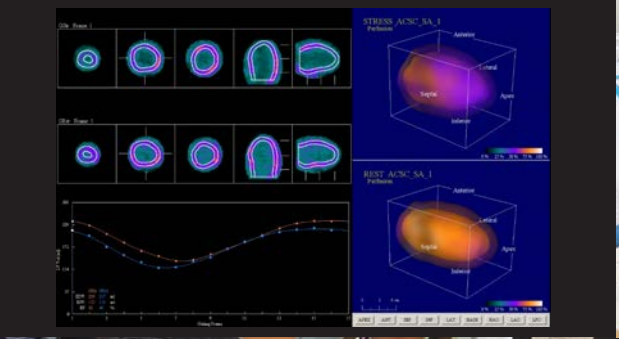

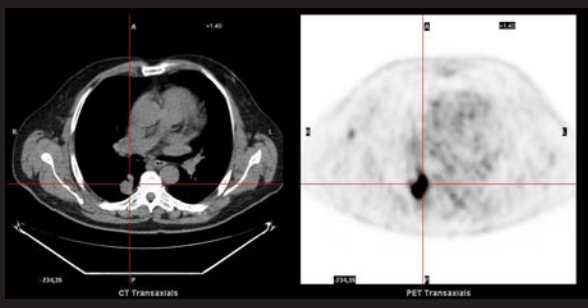

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No. 33

QUANUM 3.0: An Updated Tool for Nuclear Medicine Audits

Third Edition

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QUANUM 3.0: AN UPDATED TOOL FOR NUCLEAR MEDICINE AUDITS

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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

QUANUM 3.0: AN UPDATED TOOL FOR NUCLEAR MEDICINE AUDITS

THIRD EDITION

INTERNATIONAL ATOMIC ENERGY AGENCY
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FOREWORD

The IAEA has a long history of aiding its Member States in the field of nuclear medicine through initiatives based on current trends in technology and clinical applications aimed at improving clinical practice. An important initiative has been the development and implementation of an effective system — the Quality Management Audits in Nuclear Medicine Practices (QUANUM) programme — that integrates all aspects of quality management into modern nuclear medicine services in Member States. For that purpose, the Quality Management Audits in Nuclear Medicine Practices (QUANUM) programme has been developed and implemented. Numerous IAEA publications, such as the Nuclear Medicine Resources Manual, serve to support the increasing use of standardized clinical protocols and evidence based medicine being adopted by nuclear medicine services globally in order to improve the provision of nuclear medicine services. Additional contributions by the IAEA include its General Safety Requirements (GSR Parts 1–3) in the IAEA Safety Standards Series on management systems for all facilities.

The QUANUM programme has proven to be applicable to many nuclear medicine services across a variety of economic circumstances. The QUANUM programme considers the diversity of nuclear medicine practices around the world and covers multidisciplinary contributions, clinical applications, technical aspects, radiochemistry, radiopharmacy, medical physics and radiation safety.

The present revision, QUANUM 3.0, follows the principle of continuous improvement in quality and reflects new scientific developments. It has also drawn on valuable lessons learned from more than a decade of global implementation of QUANUM with the assistance of experienced nuclear medicine professionals and the support of the IAEA technical cooperation programme.

This publication is intended for use by all professionals in the nuclear medicine field and is not limited to quality assurance experts. This new version will also be supplemented by a web based application developed by the IAEA for wider outreach.

Auditing helps to identify strengths, weaknesses and gaps in health care delivery in an area or region and provides data that are vital to defining evidence based strategies to address observed and emerging needs. Outputs from audits can contribute to efficient planning and implementation of ongoing technical cooperation programmes by the IAEA as well as planning of future support to Member States.

To that end, a group of consultants met at the IAEA in April and May 2019, to update the QUANUM manual, resulting in this third edition of the publication. QUANUM 3.0 includes updated and revised checklists that have been modified for greater clarity and improved prioritization. This revision aims at strengthening

the culture of quality and reviewing all processes of the nuclear medicine service for the continuous improvement of clinical practices. However, as the QUANUM documentation cannot be all inclusive, professional judgement remains essential to ensure a safe and risk free clinical practice.

The work of contributors to the first two versions of the QUANUM programme (2009 and 2015) is acknowledged. The IAEA officers responsible for this publication were M. Dondi and F. Giammarile of the Division of Human Health.

EDITORIAL NOTE

CONTENTS

1. INTRODUCTION

1.1. BACKGROUND

The IAEA has more than 50 years of history of aiding its Member States in the field of nuclear medicine. Following the decision to develop a quality management audit manual for nuclear medicine, the IAEA convened the first expert group in 2006, which was composed of nuclear medicine 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 field and the lessons learned through its first implementation, the IAEA recognized the necessity for an updated manual to reflect current best practice in nuclear medicine services (NMSs). During 2012–2013 the initial version of the QUANUM manual and checklists was revised and updated, introducing improved and quantitative scoring [2]. This allowed setting up key performance indicators in nuclear medicine as well as graphical summary representation of audit results.

The present revision, QUANUM 3.0, follows the principle of continuous improvement in quality and considers the release of new General Safety Requirements by the IAEA, including IAEA Safety Standards Series No. GSR Part 2, Leadership and Management for Safety, General Safety Requirements [3], IAEA Safety Standards Series No. GSR Part 3, Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards [4] and IAEA Safety Standards Series No. SSG-46, Radiation Protection and Safety in Medical Uses of Ionizing Radiations [5].

This document also reflects new scientific developments and lessons learned in more than 10 years of global implementation and use of QUANUM [6–8]. As in the past, this document is intended for use by all professionals in the field, not limited to quality assurance (QA) experts.

Adopting a culture of auditing through peer review is essential and enhances the contribution of nuclear medicine to safe practice and optimal patient care. As originally designed, the assessment methodology is applicable to the full spectrum of NMSs. Where local or national audit guidelines are available, this new manual can strengthen them and add an international perspective. The goal of the QUANUM programme is to ultimately foster a culture of auditing and provide a standardized tool to facilitate the audit process. The role of the IAEA is to guide this process, with the aim of gradually developing the ability to perform

external audits at regional and national levels and enabling Member States to become self-sufficient.

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). To ensure adequate quality of practice in nuclear medicine, both internal and independent external audits (peer reviews) need to be carried out on a regular basis (e.g. annually for internal audits and at least once every three years for external audits). A quality audit process must be patient oriented, systematic and evidence based, with a strong focus on no-blame culture. It should follow a typical PDCA (plan, do, check, act) process that includes regular monitoring, assessment and review, as well as meticulous follow-up on findings. Successive audits will result in continuous incremental improvement and further reinforcement of the system of documentation [9, 10].

1.2. OBJECTIVE

The present publication defines an updated methodology and tools for comprehensive auditing, including all aspects of nuclear medicine. Adopting these guidelines will allow an 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, not all checklists or requirements are expected to be addressed by each audited centre, only those that are applicable in the specific NMS. The quantitative score provided by the QUANUM programme is a metric not intended for comparing different NMSs, but rather for providing an overall indicator of the performance and continuous improvement within a given NMS. The overall quality depends on the inventory of strengths and weaknesses, together with the critical appraisal of the variables as observed in practice.

1.3. SCOPE

A comprehensive quality audit takes into account the complex process structure and multidisciplinary nature of nuclear medicine, including the following key areas:

— Management, administration and human resources development;
— Safety aspects relating to patients, staff, the public and the environment;

— Equipment QA, reliability and performance;
— Clinical services (diagnosis and therapy);
— Hospital radiopharmacy and laboratories.

1.4. STRUCTURE

Following a brief introduction to quality management systems (QMSs) and quality management audits, this publication covers a series of checklists. Digital files are provided as an Excel tool accessible on the IAEA Human Health Campus web site [11]. For each requirement/question of individual checklists, reference documents are also provided as links. These lists can be followed sequentially or independently of one another. Upon completion of the audit, a comprehensive report indicating priorities, together with an action plan, is formulated. The details of formulation and content of a typical audit report are also addressed in this publication.

2. CONSIDERATIONS FOR THE IMPLEMENTATION OF A QUALITY SYSTEM IN NUCLEAR MEDICINE

Quality management systems (QMSs) are an integral part of achieving effectiveness, safety and efficiency in nuclear medicine services, enabling nuclear medicine professionals to provide a high-quality service that satisfies their customers and improve professionalism in the speciality. Regular quality management audits are vital tools for assisting with continuous improvement of NMSs.

This section describes the basic requirements and essential components of a quality system and its auditing.

2.1. LEADERSHIP AND MANAGEMENT

The institution and NMS senior management should express and demonstrate continuous commitment to QMS (GSR Part 2 [3]):

— Managers should demonstrate leadership and commitment to quality and safety;

— Senior management of the NMS should be responsible for operationally establishing, applying, sustaining and continuously improving a QMS;
— Senior management should establish goals, plans and objectives consistent with the QMS, and formulate them in a quality manual;
— Appropriate interactions with all interested parties (such as administrators, referring physicians, patient advocates) should be ensured;
— The QMS should integrate safety, environmental security, quality, human and organizational factors;
— The QMS should be properly documented and each component readily available at the appropriate point of use;
— Managers should determine competences and provide resources to carry out planned activities;
— Processes performed by the NMS should be identified, developed and effectively managed (Fig. 1);
— The organization should have proper arrangements with all vendors, contractors and suppliers.

2.2. QUALITY MANAGEMENT SYSTEMS IN NUCLEAR MEDICINE

The adoption of a QMS should be a strategic decision of an NMS. The design and implementation are influenced by various needs and constraints, 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, graded according to the context, which should be continuously improved in accordance with the requirements of professional, regulatory, accrediting or standardization bodies. A QMS aims to enable the NMS to achieve the expectations set forth in its quality policy and to satisfy its customers (both patients and referrers).

The QMS documentation of an NMS typically includes:

— All applicable licence information;
— A quality manual, which should clearly detail mission, vision, strategy, quality policies and objectives, and a description of the organization and its structure;
— Written (hard copy or electronic) standard operating procedures (SOPs) for primary (diagnosis and therapy) management and support processes as described by the process map (Fig. 1);
— External/reference documents;
— Records of indicators and parameters;
— Records of non-conformances, preventive/corrective actions;

— Records of customer (patients; referring physicians; insurers and other health management organizations) satisfaction;
— Risk evaluations;
— Registrations of incidents and adverse reactions reporting systems
— Equipment inventory, including life cycle and QA/QC recordings;
— Records of meetings available for review.

Documentation, either in hard or soft copy (quality manual, SOPs, reports of measurable indicators and parameters, records, etc.), is essential. All documentation should be updated regularly and current practices described. Version management/control will effectively track and control any changes, including name of author, date of authorization, name of approver and date of next review. Documents should be distributed and made available in all appropriate sites of use. New procedures and related training should be communicated appropriately and obsolete versions should be archived.

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

2.3. OBJECTIVE OF THE AUDIT AND COMPOSITION OF THE AUDIT TEAM

The objective of audits is to review and evaluate by observing and collecting evidence about the practices of an NMS, with a special focus on the quality aspects of the service, according to QUANUM criteria. This includes elements involved in the different processes (Fig. 1), such as commitment to quality, optimal patient care, best practice standards for imaging and radionuclide therapy, adequacy of facilities and staffing, and professional competence. It should also cover equipment and procedures, protection and safety (including radiation protection and radiation safety) of patients, staff, the general public and the environment. The overall performance of the NMS, as well as its interaction with other departments in the institution and with external services and providers, should also be assessed.

Given the different aspects and the complexity of the processes, a multidisciplinary team is needed to carry out such a comprehensive audit.

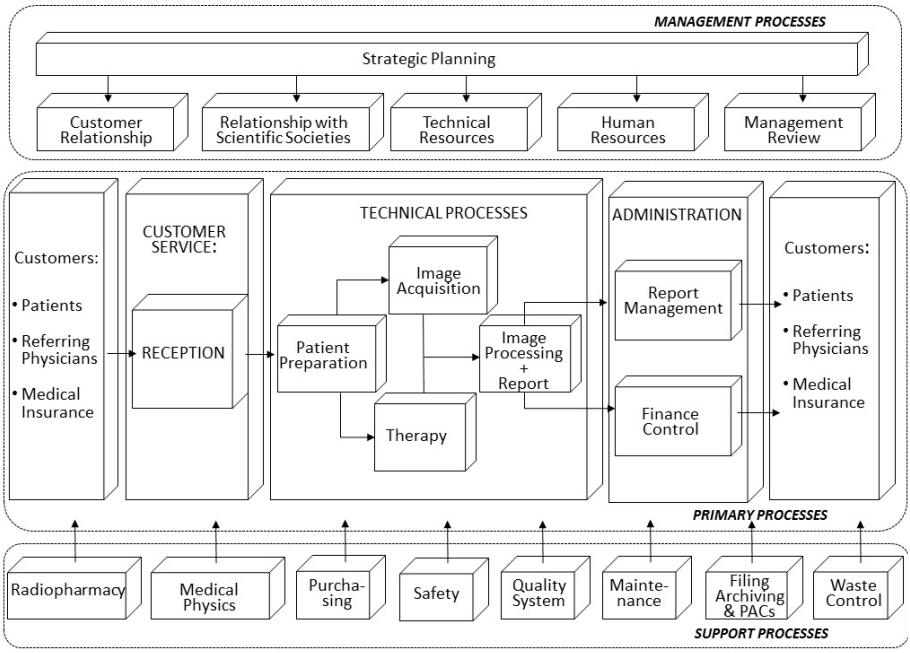

FIG. 1. Example of a process map for a nuclear medicine service, showing the primary, management and support processes. PAC — picture archiving and communication (adapted with permission from the Committee for Accreditation of Nuclear Medicine Department of the European Association of Nuclear Medicine).

Before the actual audit, the final composition of the audit team should be communicated to the staff of the NMS. A similar team may also be required to follow up on the audit's findings and recommendations.

The IAEA has developed this tool and recommends its use primarily to carry out self-assessments (internal audits), with the intention of applying good clinical practice and identifying opportunities for improvement.

2.4. CONTINUING IMPROVEMENT AND THE ROLE OF QUALITY AUDITS

Elements of the cycle of continuous improvement are shown in Fig. 2. The concept of PDCA is reflected in this figure.

The completion of the IAEA web based nuclear medicine database referred to as NUMDAB [12], which provides basic information and essential details on

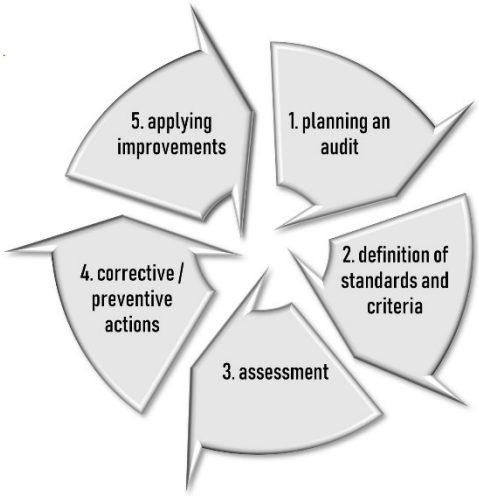

FIG. 2. The concept of the cycle of continuous improvement.

the operational and technical aspects of an NMS is a prerequisite for an NMS planning a QUANUM audit.

Figure 3 shows a general flow chart of the nuclear medicine audit procedure. The audit process should be an integral part of the quality management programme and should be carried out periodically, as specified in IAEA Safety Standards Series No. GS-G-3.1, Application of the Management System for Facilities and Activities [13].

The quality management programme is vital for better patient care and is an essential tool in the modern health system. It also provides an objective tool for prioritization and rational justification of the use of limited resources. All aspects connected with safety should receive specific attention and be prioritized. Implementing a timetable for both internal and external audits should become part of the NMS's calendar. Internal audits could be spread over several months, completing a few checklists each month. A busy clinical environment should not be an excuse for neglecting the audit process.

Explanatory notes to the flow chart (Fig. 3) include the following:

(a) Internal audits (all activities inside the dotted lines):
    (i) NMSs should undergo an internal audit on an annual basis.
    (ii) An audit may be limited to a part of the processes involved in delivering clinical services.
    (iii) An internal audit team should be formed, typically including representative staff members from a range of disciplines.

