NuCline **ESPERANTO** for Nuclear Medicine

Co-funded by the European Union

CLAUD·IT

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Disclaimer

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Table of Contents

1

Introduction

NuCline is a comprehensive guide to clinical audits in nuclear medicine, facilitating their performance with a final goal of supporting best practices and compliance with regulatory frameworks. This document builds upon the foundational principles outlined in "Esperanto Guide to Clinical Audits in Radiology" while tailoring its content to the unique processes and challenges of nuclear medicine. It incorporates key recommendations from Commission Recommendation (EU) 2024/1112 [1] to ensure harmonization with the latest European guidelines.

Clinical audit represents a cornerstone for ensuring high standards of patient care and safety in nuclear medicine. Its processes enable healthcare providers to measure current practices against established benchmarks, fostering improvements in quality and outcomes. Unlike other areas of medical imaging, nuclear medicine involves the use of radiopharmaceuticals for therapy and hybrid imaging modalities such as PET–CT, PET–MR and SPECT–CT. These unique characteristics necessitate specialized audit protocols that address the complexity of diagnostic and therapeutic workflows.

The adoption of clinical audit ensures adherence to both local and international guidelines such as Council Directive 2013/59/Euratom, the Basic Safety Standards Directive (BSSD) [2]. Commission Recommendation (EU) 2024/1112 emphasizes the integration of audits into wider healthcare systems, ensuring harmonization at a national and European level. Clinical audit serves as an essential tool for continuous quality improvement, aligning with broader healthcare objectives like Europe's Beating Cancer Plan [3].

Audits in nuclear medicine not only prioritize patient safety by ensuring minimal radiation exposure but also focus on optimizing resource utilization and improving operational efficiency. This is accomplished through several analytical processes such as evaluation of the quality control systems of imaging and other clinically relevant devices, review of patient exposures, and evaluation of the systems designed for radiopharmaceutical production, paving the way for iterative improvements and excellence in clinical care.

2

Clinical Audit, the EANM and the European Legal Perspective

The European legal framework for clinical audits in nuclear medicine is primarily governed by the BSSD. This directive sets the requirements for radiation protection and safety standards across the European Union (EU) with the aim to protect patients, workers and the public from the dangers of ionizing radiation. Clinical audit is a crucial component of this framework, ensuring that medical radiological practices, including nuclear medicine, adhere to high standards of quality and safety.

The European Association of Nuclear Medicine (EANM) plays a significant role in promoting and supporting clinical audits in nuclear medicine across Europe.

The EANM views clinical audit as an essential tool for continuous quality improvement in nuclear medicine. The EANM believes that systematic reviews of clinical practices help identify areas for enhancement, ensuring that patient care is safe, effective and up to date. Clinical audit is also seen as critical for ensuring compliance with the BSSD. The EANM emphasizes that audits help maintain high standards of radiation protection and patient safety.

EANM Approaches to Clinical Audits

- **Guidelines and standards:** The EANM collaborates with other organizations such as the European Society of Radiology (ESR) and International Atomic Energy Agency (IAEA) to develop guidelines and standards for clinical audit. These guidelines provide a framework for conducting audits effectively and consistently across different countries.
- **Training and education:** The EANM is actively involved in training and educating healthcare professionals on the importance and implementation of clinical audit, organizing training programs to build the necessary skills and knowledge.

EANM Activities Supporting Clinical Audits

- **QuADRANT project:** The EANM was a key partner in the QuADRANT project, which aimed to improve the uptake and implementation of clinical audits in radiology, radiotherapy and nuclear medicine. This project, funded by the European Commission (EC), provided recommendations and best practices for setting up and maintaining national audit systems.
- **CLAUD-IT project:** Another significant initiative is the CLAUD-IT project, which focuses on developing and implementing clinical audit methodologies for radiology and nuclear medicine in EU Member States. As part of the project, the EANM contributes to the creation of resources and tools that facilitate clinical audits. This includes developing templates, checklists and online tools that healthcare facilities can use to conduct thorough and effective audits.

EANM Future Directions

Looking ahead, the EANM aims to continue its efforts in promoting clinical audits through:

a. **Enhanced collaboration:** Strengthening partnerships with other organizations to share best practices and harmonize audit standards across Europe.
b. **Technological integration:** Leveraging advancements in technology to support more efficient and comprehensive clinical audits.
c. **Ongoing education:** Continuing to provide education and training programs to ensure that healthcare professionals are well-equipped to conduct clinical audits.

In conclusion, the European legal perspective on clinical audit in nuclear medicine, as outlined in the BSSD, emphasizes the importance of systematic reviews to ensure high standards of radiation protection and patient care. While challenges remain in the implementation of these audits, ongoing efforts by European organizations and initiatives like the CLAUD-IT project are helping to address these issues and promote continuous quality improvement in nuclear medicine.

3

What is Clinical Audit?

There is ample understanding on a definition of clinical audit and below are several in the context of procedures involving ionizing radiations in health.

1. **BSSD:** The directive defines clinical audit as a systematic analysis of medical radiological procedures aimed at improving the quality and outcome of patient care. This involves examining practices, procedures and results against agreed standards for good medical radiological procedures, with the goal of modifying practices where appropriate and applying new standards as necessary [2].
2. **European Union of Medical Specialists / European Board of Nuclear Medicine:** According to these two organizations, clinical audit is a tool designed to improve the quality of patient care, experience and outcome through formal review of systems against defined standards. The Committee on Accreditation of Nuclear Medicine Departments of the European Board of Nuclear Medicine mandates that any department applying for accreditation must implement a quality management system. One available option is the adoption of a clinical audit process validated by the national society [4].
3. **ESR:** Clinical audit is a tool designed to improve the quality of patient care, experience and outcome through formal review of systems, pathways and outcome of care against defined standards and the implementation of change based on the results [5].
4. **The ALPINE concept:** As introduced in the "Esperanto" guidelines, the ALPINE criteria emphasize that clinical audits should be Achievable, Local, Practical, Inexpensive, Non-threatening, and Easy to implement. This concept ensures that audits remain accessible and effective across diverse healthcare settings [6].

