Basic of Quality Management for Nuclear Medicine Practices

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FOREWORD

According to the World Health Organization (WHO), “A quality health service 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”.

Indeed, quality improvement poses challenges to many countries striving to deliver optimal patient care which meets international standards. Public expectations of healthcare are now much higher than previously, in line with improving healthcare standards globally. These expectations have to be met amidst the challenges of rising costs of healthcare, skill shortages in some areas of medicine, and increasing patient activity.

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

This publication is built upon the experience gained from implementing a programme developed by the IAEA more than a decade ago, which has successfully been implemented in more than 80 countries worldwide: the QUANUM programme.

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

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1. INTRODUCTION

1.1. BACKGROUND

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

- patient quality (what patients want and experience);
- professional quality (what patients need and following best practice);
- management quality (efficiency and meeting regulations).

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

1.2. OBJECTIVE

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

This document is pertinent to:

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

1.3. SCOPE

This publication covers the basics of a QMS as applied to Nuclear Medicine Services (NMS) and is based upon the methodology, the reasoning and assumptions underlying the IAEA QUANUM programme [6].

1.4. STRUCTURE

The publication is separated into ten chapters, beginning by explaining 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, and the safety of patients and personnel. Advice is also provided on the preparation and control of the documentation system, from the preparation of a quality manual, formulation
of standard operating procedures, and preparation and use of indicators to keep the NMS running in the best possible way.

1.5. CLINICAL GOVERNANCE

Clinical Governance (CG) is a strategy by which health organisations, which are responsible for continuous improvement of the quality of services and achieving/maintaining high standards, encourage the creation of an environment that fosters professional excellence [7].

CG requires a different orientation of the organisational structure of healthcare providers, who are often seconded to an active role in the development of quality standards that must be defined, maintained and verified by the professional component [6]. 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 CG is dependent 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. CG 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 CG are risk management; 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 briefly discussed below.
2. RISK MANAGEMENT

Risk management is the systematic process, including both clinical and management dimensions, which 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 minimising risks by:

- using appropriate, scientifically-based tools to identify in advance what could go wrong during care, i.e. failure to plan and/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 resulting in unintentional and undesirable harm to the patient. Adverse events can be preventable or not preventable. An adverse event attributable to an error is "a preventable adverse event" and this includes ‘near misses’. A ‘near miss’ is an error which has the potential to cause an adverse event but by chance, because it is intercepted or because it has no adverse consequences for the patient it does not occur [9];

- identifying “sentinel events”, serious adverse events, potentially indicative of a significant malfunction in the system, which can result in death or serious harm to the patient. The high-risk level dictates that a sentinel event occurs only once for 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 do their job and duties to a high standard. They should be given opportunities to update and enhance their skills to keep abreast with the latest developments in the profession, as well as 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 defines any health intervention, be it preventive, diagnostic, therapeutic, or rehabilitative, related to the need of the patient (or the community). To be considered appropriate, those interventions should be based on recognized science and standards, and timely provided within acceptable timeframes, after appropriate analysis of budget, risks and benefits.

2.3. EXPERIENCE AND INVOLVEMENT OF PATIENTS, REFERRELS AND CARERS

In order for the NMS to offer the highest quality of care, it is important that it works in partnership with all stakeholders, such as patients, referrers and carers. This will assist 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. 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

CG is based on the pre-definition of indicators, i.e. a quantitative (measurable) or qualitative (comparable) characteristic of an object or phenomenon that allows judgments to be made about it. The result of the observation of the characteristic in question defines the 'value' or 'data' (measure of the indicator).

Indicators can measure:

- Structure: In this particular area it does not refer to the specific location, but rather to the quantitative and organizational aspects of the activity under consideration.

- Process: Structured succession of activities aimed at producing a result (product, service, etc.) that has value for the end customer (patient, referring clinician).

- Results: (output, outcome, result, product): Performance or service originating from a process.

- Outcome: In clinical practice the outcome refers to the effect or the impact of an output (e.g. discharge after therapeutic procedure or effective diagnostics). Longer term outcome measures, such as 1- and 5-year survival, might also be considered in case of therapies. However, this information might be available too late to be of much use for CG. They may be used for setting and adjusting clinical guidelines on national or international levels.

Measurable indicators are based on standards, i.e. 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 / component of the organization or process.

Indicators are fundamental to two of the instruments of clinical governance, i.e. internal reviews and audits, which should not be used only on an occasional basis or confined exclusively to the professional sphere. Instead, they should be integrated consistently into all governance processes.

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 performed by the management of the NMS, with the support of specifically designed 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 and are conducted in a methodical manner. They are designed to evaluate various aspects of the processes accomplished by the NMS. For example, to:
• 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 administration of the radiopharmaceutical;

• check if injected activities for the spectrum of nuclear medicine procedures performed lie within recommended Diagnostic Reference Levels (DRLs) and adhere to Basic Safety Standards (BSS);

• check if there was appropriate clinical handover;

• analyse up-time and performance monitoring of key equipment;

Internal reviews are closely connected with the measurement of indicators and can also, for example, be used 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 ISO Standards on Quality Management Systems, “the audit is the systematic and independent review of the system’s activities in order to verify the achievement of stated objectives” [10].

Clinical audits allow doctors, nurses and other healthcare 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 if the implemented changes have achieved the aim.

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

• procedures used for diagnosis, therapy and care (product);

• the associated use of available resources (process); and

• patient outcomes and quality of life.

Auditing the clinical component of an activity is essential, but 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 activity, which are dependent on structural deficiencies of the organization. This is one of the important reasons to introduce an overarching quality management system.

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, either ISO [11], EFQM [12], accreditation bodies or other programs, such as the IAEA 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 also characterized by their mandate, which could be from internal management, from an accreditation body, or from a client outside of the organization being evaluated, for example, buyer or customer(s). 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 nuclear medicine service to evaluate if 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 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.

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 competences, such as a national association for nuclear medicine.

A comprehensive audit is very important, but it can be complex to perform in routine practice. A more practical option is often adopted by performing partial internal audits, or sector-by-sector, according to a program that leads to "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:

- compliance with the expectations and/or 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, their booking and appointment allocation in a timely fashion;
- management of radiation within safety standards as prescribed by regulatory bodies such as IAEA, EANM, SNMMI;
- patient identification in accordance with international and national guidelines for patient identification;
- appropriateness or clinical justification of diagnostic/therapeutic procedures;
- compliance with hospital infection control policies.

In adopting an internationally recognized auditing scheme such as the IAEA 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 done over the course of approximately one year.
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 their services. Steps typically involved in an audit cycle (Figure 1) are:

1. An audit (internal or external) is planned, for which specific focuses may be defined;

2. Standards and criteria are defined (such as QUANUM), which will serve as a reference for the auditors;

3. The actual audit visit takes place, with auditors conducting interviews, observing ongoing concerned activities, assessing the facilities and probing the quality management system, documentation, acquisition, processing and clinical reporting of scans, QC and radiation safety procedures, etc;

4. The audit output can be a list of findings and non-conformances (NC), requiring corrective or preventive actions to be taken by the NMS management;

5. Actual improvements are planned and applied;

Finally, at regular intervals (or earlier when needed to eliminate critical non-conformances) this whole cycle is repeated and is a well-accepted way of achieving continuous improvement, step by step.

*Figure 1. The audit cycle*
3. CULTURE FOR QUALITY

In healthcare, the concept of quality as an integral part of day-to-day 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 a contemporary NMS is to deliver accurate diagnosis and effective radionuclide therapy to patients, which can only be achieved 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 – e.g. arrival at the NMS, registration at reception, patient interview, preparation, administration/infusion of radiopharmaceutical (RP), imaging, image reconstruction, post processing, display, report generation, study archival and results communication.

3.1. FOSTERING A CULTURE OF QUALITY

It is important for all staff – administrative, medical, technical and nursing, as well as radiochemists, radiopharmacists, medical physicists and patient service assistants to realise that each individual staff member plays a role in the patient experience and in the final report that is generated. As such, the service that is provided at each point has to be “under control”, i.e. undergo a quality assurance process to ensure that policies, procedures and guidelines have been adhered to. This goal can be achieved in many ways.

- **Education** of staff across the multiple disciplines in an NMS.

- Maintaining high standards through **leading by example**. 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.

- An up to date, **robust documentation system** that outlines departmental policies, procedures, guidelines and records, that are 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 PDCA cycle [13], which will identify gaps in practices and a mechanism to address these gaps.

- **Be receptive to feedback** and ongoing changes within the QM framework.

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

Finding the best way to implement a quality program in a manner that will be accepted and practiced is vital in fostering a culture of quality. The quality program should involve all staff and be clear, concise, methodical, easy to implement and maintain. It should not be daunting, boring 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 avoids bureaucracy will result in saving time and resources. A QMS should be:
• low maintenance (i.e. not requiring excessive interventions);
• operational in the background;
• complementing, 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; interactive feedback should be encouraged. Such meetings are a great opportunity to engage staff, to 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 program 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 program 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 program.

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

3.3. LEADERSHIP AND RESPONSIBILITY FOR QUALITY

Leadership in quality, which includes risk management and protection matters, must 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 quality culture, as previously discussed.

The term ‘management system’ reflects and includes the concept 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) [14].

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

Senior management is responsible for:

• establishing, applying, sustaining and continuously improving the management system to ensure quality;
• commitment to risk management, applying a proportional or graded approach;
• determining the competences and resources necessary to carry out the activities of the organization safely, and providing them;
• establishing good work ethics – a sense of values and ethics should be instilled in the department’s culture of quality by management and senior staff, with them 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, which 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:

• be proactive and lead through 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 which 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 the definition and implementation of the department’s milestones, goals and future directions.

