



HERCA Position Paper Clinical Audit in medical Radiological practices

October 2019

Title: **Clinical audit in medical radiological practices**

Subtitle: Clinical audit in diagnostic radiology, image-guided interventional procedures, nuclear medicine and radiotherapy

Summary: Clinical audit is an important tool for the delivery of high quality healthcare. Recognising this, the EC Basic Safety Standards Directive (BSSD) 2013/59/Euratom (1) includes a requirement that Member States shall ensure that clinical audits are carried out in accordance with national procedures. This is consistent with a similar requirement in the EC Medical Exposure Directive 97/43/Euratom (2). The concept of clinical audit within the area of medical exposure is not new.

HERCA became aware of some lack of understanding within the radiological community on how regulatory requirements for clinical audit should be met. Results from a coordinated inspection week on justification in radiological medical imaging facilities (HERCA European Action Week) performed in November 2016 revealed that the concept of clinical audit is not fully understood and rarely performed within medical imaging. Review of national regulatory frameworks among the participating countries also indicated that clinical audits were not fully implemented at a national level (3).

This document is intended to address requirements for and differences between clinical audit and inspection, as specified in Articles 58 and 104 respectively, of the current BSSD 2013/59/Euratom, and to express the views and expectations of the regulator regarding clinical audit.

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HERCA Position Paper

Clinical Audit in medical radiological practices

Key Messages

1. BSSD Article 58(e) requires that national procedures are put in place by Member States to ensure clinical audit is carried out.
2. National legislations and regulations that transpose the BSSD require clinical audit to be carried out, in relation to medical radiological practice.
3. Clinical audits and inspections differ on several points. Clinical audits are carried out by a peer review system to review practices against agreed standards. Inspections are carried out by the competent authorities for radiation protection to verify compliance with national legal requirements.
4. Clinical audits are not meant to replace inspections as a means of demonstrating regulatory compliance. HERCA is of the opinion that the two processes, clinical audit and inspection, are complementary.
5. HERCA is of the opinion that whatever form of clinical audit is in place, its primary role is to ensure improvements in the quality and outcome of patient care in the process of justification and optimisation of radiation protection. When conducted on a national scale, clinical audit may also provide a mechanism for transfer of best practice between institutions, as well as the setting of higher and more appropriate standards.
6. Clinical audit demonstrates the importance of teamwork and multidisciplinary cooperation in order to achieve improvements in healthcare.
7. HERCA is of the opinion that for clinical audit to be implemented financial and human resources need to be made available and particularly education and training of auditors needs to be put in place.
8. The establishment of a national auditing organisation that will coordinate and develop clinical audit could be a good solution for clinical audit implementation.
9. HERCA is of the opinion that it is the responsibility of those who carry out clinical audit, whether internal staff or external audit organisations, to bring non-compliance with radiation protection principles and specific regulatory requirements to the attention of the audited organisation/undertaking. It is the undertaking's responsibility to carry out corrective measures. In extreme cases, where there is clear breach of regulation, the results of clinical audits should form part of any report that the undertaking makes to the competent authority.

Clinical audit in diagnostic radiology, image-guided interventional procedures, nuclear medicine and radiotherapy

1. Introduction and background

Clinical audit is a quality improvement process central to patient care. Its key features are systematic review of care against agreed standards, seeing that the standards are met and if necessary the subsequent identification of an approach to make improvements. Clinical audit has long been applied in different areas of healthcare. In general, it is usually introduced as a requirement of Health Ministries and their local equivalents and professional bodies through the establishment of quality systems.

While clinical audit may have been recognised as a useful tool in some areas of healthcare, it was not largely implemented until the late 1980s and 1990s. In the UK, a 1989 White Paper entitled "**Working for patients**" defined clinical audit as a review of the delivery of healthcare to ensure that best practice is being carried out and introduced it as part of professional practice (4). Medical consultants in England are now required to conduct clinical audit as part of their contract.