4

Significance of Clinical Audits in Nuclear Medicine

The critical importance of clinical audit in nuclear medicine lies in its capacity to guarantee safety and efficacy, thereby complying with evidence-based guidance and regulations. Given the possible risks related to the use of ionizing radiation and radiopharmaceuticals, audits ensure adherence to BSSD while maintaining diagnostic accuracy and therapeutic effectiveness as defined by specialist guidelines. They provide a structured mechanism to evaluate clinical practices, identify inefficiencies and implement evidence-based changes.

Commission Recommendation (EU) 2024/1112 highlights the role of clinical audit in promoting a culture of no-blame, holistic improvement and shared responsibility. By fostering collaboration among healthcare providers and integrating patient feedback, audits contribute to both immediate and long-term advancements in nuclear medicine practices. These processes align with regulatory requirements and support overarching goals like improved diagnostic and therapeutic care and enhanced patient outcomes.

5

Clinical Audit vs Research

Clinical audit and research share several similarities such as their rigorous approach to methodology, procedures, data analysis and interpretation. However, they also differ significantly. Clinical audits can be conducted in either regulatory or non-regulatory contexts. For regulatory purposes such as supporting the BSSD requirements, clinical audits must adhere to specific targets or standards. These standards are predefined and mandatory, as stipulated in the directive [2]. Conversely, in non-regulatory contexts, clinical audits should align with guidelines and best practices.

CLINICAL AUDIT (non-regulatory)	**RESEARCH**
Measures against a standard/some standards	Aims to examine the validity of a hypothesis
Evaluates if clinical practice or service provision complies with set standards	To determine if an innovation can optimize existing methods
Reviews of localized practices for assessment	Develop findings that are replicable and transferable
Focus on improving service delivery	Aim to generate new knowledge
Enhances existing practices	To establish new practices

6

Undertaking a Clinical Audit

Conducting a clinical audit in nuclear medicine involves several meticulous steps to ensure meaningful outcomes. Each step requires careful planning, execution and follow-up to address identified gaps effectively. A general formulation is represented in Figure 1. Commission Recommendation (EU) 2024/1112 highlights the importance of adequate training for auditors and inclusion of educational resources in curricula for healthcare professionals. This ensures that audit teams are equipped with the necessary expertise to perform effective evaluations and implement meaningful changes.

A clinical audit can be performed in the following order.

1. **Define objectives:** Clearly state the purpose of the audit. Objectives should be specific, measurable, achievable, relevant and time-bound (SMART).
2. **Assign resources:** Identify an audit lead and assemble a multidisciplinary team, including medical physicists, technologists, nurses, nuclear medicine physicians, IT and administrative staff such as quality management officers. Allocate time, tools and support for data collection and analysis.
3. **Set standards:** Reference standards from reference or standardisation bodies, such as the EANM, BSSD, European Medicines Agency (EMA) or International Organization for Standardization (ISO) .
   Standards may vary for diagnostic imaging, therapeutic procedures and quality control of radiopharmaceuticals.
4. **Collect data:** Choose retrospective or prospective data collection based on the audit scope.
5. **Analyse results:** Compare findings against established standards. Identify trends, deviations and potential causes of non-compliance.
6. **Action plan:** Develop a detailed plan to address deficiencies. Assign responsibilities and set deadlines for implementing corrective actions.
7. **Re-audit:** Schedule follow-up audits to assess the effectiveness of implemented changes. Use results to refine processes further and sustain improvements.

Best practices for conducting clinical audits include the following. By adhering to these steps, nuclear medicine departments can effectively use clinical audits to enhance their services, ensuring better outcomes for patients and compliance with regulatory requirements.

- **Engage stakeholders:** Involve all relevant personnel to ensure uptake and comprehensive perspectives.
- **Maintain transparency:** Document every stage of the audit process for accountability.
- **Foster a learning culture:** Frame audits as opportunities for improvement rather than punitive measures.