• develop trust and react appropriately to resistance or even 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.
<table>
<thead>
<tr>
<th>Domain and activity</th>
<th>NMS management</th>
<th>NM Professionals (Physicians, Technologists, Physicists, Radiopharmacists)</th>
<th>Other</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>• Have instruments in operation for incident reporting and risk management.</td>
<td>• Participate in (multidisciplinary) prospective risk analysis.</td>
<td>Hospital management:</td>
</tr>
<tr>
<td></td>
<td>• Identify sentinel events.</td>
<td>• Be perceptive to risks and contribute to process optimisation.</td>
<td>• Define hospital wide policies on risk management.</td>
</tr>
<tr>
<td></td>
<td>• Monitor outcomes.</td>
<td>• Report incidents.</td>
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<tr>
<td></td>
<td>• Verify that corrective and preventive actions are defined and taken.</td>
<td>• Define and take corrective and preventive actions.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Report serious incidents and status of risk management to hospital management.</td>
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<td></td>
</tr>
<tr>
<td>Clinical Governance</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>RISK MANAGEMENT</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Seek to improve the quality and outcomes of healthcare through a structured peer review.</td>
<td>• Have a working knowledge of the quality standards adopted by NMS, e.g. IAEA QUANUM 3.0.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Adopt an appropriate quality standard, e.g. IAEA QUANUM 3.0.</td>
<td>• Participate in audits as an auditee or as an auditor, if required.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Plan internal and external audits on a regular basis.</td>
<td>• Participate in an audit at other departments or hospitals; this can be very instructive.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Define areas in need of such a review.</td>
<td>• Act upon audit findings.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Verify that audit findings are acted upon to continuously achieve incremental improvements.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Clinical Governance</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CLINICAL AUDIT AND QUALITY</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Be proactive and lead by example.</td>
<td>• Be proactive and lead by example.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Maintain proper documentation outlining departmental policies, procedures, guidelines and records.</td>
<td>• Verifying the appropriateness, effectiveness and quality of clinical performance.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Facilitate CPD of staff, across all the disciplines present.</td>
<td>• Follow policies, procedures and protocols set out, and stay informed on changes.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Be receptive to feedback and ongoing changes within the QM framework.</td>
<td>• Inform management on shortcomings in processes, methods and means; suggest improvements.</td>
<td></td>
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<tr>
<td>Culture for Quality</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>FOSTERING A CULTURE OF QUALITY</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Domain and activity</td>
<td>NMS management</td>
<td>NM Professionals (Physicians, Technologists, Physicists, Radiopharmacists)</td>
<td>Other</td>
</tr>
<tr>
<td>---------------------</td>
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<td>----------------------------------------------------------------------------</td>
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</tr>
</tbody>
</table>
| Culture for Quality | • Communicate with external stakeholders and professionals (nursing staff, referring clinicians, hospital 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 accountability and be accountable. Promote the safe use of feedback. | • Be accountable.  
• Warrant 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. |
| LEADERSHIP | | | |
| Quality Management | • Define vision and mission.  
• Define mid- to long-term planning (3 to 5 years), by initiating a strategic discussion, involving all NMS staff, as well as personnel from other departments that impact the nuclear medicine services.  
• Deliverables: strategic goals, aligned with institutional strategic objectives; action plan and specific milestones. | • Contribute to defining vision and mission.  
• Contribute to defining mid- to long-term planning. | Hospital management:  
• provide institutional strategic objectives. |
| GOALS OF QMS | | | |
| Human Resources | • Define job descriptions for all staff, clearly setting out duties, responsibilities and reporting lines.  
• Periodically organise performance appraisals of each staff member. | • Contribute to establishing job description.  
• Proactively take part in performance appraisal. | Hospital management | • Periodically give performance appraisal of NMS management. |
<table>
<thead>
<tr>
<th>Domain and activity</th>
<th>NMS management</th>
<th>NM Professionals (Physicians, Technologists, Physicists, Radiopharmacists)</th>
<th>Other</th>
</tr>
</thead>
<tbody>
<tr>
<td>Human Resources</td>
<td>Teach, train and mentor employees.</td>
<td>Set personal goals.</td>
<td>Hospital management: Allocate budget for professional development.</td>
</tr>
<tr>
<td>PERSONAL DEVELOPMENT</td>
<td>Identify needs for training and further professional development.</td>
<td>Consider and discuss options for performance improvement and professional development.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Foster constant growth and development across the organisation by defining</td>
<td>Work on CPD by attending seminars, workshops and conferences, prepare presentations at department meetings and journal clubs.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>challenging objectives and targets.</td>
<td>Be actively involved in quality management initiatives or research projects.</td>
<td></td>
</tr>
<tr>
<td>Fundamentals of QMS</td>
<td>Before beginning or substantially changing an activity or process, perform a</td>
<td>Participate in risk analysis, which is often a multidisciplinary process.</td>
<td>Radiation Protection Officer:</td>
</tr>
<tr>
<td>RISK ASSESSMENT</td>
<td>prospective risk assessment, in particular for all activities which may give</td>
<td>NM physician: Perform justification analysis for individual patient exposure.</td>
<td>Classify working areas (controlled vs. supervised areas).</td>
</tr>
<tr>
<td></td>
<td>rise to radiation risks.</td>
<td>NM physicist: Evaluate accidental exposure of patients.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Evaluate incidents reported, identifying their root causes, and reduce or</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>mitigate the risk.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fundamentals of QMS</td>
<td>Set up document management to allow for a properly organized QMS.</td>
<td>Radiopharmacist: Define SOPs for QC of radiopharmaceuticals.</td>
<td>Radiation Protection Officer:</td>
</tr>
<tr>
<td>SOPs FOR RADIATION</td>
<td>Specific SOPs should be in place in order to keep occupational and patient</td>
<td>Technologist: Contribute to defining and continuously adapting / improving SOPs for radiopharmacy, diagnostic imaging, therapy, surveys for radioactive contamination.</td>
<td>Define SOP for review and analysis of individual dosimeter readings.</td>
</tr>
<tr>
<td>PROTECTION</td>
<td>exposure ALARA.</td>
<td>NM physicist: Define SOP for accountability and leakage checks of sealed sources.</td>
<td></td>
</tr>
</tbody>
</table>

Legend to Table 1: CPD=continuous professional development; SOP=Standard Operating Procedure

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 concomitant aspects of safety and risk management.

The quality committee supports senior management in applying clinical governance, implementing and maintaining the quality and risk management framework within the department, and provides relevant quality monitoring information for internal review by management. This committee oversees the implementation and evaluation of quality and risk.
improvement initiatives, to optimise outcomes and safety for patients and staff. These initiatives are aligned with legislative, organisational 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, who provide guidance based on the organisation’s priorities to assist with 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, quality assurance 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 Chapter 6).

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

3.5. TASKS IN QUALITY MANAGEMENT FOR THE QUALITY COMMITTEE

QM involves identifying new and emerging issues, and opportunities to drive best practice and minimise clinical risk (see Chapter 2), and ensures:

- effective systems to achieve department quality outcomes;
- department compliance with any existing national accreditation program;
- completion of an annual action plan to support the departmental planning;
- adherence to international guidance given by intergovernmental organisations such as the IAEA;
- consistency with national/international nuclear medicine practice guidelines and recommendations as set by organisations such as SNMMI and EANM;
- benchmarking with similar organisations locally and internationally, as appropriate;
- preparation of an annual plan for audit activities;
- implementation of non-conformances registration and risk registry (see chapter 9);
- implementation, review and follow-up customer satisfaction;
- evaluation of quality programs 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 chapter 6.

3.6. SUPPORTING SENIOR MANAGEMENT

The quality committee supports senior management by providing advice on:
• 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 up-to-date documentation and records of evidence;

• defining and monitoring key performance indicators. See also chapter 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 management process. These are further discussed in chapter 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 applies also 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 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, etc. 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 quality management system such as the Standard Operating Procedures (SOPs) for control of documents, control of non-conformances, internal audits, preventive and corrective actions, performance of clinical activities. The way in which the service meets the requirements and ensures that the NMS is compliant with the national and/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, EANM and IAEA, and can be used by any NMS as a guide to formulating their own quality manuals [15]. An example is in Annex 1.

Many of the topics covered by the current 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 of each type of activity aiming 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 in case of detection of serious non-conformance, after discussing with management.

Therefore, it is strongly recommended that each NMS defines and establishes 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 offered services, stating the available resources and operational conditions.
• The vision should provide a clear and comprehensive ‘picture’ of the nuclear medicine service 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 to achieve the expected results.

Examples of mission and vision are provided below. Note that strategic objectives should be linked to the mission and vision as defined.

**4.2.1. MISSION (EXAMPLE)**

*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 the patient.*

**4.2.2. VISION (EXAMPLE)**

*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 of their personal integrity as a fundamental value in any process (diagnosis and treatment), aiming to re-establish 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 at:*

- providing high quality education to our staff;
- becoming a national reference centre, in the next 3 years, for didactic activities and training.

**4.3. PROCESS IDENTIFICATION AND PROCESS MAP**

According to ISO definitions [16], a process is a set of interrelated or interacting activities that transforms “inputs into outputs”. This general definition must 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 an audit in order to understand if there is complete understanding and management of all the activities within in the department.

It is imperative in a complex organization such as a nuclear medicine department 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 generically shown in Figure 2. The processes should be ideally shown with the names of staff members responsible for each process, as well as with lines of communication with other departments in the institution.

Figure 2. Example of a generic process map. Such type of flow charts could be tailored to the specific situation.

The various diagnostic and therapeutic processes constitute the primary processes of a nuclear medicine department.

Supporting and managerial processes are necessary activities allowing the NMS to carry out the primary processes, which are the core activities of the department which may produce institutional revenues, depending on the nature of the institution and of the healthcare system. Other essential activities (e.g., QA/QC of equipment and/or radiopharmaceuticals) 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 Standardized Operating Procedure. From the administrative point of view, it has a specific tariff and could be part of a contractual agreement with one or more health management organizations, insurances, 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 as primary.

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

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

4.4. SHORT- AND LONG-TERM STRATEGIC PLANNING

Short- and long-term planning is one of the key aspects of the QMS. The achievement of the objectives impacts positively 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.

Mid- to long-term planning (3 to 5 years) begins with a strategic discussion, involving all staff in the department as well as personnel from other departments that impact the nuclear medicine service. The process begins with an analysis of the situation of the nuclear medicine service with respect to its internal and external environment which involves identifying strengths, weaknesses, opportunities and threats (SWOT analysis); 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.

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

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

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

- institutional priorities, both internal and external, (e.g. necessity of developing oncological or cardiological activities; implementation of transverse, multi-departmental programmes, such as breast cancer multi departmental meeting, etc.);
- diagnostic and therapeutic nuclear medicine services: current and projected future demands;
- literature review and inputs of evidence-based medicine on current trends in nuclear medicine;
- research and development plans (R&D);
- human resources;
- legislation (licensing and compliance);
- audit and inspection results; benchmarking;
- incidents and non-conformities;
- 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 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 PET/CT scanner and/or develop appropriate radionuclide therapy services. This would include aspects such as performing a risk analysis, licensing, availability of radiopharmaceuticals, recruiting necessary human resources, acquiring necessary infrastructure, IT solutions and logistics such as radiopharmaceuticals supply; waste management, etc.

4.5. DOCUMENTATION SYSTEM AND DOCUMENT CONTROL

The development of a documentation system (DS) is an important component of managerial activities. Document control serves many purposes, such as ensuring NMS compliance with regulatory requirements, quality improvement, 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. In addition, it enables traceability and provides information for the quality management audits.

The NMS documentation system must meet the requirements of all interested parties in an integrated manner, avoiding 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 SOP 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 which 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 carries 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 must be established for the development of new documents and modification of existing ones. It is worth mentioning that at this point, if an SOP does not exist describing how an SOP should be written, that this be identified as an important document to be formulated (see 4.4). This “SOP for SOP” 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 Figure 3.

*Figure 3. Flow chart of the documentation system control process*
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 they must be located for filling, measures to maintain them, 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.

4.5.2. Implementation of the documentation system

Once a document is approved, it should be incorporated into the documentation system and it 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, it is recommended to use appropriate tools, such as a specific software. To achieve this purpose, as indicated in the IAEA BSS par.3.15, operating procedures should be in place and periodically reviewed and updated. [14]

4.5.3. Issue and distribution of documents

- Add document to the SOP registry;
- Upload documents to the local network, shared drives, local intranet, etc. It is preferable not to 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 document location;
- Request staff using the SOP to confirm having read the latest version of this SOP.
4.5.4. Control change of document

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

4.5.5. Cancellation of a document

- Archive document;
- Communication to the staff involved.

4.5.6. Common problems

- The required document does not exist;
- Unauthorized modifications;
- Loss of documents;
- Outdated documents in circulation.
5. LICENSING AND COMPLIANCE

5.1. LICENSING

Every medical facility requires a series of authorizations and licenses 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 licenses and permits to be obtained includes, but is not limited to:

- 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 is assessed

Obtaining these licenses is a complex, multi-step process, as detailed in Figure 4 below.

*Figure 4. A scheme of the gradual series of licenses, permits and accreditation needed for a medical facility to operate.*

However, the most important license 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 license'. Furthermore, regardless of differences between 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.
5.1.1. License for the construction of radiological facilities

Any new construction or significant modification of an existing building to host a radiological facility will have an impact 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 authorization

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 is used 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 healthcare 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. Licenses for radiopharmaceuticals production

In most cases, radiopharmaceuticals for clinical use must be prepared locally. Radiopharmaceuticals, being medicinal products, must meet quality, safety and efficacy requirements. For this type of product, generally with short half-lives, quality is vital to support both safety and efficacy.

In addition, since radiopharmaceuticals incorporate 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 healthcare 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 ‘the BSS’, requirement 2 [14]. 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).

The principal parties responsible for protection and safety are:

- registrants or licensees, or the person or organization responsible for facilities and activities;
- employers, in relation to occupational exposure;
- radiological medical practitioners and referring medical practitioners, for what concerns procedure appropriateness/justification in relation to medical exposure;
- medical physicists;
- medical radiation/nuclear medicine technologists;
- radiation protection officers/radiation safety officers;
• qualified experts;
• suppliers of sources, providers of equipment and software;
• ethics committees,
• internal review boards (IRBs)

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).

As stated in the IAEA GSR part 2, requirement nr 6, “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”.

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 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, and to open and operate an NMS it is typically necessary to obtain authorization (GS-G-1.5, par. 4.3) from the regulatory authority. This authorization will take the form of either a registration or a license 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:

• prepare a prospective risk assessment, taking into account the nature, likelihood and magnitude of expected exposures due 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 license has been granted.

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

• 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 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 co-operative 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 license may require periodical 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 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 for the collection of waste, or to a commercial service, which takes the responsibility of the waste for further processing, storage or disposal, as appropriate.

Radioactive waste is just one of several types of waste produced in nuclear medicine activities.

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

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

• storage until radioactivity has decreased to below exemption levels, then disposal as waste, the classification of which depends on the origin:
  - as biohazard waste – materials that derive from the administration of radionuclides to patients and contain, or have been in contact with, the patient's body fluids;
  - as 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 between 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 short half-life radionuclides. For those with a half-life of more than a few weeks, it is generally preferable to outsource. 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, 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 licenses and ensure proper, uninterrupted operation of waste management.
6. HUMAN RESOURCES MANAGEMENT

As defined in the IAEA Publication 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” [17].

Human resource management is an institutional process including 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, a department/service is an organization of a group of people and facilities for which there exists an arrangement of responsibilities, authorities and relationships, as well as identifiable objectives [18]. It is expected that these relationships are formalized in written documents, available to all the members of the organization. The most frequent approach to this is a document often entitled “Responsibility and Authority” (R&A) being issued by the head of the department.