In 1996, the UK's Royal College of Radiologists (RCR) published its "Clinical Audit in Radiology. 100+ Recipes" edited by de Lacey, Godwin and Manhire. This provided a practical resource which explained audit and choosing audits. In 2000, the same authors published "Clinical Governance and Revalidation A Practical Guide" relating to evidence of quality of care in radiology. Updating of these documents was undertaken in the following years, resulting in the current free online resource "Auditlive" (5). This provides a fully searchable menu of topics for clinical audit, providing assistance, templates and data collection tools for local use. It promotes regional and national audits and has a multi-columns approach.

The development of clinical audits in Finland has given rise to two international meetings organised in Finland, and Finland's leading role in a European Commission project for preparing guidance on clinical audit (6) (7).

Clinical audit was introduced specifically for medical radiological procedures through the EC Medical Exposure Directive 97/43/Euratom and more recently through the EC Basic Safety Standards Directive (BSSD) 2013/59/Euratom.

During 2017 and 2018, HERCA's Working Group on Medical Applications (HERCA WGMA) met with representatives of three major European professional societies (ESR, EANM and ES- TRO) to discuss their activities regarding clinical audit and their understanding of the differences between audit and inspection. This document is intended to address requirements for and differences between clinical audit and inspection, as specified in Articles 58 and 104 respectively, of the current BSSD 2013/59/Euratom, and to express the views and expectations of the regulator regarding clinical audit.

2. Definitions of clinical audit and the clinical audit cycle

There are many definitions and representations of clinical audit and the clinical audit cycle. However there are common elements in all of these. In 1997, the UK's National Institute for Health and Clinical Excellence (NICE) published the paper "Principles for best practice in clinical audit" (8) and defined clinical audit as

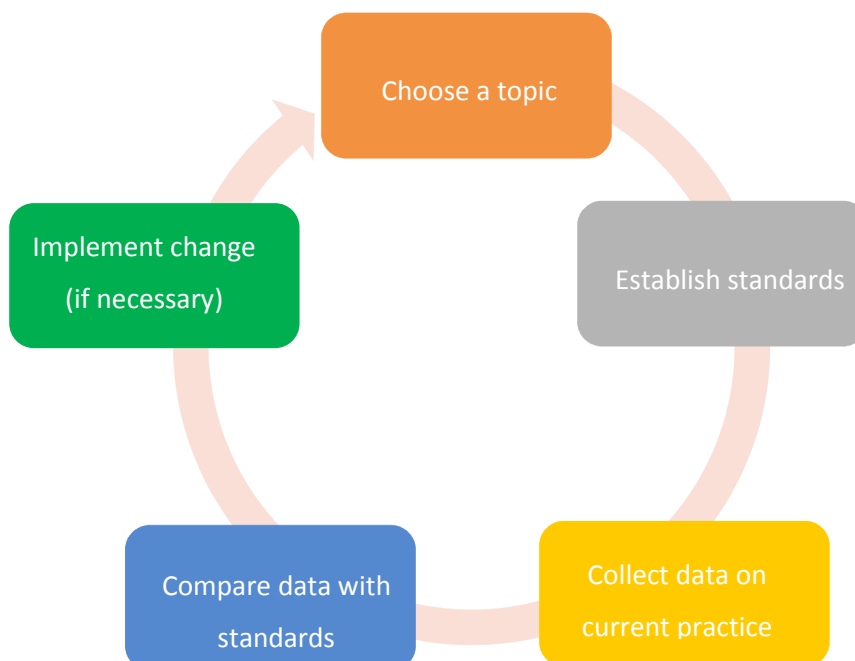
"a quality improvement process that seeks to improve patient care and outcomes through systematic review of care against explicit criteria and the implementation of change. Aspects of the structure, process and outcomes of care are selected and systematically evaluated against explicit criteria. Where indicated, changes are implemented at an individual, team, or service level and further monitoring is used to confirm improvement in healthcare delivery"

Clinical audit is often described in terms of a cycle or spiral. The key components of the clinical audit cycle or spiral are the following:

1. Selection of a practice to be audited
2. Establishment of criteria and standards of best practice
3. Observation and comparison of the practice under consideration against these criteria and standards
4. Implementation of changes where necessary so that these criteria and standards are met or improved
5. Further monitoring to demonstrate that the standard of best practice is maintained.

