

IAEA HUMAN HEALTH SERIES No. 43

Basics of Quality Management for Nuclear Medicine Practices



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BASICS OF QUALITY MANAGEMENT FOR NUCLEAR MEDICINE PRACTICES

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Human Health Series No. 43

BASICS OF QUALITY MANAGEMENT FOR NUCLEAR MEDICINE PRACTICES

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FOREWORD

Quality improvement poses challenges to many countries striving to deliver optimal patient care that meets international standards for clinical care, safety and other areas. Public expectations of health care are now much higher than previously, in line with improving health care standards globally. These expectations have to be met amid the challenges of rising costs of health care, skill shortages in some areas of medicine and increasing patient activity.

Health care systems have a complex socioeconomic structure with various stakeholders, each with its own roles, interests and multiple interactions. All countries have health care professionals, managers, patients, financers and others who are invested in improving safety and quality in health care practices.

This publication is built upon the experience gained from implementing the Quality Management Audits in Nuclear Medicine Practices (QUANUM) programme, which was developed by the IAEA more than a decade ago and has been successfully implemented in more than 80 countries worldwide.

The purpose of this publication is to assist nuclear medicine professionals, middle management and executive teams at the hospital level in developing strategies that support quality improvement in nuclear medicine practices and help protect the public from unsafe or substandard practices.

The technical officers responsible for this publication were M. Dondi and D. Paez of the Division of Human Health.

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1. INTRODUCTION

1.1. BACKGROUND

The definition of quality health service, as set out by the World Health Organization (WHO) [1], recognizes the need for safe care and the requirement for stringent laws demanding a high level of standards and human rights in the context of health care. It also covers the following three perspectives on quality:

- Patient quality (what patients want and experience);
- Professional quality (what patients need, in line with best practice);
- Management quality (efficiency and meeting regulations).

Quality improvement contributes to addressing the challenges confronting health systems in many countries. Patients expect more from health care than previously and have changing health needs. Improvement means defining and measuring aspects of each of the above perspectives and setting appropriate standards. There is indeed evidence that some health care might be ineffective [2, 3] and that resources are often wasted [4, 5].

1.2. OBJECTIVE

The objective of this publication is to provide a framework for quality management systems (QMSs) to be holistically implemented and managed in an ongoing fashion in nuclear medicine departments, keeping in mind that nuclear medicine has always taken quality aspects into account, although often limited to equipment management and radiopharmaceutical preparations.

This publication is pertinent to the following audiences:

- Key players in delivering health care, such as hospital managers; professionals such as physicians, physicists, radiopharmacists, technologists, radiographers and nurses; and allied health professionals involved in nuclear medicine services (NMSs).
- Customers (patients and/or referring clinicians) requesting or requiring the services provided by professionals and organizations, on the basis of a common understanding of illness and disease and using accepted medical interventions to help patients stay healthy or get better, or to prevent further disabilities or deterioration of patients.

Guidance and recommendations provided here in relation to identified good practices represent expert opinion but are not made on the basis of a consensus of all Member States.

1.3. SCOPE

This publication covers the basics of a QMS as applied to NMS and is based on the methodology, the reasoning and assumptions underlying the IAEA's QUANUM programme [6].

1.4. STRUCTURE

The publication is separated into eleven sections and six annexes, beginning with an explanation of the concept of clinical governance as a strategy to keep clinical services and their quality under control, and covering all activities involved, from promoting the culture of quality to measuring the QMS. Insight is provided on how to structure the QMS and how to manage human resources, risks and radiation protection as well as the safety of patients and personnel. Advice is also provided on the preparation and control of the documentation system, including the preparation of a quality manual, formulation of standard operating procedures and the preparation and use of indicators to keep the NMS running in the best possible way.

1.5. CLINICAL GOVERNANCE

Clinical governance is a strategy by which health organizations, which are responsible for continuously improving the quality of services and for achieving and maintaining high standards, encourage the creation of an environment that fosters professional excellence [7].

Clinical governance necessitates a distinct orientation of the organizational structure of health care providers, who are often seconded to an active role in the development of quality standards that are to be defined, maintained and verified by the professional component of health care workers, who provide medical assistance and are responsible for verifying and accepting quality standards defined by the organizations. Governance should not be imposed from above or from the outside, but ideally arises from the interaction of multiple self-governing factors, influencing and interacting with each other. The effectiveness of clinical governance depends on its ability to permeate all levels of the health

organization, which in turn will enable professionals to achieve and maintain high standards of care. Clinical governance tends to narrow the gap between professionals (who have a wide breadth of professional freedom) and managers (who often are restricted by a limited corporate budget).

The main components of clinical governance are risk management; clinical audit; education, training and continuing professional development; evidence based care and effectiveness; patient and carer experience and involvement; staffing and staff management; indicators; internal review and audit [8]. These components are discussed below.

2. RISK MANAGEMENT

Risk management is a systematic process, including both clinical and management dimensions, that employs a set of methods, tools and actions to enable managers to identify, analyse, assess and treat risks in order to improve process continuity as well as staff and patient safety.

Risk management focuses on minimizing risks by doing the following:

- Using appropriate science based tools to identify in advance what could go wrong during care (i.e. failure to plan or execute a sequence of actions that results in the desired goal not being reached) and understanding the factors that influence this.
- Learning lessons from any adverse events (i.e. unexpected events related to the care process and result in unintentional and undesirable harm to the patient), whether preventable or not. An adverse event attributable to an error is 'a preventable adverse event,' and this includes 'near misses' (an error that has the potential to cause an adverse event but, either because it was intercepted or because it had no adverse consequences for the patient, did not occur) [9].
- Identifying 'sentinel events' (i.e. serious adverse events that are potentially indicative of a significant malfunction in the system and can result in death or serious harm to the patient). The high risk level dictates that a sentinel event occurs only once in an organization to warrant an immediate investigation and root cause analysis to ascertain the causes and implement appropriate corrective measures.

2.1. EDUCATION, TRAINING AND CONTINUING PROFESSIONAL DEVELOPMENT

It is vital that staff caring for patients have the knowledge and skills to carry out their duties to a high standard. They should be given opportunities to update and enhance their skills to keep current with the latest developments in the profession as well as to learn new skills as required.

2.2. EVIDENCE BASED CARE AND EFFECTIVENESS

Care for patients should be based on good quality evidence from research. Appropriateness in health care concerns any health intervention, be it preventive, diagnostic, therapeutic or rehabilitative, related to the needs of the patient (or the community). To be considered appropriate, those interventions should be based on recognized science and standards and be provided within acceptable time frames, after appropriate analysis of the budget, risks and benefits.

2.3. EXPERIENCE AND INVOLVEMENT OF PATIENTS, REFERRERS AND CARERS

In order for the NMS to offer the highest quality of care, it is important for it to work in partnership with all stakeholders, such as patients, referrers and carers. This will assist them in gaining a better understanding of the priorities and concerns of those who use the NMS.

2.4. STAFFING AND STAFF MANAGEMENT

Optimal staffing and efficient staff management are vital if the NMS is to provide high quality care. The NMS should make concerted efforts to have an appropriate number of highly skilled staff working as an efficient team in a well supported environment.

2.5. INDICATORS

Clinical governance is based on the predefinition of indicators, specifically those that permit judgements to be made about the quantitative (measurable) or qualitative characteristics of an object or phenomenon. Qualitative indicators can further integrate quantitative data, making it possible to evaluate additional non-quantifiable aspects, which are nonetheless useful for the interpretation of quantitative observations. For example, the opening hours of a service are quantitative data; a specific distribution of opening hours, with coverage of certain time slots or days is additional information. The result of the observation of the characteristic in question defines the 'value' or 'data' (measure of the indicator).

Indicators can measure the following:

- Structure: In this particular area, it refers to the quantitative and organizational aspects of the activity under consideration, not to a specific location.
- Process: Structured succession of activities aimed at producing a result (product, service, etc.) that has value for the end customer (patient or referring clinician).
- Results: Performance or service originating from a process (output, outcome, result, product).
- Outcome: In clinical practice, the effect or influence of an output (e.g. discharge after therapeutic procedure or effective diagnostics). Longer term outcome measures, such as one and five year survival rates, might also be considered in the case of therapies. However, this information might be available too late to be of much use for clinical governance and may be used for setting and adjusting clinical guidelines on national or international levels.

Measurable indicators are based on standards; that is, their expected value on a quantitative or on a reference 'scale'. Indicators are used to monitor relevant and critical issues in the operation of the NMS, measuring the degree of performance of an element or component of the organization or process.

Indicators are fundamental to two instruments of clinical governance, namely internal reviews and audits, which should be integrated consistently into all governance processes rather than being used only on an occasional basis or confined exclusively to the professional sphere.

2.6. INTERNAL REVIEWS

An internal review is a formal, documented and systematic examination of the organization, or parts of it, and its quality system, which is performed by the NMS management with the support of specifically designated staff (e.g. quality manager or quality committee). Its aims are to evaluate system requirements and the capability of the system to meet those requirements, and to identify problems and propose solutions.

Internal reviews are a component of the process conducted methodically. They are designed to evaluate various aspects of the processes accomplished by the NMS, such as to do the following:

- Monitor the workload of the NMS, in comparison with expectations or with an equivalent period of the previous year;
- Check if a patient was identified appropriately before the radiopharmaceutical was administered;
- Check if injected activities for the spectrum of nuclear medicine procedures performed lie within recommended diagnostic reference levels (DRLs) [10] and adhere to the Basic Safety Standards (BSS) [11];
- Check if there was appropriate clinical handover;
- Analyse uptime and performance monitoring of key equipment.

Internal reviews are closely connected with the measurement of indicators and can also be used, for example, to introduce a new indicator to monitor a specific aspect and to review the results after a period of operation.

2.7. AUDITS

As defined by the International Organization for Standardization (ISO) standards on QMS, "an audit is systematic, independent and documented process for obtaining objective evidence and evaluating it objectively to determine the extent to which the audit criteria are fulfilled" [12].

Clinical audits allow doctors, nurses and other health care professionals to objectively measure the quality of the care they provide. They compare performance against an accepted standard to assess the efficiency of clinical and technical operations and identify opportunities for improvement by performing a gap analysis. Changes can then be made with the aim of closing the gaps, followed by further audits to assess whether the implemented changes have achieved the aim.

Clinical audits consist of the systematic and critical analysis of the quality of medical care including the following:

- Procedures used for diagnosis, therapy and care (product);
- The associated use of available resources (process);
- Patient outcomes and quality of life.

Auditing the clinical component of an activity is essential but is not sufficient to guarantee that the whole process is 'under control'. The lack of a comprehensive approach may lead to weaknesses in the deployment of clinical activities resulting from structural deficiencies of the organization. This is one of the important reasons to introduce an overarching QMS.

In the realm of quality management, quality audits are systematic, independent reviews to determine whether the activities carried out for quality, and the results obtained, are in accordance with the established reference model from ISO [13], EFQM [14], accreditation bodies or other programmes such as the IAEA's QUANUM programme [6]. They also assess whether what is established is carried out effectively and is suitable for the stated objectives.

Quality audits are systematic and independent, but are also characterized by their mandate, which could come from internal management, from an accreditation body or from a client outside of the organization being evaluated, such as a buyer or customer. In the case of the QUANUM programme, the mandate is to assess adherence to predefined international standards. Audits can be performed either internally or externally.

2.7.1. Internal audits

Internal audits are planned checks of critical aspects of the NMS to evaluate whether it is providing a clinical service of high quality with minimal risk. Members of staff can be trained and qualified as quality system evaluators to perform regular audits of the quality system's operation. Internal audits can also be performed either by other members of hospital staff or through a peer review conducted by professionals from other institutions.

By adopting an internationally recognized auditing scheme such as QUANUM, partial internal audits could be performed regularly (e.g. one worksheet per month) in order to have a complete internal audit of the NMS carried out over the course of approximately one year.

2.7.2. External audits

External audits are usually conducted by evaluators from an accreditation or certifying body, by an external independent body such as the IAEA, or by a scientific association that organizes peer reviews in the frame of their competencies, such as a national association for nuclear medicine.

A comprehensive audit is very important, but it can be complicated to perform in routine practice. A more practical option often adopted is to perform partial internal audits, or sector by sector audits, according to a programme that results in 'distributing' a complete audit over a period of one year or even two. For example, partial internal audits can be applied to specific aspects, such as the following:

- Compliance with the expectations and standards set by the National Safety and Quality Health Service Standards;
- Provision of good quality imaging and therapeutic services in a safe environment;
- Triage of referrals, with timely booking and appointment allocation;
- Management of radiation within safety standards as prescribed by regulatory bodies such as the IAEA, the European Association of Nuclear Medicine (EANM) or the Society of Nuclear Medicine and Molecular Imaging (SNMMI);
- Patient identification in accordance with international and national guidelines;
- Appropriateness or clinical justification of diagnostic or therapeutic procedures;
- Compliance with hospital infection control policies.

2.7.3. The audit cycle

Performing audits on a regular basis helps an NMS to achieve continual improvement in the quality and safety of its services. Steps typically involved in an audit cycle (Fig. 1) are the following:

- An audit (internal or external) is planned, for which specific focuses may be defined;
- Standards and criteria are defined (such as those put forth in QUANUM), which will serve as a reference for the auditors;
- The actual audit visit takes place, with auditors conducting interviews, observing ongoing relevant activities, assessing the facilities and probing the QMS, documentation, acquisition, processing and clinical reporting of scans, quality control (QC) and radiation safety procedures, etc.;
- The audit results in a list of findings, potentially including non-conformances requiring corrective or preventive actions by NMS management;
- Actual improvements are planned and applied;
- Finally, this whole cycle is repeated at regular intervals (or as needed to eliminate critical non-conformances) as a well accepted way of achieving continuous improvement, step by step.



FIG. 1. The audit cycle.

3. CULTURE OF QUALITY

In health care, the concept of quality as an integral part of daily work culture aims to achieve uniform (where adequate) and tailored (when needed), consistent, safe and high quality patient care in hospitals and health services. The responsibility of an NMS is to deliver accurate diagnoses and effective radionuclide therapy to patients, which can be achieved only by sound and well tested quality assurance (QA) measures at every step of the patient journey.

The patient journey in an NMS begins with the receipt of a referral for a diagnostic or therapeutic nuclear medicine procedure. The culture of quality also begins at this point and, ideally, should be present at every subsequent step of the patient journey — such as arrival at the NMS, registration at reception, patient interview, preparation, administration or infusion of radiopharmaceutical (RP), imaging, image reconstruction, post-processing, display, report generation, study archiving and communication of results.

3.1. FOSTERING A CULTURE OF QUALITY

It is important for all staff — administrative, medical, technical and nursing staff as well as radiochemists, radiopharmacists, medical physicists and patient service assistants — to realize that each individual staff member plays a role in the patient experience and in the final report that is generated at the end of the audit. As such, the service that is provided at each point has to be 'under control', that is, undergo a QA process to ensure adherence to policies, procedures and guidelines. This goal can be achieved in many ways:

- Education of staff across the multiple disciplines in an NMS.
- Leading by example to maintain high standards. This is the responsibility of the management team and senior staff within the NMS, who should clearly express their commitment not only by means of statements, but also by actions.
- A robust documentation system that is up to date and outlines departmental policies, procedures, guidelines and records in a way that is formulated to ensure that safe, traceable and high standard patient care is provided.
- Conducting regular internal reviews as well as internal and external audits, thereby engaging in the plan-do-check-act cycle [15], which will identify gaps in practices and a mechanism to address these gaps.
- Being receptive to feedback and ongoing changes within the quality management framework.

3.2. ENGAGING STAFF IN IMPLEMENTING A QUALITY PROGRAMME IN A CULTURE OF QUALITY

Finding the best way to implement a quality programme in a manner that will be accepted and practiced is vital in fostering a culture of quality. The quality programme should involve all staff and be clear, concise and methodical as well as easy to implement and maintain. It should not be daunting, tedious or time consuming. On the contrary, it should be easily assimilated into an efficient daily workflow, with minimal redundancies and clearly defined benefits.

A well constructed QMS that minimizes bureaucracy will save time and resources. A QMS should have the following characteristics:

- Low maintenance (i.e. not requiring excessive interventions);
- Operational in the background;
- Complementary, not hindering the work of an NMS;
- Flexible enough to allow an NMS to choose its own working methods;

— Shared and openly discussed at staff meetings, encouraging interactive feedback (such meetings are a great opportunity to engage staff and make every individual realize that they are an essential part of the quality focus of the department).

The term 'quality' can be interpreted in many ways, and a QMS can be built in different ways. A successful quality programme is achieved when many ideas are combined to create a system suitable for the department. For instance, the design of the documentation system is an opportunity to involve all staff according to their role and expertise. The terms of reference for the quality programme should have input from senior staff in the department. The management team should then encourage and empower staff to take ownership and implement aspects of the quality programme.

In the initial phase, hiring an external quality management consultant to help design and implement the QMS may be an option.

3.3. LEADERSHIP AND RESPONSIBILITY FOR QUALITY

Leadership in quality, which includes risk management and protection matters, is to be demonstrated at the highest levels in an organization and be achieved and maintained by means of an effective QMS integrating all elements of management. The application of the management system should also ensure the promotion of a culture of quality, as previously discussed.

The term 'management system' reflects and includes the concepts of 'quality control' (controlling the quality of products) and its evolution through 'quality assurance' (the system for ensuring the quality of products), and 'quality management system' (the system for overall management of quality) [11, 16].

All staff in an NMS should be encouraged to lead where quality is concerned, not merely to participate. Managers should encourage, involve and support individuals in achieving quality management goals and performing their tasks safely.

Senior management is responsible for the following:

- Establishing, applying, sustaining and continuously improving the management system to ensure quality.
- Committing to risk management, applying a proportional or graded approach.
- Determining and providing the competencies and resources necessary to carry out the activities of the organization safely.
- Establishing good work ethics. The organization's ethical standards and values should be instilled in the department's culture of quality by

management with senior staff acting as role models to inspire their junior staff to be a part of quality management initiatives.

— Developing a culture of accountability with a well developed range of strategies, including responsible management of resources, that can be adopted by all staff in the department. Accountability enables a department to deliver its quality goals and vision and assists in a comprehensive improvement in quality.

All staff members ideally should do the following:

- Be proactive and lead by example to incorporate quality in daily activities, from basic administrative tasks to complex data processing, which will improve the quality of the patient experience in the NMS. Senior staff should actively lead in implementing and following through on actions.
- Understand and adjust to fluctuations in the external environment. Staff members often work with external stakeholders and professionals such as nursing staff, referring clinicians, hospital management and other allied health professionals. These stakeholders can form a vital part of the quality management process and can contribute to the success of the NMS. A lack of proper communication with external stakeholders is a potential risk that should be avoided.
- Establish a clear view of the department's vision. Staff, in close consultation with management of the department, should be involved in defining and implementing the department's milestones, goals and future directions.
- Develop trust and react appropriately to resistance to or fear of change. This, in turn, will form cohesiveness in the NMS, thereby promoting team spirit and the desire to work towards common goals.

Table 1 summarizes some important roles and responsibilities for QMS implementation according to the different domains and professional groups.

3.4. QUALITY COMMITTEE

A necessary step for the design, implementation and maintenance of a QMS is the establishment of a quality committee. This committee may gradually expand its scope to include related aspects of safety and risk management.

Text cont. on p. 20.

Domain and activity	NMS management	Nuclear medicine professionals (physicians, technologists, physicists, radiopharmacists)	Other
Clinical governance Risk management	 Have instruments in operation for incident reporting and risk management Identify sentinel events Monitor outcomes 	 Participate in (multi- disciplinary) prospective risk analysis Be perceptive to risks and contribute to process 	Management: — Define hospital wide policies on risk management
	 Very unaconcerve and preventive actions are defined and taken Report serious incidents and risk management status to management 	 — Report incidents — Define and take corrective and preventive actions 	

Y MANAGEMENT
QUALITY
FOR
RESPONSIBILITIES
AND
ROLES
TABLE 1.

omain and activity	NMS management 	Nuclear medicine professionals (physicians, technologists, physicists, radiopharmacists)	Other External accreditation hody:
linical audit and quality	outcomes of health care through a structured peer review — Adopt an appropriate quality standard (e.g. QUANUM 3.0) — Plan internal and external audits on a regular basis — Define areas in need of such a review — Verify that action is taken on audit findings to continuously achieve gradual improvements	the quality standards adopted by NMS (e.g. QUANUM 3.0) Participate in audits as an auditee or as an auditor, if required Participate in an audit at other departments or hospitals, as this can be very instructive Act upon audit findings	 Report audit findings, including recommendations and NCs, if any, to NMS management Monitor follow-up reported by the NMS

TABLE 1. ROLES AND RESPONSIBILITIES FOR OUALITY MANAGEMENT (cont.)

TADLE 1. NULES AN	D VESTONSIBILITES FOR QU	ALLI I MANAULIVIEN I (COIIC.)	
Domain and activity	NMS management	Nuclear medicine professionals (physicians, technologists, physicists, radiopharmacists)	er
Culture of Quality Fostering a culture of quality	 Be proactive and lead by example Maintain proper documentation outlining departmental policies, procedures, guidelines and records Facilitate CPD of staff, across all the disciplines present Be receptive to feedback and ongoing changes within the quality management framework 	 Be proactive and lead by example Verify the appropriateness, effectiveness and quality of clinical performance Follow policies, procedures and protocols set out, and stay informed on changes Inform management on shortcomings in processes, methods and means, and suggest improvements 	

TARIF1 ROLES AND RESPONSIBILITIES FOR OUALITY MANAGEMENT (cont.)

