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Review Article

Quality Assurance and Accreditation in Nuclear Medicine

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Abstract

Nuclear medicine is a complex healthcare specialty that needs specific management methodologies and quality policies. Healthcare leaders as quality managers, nuclear medicine practitioners and department headers play a fundamental role in ensuring quality standards in nuclear medicine facilities. This review describes the recommendations to implement best practices in nuclear medicine to achieve high quality of services through a governance-oriented guideline.

Introduction

It is well known that hospitals are prone to many serious risks to the patients and staff while providing patient treatment and diagnosis. The median overall incidence of adverse events is estimated to be nearly 10%, calling attention of healthcare providers for means of prevention [1].

Therefore, aiming to reduce the risks for patients and staff some organizations provide systematic assessment of hospitals against accepted standards and thus increase the safety and quality of healthcare assistance [2]. In this context, healthcare practitioners are aware that some specialties rely on very specific risks and thus should implement specific process monitoring and quality standards. In this communication we will focus on the safety and quality aspects of nuclear medicine: a medical specialty that makes use of radioactive substances to diagnose and/or treat diseases. Nuclear medicine practice face challenges due to complex processes variability, radiological risks and radioactive disintegration which result in management difficulties, image quality variations, and specific risks to patients and workers [3,4].

Most countries' regulation implemented universal nuclear medicine best practices recommended by international organizations, for example the International Atomic Energy Agency (IAEA), the Society of Nuclear Medicine and Molecular Imaging (SNMMI) and the European Association of Nuclear Medicine (EANM). However, refinements are usually made case by case due to local needs and resources so that not all recommendations of specific organization are made regulatory. For this reason, it is not rare that nuclear medicine facilities still have the opportunity to gather additional pieces of information from different sources in order to boost the quality of medical services. Thus, institutional quality policies and independent accreditation programmes would provide an indicator of high nuclear medicine standards.

This review aims at highlighting to nuclear medicine practitioners, quality professionals and director staff the potential risks, processes pitfalls, staff competencies and specific quality assurance and accreditation programs for a nuclear medicine department. After reading this manuscript, the reader shall be able to

- identify major needs and potential risks in a nuclear medicine operation;
- define the basic requirements for a quality assurance program;
- recognize the main accreditation programmes for nuclear medicine;

Quality Assurance

Many nuclear medicine practitioners usually make confusion about the differences between quality assurance (QA) and quality control (QC). Quality assurance refers to every step that ensure the best standards of medical services, while quality control refers to monitoring the imaging system (and other equipments) by testing and validating the system performance. The quality management system (QMS) is the programme that controls how quality is maintained and ensured throughout an organization [5,6].

Quality assurance encompasses various aspects based on specific indicators, for example:

- Patient recalls for repetition of examinations;
- Radiation dosimetry of staff;
- Radiopharmaceutical dosing;
- Execution of equipments/ radiopharmaceutical quality controls and documentation;
- Number of examinations performed;

- The satisfaction of patients with their care;
- The credentials of the staff;
- Any continuing education of the hospital staff.

The QMS defines what steps will be taken to ensure that the desired level of care is maintained. To this extent, organizations shall document the evidences through the whole nuclear medicine processes, for example but not limited to: i) patient scheduling, ii) radiopharmaceutical and patient identification, iii) registration of the right time and professional name for every steps through the process, iv) imaging protocol, v) registration of patient needs and patient/ family feedbacks, vi) documentation and communication of critical findings, and v) imaging and processes review before the patient leaves the nuclear medicine facility.

It is important to stress that despite the widely available literature on best practices of how nuclear medicine should operate, in the experience of the authors local regulations and institutional needs are not homogeneous and a thorough planning involving the multi-professional team should be taken. Therefore, before the beginning of a new nuclear medicine practice every process shall be discussed, reviewed, validated and documented. Furthermore, the head of department shall define often revision and audits during the operation to ensure that quality and safety standards are maintained as illustrated in Figure 1.