Subsequent cycles are intended to improve quality, where higher standards or new criteria have been established.

A diagram such as the one below is often used to represent the audit cycle:



3. Clinical audit relating to Euratom

Introduction of requirements for clinical audit in 97/43/Euratom

The importance of clinical audit within healthcare was recognised by Member States and the European Commission during negotiation of the Medical Exposure Directive 97/43/Euratom. Medical exposures using ionising radiation are an integral part of healthcare and clinical audit was identified as a method of ensuring the health protection of individuals against the dangers of ionising radiation in relation to medical exposures. The Directive of 1997 replaced a previous Directive (84/466/Euratom) and introduced clinical audit for the first time, including it within the article relating to procedures.

The Directive defined clinical audit as

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

The definition is consistent in its approach with other definitions of clinical audit, but recognises the context of the Directive and is therefore specific to medical radiological procedures. In addition, the definition makes no reference to the methodology of the review. However some definitions of audit, include a requirement for external review or oversight.

The Directive includes requirements for clinical audit under Article 6, relating to Procedures, and states

“clinical audits shall be carried out in accordance with national procedures”

This requirement recognises that clinical audit extends far beyond medical radiological procedures and does not seek to influence unduly any national procedures already in place. The requirement is not prescriptive in itself, but its inclusion in the Directive, which should be transposed through a legal framework, implies that Member States should include some requirement for clinical audit in their legislation and regulations relating to radiation protection.

The Medical Exposure Directive pre-dates HERCA's inception and HERCA did not prioritise approaches to clinical audit within its early work programme. HERCA was however aware of some lack of understanding within the radiological community on how regulatory requirements for clinical audit should be met.

European guidelines on clinical audit for medical radiological practice (RP No.159)

Recognition of this lack of understanding was not restricted to HERCA. In 2006, the European Commission's Working party of Medical Exposure under the Article 31 Group of Experts advised that European guidance should be developed on implementation of clinical audit of medical radiological procedures. In 2009, the Article 31 group of Experts endorsed work undertaken by the Radiation and Nuclear Safety Authority (STUK) of Finland and others.

This was published as **European Commission report No RP 159 – European Commission guidelines on clinical audit for medical radiological practices (diagnostic radiology, nuclear medicine and radiotherapy)** (7).

The report described basic principles and prerequisites and the interrelation of clinical audit with other audit systems and regulatory control as well as providing practical guidance on implementation. It also considers the value of internal and external audits, the latter carried out by an external auditing body. Usefully, it acknowledges that clinical audit does not replace regulatory activity.

Requirements for clinical audit in the EC Basic Safety Standards Directive (BSSD) 2013/59/Euratom

Article 58(e), relating to Procedures, of the BSSD repeats previous requirements for clinical audit, making clear that Member States shall ensure the requirements are met. The definition of clinical audit is largely unchanged from 1997, with only “where appropriate” replacing “where indicated” in relation to the modification of practices.

While there is little change in the text, the importance of clinical audit as a tool for the improvement of the quality of healthcare, including safety, is now far better understood across Europe and its increased prominence is recognised and welcomed by Professional Bodies and HERCA alike.

HERCA organized a European Action Week with the scope of performing coordinated inspections of the implementation of the justification principle in radiological medical facilities in Europe in 2016 (3). In total, 17 countries participated and 148 inspections were carried out. A review of the implementation of relevant articles from BSSD was performed as part of this HERCA initiative. This review indicated that only half of the participating countries had fully implemented clinical audit for radiological practices in their national legislation and about one third of the countries had established national procedures for clinical audits. During the inspections it was revealed that the concept of clinical audit was not fully understood and that clinical audits were rarely performed within medical imaging. Considering the fact that there have been requirements for clinical audit since 1997, HERCA saw the need for clarification of the concept of clinical audit and the need to address and discuss approaches on how clinical audit can be implemented at national level with the radiological community and relevant stakeholders.

