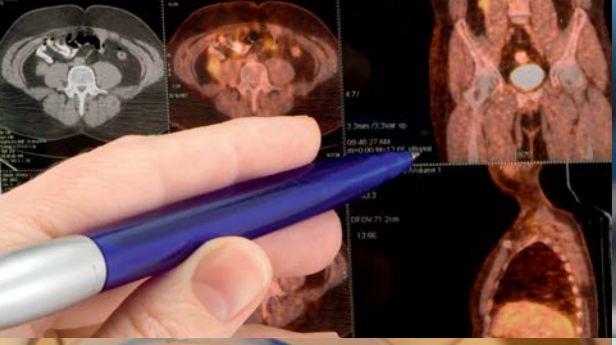

IAEA HUMAN HEALTH SERIES

No. 33

Quality Management Audits in Nuclear Medicine Practices

Second Edition

IAEA
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QUALITY MANAGEMENT AUDITS IN NUCLEAR MEDICINE PRACTICES

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The Agency's Statute was approved on 23 October 1956 by the Conference on the Statute of the IAEA held at United Nations Headquarters, New York; it entered into force on 29 July 1957. The Headquarters of the Agency are situated in Vienna. Its principal objective is "to accelerate and enlarge the contribution of atomic energy to peace, health and prosperity throughout the world''.

IAEA HUMAN HEALTH SERIES No. 33

QUALITY MANAGEMENT AUDITS IN NUCLEAR MEDICINE PRACTICES

SECOND EDITION

INTERNATIONAL ATOMIC ENERGY AGENCY
VIENNA, 2015

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Marketing and Sales Unit, Publishing Section
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PO Box 100
1400 Vienna, Austria
fax: +43 1 2600 29302
tel.: +43 1 2600 22417
email: sales.publications@iaea.org
http://www.iaea.org/books

Printed by the IAEA in Austria
September 2015
STI/PUB/1683

IAEA Library Cataloguing in Publication Data

Quality management audits in nuclear medicine practices, 2nd edition. — Vienna : International Atomic Energy Agency, 2015.
p. ; 24 cm. — (IAEA human health series, ISSN 2075–3772 ; no. 33)
STI/PUB/1683
ISBN 978–92–0–101715–4
Includes bibliographical references.

1. Nuclear medicine — Quality control. 2. Nuclear medicine — Equipment and supplies — Quality control. 3. Radiation — Safety measures. I. International Atomic Energy Agency. II. Series.

IAEAL 15–00980

FOREWORD

The IAEA has a long history of providing assistance in the field of nuclear medicine to its Member States. It updates its initiatives based on current trends in the technology and practice of nuclear medicine worldwide in order to improve the profession. The aim of these initiatives is in part to improve the clinical practice of the speciality through an effective management system that integrates quality management into modern nuclear medicine services in Member States. Quality management systems are essential and need to be maintained with the intent of continuously improving effectiveness and efficiency, enabling nuclear medicine to achieve the expectations of its quality policy, satisfy its customers and improve professionalism in the speciality.

Regular quality audits and assessments are vital for modern nuclear medicine services. More importantly, the entire quality management and audit process has to be systematic, patient orientated and outcome based. The management of services should also take into account the diversity of nuclear medicine services around the world and should invite multidisciplinary contributions. The latter include clinical, technical, radiopharmaceutical, medical physics and radiation safety procedures.

The IAEA, in its Safety Standards Series, has published a Safety Requirements publication (GS-R-3) and a Safety Guide (GS-G-3.1) on management systems for all facilities. These publications address the application of an integrated management system approach that is also applicable to nuclear medicine organizations. Aspects of radiation safety and patient protection should also be integral to the process. Such an approach ensures consistency in providing safe, high quality and high level services to patients and staff. Increasingly, standardized clinical protocols and evidence based medicine are used in nuclear medicine services; some of these are recommended in numerous IAEA publications, for example, the Nuclear Medicine Resources Manual. Reference can also be made to other IAEA publications such as the IAEA Safety Standards Series, which includes regulations for the safe transport of nuclear material and for waste management. All of these have an impact on the provision of nuclear medicine services.

The first edition of Quality Management Audits in Nuclear Medicine Practices (often referred to as the QUANUM manual) was published in 2009, and has been successfully applied worldwide in recent years. However, developments in the area and lessons learned through its implementation led to a need for an update of the annual systematic audit process to match current or best practice in nuclear medicine services. Therefore, in 2012, the IAEA and a group of experts began collaborating to update the QUANUM manual, resulting in this second edition of the publication.

The publication includes a series of checklists containing questions related to specific components. The questionnaires have been modified to update and enlarge the scope of the audit review. The present version will increase the understanding of the user and facilitate objective assessment. The questions are not all inclusive, and professional judgement is essential to ensure that they are addressed adequately. The quality management audit methodology for nuclear medicine, which is introduced in this publication, is designed to be applied to a variety of economic circumstances. A key outcome should be a culture of reviewing all processes of the nuclear medicine service for continuous improvement in nuclear medicine practice.

The IAEA officers responsible for this publication were D. Paez and T. Pascual of the Division of Human Health.

CONTENTS

1. INTRODUCTION

1.1. BACKGROUND

The IAEA has a long history of providing assistance in the field of nuclear medicine (NM) to its Member States. Following the decision to develop a quality management (QM) audit manual for NM, the IAEA convened the first expert group in 2006, which was composed of NM physicians, medical physicists, radiopharmacists and technologists. The aim was to encourage a routine of conducting periodic and systematic audits in the clinical environment. As a result, a publication entitled Quality Management Audits in Nuclear Medicine Practices (often referred to as the QUANUM manual) was published in 2009 [1]. Owing to the successful application of this tool worldwide in recent years, the rapid development of the speciality and the lessons learned through its first implementation, the IAEA recognized the necessity for an updated manual to match current or best practice in nuclear medicine services (NMSs). This present edition is the result of a cooperation that began in 2012 between the IAEA and a group of experts with extensive experience in QM.

The assessment methodology was designed to be applicable to a variety of available resources. It was agreed that new tools were needed to maintain a comprehensive approach to QM audits in the diagnosis, treatment and follow-up of patients using NMSs. Where local or national audit guidelines are available, those would be applicable; this manual can strengthen them and add an international perspective. In any case, adopting a culture of auditing through peer review is essential and enhances the contribution of NM to patient care.

A quality audit process has to be patient orientated, systematic and outcome based. It should include regular internal checking, assessment and review. It will further reinforce the system of documentation in a busy clinical setting. Independent external audits (peer reviews) should be carried out on a regular basis to ensure adequate quality of practice in NM.

To determine the actual level of performance of an NMS, internal and external audits should take into consideration the management, operating and safety procedures, facilities, equipment and human resources and their impacts on clinical practice. Audits may either review specific components (partial audit) or assess the entire process (comprehensive audit).

1.2. OBJECTIVE

The present publication aims at defining a methodology and tools for comprehensive auditing, including all aspects of NM. Adopting them will allow the NMS to demonstrate the level of efficiency, quality, safety and reliability in delivering clinical services.

With respect to the vast diversity of nuclear medicine practice at the international level, the mere fact that one NMS can address all the questions posed in the evaluation forms does not make it superior to those that have only been able to address a few questions in each section. It is not the quantity but the quality of response that is important. The overall quality depends on the inventory of strengths and weaknesses, together with the critical appraisal of the variables as observed in practice.

Guidance provided here, describing good practices, represents expert opinion but does not constitute recommendations made on the basis of a consensus of Member States.

1.3. SCOPE

A comprehensive audit is recommended periodically to maintain a high level of service. Taking into account the multidisciplinarity of NM, this publication includes the following key areas:

— Management;
— Human resources development;
— Safety aspects relating to patients, staff, the public and the environment;
— Equipment reliability and performance;
— Clinical services (diagnosis and therapy);
— Hospital radiopharmacy and laboratories.

1.4. STRUCTURE

Following a brief introduction to QM systems and QM audits, this publication includes a series of checklists; files are provided on the attached CD-ROM to be printed out and used. These lists can be followed sequentially or independently of one another. A comprehensive audit report indicating priorities, together with an action plan, is recommended.

1.4.1. Management commitment

The head of the NMS expresses commitment to the development, implementation and improvement of the QM system by:

— Establishing a quality policy;
— Ensuring that quality objectives are defined;
— Communicating with NMS staff members on the importance of meeting customer needs as well as statutory and regulatory requirements;
— Planning and properly managing resources;
— Conducting management reviews.

1.4.2. Quality management systems in nuclear medicine

The adoption of a quality management system (QMS) should be a strategic decision of an NMS. The design and implementation of an NM QMS is influenced by various needs and constraints, particular objectives, the nature of services provided, the processes employed and the size and structure of the NMS. An NMS should implement, document and maintain a QMS. Its effectiveness should be continuously improved in accordance with the requirements of professional, regulatory, standardization or accrediting bodies. A QMS aims to enable the NMS to achieve the expectations set forth in its quality policy and to satisfy its customers.

The QMS documentation of an NMS typically includes:

— Documentation of a quality policy and quality objectives;
— A quality manual;
— Written standard operating procedures (SOPs)[1] for primary (diagnosis and therapy) management and supporting processes (see Fig. 1);
— External/reference documents;
— Records of indicators and parameters.

The QMS standardizes the processes to guarantee consistency in providing high level services to patients, referring physicians and other stakeholders in a safe environment. The NMS management ensures the availability of necessary resources and information to support the operation and for monitoring of processes. The management also ensures the effectiveness of the QMS through self-assessments, data analysis, verification of activities and management reviews.

[1] If an NMS adopts internationally recognized SOPs (Society of Nuclear Medicine and Molecular Imaging, European Association of Nuclear Medicine, etc.), they do not need to be rewritten.

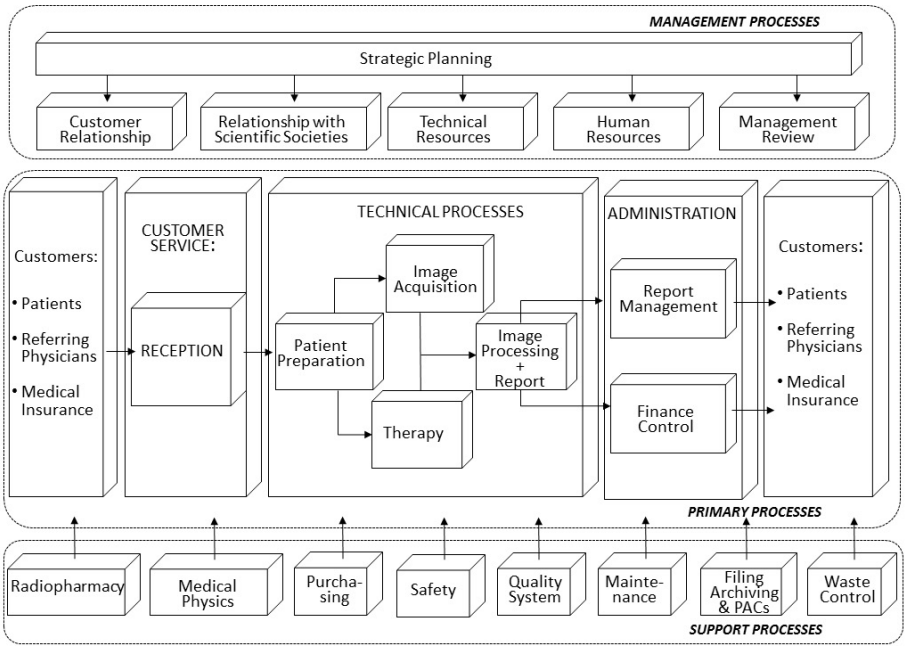

FIG. 1. Example of a process map for a nuclear medicine service, showing the primary, management and support processes (adapted with permission from the Committee for Accreditation of Nuclear Medicine Department of the European Association of Nuclear Medicine). PAC: picture archiving and communication.

1.4.3. Objective of the quality management audit and composition of the audit team

The objective of audits is to review and evaluate the quality of all elements involved in the different processes, such as staff and their professional competence, equipment and procedures, patient protection and safety, and the overall performance of the NMS as well as its interaction with external services. Audits assist NMSs in maintaining and improving the quality of service for patients, referring physicians and other stakeholders.

A multidisciplinary team, including experienced NM physicians, medical physicists, radiopharmacists and NM technologists / radiographers, should carry out internal and external audits. If appropriate, other professionals such as quality experts, administrators or nurses might join the team. In some instances, a laboratory service specialist in radioimmunoassay may be needed to provide additional support. The final composition of the audit team should

be communicated to the staff before the actual audit. A similar team may also be required for follow-up.

The IAEA recommends using the present publication as a tool to carry out self-assessments (internal audits) with the intention of applying good clinical practice and to identify opportunities for improvement.

1.4.4. General flow chart of the nuclear medicine audit procedure

The assessment methodology is designed to be applicable to a variety of circumstances. Even if local or national guidelines for auditing QMS in NMSs exist, this publication maintains its relevance by introducing an international perspective. Adopting a culture of peer review as an auditing tool is essential for quality improvement of NMSs.

The quality audit process has to be patient orientated, systematic and outcome based. The audit process is a continuous cycle of internal and external audits. It includes regular internal checking, assessment and review. In addition to internal audits, independent external audits should be carried out on a regular basis.

To capture the actual level of competence of a service, internal and external audits should take into consideration the management, operating procedures, facilities, equipment and human resources and their impact on clinical practice. The completion of the IAEA web based NM database referred to as NumDAB (http://nucmedicine.iaea.org/) provides basic information and essential details on operational and technical aspects and is a prerequisite for external audits. The questions are not all-inclusive, and professional judgement is necessary to ensure that they are addressed adequately.

Figure 2 shows a general flow chart of the NM audit procedure. The internal audit process should be an integral part of the QM programme and should be carried out periodically, as specified, for example, in the IAEA publication Application of the Management System for Facilities and Activities [2].