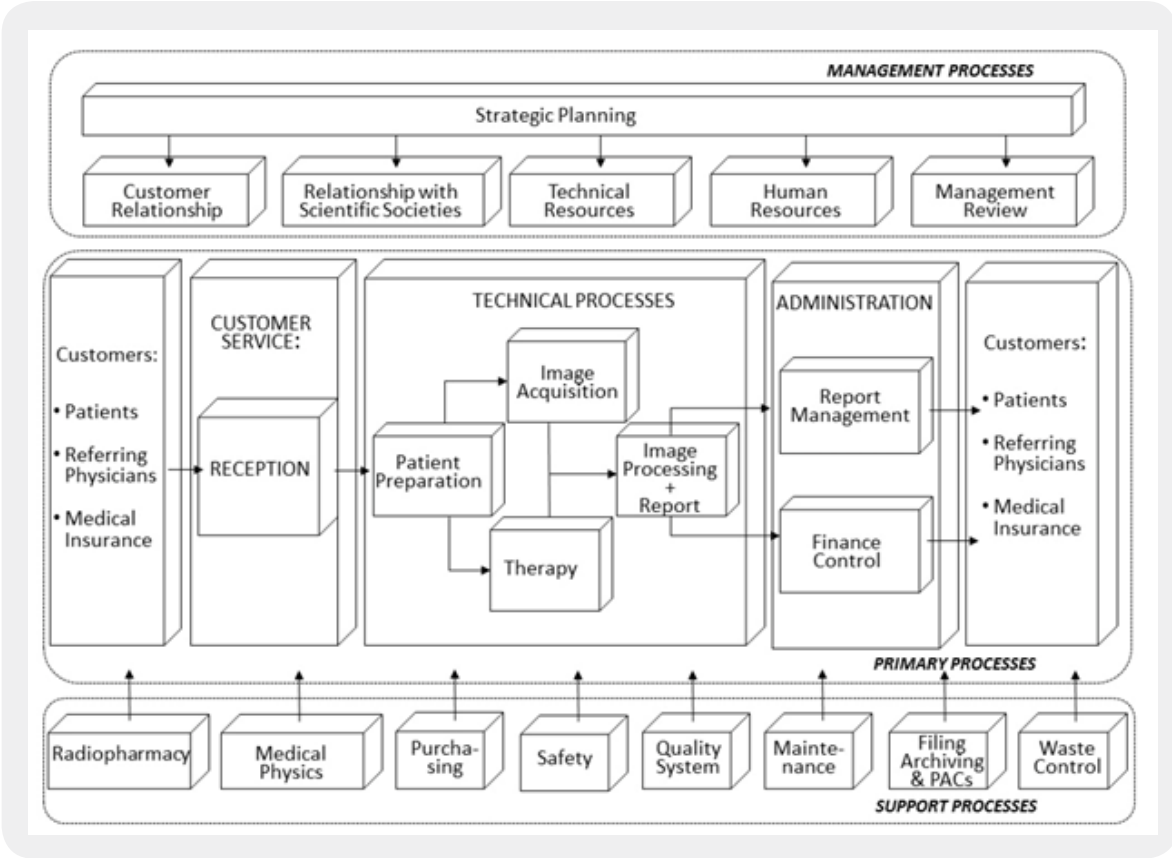

Figure 1: *Example of a process map for a nuclear medicine service, showing the primary, management and support processes [7,8]*

Infrastructure

Nuclear medicine infrastructure is among the first steps into planning and operating the facility. The main aspects of infrastructure will depend on institutional objectives (e.g.: radionuclide therapy and/ or diagnostic, medical specialties expertise of hospital) and should involve nuclear medicine experts in every step of infrastructure preparation. Nuclear medicine experts should give consultancy for different aspects of physical and technological infrastructure, providing details of the required instrumentation as well as instructions on maintenance and optimization of performance.

Minimum Staff

Once the objectives of nuclear medicine facilities are clear, it is simple to forecast human resource needs. The number of professionals and qualifications relies on the objectives and complexity of operations. For example, whether performing radionuclide therapy, Single Photon Emission Tomography (SPECT) or Positron Emission Tomography (PET) studies; the number of examinations per day; the number of scanners and the radiopharmacy laboratory infrastructure. Such prior information is imperative to define the profile of the nuclear medicine workforce, the qualifications and experience [9].

Ideally, the nuclear medicine facility shall have the minimum staff:

- Nuclear medicine physician,
- Technologist,
- Radiopharmacist,
- Medical Physicist,
- Nurses.