4. Clinical audit, other audits and inspection of radiological practices

Clinical audit

The definition of clinical audit provided by the BSSD 2013/59/Euratom includes all the important elements: a review of a practice, assessment against agreed standards, modification, evaluation and further monitoring. An essential aspect of clinical audit is the intention to improve the outcome of patient care. This latter aspect may not always be a direct factor in other types of audit.

When undertaking clinical audit, the scope and aims of the clinical audit should be specified in advance. The aims describe the intent and basis for the audit. In general terms, the aim is to facilitate continuous improvement. In addition, the specific objectives for each audit process also need to be defined. These relate to measurable parts of the aims and should take into consideration existing standards and how the aims are to be achieved. In many cases, the expected outcomes of the clinical audit will be discussed in advance of setting the objectives.

Clinical audit should be systematic and on-going. There is a role for both internal clinical audit and external clinical audit. Internal clinical audit is carried out by the organisation on its own initiative or in accordance with directions from an external body. External clinical audit is carried out by an external body.

It is recommended that all audits whether external or internal should be independent and carried out by individuals with a comprehensive understanding of audit technique. Moreover, auditors performing external clinical audits should be independent to the audited organisation in order to evaluate the practice of their peers without any bias. For internal clinical audits this independence can be implemented by nominating auditors from another department of the organisation. Should this not be possible the internal audit can be carried out by auditors from the audited department in the form of a self-assessment.

HERCA recognises that this may provide difficulties for small undertakings that conduct internal clinical audit. Nevertheless, internal audit, when conducted to high standards, can be extremely valuable. This value can be increased if externally coordinated or directed, and the resulting information can generate new standards that are adopted at national level. External clinical audits can be carried out by international, national or regional audit organisations and provide immediately a broader perspective.

Other audits

Audit of aspects of radiological practices and services are not new to radiology, nuclear medicine and radiotherapy services.

Dose audits, of staff and patient dose are conducted regularly in most departments, whether as part of internal assessment or as part of a national programme. These might help to benchmark a particular department's performance against that of others or provide data to help generate information at a national level. Dose audits have contributed to the generation of diagnostic reference levels in radiology and demonstrated consistency of planning approaches and calibrations in radiotherapy.

Healthcare audits have been particularly important in the improvement of aspects of clinical services which are not directly related to clinical outcomes. Audits of waiting times in an institution, or mechanisms of referral for multiple procedures may help to improve an important aspect of a patients' healthcare experience, but may not always have a direct impact on outcome.

Some healthcare activities are directly subject to regulation (such as abortion for instance). Most clinical activities are controlled through administrative means and professional standards. Radiological practices however, because of the BSSD, are controlled through national legislation and regulation.

Regulatory audit is an emerging type of audit that verifies compliance with regulations and standards. This type of audit is almost exclusive to these practices and the requirement for transposition of the BSSD in 2018 has led to significant activity in this area. It is appealing to an undertaking to know whether it complies with national regulations, not only to improve patient safety but also to give confidence that it can satisfy the competent authority during inspections. It should be noted however, that the standards set in such audits will require 100% compliance when the standard to be met is the regulation itself. While regulatory audit is helpful to the employer, it does not replace the need for inspection.

Inspection

The BSSD places clear responsibilities on competent authorities to have inspection systems and programmes and to make available the results of the inspections to relevant institutions, manufacturers and the public. It defines inspection as "an investigation by or on behalf of any competent authority to verify compliance with national legal requirements".

There are significant differences between clinical audit and inspection. Both are required. In general, inspection can be considered as a more absolute process, purely because of the mandatory nature of legislation and regulation and the status of associated processes. An Inspection will result in a “passed” or “failed/measures have to be taken” outcome whereas a clinical audit will result in recommendations and suggestions for improvement. These differences can be demonstrated by considering five factors which relate to both – basis, outcome, organisation, teams undertaking the- se activities, and scope. In each case, there are marked differences between the two processes.

