Quality Management Audits in Nuclear Medicine Practices

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QUALITY MANAGEMENT AUDITS IN NUCLEAR MEDICINE PRACTICES

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FOREWORD

An effective management system that integrates quality management (QM) is essential in modern nuclear medicine departments in Member States. The IAEA, in its Safety Standards Series, has published a Safety Requirement (GS-R-3) and a Safety Guide (GS-G-3.1) on management systems for all facilities. These publications address the application of an integrated management system approach that is applicable to nuclear medicine organizations as well.

Quality management systems are maintained with the intent to continuously improve effectiveness and efficiency, enabling nuclear medicine to achieve the expectations of its quality policy, and to satisfy its customers. The IAEA has a long history of providing assistance in the field of nuclear medicine to its Member States.

Regular quality audits and assessments are essential for modern nuclear medicine departments. More importantly, the entire QM and audit process has to be systematic, patient oriented and outcome based. The management of services should also take into account the diversity of nuclear medicine services around the world and multidisciplinary contributions. The latter include clinical, technical, radiopharmaceutical and medical physics procedures. Aspects of radiation safety and patient protection should also be integral to the process. Such an approach ensures consistency in providing safe, quality and superior services to patients.

Increasingly standardized clinical protocol and evidence based medicine is used in nuclear medicine services, and some of these are recommended in numerous IAEA publications, for example, the Nuclear Medicine Resources Manual. Reference should also be made to other IAEA publications such as the IAEA Safety Standards Series, which include the regulations for the safe transport of nuclear material and on waste management as all of these have an impact on the provision of nuclear medicine services.

The main objective of this publication is to introduce a routine of conducting an annual systematic audit process into the clinical arena. Each section is set out as a series of questions related to specific components of nuclear medicine services. The questions are not all-inclusive and professional judgement is essential to ensure that the questions are addressed adequately. It is not intended that all questions will be addressed. The QM audit methodology which is introduced in this publication is designed to be applied to a variety of economic circumstances. A key outcome should be a culture of reviewing essential elements of the clinical service for continuous improvement in nuclear medicine.

This publication should be of interest to nuclear medicine physicians, radiologists, radiopharmacists, medical physicists, medical technologists and educationalists. It should also interest those dealing with QM and audit systems. The attached CD-ROM contains the checklists given in this publication for self-appraisal. They can also be used by multidisciplinary teams involved in annual QM checks and audits.

The IAEA gratefully acknowledges the inputs of the contributors to this publication as well as the reviewers.

The IAEA officers responsible for the publication were K.K. Solanki and M. Dondi of the Division of Human Health.

CONTENTS

1. INTRODUCTION

1.1. BACKGROUND

The IAEA has a long history of providing assistance in the field of nuclear medicine to its Member States. Following the decision to develop a quality management (QM) audit manual for nuclear medicine, the IAEA convened an expert group in 2006, comprising nuclear medicine physicians, medical physicists and radiopharmacists. The aim was to encourage a routine of conducting an annual systematic audit process in the clinical arena.

The assessment methodology should be designed and be applicable to a variety of economic circumstances. It was agreed that new tools were needed to maintain a comprehensive approach to QM audits in the diagnosis, follow-up and treatment of patients using nuclear medicine services. If there are local or national audit guidelines, then those would be more applicable and this manual could strengthen them or promote an international perspective. However, it was felt that adopting a culture of review was essential for positive growth in nuclear medicine services. More importantly, the whole quality audit process has to be patient oriented, systematic and outcome based.

The audit process should include regular internal checking, assessment and review. This will encourage a culture of regular review and updating. It will further strengthen the system of documentation in a busy clinical setting. Any assessment, if documented, can be useful for external review processes such as the IAEA's organizational audit. Independent external audits (peer reviews) should be carried out on a regular basis to ensure adequate quality of practice and delivery of diagnostic, treatment and other nuclear medicine services.

To determine the actual level of competence of a department, internal and external audits should take into consideration the available equipment, infrastructure and operations related to clinical practice. The completion of the IAEA web based nuclear medicine database (http://www-naweb.iaea.org/nahu/NMDatabase/default.asp) provides basic information and essential details on operational and technical aspects. Each section is set out as a series of questions related to specific components of the nuclear medicine service. The questions are not all-inclusive, and professional judgement is essential to ensure that the questions are addressed adequately. It is not intended that all questions must be addressed. The quality audits can be of various types and levels, either reviewing specific critical parts of the nuclear medicine process (partial audit) or assessing the entire process (comprehensive audit).

1.2. OBJECTIVE

The ultimate objective of QM audits in nuclear medicine is a means by which nuclear medicine facilities can demonstrate the level of patient care they provide by following a process of self and external evaluation. It implies a commitment to quality care.

1.3. SCOPE

A comprehensive audit is recommended annually to maintain quality and a high level of service. Taking into account the multidisciplinary team in nuclear medicine services, this publication includes the following key areas:

— Management and human resources development;
— Risk management;
— General clinical services;
— Radiopharmacy;
— Tumour market services.

1.4. STRUCTURE

Following a brief introduction to QM audit, this publication presents a series of audit lists. To the professionals in nuclear medicine these require little or no explanation. The audit list can be followed sequentially or independently. However, a composite audit report setting out priorities together with an action plan is recommended.

1.5. OBJECTIVE OF A QM REVIEW AND AUDIT TEAM

The objective of quality audits is to evaluate the quality of all components related to the nuclear medicine practice applied at an institution, including its professional competence, with a view for quality improvement. A multidisciplinary team comprising experienced nuclear medicine physicians, a medical physicist, a radiopharmacist and a senior administrator should carry out both internal and external audits. In some instances, a laboratory service specialist in radioimmunoassay or a radiographer may be needed to provide additional support for the audit team. Such an audit team can carry out internal and/or external audits. The final composition and size of the audit team should be

pre-stated before the actual audit. A similar team may also be required for follow-up.

The aim of a quality audit process in nuclear medicine is to assist nuclear medicine departments/laboratories in maintaining or improving the quality of service for their patients. The audit should review and evaluate the quality of all elements involved, including staff, equipment and procedures, patient protection and safety, the overall performance of the nuclear medicine department as well as its interaction with external service providers.

The IAEA, through its technical cooperation programme, has received numerous requests from developing countries to perform quality audits of their nuclear medicine services. Several African countries have already participated in nuclear medicine audits. The IAEA audits normally take place at a national level; however, routine audits of individual institutions are essential. The IAEA recommends that nuclear medicine departments use this publication as a tool to carry out self-reviews with the intention of applying good clinical practices by identifying those improvements which can be implemented using their own resources.

1.6. GENERAL FLOW CHART OF THE NUCLEAR MEDICINE AUDIT PROCEDURE

Figure 1 shows a general flow chart of the nuclear medicine audit procedure. The internal audit process should be carried out annually [1, 2]. In exceptional cases it can be a periodic event; however, it should still be an integral part of the QM programme. Developing a regular timetable for undertaking both internal and external audits should become a part of the calendar of nuclear medicine departments. Developing a culture of ongoing assessment is considerably more challenging. A busy clinical environment should not be an excuse for foregoing the audit process. A QM programme is vital for better patient care and an essential tool in the modern health system. It also provides an objective tool for prioritization and rational justification in a world of finite resources. The first priority should always be to put patients' requirements and safety into clinical practice.

Explanatory notes to the flow chart (Fig. 1) must include the following:

(a) Nuclear medicine departments should undergo a review on an annual basis.
(b) Individual components of the process can be performed at different times.

