QUALITY AUDITS OF NUCLEAR MEDICINE PRACTICES IN NAMIBIA

by

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Declaration

I, Magdalena Lutaka, declare that the contents of this dissertation/thesis represent my unaided work and that the dissertation/thesis has yet to be submitted for academic examination towards any qualification. Furthermore, this work expresses my own opinions, not those of the Cape Peninsula University of Technology.

Signed **Date:** 02 Feb 2023

Abstract

Introduction

The International Atomic Energy Agency (IAEA) introduced a Quality Management Audits in Nuclear Medicine (QUANUM) programme, to improve nuclear medicine practice standards aligned with international standards through self-assessments. The absence of quality management audits in nuclear medicine departments could potentially result in a compromise in the safety and quality of patient care. To date, there is no evidence that quality audits have been conducted in nuclear medicine departments of this middle-income country. This quality audit therefore assessed conformance to the IAEA QUANUM programme in four nuclear medicine departments.

Methods

The study adopted a quantitative methodological exploratory approach. The IAEA QUANUM programme was used and data collected via document analysis in four nuclear medicine departments within a middle-income African setting. This quality audit was done to evaluate each department's overall conformance. QUANUM comprises a series of checklist questionnaires designed to audit nuclear medicine services' overall activity such as clinical practice, management, radiopharmacy, general and radiation safety, quality assurance, operations and services amongst others with the intention of continuous service improvement. Each checklist has criteria that are referred to as counts. The checklists were scored based on conformance or non-conformance during the audit. The four nuclear medicine departments were identified as Sites A – D.

Results

Overall results showed that Site A conformed with 247 out of 370 (67%) counts and non-conformed with 123 out of 370 (33%) counts whilst Site B conformed with 205 out of 342 (60%) counts and non-conformed with 137 out of 342 counts (40%). Site C conformed with 259 out of 345 (75%) counts and non-conformed with 86 out of 345 (25%) counts. Site D conformed with 166 out of 349 (48%) counts and non-conformed with 183 out of 349 (52%) counts. The study yielded 125 overall recommendations.

Conclusions

All the sites demonstrated good compliance to international standards in radionuclide therapy. Site A complied poorly in strategies and policies, whilst Site B complied poorly in quality control of equipment. Site C showed poor compliance to human resource development and Site D showed aspects pertaining to administration and management as well as evaluation of quality systems.

Keywords: QUANUM, quality, audit, international reference standards, conformance.

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List of abbreviations

ACE	Angiotensin converting enzyme
ALARA	As low as reasonably achievable
BAEC	Bangladesh Atomic Energy Commission
BLS	Basic life support
BSS	Basic safety standards
CPUT	Cape Peninsula University of Technology
CT	Computed tomography
DMSA	Dimercaptosuccinic acid
DRLs	Diagnostic reference levels
EANM	European Association of Nuclear Medicine
EC	European Commission
HMPAO	Hexamethylpropyleneamine oxime
HOD	Head of Department
HR	Human resource
HRD	Human resource development
IAEA	International Atomic Energy Agency
ICRP	International Commission on Radiological Protection
IEC	International electrotechnical commission
ISO	International Organisation for Standardisation
IT	Information technology
IV	Intravenous
JCAHO	Joint Commission on Accreditation of Healthcare Organisations (USA)
LAF	Laminar airflow
LoC	Level of conformance

MIBG	Metaiodobenzylguanidine
MOHSS	Ministry of Health and Social Services (Namibia)
Mo-99	Molybdenum- 99
MRI	Magnetic resonance imaging
MUGA	Multigated acquisition scan
NEMA	National Electrical Manufacturers Association (North America)
NHMRC	National Health and Medical Research Council (Australia)
NHPSPs	National health policies strategies and plans
NINMAS	National Institute of Nuclear Medicine and Allied Sciences
NMDI	Nuclear medicine and diagnostic imaging
NMS	Nuclear medicine service
NRPA	National Radiation Protection Authority (Namibia)
PACS	Picture archiving and communication system
QA	Quality assurance
QC	Quality control
QM	Quality management
QMS	Quality management system
QUAADRIL	Quality assurance audit for diagnostic radiology improvement and learning
QUANUM	Quality management audits in nuclear medicine
QUATRO	Quality assurance team for radiation oncology
RBC	Red blood cell
REC	Research ethics committee
RIS	Radiology information system
SNMMI	Society of Nuclear Medicine and Molecular Imaging (USA)
SOPs	Standard operating procedures