Implementing a timetable for both internal and external audits should become part of the NMS's calendar. Development of a culture of ongoing assessment is challenging. A busy clinical environment should not be an excuse for foregoing the audit process. The QM programme is vital for better patient care and an essential tool in the modern health system. It also provides an objective tool for prioritization and rational justification in a world of finite resources. Patient requirements and safety should be considered the first points of interest during review of the clinical practice.

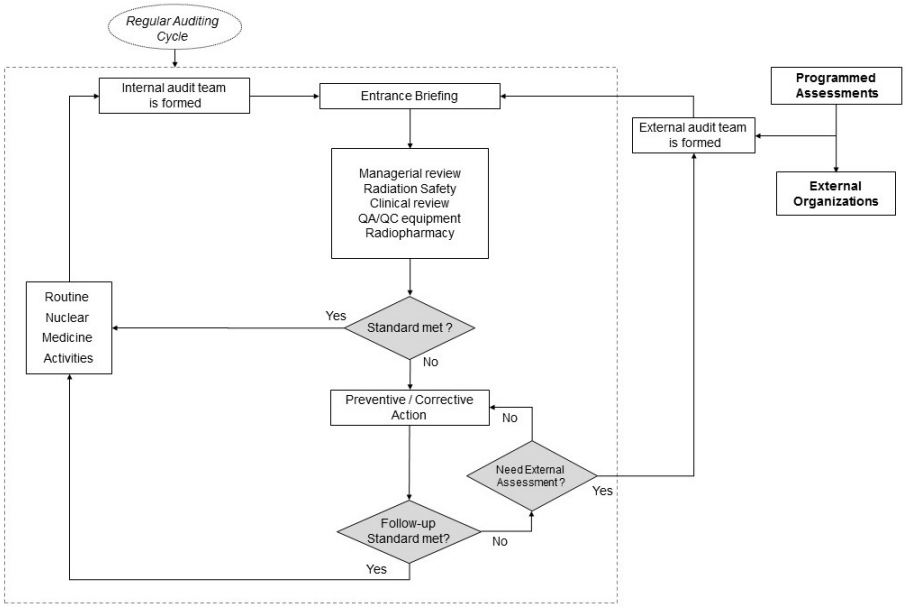

FIG. 2. Audit components. QA: quality assurance; QC: quality control.

Explanatory notes to the flow chart (Fig. 2) include the following:

(a) NMSs should undergo review on a regular (annual) basis.
(b) An audit does not necessarily have to check all the components shown in Fig. 2, but may be limited to a part of the processes involved in delivering NMSs.
(c) Written documentation (quality manual, SOP, measurable indicators and parameters, etc.) is a priority; it should be clearly and formally established, regularly updated and kept under control (distribution, training, communication, elimination of obsolete copies, etc.).
(d) An internal audit team should be formed, typically including a representative number of staff members from a range of disciplines.
(e) The audit checklists, which are part of this publication, are designed to allow internal as well as external auditors to assess the service's performance against accepted standards.
(f) Following the completion of the questionnaire, the details need to be analysed and summarized, as suggested in Section 3.
(g) If potential risks, deficiencies or non-conformances are identified, action plans need to be established. Any action should be defined and documented.

(h) Such action plans should include preventive or corrective actions, which should be prioritized and implemented in a timely manner. If opportunities for improvement are identified, corresponding actions can be considered and set up as quality objectives of the NMS.
(i) When standards are met, or preventive/corrective actions have been successfully implemented, routine activities are continued until the next planned periodic internal audit is performed. In particular situations (e.g. major changes or implementation of new procedures), earlier review may be needed.
(j) External support may be needed for implementing corrective/preventive actions.
(k) Periodic external and independent audits should be part of the NMS's QMS.
(l) External audits can also be organized in conjunction with external authorities.

1.4.5. Prioritization

All questions should be addressed, and any shortcomings or deficiencies identified. Priorities for corrections should be classified into three categories: 'critical', 'major' and 'minor'. Shortcomings that are likely to have serious patient implications or to represent risks to the staff or environment are prioritized as 'critical' or 'major'.

1.4.6. Limitations

1.4.6.1. General limitations

The audit checklists are not designed for:

(a) Regulatory purposes

Audit teams are not convened as an enforcing tool but solely as an impartial source of advice on quality improvement in collaboration with the NMS.

(b) Investigation of accidents

The audit teams are not convened to investigate accidents or reportable medical events (e.g. misadministration). In such an event, a more focused and specific technical investigation is required.

(c) Clinical research

This publication is not meant for assessing the quality and safety of clinical research nor the eligibility of institutes for entry into cooperative clinical trials. Such assessments are conducted by peers involved in the study, who will focus on the strict adherence of an institute to a single, specified clinical protocol in a selected group of patients, including the associated quality controls.

(d) Interdepartmental comparison

This publication is not intended to be used for interdepartmental comparison.

1.4.6.2. Checklist limitations

The checklists of this publication are intended as a comprehensive, non-exhaustive tool for quality assessment. Users are advised to consider updated IAEA publications and scientific literature as well as NM professional society guidelines. Professional judgement is advised to ensure an adequate level of assessment.

1.4.6.3. Responsibility for action

It should be understood that while it is the responsibility of the audit team to discuss shortfalls in the audited institution, it is the responsibility of the NMS, if necessary in conjunction with the hospital and/or national authorities, to correct identified deficiencies.

2. AUDIT REVIEW STRUCTURE

2.1. PURPOSE

Auditing is essential to ensure a well functioning NMS, and should be performed on a regular basis; a reasonable frequency would be every year for internal audits and every three years for external audits. A comprehensive audit of the service should address all aspects of the NMS as specified in Checklists 1–17 in Section 3. It should be an integral part of the accepted QM programme.

As part of the ongoing process of improvement, other aspects, such as significant changes in structure and operation, project planning, budgetary planning, etc., should be used as inputs to adapt internal audit planning.

2.2. ESTABLISHING THE AUDIT PLAN

The head of the NMS is responsible for setting up the audit process. Planning internal audits is an in-house process, whereas for external audits, cooperation and coordination with external local, national or international bodies, or with organizations such as the IAEA, are necessary.

2.3. COMPOSITION OF THE AUDIT TEAM

For the *internal* audit, the head of the NMS selects the audit team leader who will be in charge of the audit and selects the other members. The audit team consists of staff members with extensive knowledge of the current procedures of the NMS. An audit team may include the following members: NM physician, medical physicist, radiopharmacist, NM technologist / radiographer, radiation safety officer, delegates of NM administrative and nursing staff and a representative from the hospital administration and QM. It is advisable to include independent persons from other services of the institution representing the end user group (e.g. oncologists, cardiologists, endocrinologists, nephrologists). An audit team should consist of not less than three members.

Members of the team should have the necessary expertise, and, whenever possible, have undergone basic training and briefing in auditing techniques. A timetable for the audit should be agreed on by the team and the person in charge of the NMS. All relevant documentation of previous audits should be made available for audit planning.

For the *external* audit, the composition of the team is agreed upon between the parties; the criteria of multidisciplinarity, auditing competences and independence should be adopted as indicated above for the internal audit team.

2.4. PREPARATION FOR THE AUDIT

The success of an audit depends on the thorough preparation of all parties involved. The audited NMS's role is to:

- Prepare all relevant documentation and submit it to the audit team before the start of the audit;
- Make available the results of the previous internal audit (self-assessment according to QUANUM) and any consecutive action plan;
- Inform the entire staff, hospital management and other relevant persons and/or institutions involved of the audit and its schedule;
- Identify and ensure the participation of staff members (the audit team should be free to interview any staff member they deem appropriate);
- Ensure access of the audit team to any areas and premises related to the scope of the audit;
- Provide records requested by the audit team relevant to the reviewed field, including those from outside the service, although the audit team should be free to review any records, even those subject to confidentiality;
- Set up any meetings with stakeholders necessary for the successful completion of the audit;
- Ensure the availability of any resources needed for the audit activity.

In addition to self-assessment based on QUANUM, the completion of the IAEA web based NM database (http://nucmedicine.iaea.org/) is a prerequisite for IAEA external audits.

2.5. COMPONENTS OF THE AUDIT AND RESPONSIBILITIES OF THE AUDIT TEAM

Auditors should be independent, discrete, impartial and fair; they should observe an ethical and professional attitude. It is essential to perform audits according to standardized audit practices including:

- Entrance briefing;
- Assessment with systematic review of the questionnaires;
- Establishment of a set of minimum requirements;
- Definition of conformance and non-conformance;
- Exit briefing;
- Reporting.

2.5.1. Entrance briefing

The entrance briefing is required to introduce the audit team and present the staff, to finalize the agenda, and to discuss the objectives, methods and details of the audit. The auditors should assure the staff that confidentiality (including patient confidentiality) will be respected, and if required by the host, a proper document to this effect will be signed. Audit teams nominated by the IAEA will have signed such a confidentiality document before the audit.

2.5.2. Assessment

The overall activity of the NMS, from the initial referral of the patient, radiopharmaceutical preparation, patient preparation, execution of the procedure and data analysis through to the reporting and follow-up, will be evaluated. The facility, including premises, layout and classification of areas, equipment and staff, will be assessed.

A series of checklists in this publication have been designed to organize the audit in a standardized way and to ensure coverage of all relevant topics. The assessment includes:

— A complete tour of the premises;
— The review and evaluation of procedures and all relevant documentation, including review of treatment records;
— Observation of practical implementation of working procedures;
— Staff interviews;
— Meeting with the management of the institution and/or associated educational institution;
— Review of the previous audit (self-assessment according to QUANUM);
— Filling out the audit checklists.

To complement the audit activities, a spreadsheet has been developed, which is available at http://nucleus.iaea.org/HHW/NuclearMedicine/QualityPractice/index.html. This tool allows selection of the level of conformance for all the checklist requirements in an operational and user friendly environment. It also automatically creates summaries and plots of the audit results.

It is part of the responsibilities of the audit team to collect all management and operational information, such as (but not limited to):

— Updated copies of licences / accreditation documents;
— Organizational flow chart and function descriptions;
— Samples of SOPs;

— Samples of study reports;
— Copies of data regarding patient waiting times;
— Updated information on waiting lists;
— Copies of quality control data for relevant equipment and radiopharmaceuticals;
— Radiation safety records;
— Copies of letters of appraisal / complaints;
— List of deviations and non-conformances;
— Customer/stakeholder satisfaction surveys.

The above mentioned spreadsheet includes examples of the expected results or types of evidence for all the checklist requirements.

2.5.3. Minimum requirements

The application of standardized practices and professionally accepted norms is essential. The IAEA has issued a series of publications on site planning, standardization, quality assurance (QA), safety, clinical practice, radiopharmacy, training, etc., which are specified in the checklists. Minimum requirements are contained in these publications.

2.5.4. Conformance and non-conformance statements

QUANUM is intended to provide a working format for self-assessment using a systematic approach. Even if not all questions apply to all services, the result should accurately reflect the level of operation and/or service. It is perfectly acceptable to give the answer 'not applicable' (n.a.) and this should not be deemed poor performance.

A scoring system, shown in Table 1, has been designed to evaluate the level of conformance (LC). Items marked as n.a. will not be included in the assessment of final scores. This scoring system could be explained using the example of the documentation of clinical procedures.

The scores are used to build a radar plot[2] to enable visual presentation of the overall results. Figure 3 shows such a radar plot. The corresponding scores for the therapeutic procedures are shown in Table 2. In addition, specific radar plots will be produced for analysis of clinical observations (Fig. 4).

[2] A radar plot is a graphical illustration of the level of conformance achieved during the quality assessment. Each spot represents the LC for one specific checklist.

TABLE 1. EXAMPLE OF SCORING DOCUMENT SYSTEM REQUIREMENTS

Score	Classification	Description	Example
0	Non-conformance	Absent or inappropriate	No documents available
1		Planned or approximate	Documentation is planned or exists as an informal draft
2		Partial conformance or partial implementation	A limited number of standard operating procedures (SOPs) is complete or most SOPs exist, but lack important parts
3	Conformance	Near full conformance or near full implementation	Most of the SOPs are complete, but some information is missing (e.g. reference to guidelines, dosimetry data) or documents are not regularly updated
4		Full conformance or full implementation	All SOPs are complete and reviewed

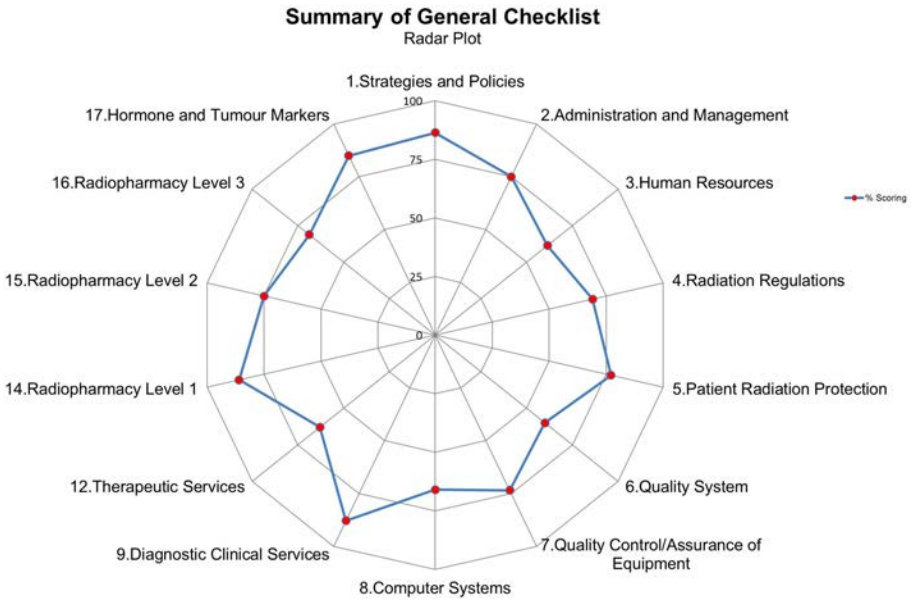

FIG. 3. Radar plot of overall quality system (example).