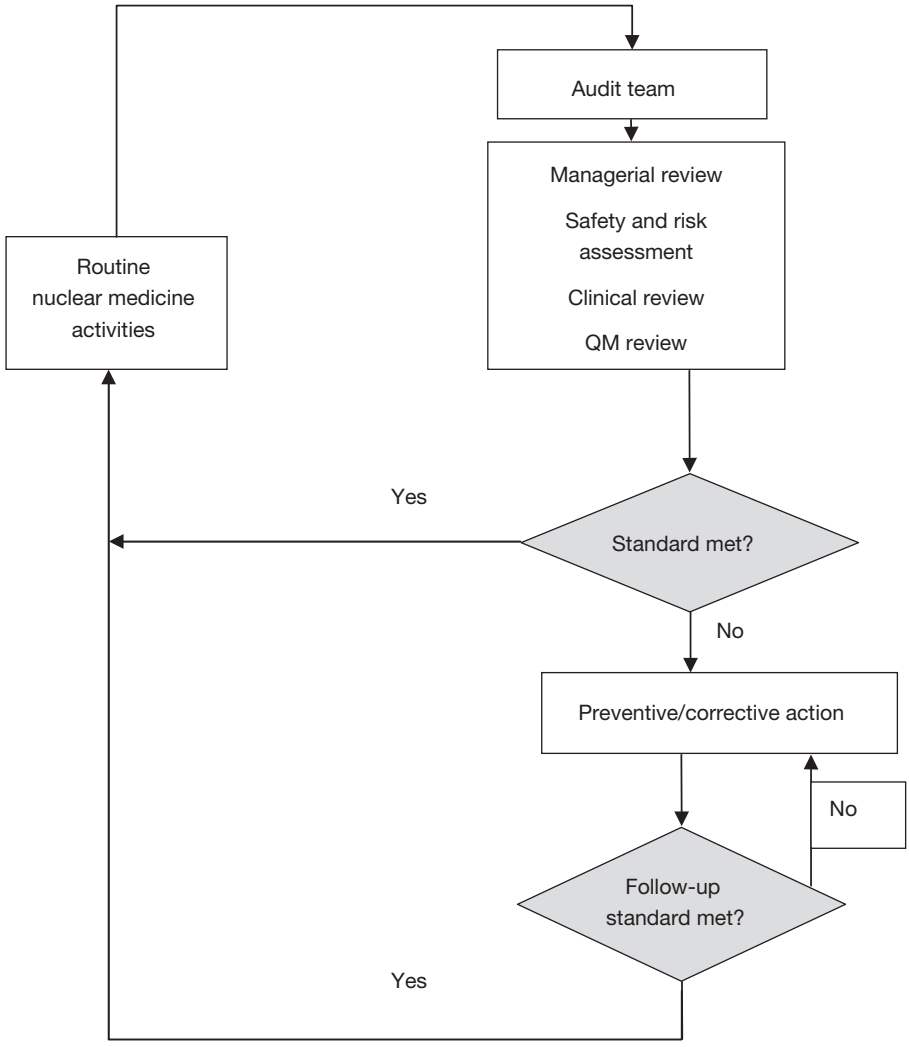

FIG. 1. Audit components.

(c) A quality manual or standard operating procedures (SOPs) should be clearly and formally established (e.g. written operating procedures, tables of quantitatively measurable reference parameters).
(d) If no SOPs exist, their formulation should be a priority.
(e) An internal audit team should be formed, typically including several staff members from a range of disciplines.

(f) The audit questionnaire which forms part of this publication is designed to allow internal as well as external reviewers to assess the department's performance against existing standards.
(g) Following the completion of the questionnaire, the details need to be analysed and summarized as suggested in this publication.
(h) If deficiencies or non-conformities are found, follow-up actions and an implementation schedule need to be established. Any action should be defined and documented. Depending on the nature of the problems identified, action should be planned accordingly.
(i) This implementation plan must include preventive or corrective actions, which should be implemented in a timely manner and according to priority. If an opportunity for improvement is identified, corresponding actions can be considered and set up as departmental objectives.
(j) In case the standards are met, or preventive/corrective actions have been successfully implemented, routine activities are continued until the next planned periodical internal review is performed. This may not necessarily be the next annual review, but could be earlier if needed (e.g. major change or implementation of new procedures).
(k) External support/review may be needed for implementing remedial actions.
(l) In addition, a periodic external, independent review and assessment should be a part of the nuclear medicine departmental QM system.

1.7. PRIORITIZATION

Where possible, all questions, and not just category 'A', should be addressed. Any shortcomings or deficiencies that are identified are important. To assist with setting individual priorities for change, the corrective summary is divided into three categories: 'Critical', 'Major' and 'Minor'. Shortcomings which are likely to have serious patient implications are automatically prioritized as 'Critical' or 'Major'.

1.8. LIMITATIONS

The series of questions mentioned above are not designed for the following instances.

1.8.1. Regulatory purposes

The audit teams under QM are not convened as an enforcing tool but solely as an impartial source of advice on quality improvement in collaboration with the department.

1.8.2. Investigation of accidents

The audit teams under QM are not convened to investigate accidents or reportable medical events (misadministration). In the event of an investigation specifically into these aspects, a more focused investigation is required.

1.8.3. Clinical research

This report is not meant to assess the eligibility of institutes for entry into cooperative clinical research studies, as this is conducted by peers within the group involved in the study. Rather, these peers focus on the strict adherence of an institute to a single, specified clinical protocol in a selected group of patients.

1.8.4. Interdepartmental comparison

This publication is not intended for interdepartmental comparison. Due to the extreme diversity at the international level, assessors should consider their response in the context of the nuclear medicine service provided. The mere fact that one department addresses all the questions posed in the evaluation forms does not make its nuclear medicine service superior to those that have only been able to address a few questions in each section. It is not the quantity but the quality of response that is important. The overall quality depends on the strengths and weaknesses, together with the critical appraisal, of the 'variables' as observed in practice.

1.8.5. Checklist limitations

This publication provides essential checklists rather than exhaustive lists. Therefore, users are advised to refer to the guidelines of nuclear medicine professional societies. Professional judgement is advised to ensure an adequate level of assessment.

1.8.6. Responsibility for change

It should be understood that while it is the responsibility of the audit team to discuss shortfalls in the services of the audited institution, it is not the 'authority' (hospital authority, national authority or the IAEA) to rectify deficiencies identified.

2. INTERNAL REVIEW STRUCTURE

2.1. PURPOSE

Internal review is essential to ensure a well-functioning nuclear medicine department. Auditing should be performed on a regular basis, at least annually for internal audits and at least every three years for external audits. A comprehensive review of the service should address the following:

(a) Assess significant changes in the departmental structure and operation;
(b) Assist with project planning;
(c) Assist with pre-budgetary planning.

It could be also an integral part of the accepted QM programme.

2.2. PREPARATION FOR THE AUDIT: AUDITED INSTITUTION'S RESPONSIBILITIES

The success of an audit depends greatly on thorough preparation by all parties involved. Use of the IAEA's web based nuclear medicine database (http://www-naweb.iaea.org/nahu/NMDatabase/default.asp) can provide essential details; however, more operational and practice details are needed for proper assessment.

The audited institution's role is to:

— Prepare data, quality manuals and relevant documentation, and submit these to the audit team before the start of the audit, to enable the auditors to complete their evaluation according to the format of this publication;

— Inform the entire department, hospital management and other relevant persons and/or institutions involved of the audit and its timing;
— Identify and ensure participation of the staff members needed for the audit, although the audit team should be free to interview any staff member it deems appropriate;
— Ensure access of the audit team to any relevant areas and premises related to the scope of the audit;
— Provide records requested by the audit team, although the audit team should be free to review any records, even those subject to patient confidentiality;
— Provide clinical records from outside the department, relevant to the reviewed cases, subject to patient confidentiality;
— Set up any necessary meetings with stakeholders needed for the successful completion of the audit.

2.3. COMPOSITION OF THE AUDIT TEAM

The medical professional in charge of the nuclear medicine department ('Manager') is responsible for setting up the audit procedure, including the selection of the audit team leader (Quality Control Administrator or QCA). The QCA selects the other members of the audit team. The audit team consists of departmental staff members with extensive knowledge of the current procedures and protocols within the department. An audit team may consist of the following members: QCA, person in charge of the nuclear medicine department, medical physics supervisor, chief technologist (and/or radiographer), a representative from the hospital administration (ideally from internal review), a radiopharmacist, and a representative from the nursing staff. It is advisable to include an independent person from another department of the institution as a team member representing the end-user group (medical oncologist, cardiologist, endocrinologist, nephrologist, etc.). An audit team should not consist of less than three members.

Members of the team should have the necessary expertise and, where possible, have undergone basic training and briefing in auditing techniques. A timetable for the audit should be agreed upon between the team and the person in charge of the nuclear medicine department.

It is part of responsibilities of the internal audit team to collect all management and operational information, including documental proofs of the evaluated issues, e.g. samples of SOPs, samples of study reports, copies of data regarding patients' waiting times, updated information on waiting lists, copy of quality control data for relevant equipment, copy of letters of appraisal/complaint, etc.

2.4. GUIDING PRINCIPLES AND PROCEDURES

The following are needed: standardized audit practices, including entrance briefing, style of observation, ensuring minimum standards, systematic follow-up of the questionnaires, summarizing findings, exit briefing and reporting.

2.4.1. Entrance briefing

The entrance briefing is required to decide on the selection of topics, audit trail and various staff members, and to discuss the methods, objectives, as well as the details of the audit. If required by the host, the audit team will sign a document ensuring confidentiality. The auditors should reassure the department that confidentiality (including patient confidentiality) will be respected.