SPECT	Single-photon emission computed tomography
SPECT-CT	Single-photon emission computed tomography- computed tomography
SPO	Structure, process and outcome
SDGs	Sustainable developmental goals
Tc-99m	Technetium-99m
TQM	Total quality management
UN	United Nations
WBC	White blood cell
WHO	World Health Organisation
WMA	World Medical Association
XLS	Microsoft Excel spreadsheet

CHAPTER ONE

INTRODUCTION

1.1 Introduction

The International Atomic Energy Agency (IAEA) defines nuclear medicine as a medical speciality that uses a trace amount of radiopharmaceuticals to diagnose and treat health conditions such as certain types of cancer and neurological and heart diseases (IAEA, 2017). The non-invasive nature of nuclear medicine procedures has led to dramatic differences in patient care. Imaging Sites constantly seek to improve their practices to ensure reliable diagnosis (Farrell & Abreu, 2012:211). Farrell and Abreu (2012:211) state that ongoing performance assessment [for nuclear medicine departments] is critically required to provide accurate, high-quality images. Performance assessments should be conducted continuously through a clinical audit, which is by definition a method for improving the quality of patient care, experience, and outcomes by conducting an official assessment of systems, processes, and care outcomes. These performance assessments must be measured against predetermined standards and implementing adjustments based on the findings (Mirzaie, Maffoli & Hilson, 2010:3). Clinical audits help in maintaining a quality management system (QMS) in accredited nuclear medicine departments. This maintenance results in improved radiation protection of patients, health personnel, and the public and helps discover the existence of incorrect practices and avoids and foresees accidents (García-Burillo, Hilson & Mirzaei, 2012:1645).

A QMS is used to benchmark evidence-based records to improve safety and ensure quality health care (Korir, Wambani, Korir, Tries & Mulama, 2013:84). According to Dondi *et al.,* (2017a:680), having this in mind, the IAEA introduced a Quality Management Audits in Nuclear Medicine (QUANUM) program, which aims at improving the standards of nuclear medicine practices to accepted international standards through self-assessments. QUANUM comprises a series of checklist questionnaires designed to audit nuclear medicine services' overall activity: clinical practice, management, radiopharmacy, general and radiation safety, quality assurance (QA), operations, and services with the intention of continuous improvement (Dondi *et al*., 2017a:680).

The QUANUM program conformance criteria are based on a publication of the IAEA and the International Commission on Radiological Protection (ICRP), the Society of Nuclear Medicine and Molecular Imaging (SNMMI), and the European Association of Nuclear Medicine (EANM) (Dondi *et al*., 2017a: 680). QUANUM helps IAEA member states verify the status of their nuclear medicine practices and establishes minimum requirements to conform to internationally recognised quality standards

(Dondi *et al.*, 2017a: 680). The Namibian government provides healthcare services via the Ministry of Health and Social Services (MOHSS). Currently, there are four nuclear medicine departments in the country: two in the public sector and two in the private sector. Nuclear medicine practice involves a safe, efficient, and productive integration of several processes, such as equipment and imaging procedures, staff and professional competence, safety and patient protection, and the overall performance of a nuclear medicine service (NMS) and their interaction with external services. Thus, each process will potentially impact a clinical nuclear medicine procedure's overall quality, patient diagnosis, and management (IAEA, 2015:4).

To the researcher's knowledge nuclear medicine departments in Namibia conduct regular quality control tests on their equipment. However, it would appear that no auditing of any of the nuclear medicine departments took place to date. It was therefore deemed necessary to address this gap. This study utilised an IAEA QUANUM tool to audit four nuclear medicine departments which served as the research sites. The purpose of this study to conduct a quality audit of four nuclear medicine departments in order to compare the level of efficiency, safety and reliability in delivering clinical services and therefore the performance of the Nuclear Medicine Service compared to international standards.