IABLE I. NULES AND	NESTURABILITIES FUR UN	ALLI I MANAUEMEN I (COUL)	
Domain and activity	NMS management	Nuclear medicine professionals (physicians, technologists, physicists, radiopharmacists)	Other
Culture of quality – – – – – – – – – – – – – – – – – – –	 Communicate with external stakeholders and professionals (nursing staff, referring clinicians, facility management, and other allied health professionals) Establish, apply, sustain and continuously improve the QMS to ensure quality Demonstrate commitment to risk management, applying a graded approach Develop a culture of accountable Promote the safe use of feedback 	 Be accountable Ensure compliance with regulations Perform systematic and critical analysis of the quality of medical care Continuously seek options to improve quality of care Be receptive to feedback and give feedback to colleagues 	External stakeholders: — Communicate regularly with NMS management on issues such as type, quality and volume of services they provide, and expected changes to these

+ TAPIE 1 POLES AND BESDONSIBILITIES COD OLIVITED MANAGEMENT

KESPONSIBILITIES FOR QUALITY MANAGEMENT (cont.)	Nuclear medicine professionals NMS management Other NMS management (physicians, technologists, physicists, physicists, control of the state) Other	Define vision and mission; Define mid to long term planning (three to five years), by initiating a strategic discussion, involving all NMS staff; as well as personnel from other departments that affect the NMSs— Contribute to defining wision and mission mission mission planningManagement: provide institutional strategic objectivesDefine mid to long term planning (three to five years), by involving all NMS staff; as well as personnel from other departments that affect the NMSs— Contribute to defining mid to objectives involving all NMS staff; as well as personal from other departments that affect the NMSsDeliverables: strategic goals, aligned with institutional strategic objectives; action plan	Define job descriptions for all staff, clearly setting out duties, responsibilities and reporting— Contribute to establishing job descriptionManagement: — Periodically give performance appraisal of NMS management performance appraisalDefine job descriptions responsibilities and reporting lines— Contribute to establishing job description — Periodically give performance appraisalDefine job descriptions responsibilities and reporting lines— Periodically give performance appraisal performance appraisalPeriodically organize performance appraisals of each staff member— Contribute to establishing job
ES AND RESPONSIBILITIES FOR QU	y NMS management	 nt — Define vision and mission; — Define mid to long term planning (three to five years), by initiating a strategic discussion, involving all NMS staff, as well as personnel from other departments that affect the NMSs — Deliverables: strategic goals, aligned with institutional strategic objectives; action plan and specific milestones 	 Define job descriptions for all staff, clearly setting out duties, responsibilities and reporting lines Periodically organize performance appraisals of each staff member
TABLE 1. ROLE	Domain and activity	Quality managemen Goals of QMSs	Human resources Job description

rofessionals ists, physicists, Other cists)	Management: ass options for — Allocate budget for CPD ovement and titending ps and tring epartment al clubs ed in quality tives or	analysis, Radiation Protection Officer: — Classify working areas process (controlled vs supervised areas form is for exposures unate e of patients
Nuclear medicine p (physicians, technologi radiopharma	 Set personal goals Consider and disculation Consider and disculation Derformance improduction Mork on CPD by a seminars, worksho Work on CPD by a seminars, worksho Conferences, prepa presentations for d meetings and journ Be actively involvemangement initia research projects 	 Participate in risk a which is often a which is often a multidisciplinary p in - NM physician: Per dich justification analys ich justification analys - NM physicist: Eva and accidental exposur and
NMS management	 Teach, train and mentor employees Identify needs for training and further professional developm Foster constant growth and development across the organization by defining challenging objectives and targets 	 Before beginning or substantially changing an activity or process, perform a prospective risk assessment, i particular for all activities wh may give rise to radiation risk Evaluate incidents reported, identifying their root causes, reduce or mitigate the risk
Domain and activity	Human resources Personal development	Fundamentals of QMS Risk assessment

TABLE 1. ROLES AND RESPONSIBILITIES FOR OUALITY MANAGEMENT (cont.)

Domaiı	1 and activity	NMS management	Nuclear medicine professionals (physicians, technologists, physicists, radiopharmacists)	Other
Fundari SOPs fr protecti	nentals of QMS or radiation on	 Set up document management to allow for a properly organized QMS Place specific SOPs in order to keep occupational and patient exposure ALARA 	 Radiopharmacist: Define SOPs for QC of radiopharma-ceuticals Technologist: Contribute to defining and continuously adapting and improving SOPs for radiopharmacy, diagnostic imaging and therapy, surveys for radioactive contamination NM physicist: Define SOP for accountability and leakage checks of sealed sources 	Radiation Protection Officer: — Define SOP for review and analysis of individual dosimeter readings
Note:	ALARA — as nuclear medici	low as reasonably achievable; CPD — cc ne; SOP — standard operating procedure	ontinuous professional development; NC	C — non-conformance; NM —

TABLE 1 ROLES AND RESPONSIBILITIES FOR OLIALITY MANAGEMENT (cont.)

The quality committee supports senior management in applying clinical governance and implementing and maintaining the quality and risk management framework within the department. It also provides relevant quality monitoring information for internal review by management. This committee oversees the implementation and evaluation of quality and risk improvement initiatives to optimize outcomes and safety for patients and staff. These initiatives are aligned with legislative, organizational and accreditation requirements with an emphasis on evidence based practice principles and supporting management in conducting internal reviews to maintain continuous improvement of practices.

The departmental quality committee typically reports to the institution's quality committee as required, which provides guidance based on the organization's priorities in order to assist in the implementation of the quality management frameworks for the department.

Members of the quality committee could be recruited from all professional categories present in the department. Their remit should cover the key areas of governance, QA and risk management. Minutes of meetings and documentation should be retained as appropriate. Depending on local circumstances, the core activities of the quality committee could be assigned to the appointed quality manager (see Section 6).

The quality committee should have defined objectives for leading quality management and supporting senior management, as detailed in Section 3.5.

3.5. TASKS IN QUALITY MANAGEMENT FOR THE QUALITY COMMITTEE

Quality management involves identifying new and emerging issues and opportunities to drive best practice and minimize clinical risk (see Section 2), and ensures the following:

- Effective systems to achieve department quality outcomes;
- Department compliance with any existing national accreditation programme;
- Completion of an annual action plan to support departmental planning;
- Adherence to international guidance given by intergovernmental organizations such as the IAEA;
- Consistency with national/international nuclear medicine practice guidelines and recommendations as set by organizations such as SNMMI and EANM;
- Benchmarking with similar organizations locally and internationally, as appropriate;
- Preparation of an annual plan for audit activities;

- Implementation of non-conformances registration and risk registry (see Section 9);
- Implementation, review and follow-up on customer satisfaction;
- Evaluation of quality programmes for imaging, equipment, laboratory and patient activities in cooperation with relevant professionals;
- Compliance of the service with professional development of human resources, including training on QMS (see also Section 6).

3.6. SUPPORTING SENIOR MANAGEMENT

The quality committee supports senior management by providing advice on carrying out the following:

- The delivery of safe, high quality care within a robust clinical governance and risk management framework;
- Annual quality planning, including internal mechanisms and processes to maintain documentation and records of evidence that are up to date;
- Defining and monitoring key performance indicators (see Section 11 on measurements and indicators);
- Fostering a culture of quality;
- Identifying new and emerging issues and opportunities to lead the profession, improve practices and streamline processes with measurable outcomes.

The quality committee also has responsibilities regarding the risk assessment process. These are further discussed in Section 7.

4. MANAGEMENT AND STRUCTURE OF A QUALITY MANAGEMENT SYSTEM

Management is usually referred to as the set of tasks involved in the administration of any activity. This definition also applies to the management of an NMS, including setting the mission, vision and strategic activities to accomplish its objectives. In the managerial tasks that are involved in running a department, the application of criteria and tools that are pertinent to the QMS is recommended.

4.1. QUALITY MANUAL

The quality manual is an essential component of the documentation system of a QMS and is used to describe the quality system in operation at the NMS. It provides a general description of the nuclear medicine processes and how they are organized to ensure that the diagnostic and therapeutic services provided are of the highest quality. The quality manual provides information on how the nuclear medicine department meets all necessary requirements, with an emphasis on customer requirements and expectations.

The quality manual contains a general description of the NMS and its structure, a catalogue of services, the organizational chart, the quality management structure and so forth. Furthermore, it addresses the quality policy, mission and vision statements, specific and measurable quality objectives, as well as a description of the documentation system and its structure; it lists the documented procedures involved in the QMS, such as the standard operating procedures (SOPs) for the control of documents, control of non-conformances, internal audits, preventive and corrective actions, and performance of clinical activities. The way in which the service meets the requirements and ensures that the NMS is compliant with the national or international standards is also described in general terms. Relevant requirements from scientific societies and all nuclear medicine stakeholders are commonly detailed in this document.

Templates for a quality manual have been proposed by international organizations such as WHO, the EANM and the IAEA, and can be used by any NMS as a guide to formulating their own quality manuals [17]. A sample table of contents for such a manual is given in Annex I.

Many of the topics covered in the present publication on the basics of a QMS could fit within the quality manual of an NMS.

4.2. MISSION AND VISION

The mission and vision declarations are key components of the QMS for each type of activity it aims to deliver in a quality driven manner. These statements officially represent the commitment to quality by the NMS, even though they may appear to be merely 'formal' declarations of what is practiced. Auditors frequently refer to these declarations, particularly when a serious non-conformance is detected, after discussing the concern with management.

Therefore, it is strongly recommended that each NMS define and establish the mission and vision for its activities and operations:

- The mission should describe the current structure of the NMS, its functions and goals. It should outline the primary customers and include a short statement of the services offered, stating the available resources and operational conditions.
- The vision should provide a clear and comprehensive depiction of the NMS in the near future; it should outline how the institution plans to satisfy its customers. In describing what the NMS wants to become to be successful in the future, it is defining direction. It should preferably also state the timeline for achieving the expected results.

Examples of mission and vision declarations are provided in Sections 4.2.1. and 4.2.2. Note that strategic objectives should be linked to the mission and vision as defined.

4.2.1. Sample mission declaration

To provide diagnostic and therapy services based on nuclear medicine techniques, with state of the art technology and medical procedures and highly trained human resources, meeting the parameters of quality, efficiency and safety within the framework of responsibility, high quality treatment and respect for patients.

4.2.2. Sample vision declaration

The nuclear medicine department aims to operate with high quality standards, with reference to international guidelines and the most recent results of evidence based medicine. All activities performed are aimed at providing the best possible services to:

- Our patients: considering their rights, respect for their personal integrity as a fundamental value in any process (diagnosis and treatment), aiming to reestablish and preserve their health;
- Referring physicians and the departments of different specialties with which we are collaborating, providing diagnoses and treatments required in a timely fashion.

The nuclear medicine department also aims to:

- Provide high quality education to our staff;
- Become a national reference centre for didactic activities and training in the next three years.

4.3. PROCESS IDENTIFICATION AND PROCESS MAP

According to ISO definitions [12], a process is a set of interrelated or interacting activities that transforms 'inputs into outputs'. This general definition needs to be adapted and translated in each specific sector of activity.

A process is a series of activities that a nuclear medicine department develops in order to reach a final goal. An analysis of the processes performed is a typical request in an accreditation or audit process in order to determine if there is complete understanding and management of all the activities within in the department.

In a complex organization such as a nuclear medicine department, it is imperative to avoid verbally communicated instructions or temporary solutions becoming permanent without evaluation and supporting analysis.

Defining processes is relevant to the budgetary management of a department; it is typically through its processes that a department produces institutional revenues. Therefore, the establishment of a process map is a managerial requirement, and has been adopted in the QUANUM scheme of auditing [6].

Processes can be broadly grouped as primary, managerial and supporting processes, as is generically shown in Fig. 2. The processes should ideally be shown with the names of staff members responsible for each process, as well as with lines of communication with other departments in the institution.

The various diagnostic and therapeutic processes constitute the primary processes of a nuclear medicine department. Supporting and managerial processes are necessary activities that allow the NMS to carry out the primary processes, which are the core activities of the department that may produce institutional revenues, depending on the nature of the institution and of the health care system. Other essential activities (e.g. QA/QC of equipment and/or radiopharmaceuticals) that are required for carrying out core activities, but whose cost is reflected on the primary processes, are classified as support processes.

A process should not be confused with a single procedure. For example, a whole body bone scan with the appropriate ^{99m}Tc-labelled compound is a single procedure. It should be described in a detailed SOP. From the administrative point of view, it has a specific tariff and could be part of a contractual agreement


FIG. 2. Sample generic process map that could be tailored to a specific situation.

with one or more health management organizations, insurance sources or governmental bodies.

In many cases, diagnostic and therapeutic procedures are the only primary processes of a nuclear medicine department, while other activities, such as the preparation and dispensing of unit doses of radiopharmaceuticals, are typically support processes. However, in some instances, a nuclear medicine department includes a radiopharmacy department, which produces unit doses for distribution to other facilities. In these instances, these processes should be considered primary processes.

Analysing processes is an essential component of quality management culture. This analysis should be undertaken within the department and documented using graphical tools such as a process map in the form of a table or a text description, depending on the preference of the department and the style of documentation at the institution. Such an analysis should consider the interconnection with human resources management documents such as the organizational flow chart and the responsibility and authority document.

Finally, it should be borne in mind that there are processes that are entirely internal to the nuclear medicine department, but some may involve other departments or units. For example, breast cancer management typically also involves breast units, nuclear medicine, radiology, radio-oncology and oncology.

4.4. SHORT AND LONG TERM STRATEGIC PLANNING

Short term and long term planning are key aspects of the QMS. The achievement of the objectives has a positive effect on the quality of the service and on the effectiveness of the QMS and, consequently, on the satisfaction and trust of customers and other stakeholders.

Medium term to long term planning (three to five years) begins with a strategic discussion involving all staff in the department as well as personnel from other departments that influence the NMS. The process begins with an analysis of the situation of the NMS with respect to its internal and external environment. This analysis involves the identification of strengths, weaknesses, opportunities and threats, as well as the level of communication (e.g. agreements, contracts) with any interested parties that may benefit from the performance of the service, including but not limited to other departments or other hospitals.

On the basis of this analysis, strategic goals that are aligned with institutional strategic objectives are then identified and clearly formulated together with an action plan and indicators that allow their implementation to be checked at specific milestones and consequently ensure the allocation of resources by the senior management. These objectives need to be communicated to, and understood by, all staff at all levels and in all functions.

Any organizational change, such as hiring personnel or introducing new technologies and services, should be carefully planned together with a QMS update to avoid affecting the quality of service.

During strategic planning, the need to maintain the level and quality of operation performance and outcome should be carefully considered. This typically includes an analysis of internal and external sources that may have an effect on the provision of services, such as:

- Institutional priorities, both internal and external (e.g. the necessity of developing oncological or cardiological activities; implementation of transverse, multidepartmental programmes such as breast cancer multidepartmental meetings, etc.);
- Diagnostic and therapeutic NMS: current and projected future demands;
- Literature review and inputs of evidence based medicine on current trends in nuclear medicine;
- Research and development plans;
- Human resources;
- Legislation (licensing and compliance);
- Audit and inspection results (benchmarking);
- Incidents and non-conformances;
- Feedback from patients and/or referring physicians;

- Risk assessment;
- Cost/benefit analysis and budget implications;
- Introduction of new technologies;
- Status of internal and external communication.

Strategic planning can be formulated as a preventive action (see Section 9.3) or an action plan, as formally documented in the QMS.

Preparing a new institutional plan, such as developing a comprehensive cancer centre, could be taken as a practical example. In this case, the NMS should apply a step by step analysis and develop its strategic plan to acquire a state of the art positron emission tomography (PET) or computed tomography (CT) scanner or develop appropriate radionuclide therapy services. This would include aspects such as performing a risk analysis, licensing, sourcing of radiopharmaceuticals, recruiting necessary human resources, acquiring necessary infrastructure and IT solutions, and logistics such as waste management, etc.

4.5. DOCUMENTATION SYSTEM AND DOCUMENT CONTROL

The development of a documentation system is an important component of managerial activities. Document control serves many purposes, such as ensuring NMS compliance with regulatory requirements, improving quality, providing evidence of how processes are carried out and improving internal and external communication. Additionally, the documentation system retains and shares institutional knowledge and is a basic tool for professional training. Furthermore, it allows for traceability and provides information for the quality management audits.

The NMS documentation system has to meet the requirements of all interested parties in an integrated manner, avoid duplication of documents and be consistent with established institutional policies. This can be achieved by the following steps:

- Review institutional policies and standards: Documentation systems exist at institutional levels and can include various types of documents, such as SOPs for document control, information on privacy and protection policies (especially for patients), computer security, etc. It would be useful as a first step to determine what policies exist at the institutional level. It could be a source for standard institution templates and corporate logos for documentation.
- Review and determine documentation requirements of the NMS: Institutional policies that can be incorporated and applied to the NMS should be identified, such as the standard management model and relevant current regulations,

human resources processes, such as documents pertaining to job descriptions, performance appraisals and training records of personnel.

— Perform an internal inventory and quality audit of existing documents: Before modifying the documentation system, it is recommended that the NMS carry out an audit to assess the quality and consistency of the current documentation. This would avoid having to formulate documents from the beginning. Following this audit, an action plan needs to be established for the development of new documents and modification of existing ones. It is worth mentioning that at this point that, if an SOP describing how an SOP should be written does not exist, this should be identified as an important document to be formulated (see Section 4.4). This 'SOP for SOPs' should include at least the following aspects: coding to be used for the identification of each document, responsibilities and how each stage of the life cycle of a document will be implemented (planning, drafting, review and revision, approval, distribution and archiving).

The process of developing and maintaining a documentation system is represented in Fig. 3.

4.5.1. Developing the documentation system

The NMS should consider the following recommendations at this key stage:

- (1) Define responsibilities for each step of the process of writing, reviewing and approval of documents;
- (2) Involve all staff whose input is required for the process, including those from other areas of the institution;
- (3) Use flow charts as tools to define activities or stages of a process;
- (4) Begin with documents that constitute regulatory requirements or that are related to patient or staff safety;
- (5) Adjust each document to local circumstances and standards (use documents from other institutions for reference, but avoid copying them);
- (6) Whenever possible, avoid writing very complex documents;
- (7) Identify a recording system that guarantees traceability (e.g. digital recording with backup);
- (8) For each record, carefully consider the importance and usefulness of the required data and avoid redundancies;
- (9) For each record, establish the required retention time, where it is to be filed, measures to maintain it, and person(s) responsible for the processing and analysis of the data;
- (10) Acquire or develop tools for the processing and analysis of QMS data.



FIG. 3. Flow chart of the documentation system control process.

4.5.2. Implementation of the documentation system

Once a document is approved, it should be incorporated into the documentation system and can then be implemented in the NMS. Prior to this, and to ensure minimum staff resistance to change and correct application, training of personnel involved should take place. Furthermore, a staff member, typically the quality manager, should be in charge of supervising the approved document. For that purpose, the use of appropriate tools, such as a specific software, is recommended. To achieve this purpose, as indicated in para. 3.15 of the IAEA BSS [11], operating procedures should be in place and periodically reviewed and updated.

4.5.3. Issue and distribution of documents

Typical steps for issuing and distributing documents include the following:

- Add documents to the SOP registry.
- Upload documents to the local network, shared drives, local intranet, etc. It is preferable to not have hard copy versions of documents, as they may quickly become outdated.
- Create distribution lists and communicate the location of documents to staff.
- Grant staff access to the electronic documents' location.
- Request staff using the SOP to confirm having read the latest version of this SOP.

4.5.4. Control change of document

Typical steps for controlling changes to documents include the following:

- Archive obsolete versions;
- Check if the change affects other documents and update hyperlinks;
- Communicate changes to the staff involved.

4.5.5. Cancellation of a document

Typical steps for cancelling a document include the following:

- Archive the document in all locations (see Section 4.5.3);
- Communicate the cancellation to the staff involved.

4.5.6. Common problems

Some common problems with documents include the following:

- The required document does not exist;
- Unauthorized modifications occurred;
- Documents are lost;
- Outdated documents remain in circulation.

5. LICENSING AND COMPLIANCE

5.1. LICENSING

Every medical facility requires a series of authorizations and licences in order to operate. This is particularly true for activities that include sophisticated technologies, potentially risky agents and high cost procedures. All of these conditions apply to nuclear medicine.

The range of licences and permits to be obtained includes, but is not limited to the following:

- The construction of any new building;
- The installation of high technology equipment;
- Operating as a medical service;
- Radiation protection and operation of the facility;
- The local production and administration of radiopharmaceuticals;
- The management, storage and disposal of radioactive waste;
- The use of sealed radioactive sources for calibration purposes;
- The use of a public facility, stating its fire safety has been assessed.

Obtaining these licences is a complex, multistep process, detailed in Fig. 4.

However, the most important licence for a nuclear medicine facility is typically connected with the authorization to use radioactive material and all related radiation protection aspects. This is often referred to as the 'radiation management licence'. Furthermore, regardless of differences among countries and regions, international regulatory agencies such as the IAEA BSS have mandated a certain level of uniformity and minimum standards. Radiation protection licensing is specifically dealt with in the next section.



FIG. 4. A diagram of the gradual series of licences, permits and accreditation needed for a medical facility to operate.

5.1.1. Licence for the construction of radiological facilities

Any new construction or significant modification of an existing building to host a radiological facility will have an effect on its environment. This is to be regulated in accordance with local regulations of each country. Special attention should be dedicated to all aspects connected with the environmental impact.

5.1.2. Health authorizations

Health authorization enables an entity to carry out medical activities with due diligence and governance. In addition, in many countries there is a national accreditation system, which serves to verify that the organization possesses and fulfils the structural, technical and organizational requirements that guarantee the provision of health services according to predetermined standards.

Those requirements generally respond to the need for health care facilities to possess a predefined series, specific for the type of activity carried out. They also cover quality and safety control processes of the organization, the services provided and the results achieved. The same concept applies to the managerial and transverse processes of the entire organization.

5.1.3. Licences for radiopharmaceutical production

In most cases, radiopharmaceuticals for clinical use have to be prepared locally. Radiopharmaceuticals, being medicinal products, have to meet quality, safety and efficacy requirements. For this type of product, which generally has a short half-life, quality is vital to support both safety and efficacy. In addition, since radiopharmaceuticals include a radioactive element, they are also subject to specific and additional regulations, related to radioprotection issues. For these reasons, radiopharmaceutical production, although limited to internal use in the same health care facility (i.e. not intended for commercial use) is also subject to specific authorizations.

5.2. AUTHORIZATION FOR THE USE OF RADIOACTIVE MATERIALS AND RADIATION PROTECTION

In each country in which an NMS operates there should be a properly maintained regulatory framework for protection against ionizing radiation; this is a clear responsibility of the government, as defined by IAEA GSR Part 3, BSS requirement 2 [11]. This publication also states that the prime responsibility for protection and safety rests with the person or organization responsible for facilities and activities that give rise to radiation risks; this responsibility cannot be delegated (IAEA GSR Part 3, requirement 4 [11]).

The principal parties responsible for protection and safety are the following:

- Registrants or licensees, or the person or organization responsible for facilities and activities;
- Employers, with respect to occupational exposure;
- Radiological medical practitioners and referring medical practitioners, for what concerns appropriate or justified procedures related to medical exposure;
- Medical physicists;
- Medical radiation or nuclear medicine technologists;
- Radiation protection or radiation safety officers;
- Qualified experts;
- Suppliers of sources and providers of equipment and software;
- Ethics committees;
- Internal review boards.

Within the organizations for which they are responsible, management shall demonstrate commitment to protection and safety at the highest levels. The QMS should be designed and implemented to enhance protection and safety (IAEA GSR Part 3, requirement 5 [11]).

As stated in the IAEA GSR Part 3, requirement 2, "The government shall ensure that a graded approach is taken to the regulatory control of radiation exposure, so that the application of regulatory requirements is commensurate with the radiation risks associated with the exposure situation"; that is: in proportion or in balance with the characteristics of the practice, the types of sources within that practice, and the magnitude and likelihood of the exposures [11].

According to the graded approach, the first step for the introduction of a new activity involving the use of ionizing radiation is either notification or application for authorization. Notification requires a simple communication to the competent authorities, informing them that a new practice not requiring a formal authorization is going to be started.

In the majority of cases for an NMS, a simple notification will not be sufficient. To open and operate an NMS it is typically necessary to obtain authorization GSG-12 and GSG-13 [18, 19] from the regulatory authority. This authorization will take the form of either a registration or a licence and will consider the number, type and activity of sources, their use and the type procedures being performed.