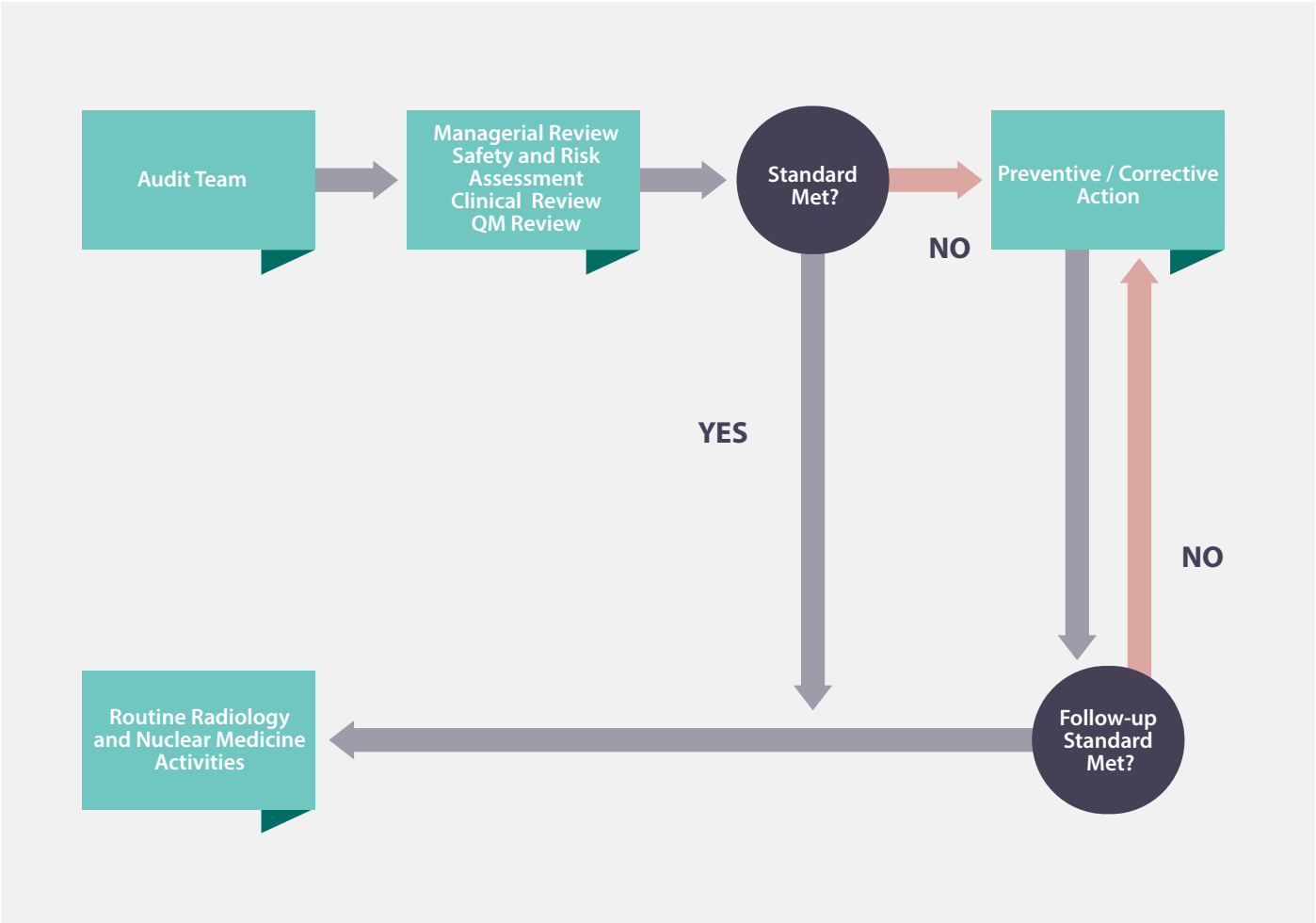

Figure 1 - *Basic structure and processes involved in clinical audits. QM: Quality Management. Adapted from [7].*

7

QuADRANT – A European Initiative with an Emphasis on Clinical Audit

In 2019 the EC released a proposalt for tender, ENER/D3/2019-231-2, entitled "Constant Improvement in Quality and Safety of Radiology, Radiotherapy and Nuclear Medicine through Clinical Audit." The specifications included the key specific objectives below.

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

The EANM participated in the consortium together with the European Society of Radiotherapy and Oncology and ESR, the latter leading the project. This consortium was successful in the tender application, with the acronym QuADRANT [8] (Quality Improvement through Clinical Audit in Diagnostic, including Interventional, Radiology, Radiotherapy and Nuclear Medicine, including Therapies). The project started in January 2020, spanning 30 months in duration and comprising 5 work packages, including two conferences and a pan-European survey to establish current clinical audit status, challenges and barriers. The final project report for the EC will provide a collection of the best practices suitable for wider implementation and guidance and recommendations on improving the implementation and integration of clinical audit into European Member State healthcare systems. QuADRANT is an important piece of work and is likely to be fundamental in providing a European roadmap for enhancing clinical audit uptake across Europe and improving experiences and outcomes for patients.

8

Acknowledgements

The NuCline guide was produced in the context of the CLAUD-IT EU4Health project.

Appendices – Audit Templates and Topics

Clinical audits are hereby defined among the core topics of nuclear medicine, including clinical, quality control for devices, radiopharmacy and regulatory topics.