1.2 Statement of the problem

As stated before, according to the researcher's understanding, there was no evidence of quality audits being conducted in the nuclear medicine departments in Namibia. This omission could potentially compromise patient care, safety, quality and non-conformance to international reference standards. The National Radiation Protection Authority (NRPA) is responsible for radiation safety in Namibia via the Atomic Energy and Radiation Act of 2005 (Namibia, 2005). This act states: *'The QA program is designed to ensure that Sites in nuclear medicine and associated equipment are designed, constructed and operated in accordance with specified requirements for safe operation'* (Namibia, 2005). Korir *et al.*, (2013:86) argue that these radiation protection measures require regular checks, status confirmation, and record keeping. According to Hirvonen-Kari (2013:10), internal and external audits are essential for improving patient outcomes in healthcare and radiology. Audits are integral for overall quality improvement and management and should be conducted at intervals not exceeding five years. Dondi *et al*., (2017a:680) also state that audits establish minimum requirements which need to conform to internationally recognised quality standards. To the authors knowledge there are currently no record of internal or external audits available. Therefore, this study focussed on conducting a quality assessment audit of four nuclear medicine departments in Namibia to provide baseline information on their quality standards and to what extent these conform to international recognised standards.

1.3 Aim of study

This quantitative cross-sectional study aimed to assess the compliance of performance of nuclear medicine practices to the IAEA QUANUM standards and to generate baseline reports of their quality systems that could be used for improving safety and ensuring quality healthcare where and if the need arises. Furthermore, this study aimed to evaluate the ease of the use of the IAEA QUANUM tool.

1.4 Research objectives

The research objectives for this study were to.

- Conduct a quality audit of four nuclear medicine departments in order to compare the QMS statuses of these departments against the IAEA QUANUM tool.
- Provide an outline of areas where these performance standards met best practice standards and those that did not.
- To assess the ease of the use of the IAEA QUANUM tool

1.5 Significance of the study

All nuclear medicine departments in Namibia have QMS in place. Anecdotal evidence suggests conformance to the IAEA's reference standards needs assessment. Thus, at the design of this study was envisaged that such a study could assist these departments in the following manner:

- Develop baseline data and measure adherence status to the IAEA QUANUM reference standards for the relevant departments.
- Identify areas of deficiency in quality service delivery to patients, if any.
- If evident, suggest areas for improvement in current nuclear medicine practices.
- Benchmark their performance against international standards.

At the conceptualisation of this study, it was postulated that baseline data can be used to measure future audits against. Furthermore, a major benefit of such an audit would be to identify areas of excellence as well as areas of shortcomings. This audit should benefit clinical nuclear medicine departments as they will have a holistic view of the status of their QMS and areas where improvements would be required, where and if evident. The ultimate aim of such an audit is thus to improve quality standards and ultimately patient care and safety. The findings of this audit can therefore be compared against the audits of other similar nuclear medicine departments in third and first world countries. As stated above, anecdotal evidence suggests that no such audits have been conducted therefore the

findings of this study will arguably be beneficial to such departments in a variety of ways. These benefits are highlighted in Chapter Six.

1.6 Suitability of the researcher to conduct this study

1. The researcher assumes she has the relevant clinical and managerial experience to conduct the audit. She is a nuclear medicine radiographer and has more than 10 years' experience in this field and has worked at two of the selected research sites. She was supervised by three experienced academics, serving as supervisors in this study.
2. The researcher assumes that there is no evidence of quality audits in the Namibian nuclear medicine departments.
3. The researcher assumes that recommendations/corrective action will result in optimal service delivery.

1.7 Delimitations

The research study was limited to two public and two private nuclear medicine Sites in Namibia. The researcher excluded Checklist 11: Assessment of non-imaging diagnostic procedure, Checklist 16: Radiopharmacy operational level 3 and Checklist 17: Hormones and tumour markers - as the research sites do not conduct these services.

1.8 Overview of the chapters

1.8.1 Chapter two: Literature review

The focus of the literature review is quality in healthcare, and nuclear medicine practices in Namibia. Quality audits in nuclear medicine are discussed as well as the QUANUM tool entailing the component criteria for all the checklists which include concepts such as administration and management, human resource development, radiation regulations and safety compliance. Related literature in other countries is highlighted. A theoretical framework that underscores this study's design and methodology is presented.