This document describes the founding principles of the department, and sets out the updated structure, lines of authority and responsibility of staff members.

It also includes a clarification of any necessary delegation of authority (DoA) 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;
- radiopharmacist/radiochemist to delegate radiopharmaceutical preparations to other staff, e.g. properly trained technologists/radiographer, under the licensing regulations.

The R&A document also sets internal rules for appropriate management of staff leave whilst ensuring adequate personnel to maintain departmental operations.

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

- organizational chart;
- individual job description;
- roster of persons in charge for specific duties.

6.2. ORGANISATIONAL 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 organisational flowchart 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 general chart (Figure 6), illustrating the position of the NMS within the institution and its relationships.
6.3. JOB DESCRIPTION

All staff members should have a written job description (Table 2), which clearly sets out their duties, responsibilities and specific resources/staff allocation, as well as reporting lines as seen in the organizational flowchart. Staff qualifications should match those indicated in the job description [17]. 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, fire warden.

TABLE 2. EXAMPLE OF A JOB DESCRIPTION FOR A TECHNOLOGIST (MODIFIED FROM EANM ISO DOCUMENTATION) [19]

<table>
<thead>
<tr>
<th>Nuclear medicine Service</th>
<th>JOB DESCRIPTION</th>
<th>HRP-REC-001</th>
</tr>
</thead>
<tbody>
<tr>
<td>Job title:</td>
<td>Nuclear Medicine Technologist Grade (x)</td>
<td></td>
</tr>
<tr>
<td>Education:</td>
<td>Bachelor’s degree OR Diploma in Radiography or Nuclear</td>
<td></td>
</tr>
<tr>
<td>Training:</td>
<td>Minimum 2 years of clinical experience as a nuclear medicine technologist</td>
<td></td>
</tr>
<tr>
<td>Expertise:</td>
<td>Desirable to have experience in common imaging procedures in nuclear medicine such as bone scans, renal scans, thyroid scan, cardiac scans and gated blood pool scans. Experience in hot laboratory procedures such as eluting the $^{99m}$Tc generator, radiopharmaceutical kit reconstruction and QC of radiopharmaceuticals will be viewed favourably. Some basic experience with FDG PET scanning is also desirable.</td>
<td></td>
</tr>
<tr>
<td>Memberships:</td>
<td>Membership with local/international nuclear medicine societies, desirable but not essential</td>
<td></td>
</tr>
<tr>
<td>Personal Attributes:</td>
<td>Motivated, proactive, self-guided, ability to work independently as well as within a team, able to troubleshoot, take initiative, ability to receive feedback, ability to manage time efficiently</td>
<td></td>
</tr>
</tbody>
</table>
Responsibilities:
- Scanner QC
- Scanner preparation
- Patient set up for scanning
- Perform scan, image reconstruction, image processing and displaying
- Patient release (after attending physician evaluation)

Change Control

<table>
<thead>
<tr>
<th>Creation</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Revision 1</td>
<td>Date:</td>
</tr>
</tbody>
</table>

For each job role and workplace, the NMS must have documents for the selection, orientation and induction of new staff. Locally required competences 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 professional, specifically trained in staff appraisal. Such an evaluation typically includes:

- recognition of achievements;
- setting personal goals;
- review of status of individual licences and accreditation;
- personal attitudes and behaviour;
- adherence to institutional and specific departmental values;
- giving and receiving feedback;
- capability in the use of QMS tools such as medical information systems, reporting of incidents and non-conformances;
- identifying training needs;
- further professional development, taking into account the department's strategic planning.

Such an appraisal is generally performed by senior management, signed by both parties 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 lesson-learning and sharing 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 organisation, by continuously adjusting target performance levels within each department.

- **Inspire, motivate and recognise** 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 organisation to work together to implement improvement strategies, and as a leader, the role is to foster open communication from all employees.

- **Stimulate continuous professional development (CPD)** – attendance at seminars, workshops and conferences. 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 as 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 the staff of the department in operating the system, the role can be taken over by an internally appointed quality manager. This internally appointed quality manager will then have the advantage of being a person with detailed knowledge of QMS coupled with specific expertise in nuclear medicine and operations of the department. The function of the quality manager can then be considered as 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 quality service of the institution. 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 it will occur. There are two major classes of approach to analyse risks:

- retrospective (or reactive) risk analysis methods; and
- prospective risk analysis methods.

7.1. RETROSPECTIVE (OR REACTIVE) RISK ANALYSIS METHODS

These methods deal with (near) incidents which were reported. Each (near) incident and the circumstances in which it occurred, its possible consequences and frequency of occurrence are analysed. 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 (RCA) is a formal method, frequently used to systematically perform a retrospective risk analysis (Figures 7 and 8), and to identify the actual root causes which require elimination or mitigation. [20-24] Readers are advised to refer to the IAEA SAFRON E-learning modules [25] and to ad hoc training lectures [26].

Figure 7. This fishbone diagram can help trace the link between the event and possible sources of basic causes. [25]
Figure 8. Cause and effect diagram, developed during an investigation of a hypothetical incident during a nuclear medicine imaging procedure, resulting in an unjustified patient exposure. The tree shows relevant causes in their hierarchy. The items to the far right of the diagram are considered root causes.

7.2. PROSPECTIVE RISK ANALYSIS METHODS

These 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 the occurrence of 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) [26, 27] and Fault Tree Analysis (FTA) [26] are methods often used to prospectively analyse systems for weaknesses. FMEA is a systematic method for process evaluation to identify the ways in which it 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.

For each step a risk priority number R 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: R=OxSxD. Unacceptably high-risk scores require interventions.
7.4. FAULT TREE ANALYSIS

FTA complements FMEA. A fault tree analysis is a detailed description of a failure pathway, identifying steps that may contribute to the occurrence of a failure. FTA can be regarded as a hypothetical RCA and a safety assessment for use of radiation. [28]

A fundamental safety objective is to protect people – individually and collectively – and the environment from harmful effects of ionizing radiation. A specific document [29] focuses on those risks associated with the use of ionizing radiation.

Management is responsible for ensuring that protection and safety is optimized, that applicable dose limits are complied with, 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 in such a safety assessment. [15].

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

- identify the ways in which exposures could be incurred. The three factors relevant to dose reduction – time, distance and shielding – should be combined 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 3, 3.31, 3.32]:

- 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 and includes:

- 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 constraints\(^1\) to be applied to occupational exposure and to public exposure for optimization of protection and safety.

7.5. INCIDENTS

According to the IAEA Basic Safety Standards [15] 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”.

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 [15] 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 commensurate with the effective radiological risk.

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 [30].

Furthermore, Martin et al reviewed literature and analysed relevant processes within nuclear medicine, aiming to give guidelines related to incident prevention [31]. Martin’s paper makes it clear that key nuclear medicine processes are risk- and error-prone, requiring proper risk management. His findings emphasize once more that a detailed and comprehensive QMS is key to identifying and controlling risks.

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\(^1\) Note: 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. [IAEA GSR 3, 4.64 and 4.65; IAEA GSG-7, para 3.28]
Figure 9. Pie chart showing proportions of different types of 189 incidents in nuclear medicine departments in the west of Scotland reported over a 10-year period.

Figure 10. Pie chart showing proportions of different types of patient exposure incidents in imaging departments in nuclear medicine, involving 71 reported incidents.
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.

**TABLE 3. ERRORS THAT MAY CONTRIBUTE TO INCIDENTS DURING THE PREPARATION OF A RADIOPHARMACEUTICAL [31].**

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

Table 4 and 5 report a list of possible errors that might end in possible incidents for patient preparation and for imaging.

**TABLE 4. FACTORS THAT COULD CONTRIBUTE TO AN INCIDENT DURING PATIENT PREPARATION AND ADMINISTRATION [31].**

<table>
<thead>
<tr>
<th>Component of the process</th>
<th>Possible errors</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient preparation</td>
<td>• Incomplete instructions given to the patient or instructions not communicated accurately</td>
</tr>
<tr>
<td></td>
<td>• Fasting status of patient not checked before administration of radiopharmaceuticals</td>
</tr>
<tr>
<td></td>
<td>• Pregnancy or lactation not verified before administration of radiopharmaceuticals</td>
</tr>
<tr>
<td></td>
<td>• Biochemical tests omitted (e.g. glucose level)</td>
</tr>
<tr>
<td>Stress testing/pharmacological stimulation</td>
<td>• Errors in the procedure.</td>
</tr>
<tr>
<td></td>
<td>• Errors in timing.</td>
</tr>
</tbody>
</table>
### 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 [31].

<table>
<thead>
<tr>
<th>Component of the process</th>
<th>Possible errors</th>
</tr>
</thead>
</table>
| Gamma camera setup                        | • 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 setup                         | • Incorrect daily QC procedure (e.g. detector block is not working)              |
| Multi-modality scans                       | • Wrong or poorly optimised CT protocol selected                                 |
| In all nuclear medicine imaging modes     | • Sub-optimal 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 standardised uptake value (SUV) results.  
                                            | • Omitted or outdated calibrations of gamma cameras and in vivo counting systems, e.g. thyroid uptake counters. |
| Mechanical safety                          | • Patient has not been secured to the imaging bed.  
                                            | • Moving components of the scanner have not been checked.  
                                            | • Tools, furniture or other objects lie in the trajectory of motion. |

All the risks listed above 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”, which must 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 quality management system, 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, within the scope of the QMS, a department-specific reporting tool should be developed.

It is important to note that the IAEA has developed an anonymous online incident reporting tool, the SAFRON-NM [31], 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, 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 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 to, e.g. nuclear medicine referrers to report incidents involving the NMS, and vice versa. Insight into 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 occurring, rather than ‘blaming’ the individual or promoting a culture of blame.

The IMS should provide governance which clearly outlines individual/NMS responsibilities in incident management and ensure consistency in approach to incident management in the NMS. It should also align with incident management across the health organisation.

Incidents should ideally be managed in an electronic reporting system, which allows an easy way of recording incidents or near misses, and has options to allocate an incident severity rating (ISR), using the principles of 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 2014 edition of the IAEA Basic Safety Standards [32] sets out requirements both for minimizing the likelihood of unintended and accidental medical exposures, and for the ensuing investigation if such exposures occur.

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, a reduction in the probability of unintended or accidental medical exposures in nuclear medicine can be brought about by:
a) the introduction of “safety barriers” at identified critical points in the nuclear medicine pathway, with specific quality control checks at these points.

b) encouraging a culture of always working with awareness and alertness;

c) providing detailed protocols and procedures for each process;

d) providing sufficient (educated and trained) staff, and an effective organization;

e) CPD and practical/applications training of all staff;

f) clear definitions of the roles, responsibilities and functions of 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.

A number of significant reports is available in current scientific literature [20-24].

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 and/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, to prevent future re-occurrence of the same errors (Table 6).

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

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not punitive</td>
<td>Reporters are exempt from retaliation or punishment from others</td>
</tr>
<tr>
<td>Confidential</td>
<td>The identity of the patient and of those who report is not disclosed to third parties</td>
</tr>
<tr>
<td>Independent</td>
<td>The system does not depend on any authority with the power to punish those who report</td>
</tr>
<tr>
<td>Timely</td>
<td>Reports are analysed promptly and recommendations are quickly disseminated to those who need to know them, especially when serious risks have been identified</td>
</tr>
<tr>
<td>System oriented</td>
<td>The recommendations target changes in systems, processes or products, rather than individual interventions or practices</td>
</tr>
</tbody>
</table>
The types of events to be reported are generally schematised according to an increasing severity level (Table 7).

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

<table>
<thead>
<tr>
<th>Type of event</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>“Near miss”</td>
<td>Unexpected event which was detected and avoided just before happening</td>
</tr>
<tr>
<td>Events without results</td>
<td>Unexpected events which did not result in injury, illness or damage – but had the potential to do so</td>
</tr>
<tr>
<td>Adverse event</td>
<td>Unexpected events related to the care process that result in unintentional and undesirable patient harm</td>
</tr>
<tr>
<td>Sentinel event</td>
<td>Adverse events of particular severity, potentially avoidable, which may result in death or serious harm to the patient</td>
</tr>
</tbody>
</table>

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

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

- 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 healthcare.

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, [25] a web-based system for incident reporting in radiotherapy, that has been generalized, introducing also a module on incidents in radionuclide therapy.