2.4.2. Assessment

Both the infrastructure of the department and the overall nuclear medicine programme will be audited. The infrastructure includes staffing, equipment and premises. Further, the entire nuclear medicine department will be evaluated, from the initial referral of the patient, radiopharmaceutical preparation, patient preparation, execution of the procedure and data analysis, to the reporting and follow-up.

A series of checklists in this publication have been designed to help the auditors to organize the audit programme to ensure coverage of all relevant topics. The audit may be aimed at evaluating one or more components of all nuclear medicine activities. The tools available include:

— Complete tour of the premises;
— Review and evaluation of procedures and all relevant documentation, including treatment records;
— Observation of practical implementation of working procedures;
— Staff interviews;
— Meeting with management of the institution and/or associated educational institution.

2.4.3. Minimum requirements

At the heart of any service is the application of standardized practices and professionally accepted norms. Recently, the IAEA has published some basic

TABLE 1. MINIMUM PROFESSIONAL REQUIREMENTS

Professional	Requirements
Nuclear medicine specialist	Degree in medicine and a registered doctor with a minimum of two years of postgraduate training (major in nuclear medicine), or ideally a Masters qualification (e.g. MSc) in nuclear medicine.
Nuclear medicine technologist	Bachelor of Science (BSc), plus one year of practice qualification, or a minimum of three years of practice qualification, plus an IAEA–DAT certificate.
Radiographer	BSc with a major in nuclear medicine.
Medical physicist	Postgraduate to MSc in medical physics with a major in nuclear medicine.
Hot laboratory assistance with no qualified radiopharmacist support	Nationally/professionally approved training, or at least participation in an IAEA competency based programme with a three month internship.
Radiopharmaceutical scientist and radiopharmacist for large nuclear medicine facilities including positron emission tomography (PET) centres	Qualified and registered pharmacist, ideally with postgraduate qualification and experience with radiopharmaceuticals, or radiopharmaceutical scientist with MSc recognized as authorized or a qualified person.
Nurse	Qualified and registered nurse with an internship in nuclear medicine

practices in the Nuclear Medicine Resources Manual [3]. The minimum requirements for a nuclear medicine facility include a clearly defined 'cold' and 'hot' area. The hot area should be restricted to authorized individuals and should include a hot laboratory, an injection area, a separate waiting area, together with toilets for radioinjected patients, a waste management room, a cardiac stress room (if applicable), an in vitro/radioimmunoassay laboratory (if applicable), a diagnostic room, and a separate common room for technologists/radiographers. Table 1 provides the minimum requirements for professional profiles.

2.4.4. Conformance and non-conformance statement

Certain parts of the audit form are designed to allow comparison of the audited nuclear medicine department against external standards. These standards are set at three levels:

(1) ‘A’ standards are those required by legislation, IAEA technical publications or other external standard setting bodies. Any failure to reach an ‘A’ standard is therefore regarded as serious, and urgent corrective action should be instituted.
(2) ‘B’ standards are those that are not compulsory, but are expected to be reached by all departments. In the case of failure, corrective action is recommended.
(3) ‘C’ standards are desirable, but not essential. Corrective actions may improve the overall function of the department.

This publication is intended to provide a working format for self-review and to encourage a systematic approach. Not all questions, even the ones marked as class ‘A’, should be addressed. It is far more important to address all questions that reflect the level of operation and/or service. Therefore, an answer marked ‘not applicable (NA)’ is perfectly acceptable and should not be deemed as poor performance.

2.4.5. Guide to audit questionnaires

The questionnaire entries can be best accommodated using a digital format of the audit questionnaire. The actual questionnaire normally starts with more general questions and then moves to specific issues. In most cases comments are requested. Any specific observations or issues should be recorded in the column marked “Comments/planned action”. If any change is required, it can also be stated in this column.

All instances of non-compliance should be noted; however, prioritization is based on the implication for patients. The patients remain the main focus of the QM audit. The “Review” section enables the reader/auditor to see the total list of issues and concerns and helps to draw up a more practical list of priorities. The priority can be defined as ‘Critical’, ‘Major’, or ‘Minor’, which is different from conventional QM reporting, mainly as the criteria focus on risk to the patient. The relative risks and how these risks have to be managed become very important. Clear solutions are required to reduce these risks, and therefore such a critical review is needed.

The final column, labelled “Date achieved”, should be completed after each of the issues is resolved and specific action has been undertaken. These steps should lend themselves to a self-evaluation process which is valuable for QM.

2.4.6. Exit briefing

It is essential that the preliminary feedback of the auditors is documented and presented to everyone at the departmental level. Upon the completion of the audit, the auditors will convene concerned members of the department, who were previously interviewed, for an interactive exit briefing. This includes time for questions and a detailed and open discussion on all the findings of the experts. The institution should be encouraged to give an immediate response to the assessment. The steps intended by the institution to respond to the recommendations and improve the activities of the department should also be discussed and recorded.

Particularly where an instance of non-compliance with an 'A' standard has been found, the audit team should make clear that a written corrective action plan needs to be prepared urgently and sent to the audit team for further interaction and advice. If appropriate, the department should be informed that they have the responsibility of appraising the regulatory authorities.

When measurements have been performed as part of the audit, copies of the completed forms and calculations should be kept with the institution record.

2.5. CONCLUSION AND REPORT

A useful report should contain conclusions formulated in an unambiguous way, with clear and practical recommendations. This should meet internal requirements.

The overall conclusion of the audit team can be one or a combination of the following:

— Identifying areas that can be easily improved. These may be changes which are easy to implement, or major changes that require modification in the institute's infrastructure, but are feasible for the department. These proposals will be included in the detailed recommendations of the audit team.
— Identifying major problems, that cannot be resolved by the nuclear medicine department alone, without significant assistance and/or contribution from other institutions outside the hospital or without significant resources.

The recipients of the report (the head of nuclear medicine), ideally through the hospital director, should confirm to the auditing team how they

plan to report the agreed action plan to resolve 'A' non-compliance. Since these failures refer to legislative, regulatory or major safety requirements, the recipients should be reminded that it is their professional duty to take corrective action; this may include appraising the regulatory authorities.

If the department wishes to expand to new areas of expertise, additional recommendations should be made. Any business case has to be undertaken separately.

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

2.6. DISSEMINATION OF REPORT

The full report should be sent to those people identified during the exit briefing, for example the director of the hospital, the head of the department, the chief medical physicist and other staff members who were significant to this audit. An executive summary of this report may differ from the full report insofar as it should refer only to essential, verifiable facts and exclude all subjective judgements. If the audit was commissioned through local or national authorities, the audit team's report must be submitted to them for dissemination according to their requirements. Recommendations made in the report need to be directed to the respective institution and its national authority. Recommendations to the authority must be confined to general statements, for example the need for a follow-up visit. Only if the audit is performed in the context of a local or national development programme, should specific interventions for training or equipment be recommended.

3. MANAGEMENT AND HUMAN RESOURCES DEVELOPMENT

3.1. STRATEGY AND OBJECTIVES

A clear strategy and efficient management is essential for the success of any undertaking, and nuclear medicine is no exception.

CHECKLIST 1. STRATEGIES AND POLICIES

No.	Component	Class	Yes/ No	Comments/ planned action	Date achieved
3.1.1.	Is the nuclear medicine service guided by specific objectives developed at the national level?	B			
3.1.2.	Is the nuclear medicine service guided by specific objectives developed by the hospital management?	B			
3.1.3.	Is there adequate coordination with radiology, oncology and cardiology?	C			
3.1.4.	Has the nuclear medicine department a written organizational chart? Is it up to date?	B			
3.1.5.	Does the organizational chart indicate channels of communication and lines of authority within the nuclear medicine department?	B			
3.1.6.	Is the range of specific nuclear medicine diagnostic imaging and therapeutic services appropriate to the size and scope of the hospital's clinical service?	B			
3.1.7.	Do the objectives of the nuclear medicine service include the provision of services for urgent requests?	B			
3.1.8.	Do the objectives of the nuclear medicine service include the provision and maintenance of high quality care through clinical audit and quality control?	A			
3.1.9.	Does the department have a business plan?	B			
3.1.10.	Does the department have a strategy regarding new developments in diagnosis and treatment?	B			

CHECKLIST 1. STRATEGIES AND POLICIES (cont.)