1.8.2 Chapter three: Methodology

In this chapter, the research design and scope are presented. A brief overview of the research sites is presented as well as sampling strategies employed, the research instrument (i.e., the QUNAM tool), data collection methods employed, the inclusion and exclusion criteria, and concepts such as validity and reliability. In addition, ethical considerations, which underpinned this study, are described as well.

1.8.3 Chapter four: Research results

The findings of this study, using the IAEA QUANUM tool applied in the four research Sites, are presented. The results for each research site (A to D) are described in relation to Checklists 1 – 10 and 12-15 as they pertain to services offered by the four NMS in Namibia.

1.8.4 Chapter five: Discussion

This chapter discusses the respective conformities and non-conformities at the research sites in order to emphasise their impact on patient, staff and nuclear medicine practice as a whole. Conformities and non-compliance are discussed under the different checklist as highlighted in the results chapter. Additionally, the chapter also discussed the ease of the use of the QUANUM tool.

1.8.5 Chapter six: Recommendations

The three priorities, under which the recommendations are categorised, are defined in this chapter. Each recommendation is categorised according to Site and level of priority. Conclusions drawn from the study are described. The thesis ends with a discussion of areas for future research which can emanate from the study.

CHAPTER TWO

LITERATURE REVIEW

2.1 Introduction

This literature review focuses on quality in healthcare. A brief history of nuclear medicine practices in Namibia is presented. Quality audits in nuclear medicine are discussed in terms of the QUANUM tool pertaining to conformance criteria. Also covered in this chapter is quality assurance from a global view. In addition, total quality management as a theoretical framework is presented.

2.2 Quality in healthcare

Rafeh and Hatzel (2017:6) define quality as a provider's technical standards and patient's expectations. Quality is a comprehensive and multifaceted concept with definitions ranging from traditional to strategic (Aggar, Aeran & Rathee, 2019:180). According to Aggar *et al*. (2019:180) the broader internationally accepted definition of quality is a strategy aimed at customers' needs. Healthcare definitions underscores quality as the extent that healthcare services for persons and populations increase the likelihood of desired outcomes and are consistent with current professional knowledge (Seelbach & Brannan, 2022).

Although health services propose to meet the healthcare demands of their respective communities, they are frequently unsure of how to allocate their resources to achieve the best results (Reddy & Tavares, 2020:1). Reddy and Tavares (2020:1) maintain that in an era of tight budgets and a growing amount of chronic diseases, it is critical to maximise available resources to ensure long-term healthcare delivery. These authors add that because finances will always be inadequate in relation to increasing need, appropriate decisions must be made. Therefore decision-makers prioritise resources for options which provide the most significant benefit, whether for public health or economic reasons (Daniels, 2016; Reddy & Tavares, 2020:1). Technological advances have led to an increase in healthcare data in terms of data collection therefore accessibility of information to make these decisions has not been an issue (Dash, Shakyawar, Sharma & Sande Kaushik, 2019:1-2; Reddy & Tavares, 2020:1). It is somewhat necessary for a suitable framework to guide decision-makers on what should be prioritised (El-Harakeh, Morsi, Fadlallah, Bou-Karroum, Lotfi & Akl, 2019:1-2; Reddy & Tavares, 2020:1) In this regard, evaluation, particularly evaluation of health outcomes, has been useful as a framework for guiding appropriate health service planning and implementation (Clarke, Conti, Wolters & Steventon, 2019:1; Reddy & Tavares, 2020:1).

According to Aggarwal *et al*., (2019:180), the Donabedian triad concept, consisting of structure, process, and outcome (SPO) is used to evaluate quality healthcare and is defined as follows: The structure aspect comprises organisation of care and the qualifications of the care provider with respect to the physical setting in which care is provided; the process includes individual components of care as well as their interactions; and the outcome in healthcare pertains to recovery, restoration of function, and survival of a patient and degree of their satisfaction, for example. Donabedian proposed that SPO constructs are linked based on the premise that exceptional structure should support good processes, promoting good outcomes (Aggarwal *et al*., 2019:180). In the event of healthcare quality being called into question, then conducting an audit of adverse outcomes may provide information that allows for improvements (Aggarwal *et al*., 2019:180).