The main characteristics of SAFRON are:
• it is a non-punitive, anonymous, voluntary, educational, international system;

• it does not replace the regulatory reporting requirements of an institution;

• it allows performing statistical 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 read 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 in entering the main data of the event to be reported (e.g. radionuclide, activity, etc); of the step in the process in which the incident was generated; of the point in the process in which the errors was detected; of possible causes etc. Furthermore, a free text field allows for entering a detailed description. 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 [15, 30, 33-41].
8. STANDARD OPERATING PROCEDURES

Standard operating procedures (SOPs) 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 into use in the NMS. Use of (inter)national 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 inputs from relevant staff groups.

Occasional deviations from SOPs should be noted and explained (see also 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 must 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 chapter will address some of the essential SOPs and provide indications on how to prepare them.

**8.1. HOW TO WRITE A STANDARD OPERATING PROCEDURE (SOP)**

The following SOP provides a guideline on how to write a Standard Operating Procedure including how to format the document.

**8.1.1. Background, scope and purpose**

The purpose of a SOP is to provide detailed instructions on how to carry out a task so that any team member can carry out the task correctly every time. SOPs are issued to specifically instruct employees/team members in areas of responsibility, work instructions, appropriate specifications and required records. SOPs outline procedures, which can take the form of a narrative, a flow chart, a process map, computer screen printouts or combination of all or any other suitable form. See examples of suitable forms in Annex 2.

The purpose or objective of a SOP should restate and expand a well-written 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 local language. In the case of international certification or accreditation, an English version is highly recommended.
8.1.2. Responsibilities

SOP author has the duty of

- drafting SOP in consultation with the intended users;
- correcting SOP according to feedback;
- making SOP available to intended users;
- amending SOP if required.

The quality committee or quality manager has the duty of

- reviewing SOP’s initial draft and consecutive amendments;
- releasing and formally approving SOP versions;
- making SOP available to the rest of staff;
- ensuring compliance of SOP by all intended users;
- 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.
- The author of the SOP should be familiar with the procedure to be described in the SOP.
- Describe in detail how the procedure is being carried out.
- List the steps in a chronological order as in 8.2.
- Indicate in the “Responsibilities” section who is doing what. Do not use the name of the person, use functions and job title e.g. laboratory technician, 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.
- If required add visual displays and cues.
- Have a specific reader in mind. Know the type of person who will be reading the procedure and write according to the end user.
- Avoid ambiguous instructions such as “do this or alternatively do that”.
- Each SOP should have a unique identifier, the version number and version date.
• Use acronyms referring to the type of the procedure (LAB: for laboratory SOP; DOC: for SOP related to documentation management; CLIN: for clinical SOP; QUAL: for SOP related to Quality Assurance (QA) and Quality Control (QC)).

• If the procedure is a lengthy one, then use subheadings. e.g. ‘3.1’.

• On each page of the SOP indicate:
  - 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 SOP author/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.

• Each consecutive version and reason for/description of each modification made to the SOP should appear in the “Document History” section at the end of the SOP.

• A process must be decided for ensuring obsolete versions are not in circulation.

• Processes must be decided for circulation of current version of SOP and that the same version is accessed by all staff.

• The SOP should state authors of SOP, authorising staff/committees and version control.

8.1.5. References, associated documents and annexes

Whenever needed.

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 depending on the type and complexity of the procedure. Specific responsibility should be assigned for each different step of the procedure depending on expertise or competences, if applicable. Screen captures may help clarify specific steps. For a detailed SOP template, see Annex 2. Two examples are given in Annex 3.

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

• Identification of procedure.

• Clinical indications.

• Restrictions/contraindications/allergy risks.

• Paediatric/adult.
• Professional(s) in charge.
• Patient preparation before radiopharmaceutical administration.
• Activity to be administered; activity 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, image acquisition SOPs, all specific parameters of the camera setting need to be accounted for.

In the case of SPECT imaging this will include:

- type of collimator;
- matrix size;
- speed and time of acquisition;
- zoom level, etc.

In 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 brand, individual SOPs must be in place for every different model and make. Similarly, for image reconstruction and processing, all settings must be included in the SOPs, and different SOPs should exist if different reconstruction software are 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, both for patients and workers. For this reason, so they must be developed in conjunction with the nuclear medicine physician, medical physicist, radiation protection officer and, in the instance of in-patient 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. Due to frequent rotation of nurses and other personnel in these clinical areas, clear and readily accessible SOPs for managing radionuclide therapy patients must be in place. There should be processes in place to ensure that staff have read and understood SOPs.

Treatment specific SOPs should be in place to cater for:

- the different treatments provided by the NMS ($^{131}$I, $^{177}$Lu or $^{90}$Y labelled peptides, etc.);
- instructions on 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 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 a SOP describing the process for patient identification; this should be aligned with the organisational policy on patient identification.

The purpose of such a SOP is to ensure that patients are correctly identified in all steps of the clinical process (see also chapter 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 patient’s identification: the staff member, in conjunction with patient/carer/relative, confirms the patient’s identity using approved patient identifiers whilst simultaneously checking these against clinical information/documentation available.
8.5.1. Responsibility of staff for patient identification

The staff member must:

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 against details specified in clinical records of the patient.

If the patient is unable to identify themselves (e.g. confused or unconscious patients, non-native language speaking patients, or paediatric patients), Step 1 may be omitted, but ALL information on the ID bracelet must be matched to accompanying documentations and/or confirmed by the guardian/parent/carer.

8.5.2. Approved patient identifiers

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

- patient name – last names and full name;
- date of birth;
- address;
- medical record number - could be included in id band/bracelet or with barcode;
- national ID/passport number;
- social security/insurance number.

It is recommended to identify a patient by 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 and/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 the commencement of the planned activity. If the patient’s identity cannot be verified, the planned activity must not 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 ability to trace all processes of the NMS from referral to delivering the final report, and to be able 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 and/or time outs in the process. It will also provide elements for root-cause analysis 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 non-conformances and enables 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 and/or intervention, at start of procedure, 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/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 paper trail.

Traceability is widely used in nuclear medicine services for improving patient safety, reducing the risk of misadministration, minimizing non-conformances that may necessitate repeating the study, enabling pharmaco-vigilance, all of which strengthen the QMS. An example of a paper trail is shown in Figure 11.
8.7. FORMALIZATION OF COORDINATION AND INTERACTIONS: “CONTRACTS”

An NMS, in its normal operations, 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 supply this in a consistent way, ensuring 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.

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

- 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 NMS;
- surgery, for radioguided interventions;
- oncology, if the radionuclide therapy wards are within their facilities;
- bioengineering, if they provide preventive/corrective maintenance and organise service by external parties;
- information and communication technologies, if this department provides services regarding PACS, 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); 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 an outside institution, responsibility for the patient’s safety aspects in this scenario, as well as 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 warrant adequate management of these risks. Examples of topics requiring that SOPs are defined, are:

- **Facility requirements.** Adequate facilities should be available at the nuclear medicine service to ensure the safety and efficacy of the activities composing the nuclear medicine processes. SOPs describing key nuclear medicine tasks must consider the availability of these facilities and the expected conditions (e.g. availability of ventilation systems to manage $^{131}$I solutions and their periodical checks and maintenances), as they are important requirements of the local and/or international regulations such as BSS. (SSG-46 § 4.8-4.10).

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 as important elements of the institutional quality assurance programs.

Room design and location must consider the ‘defense in depth’ principle [42] 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, emphasizing on special categories such as pregnant and breast-feeding women.

- **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, for the hands, for staff that is involved in operations like labelling and dispensing of radiopharmaceuticals and their QC.

Optional but very useful are electronic pocket dosimeters, which show dose rate and integrated dose. It is 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 working hours [30]. Dosimeters that are not consistently worn at the correct position will give results that are not fully comparable. As an example, consider a hand dosimeter for staff...
administering radiopharmaceuticals: all of them should wear them on their non-dominant hand, high on their index finger and oriented inwards.

- **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 [30]. The results of occupational exposure data should be regularly reviewed by a qualified professional; proper action levels should be defined, based on constraints for the activities performed. Some action levels could exist at national level or could be defined by the dosimetry laboratory. Nevertheless, within the QMS internal action levels should be defined, 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 analysis and averages for the professional profile (Figure 12).

- If a trend or extrapolated annual exposure exceeds an action level that was set, it requires interpreting the unexpected results. Early corrective actions can be taken [30].

*Figure 12. Histogram showing occupational 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 which $^{131}$I, for which a therapy ward with four rooms for in-patients is available.*

- **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 leakage. 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 excluded. 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 such type of quality control. 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 [30].

- **Storage of sources:** Radioactive sources should be stored in a shielded and locked place/
  vault which 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 out of place,
  or any contamination previously unnoticed. The results of this type of inspection are
  usually only qualitative and are frequently reported in a form with check boxes. The
  SOP should indicate the people to be informed and the actions to be taken in case of NC
  or deviations [15, 30].

- **Periodic radiation surveys:** The radiation protection program 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 [30]. A
detailed SOP should be in place to specify the equipment, modality and position of
  routine dose/dose rate checks [15, 30].

- **Routine monitoring of surface contamination:** One of the specific risks in nuclear
  medicine, in addition to external exposure, is the risk of internal exposure, due to
  contamination and accidental intake of radionuclides if appropriate working procedures
  are not carefully adopted. In addition to the above-mentioned quick workplace monitoring,
a regular program of control of surface contamination should be in place. According to IAEA SSG-46 par. 4.113 [30], this monitoring is particularly required for:
  
  o 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;
  
  o workstations, ventilation systems and drains, when any of these needs to be
    accessed for maintenance purposes;
  
  o protective and personal clothing, and shoes, particularly when the wearer is
    leaving a controlled area (monitors should be available near the exit);
  
  o 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 [30]. 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 (see above).

- **Decontamination kit:** Prompt response in the case of a spill of radioactivity should be properly managed. To this end, one of the most diffused 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 when referring to the availability of a decontamination kit, it is neither intended nor desirable that there be only one such a kit available at 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, also indicating the method of checking replenishing kits, to warrant their functionality.

- **Procedures following a spill:** In an NMS the event of spill is not an “incident”, in the proper meaning of the term, but it is rather a non-desired component of routine activities. All working procedures should aim to minimize the risk of spill and of surface contamination [30] 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 on 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. 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 time intervals. This includes instructions on appropriate showering and eye washing [30].

- **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 [30] 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 in 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 at 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:** Whilst 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 minimise contamination and infection risks. Staff must be familiar with the institutional policies regarding infection control and practice infection control measures when dealing with biohazard materials. Aspects to be considered are: injecting patients and management of sharps; management of blood and other fluids samples, including urine bags; 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 [43, 44].

- **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 they can also represent a risk, e.g. in case they fall. Similarly, shielded and therefore heavy hot cells 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 in the SOPs of the relevant processes.

8.9. **SOPs FOR RADIATION PROTECTION OF PATIENTS**

- **Appropriate use criteria (AUC) and justification of medical exposure in NM:** AUC, sometimes referred to as appropriateness criteria, are based on evaluating if 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. AUC 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 based on consensus of international panels. When a procedure involves radiation exposure, it must be clinically justified by weighing the expected diagnostic or therapeutic benefits that they yield against the radiation detriment that they might cause. Alternative modalities that do not involve medical exposure, should be considered.

  Justification is a “multi-layer” process: firstly, 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 [45].

  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 [15, 30].

- **Justification of nuclear medicine procedures** 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 (DRL):** The NMS must define and implement SOPs to introduce and regularly review the local DRL. This includes both the DRL with respect to the activity levels of radiopharmaceuticals administered to patients, and the appropriate quantity (e.g. the computed tomography dose index (CT DOSE INDEX)) regarding the CT component of multi-modality studies. Assessments of the local DRLs must 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 (FRL); their estimations constitute a valuable tool for the optimization of the medical exposures of all diagnostic nuclear medicine procedures [15, 30]. For further guidance and information see also the EU Radiation Protection Series No. 180, part 1 and 2 [46].

- **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 multi-modality examinations (see GSR-3 par. 3.165 & SSG-46 par.4.175). 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 (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 ‘Pediatric Injected Activity Tool’, as published by the SNMMI. The prescribed typical dose (radiopharmaceutical 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 [15]. 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, 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 an adequate image quality), optimization of patient preparation and radiopharmaceutical administration, correct radiopharmaceutical selection, etc [30]. This optimization process might even lead to an increment of the radiation dose, if otherwise the image quality is 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 risks and target volumes).
For nuclear medicine diagnostic examinations, the administered activity (in 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-3 par 3.168 & SSG-46 par.4.203-4.212).

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 ICRP, SNM, 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 based on 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 woman.

- 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 female patients:** Appropriate SOPs must be established in the NMS, in order to ensure the radiation protection of pregnant or lactating female patients requiring diagnostic or therapeutic nuclear medicine procedures (see IAEA GSR Part 3 Paragraphs 3.175–3.177 and IAEA SSG-46 Paragraphs 4.241-4.245).