(iv) Assessment should be based on observed evidence, including but not limited to written documentation, SOPs, practices, on-site pictures and staff interviews.

(v) 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 measured against accepted best practice standards.

(vi) If potential risks, deficiencies or non-conformances are identified, action plans need to be established.

(vii) Action plans should include preventive or corrective actions, which should be prioritized, assigned to a responsible person 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.

(viii) When standards are met, or preventive/corrective actions have been successfully implemented, routine activities are continued until the next planned periodic internal audit. If major changes or implementation of new procedures are required, earlier review may be needed.

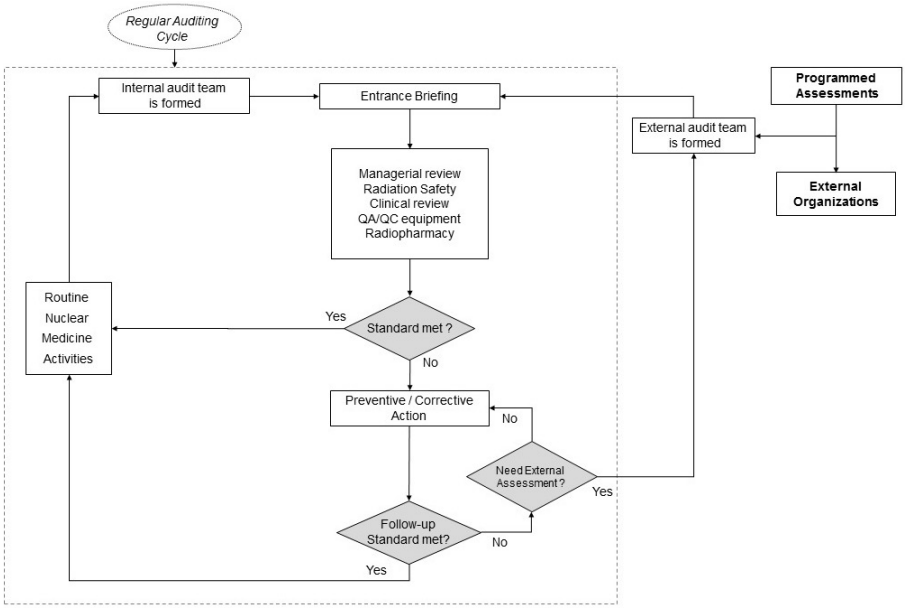

FIG. 3. Audit components. QA — quality assurance; QC — quality control.

(b) External audits (originates outside the dotted line):
    (i) External support may be needed for implementing corrective and/or preventive actions, resulting from an internal audit.
    (ii) Regular external audits every three years should be part of the NMS's QMS.
    (iii) External audits can also be organized in conjunction with external bodies other than the IAEA, such as national or regional nuclear medicine societies or relevant regulatory authorities.

2.5. PRIORITIZATION

All applicable questions should be addressed and non-conformance should be identified. Priorities for corrections are classified into three categories: 'critical', 'major' and 'minor' (see Section 3.5.5). Shortcomings that are likely to have serious implications for patient care or present risks to the staff or environment are prioritized as 'critical' or 'major'. In QUANUM 3.0, a default priority level is automatically assigned in the checklists, based on the content of each specific requisite and the experience gained in previous audits. However, final priority level is based on the auditors' judgement, taking into consideration the local circumstances and evidence.

2.6. CHECKLIST LIMITATIONS

The checklists of this programme are intended as a comprehensive, but not exhaustive tool for quality assessment. An audit is an observation at a certain point in time, therefore the sample of collected evidence may be limited.

Users are advised to consider updated IAEA publications and scientific literature, as well as nuclear medicine professional society guidelines. It should be noted that professional judgement is always required for an adequate assessment.

Furthermore, audit checklists are not designed for the following:

(a) Regulatory purposes: Audit teams are not convened as an enforcing tool but solely as an impartial source of advice on quality improvement.
(b) Investigation of accidents: The audit teams are not convened to investigate accidents or reportable medical events (e.g. misadministration). In such cases, a more focused and department specific technical investigation is required [14].
(c) Research: This programme is not meant for assessing the quality and safety of any type of research or 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 for a select group of patients, including the associated quality control (QC).

(d) Interdepartmental comparison: This programme is not intended to be used for interdepartmental comparison.

(e) Training programs: This programme is not intended to be used for evaluation of the quality of training programmes in which an NMS may be involved.

2.6.1. Responsibility for action

It should be understood that while it is the responsibility of the audit team to identify deviations and non-conformances in the audited institution, it is solely the responsibility of the NMS and the institution to take corrective actions to address them.

3. AUDIT REVIEW STRUCTURE

3.1. PURPOSE

Auditing is a very important instrument in ensuring the well-functioning of an NMS. It should be performed on a regular basis: every year for internal audits and every three years for external audits. A comprehensive audit should address all aspects of the NMS as specified in checklists 1 to 14 in Section 4. It should become an integral part of any existing or future institutional quality management programme.

As the QMS improves, it should be integrated with the general aspects of institutional operations; for example, in strategic planning, for the procurement and installation of new equipment and technologies, the introduction of new procedures, budgetary planning and expenditure review. The QMS typically includes tools for preventive actions/improvement plans and for monitoring indicators. These could become of interest also in the audit.

3.2. ESTABLISHING THE AUDIT PLAN

For internal audits, planning is an in-house process (Fig. 3). The head of the NMS is responsible for initiating the audit process and appointing a quality

manager/quality team. The quality manager selects the audit team leader who will be in charge of the audit and assign responsibilities of other members of the audit team.

For external audits, cooperation and coordination with external local, national or international bodies, or with organizations such as the IAEA, is necessary.

3.3. COMPOSITION OF THE AUDIT TEAM

An audit team may include the following members:

— Nuclear medicine physician;
— Medical physicist;
— Radiopharmacist;
— Nuclear medicine technologist/radiographer;
— Nurse;
— Administrative staff member;
— Representative of the institutional quality department.

It is advisable to include appropriate staff from other services of the institution (e.g. radiology, oncology, cardiology). An audit team should consist of a minimum of three members.

For an internal audit, the team consists of staff members with extensive knowledge of the current procedures of the NMS.

Auditors should be independent, discreet, impartial and fair; they should maintain an ethical and professional demeanour and respect confidentiality. For external audits supported by the IAEA, all auditors are required to sign a confidentiality statement.

Members of the team should have the necessary expertise and, whenever possible, have undergone basic training and briefing in auditing techniques (GSR Part 2 [3], [15]).

For an external audit, the composition of the team is discussed between the parties, adopting the required multidisciplinary and auditing competences and independence as indicated above.

3.4. PREPARATION FOR THE QUANUM AUDIT

The success of an audit depends on the thorough preparation of all parties involved. A timetable for the audit should be agreed on by the team and the

person in charge of the NMS (Table 1). All relevant documentation of previous audits should be made available to the audit team in a timely manner.

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 previous audits, particularly the latest self-assessment based on QUANUM, and any consecutive action plan.
— All the above should be made available on-site in electronic form.
— Inform and involve the entire staff, hospital management and other relevant persons and/or institutions.
— Notify all stakeholders about the audit schedule.
— Identify and ensure the participation of staff members (the audit team should be free to interview any staff member it deems appropriate).
— Ensure access of the audit team to any areas and premises related to the scope of the audit, and include appropriate clothing and dosimeters, as necessary.
— Upon request, provide records relevant to the reviewed field in a timely manner.
— According to the agenda and upon request, set up any meetings with stakeholders.
— Ensure the availability of any resources needed for the audit activity.
— In case of an external audit:
    - Prepare an introductory presentation about the health institution (history, size, workload and quality policies), with particular reference to the NMS;
    - Make available a meeting room with internet access and a projector.

In addition to a self-assessment based on QUANUM, the completion of the IAEA web based NUMDAB [12] is a prerequisite for IAEA external audits.

3.5. COMPONENTS OF THE AUDIT AND RESPONSIBILITIES OF THE TEAM

Before an audit, the team leader should draft an agenda in conference with the auditees and other team members. See Table 1 for an example of an IAEA QUANUM audit agenda.

TABLE 1. EXAMPLE OF A QUANUM AUDIT AGENDA

QUANUM AUDIT SCHEDULE — mm/dd/yyyy
Name of audited centre

Audit team: Pre-visit preparation	Auditors' breakfast meeting: Review of the self-assessment and audit plan	Agree on activities for the day	Agree on activities for the day	Agree on activities for the day	Agree on activities for the day
Morning	Entrance briefing: • Introduction of team members • Meeting officials • Meeting with the local key staff • Agree on audit work plan Organizational chart review Tour of the facility Management checklist 1 Review and evaluation of procedures and all relevant documentation	Meeting with dept. manager / preparation of the day's work Radiation safety and patient radiation protection checklist 2 and 3 Review and evaluation of procedures and all relevant documentation Clinical checklists 7, 8, 9, 10	Meeting with dept. manager / preparation of the day's work Radiopharmacy checklists 11, 12, 13 Review and evaluation of procedures and all relevant documentation Observation: Physics and equipment checklist 4, 5, 6 Review and evaluation of procedures and all relevant documentation Staff interviews	Clinical checklists 7, 8, 9, 10 Review and evaluation of procedures and all relevant documentation Audit team private meeting: • Prioritization • Preparation of report	Exit briefing: • Exit meeting with the local staff • Exposition of the general lines of the report • Discussion and clarifications • Agree on action plan Preparation of the end of mission report (IAEA audits) Summary and any other business

TABLE 1. EXAMPLE OF A QUANUM AUDIT AGENDA (cont.)

QUANUM AUDIT SCHEDULE — mm/dd/yyyy Name of audited centre					
Audit team: Pre-visit preparation	Auditors' breakfast meeting: Review of the self-assessment and audit plan	Agree on activities for the day	Agree on activities for the day	Agree on activities for the day	Agree on activities for the day
Afternoon	Radiation safety and patient radiation protection checklist 2 and 3 Review and evaluation of procedures and all relevant documentation	Radiopharmacy checklists 11, 12, 13 Review and evaluation of procedures and all relevant documentation	Staff interviews	Audit team private meeting: • Preparation of report • Action plan • Auditors' final deliberation	

It is essential to perform audits according to standardized audit practices, which include the following:

(a) Entrance briefing.
(b) Assessment:
    (i) Tour of the facility;
    (ii) Systematic review of each checklist;
    (iii) Practical observation of working practice.
(c) Scoring of conformance and non-conformance.
(d) Explanation of minimum requirements.
(e) Prioritization of findings with justification of any deviations from default.
(f) Exit briefing, including discussion of the findings and possible corrective actions.
(g) Reporting.

3.5.1. Entrance briefings

The entrance briefings are required at both the departmental and institutional level. The audit team is introduced and presented to staff; the institution is presented to external auditors; the agenda is finalized; and objectives, methods and details of the audit are discussed.

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.

3.5.2. 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 the following:

(i) Complete tour of the premises;
(ii) Review and evaluation of procedures and all relevant documentation, including a review of treatment records;
(iii) Observation of the practical implementation of working procedures;

(iv) Staff interviews;
(v) Meetings with referring (clinicians) and supporting departments (information technology, pharmacy, clinical engineering, medical physics);
(vi) Review of the previous audit (self-assessment according to QUANUM) and possibly reports of recent internal audits and the status of their follow-up;
(vii) Systematic scoring of checklists (QUANUM tool) with acquisition of evidence.

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

(i) Updated copies of licences/accreditation documents;
(ii) Reports of recent inspections like those by the national radiation protection authority, if any;
(iii) Organizational flow chart and job descriptions;
(iv) Samples of SOPs;
(v) Samples of anonymized study reports;
(vi) Examples of performance indicators (copies of data regarding patient waiting times, updated information on waiting lists);
(vii) Examples of patient information leaflets (preparation, pregnancy, breastfeeding); informed consent forms;
(viii) Copies of QC data for relevant equipment and radiopharmaceuticals;
(ix) Radiation safety records;
(x) Copies of letters of appraisal/complaints;
(xi) Records of deviations and non-conformances;
(xii) Records of follow-up/corrective actions;
(xiii) Customer/stakeholder satisfaction surveys.

Patient workflow within the NMS should be systematically observed in its entirety, starting from justification and scheduling of procedures, patient identification and traceability (at reception, before administration of any radiopharmaceutical, before pharmacologic intervention, at scanning room and discharge). The existence of procedures for proper exclusion of pregnancy for women of childbearing age, and information about lactation, if applicable, should also be checked.

The auditors should observe the performance of diagnostic studies (patient preparation and positioning, camera set-up, image acquisition, data processing) as well as therapies (activity measurement and administration, discharge procedures, contamination assessment).

QA/QC procedures for major equipment and radiopharmacy practices should also be observed.

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

3.5.3. Scoring conformance and non-conformance

QUANUM is based on 14 checklists, each of them addressing different areas and structured into several requirements. It is intended to provide a working format for self-assessment using a systematic approach. A scoring system, shown and detailed in Table 2, will appear in the spreadsheet as a pulldown menu and has been designed to evaluate the level of conformance. Results will reflect the level of conformance for applicable requisites. In case a requisite or an entire checklist is not applicable, option 'non-applicable' may be selected without affecting the level of conformance; this should not be deemed poor performance.

This scoring system is defined in Table 2 and illustrated using examples of an evaluation of the documentation system.

Any non-conformance should be explained and discussed by the auditors with relevant staff. The priority and urgency of corrective/preventive actions should be openly discussed, and suggestions made for implementing root cause analysis and action plan. Corrective/preventive actions provide opportunities for improvement of the NMS and auditors are encouraged to remind staff that the identification of non-conformances is not intended to attribute blame.

3.5.4. Minimum requirements

A series of publications have been issued on safety requirements [4, 5], site planning [16, 17], standardization, quality assurance (QA) [18, 19–21], clinical practice [22–28] and radiopharmacy [29, 30]. These publications contain minimum requirements and they are specified in the checklists.

In carrying out the audit, reference will be made to these publications of the IAEA, and of other professional or standardization bodies and evidence based medical literature. The QUANUM tool contains one or more references to relevant documents for each requirement (see last column of each worksheet).

3.5.5. Prioritization of findings

With the aim of defining priorities, non-conformances are classified as:

(i) *Critical priority:* Issues affecting the safety of patients, staff, caregivers and/or the environment for which corrections should be immediately addressed or initiated within days or weeks, depending on their severity.

(ii) *Major priority:* Issues or potential threats affecting the capacity of the NMS to adequately perform, which should be addressed in a timely manner (e.g. within 3–6 months).
(iii) *Minor priority:* Issues requiring optimization, to be fixed within a defined time period and re-evaluated during the next audit.

A default priority level is automatically assigned in the checklists. Auditors, based on their own experience, the available evidence and local circumstances, can modify the level of priority but need to provide a motivation for that modification.

TABLE 2. DEFINITION OF THE SCORING SYSTEM

Score	Classification	Description	Example
Not applicable		This checklist/ requirement does not apply	Activities are not performed in the audited NMS
0	Non-conformance	Absent or inappropriate	No evidence/documents available
1		Planned or approximate	Documentation is planned or exists as an informal draft
2		Partial conformance or partial implementation	Only some SOPs for the requisite exist or important components are missing
3	Conformance	Mostly conforming and/or mostly implemented	Most SOPs are complete, but some information is missing (e.g. reference to guidelines, dosimetry data) or documents are not regularly updated
4		Fully conforming and fully implemented	All SOPs are complete and are reviewed at least once and history of revision can be tracked

Note: NMS — nuclear medicine service; SOP — standard operating procedure.

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.

3.5.6. Exit briefing

The immediate 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 requires preparation of a detailed presentation summarizing and illustrating the findings and reporting the priority list aimed at the preparation of an action plan. Time should be allotted for questions and for an open discussion.

The auditee(s), in the case of an internal audit, or the head of the NMS, in the case of an external audit, are requested to finalize and forward to the audit team leader a detailed action plan based on the recommendations within two weeks.