When applying for authorization, the responsible professional within the NMS or the institution should carry out the following:

- Prepare a prospective risk assessment, taking into account the nature, likelihood and magnitude of expected exposures owing to the use of the radioactive sources, and take all necessary measures for protection and safety of patients, staff and public;
- Also consider in the risk assessment unintended but foreseeable accidental exposures and incidents;
- Evaluate radiological environmental impacts, commensurate with the radiation risks associated with the facility;
- Submit the relevant information necessary to support the application to the regulatory body;
- Refrain from carrying out any activity until the licence has been granted.

For various reasons, an NMS may have more than one licence for its operation (e.g. because the facilities for imaging and those for therapy may be located on different sites, or for historical reasons). Management of these licences is a strategic activity, and it can be a complex one. It requires the following:

- Proper definition of the responsibilities of the NMS.
- Planning: this complex sequence of activities cannot be left to an unstructured approach.
- Risk management in a prospective way as well as in a reactive way (see Section 2.1).
- Defining, producing and frequently analysing proper quantity, quality and safety indicators to monitor processes. The analysis includes making future projections of evolution of the workload.

- Compliance monitoring, to ensure that NMS activities stay compliant with relevant external standards and regulations, which are frequently evolving.
- Building and maintaining cooperative relationships with inspectors and the regulatory body by showing, for instance, that an evaluation of the combined exposure of the environment caused by the sum of the activities covered by separate licences is performed on a regular basis.

A licence may require periodic renewal, depending on national laws and the policies of the national regulatory authority.

5.3. WASTE MANAGEMENT

In an NMS, a variety of waste is produced in key processes. This waste is collected and temporarily stored, meaning it is held with the intention of being able to retrieve it before proceeding to the next step. The disposal is managed autonomously, or more commonly entrusted to a hospital facility or to a commercial service, which takes responsibility for the waste for further processing, storage or disposal, as appropriate. Radioactive waste is just one of several types of waste produced by nuclear medicine activities.

A specific authorization is generally required, pursuant to national legislation, to store radioactive waste and to proceed with its final disposal. This also depends on the level of exemption (or 'clearance') that exists in the country.

There are several possible strategies for the management of radioactive waste. The main options usually are the following:

- Storage until radioactivity has decreased to below exemption levels, then disposal as waste, the classification of which depends on the origin:
 - Biohazard waste materials that derive from the administration of radionuclides to patients and contain, or have been in contact with, the patient's bodily fluids.
 - Conventional municipal waste for other materials originating from controlled areas.
- Outsourcing to a contractor licensed for the collection and disposal of radioactive waste.

The choice among the different options depends on a series of parameters, such as the half-life of radionuclides, the volumes produced and the infrastructures existing in the country. The storage option until sufficient decay applies only to radionuclides with a short half-life. For those with a half-life of more than a few weeks, it is generally preferable to outsource their disposal. Often, the solution adopted is a combination of the two options, depending on the characteristics of the radionuclides.

Specific conditions for the collection and disposal of radioactive waste can be provided in the general authorization of radiological protection or, alternatively, can be subject to a specific authorization.

Similarly, the disposal of potentially infectious hospital waste is regulated. The NMS should be aware of all relevant regulations, and its QMS should include detailed SOPs for all procedures which are required to safely manage waste, obtain and maintain all necessary licences and ensure proper, uninterrupted operation of waste management.

6. HUMAN RESOURCES MANAGEMENT

As defined in the IAEA Nuclear Medicine Resource Manual, "Human resources can be defined as the total knowledge, skills, creative abilities, talents and aptitudes of the workforce in a given organization, including the values and attitudes of the individuals making up the organization" [20].

Human resource management is an institutional process that includes various activities: manpower planning, recruitment, selection, induction, training, professional development, competencies and performance evaluation.

6.1. PROFESSIONAL RESPONSIBILITY AND AUTHORITY

According to ISO 26000:2010, an organization is an entity or group of people and facilities with an arrangement of responsibilities, authorities and relationships and identifiable objectives, whereas service is an action of an organization to meet a demand or need [21]. It is expected that these relationships are formalized in written documents, available to all members of the organization. The most frequent approach to this is a document entitled Responsibility and Authority (R&A), which is issued by the head of the department.

This document describes the founding principles of the department and sets out the updated structure and lines of R&A of staff members.

It also includes a clarification of any necessary delegation of authority for coverage when the head of department is on leave or for any sector within the department. The R&A could also include operational arrangements, such as the degrees of autonomy when performing some specific duties concerning:

- Administrative staff in their activities;
- Nuclear medicine technologists in permitting them to deviate from SOPs in response to specific patient circumstances or other circumstances which may otherwise compromise the final results;
- Medical physicists in giving direct information to patients;
- Radiopharmacists or radiochemists to delegate radiopharmaceutical preparations to other staff, such as properly trained technologists or radiographers, under the licensing regulations.

The R&A document also sets internal rules for the appropriate management of staff leave while ensuring there will be adequate personnel to maintain departmental operations.

Furthermore, the R&A is frequently used as the 'parent' document from which other relevant documents are derived, such as the:

— Organizational chart;

- Individual job description;
- Roster of persons in charge for specific duties.

6.2. ORGANIZATIONAL CHART

Within the department, senior management should establish an organizational chart illustrating the structure, lines of responsibilities and key functions matching departmental functionality and workload. It should be updated whenever changes occur.

Figure 5 is a detailed example of an organizational flow chart of an NMS, reporting the internal structure and lines of communication within the service. This does not aim to be applicable to all situations but could be used as a basic template to be adapted.

The departmental organizational chart should be aligned to the institution's general organizational chart (Fig. 6), illustrating the position of the NMS within the institution and its relationships to other aspects.



FIG. 5. Sample organization flow chart of an NMS.



FIG. 6. Sample organization flow chart at the hospital level.

6.3. JOB DESCRIPTION

All staff members should have a written job description (using a structure such as the example in Table 2) that clearly sets out their duties, responsibilities and specific resources and staff allocation, as well as the reporting lines as seen in the organizational flow chart. Staff qualifications should match those indicated in the job description [22]. Additional requirements such as committee membership should be stated. Examples of additional assignments include radiation protection officer, roles in inventory and management of equipment, professional development and training and fire warden.

TABLE 2. SAMPLE JOB DESCRIPTION FOR A TECHNOLOGIST (BASED ON EANM BENCHMARK DOCUMENT ON NUCLEAR MEDICINE TECHNOLOGISTS' COMPETENCIES [22])

Nuclear medicine service	Job description	HRP-REC-001
Job title:	Nuclear Medicine Technologist Gra	de (x)
Education:	Bachelor's degree OR diploma in R Medicine	adiography or Nuclear
Training:	Minimum 2 years of clinical experies medicine technologist	ence as a nuclear
Expertise:	Desirable to have experience in comprocedures in nuclear medicine such scans, thyroid scan, cardiac scans ar scans. Experience in hot laboratory eluting the 99Mo/99mTc generator, reconstruction and QC of radiophart viewed favourably. Some basic expersions is also desirable.	imon imaging a s bone scans, renal ad gated blood pool procedures such as radiopharmaceutical kit maceuticals will be erience with FDG PET
Memberships:	Membership with local/internationa societies is desirable but not essentia	l nuclear medicine al.
Personal attributes:	Motivated, proactive, self-guided, al independently as well as within a tea initiative, receive feedback, able to	ble to work am, troubleshoot, take manage time efficiently.

TABLE 2. SAMPLE JOB DESCRIPTION FOR A TECHNOLOGIST (BASED ON EANM BENCHMARK DOCUMENT ON NUCLEAR MEDICINE TECHNOLOGISTS' COMPETENCIES [22]) (cont.)

Nuclear medicine service	Job	description	HRP-REC-001	
Responsibilities:				
Scanner QC;				
Scanner preparation;				
Patient set-up for scanning;				
Perform scan, image reconstr	uction, ima	ge processing and	displaying;	
Patient release (after attendin	g physician	's evaluation).		
Change Control				
Creation	Date:			
Revision 1	Date:	Approved by	/:	Page

For each job role and workplace, the NMS needs to have documents for the selection, orientation and induction of new staff. Locally required competencies and rules should be clearly explained and documented.

6.4. PERSONNEL EVALUATION

Such an evaluation is generally performed by senior management, or by some qualified professionals, who are specifically trained in staff appraisal. Such an evaluation typically includes the following:

- Recognition of achievements;
- Setting personal goals;
- Reviewing status of individual licences and accreditation;
- Assessing personal attitudes and behaviour;
- Verifying adherence to institutional and specific departmental values;
- Giving and receiving feedback;
- Checking capability in the use of QMS tools such as medical information systems, reporting of incidents and non-conformances;
- Identifying training needs;
- Proposing further professional development, taking into account the department's strategic planning.

Such an appraisal is generally performed by senior management, signed by both the appraiser and the staff being appraised, and filed.

It is the responsibility of senior management to encourage teamwork and knowledge exchange among all staff through initiatives such as meetings, internal workshops, case studies, journal clubs and quality circles, as well as to make available tools that facilitate the access and recovery of information.

Periodic discussion and review of reports and clinical results by all medical staff of the department in a blame-free atmosphere is recommended to stimulate constructive learning and sharing of specific expertise.

6.5. PERSONNEL DEVELOPMENT

To develop personnel, managers should consider the following:

- Teach, train and mentor employees Through learning and coaching on various improvement strategies and other initiatives, employees gain a better understanding not only of what they are doing, but why they are performing their tasks;
- Develop challenging objectives and targets Through goal setting, leaders can foster constant growth and development across the organization, by continuously adjusting target performance levels within each department;
- Inspire, motivate and recognize contributions from employees at all levels — The ability to inspire and motivate staff across all levels allows employees to be actively involved and invested in quality management initiatives;
- Foster open and honest communication Communication is essential for all levels within the organization to work together to implement improvement strategies and it is the leader's role to do so;
- Stimulate continuous professional development (CPD) Facilitate attendance at seminars, workshops and conferences as well as participating in presentations at department meetings and journal clubs;
- Assign projects that staff can work on These may be major projects that can be presented at conferences, but could also include small, personalized projects to improve departmental practices;
- Run performance appraisal and development This is an opportunity for open, face-to-face personal communication.

For some of the medical staff, national professional and scientific associations may have a system in place of formal recognition and registration as a professional. Maintaining this formal recognition (to be considered a licence) may also require periodic renewal of registration, as set by the national medical college and by law, based upon documented proof of sufficient CPD during this period.

6.6. NMS QUALITY MANAGER

The quality manager is a specific role delegated by the head of the department to implement and maintain a QMS. Initially, this function could be covered by an external, specifically trained consultant. With the development of the QMS and growing experience of department staff in operating the system, the role can be taken over by an internally appointed quality manager who then has the advantage of detailed knowledge of the QMS coupled with specific expertise in nuclear medicine and department operations. The function of the quality manager can then be considered one of the 'additional functions' previously referred to in the job description.

The quality manager will be the main person responsible for quality activities and will liaise with the institution's quality service. The quality manager might also be the chair of the departmental quality committee.

7. RISK ASSESSMENT

As already discussed, risk assessment is the process of identifying hazards and assessing the severity of harm, and the likelihood that they will occur. There are two major classes of approach to analysing risks:

- Retrospective (or reactive) risk analysis methods;
- Prospective risk analysis methods.

7.1. RETROSPECTIVE (OR REACTIVE) RISK ANALYSIS METHODS

These methods deal with (near) incidents that were reported. Each (near) incident is analysed along with the circumstances in which it occurred, its possible consequences and frequency of occurrence. To provide ample input for such risk analyses, it is essential to have an incident learning system in operation that is easily accessible, blame-free and well accepted by all staff.

Examples of incident consequences to be considered are those related to the safety of patients or employees, to quality, continuity or cost of care. When the observed frequency of an incident is found to be too high or the consequences not acceptable, the process, protocols, workflow or facilities involved, or management will need to be adapted. Root cause analysis is a formal method frequently used to systematically perform a retrospective risk analysis (Figs 7 and 8) and to identify the actual root causes that require elimination or mitigation [23–27]. Readers are advised to refer to the IAEA SAFRON E-learning modules [28] and to ad hoc training lectures [29].

The fishbone diagram may be used retrospectively to visually document and organize the possible causes of a process failure or incident and to uncover its root causes. Steps involved are listed below:

- (1) State the problem to be analysed. The head of the fish is a very brief but accurate description of the problem or incident, the undesired effect. It is often the outcome of the interplay of multiple different causes.
- (2) Label each of the fish bones with possible categories of conceivable causes. Those with the suspected largest influence may be placed closest to the fish head.
- (3) Within each category, try to identify and list all conceivable causes that may have had an effect on the process outcome (brainstorm phase). To actually capture root causes during this step, it helps to keep asking 'why' until an underlying root cause or bottleneck is uncovered, on which it is possible to act.
- (4) Analyse the diagram and identify critical root causes. Think of ways to eliminate them or to mitigate the risk of their occurrence. Using this tool, actual critical root causes can be identified by a team and subsequently addressed.



FIG. 7. Schematic example of a fishbone diagram or cause and effect diagram.

7.2. PROSPECTIVE RISK ANALYSIS METHODS

Risk analysis methods involve the proactive analysis of a (clinical) process with the aim of identifying potential future incidents, considering what could go wrong, the probability that it could go wrong, and the possible consequences (severity). Subsequently, preventive measures can be defined to pre-empt an incident or, where prevention is not possible, to reduce the risks by defining mitigating measures. Interventions are prioritized by risk estimates, assigning resources to where they are most effective.

7.3. FAILURE MODES AND EFFECTS ANALYSIS

Failure modes and effects analysis (FMEA) [30, 31] and fault tree analysis [31] are methods often used to analyse systems for possible weaknesses. FMEA is a systematic method for process evaluation to identify the ways in which the process might potentially fail (failure modes), and the effects of a failure mode upon the performance of the process. The purpose of performing an FMEA is to support decisions that reduce the likelihood of failures and their effects and thus contribute to improved outcomes.



FIG. 8. Cause and effect flow chart developed during an investigation of a hypothetical incident during a nuclear medicine imaging procedure that resulted in an unjustified patient exposure. The tree shows relevant causes in their hierarchy. The items to the far right of the diagram are considered to be root causes.

For each step in the FMEA, a risk priority number (*RPN*) is computed, multiplying the probability of occurrence score (*O*) of a failure mode by the severity of effect score (*S*) and by the detectability score (*D*): $RPN = O \times S \times D$. Unacceptably high risk scores require interventions.

7.4. FAULT TREE ANALYSIS

A fault tree analysis complements the FMEA with a detailed description of a failure pathway, identifying steps that may contribute to a failure. This can be regarded as a hypothetical root cause analysis and a safety assessment for the use of radiation [31].

A fundamental safety objective is to protect all people and the environment from harmful effects of ionizing radiation. References [32, 33] focus on those risks associated with the use of ionizing radiation.

Management is responsible for ensuring that protection and safety are optimized, that applicable dose limits are maintained and that appropriate radiation protection programmes are established and implemented. Therefore, before beginning any activity that involves the use of sources of ionizing radiation, a dedicated safety assessment should be carried out for all applications of technology that give rise to radiation risks. Prospective as well as retrospective methods of risk analysis may be incorporated into such a safety assessment [16].

Safety assessments should be conducted at different stages of the planning process, including choosing and preparing the site, and the design, manufacture, construction, assembly, commissioning, operation, maintenance and decommissioning of facilities in order to accomplish the following:

- Identify the ways in which exposures could be incurred;
- Combine the three factors relevant to dose reduction —time, distance and shielding — in the design to optimize radiation protection;
- Determine the expected likelihood and magnitudes of exposures in normal operation;
- Assess potential exposures (i.e. unintentional but not improbable);
- Assess the adequacy of the provisions for protection and safety.

The safety assessment shall include a systematic critical review of (adapted from IAEA GSR Part 3, paras 3.31 and 3.32 [11]) the following:

 The ways in which structures, systems and components, including software and procedures relating to protection and safety might fail (singly or in combination), or might otherwise give rise to exposures, and the consequences of such events;

- The ways in which operating procedures relating to protection and safety might be erroneous, and the consequences of such errors;
- The implications for protection and safety of any modifications;
- The implications for protection and safety of security measures or of any modifications to security measures.

The same safety assessment also provides adequate input into an independent verification and regulatory review. This includes the following:

- Justification for the selection and analysis of certain anticipated operational occurrences and accident conditions;
- Results of the performance analysis of the facility or activity, the radiation risks incurred and a discussion of the underlying uncertainties;
- Conclusions on the acceptability of the level of safety achieved and the identification of necessary improvements and additional measures;
- Classification of working areas (controlled vs supervised areas);
- Dose constraints¹ to be applied to occupational exposure and to public exposure for optimization of protection and safety [34].

7.5. INCIDENTS

According to the IAEA BSS, an incident is defined as "any unintended event ... the consequences or potential consequences of which are not negligible from the point of view of protection and safety" [11].

Unintended events significantly affecting only the quality or continuity of care should also be considered incidents worth reporting and analysing.

7.5.1. Incident prevention

GSR Part 3 [11] requires implementation of an appropriate system for the prevention, record keeping and analysis of events involving or potentially involving accidental or unintended medical exposures, the depth of analysis being in proportion to the effective radiological risk.

¹ Dose constraints are not dose limits: exceeding a dose constraint does not represent non-compliance with regulatory requirements, but it could result in follow-up actions. See IAEA GSR Part 3, para 1.22 [11]; IAEA GSG-7, para. 3.28 [34].

Moreover, the incident prevention system requires reporting of significant events to the regulatory body and to the relevant health authority, if appropriate. Additional information and specific guidelines on implementation of the requirements of GSR Part 3 in medicine are provided in the IAEA Specific Safety Guide SSG-46 [33].

Furthermore, Martin et al. reviewed literature and analysed relevant processes within nuclear medicine, aiming to give guidelines related to incident prevention [35]. That paper makes it clear that key nuclear medicine processes are prone to risk and error, requiring proper risk management. Their findings emphasize once more that a detailed and comprehensive QMS is key to identifying and controlling risks (Figs 9, 10).

In relation to radiopharmaceutical preparations, which seem to be the main source of unintended patient exposure, Table 3 reports a list of the main errors that may occur.

Tables 4 and 5 list possible errors that might end in incidents relating to patient preparation and for imaging. All the risks listed in these tables should be carefully considered in a prospective risk analysis.

When an unintended event did not result in an incident but had the potential to do so, it is defined a 'near miss' and has to be treated as an incident.

Examples of possible corrective measures required to further mitigate certain risks identified in this process are the inclusion of specific SOPs in the nuclear medicine QMS, or the insertion of specific components into process SOPs.

7.5.2. Incident management

Management of incidents involves their identification, reporting, reviewing, monitoring and evaluation, including the timely rectification and effective actions to restore a safe environment for patients, staff, contractors, volunteers and visitors.

The optimal situation includes the existence of a fully functional institutional incident management system (IMS), including specific provision for managing NMS incidents. In this case the NMS is generally expected to abide by the IMS.

In the case of an institutional IMS not being available, a departmentspecific reporting tool should be developed within the scope of the QMS.

It is important to note that the IAEA has developed an anonymous on-line incident reporting tool, the SAFRON-NM [28, 29], applicable to radionuclide therapy services. This tool can be used to report in a global database, identifying errors that have occurred with radionuclide therapies, or as an internal reporting system for helping the NMS to learn from incidents.

Generally, the IMS is designed to promote a culture where incidents and near misses in departments such as the NMS are reported to hospital management



FIG. 9. Proportions of different types of 189 incidents in nuclear medicine departments in the west of Scotland reported over a 10-year period. (Reproduced from [25].)



FIG. 10. Proportions of different types of patient exposure in 71 reported incidents in imaging departments in nuclear medicine. (Reproduced from [25].)

and executive. The relevance of a wide IMS is in the use of statistical tools of analysis of a large enough number of previously reported incidents, and the beneficial option it offers; for example, referrers to nuclear medicine report

TABLE 3. ERRORS THAT MAY CONTRIBUTE TO INCIDENTS DURING THE PREPARATION OF A RADIOPHARMACEUTICAL [35]

Component of the process	Possible errors
Storage of precursors, kits, cassettes, etc.	 Wrong environmental conditions may alter the products A product may have expired and not be taken out of use Poor demarcation of storage areas, leading to the selection of the wrong agent
Biological contamination during synthesis	 A module or vial may not have been sealed adequately Aseptic conditions in a hot cell or laboratory may not be adequate, resulting in microbial contamination of the product
Labelling of kits/synthesis of radiopharmaceuticals	 Incorrect set-up of ¹⁸F synthesis module (e.g. failure to seal module effectively or wrong loading of reagents or cassette) Incorrect preparation of kits (e.g. exposure of MDP to air or wrong heating cycle for Sestamibi) resulting in low radiochemical purity
QC of the radiopharmaceutical	 Errors in laboratory procedures Inaccurate calibrations or equipment with poor sensitivity Components of the QC tests omitted
Dispensing of the radiopharmaceutical	 Poor procedures or environmental conditions that may contaminate the product Inaccurate activity or mixing up of different products resulting from simultaneous dispensing of many vials before their administration Missing, inaccurate or ambiguous labels or colour coding for vials and syringes Lack of protective shields or poor compliance in their use
Receipt and control of vials containing radiopharmaceutical	 Poor system for checking orders at the facility where the radiopharmaceutical is administered to confirm that the contents of each vial that has been delivered are correct

MDP = methyl diphosphonate

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incidents involving the NMS, and nuclear medicine staff can likewise report on incidents caused by the referrers, such as a request for a wrong study. Insight into

TABLE 4. FACTORS THAT COULD CONTRIBUTE TO AN INCIDENT DURING PATIENT PREPARATION AND ADMINISTRATION [35]

Component of the process	Possible errors
Patient preparation	 Incomplete instructions given to the patient or instructions not communicated accurately Fasting status of patient not checked before administering radiopharmaceuticals Pregnancy or lactation not verified before administering radiopharmaceuticals Biochemical tests omitted (e.g. glucose level)
Stress testing/ pharmacological stimulation	Errors in the procedureErrors in timing
Patient identification	 Identification not confirmed Lack of physical tools for identification (e.g. wristband) Poor management of patients with same name
Administration of radiopharmaceuticals	 Errors in the procedure Wrong radiopharmaceutical/activity administered Extravasation of injection (Section 3.2.3) Contraindications not checked Wrong iodine therapy capsules or liquid administered, failure to check patient has consumed all capsules or liquid prescribed, or administration of two prescriptions to the same patient

TABLE 5. FACTORS THAT COULD BE NEGLECTED OR SET INCORRECTLY DURING IMAGING [35]

Component of the process	Possible errors
Gamma camera set-up	 Wrong collimator/selection of radionuclide/scan duration/ matrix size or other acquisition parameters Omitted or inadequate daily QC tests may result in sub-optimal performance of the system (e.g. poor uniformity) or missed detection of faults (e.g. a photomultiplier tube not working)
PET scanner set-up	 Incorrect daily QC procedure (e.g. detector block is not working)

TABLE 5. FACTORS THAT COULD BE NEGLECTED OR SET INCORRECTLY DURING IMAGING [35] (cont.)