- The purpose of these procedures should be to identify the status of female patients of a childbearing age before prescribing any administration of radiopharmaceuticals, to use this information when evaluating the study justification (IAEA SSG-46 Paragraphs 4.162-b), and also to optimize the medical exposure of the patient and her foetus or baby (IAEA SSG-46 Paragraphs 4.195, 4.196).

- To identify and inform pregnant and breast-feeding patients, it is suggested to use various methods such as posting clear signs in public places of the facility (in local languages with proper pictures or drawings), inviting these female 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 these 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 must be available. They must 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 8.5.

- **Minimizing the risk of accidental exposures (e.g. mis- and mal-administrations and unnecessary multiple medical exposures):** To minimize the likelihood of accidental medical exposures, detailed procedures should be defined and implemented in the NMS, with emphasis on the prevention of unexpected radiopharmaceutical mis-administrations and mal-administrations, and of unnecessary multiple exposures (SSG-46 Paragraphs 4.250). 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 recently went through any similar diagnostic procedure, querying of RIS/PACs systems, etc. Furthermore, links to the procedure for corrective/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, combining 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 during the formulation by chemical, biological, microbiological and radionuclidic impurities. This is particularly important since the majority of radiopharmaceuticals are administered intravenously. A thorough quality management system is then necessary to ensure safety, efficacy and quality of radiopharmaceutical products [47].

The IAEA classifies the operations in radiopharmacy in three different levels of increasing complexity (Table 8) and, consequently, each operational level will have specific requirements. [48] The following sections give a general (though not exhaustive) description of the main components of the specific quality system for radiopharmacy.

#### TABLE 8. CLASSIFICATION OF RADIOPHARMACY LABS ACCORDING TO IAEA “OPERATIONAL GUIDANCE ON HOSPITAL RADIOPHARMACY: A SAFE AND EFFECTIVE APPROACH”.

<table>
<thead>
<tr>
<th>Radiopharmacy Operational level 1</th>
<th>Operational level 1a is the dispensing of radiopharmaceuticals purchased or supplied in their final form from recognized and/or authorized manufacturers or centralized radiopharmacies. This includes unit doses or multiple doses of prepared radiopharmaceuticals for which no compounding is required</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Operational level 1b is the dispensing of radiiodine and other ready to use radiopharmaceuticals for radionuclide therapy or palliation. This includes ready to use injections of strontium and samarium for pain palliation.</td>
</tr>
<tr>
<td>Radiopharmacy Operational level 2</td>
<td>Operational level 2a is the preparation of radiopharmaceuticals from prepared and approved reagent kits, generators and radionuclides (closed procedure). This is the most common activity in nuclear medicine departments, with routine use of a technetium generator and reconstitution of pre-sterilized radiopharmaceutical cold kits. Operational level 2b is the radiolabelling of autologous blood cells. This includes radiolabelling of red blood cells, platelets and white cells commonly used for infection or inflammation imaging.</td>
</tr>
<tr>
<td>Radiopharmacy Operational level 3</td>
<td>Operational level 3a is the compounding of radiopharmaceuticals from ingredients and radionuclides for diagnostic application (including open procedure); modification to existing commercial kits; in-house production of reagent kits from ingredients, including freeze dried operation; related research and development. Operational level 3b is the compounding of radiopharmaceuticals from ingredients and radionuclides for therapeutic application (including open procedure) together with related research and development. Examples include radio-iodination of meta-iodobenzyl guanidine (MIBG-iobenguane) and rhenium labelled lipiodol. Operational level 3c is the synthesis of positron emission tomography (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) — mostly related research and development — also falls under operational level 3c.</td>
</tr>
</tbody>
</table>

8.10.1. Competences and training

The local regulations for production of pharmaceuticals in a hospital or health structure should be applied. If such regulations and/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, quality control 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 or SOPs 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 delivery dates and times, the lot number, the calibration of the product activity, as well as the expiry date and time should be specified in detail. 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, also from a legislative point of view. For example, they should know the difference between a product that has a marketing
authorization, a galenic formulation\(^2\) or a prescription compounding, or 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 also some radiometric data be checked and recorded (e.g. transport index, level of radioactive contamination on the surface of containers, etc). Purchase orders (request forms) of 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, 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 preparation. These SOPs should indicate the conditions for the preparation (e.g. which LAF or hot cells can be used, and their predisposition and testing), details on aseptic operations, and in particular on dispensing, as applicable. These SOPs should clearly reference the information given in the Summary of Product Characteristics (SPC) issued by the manufacturer of the product / kit; however, the SPC or any possible instruction given by the manufacturer, cannot be used as a surrogate of a locally developed and approved SOP. Only such a type of document can give the detail of operations to be performed, and how to apply the methods using the locally 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 is due to safety aspects for the patient and / or for the operators, that these preparations can present.

These include:

- preparation, dispensing and activity checking of therapeutic radiopharmaceuticals. This is particularly the case for \(^{131}\text{I}\) radiopharmaceuticals, both in case of use of a liquid solution and of capsules. However, in general, the same criteria apply to the majority of therapeutic radiopharmaceuticals.

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\(^2\) Galenic formulation deals with the principles of preparing and compounding medicines in order to optimize their absorption. Galenic formulation is named after Claudius Galen, a 2nd Century AD Greek physician, who codified the preparation of drugs using multiple ingredients.
• the labelling of autologous cells, such as white blood cells. These procedures can present a very high risk for patients. For this, the operators involved should be specifically trained, and their preparation should be validated.

8.10.7. Batch record

Such a document should exist and be stored for every production, according 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 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 a mandatory requirement that the products are sterile in order to grant patients safety and health. 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 is used in that proper control of the process is in place, and to ensure that environmental control systems in clean rooms are effective. The methods used in environmental monitoring include:

• monitoring of air, including air sampling; these aspects are discussed in other paragraphs in this document;

• plates and surface sampling; these include 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 9) should be in place and documented in an SOP, including locally defined action levels.

TABLE 9. ANNUAL MICROBIOLOGICAL MONITORING REVIEW, SUMMARIZING DAILY SETTLE PLATE READINGS (FOR ISOLATOR AIR QUALITY) AND FINGER DABS.
8.10.9. SOP for quality control of all radiopharmaceutical products

It is important to understand that appropriate quality control is necessary for each type of radiopharmaceutical. This applies to all levels of operation, including level 1. Depending on the type of product, there is a step-wise approach to the requisites for the NMS. When a service operates only at level 1 and ready-to-use radiopharmaceuticals are received 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 quality control reports). As the level increases and local production becomes more complex, also the requisites, type, and frequency of QCs requested increase. In most cases, the modalities of QC are exhaustively described in the pharmacopoeia; in the case a national pharmacopoeia is not available, or does not include radiopharmaceuticals, reference can be made to the EU or USA pharmacopoeias. Detailed guidance is given in the IAEA “Operational guidance on hospital radiopharmacy: a safe and effective approach”. Vienna, International Atomic Energy Agency, 2008 [48].

8.10.10. SOP for terminal sterilization

Operation at level 3 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, must 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 exists 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 must 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 risks assessed. It should be noted that shielded transport containers must 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 labelling of kits, the SOPs should correspond with the instruction 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.

In the case of operation at level 3b (e.g. synthesis of PET radiopharmaceuticals), deviations and changes must 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 at receipt of incoming materials, and should be consistent used in 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 record 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 the case that a product, be it single photon, beta or positron emitters, does not meet those specifications, operators require a procedure to follow to prevent the release of the specific lot
of radiopharmaceutical, 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 quality control is completed and officially released for clinical use. In this case, should a product not meet specifications, a “recall” is needed, requiring an SOP detailing the correct modality for informing the final user of the need to wait for final liberation of the product before administering to patients. The “recall SOP” should also define the modality for safe and timely communication to the final user the confirmation – or not – for clinical use, 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 to have a specific SOP for it.

8.10.15. Maintenance and QA/QC of radiopharmacy equipment

Radiopharmacy facilities of all levels require an appropriate program of maintenance and QA/QC of equipment. This includes the components of the HVAC (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 HEPA filter, check of air speed and ventilation rate, etc.) should be performed when the unit is initially installed and regularly repeated. Unless different recommendations are given at the national level, it is typically requested that these are repeated at least yearly to ensure the desired air quality aimed to protect

8.10.16. SOPs for QA/QC of all radiopharmacy equipment

Calibration, qualification testing programs and routine QA/QC should be active for all laboratory equipment, including activity meters, HPLC or TLC scanners, gas-chromatography, pH meter, as well as basic equipment, such as refrigerators, scales, thermometers and micro-pipettes.

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

Sophisticated synthesis modules used in the production of PET radiopharmaceuticals typically include routines for automated or semi-automated 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, in the radiopharmacy lab, hygienic conditions should be strictly maintained, which requires carefully prepared procedures for radioactive and/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” (NC) occurs when a standard is not fulfilled. This requires that standards are set for the activities of an NMS (see 11.1). The recording of NC is one of the key aspects in a QMS; frequently, one of the most important parameters that auditors consider; the lack of registration of NC, is a clear sign of a non-mature or definitely non-functioning QMS.

In some cases, standards exist independently of the NMS, because they are deriving from legislation or a technical standard (e.g. ISO, IEC or others), from international guidance (IAEA standards), or from national/international 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, 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 activity of an NMS. For their registration there are different possibilities: some institutions have a centralized database, including the possibility 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 other cases, it is preferred to have separate database for NC recording for the different areas of work, e.g. there can be a database for recording NC in clinical imaging, a separate one for radiopharmacy activities, yet another one regarding equipment, etc. Either solution is acceptable if they are correctly managed and consistently documented in SOPs.

When a NC involves risk for a patient, a staff member or the environment, it should be considered as an incident and treated accordingly (see chapter 7.6.2).

9.1. MANAGEMENT OF NC

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

The registration should include at least:

- date of opening on the NC
- a registration / identification number
- classification for sector of work / type / level of risk of NC
- a keyword or short identification description
- an open text for description of the problem (e.g. 400 – 500 characters)
• ID of the operator notifying the NC
• an open text for description of the actions taken
• link to a possible corrective action
• a short, open text for description of results and closure of the NC
• date of closure
• links to external documents (pdf, doc, etc)

The modality of management of NC 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 NCs 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 NC 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 NC to all relevant members of staff, particularly the quality manager/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 7.6.3). In any case, timely reactions are a key point that should always kept in mind.

Furthermore, it could be necessary to record the NC as an incident, in other specific registers (see chapter on incident reporting).

9.2. CATEGORIZATION OF NC

Categorization is important to help the process of analysis of NCs and in determining root events. This can consider specific risk levels of potential NCs in different components of the processes or areas of the NMS. Searching previous records and other documents such as the risk registry using keywords may help revise risk levels appropriately.

Non-Conformances should be periodically reviewed: the number and types of NCs recorded is an indicator of the QMS. The quality manager or the quality committee, should continuously monitor the data on NC. 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, and 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, including calling the manufacturer representative for service.
When doing the daily QC on this camera, using a flood source of 57Co and LEHR Collimator according to SOP, the nuclear medicine technologists in charge of that camera noticed a clear area of absence of counts at the top border of the field of view; most likely a PM tube is not working properly. The calculated value of the integral uniformity is 85%, while the CFOV 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 normal operation, but the latter is not a “standard” defined by the NMS: the camera is a device, it is not emitting specification, nor any company could grant that any device will show 0% faults! 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 HoD decides to swap the program between cameras, considering that the defect on the border of the FOV 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 HoD. 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 was agreed that an engineer will intervene at 8:00am the following day; confirmation was sent by e-mail. The chief technologists then re-scheduled all studies for the camera until after 10:00. The following day, the field engineer of the company arrived at 11:00am. Is this a Non-Conformance?

Answer: Yes.

Maintenance was planned and confirmed for 8:00am. The delay means that studies had 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 notified 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 to a centralized radiopharmacy 15 unit doses, to be delivered by 8:00am; these include 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, weight 16 kg, and a reduced activity of 30 MBq at the hour of injection was placed in the order. The order was regularly sent by 17:00 of the day before, according to the contract.

When receiving the order, the chief technologists noticed that all of the unit doses have the same activity of 70 MBq, at scaling time of injection.

- Question 1: is this a NC?

Answer: Yes.

The order should match the request. The NC should be recorded and notified to the centralized radiopharmacy.

Question 2: Following the receipt of a prompt phone complain, the radiopharmacy replies, refusing the NC, since the activity they sent is more than the requested, and 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 this range. The NC should be confirmed and officially notified, 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.

Scaling of the activity is possible. There should be a proper procedure in place for doing this safely, both with regard to pharmaceutical and radiation protection aspects. Relatively simple and foreseeable non-conformities should be foreseen in the appropriate SOPs, or in problem solving tables annexed to SOPs.