Additionally, the hospital shall appoint a qualified person as the radiation safety officer (RSO) with the responsibility for overseeing radiation safety practices. Nuclear medicine physicists, physicians or technologists are usually good candidates for this role. Physicians and technologists are the basis of nuclear medicine daily practice, and it is sometimes usual that they incorporate additional capabilities (radiation safety, radiopharmacy, physics and nursing) while operating smaller facilities or in developing countries where is challenging to find experts in these fields.

In every way it is good to keep in mind that practicality should be given preference over perfection. Moreover, it is important that staff meets the demands of changing technologies, thus the healthcare institution shall facilitate continuous education for the staff and prior planning whenever purchasing and implementing newer technologies.

Radiation Safety

Radiation safety is the field of the QMS that provides adequate standards for the safety of humans and environment without limiting the benefits of radiological practice. Therefore, the QMS shall include actions to prevent incidents and planning to mitigate their consequences if they occur.

A series of good practices concerning radiation safety is easily found in many publications [10-12], however, in this review we will focus on the general governance aspects of radiation safety.

Concerning radiation safety, the leadership must be demonstrated at the highest levels in an organization. Thus, the prime responsibility for radiation safety rests with the person (director) responsible for the healthcare institution, supported by the consultancy and recommendations of the RSO who is the co-responsible for the radiation protection issues. Then, both instances (RSO and director) shall implement and report the concerns on radiation protection to the hospital staff and the national regulatory body.

We highlight three basic principles that must be addressed for any medical radiological practice [9,13]:

- Optimization: protection must be optimized to provide the highest level of safety that can reasonably be achieved while performing the radiological practice.
- Dose limits: the responsibles must implement measures for controlling the occupational radiation exposure, ensuring that no worker exceeds the dose limits.
- Justification: every radiological application must be justified in relation to other non-radiological techniques as to produce a net positive benefit.

Despite the above basic principles are noticed, nuclear medicine daily practice is complex and prone to several radiological risks: processual, technological or human related. Therefore, the QMS must integrate all operational elements so that requirements for radiation protection are established and checked against failure. Since a pitfall is identified in the QMS, it is recommended that leaders apply quality management methodologies like PDCA and Lean Six Sigma to improve the QMS [4].

Patient Safety

Patient safety is the core of any quality policy. In nuclear medicine, the same recommendations as other fields are applied [2], which we highlight the following actions:

- conduct a performance evaluation of all nuclear medicine and PET imaging equipment and a maintenance program;
- the radiopharmaceuticals labelling should follow the pharmacopoeia recommendation and the national or international good manufacturing practice (GMP) guidelines;
- prior to conducting any nuclear medicine study, the organization must verify the patient identification and the medical prescription, consider the patient's age and recent imaging tests to avoid unnecessary examinations;
- before administering the radiopharmaceutical, the staff must discard the risk of pregnancy and breastfeeding and verify if the posology was prescribed according to the recommendation of the guidelines.

To evaluate the overall performance of the nuclear medicine department by an independent evaluator, the organization is encouraged to engage in quality accreditation programmes.

Accreditation Programs

American College of Radiology (ACR) Accreditation:

The ACR accreditation program is based on the ACR Practice Guidelines and Technical Standards with the main goal of improving patient care [8,9]. The process of accreditation has two steps:

- Evaluation of practices, including policies, procedures, personnel qualifications and equipment modalities;
- Evaluation of clinical and phantom images, QC and QA programs and clinicals procedures (report, radiopharmaceutical procedures, radiation safety, and laboratory safety).

The healthcare organization may choose among the modules for nuclear medicine and/ or PET: general nuclear medicine (planar), SPECT, nuclear cardiology, oncology or brain imaging [13,14].

During the certification process all documents and images are uploaded to the ACR platform to be evaluated by qualified physicians and medical physicists. If the facility meets the criteria it will be awarded a 3 years accreditation, and receive a certificate, and a decal for each approved module performed [13].

Quality Management Audits in Nuclear Medicine (QUANUM)

The QUANUM program was designed by Nuclear Medicine Diagnostic Imaging experts from the International Atomic Energy Agency (IAEA) Human Health program (2013), based on international regulations, clinical guidelines, and managerial strategies. It consists in internal and external audits that are structured to cover all aspects of nuclear medicine practice (table 1). Its aim is the implementation of an annual program of internal audits, adoption of regular analyses and reviews of internal processes and introduce a QMS that is patient oriented, systematic and outcome based [7,8].