In the case of IAEA managed external audits, the following documents are made available at the exit briefing:

— Exit briefing presentation, including list of key priorities and non-conformances and a suggested time frame to address non-conformances;
— Spreadsheet of the audit results;
— Proof of QUANUM audit.

3.5.7. Reporting

The audit report should contain conclusions formulated in an unambiguous way, with critical, major and minor priorities clearly identified and with practical recommendations. All auditors should contribute to and agree on the final report. Key findings and observations should be described, including not only non-conformances but also strengths of the audited centre.

The report should also identify the following issues:

— Issues that can be improved or implemented by the NMS itself, for an immediate response/action.
— Issues that cannot be resolved by the NMS alone, without significant financial, technical, managerial or professional contributions from the outside.

In the case of an IAEA external audit (see also Section 6.2), typical annexes to the report include the following:

(1) Agenda;
(2) NUMDAB form;
(3) Presentation of audited institution (if available);
(4) Organizational chart;
(5) Self-assessment spreadsheet;
(6) Layout of the NMS;
(7) Exit briefing presentation;
(8) External audit spreadsheet;
(9) Comparison of the radar plots;
(10) Action plan.

It should be understood that while it is the responsibility of the audit team to highlight deviations in the services of the audited institution, the audit team is not accountable for rectifying the identified deficiencies.

3.5.8. 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.

In the case of regularly held internal audits, the corrective actions are expected to be completed within the agreed time frame.

The same applies in the case of IAEA managed external audits. Furthermore, a new self-assessment using the QUANUM tool should be repeated within one year and submitted to the IAEA for proper monitoring of results. This information could be useful for assessing the needs of any future support from the IAEA.

4. GUIDE TO THE AUDIT CHECKLISTS

All information gathered during the audit is compiled into a questionnaire consisting of fourteen checklists that are based on Excel worksheets and cover all the aspects of the audit. The questionnaire starts with checklists related to management and the quality system. It then moves to specific issues regarding radiation safety, QA/QC of equipment, clinical services and the radiopharmacy/laboratory. Using the drop-down menu (Fig. 4) and the established score mechanism (Table 2), all applicable items need to be scored

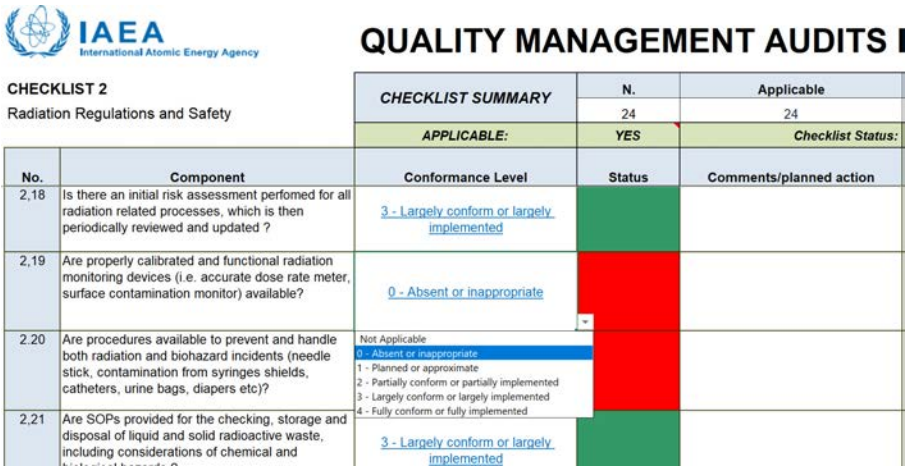

FIG. 4. Example of a dropdown menu.

according to their level of conformance (Section 3.5.3). Non-applicable items should be marked as such, also using the corresponding descriptor from the drop-down menu.

The auditor should complete the adjacent column with notes and comments justifying the score.

The spreadsheet tool, described in Section 3.5.3, contains the following elements:

— A colour code is provided for quick visualization of the conformance status.
— For each item of every checklist, an example of the type of results and evidence to be collected is provided and a link to major reference documents is given.
— Spaces for comments and planned actions are provided; 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 ‘not applicable’ will not be used in assessing the final scores.

4.1. MANAGEMENT

Quality management standards are details of requirements that NMSs should consistently meet in order to ensure that they meet the needs of their users.

Checklist 1 evaluates the aspects related to strategies and policies, administration and management and human resources [22, 28–33]. All are essential for the success of any undertaking.

CHECKLIST 1. Management		
No.	**Component**	**Example of result/Type of evidence**
Strategies and policies		
1.1	Does the nuclear medicine service (NMS) have a quality manual containing its mission, vision, quality policy and strategy?	Written documents showing the strategies of the NMS and the objectives at national/ regional levels
1.2	Does the NMS have documents of service coordination with other relevant departments (radiology, oncology, cardiology, paediatrics, surgery, etc.)?	Written documents describing agreement conditions with other services
1.3	Does the NMS have an updated written organizational chart, indicating channels of communication and lines of authority?	Copy of the organizational chart
1.4	Does the NMS have resources to match the current clinical demand?	Check the patient roster/verify if there is a waiting list
1.5	In the case of services exchange with other hospitals/institutions, are there written agreements and clear definition of responsibilities?	Check the definitions of responsibilities in the standard operating procedures (SOPs) of the offered services
Administration and management		
1.6	Has the service defined the primary, management and supporting processes (process map)?	Check in the written procedure the data regarding the document updates
1.7	Does the NMS have appropriate documentation for the main managerial tasks (i.e. delegation of authority, working shifts, leave, budget control)	Check the instruction for dealing with special categories of patients

CHECKLIST 1. Management (cont.)		
No.	**Component**	**Example of result/Type of evidence**
1.8	Is there formal documentation for scheduling, receiving and discharging patients?	Check the SOPs related to diagnosis and therapy
1.9	Are there specific provisions to accommodate special categories of patients (e.g. access ramp, special toilets, spaces for children)?	Check the SOPs related to management processes
1.10	Is a responsible qualified physician rostered for the daily activity?	Check the definitions of responsibilities in the clinical SOPs
1.11	Is there a quality committee to support the clinical governance of the department, including evidence of regular meetings?	Check the organizational chart and the definitions of responsibilities
1.12	Are there regular, documented departmental meetings involving all the staff?	Check the organizational chart and the definitions of responsibilities.
Human resources		
1.13	Do all staff members have a written job description that clearly sets out their current duties, responsibilities and training level?	Example of a record (job description)
1.14	Do competences of all staff meet their assigned responsibilities?	Example of a record (personnel card)
1.15	Do all NMS staff receive appropriate, continuous training on radiation safety, patient safety and safe use of medical devices?	Example of a record (training report)
1.16	Are there provisions for continuing professional education and development opportunities for all staff categories?	Check the training SOPs
1.17	Is there a regular review of competences to identify training needs, considering the case mix of the NMS and the mission of the institution?	Check the training SOPs

CHECKLIST 1. Management (cont.)		
No.	**Component**	**Example of result/Type of evidence**
1.18	Do staff members have access to educational and scientific resources?	Check available educational materials
1.19	Is quality management part of the training programmes for professionals involved in nuclear medicine?	Example of a record (personnel card)

4.2. RADIATION REGULATIONS AND SAFETY

These regulations are aimed to make sure that patients and workers are protected from any risk when exposed to ionizing radiation. Compliance with all relevant regulations and good radiation practice in nuclear medicine are of the utmost importance (GSR Part 3 [4], SSG-46 [5], [34]). Checklist 2 evaluates aspects of this compliance. This checklist also addresses non-radiation risks, such as biohazards and other physical risks.

CHECKLIST 2. Radiation regulation and safety		
No.	**Component**	**Example of result/Type of evidence**
2.1	Is the service formally authorized/licensed by competent national institutions?	Copy of the licence
2.2	Do the standard operating procedures (SOPs) dealing with radiation safety and protection refer to national guidelines or cross refer to international regulations?	Cross-check references in SOPs with the first page of the law/regulation
2.3	Do all personnel of the nuclear medicine service (NMS) receive radiation protection training and instructions on local procedures, confirmed by signature or other means?	Check/copy the records

CHECKLIST 2. Radiation regulation and safety (cont.)		
No.	**Component**	**Example of result/Type of evidence**
2.4	Are all radioactive materials kept, identified, controlled and stored as specified in licences and SOPs?	Observation on site/photos
2.5	Are sealed calibration sources checked periodically, cross-accounted and checked for any leakage?	Observation on site/photos/ logbook
2.6	Is there routine monitoring by nuclear medicine personnel for radiation exposure (e.g. whole-body badges, hand/finger monitoring, as appropriate)?	Observation on site/copy of the records
2.7	Is staff personal dosimetry monitoring regularly reviewed and communicated, including reporting and initiating appropriate actions in the case of unexpected results?	Check/copy the records
2.8	Are there periodic medical checks for radiation workers according to the IAEA's International Basic Safety Standards (BSS)?	Check/copy the records
2.9	Is personal protective equipment (e.g. gloves, syringe shields, handling tongs) available and used?	Observation on site/photos
2.10	Are there adequate facilities for diagnostic and therapeutic radiopharmaceutical administration, including radioactive aerosols (ventilation, shielding, decontaminability)?	Observation on site/photos
2.11	Are there adequate separate waiting areas for patients before and after administration of radiopharmaceuticals?	Observation on site/photos
2.12	Are diagnostic rooms adequately equipped (e.g. air conditioning, ventilation, surfaces, structural shielding or mobile barriers)?	Observation on site/photos

CHECKLIST 2. Radiation regulation and safety (cont.)		
No.	**Component**	**Example of result/Type of evidence**
2.13	Have areas been classified as ‘supervised’ or ‘controlled’ according to the BSS and/or local regulations?	Observation on site/photos
2.14	Is there a procedure for surface contamination monitoring of all controlled areas at adequate time intervals, including data recording?	Check the procedure
2.15	Is there a SOP for dealing with a radioactive spillage/contamination incident and are ready to use decontamination kits available?	Check the procedure/check the decontamination kit
2.16	Is unauthorized access to supervised or controlled areas prevented?	Observation on site/photos
2.17	Are radiation signs (in local language(s)) prominently displayed at the entrance to supervised and controlled areas?	Observation on site/photos
2.18	Is an initial risk assessment performed for all radiation related processes, which is then periodically reviewed and updated?	Check the procedure
2.19	Are properly calibrated and functional radiation monitoring devices (i.e. accurate dose rate meter, surface contamination monitor) available?	Observation on site/photos
2.20	Are procedures available to prevent and handle both radiation and biohazard incidents (e.g. needle stick, contamination from syringes shields, catheters, urine bags, diapers)?	Check the procedure/ observation on site
2.21	Are SOPs provided for the checking, storage and disposal of liquid and solid radioactive waste, including considerations of chemical and biological hazards?	Observation on site/photos/ check the procedure
2.22	Are shielding barriers and heavy containers secured and used safely, to reduce the risk of mechanical injury?	Check the procedure/check the records

CHECKLIST 2. Radiation regulation and safety (cont.)		
No.	**Component**	**Example of result/Type of evidence**
2.23	Are there policies or SOPs for internal movement of radioactive materials (e.g. radiopharmaceuticals to be administered in other departments, radioactive waste, sources)?	Check the procedure
2.24	Is there a formal emergency plan provided in the case of accidents (e.g. fire, floods, power outage)?	Check the procedure

4.3. PATIENT RADIATION PROTECTION

Patient focus includes due consideration of optimization of their radiation protection (GSR Part 3 [4], SSG-46 [5], [34]). In nuclear medicine, this starts earlier than at the point of scanning and includes justification, patient identification, choice of the proper radiopharmaceutical and activity, patient preparation and radiopharmaceutical administration. Checklist 3 evaluates radiation protection considerations.

CHECKLIST 3. Patient radiation protection		
No.	**Component**	**Example of result/Type of evidence**
3.1	Are there standard operating procedures (SOPs) available to ensure correct identification of the patient, including possible pregnancy and breastfeeding status, prior to administration of the radiopharmaceutical?	Check the procedure/ observation on site
3.2	Is there appropriate signage for alerting female patients of childbearing age to report any potential pregnancy or breastfeeding?	Check the procedure/ observation on site
3.3	Is verbal and written information provided to patients about their procedure before and after administration of radiopharmaceuticals?	Observation on site/copy of the instructions

CHECKLIST 3. Patient radiation protection (cont.)		
No.	**Component**	**Example of result/Type of evidence**
3.4	Is the activity of each patient dose confirmed by measuring prior to administration and entered into the patient's file?	Observation on site/copy of the instructions
3.5	Is there an SOP establishing local diagnostic reference levels (DRLs) for administered activity, cross-referring to national or international regulations or guidelines?	Check the procedure/check the quality manual
3.6	In case of multimodality imaging: Is there an SOP establishing local DRLs for X ray dose, cross-referring to national or international regulations or guidelines?	Check the procedure/check the quality manual
3.7	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
3.8	In the case of multimodality imaging: Is there a trained person available to estimate the risk due to X ray exposure or radiofrequency due to magnetic resonance?	Observation on site/check the job description
3.9	Are there adequate SOPs to minimize the risk of misadministration (mismatch patient/ radiopharmaceutical) and/or maladministration (extravasation) of radiopharmaceuticals?	Check the procedure/ observation on site
3.10	Are there mechanisms in place (query of radiology information system/picture archiving and communication system (RIS/PACS), search for previous investigations, ask the patient) to minimize the risk of unnecessary repetition of investigations involving radiation exposure?	Check the procedure
3.11	Is there a specific SOP addressing deviations, incidents, near misses and other non-compliance in patient exposures, including reporting and corrective actions?	Check the procedure

CHECKLIST 3. Patient radiation protection (cont.)		
No.	**Component**	**Example of result/Type of evidence**
3.12	Is there a specific SOP for dealing with women who are pregnant or breastfeeding who need a nuclear medicine procedure?	Check the procedure

4.4. EVALUATION AND ASSURANCE OF QUALITY SYSTEM

A QMS contributes to the increase of the level of safety, effectiveness and reliability of clinical services. It should be continuously reviewed to ensure improvement and compliance with evolving standards and challenges (GSR Part 2 [3], [20–22]. Checklist 4 evaluates the QMS.

CHECKLIST 4. Evaluation of assurance of quality management system		
No.	**Component**	**Example of result/Type of evidence**
4.1	Are indicators defined for the nuclear medicine service (NMS), including: time between referral and study, classified as urgent and routine; time between study and report; existence and length of waiting lists; repeated examinations?	Check the established objectives and standards
4.2	Is there regular monitoring by involved personnel (e.g. head of department, chief technologist, quality committee) and planned review of the indicators defined above?	Check the procedures and examples of the criteria used for acceptability
4.3	Is the service regularly internally audited (e.g. annually) by independent members of the staff (other than those in charge of the monitoring)? Is there a documented follow-up of lessons learned?	Check the audit records and reports/check the audit procedures
4.4	Is there a system to assess satisfaction (patient, referring physicians, other stakeholders)?	Check the procedures for assessing satisfaction/check the records

CHECKLIST 4. Evaluation of assurance of quality management system (cont.)		
No.	**Component**	**Example of result/Type of evidence**
4.5	Is there a standard operating procedure (SOP) for recording and handling of non-conformances and deviations?	Check the SOP/check the records/check the list of corrections/ prevention plans
4.6	Is there an SOP for preventive and corrective actions, aimed at quality improvement and risk reduction?	Check the procedures describing the mechanism to ensure quality improvements
4.7	Is all equipment, clinically used for patients, appropriately marked (e.g. Conformité Europèenne (CE) mark, Food and Drug Administration (FDA) clearance or approval by a national authority)?	Check the records of the monitoring and reviewing
4.8	Are there written policies/SOPs for specifying, procuring and testing new imaging equipment? Are all goods and equipment purchased according to specifications set up by all involved parties, including the nuclear medicine department?	Check the purchase procedure/ review the records
4.9	Are technical specifications used for the acceptance testing of goods and equipment?	Check the procedure/ observation on site
4.10	Is there a quality assurance (QA) programme, with regular calibration and inspection of all equipment (including activity meter, beta and gamma counters and probes, radiation survey monitors, aerosol delivery systems, laboratory equipment) in accordance with the IAEA International Basic Safety Standards (BSS), international/local standards and regulations?	Observation on site/check the procedure/check the records
4.11	Is there a regularly updated inventory of all the equipment?	Check the records
4.12	Is there a procedure to ensure that any equipment or material that fails a quality test is quarantined?	Check the records/check the procedures

CHECKLIST 4. Evaluation of assurance of quality management system (cont.)		
No.	**Component**	**Example of result/Type of evidence**
4.13	Are action levels and responsibilities defined to determine when equipment should be repaired, replaced or taken out of service?	Check the procedures/check the organizational chart and job descriptions
4.14	Are there plans for maintenance (preventive/corrective) and replacement of all major equipment?	Check the procedures/check the records
4.15	Does the service participate in external quality management/quality assurance/quality control (QM/QA/QC) programmes (e.g. International Organization for Standardization (ISO) certification, Joint Commission International for accreditation standards (JCI), American College of Radiology (ACR), resEARch for Life (EARL), etc.)?	Check the records related to the external QM, QA, QC programmes/Check the audit reports

4.5. QUALITY CONTROL OF EQUIPMENT

A comprehensive system of QA/QC for all imaging equipment is essential for optimal patient examinations in nuclear medicine [18–21]. This involves not only regularly performed routine QC tests, but also starts when specifying, procuring, installing and verifying the performance of new equipment.