Component of the process	Possible errors
Multimodality scans	— Wrong or poorly optimized CT protocol selected
All nuclear medicine imaging modes	 Suboptimal balance between acquisition time and administered activity that ultimately determines image noise levels (count statistics)
System calibration	 Omitted or outdated calibrations of a SPECT system (e.g. energy, linearity, uniformity, centre of rotation) may result in poor image quality Omitted or outdated calibrations of a PET system (e.g. uniformity, cross-calibration between the activity meter and the PET scanner) may result in poor image quality or inaccurate SUV results Omitted or outdated calibrations of gamma cameras and in vivo counting systems (e.g. thyroid uptake counters) may result in poor image quality.
Mechanical safety	 Patient not secured to the imaging bed Moving components of the scanner not checked Tools, furniture or other objects lie in the trajectory of motion

SPECT = single-photon emission computed tomography; SUV = standardized uptake value

incidents reported by other departments/institutions can also be of help. A review of risk rates and analysis, and preparation of preventive actions, will help to learn lessons from previous incidents. Once an incident occurs, the IMS helps to focus on corrective actions and to address the circumstances that led to the error, rather than blaming an individual or promoting a culture of blame.

The IMS should provide governance that clearly outlines individual and NMS responsibilities in incident management and ensures consistency in the approach to incident management in the NMS. It should also align with incident management across the health organization.

Incidents should ideally be managed in an electronic reporting system, which allows for an easy way of recording incidents or near misses and has options to allocate an incident severity rating using the principles of an open disclosure process. An electronic system should have the capacity to conduct a review and statistical analysis of all incidents.

7.5.3. Incident reporting

The 2018 edition of the Radiation Protection and Safety in Medical Uses of Ionizing Radiation, IAEA Safety Standards Series No. SSG-46 sets out requirements both for minimizing the likelihood of unintended and accidental medical exposures and for the ensuing investigation if such exposures occur [33].

In addition, quality breaches resulting in lower quality of care — even when not related to radiation exposure — should also be reported and used for improving consistency of quality of care and its continuity.

According to the approach given in the BSS [11], a reduction in the probability of unintended or accidental medical exposures in nuclear medicine can be brought about by the following steps:

- (a) The introduction of safety barriers at identified critical points in the process, with specific quality control checks at these points. Quality control should not be confined to physical tests or checks but can include actions such as the correct identification of the patient.
- (b) Actively encouraging a culture of always working with awareness and alertness.
- (c) Providing detailed protocols and procedures for each process.
- (d) Providing sufficient staff who are educated and trained to the appropriate level, and an effective organization, ensuring reasonable patient throughput.
- (e) Continuous professional development and practical training and training in applications for all staff involved in providing radiology services.
- (f) Clear definitions of the roles, responsibilities and functions of staff in the radiology facility that are understood by all staff.

Most of the measures in the above list are not related to infrastructure, equipment and hardware, but rather to safety culture, procedures, training and professional development. These aspects are closely related to the QMS, and this shows once more that quality and safety are highly interdependent.

Nevertheless, even when processes are properly described and performed, risks will be lower but never zero. Unexpected events or unforeseeable circumstances may (and will) lead to inappropriate or misadministration of radiopharmaceuticals, suboptimal or incorrect delivery of therapy, undesired/unintended patient exposure or other consequences potentially harmful to patients, and to staff as well.

TABLE 6. GENERAL CHARACTERISTICS OF HOSPITAL-BASED INCIDENT REPORTING SYSTEMS

Characteristic	Description
Not punitive	Reporters are exempt from retaliation or punishment from others
Confidential	The identity of the patient and of those who report is not disclosed to third parties
Independent	The system does not depend on any authority with the power to punish those who report
Timely	Reports are analysed promptly and recommendations are quickly disseminated to those who need to know them, especially when serious risks have been identified
System oriented	The recommendations target changes in systems, processes or products rather than individual interventions or practices

A number of significant reports are available in current scientific literature [23–27].

These aspects are well known in the current practice of medicine, and various incident reporting systems have been developed to collect and manage information on these events.

Incident reporting systems may be either of general use or specific to radiological incidents. Furthermore, voluntary as well as mandatory reporting systems are in use.

A hospital reporting system is an example of a voluntary reporting system. It consists of a structured collection of alerts to feed a database of incidents that can provide data, the analysis of which can help in preparing strategies and corrective actions in order to prevent future recurrence (Table 6).

The types of events to be reported are generally schematized according to an increasing level of severity (Table 7).

In a large number of countries, it is mandatory to report to the regulatory authorities any incidental situation that may have involved a radiation exposure above a predefined threshold, both when staff members and when patients are involved. Frequently the threshold level is established at 10 mSv of effective dose, or at 10 mGy of organ dose.

TABLE 7. CLASSIFICATION OF EVENTS, ACCORDING TO A WIDELY ACCEPTED TERMINOLOGY

Type of event	Description
'Near miss'	Unexpected event which was detected and avoided just before happening
Events without results	Unexpected events which did not result in injury, illness or damage — but had the potential to
Adverse event	Unexpected events related to the care process that result in unintentional and undesirable patient harm
Sentinel event	Adverse events of particular severity, potentially avoidable, which may result in death or serious harm to the patient

However, local and national incident reporting systems suffer from several limitations and shortcomings, including the following:

- Unavailability of an adequate reporting system;
- Fear of punitive action;
- Poor safety culture in an organization;
- Lack of understanding among clinicians about what should be reported;
- Lack of awareness of how the reported incidents may be analysed;
- Lack of awareness on how the reports may lead to changes which can improve safety.

In the medical context, lack of systematic analysis of the reports and feedback directly to the clinicians and professionals is probably one the major barriers to engagement.

Learning from errors that do occur is a key factor in reducing the risk of repeating mistakes, or at least in decreasing the severity of their consequences, and in maintaining and improving the quality of health care.

In addition to the internal reporting within the nuclear medicine department, incident reporting and analysis at a larger (regional, national or international) scale is beneficial in identifying less obvious risks and more subtle trends. This kind of upscaling can help to improve safety culture. Therefore, in 2012 the IAEA introduced SAFRON [28], a web-based system for incident reporting in radiotherapy that has been updated and extended, including a module on incidents in radionuclide therapy.

The main characteristics of SAFRON are the following:

- It is a non-punitive, anonymous, voluntary, educational, international system.
- It does not replace the regulatory reporting requirements of an institution;
- It allows statistical analysis to be performed analysis on reported events, providing benchmarking capabilities;
- It collaborates with other reporting systems and contains incident information gathered by the IAEA, ROSIS, CRCPD, ASN, Norway, Spain and registered participants.
- It allows querying for a specific type of incident and reading the full (anonymous) report.
- Statistics can be extracted for the subscriber's own centre or for the whole database.

Reporting in SAFRON is straightforward. The user is guided through entering the main data relating to the event to be reported (e.g. radionuclide, activity, etc.) of the step in the process in which the incident was generated; to the point in the process in which the errors were detected; to possible causes; etc. Furthermore, a text field allows a detailed description to be entered. The database is accessible online and can be updated as new information about an incident becomes available.

The SAFRON component for nuclear medicine therapy incident reporting is a safe and effective incident reporting and learning tool. Facilities are encouraged to use SAFRON nuclear medicine as their local incident learning system, as well as to contribute to it [17, 27, 28, 32, 36–44].

8. STANDARD OPERATING PROCEDURES

Standard operating procedures are at the heart of every QMS and an integral part of the documentation system. An SOP is the reference document for a specific procedure. This document should include all the different aspects involved in the procedure, following a step by step approach, in a clear and straightforward manner. In complex procedures the SOP may include specific references to other documents in the NMS documentation system, guidelines, etc.

A well-structured SOP should enable any designated staff member to comprehensively perform a specific process. SOPs should be regularly and continuously reviewed and updated according to guidelines and evidence based data. This is especially necessary when new software or equipment comes to the NMS. The use of national and international guidelines as reference documents is encouraged, but they cannot replace a local SOP. Each NMS should formulate tailored SOPs according to their local circumstances with input from relevant staff groups.

Occasional deviations from SOPs should be noted and explained (see also Section 8.6). If they become substantial, updating the SOP in order to consider these deviations is necessary. All staff members should be familiar with SOPs, which should be easily accessible, preferably in digital form. If SOPs are printed, it needs to be ensured that only the most current version is in circulation. Obsolete versions should be archived. Informal printouts or 'cheat sheets' of SOPs should be discouraged.

In the context of an NMS, SOPs will cover all clinical activities, radiopharmacy operations, radioprotection issues as well as medical physics activities related to nuclear medicine practice.

This section addresses some of the essential SOPs and provides indications on how to prepare them.

8.1. HOW TO WRITE A STANDARD OPERATING PROCEDURE

The following SOP provides a guideline on how to write an SOP, including how to format the document.

8.1.1. Background, scope and purpose

The purpose of an SOP is to provide detailed instructions so that any team member can carry out the task correctly every time. SOPs are issued to specifically instruct employees or team members in areas of responsibility, work instructions, appropriate specifications and required records. SOPs outline procedures in the form of a narrative, a flow chart, a process map, computer screen printouts, a combination of all of these or any other suitable form. See examples of suitable forms in Annex II.

The purpose or objective of an SOP should restate and expand on a wellwritten title. A well-written SOP will facilitate training. The best SOP is one that accurately transfers the relevant information and facilitates compliance with reading and using the SOP. This SOP for SOPs is aimed at senior staff, management staff, leaders and quality leads.

SOPs can be written in the local language. In the case of international certification or accreditation, an English version is highly recommended.

8.1.2. Responsibilities

The SOP author has the duty of:

- Drafting the SOP in consultation with the intended users;
- Correcting the SOP according to feedback;
- Making the SOP available to intended users;
- Amending the SOP if required.

The quality committee or quality manager has the duty of:

- Reviewing the initial draft and consecutive amendments of the SOP;
- Releasing and formally approving SOP versions;
- Making the SOP available to the rest of the staff;
- Ensuring that all intended users comply with the SOP;
- Ensuring the SOP version used is the most recent one approved.

8.1.3. Procedure/steps

- Write one SOP per study related activity. Do not mix too many activities in one SOP.
- Choose an author familiar with the procedure described in the SOP.
- Describe in detail how the procedure is being carried out.
- List the steps in a chronological order.
- Indicate in the 'Responsibilities' section who does what. Do not use the name of the person; use functions and job title (e.g. laboratory technician or physician).
- Include all necessary information to perform the procedure, not more.
- Use the fewest possible words; if different steps are involved in the activity, use bullet points.
- Add visual displays and cues, if required.
- Have a specific reader in mind; write for the person who will be reading the procedure.
- Avoid ambiguous instructions, such as describing alternatives.
- Give each SOP a unique identifier, version number and version date.
- Use acronyms referring to the type of the procedure (e.g. LAB = laboratory SOP; DOC = SOP related to documentation management; CLIN = clinical SOP; QUAL = SOP related to QA and QC).
- Use subheadings (e.g. 3.1) if the procedure is a lengthy one.
- Indicate on each page of the SOP:
 - The SOP number, the version number and version date.

— The page number and the total number of pages.

8.1.4. Review and version control of SOPs

- Each SOP should be regularly reviewed by the SOP author or manager.
- Version nomenclature should be decided.
- The first draft should be circulated as version 0. Comments and corrections should be incorporated in this draft to create version 1.
- Each consecutive version and reason for or description of each modification made to the SOP should appear in the 'document history' section at the end of the SOP.
- A process needs to be decided for ensuring obsolete versions are not in circulation.
- A process needs to be decided for circulation of the current SOP version and to ensure that the same version is accessed by all staff.
- The SOP should state who its authors were, the authorizing staff and committees and the version number.

8.1.5. References, associated documents and annexes

To maintain an efficient quality system, all documents should be produced and updated whenever needed, for example, when new technologies are introduced, guidelines are changed, the internal workflow is modified, new regulatory requests are made, etc.

8.2. SOPS FOR CLINICAL ACTIVITY

Clinical SOPs should be in place for every clinical procedure performed at the NMS. A defined structure is suggested in accordance with the type and complexity of the procedure. Specific responsibility should be assigned for each different step of the procedure depending on expertise or competencies, if applicable. Screen captures may help clarify specific steps. For a detailed SOP template, see Annexes II and III.

The following list illustrates the contents of an SOP for a diagnostic test in an NMS:

- Identification of procedure;
- Clinical indications;
- Restrictions, contraindications and allergy risks;
- Paediatric or adult application;

- Professional(s) in charge;
- Patient preparation before radiopharmaceutical administration;
- Activity to be administered and its measurement;
- Activity effectively administered and time of administration;
- Equipment and its preparation;
- Eventual references to specific booking (front desk) aspects;
- Patient info input;
- Effective dose estimate/CT dose index and DLP in case of multimodality;
- Study processing and results production;
- General indications on report structure;
- Archiving of data.

8.3. PROCEDURAL SOPS

For every clinical application and image acquisition SOP, all specific parameters of the camera setting need to be accounted for.

In the case of single-photon emission computed tomography (SPECT) imaging, this will include the following:

- Type of collimator;
- Matrix size;
- Speed and time of acquisition;
- Zoom level, etc.

In the case of PET imaging:

- Matrix size;
- Number of bed positions;
- Time for beds;
- Optional gating parameters.

If the NMS has more than one scanner, or scanners of different models or brands, individual SOPs have to be in place for every different model and make. Similarly, for image reconstruction and processing, all settings have to be included in the SOPs, and different SOPs should exist if different reconstruction software is used, or even for different software versions.

Hybrid imaging equipment will require more complex SOPs, covering settings for both modalities as well as reconstruction, image fusion and display parameters.
8.4. SOP FOR RADIONUCLIDE THERAPY

In addition to describing how a particular radionuclide therapy will be performed, radionuclide therapy SOPs should also cover dosimetry and radiation protection aspects for both patients and workers. For this reason, they need to be developed in conjunction with the nuclear medicine physician, medical physicist, radiation protection officer and, in the instance of inpatient treatment, the nursing staff of the therapy ward. This ward is frequently located outside the NMS in a clinical area where other professionals may be involved. In the light of the frequent rotation of nurses and other personnel in these clinical areas, clear and readily accessible SOPs for managing radionuclide therapy patients need to be in place. Processes should be developed to ensure that staff have read and understood SOPs.

Treatment specific SOPs should be in place to cater for the following:

- The different treatments provided by the NMS (131I, 177Lu or 90Y labelled peptides, etc.);
- Instructions for carefully checking patient preparation and any possible contraindication (e.g. reliably ruling out pregnancy);
- The different risks involved in each situation;
- Accounting for activity administered and its method of calculation should be indicated, particularly for multiple treatments;
- Criteria for discharging patients;
- Waste storage and disposal procedures.

Infrequent therapies should also be properly documented.

SOPs describing the proper use of available radiation detectors as well as other radiation protection equipment in this area is also necessary. Specific training in radiation protection should be addressed on SOPs, detailing frequency and depth of training.

8.5. SOP FOR IDENTIFICATION OF PATIENTS

Each NMS should have an SOP describing the process for patient identification; this should be aligned with the organization's policy on patient identification.

The purpose of such an SOP is to ensure that patients are correctly identified in all steps of the clinical process (see also Section 8.6, on traceability). It should outline the steps to be taken to ensure correct identification of patients. The following steps should be included in the SOP for a patient's identification: the staff member, in conjunction with patient, carer or relative, confirms the patient's identity using approved patient identifiers while simultaneously checking these against available clinical information and documentation.

8.5.1. Responsibility of staff for patient identification

The staff member needs to:

- (1) ASK the patient to state their full name and date of birth (the so-called positive patient identification);
- (2) LOOK and CHECK that these identifiers match details specified in clinical records of the patient.

If the patient is unable to identify themselves (e.g. confused or unconscious patients, patients who do not speak the language or paediatric patients), Step 1 may be omitted, but ALL information on the ID bracelet has to be matched to accompanying documentation and/or confirmed by the guardian, parent or carer.

8.5.2. Approved patient identifiers

Depending on national, regional or local regulations, the following items of information might be accepted as patient identifiers:

- Patient's full name;
- Date of birth;
- Address;
- Medical record number could be included in ID band or bracelet or with barcode;
- National ID or passport number;
- Social security or insurance number.

It is recommended that a patient be identified using at least three of the above identifiers. In case of patients with similar names, an alert or warning should be issued to the staff to avoid the risk of mis-administrations.

8.5.3. Timing of patient identification

Within the NMS, patient identification should occur at each of the following steps:

- Upon registration or admission at the department;
- Prior to any procedure, including administration of medications and radiopharmaceuticals, sedation and anaesthesia;
- Prior to treatment with radionuclide therapy;
- Prior to the collection of blood samples;
- On direct handover, referral or transfer of care of the patient;
- Prior to discharge, especially for patients receiving radionuclide therapy.

The staff member in charge of radiopharmaceutical administration or radionuclide therapy carries the ultimate responsibility for ensuring that the patient has been correctly identified prior to starting the planned activity. If the patient's identity cannot be verified, the planned activity cannot proceed until identity is confirmed.

If an adverse event (actual or near miss) is associated with identifying patients, an incident report should be submitted to the IMS.

8.6. SOP FOR TRACEABILITY

Traceability is the capacity for all processes of the NMS to be traced from referral to delivery of the final report and to clarify when, where and how each activity was performed. Traceability involves monitoring all steps and is based on the introduction of specific control points or timeouts in the process. It will also provide elements for analysing the root cause in case of incidents. This should extend from booking procedures through all steps of patient management including the radiopharmacy component, image acquisition and processing to report generation and delivery.

Traceability will ensure patient safety, in particular by assuring that the correct radiopharmaceutical preparation is appropriately administered at the correct amount to the correct patient.

It also helps to identify the root cause of unexpected results or nonconformances and permits corrective actions to the process components. The NMS can better prepare objective responses and timely follow-up to complaints when traceability is possible. Traceability should cover all components of an NMS:

- Administrative procedures, including all steps needed to set an appointment;
- Patient identification at all relevant steps (registration, any pharmaceutical administration or intervention, at the start of a procedure and at discharge);
- Proper procedure information including radiation protection instruction, given to the patient, parents or guardians;
- Proper surveillance of the patient throughout the procedure;
- Radiopharmaceutical preparation, QC and dispensing, including appropriate identification of the final unit dose;
- Associated medication or tests;
- All individual steps of the diagnostic or therapeutic procedure;
- QA/QC of all equipment involved;
- Image processing, display and archiving;
- Data management and report preparation.

Detailed SOPs should be available to describe traceability within the NMS. Digital tools can facilitate these tasks. However, when such resources are not at hand, satisfactory traceability can also be achieved by a paper trail.

Traceability is widely used in NMS for improving patient safety, reducing the risk of misadministration, minimizing non-conformances that may necessitate repeating the study and permitting pharmacovigilance, all of which strengthen the QMS. An example of a paper trail is shown in Fig. 11.

8.7. FORMALIZATION OF COORDINATION AND INTERACTIONS: 'CONTRACTS'

During its normal operations, an NMS fulfils the requests of referring physicians or other departments. The request for an examination is a basic example of what, in quality terms, is referred to as a 'contract': it involves supplying a specific product (e.g. a whole body skeletal scan) with its specific characteristics (e.g. time for the execution of the study, time for delivery of the report, etc.) to a certain patient.

An NMS, with a properly managed QMS, is typically able to provide this in a consistent way, ensuring the satisfaction of the 'customers' (i.e. the patient and the referring physician).

The full range of quality standards can be achieved only if the culture of quality has been adopted by the institution as a whole. Current nuclear medicine departments are typically a component of a wider organization: the maturity level of quality concepts, the combination of concurring needs and requests may be different among departments.

Regardless of the maturity level of the QMS in the whole institution, the NMS should strive to strengthen its own QMS. This improves processes while reducing possible non-conformances in the interaction with other units.

	Example of Paper Trail for NM	Procedure	Front desk Nurse Technologist Physician
1	<u>Family name:</u> ID#: Da Referral physician:	First Name: ate of birth Weight	Gender: M_F_ Height Signature/initials:
2	<u>Study:</u> Referral diagnosis: Pregnancy? Contraindicat	Dat	re:Prior studies: Yes No Signature/Initials:
3	<u>Radipharmaceutical:</u> Comments:	Provider :	Activity mCi/MBq Dispatcht time Signature/Initials:
4	Injection time: Site (fore ID check Pregnancy? Comments:	earm, hand): Right: Left: _ Correct preparation Weight	Difficulty: YesNo Height Signature/Initials:
5	Acquisition time: ID check Comments:	PlanarDynamicSPECT!	SPECT/CT
6	Processing time: Comments:	Print results: YesN Uploade	No CD: Yes No d to PACS: Yes No Signature/Initials:
7	<u>Report</u> (date and time): Comments:	Crit	ical findings: YesNo Signature/Initials:

FIG. 11. Sample paper trail for patient traceability.

Formal agreements are required with other departments or units for purposes of collaboration and the common use of resources. Common examples include the following:

- Cardiology, if nuclear cardiology studies are performed;
- Radiology, for proper coordination of diagnostic processes and common use of some resources;
- Paediatrics and anaesthesiology, for paediatric diagnostic procedures;
- Medical physics or radiopharmacy, when they are external to the NMS;
- Surgery, for radioguided interventions;
- Oncology, if the radionuclide therapy wards are within their facilities;
- Bioengineering, if they provide preventive or corrective maintenance and organize service by external parties;
- Information and communication technologies, if that department provides picture archiving and communication system (PACS) services, dedicated nuclear medicine software, etc.

The contracts should clarify the responsibility for patient management at each stage of the different processes including management of events (e.g. cardiac complication in cardiac stress tests) and the organization of prompt remedial action. It will also include information on safety equipment available in the NMS, such as an emergency cart. Annual evaluation of the services received under these contracts allows for their continuous improvement.

Likewise, in the case of procedures carried out in another institution, the responsibility for the patient's safety aspects in this scenario, as well as the QA/QC of equipment, should be properly defined and contractually clarified.

8.8. SOPS FOR STAFF RADIATION PROTECTION AND SAFETY

The operation of an NMS involves a variety of potential risks. Among these, radiation risk is the principal and most evident. In a properly organized QMS, specific SOPs should be in place in order to ensure adequate management of these risks. Examples of topics requiring defined SOPs include the following:

— Facility requirements: Adequate facilities should be available at the NMS to ensure the safety and efficacy of the activities comprising the nuclear medicine processes. SOPs describing key nuclear medicine tasks need to consider the availability of these facilities and the expected conditions (e.g. availability of ventilation systems to manage ¹³¹I solutions and their periodical checks and maintenances), as they are important requirements of

the local or international regulations such as BSS (SSG-46 § 4.8–4.10 [33]). There are specific, detailed requirements for nuclear medicine areas and some of the very specific activities performed there, such as radiopharmaceutical preparations, image acquisition and processing, specific waiting areas for injected patients, isolated wards for subjects undergoing radionuclide therapy procedures, separate toilet for injected patients, suitable rooms for radioactive waste storage, etc. Special conditions concerning surfaces (floor, walls, tables, etc.), structural shielding, room temperature, ventilation systems, light systems, etc. are required at these working areas and should be considered important elements of the institutional QA programmes. Room design and location need to consider the 'defence in depth' principle [45] and should take into account the workload, radioactivity workflow and patient flow. Access control should be established to ensure that radioactive sources (radionuclide generators, calibration sources, etc.) are safe and that members of the public or non-authorized staff are not allowed access. Clear and visible signs should be placed to define the controlled and supervised areas; they provide relevant information for the radiation protection of public members and patients, with emphasis on special categories such as patients who are pregnant or breast-feeding.