Table 1: *Structure of the Excel Spreadsheet*

Nr Section/Title	Description
Strategies and policies Description	A clear strategy and policy must be in place for an efficient management and is essential for the success of any undertaking.
Administration and management	Administration and management are central to an efficient and successful enterprise.
Human resources development	Human resources can be defined as the total knowledge, skills, creative abilities, talents, and aptitudes of the workforce.
Radiation regulations and safety	Compliance with all relevant regulations and good radiation practice in NM are of utmost importance.

Patient radiation protection	This includes all due considerations relating to radiation protection of patients.
Evaluation and assurance of quality system	The quality management system should be implemented and regularly reviewed to ensure compliance with standards.
QC of imaging equipment	A comprehensive system of QC for all imaging equipment is essential for optimal patient examinations in NM.
Computer system and data handling	Computers have been central to the practice of NM for many years, as the extraction of functional information commonly requires patient image analysis.
General clinical services	The conformance of general diagnostic clinical services requirements is essential to ensure the safety and efficacy of imaging and non-imaging procedures.
Assessment of imaging procedures	The auditing team has to assess up to five files of patients. Clinical information, technical aspects and procedures, patient preparation, traceability, reporting, and follow-up will be considered.
Assessment of non-imaging procedure	The auditing team must evaluate nonimaging procedures like thyroid uptake and radio guide surgery.
General radionuclide therapy	Reviews essential aspects of the radionuclide therapy service.
Assessment of therapy	The auditing team has to assess up to three files of patients as in item 10.
Radio pharmacy operational level 1, 2 or 3	This section of the audit focuses on all aspects of the preparation, labelling and dispensing of radiopharmaceuticals, considering the radio pharmacy's classification; including the evaluation of team qualification, equipment, QC tests and documentation.
Hormones and tumour markers	This audit section focuses on the clinical use of hormones and tumour markers for NMSs using radioimmunoassay.

From: adapted from reference 7.

The QUANUM program considers also administrative processes; the proper management of human resources, including training and clinical competence; QA and QC procedures for main imaging equipment, for all relevant equipment; and the assessment of safety conditions for patients and staff, in relation to radiation exposure, and other risks like microbiological, mechanical and electrical. Finally, it includes a detailed analysis of the components related to patient management (booking, preparation, interviews, medications, and surveillance) as well as a synthetic evaluation of the quality of reports [7].

The current spreadsheet is structured into 17 different sections, each section is laid out as a series of questions related to specific components of the nuclear medicine service, for a total of 263 requirements. The Level of Conformance in each requirement is checked by a team of external auditors including one physician,

one radiopharmacist, one medical physicist and one technologist, chosen among a pool of qualified professionals already trained in the QUANUM methodology [7].

To help us to understanding QUANUM program, the IAEA has issued a series of publications on site planning, standardization, QA, safety, clinical practice, radiopharmacy and training, with minimum requirements contained in these publications [8].

The flowchart in figure 2 summarizes the decisional process of QUANUN methodology.