9.2.3. Example 3: modified scanner setup

An 86-year-old male is booked for a whole-body bone scan. At the time of examination, the technologist realizes that the patient, even if collaborating, has difficulty in standing still on the bed for the time foreseen for the study. Since the patient has already been injected, the technologist decides 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 NC?

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 NC, mitigating its negative effects once the NC has occurred, and preventing its recurrence.

The same approach is used if a potential NC 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 NC.

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 CAPA management is another essential element of a QMS, following management of NC. It is a key point as regards the concept of continuous improvement: it is expected that not only the current problem is solved, but that actions are taken to prevent that the same problem will be repeated 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;
- assign responsibility for taking corrective action;
- 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 CAPA, applying the previous steps, is setting up a focus group which draws up an action plan, defining methods, responsibilities and timelines. The quality manager/quality committee will follow the development of the action and monitor its progress together with the work group. Finally, the group and the committee will carry out a verification of the effectiveness of the action proposed and initially tested.
If the verification is positive, the action can be closed, and will be duly registered. If the results obtained are not yet, the cycle will be repeated, suggesting adjustments and new solutions, which once again will be tried and assessed. Figure 13 reports a flowchart for the implementation of corrective actions.

*Figure 13. Example of flow chart of corrective action*
9.3.2. Examples of Root Cause Analysis

9.3.2.1. Example 1 – Corrective Action (CA)

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

This operation must be performed inside a laminar flow hot cell; the technologist most trained in this type of operation was on leave, so another technologist with relevant general experience, but not in the manipulation of microspheres, has to take the task.

While adjusting the volume to be dispensed, the suspension of microspheres (that is very dense) obstructed the needle. Pushing the piston of the syringe produces a spray of the product exiting 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, but whose forearm was not protected.

Decontamination was instantly attempted, but with limited success.

Follow-up: A work 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 NC in the register of the department.

The medical physicist evaluated a surface of about 10 x 3 cm² 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 (RADIATION PROTECTION DOSIMETRY Vol. 98 No 1, 2002), 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 periodical monitoring by the occupational medicine service.

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

9.3.2.2. Example 2 – Preventive Action (PA)

Implementation of 223Ra dichloride therapy. During one of the first administrations, the nuclear medicine physician suspected that there could be an extravasation. The injection was immediately suspended. The injection line was re-positioned 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 bio-distribution, 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 work group was established, including the nuclear medicine physician, chief technologist, chief nurse of oncological chemotherapy and a medical physicist.

They evaluated the scenario and decide 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 can have an influence and can 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.

At completion of these activities, the modality of injection of 223Ra dicloride was updated: a new type of cannula adopted; a systematic check of flow with saline was introduced. A specific form to be completed, with boxes to tick for every step, was introduced. 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 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 appropriate control of all equipment and instrumentation, including analytical, and manage their whole life cycle.

10.1. GENERALITIES

Strategic planning at hospital level should derive from national/regional priorities defined for healthcare (e.g. national cancer control plan; national plan for availability of orphan drugs including 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 above. Availability of space and specifically the space required for the NMS should be carefully assessed. When needed, this assessment will include space for wards for radionuclide therapy; for a dedicated building for a cyclotron; for a new radiopharmacy; as well as renovations or relocations to host PET/CT scanners. Special consideration should be given to logistic and construction aspects, such as, but not limited to patient flow, radiation shielding and spatial separation of hot and cold areas, 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 [IAEA SSG-46, p126]. 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 IAEA SSG-46, p126 and in Annex 3 of EudraLex - Volume 4 - Good Manufacturing Practice (GMP) guidelines [49].

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

- an analysis of the projected growth of clinical services to match demand, adoption of new types of services and new technologies available for scanning and laboratory operations; and
- an analysis of 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 instrumentation and should include the following information [50]:

- unique identifier for each piece of equipment
- certification and quality marks
- description and photograph
• price and estimated cost in case of 1:1 replacement
• date of purchase and (updatable) expected life
• manufacturer / purchase supplier
• present location
• results of acceptance and commissioning
• service providers, protocols and schedule of maintenance. Contact information
• history of maintenance (preventive and corrective)
• history of use
• calibration procedure and frequency and latest results
• operating status: in service / out of service / restricted service
• documentation including instruction manuals
• QA/QC results (may have separate register)
• software version
• depreciation and projected year of replacement

The equipment inventory, combined with the NMS strategic/business plan which defines expected future changes in the types and capacity of nuclear medicine services (see also 4.4), will allow senior management to build a 5-year plan for capital equipment, small equipment, infrastructure and human resources, and the necessary annual budget, appropriately allocating financial resources and 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 2 years).

10.3. MANAGEMENT OF THE EQUIPMENT LIFE CYCLE

As previously discussed, an assessment of the total cost of ownership (TCO) 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 according to the history of use, maintenance and failures of equipment. Figure 18 shows the failure rate with 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:

• transport and installation costs
• training costs
- staff costs
- operating costs and consumables
- costs of preventive maintenance and repairs
- administration and supply costs
- IT costs
- refurbishing or upgrading cost
- cost of removal

Four phases in this life cycle could be considered:

a) Start up. Immediately after installation, the failure rate can be relatively high, requiring frequent corrective actions (typically 18-20 months);

b) Normal working life. The equipment operates satisfactorily with an acceptable low failure rate (typically until year 7-8);

c) Worn out. After phase B, due to aging and wear and tear, failure rates start to increase substantially. This should be considered as a trigger to begin preparations to replace or refurbish the equipment;

d) End of life. Failure rates become unacceptably high. One of the factors behind this increased failure rate can be that the equipment is no longer supported by the manufacturer (end of service).

Figure 14. The bathtub curve illustrates the typical failure rate pattern of a piece of complex equipment with time during its full life cycle. A) Start up; B) Normal working life; C) Worn out; D) End of working life. X-axis: years of activity; Y-axis: number of failures
As illustrated in Figure 14, when newly installed, a scanner can have several issues, small or big premature failures, some of which may even need to be resolved before it can be released for clinical use. In the first few months this start up failure rate can be high, but it will rapidly decrease as the number of new problems identified within a time interval becomes lower than the number that gets resolved. Eventually, the downtime of the scanner becomes stable and acceptably low and remains so for several years to come (‘normal life’ phase). Continuous use increases down-time 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 a busy NMS with a fully occupied scanner, increased down-time 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 Figure 18, supported by inventory and maintenance data.

If the red flag of rising failure rates during phase C is ignored, these rates can become unacceptably high (phase D, end of life), 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 quality control, proper maintenance of all equipment, in particular medical devices, is required to warrant its safety, reliability and quality of performance. For a busy NMS it is also important that down-time of crucial medical equipment such as the imaging modalities and the image processing and archiving systems, be kept at a low level and mainly be planned downtime. Scheduled preventive maintenance of scanners, as well as their corrective maintenance (repairs), should take just a few percent of the total working time on an annual basis ideally, 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 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. This evaluation should be based on documented indicators of performance such as total up-time, unplanned down-time, 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 maintain the equipment fully operational, or corrective when a detected failure needs to be fixed. Figure 15 shows a typical flowchart of operations to keep any equipment under control.
10.5. THE CYCLE OF QA/QC

Equipment quality control 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 of each piece of equipment starts prior to the purchase, with the specification of requirements and the selection from competing alternatives. All aspects which may influence performance should be considered at an early stage, including choice of appropriate site for installation, all necessary accessories (collimators, workstations, etc) and include object tests and phantoms for QA/QC.

Considerations for site choice may include:

- influence of interference from adjacent sources of radiation (other scanners, therapy wards, waiting rooms for injected patients)
- interfering magnetic fields
- sunlight entering reading/reporting rooms or scanner room
- installation planning should factor accessibility for large crates and smooth workflow
- structural characteristics (floor reinforcement)
- reliability and safety of power supply
- room environment (temperature, relative humidity)
10.5.1. Acceptance tests and commissioning

Before clinical use, detailed acceptance tests and commissioning are required [15]. Acceptance tests can be performed at different instances: at the factory (factory acceptance tests, FAT) and at the site (site acceptance tests, SAT) after completion of installation and just before warranty expiration. Acceptance tests should check performance against the manufacturer’s specifications and user’s requirements. This test should be performed by experts of the institution and may be counterchecked by the experts/engineers of 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 to be used 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 (IQ), Operational Qualification (OQ) and Performance Qualification (PQ) for radiopharmacy equipment.

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

Key components of the QA/QC program should include at least [52-55]:

1. set of requirements for 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, maintenance;
5. definition of responsibilities for QA/QC, reporting NC and deviations, etc.;
6. implementing the routine QA/QC program 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 Figure 15 which illustrates the value of frequent quality control of a scintillation camera. Monitoring of the intrinsic uniformity of a scintillation detector (one of several parameters monitored) reveals gradual performance degradation. A detector reburn was performed, to correct for non-linearities emerging. As a consequence, uncorrected uniformity improved dramatically, especially in the periphery of the field of view. After the reburn uniformity degrades again, very slowly, indicating the future 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.

Figure 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 stands for the larger Useful Field of View. The green arrow indicates action taken after UFOV action level was exceeded. [56]

The activities included in the quality control programs of nuclear medicine equipment are schematically shown as a flowchart on Figure 17.

Figure 17. Flow chart of quality control programs for nuclear medicine equipment
10.6. ROLES AND RESPONSIBILITIES IN EQUIPMENT MANAGEMENT

Table 10 summarizes the different levels of management and staff involved.
## TABLE 10. ROLES AND RESPONSIBILITIES IN EQUIPMENT MANAGEMENT

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

### 10.7. END OF SERVICE LIFE AND EQUIPMENT DISPOSAL

End of service life is the condition of an equipment for which the manufacturer no longer provides service or spare parts. When it has reached this condition, or when proper operation is no longer achievable, or cost of repairment is disproportionately high, the equipment should be taken out of service.

Equipment which was donated or acquired under a grant may have specific disposal conditions. Radioactive components in equipment, as well as vacuum-packed components such as photomultiplier tubes, require specific arrangements to be disposed as waste.

### 10.8. PROVISION AND MANAGEMENT OF RESOURCES

#### 10.8.1. Purchase of equipment, products and services

Regarding the evaluation of suppliers, typically an NMS does not issue orders directly for the acquisition of new products, but must comply with regulations and institutional processes for procurement and 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 must 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 [IAEA SSG-46, par. 4.8 p126].

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/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 (FDA clearance, and/or CE mark for medical devices; 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/product.

During the pre-purchase 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-economic evaluations (cost/quality analysis), the final purchase order is issued.

Before clinical use, the new equipment/product should undergo detailed acceptance tests as defined previously (see section 10.5.1).

Generally, there are at least two different levels for the procurement of goods/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 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 well as acceptance test complexity. 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 above aspects, 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 radiopharmaceuticals products is a key factor for the operation of an NMS, and specific regulations exist. In addition to the information in 10.7.1 (above), these aspects are also discussed in 8.10.2.

Here, it may be worthwhile remembering 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 offices, should regularly monitor the level of expenditure against the workload performed and the yearly available budget (see 11.3).

10.8.2.1. Examples concerning acquisitions:

10.8.2.2. Syringes, needles, cannulas, butterfly lines, etc.

All of these are fundamental for proper administration of radiopharmaceuticals and should have adequate quality in order to avoid risk of spillage, reduce the risk of extravasation, etc., given 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 sub-optimal injection can potentially hinder the quantitative aspects of a procedure.

Question: Do acceptance tests apply also to this type of products?

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 applies also to devices that have a minimal unitary cost. It should be borne in mind that, even if the cost of a single syringe is low, their total consumption may sum up a significant budget. Given the previously commented aspects on safety, it should be clear that all components and devices need careful testing before being accepted and placed in routine use.

10.8.2.3. Gloves

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

Question: Are all type 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. In the case of low risk of contamination, and in activities with short lived radionuclides for diagnostic use, latex gloves are generally adequate.

In case of increased risk, as when manipulating beta or alpha emitters for therapy, in order to further reduce the risk of contamination it could be useful to consider alternatives, such as nitril gloves. Testing of gloves can be done both in the laboratory and practically using them and asking the operators to report on their experience and feeling when using different types.

10.8.2.4. Radiopharmacy

A great number of nuclear medicine departments operate at Radiopharmacy Level 1, which means receiving ready to use radiopharmaceuticals from a centralized radiopharmacy, or an industrial provider.

Question: When receiving ready to use unit doses, is some QC necessary?

Answer: Yes.

The QC necessary to release the batch of production was made 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 delivered: condition and cleanliness of the carrying containers, no. 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 Non-Conformance notified the provider.