- Use of personal dosimeters: To monitor their occupational exposure, nuclear medicine staff exposed to radiation should have a personal dosimeter at their disposal. The availability of dosimeters should be considered the first step of personal dosimetry. This includes a dosimeter for the whole body and, optionally, a specific dosimeter for the extremities (e.g. for the hands) for staff who are involved in operations like the labelling and dispensing of radiopharmaceuticals and their OC. Optional but very useful are electronic pocket dosimeters, which show dose rate and integrated dose. These are especially useful for new staff members without previous experience in working with radioactivity, and for staff members during pregnancy, if local rules allow them to remain on duty. Apart from their medico-legal aspects, personal dosimeters are required to confirm good working practices and regulatory compliance and they also serve as a tool for optimization. There should be a detailed SOP indicating the correct method of use of each dosimeter, including the method of collection and return, the correct position for them to be worn and where they should be stored outside of working hours [33]. Dosimeters that are not consistently worn in the correct position will give results that are not fully comparable. As an example, consider a hand dosimeter for staff administering radiopharmaceuticals: it should be worn on the non-dominant hand, high on the index finger and oriented inward.



FIG. 12. Exposure of the staff of an NMS, in relevant exposure intervals. This NMS performs conventional nuclear medicine diagnostics with three gamma cameras, PET diagnostics with one PET-CT and radionuclide therapies with various radioisotopes, among them ¹³¹I, for which a therapy ward with four rooms for in-patients is available.

- Review and analysis of individual dosimeter readings: Monitoring involves more than just measurement. It includes interpretation, assessment, investigation and reporting, which may lead to corrective measures, if necessary [33]. The results of occupational exposure data should be regularly reviewed by a qualified professional; proper action levels should be defined in view of constraints for the activities performed. Some action levels could exist at the national level or could be defined by the dosimetry laboratory. Nevertheless, internal action levels should be defined within the QMS, since monitoring and controlling occupational exposures is a task that requires detailed knowledge of the local processes and procedures. The review of occupational exposure may include time-trend analyses and averages for the professional profile (Fig. 12). If a trend or extrapolated annual exposure exceeds a set action level, the unexpected results require interpretation. Early corrective actions can be taken [33].
- Accountability of sources: All sealed sources should be 'under control.' First of all, this requires setting up a detailed inventory, including all identification and relevant data for each source, as well as their storage position and condition. All sealed sources, including those optionally

permanently installed within equipment (internal reference sources), should be regularly (e.g. annually) checked for leaks. Sealed sources are typically certified and tested by the manufacturer; however, their durability is limited, and production errors may be rare but cannot fully be eliminated. In addition, wear and damage may occur during their clinical use. For some sources, manufacturers indicate a date of expiry. Wipe or smear tests are used for QC of this type. A radiation detector with sufficient sensitivity, preferably equipped with a spectrum analyser, should be used to assess the activity (in Bq/cm²) of these wipes. SOPs for this detection system, including its calibration, should be in place [33].

- Storage of sources: Radioactive sources should be stored in a shielded and locked place or vault that protects them from theft and from the heat of an accidental fire.
- Check of workplace conditions: An NMS uses a variety of hazardous materials (chemicals, radiopharmaceuticals, sealed sources, etc.), and staff members frequently operate in shifts. Good housekeeping habits and rules should be consistently applied to ensure a safe working environment. An SOP should be in place for daily quick checks of the safety conditions, including a general inspection of diagnostic rooms and laboratories, checking environmental conditions and the general condition of equipment, noting any deviation and item that is out of place. Quick survey monitoring with a robust, easy to use radiation detector will help in detecting sources that are out of place or any contamination previously unnoticed. The results of this type of inspection are usually only qualitative and are frequently reported on a form with check boxes. The SOP should indicate the people to be informed and the actions to be taken in case of non-conformances or deviations [17, 33].
- Periodic radiation surveys: The radiation protection programme should include regular surveys to check the level of exposure in the area of the NMS and during specific operations (e.g. administration of therapeutic radiopharmaceuticals). These surveys should be made using appropriate and properly well-calibrated equipment. A detailed SOP should be in place to specify the equipment, modality and position of routine dose or dose rate checks [17, 33].
- Routine monitoring of surface contamination: One of the specific risks in nuclear medicine, in addition to external exposure, is the risk of internal exposure owing to contamination and the accidental intake of radionuclides if appropriate working procedures are not carefully adopted. In addition to the quick workplace monitoring mentioned above, a regular control

programme for surface contamination should be in place. According to IAEA SSG-46 para. 4.113 [33], this monitoring is particularly required for:

- All work surfaces (including the interior of enclosures), tools, equipment and devices (including dosimetry systems, computers and peripherals, and stress testing units), the floor and any items to be removed from these areas;
- Workstations, ventilation systems and drains, when any of these needs to be accessed for maintenance;
- Protective and personal clothing and shoes, particularly when the wearer is leaving a controlled area (monitors should be available near the exit);
- Clothing, bedding and utensils used by radiopharmaceutical therapy patients.

Periodic monitoring using a contamination monitor or wipe testing should be conducted for controlled as well as supervised areas. The equipment for assessing surface contamination should be calibrated in appropriate units [33]. A detailed SOP should be in place to specify the equipment, method and position of routine contamination checks, as well as the frequency and statistical method for the necessary periodic review and analysis of these results and those of quick workplace monitoring.

- Decontamination kit: Prompt response in the case of a spill of radioactive material should be properly managed. To this end, one of the most widely available tools is a decontamination kit [29]. Although commercial kits are available, a relatively inexpensive decontamination kit could be prepared using cleaning material and items that are normally available in a hospital. This is important, since it is neither intended nor desirable for only one decontamination kit to be available in the whole NMS. Rather, a kit should be available at each location where there is a significant risk of contamination (e.g. in the radiopharmacy laboratory, in injection sites, in the therapy ward, etc.). If a single decontamination kit is stored in a position that makes it less readily available, there is the risk of spreading contamination and of a more complicated cleaning and restoring operation. The contents and position of decontamination kits should be included in a detailed SOP, which should also indicate the method of checking the replenishment of the kits to ensure their functionality.
- Procedures following a spill: In an NMS, the occurrence of a spill is not an 'incident,' in the proper meaning of the term, but it is rather an undesired component of routine activities. All working procedures should aim to minimize the risk of spills and of surface contamination [33], but complete

elimination of this risk is not a realistic goal. In the event of a spill, it is important to have a detailed SOP in place giving clear instructions about the actions to be taken to reduce the spread of contamination, to limit the risk of accidental intake by staff members, and remedial actions if such intake might nevertheless occur. This SOP should be particularly well known to staff in the NMS. According to para. 4.109: "All staff working with unsealed sources should be trained in the procedures for dealing with accidents, spills or contaminated persons, with refresher training at appropriate intervals. This includes instructions on appropriate showering and eye washing" [33].

- Management of radioactive waste: This requires specific attention and management within the QMS. Waste is relevant as a potential source of irradiation for the environment, for the general public and for staff. Apart from the apparent radiological risk, other types of risks such as biohazard, the risk of puncturing and accidental cutting (and subsequent infection) with sharp and non-sterile objects, should be considered. IAEA SSG-46 [33] gives detailed instructions in paragraphs 4.274–4.280 on proper waste management in relation to both diagnostic and therapeutic activities of an NMS. Detailed SOPs should be prepared in order to cover these aspects. In addition to this, concise warnings and instructions may also be incorporated into other SOPs (e.g. for the management of therapeutic patients, radiopharmacy, etc.).
- Transportation of sources: Internal transportation of sources within different areas of the same hospital or facility may occur in a variety of scenarios. For example, therapeutic doses may need to be transported from a radiopharmacy lab to the therapy ward; ready-to-inject diagnostic radiopharmaceuticals may need to be administered in other departments (e.g. for sentinel lymph node procedures); devices such as microspheres labelled with beta emitters may need to be prepared by the NMS to be administered in an angiography suite in the radiology department. For all these applications, proper transport management is required. Specific containers and transportation carts should be available and detailed SOPs should be in place to ensure that each type of such a transportation is well controlled.
- Biohazard: While radiation is the most important source of risk in an NMS, other concurrent types of risks should be considered, too. Patients could potentially be a source of microbiological contamination, and therefore staff should be adequately protected, and proper working procedures should be in place to minimize contamination and infection risks. Staff need to be familiar with the institutional policies regarding infection control and need to practice infection control measures when dealing with biohazards. Aspects to be considered are injecting patients and management of sharps; the management of blood and other fluid samples, including urine bags;

the need for catheterization of patients; changing of diapers of paediatric or non-autonomous patients, etc. According to the workload and case mix of an NMS, there should be one or more specific SOPs establishing approved working methods to prevent biohazard risks [46, 47].

— Mechanical risk: Heavy loads, like syringe shields and transport containers, lead bricks, etc., are typical in an NMS. They serve the purpose of protecting staff but can also represent a risk (e.g. if they fall). Similarly, shielded and therefore heavy hot cell doors can cause severe damage to an operator's fingers. Depending on the type of activity and workload, it could be useful to have specific SOPs to take into account and manage these risks or to incorporate specific instructions into the SOPs of the relevant processes.

8.9. SOPS FOR RADIATION PROTECTION OF PATIENTS

The following SOPs are required in order to protect patients from radiation:

— Appropriate use criteria and justification of medical exposure in nuclear medicine: Appropriate use criteria, sometimes referred to as AUC or appropriateness criteria, are based on an evaluation of whether a certain procedure may carry health benefits exceeding possible health risks. Typically, a procedure or investigation can be deemed appropriate if it results in a change in management frequently enough. Appropriate use criteria are usually based on scientific and clinical evidence. They are typically classified in terms of the quality of the evidence on which they are based and are endorsed by medical professional societies. Appropriateness can be established on the consensus of international panels. When a procedure involves radiation exposure, it has to be clinically justified by weighing the expected diagnostic or therapeutic benefits that it yields against the radiation detriment that it might cause. Alternative modalities that do not involve medical exposure should be considered. Justification is a multilayer process: first, a 'generic justification' of any procedure shall be carried out by the health authority of a country, along with appropriate professional bodies, and be reviewed from time to time, taking into account new evidence in science and technological developments [11]. A fundamental layer is the final justification for each individual patient: this can only be performed by a physician who is a specialist in the specific field. Therefore, nuclear medicine procedures shall also be justified for each individual patient, requiring proper evaluation of each clinical request [11, 32].

- Justification of nuclear medicine procedures: Justification should be made by a medical specialist qualified in nuclear medicine, according to national requirements. In the case of radionuclide therapy procedures, the involvement of a multidisciplinary team is typically required to achieve the best approach to treatments.
- Assessment of local diagnostic reference levels: The NMS needs to define and implement SOPs to introduce and regularly review the local DRLs. This includes the DRL with respect to both the activity levels of radiopharmaceuticals administered to patients and the appropriate quantity (e.g. the CT dose index) regarding the CT component of multimodality studies. Assessments of the local DRLs have to be based on the analysis of patient dosimetry and the assessed image quality for each diagnostic procedure. The relevant DRLs at regional, national or international levels are typically used as a reference to assess the local DRL of a facility, sometimes referred to as facility reference level (sometimes called FRL); their estimations constitute a valuable tool for the optimization of the medical exposures of all diagnostic nuclear medicine procedures [11, 33]. For further guidance and information, see also the EC Radiation Protection Series No. 180, Parts 1 and 2 [48].
- Radiopharmaceutical activity and X ray dose parameters: SOPs should be in place for each type of clinical procedure performed at the NMS. These procedures should include detailed information on the level of activity to be administered as well as on the CT settings to be used in multimodality examinations (see GSR Part 3 para. 3.165 [11] and SSG-46 para. 4.175 [33]). Criteria to determine the radiopharmaceutical activity (typical values) are usually based on the body weight or body surface area. Procedure guidelines published by national bodies or authorities, international professional bodies (e.g. the IAEA) and scientific associations (e.g. EANM, SNMMI, etc.) may provide guidance. Dedicated guidelines have been suggested on the radiopharmaceutical activity levels to be administered to paediatric patients, such as the proposals by the EANM dosage card working group and the EANM/SNMMI Pediatric Dosage Harmonization Working Group. Another user friendly tool for dose assignment in paediatric nuclear medicine studies is the Paediatric Injected Activity Tool published by the SNMMI. The prescribed typical dose (radiopharma ceutical activity) should be measured on an activity meter before administration to patients and filed in their medical records. X ray doses should also be recorded when hybrid SPECT-CT or PET-CT studies are performed.
- Optimization of patient dose: Optimization is a precise requirement [11].
 Procedures should be in place in order to select and use the appropriate medical radiological equipment, software and radiopharmaceuticals

and to optimize the radiopharmaceutical activity and the X ray doses to be delivered to patients, thereby ensuring adequate image quality with a minimum radiation dose to patients. It involves several actions such as the optimization of image acquisition and processing protocols (including the selection of optimum parameter settings to obtain adequate image quality), optimization of patient preparation and radiopharmaceutical administration, correct radiopharmaceutical selection, etc. [11, 33]. This optimization process might even result in an increment of the radiation dose if the image quality is otherwise not good enough to allow for an accurate diagnosis.

- Patient Dosimetry: SOPs should be established in order to assess and record the patient dosimetry. Typical doses should be estimated for each diagnostic procedure (e.g. absorbed doses and effective doses) and for therapeutic procedures (e.g. absorbed doses to organs at risk and target volumes). For nuclear medicine diagnostic examinations, the administered activity (measured in megabecquerels, MBq) is the quantity of interest, as a surrogate of the absorbed and effective doses. In fact, well established methods and tools are documented and available to estimate the absorbed and effective doses from the injected radiopharmaceutical activities (see GSR Part 3 para. 3.168 [11] and SSG-46 paras 4.203-4.212 [33]). A medical physicist should undertake or supervise these tasks; the local SOPs should be based on well-established dosimetry protocols, proposed by (inter)national bodies and scientific societies such as the International Commission on Radiological Protection, SNMMI, EANM, etc For multimodality studies using the SPECT-CT and PET-CT systems, the dosimetry calculations should combine the absorbed and effective doses from both components:
 - In therapeutic nuclear medicine procedures, high absorbed doses are delivered to target volumes and also to non-target tissues. The radiopharmaceutical toxicity and treatment responses are closely related to the absorbed doses values. Therefore, when dosimetry calculations are recommended, state of the art accuracy methods for dose estimations are required on the basis of individual patient dose calculations for those treatments. For diagnostic nuclear medicine procedures there are specific situations requiring individual dose estimations when unintended medical exposures occur. For example, the unintended irradiation of a foetus or embryo during the nuclear medicine examination of a pregnant patient.
 - Finally, it should be noted that patient dosimetry in nuclear medicine is a key component to optimize the doses delivered to patients and to implement the DRLs at the nuclear medicine levels.

- Management of pregnant or breast-feeding patients: Appropriate SOPs need to be established in the NMS, in order to ensure the radiation protection of pregnant or lactating patients requiring diagnostic or therapeutic nuclear medicine procedures (see GSR Part 3 [11] paras 3.175–3.177 and SSG-46 [33] paras 4.241–4.245):
 - The purpose of these procedures should be to identify the status of female patients of childbearing age before prescribing any administration of radiopharmaceuticals, to use this information when evaluating the study justification (SSG-46 [33] para. 4.162-a) and also to optimize the medical exposure of the patient and the foetus or baby (SSG-46 [33] paras 4.195, 4.196).
 - To identify and inform pregnant and breast-feeding patients, it is suggested various methods be used, such as posting clear signs in public places of the facility (in local languages with proper pictures or drawings) inviting these patients to inform the nuclear medicine staff about their real or potential pregnancy or their lactation status. In addition, during consultation the nuclear medicine physician should ask patients about their real or potential pregnancy.
 - Specific SOPs describing the use of accurate laboratory pregnancy tests are mandatory in case of therapeutic procedures. SOPs to optimize the medical exposure of these patients need to be available. They are to include specific instructions concerning the patient management, radiopharmaceutical administration, image acquisition and processing procedures, as well as instructions on how to minimize the radiation exposure to a foetus or baby during a nuclear medicine procedure regarding a pregnant or breast-feeding patient.
- Patient identification: This is a fundamental step to ensure a patient's safe exposure. Details are given in Section 8.5.
- Minimizing the risk of accidental exposures: To minimize the likelihood of accidental medical exposures, including mis- and mal-administrations and unnecessary multiple medical exposures, detailed procedures should be defined and implemented in the NMS, with emphasis on the prevention of such exposures and unnecessary multiple exposures (SSG-46 para. 4.250 [33]). These procedures should include aspects related to correct patient identification, staff training on technical tasks (e.g. training on correct radiopharmaceutical administrations to avoid extravasations), encouraging staff to work with awareness and alertness, availability of updated and detailed SOPs for all steps of the clinical processes involved, etc. To avoid unnecessary repetition of nuclear medicine studies, the SOPs should include appropriate methods such as asking patients if they have recently undergone

any similar diagnostic procedure, querying of RIS/PACS systems², etc. Furthermore, links to the procedure for corrective or preventive actions and, when applicable, to the procedure for incident reporting, should be included in SOPs.

8.10. SOPS FOR RADIOPHARMACY

Radiopharmacy is a special component of nuclear medicine that combines expertise in radiochemistry, including the skills needed to handle radioactive materials, and in pharmaceutical preparation. The administration of radiopharmaceuticals is not generally associated with major clinical side effects. However, in their clinical use, there are combinations of different risk factors associated with radiation exposure but also with possible contamination by chemical, biological, microbiological and radionuclidic impurities during the formulation. This is particularly important, since the majority of radiopharmaceuticals are administered intravenously. A thorough QMS is then necessary to ensure the safety, efficacy and quality of radiopharmaceutical products [49].

The IAEA classifies the operations in radiopharmacy into three different levels of increasing complexity (listed below) and, consequently, each operational level will have specific requirements [50]. The following sections give a general (though not exhaustive) description of the main components of the specific quality system for radiopharmacy.

- Radiopharmacy operational level 1: Operational level 1a is the dispensing of radiopharmaceuticals purchased or supplied in their final form from recognized or authorized manufacturers or from centralized radiopharmacies. This includes unit doses or multiple doses of prepared radiopharmaceuticals for which no compounding is required. 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 [50].
- Radiopharmacy operational level 2: 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 presterilized radiopharmaceutical cold kits.

 $^{^2\,}$ "Integrated radiological information systems and picture archiving and communication systems."

Operational level 2b is the radiolabelling of autologous blood cells. This includes radiolabelling of red bloods cells, platelets and white cells commonly used for infection or inflammation imaging [50].

Radiopharmacy operational level 3: 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; and related research and development. 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 metaiodobenzyl guanidine and rhenium labelled lipiodol. Operational level 3c is the synthesis of PET radiopharmaceuticals. This includes the increasingly popular fludeoxyglucose (¹⁸F) injections (FDG). The compounding of radiopharmaceuticals produced from unauthorized or long lived generators such as gallium (⁶⁸Ga) or rhenium (¹⁸⁸Re), which is mostly related to research and development, also falls under operational level 3c [50].

8.10.1. Competences and training

The local regulations for the production of pharmaceuticals in a hospital or health structure should be applied. If such regulations or a qualified radiopharmacist are not available, it is suggested that all operations should be carried out under the authority and supervision of the nuclear medicine physician in charge.

A specific training manual encompassing all grades of staff should be written, and records of training should be documented. This applies for operation at each level of hospital radiopharmacy — specific, detailed training material should be available for each different level. In addition to general training, all staff should also receive practical training in preparation, QC and analytical techniques, transport of radioactive material, laboratory cleaning and maintenance, equipment calibration and maintenance, dispensing of individual doses and other aspects, as detailed in the appropriate paragraphs.

8.10.2. SOP(s) for purchase of products

The purchase of any radiopharmaceutical product is important from an administrative and economic point of view, but it also involves significant aspects related to patient safety. Every order should be clear and indicate all necessary product characteristics. Additionally, considering the rapid decay of radioactive products, the order should specify the delivery dates and times, the lot number, the calibration of the product activity as well as the expiry date and time. Staff members who can place orders or request orders from the relevant hospital offices should be identified and expressly authorized. These professionals should have received specific training on radiopharmaceuticals and the applicable legislation in order to know the different products and understand their characteristics and related legislation. For example, they should know the difference between a product that has a marketing authorization, a galenic formulation³ or a prescription compounding, and a new product under investigation.

8.10.3. SOP for checking all materials delivered

On receipt of the ordered products, an inspection and a series of checks should be made. The order date, name of the radiopharmaceutical, amount of radioactivity, patient's name, lot number and name of person who received the goods should be inspected and recorded. In some countries, local regulations require that some radiometric data also be checked and recorded (e.g. transport index, level of radioactive contamination on the surface of containers, etc.). Purchase orders (request forms) for radiopharmaceuticals issued by the radiopharmacy should be kept for future reference.

8.10.4. SOPs for storage of products

All materials received should be properly stored and retained, taking into account the manufacturer's instructions (e.g. materials to be stored under specific temperature conditions). Depending on needs, it may be necessary to establish a register of input and output materials. In any case, it is necessary to ensure that there is no confusion between valid products, which are intended for use, and expired products, which should be promptly removed.

8.10.5. Process SOPs

For every different type of radiopharmaceutical prepared locally there should be an SOP giving detailed, step by step instructions for its preparation. These SOPs should indicate the conditions for the preparation (e.g. which laminar air flow or hot cells can be used, and their predisposition and testing), details

³ Galenic formulations are drugs prepared in a pharmacy, in this case the hospital radiopharmacy, on the basis of a medical prescription intended for a specific patient; all the mixtures, dilutions, divisions, etc. carried out for the individual patient on medical indication are also technically comparable to master, or galenic, preparations.

on aseptic operations and, in particular, on dispensing, as applicable. These SOPs should clearly reference the information given in the summary of product characteristics issued by the manufacturer of the product or kit; however, any instruction given by the manufacturer cannot be used as a surrogate of a locally developed and approved SOP. Only the SOP can give the details of operations to be performed and how to apply the methods using the available equipment within the local facility.

8.10.6. Specific SOPs for particularly relevant cases

There are several special cases for which specific and highly detailed SOPs are required. This relates to safety concerns for the patient and operators that these preparations can present. These include:

- Preparation, dispensing and activity checking of therapeutic 131I for radiopharmaceuticals. This is particularly the case radiopharmaceuticals, in both liquid and capsule form. However, in general, the same criteria apply to the majority of therapeutic radiopharmaceuticals.
- The labelling of autologous cells, such as white blood cells. These procedures can present a very high risk for patients. The operators involved should be specifically trained for this, and their preparation should be validated.