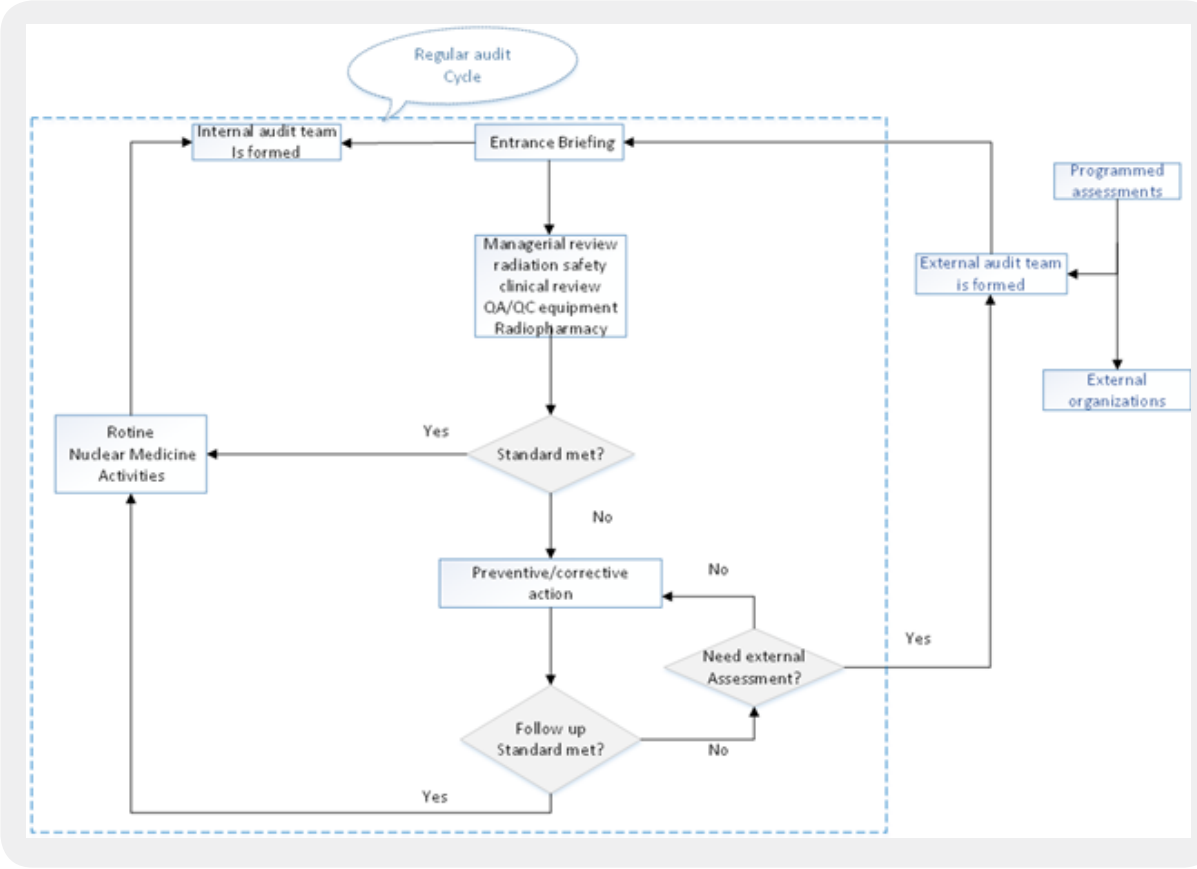

Figure 2: *Flowchart of the QUANUM methodology for nuclear medicine audits process [7,8]*

EANM Research Ltd (EARL) FDG PET/CT Accreditation

The European Association of Nuclear Medicine (EANM) launched the EANM Research Ltd (EARL) as an initiative to improve nuclear medicine and its practice, facilitate multicenter research projects and enhance the comparability of data acquired by molecular imaging. The EARL FDG PET/CT Accreditation is a branch of the EARL program focused on the PET/CT procedures to help PET/CT facilities to meet the standard requirements indicated in the EANM PET/CT guidelines [15].

Since we have previously described most important aspects of nuclear medicine QMS and accreditation programs, we will take this section to highlight an important issue of the EARL FDG PET/CT Accreditation which concerns the standardization and image quantification.

The ability of PET/CT to measure the metabolic activity of tumors has increased the interest in standardization of methodology, including patient preparation, scan acquisition, image processing and analysis to enable accurate, reproducible and consistent quantitative assessment. Therefore, the EARL FDG PET/CT Accreditation provides comparable scanner performance across multiple sites through harmonization of imaging protocols to reduce the variability in image quantification and interpretation [16,17]. Thus, PET/CT departments can compare, exchange and combine FDG-PET/CT findings though regular calibration and standardized QC procedures and analysis.

Discussion

The concept of quality in nuclear medicine covers aspects that go far beyond the usual QA/QC of instrumentation. A QA or accreditation program helps to evaluate managerial aspects, safety (patients and workers) and clinical practice. It provides an overview about all processes allowing to process monitoring for continuous improvement.

Finally, the commitment of multi professional team, the adjustment to the guidelines and the search for continuous improvement are fundamental aspects to reach the excellence of quality.

Conclusion

We presented the major aspects for healthcare organizations to achieve a high level of nuclear medicine service through quality assurance programs and accreditation. To the best of our knowledge, this is one the few manuscripts that summarizes the main steps to achieve the high quality of nuclear medicine services through a leadership oriented guideline.

Conflicts of interest

The authors declare no conflict of interest.

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