No.	Component	Class	Yes/ No	Comments/ planned action	Date achieved
3.1.11.	If the hospital itself does not provide a full range of nuclear medicine services, does the department have a strategy/policy to recommend access to diagnostic investigations, as required for adequate patient care elsewhere?	B			
3.1.12.	Where satellite services are provided (e.g. technical and clinical support for other hospitals), is the responsibility for the provision of these services clearly defined?	B			

3.2. ADMINISTRATION AND MANAGEMENT

Administration and management are central to an efficient and successful enterprise; this applies equally to the field of nuclear medicine.

CHECKLIST 2. ADMINISTRATION AND MANAGEMENT

No.	Component	Class	Yes/ No	Comments/ planned action	Date achieved
3.2.1.	Is there a regular review of the work procedures used in the reception areas?	B			
3.2.2.	Is there a protocol for dealing with incomplete request forms?	B			
3.2.3.	What quality factors are in place to accommodate peak scheduling demands?	B			
3.2.4.	Are all requests reviewed, justified and approved by a nuclear medicine physician?	A			

CHECKLIST 2. ADMINISTRATION AND MANAGEMENT (cont.)

No.	Component	Class	Yes/ No	Comments/ planned action	Date achieved
3.2.5.	Does the department have written SOPs for all tasks, including operational, administrative, technical and clinical tasks?	A			
3.2.6.	Do the SOPs identify the level of competent operators/professionals?	A			
3.2.7.	Does the final responsibility for a nuclear medicine procedure lie with an appropriately qualified physician?	A			
3.2.8.	Is there a regular review of QM by an appointed medical physicist?	A			
3.2.9.	Is there a regular review of QM by a registered pharmacist?	A			
3.2.10.	Is there a mechanism for dealing with shortcomings or deficiencies?	B			

3.3. HUMAN RESOURCES DEVELOPMENT

Human resources can be defined as the total knowledge, skills, creative abilities, talents and aptitudes of the workforce. Human resources act as the hub that drives all other resources in an enterprise. This is also true in nuclear medicine.

CHECKLIST 3. HUMAN RESOURCES DEVELOPMENT

No.	Component	Class	Yes/ No	Comments/ planned action	Date achieved
3.3.1.	Are all staff members appropriately trained and qualified specialists for their job description?	B			
3.3.2.	Do all staff members within the department have a written job description which sets out duties and responsibilities clearly?	B			
3.3.3.	Is there continuous professional education and development for all staff categories?	B			
3.3.4.	Are there specialist training programmes for nuclear medicine technologists or radiographers to work in nuclear medicine?	B			
3.3.5.	Are all 'hot laboratory' staff members trained in the safe handling of radiopharmaceuticals?	B			
3.3.6.	Are there adequate tools available for objective monitoring of any training?	B			
3.3.7.	Is there a regular performance review to identify training needs?	B			
3.3.8.	Is there regular professional training in radiation safety and radiation protection?	B			
3.3.9.	Do staff members have access to web based learning, up to date books and journals?	B			

4. RISK MANAGEMENT

4.1. RADIATION, REGULATORY AND SAFETY COMPLIANCE

Compliance with all relevant regulations and good radiation practice in nuclear medicine are of utmost importance.

CHECKLIST 4. RADIATION, REGULATION AND SAFETY COMPLIANCE

No.	Component	Class	Yes/ No	Comments/ planned action	Date achieved
4.1.1.	Is the department formally authorized by a recognized national authority?	A			
4.1.2.	Do the radiation rules refer to national guidelines or cross-refer to international rules?	A			
4.1.3.	Have all staff members signed to confirm that they have read and understood the local rules?	A			
4.1.4.	Are all radioactive sources identified and stored appropriately?	A			
4.1.5.	Are sealed calibration sources checked periodically, cross-accounted and checked for any leakage?	A			
4.1.6.	Is there routine nuclear medicine personnel monitoring for radiation exposure including: —Thermoluminescent dosimetry badges; —Injection personnel hand/finger monitoring; —Dispensing staff hand/finger and occasional eye monitoring?	A			
4.1.7.	Are protective clothing, gloves, syringe shields, handling tongs, etc., available?	A			

CHECKLIST 4. RADIATION, REGULATION AND SAFETY COMPLIANCE (cont.)

No.	Component	Class	Yes/ No	Comments/ planned action	Date achieved
4.1.8.	Are there adequate facilities for administration of radiopharmaceuticals, therapy and radioactive aerosols?	B			
4.1.9.	Have areas been classified as 'supervised' or 'controlled' according to the Basic Safety Standards (BSS) [4] and/or local regulations?	A			
4.1.10.	Is there a procedure for dealing with a spillage or contamination incident?	A			
4.1.11.	Are there means to prevent unauthorized access to supervised and controlled areas?	A			
4.1.12.	Are radiation signs (in local language(s)) displayed prominently on entry to supervised and controlled areas?	A			
4.1.13.	Do all departmental personnel receive instructions and training on local procedures, safety precautions for the protection of the patient and staff when they start working in nuclear medicine?	A			
4.1.14.	Are formal risk assessments and/or surveys of the department and equipment performed by designated staff?	A			
4.1.15.	Are there suitably calibrated and functional radiation monitoring devices available?	A			
4.1.16.	Are there detailed procedures for handling patients' specimens (blood, urine, etc.)?	A			

CHECKLIST 4. RADIATION, REGULATION AND SAFETY COMPLIANCE (cont.)

No.	Component	Class	Yes/ No	Comments/ planned action	Date achieved
4.1.17.	Are there formal procedures for the disposal of liquid and solid radioactive waste?	A			
4.1.18.	Is the level of waste checked routinely against the authorized disposal limit?	A			
4.1.19.	Is there a policy on the transport of radioactive material?	A			

4.2. RADIATION PROTECTION OF THE PATIENT

Patient focused service is fundamental to the success of nuclear medicine, and that includes all due considerations with regards to radiation protection of the patient.

CHECKLIST 5. RADIATION PROTECTION OF THE PATIENT

No.	Component	Class	Yes/ No	Comments/ planned action	Date achieved
4.2.1.	Are there SOPs to identify patients correctly prior to the administration of radiopharmaceuticals?	A			
4.2.2.	Are there SOPs for enquiring whether females of child bearing age are pregnant or breast feeding?	A			
4.2.3.	Are written and verbal instructions given to patients before and following administration of radiopharmaceuticals?	B			

CHECKLIST 5. RADIATION PROTECTION OF THE PATIENT (cont.)

No.	Component	Class	Yes/ No	Comments/ planned action	Date achieved
4.2.4.	Is the activity in each patient dose measured prior to administration and entered into the patient's record?	A			
4.2.5.	Is there an SOP for checking that radioactivity doses do not exceed the reference values given in the BSS [4], national or international regulations or guidelines?	A			
4.2.6.	Is an adequately trained person available in the institute who can estimate the effective radiation dose to patients following administration of radiopharmaceuticals?	C			
4.2.7.	Are written instructions for staff available to decide when to release patients after therapy administration?	B			
4.2.8.	Are there adequate SOPs to minimize the risk of misadministration of radiopharmaceuticals?	B			
4.2.9.	Are there adequate SOPs to minimize the risk of multiple exposures?	B			

4.3. EVALUATION AND ASSURANCE OF THE QUALITY SYSTEM

Quality manuals and quality systems should be regularly reviewed to ensure compliance with standards.

CHECKLIST 6. EVALUATION AND ASSURANCE OF THE QUALITY SYSTEM

No.	Component	Class	Yes/ No	Comments/ planned action	Date achieved
4.3.1.	Are standards set for the nuclear medicine service, preferably in the form of a quality manual (includes operational flow charts, SOPs, etc.)?	B			
4.3.2.	Are there systems for monitoring compliance with standards, with defined criteria of acceptability?	B			
4.3.3.	Does the department regularly perform self-assessments/audits?	B			
4.3.4.	Is there a system for assessing customer satisfaction and for assessing the satisfaction level of the referring physicians?	B			
4.3.5.	Is there an SOP for handling instances of non-compliance, including recording and correction/ prevention?	B			
4.3.6.	Is there a mechanism for monitoring data to ensure quality improvement?	B			
4.3.7.	Are all staff members involved in formal reviewing and monitoring of quality?	B			
4.3.8.	Are all items of equipment purchased against technical specifications prepared by a competent person in conjunction with the users?	B			

CHECKLIST 6. EVALUATION AND ASSURANCE OF THE QUALITY SYSTEM (cont.)