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 (QI) in nuclear medicine are well-defined metrics used to monitor, analyse and improve all of the processes in the process map (Figure 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 indicators data should be carried out to evaluate key components of the NMS, such as clinical activities, radiation protection, radiopharmacy, operation, equipment performance, NC statistics, etc. Systematic use of indicators is also very helpful to assess and enhance administrative and managerial activities and processes. Relevant aspects such as NCs, 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 with the acronym SMART. Selected quality indicators are assigned as key performance indicators (KPI) for an NMS, allowing the monitoring of pertinent activities. Within the framework of continuing improvement, the set of KPIs is dynamically adapted over time. Indicators should be selected according to an analysis of needs, the existing situation and considering the mission vision and strategic plans. Table 1 gives an indication on the variety of dimensions of care that are relevant. Table 11 provide a list of indicators which should be regularly controlled to keep clinical services operational and in quality.

TABLE 11: DIMENSIONS OF CARE AS THEY RELATE TO PERFORMANCE INDICATORS

<table>
<thead>
<tr>
<th>Dimension of care</th>
<th>Performance indicators</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient safety</td>
<td>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.</td>
</tr>
<tr>
<td>Effectiveness</td>
<td>Outcomes measures for procedures; appropriateness of imaging studies; positive predictive rates for modalities; physician performance assessment and peer review.</td>
</tr>
<tr>
<td>Efficiency</td>
<td>Reduction of unnecessary studies; number of technologists per scanner; scanner utilization, scanning room turnaround time; equipment downtime for maintenance.</td>
</tr>
<tr>
<td>Patient-centeredness</td>
<td>Patient satisfaction surveys; analysis and management of customer complaints; communication and follow-up of abnormal results and unexpected/significant findings.</td>
</tr>
<tr>
<td>Timeliness</td>
<td>Waiting list; report turnaround time; patient throughput in nuclear medicine scanner; patient wait times inside the department.</td>
</tr>
</tbody>
</table>
## Table 12: Examples of Indicators Regularly Controlled in Nuclear Medicine Services.

<table>
<thead>
<tr>
<th>Code</th>
<th>Indicator</th>
<th>Key Area</th>
<th>Comment/Justification</th>
</tr>
</thead>
<tbody>
<tr>
<td>CLS-01</td>
<td>Achieved clinical demand</td>
<td>Clinical Activities</td>
<td>Ratio between studies currently performed vs. a reference period, or vs. an assigned goal (clinical services should match the demand).</td>
</tr>
<tr>
<td>CLS-02</td>
<td>Report release time (turnaround time)</td>
<td>Clinical Activities</td>
<td>Average times between study completion and report release for different study types.</td>
</tr>
<tr>
<td>CLS-03</td>
<td>Wait lists for different type of studies</td>
<td>Clinical Activities</td>
<td>Average times between receipt of referral, booking and study undertaken.</td>
</tr>
<tr>
<td>CLS-04</td>
<td>Study repetition rate due to technical issues</td>
<td>Clinical Activities</td>
<td>Ratio between patients requiring study repetition and total number of studies performed.</td>
</tr>
<tr>
<td>RP-01</td>
<td>Number of kits labelled, or synthesis performed, for most relevant type of radiopharmaceuticals</td>
<td>Radio-pharmacy Activities</td>
<td>Ratio between the dispensed radiopharmaceutical doses and the number of labeling/synthesis (acceptable criteria will vary for different products).</td>
</tr>
<tr>
<td>RP-02</td>
<td>Number of kits labelled or synthesis of radiopharmaceuticals that did not meet quality criteria and were not released for use</td>
<td>Radio-pharmacy Activities</td>
<td>Percent of rejected radiopharmaceutical labeling/synthesis that do not meet the requirements (radiochemical or radionuclidic purity, labelling/synthesis yield, or other pharmacopeia parameters.</td>
</tr>
<tr>
<td>RP-03</td>
<td>Adverse effects or other incidents related to radiopharmaceutical administrations</td>
<td>Radio-pharmacy Activities</td>
<td>Percent of patients with adverse effects vs number of performed studies.</td>
</tr>
<tr>
<td>RPr-1</td>
<td>Optimization of occupational exposure</td>
<td>Radiation Protection</td>
<td>95% or more of employee annual radiation doses &lt; of the established constraint (e.g. 2 mSv).</td>
</tr>
<tr>
<td>RPr-2</td>
<td>Number of NC related with radiation protection (e.g. spills, surface contamination, etc.)</td>
<td>Radiation Protection</td>
<td>Total number of NCs related to the management of radioactive materials should be below the established threshold levels</td>
</tr>
<tr>
<td>IEq-1</td>
<td>Preventive maintenance of nuclear medicine equipment</td>
<td>Nuclear medicine equipment</td>
<td>Ratio between the delivered preventive maintenance and the annual plan.</td>
</tr>
<tr>
<td>IEq-2</td>
<td>Completion of quality control activities of nuclear medicine equipment</td>
<td>Nuclear medicine equipment</td>
<td>Ratio between numbers of performed QC vs planned QC activities.</td>
</tr>
<tr>
<td>Code</td>
<td>Indicator</td>
<td>Key Area</td>
<td>Comment/Justification</td>
</tr>
<tr>
<td>-------</td>
<td>---------------------------------------------------------------------------</td>
<td>----------------------</td>
<td>----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>IEq-3</td>
<td>Uptime of major equipment and number of lost studies due to problems with medical equipment</td>
<td>Nuclear medicine equipment</td>
<td>Total up time (no. of hours of availability vs. total no. of working hours), e.g. &gt; 98%. Number of lost studies due to problems with the nuclear medicine equipment, e.g. &lt; 2% of total number of studies performed.</td>
</tr>
<tr>
<td>HR-01</td>
<td>Training of nuclear medicine staff on radiation protection topics</td>
<td>Human Resources</td>
<td>Percent of delivered training vs annual training plan on RadProt topics.</td>
</tr>
<tr>
<td>MgS-01</td>
<td>Customer complaints (patients, referring physicians, etc)</td>
<td>Management</td>
<td>Ratio between number of clients complains and total amount of performed studies.</td>
</tr>
<tr>
<td>MgS-02</td>
<td>Patient satisfaction evaluation</td>
<td>Management</td>
<td>Percent of patients providing positive criteria of satisfaction versus total number of surveys.</td>
</tr>
<tr>
<td>MgS-03</td>
<td>Monitoring of budgetary expenditure</td>
<td>Management</td>
<td>Percent of executed vs planned budget for nuclear medicine activities.</td>
</tr>
<tr>
<td>MgS-04</td>
<td>Achievement of quality objectives</td>
<td>Management</td>
<td>Ratio of achieved vs planned objectives.</td>
</tr>
</tbody>
</table>

11.2. EXAMPLES OF PARAMETERS AND INDICATORS VAULES.

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

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

Indicator: Productivity current period

\[
\text{Indicator Value} = \frac{100 \times \text{Performed studies current period}}{\text{Performed studies reference period}} \times \%
\]

Definition/Formula:

Unit: %

Acceptable range for the indicator: Minimum value of 95%

Evaluation Periodicity: Monthly

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

Clarifications: The expected tendency is increasing

Indicator Code: CLS-1

Key area or process: Clinical services
11.2.2. Indicator Code: CLS-2 Key area or process: Clinical Services

Objective: To provide nuclear medicine services on a mean period lower or equal to 2 weeks, after examinations requests.
Indicator: Mean time between request and study completion.

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

Definition/Formula:
Unit: number of days
Acceptable range for the indicator: Mean value equal to or lower than 14
Evaluation Periodicity: quarterly
Responsible (Data collection and analysis): Physicians leading clinical activities.
Clarifications: Maximum value for a single data should be lower than 3 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

\[
\text{Indicator value} = \frac{100 \times \text{number of TOEs with Eff. Doses < 1.5mSv}}{\text{Total number of TOEs}}\%
\]

Definition/Formula:
Unit: (%)
Acceptable range for the indicator: Minimum Value = 95%
Evaluation Periodicity: 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. 6mSv). Maximum value of one single measurement should be lower than 1 month.

11.2.4. Indicator Code: RPh-1 Key area or process: Radiopharmacy

Objective: To guarantee that preparations and dispensation of radiopharmaceuticals doses match the planned clinical studies.
Indicator: Dispensed radiopharmaceutical doses.
Indicator value = \frac{100 \times \text{Dispensed radiopharmaceutical doses}}{\text{Planned radiopharmaceutical doses}} (\%) 

Indicator: Dispensed radiopharmaceutical doses.

Definition or Formula:

Unit: (\%)

Acceptable range for the indicator: Minimum value of 98%

Evaluation Periodicity: 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: RPh-1 Key area or process: Radiopharmacy

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

Indicator: Dispensed radiopharmaceutical doses.

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

Indicator: Dispensed radiopharmaceutical doses.

Definition or Formula:

Unit: (\%)

Acceptable range for the indicator: Minimum value of 98%

Evaluation Periodicity: Monthly

Responsible (Data collection and analysis): Director of radiopharmacy Lab.

Clarifications: This indicator provides a global measurement of the radiopharmacy activities.

11.2.6. Indicator Code: RPh-1 Key area or process: Radiopharmacy

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

Indicator: Dispensed radiopharmaceutical doses.
Indicator value = \frac{100 \times \text{Dispensed radiopharmaceutical doses}}{\text{Planned radiopharmaceutical doses}} (%) \\

Indicator: Dispensed radiopharmaceutical doses.

Definition or Formula:
Unit: (%)
Acceptable range for the indicator: Minimum value of 98%
Evaluation Periodicity: 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 clinical through a regular program of preventive maintenance.

Indicator: Performed the maintenance program of nuclear medicine equipment.

\[
\text{Indicator value} = \frac{100 \times \text{Number of performed maintenances}}{\text{Planned maintenances}} \times \%
\]

Definition or Formula:
Unit: (%)
Acceptable range for the indicator: Minimum value of 90%
Evaluation Periodicity: annually
Responsible (Data collection and analysis): Bio-engineer specialists.
Clarifications: Indicator related to maintenance of imaging and complementary equipment

11.3. CUSTOMER SATISFACTION

The nuclear medicine service must implement procedures to track its customers perceptions (from patients, referring physicians, patient’s relatives, etc) about the degree to which their needs and expectations are 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/surveys, regular collection of customer’s 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 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, etc.

Based on customer satisfaction surveys and on the institutional continuous improvement policy, the QM should agree with the nuclear medicine management 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, with space for free text 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 nuclear medicine service. An example of questions and the evaluation of patient satisfaction is shown in Figure 22.

### TABLE 13. EXAMPLE OF ASSESSMENT OF CUSTOMER SATISFACTION

<table>
<thead>
<tr>
<th>Aspect of customer satisfaction</th>
<th>Nr of patients</th>
<th>% score</th>
<th>Preliminary target</th>
<th>Target type</th>
</tr>
</thead>
<tbody>
<tr>
<td>I received NM information brochure before study</td>
<td>83</td>
<td>81%</td>
<td>90%</td>
<td>min</td>
</tr>
<tr>
<td>NM information brochure explained the procedure in detail and was easy to understand</td>
<td>74</td>
<td>70%</td>
<td>90%</td>
<td>min</td>
</tr>
<tr>
<td>The information brochure answered all my questions</td>
<td>59</td>
<td>58%</td>
<td>70%</td>
<td>min</td>
</tr>
<tr>
<td>The information brochure answered some of my questions</td>
<td>29</td>
<td>28%</td>
<td>50%</td>
<td>max</td>
</tr>
<tr>
<td>I could reach the NMS by phone or email directly</td>
<td>84</td>
<td>82%</td>
<td>95%</td>
<td>min</td>
</tr>
<tr>
<td>I did not informed that the NMS can be reached directly by a phone number or email</td>
<td>16</td>
<td>16%</td>
<td>20%</td>
<td>max</td>
</tr>
<tr>
<td>More information should have been included in the information brochure</td>
<td>65</td>
<td>64%</td>
<td>40%</td>
<td>max</td>
</tr>
<tr>
<td>The NMS premises were clean</td>
<td>72</td>
<td>71%</td>
<td>80%</td>
<td>min</td>
</tr>
<tr>
<td>The personnel looked professional</td>
<td>67</td>
<td>66%</td>
<td>80%</td>
<td>min</td>
</tr>
<tr>
<td>Staff identified themselves</td>
<td>93</td>
<td>91%</td>
<td>95%</td>
<td>min</td>
</tr>
<tr>
<td>The service delivery was satisfactory</td>
<td>72</td>
<td>71%</td>
<td>80%</td>
<td>min</td>
</tr>
<tr>
<td>The service delivery was not satisfactory</td>
<td>44</td>
<td>43%</td>
<td>20%</td>
<td>max</td>
</tr>
<tr>
<td>The technologists were able to answer my questions</td>
<td>86</td>
<td>84%</td>
<td>80%</td>
<td>min</td>
</tr>
<tr>
<td>I received a kind treatment and felt comfortable during the entire procedure</td>
<td>62</td>
<td>61%</td>
<td>80%</td>
<td>min</td>
</tr>
<tr>
<td>Front desk service was satisfactory</td>
<td>81</td>
<td>79%</td>
<td>80%</td>
<td>min</td>
</tr>
<tr>
<td>Front desk service was not satisfactory</td>
<td>45</td>
<td>44%</td>
<td>20%</td>
<td>max</td>
</tr>
<tr>
<td>The room temperature was comfortable</td>
<td>76</td>
<td>75%</td>
<td>70%</td>
<td>min</td>
</tr>
<tr>
<td>I was seen on time</td>
<td>82</td>
<td>80%</td>
<td>80%</td>
<td>min</td>
</tr>
<tr>
<td>I was seen on time</td>
<td>14</td>
<td>14%</td>
<td>20%</td>
<td>max</td>
</tr>
<tr>
<td>Staff were professional and knowledgable</td>
<td>89</td>
<td>87%</td>
<td>80%</td>
<td>min</td>
</tr>
</tbody>
</table>

**Total number of questionnaire responses received and analysed:** 102
**Total number of green scores (equal to, or better than target):** 7 35%
**Total number of red scores (target not met):** 13 65%

11.4. PERFORMING MANAGERIAL REVIEW

The head of department (HoD) is responsible for planning and conducting managerial reviews, with the support of the quality committee/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 / quality manager (QC/QM) and submitted to management for further examination and discussion during the managerial review meeting.