Checklist 5 addresses the most important aspects of QC.

CHECKLIST 5. Quality control of imaging equipment		
No.	**Component**	**Example of result/Type of evidence**
5.1	Have detailed acceptance tests been performed (independently from the vendor) and the most relevant performance parameters been recorded for all imaging equipment?	Observation on site/example records/check the procedure

CHECKLIST 5. Quality control of imaging equipment (cont.)		
No.	**Component**	**Example of result/Type of evidence**
5.2	Are the results of acceptance tests and the initial performance assessment used to establish baseline reference values for routine quality assurance/quality control (QA/ QC)?	Observation on site/check logbook/check the procedures
5.3	Are there written standard operating procedures (SOPs) available on the operation and QA/QC for all imaging equipment in clinical use, consistent with manufacturer's instruction manuals?	Check the procedures
5.4	Is there a policy on long term storage of QA/QC results, according to national regulations, guidelines or other bodies?	Observation on site/example records/check the procedure
5.5	Is there a regular, documented physical inspection of the hardware, including the detector head(s), collimator(s), shielding?	Observation on site/example records/check the procedure
5.6	Are the most relevant planar/single photon emission computed tomography (SPECT) parameters regularly checked, reviewed and recorded — including trend analysis — uniformity, spatial resolution, centre of rotation (COR), SPECT performance, as well as other parameters considered critical in the internal QA programme?	Observation on site/example records/check the procedures
5.7	Are the most relevant QA/QC procedures for PET systems regularly checked, reviewed and recorded, including trend analysis: daily QC according to manufacturer's instructions, detector normalization, 2D–3D radioactivity concentration calibration, as well as other parameters considered critical in the internal QA programme?	Observation on site/example records/check the procedures

CHECKLIST 5. Quality control of imaging equipment (cont.)		
No.	**Component**	**Example of result/Type of evidence**
5.8	Are the most relevant QA/QC procedures for multimodality imaging systems regularly checked, reviewed (including trend analysis) and recorded: all parameters listed in 5.6 or 5.7, computed tomography (CT) parameters (CT number, image uniformity, image noise, image artefacts, high contrast modulation, radiation dose), magnetic resonance (MR) parameters (image uniformity, noise, distortion and artefacts, specific absorbed ratio (SAR)), image registration and other parameters considered critical in the internal QA programme?	Observation on site/example records/check the procedures
5.9	Do the QA/QC SOPs include specific instructions on corrective actions in the case of deviations or non-conforming results?	Check the SOPs

4.6. COMPUTER SYSTEM AND DATA HANDLING

Computers have been central to the practice of nuclear medicine for many years, as the extraction of functional information commonly requires patient image analysis [22]. Complex modern IT systems, such as hospital information system/radiological information system/picture archiving and communication system (HIS/RIS/PACS), reinforce the need for assuring quality, safety and data integrity in this field.

Checklist 6 evaluates aspects of computer systems and data handling.

CHECKLIST 6. Computer systems and data handling		
No.	**Component**	**Example of result/Type of evidence**
6.1	Are there written policies available for specifying, procuring and testing of radiological information system (RIS), picture archiving and communication system (PACS) and third party image processing and analysis workstations?	Check the procedure
6.2	Do these policies require the certification of all equipment to be acquired (e.g. Conformité Europèenne (CE) mark, Food and Drug Administration (FDA) clearance or approval by a national authority)?	Check the procedure
6.3	Is a validation of any new medical software performed, to ensure consistency of results with precursors?	Check the procedure
6.4	Is an assessment done (independent of the vendor) of the performance of the delivered equipment and software and documented against the specifications of the tender?	Observation on site/example records/check the procedure
6.5	Is there a policy for security assessment of all IT (information technology) systems (e.g. against viruses, intruders)?	Check the procedure
6.6	Is there a policy for ensuring integrity, security and privacy of data, including remote access?	Check the procedure
6.7	For PACS systems: Is there a standard operating procedure (SOP) 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
6.8	For PACS systems and third-party image analysis workstations: Is there an SOP for quality assurance/quality control (QA/QC) of image display monitors?	Observation on site/example records/check the procedure

CHECKLIST 6. Computer systems and data handling (cont.)		
No.	**Component**	**Example of result/Type of evidence**
6.9	Is there an SOP to ensure consistency of data acquisition, processing and analysis protocols after workstation maintenance or major software revisions, also considering any site customization?	Check the procedure
6.10	Is there a policy on quality management (QM) of 'in-house' or non-registered software intended to support clinical use?	Observation on site/example records/check the procedure
6.11	Is there a policy for backup and maintaining patient data files?	Check the procedure

4.7. DIAGNOSTIC CLINICAL SERVICES

The conformance to quality standards of diagnostic clinical services is central to ensure the safety and effectiveness of imaging and non-imaging procedures in nuclear medicine (GSR Part 3 [4], [22–28]). A thorough check is required to ensure that results are accurate and delivered in a timely manner. Checklist 7 evaluates the requirements for these services.

CHECKLIST 7. Diagnostic clinical services		
No.	**Component**	**Example of result/Type of evidence**
7.1	Are standard operating procedures (SOPs) based on national/international guidelines in place for all types of examinations performed?	Check the clinical SOPs or procedure manual
7.2	Is a mechanism in place to regularly update internal SOPs, archive obsolete versions and distribute new ones, to all relevant workplaces?	Written documents describing the mechanism to update the clinical SOPs

CHECKLIST 7. Diagnostic clinical services (cont.)		
No.	**Component**	**Example of result/Type of evidence**
7.3	Is every clinical request checked for justification/clinical appropriateness by a qualified physician of the nuclear medicine staff?	Check some records including the authorization of the nuclear medicine (NM) physician
7.4	Are instructions in place to check for contraindications preventing the examination or parts of it?	Check the instructions/ observation on site
7.5	Are procedures in place for the correct identification of patients throughout all steps of the examination?	Check the procedures for identifying patients during the examinations/observation on site
7.6	Are verbal and written instructions for patient preparation given at the time of appointment and is the procedure explained before the examination is performed?	Check the written instructions
7.7	Are patients' privacy and dignity maintained during his/her time at the NM service (e.g. appropriate covering of women's chests during stress test)?	Observation on site
7.8	Is a procedure in place to inquire about pregnancy and lactation before any administration of radiopharmaceuticals?	Check the written procedure
7.9	Does every patient receive appropriate information related to the examination, including risk evaluation, and, if applicable, does the patient give informed consent?	Check the written procedures describing the information provided to the patients
7.10	Do all procedure protocols (SOPs) also include detailed information on radiopharmaceuticals, computed tomography (CT) settings and contrast media, if applicable?	Check the SOPs
7.11	Are radiopharmaceuticals clearly identified in relation to the individual patient and is traceability ensured?	Check the instruction for dose assignments and traceability

CHECKLIST 7. Diagnostic clinical services (cont.)		
No.	**Component**	**Example of result/Type of evidence**
7.12	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/ Society of Nuclear Medicine and Molecular Imaging (EANM/SNMMI) dose card)?	Check the instruction for dose assignments and patient records
7.13	Are procedures in place to avoid misadministration (mismatch of patient and radiopharmaceutical) and/or maladministration (extravasation) of pharmaceuticals and radiopharmaceuticals?	Check the written procedures
7.14	Is there an SOP available for dealing with the administration of non-licensed or off label radiopharmaceuticals?	Check the procedures
7.15	Is an SOP in place to deal with emergency requests?	Check the SOP
7.16	Is there a process to ensure that physicians or appropriate staff are available to answer patients' questions?	Check written documents establishing the availability of medical doctors to answer patients' questions
7.17	Are there SOPs for specific measures applicable to paediatric patients (e.g. selection of appropriate material type, quality and size, IV-line, sedation, anaesthesia, bladder catheter, pharmacological challenge)?	Check the SOPs
7.18	Is appropriate medical supervision available during NM interventions (e.g. diuretics, ACE inhibitors, stress testing)?	Check the clinical SOPs
7.19	Are procedures in place to properly address and report any adverse event?	Check the written procedures
7.20	Is there a procedure for timely communication of urgent findings to the referring physician?	Check the written procedures

CHECKLIST 7. Diagnostic clinical services (cont.)		
No.	**Component**	**Example of result/Type of evidence**
7.21	Is there a policy on surveillance of patients during their entire stay in the department?	Check the written procedures/ observation on site
7.22	Are a fully equipped emergency cart, oxygen and suction pump available?	Check the available equipment
7.23	Is there an SOP to ensure that the emergency cart is checked and replenished on a regular basis?	Check the SOP
7.24	Are staff regularly trained in basic/advanced (as appropriate) life support?	See SOP and check a record (personnel card)
7.25	Are procedures in place for obtaining rapid assistance in case of emergency? Are corresponding phone numbers readily displayed?	Check the written procedures/ observation on site
7.26	Is a mechanism of incident reporting and consequent introduction of corrective actions in place?	Check the written procedure describing the mechanism
7.27	Are the medical staff regularly involved with multidisciplinary meetings and boards?	Check the written procedure
7.28	Are there regular internal meetings to review the quality of reports?	Check the SOP

4.8. ASSESSMENT OF DIAGNOSTIC PROCEDURES

The auditing team has to assess up to five clinical studies as examples of diagnostic procedures, selected from those most frequently performed. If relevant, at least one non-imaging procedure, such as sentinel lymph node detection (SLND), glomerular filtration rate (GFR) or dual-energy X ray absorption (DEXA) should be included. Cases should be randomly selected from current or archived files.

This evaluation should cover clinical information, technical aspects, patient preparation, related QA/QC information and traceability, as well as reporting and

follow-up. The results of each of these items are compiled and scored according to the scheme introduced in Section 2.5.3. They are presented as a specific radar plot. Average results for all assessed procedures are also included in the overall radar summary (see Section 5). Checklists from 8.1 to 8.5 are used for evaluating selected diagnostic procedures. Checklist 8.1 is shown as an example.

CHECKLIST 8.1 Assessment of diagnostic procedures		
No.	**Component**	**Example of result/Type of evidence**
Clinical component		
8.1	Relevant clinical information collected	Check the records/check the standard operating procedures (SOPs)
8.2	Contraindications and allergies, including to iodine contrast media (if applicable)	Check the records
8.3	Annotation and justification of any possible deviation from the SOP	Check the records/ check the SOPs
8.4	Information from other imaging (radiology and nuclear medicine) and laboratory results checked for	Check the records
Technical procedure: Check if done according to SOP		
8.5	Scanner and/or probe set up (imaging device, collimator, energy window settings, as applicable)	Check the records/ check the SOPs
8.6	Radiopharmaceutical and activity administered	Check the records/ check the SOPs
8.7	If contrast medium was used: type, concentration, administration route, injection speed, if IV	Check the records/ check the SOPs
8.8	Acquisition parameters (time from administration, positioning, acquisition mode and time, matrix, as applicable)	Check the records/ check the SOPs

CHECKLIST 8.1 Assessment of diagnostic procedures (cont.)		
No.	**Component**	**Example of result/Type of evidence**
8.9	Computed tomography parameters, if applicable	Check the records/ check the SOPs
8.10	Data processing and archiving	Check the records/ check the SOPs
Patient preparation: Check if done according to SOP		
8.11	Patient identification	Check the records/ check the SOPs
8.12	Current medication/date of last therapies	Check the records/ check the SOPs
8.13	Patient condition and/or treatment related interference with the procedure? If yes, note in the comments section	Check the records/ check the SOPs
8.14	Patient preparation (e.g. fasting, hydration, glucose)	Check the records/ check the SOPs
8.15	Possible pregnancy, information on lactation and counselling, if applicable	Check the records/ check the SOPs
8.16	For paediatric patients: dose adjustment (radiopharmaceuticals, other medication), sedation, etc.	Check the records/ check the SOPs
8.17	Patient positioning and containment	Check the records/ check the SOPs
Quality assurance/quality control: Check if done according to SOP		
8.18	Quality control (QC) of the radiopharmaceutical(s)	Check the records/ check the SOPs
8.19	Documentation of QC in case of external procurement of radiopharmaceutical	Check the records/ check the SOPs

CHECKLIST 8.1 Assessment of diagnostic procedures (cont.)		
No.	**Component**	**Example of result/Type of evidence**
8.20	Latest QC of imaging equipment relevant for the specific examination	Check the records/ check the SOPs
8.21	Check and account for maladministration (extravasation) at the injection site	Check the records/ check the SOPs
8.22	QC of processing parameters and analysis	Check the records/ check the SOPs
8.23	Overall quality of images (e.g. patient movement, regions of interest, gating)	Check the records/ check the SOPs
8.24	Overall quality and adequacy of images for distribution to the referring physician	Check the records/ check the SOPs
8.25	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 the records showing traceability
8.26	Filing of batch number, dosing and time of administration of any study-related pharmaceutical	Check the records
8.27	Handling and documentation of any adverse event or other incident (patient related or not)	Check the records
Reporting and follow-up		
8.28	Report structured as indicated	Check the records/ check the SOPs
8.29	Report answers the clinical question	Check the records
8.30	Interval between study execution and sending of report	Check the records
8.31	Report includes clinically relevant incidental findings	Check the records

4.8.1. Summary of imaging procedures

A radar plot will be produced for analysis of clinical observations using the scheme described in Section 3.5.3 (Fig. 5). The radar plot will display both the mean and minimum scores. Corresponding values for each component of the assessed diagnostic procedures are shown just above the radar plot representation.

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	75,0	0	68,8	1	75,0	0	75,0	0	75,0	0	73,8	68,8
TECHNICAL/PROCEDURE	75,0	0	70,8	1	75,0	0	75,0	0	75,0	0	74,1	70,8
PATIENT PREPARATION	75,0	0	67,9	1	75,0	0	75,0	0	75,0	0	73,6	67,9
QA/QC	72,5	1	72,5	1	75,0	0	75,0	0	75,0	0	74,0	72,5
REPORTING AND FOLLOW-UP	66,7	1	68,8	1	75,0	0	75,0	0	75,0	0	72,4	66,7
GENERAL RESULTS	**Number of Applicables:**		153	**Non Conformances:**		7	**Total Score:**		451	**% Scoring**		73,7

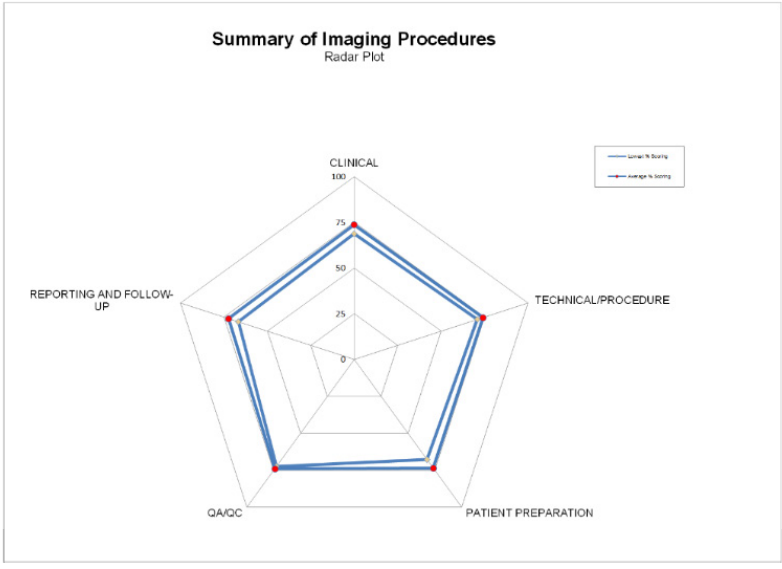

FIG. 5. Summary and radar plot of the assessment of diagnostic imaging procedures (example). NC — Non-conformance; QA — quality assurance; QC — quality control.