No.	Component	Class	Yes/ No	Comments/ planned action	Date achieved
4.3.9.	Are these specifications used for the acceptance testing of equipment?	B			
4.3.10.	Is there a quality assurance programme, with regular calibration and inspection of all equipment (e.g. calibrator, beta and gamma counters, radiation survey monitors, planar and tomographic gamma cameras, PET and PET/computed tomography (CT) scanners, thyroid counters, gamma probes, aerosol delivery systems, etc.) in accordance with the BSS [4], international and local standards and regulations?	A			
4.3.11.	Are the results of all of the above QM programmes recorded, evaluated and regularly reviewed?	B			
4.3.12.	Is there a procedure to ensure that any equipment or material which fails a quality test is not used unless specifically authorized by a designated member of staff?	A			
4.3.13.	Are action levels and responsibilities defined to determine when equipment should be repaired, replaced, or taken out of service?	A			
4.3.14.	Are plans for maintenance, repair and replacement established for all major equipment (either in-house or external)?	B			
4.3.15.	Does the department participate in external QM programmes?	B			

4.4. QUALITY CONTROL FOR IMAGING EQUIPMENT

A comprehensive system of quality control for all imaging equipment is essential for optimal patient investigations in nuclear medicine. The list given below is not comprehensive, but rather provides an essential checklist.

CHECKLIST 7. QUALITY CONTROL FOR IMAGING EQUIPMENT

No.	Component	Class	Yes/ No	Comments/ planned action	Date achieved
4.4.1.	Are there documented policies and protocols on the operation, quality control and assurance for all imaging equipment in clinical use?	B			
4.4.2.	Do these policies conform to the manufacturers' instruction manuals?	A			
4.4.3.	Are there documents detailing actual results of quality control and measurements from gamma camera performance?	B			
4.4.4.	Is there a written policy for specifying, procuring and testing new imaging equipment?	B			
4.4.5.	Is there a regular physical inspection of the hardware including the detector head(s), shielding, etc.?	A			
4.4.6.	Is there regular checking, review of results and trend analysis of: — Uniformity; — Intrinsic uniformity; — Intrinsic uniformity versus energy windows; — Intrinsic uniformity for various energies; — System uniformity?	A			

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

No.	Component	Class	Yes/ No	Comments/ planned action	Date achieved
4.4.7.	Is there regular checking, review of results and trend analysis of: — Spatial resolution; — Intrinsic spatial resolution (qualitative); — Intrinsic spatial resolution (quantitative); — System spatial resolution (qualitative); — System spatial resolution (quantitative)?	A			
4.4.8.	~~Is~~ there regular checking, review of ~~r~~results and trend analysis of: — Spatial linearity (distortion); — Intrinsic spatial linearity; — System spatial linearity?	A			
4.4.9.	Is there regular checking, review of results and trend analysis of: — Count rate performance; — Intrinsic count rate performance; — Maximum count rate performance; — System count rate performance?	A			
4.4.10.	Is there regular checking, review of results and trend analysis of: — System sensitivity; — Point source sensitivity; — Plane sensitivity?	A			
4.4.11.	Is there regular checking and review of: — Multiple window spatial registration; — Angular variation of spatial position; — Whole body imaging spatial resolution?	A			

4.5. COMPUTER SYSTEMS AND DATA HANDLING

Computers have been central to the practice of nuclear medicine for many years, particularly as the extraction of functional information commonly necessitates patient image analysis.

CHECKLIST 8. COMPUTER SYSTEMS AND DATA HANDLING

No.	Component	Class	Yes/ No	Comments/ planned action	Date achieved
4.5.1.	Is there a policy for computer procurement, installation, and acceptance of hardware and software?	B			
4.5.2.	Is there a written policy on computer hardware and software upgrades?	B			
4.5.3.	Is there a written procedure for assessing integrity of data following a major software revision for: —Count rate losses; —Data framing; —Imaging quantification; —Image arithmetic; —Activity–time curve arithmetic?	B			
4.5.4.	Is there a policy on QM of 'in-house' software?	B			

4.6. ACCEPTANCE TESTS

The first crucial step after installation of the imaging equipment is the initial evaluation or acceptance testing. This includes not only confirmation that the instrument performs according to the specifications, but also evaluation of its performance under conditions that will be encountered in clinical practice. These tests should be independent of the ones undertaken by the manufacturer. Supporting elements are in the IAEA's Nuclear Medicine Resources Manual [3].

These tests should be carried out immediately after installation. The user should not accept an instrument that fails to conform to specifications. No instrument should be put into routine use unless it has proven through

acceptance testing to perform optimally. Provided the equipment is operating according to specifications and has demonstrated to be safe, a limited number of patient studies should be performed as part of the acceptance procedure.

Acceptance tests require special test devices, phantoms and evaluation software. Quantification of tests is essential in order to compare results with specifications and to receive baseline values for future comparison. Therefore, it is recommended that specialized instruments and software are provided by the vendor to perform acceptance testing, and that these tests are carried out on-site by the company's engineer under the supervision of the user. The user may choose to perform additional tests to confirm the performance of the equipment and may use these results as a reference for future quality controls. If necessary, the user should invite a competent expert to participate in the acceptance tests and the evaluation of the results. The list given below is not comprehensive, but rather provides an essential checklist.

CHECKLIST 9. ACCEPTANCE TESTS

No.	Component	Class	Yes/ No	Comments/ planned action	Date achieved
4.6.1.	Is there a policy for acquiring equipment certified with 'CE' mark or that has undergone review by a national authority (similar to FDA)?	A			
4.6.2.	Do the above policies conform to IAEA/International Electrotechnical Commission (IEC)/ National Electrical Manufacturers Association (NEMA) publications *and* the manufacturer's instruction manual?	A			
4.6.3.	Is there documentation that compares the tender with the actual delivery?	B			
4.6.4.	How do the manufacturers' test results compare with independent acceptance tests?	B			
4.6.5.	Are intrinsic NEMA procedures undertaken for: —Energy resolution; —Flood field uniformity; —Spatial resolution; —Spatial linearity;	A			

CHECKLIST 9. ACCEPTANCE TESTS (cont.)

No.	Component	Class	Yes/ No	Comments/ planned action	Date achieved
4.6.5.	—Count rate performance and maximum count rate; —Multiple window spatial registration?	A			
4.6.6.	Are extrinsic (system) NEMA procedures undertaken for: —Flood field uniformity; —Spatial resolution with and without scatter; —Sensitivity for each collimator; —Detector head shielding leakage?	A			
4.6.7.	Are the following acceptance tests for single photon emission computed tomography (SPECT) (non-NEMA) undertaken for: —SPECT centre of rotation; —Angular linearity errors; —Uniformity; • Tomographic slice uniformity; • Rotational uniformity; —System volume sensitivity (NEMA); —Tomographic resolution; • Tomographic resolution in air (NEMA); • Tomographic resolution in a scatter medium (NEMA); —Test of slice thickness (IAEA); —Total performance check (data spectrum phantom) (American Association of Physicists in Medicine (AAPM)): • Tomographic uniformity; • Tomographic resolution (spheres and rods); • Contrast?	A			
4.6.8.	Are specific tests for multiple detector systems undertaken for: —Multiple detector registration; —Matched sensitivity; —Matched pixel calibration; —Matched centre of rotation?	A			

5. GENERAL CLINICAL SERVICES

Nuclear medicine services vary from one country to another, although cardiology and nuclear oncology are generally the most commonly performed studies. In certain regions, renal studies, infection localization and even liver–spleen scans are still very important. Many of these have been referenced in the IAEA's Nuclear Medicine Resources Manual [3] (Section 5).

Planning a nuclear medicine department should be preceded by a study of the population's demographics and the prevalence of diseases in the country. These data and analysis allow for prioritization and planning of an appropriate nuclear medicine service. Since nuclear medicine serves both in-patients and out-patients, the location of the site should give easy access to both groups.

The following guidelines are useful for the operation of a nuclear medicine service:

(a) Departmental policies should be recorded in writing and explained to staff. There should be a clear chain of management, which should be made apparent.
(b) A copy of the procedures manual should be available in all imaging rooms and technical staff should be briefed on these procedures.
(c) Patient preparation forms should be easily accessible to the receptionist and the person who schedules studies.
(d) Nuclear medicine request forms must include: the patient information (including name, age, gender, hospital identification number, address and telephone number); and the patient's medical profile (including name, address and telephone number of the referring physician, clinical background and clinical data) as well as preliminary diagnoses and any tests required. Nuclear medicine physicians should examine each request for quality. They should positively justify and approve the test before it is performed and, if appropriate, modify it after consulting with the referring physician. Request forms should provide space to indicate physician's approval of the test, radiopharmaceuticals used, as well as dosage and route of administration. The form must be signed by the person(s) involved. Patients must, in the presence of a witness, sign the correct consent form (if applicable — specifically for therapy dose) during the interview. The patient's records should be reviewed and the findings of other imaging modalities verified. Any special technical modification should be written on the request form for technical staff to review.