The QC/QM is also responsible for preparing reports of the review meetings, as well as the preparation of the quality plan and corrective/preventive actions (see 9.3.1).
Reviews should be performed at regular intervals, according to a pre-established calendar, typically 3-4 times a year, and usually consist of an analysis of pre-defined indicators (objective elements that help assess the current situation). These indicators (see 11.1) are selected to become significant markers of the quality system performance, to assess the achievement of the stated objectives as defined in the quality policy, in the yearly plans, or assigned by the higher management of the institution. Other useful quality indicators are included, e.g. 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 QC/QM. This is often prepared in the form of a matrix or table (see Table 13): specific objectives or plans are identified in each row, while expected and achieved results for each evaluated period are reported in the columns.

**TABLE 14. EXAMPLE OF FORM FOR HANDLING A MANAGERIAL REVIEW**

<table>
<thead>
<tr>
<th>LOGO</th>
<th>REPORT FOR MANAGERIAL REVIEW</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>LOGO</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>REPORT FOR MANAGERIAL REVIEW</th>
<th>Report No.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Rev. 1</td>
</tr>
<tr>
<td></td>
<td>Pag. 1/1</td>
</tr>
<tr>
<td>Date of applicability:</td>
<td>DD/MM/YYYY</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>OBJECTIVES</th>
<th>Expected result 1st quarter</th>
<th>Achieved result 1st quarter</th>
<th>Expected result 2nd quarter</th>
<th>Achieved result 2nd quarter</th>
<th>Expected result 3rd quarter</th>
<th>Achieved result 3rd quarter</th>
<th>Expected result 4th quarter</th>
<th>Achieved result 4th quarter</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date of review</td>
<td>dd/mm/yyyy</td>
<td>dd/mm/yyyy</td>
<td>dd/mm/yyyy</td>
<td>dd/mm/yyyy</td>
<td>dd/mm/yyyy</td>
<td>dd/mm/yyyy</td>
<td>dd/mm/yyyy</td>
<td>dd/mm/yyyy</td>
</tr>
</tbody>
</table>

1.0 OBJECTIVES SET OUT BY THE INSTITUTION MANAGEMENT

1.1 OBJECTIVES SET OUT BY THE DEPARTMENT

1.2 OTHER OBJECTIVES

CUSTOMER SATISFACTION

CONTROL OF EXPENDITURE

Signature of the QM

Signature of the HoD

Meeting participants:

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 HoD and the QC/QM 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.
12. REFERENCES


[9] Safety pros: Should the term "near miss" be replaced by a different term, such as "near hit"?, (2016) https://www.safetyandhealthmagazine.com/articles/14711-safety-pros-should-the-term-near-miss-replaced-by-a-different-term-such-as-near-hit


13. GLOSSARY OF TERMS

CA – Corrective Actions
CAPA - Corrective and Preventive Actions
CG – Clinical Governance
CPD – Continuous Professional Development
CTDI - Computed Tomography Dose Index
DRL - Diagnostic Reference Levels
DS - Documentation System
HoD - Head of Department
ISO – International Organization for Standardization
KPI - Key performance indicators
NC - non-conformances
NMS – Nuclear Medicine Service
PA – Preventive Actions
QA – Quality Assurance
QC – Quality Control
QC/QM – Quality Committee/Quality Manager
QI – Quality Indicators
QMS - Quality Management System
RP –Radiopharmaceutical
SOPs – Standardized Operating Procedure
14. ANES

14.1. ANNEX 1. EXAMPLE OF A TABLE OF CONTENTS FOR A QUALITY MANUAL
(FROM REF 16)

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) Mid-term 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 resources
   b) Financial resources
   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
### 14.2. ANNEX 2. EXAMPLE OF A FORM FOR A SOP FOR DIAGNOSTIC PROCEDURES

<table>
<thead>
<tr>
<th>EXAMINATION PROCEDURE GUIDELINE</th>
<th>CODE</th>
<th>DATE</th>
<th>REV.</th>
<th>AUTHOR</th>
<th>APPROVED BY</th>
</tr>
</thead>
<tbody>
<tr>
<td>Description of change: Initial release</td>
<td>CL-XXX</td>
<td>dd/mm/yyyy</td>
<td>01</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Type of examination**

**Purpose**

**Clinical indications**

**Contra-indications**

**Pre-examination procedure**

- Patient preparation
- Pre injection
- Injection, dosage and administration
- Post injection
- Possible side-effects

**Radiopharmaceutical**

- Type
- Description
- Preparation
- Injected activity
- Quality control
- Special precautions

**Scanner set-up**

**Quality control**

**Image acquisition**

- Equipment
  - Detector
  - Collimator
  - Window

- Acquisition modality
<table>
<thead>
<tr>
<th>Optional images</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Image processing</td>
<td></td>
</tr>
<tr>
<td>Sources of error</td>
<td></td>
</tr>
<tr>
<td>Disclaimer</td>
<td></td>
</tr>
<tr>
<td>Dosimetry</td>
<td></td>
</tr>
</tbody>
</table>

### ASSOCIATED DOCUMENTS

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
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</table>

### RECORDS

<table>
<thead>
<tr>
<th>Title</th>
<th>Code</th>
<th>File Location</th>
<th>Record Custodian</th>
<th>Retention Period</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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</tr>
</tbody>
</table>
### 14.3. ANNEX 3. EXAMPLE OF A FORM FOR A SOP FOR THERAPY PROCEDURES

<table>
<thead>
<tr>
<th>Name of Dept / Institution</th>
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</table>

**THERAPY PROCEDURE GUIDELINE**

<table>
<thead>
<tr>
<th>CODE</th>
<th>DATE</th>
<th>REV.</th>
<th>AUTHOR</th>
<th>APPROVED BY</th>
</tr>
</thead>
<tbody>
<tr>
<td>TH-XXX</td>
<td>dd/mm/yyyy</td>
<td>01</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Description of change:**
- Initial release

<table>
<thead>
<tr>
<th>Type of therapy</th>
</tr>
</thead>
</table>

**Purpose**

<table>
<thead>
<tr>
<th>Indications</th>
<th>Contra-indications</th>
</tr>
</thead>
<tbody>
<tr>
<td>Type of disease</td>
<td>Radio-pharmacy</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Radiopharmaceutical</th>
<th>Dose calculation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Route of Administration</td>
<td>Hospital admission required?</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Facility</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient preparation</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Precautions</th>
<th>Dose</th>
<th>Sources of error</th>
</tr>
</thead>
</table>

**Issues requiring clarification**

**Disclaimer**

**Dosimetry**

**Discharge**

**ASSOCIATED DOCUMENTS**

**RECORDS**

<table>
<thead>
<tr>
<th>Title</th>
<th>Code</th>
<th>File Location</th>
<th>Record Custodian</th>
<th>Retention Period</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
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<td></td>
</tr>
</tbody>
</table>
### 14.4. ANNEX 4. EXAMPLES OF A CLINICAL SOP FOR DIAGNOSTICS WITH SINGLE-PHOTON EMITTERS

<table>
<thead>
<tr>
<th>Title: Bone Studies</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Version Nr:</strong></td>
</tr>
<tr>
<td>---</td>
</tr>
<tr>
<td>---</td>
</tr>
</tbody>
</table>

**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. three to four glasses of any fluid). Patient should void just prior to scan commencing.

**RADIOPHARM.:** $^{99m}$Tc MDP (Medronate)

**DOSE:** 600-700 MBq

**EQUIPMENT:** Dual Head SPECT/CT (specify brand and model). Each different system should have their 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
- 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. See table below.

<table>
<thead>
<tr>
<th>Patient’s BMI</th>
<th>Acquisition Type</th>
<th>Sec/Step</th>
<th>CT Parameters (kVp/mA)</th>
</tr>
</thead>
<tbody>
<tr>
<td>≤22</td>
<td>SPECT/CT (S)</td>
<td>18</td>
<td>100/Dose Mod mA</td>
</tr>
<tr>
<td>22.1 – 34.9</td>
<td>SPECT/CT (M)</td>
<td>20</td>
<td>120/Dose Mod mA</td>
</tr>
<tr>
<td>&gt;35</td>
<td>SPECT/CT (L)</td>
<td>22</td>
<td>140/Dose Mod mA</td>
</tr>
</tbody>
</table>

**WB SPECT/CT:**

<table>
<thead>
<tr>
<th>Patient’s BMI</th>
<th>Acquisition Type</th>
<th>Sec/Step</th>
<th>CT Parameters (kVp/mA)</th>
</tr>
</thead>
<tbody>
<tr>
<td>≤22</td>
<td>SPECT/CT (S)</td>
<td>14</td>
<td>100/Dose Mod mA</td>
</tr>
<tr>
<td>22.1 – 34.9</td>
<td>SPECT/CT (M)</td>
<td>16</td>
<td>120/Dose Mod mA</td>
</tr>
<tr>
<td>&gt;35</td>
<td>SPECT/CT (L)</td>
<td>18</td>
<td>140/Dose Mod mA</td>
</tr>
</tbody>
</table>

**PROCESSING & 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.
### Title: Standard 18F-FDG Whole Body PET/CT protocol

<table>
<thead>
<tr>
<th>Version Nr:</th>
<th>Reviewed by:</th>
<th>Date:</th>
<th>Next Review:</th>
</tr>
</thead>
</table>

**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 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

<table>
<thead>
<tr>
<th>Patient's BMI</th>
<th>Dose (MBq)</th>
<th>Time/bed (mins/bed)</th>
</tr>
</thead>
<tbody>
<tr>
<td>≤22</td>
<td>220</td>
<td>2</td>
</tr>
<tr>
<td>22.1 – 26</td>
<td>250</td>
<td>2</td>
</tr>
<tr>
<td>26.1 – 28</td>
<td>250</td>
<td>2.5</td>
</tr>
<tr>
<td>&gt;28</td>
<td>300</td>
<td>3</td>
</tr>
</tbody>
</table>

**SCANNING:**
Scanning should commence 60 minutes post injection of 18F-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: is 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 ie. lymphoma of the orbit or tonsil.

Melanoma: Standard WB. The primary site and/or all known sites of melanoma must be included. For unknown primary, scan head to toe.

Lung, rectum & other diseases: Standard WB.

Head & Neck: Standard WB. Scan arms down and image H&N first.

PUO & 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 NIS for reporting. If an external prior study is provided, upload images to PACS for comparison.
### Title: Radioiodine Therapy Procedure (in-patients)

<table>
<thead>
<tr>
<th>Version Number:</th>
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</tr>
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</table>

**PURPOSE:** To instruct all healthcare personnel involved in managing in-patients that 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 must 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 must be handed to patients. Blood samples must be drawn if indicated by treating physician (TSH, Thyroglobulin, Anti Thyroglobulin antibodies and B-HCG if applicable).

**RADIOPHARMACEUTICAL:** 131Iodine (\(^{131}\)I) (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 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 must 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 meter 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 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.
15. CONTRIBUTORS TO DRAFTING AND REVIEW

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