4.9. RADIONUCLIDE THERAPY

The conformance to quality standards of therapeutic services is central to ensure their clinical effectiveness and safety (GSR Part 3 [4], [22, 27, 28, 33, 35–38]). Checklist 9 evaluates the requirements for these services.

Checklist 9. Radionuclide therapy		
No.	**Component**	**Example of result/Type of evidence**
9.1	Are standard operating procedures (SOPs) based on national/international guidelines available for all types of treatments?	Check the SOPs for radionuclide therapy
9.2	For oncology treatments, has the decision to treat been taken after multidisciplinary evaluation?	Check the patient's records
9.3	Are conditions (medical, psychological, social) potentially interfering with the treatment checked for?	Check the instructions or SOPs for patient preparation
9.4	Is patient preparation related to the specific treatment addressed?	Check the SOP instructions and the patient's records
9.5	Does every patient receive information about the treatment, including indication; other treatment options; the need to stop lactation; side effects; preparation; therapy procedure; isolation, if applicable; and aftercare?	Check the procedures and the information provided to the patients before and after therapy
9.6	For paediatric patients: Are relatives/caregivers informed about the radiation protection measures to be taken and the risks of attending the child during therapy?	Observation on site/check the therapeutic procedures/check the written instructions
9.7	Is pregnancy ruled out by an appropriately timed laboratory test before therapy?	Check the SOP
9.8	Are instructions provided to the patient on the necessity and duration of contraception after therapy?	Check the written instructions to the patients

Checklist 9. Radionuclide therapy (cont.)		
No.	**Component**	**Example of result/Type of evidence**
9.9	Is informed consent obtained before therapy, consistent with national rules?	Check the written procedures of obtaining informed consent
9.10	Is there a SOP for the procurement, preparation and quality control (QC), if applicable, of therapeutic radiopharmaceuticals?	Check the written SOPs
9.11	Is the therapy timely, in line with clinical needs?	Check the records/check patient's file
9.12	Is the therapeutic activity prescribed in accordance with national/international guidelines, considering the target and non-target dose estimated by a medical physicist?	Check the SOPs for activity assignments
9.13	Is the administered activity individually measured and checked by an activity meter, which is calibrated and quality checked for the given radionuclide?	Check the records
9.14	Are SOPs on radiation protection measures in place for contamination, waste, etc., to reduce doses to caregivers and the public?	Observation on site
9.15	In case of in-patient therapy: Are facilities available with appropriate surface, shielding, sanitation, ventilation, waste management, etc.?	Check the SOPs and written documents/observation on site
9.16	In case of in-patient therapy: Is 24h/day nursing care provided?	Check the SOPs and written documents/observation on site
9.17	Has the nursing staff received appropriate radiation protection training to care for patients during treatment?	Check the corresponding SOPs and the nurses' personnel cards
9.18	In case of in-patient therapy: Is medical staff available for emergencies 24h per day?	Observation on site/check the SOPs and the organizational chart

Checklist 9. Radionuclide therapy (cont.)		
No.	**Component**	**Example of result/Type of evidence**
9.19	In case of in-patient therapy: Is a qualified person available outside normal working hours to handle urgent radioprotection issues?	Observation on site/check the SOPs and the organizational chart
9.20	Do the SOPs provide clear instructions for discharging patients in accordance with national regulations?	Check the SOPs
9.21	Is the patient's emitted dose rate measured and recorded in his or her file before discharge from the nuclear medicine service?	Check the written instruction/ check the patient's records
9.22	Are written instructions available for the patient and family/caregivers after discharge?	Check the written instructions/check the patient's records
9.23	Are procedures in place to make sure that these instructions have been understood by the patient/family/caregivers?	Check the SOP
9.24	Are there specific SOPs to prevent or manage misadministration (mismatch of patient and radiopharmaceutical) and/or maladministration (extravasation) of therapeutic radiopharmaceuticals?	Check the SOP
9.25	Is a comprehensive treatment report issued and made available to involved physicians and the patient?	Check an example of the report
9.26	Is there timely clinical follow-up of patients, with multidisciplinary review in the case of oncology patients?	Check the patient's records

4.10. ASSESSMENT OF THERAPY

The auditing team has to assess up to three therapy cases, selected from those most frequently performed.

This evaluation should cover clinical information, technical and radiation protection aspects, patient preparation, related QA/QC information and traceability, as well as reporting and follow-up. The results of each of these items are scored according to the scheme introduced in Section 3.5.3 and presented as a specific radar plot. Average results for all assessed procedures are also included in the overall radar summary (see Section 5). Cases should be randomly selected from current or archived files. Checklists 10.1, 10.2 and 10.3 are used to evaluate aspects of selected therapy procedures. Checklist 10.1 is provided as an example.

Checklist 10.1 Assessment of therapy		
No.	**Component**	**Example of result/Type of evidence**
	Clinical	
10.1	Appropriateness of this therapy based on a multidisciplinary evaluation and formally approved by the physician in charge of the treatment	Check the records/check the standard operating procedures (SOPs)/ check the related international guidelines
10.2	Treatment within a clinically appropriate time	Check the patient records
10.3	Possible interferences or contraindications to the therapy identified (e.g. patient condition, allergies, concurrent diseases, socioeconomic issues)	Check the patient records/ check the SOPs
10.4	Results of all relevant diagnostic procedures available (considering both patient history and current workup)	Check the records/ observation on site
10.5	Pregnancy excluded by laboratory test	Check the records/ observation on site
10.6	Was information about previous treatments, including previous radionuclide therapy, available?	Check the records

Checklist 10.1 Assessment of therapy (cont.)		
No.	**Component**	**Example of result/Type of evidence**
10.7	Was information about ongoing medical therapy available and checked for any potential interference with the current radionuclide therapy?	Check the records
Technical/Procedure: Check if done according to SOP		
10.8	Patient identification	Check the records/ check the SOPs
10.9	Was the correct radiopharmaceutical prescribed and was the activity based on the estimated dose to target and non-target tissues?	Check the records/ check the SOPs
10.10	Activity measured before administration, using a calibrated activity meter	Check the records
10.11	Prevention of misadministration (mismatch of patient and radiopharmaceutical) and/or maladministration (extravasation) of the radiopharmaceutical	Check the records/ check the SOPs
10.12	Information concerning subsequent contraception provided	Check the records
10.13	Imaging performed, when required, to check the biodistribution of the radiopharmaceutical	Check the records
Patient preparation: Check if done according to SOP		
10.14	Has the patient been fully informed and has consent been obtained as described?	Check the records/check the SOPs/observation on site
10.15	Instructions concerning treatment related medication and any other preparations given	Check the records/check the SOPs/observation on site
10.16	Patient medical condition and/or treatment related interference with the procedure checked	Check the records/ check the SOPs

Checklist 10.1 Assessment of therapy (cont.)		
No.	**Component**	**Example of result/Type of evidence**
10.17	Patient instructed on the necessity of avoiding pregnancy for a specified time after therapy. Relevant counselling on lactation given	Check the records/ check the SOPs
10.18	For paediatric patients: relatives/caregivers informed about radiation protection issues	Check the records/ check the SOPs
Radiation protection: Check if done according to SOP		
10.19	Double check of dose estimates/activity to be administered	Check the records/ check the SOPs
10.20	Precautions for protection of visitors, relatives/ caregivers (time, distance, preventing contamination, optional dosimeters)	Check the records/ check the SOPs
10.21	Measurement of dose rate at discharge	Check the records/ check the SOPs
10.22	Instruction at discharge, to limit dose to family, the public and contamination of environment	Check the records/ check the SOPs
10.23	Contamination monitoring of the ward	Check the records/ check the SOPs
Quality assurance/quality control: Check if done according to SOP		
10.24	Patient preparation ascertained	Check the records/ observation on site
10.25	Documentation of quality control (QC) of the radiopharmaceutical, including in the case of external procurement	Check the records/ check the SOPs
10.26	Filing of batch number, dosing and time of administration of any therapy related pharmaceutical	Check the records
10.27	Handling and documentation of any incidents (e.g. spilling, extravasation at the injection site, vomiting) or any adverse events	Check the records/ check the SOPs

Checklist 10.1 Assessment of therapy (cont.)		
No.	**Component**	**Example of result/Type of evidence**
10.28	Traceability of all patients and treatment related data (e.g. radiopharmaceutical, administered activity, route)	Observation on site/check all records for traceability
Reporting and follow-up		
10.29	Was a comprehensive treatment report issued and made available to all involved parties?	Check the report/ check the SOPs
10.30	Was the report drafted as specified in the relevant SOP?	Check the report/ check the SOPs
10.31	Was any feedback received after therapy properly documented and managed?	Check the records/ check the SOPs

4.10.1. Scoring therapy procedures

A radar plot will be produced to analyse the clinical observations of therapy procedures selected by the auditors. As shown in Fig. 6, the radar plot will display both the mean and minimum scores. For the diagnostic procedures, corresponding values for each component of the assessed therapeutic procedures are shown just above the radar plot representation.

4.11. RADIOPHARMACY

The range of facilities required varies markedly, depending on the operational category of the laboratory. Whatever functions are performed, it is crucial that laboratories offer protection to the operator, the product and the environment, including patients. Reference [30] categorizes hospital radiopharmacy (also known as ‘hot laboratory’) operations into three levels. It provides essential details (staffing, scope of operations, equipment, staff qualification, record keeping, level of quality management and QC) at each operational level (Table 3).

QUALITY MANAGEMENT AUDITS IN NUCLEAR MEDICINE

OVERALL SCORE OF THERAPEUTIC PROCEDURES

(Based on the evaluation of spreadsheets #12.1 through 12.3 up to 3 most frequent therapetic procedures)

Evaluated parameters	Enter title of therapeutic procedure 1		Enter title of therapeutic procedure 2		Enter title of therapeutic procedure 3		Average	Lowest result
	% Scoring	NC	% Scoring	NC	% Scoring	NC	% Scoring	% Scoring
CLINICAL	75,0	0	75,0	0	75,0	0	75,0	75,0
TECHNICAL/PROCEDURE	66,7	1	75,0	0	75,0	0	72,2	66,7
PATIENT PREPARATION	65,0	1	75,0	0	75,0	0	71,7	65,0
QA/QC	75,0	0	75,0	0	75,0	0	75,0	75,0
REPORTING AND FOLLOW-UP	75,0	0	66,7	1	75,0	0	72,2	66,7
GENERAL SCORE	Number of Applicables:	78	Non Conformances:	3	Total Score:	229	% Scoring	73,4

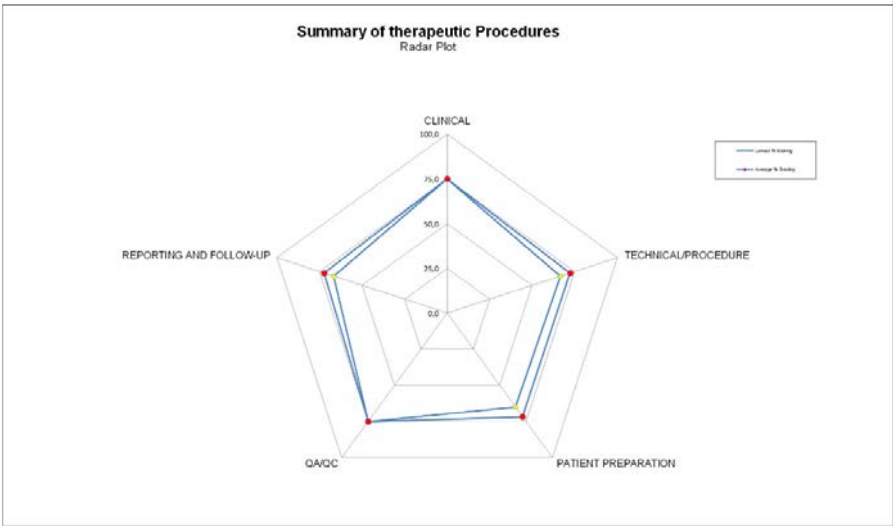

FIG. 6. Summary and radar plot of the assessment of therapeutic procedures (example). NC — non-conformance; QA — quality assurance; QC — quality control.

TABLE 3. OPERATIONAL LEVELS IN HOSPITAL RADIOPHARMACY

Operational level	Scope	Example
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.	Only unitary doses of ready to use radiopharmaceuticals, prepared by a manufacture or centralized radiopharmacy, are used.

TABLE 3. OPERATIONAL LEVELS IN HOSPITAL RADIOPHARMACY (cont.)

Operational level	Scope	Example
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.	Liquid solution and/or capsules of ^{131}I are in use.
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 sterilized radiopharmaceutical cold kits.	Generators of ^{99}Mo/^{99m}Tc are used, and commercially available kits of radiopharmaceuticals labelled. Therefore, complete checklist for level 1 and 2.
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.	^{99m}Tc or ^{111}In are used and cells, such as white blood cells, are labelled.
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 fall frequently under operational level 3a.	Kits are modified or are prepared in house and lyophilized for labelling. Therefore levels 1, 2 and 3 should be completed.
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.	Therapeutic radiopharmaceuticals are synthetized, based on commercially available precursor radionuclides, like ^{177}Lu chloride.

TABLE 3. OPERATIONAL LEVELS IN HOSPITAL RADIOPHARMACY (cont.)

Operational level	Scope	Example
3c	This operational level refers to the following: 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.	PET radiopharmaceuticals are syntheses starting from cyclotron or generator produced radionuclides. Use of PET generators (e.g. ^{68}Ga).

Many radiopharmacies at levels 1 and 2 do not have a trained radiopharmacist when radiolabelled compounds are for in-house use only. In the majority of these cases, the legal oversight is provided by the physician in charge if a trained pharmacist is not available. At OGHR operational level 3, a specialist radiopharmacist, radiochemist or a 'qualified person' is required to provide legal oversight. Advanced pharmaceutical QC and microbiology are expected [39–43].

Checklists 11, 12 and 13, respectively, address the three levels and are therefore structured in a sequential operational fashion. If the laboratory operates at level 2, checklists for both level 1 and level 2 have to be completed. The same concept applies for radiopharmacy level 3, which requires that the previous levels are to be completed.

