Esperanto

ESR Guide to Clinical Audit in Radiology and the ESR Clinical Audit Tool

EUROPEAN SOCIETY OF RADIOLOGY

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Contents

1) Esperanto – Purpose and Scope

This second 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.

There is a strong emphasis in Esperanto on compulsory and legally required audit (regulatory) relating to the regulation of medical exposures involving ionising radiation. The document also covers (non-regulatory) clinical audit processes involved in service provision and clinical practice. A series of example audit templates is included to facilitate local departmental participation in audit.

This clinical audit guide also discusses how audit activity may occur within a radiology department-namely, internal audit at the departmental level (a key focus of the guide), external audit (which may be co-ordinated across many departments, possibly by a national society for example) or 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 in those departments early-on in the process of incorporating clinical audit into everyday working practice, there will be prioritisation given to the compulsory, regulatory radiation protection audits. The importance of participation in non-regulatory clinical audit in improving patient care and outcomes is also recognised and encouraged.

2) 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

3) Clinical Audit – the ESR and the 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, 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).

After entry into force of the BSSD on 6 February 2014, Member States had four years (i.e. until 6 February 2018) to bring into force the laws, regulations and administrative provisions necessary to comply with this 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 danger 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 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].

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:

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

4) <u>What is Clinical Audit</u>

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.

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.

5) Clinical Audit – Importance and Scope

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

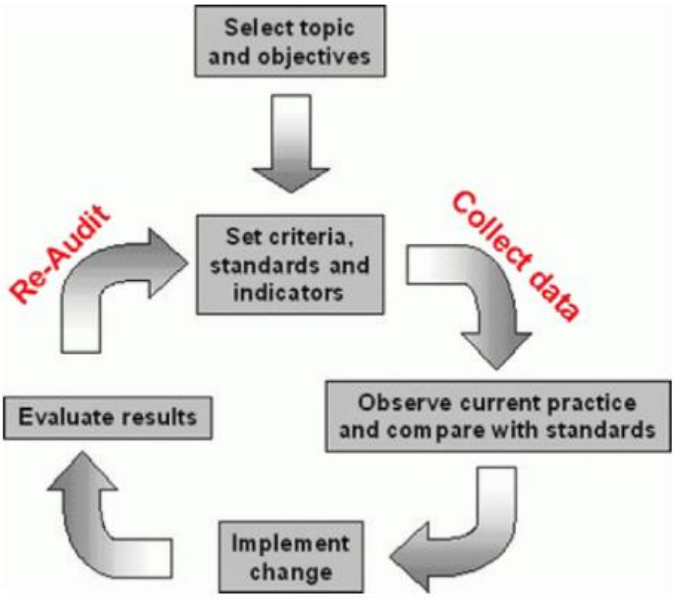
- Promotes and facilitates high quality medical care
- Provides educational, teaching and interdisciplinary collaborative opportunities
- Can be used to drive improvements in quality of care
- Allows departments to demonstrate a commitment to patient/staff safety and compliance, according to the requirements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

6) 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.

7) Clinical Audit vs Research

Clinical audit, like research projects, should be undertaken 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 regulatory or non-regulatory (relating to service provision/clinical practice), is based around compliance with targets/standards. In regulatory audit standards are fixed and mandatory [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

8) 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 audit templates are included in appendix 2 (regulatory, relating to regulation of medical exposures using ionising radiation) and appendix 3 (non-regulatory, relating to service provision and clinical practice).

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 contained in appendices 2 and 3.

Steps within the audit cycle

i) 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

ii) Identify Resources

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

iii) 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)

iv) Confirm Item/Variable(s) to be Audited

v) Data Collection

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

vi) 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

vii) Analyse Data

- Compare actual performance with the set standard
- Review if standard(s) (target) met

- Document reasons, possibilities for failure to meet a standard

viii) 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

9) Clinical Audit: Internal Departmental vs. External and the Relationship to 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, regulatory 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 clinical 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). Inspection is a requirement of the BSSD. Evidence of such audit activity is likely to be looked upon favourably by inspectors, but will not replace the absolute requirement for inspection.

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. An alternative approach is internal audit with external direction – from 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.