2.3 Quality/ clinical audits in nuclear medicine

A clinical audit can be defined as:" A quality improvement process that seeks to improve patient care and outcomes through a systematic review of care against explicit standards and implementing change" (Bennadi, Konekeri, Siluvai, Kshetrimayum & Reddey, 2014:50). Audits are one of the pillars of clinical governance; they measure quality improvements in imaging departments (Limb, Fowler, Gundogan, Koshi & Agha, 2017:2). Clinical audit cycles consist of several steps: identify the problem, define standards/criteria, collect data, analyse, implement change, and re-audit (Limb *et al*., 2017:2). Bennadi *et al*., (2014:50) described types of clinical audits: standard-based audits involve defined standards collecting data to measure current practice against these standards, and implementing necessary changes; adverse occurrence screening and critical incident monitoring include reviewing cases with a particular concern or unexpected outcomes and reflect on the way the team's function aids learning for the future; peer review involves discussion of individual cases by peers in order to determine whether the best care was given; and patient surveys and focus groups pertain to opinions of patients regarding the care received.

Audits can be internal ones conducted within a department or institution, or external ones conducted by professionals from outside a department or institution (Bennadi *et al*., 2014:50). Regulators, national health systems, healthcare insurers, and other third parties increasingly request evidence of clinical practice quality and adherence to quality standards. These aspects are relevant to nuclear medicine (Dondi *et al*., 2017a:681). Clinical audits in nuclear medicine services are a comprehensive peer review of all service delivery components against predetermined standards with the aim to improve department services (Dondi *et al*., 2017a:681). Peer review requires commitment from various professional groups in nuclear medicine because the focus is on patients and clinical effectiveness (Dondi *et al*., 2017a:681). The purpose of this research study was to evaluate all aspects of the NMS in Namibia in order to improve service delivery.

2.4 Nuclear medicine practices in Namibia

Nuclear medicine has been established since 1982 (Von Wenzel, Rubow, Ellman, 2004:108). The author is aware that there are four established nuclear medicine practices in Namibia.

According to the authors knowledge namibian nuclear medicine professionals undergo training in South Africa. The author is informed that there are currently three nuclear medicine physicians, nine nuclear medicine radiographers, and two medical physicists employed in Namibia. These four research sites were thus ideally suited for data collection for this study.

The author is aware that the Namibian nuclear medicine Sites' imaging equipment includes single-photon emission computed tomography (SPECT), single-photon emission computed tomography-computed tomography (SPECT-CT), and planar gamma cameras. Nuclear medicine provides valuable input in managing increased chronic and non-communicable disease burdens (IAEA, 2018). There is therefore a need for regular quality audits to maintain quality systems, enabling nuclear medicine services to achieve the expectations of their quality policy and satisfy their customers (Dondi *et al*., 2013). There is a perceived lack of clinical audits in nuclear medicine departments in Namibia thus it is reasonable to argue that such a lack allows one to question the maintenance of the existing QMS and service delivery of nuclear medicine practices.

2.5 QUANUM program

Nuclear medicine practices in some the lower middle-income countries have inadequate clinical and procedure guidelines and lack a quality management (QM) culture necessary to keep the level of practice at recognised, internationally accepted levels (Dondi *et al*., 2017a:681). The IAEA Nuclear Medicine Diagnostic Imaging (NMDI) subprogram launched QUANUM to tackle this problem. These audits help member states assess their respective nuclear medicine service standards and to then improve them to accepted international standards (Dondi *et al*., 2017a:681). According to Dondi *et al.* (2017a:681), the QUANUM program has three main aims.

- To encourage the institution of a routine process of conducting annual systematic audits in a clinical area
- To encourage a culture of regular analysis and reviews of internal processes
- To introduce a quality audit process that is patient-oriented, systematic, and outcome-based.

Nuclear medicine departments traditionally only develop and apply methodologies for QA and QC of imaging equipment and radiopharmaceuticals whereas the QUANUM program considers a holistic approach. The approach involves administration processes; proper management of human resources

including training and clinical competence; QA/QC procedures for relevant equipment; assessment of safety conditions concerning radiation exposures (for patients and staff), microbiological, mechanical and electrical, amongst others; and detailed analysis of components related to patient management and synthetic evaluation of the quality of reports (Dondi *et al.*, 2017a:685).