5.1. GENERAL ASPECTS — CLINICAL SERVICES

The purpose of this section is to review aspects of clinical services.

CHECKLIST 10. GENERAL ASPECTS — CLINICAL SERVICES

No.	Component	Class	Yes/ No	Comments/ planned action	Date achieved
5.1.1.	Are the BSS principles applied in clinical nuclear medicine services?	A			
5.1.2.	Is a regular review of timelines undertaken from booking to performance of the scan to reporting?	B			
5.1.3.	Are doctors available to answer patient's questions?	B			
5.1.4.	Is there a system of patient surveillance during the time the patient is in the nuclear medicine department?	B			
5.1.5.	Is there a specific policy for paediatric nuclear medicine patients including dose adjustment, sedation, etc.?	A			
5.1.6.	Is there appropriate medical supervision during nuclear medicine interventions such as diuretics, ACE inhibitors, etc.?	A			
5.1.7.	Is medical advice given before obtaining patient informed consent — specifically for therapy?	B			

5.2. CLINICAL PROCEDURES — DIAGNOSTIC

5.2.1. Imaging procedures

The institute should provide the audit team with detailed information on the following for each type of clinical procedure, e.g. planar, dynamic or tomographic studies. Several examples of at least the following investigations should be included: thyroid scan (and/or other planar scintigraphy), whole body bone scan, renography, several types of tomographic studies (e.g. bone, tumour) myocardial perfusion planar and/or SPECT. For further details see Chapter 5 of the Nuclear Medicine Resources Manual [3].

5.2.2. Assessment of clinical imaging studies

- *Clinical problem.* When assessing this parameter, auditors should consider at least the following points: appropriateness of the clinical request; information about previous interventions and diagnostic studies.
- *Patient preparation.* When assessing this parameter, auditors should consider at least the following points: was proper information given? Was information about pregnancy/lactation, hydration, fasting, etc., obtained? Issues about therapy that may influence the study should be recorded. Was informed consent obtained, especially for radionuclide therapy?
- *Radiopharmaceuticals.* When assessing this parameter, auditors should consider at least the following points: was the correct radiopharmaceutical chosen? Is the activity in accordance with national/international guidance levels? What QC procedures are performed? What measures were in place, for example patient identification, reading the syringe label, etc., to avoid misadministration (radiopharmaceutical and activity).
- *Acquisition parameters.* When assessing this parameter, auditors should consider at least the following points: type of study (planar versus SPECT, static versus dynamic, etc.); equipment set-up (collimator, matrix size, total counts/acquisition time, etc.).
- *Processing parameters,* if applicable. When assessing this parameter, auditors should consider at least the following point: has the correct choice been made of a validated algorithm for image reconstruction and analysis?
- *Images.* When assessing this parameter, auditors should consider at least the following points: completeness of the acquired study; artefacts due to camera acquisition technique; patient related factors; overall quality; and unexpected biodistribution of the radiopharmaceutical.

— *Final report.* When assessing this parameter, auditors should consider at least the following point: Evaluate whether the report conforms to national/international guidelines and answers the clinical question.
— *Feedback,* if available. (Correlative imaging, other clinical tests, final clinical and/or histopathological diagnosis, etc.).

5.2.3. Review of clinical practices

Clinical procedures need to be assessed applying the criteria of evidence based medicine, according to internationally accepted standards, as can be found in published guidelines and up to date literature. Applying these standards, the studies should be evaluated and graded according to the following categories:

— Grade I: Conforming completely to the published (national, international) guidelines;
— Grade II: Acceptable, but could be improved to meet Grade I;
— Grade III: Non-conforming in terms of the criteria of good clinical practice.

For internal audits, use this assessment to evaluate the quality of your clinical studies. External auditors will follow the same process to evaluate the studies presented to them.

Recommendations: For diagnostic procedures, Grade III should be corrected within four weeks, and for Grade II corrections should be made within six months.

5.2.4. Imaging diagnostic procedures — Final summary table

A selection of each different type of investigation should be undertaken to assess good clinical practice.

CHECKLIST 11. SUMMARY OF IMAGING DIAGNOSTIC PROCEDURES

Type of investigation	Type of study	Clinical problem	Patient preparation	Radio-pharmaceutical and activity	Acquisition parameters	Processing parameters	Images	Final report	Recommendations
Planar	Thyroid								
Planar whole body	Bone								
Dynamic	Renography								
SPECT	Forexample, bone								
Cardiac SPECT	MPS								

5.2.5. Clinical procedures — Non-imaging procedures

If non-imaging procedures are carried out, studies must be made available with information on the following for each type of procedure. Specifically, the following studies should be included: glomerular filtration rate (GFR) determination, blood volumes, Schilling test, and sentinel node lymphoscintigraphy.

5.2.5.1. Assessment of clinical non-imaging studies

- *Clinical problem.* When assessing this parameter, auditors should consider at least the following points: appropriateness of the clinical request; information about previous interventions and diagnostic studies, etc.
- *Patient preparation.* When assessing this parameter, auditors should consider at least the following points: was proper information provided? Was information about pregnancy/lactation, hydration, fasting, etc., obtained? Issues about therapy that may influence the study should be recorded; Was informed consent obtained (if applicable)?
- *Radiopharmaceuticals.* When assessing this parameter, auditors should consider at least the following points: correct choice of the radiopharmaceutical; activity in accordance with national/international guidance levels; QC procedures; patient identification; avoiding misadministration (radiopharmaceutical and activity).
- *Study protocol.* When assessing this parameter, auditors should consider at least the following point: does the study protocol used adhere to national/international guidelines?
- *Calculation methods,* if applicable. When assessing this parameter, auditors should consider at least the following point: correct choice of validated algorithm for data analysis.
- *Final report.* When assessing this parameter, auditors should consider at least the following point: does the report conform to national/international guidelines and answer the clinical question?
- *Feedback,* if available. (for example, other clinical tests, final clinical and/or histopathological diagnosis, etc.).

5.2.5.2. Non-imaging diagnostic procedures — Final summary table

A selection of each different type of non-imaging investigation should be undertaken to assess good clinical practice.

CHECKLIST 12. SUMMARY OF NON-IMAGING DIAGNOSTIC PROCEDURES

Type of study	Clinical problem	Patient preparation	Radio-pharmaceutical and activity	Study protocol	Calculation methods	Final report	Recommendations
GFR							
Schilling test							
Blood volumes							
Red cell survival							
Sentinel node							
Iron kinetics							

5.3. RADIONUCLIDE THERAPY

The purpose of this section is to review essential aspects of radionuclide therapy service.

CHECKLIST 13. GENERAL ASPECTS — RADIONUCLIDE THERAPY SERVICE

No.	Component	Class	Yes/ No	Comments/ planned action	Date achieved
5.3.1.	Are the BSS principles applied in the radionuclide therapy service from nuclear medicine?	A			
5.3.2.	Is there a written SOP for radionuclide therapy service?	B			
5.3.3.	Is the appropriateness of the clinical indications for the requested therapy reviewed and approved by the nuclear medicine department or equivalent specialist?	A			
5.3.4.	Is the radioactive dose to be administered to the patient in concurrence with a medical physicist (calculation of the effective dose absorbed), nuclear medicine physician or equivalent specialist?	A			
5.3.5.	Is the administrated activity individually measured and checked in a standardized calibrator which has been quality checked with the radionuclide concerned?	A			
5.3.6.	Are appropriate facilities (dedicated rooms) for out and in-patients available?	B			
5.3.7.	Is there a multidisciplinary clinical follow-up of these patients?	B			
5.3.8.	Are written rules available for discharging patients?	B			
5.3.9.	Is patient's activity/emitted dose measured and recorded in the patient's file before discharge from the department?	B			
5.3.10.	Are written instructions available for the patient on discharge?	B			

5.4. CLINICAL EVALUATION

For three therapeutic procedures the audited institute is required to provide the following information:

- *Clinical problem.* When assessing this parameter, auditors should consider at least the following points: appropriateness of the request for therapy. Was information about previous therapies, interventions, diagnostic studies, etc., obtained?
- *Patient preparation.* When assessing this parameter, auditors should consider the following points: was proper information given? Was information about pregnancy/lactation, hydration, fasting, etc., taken into account? Was informed consent obtained? Were any other issues about therapy that may influence the radionuclide treatment recorded? Was the patient identification protocol strictly followed to avoid misadministration?
- *Radiopharmaceuticals.* When assessing this parameter, auditors should consider the following points: correct choice of the radiopharmaceutical. Activity in accordance with national/international guidance levels; QC procedures.
- *Therapy protocol.* When assessing this parameter, auditors should consider the following point: does the protocol used adhere to national/international guidelines?
- *Calculation methods.* When assessing this parameter, auditors should consider the following point: correct choice of validated algorithm for dosimetric calculations.
- *Discharge report.* When assessing this parameter, auditors should consider the following point: do discharge letters and other documents (e.g. report of radiation monitoring) conform to national/international guidelines?
- *Post-therapy follow-up.* For example, efficacy of therapy; clinical outcome.