TABLE 2. OVERALL SCORES FOR THERAPEUTIC PROCEDURES

	1	2	3	4	5	6	7	8	9	12	14	15	16	17	
Checklist	Strategies & policies	Administration & management	Human resources	Radiation regulations	Patient radiation protection	Quality system	QC/QA equipment	Computer systems	Diagnostic clinical services	Therapeutic services	Radiopharmacy			Hormone & tumour Markers	Total
											Level 1	Level 2	Level 3		
No. questions	12	17	11	25	12	15	17	11	31	25	16	20	30	21	263
No. applicable	11	16	11	25	12	15	17	11	31	25	16	19	28	20	257
N/A	1	1	0	0	0	0	0	0	0	0	0	1	2	1	6
Total score	38	48	27	69	37	36	50	29	109	63	55	57	77.0	68	763
% scoring	86.4	75.0	61.4	69.0	77.1	60.0	73.5	65.9	87.9	63.0	85.9	75.0	68.8	85.0	74.2
No. of non-conformances	1	4	5	8	3	7	5	5	3	11	2	4	5	0	63

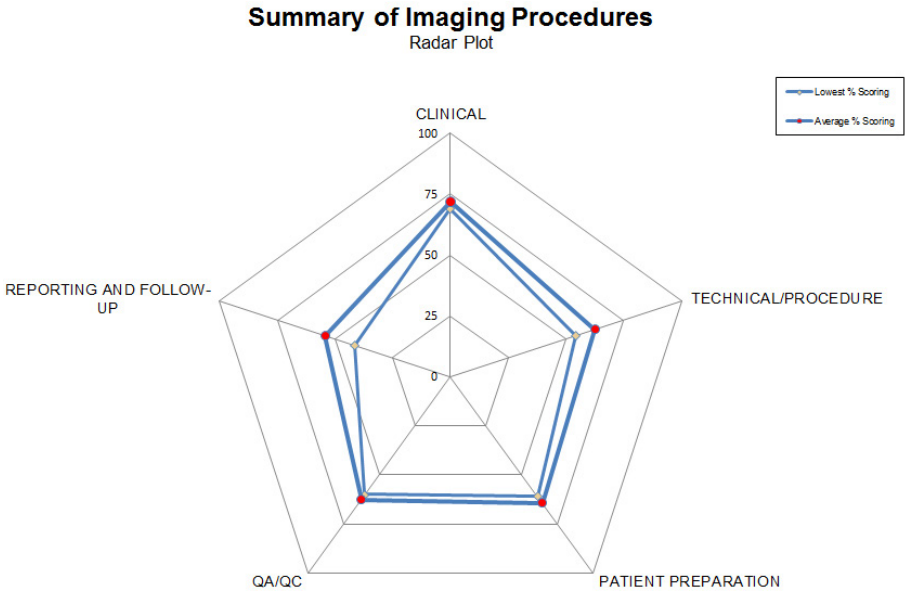

FIG. 4. Radar plot of an analysis of clinical observations (red and yellow markers correspond to average and lowest values, respectively) (example). QA: quality assurance; QC: quality control.

In general, when carrying out the audit, reference will be made to IAEA technical publications or other external standard setting bodies. Any non-conformance will be spelled out by the auditors. The seriousness and urgency of corrective actions should be transparently discussed and agreed on by the auditors and auditees. Corrective actions provide opportunities for improvement of the NMS.

2.5.5. Exit briefing

The preliminary feedback of the auditors will be documented and presented to the staff of the NMS and any other relevant key person during an interactive exit briefing. This includes time for questions and an open discussion on all the findings of the auditors. The institution should be encouraged to give an immediate response to the assessment. The steps intended by the institution to react to the recommendations should be part of the action plan.

With the aim of defining priorities, non-conformances should be characterized as:

— *Critical:* Issues affecting the safety of the patients, staff, caregivers and/or environment that should be promptly addressed (within days or weeks). Immediate discontinuation of the activity concerned might need to be considered.
— *Major:* Issues affecting the capacity of the NMS to adequately perform its activities that should be addressed in a timely manner (e.g. 3–6 months).
— *Minor:* Issues that may be the object of optimization, to be accomplished within a defined time period and re-evaluated during the next audit.

In particular, where a critical non-conformance has been found, the action plan should be sent to the audit team for further interaction. If appropriate, the service is responsible for notifying the regulatory authorities.

2.5.6. Conclusions and reporting

The audit report should contain conclusions formulated in an unambiguous way, identifying critical, major and minor priorities with clear and practical recommendations.

Moreover, the report should identify:

— Issues that can be improved or implemented by the NMS itself;
— Issues that cannot be resolved by the NMS alone, without significant financial, technical, managerial or professional contributions from outside.

If the service wishes to expand or introduce new activities, additional recommendations can be made. It should be understood that while it is the responsibility of the audit team to highlight shortfalls in the services of the audited institution, the audit team is not accountable for rectifying the identified deficiencies.

2.6. DISSEMINATION OF THE REPORT

The full report of the audit should be sent to those people identified during the exit briefing, e.g. the director of the hospital, head of the NMS, medical physicist, radiopharmacist and other staff members who played a significant part in the audit.

The report of audits managed by the IAEA will be sent by the audit team to the IAEA, which will forward it to the relevant counterparts. If the audit was commissioned through local or national authorities, the audit team's report should be submitted to them for dissemination according to their requirements. Recommendations made in the report should be directed to the respective institution and the referring organization, if applicable.

2.7. FOLLOW-UP

The purpose of the follow-up is to verify that the NMS has fulfilled the action plan as previously agreed with the audit team. Some activities, such as reviewing documents and records, conducting new interviews and performing tests, could be carried out to verify implementation of the corrective actions. A report should be delivered by the team involved in the follow-up activities describing whether the problems were satisfactorily corrected or if it is necessary to organize and perform new actions to solve the pending non-conformances or problems. Expected dates, responsibilities and actions should be included.

In the case of external audits organized by the IAEA, follow-up could be organized and performed by sharing electronic reports, emails, interviewing the staff members with web based tools, etc. If a follow-up audit is organized to check the completion of the action plan and the improvements achieved in the NMS, it will ideally be carried out by the same audit team.

3. AUDIT CHECKLISTS

3.1. GUIDE TO THE AUDIT QUESTIONNAIRE

The questionnaire starts with checklists related to the management and the quality system. It then moves to specific issues regarding radiation safety, QA / quality control (QC) of equipment, clinical services and the radiopharmacy/ laboratory. All items need to be scored according to their LC (Section 2.5.4); however, an answer marked as n.a. is acceptable.

When using the spreadsheet tool (http://nucleus.iaea.org/HHW/NuclearMedicine/QualityPractice/index.html, as described in Section 2.5.2 above):

— A colour code is provided to show the conformance status.
— For each item, an example of the type of results and evidence to be collected is suggested and a link to major reference documents is supplied.
— Spaces for comments and planned actions are provided, and the proposed date of achievement should be indicated.
— At the top of each checklist, a summary reports the results, including the number of non-conformances.
— Items marked as n.a. will not be included in the assessment of the final scores.

3.2. STRATEGIES AND POLICIES

A clear strategy and efficient management is essential for the success of any undertaking, and NM is no exception. Checklist 1 evaluates these aspects.

CHECKLIST 1. STRATEGIES AND POLICIES

No.	Component	LC	Example of result / type of evidence
1.1	Is the strategy of the nuclear medicine service (NMS) in accordance with specific objectives developed on the national/regional level?		Written documents showing strategies of the NMS and objectives at national/regional level
1.2	Is the strategy of the NMS in accordance with specific objectives developed by hospital management?		Written documents showing the NMS and institutional strategies
1.3	Is coordination with other services of the institution defined (radiology, oncology, cardiology, paediatrics, surgery, etc.)?		Written documents describing agreements with other services and their conditions
1.4	Does the NMS have an up to date written organizational chart, indicating channels of communication and lines of authority?		A copy of the organizational chart (it could be also verified using the quality manual)

CHECKLIST 1. STRATEGIES AND POLICIES (cont.)

No.	Component	LC	Example of result / type of evidence
1.5	Do the nuclear medicine diagnostic imaging and therapeutic services match the clinical demand?		Check the patient roster / verify if there is a waiting list
1.6	Do the objectives of the NMS include sufficient flexibility to accommodate urgent requests and emergency examinations?		Check relevant standard operating procedures (SOPs) and patient workflow
1.7	Do the objectives of the NMS include commitment to quality improvement through use of internal/external clinical audits?		Check quality objectives of the NMS
1.8	Does the NMS have a strategic development plan for its global activities?		Written documents establishing strategic development plans
1.9	Does the service have a plan to provide new developments in diagnosis and therapy?		Written documents describing new developments (may be verified using quality management)
1.10	If the NMS does not provide a full range of nuclear medicine services, is there a strategy/policy to guide access to such services in another institution?		Written agreements with other NMSs / general SOPs for clinical and therapeutic services
1.11	When providing services (e.g. technical and clinical) by using services of other hospitals, are responsibilities clearly defined?		Check definitions of responsibilities in the SOP of offered services
1.12	Is there a formal process ensuring the participation of the service in decision making of the hospital/institution?		Written SOP describing the process to ensure the role of the NMS in hospital decision making

Note: LC: level of conformance (range 0–4). 0: absent or inappropriate; 1: planned or approximate; 2: partial conformance or partial implementation; 3: near full conformance or near full implementation; 4: full conformance or full implementation.

3.3. ADMINISTRATION AND MANAGEMENT

Administration and management are central to an efficient and successful enterprise; this applies equally to the field of NM. Checklist 2 evaluates aspects of administration and management.

CHECKLIST 2. ADMINISTRATION AND MANAGEMENT

No.	Component	LC	Example of result / type of evidence
2.1	Has the service defined the primary, management and supporting processes (process map)?		Check the process map
2.2	Does the service have written standard operating procedures (SOPs) for all tasks regarding the management processes?		Check SOPs related to management processes
2.3	Does the service have written SOPs for all tasks of the supporting processes?		Check SOPs related to supporting processes
2.4	Do the SOPs identify the responsibility level of operators involved in the process?		Check definitions of responsibilities in SOPs
2.5	Does the service have written SOPs for all tasks regarding diagnosis and therapy (primary processes)?		Check SOPs related to diagnosis and therapy
2.6	Is there a regular review of the SOPs used in reception areas?		Check data regarding document updates in the written procedure
2.7	Is there an instruction for dealing with special categories of patients (disabilities, children, pregnancy, etc.)?		Check the instruction for dealing with special categories of patients
2.8	Is there an instruction for dealing with incomplete request forms?		Check the instruction for dealing with incomplete request forms
2.9	Is there an instruction in place to accommodate peak scheduling demands?		Check the instruction to accommodate peak scheduling demands

CHECKLIST 2. ADMINISTRATION AND MANAGEMENT (cont.)

No.	Component	LC	Example of result / type of evidence
2.10	Does the final responsibility for a nuclear medicine procedure lie with a qualified physician?		Check definitions of responsibilities in clinical SOPs
2.11	Are the time between request and performance of the study, the existence of waiting lists and any delays regularly reviewed and are measures identified to shorten delays?		Check records/reports of periodic management reviews
2.12	Is the time interval between performance of any examination and delivery of the report to the referring physician regularly reviewed?		Check records/reports of periodic reviews
2.13	Are indicators 2.11 and 2.12 as well as other performance parameters of the nuclear medicine service used in managerial processes?		Check records/reports of periodic manager reviews
2.14	Is there a mechanism for dealing with any kind of unforeseen/unintended events regarding non-conforming situations in the service's management and administration activities?		Check written instructions to deal with unforeseen events
2.15	Is there a mechanism for dealing with staff concerns (e.g. periodic meetings)?		Check written instructions to deal with staff concerns
2.16	Is there a regular review of the quality management system (QMS) by a qualified professional in medical physics?		Check the organizational chart and responsibility definitions
2.17	Is there a regular review of the QMS by a qualified professional in radiopharmacy?		Check the organizational chart and responsibility definitions

Note: LC: level of conformance (range 0–4). 0: absent or inappropriate; 1: planned or approximate; 2: partial conformance or partial implementation; 3: near full conformance or near full implementation; 4: full conformance or full implementation.

3.4. HUMAN RESOURCES DEVELOPMENT

Human resources can be defined as the total knowledge, skills, creative abilities, talents and aptitudes of the workforce. Human resources act as the hub that drives all other resources in an enterprise. This is also true in NM. Checklist 3 evaluates aspects of human resources development.

CHECKLIST 3. HUMAN RESOURCES DEVELOPMENT

No.	Component	LC	Example of result / type of evidence
3.1	Do all staff members have a written job description that clearly sets out their duties and responsibilities?		Example of a record (job description)
3.2	Are all staff members appropriately trained and qualified, as specified in their job description?		Example of a record (personnel file)
3.3	Does the service offer specific training for technologists to work in nuclear medicine (NM)?		Example of a record (training report)
3.4	Does the service offer specific training for nurses to work in NM?		Example of a record (training report)
3.5	Are all staff members suitably trained in handling radioactive sources?		Example of a record (training report)
3.6	Does the service have adequate tools for objective monitoring of any training?		Check written instructions describing tools for training monitoring
3.7	Does the service have mechanisms to provide professional education and development opportunities for all staff categories?		Check the training standard operating procedure (SOP)
3.8	Is there a regular internal review of competences to identify training needs?		Check the training SOP

CHECKLIST 3. HUMAN RESOURCES DEVELOPMENT (cont.)