8.10.7. Batch record

A batch record should exist and be stored for every production, in accordance with national regulations. The batch record is a document describing how the preparation of a specific batch of a pharmaceutical has been carried out. The entire preparation process should be pre-established and other documents fully described, such as the SOP for performing the preparation. The batch recording should include documentation to show that each significant step in the preparation was accomplished according to the SOP. Control records of each critical step should be included. Critical steps include the process step, process conditions, or other relevant parameters that are controlled within predetermined criteria to ensure that the final product meets its specification. The batch record can be very simple in the case of operation at level 2a (e.g. a lot of ^{99m}Tc radiopharmaceutical) prepared using an approved kit. It is generally a more extensive and complex document in the activities at level 3 (e.g. synthesis of PET radiopharmaceuticals).

8.10.8. SOP for routine microbiological monitoring

In the case of injectable pharmaceuticals, it is mandatory that the products be sterile in order to ensure the safety and health of patients. In radiopharmacy, many such products are initially sterile (e.g. kits for labelling with ^{99m}Tc), and sterility should be maintained by adopting strict aseptic procedures. In other cases, products are terminally sterilized (e.g. synthesis of PET radiopharmaceuticals). In either situation, environmental monitoring ensures that proper control of the process is in place and that environmental control systems in clean rooms are effective. The methods used in environmental monitoring include:

- Monitoring of air, including air sampling (discussed elsewhere in this document);
- Plates and surface sampling, including 90 mm settle agar plates and swabs that can be used to sample specific items or positions;
- Personnel monitoring.

Depending on the level of operation, an appropriate level of microbiological monitoring (Table 8) should be in place and documented in an SOP, including locally defined action levels.

8.10.9. SOP for QC of all radiopharmaceutical products

It is important to understand that appropriate QC is necessary for each type of radiopharmaceutical. This applies to all levels of operation, including level 1 (described in Section 8.10). Depending on the type of product, there is a stepwise approach to the requisites for the NMS. When a service operates only at level 1 and radiopharmaceuticals are received ready to use from an external radiopharmacy, the requisites are minimal (e.g. checking the material delivered vs the order, the integrity of the package and the activity of the products, and asking the provider to send copy of their QC reports). As the level increases and local production becomes more complex, there is also an increase in the requisites, type and frequency of QCs requested. In most cases, the modalities of QC are exhaustively described in the pharmacopoeia; if a national pharmacopoeia is not available or does not include radiopharmaceuticals, reference can be made to the EU or US pharmacopoeias. Detailed guidance is given in the IAEA "Operational Guidance on Hospital Radiopharmacy: A Safe and Effective Approach" [50].

78 2.0 AB		0.0		
80 1.3 AB	1 2		0.0	60 0.0 60 0.0
84 7.1 AB	9		3.2	63 3.2
84 7.1 ST	9		6.3	63 6.3
84 0.0 ST	0	1	3.0	66 3.0

TABLE 8. SAMPLE ANNUAL MICROBIOLOGICAL MONITORING REVIEW, SUMMARIZING DAILY SETTLE

FLAIE N	CONTRACT		ALUK	AIK QUA	LIIY) AND	FINGE	K DABS (cor	II.)		
Hospital XX	K – Radiophaı	rmacy Unit N	f icrobiolc	gical monit	oring					
			Isolé	ator 1						
010		Settle plates			Finger dabs		(Daily file) Ecrimits	Trending	Checked	GMP
6107	No. of plates with J growth	No. of plates used	%	No. of plates with growth	No. of plates used	%	checked by	by	by	QER
Aug	1	63	1.6	0	84	0.0	ST	KL	ΜΛ	
Sep	0	55	0.0	0	70	0.0	ST	KL	OP	
Oct	0	45	0.0	0	60	0.0	НŊ	KL	OP	
Nov	0	40	0.0	0	52	0.0	НŊ	KL	OP	
Dec	0	42	0.0	0	56	0.0	GH	KL	OP	
Total/ year	6	678	1.3	16	894	1.8				
Monthly limits		<3.0			<5.0					

TABLE 8. SAMPLE ANNUAL MICROBIOLOGICAL MONITORING REVIEW, SUMMARIZING DAILY SETTLE (+ -DI ATE DE A DINGS (EGD 1501 ATOD A ID OLIAI ITY) AND EINGED D'A DS (~

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PLATE I PLATE I Hospital X	READINGS (FOR ISOI X - Radiopharmacy Unit N	ATOR AIR (QUALITY monitoring) AND FI	NGER DABS (co	nt.)		
		Isolator 1						
0100	Settle plates		Finge	ır dabs	(Daily file)	Trending	Checked	GMP
6107	No. of No. of plates with plates used growth	% No plate: gro	. of No s with plates wth	, of 9	% checked by	by	by	QER
When lim Exception	tts are breached and more th Report)	ian 30 plates ha	ve been used	d within the	month, open GMP (JER (Good Man	ıfacturing Practi	ce Quality

8.10.10. SOP for terminal sterilization

Operation at level 3 (described in Section 8.10) in general requires a terminal sterilization of the products, typically done by microfiltration, but other techniques have also been used (e.g. autoclaving). A specific SOP should be in place to describe local modalities, precautions and testing (e.g. filter integrity or 'bubble point' test).

8.10.11.SOP for proper packaging and labelling

Radiopharmaceuticals produced in the internal radiopharmacy and ready to be sent to the clinical area are to be clearly identified by proper labelling indicating the type of product, activity and reference time and the date and time of expiry. In the case of unit doses, frequently the name of the individual patient for which the preparation is made is included. Regulations on the type and contents of labels may exist at the national level; as in other cases, should there be a lack of national regulations or guidelines, reference can be made to international pharmacopoeias. Internal transportation from the radiopharmacy to the different points of use should also be carefully managed and described in an SOP. In a limited number of cases, administration has to be made outside of the NMS (e.g. in surgical or angiography room, or at the bed of the patient). These cases should be specifically studied and the risks assessed. It should be noted that shielded transport containers need to be sanitized after each use. Local SOPs should give the necessary instructions.

8.10.12. Documentation and record of changes

The preparation of radiopharmaceuticals should always be made according to the SOPs.

In the case of operation at level 2 and the labelling of kits, the SOPs should correspond with the instructions issued by the manufacturer of the kit. Since the latter are part of the approval and marketing authorization of the product, any change requires special consideration, since these fall into operation at level 3a. (Levels are described in Section 8.10.)

In the case of operation at level 3b (e.g. synthesis of PET radiopharmaceuticals), deviations and changes are to be recorded and included in the batch report. This information should be properly considered before the final release of the product.

8.10.13. Traceability from single preparation dose back to prescription

One of the base pillars of a QMS is the use of a properly organized documentation system, including all reference documents and operational records collected at each step of the process. This applies particularly to radiopharmaceutical preparation to assure the traceability of the entire process. The application of the concept of traceability starts with the records taken on receipt of materials and should be consistent with the following steps:

- Storage of each material;
- Predisposition of the production, and records of the QA test performed (e.g. on the hot cell or on the synthesis module, etc.);
- The production itself and all records taken in this phase;
- QC of the product;
- Data on the dispensing of unit dose.

All of this information should be cross-linked, in order to make it possible to trace every unit dose to the production process, the environmental conditions recorded during production, results of QC and the final approval for release by the responsible person.

8.10.14. SOP for out of specification and recall of products — complaints

Any radiopharmaceutical has to comply not only with the requirements specified in the pharmacopoeia (e.g. radiochemical or radionuclidic purity levels) but also with internally developed acceptance levels (e.g. synthesis yield for PET tracers), as detailed in local SOPs. In cases where a product, be it single photon, beta or positron emitters, does not meet those specifications, operators require a procedure to follow in order to prevent the release of the specific lot of radiopharmaceutical and patients receiving products of substandard quality. SOPs should include all necessary information and indications.

In some cases, considering time constraints and the short half-life of many radiopharmaceuticals, the dispensing or delivery of radiopharmaceuticals to the final users may begin before QC is completed and officially released for clinical use. In this case, should a product not meet specifications, a recall is needed, which requires an SOP detailing the correct modality for informing the final user of the need to wait for final release of the product before administering it to patients. The recall SOP should also define the modality for safe and timely communication to the final user, that it is confirmed for clinical use (or not) and the necessary records. Finally, the general requirement of having a procedure for receiving and treating complaints has a special application in radiopharmacy, and it is worth having a specific SOP for it.

8.10.15. Maintenance and QA/QC of radiopharmacy equipment

Radiopharmacy facilities of all levels require an appropriate programme of maintenance and QA/QC of equipment. This includes the components of the heating, ventilation and air-conditioning system, air handling units, isolators, hot cells, laminar flow cabinets, hoods and all laboratory equipment. SOPs should be in place for all these systems.

For workstations in which aseptic procedures are performed, qualification testing (integrity testing of the high efficiency particulate air (HEPA) filter, check of air speed and ventilation rate, etc.) should be performed when the unit is initially installed and repeated regularly. Unless different recommendations are given at the national level, it is typically requested that these be repeated at least yearly to ensure the desired air quality aimed to protect patients.

8.10.16. SOPs for QA/QC of all radiopharmacy equipment

Calibration, qualification testing programmes and routine QA/QC should be active for all laboratory equipment, including activity meters, high performance liquid chromatography or thin layer chromatography scanners, gaschromatography and pH meter, as well as basic equipment such as refrigerators, scales, thermometers and micropipettes.

Regular maintenance and QA/QC of hot cells, including the testing of gloves, gauntlets, etc., is also necessary.

Sophisticated synthesis modules used in the production of PET radiopharmaceuticals typically include routines for automated or semiautomated testing of working conditions (e.g. operation of main components, test of tightness of the reactor, etc.) to be performed and documented before each synthesis.

8.10.17. Specific SOP for waste management

In radiopharmacy, the management of all types of waste, and particularly radioactive waste, has specific relevance and requires specific SOPs. Furthermore, hygienic conditions should be strictly maintained in the radiopharmacy lab. This requires carefully prepared procedures for radioactive or potentially infectious waste, sharps and general waste. The different types of waste should be separately collected in approved containers. It is of paramount importance to avoid storing waste in the same storage area designated for pharmaceuticals and sterile products.

9. DETECTION AND MANAGEMENT OF NON-CONFORMANCES

Using the language of ISO standards, a non-conformance occurs when a standard is not fulfilled. This requires standards to be set for the activities of an NMS (see Section 11.1). The recording of non-conformances is one of the key aspects in a QMS; frequently, one of the most important parameters that auditors consider is the failure to register non-conformances, as it is a clear sign of an immature or even a non-functioning QMS.

In some cases, standards exist independently of the NMS because they are derived from legislation or a technical standard (e.g. ISO, IEC or others), from international guidance (IAEA standards) or from nationally or internationally recognized guidelines (e.g. EANM, SNMMI, national bodies and associations, etc.). Therefore, it is necessary for the QMS of an NMS to be regularly updated in order to take into account the dynamics of changes in a rapidly evolving, highly technological field like nuclear medicine.

Non-conformances can be of different types and be present in all the sectors of NMS activity. There are different possibilities to register them. Some institutions have a centralized database, including the option of classification according to type and managing the follow-up. In other cases, particularly for relatively small NMS, there may not be a centralized registration system.

In some cases, a single, overall scheme of registration is adopted; in still other cases, it is preferred to have a separate database for non-conformance recording for the different areas of work. For example, there can be a database for recording non-conformance in clinical imaging, a separate one for radiopharmacy activities, yet another one regarding equipment, etc. Any solution is acceptable if it is correctly managed and consistently documented in SOPs.

When a non-conformance involves risk for a patient, a staff member or the environment, it should be considered an incident and treated accordingly (see Section 7.5.2).

9.1. MANAGEMENT OF NON-CONFORMANCE

Internally managed recording of non-conformances can be made in a variety of ways; even recording in a handwritten logbook is acceptable. However, a handwritten log is not a recommended solution. Analysis of handwritten data is not straightforward, hindering one of the most essential aspects of the practice of recording non-conformances, namely learning from previous lessons and avoiding a recurrence of the same issues. Furthermore, handling large numbers of records may be prohibitive without a digital registration system. A relatively simple electronic spreadsheet for recording non-conformances can be achieved by any NMS.

The registration should include at least the following:

- Date of opening on the non-conformance;
- Registration or identification number;
- Classification for sector of work, type or level of risk;
- Keyword or short description;
- Open text field for description of the problem (e.g. 400–500 characters);
- ID of the operator notifying the non-conformance;
- Open text field for description of the actions taken;
- Link to a possible corrective action;
- Open text field for a description of the results and closure of the nonconformance;
- Date of closure;
- Links to external documents, such as national or international standards.

The modality of management of non-conformance should be described in general terms in a specific SOP; furthermore, specific information should be given in each SOP for primary and supporting processes.

The management of non-conformances may require different approaches. One could be a basic, easy solution, which could be directly explained as an example in the SOPs for the corresponding process, or a solution which could require the knowledge of a qualified professional in charge of the process. In other cases, a non-conformance could require a solution which might not be straightforward, and several staff should work together to find a solution. In all cases, there should be a proper notification of each non-conformance to all relevant members of staff, particularly the quality manager or quality committee. They should be able to review this data quickly and decide if it is necessary to initiate a corrective or preventive action (see Section 7.5.3). In any case, timely reactions are a key point that should always kept in mind.

Furthermore, it could be necessary to record the non-conformance as an incident, in other specific registers (see Section 7.5.3 on incident reporting).

9.2. CATEGORIZATION OF NON-CONFORMANCE

Categorization is important to help the process of analysing nonconformances and in determining root events. This can consider specific risk levels of potential non-conformances in different components of the processes or areas of the NMS. Searching previous records and other documents such as the risk registry using keywords to locate and review related incidents may help revise risk levels appropriately.

Non-conformances should be periodically reviewed: the number and types of non-conformances recorded is an indicator of the QMS. The quality manager or the quality committee should continuously monitor the data on nonconformance. Management of the NMS should be informed of the data during the periodical managerial review activities and give instructions as appropriate. Some examples are discussed below.

9.2.1. Example 1: Lack of uniformity

A nuclear medicine department has two SPECT cameras. The SOP for QA/QC of gamma cameras indicates that the daily uniformity test should give an acceptable uniformity at visual inspection and a quantitative result better than 6.0% for the integral uniformity for the useful field of view as well as a quantitative result better than 3.0% for the integral and differential uniformity in the central field of view. If these parameters are exceeded, the chief technologist, the medical physicist and the head of department should be notified in order to evaluate and manage the situation, which includes calling the manufacturer's representative for service.

When carrying out the daily QC on this camera using a flood source of ⁵⁷Co and a low energy, high resolution collimator according to SOP, the nuclear medicine technologists in charge of that camera noticed a clear area lacking counts at the top border of the field of view; most likely a photomultiplier tube was not working properly. The calculated value of the integral uniformity was 85%, while the central field of view parameters were both better than 3%.

— *Question 1:* Is this lack of uniformity a non-conformance?

Answer: No. This is a deviation from what is expected for the camera that is in normal operation, but the latter is not a standard defined by the NMS: the camera is a device. The deviation must be recorded and notified.

— Question 2: The technologist, having checked the work list of the day decides to start with the first whole body scan: is this a non-conformance?

Answer: Yes. According to the SOP he should have notified the responsible staff in the department and let them take this decision.

— Question 3: Waiting for service, the head of department decides to swap the program between cameras, considering that the defect on the border of the field of view would not affect the quality of result for the studies booked on the second camera. A sign with notification of the problem is placed on the workstation and communication is given to all staff in a chat for the personnel. Is this a Non-Conformance?

Answer: No. The capacity to manage the situation is one of the duties of the head of department. According to SOPs, service is called for and all staff are notified. All of this follows what is specified in the SOP and it is then conforming.

— Question 4: Following the call to the manufacturer service, it is agreed that an engineer will intervene at 8:00 am the following day; confirmation is sent by e-mail. The chief technologists then reschedule all studies for the camera until after 10:00 am. The following day, the field engineer of the company arrives at 11:00 am. Is this a non-conformance?

Answer: Yes. Maintenance was planned and confirmed for 8:00 am. The delay means that studies have to be rescheduled. This is a problem and potentially a risk for patients who will not receive a timely diagnosis, and a lack of performance for the department. The NC should be recorded and notice sent to the quality manager of the company.

9.2.2. Example 2: Dose activity mismatch

A nuclear medicine department operating at hospital radiopharmacy level 1 ordered 15 unit doses to be delivered by 8:00 am; these included four unit doses of ^{99m}Tc-MAG3 for renal dynamic scintigraphy. Three were for adult patients, and an activity of 70 MBq at the time of injection was requested. The fourth patient was paediatric, weighing 16 kg, and a reduced activity of 30 MBq at the hour of injection was placed for this order. The order was sent by 5:00 pm the day before, as normal according to the contract.

When receiving the order, the chief technologists noticed that all of the unit doses had the same activity of 70 MBq, scaled to the time of injection.

— *Question 1:* Is this a non-conformance?

Answer: Yes. The order should match the request. The non-conformance should be recorded and reported to the centralized radiopharmacy.

- Question 2: Following receipt of a prompt phone complaint, the radiopharmacy replies by refusing the non-conformance, since the activity they sent is more than the level requested, not less. Is this acceptable? Answer: No. The order delivered should match the request. There may be accepted tolerances, but a deviation of more than 100% is clearly out of this range. The non-conformance should be confirmed and officially reported for any further consequence on the contract.
- *Question 3*: Is on-site scaling of the activity possible without altering the pharmaceutical quality of the product? *Answer:* Yes. There should be an SOP in place for doing this safely, both with regard to pharmaceutical and radiation protection aspects. Relatively simple and foreseeable non-conformances should be addressed in the appropriate SOPs or in problem solving tables annexed to SOPs.

9.2.3. Example 3: Modified scanner set-up

An 86-year-old male was booked for a whole body bone scan. At the time of examination, the technologist realized that the patient, even if cooperating, had difficulty sitting still on the bed for the time foreseen for the study. Since the patient had already been injected, the technologist decided to increase the scan speed, from 12 cm/min as prescribed in the SOP to 18 cm/min, in order to lower the total examination time.

— *Question 1*: Is this a non-conformance? *Answer:* No, provided that the deviation from the SOP is properly documented in the patient file so that the nuclear medicine physician can properly interpret the images.

9.3. CORRECTIVE AND PREVENTIVE ACTIONS

Corrective actions are a set of coordinated initiatives aimed at eliminating the cause (or causes) of a non-conformance, mitigating its negative effects once it has occurred and preventing its recurrence.

The same approach is used if a potential non-conformance is detected before it occurs: in this case we speak of preventive action. A preventive action is aimed at eliminating potential causes and preventing the occurrence of a non-conformance.

For this reason, both corrective actions and preventive actions are typically addressed in one single procedure, which is referred to as corrective/preventive actions procedure (frequently, the acronym CAPA is used).

9.3.1. Root cause analysis

The management of a corrective/preventive actions procedure is another essential element of a QMS, following the management of non-conformance. It is a key point in continuous improvement: it is expected not only that the current problem is solved, but that actions are taken to prevent that the same problem in the future.

This requires the identification of the root cause(s), typically by running through the following steps:

- Identify the problem;
- Assign responsibility for taking corrective action;
- Evaluate the importance of the problem;
- Investigate possible cause(s) of the problem;
- Analyse the situation in view of possible solutions;
- Define actions to prevent recurrence of this or similar problems;
- Implement new process controls as necessary;
- Determine what to do with the current occurrence (mitigation);
- Record permanent changes in process documentation.

One of the most frequently adopted methods for setting up a corrective/preventive actions procedure, applying the previous steps, is setting up a focus group which draws up an action plan defining methods, responsibilities and timelines. The quality manager or quality committee will follow the development of the action and monitor its progress together with the working group. Finally, the group and the committee will verify the effectiveness of the action proposed and initially tested.

If the verification is positive, the action can be closed and duly registered. If the results obtained are not yet satisfactory, the cycle will be repeated, suggesting adjustments and new solutions which, once again, will be tried and assessed. Figure 13 reports a flow chart for the implementation of corrective actions.

9.3.2. Examples of root cause analysis

9.3.2.1. Example 1: Corrective action

Administration of ⁹⁰Y microspheres: The product in use is not ready and the required activity needs to be dispensed in a vial before the administration.

This operation is to be performed inside a laminar flow hot cell; the technologist with the most training in this type of operation was on leave, so



FIG. 13. Sample flow chart of corrective action.

another technologist with relevant general experience, but no experience in the manipulation of microspheres, had to take on the task.

While adjusting the volume to be dispensed, the suspension of microspheres (which is very dense) obstructed the needle. Pushing the piston of the syringe produced a spray of the product from the cone of the syringe; a simple cone fitting was used, not a Luer lock type. The spray contaminated the skin of the right forearm of the technologist, who was wearing a short-sleeved shirt and gloves, meaning their forearm was not protected.

Decontamination was instantly attempted, but with limited success.

Follow-up: A working group was immediately set up, comprising a nuclear medicine physician, a medical physicist and a nuclear medicine technologist; a physician in the occupational medicine service was consulted.

The event was reported as an incident in the hospital database. It was also recorded as a non-conformance in the department's register.

The medical physicist evaluated a surface of about $10 \times 3 \text{ cm}^2$ showing non-removable contamination that was estimated to 60 Bq/cm², for a total of 1.8 kBq. Using the contamination skin dose factor reported by Delacroix [51], the projected integral dose to the skin was estimated as 340 mSv.

It was decided that no further medical actions were required but that there should be periodic monitoring by the occupational medicine service.

The SOP for dispensing ⁹⁰Y products was carefully reviewed and updated. The type of syringe and needle to be used in dispensing was clarified. The paragraph indicating the clothing worn by staff during these operations was rewritten, emphasizing the need for proper protection against contamination.

9.3.2.2. Example 2: Preventive action

During one of the first administrations of ²²³Ra dichloride therapy, the nuclear medicine physician suspected that there could be an extravasation. The injection was immediately suspended. The injection line was repositioned and flushed with saline. Once the situation appeared to be satisfactory, administration was resumed and completed successfully. Gamma camera images of thorax and abdomen, taken to confirm biodistribution, and including the two injection sites, showed that in the first injection site there was a minimal retention, evaluated as approximately 2% of the total administered activity.

Nevertheless, the nuclear medicine physician recorded the event as an incident and a non-conformity.

Follow-up: A working group was established, including the nuclear medicine physician, chief technologist, chief nurse of oncological chemotherapy and a medical physicist.

They evaluated the scenario and decided to prepare a preventive action to prevent recurrences.

The nuclear medicine physician assumed the responsibility of undertaking a literature search to cross-check any recommendation and the possible, immediate action to be taken in case of an extravasation. The chief technologist, in cooperation with the nurse, checked the quality of needles and cannulas used to verify whether the quality of the material used for injection could have an influence and could be optimized. The medical physicist prepared a calibration of a portable contamination meter to allow for quick quantitative monitoring of extravasation, and a basic model for dosimetry to the skin.

Following these activities, the modality of injection of ²²³Ra dichloride was updated: a new type of cannula was adopted, and a systematic check of flow with saline was introduced. A specific form to be completed was introduced, with boxes to tick for every step. A kit containing dry ice and other first intervention aids was prepared. The calibration of the contamination meter was cross-checked with the activity meter, and a basic dosimetric model was prepared. The SOP for administration of all therapeutic radiopharmaceuticals was updated.