2.6 Components of the QUANUM Tool

The IAEA QUANUM tool consists of the following concepts:

2.6.1 Strategies and policies

Medical care organisations encounter formidable obstacles, especially in quality, effectiveness, and productivity (Parvaneh, Ali Mohammad & Ali, 2018:563). Therefore, to keep up with the complexity of the healthcare business, and to adapt their organisations to changing internal and external settings, healthcare managers and leaders should adopt innovative techniques (Parvaneh *et al.*, 2018:563). The best way to address these issues is through strategic management as this enables managers to capitalise on any environmental changes and produce the best results (Parvaneh *et al.*, 2018:563). According to the IAEA QUANUM assessment criteria (2015:18), ensure that nuclear medicine departments develop a clear strategy and effective management. This is provided by means of written documents demonstrating strategies and the objectives at a national, hospital management, regional and global level, respectively, and to have updated organisational charts with clear communication channels and lines of commands (IAEA, 2015:18; IAEA, 2021:22). Documentation should clearly define coordination with other departments (i.e., radiology) and should ensure that diagnostic imaging and therapeutic services are consistent with clinical requests (IAEA, 2015:18). Nuclear medicine departments should have flexible objectives that can accommodate critical requests and emergency acquisitions and include quality improvement through audits (IAEA, 2015:18). Nuclear medicine should establish and implement strategies/policies to guide access to nuclear medicine services are not offered at one Site and when services are provided by other hospitals and institutions (IAEA, 2015:18). Nuclear medicine departments should ensure participation of its services in the hospital/institution decision making as a formal process (IAEA, 2015:18).

2.6.2 Administration and management

According to the IAEA QUANUM assessment criteria (2015:20), successful and efficient nuclear medicine departments should make administration and management functions fundamental. This requires them to have clearly defined primary management and supportive processes (IAEA, 2015:20).

Management, reception areas, support services, diagnosis and therapy should operate under regularly reviewed written standard operating procedures (SOPs) (IAEA, 2015:20). Also, there should be instructions dealing with particular groups of patients (i.e., those with disabilities), incomplete patient requests and how to cater for highly scheduled demands (IAEA, 2015:20). It is further important to ensure there are procedures dealing with unanticipated events in management, administrative activities and staff concerns and have QMS assessments conducted regularly by a medical physicist and radiopharmacist (IAEA, 2015:20).

2.6.3 Human resource development (HRD)

HRD was first introduced as a concept in the United States by Dr Nadier Melis. It is defined as *"the part of human resource management that specifically deals with training and development of the employees"*. HRD includes training, providing opportunities to learn new skills, and distributing resources beneficial for employees' tasks (Melis, 2018).

According to the IAEA QUANUM assessment criteria (2015:22), HRD serves as a nucleus that drives all the resources in nuclear medicine departments. This means such departments should have appropriately skilled and competent staff, who work according to their job descriptions (IAEA, 2015:22; Pillai, Senthilraj & Swaminathan, 2019: 233). All staff should receive specialised training involving management of radioactive sources. Management should ensure there are channels of continuous professional development and education for all and consistently assess their competencies to determine training needs (IAEA, 2015:22; Pillai et al., 2019: 234). Furthermore, Pillai *et al*., (2019: 228) suggest that the competency assessments should be carried out at the beginning of employment and at periodical intervals. A department should also ensure that their staff members have access to education and scientific resources (IAEA, 2015:22).

2.6.4 Radiation regulations and safety compliance

It is of utmost importance, and good radiation protection practice, that nuclear medicine departments comply with all relevant regulations (Frane & Bitterman, 2022). According to the IAEA QUANUM assessment criteria (2015: 23-26) nuclear medicine departments must be licensed to operate by an appropriate licensing authority. As per regulation, upon recruitment of new staff members, training on local procedures and safety precautions should be conducted during orientation/induction and signatures obtained confirming receipt of training (IAEA, 2015: 23-26). The Sites should have radiation safety and protection SOPs that refer to national or international guidelines or regulations (IAEA, 2015: 23-26). All radioactive materials should be recorded (acknowledged), monitored, and stored as