No.	Component	LC	Example of result / type of evidence
3.9	Does the service provide continuing training in radiation safety and radiation protection?		Example of a record (personnel file)
3.10	Do staff members have access to educational and scientific resources?		Check available educational materials
3.11	Is quality management part of training programmes for professionals involved in NM?		Example of a record (personnel file)

Note: LC: level of conformance (range 0–4). 0: absent or inappropriate; 1: planned or approximate; 2: partial conformance or partial implementation; 3: near full conformance or near full implementation; 4: full conformance or full implementation.

3.5. RADIATION REGULATIONS AND SAFETY COMPLIANCE

Compliance with all relevant regulations and good radiation practice in NM are of utmost importance. Checklist 4 evaluates aspects of this compliance.

CHECKLIST 4. RADIATION REGULATIONS AND SAFETY COMPLIANCE

No.	Component	LC	Example of result / type of evidence
4.1	Is the service formally authorized/ licensed by competent national institutions?		Copy of the licence
4.2	Do standard operating procedures (SOPs) for radiation safety and protection refer to higher level guidelines and regulations (i.e. national or international guidelines or regulations)?		Cross-check references in SOPs with the first page of the law/regulation

CHECKLIST 4. RADIATION REGULATIONS AND SAFETY COMPLIANCE (cont.)

No.	Component	LC	Example of result / type of evidence
4.3	Do all personnel of the nuclear medicine service receive instructions and training on local procedures and safety precautions for protection of patients and staff when they start working in nuclear medicine (NM)?		Check/copy records
4.4	Have all staff members signed to confirm that they have read and understood the local policies and SOPs?		Cross-check with all personnel records
4.5	Are all radioactive materials kept, identified, controlled and stored as requested in licences and SOPs?		Observation on-site / photographs
4.6	Are sealed calibration sources checked periodically, cross-accounted for and checked for any leakage?		Observation on-site / photographs / log book
4.7	Is there routine NM personnel monitoring for radiation exposure (e.g. whole body badges, hand/finger monitoring, etc., as appropriate)?		Observation on-site / copy of records
4.8	Is staff personal dosimetry monitoring regularly reviewed and communicated, including reporting and initiation of appropriate actions in the case of unexpected results?		Check/copy records
4.9	Are there appropriate health surveillance procedures for exposed workers, in accordance with the local regulatory body?		Check/copy records
4.10	Is protective clothing (e.g. gloves, syringe shields, handling tongs, etc.) available?		Observation on-site / photographs

CHECKLIST 4. RADIATION REGULATIONS AND SAFETY COMPLIANCE (cont.)

No.	Component	LC	Example of result / type of evidence
4.11	Are there adequate facilities available for the administration of radiopharmaceuticals, therapy and radioactive aerosols, including radiation protection tools, as necessary?		Observation on-site / photographs
4.12	Are there adequate separate waiting areas for patients before and after administration of radiopharmaceuticals?		Observation on-site / photographs
4.13	Are diagnostic rooms adequately equipped (e.g. air-conditioning, ventilation, surfaces and structural shielding or mobile barriers)?		Observation on-site / photographs
4.14	Have areas been classified as ‘supervised’ or ‘controlled’ according to the Basic Safety Standards and/or local regulations?		Observation on-site / photographs
4.15	Is there a procedure for regular monitoring of workplace contamination?		Check the procedure
4.16	Is there a procedure for dealing with a spillage or contamination incident?		Check the procedure / check the decontamination kit
4.17	Are there means to prevent unauthorized access to supervised and controlled areas?		Observation on-site / photographs
4.18	Are radiation signs (in local language(s)) prominently displayed at the entrance to supervised and controlled areas?		Observation on-site / photographs
4.19	Are formal risk assessments and surveys of working areas and equipment performed and documented by designated staff?		Check the procedure

CHECKLIST 4. RADIATION REGULATIONS AND SAFETY COMPLIANCE (cont.)

No.	Component	LC	Example of result / type of evidence
4.20	Are suitably calibrated and functional radiation monitoring devices available?		Observation on-site / photographs
4.21	Are detailed procedures provided to handle patient specimens (blood, urine, etc.) and devices (syringes, urine bags, etc.), including radiation and microbiological safety aspects?		Check the procedure / observation on-site
4.22	Are formal procedures provided for the management (storage and disposal) of liquid and solid radioactive waste, including considerations for chemical and biological hazard safety aspects?		Observation on-site / photographs / check the procedure
4.23	Is the level of waste regularly checked against the authorized disposal limit and recorded?		Check the procedure / check records
4.24	Is there a policy on transportation (within and outside the service) of radioactive material?		Check the procedure
4.25	Is a formal emergency plan provided regarding action in the case of accidents (fire, flood, power blackout, etc.)?		Check the procedure

Note: LC: level of conformance (range 0–4). 0: absent or inappropriate; 1: planned or approximate; 2: partial conformance or partial implementation; 3: near full conformance or near full implementation; 4: full conformance or full implementation.

3.6. RADIATION PROTECTION OF PATIENTS

Patient focused service is fundamental to the success of NM. This includes all due considerations relating to radiation protection of patients. Checklist 5 evaluates aspects of these considerations.

CHECKLIST 5. RADIATION PROTECTION OF PATIENTS

No.	Component	LC	Example of result / type of evidence
5.1	Are standard operating procedures (SOPs) available to ensure correct identification of the patient prior to administration of the radiopharmaceutical?		Check the procedure / observation on-site
5.2	Are SOPs and appropriate signage provided to alert female patients of child bearing age to report any potential pregnancy or breast feeding?		Check the procedure / observation on-site
5.3	Are written instructions available and verbal instructions given to patients before and after administration of radiopharmaceuticals?		Observation on-site / copy of the instructions
5.4	Is the activity of each patient dose measured prior to administration and entered into the patient's record?		Observation on-site / copy of the instructions
5.5	Is there an SOP to ensure that the administered amounts of radioactivity do not exceed the reference values given in the Basic Safety Standards (BSSs), national or international regulations or guidelines?		Check the procedure / check the manual
5.6	In the case of multimodality imaging, is there an SOP to ensure that relevant dose indicators from X rays do not exceed the reference values given in the BSSs, national or international regulations or guidelines?		Check the procedure / check the manual
5.7	Is there a trained person available to estimate the effective radiation dose to patients following administration of radiopharmaceuticals?		Observation on-site / check the job description

CHECKLIST 5. RADIATION PROTECTION OF PATIENTS (cont.)

No.	Component	LC	Example of result / type of evidence
5.8	In the case of multimodality imaging, is there a trained person available to estimate the effective radiation dose to patients owing to X ray exposure?		Observation on-site / check the job description
5.9	Are there adequate SOPs to minimize the risk of misadministration of radiopharmaceuticals?		Check the procedure / observation on-site
5.10	Are there adequate SOPs provided to minimize the risk of multiple radiation exposures?		Check the procedure
5.11	Is there a specific SOP addressing non-compliance in patient exposures, including reporting and corrective actions?		Check the procedure
5.12	Is there a specific SOP for dealing with pregnant and breast feeding women who need a nuclear medicine examination?		Check the procedure

Note: LC: level of conformance (range 0–4). 0: absent or inappropriate; 1: planned or approximate; 2: partial conformance or partial implementation; 3: near full conformance or near full implementation; 4: full conformance or full implementation.

3.7. EVALUATION AND ASSURANCE OF THE QUALITY MANAGEMENT SYSTEM

The implementation of a QMS will contribute to increasing the level of safety and reliability in delivering clinical services. It should be regularly reviewed to ensure compliance with standards. Checklist 6 evaluates the QMS.

CHECKLIST 6. EVALUATION OF THE QUALITY MANAGEMENT SYSTEM

No.	Component	LC	Example of result / type of evidence
6.1	Are objectives defined and standards set for the nuclear medicine service performance?		Check established objectives and standards
6.2	Are there systems for monitoring compliance with standards, with defined criteria of acceptability?		Check procedures and examples of the criteria used for acceptability
6.3	Does the service regularly perform self-assessments/audits?		Check audit records and reports / check audit procedures
6.4	Is there a system to assess satisfaction (patient, referring physician / third party)?		Check procedures for assessing satisfaction / check records
6.5	Is there a standard operating procedure (SOP) for handling non-compliance, including recording and correction/ prevention?		Check the SOP / check records / check the list of corrections / prevention plans
6.6	Is there a mechanism for monitoring data to ensure quality improvement?		Check procedures describing the mechanism to ensure quality improvements
6.7	Are formal quality monitoring and reviewing organized for all staff members?		Check monitoring and reviewing records
6.8	Are all goods and equipment purchased according to specifications set up by all involved parties?		Check the purchase procedure / review records
6.9	Are technical specifications used for acceptance testing of goods and equipment?		Check the procedure / observation on-site

CHECKLIST 6. EVALUATION OF THE QUALITY MANAGEMENT SYSTEM (cont.)

No.	Component	LC	Example of result / type of evidence
6.10	Is there a quality assurance programme, with regular calibration and inspection of all equipment (activity meter, β and γ counters and probes, radiation survey monitors, imaging equipment, aerosol delivery systems, etc.) in accordance with the Basic Safety Standards, national or international standards and regulations?		Observation on-site / check the procedure / check records
6.11	Does a formal managerial review of quality data exist?		Check records
6.12	Is there a procedure to ensure that any equipment or material that fails a quality test is not used unless specifically authorized by a designated member of staff?		Check records / check procedures
6.13	Are action levels and responsibilities defined to determine when equipment should be repaired, replaced or taken out of service?		Check procedures / check the organizational chart and job descriptions
6.14	Are there plans for maintenance (preventive/corrective) and replacement for all major equipment?		Check procedures / check records
6.15	Does the service participate in external quality management, quality assurance / quality control (QM, QA/QC) programmes?		Check records related to external QM, QA, QC programmes / check audit reports

Note: LC: level of conformance (range 0–4). 0: absent or inappropriate; 1: planned or approximate; 2: partial conformance or partial implementation; 3: near full conformance or near full implementation; 4: full conformance or full implementation.

3.8. QUALITY CONTROL FOR IMAGING EQUIPMENT

A comprehensive system of QC for all imaging equipment is essential for optimal patient examinations in NM. Checklist 7 is not exhaustive, but rather provides an essential checklist.

CHECKLIST 7. QUALITY CONTROL FOR IMAGING EQUIPMENT

No.	Component	LC	Example of result / type of evidence
7.1	Are there written policies for specifying, procuring and testing new imaging equipment?		Check the procedure
7.2	Do these policies require certification of all equipment that will be acquired (e.g. 'CE' mark, United States Food and Drug Administration clearance or approval by a national authority)?		Check the procedure
7.3	Are the above policies in line with recommendations made in IAEA / International Electrotechnical Commission / National Electrical Manufacturers Association publications?		Check the procedure
7.4	Is an independent assessment of performance of the actual delivered equipment performed and documented against the specifications of the tender?		Check the procedure
7.5	In the case of γ cameras, have detailed acceptance tests been performed and the most relevant planar performance parameters recorded?		Observation on-site / example records / check the procedure
7.6	In the case of single photon emission computed tomography (SPECT) systems, have detailed acceptance tests been performed and the most relevant tomographic performance parameters recorded?		Observation on-site / example records / check the procedure

CHECKLIST 7. QUALITY CONTROL FOR IMAGING EQUIPMENT (cont.)

No.	Component	LC	Example of result / type of evidence
7.7	In the case of positron emission tomography (PET) systems, have detailed acceptance tests been performed and the most relevant emission tomographic performance parameters recorded?		Observation on-site / example records / check the procedure
7.8	In the case of multimodality equipment, have detailed acceptance tests been performed for all components and the most relevant performance parameters recorded?		Observation on-site / example records / check the procedure
7.9	Are results of acceptance tests and initial performance assessment used to establish baseline reference values for routine quality assurance (QA) / quality control (QC)?		Observation on-site / check the log book / check procedures
7.10	Are written SOPs available on the operation and QA/QC for all imaging equipment in clinical use?		Check procedures
7.11	Are these SOPs in agreement with manufacturer instruction manuals?		Check procedures
7.12	Is there a policy on long term storage of QA/QC results?		Observation on-site / example records / check the procedure
7.13	Is there a regular physical inspection of the hardware including the detector head(s), collimator(s), shielding, etc.?		Observation on-site / example records / check the procedure
7.14	Are the most relevant planar/SPECT parameters regularly checked, reviewed and recorded, including trend analysis: uniformity, spatial resolution, centre of rotation, SPECT performance, as well as other parameters that are considered critical in the internal QA programme?		Observation on-site / example records / check procedures

CHECKLIST 7. QUALITY CONTROL FOR IMAGING EQUIPMENT (cont.)

No.	Component	LC	Example of result / type of evidence
7.15	Are the most relevant QA/QC procedures for PET systems regularly checked, reviewed and recorded, including trend analysis: daily QC according to manufacturer instructions, detector normalization, two to three dimensional radioactivity concentration calibration, as well as other parameters considered critical in the internal QA programme?		Observation on-site / example records / check procedures
7.16	Are the most relevant QA/QC procedures for multimodality imaging systems regularly checked, reviewed — including trend analysis — and recorded: all parameters listed in 7.14 or 7.15, computed tomography (CT) parameters (CT number, image uniformity, image noise, image artefacts, high contrast modulation), CT radiation dose, image registration and other parameters that are considered critical in the internal QA programme?		Observation on-site / example records / check procedures
7.17	Do QA/QC SOPs include specific instructions on corrective actions in the case of non-conforming results?		Check SOPs

Note: LC: level of conformance (range 0–4). 0: absent or inappropriate; 1: planned or approximate; 2: partial conformance or partial implementation; 3: near full conformance or near full implementation; 4: full conformance or full implementation.

3.9. COMPUTER SYSTEMS AND DATA HANDLING

Computers have been central to the practice of NM for many years, as the extraction of functional information commonly requires patient image analysis. Checklist 8 evaluates aspects of computer systems and data handling.