Therapeutic procedures need to be assessed according to the following categories, and graded as:

- Grade I: Conforming completely to the published (national, international) guidelines.
- Grade II: Acceptable, but could be improved to meet Grade I.
- Grade III: Not conforming to the criteria of good clinical practice.

For internal audit, use this assessment to evaluate the quality of your therapeutic procedures. External auditors will use the same process to evaluate the therapeutic procedures presented to them.

Recommendations: For therapeutic procedures, Grade III should be corrected *immediately*; Grade II corrections should be made within six months.

For more information see Chapter 6 of the Nuclear Medicine Resources Manual [3].

5.5. CLINICAL RADIONUCLIDE THERAPY — FINAL SUMMARY TABLE

A selection of each different type of radionuclide therapy should be undertaken to assess good clinical practice.

CHECKLIST 14. SUMMARY OF THERAPEUTIC PROCEDURES

Type of therapy	Clinical problem	Patient preparation	Radio-pharmaceutical	Activity	Treatment protocol	Calculation methods	Discharge report	Post-therapy follow-up	Recommendations
Thyroid									
Pain palliation									
Tumour therapy									
Radiosynovectomy									

6. RADIOPHARMACY

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

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

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

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

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

6.1. IAEA OPERATIONAL GUIDANCE ON HOSPITAL RADIOPHARMACY

The IAEA's publication on Operational Guidance on Hospital Radiopharmacy: A Safe and Effective Approach [5] (IOG) categorizes hot laboratory operations according to three levels. It provides essential details (staffing, scope of operations, equipment, staff qualification, record keeping, level of QM and QC) at each operational level (Table 2).

This audit process is mainly designed to cover the requirements at IOG operational levels 1 and 2. Many nuclear medicine departments operate at IOG

TABLE 2. ESSENTIAL HOSPITAL RADIOPHARMACY OPERATIONAL LEVELS

Operational level	Scope	Key points/ comments
1a	All radiopharmaceuticals are procured in their final form from a recognized/authorized manufacturer or a centralized radiopharmacy. They may include unit doses or multiple dose vial radiopharmaceuticals. In any case, no further preparation is required.	
1b	Radioiodine preparations, either in liquid or capsule form, are purchased from recognized/authorized manufacturers. Typically, no further compounding is required. Any dilution of the product should be undertaken within product specifications.	
2a	This 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 pre-sterilized radiopharmaceutical cold kits.	
2b	This level describes laboratory practices and environmental conditions necessary for safe manipulation and radiolabelling of autologous blood cells and components for re-injection into the original donor/patient.	
3a	This level refers to the compounding of radiopharmaceuticals from radionuclides for diagnostic application; modification to existing commercial kits; and 'in-house' production of reagent kits from ingredients (including freeze-dried operation). Research and development falls frequently under operational level 3a.	
3b	This level refers to the compounding of radiopharmaceuticals from basic ingredients or unlicensed intermediates and radionuclides for therapeutic application (open procedure) and/or related research and development.	
3c	This level refers to: • Synthesis of PET radiopharmaceuticals; • Compounding of radiopharmaceuticals produced from unauthorized or not registered long lived generators such as (^{68}Ga) gallium or (^{188}Re) rhenium. Plus related research and development.	

levels 1 and 2 because they do not always have a trained radiopharmacist. At IOG operational levels 1 and 2 the prepared radiopharmaceutical products cannot be distributed beyond the hospital's boundaries. In the majority of cases the legal oversight is provided by the physician in charge.

At IOG operational level 3, a specialist radiopharmacist, radiochemist or 'qualified person' is required as many specialist products and services are provided including the management of a centralized radiopharmacy service and PET radiopharmaceuticals. National legal requirements are considerably more involved and therefore the auditing process requires more details. This is beyond the scope of this publication.

6.2. HOSPITAL RADIOPHARMACY — OPERATIONAL LEVEL 1

CHECKLIST 15. HOSPITAL RADIOPHARMACY — OPERATIONAL LEVEL 1

No.	Component	Class	Yes/ No	Comments/ planned action	Date achieved
	Staffing				
6.2.1.	Is the radiopharmacy unit operated under the direction of a person with appropriate training as defined by local or national regulations?	A			
6.2.2.	Are there written staff training manuals for all grades of staff?	B			
	Facilities				
6.2.3.	Does the unit have appropriately finished rooms (including adequate lighting, appropriate finishes to walls, floors, ceilings and ventilation) and a shielded dispensing station?	A			
6.2.4.	For operational level 1b: Is there a well ventilated area or a shielded dispensing station for radioiodine capsules?	A			

CHECKLIST 15. HOSPITAL RADIOPHARMACY — OPERATIONAL LEVEL 1 (cont.)

No.	Component	Class	Yes/ No	Comments/ planned action	Date achieved
6.2.5.	Is there a validated (annual check of air flow, safety and challenge testing) fume hood with suitable filters for handling radioiodine solutions?	A			
	Purchase of materials				
6.2.6.	Are there suitable protocols and trained staff for the purchase of approved or marketing authorized radiopharmaceuticals?	A			
6.2.7.	Are all goods received checked and recorded against the order for correctness of delivery?	B			
	Dispensing protocols				
6.2.8.	Under operational level 1a: Are there written procedures for the aseptic dispensing and labelling of unit doses of ready to use radiopharmaceuticals?	B			
6.2.9.	For operational level 1b: Is a shielded dispensing station and/or a fume hood available? (Is there a fume cupboard with suitable filters for volatile radioactive materials such as ^{131}I solutions?) (If only radioiodine capsules are handled, is the package opened in a well ventilated area?)	A			
6.2.10.	For operational level 1b: Do the written procedures contain clear safety and monitoring instructions for dispensing radioiodine solutions or capsules?	A			

CHECKLIST 15. HOSPITAL RADIOPHARMACY — OPERATIONAL LEVEL 1 (cont.)

No.	Component	Class	Yes/ No	Comments/ planned action	Date achieved
6.2.11.	Can the audit and documentation for each radiopharmaceutical batch be traced from the prescription to the actual administration of individual patient doses?	A			
	QA/QC				
6.2.12.	Are periodic quality checks on radiopharmaceuticals performed?	B			
6.2.13.	Is there a written procedure for dealing with products that do not meet the required standards and/or for which a complaint has been received?	B			
	Waste				
6.2.14.	Are there written procedures for the disposal of radioactive and non-radioactive waste specific to the radiopharmacy?	A			

6.3. HOSPITAL RADIOPHARMACY — OPERATIONAL LEVEL 2

It is essential that requirements for operational level 1 are met while working at level 2.

CHECKLIST 16. HOSPITAL RADIOPHARMACY — OPERATIONAL LEVEL 2

No.	Component	Class	Yes/ No	Comments/ planned action	Date achieved
	Staffing				
6.3.1.	Are there specific staff training and assessment of competency at operational level 2, including in aseptic practice?	A			
6.3.2.	Is training provided for staff required to perform final checks on all products prepared before release for patient use?	A			
6.3.3.	Before release of radiolabelled RBC (red blood cells) and WBC (white blood cells) labelling is there confirmation of training?	A			
	Facilities				
6.3.4.	For operational level 2: Are there regular checks on validated Class II type B microbiological safety cabinets located in a dedicated room?	A			
6.3.5.	For negative pressure isolators: Before preparation takes place, are gloves or gauntlets visually inspected and integrity tests carried out and recorded?	B			
	Preparation protocols				
6.3.6.	In practice, have all systems of work and documentation related to radiopharmaceutical preparation and processing been formally approved?	B			
6.3.7.	Do all products, kits and generators have product approval, marketing authorization, or bear a product licence number?	A			

CHECKLIST 16. HOSPITAL RADIOPHARMACY — OPERATIONAL LEVEL 2 (cont.)