indicated in licenses and SOPs; regular cross-accounting and leakage inspection on calibrated sources should be conducted (IAEA, 2015: 23-26). The Sites should schedule radiation exposure supervision for all nuclear medicine personnel, namely, to check, communicate and report and commence appropriate action in case of unpredicted results (IAEA, 2015: 23-26; Akram & Chowdhury, 2022). Regarding radiation and infection control, a department should ensure accessibility to protective clothing (IAEA, 2015: 23-26; Niu, Xian, Lei, Liu & Sun, 2020). Based on the actual or potential radiation or contamination levels, departments should adequately equip diagnostic rooms and have a department with areas classified as 'supervised' or 'controlled' according to (IAEA Basic Safety Standards (BSS) 2015: 23-26). Consistent monitoring and dealing with contamination/spillage, management of patient specimens, and devices, including radiation and microbiological safety features, should be in place (IAEA, 2015: 23-26; National Health and Medical Research Council (NHMRC, Australia), 2019).

2.6.5 Patient radiation protection

In nuclear medicine procedures, patient radiation protection is achieved by optimisation. Optimisation ensures radiation dose is kept as low as reasonably achievable (ALARA) (Cho, Kim & Song, 2017:12). ALARA is applied to reduce administered radiopharmaceutical activity in nuclear medicine procedures by implementing diagnostic reference levels (DRLs) (Cho, Kim & Song, 2017:12).

A department's success depends on providing a patient-focused service and includes considerations relating to radiation protection (IAEA, 2015: 26-28). QUANUM criteria require departments to develop SOPs in this regard. According to Shestopalova and Gololobova (2018:131) SOPs are effective in increasing healthcare and safety and should be regularly reviewed and updated to reflect current requirements. Departments should develop SOPs that safeguard accurate patient identification before administration of the radiopharmaceutical (IAEA, 2015:26-28). SOPs are meant to guarantee that the administered quantity of radioactivity and relevant dose guides from X-rays do not surpass reference levels as established in BSSs and national or international law or rules in the event of multimodality imaging (IAEA, 2015:26-28). SOPs should also serve to decrease misadministration hazard of radiopharmaceuticals and compound radiation exposures and tackling non-conformity inpatient exposures, informing, remedial actions, and to inform pregnant or lactating women about the dangers of radiation when required to undergo nuclear medicine investigations (IAEA, 2015:26-28). Patient radiation protection should be ensured by having suitable signage forewarning possible pregnant and lactating female patients (IAEA, 2015:26-28). There should be easily accessible written and verbal documented directives with respect to before and after administration of the radiopharmaceutical, assessment of individual patient dose before administration, and have competent personnel to approximate effective patient radiation dose after administration of radiopharmaceuticals and X-ray exposure in case of multimodality imaging (IAEA, 2015:26-28).

2.6.6 Evaluation of quality system

The implementation of QMS contributes to increased safety and reliability in clinical services and requires regular reviewing to ensure compliance with international standards (IAEA, 2015: 28-30; Seelbach & Brannan, 2022). According to the QUANUM assessment criteria, nuclear medicine departments should have defined aims and measures for their service performance, procedures for authenticating conformance with clear standards of adequacy and measuring satisfaction (i.e., patient satisfaction), and perform self-evaluations or audits frequently (IAEA, 2015: 28-30). All Sites should have a QA program, including systematic calibration and checks of all equipment according to BSS, national or international standards (IAEA, 2015: 28-30). During the acquisition of goods and equipment, an assessment, using technical specifications, should be conducted (IAEA, 2015: 28-30). QM for equipment should also have strategies for pre-emptive maintenance and replacement for significant equipment, identify distinct responsibilities and levels of action to determine equipment repair, replacement and discontinuation, and supervised by SOPs for non-conformance, documentation, and rectification/prevention (IAEA, 2015: 28-30).

2.6.7 Quality control of imaging equipment

According to the European Association of Nuclear Medicine (EANM) (2017:10) QC is a product-focused concept intended to ensure that a manufactured product or performed services meet a defined set of performance criteria (EANM, 2017:11). QC techniques are concerned directly with the equipment that can affect the quality of an image (EANM, 2017:11). The fundamental principle in QC of nuclear medicine instruments is that it should be an integral part of a department (EANM, 2017:11).