CHECKLIST 8. COMPUTER SYSTEMS AND DATA HANDLING

No.	Component	LC	Example of result / type of evidence
8.1	Are written policies available for specifying, procuring and testing new Radiology Information System, picture archiving and communication systems (PACSs) and image processing and analysis workstations?		Check the procedure
8.2	Do these policies require certification of all equipment that will be acquired (e.g. CE mark, United States Food and Drug Administration clearance or approval by a national authority)?		Check the procedure
8.3	Are the above policies in line with recommendations made in IAEA / International Electrotechnical / National Electrical Manufacturers Association publications?		Check the procedure
8.4	Is an independent assessment of the performance of the actual delivered equipment performed and documented against specifications of the tender?		Observation on-site / example records / check the procedure
8.5	Is there a policy for security assessment of all information technology systems (against viruses, intruders, etc.)?		Check the procedure
8.6	Is there a policy for ensuring integrity, security and privacy of data, including remote access?		Check the procedure
8.7	For PACSs, is there a standard operating procedure (SOP) available for monitoring and correcting mismatches between image files and patient data and/or other non-conforming situations?		Observation on-site / example records / check the procedure
8.8	For PACSs, is there an SOP for quality assurance / quality control of image display monitors?		Observation on-site / example records / check the procedure

CHECKLIST 8. COMPUTER SYSTEMS AND DATA HANDLING (cont.)

No.	Component	LC	Example of result / type of evidence
8.9	Is there a policy to ensure consistency of data acquisition, processing and analysis protocols after major software revisions, also taking into account any site customization?		Check the procedure
8.10	Is there a policy available on quality management of 'in-house' or non-registered software intended to support clinical use?		Observation on-site / example records / check the procedure
8.11	Is there a policy for granting backup and maintaining patient data files?		Check the procedure

Note: LC: level of conformance (range 0–4). 0: absent or inappropriate; 1: planned or approximate; 2: partial conformance or partial implementation; 3: near full conformance or near full implementation; 4: full conformance or full implementation.

3.10. GENERAL DIAGNOSTIC CLINICAL SERVICES

The conformance of general diagnostic clinical services requirements is essential to ensure the safety and efficacy of imaging and non-imaging procedures in NM practice. Checklist 9 evaluates aspects of these services.

CHECKLIST 9. GENERAL DIAGNOSTIC CLINICAL SERVICES

No.	Component	LC	Example of result / type of evidence
9.1	Are written standard operating procedures (SOPs) based on national/international guidelines in place for all types of examinations performed?		Check clinical SOPs or the procedure manual
9.2	Is a mechanism in place to regularly update internal SOPs according to national/international guidelines and medical evidence?		Written documents describing the mechanism to update clinical SOPs

CHECKLIST 9. GENERAL DIAGNOSTIC CLINICAL SERVICES (cont.)

No.	Component	LC	Example of result / type of evidence
9.3	Is there an SOP on document distribution ensuring that only the most recent manual containing the complete description of all procedures is available at all work places?		Check SOPs for document distribution and check distributed documents
9.4	Is there an SOP to ensure that all staff are aware of this manual and familiar with its use?		Check the SOP/observation on-site
9.5	Is every request checked for justification, and approved by a nuclear medicine (NM) physician?		Check some records, including authorization of the NM physician
9.6	Are instructions in place to check for contraindications preventing the examination or parts of it?		Check instructions / observation on-site
9.7	Are procedures in place for correct identification of patients throughout all steps of the examination?		Check procedures for identifying patients during examinations / observation on-site
9.8	Are instructions for patient preparation given at the time of appointment and before the examination is performed?		Check written instructions
9.9	Are patients' privacy and intimacy maintained during their visits to the nuclear medicine service (NMS) (e.g. appropriate coverage of women's chests during stress test)?		Observation on-site
9.10	Is a procedure in place to enquire about pregnancy and lactation before any administration of radiopharmaceuticals?		Check the written procedure
9.11	Does every patient receive appropriate information (written/oral, according to national/local regulations) related to the examination including risk evaluation, preparation and aftercare details (if applicable) before giving informed consent?		Check written procedures describing information provided to patients

CHECKLIST 9. GENERAL DIAGNOSTIC CLINICAL SERVICES (cont.)

No.	Component	LC	Example of result / type of evidence
9.12	Do all procedure protocols (SOPs) also include detailed information on radiopharmaceuticals, computed tomography settings and contrast media, if applicable?		Check SOPs
9.13	Is the radiopharmaceutical dose clearly identified in relation to the individual patient and is traceability ensured?		Check the instruction for dose assignments and traceability
9.14	Are there instructions to optimize radiopharmaceutical activity according to body habitus (e.g. weight), with special attention to paediatric patients (e.g. European Association of Nuclear Medicine dosing card, Society of Nuclear Medicine Consensus Guidelines)?		Check the instruction for dose assignments and patient records
9.15	Are procedures in place to avoid misadministration of radioactive and non-radioactive pharmaceuticals?		Check written procedures
9.16	Is there an SOP available for dealing with administration of non-licensed or off label radiopharmaceuticals?		Check procedures
9.17	Is an SOP in place to deal with emergency requests?		Check the SOP
9.18	Is there a process to ensure that physicians or appropriate staff are available to answer patient questions?		Check written documents establishing the availability of medical doctors to answer patient questions
9.19	Are there SOPs for specific measures applicable to paediatric patients (e.g. inserting intravenous lines, sedation, anaesthesia, bladder catheters, pharmacological challenges, etc.)?		Check SOPs

CHECKLIST 9. GENERAL DIAGNOSTIC CLINICAL SERVICES (cont.)

No.	Component	LC	Example of result / type of evidence
9.20	Is appropriate medical supervision available during NM interventions such as diuretics, ACE (angiotensin converting enzyme) inhibitors, stress testing, etc.?		Check clinical SOPs
9.21	Are procedures in place to properly address and report any adverse event?		Check written procedures
9.22	Are procedures in place to timely report any finding that is potentially critical for appropriate patient management to the referring physician?		Check written procedures
9.23	Is there a policy on surveillance of patients during their presence in the NMS, including preparation and waiting times?		Check written procedures / observation on-site
9.24	Are a fully equipped emergency cart, oxygen and suction pump available?		Check available equipment
9.25	Is there an SOP to ensure that the emergency cart is checked and replenished on a regular basis?		Check the SOP
9.26	Are staff trained in basic life support and use of available equipment?		See SOP and check a record (personnel file)
9.27	Is there a regular update of training in basic and advanced life support, as appropriate?		See SOP and check a record (personnel file)
9.28	Are procedures in place for obtaining rapid assistance in case of emergency? Are corresponding phone numbers readily displayed?		Check written procedures / observation on-site
9.29	Is a mechanism for incident reporting and consecutive introduction of corrective actions in place?		Check the written procedure describing the mechanism

CHECKLIST 9. GENERAL DIAGNOSTIC CLINICAL SERVICES (cont.)

No.	Component	LC	Example of result / type of evidence
9.30	Is there a procedure in place to document additional information and/or feedback received after the examination was performed/reported?		Check the written procedure
9.31	Is there an SOP to regularly review the number of and reasons for repeated NM examinations?		Check the SOP

Note: LC: level of conformance (range 0–4). 0: absent or inappropriate; 1: planned or approximate; 2: partial conformance or partial implementation; 3: near full conformance or near full implementation; 4: full conformance or full implementation.

3.11. ASSESSMENT OF DIAGNOSTIC IMAGING PROCEDURES

The auditing team has to assess up to five files of patients who have undergone a diagnostic imaging procedure that is both frequently performed in the service and relevant. Clinical information, technical aspects and procedures, patient preparation, related QA/QC information and traceability, reporting and follow-up will be considered. The results of each of these items are scored according to the scheme introduced in Section 2.5.4 and presented as a radar plot. Cases should be randomly selected from current or archived files. Checklist 10 evaluates aspects of diagnostic imaging procedures.

CHECKLIST 10. ASSESSMENT OF DIAGNOSTIC IMAGING PROCEDURES

No.	Component	LC	Example of result / type of evidence
	Clinical		
10.1	Was relevant clinical information available as detailed in the corresponding standard operating procedure (SOP)?		Check records / check SOPs

CHECKLIST 10. ASSESSMENT OF DIAGNOSTIC IMAGING PROCEDURES (cont.)

No.	Component	LC	Example of result / type of evidence
10.2	Were contraindications and allergies, including to contrast media (if applicable), checked for?		Check records
10.3	If the procedure was different from that specified in the SOP, was the deviation noted and justified?		Check records / check SOPs
10.4	Was the availability of other imaging (radiology and nuclear medicine) and laboratory results checked for?		Check records
	Technical procedure: Check if done according to the SOP		
10.5	Scanner set-up (imaging device, collimator, energy window settings, as applicable)		Check records / check SOPs
10.6	Radiopharmaceutical and activity administered		Check records / check SOPs
10.7	If contrast medium was used: type, concentration, administration route, injection speed if IV		Check records / check SOPs
10.8	Acquisition parameters (time from administration, positioning, acquisition mode, matrix) concordant to the SOP		Check records / check SOPs
10.9	Computed tomography parameters, if applicable		Check records / check SOPs
10.10	Data processing and archiving		Check records / check SOPs
	Patient preparation: Check if done according to the SOP		
10.11	Patient identification		Check records / check SOPs
10.12	Current medication / date of last chemotherapy / date of end of radiotherapy		Check records / check SOPs

CHECKLIST 10. ASSESSMENT OF DIAGNOSTIC IMAGING PROCEDURES (cont.)

No.	Component	LC	Example of result / type of evidence
10.13	Patient condition and/or treatment related interference with the procedure? If yes, note in the comments section		Check records / check SOPs
10.14	Study preparation		Check records / check SOPs
10.15	Exclusion of pregnancy, information on lactation and counselling, if applicable		Check records / check SOPs
10.16	For paediatric patients: dose adjustment (radiopharmaceuticals, other medication), sedation, etc.		Check records / check SOPs
10.17	Patient positioning and containment		Check records / check SOPs
	Quality assurance (QA) / quality control (QC): Check if done according to the SOP		
10.18	QC of the radiopharmaceutical(s)		Check records / check SOPs
10.19	Documentation of QC in case of external procurement of radiopharmaceutical		Check records / check SOPs
10.20	Latest QC of imaging equipment relevant for the specific examination		Check records / check SOPs
10.21	Check and account for extravasation (infiltration) at the injection site		Check records / check SOPs
10.22	QC of processing parameters and analysis		Check records / check SOPs
10.23	Overall quality of images, e.g. patient movement, regions of interest, gating		Check records / check SOPs
10.24	Overall quality and adequacy of images for distribution to the referring physician		Check records / check SOPs

CHECKLIST 10. ASSESSMENT OF DIAGNOSTIC IMAGING PROCEDURES (cont.)

No.	Component	LC	Example of result / type of evidence
10.25	Traceability of all patient related data, e.g. radiopharmaceutical, administered activity and injection site, acquisition parameters, name of technologist and doctor in charge		Observation on-site / check all records showing traceability
10.26	Filing of batch number, dosing and time of administration of any study related pharmaceutical		Check records
10.27	Handling and documentation of any adverse event or other incident (patient related or not)		Check records
	Reporting and follow-up		
10.28	Was the report structured as requested in the SOP?		Check records / check SOPs
10.29	Does the final report address the clinical question?		Check records
10.30	Was any feedback received after reporting properly documented and managed?		Check records

Note: LC: level of conformance (range 0–4). 0: absent or inappropriate; 1: planned or approximate; 2: partial conformance or partial implementation; 3: near full conformance or near full implementation; 4: full conformance or full implementation.

3.11.1. Summary of imaging procedures

A radar plot will be produced for analysis of clinical observations using the scheme described in Section 2.5.4 (Fig. 5).

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QUALITY MANAGEMENT AUDITS IN NUCLEAR MEDICINE

OVERALL SCORE OF IMAGING DIAGNOSTIC PROCEDURES

Based on the evaluation of spreadsheets #10.1 through 10.5 on up to 5 most frequent diagnostic procedures

Evaluated parameters	Enter title of imaging procedure 1		Enter title of imaging procedure 2		Enter title of imaging procedure 3		Enter title of imaging procedure 4		Enter title of imaging procedure 5		Average	Lowest result
	% Scoring	NC	% Scoring	NC	% Scoring	NC	% Scoring	NC	% Scoring	NC	% Scoring	% Scoring
CLINICAL	68.8	2	75.0	1	0.0	0	0.0	0	0.0	0	71.9	68.8
TECHNICAL/PROCEDURE	70.8	2	54.2	3	0.0	0	0.0	0	0.0	0	62.5	54.2
PATIENT PREPARATION	60.7	4	67.9	3	0.0	0	0.0	0	0.0	0	64.3	60.7
QA/QC	65.0	5	60.0	4	0.0	0	0.0	0	0.0	0	62.5	60.0
REPORTING AND FOLLOW-UP	66.7	1	41.7	2	0.0	0	0.0	0	0.0	0	54.2	41.7

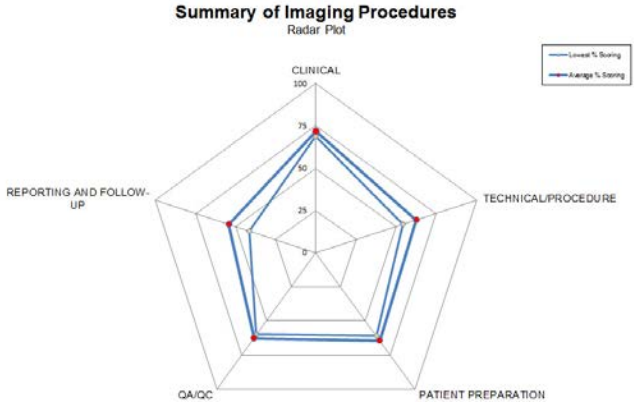

FIG. 5. Summary and radar plot of the assessment of diagnostic imaging procedures (example). NC: Non-conformance; QA: quality assurance; QC: quality control.