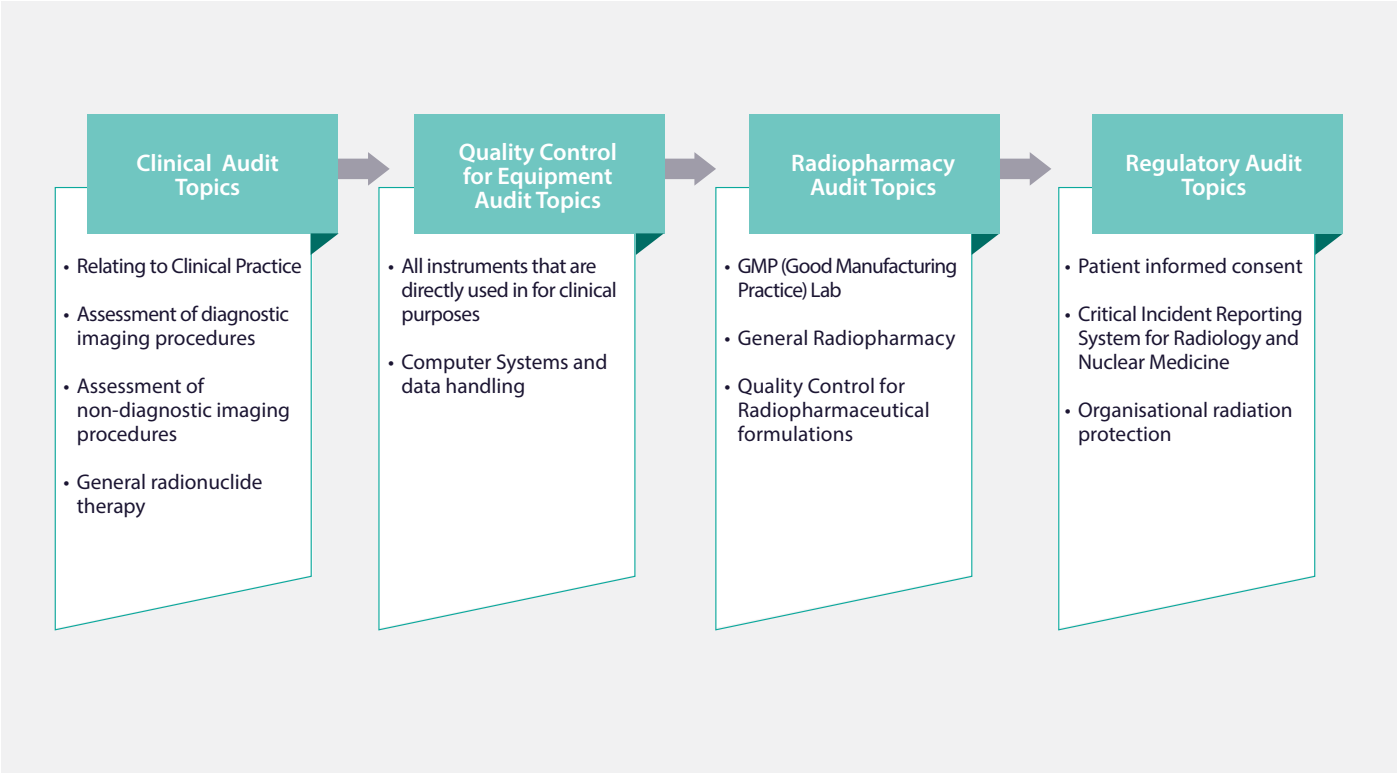

***Figure 2** – Audit topics definition, including orientations for the inclusion on the core topics of nuclear medicine.*

GENERIC AUDIT TEMPLATE

Audit Title

Standard against which the audit topic is to be compared

Sources of standards (or reference documents)

Type of audit:

Target / compliance percentage to be achieved

Item or variable to be audited

Method: Retrospective, Prospective / Other

Data or information to be collected

Tool used for the collection of data

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

Target achieved

Actions to be taken if the target is not met

Timing for re-audit (provide time window for re-audit)

Appendices - Clinical Audit Topics

1	Auditing the appropriateness of FDG PET/CT referrals in breast cancer
2	Quality for uploaded scintigraphic reports – bone scan planar and tomographic imaging
3	Somatostatin Receptor-targeted therapy. [^{177}Lu]Lu-oxodotreotide administration
4	Prostate-Specific Membrane Antigen-targeted therapy. [^{177}Lu]Lu-PSMA-617 administration
5	Information for patients before, during and after ^{131}I therapy

AUDIT TEMPLATE 1

Audit Title

Auditing the appropriateness of FDG PET/CT referrals in breast cancer

Standard against which the audit topic is to be compared

The standard would be alternative imaging techniques that can be performed in the place of FDG PET/CT. Local standard practice should be considered

Sources of standards (or reference documents)

Published literature, guidance, local, national or international guidelines, consensus, others

Type of audit:

Clinical audit, workflow/requests, BSSD related

Target / compliance percentage to be achieved

In accordance with local requirements or guidelines

Item or variable to be audited

The appropriateness of referrals for FDG PET/CT procedures, do they align with best practice guidance and recommendations

Method: Retrospective, Prospective / Other

Both retrospective and prospective

Data or information to be collected

Clinical information provided in support of FDG PET/CT request and assessment of appropriateness

Tool used for the collection of data

Excel/access/others

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

It would be locally decided, regarding the number of patients and time period

Target achieved

Yes/No

Actions to be taken if the target is not met

- Educational program
- Review of the local practices
- Education of the NM staff around rejection of inappropriate imaging requests

Timing for re-audit (provide time window for re-audit)

6 months

AUDIT TEMPLATE 2

Audit Title

Quality for uploaded scintigraphic reports – Bone Scan planar and tomographic imaging

Standard against which the audit topic is to be compared

National and international guidelines and/or published literature.

Sources of standards (or reference documents)

Local standard protocols

Type of audit:

Clinical audit non-regulatory

Target / compliance percentage to be achieved

90%

Item or variable to be audited

Reported images for each diagnostic scintigraphic procedure and the generated report.
Answer the question: Did the requested images perform as prescribed?

Method: Retrospective, Prospective / Other

Prospective. Daily.

Data or information to be collected

Record of errors found by an expert technician

Tool used for the collection of data

Excel. Redcap platform.

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

Patients submitted to scintigraphic diagnostic procedures. Daily basis: 25–30 scans per day.
Collection time: 3 months.

Target achieved

Yes/No

Actions to be taken if the target is not met

Formation programs, prolonged initial supervision by experienced partners, continuing education.

Timing for re-audit (provide time window for re-audit)

12 months

AUDIT TEMPLATE 3

Audit Title

Somatostatin Receptor-targeted therapy. [^{177}Lu]Lu-oxodotreotide administration

Standard against which the audit topic is to be compared

Local/national agreed standard, BSSD or relevant IAEA publications

Sources of standards (or reference documents)

EMA, Lutathera : EPAR - Product information
(https://www.ema.europa.eu/en/documents/product-information/lutathera-epar-product-information_en.pdf)

IAEA Human Health Series No. 20, Practical Guidance on Peptide Receptor Radionuclide Therapy (PRRT) for Neuroendocrine Tumours
(https://www-pub.iaea.org/MTCD/Publications/PDF/P1560_web.pdf)

Type of audit

Clinical non-regulatory

Target / compliance percentage to be achieved

100%

Item or variable to be audited

Easily accessible documents explaining the administration of [^{177}Lu]Lu-oxodotreotide

Method: Retrospective / Prospective / Other

Prospective

Data or information to be collected

Standard operating procedures

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

The complete documentation as stated on the previous point

Target achieved

Yes/No

Actions to be taken if the target is not met

Discussing the local administration of [^{177}Lu]Lu-oxodotreotide
Choosing a person/people who is/are responsible for completing the task at hand.