10) 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 also health 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 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 – a series of suggested regulatory audit topics, initially developed via a piloting project amongst several EuroSafe Imaging Star radiology departments.
- Appendix 3 – a series of clinical audit topics (relating to service provision and clinical practice).

The regulatory audit templates in Appendix 2 are audit topics defined by the BSSD; these are compulsory (targets 100%) and should be the priority, especially for departments just beginning to undertake clinical audit.

A selection of clinical audit topics (service provision/clinical practice) is included in Appendix 3. These give examples of clinical areas which would be suitable for audit. There is a free and open-access, extensive resource of audit templates covering many clinical topics available via the Royal College of Radiologists, London, UK – Auditlive [5]. 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 often the standards/targets for an audit may not be met. This is to be expected in many cases. What is important is 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 reinforce 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.

11) Summary

Engagement with clinical audit is an indicator of good clinical practice and is now a requirement under 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.

12) References

[1] Council Directive 2013/59/Euratom on basic safety standards for protection against the dangers arising from exposure to ionising radiation and repealing directives 89/618/Euratom, 90/641/Euratom, 96/29/Euratom, 97/43 Euratom and 2003/122/Euratom. 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] Auditlive. Royal College of Radiologists, London, UK. [https://www.rcr.ac.uk/clinical-radiology/audit-and-qi/auditlive]

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)

1. Audit Title

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

3. Source of standard (or reference document)

4. Type of audit – clinical regulatory or clinical non-regulatory

5. Target / compliance percentage to be achieved

6. Item or variable to be audited

7. Method: Retrospective / Prospective / Other

8. Data or information to be collected

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

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

11. Actions to be taken if the target is not met.

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

Appendix 2

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.

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 for appropriate training for individuals with delegated responsibility (in the case of non-radiologists) for the justification process?
8. Is there a departmental mechanism to confirm 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
   European Council Directive

3. Source of standard
   Council Directive 2013/59/Euratom, Article 57

4. Type of audit – Clinical, regulatory
   Compulsory. Legal requirement

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
   European Council Directive

3. Source of standard
   Council Directive 2013/59/Euratom, Article 63

4. Type of Audit – Clinical, regulatory
   Compulsory: legal requirement

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. Action to be taken if the target is not met.
    Creation of appropriate resource, review department policies on recording and analysing accidental or unintended exposures of this nature

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
   European Council Directive

3. Source of standard
   Council Directive 2013/59/Euratom, Article 63

4. Type of Audit – Clinical, regulatory
   Compulsory. Legal requirement

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
   European Council Directive

3. Source of standard
   Council Directive 2013/59/Euratom, Article 63

4. Type of Audit – Clinical, regulatory
   Compulsory. Legal requirement.

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
   European Council Directive

3. Source of standard
   Council Directive 2013/59/Euratom, Article 63

4. Type of Audit – Clinical, regulatory
   Compulsory: legal requirement

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
   Council Directive

3. Source of standard
   Council Directive 2013/59/Euratom, Article 63

4. Type of Audit – Clinical, regulatory
   Compulsory. Legal requirement

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/prospective

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 for appropriate training for individuals with delegated responsibility (in the case of non-radiologists), for the justification process?

2. Standard against which the audit topic is to be compared
   Council Directive

3. Source of standard
   Council Directive 2013/59/Euratom, Article 57

4. Type of Audit – Clinical, regulatory
   Compulsory. Legal requirement

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 and document the non-pregnancy status of individuals undergoing medical exposures?

2. Standard against which the audit topic is to be compared
   Council Directive

3. Source of standard
   Council Directive 2013/59/Euratom, Article 62

4. Type of Audit – Clinical, regulatory
   Compulsory: legal requirement

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
   Council directive

3. Source of standard
   Council Directive 2013/59/ Euratom, Article 57

4. Type of Audit – Clinical, regulatory
   Compulsory: legal requirement

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
   Council Directive

3. Source of standard
   Council Directive 2013/59/Euratom, Article 55.2.h

4. Type of Audit – Clinical, regulatory
   Compulsory. Legal requirement

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
   European Council Directive

3. Source of standard
   Council Directive 2013/59/Euratom, Article 55

4. Type of Audit – Clinical, regulatory
   Compulsory. Legal requirement

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
   European Council Directive