3.12. ASSESSMENT OF NON-IMAGING DIAGNOSTIC PROCEDURES

The auditing team has to assess up to three files of patients who have undergone a diagnostic imaging procedure that is both frequently performed in the service and relevant. Clinical information, technical aspects and procedures, patient preparation, related QA/QC information and traceability, reporting and follow-up will be considered. The results of each of these items are scored according to the scheme introduced in Section 2.5.4 and presented as a radar plot. Cases should be randomly selected from current or archived files. Checklist 11 evaluates aspects of non-imaging diagnostic procedures.

CHECKLIST 11. ASSESSMENT OF NON-IMAGING DIAGNOSTIC PROCEDURES

No.	Component	LC	Example of result / type of evidence
	Clinical		
11.1	Was the relevant clinical information available as detailed in the corresponding standard operating procedure (SOP)?		Check records / check SOPs
11.2	Were contraindications and allergies checked for?		Check records
11.3	If the procedure was different from the one specified in the SOP, was the deviation noted and justified?		Check records / check SOPs
	Technical procedure: Check if done according to the SOP		
11.4	Probe/well counter settings		Check records / check SOPs
11.5	Radiopharmaceutical, labelled cells, activity		Check records / check SOPs
11.6	Sampling/acquisition parameters: timing, positioning		Check records / check SOPs
11.7	Processing, archiving		Check records / check SOPs
	Patient preparation: Check if done according to the SOP		
11.8	Patient identification		Check records / check SOPs
11.9	Patient condition and/or treatment related interference with the procedure		Check records / check SOPs
11.10	Study preparation		Check records / check SOPs
11.11	Exclusion of pregnancy, information on lactation and counselling, if applicable		Check records / check SOPs

CHECKLIST 11. ASSESSMENT OF NON-IMAGING DIAGNOSTIC PROCEDURES (cont.)

No.	Component	LC	Example of result / type of evidence
11.12	For paediatric patients: dose adjustment (radiopharmaceuticals, other medication), sedation, etc.		Check records / check SOPs
	Quality assurance (QA) / quality control (QC): Check if done according to the SOP		
11.13	QC of the radiopharmaceutical(s) or labelled blood cells, including standard and background		Check records / check SOPs
11.14	Documentation of QC in case of external procurement of radiopharmaceutical		Check records / check SOPs
11.15	Latest QC of the probe / well counter relevant for the specific examination		Check records / check SOPs
11.16	Check for extravasation (infiltration) at the injection site		Check records / check SOPs
11.17	QC of processing parameters including cross-checking calculations, standards and controls		Check records / check SOPs
11.18	Traceability of all patient related data, e.g. radiopharmaceutical, administered activity and injection site, acquisition parameters, sampling conditions, name of technologist and doctor in charge		Observation on-site / check all records showing traceability
11.19	Handling and documentation of any adverse event or other incident (patient related or not)		Check records / check SOPs
	Reporting and follow-up		
11.20	Was the report structured as requested in the SOP, including trends if appropriate?		Check the report / check SOPs

CHECKLIST 11. ASSESSMENT OF NON-IMAGING DIAGNOSTIC PROCEDURES (cont.)

No.	Component	LC	Example of result / type of evidence
11.21	Does the final report address the clinical question, if appropriate?		Check the report and records
11.22	Was any feedback received after reporting properly documented and managed?		Check records

Note: LC: level of conformance (range 0–4). 0: absent or inappropriate; 1: planned or approximate; 2: partial conformance or partial implementation; 3: near full conformance or near full implementation; 4: full conformance or full implementation.

3.12.1. Summary of non-imaging procedures

A radar plot will be produced for analysis of clinical observations using the scheme described in Section 2.5.4 (Fig. 6).

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QUALITY MANAGEMENT AUDITS IN NUCLEAR MEDICINE

OVERALL SCORE OF NON-IMAGING DIAGNOSTIC PROCEDURES

Based on the evaluation of spreadsheets #11.1 through 11.3 on up to 3 most frequent diagnostic procedures

Evaluated parameters	Enter title of non-imaging procedure 1		Enter title of non-imaging procedure 2		Enter title of non-imaging procedure 3		Average	Lowest result
	% Scoring	NC	% Scoring	NC	% Scoring	NC	% Scoring	% Scoring
CLINICAL	58.3	1	75.0	1	0.0	0	66.7	58.3
TECHNICAL/PROCEDURE	75.0	2	62.5	2	0.0	0	68.8	62.5
PATIENT PREPARATION	65.0	2	45.0	4	0.0	0	55.0	45.0
QA/QC	67.9	2	67.9	3	0.0	0	67.9	67.9
REPORTING AND FOLLOW-UP	66.7	1	75.0	0	0.0	0	70.8	66.7

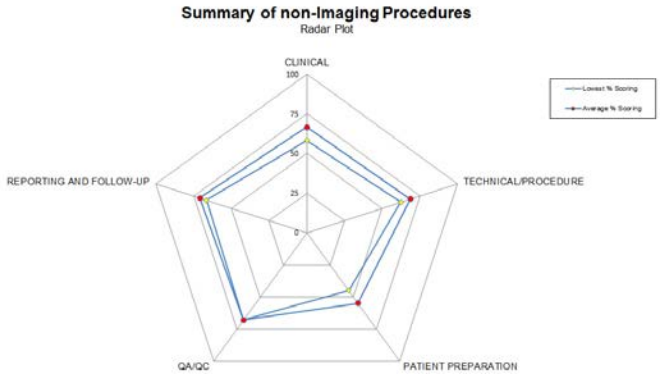

FIG. 6. Summary and radar plot of the assessment of diagnostic non-imaging procedures (example). NC: Non-conformance; QA: quality assurance; QC: quality control.

3.13. GENERAL RADIONUCLIDE THERAPY

Checklist 12 reviews essential aspects of the radionuclide therapy service.

CHECKLIST 12. GENERAL RADIONUCLIDE THERAPY

No.	Component	LC	Example of result / type of evidence
12.1	Are written standard operating procedures (SOPs) based on national/international guidelines available for any type of treatment?		Check SOPs for radionuclide therapy
12.2	Has the decision to treat been taken after multidisciplinary evaluation of the patient's condition and fully approved by the nuclear medicine (NM) physician in charge of treatment?		Check patient records
12.3	Are SOPs available for patient preparation regarding all types of treatment?		Check instructions or SOPs for patient preparation
12.4	Are contraindications (e.g. allergies) and other conditions (medical, psychological, social) potentially interfering with the treatment checked for?		Check SOPs, instructions and patient records
12.5	Does every patient receive appropriate information about the treatment, including indication, other treatment options, expected/possible early and late side effects, preparation, detailed therapy procedure, hospitalization and isolation, if applicable, and aftercare?		Check procedures and information provided to patients before and after therapy
12.6	For paediatric patients, were relatives/caregivers clearly informed about radioprotection measures to be taken and risks inherent with attending the child during therapy?		Observation on-site / check therapeutic procedures / check written instructions

CHECKLIST 12. GENERAL RADIONUCLIDE THERAPY (cont.)

No.	Component	LC	Example of result / type of evidence
12.7	Is an SOP in place to rule out pregnancy and to deal with lactation before therapy?		Check the SOP
12.8	Does patient information include instructions on necessity and duration of ongoing contraception after therapy?		Check written instructions to patients
12.9	Are procedures in place to describe the process of obtaining informed consent before therapy?		Check written procedures of obtaining informed consent
12.10	Is there a written SOP describing the procurement, preparation and quality control, if applicable, of therapeutic radiopharmaceuticals/radionuclides?		Check written SOPs
12.11	Is the therapeutic activity prescribed taking into account the target and non-target dose estimated by a medical physicist, NM physician or equivalent specialist, in accordance with national/international guidelines?		Check SOPs for activity assignments
12.12	Is the administered activity individually measured and checked in an activity meter that has been specifically calibrated and quality checked for the given radionuclide?		Check records
12.13	In the case of in-patient therapy, are designated facilities (with appropriate surface, shielding, sanitation, ventilation, etc.) available?		Observation on-site
12.14	In the case of in-patient therapy, are SOPs and appropriate radioprotection measures (concerning caregivers and public, contamination, transport, waste, etc.) in place?		Check SOPs and written documents / observation on-site

CHECKLIST 12. GENERAL RADIONUCLIDE THERAPY (cont.)

No.	Component	LC	Example of result / type of evidence
12.15	In the case of in-patient therapy, is 24 h/d nursing care provided?		Check SOPs and written documents / observation on-site
12.16	Have the nursing staff received appropriate training in radiation science and radiation protection to take care of patients during treatment with radiopharmaceuticals?		Check corresponding SOPs and nurse personnel files
12.17	In the case of in-patient therapy, are qualified staff accessible for managing medical emergency situations 24 h/d?		Observation on-site / check SOPs and the organizational chart
12.18	In the case of in-patient therapy, is a qualified person available outside normal working hours to handle urgent radioprotection issues?		Observation on-site / check SOPs and the organizational chart
12.19	Do SOPs provide clear instructions for discharging patients in accordance with national regulations?		Check SOPs
12.20	Is patient activity / emitted dose rate measured and recorded in the patient file before discharge from the nuclear medicine service?		Check the written instruction / check patient records
12.21	Are written instructions available for the patient and family/caregivers after discharge?		Check written instructions / check patient records
12.22	Are procedures in place to ensure that these instructions have been understood by the patient/family/caregivers?		Check the SOP
12.23	Are there specific SOPs dealing with misadministration of therapeutic radiopharmaceuticals?		Check the SOP

CHECKLIST 12. GENERAL RADIONUCLIDE THERAPY (cont.)

No.	Component	LC	Example of result / type of evidence
12.24	Is a comprehensive treatment report issued and made available to all involved physicians and, if applicable, to patients?		Check an example of a report
12.25	Is multidisciplinary clinical follow-up of patients provided?		Check a patient record

Note: LC: level of conformance (range 0–4). 0: absent or inappropriate; 1: planned or approximate; 2: partial conformance or partial implementation; 3: near full conformance or near full implementation; 4: full conformance or full implementation.

3.14. ASSESSMENT OF THERAPY

The auditing team has to assess up to three files of patients who have undergone a diagnostic imaging procedure that is both frequently performed in the service and relevant. Clinical information, technical aspects and procedures, patient preparation, related QA/QC information and traceability, reporting and follow-up will be considered. The results of each of these items are scored according to the scheme introduced in Section 2.5.4 and presented as a radar plot. Cases should be randomly selected from current or archived files. Checklist 13 evaluates aspects of therapeutic procedures.

CHECKLIST 13. ASSESSMENT OF THERAPY

No.	Component	LC	Example of result / type of evidence
	Clinical		
13.1	Was the decision to treat this patient based on national/international guidelines?		Check records / check SOPs / check related international guidelines
13.2	Was the appropriateness of this therapy based on a multidisciplinary evaluation and formally approved by the physician in charge of treatment?		Check patient records

CHECKLIST 13. ASSESSMENT OF THERAPY (cont.)

No.	Component	LC	Example of result / type of evidence
13.3	Have other issues (patient condition, allergies, concurrent diseases, socioeconomic issues, etc.) possibly interfering with or contraindicating the radionuclide therapy been identified?		Check patient records / check SOPs
13.4	Were results of all relevant diagnostic procedures available?		Check records / observation on-site
13.5	Was information about previous treatments (including previous radionuclide therapy) available?		Check records
13.6	Was information about ongoing medical therapy available and checked for any potential interference with the current radionuclide therapy?		Check records
Technical procedure: Check if done according to the standard operating procedure (SOP)			
13.7	Has the patient been identified according to the SOP?		Check records / check SOPs
13.8	Was the correct radiopharmaceutical prescribed and was the activity based on the estimated dose to target and non-target tissues?		Check records / check SOPs
13.9	Was the activity measured before administration?		Check records
13.10	Was the procedure to avoid misadministration of the radiopharmaceutical followed?		Check records / check SOPs
13.11	Was pregnancy/lactation excluded and understanding of information concerning subsequent contraception checked?		Check records

CHECKLIST 13. ASSESSMENT OF THERAPY (cont.)

No.	Component	LC	Example of result / type of evidence
13.12	Was imaging performed, if appropriate, to check the biodistribution of the radiopharmaceutical?		Check records
Patient preparation: Check if done according to the SOP			
13.13	Has the patient been fully informed and has consent been obtained as described?		Check records / check SOPs / observation on-site
13.14	Were instructions concerning treatment related medical therapy (hormones, bisphosphonates, calcium, thyroid blocking medications, etc.) and any other preparations (hydration, fasting, etc.) given?		Check records / check SOPs / observation on-site
13.15	Was patient condition and/or treatment related interference with the procedure checked?		Check records / check SOPs
13.16	Were patients instructed on the necessity of avoiding pregnancy during and for a specified time after therapy? Was relevant counselling on lactation given?		Check records / check SOPs
13.17	For paediatric patients, were relatives/caregivers appropriately informed about radiation protection issues?		Check records / check SOPs
Quality assurance (QA) / quality control (QC): Check if done according to the SOP			
13.18	Patient preparation ascertained		Check records / observation on-site
13.19	Documentation of QC of the radiopharmaceutical including in the case of external procurement		Check records / check SOPs

CHECKLIST 13. ASSESSMENT OF THERAPY (cont.)

No.	Component	LC	Example of result / type of evidence
13.20	Filing of batch number, dosing and time of administration of any therapy related pharmaceutical		Check records
13.21	Handling and documentation of any incidents (spilling, extravasation at the injection site, vomiting, etc.) or adverse events (patient related or not)		Check records / check SOPs
13.22	Traceability of all patient related data, e.g. radiopharmaceutical, administered activity and injection site (if applicable), name of technologist and doctor in charge		Observation on-site / check all records showing traceability
	Reporting and follow-up		
13.23	Was a comprehensive treatment report issued and made available to all involved parties?		Check the report / check SOPs
13.24	Was the report drafted as specified in the relevant SOP?		Check the report / check SOPs
13.25	Was any feedback received after therapy properly documented and managed?		Check records / check SOPs

Note: LC: level of conformance (range 0–4). 0: absent or inappropriate; 1: planned or approximate; 2: partial conformance or partial implementation; 3: near full conformance or near full implementation; 4: full conformance or full implementation.