Checklist 11. Radiopharmacy operational level 1		
No.	**Component**	**Example of result/Type of evidence**
Staffing		
11.1	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
11.2	Are there written staff training manuals for all categories of radiopharmacy staff?	Check the training standard operating procedure (SOP)/ check the personnel cards

Checklist 11. Radiopharmacy operational level 1 (cont.)		
No.	**Component**	**Example of result/Type of evidence**
Facilities		
11.3	Does the unit have appropriately finished rooms (including adequate lighting, walls, floors, ceilings, ventilation) and a shielded dispensing station?	Evaluation on site
11.4	Is there a validated (annual check on air flow, safety and challenge testing) fume hood with suitable filters for handling volatile radioactive material?	Evaluation on site
11.5	Are materials stored in specified and controlled conditions (e.g. in fridge), and are expired products removed?	Check the records/evaluation on site
Purchase of materials		
11.6	Are there SOPs for the purchase of radiopharmaceuticals?	Check SOPs/check the job description and personnel cards
11.7	Are all goods received checked and recorded against the order for correctness of delivery?	Check the records/check the purchase SOPs
Dispensing protocols		
11.8	Are there SOPs for the aseptic dispensing and identifying (labelling, marking, colour coding) of ready to use radiopharmaceuticals?	Check the SOPs
11.9	Is there a shielded fume cupboard with suitable filters, in case of volatile radioactive materials (e.g. ^{131}I, ^{219}Rn)?	Evaluation on site
11.10	Do SOPs contain safety and monitoring instructions for dispensing and manipulating radioiodine?	Check the SOPs

Checklist 11. Radiopharmacy operational level 1 (cont.)		
No.	**Component**	**Example of result/Type of evidence**
11.11	Can the documentation for each radiopharmaceutical batch be traced from the prescription to the administration of individual patient preparation?	Check the records/evaluation on field of radiopharmaceutical traceability
11.12	Is all documentation for each batch of radiopharmaceutical archived according to national regulations?	Check the records/check traceability
Quality assurance/Quality control		
11.13	Are radiopharmaceutical QCs performed or related documentation checked and eventual recalls properly managed?	Check the records/check the SOPs
11.14	Are daily activity meter checks performed using long lived radionuclide(s) to include the range of radioisotopes for patients?	Check the records/check the SOPs
11.15	Are there documented activity meter checks and calibration assays made of each radionuclide with a certified reference source (including checks on geometry, container type)?	Check the records/check the SOPs
11.16	Is there an SOP for complaints and for dealing with products not meeting the required standards?	Check the procedures
Waste		
11.17	Are there specific radiopharmacy SOPs for the disposal of radioactive and non-radioactive waste?	Check the procedures/ observation on site

Checklist 12. Radiopharmacy operational level 2		
No.	**Component**	**Example of result/Type of evidence**
Staffing		
12.1	Is there specific staff training and assessment of competency at operational level 2, including aseptic practice?	Check the training standard operating procedure (SOP)/ check the personnel cards
12.2	Are staff trained to perform final checks on all products before release for patient use?	Check the personnel cards
12.3	Is there regular confirmation of training for staff performing cell labelling?	Check the training SOP
Facilities		
12.4	Is there a Class II Type B microbiological safety cabinet in a dedicated, pharmacy classified room?	Check the records
12.5	For isolators, are gloves or gauntlets visually inspected, and integrity tests carried out and recorded before preparation takes place?	Check the records/evaluation on site
12.6	Is there an adequate heating, ventilation, air-conditioning (HVAC) system installed and regularly maintained?	Check the records/evaluation on site
12.7	Are all laminar flow hot cell, isolators, etc., validated and regularly checked?	Check the records/evaluation on site
Preparation protocols		
12.8	Are all methods and preparations documented in SOPs?	Check the approved documentation
12.9	Do all products, kits and generators have product approval, marketing authorization, or bear a product licence number?	Check the records/check the purchase SOP

Checklist 12. Radiopharmacy operational level 2 (cont.)		
No.	**Component**	**Example of result/Type of evidence**
12.10	Is the preparation of ^{99m}Tc radiopharmaceuticals from kits and generators carried out in a laminar air flow (LAF) cabinet?	Evaluation on site
12.11	Can each individual patient preparation be traced to a specific generator and kit batch number?	Check the records/evaluation on field of traceability
12.12	Do SOPs for autologous cell labelling include instructions on safety (i.e. doing a single patient preparation at a time), cleaning and decontamination after each preparation?	Check the SOPs/observation on site
12.13	Are there SOPs for the preparation and dispensing of radio-labelled biologicals (e.g. monoclonal antibodies, peptides from approved kit formulations)?	Check the procedures/ observation on site
Quality assurance/Quality control		
12.14	Have quality control (QC) criteria been set for the release of preparations before patient administration?	Check the procedures
12.15	Is a record of approval/release made by an authorized person before a product is administered to a patient?	Check the records
12.16	Is there a SOP for regular QC of ^{99}Mo/^{99m}Tc generator eluate (including ^{99}Mo breakthrough, Al contents, pH, radiochemical purity)	Check the procedures/check the records
12.17	Is there a SOP for regular QC of ^{99m}Tc labelled kits?	Check the procedures/check the records
12.18	Before patient use, are radiochemical purity tests performed on all new batches or newly delivered radiopharmaceutical kits?	Check the procedures/check the records

Checklist 12. Radiopharmacy operational level 2 (cont.)		
No.	**Component**	**Example of result/Type of evidence**
12.19	To assess aseptic dispensing, is there routine microbiological monitoring (e.g. 90 mm agar plates, contact plates and swabs)?	Check the procedures/check the records
12.20	Are changes in the use of kits, diluents or vehicles, needles, syringes, swabs and sterile containers recorded?	Check the procedures/check the records

Checklist 13. Radiopharmacy operational level 3		
No.	**Component**	**Example of result/Type of evidence**
	Staffing	
13.1	Is the radiopharmacy operational level 3 unit operated under the direction of a person with appropriate training and qualification as defined by local or national regulations?	Check the training standard operating procedure (SOP)/ check the personnel cards
13.2	Is there specific staff training and assessment of competency at operational level 3, including all risks, deviations and change control, pharmaceutical formulation, quality control (QC), validation, and aseptic practice?	Check the training SOP/check the personnel cards
13.3	Are there appropriately trained staff members (minimum 3 of them) for compounding of diagnostics, therapies or cold-kits, or sub-dispensing of commercial kits and validation/release of the final product?	Check the training SOP/check the personnel cards
13.4	Are there QC staff (independent from those involved in specific production) trained to perform final checks and batch release on all products prepared for patient use?	Check the training SOP/check the personnel cards

Checklist 13. Radiopharmacy operational level 3 (cont.)		
No.	**Component**	**Example of result/Type of evidence**
	Facilities	
13.5	Are there clean rooms with anteroom facilities fitted with HEPA filters meeting USP/EU standards, Class D for use with isolators and Class C with laminar air flow (LAF) cabinets?	Check the records/evaluation on the field
13.6	Is there a heating, ventilation, air-conditioning (HVAC) system installed, validated and maintained?	Check the records/evaluation on the field
13.7	Are these facilities and all critical equipment regularly monitored and under control (e.g. differential pressure, airflow rates, particle counts, microbiological contamination)?	Check the records/evaluation on the field
13.8	Is all analytical equipment (high performance liquid chromatography (HPLC), gamma counter (GC), thin-layer chromatography (TLC), weighing scales, etc.) validated and maintained? Are records kept of cleaning, routine calibration and maintenance?	Check the records/evaluation on the field
13.9	Does the terminal sterilization and dispensing take place under ISO 5, Class 100 or EU Grade A conditions? Is this supported by controls such as microbiological plate and broth, and filter integrity tests?	Check the records/evaluation on the field
	Operational protocols	
13.10	Are synthesis modules tested for tightness and integrity/function before starting each synthesis?	Check the records

Checklist 13. Radiopharmacy operational level 3 (cont.)		
No.	**Component**	**Example of result/Type of evidence**
13.11	Is there an SOP for material management, including control and checks on all raw materials (chemicals or gas)? If applicable, are only ingredients and reagents of pharmaceutical grade used and does all glassware or all consumables have quality mark?	Check the records/evaluation on the field
13.12	Is there an SOP for control of material storage conditions (e.g. storage in fridge/freezer/ desiccator/at room temperature) and does each item have a QC traceable tag?	Check the records/evaluation on the field
13.13	Are the environmental conditions compliant during production, and is the preparation of each stage of radiopharmaceutical compounding carried out in a laminar air flow (LAF) cabinet?	Check the records/evaluation on the field
13.14	Is each step checked and cross-checked on the working document when the task is completed?	Check the records/evaluation on the field
13.15	Can each individual patient preparation and/or batch number be traced back by an operational documentation system to the starting material, equipment used, operators, cyclotron run, specific generator and/or kit, QC processes and final release?	Check the records/evaluation on the field
13.16	Are there SOPs with instructions on safety, cleaning, line clearance and decontamination for prevention of any cross-contamination?	Check the procedure, records/ evaluation on the field
13.17	Are all critical checks (including visual), changes and amendments during the process of preparation of individual radiopharmaceuticals, kits, PET modules, therapies formally controlled, approved, timed and dated?	Check the records/change control documentation/ evaluation on the field

Checklist 13. Radiopharmacy operational level 3 (cont.)		
No.	**Component**	**Example of result/Type of evidence**
13.18	Does the batch master file specify an approved label that includes pharmacopeia name, activity, reference and expiry time, 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 batch?	Check the records/evaluation on the field
13.19	Does the production manager check before batch handover to QC for final release to the patient?	Check the records/evaluation on the field
Quality assurance/Quality control		
13.20	Are there SOPs for QA/QC, based on pharmacopeia or equivalent validated methods?	Check the procedure, records/ evaluation on the field
13.21	Does the quality controller independently check environmental compliance, material, documentation, equipment, operator, cleaning, etc.?	Check the procedure, records/ evaluation on the field
13.22	Is a validation done before starting a new or significant modification to an existing method of synthesis?	Check the procedure, records/ evaluation on the field
13.23	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, plates controls, end of broth, contact plates, sterility testing, etc.?	Check the procedure, records/ evaluation on the field
13.24	Is there an annually tested product recall procedure to ensure radiopharmaceuticals are not administered to patients before receipt of the product release document?	Check the procedure, records/ evaluation on the field

Checklist 13. Radiopharmacy operational level 3 (cont.)		
No.	**Component**	**Example of result/Type of evidence**
13.25	Have all critical assessments been performed and any changes been approved by a qualified person before release for patient administration?	Check the procedure, records/ evaluation on the field
13.26	Is there an SOP for packing and safe transportation requirements in accordance with IAEA guidelines?	Check the procedure, records/ evaluation on the field
13.27	Is there timely transmission of a product release document/certificate of analysis to end users and follow-up of deficiencies, complaints and feedback?	Check the procedure, records/ evaluation on the field
13.28	Is there an annual programme of self-assessment and audit of quality management system (QMS) at radiopharmacy operational level 3?	Check the procedure, records/ evaluation on the field
13.29	Are there proper UN compliant waste disposal practices including separate lead shielding for radioactive waste and waste containers for solvents and biological waste?	Check the procedure, records/ evaluation on the field

4.12. HORMONES AND TUMOUR MARKERS

Checklist 14 focuses on the clinical use of hormones and tumour markers for NMSs using radioimmunoassay. It may not apply to all audited NMSs. In this case, it should be marked as ‘non-applicable’. This audit is divided into three components: pre-analytical, analytical and post-analytical.

Checklist 14. Hormones and tumour markers		
No.	**Component**	**Example of result/Type of evidence**
Good laboratory practices		
14.1	Does the radioimmunoassay service have formal authorization from a recognized national authority?	Check the written authorization from the national authority
14.2	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
14.3	Is there a clear protocol stating the action required in a follow-up of suspected result errors in the laboratory?	Check the protocol
14.4	Is there a mechanism to check why its recent results are 20% lower, while all previous results have been within 10% of the target?	Check the mechanism
14.5	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
14.6	Is there a mechanism to double-check records of reported 'undetectable' when the expected result would have been clinically significant?	Check the mechanism
Pre-analytical phase		
14.7	Is there a procedure to follow when the clinical user does not provide the necessary information or the correct specimen?	Check the written procedure
14.8	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 the records

Checklist 14. Hormones and tumour markers (cont.)		
No.	**Component**	**Example of result/Type of evidence**
14.9	Is there a periodic review of the appropriateness and integrity of the sample transport system?	Check the records
14.10	Is there a periodic review to ensure that the confidentiality of patient results is guaranteed?	Check the records
14.11	Is there a periodic review to ensure biological safety?	Check the records
Analytical phase		
14.12	Are there records of regression line analyses with a known amount of the international standard in serum?	Check the records
14.13	Are there records of recovery experiments to validate a new method?	Check the records
14.14	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 the records
14.15	Is there a Levey–Jennings plot, including controls and standards for each assay?	Check the records
14.16	Is there a clear written protocol when points are outside the 2 standard deviation limits?	Check the written protocol
14.17	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		
14.18	Is there a standard format for reporting laboratory results that includes the laboratory's name, patient details, requesting person, test description, sample type (e.g. serum, urine), results (plus reference values), interpretative comments (if any) and signature of authorized professional?	Check the procedures/check the reports

Checklist 14. Hormones and tumour markers (cont.)		
No.	**Component**	**Example of result/Type of evidence**
14.19	Is there a list of authorized staff members who are designated to amend patient notes or reports and to communicate results?	Check the procedures/check the reports
14.20	Are reference values based on national or regional findings available for each assay type?	Check the written procedures
14.21	Is feedback from clinical interpretative services documented?	Check the records

5. RADAR SUMMARY

Using the Excel tool available at the IAEA Human Health Campus (see Ref. [11]) and the scores, assigned as explained in Section 3.5.3, the percentages of conforming requisites for each checklist could be calculated; the summary is presented as a radar plot. In the radar plot, each spoke represents the percentage of conformance for each specific checklist (Fig. 7). Also, for each of the general checklists, the upper part of the page shows the number of applicable requirements, the total score, the number of non-conformance and the percentage of scoring. This radar summary does not include diagnostic and therapeutic procedures which are represented with their own radar plot as described in Sections 4.8.1 and 4.10.1.

The third row in the rightmost column represents the percentage of the total score received by the auditors toward the maximum achievable score (i.e. the number of applicable questions multiplied by 4), which is the maximum achievable score for each requirement. The program provides the score for each individual checklist, as well as the overall total score.

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(TABULAR AND GRAPHICAL PRESENTATION)

General Checklist	1. Strategies	2. Radiat Reg	3. Patient R.Prot	4. QA System	5. Equip. QA/QC	6. IT Syst	7. Clin Serv	8. Spec.Diag. P	9. Ther Serv	10. Spec. Ther.P	11. RP Lev 1	12. RP Lev 2	13. RP Lev 3	14. H&T Markers	TOTAL
Applicables	19	24	12	15	9	11	28	153	26	78	17	18	27	21	458
Total Score	54	68	34	42	17	33	82	451	72	229	39	37	78,0	61	1297
% Scoring	71,1	70,8	70,8	70,0	47,2	75,0	73,2	73,7	69,2	73,4	57,4	51,4	72,2	72,6	70,8
N. of NC	2	3	2	2	6	0	2	7	4	3	8	10	3	1	53

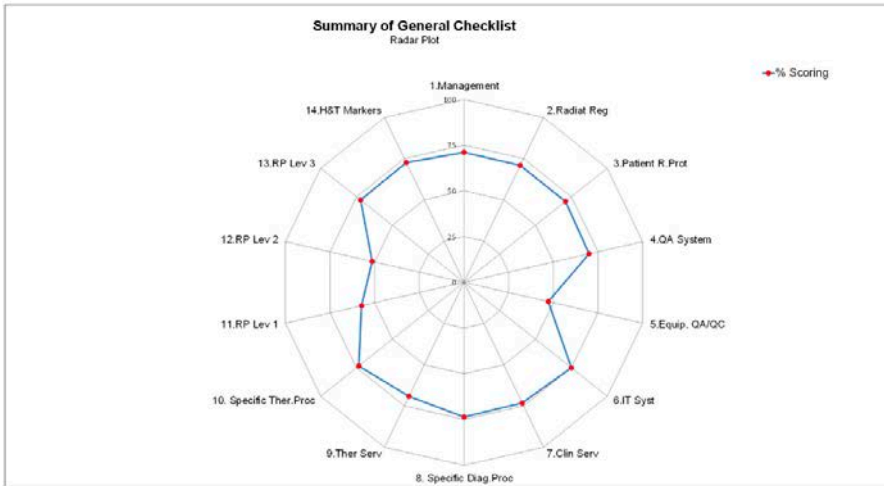

FIG. 7. Total scoring (rows in the upper third of the image) and corresponding radar plot.

6. AUDIT REPORT

6.1. PRIORITIZATION OF NON-CONFORMANCES

Prioritization of non-conformances is important. In the QUANUM programme three levels of prioritization are considered: 'critical', 'major' and 'minor' (see also Section 3.5.5), as follows:

Critical priority: Issues affecting the safety of the patients, staff, caregivers and/or environment for which corrections should be immediately addressed or initiated within days or weeks, depending on severity.