These can be summarised in the table below:

	Inspection	Audit
Basis	Legislation and regulation	Standards and good practices
Outcome	Requirements and enforcement	Recommendations and suggestions
Organization	Competent authority	Undertaking/ peer review systems
Teams	Inspectors and advisors	Professionals
Scope	Constrained	Comprehensive

As representatives of European radiation protection competent authorities, HERCA recognises the value and advantages of all types of audits and considers these as complementary to inspection activities. For example, inspection against regulatory requirements alone cannot bring into place some of the improvements in service that clinical audit can. Clinical audit and other audits have the potential to address matters which extend beyond the regulatory control of radiation protection legislation. The differences highlighted above clarify why inspection is needed, regardless of the level and sophistication of clinical audit. Clinical audit is neither primarily intended to assess regulatory compliance nor carried out by trained inspectors of the competent authority.

5. Expectations of competent authorities regarding clinical audit

The inclusion of clinical audit within the BSSD and subsequently within national legislation and regulation means that inspections undertaken by radiation protection competent authorities must address whether or not clinical audit relating to medical radiological exposures is being carried out in accordance with its definition. At the fundamental level, this seems to be sufficient to satisfy requirements.

HERCA recognises however that clinical audit provides an on-going assessment of clinical practice, in a way that inspection cannot. Clinical audit is, by its nature, a continuous process and can demonstrate whether quality and safety culture are embedded within a service. In contrast, inspection takes place periodically, has a short duration within a restricted time frame and only focuses on legal compliance.

If applied appropriately, clinical audit can provide on-going assessment of compliance with key radiation protection principles such as justification and optimisation. The compliance with regulation on the other

hand is the role of inspection. For example, an inspection of justification would include discussions concerning the process itself and responsibilities, while an audit relating to justification might focus on the impact of a procedure on patients' healthcare management and outcome. Similarly, inspection of optimisation might include verification that QA programmes, protocols and diagnostic reference levels are in place, while an audit might address the impact of reducing exposure factors on resulting diagnostic accuracy and subsequent patient management. In both of these cases, audit can demonstrate effectively that an institution recognises the importance of radiation protection principles within the context of the services it provides.

The primary purpose of radiation protection regulations for medical exposures is to improve safety for patients and others such as carers and comforters, rather than to improve outcomes. There is a growing belief among regulators that clinical audit, when applied in a radiological context and relating to key radiation protection principles can achieve both. When conducted on a national scale, clinical audit may also provide a mechanism for transfer of best practice between institutions, as well as the setting of higher and more appropriate standards.

As already described, clinical audit has promoted inclusivity within clinical services and this is clearly relevant in radiological practices, which are truly multi-disciplinary. Clinical audit can demonstrate cooperation between professional groups, which is a key element of optimisation in particular and is therefore of interest to the regulator.

HERCA emphasizes that successful regulatory activity must recognise the wider context and welcomes alternative mechanisms that contribute to demonstrating safety, such as clinical audit. An undertaking can demonstrate its compliance with regulation directly and indirectly by providing examples of targeted clinical audits.

It is possible that clinical audits could demonstrate non-compliance with radiation protection principles and specific regulatory requirements. HERCA is of the opinion that it is the responsibility of those who carry out clinical audit, whether internal staff or external audit organisations, to bring such occurrences to the attention of the undertaking in order that remedial action can be taken. This can be shared with the competent authority during routine inspections and used as examples of the undertakings willingness to improve radiation safety within the services it provides. In extreme cases, however, where there is clear breach of regulation, the results of such clinical audits should form part of any report that the undertaking makes to the competent authority.

6. Challenges for implementing clinical audit

Clinical audit aims at the continuous improvement of medical practice. However, its implementation can be a challenge for a number of reasons since it requires the execution of many different tasks.

1. For internal clinical audits to take place:
 - a. Education and training of staff in clinical audit is required.
 - b. All healthcare professionals need to understand the principles of clinical audit, and the organisations in which they work must support them in undertaking clinical audit. In this context, communication is essential, which requires time and resources.
 - c. The time dedicated to planning audits has not to be underestimated since it requires the availability of all auditors and the audited organisation. At the end of an audit cycle, time will be again necessary to analyse the audit reports in order to evaluate the situation and prepare the strategy for the next cycle.