3.14.1. Summary of therapeutic procedures

A radar plot will be produced for analysis of clinical observations using the scheme described in Section 2.5.4. Figure 7 shows such a radar plot. The corresponding scores for the therapeutic procedures are shown in Table 3.

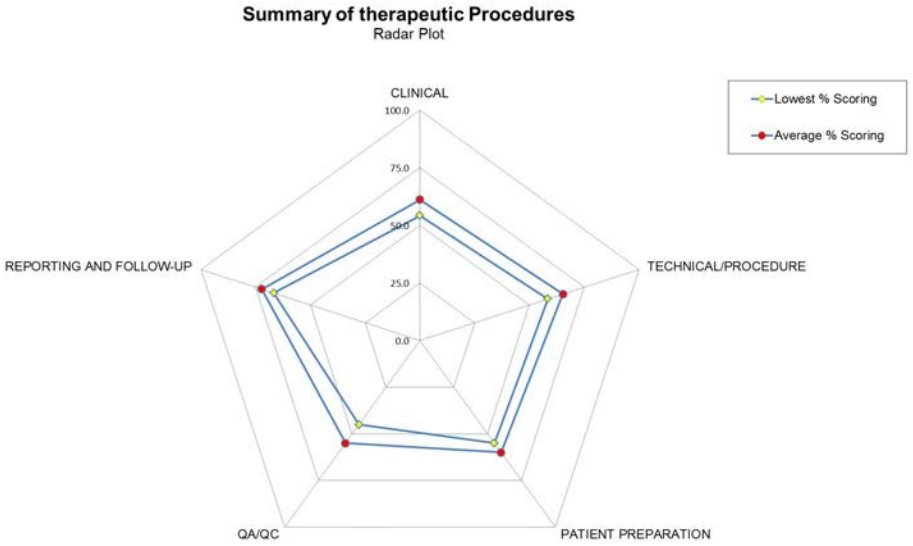

FIG. 7. Summary and radar plot of the assessment of therapeutic procedures (example). NC: non-conformance; QA: quality assurance; QC: quality control.

TABLE 3. OVERALL SCORES FOR THERAPEUTIC PROCEDURES

Evaluated parameters	Title of therapeutic procedure 1		Title of therapeutic procedure 2		Title of therapeutic procedure 3		Average	Lowest result
	% Scoring	NC	% Scoring	NC	% Scoring	NC	% Scoring	% Scoring
Clinical	54.2	4	70.8	2	58.3	3	61.1	54.2
Technical/procedure	58.3	3	66.7	3	70.8	3	65.3	58.3
Patient preparation	65.0	1	60.0	1	55.0	3	60.0	55.0
QA/QC	50.0	3	45.0	4	70.0	2	55.0	45.0
Reporting and follow-up	75.0	1	66.7	1	75.0	0	72.2	66.7

3.15. RADIOPHARMACY

The range of facilities required varies markedly, depending on the operational category of the laboratory. The radiopharmacy requires the equipment necessary to provide radiopharmaceuticals of the desired quality for patient administration. The facilities should be adapted to suit the radioactive nature of the product and the fact that many radiopharmaceuticals are injectable and therefore need to be sterile. The radiopharmacy also requires QC procedures, as well as areas for receipt and storage of radioactive materials and for the storage of radioactive waste prior to its disposal. Whatever functions are performed, it is crucial that laboratories offer protection to the operator, the product and the environment.

The operator needs to be protected from radiation emitted by the products, and facilities must minimize both external radiation hazards and internal hazards arising from unintended ingestion of radioactive materials, particularly via the inhalation of volatile products. In addition, there may be chemical hazards arising from the product. In situations where blood labelling is performed, there is a potential biological hazard to the operator.

The product needs protection from unintended contamination arising during its preparation. This contamination may be chemical, radionuclide, particulate or microbial.

The environment needs to be protected from unintentional discharges of radioactive material from the radiopharmacy. The majority of radioactivity handled is in the form of unsealed sources with an existing potential for accidents and spillages.

Recently, there has been greater emphasis on being proactive and developing a culture of ongoing evaluation and monitoring. This section of the audit encourages these modern, daily practices essential for safe preparation of radiopharmaceuticals.

3.15.1. Operational guidance on hospital radiopharmacy

The IAEA publication Operational Guidance on Hospital Radiopharmacy: A Safe and Effective Approach (OGHR) [3] categorizes hospital radiopharmacy (‘hot laboratory’) operations into three levels. It provides essential details (staffing, scope of operations, equipment, staff qualification, record keeping, level of QM and QC) at each operational level (Table 4).

TABLE 4. ESSENTIAL HOSPITAL RADIOPHARMACY OPERATIONAL LEVELS

Operational level	Scope
1a	All radiopharmaceuticals are procured in their final form from a recognized/authorized manufacturer or a centralized radiopharmacy. This may include unit doses or multiple dose vial radiopharmaceuticals. In any case, no further preparation is required.
1b	Radioiodine preparations, either in liquid or capsule form, are purchased from recognized/authorized manufacturers. Typically, no further compounding is required. Any dilution of the product should be undertaken within product specifications.
2a	This operational level refers to the preparation of radiopharmaceuticals from prepared and approved reagent kits, generators and radionuclides for diagnostic or therapeutic purposes (closed procedure). This is the main activity in most nuclear medicine departments, with routine use of a technetium generator and reconstitution of presterilized radiopharmaceutical cold kits.
2b	This operational level describes laboratory practices and environmental conditions necessary for safe manipulation and radiolabelling of autologous blood cells and components for reinjection into the original donor/patient.
3a	This operational level refers to compounding radiopharmaceuticals from radionuclides for diagnostic application, modification to existing commercial kits and in-house production of reagent kits from ingredients (including freeze-dried operation). Research and development falls frequently under operational level 3a.
3b	This operational level refers to compounding of radiopharmaceuticals from basic ingredients or unlicensed intermediates and radionuclides for therapeutic application (open procedure) and/or related research and development.
3c	This operational level refers to: The synthesis of positron emission tomography radiopharmaceuticals; compounding of radiopharmaceuticals produced from unauthorized or unregistered long lived generators such as (^{68}Ga) gallium or (^{188}Re) rhenium and related research and development.

This audit process is mainly designed to cover the requirements at OGHR operational levels 1 and 2. Many NMSs operate at OGHR levels 1 and 2 and do not always have a trained radiopharmacist. At OGHR operational levels 1 and 2, the prepared radiopharmaceutical products cannot be distributed beyond the hospital's boundaries. In the majority of cases, the legal oversight is provided by the physician in charge.

At OGHR operational level 3, a specialist radiopharmacist, radiochemist or a 'qualified person' is required because many specialist products and services are provided, including the management of a centralized radiopharmacy service and positron emission tomography radiopharmaceuticals. For level 3 radiopharmacy, a simplified checklist has been included in the present publication; however, owing to the complexity at this operational level, a more exhaustive audit should be performed, which is beyond the scope of this publication. Checklists 14, 15 and 16 provide criteria to evaluate the operational level of the hospital radiopharmacy.

3.16. RADIOPHARMACY OPERATIONAL LEVEL 1

CHECKLIST 14. RADIOPHARMACY OPERATIONAL LEVEL 1

No.	Component	LC	Example of result / type of evidence
	Staffing		
14.1	Is the radiopharmacy unit operated under the direction of a person with appropriate training as defined by local or national regulations?		Check the job description and the personnel card of the person in charge
14.2	Are there written staff training manuals for all grades of staff?		Check the training standard operating procedure (SOP) / check personnel files
	Facilities		
14.3	Does the unit have appropriately furnished rooms (including adequate lighting, walls, floors, ceilings and ventilation) and a shielded dispensing station?		Evaluation on-site

CHECKLIST 14. RADIOPHARMACY OPERATIONAL LEVEL 1 (cont.)

No.	Component	LC	Example of result / type of evidence
14.4	For operational level 1b, is there a well ventilated area or a shielded dispensing station for radioiodine capsules?		Evaluation on-site
14.5	Is there a shielded and validated (annual check on airflow, safety and challenge testing) fume hood with suitable filters for handling radioiodine solutions?		Check records / evaluation on-site
	Purchase of materials		
14.6	Are there suitable protocols and trained staff for the purchase of approved or authorized radiopharmaceuticals?		Check purchase SOPs / check the job description and personnel files
14.7	Are all goods received checked and recorded against the order for correctness of delivery?		Check records / check purchase SOPs
	Dispensing protocols		
14.8	Under operational level 1a, are there written procedures for the aseptic dispensing and labelling of unit doses of ready to use radiopharmaceuticals?		Check SOPs
14.9	For operational level 1b, is a shielded dispensing station and/or a fume hood available?		Evaluation on-site
14.10	Is there a fume cupboard with suitable filters for volatile radioactive materials such as I-131 solutions?		Evaluation on-site
14.11	If only radioiodine capsules are handled, is the package opened in a well ventilated area?		Evaluation on-site
14.12	For operational level 1b, do the written procedures contain clear safety and monitoring instructions for dispensing radioiodine solutions or capsules?		Check SOPs

CHECKLIST 14. RADIOPHARMACY OPERATIONAL LEVEL 1 (cont.)

No.	Component	LC	Example of result / type of evidence
14.13	Can the audit and documentation for each radiopharmaceutical batch be traced from the prescription to the actual administration of individual patient doses?		Check records / evaluation of radiopharmaceutical traceability
	Quality assurance / quality control		
14.14	Are periodic quality checks on radiopharmaceuticals performed?		Check records / check SOPs
14.15	Is there a written procedure for dealing with products that do not meet the required standards and/or for which a complaint has been received?		Check procedures
	Waste		
14.16	Are there written procedures for the disposal of radioactive and non-radioactive waste specific to the radiopharmacy?		Check procedures / observation on-site

Note: LC: level of conformance (range 0–4). 0: absent or inappropriate; 1: planned or approximate; 2: partial conformance or partial implementation; 3: near full conformance or near full implementation; 4: full conformance or full implementation.

3.17. RADIOPHARMACY OPERATIONAL LEVEL 2

CHECKLIST 15. RADIOPHARMACY OPERATIONAL LEVEL 2

No.	Component	LC	Example of result / type of evidence
	Staffing		
15.1	Is there specific staff training and assessment of competency at operational level 2, including aseptic practice?		Check the training standard operating procedure (SOP) / check personnel files
15.2	Is there training provided for staff required to perform final checks on all products prepared before release for patient use?		Check personnel files
15.3	Before release of radiolabelled red blood cell (RBC) and white blood cell (WBC) labelling, is there confirmation of training?		Check the training SOP
	Facilities		
15.4	For operational level 2, are there regular checks on validated class II type B microbiological safety cabinets located in a dedicated room?		Check records
15.5	For negative pressure isolators, before preparation takes place, are gloves or gauntlets visually inspected and integrity tests carried out and recorded?		Check records / evaluation on-site
	Preparation protocols		
15.6	In practice, have all systems of work and documentation related to radiopharmaceutical preparation and processing been formally approved?		Check approved documentation

CHECKLIST 15. RADIOPHARMACY OPERATIONAL LEVEL 2 (cont.)

No.	Component	LC	Example of result / type of evidence
15.7	Do all products, kits and generators have product approval, marketing authorization or bear a product licence number?		Check records / check the purchase SOP
15.8	Is the preparation of Tc-99m radiopharmaceuticals from kits and generators carried out in a laminar airflow cabinet?		Evaluation on-site
15.9	Can each individual patient dose be traced to a specific generator and kit batch number?		Check records / evaluation of traceability
15.10	Under operational level 2b, do the written procedures for any autologous preparation, e.g. RBCs and WBCs, include clear instructions on safety, cleaning and decontamination?		Check SOPs / observation on-site
15.11	Are there written procedures for the preparation and dispensing of radiolabelled biologicals, e.g. monoclonal antibodies, peptides from approved kit formulations?		Check procedures / observation on-site
	Quality assurance / quality control (QC)		
15.12	Are there set QC criteria prior to release for preparation before patient use?		Check procedures
15.13	Is a record of approval/release made by an authorized person before a product is administered to a patient?		Check records
15.14	For operational level 2, is Mo-99 molybdenum breakthrough measurement performed on the first eluate of each Tc-99m generator and repeated when the generator is moved?		Check procedures / check records

CHECKLIST 15. RADIOPHARMACY OPERATIONAL LEVEL 2 (cont.)

No.	Component	LC	Example of result / type of evidence
15.15	Is aluminium ion breakthrough checked on the first eluate from a Tc-99m generator?		Check procedures / check records
15.16	Before patient use, are radiochemical purity tests performed on all new batches or newly delivered radiopharmaceutical kits?		Check procedures / check records
15.17	Is there routine microbiological monitoring of preparation and aseptic dispensing areas in the radiopharmacy?		Check procedures / check records
15.18	Are changes in the use of kits, diluents or vehicles, needles, syringes, swabs and sterile containers recorded?		Check procedures / check records
15.19	Are pH tests carried out regularly?		Check procedures / check records
15.20	Are rapid alternative methods employed for swift prospective QC, e.g. for the determination of the radiochemical purity of Tc-99m-HMPAO (hexamethylpropyleneamine oxime)?		Check procedures / check records

Note: LC: level of conformance (range 0–4). 0: absent or inappropriate; 1: planned or approximate; 2: partial conformance or partial implementation; 3: near full conformance or near full implementation; 4: full conformance or full implementation.