The preventive action was reported and closed.

10. MANAGEMENT OF EQUIPMENT AND OTHER MEDICAL DEVICES

The QMS should address requirements for the appropriate control of all equipment and instrumentation, including analytical devices, and manage their whole life cycle.

10.1. GENERALITIES

Strategic planning at the hospital level should derive from national or regional priorities defined for health care (e.g. a national cancer control plan or national plan for availability of orphan drugs that include PET tracers). Planning the introduction of high-end technologies, typically sophisticated and costly, is an important entry in the budget of a medical institution and a driver of innovation. Specific inputs are required from the professionals of each area, and this is particularly true for the NMS.

Planning for the availability of proper buildings and facilities is required to facilitate the projected changes in clinical services mentioned in this publication. The availability of space, specifically, the space required for the NMS, should be carefully assessed. When needed, this assessment will include space for radionuclide therapy wards, a dedicated building for a cyclotron and a new radiopharmacy. It should also include renovations or relocations to host PET/CT scanners. Special consideration should be given to logistical and construction aspects, such as, but not limited to, patient flow, radiation shielding and the

spatial separation of hot and cold areas as well as escape routes for emergency evacuations. Optimal relative positioning of the reception area, patient waiting area, physicians' offices, injection rooms, scanner rooms and laboratories can help improve the throughput and efficiency of clinical processes as well as reducing occupational radiation exposure of NMS staff [33, p. 126]. A laboratory for the preparation and dispensing of radiopharmaceuticals has very specific requirements concerning quality of air, ventilation, air pressure regime, etc., as specified in Ref. [33, p. 126] and in annex 3 of EudraLex — Volume 4 — Good Manufacturing Practice (GMP) guidelines [52].

Some of the topics relevant for this strategic planning include long term perspectives, which require analysis of:

- Projected growth of clinical services to match demand, adoption of new types of services and new technologies available for scanning and laboratory operations;
- Equipment to be acquired, with annual and long term (five years) investment planning including total cost of ownership, all forms of acquisition (capital cost, leasing, etc.) and maintenance.

10.2. EQUIPMENT INVENTORY

An accurate inventory of existing equipment in the NMS is necessary to plan any further acquisition or timely replacement. Ideally, electronic records should be available for each instrument and should include the following information [53]:

- Unique identifier for each piece of equipment;
- Certification and quality marks;
- Description and photograph;
- Price and estimated cost in case of replacement;
- Date of purchase and (updatable) expected life;
- Manufacturer and purchase supplier;
- Present location;
- Results of acceptance and commissioning;
- Service providers, protocols and schedule of maintenance (with contact information);
- History of maintenance (preventive and corrective);
- History of use;
- Calibration procedure, frequency and latest results;
- Operating status: in service, out of service or service restrictions;
- Documentation including instruction manuals;
- QA/QC results (may have a separate register);
- Software version;
- Depreciation and projected year of replacement.

The equipment inventory, combined with the NMS strategic or business plan, which defines expected future changes in the types and capacity of NMSs (see also Section 4.4), will allow senior management to develop a five-year plan for capital equipment, small equipment, infrastructure, human resources and the necessary annual budget, appropriately allocating financial resources to avoid untimely spikes of expenditures.

The life span of most types of equipment is typically 8–10 years, according to local regulations. Some elements may have a shorter lifetime (e.g. diagnostic displays, personal computers and software may require replacement every two years).

10.3. MANAGEMENT OF THE EQUIPMENT LIFE CYCLE

As previously discussed, an assessment of the total cost of ownership is a necessary component in the process of keeping equipment 'under control'. This is not a static figure but rather a dynamic one that should be continuously updated in accordance with the history of use, maintenance and failures of equipment. Figure 14 shows the failure rate over time during the life cycle of a piece of equipment (e.g. a PET/CT scanner). This requires contingency budgetary planning. Every manager should be aware that purchasing costs are only a fraction of the total cost of ownership. Additional 'hidden costs' should be considered, including the costs of the following:

- Transport and installation;
- Training;
- Staff;
- Operation and consumables;
- Preventive maintenance and repairs;
- Administration and supply;
- IT support;
- Refurbishing or upgrading;
- Removal.

Four phases in this life cycle could be considered:

- (a) Startup: Immediately after installation, the failure rate can be relatively high, requiring frequent corrective actions (typically spanning 18–20 months).
- (b) Normal working life: The equipment operates satisfactorily with an acceptable low failure rate (typically until year seven or eight).
- (c) Worn out: After phase (b), due to ageing and wear and tear, failure rates start to increase substantially, indicating that preparations should begin to replace or refurbish it.
- (d) End of life: Failure rates become unacceptably high, sometimes due in part to the equipment no longer being supported by the manufacturer (end of service).

As illustrated in Fig. 14, a scanner can have several issues when newly installed, minor or major premature failures, some of which may need to be resolved before it can be released for clinical use. In the first few months, this startup failure rate can be high, but it will rapidly decrease as the number of new problems identified becomes lower than the number that get resolved. Eventually, the downtime of the scanner becomes stable and acceptably low and remains so for several years to come (the 'normal working life' phase). Continuous use increases downtime near the end of the lifetime of the scanner. Certain parts begin to wear, and it is not feasible or economically viable to replace these parts. For



FIG. 14. The bathtub curve illustrates the typical failure rate pattern of a piece of complex equipment over its full life cycle. (A) Startup; (B) Normal working life; (C) Worn out; (D) End of working life.

a busy NMS with a fully occupied scanner, increased downtime will be a reason to start considering replacement. Better yet, the replacement process should have started earlier, as part of the strategic planning considering the up slope of the curve in Fig. 14, supported by inventory and maintenance data.

If the red flag of rising failure rates during the 'worn out' phase is ignored, these rates can become unacceptably high (resulting in the end of working life phase), seriously endangering continuity of care and thus forcing management to take (more expensive) short term decisions to replace the equipment.

10.4. MAINTENANCE AND ITS EVALUATION

In addition to QC, proper maintenance of all equipment, in particular medical devices, is required to ensure its safety, reliability and quality of performance. For a busy NMS, it is also important for downtime of crucial medical equipment such as the imaging modalities and the image processing and archiving systems to be kept at a low level and mainly be *planned* downtime. Scheduled preventive maintenance of scanners, as well as their corrective maintenance (repairs), should ideally take just a few per cent of the total working time on an annual basis, if well organized. To achieve this goal, preferably the NMS management and professionals in charge (clinical engineering, medical physics, certified commercial service provider) agree on a maintenance contract. This could be challenging in some regions due to the limited availability of professionals or service providers with the adequate experience and access to spare parts. Annual evaluation by the NMS manager and a medical physicist, of the service level offered by various service providers is necessary.

The availability of electronic records of inventory and maintenance is fundamental to enable a detailed analysis and evaluation of the service performance to be carried out. This evaluation should be based on documented indicators of performance such as total up time, unplanned downtime, time for completion of a repair, the frequency of repeated faults, cost of repairs, etc.

Maintenance is aimed at reducing equipment failure as much as possible and can be preventive (i.e. a routinely planned series of checks to keep the equipment fully operational) or corrective when a detected failure needs to be fixed. Figure 15 shows a typical flow chart of operations to keep any equipment under control.

10.5. THE CYCLE OF QA/QC

Equipment QC is an integral part of the routine work of the NMS. It should be performed by competent staff of the NMS in collaboration with the medical physicist and the staff performing the maintenance. The cycle of QA/QC for each piece of equipment starts prior to the purchase with the specification of requirements and the selection from competing alternatives. All aspects that may influence performance should be considered at an early stage, including the choice of appropriate site for installation, all necessary accessories (collimators, workstations, etc.) and object tests and phantoms for QA/QC.

Considerations for site choice may include the following:

- Influence of interference from adjacent sources of radiation (e.g. other scanners, therapy wards, waiting rooms for injected patients);
- Interfering magnetic fields;
- Sunlight entering the reading, reporting, or scanner rooms;
- Accessibility for large crates and smooth workflow;
- Structural characteristics (floor reinforcement);
- Reliability and safety of the power supply;
- Room environment (e.g. temperature and relative humidity).



FIG. 15. Equipment management flow chart modified from Ref. [53].

10.5.1. Acceptance tests and commissioning

Before clinical use, detailed acceptance tests and commissioning are required [17]. Acceptance tests can be performed at different instances: at the factory (factory acceptance tests, also known as FAT), at the site (site acceptance tests, also known as SAT) after installation and just before warranty expiration. Acceptance tests should check performance against the manufacturer's specifications and user's requirements. These tests should be performed by experts of the institution and may be counterchecked by the experts or engineers from the supplier company in instances of disagreement. The above applies also to equipment donated or acquired through grants.

During the commissioning phase, reference values of performance parameters should be obtained for use in monitoring subsequent results of routine tests. Finally, other tests may be necessary to validate the characteristics, at least for specific classes of equipment such as installation qualification, operational qualification and performance qualification for radiopharmacy equipment.

Results from all of these tests should be kept and linked to the equipment inventory. Any non-conformance, deviation or unsatisfactory performance should result in appropriate corrective actions.

Key components of the QA/QC programme should include at least the following [54–58]:

- (1) Set of requirements for the procurement process, including formal vendor response;
- (2) Equipment inventory;
- (3) Education and training of human resources;
- (4) Establishment of documentation including SOPs on use, QA/QC and maintenance;
- (5) Definition of responsibilities for QA/QC, reporting non-conformance and deviations, etc.;
- (6) Implementing the routine QA/QC programme considering manufacturer information and international guidelines;
- (7) Communicating status of equipment to users;
- (8) Managing accessories (phantoms, sealed sources, dosimeters, etc.);
- (9) Monitoring of preventive maintenance;
- (10) Initiating corrective actions as required;
- (11) Periodical audits on QA/QC.

Examples of results of QA/QC tests, their analysis (e.g. time trend curves) and actions taken are given in Fig. 16 which illustrates the value of frequent QC for a gamma camera. Monitoring of the intrinsic uniformity of a scintillation detector

(one of several parameters monitored) reveals gradual performance degradation. A detector reburn was performed in this example to correct for emerging nonlinearities. As a consequence, uncorrected uniformity improved dramatically, especially in the periphery of the field of view. Afterward, the reburn uniformity degraded again, very slowly, indicating the need for another reburn.

Setting action levels is helpful in deciding when to initiate corrective maintenance. It also helps to demonstrate that corrective maintenance has successfully restored uniformities to proper levels.

The activities included in the QC programmes of nuclear medicine equipment are shown as a flow chart in Fig. 17.

10.6. ROLES AND RESPONSIBILITIES IN EQUIPMENT MANAGEMENT

Table 9 summarizes the different levels of equipment management and staff involved.



FIG. 16. Time series of monthly acquired intrinsic uniformities of a gamma camera. CFOV values represent the uniformities in the smaller central field of view area. UFOV = (larger) useful field of view. The large arrow at the top indicates when corrective action was taken after the UFOV action level was exceeded [56].



FIG. 17. Flow chart of QC programmes for nuclear medicine equipment.

TABLE 9. ROLES AND RESPONSIBILITIES IN EQUIPMENT
MANAGEMENT

Activity	Hospital/institution management	NMS management	NM technologist	Medical physicist
Equipment purchase	Approve purchase and cost of ownership	Specify requirements	Specify requirements	Specify requirements
Equipment acceptance	Manage follow-up in case of any NC	Specify acceptance criteria	Functional acceptance	Perform acceptance test; monitor corrective actions
Equipment use	Provide backup power for critical instruments	Authorize users; review performance periodically	Be well-trained and responsible users; report performance deviations	Approve purpose; Review performance.
QC; calibration	Manage follow-up in case of any NC	Review QC and calibration status	Perform user QC; report deviations	Review QC and calibration status; perform selected tests.
Maintenance and repair	Provide funds	Periodically evaluate maintenance services	Report deviations and malfunctioning	(Perform or request QC before) clearance for clinical use
Inventory control	None	Perform inventory control	None	Assist in inventory control

NC = non-conformance; NM = nuclear medicine; NMS = nuclear medicine service

10.7. END OF SERVICE LIFE AND EQUIPMENT DISPOSAL

End of service life is the condition of equipment for which the manufacturer no longer provides service or spare parts. When it has reached this condition, when proper operation is no longer achievable, or when the cost of repair is disproportionately high, the equipment should be taken out of service. Equipment that was donated or acquired under a grant may have specific disposal conditions. Radioactive components in equipment, as well as vacuumpacked components such as photomultiplier tubes, require specific arrangements for disposal as waste.

10.8. PROVISION AND MANAGEMENT OF RESOURCES

10.8.1. Purchase of equipment, products and services

Regarding the evaluation of suppliers, an NMS typically does not issue orders directly for the acquisition of new products but needs to comply with regulations and institutional processes for procurement as well as relevant legislation.

The NMS has the responsibility to define technical specifications for goods or services to be purchased as well as for any new siting requirements that come with the new equipment. Provisions for the incorporation of radiation protection and safety features that have been made at the facility design stage may no longer be sufficient. For example, when a SPECT camera is to be replaced by a SPECT-CT camera, room shielding needs to be re-assessed and increased shielding material may be required. A similar evaluation is required regarding the power supply because of the added CT. The siting and layout should take into account workload and patient flow within the nuclear medicine facility [33, para. 4.8].

It is typically the responsibility of the procurement office to action the purchase. Recommended steps are as follows:

- The head of the NMS, in collaboration with the appropriate staff in the department (e.g. the most experienced physicians, the medical physicist or the radiopharmacist, the chief technologist and the coordinator of the nurses, etc., as needed), defines the requirements and technical specifications of the equipment or product.
- In case of large investment projects, the assignment of a dedicated project manager may be considered, as proper project management is an expertise and it can represent a substantial workload.
- Technical specifications should include provisions for all applicable certifications and quality marks (such as US Food and Drug Administration clearance, the European CE mark for medical devices or marketing authorization for radiopharmaceuticals).
- Technical specifications should be drafted and distributed to all staff involved for feedback.

- The purchase request should accurately specify the desired materials, in specific quantities and within a specified time, taking into account the institutional timeframe.
- The request should be suitably documented and, if appropriate, contain a cost-benefit analysis of the introduction of the new good, equipment or product.

During the prepurchase phase (market research and/or technical checks), the head of the NMS, in collaboration with appropriate staff, should be involved in the evolution of the process, participate in the assessment phases of competence and, if necessary, participate in the tender commission.

At the end of the technical and economic evaluations (such as a cost and quality analysis), the final purchase order is issued.

Before clinical use, the new equipment or product should undergo detailed acceptance tests as defined in Section 10.5.1.

Generally, there are at least two different levels governing the procurement of goods and services:

- (a) Below a specified threshold for the total cost, purchasing procedures may be simplified (e.g. requiring three offers from different vendors), and the supplier may be assigned directly.
- (b) Above a specified monetary threshold, it may be necessary to go through a formal tender process.

This differential approach should correspond to a graded involvement of the NMS. The level of detail requested for the specifications may differ, as may the complexity of the acceptance test. Nevertheless, an adequate level of involvement is always necessary and should be properly documented.

Purchase procedures of the NMS should be documented, containing a description of the aspects detailed in Section 10.8.1 and how they are implemented. This approach should be applied to all products, devices and equipment. Both major and minor equipment should be under control.

10.8.2. Selection, ordering and control of acquired radiopharmaceuticals, kits

The purchase of radiopharmaceutical products is a key factor in the operation of an NMS, and specific regulations exist. In addition to the information in Section 10.8.1, these aspects are discussed in Section 8.10.2.

Here, it may be worthwhile to remember that the expenditure for radiopharmaceuticals is a running cost, spread throughout the year. The head of the NMS, in collaboration with the appropriate staff in the department (e.g. the radiopharmacist, the chief technologist) and with the institution's offices, should regularly monitor the level of expenditure against the workload performed and the yearly available budget.

10.8.2.1. Example 1: Acquisition of syringes, needles, cannulas, butterfly lines, etc.

These supplies are fundamental for proper administration of radiopharmaceuticals and should be of sufficient quality to avoid risk of spillage, reduce the risk of extravasation, etc., given that these aspects are of particular relevance when the pharmaceuticals in use are radioactive. It should be considered that nuclear medicine procedures are in many cases quantitative, and a suboptimal injection can potentially hinder the quantitative aspects of a procedure.

- *Question*: Do acceptance tests also apply to products such as syringes, needles, cannulas and butterfly lines?
- Answer: Yes. Tests may include checking the accurate tightness of the piston of syringe, the eventual absorption of radioactive material in the piston seal, the accuracy of the volume graduation, etc. There is a lot of testing that is feasible and also applies to devices that have a minimal unit cost. It should be borne in mind that, even if the cost of single syringes is low, their total consumption may result in a significant budget. Given the previously discussed aspects of safety, it should be clear that all components and devices need careful testing before being accepted and placed in routine use.

10.8.2.2. Example 2: Acquisition of gloves

Gloves are typically used in nuclear medicine procedures for hygienic reasons and to prevent radioactive contamination.

- Question: Are all types of gloves effective in controlling contamination?
- Answer: In general, every type of glove can be useful in at least reducing the risk of radioactive contamination as well as in diminishing the biohazard. However, it should be noted that the most frequently used type of latex gloves, generally adopted for medical examination, are not fully 100% leak proof; some liquid could filter through the surface of these gloves. When there is a low risk of contamination, and in activities with short lived radionuclides for diagnostic use, latex gloves are generally adequate. When there is increased risk of contamination, as when manipulating beta or alpha emitters for therapy, it could be useful to consider nytril gloves and

other alternatives to latex in order to further reduce the risk of contamination. Testing of gloves can be done both in the laboratory and practically, by using them and asking the operators to report on their personal experience when using different types.

10.8.2.3. Example 3: Acquisition of radiopharmaceuticals

A great number of nuclear medicine departments operate at radiopharmacy level 1 (see Section 8.10), which means receiving ready-to-use radiopharmaceuticals from a centralized radiopharmacy or an industrial provider.

- *Question*: When receiving unit doses that are ready to use, is some QC necessary?
- Answer: Yes. The QC necessary to release the batch of production was carried out by the manufacturer, and this should be trusted. However, the concept of QC does not apply only to tests such as radiochemical purity, pH, etc. Testing unit doses includes carefully checking whether what was ordered corresponds with what was with: condition and cleanliness of the carrying containers, number of unit doses, type of pharmaceutical, activity and reference time should be regularly checked and reported. Any deviation from what was expected should be recorded and the provider should be notified of the non-conformance. Careful recording and periodical statistical analysis of this data is of primary importance to evaluate the supplier at the time of the renewal of the contract.

11. MEASUREMENT, ASSESSMENT AND IMPROVEMENT IN QMS

11.1. DEFINITION OF INDICATORS AND RECORDING METHODS

Quality indicators in nuclear medicine are well defined metrics used to monitor, analyse and improve all of the processes in the process map (Fig. 2). This is particularly applicable for diagnostic and therapeutic procedures but should also be applied to supporting and managerial processes.

Regular collection and appropriate analysis of quality indicator data should be carried out to evaluate key components of the NMS, such as clinical activities, radiation protection, radiopharmacy, operation, equipment performance, nonconformance statistics and the like. Systematic use of indicators is also very helpful to assess and enhance administrative and managerial activities and processes. Relevant aspects such as non-conformances, corrective preventive actions, patient satisfaction, staff compliance for CPD and the achievements of the quality objectives should be regularly monitored and evaluated.

The quality indicators should be 'specific, measurable, achievable, relevant and time-bound' — typically referred to by the acronym SMART. Selected quality indicators are assigned as key performance indicators for an NMS, allowing the monitoring of pertinent activities. Within the framework of continuing improvement, the set of key performance indicators is dynamically adapted over time. Indicators should be selected according to an analysis of needs and the existing situation as well as in consideration of the mission vision and strategic plan. Table 10 indicates the variety of dimensions of care that are relevant. Table 11 provides a list of indicators that should be regularly monitored to keep clinical services operational and at high quality.

11.2. SAMPLE PARAMETER AND INDICATOR VAULES

11.2.1. Indicator Code: CLS-1 — Key area or process: Clinical activities

Objective: The nuclear medicine diagnostic imaging and therapeutic services should match with the clinical demand

Indicator: Productivity in the current period *Definition/formula:*

 $Indicator Value = \frac{100 \times Performed \ studies \ in \ current \ period}{Performed \ studies \ in \ reference \ period} (\%)$

Unit: % Acceptable range for the indicator: Minimum value of 95% Periodicity of evaluation: Monthly Responsible (data collection and analysis): Physicians le

Responsible (data collection and analysis): Physicians leading clinical activities

Clarifications: The expected tendency is increasing

11.2.2. Indicator Code: CLS-2 — Key area or process: Clinical activities

Objective: To provide NMS on a mean period lower or equal to two weeks after examination requests

Indicator: Mean time between request and study completion

TABLE 10. DIMENSIONS OF CARE AS THEY RELATE TO PERFORMANCE INDICATORS

Dimension of care	Performance indicators					
Patient safety	Patient falls Reactions and extravasations Minor and major procedural complications Physician compliance with hand washing requirements Compliance with preprocedural time outs Verification and documentation of patient identification Radiation dose reduction for CT component of SPECT/CT and PET/CT scans					
Effectiveness	Outcomes measures for procedures Appropriateness of imaging studies Positive predictive rates for modalities Physician performance assessment and peer review					
Efficiency	Reduction of unnecessary studies Number of technologists per scanner Scanner use Scanning room turnaround time Equipment downtime for maintenance					
Patient- centredness	Patient satisfaction surveys Analysis and management of customer complaints Communication and follow-up of abnormal results and unexpected or significant findings					
Timeliness	Waiting list Report turnaround time Patient throughput Patient wait times inside the department					

Definition/formula:

Indicator Value =
$$1/N\sum_{i=1}^{N} [StudyDate(i) - RequestDate(i)]$$

Unit: Number of days

Acceptable range for the indicator: Mean value equal to or lower than 14 *Periodicity of evaluation:* Quarterly

TABLE 11. EXAMPLES OF INDICATORS REGULARLY CONTROLLED IN AN NMS

Code	Indicator	Key Area	Comment/Justification
CLS-01	Achieved clinical demand	Clinical activities	Ratio between studies currently performed vs a reference period, or vs an assigned goal. (Clinical services should match the demand.)
CLS-02	Report release time (turnaround time)	Clinical activities	Average times between study completion and report release for different study types.
CLS-03	Wait lists for different types of studies	Clinical activities	Average times between receipt of referral, booking and the study being undertaken.
CLS-04	Study repetition rate due to technical issues	Clinical activities	Ratio between patients requiring study repetition and the total number of studies performed.
RP-01	Number of kits labelled, or synthesis performed, for most relevant types of radiopharmaceuticals	Radiopharmacy activities	Ratio between the dispensed radiopharmaceutical doses and the number of labelling/ synthesis performed (acceptable criteria will vary for different products).
RP-02	Number of kits labelled or synthesis of radiopharmaceuticals that did not meet quality criteria and were not released for use	Radiopharmacy activities	Per cent of rejected radiopharmaceutical labelling/synthesis that do not meet the requirements (radiochemical or radionuclidic purity, labelling/synthesis yield, or other pharmacopoeia parameters).