Timing for re-audit

Realistic timespan, which should be discussed with local authorities (physicians, medical physicists) – ideally 12 months

AUDIT TEMPLATE 4

Audit Title

Prostate-specific membrane antigen-targeted therapy. [^{177}Lu]Lu-PSMA-617 administration

Standard against which the audit topic is to be compared

Local /national agreed standard, BSSD or relevant IAEA publications

Sources of standards (or reference documents)

IAEA Human Health Series No. 20, Practical Guidance on Peptide Receptor Radionuclide Therapy (PRRT) for Neuroendocrine Tumours
(https://www-pub.iaea.org/MTCD/Publications/PDF/P1560_web.pdf)

EMA, Pluvicto : EPAR - Product information
(https://www.ema.europa.eu/en/documents/product-information/pluvicto-epar-product-information_en.pdf)

Type of audit

Clinical non-regulatory

Target / compliance percentage to be achieved

100%

Item or variable to be audited

Easily accessible documents explaining the administration of [^{177}Lu]Lu-PSMA-617

Method: Retrospective / Prospective / Other

Prospective

Data or information to be collected

Standard operating procedures

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

The complete documentation as stated on the previous point

Target achieved

Yes/No

Actions to be taken if the target is not met

Discussing the local administration of [^{177}Lu]Lu-PSMA-617
Choosing a person/people who is/are responsible for completing the task at hand

Timing for re-audit

Realistic timespan, which should be discussed with local authorities (Physicians, Medical Physicists) – ideally 12 months

AUDIT TEMPLATE 5

Audit Title

Information for patients before, during and after ^{131}I therapy

Standard against which the audit topic is to be compared

IAEA, International Commission on Radiological Protection, Society of Nuclear Medicine and Molecular Imaging, local legislation should be considered

Sources of standards (or reference documents)

- IAEA Safety Report Series No. 63, Release of Patient after Radionuclide Therapy (https://www.iaea.org/publications/8179/release-of-patients-after-radionuclide-therapy)
- IAEA Nuclear Medicine Resources Manual (https://www.iaea.org/publications/7038/nuclear-medicine-resources-manual)
- IAEA-TECDOC-1608, Nuclear Medicine in Thyroid Cancer Management: A Practical Approach (https://www.iaea.org/publications/7947/nuclear-medicine-in-thyroid-cancer-management-a-practical-approach)
- ICRP 84 pregnancy and Medical Radiation
- The SNMMI practice guideline for the Thyroid Disease with ^{131}I (https://jnm.snmjournals.org/content/53/10/1633)

Type of audit:

Clinical regulatory

Target / compliance percentage to be achieved

90%

Item or variable to be audited

Information forms, radiation protection forms, post therapy card

Method: Retrospective, Prospective / Other

Retrospective

Data or information to be collected

Information forms, radiation protection forms, post therapy card

Tool used for the collection of data

Hospital/radiology iInformation system, patient records, Microsoft Excel or similar spreadsheet, others

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

Minimum 30 patients (in the last 6 months)

Target achieved

Yes/No

Actions to be taken if the target is not met

Secure proper documentation
Education of the nuclear medicine staff

Timing for re-audit (provide time window for re-audit)

12 months

Appendices - Quality Control for Nuclear Medicine Equipment

6	Dose calibrators documentation
7	Quality control of planar and SPECT imaging modalities in hybrid SPECT/CT scanner
8	Quality assurance schedule within tolerance limits of PET

AUDIT TEMPLATE 6

Audit Title

Dose calibrators documentation

Standard against which the audit topic is to be compared

Manufacturer and regulatory standards

Sources of standards (or reference documents)

Manufacturer certifications

Type of audit

Clinical quality control

Target / compliance percentage to be achieved

90%

Item or variable to be audited

Constancy, accuracy, linearity

Method

Retrospective/prospective

Data or information to be collected

Calibration reports, manufacturer certifications

Tool used for the collection of data

Excel report files, instrumentation reports audit

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

3 months collection time (or the last two tests, for semi-yearly intervals).

Target achieved

Yes/No

Actions to be taken if the target is not met

If target is not met, the cause must be identified. Review protocols and procedures. Education/discussion and review quality controls procedures.

Timing for re-audit

12 months

AUDIT TEMPLATE 7

Audit Title

Quality control of planar and SPECT imaging modalities in hybrid SPECT–CT scanner

Standard against which the audit topic is to be compared

Manufacturer and national regulatory standards

Source of standard (or reference document)

National regulation

Type of audit

Clinical quality control

Target / compliance percentage to be achieved

90%

Item or variable to be audited

All tests defined by the manufacturer and national regulatory standards

Method

Retrospective/prospective and other - comparison with acceptance parameters of the equipment

Data or information to be collected

All quality control protocols approved in the department that are defined by the manufacturer and required by national regulatory standards

Tool used for the collection of data

Word report files, instrumentation report audit

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

Collection time period – weekly, monthly and every 6 months

Target achieved

Yes/No

Actions to be taken if the target is not met

If target is not met, the cause must be identified. Review protocols and procedures.
Education/discussion and review quality controls procedures.