Important changes of personnel might be another challenge to overcome. The search of resources and funding for clinical audit is therefore a challenge to overcome since their allocation should last for years (9).

2. For external audits, additional challenges have to be considered:
 - a. Need for well-trained and independent auditors.
 - b. Financing.
 - c. Conflict of interest

The establishment of a national auditing organisation that will coordinate and develop clinical audit could be a good solution for clinical audit implementation. Scientific and professional bodies can play an important role in the development of clinical audits (9). Such a collaboration might slow down the implementation of clinical audits due to the higher work coordination required. However, it allows taking on board the main stakeholders, which might be beneficial in the long term for the communication and the acceptance of clinical audits.

In countries with several national languages, the organisation has to consider this important issue in the planning of the audits, in particular the allocation of clinical auditors with the corresponding linguistic proficiency. In addition, the multiple cultures might induce differences in the medical practice that are influenced by the surrounding countries. This might represent an issue in defining standards.

7. Conclusions

Clinical audit is a requirement of the BSSD 2013/59/Euratom and has to be transposed into national legislation and implemented in the European Union. It is an excellent tool for improving the quality of healthcare and has to be undertaken by the undertaking or a peer review system. It appears however that clinical audit is not fully understood and is rarely performed within medical imaging. There also seems to be confusion as to the differences between clinical audit and inspection. In this position paper HERCA introduces clinical audit and clarifies the differences between clinical audit and inspection. HERCA acknowledges that there are challenges facing the implementation of clinical audit in the medical practice. HERCA considers that there is a real need for education and training of the undertaking in clinical audit as well as the need of education and training of auditors. There is a need for availability of staff and financing for clinical audits and this issue needs to be addressed in order to improve the implementation of clinical audit in the medical practice. HERCA also considers that the establishment of a national auditing organisation that will coordinate and develop clinical audit could be a good solution for clinical audit implementation.

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Appendix

International and European initiatives relating to clinical audit

International initiative:

International Atomic Energy Agency (IAEA)

The international atomic energy agency has developed a mechanism and guidance to provide comprehensive clinical audits, through technical cooperation programmes, to a number of health care units of the IAEA member states. The IAEA has developed three excellent tools for carrying out clinical audits in diagnostic radiology, nuclear medicine and radiotherapy:

1. Comprehensive Clinical Audits of Diagnostic Radiology Practices: A Tool for Quality Improvement

Quality Assurance Audit for Diagnostic Radiology Improvement and Learning (QUAADRIL) IAEA Human Health Series No. 4

QUAADRIL was set up to advise on standards and processes used for comprehensive clinical audits of diagnostic radiology services. To improve quality of such services, it focuses on clinical management and infrastructure, patient related and technical procedures, and education and research.

2. Quality Management Audits in Nuclear Medicine Practices, IAEA Human Health Series No. 33

QUANUM provides independent quality audits through comprehensive reviews of nuclear medicine practices. To improve quality of nuclear medicine practices, it focuses on peer reviews of nuclear medicine practices and management at a nuclear medicine centre.

A quality audit of a programme has two principal components: a review of the policies, procedures and critical data; and a site visit to confirm that equipment and clinical processes are functioning as they should be. The QUANUM methodology gives guidance on the implementation of such audits.

3. Comprehensive Audits of Radiotherapy Practices: A Tool for Quality Improvement. Quality Assurance Team for Radiation Oncology (QUATRO), IAEA 2007

QUATRO provides independent quality audits through comprehensive reviews of radiotherapy practices. It focuses on peer review of and evaluation of the quality of all components of the practice of radiotherapy at a cancer centre, with a view to quality improvement.

QUATRO audits help radiotherapy centres attain the best level of practice possible for their economic circumstances. They assess: the radiotherapy infrastructure; patient and equipment procedures; radiation protection aspects; staffing levels; and professional training programs for the local radiotherapy staff. An audit is carried out by a multidisciplinary team of experts, typically comprising a radiation oncologist, a medical physicist and a radiation therapist.