Major priority: Issues or potential threats affecting the capacity of the NMS to adequately perform, which should be addressed in a timely manner (e.g. within 3–6 months).

Minor priority: Issues requiring optimization, to be fixed within a defined time period and re-evaluated during the next audit.

In QUANUM 3.0, a default priority level is automatically assigned in the checklists, based on a consideration of the content of each specific requisite and the experience gained in previous audits. If needed, however, auditors can modify the level of priority, based on their own experience, the available evidence and local circumstances. In this case, an explanation should be provided in the appropriate comments section. Figure 8 shows an example taken from a test spreadsheet where non-conformances are recorded according to their priority.

The audit report sheet, as shown in Fig. 9, will also identify the function(s) in charge of the corrective actions and the date for their achievement.

6.2. IAEA EXTERNAL AUDIT FINAL REPORT

In addition to the standard report produced with the help of the spreadsheet, further documentation and information is requested for IAEA managed external audits, such as other comments on the international aspect of IAEA audits and the formal process of data made by the IAEA. In addition to the general information given in Section 3.5.7, specific guidance is provided in Table 4.

TABLE 4. STRUCTURE OF IAEA AUDIT REPORT

Structure of report	Comments
Introduction	Background, demographics, public health system, national funding
Terms of reference	Activities of the auditing team
Quality management	Mission, vision, quality policy, documentation 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

TABLE 4. STRUCTURE OF IAEA AUDIT REPORT (cont.)

Structure of report	Comments
Equipment	Imaging and ancillary equipment, computer systems and data handling, QA/QC 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
Major strengths and deficiencies	Major strengths should be listed; any deficiencies should be recorded, with an indication as to 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	Any documentation supporting the final report and recommendations

No.Req.	Requirement	Comment	Priority
2.20	Are procedures available to prevent and handle both radiation and biohazard incidents (needle stick, contamination from syringes shields, catheters, urine bags, diapers etc)?	It was observed that staff systematically recaps syringes by hand, with the risk of puncturing.	CRITICAL
3,2	Is there appropriate signage for alerting female patients of child bearing age to report any potential pregnancy or breast-feeding?	The signs regarding pregnancy are not present in all of the administration rooms.	CRITICAL
9,7	Is pregnancy ruled out by an appropriately timed laboratory test before therapy ?	Pregnancy is only ruled out by inquiring the patient, and not by accurate lab-tests.	CRITICAL
9,12	Is the therapeutic activity prescribed, taking into account the target and non-target dose estimated by qualified person, in accordance with national/international guidelines?	Fixed activities are used,and non-target dose is not assessed.	MINOR CRITICAL MAJOR
11,9	Is there a shielded fume cupboard with suitable filters, in case of volatile radioactive materials (131I, 219Rn, etc) ?	No dedicated iodine cupboard.	CRITICAL
11,13	Are radiopharmaceuticals quality controls performed or related documentation checked and eventual recalls properly managed ?	Correspondence between order and received products is not checked.	CRITICAL
2,14	Is there a procedure for surface contamination monitoring of all controlled areas at adequate time intervals , including data recording ?	SOP is present, but surveys are made only every two months. This frequency should be improved (at least weekly).	MAJOR
2,19	Are properly calibrated and functional radiation monitoring devices (i.e. accurate dose rate meter, surface contamination monitor) available?	A limited number of portable monitoring instruments is available. This needs to be improved, considering the size of the department.	MAJOR

FIG. 8. Example of a report page with non-conformances; auditors' comments to justify assigned priority level and corresponding priority level. The figure also shows that using the drop-down menu of the corresponding cell, the priority could be modified if required by observation of local circumstances.

No.Req.	Requirement	Comment	Priority	Responsible Person	Date achieved
2.9	Is personal protective equipment (e.g. gloves, syringe shields, handling tongs, etc.) available and used?	Adequate means for radiation protection of workers when managing radiopharmaceuticals should be available and their use required in relevant SOPs	CRITICAL	Radiation protection officer	1-month post-audit
7.22	Is a fully equipped emergency cart, oxygen and suction pump available?	A fully equipped emergency cart, oxygen and suction pump should be in place and checked and replenished on a regular basis.	CRITICAL	Responsible of technologist area	1-week post-audit
11.9	Is there a shielded fume cupboard with suitable filters, in case of volatile radioactive materials (131I, 219Rn, etc.)?	Handing of radioiodine solutions must be performed in an appropriated fume cupboard with suitable filters, or in a well-ventilated area in the case of radioiodine capsules.	CRITICAL	Responsible of radiopharmacy area	1-month post-audit
3.3	Is verbal and written information provided to patients about their procedure before and after administration of radiopharmaceuticals?	It is required to establish detailed SOPs to provide verbal and written instructions to patients before and after their nuclear medicine studies.	MAJOR	Responsible of technologist area	3 months post-audit
5.6	Are the most relevant planar/SPECT parameters regularly checked, reviewed and recorded, including trend analysis: uniformity, spatial resolution, COR, SPECT performance, as well as other parameters considered critical in the internal QA program?	A QA/QC program should be implemented, and SOPs prepared. Data on quality checks should be duly recorded in logbooks	MAJOR	Medical physicist	6 months post-audit
7.2	Is a mechanism in place to regularly update internal SOPs, archive obsolete versions, and distribute new ones, to all relevant work places	Clinical SOPs should be reviewed, updated and properly distributed to the work places	MINOR	Quality manager	6 months post-audit
1.3	Does the nuclear medicine service have an updated written organizational chart, indicating channels of communication and lines of authority?	The organizational chart and lines of authority should be reviewed and updated including the new areas to provide PET-CT services.	MINOR	Quality manager	6 months post-audit

SUMMARY - NON-CONFORMANCES	
CRITICAL	3
MAJOR	2
MINOR	2
TOTAL	7

FIG. 9. Example of a worksheet reporting non-conformances, their priority level, comments to support prioritization, summary of non-conformances and function(s) in charge of the corrective actions and date for achievement.

Appendix

GLOSSARY

acceptance test. A test carried out to prove that a newly acquired piece of equipment or system is in accordance with the specification established in the procurement phase. An acceptance test generally consists of measurements of the performance and functional parameters of the components and accessories of a new equipment/system. These measurements can be done at the manufacturing site (factory acceptance test, FAT) and/or confirmed by measurements taken in the diagnostic department (site acceptance test, SAT) after the device has been installed. (ISO 8402 [44]; IEC 1223-1 [45])

action level. A pre-set reference level of a measurable parameter that, when exceeded, is considered sufficient to warrant a remedial action. (QUANUM 3.0 [11])

appropriateness. Appropriateness is a complex issue with various dimensions and variable definitions in different countries or regions. Most definitions of appropriateness address a number of key requirements: that care is effective (based on valid evidence); efficient (cost-effectiveness); and consistent with the ethical principles and preferences of the relevant individual, community or society. (WHO-EU, European Health 21, 2000 [46])

aseptic processing. Handling of sterile products, containers and/or devices in a controlled environment, in which the air supply, materials, equipment and personnel are regulated to maintain sterility. (ISO/TS 19930:2017 [47]; ISO 11139:2018 [48])

audit. A systematic, independent and documented process for obtaining evidence and evaluating it objectively to determine the extent to which audit criteria and/or standard requirements are fulfilled. Audits are based on a sample and are independent of the process or product being audited, unlike review and verification activities, which are part of a process. (ISO 19011:2018 [49]; ISO/IEC 17000:2004 [50])

audit (external). External audits include those generally called second and third party audits. Second party audits are conducted by parties having an interest in the organization, such as customers, or by other individuals on their behalf. Third party audits are conducted by independent

auditing organizations, such as those providing certification/registration of conformity or governmental agencies**.** (ISO 19011:2018 [49]; ISO/IEC 17000:2004 [50])

audit (internal). Internal audits, sometimes called first party audits, are conducted by, or on behalf of, the organization itself. (ISO 19011:2018 [49]; ISO/IEC 17000:2004 [50])

authorization. The granting by a regulatory body or other governmental body of written permission for a person or organization (the operator) to conduct specified activities. (GSR Part 3 [4])

calibration. Calibration establishes a relation between the quantity value provided by a measurement standard and the corresponding indication provided by a measuring instrument or system. Calibration also requires determination of the uncertainties associated with the measurements performed. (JCGM 200: 2012 [51])

competence. Demonstrated personal attributes and demonstrated ability to apply knowledge and skills to achieve intended results. (ISO 9000:2015 [52]; ISO 14025:2006 [53]; ISO 44001:2017 [54])

complaint. Reported, written, electronic or verbal expression of dissatisfaction made to an organization, related to its products or service, or the complaints handling process itself, where a response or resolution is explicitly or implicitly expected. (ISO 9000:2015 [52])

compounding. Formulation of radiopharmaceutical reagent kits from raw ingredients for the preparation of radiopharmaceuticals by the addition of radioisotopes, adding reagents to commercial kits to modify or enhance the performance of radiopharmaceuticals (shelf life extension, fractionation) and/or synthesis from raw materials. (Operational Guidance on Hospital Radiopharmacy, IAEA, 2008 [38])

corrective action. Action to eliminate the cause of a non-conformity or other undesirable situation and to prevent recurrence. (ISO 9000:2015 [52])

deviation. A difference between expected and actual implementation of a process, or in the comparison of performance indicators, as the difference of an observed value from the benchmark applied. (ISO 24523:2017 [55])

diagnostic reference levels. Dose levels in medical radiodiagnostic practices or, in the case of radiopharmaceuticals, levels of activity, for typical examinations for groups of standard sized patients or standard phantoms for broadly defined types of equipment. Periodic assessments are performed of typical doses or activity of the radiopharmaceuticals administered in a medical facility. If comparison with established diagnostic reference levels shows that the typical doses or activity of the radiopharmaceuticals administered are either too high or unusually low, a local review is to be initiated to ascertain whether protection and safety has been optimized and whether any corrective action is required. (GSR Part 3 [4])

emergency. A non-routine situation that necessitates prompt action, primarily to mitigate a hazard or adverse consequences for human health and safety, quality of life, property or the environment. This includes nuclear or radiological emergencies and conventional emergencies such as fires, release of hazardous chemicals, storms or earthquakes. It includes situations for which prompt action is warranted to mitigate the effects of a perceived hazard. (GSR Part 3 [4])

indicator. A measurable parameter or quantity that assesses the degree to which a set of characteristics fulfils requirements. A measure can be expressed, for example, as % yield, % defects, etc. Quality indicators can measure how well an organization meets the needs and requirements of users and the quality of all operational processes. (ISO 15189:2012 [56])

interested party/stakeholder. A person, organization or company that can be affected by, or perceive itself to be affected by, the activities and performance of an organization, business, system, etc. (GSR Part 3 [4]; ISO 28007-1: 2015 [57])

job description. A list of specific or general tasks or functions and goals or responsibilities of a position, as well as the organizational conditions under which those tasks and functions are to be performed. A job description can include the organizational structure. (ISO 30400:2016 [58])

maladministration. An error in the administration of a radiopharmaceutical (e.g. leading to extravasation or infiltration of the product around the injection site). (QUANUM 3.0 [11])

management system. A set of interrelated or interacting elements (system) for establishing policies and objectives and enabling the objectives to be achieved in an efficient and effective manner. (GSR Part 3 [4])

manufacturing. The manufacturing licence issued by competent authorities, for example, the FDA process, ensures that manufacturers have approval from government authorities for pharmaceutical production. The manufacturers have approval from the government to supply products that are registered or approved for safety, quality and efficacy. The manufacturer should follow national or international good manufacturing practice (GMP) guidelines. Generally, the regulations for manufacturing are not applied for compounding. (Operational Guidance on Hospital Radiopharmacy, IAEA, 2008 [38])

medical device. Any instrument, apparatus, appliance, material or other article, whether used alone or in combination, including the software necessary for its proper application, intended by the manufacturer to be used for human beings for several purposes such as diagnosis, treatment, alleviation of disease and more. (EU Directive 93/42/EEC [59]) An instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part or accessory, which is intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or intended to affect the structure or any function of the body in man or other animals, and which does not achieve any of its primary intended purposes through chemical action within or on the body in man or other animals and which is not dependent upon being metabolized for the achievement of any of its primary intended purposes. (US 21 CFR 80–1299 [60])

misadministration. A mismatch between the patient and the radiopharmaceutical to be administered, leading to an unjustified exposure. (QUANUM 3.0 [11])

mission. The purpose of an institution/organization as expressed by the management. (ISO 9000:2015 [52])

non-conformance. Non-fulfilment of a requirement (i.e. need or expectation that is stated, generally implied or obligatory). (ISO 9000:2015 [52])

operational level 1a. Operational level 1a is the dispensing of radiopharmaceuticals purchased or supplied in their final form from

recognized and/or authorized manufacturers or centralized radiopharmacies. This includes unit doses or multiple doses of prepared radiopharmaceuticals for which no compounding is required. (Operational Guidance on Hospital Radiopharmacy, IAEA, 2008 [38])

operational level 1b. Operational level 1b is the dispensing of radioiodine and other ready to use radiopharmaceuticals for radionuclide therapy or palliation. This includes ready to use injections of strontium and samarium for pain palliation. (Operational Guidance on Hospital Radiopharmacy, IAEA, 2008 [38])

operational level 2a. Operational level 2a is the preparation of radiopharmaceuticals from prepared and approved reagent kits, generators and radionuclides (closed procedure). This is the most common activity in nuclear medicine departments, with routine use of a technetium generator and reconstitution of pre-sterilized radiopharmaceutical cold kits. (Operational Guidance on Hospital Radiopharmacy, IAEA, 2008 [38])

operational level 3a. Operational level 3a is the compounding of radiopharmaceuticals from ingredients and radionuclides for diagnostic application (including open procedure); modification to existing commercial kits; in-house production of reagent kits from ingredients, including freeze dried operation; related research and development. (Operational Guidance on Hospital Radiopharmacy, IAEA, 2008 [38])

operational level 3b. Operational level 3b is the compounding of radiopharmaceuticals from ingredients and radionuclides for therapeutic application (including open procedure) together with related research and development. Examples include radio-iodination of meta-iodobenzyl guanidine (MIBG) and rhenium labelled lipiodol. (Operational Guidance on Hospital Radiopharmacy, IAEA, 2008 [38])

operational level 3c. Operational level 3c is the synthesis of positron emission tomography (PET) radiopharmaceuticals. This includes the increasingly popular fluorodeoxy-glucose (^{18}F) injections (FDG). The compounding of radiopharmaceuticals produced from unauthorized or long lived generators such as gallium (^{68}Ga) or rhenium (^{188}Re) — mostly related research and development — also falls under operational level 3c. (Operational Guidance on Hospital Radiopharmacy, IAEA, 2008 [38])

policy. Intentions and direction of an institution/organization as formally expressed by its top management. (ISO 9000:2015 [52])

preventive action. Action to eliminate the cause of a potential non-conformity or other potential undesirable situation. (ISO 9000:2015 [52])

process. A set of interrelated or interacting activities that use inputs to deliver an intended result. Processes in an organization are generally planned and carried out under controlled conditions to add value. (ISO 9000:2015 [52])

quality assurance. The function of a management system that provides confidence that specified requirements will be fulfilled. (https://asq.org/quality-resources/quality-assurance-vs-control)

quality committee. The quality committee supports, in its implementation, the quality policy defined by the management, supervises the appropriate and uniform application of the quality assurance procedures, recommends quality assurance tools and provides training and information for their implementation. Furthermore, it engages in self-assessment and periodic evaluation of the quality management system. (QUANUM 3.0 [11])

quality manual. Specification (stated requirements) for the quality management system of an institution/organization. (ISO 9000:2015 [52])

quality mark. A mark of conformity, approval or certification mark on a commercial product indicates that there are accepted product standards or regulations and shows that compliance has been verified with those standards or regulations. (QUANUM 3.0 [11])

quarantine. Also indicated as segregation. Enforced separation of non-conforming products from products that conform to the requirements. It is aimed at segregating any discrepant material or take out of service any equipment that is temporarily in non-operational condition. (ISO 22006:2009 [61]; QUANUM 3.0 [11])

review. Determination of the suitability, adequacy or effectiveness of a process, product or system to achieve established objectives (e.g. management review, review of customer satisfaction data, review of corrective action). (ISO 9000:2015 [52])

risk. A combination of the probability of occurrence of harm and the severity of that harm. (ISO/IEC Guide 51:2014 [62])

risk assessment. Also termed safety assessment. Regular assessment of performance for protection and safety, and the application of lessons learned from experience. (GSR Part 3, Requirements 5, 13 [4])

risk management. The systematic application of management policies, procedures and practices to the task of analysing, evaluating, controlling and monitoring risk. (ISO 14971:2007 [63])

sanitization. Operation used to reduce undesirable micro-organisms on objects and surfaces to a desired level for pharmaceutical processing. (ISO 22716:2007 [64]; QUANUM 3.0 [11])

services exchange. A form of outsourcing, or arrangement in which an institution/organization performs part of the functions or processes of another institution/organization. (ISO 9000:2015 [52])

standard operating procedure (SOP). A document in written or electronic form, whose emission is authorized, and whose revision is under control, that specifies the way to carry out an activity or a process within an institution/organization. QUANUM does not set limits on the format of an SOP; depending on the needs, an SOP can be a descriptive text, a table or a flow chart. (QUANUM 3.0 [11]; ISO 9000:2015 [52])

sterilization. Validated process used to render a product free of all forms of viable micro-organisms. (ISO 22442-3:2007 [65])

strategy. A plan to achieve a long term or overall objective. (ISO 9000:2015 [52])

traceability. Ability to trace the history, application or location of an object or product. (ISO 9000:2015 [52])

validation. Confirmation, through the provision of objective evidence, that the requirements for a specific intended use or application have been fulfilled. The objective evidence needed for a validation is the result of a test or other form of determination such as performing alternative calculations or reviewing documents. (ISO 9000:2015 [52])

vision. Aspiration of what an institution/organization would like to become as expressed by the management. (ISO 9000:2015 [52])

workers' health surveillance. Medical supervision intended to ensure the initial and continuing fitness of workers for their intended tasks. (GSR Part 3 [4])

REFERENCES

[1] INTERNATIONAL ATOMIC ENERGY AGENCY, Quality Management Audits in Nuclear Medicine Practices, IAEA, Vienna (2008).