Timing for re-audit

12 months

AUDIT TEMPLATE 8

Audit Title

Quality assurance schedule within tolerance limits of PET

Standard against which the audit topic is to be compared

EANM, IAEA, EFOMP publications

Sources of standards (or reference documents)

- EANM Technologists Guide, Quality Control of Nuclear Medicine Instrumentation and Protocol Standardisation (https://eanm.org/wp-content/uploads/2024/06/EANM_2017_TEchGuide_QualityControl-1.pdf)
- IAEA Human Health Series No. 1, Quality Assurance for PET and PET/CT Systems (https://www-pub.iaea.org/MTCD/Publications/PDF/Pub1393_web.pdf)
- EFOMP'S Guideline, Quality Controls In PET/CT and PET/MR (https://www.efomp.org/uploads/10fd24d1-354d-48d6-bf8f-e93e98cb7d81/EFOMP%E2%80%99S%20GUIDELINE%20QUALITY%20CONTROLS%20IN%20PETCT%20AND%20PETMR.pdf)
- Manufacturer manuals

Type of audit:

Clinical quality control

Target / compliance percentage to be achieved

90%

Item or variable to be audited

All tests defined by the manufacturer and national regulatory standards

Method: Retrospective, Prospective / Other

Retrospective and prospective

Data or information to be collected

All quality control protocols approved in the department that are defined by the manufacturer and required by national regulatory standards

Tool used for the collection of data

Excel, PET scanner console, logbook, others

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

Locally decided according to the frequency and results of PET quality control or 1-2 samples per month of each PET quality control records.

Target achieved

Yes/No

Actions to be taken if the target is not met

Education and practise of the medical physics expert staff

Timing for re-audit (provide time window for re-audit)

12 months

Appendices - Radiopharmacy

9	Quality control of [^{18}F]-fluorodeoxyglucose
10	Quality control of ^{99m}Tc-hydroxydiphosphonate
11	^{99m}Tc reagent kit traceability
12	^{99}Mo/^{99m}Tc generator for radiopharmaceuticals

AUDIT TEMPLATE 9

Audit Title

Quality control of [^{18}F]-fluorodeoxyglucose.

Standard against which the audit topic is to be compared

European pharmacopeia, radiopharmaceuticals monographies

Sources of standards (or reference documents)

European Regulations (Euratom Directives), Italian laws (e.g., D.LGS 101/2020) and specific standards for radiopharmaceutical handling (e.g., good radiopharmacy practice, radiopharmaceutical monographies, IAEA guidelines).

Italian laws:

https://www.gazzettaufficiale.it/eli/id/2020/08/12/20G00121/sg

GMP also for radiopharmaceuticals:

https://www.nihs.go.jp/dnfi/pdf/RI_PDF/WHO2-1.pdf
https://health.ec.europa.eu/medicinal-products/eudralex/eudralex-volume-4_en
https://health.ec.europa.eu/document/download/bf281e1f-4897-469a-ba60-18d867b14a94_en?filename=2008_09_annex3_en.pdf

Example of a monograph:

https://www.ema.europa.eu/en/documents/referral/gluscan-500-article-29-referral-annex-i-ii-iii_en.pdf

Type of audit

Regulatory, radiopharmacy

Target / compliance percentage to be achieved

90%

Item or variable to be audited

Quality controls tests and radiopharmacy reports

Method:

Retrospective/prospective

Data or information to be collected

Radiopharmacy quality control reports

Tool used for the collection of data

Excel report files, instrumentations audit reports, checklist

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

3 months collection time period

Target achieved

Yes/No

Actions to be taken if the target is not met

If target is not met, the cause must be identified. Review protocols and procedures.
Education/discussion and review quality controls procedures.

Timing for re-audit

12 months

AUDIT TEMPLATE 10

Audit Title

Quality control of ^{99m}Tc-hydroxydiphosphonate

Standard against which the audit topic is to be compared

Manufacturer and regulatory standards.

Source of standard (or reference document)

European Regulations (Euratom Directives), Italian laws (e.g., D.LGS 101/2020) and specific standards for radiopharmaceutical handling (e.g., good radiopharmacy practice, radiopharmaceutical monographies, IAEA guidelines).

Type of audit

Regulatory, radiopharmacy

Target / compliance percentage to be achieved

90%

Item or variable to be audited

Quality controls tests and radiopharmacy reports

Method

Retrospective/prospective

Data or information to be collected

Radiopharmacy quality control reports

Tool used for the collection of data

Spreadsheet report files, instrumentation reports audit, standard operating procedures, checklist

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

3 months collection time

Target achieved

Yes/No

Actions to be taken if the target is not met

If target is not met, the cause must be identified. Review protocols and procedures.
Education/discussion and review quality controls procedures.

Timing for re-audit

12 months

AUDIT TEMPLATE 11

Audit Title

^{99m}Tc reagent kit traceability.

Standards against which the audit topic is to be compared

Manufacturer and regulatory standards
Sources of standards (or reference documents)
National and European legislation and good radiopharmacy practices

Type of audit

Regulatory, radiopharmacy

Target / compliance percentage to be achieved

95%

Item or variable to be audited

Certificate of analysis, shipping notes, pharmaceutical company quality controls

Method:

Retrospective/prospective

Data or information to be collected

Expiration dates, temperature, quality controls

Tool used for the collection of data

Spreadsheet report files, instrumentations audit reports, standard operating procedures, checklist

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

3 months collection time

Target achieved

Yes/No

Actions to be taken if the target is not met

If target is not met, the cause must be identified. Review protocols and procedures.
Education/discussion and review quality controls procedures.

Timing for re-audit

12 months

AUDIT TEMPLATE 12

Audit Title

^{99}Mo/^{99m}Tc generator for radiopharmaceuticals.

