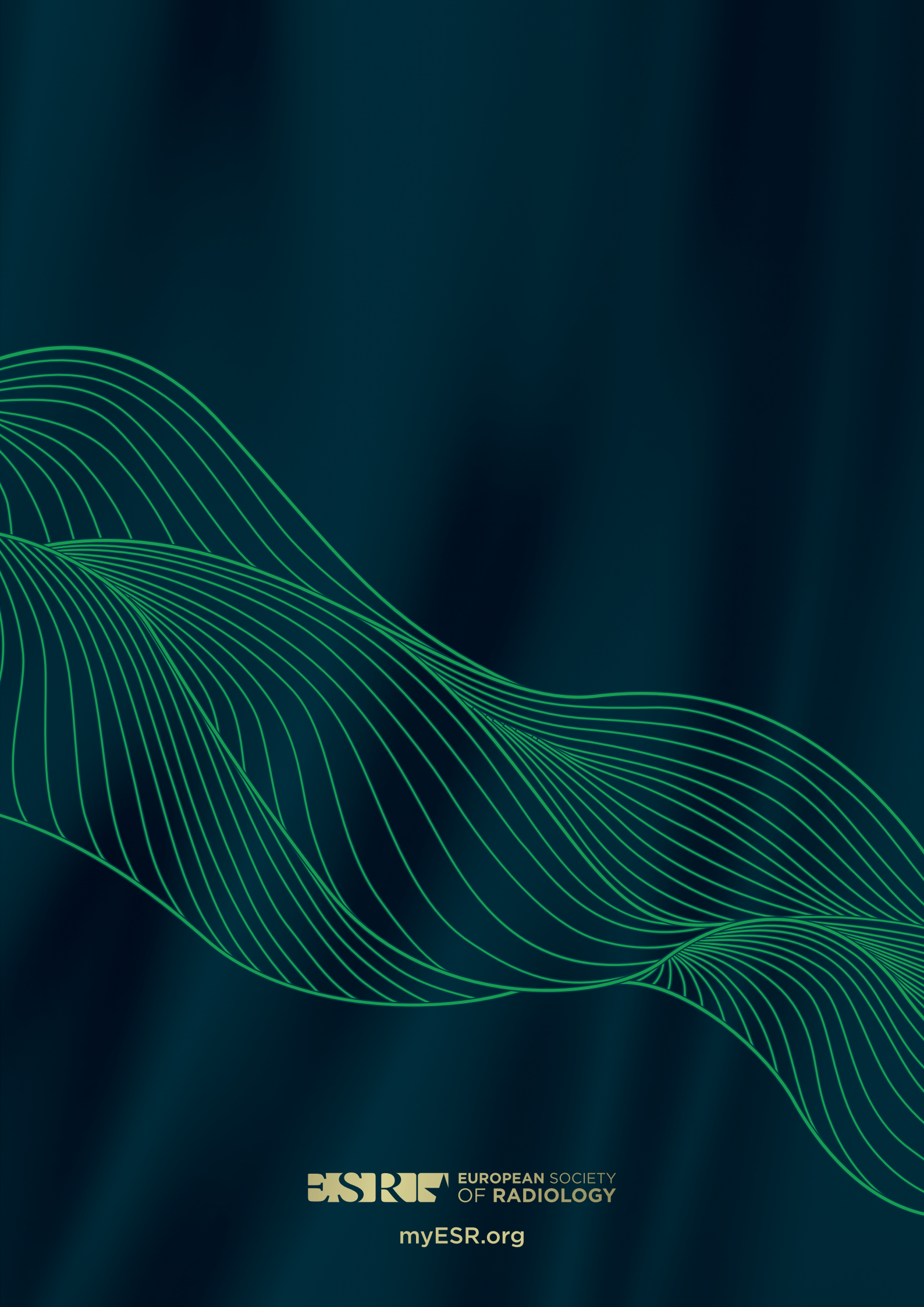
Medical physics expert tasks

The medical physics expert:

- takes responsibility for dosimetry, including physical measurements for evaluation of the dose delivered to the patient and other individuals subject to medical exposure
- optimises the radiation protection of patients and other individuals subject to medical exposure, including the application and use of diagnostic reference levels;
- Concerning medical radiological equipment
  - gives advice;
  - defines and performs quality assurance;
  - performs acceptance testing;
  - prepares technical specifications and installation design;
  - performs surveillance;
  - analyses the events involving, or potentially involving, accidental or unintended medical exposures;
  - is involved in the selection of equipment required to perform radiation protection measurements;
- performs training of practitioners and other staff in relevant aspects of radiation protection
- shall be involved:
  - in radiotherapeutic procedures other than standardised therapeutic nuclear medicine procedures;
  - in standardised therapeutical nuclear medicine procedures as well as in radiodiagnostic and interventional radiology procedures, involving high doses;
  - for other medical radiological procedures for consultation and advice on matters relating to radiation protection concerning medical exposure;
  - in the development of new clinical protocols or research;
- shall liaise with the radiation protection expert

Notes

Notes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