[2] INTERNATIONAL ATOMIC ENERGY AGENCY, Quality Management Audits in Nuclear Medicine Practices, IAEA Human Health Series No. 33, Second Edition, IAEA, Vienna (2015).

[3] INTERNATIONAL ATOMIC ENERGY AGENCY, Leadership and Management for Safety, General Safety Requirements, IAEA Safety Standards Series No. GSR Part 2, IAEA, Vienna (2016).

[4] INTERNATIONAL ATOMIC ENERGY AGENCY, Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards, IAEA Safety Standards Series No. GSR Part 3, IAEA, Vienna (2014).

[5] INTERNATIONAL ATOMIC ENERGY AGENCY, Radiation Protection and Safety in Medical Uses of Ionizing Radiations, IAEA Safety Standards Series No. SSG-46, Vienna (2018).

[6] DONDI, M., et al., Comprehensive auditing in nuclear medicine through the international atomic energy agency quality management audits in nuclear medicine (QUANUM) program, Part 1: The QUANUM program and methodology, Semin. Nucl. Med. **47** 6 (2017) 680–686.

[7] DONDI, M., et al., Comprehensive auditing in nuclear medicine through the international atomic energy agency quality management audits in nuclear medicine program, Part 2: Analysis of results, Semin. Nucl. Med. **47** 6 (2017) 687–693.

[8] DONDI, M., et al., Implementation of quality systems in nuclear medicine: Why it matters: An outcome analysis (Quality management audits in nuclear medicine Part III), Semin. Nucl. Med. **48** 3 (2018) 299–306.

[9] HEXTER, A.T., How to conduct a clinical audit: A guide for medical students, http://cures.cardiff.ac.uk/files/2014/10/NSAMR-Audit.pdf

[10] BURGESS, R., New Principles of Best Practice in Clinical Audit, National Institute for Clinical Excellence, Radcliffe Publishing, New York (2011).

[11] INTERNATIONAL ATOMIC ENERGY AGENCY, QUANUM 3.0, Excel Tool and QNUMED, http://humanhealth.iaea.org/HHW/NuclearMedicine/QUANUM_2.0_Excel_Tool_and_QNUMED/index.html

[12] INTERNATIONAL ATOMIC ENERGY AGENCY, Nuclear Medicine Data Base, https://nucmedicine.iaea.org/

[13] INTERNATIONAL ATOMIC ENERGY AGENCY, Application of the Management System for Facilities and Activities, IAEA Safety Standards Series No. GS-G-3.1, IAEA, Vienna (2006).

[14] VINCENT, C., et al., How to investigate and analyse clinical incidents: Clinical Risk Unit and Association of Litigation and Risk Management protocol, BMJ **320** (2000) 777–781.

[15] INTERNATIONAL ORGANIZATION FOR STANDARDIZATION, Guidelines for Auditing Management Systems, ISO 19011:2018, ISO, Geneva (2018).
[16] INTERNATIONAL ATOMIC ENERGY AGENCY, Planning a Clinical PET Centre, IAEA Human Health Series No. 11, IAEA, Vienna (2010).
[17] INTERNATIONAL ATOMIC ENERGY AGENCY, Cyclotron Produced Radionuclides: Guidelines for Setting Up a Facility, Technical Reports Series No. 471, IAEA, Vienna (2009).
[18] INTERNATIONAL ATOMIC ENERGY AGENCY, Quality Assurance for PET and PET/CT Systems, IAEA Human Health Series No. 1, IAEA, Vienna (2009).
[19] INTERNATIONAL ATOMIC ENERGY AGENCY, Quality Assurance for SPECT Systems, IAEA Human Health Series No. 6, IAEA, Vienna (2009).
[20] INTERNATIONAL ATOMIC ENERGY AGENCY, Quality Assurance for Radioactivity Measurements in Nuclear Medicine, Technical Reports Series No. 454, IAEA, Vienna (2006).
[21] AMERICAN ASSOCIATION OF PHYSICISTS IN MEDICINE, The Selection, Use, Calibration, and Quality Assurance of Radionuclide Calibrators Used in Nuclear Medicine, Report of AAPM Task Group 181, AAPM, College Park, MD (2012).
[22] INTERNATIONAL ATOMIC ENERGY AGENCY, Nuclear Medicine Resources Manual 2020 Edition, IAEA Human Health Series No. 37, IAEA, Vienna (2020).
[23] INTERNATIONAL ATOMIC ENERGY AGENCY, Radiolabelled Autologous Cells: Methods and Standardization for Clinical Use, IAEA Human Health Series No. 5, IAEA, Vienna (2015).
[24] INTERNATIONAL ATOMIC ENERGY AGENCY, Nuclear Cardiology: Guidance on the Implementation of SPECT Myocardial Perfusion Imaging, IAEA Human Health Series No. 23 (Rev. 1), IAEA, Vienna (2016).
[25] INTERNATIONAL ATOMIC ENERGY AGENCY, Standard Operating Procedures for PET/CT: A Practical Approach for Use in Adult Oncology, IAEA Human Health Series No. 26, IAEA, Vienna (2013).
[26] INTERNATIONAL ATOMIC ENERGY AGENCY, Appropriate Use of FDG-PET for the Management of Cancer Patients, IAEA Human Health Series No. 9, IAEA, Vienna (2010).
[27] INTERNATIONAL ATOMIC ENERGY AGENCY, Release of Patients After Radionuclide Therapy, Safety Reports Series No. 63, IAEA, Vienna (2009).
[28] INTERNATIONAL ATOMIC ENERGY AGENCY, Clinical Training of Medical Physicists Specializing in Nuclear Medicine, Training Course Series No. 50, IAEA, Vienna (2011).
[29] INTERNATIONAL ATOMIC ENERGY AGENCY, Competency Based Hospital Radiopharmacy Training, Training Course Series No. 39, IAEA, Vienna (2010).
[30] INTERNATIONAL ATOMIC ENERGY AGENCY, Operational Guidance on Hospital Radiopharmacy: A Safe and Effective Approach, IAEA, Vienna (2008).
[31] Distance Assisted Training for Nuclear Medicine Professionals, DATOL On-Line, https://humanhealth.iaea.org/HHW/NuclearMedicine/DATOL/English/index.html

[32] INTERNATIONAL ATOMIC ENERGY AGENCY, Human Health Campus, Nuclear Medicine, https://humanhealth.iaea.org/HHW/NuclearMedicine/
[33] SOCIETY OF NUCLEAR MEDICINE AND MOLECULAR IMAGING, Clinical Practice, http://www.snmmi.org/ClinicalPractice/content.aspx?ItemNumber=6414
[34] EUROPEAN COMMISSION, Council Directive 2013/59/Euratom Laying Down Basic Safety Standards for Protection Against the Dangers Arising from Exposure to Ionising Radiation, Brussels (2013).
[35] INTERNATIONAL ATOMIC ENERGY AGENCY, Storage of Radioactive Waste, IAEA Safety Standards Series No. WS-G-6.1, IAEA, Vienna (2006).
[36] INTERNATIONAL ATOMIC ENERGY AGENCY, IAEA Safety in Radiation Oncology, SAFRON NM, https://www.iaea.org/resources/rpop/resources/databases-and-learning-systems/safron
[37] EUROPEAN ASSOCIATION OF NUCLEAR MEDICINE, European Nuclear Medicine Guide (2020), https://www.nucmed-guide.app/#!/home
[38] INTERNATIONAL ATOMIC ENERGY AGENCY, Practical Guidance on Peptide Receptor Radionuclide Therapy (PRRNT) for Neuroendocrine Tumours, IAEA Human Health Series No. 20, IAEA, Vienna (2013).
[39] INTERNATIONAL ATOMIC ENERGY AGENCY, Manual of Radioisotope Production, Technical Reports Series No. 63, IAEA, Vienna (1966).
[40] INTERNATIONAL ATOMIC ENERGY AGENCY, IAEA Strategies for Clinical Implementation and Quality Management of PET Tracers, IAEA, Vienna (2009).
[41] INTERNATIONAL ATOMIC ENERGY AGENCY, Quality Control in the Production of Radiopharmaceuticals, IAEA-TECDOC-1856, IAEA, Vienna (2018).
[42] EANM RADIOPHARMACY COMMITTEE, Guidelines on Current Good Radiopharmacy Practice (cGRPP) in the Preparation of Radiopharmaceuticals, cGRPP-guidelines, version 2 (2007), https://www.eanm.org/publications/guidelines/gl_radioph_cgrpp.pdf
[43] INTERNATIONAL ORGANIZATION FOR STANDARDIZATION, Quality Management and Quality Assurance — Vocabulary, ISO 8402, ISO, Geneva (1994).
[44] INTERNATIONAL ELECTROTECHNICAL COMMISSION, Evaluation and Routine Testing in Medical Imaging Departments — Part 1: General, IEC 1223-1, IEC, Geneva (1993).
[45] WORLD HEALTH ORGANIZATION, HEALTH21: The Health for All Policy Framework for the WHO European Region, European Health for All Series No. 6, WHO, Copenhagen (1999).
[46] INTERNATIONAL ORGANIZATION FOR STANDARDIZATION, Guidance on Aspects of a Risk-Based Approach to Assuring Sterility of Terminally Sterilized, Single-use Health Care Product that Is Unable to Withstand Processing to Achieve Maximally a Sterility Assurance Level of 10-6, ISO/TS 19930:2017, ISO, Geneva (2017).

[47] INTERNATIONAL ORGANIZATION FOR STANDARDIZATION, Sterilization of Health Care Products — Vocabulary of Terms Used in Sterilization and Related Equipment and Process Standards, ISO 11139:2018, ISO, Geneva (2018).
[48] INTERNATIONAL ORGANIZATION FOR STANDARDIZATION, Guidelines for Auditing Management Systems, ISO 19011:2018, ISO, Geneva (2018).
[49] INTERNATIONAL ORGANIZATION FOR STANDARDIZATION / INTERNATIONAL ELECTROTECHNICAL COMMISSION, Conformity Assessment — Vocabulary and General Principles, ISO/IEC 17000:2004, ISO/IEC, Geneva (2004).
[50] INTERNATIONAL BUREAU FOR WEIGHTS AND MEASURES, International Vocabulary of Metrology — Basic and General Concepts and Associated Terms (VIM), 3d edn, JCGM 200: 2012, BIPM/JCGM, Sèvres, France (2012).
[51] INTERNATIONAL ORGANIZATION FOR STANDARDIZATION, Quality Management Systems — Fundamentals and Vocabulary, ISO 9000:2015, ISO, Geneva (2015).
[52] INTERNATIONAL ORGANIZATION FOR STANDARDIZATION, Environmental Labels and Declarations — Type III Environmental Declarations — Principles and Procedures, ISO 14025:2006, ISO, Geneva (2006).
[53] INTERNATIONAL ORGANIZATION FOR STANDARDIZATION, Collaborative Business Relationship Management Systems — Requirements and Framework, ISO 44001:2017, ISO, Geneva (2017).
[54] INTERNATIONAL ORGANIZATION FOR STANDARDIZATION, Service Activities Relating to Drinking Water Supply Systems and Wastewater Systems — Guidelines for Benchmarking of Water Utilities, ISO 24523:2017, ISO, Geneva (2017).
[55] INTERNATIONAL ORGANIZATION FOR STANDARDIZATION, Medical Laboratories — Requirements for Quality and Competence, ISO 15189:2012, ISO, Geneva (2012).
[56] INTERNATIONAL ORGANIZATION FOR STANDARDIZATION, Ships and Marine Technology — Guidelines for Private Maritime Security Companies (PMSC) Providing Privately Contracted Armed Security Personnel (PCASP) on Board Ships (and Pro Forma Contract) — Part 1: General, ISO 28007-1:2015, ISO, Geneva (2015).
[57] INTERNATIONAL ORGANIZATION FOR STANDARDIZATION, Human Resource Management — Vocabulary, ISO 30400:2016, ISO, Geneva (2016).
[58] THE COUNCIL OF THE EUROPEAN COMMUNITIES, Council Directive 93/42/EEC of 14 June 1993 concerning medical devices.
[59] NUCLEAR REGULATORY COMMISSION, Food and Drugs, 21 CFR 800–1299, US Govt Printing Office, Washington, DC (2019).
[60] INTERNATIONAL ORGANIZATION FOR STANDARDIZATION, Quality Management Systems — Guidelines for the Application of ISO 9001:2008 to Crop Production, ISO 22006:2009, ISO, Geneva (2009).
[61] INTERNATIONAL ORGANIZATION FOR STANDARDIZATION / INTERNATIONAL ELECTROTECHNICAL COMMISSION, Safety Aspects — Guidelines for Their Inclusion in Standards, ISO/IEC Guide 51:2014, ISO/IEC, Geneva (2014).

[62] INTERNATIONAL ORGANIZATION FOR STANDARDIZATION, Medical Devices — Application of Risk Management to Medical Devices, ISO 14971:2007, ISO, Geneva (2007).
[63] INTERNATIONAL ORGANIZATION FOR STANDARDIZATION, Cosmetics — Good Manufacturing Practices (GMP) — Guidelines on Good Manufacturing Practices, ISO 22716:2007, ISO, Geneva (2007).
[64] INTERNATIONAL ORGANIZATION FOR STANDARDIZATION, Medical Devices Utilizing Animal Tissues and Their Derivatives — Part 3: Validation of the Elimination and/or Inactivation of Viruses and Transmissible Spongiform Encephalopathy (TSE) Agents, ISO 22442-3:2007, ISO, Geneva (2007).

ABBREVIATIONS

NMS	nuclear medicine service
NUMDAB	nuclear medicine database
PDCA	plan, do, check, act
QA	quality assurance
QC	quality control
QMS	quality management system
SOP	standard operating procedure

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