European initiatives:

European Society of Radiology (ESR)

For many years, the European Society of Radiology (ESR) has explored approaches to clinical audits, recognising it as a powerful tool to improve patient care and outcome. Sessions on clinical audit have been a feature of the annual European Congress of Radiology (ECR) in Vienna. In 2011, the ESR responded to the European Commission guidelines for clinical audit, with a statement that focussed on internal clinical audit, while noting that external clinical audit should be carried out in conjunction with this.

Following the publication of the EC Basic Safety Standards Directive 2013/59/Euratom, the ESR has established specific initiatives regarding clinical audit. These follow the conventional methodology of the audit cycle and ESR has used the achievable, local, practical, inexpensive, non-threatening and easy (ALPINE) guidelines as a test for its activities.

The ESR Audit and Standards Subcommittee's major initiative in this field has been the development of Esperanto – a practical tool which includes audit topics and provides templates indicating specific steps. In 2017, a pilot project involving 17 sites across Europe identified 17 topics for consideration, focussing on radiation protection and patient safety. 5 essential audits were carried out.

In 2018, the ESR conducted surveys of EuroSafe EuroStars centres and National Radiological Societies to gauge current compliance with national radiation protection regulations and the ability to provide support to clinical audit activities (1, 2). In 2019, a revised Esperanto was launched at ECR 2019, following similar principles but providing greater clarity regarding the relationship with research and the relative value of internal and external audit and their relationship with inspection (3). The document remains practical in its approach and includes draft templates, for local adaption and adoption, suggested audit topics and an example of a questionnaire relating to patient satisfaction. The 2019 version includes 24 topics which relate to activities subject to regulation. While recognising that this may not be the long-term focus of clinical audit activities, it provides a baseline around regulatory compliance which in itself relates to patient and staff safety. In addition, 7 further topics, more focussed on clinical service provision and clinical practice, are included also. It is the intention of ESR that this section will grow with time and if collated, results from a number of centres will help to establish new standards in these areas.

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European Association of Nuclear Medicine (EANM)

EANM Statement concerning clinical audits in Nuclear Medicine

For nuclear medicine, the EANM endorses the quality management audit system that has been developed by the IAEA in 2008 (1) which is called QUANUM. Its practical implementation in several countries was described in a series of papers by Dondi et al (2-4).

The results of the audits carried out so far by the IAEA (3, 4) “speak in favour of introducing regular quality audit programs, including both internal and external periodic assessments, to improve adherence to national and international standards of quality, improving the quality of nuclear medicine practice and consequently meeting the requirements of accreditation bodies, regulatory authorities, and patient advocate organizations, therefore”.

Nuclear Medicine being a patient-oriented medical specialty, the scope of the audits should not focus solely on quality control improvement, but on improvement of patient care, experience and outcome. Indeed, clinical audit is a process that has been defined as “a quality improvement process that seeks to improve patient care and outcomes through systematic review of care against explicit criteria and the implementation of change” (2). Hence, the external audits must be performed by a dedicated team that includes NM physicians with background and experience in clinical practice.

EANM supports audit processes by providing access to material and tools useful for the entire auditing process. Every year the EANM publishes technical and clinical guidelines, the latter mainly written in cooperation with clinical societies. Furthermore, in 2018, the EANM released the Nuclear Medicine Clinical Decision Support (<https://www.eanm.org/publications/nuclear-medicine-clinical-decision-support/>) and the European Nuclear Medicine Guide (<https://www.nuclmed-guide.app#!/startscreen>) as publicly and freely available tools for decision making in Nuclear Medicine.

Obviously, the practical implementation of QUANUM in the EANM member states is dependent on the local resources and availabilities, as well as quality audit systems and procedures already in place on regional, national or international level. The EANM recommends a multidisciplinary approach covering medical, clinical, radiopharmaceutical, physical and radiation safety aspects related to the use of unsealed sources in medicine and therefore encourages national authorities not only to involve the national EANM member society of the specific country, but also to consult other stakeholders such as representatives of clinicians, physicists, radiopharmacists and last but not least patient advocacy groups before setting up any country-specific QUANUM process.