Standards against which the audit topic is to be compared

Manufacturer and regulatory standards

Sources of standards (or reference documents)

European Regulations (Euratom Directives), Italian laws (e.g., D.LGS 101/2020) and specific standards for radiopharmaceutical handling (e.g., good manufacturing practices, radiopharmaceutical monographies, IAEA guidelines).

Type of audit

Regulatory, radiopharmacy

Target / compliance percentage to be achieved

95%

Item or variable to be audited

Certificate of analysis, shipping notes, radiopharmacy quality controls

Method

Retrospective/prospective

Data or information to be collected

Generator series number, quality controls

Tool used for the collection of data

Excel report files, instrumentation reports audit, standard operating procedures

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

3 months collection time

Target achieved

Yes/No

Actions to be taken if the target is not met

If target is not met, the cause must be identified. Review protocols and procedures.
Education/discussion and review quality controls procedures.

Timing for re-audit

12 months

Appendices - Regulatory Audit Topics

13	Is there an informed consent for patients performing diagnostic nuclear medicine procedures?
14	Staffing and training
15	Is there a mechanism for record keeping and retrospective analysis of accidental extravasation of radiopharmaceuticals?
16	Releasing of patients after internal radionuclide therapy with unsealed radionuclides
17	Availability of a reporting system for ionizing radiation incidents
18	What percentage of diagnostic procedures have established diagnostic reference levels (DRL)?
19	Radiation protection instruction
20	Auditing patients' waiting time for PET–CT in the nuclear medicine department
21	Auditing the rate of radiopharmaceutical extravasations in bone scan

AUDIT TEMPLATE 13

Audit Title

Is there an informed consent for patients performing diagnostic nuclear medicine procedures?

Standards against which the audit topic is to be compared

IAEA Nuclear Medicine Resources Manual
(https://www.iaea.org/publications/7038/nuclear-medicine-resources-manual)

BSSD
National legislation
To be discussed and agreed locally

Sources of standards (or reference documents)

BSSD
National legislation
Internal standard operating procedures

Type of audit

Clinical regulatory

Target / compliance percentage to be achieved

95%

Item or variable to be audited

Specific informed consent form

Method: Retrospective, Prospective / Other

Retrospective

Data or information to be collected

The existence of Informed consent forms in patients' files.

Tool used for the collection of data

See above

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

Three months; patients who performed a diagnostic procedure in department (with a maximum of procedures that is agreed with the audit team)

Target achieved

Yes/No

Actions to be taken if the target is not met

Identify the failures and the reasons for failures
Delegate a person responsible for the task
Consulting national legislation

Timing for re-audit (provide time window for re-audit)

6 months

AUDIT TEMPLATE 14

Audit Title

Staffing and training

Standards against which the audit topic is to be compared

National and European legislation, human resources recommendations

Sources of standards (or reference documents)

Standard operating procedures, local legislation or guidelines

Type of audit

Regulatory

Target / compliance percentage to be achieved

100%

Item or variable to be audited

Recommendation on staffing including technologists, nuclear medicine physicists, nurses and medical physicists

Method

Retrospective/prospective

Data or information to be collected

Criteria for the number of professionals

Tool used for the collection of data

Documentation and standard operating procedures

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

Not applicable

Target achieved

Yes/No

Actions to be taken if the target is not met

If target is not met, the cause must be identified. Clarify the criteria for contracting, coordinating with the human resources department

Timing for re-audit

12 months

AUDIT TEMPLATE 15

Audit Title

Is there a mechanism for record keeping and retrospective analysis of accidental Extravasation of radiopharmaceuticals?

Standards against which the audit topic is to be compared

Local / national agreed standard. European Council Directive 2013/59/Euratom on BSS. IAEA

Sources of standards (or reference documents)

IAEA Safety Report Series No. 63, Release of Patients after Radionuclide Therapy
(https://www-pub.iaea.org/MTCD/Publications/PDF/pub1417_web.pdf)

Van der Pol, et al. Consequences of radiopharmaceutical extravasation and therapeutic interventions: a systematic review
(https://pubmed.ncbi.nlm.nih.gov/28303300/)

Type of audit

Clinical regulatory

Target / compliance percentage to be achieved

90%

Item or variable to be audited

Local policy rules. Pathway for follow up of extravasation. Arrangements also to be in place to inform the referrer and the practitioner

Method: Retrospective, Prospective / Other

Retrospective/prospective

Data or information to be collected

Confirmation of existence of local rules pathway for accidental exposure follow up number of cases/years
Date/Time/Reason for extravasation together with dose consequences, if any, of the exposure

Tool used for the collection of data

Web-based register or local register system

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

Implementation of clear pathway in the local rules

Target achieved

Yes/No

Actions to be taken if the target is not met

Repeat 3 months later. Develop a system to document extravasation in consultation with the clinical, technologist and physicist team

Timing for re-audit (provide time window for re-audit)

12 months

AUDIT TEMPLATE 16

Audit Title

Releasing of patients after internal radionuclide therapy with unsealed radionuclides

Standards against which the audit topic is to be compared

Local/national agreed standard. European Council Directive 2013/59/Euratom on BSS. IAEA

Sources of standards (or reference documents)

ICRP Publication 94, Release of Patients after Therapy with Unsealed Radionuclides
https://journals.sagepub.com/doi/pdf/10.1177/ANIB_34_2)

IAEA Safety Report Series No. 63, Release of Patients after Radionuclide Therapy
(https://www-pub.iaea.org/MTCD/Publications/PDF/pub1417_web.pdf)

Type of audit

Clinical regulatory

Target / compliance percentage to be achieved

100%

Item or variable to be audited

Documents including the decision-making procedures on when to release patients after therapy with unsealed radionuclides