No.	Component	Class	Yes/ No	Comments/ planned action	Date achieved
6.3.8.	Is the preparation of ^{99m}Tc radiopharmaceuticals from kits and generators carried out in a laminar air flow (LAF) cabinet?	A			
6.3.9.	Can each individual patient dose be traced to a specific generator and kit batch number?	A			
6.3.10.	For operational level 2b: Do the written procedures for any autologous preparation, e.g. RBCs and WBCs, include clear instructions on safety, cleaning and decontamination?	A			
6.3.11.	Are there written procedures for the preparation and dispensing of radiolabelled biologicals, e.g. monoclonal antibodies, peptides from approved kit formulations?	A			
	QA/QC				
6.3.12.	Are there set QC pre-release criteria for preparation before patient use?	A			
6.3.13.	Is a record of approval/release made by an authorized person before a product is administered to a patient?	A			
6.3.14.	For operational level 2: Is ^{99}Mo molybdenum breakthrough measurement performed on the first eluate from each ^{99m}Tc technetium generator and repeated when the generator is moved?	A			
6.3.15.	Is aluminium ion breakthrough checked on the first eluate from a ^{99m}Tc technetium generator?	A			

CHECKLIST 16. HOSPITAL RADIOPHARMACY — OPERATIONAL LEVEL 2 (cont.)

No.	Component	Class	Yes/ No	Comments/ planned action	Date achieved
6.3.16.	Before patient use, are radiochemical purity tests performed on all new batches or newly delivered radiopharmaceutical kits?	B			
6.3.17.	Is there routine microbiological monitoring of the preparation and aseptic dispensing area in the radiopharmacy?	A			
6.3.18.	Are changes in the use of kits, diluents or vehicles, needles, syringes, swabs and sterile containers recorded?	B			
6.3.19.	Are pH tests carried out regularly?	B			
6.3.20.	Are rapid alternative methods employed for swift prospective QC, e.g. for the determination of the radiochemical purity of ^{99m}TcHMPAO?	A			

7. TUMOUR MARKER SERVICE USING RADIOIMMUNOASSAY

This audit section focuses on the clinical use of tumour marker service using radioimmunoassay. A wide range of services and levels are provided by using radioimmunoassay or associated medical laboratories. A few laboratories are certified by the International Organization for Standardization (ISO) and most are accredited under national accreditation systems. However, many laboratories in developing countries function without any accreditation or certification process.

This audit is from the patient's perspective and is therefore divided into three components: pre-analytical; analytical; and post-analytical. There is strong emphasis on the internal quality programme as well as on the importance of belonging to the external quality assessment programme.

Medical laboratories seeking external recognition for the quality of their services need to ensure that internal and external audits are fully carried out on a regular basis. Any change should be implemented on a timely basis. This audit check should go some way towards addressing many of the issues associated with maintaining a high quality of service.

The IAEA publication Screening of Newborns for Congenital Hypothyroidism — Guidance for Developing Programmes [6] is a useful guide to good practices for newborn screening using radioimmunoassay. Part III of this publication provides useful tips to improve quality programmes in laboratories in general.

7.1. COMPONENTS OF THE TUMOUR MARKER RADIOIMMUNOASSAY SERVICE

An essential review of good laboratory practices and tumour marker services is necessary.

CHECKLIST 17. TUMOUR MARKER RADIOIMMUNOASSAY SERVICE

No.	Component	Class	Yes/ No	Comments/ planned action	Date achieved
	Good laboratory practices				
7.1.1.	Does the radioimmunoassay service have formal authorization from a recognized national authority?	A			
7.1.2.	Is there a clear written protocol for all radioimmunoassay, IRMA and ELISA analytes used in the laboratory?	A			
7.1.3.	Is there a clear protocol stating the action required in a follow-up of suspected result errors in the laboratory?	A			
7.1.4.	Is there a mechanism to check why recent results are 20% lower, while all previous results have all been within 10% of the target?	B			

CHECKLIST 17. TUMOUR MARKER RADIOIMMUNOASSAY SERVICE (cont.)

No.	Component	Class	Yes/ No	Comments/ planned action	Date achieved
7.1.5.	Is there a mechanism to follow up random errors, e.g. wrong sample on analyser, wrong specimen assayed, wrong result reported by accident?	B			
7.1.6.	Is there a mechanism to double-check records of reported 'undetectables' when the expected result was clinically significant?	B			
	Pre-analytical phase				
7.1.7.	Is there a procedure to follow when the clinical user does not provide the necessary information or the correct specimen?	B			
7.1.8.	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?	B			
7.1.9.	Is there a periodic review of the appropriateness and integrity of the sample transport system?	A			
7.1.10.	Is there a periodic review to ensure that the confidentiality of patients' results is guaranteed?	A			
7.1.11.	Is there a periodic review to ensure biological safety?	A			
	Analytical phase				
7.1.12.	Are there records of regression line analyses with a known amount of the international standard in serum?	B			
7.1.13.	Are there records of recovery experiments to validate a new method?	B			

CHECKLIST 17. TUMOUR MARKER RADIOIMMUNOASSAY SERVICE (cont.)

No.	Component	Class	Yes/ No	Comments/ planned action	Date achieved
7.1.14.	For each type of assay and/or each type of data set, is there a record of calculated mean, standard deviations and a coefficient of variation?	B			
7.1.15.	Is there a Levey–Jennings plot, including controls and standards for each assay?	A			
7.1.16.	Is there a clear written protocol when points are outside the 2 standard deviation limits?	A			
7.1.17.	Is there a system in place to guarantee safe disposal of samples and are samples treated as infectious waste?	A			
	Post-analytical phase				
7.1.18.	Is there a standard format for reporting laboratory results which includes the laboratory's name, patient details, requesting person, test description, sample type (serum, urine, etc.), results (+ reference values), interpretative comments (if any), signature of authorized professional?	A			
7.1.19.	Is there a list of authorized staff members who are designated to amend patient notes or reports and for communicating results?	A			
7.1.20.	Are reference values based on national or regional findings available for each assay type?	B			
7.1.21.	Is feedback from clinical interpretative services documented?	B			

8. AUDIT REPORT

Prioritization is important and in this publication three levels are considered — 'Critical', 'Major' and 'Minor'. Prioritization should be patient focused.

8.1. CRITICAL PRIORITY LIST

CHECKLIST 18. CRITICAL PRIORITY LIST

No.	Comment/action	Time frame	Date achieved

8.2. MAJOR PRIORITY LIST

Major priorities are only second to critical priorities as they have less impact on patient management. However, they should be addressed in a timely manner.

CHECKLIST 19. MAJOR PRIORITY LIST

No.	Comment/action	Time frame	Date achieved

8.3. MINOR PRIORITY LIST

Minor priorities are essential for proper quality management.

CHECKLIST 20. MINOR PRIORITY LIST

No.	Comment/action	Time frame	Date achieved

8.4. CHECKLIST FOR AUDIT REPORT CONTENTS

Standardized audit reports are essential for all stakeholders. The checklist below provides some guidance.

CHECKLIST 21. AUDIT REPORT CONTENTS

Contents	Included Yes/No	Comments
Introduction		Background, demographics, public health system, national funding.
Terms of reference		Activities of the auditing team.
Regulatory authority and regulations		License for use of radioactive material, radiation protection and safety programme, radiation worker doses, calibration certificate.
Nuclear medicine infrastructure including imaging systems		General, human resources, medical education, floor plan, equipment, performance of imaging equipment, computer systems and data handling, services performed, quality assurance.

CHECKLIST 21. AUDIT REPORT CONTENTS (cont.)

Contents	Included Yes/No	Comments
Clinical nuclear medicine		Request for administration of radiopharmaceuticals, examples of scintigrams and report prescription form for radiopharmaceutical treatment, patient consent form, in vitro techniques, and radionuclide therapy.
Radiopharmacy		Performance should be mainly compared with the IAEA Operational Guidance on Hospital Radiopharmacy [5].
Radioimmunoassay services		Good laboratory practices, pre-analytical, analytical and post-analytical.
Major strengths and deficiencies		Deficiencies should be recorded in the audit process, with an indication of how and when improvements will be achieved.
Summary of audit follow-up		Details of agreed changes should be stated. A follow-up mechanism should also be agreed upon.
Recommendations		These should be clearly worded, ideally in a single sentence: nuclear medicine department, host hospital, government, IAEA.
Annex		

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Quality management systems are maintained with the intent to continuously improve effectiveness and efficiency, enabling nuclear medicine to achieve the expectations of its quality policy, and to satisfy its customers. The IAEA has a long history of providing assistance in the field of nuclear medicine to its Member States. This publication introduces a routine of conducting an annual systematic audit process into the clinical arena. The quality management audit methodology introduced in this publication is designed to be applied to a variety of economic circumstances. A key outcome should be a culture of reviewing essential elements of the clinical service for continuous improvement in nuclear medicine.

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