3. Source of standard
   Council Directive 2013/59/Euratom, Article 55

4. Type of Audit – Clinical, regulatory
   Compulsory: legal requirement

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
   European Council Directive

3. Source of standard
   Council Directive 2013/59/Euratom, Article 57

4. Type of Audit – Clinical, regulatory
   Compulsory

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
   European Council Directive

3. Source of standard
   Council Directive 2013/59/Euratom, Article 57

4. Type of Audit – Clinical, regulatory
   Compulsory, legal requirement

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
   European Council Directive

3. Source of standard
   Council Directive 2013/59/Euratom, Article 60

4. Type of Audit – Clinical, regulatory
   Compulsory. Legal requirement

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
   Council Directive

   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
   Council Directive 2013/59/Euratom, Article 56

4. Type of Audit – Clinical, regulatory
   Compulsory. Legal requirement

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
   Council Directive

   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
   European directive 2013/59/Euratom, Article 60

4. Type of audit
   Clinical regulatory

5. Target / compliance percentage to be achieved
   100% - mandatory and subject to inspection

6. Item or variable to be audited
   A number of potential audit variables, including:-
   a) Fluoroscopy equipment without a device to automatically control dose rate, or without an image intensifier, is prohibited
   b) IR equipment should have the facility to inform the practitioner of the quantity of radiation produced during the procedure
   c) IR/CT equipment should have the facility to inform the practitioner at the end of the procedure of relevant parameters for assessing patient dose
   d) 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 or 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
   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 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
   Radiation Protection no. 175, Guidelines on radiation protection education and training of medical professionals in the European Union. Council Directive 2013/59/Euratom, Article 18

4. Type of audit
   Regulatory audit

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 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 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.

3. Source of standard
   Council Directive 2013/59/Euratom. Local/national agreed process.

4. Type of audit – clinical/regulatory
   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

3. Source of standard
   Council Directive 2013/59/Euratom, Article 55

4. Type of audit – clinical/regulatory
   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)*

- "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		
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,…)					
Frequency exchange					

Audit 23

Evaluation of the role and responsibilities of the medical physics expert

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

- "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

APPENDIX 3

Clinical Audit Topics (Relating to Service Provision and Clinical Practice)

This section contains a short list of example topics, which may not relate to radiation protection, although some will clearly have a radiation protection element. This section is likely to expand over time with additional templates added, please note the earlier reference to the Royal College of Radiologists Auditlive and this large, free access, reference site for a wide range of audit templates [5].

1. Does the radiology department record statistics about patient satisfaction?
2. Waiting time for outpatient ultrasound appointments
3. Protocols around radiological procedures, information in reports
4. The practice of “routine” preoperative chest x-ray
5. Audit of inpatient chest x-rays or abdominal x-rays
6. What percentage of non-Ionising imaging studies (MR/Ultrasound) are consistent with the referral guidelines?
7. Pain sensation during image-guided interventions

Audit 1

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. Importance
   High

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

Department of Clinical Radiology

There is a scoring system in place,

0 ⟶ 5 ⟶ 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)

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)

   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)

   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
Privacy	Excellent	Good	Neutral	Poor
Changing facilities	Excellent	Good	Neutral	Poor
Overall impression	Excellent	Good	Neutral	Poor

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

    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

Audit 2

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 society

4. Type of audit
   Clinical, non-regulatory

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 in to 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

Audit 3

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

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 4

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

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 or 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 5

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 /regulatory
   Clinical

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 referral guidelines

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

Audit 6

1. Audit Title
   What percentage of non-ionising imaging studies (MR/ultrasound) are consistent with the referral guidelines

2. Standard against which the audit topic is to be compared
   Clinical referrers should know and use the referral guidelines, with or without a decision support system to avoid inappropriate or incorrect investigation (radiation exposure). The BSSD and the justification process only 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 justified ionising studies

3. Source of standard
   Local /national referral guidelines (e.g. for ultrasound /MRI)

4. Type of audit – clinical(regulatory)
   (Regulatory) clinical practice, non-ionising

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 (justified)

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 7

Pain sensation during image-guided interventions

This document provides suggestions and outline guidance for an audit/QI project and can be used with additional/local guidance to develop a formal template with locally agreed targets and solutions.

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.

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.)

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?