Method: Retrospective / Prospective / Other

Prospective

Data or information to be collected

Standard operating procedures

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

The complete documentation as stated on the previous point

Target achieved

Yes/No

Actions to be taken if the target is not met

- Discussing the local way of proceeding
- Discussing radiation protection guidelines
- Choosing a person/people who is/are responsible for completing the task at hand

Timing for re-audit

Realistic timespan, which should be discussed with local authorities (physicians, medical physicists)

AUDIT TEMPLATE 17

Audit Title

Availability of a reporting system for ionizing radiation incidents

Standards against which the audit topic is to be compared

Local / national agreed standard, BSSD or relevant IAEA publications

Source of standard (or reference document)

BSSD
(https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32013L0059)

Type of audit

Clinical regulatory

Target / compliance percentage to be achieved

100%

Item or variable to be audited

Existence of a reporting system for ionizing radiation incidents

Method: Retrospective, Prospective / Other

Prospective

Data or information to be collected

A document showing the steps to report an incident, in writing and/or visually

Tool used for the collection of data

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

The complete documentation as stated on the previous point

Target achieved

Yes/No

Actions to be taken if the target is not met

- Discussing the local way of reporting an incident
- Discussing and comparing with international radiation protection guidelines
- Choosing a person/people who is/are responsible for completing the task at hand

Timing for re-audit

Realistic timespan, which should be discussed with local authorities (physicians, medical physicists)

AUDIT TEMPLATE 18

Audit Title

What percentage of diagnostic procedures have established diagnostic reference levels (DRL)?

Standards against which the audit topic is to be compared

BSSD

Please note also recent EANM published guidelines on paediatric DRLs – this would be another suitable subject for audit

European Guidelines on Diagnostic Reference Levels for Paediatric Imaging
(https://eanm.org/publications/useful-resources/dosage-card/)

Sources of standards (or reference documents)

National legislation intended to transpose and implement requirements included in Article 56 of the BSSD

Type of audit

Clinical regulatory

Target / compliance percentage to be achieved

85 %

Item or variable to be audited

Establishment and regular review of DRLs for all diagnostic procedures

Method: Retrospective, Prospective / Other

Retrospective/prospective

Data or information to be collected

Exposure levels for all diagnostic procedures compared to DRLs

Percentage in each category above the DRL

Tool used for the collection of data

Excel tables, DICOM data from RIS (Patient weight and injected activity)

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

One-month review of the previous point

Target achieved

Yes/No

Actions 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

Timing for re-audit (provide time window for re-audit)

Rolling audit programme, frequency to be agreed locally and with medical physics expert

AUDIT TEMPLATE 19

Audit Title

Radiation protection instruction

Standards against which the audit topic is to be compared

Local/national agreed standard, BSSD or relevant IAEA publications

Sources of standards (or reference document)

BSSD
(https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32013L0059)

IAEA Practical Radiation Technical Manual, Personal Protective Equipment
(https://www-pub.iaea.org/MTCD/Publications/PDF/PRTM-5_web.pdf)

Type of audit

Clinical regulatory

Target / compliance percentage to be achieved

90 %

Item or variable to be audited

Personnel yearly instruction, content and appropriateness. Attendance documentation.

Method: Retrospective, Prospective / Other

Retrospective

Data or information to be collected

Presentations, text and attendance documentation

Tool used for the collection of data

Spreadsheet tables, word documents and PDF

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

The complete documentation as stated on the previous point

Target achieved

Yes/No

Actions to be taken if the target is not met

Content: create a check list from your radiation protection authority and update the instruction contents accordingly
Documentation: make radiation protection instructions available centrally through your quality management system
Attendance: Create a quarterly schedule for instructions to ensure maximum attendance

Timing for re-audit (provide time window for re-audit)

12 months

AUDIT TEMPLATE 20

Audit Title

Auditing patients' waiting time for PET–CT in the nuclear medicine department

Standards against which the audit topic is to be compared

National and international guidelines, published literature, or institutional recommendations based on clinical priority

Sources of standards (or reference documents

Published literature, guidance, local, national or international guidelines, consensus, others.

Type of audit

Clinical regulatory

Target / compliance percentage to be achieved

95%

Item or variable to be audited

The waiting time should be the lowest as possible to minimize the delay on diagnosis and improve patients experience while performance.

Method: Retrospective, Prospective / Other

Ambispective

Data or information to be collected

Images from a pool of patients underwent bone scan in the department.

Tool used for the collection of data

Qmatic, Excel, SAP

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

Patients submitted to PET–CT scan. Monthly: means of 450–500 scans per month (variable from one centre to another). Collection time: 1 year

Target achieved

Yes/No

Actions to be taken if the target is not met

Check agendas. Review all the processes related to patients' stay in the nuclear medicine department

Timing for re-audit (provide time window for re-audit)

12 months

AUDIT TEMPLATE 21

Audit Title

Auditing the rate of radiopharmaceutical extravasations in bone scan

Standards against which the audit topic is to be compared

International and local recommendations

Sources of standards (or reference documents)

Published literature, guidance, local, national or international guidelines, consensus, others

Type of audit

Clinical regulatory

Target / compliance percentage to be achieved

95%

Item or variable to be audited

The rate of extravasation would be the lowest as possible to reduce the misinterpretation of the images

Method: Retrospective, Prospective / Other

Retrospective

Data or information to be collected

Images from a pool of patients underwent bone scan in the department

Tool used for the collection of data

Excel, Access, others

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

Patients submitted to bone scan, 300 scans in 1–2 years (both can variable from one centre to another)

Target achieved

Yes/No

Actions to be taken if the target is not met

Educational and practical programs

Timing for re-audit (provide time window for re-audit)

12 months

References

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