TABLE 11. EXAMPLES OF INDICATORS REGULARLY CONTROLLED IN AN NMS (cont.)

Code	Indicator	Key Area	Comment/Justification		
RP-03	Adverse effects or other incidents related to radiopharmaceutical administrations	Radiopharmacy activities	Per cent of patients with adverse effects vs number of studies performed.		
RPr-1	Optimization of occupational exposure	Radiation protection	95% or more of employee annual radiation doses that are lower than established constraint (e.g. 2 mSv).		
RPr-2	Number of NC related with radiation protection (e.g. spills, surface contamination, etc.)	Radiation protection	Total number of NCs related to the management of radioactive materials should be below the established threshold levels.		
IEq-1	Preventive maintenance of nuclear medicine equipment	Nuclear medicine equipment	Ratio between the delivered preventive maintenance and the annual plan.		
IEq-2	Completion of QC activities of nuclear medicine equipment	Nuclear medicine equipment	Ratio of performed QC vs planned QC activities.		
IEq-3	Up time of major equipment and number of lost studies due to problems with medical equipment	Nuclear medicine equipment	Total up time (no. of hours of availability vs total no. of working hours, e.g. >98%). Number of lost studies due to problems with the nuclear medicine equipment (e.g. <2% of total number of studies performed).		
HR-01	Training of nuclear medicine staff on radiation protection topics	Human resources	Per cent of delivered training vs annual training plan on radiation protection topics.		

TABLE 11. EXAMPLES OF INDICATORS REGULARLY CONTROLLED IN AN NMS (cont.)

Code	Indicator	Key Area	Comment/Justification
MgS-01	Customer complaints (patients, referring physicians, etc.)	Management	Ratio between number of client complaints and total amount of studies performed.
MgS-02	Patient satisfaction evaluation	Management	Per cent of patients providing positive criteria of satisfaction versus total number of surveys.
MgS-03	Monitoring of budgetary expenditure	Management	Per cent of executed vs planned budget for nuclear medicine activities.
MgS-04	Achievement of quality objectives	Management	Ratio of achieved vs planned objectives.

NC = non-conformance

Responsible (data collection and analysis): Physicians leading clinical activities

Clarifications: Maximum value for any single data point should be lower than three weeks

11.2.3. Indicator Code: RPr-1 — Key area or process: Radiation protection

Objective: To guarantee that occupational exposure is optimized based on the data analysis of personal radiation monitoring

Indicator: Optimization of occupational exposure for occupationally exposed individuals (OEI)

Definition/formula:

 $Indicator value = \frac{100 \times number of OEIs with Eff.doses < 1.5 mSv}{Total number of OEIs} (\%)$

Unit: % *Acceptable range for the indicator:* Minimum value = 95%

Periodicity of evaluation: Annually

Responsible (data collection and analysis): Radiation protection officer *Clarifications:* 95% or more of employee radiation doses < one quarter of the regulatory constraint levels (e.g. 6 mSv). Maximum value of one single measurement should be lower than one month.

11.2.4. Indicator Code: RP-01 — Key area or process: Radiopharmacy

Objective: To guarantee that preparations and dispensation of radiopharmaceutical doses match the planned clinical studies

Indicator: Dispensed radiopharmaceutical doses *Definition/formula:*

 $Indicator \ value = \frac{100 \times Dispensed \ radiopharmaceutical \ doses}{Planned \ radiopharmacerical \ doses} (\%)$

Unit: %

Acceptable range for the indicator: Minimum value of 98% Periodicity of evaluation: Monthly

Responsible (data collection and analysis): Director of radiopharmacy lab *Clarifications:* This indicator provides a global measurement of the radiopharmacy activities.

11.2.5. Indicator Code: RP-02 — Key area or process: Radiopharmacy

Objective: To guarantee that preparations and dispensation of radiopharmaceuticals doses match the planned clinical studies

Indicator: Dispensed radiopharmaceutical doses *Definition/formula:*

 $Indicator \ value = \frac{100 \times Dispensed \ radiopharmaceutical \ doses}{Planned \ radiopharmacerical \ doses} (\%)$

Unit: %

Acceptable range for the indicator: Minimum value of 98% Periodicity of evaluation: Monthly

Responsible (data collection and analysis): Director of radiopharmacy lab *Clarifications:* This indicator provide a global measurement of the radiopharmacy activities.

11.2.6. Indicator Code: RP-03 — Key area or process: Radiopharmacy

Objective: To guarantee that preparations and dispensation of radiopharmaceuticals doses match the planned clinical studies.

Indicator: Dispensed radiopharmaceutical doses *Definition/formula:*

 $Indicator \ value = \frac{100 \times Dispensed \ radiopharmaceutical \ doses}{Planned \ radiopharmacerical \ doses} (\%)$

Unit: %

Acceptable range for the indicator: Minimum value of 98% Periodicity of evaluation: Monthly

Responsible (data collection and analysis): Director of radiopharmacy lab *Clarifications:* This indicator provide a global measurement of the radiopharmacy activities.

11.2.7. Indicator Code: IEq-1 — Key area or process: Nuclear medicine equipment

Objective: To ensure that nuclear medicine imaging equipment are able to provide good clinical services through a regular programme of preventive maintenance.

Indicator: Performed the maintenance programme of nuclear medicine equipment

Definition/formula:

 $Indicator \ value = \frac{100 \times Number \ of \ performed \ maintenances}{Planned \ maintenances} (\%)$

Unit: %

Acceptable range for the indicator: Minimum value of 90% Periodicity of evaluation: annually

Responsible (data collection and analysis): Bioengineer specialists

Clarifications: Indicator related to maintenance of imaging and complementary equipment

11.3. CUSTOMER SATISFACTION

The nuclear medicine service needs to implement procedures to track the perceptions of its customers (patients, referring physicians, patient's relatives, etc.) about the degree to which their needs and expectations were met. Therefore, the quality committee, supported by the nuclear medicine staff, should implement suitable methods to periodically collect and analyse objective and tangible results about the services provided to its customers and to improve them. It typically includes questionnaires or surveys, the regular solicitation of customer complaints, compliments or suggestions, plus other complementary and traceable feedback.

Periodical reviews and improvements of the evaluation methods (e.g. survey content) should be established. The SOPs will also contain all activities to estimate patient satisfaction such as a step by step description of data collection, processing and analysis as well as the number of subjects to be included in each study, the frequency of evaluations, responsibilities and related concerns.

Based on customer satisfaction surveys and the institution's continuous improvement policy, the quality management should agree with the nuclear medicine management on actions to meet customer expectations as far as possible and as reasonably achievable. Questions in patient surveys should allow for evaluation of the key aspects and activities, be simple and clear, and provide space for unrestrained replies or comments. Questionnaires should be tailored for a wide range of educational levels, according to the local culture and situation. The number of questions should be limited, and the content personalized for each NMS. An example of questions and the evaluation of patient satisfaction is shown in Table 12.

Aspects of customer satisfaction	No. of patients	%	Preliminary target	Target type
I received NM brochure before study	83	81*	90	min
NM information brochure explained the procedure in detail and was easy to understand	71	70*	90	min

TABLE 12. SAMPLE FINDINGS OF A CUSTOMER SATISFACTION SURVEY

TABLE 12. SAMPLE FINDINGS OF A CUSTOMER SATISFACTION SURVEY (cont.)

Aspects of customer satisfaction	No. of patients	%	Preliminary target	Target type
The information brochure answered all my questions	59	58*	70	min
The information brochure answered some of my questions	29	28	30	max
I could reach the NMS by phone or email directly	84	82*	95	min
I was not informed that NMS they could be reached by phone or email directly	16	16	20	max
More information should have been included in the brochure	65	64*	40	max
The NMS premises were clean	72	71*	80	min
The personnel looked professional	67	66*	80	min
Staff identified themselves	93	91*	95	min
The service delivery was satisfactory	72	71*	80	min
The service delivery was not satisfactory	44	43*	20	max
The technologists were able to answer my questions	86	84	80	min
I received a kind treatment and felt comfortable during the entire procedure	62	61*	80	min

TABLE 12. SAMPLE FINDINGS OF A CUSTOMER SATISFACTION SURVEY (cont.)

Aspects of customer satisfaction	No. of patients	%	Preliminary target	Target type
Front desk service was satisfactory	81	79*	80	min
Front desk service was not satisfactory	45	44*	20	max
The room temperature was comfortable	76	75	70	min
I was seen on time	82	80	80	min
I was not seen on time	14	14	20	max
Staff were professional and knowledgeable	89	87	80	min
Total number of questionnaire responses received and analysed	102			
Total number of responses equal to, or better than target	7	35		
*Total number of responses where target was not met	13	65		

11.4. PERFORMING MANAGERIAL REVIEW

The department head is responsible for planning and conducting managerial reviews with the support of the quality committee or quality manager, all section heads and/or senior staff. In some cases, management may decide to involve other staff members or even all departmental staff to keep them informed about the achievement of departmental objectives.

Data collection and support documentation is typically assembled by the quality committee or quality manager and submitted to management for further examination and discussion during the managerial review meeting.

The quality committee or quality manager is also responsible for preparing reports of the review meetings, as well as the preparation of the quality plan and corrective or preventive actions (see Section 9.3.1).

Reviews should be performed at regular intervals, according to a preestablished calendar — typically three to four times a year — and usually consist of an analysis of predefined indicators (objective elements that help assess the current situation). These indicators (see Section 11.1) are selected to become significant markers of the quality system's performance, to assess the achievement of the stated objectives as defined in the quality policy, in the yearly plans, or as assigned by the higher management of the institution. Other useful quality indicators are included, such as the number and type of non-conformances, results of customer satisfaction surveys, results of internal audits, etc.

The indicators can be supplemented or modified during the managerial review activity, as required.

Typically, the review is based on a report prepared by the quality committee or quality manager. This is often prepared in the form of a matrix or table (see Fig. 18): specific objectives or plans are identified in each row, while expected and achieved results for each evaluated period are reported in the columns.

Through this managerial review, the results of the implemented quality policy and any deviations from the objectives can be verified. Based on the results of the review, the department head and the quality committee or quality manager will have the opportunity to discuss general corrective measures and/or redefine the policy and the objectives linked to it. In general terms, the managerial review can be viewed as a tool to 'fine-tune' the QMS.

Follow-ups from former management reviews are regularly carried out in order to identify gaps and evaluate the implementation and efficacy of previously planned corrective actions and how the identified 'opportunities for improvements' were achieved.

	Report No.									
								Rev. 1		
LOGO		REPORT FOR MANAGERIAL REVIEW								
								DD/MM/YYYY		
	1		1	1	1		1			
OBJECTIVES	Expected result 1 st quarter	Achieved result 1 st quarter	Expected result 2 nd quarter	Achieved result 2 nd quarter	Expected result 3 rd quarter	Achieved result 3 rd quarter	Expected result 4 th quarter	Achieved result 4 th quarter		
Date of review	dd/mn	n/vvvv	dd/mn	n/vvvv	dd/mi	n/vvvv	de	l/mm/yyyy		
1.0 Objectives set out h	by the Institution	on Manageme	nt							
1.1 Objectives set out h	by the Departm	ient								
1.2 Other objectives										

FIG. 18. Sample managerial review form.

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Annex I

SAMPLE TABLE OF CONTENTS FOR A QUALITY MANUAL

- (1) Object and scope of the manual.
- (2) Service presentation;
 - (a) Service's general data;
 - (b) Organization chart;
 - (c) Roles and responsibilities;
 - (d) Catalogue of services/portfolio.
- (3) Quality policy and objectives;
 - (a) Mission and vision;
 - (b) Objectives for the current year;
 - (c) Midterm objectives.
- (4) Quality management system;
 - (a) General requirements;
 - (b) Documentation requirements;
 - (c) Documentation control;
 - (d) Records control.
- (5) Management responsibility;
 - (a) Management commitment;
 - (b) Patient focus;
 - (c) Quality policy;
 - (d) Planning;
 - (e) Responsibility, authority and communication;
 - (f) Management review.
- (6) Management and development of resources;
 - (a) Human recourses;
 - (b) Financial recourses;
 - (c) Infrastructure;
 - (d) Working environment.
- (7) Product realization: Providing nuclear medicine services;
 - (a) Diagnostic nuclear medicine services;
 - (b) Radiation protection and equipment control;
 - (c) Equipment control;
 - (d) Radiopharmacy.
- (8) Purchasing;
 - (a) Identification and traceability.
- (9) Measurement, analysis and improvement;
 - (a) Patients' satisfaction;

- (b) Internal audits;
- (c) Monitoring and measurement of processes;
- (d) Control of non-conforming items;
- (e) Data analysis;
- (f) Continuous improvement;
- (g) Incident reporting.
- (10) Glossary, terms and definitions.
- (11) Quality manual revision status.

Annex II

SAMPLE SOP FORM FOR DIAGNOSTIC PROCEDURES

Name of De	pt / Instituti	ion					
EXAMINA PROCEDU	FION RE GUIDEI	LINE	CODE	DATE	RE	V. AUTHOR	APPROVED BY
Description	of change:		CL- XXX	dd/mm/	01		
Type of examination				5555			
Purpose							
Clinical ind	cations						
Contraindic	ations						
			Pre-	examination p	rocedu	ıre	
Patient preparation							
Pre-injection	1						
Injection, do	sage and						
administrati	on						
Post-injection	on						
Possible sid	e effects						
			R	adiopharmace	utical		
Туре							
Description							
Preparation							
Injected acti	vity						
Quality con	rol						
Special prec	autions						
			r	Scanner set-	սթ		
Quality con	rol						
	Detector						
ant and	Collimato	or					
<u>n</u> E siti	Window						
Acqu	isition moda	ality					
드 C Optio	nal images						
Image proce	essing						
Sources of e	error						
Disclaimer							
Dosimetry							
			A	ssociated docu	ments		
				Records			
Tit	le	Co	de	File location	1	Record custodian	Retention period

ANNEX III

SAMPLE SOP FORM FOR THERAPY PROCEDURES

Name of Dept / Institution							
THERAPY PROCEDURE GUIDELINE			CODE	DATE	REV.	AUTHO	R APPROVED BY
Description of change: Initial release		Т	H-XXX	dd/mm/ yyyy	01		
Type of therapy							
Purpose							
Type of disease							
Indica	Contraindicatio	ons					
	Radiopharmac	у					
- Dose calculation							
Route of administration							
Hospital admission Required?							
	Facility						
0	Patient prepara	ation					
dure	Precautions						
oce	Dose						
Pr	Sources of erro	or					
Issues re	equiring clarification	ation					
Disclair	ner						
Dosime	try						
Dischar	ge						
			Asso	ociated docum	nents		
				Records			
Title		Code	File loc	ation	Record co	ustodian	Retention period

ANNEX IV

SAMPLE CLINICAL SOPS FOR DIAGNOSTICS WITH SINGLE PHOTON EMITTERS

Title: Bone Studies						
Version No.:	Reviewed by:	Date:	Next review:			
Purpose	To evaluate bony pathologies such as skeletal metastasis, arthritic disease, metabolic bone disease, osteomyelitis and bone fractures.					
Preparation	Explanation of the procedure including asking the patient to increase their fluid intake between the injection and scan (e.g. 3–4 glasses of any fluid). Patient should void just prior to scan commencing.					
Radiopharm.	99mTc MDP (Medronate)					
DOSE	600–700 MBq					
Equipment	Dual head SPECT/CT (specify brand and model). Each different system should have its own SOP.					
Procedure	Either a whole body or a limited bone study is performed, depending on the type of bony pathology being investigated. SPECT +/- CT imaging may also be performed upon assessment of the original images. All delayed images should be acquired using LEHR collimators (where possible) with imaging commencing a minimum of 3 hours post-injection, 4 hours for extremities.					
Patient Positioning	Head out, supine, arms straight on both sides of the trunk for WB imaging. Static acquisitions may require different positioning.					
Image acquisition parameters	 Dynamics: 3 sec/frame dynamic (for axial skeleton) or 5 sec/frame dynamic (extremities) Blood pool planar images: 240 sec with planar images positioned over the area of interest Whole body blood pool images: 20 cm/min (if required) Delayed statics: 300 sec (or 420–600 sec for extremities) Delayed whole body bone scan: 12 cm/min 					

Camera Set-up	 LEHR collimators; Number of frames = 60; 128 × 128 matrix; Orbit type — non-circular, step/shoot motion. 				
SPECT/CT	SPECT/CT acquisitions are optimized for patient body habitus with adjustments in SPECT acquisition times and CT parameters:				
	Patient's BMI	Acquisition Type	Sec/Step	CT Parameters (kVp/mA)	
	<22	SPECT/CT (S)	18	100/Dose Mod mA	
	22.1 - 34.9	SPECT/CT (M)	20	120/Dose Mod mA	
	>35	SPECT/CT (L)	22	140/Dose Mod mA	
WB SPECT/CT	Patient's BMI	Acquisition Type	Sec/Step	CT Parameters (kVp/mA)	
	<22	SPECT/CT (S)	14	100/Dose Mod mA	
	22.1–34.9	SPECT/CT (M)	16	120/Dose Mod mA	
	>35	SPECT/CT (L)	18	140/Dose Mod mA	
Processing and display	Image data should be processed and displayed ensuring all labels are correct. All raw data (excluding RAW CT) data and processed data to be transferred to PACS. Scan all appropriate documents into the NIS for reporting. If an external prior study is provided, upload images to PACS for comparison.				

LEHR = low energy, high resolution collimator; RIS = radiological information system; WB = whole body.
Annex V

SAMPLE CLINICAL SOP FOR PET/CT

Title: Standard ¹⁸ F-FDG whole body PET/CT protocol					
Version No.:	Reviewed by:	Date:	Next review:		
Purpose	To evaluate oncological patients (staging, restaging, therapy response, follow-up), hidden tumours, fever of unknown origin.				
Patient preparation	Fasting for 6 hours prior to injection time; water may be consumed in the fasting period. Insulin dependent diabetes mellitus (IDDM) patients should not have insulin within 6 hours of FDG administration unless advised otherwise by the PET consultant. The blood glucose level (BGL) should not exceed 11.0 mmol/L. Always check the timing prior to FDG administration so that a 60 minute uptake time can be achieved. To avoid extravasation of the IV, cannula for FDG administration should be checked for patency.				
PET/CT PROTOCOL	FDG dose and emission times can be tailored to patient BMI.				
	Patient's BMI	Dose (MBq)	Time/bed (mins/bed)		
	≤22	220	2		
	22.1–26	250	2		
	26.1–28	250	2.5		
	>28	300	3		

Scanning	Scanning should commence 60 minutes post-injection of ¹⁸ F-FDG. During the uptake period, patient should be resting quietly in a dark room, either on a bed or recliner chair. Bladder should be emptied just prior to scan commencing or, if necessary, catheterized. Attenuation correction can be performed using low dose CT scan or dose modulated CT scan. Standard WB acquisition: Defined as vertex upper thigh. Lymphoma: Standard WB. Ensure inguinal lymph nodes are included. Scan all lymphoma patients with their arms up unless the lymphoma is specifically involving a head and neck structure (i.e. lymphoma of the orbit or tonsil). Melanoma: Standard WB. The primary site and/or all known sites of melanoma are to be included. For unknown primary, scan head to toe. Lung, rectum and other diseases: Standard WB. Head and neck: Standard WB. Scan arms down and image head and neck first. PUO and vasculitis/arteritis: Vertex toe. Sarcoma and myeloma: Vertex toe. GIST: Scan as standard WB.
Processing & archive	Image data should be processed checking appropriate PET and CT fusion. All data to be transferred to PET workstation and PACS. Scan all appropriate documents into the RIS for reporting. If an external prior study is provided, upload images to PACS for comparison.

BMI = body mass index;

FDG = Fluorodeoxyglucose;

GIST = gastrointestinal stromal tumour

RIS = radiological information system;

WB = whole body.

Annex VI

SAMPLE CLINICAL SOP FOR THERAPY

Title: Radioiodine Therapy Procedure (inpatients)			
Version Number: Reviewed by: Date: Next Review:			
Purpose	To instruct all health care personnel involved in managing inpatients who receive I-131 therapies, including radioprotection issues, and avoiding contamination or mismanagement of contaminated waste material.		
Location	Rooms 415, 416 and 417 of the oncology ward are certified by regulatory agency to be used as radioactive isolation wards (reference to authorization/permit). Proper signs indicating radioactive isolation will be placed on doors. External monitoring by closed circuit cameras and telephone need to be working properly.		
Room preparation	Prior to patient admission, cover surfaces of night table, table, telephone, handles and light switches with plastic wrapping. Check for availability of disposable gloves, plastic bags as well as paper towels.		
Patient admission and preparation	Nurses will perform regular admission (vital signs, clinical history, allergies, medication) with a specific explanation of the isolation ward rules, forms of communication, waste disposal and general procedures. Written instructions about the isolation ward rules are to be handed to patients. Blood samples have to be drawn if indicated by treating physician (TSH, thyroglobulin, antithyroglobulin antibodies and B-HCG if applicable).		

Radiopharmaceutical	¹³¹ Iodine (capsule)
Activity	1.1–7.4 GBq (30–200 mCi)
Procedure	No other personnel should be in the patient room. A water bottle and disposable cup must be in place for administration. After administration, isolation will begin. No visits are allowed. All clinical indications will be entered in the patient's digital chart.
Patient monitoring during isolation	Remote monitoring will be performed by proper professionals. Should it be necessary, entrance to the isolation ward needs to be with proper radiation protection equipment (lead apron, gloves, dosimeter). The attending nuclear medicine physician will be on call during patient hospitalization.
Food and medication	All items (food trays, bottles, medication) will be placed on a plastic wrapped table outside the isolation ward and the patient will be told by telephone to pick it up and take it into their room. Empty trays will be taken out by the patient and measured for radioactivity by a nurse using a contamination monitor. If the reading is under the threshold value, the waste will be disposed. If the reading is above threshold, patient will be instructed to return the tray into the room. (See SOP on radioactive waste.)
Discharge	The attending physician will discharge the patient when the radioactivity emission at 1 metre is at or below the acceptable level according to country legislation and if there are no clinical complications. The patient will be given written instructions to continue isolation in his house, for thyroid hormone therapy replacement and for his or her whole body scan appointment in the NMS.
Room discharge	After the patient leaves the isolation ward, the radiation protection officer will measure the room for possible contamination and will provide authorization for the cleaning and preparation for a new patient. Contaminated bed linen, towels or waste materials will be stored in radiation decay compartments until cleared for laundry or disposal.

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A quality health service, as defined by the World Health Organization, 'is one which organizes resources in the most effective way to meet the health needs of those most in need, for prevention and care, safely, without waste and within higher level requirements'. As health care standards improve globally, providing an optimal service that meets international standards and public expectations requires effective quality management. The process of quality improvement aims at defining, measuring and setting quality standards and overcoming the associated challenges that include rising costs and skills shortages. The objective of this publication is to provide a framework for quality management systems (QMS) to be implemented, managed and sustained holistically in nuclear medicine departments. It builds upon the IAEA's QUANUM programme, which has successfully been implemented in more than 80 countries worldwide.

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