3.18. RADIOPHARMACY OPERATIONAL LEVEL 3

CHECKLIST 16. RADIOPHARMACY OPERATIONAL LEVEL 3

No.	Component	LC	Example of result / type of evidence
	Staffing and training		
16.1	Is the radiopharmacy operational level 3 unit operated under the direction of a person with appropriate training as defined by local or national regulations?		Registered pharmacist, scientist or qualified personnel. Check the training standard operating procedure (SOP) / check personnel files
16.2	Is there specific staff training and assessment of competency at operational level 3, including understanding of contamination risk, pharmaceutical formulation, quality control (QC), validation and aseptic practice?		Check the training SOP / check personnel files
16.3	Are there appropriately trained staff members (minimum of three) for compounding of diagnostics, therapies or cold kits, or for subdispensing commercial kits and validation/release of the final product?		Check the training SOP / check personnel files
16.4	Are there independent QC staff (to those involved with production) sufficiently trained to perform final checks, batch release on all products prepared before release for patient use?		Check the training SOP / check personnel files
	Facilities		
16.5	Are there clean rooms with anteroom facilities fitted with high efficiency particulate air filters to give United States Pharmacopeia / European Union (EU) standards for use, class D for use with isolators and class C with laminar airflow (LAF) cabinet?		Check records / evaluation on-site

CHECKLIST 16. RADIOPHARMACY OPERATIONAL LEVEL 3 (cont.)

No.	Component	LC	Example of result / type of evidence
16.6	Is there a heating, ventilation and air-conditioning (HVAC) system installed and commissioned professionally? Is the HVAC under service contract?		Check records / evaluation on-site
16.7	Are these facilities and all critical equipment regularly monitored and under control (i.e. regular radiation, airflow rates, particle counts and microbial contamination monitored and documented), including micropipettes, refrigerator control and glove leak tests for isolators and hot cells?		Check records / evaluation on-site
16.8	Are there documented calibrator checks and calibration assays of each radionuclide (single photon emission computed tomography / positron emission tomography (PET) / therapeutic) with standardized sealed source or National Physical Laboratory standards (including checks on geometry, container type, etc.)? Are daily calibrator checks performed using long lived radionuclides to include the range of radioisotopes for patients?		Check records / evaluation on-site
16.9	Are weighing scales maintained contamination free and appropriate for the range of powders weighed? Are records of cleaning, routine calibration and maintenance kept?		Check records / evaluation on-site
16.10	Does terminal sterilization or dispensing take place under International Organization for Standardization standard 5, class 100 or EU grade A conditions? Are these followed by controls such as microbiological plates, broth and filter integrity tests?		Check records / evaluation on-site

CHECKLIST 16. RADIOPHARMACY OPERATIONAL LEVEL 3 (cont.)

No.	Component	LC	Example of result / type of evidence
	Operational protocols		
16.11	In practice, have all systems of work and documentation related to radiopharmaceutical preparation and processing been formally approved and controlled?		Check records
16.12	Is there a system for material management, including control and appropriate checks on all raw materials (chemicals or gas), used? If applicable, are only ingredients and reagents of pharmacopeia grade and all glassware or all components/plastics with CE mark (or equivalent) used?		Check records / evaluation on-site
16.13	Are material storage conditions specified and controlled (e.g. storage in fridge/freezer/desiccator at room temperature) and does each item have a QC traceable tag?		Check records / evaluation on-site
16.14	Are the production environmental conditions compliant for production, and is the preparation of each stage of radiopharmaceutical compounding, kit production, tracer manufacturing and generator elution carried out in an LAF cabinet or under appropriate conditions to reduce risks and bioburden?		Check records / evaluation on-site
16.15	Is each step checked and cross-checked on the working document in real time, i.e. at the time of completion of that task?		Check records / evaluation on-site

CHECKLIST 16. RADIOPHARMACY OPERATIONAL LEVEL 3 (cont.)

No.	Component	LC	Example of result / type of evidence
16.16	Can each individual patient dose and/or batch number be traced back by an operational documentation system to the starting material, equipment used, operators, specific generator and/or kit, QC processes and final release?		Check records / evaluation on-site
16.17	Are there written procedures with clear instructions on safety, cleaning, line clearance and decontamination for prevention of any cross-contamination?		Check procedure, records / evaluation on-site
16.18	Are all critical checks (including visual), changes and amendments during the process of preparation of individual radiopharmaceuticals, kits, PET modules and therapies formally controlled, approved, timed and dated?		Check records / change control documentation / evaluation on-site
16.19	Does the production document specify a nationally approved label that includes approved name, radiation dose, clear instructions for storage, licence number and precautions? Are copies of labels retained and is the total number of labels reconciled before final QC release of the batch?		Check records / evaluation on-site
16.20	Is there an independent production manager to check before batch handover to the quality controller for checking and final release to the patient?		Check records / evaluation on-site
	Quality assurance (QA) / QC		
16.21	Are there controlled and approved written procedures for QA/QC, based on pharmacopoeia methods (or equivalent validated methods)?		Check procedure, records / evaluation on-site

CHECKLIST 16. RADIOPHARMACY OPERATIONAL LEVEL 3 (cont.)

No.	Component	LC	Example of result / type of evidence
16.22	Does the quality controller independently check environmental compliance, material, documentation, equipment, operator, cleaning, etc.?		Check procedure, records / evaluation on-site
16.23	Does the quality controller independently perform all required physical checks, e.g. sample, batch size, in-process checks, radioactivity, chemicals, weights, high performance liquid chromatography, colloid, osmolality, residual solvent, pH, product appearance, labels?		Check procedure, records / evaluation on-site
16.24	Is there routine microbiological monitoring of the preparation area and the aseptic dispensing station in the radiopharmacy? Does the quality controller independently perform all required microbiological assessments, filter integrity tests, endotoxins, plate controls, end of broth, contact plates, sterility tests, etc.?		Check procedure, records / evaluation on-site
16.25	Is radionuclidic purity assessment undertaken, e.g. multichannel analysis, half-life, before patient use, including parent radionuclides from a generator, and especially for therapies?		Check procedure, records / evaluation on-site
16.26	Have all critical assessments been performed and any changes been approved by a nationally licensed individual before final patient release?		Check procedure, records / evaluation on-site
16.27	Is there a quality management system (QMS) for packing and safe transportation requirements in accordance with national and IAEA guidelines?		Check procedure, records / evaluation on-site

CHECKLIST 16. RADIOPHARMACY OPERATIONAL LEVEL 3 (cont.)

No.	Component	LC	Example of result / type of evidence
16.28	Is there timely faxing of the product release document / certificate of analysis to end users and follow-up of any deficiencies, complaints and feedback? Is there annual testing of the product recall procedure to ensure radiopharmaceuticals/PET/therapies are not administered to patients before receipt of the product release document?		Check procedure, records / evaluation on-site
16.29	Is there an annual programme of self-assessment and audit of the QMS at radiopharmacy operational level 3?		Check procedure, records / evaluation on-site
16.30	Are there proper United Nations waste disposal practices, including separate lead shielding for radioactive waste, waste container for solvents and biological waste?		Check procedure, records / evaluation on-site

Note: LC: level of conformance (range 0–4). 0: absent or inappropriate; 1: planned or approximate; 2: partial conformance or partial implementation; 3: near full conformance or near full implementation; 4: full conformance or full implementation.

3.19. HORMONE AND TUMOUR MARKERS

This audit section focuses on the clinical use of hormones and tumour markers for NMSs using radioimmunoassay. This audit is performed from the patient's perspective and is therefore divided into three components: pre-analytical, analytical and post-analytical. Checklist 17 evaluates the clinical use of hormones and tumour markers.

CHECKLIST 17. HORMONE AND TUMOUR MARKERS

No.	Component	LC	Example of result / type of evidence
	Good laboratory practices		
17.1	Does the radioimmunoassay service have formal authorization from a recognized national authority?		Check written authorization from the national authority
17.2	Is there a clear written protocol for using all radioimmunoassay, IRMA (immunoradiometric assay), ELISA (enzyme linked immunosorbent assay) analytes used in the laboratory?		Check the written protocol
17.3	Is there a clear protocol stating the action required in a follow-up of suspected result errors in the laboratory?		Check the protocol
17.4	Is there a mechanism to check why its recent results are 20% lower, while all previous results have all been within 10% of the target?		Check the mechanism
17.5	Is there a mechanism to follow-up random errors, e.g. wrong sample on analyser, wrong specimen assayed, wrong result reported by accident?		Check the mechanism
17.6	Is there a mechanism to double check records of reported ‘undetectables’ when the expected result would have been clinically significant?		Check the mechanism
	Pre-analytical phase		
17.7	Is there a procedure to follow when the clinical user does not provide the necessary information or the correct specimen?		Check the procedure

CHECKLIST 17. HORMONE AND TUMOUR MARKERS (cont.)

No.	Component	LC	Example of result / type of evidence
17.8	Is there a periodic review to prevent pre-analytical errors, e.g. use of inappropriate specimen collection tubes, specimen mix-ups, incorrectly labelled or mixed up requests from the requesting unit or laboratory?		Check records
17.9	Is there a periodic review of the appropriateness and integrity of the sample transport system?		Check records
17.10	Is there a periodic review to ensure that the confidentiality of patient results is guaranteed?		Check records
17.11	Is there a periodic review to ensure biological safety?		Check records
	Analytical phase		
17.12	Are there records of regression line analyses with a known amount of the international standard in serum?		Check records
17.13	Are there records of recovery experiments to validate a new method?		Check records
17.14	For each type of assay and/or each type of data set, is there a record of calculated mean, standard deviations and coefficient of variation?		Check records
17.15	Is there a Levey-Jennings plot, including controls and standards for each assay?		Check records

CHECKLIST 17. HORMONE AND TUMOUR MARKERS (cont.)

No.	Component	LC	Example of result / type of evidence
17.16	Is there a clear written protocol when points are outside the 2 standard deviation limits?		Check the written protocol
17.17	Is there a system in place to guarantee safe disposal of samples and are samples treated as infectious waste?		Observation on-site
	Post-analytical phase		
17.18	Is there a standard format for reporting laboratory results that includes the laboratory's name, patient details, requesting person, test description, sample type (serum, urine, etc.), results (plus reference values), interpretative comments (if any) and signature of authorized professional?		Check procedures / check reports
17.19	Is there a list of authorized staff members who are designated to amend patient notes or reports and for communicating results?		Check procedures / check reports
17.20	Are reference values based on national or regional findings available for each assay type?		Check written procedures
17.21	Is feedback from clinical interpretative services documented?		Check records

Note: LC: level of conformance (range 0–4). 0: absent or inappropriate; 1: planned or approximate; 2: partial conformance or partial implementation; 3: near full conformance or near full implementation; 4: full conformance or full implementation.

3.19.1. General radar plot

The overall results of the audit will be summarized and shown in a radar plot using the tool described in Section 2.5.2 (Fig. 3).

4. AUDIT REPORT

4.1. PRIORITIZATION OF NON-CONFORMANCES

Prioritization of non-conformances is important, and in this publication, three levels of prioritization are considered: 'critical', 'major' and 'minor' (see Sections 1.8 and 2.5.5). Figure 8 shows an example grid for recording non-conformances according to their priority.

Critical priority: Issues affecting the safety of the patients, staff, caregivers and/or environment that should be promptly addressed (within days or weeks).

Major priority: Issues affecting the capacity of the NMS to adequately perform its activities that should be addressed in a timely manner (e.g. 3–6 months).

Minor priority: Issues that may be the object of optimization, to be accomplished within a defined time period and re-evaluated during the next audit.

4.2. AUDIT REPORT CONTENTS

Standardized audit reports are essential to all stakeholders; some guidance is provided in Table 5.

Issues of critical priority			
No.	Comment/action	Time frame	Date achieved

Issues of major priority			
No.	Comment/action	Time frame	Date achieved

Issues of minor priority			
No.	Comment/action	Time frame	Date achieved

FIG. 8. Example grid for recording non-conformances according to their priority.

TABLE 5. CONTENTS OF A STANDARDIZED AUDIT REPORT

Contents	Checkboxes for audit report compiler	Comments
Introduction	□	Background, demographics, public health system, national funding
Terms of reference	□	Activities of the auditing team
Quality management	□	Mission, vision, quality policy, documental system
Regulatory authority and regulations	□	Licences
Radiation safety	□	Radiation protection and safety programme, radiation worker personal doses and area monitoring records, calibration certificates
Nuclear medicine premises	□	Overall space, floor plan, furniture, ventilation system, toilets, laboratories
Human resources	□	Staffing, organizational chart, education and training, competences, job descriptions
Equipment	□	Imaging and ancillary equipment, computer systems and data handling, quality assurance / quality control of equipment
Clinical nuclear medicine	□	Requests, examples of imaging and non-imaging procedures and therapy, one example of a patient consent form
Radiopharmacy	□	Performance indicators related to IAEA publications
Radioimmunoassay services	□	Good laboratory practices, pre-analytical, analytical and post-analytical

TABLE 5. CONTENTS OF A STANDARDIZED AUDIT REPORT (cont.)

Contents	Checkboxes for audit report compiler	Comments
Major strengths and deficiencies	□	Major strengths should be listed; any deficiencies should be recorded in the audit process, with an indication on how and when improvements will be achieved
Recommendations	□	These should be precise and clearly worded to the nuclear medicine service or according to IAEA instructions
Annexes	□	

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Consultants Meetings

Vienna, Austria: 7–11 May 2012, 20–22 February 2013, 8–10 July 2013

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The quality management audit methodology for nuclear medicine practice, which is introduced in this publication, is designed to be applied in a variety of economic circumstances. A key outcome of the methodology is the creation of a culture of reviewing all the processes of the clinical service for continuous improvement in nuclear medicine practice. Regular quality audits and assessments are vital for modern nuclear medicine services. More importantly, the entire quality management and audit process has to be systematic, patient orientated and outcome based. The management of services should also take into account the diversity of nuclear medicine services around the world, and contributions from other disciplines, which may include clinical, technical, radiopharmaceutical, medical physics and radiation safety.

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INTERNATIONAL ATOMIC ENERGY AGENCY
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ISBN 978–92–0–101715-4
ISSN 2075–3772