The EANM is strongly committed to collaborate with clinical and scientific societies, national and European institutions, including the European Commission and the Heads of the European Radiation Protection Competent Authorities (HERCA) to increase awareness of clinical audit within the nuclear medicine community and for shaping the best conditions for optimal patient care in Europe.

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European Society for Radiotherapy and Oncology (ESTRO)

ESTRO Position on Clinical Audit

Whilst not directly involved in the process of clinical audit, as a professional and scientific society, ESTRO fully supports the concept of clinical audit as a key component in quality management in Radiation Oncology. The ESTRO vision 2030 is Radiation Oncology, Optimal Health for all, together, a vision in which quality and safe treatment is central. Clinical audits; internal, external, single focus or comprehensive, are a key tool in achieving this vision ensuring the highest quality treatment, key to achieving the optimum outcome for patients.

ESTRO fully endorses the International Atomic Energy Agency (IAEA) Quality Assurance Team for Radiation Oncology (QUATRO) the aim of which is "To improve quality of radiotherapy treatment by focussing on peer review and evaluation of the quality of all components of the practice of radiotherapy at a cancer centre, with a view to quality improvement". Many of the QUATRO team members are also active ESTRO members and bring their knowledge and skills to the process.

ESTRO is aligned to the QUATRO audit philosophy in which it is stressed that audits are not a regulatory procedure, but a collaboration between the auditors and the auditees with the view to improving practice. A clinical audit is an appraisal that seeks to improve patient care and outcomes through systematic review of the current care against explicit criteria, and to suggest areas where the quality or safety of the processes could be improved.

Indirectly ESTRO supports clinical audit through education and research into aspects of quality and safety in radiotherapy practice.

- The Health Economics in Radiation Oncology (HERO) "is developing a knowledge base estimating the national cost, need and availability of radiotherapy in Europe in order to empower health professionals with data to advocate for better funding for radiotherapy, better resource planning and ultimately better care for cancer patients." This project has already collected a great deal of data and has involved the radiotherapy National Societies in the project. The 'tool' will be made available to the radiotherapy community ultimately.
- More recently the Global Impact of Radiotherapy in Oncology (GIRO) "is building on the Global Task Force on Radiotherapy for Cancer Control (GTFRCC), HERO and the IAEA knowledge base to provide answers on how to close the gap in radiotherapy access, with the ultimate objective to save one million lives by 2035".

- Through the Radiation Oncology Safety Education and Information System (ROSEIS) ESTRO promotes safer radiotherapy practice through the provision of a reporting and learning and education platform which aims to support advancements in radiation safety through the inclusion of new approaches, to encourage reporting and sharing information on incidents and near incidents with the wider community and to assist members to meet the requirements of the EU Directive 2013/59/EURATOM.
- In conjunction with the European Organisation for the Research and Treatment of Cancer (EORTC) a new initiative has been launched to “put in place a pan-European infrastructure for clinical trials and data sharing. The collaboration will generate robust data to evaluate patterns-of-care and patterns-of-outcome of radiotherapy (outcome Quality Indicators) and provide evidence on its role in the treatment of cancer. ESTRO sits as an observer on the Global Harmonisation for Quality Assurance in Clinical Trials Group.
- ESTRO provides a wide range of education programmes for all radiotherapy professionals aimed to increase knowledge and skills in all aspects of radiotherapy. In this way increasing the quality of care given to patients receiving radiotherapy as part of their treatment. The bi-annual short course Comprehensive Quality Management in Radiotherapy – Quality Assessment and Improvement focusses specifically on Quality with a multidisciplinary faculty.
- Dosimetry audits are independent of clinical audits generally but are a key component of safe practice and evidence is sought as part of the clinical audit procedure of participation in a dosimetry audit. Dosimetry measurement is also carried out as a component of the IAEA QUATRO. A course on Dosimetry audit is therefore currently being developed and is hoped to trial in 2020 and which will be run in collaboration with IAEA.
- The importance of clinical audit is incorporated into the three ESTRO core curricula for Radiation Oncologists, Radiotherapy Medical Physicists and RTTs through publications in the three ESTRO journals, presentations at the annual conference and reflection in many of the short course delivered across Europe and internationally.