Nuclear medicine departments, according to the IAEA QUANUM assessment criteria (2015:31-33), should have written guidelines that stipulate, acquire and examine new equipment, ascertain the need for certification of all acquired equipment approved by an international or national authority; guidelines on extensive storage of QA/QC results (IAEA, 2015:31-33). These Sites should have SOPs agreeing to manufacturer instruction guides and QA/QC SOPs that include data on non-compliance and remedial actions (IAEA, 2015:31-33). Comprehensive acceptance assessments on applicable planar and tomographic performance limits for gamma cameras should be conducted and recorded and used in the formation of reference levels for routine QA/QC (IAEA, 2015:31-33). All departments should ensure an independent evaluation of the performance of delivered equipment assessed and documented against tender requirements (IAEA, 2015:31-33). An effective internal QA program should include reviews periodically and records QA/QC procedures of appropriate planar/SPECT/multimodality parameters, written operative and QA/QC SOPs accessible for all imaging

equipment and consistent physical checks of hardware, including detector heads, collimators, and shielding (IAEA, 2015:31-33).

2.6.8 Computer systems and data handling

Computers play a vital role in functional information extraction and patient image analysis (IAEA, 2015:33-35). Nuclear medicine departments, according to the QUANUM assessment criteria, should have accessible written guidelines that stipulate the acquisition and testing of radiology information system (RIS), picture archiving and communication system (PACS), image processing, and analysis workstations (IAEA, 2015:33-35). Guidelines, pertaining to the need for certification of all acquired equipment approved by an international or national authority and which are in line with endorsements made in IAEA/international/national manufacturers' association periodicals, should be adopted (IAEA, 2015:33-35). The departments should have procedures for evaluating information technology systems and ensuring security, integrity, data privacy, and remote access (IAEA, 2015:33-35). SOPs for checking and correcting disparities between image files and patient data and non-compliance for PACS and QA/QC SOPs for PACS image display monitors should be implemented (IAEA, 2015:33-35). There should be documentation ensuring the reliability of site customisation, data acquisition, testing protocols, and processing subsequent significant software amendments (IAEA, 2015:33-35). A policy that provides quality management of 'in-house' software supplementing clinical practice and backup and maintains patient information files should be developed and implemented (IAEA, 2015:33-35).

2.6.9 General diagnostic clinical services

In nuclear medicine, general diagnostic and clinical requirements need to conform to and ensure the safety and efficacy of imaging (IAEA, 2015:35). QUANUM assessment criteria require departments to have written SOPs based on international/national guidelines for all types of examinations. There should be a mechanism that regularly updates these SOPs for distribution of documents/manuals containing all procedures that are offered and should ensure that all staff are aware and familiar with its contents (IAEA, 2015:35). SOPs should include the administration of non-licensed or off label radiopharmaceuticals, emergency requests for specific preparation relevant to paediatrics, i.e., sedation and for appropriate medical supervision during interventions (diuretics, stress testing). SOPs must regularly review the number of and reasons for repeated nuclear medicine examination (IAEA, 2015:35). All nuclear medicine Sites should have written instructions on dose assignment and traceability, dose optimisation according to weight for paediatrics, and patient preparation at the time of appointment and before an examination (IAEA, 2015:35).

Departments of nuclear medicine should have written policies: outlining information that patients should receive before giving their informed consent; validating a doctor's availability to answer patients' questions; addressing and reporting adverse reactions/events; timely reporting of any findings to the referring physician for critical patient management; for rapid assistance in case of emergency (i.e., phone numbers displayed), and outlining a mechanism for reporting an incident and introducing corrective actions (IAEA, 2015:35). Nuclear medicine physicians should check all requests for justification and approval before the acquisition (IAEA, 2015:35). There should be instructions that check for contraindications and prevent the examination or part of it (IAEA, 2015:35) There should be procedures for correct identification of patients during the acquisition and privacy of patients maintained during their visit (IAEA, 2015:35). Radiation safety and protections require the departments to have procedures that enquire about pregnancy and lactation before any radiopharmaceutical administration, that avoid misadministration of radioactive and non-radioactive pharmaceuticals, and procedure protocols containing detailed information on radiopharmaceuticals, CT settings, and contrast media (IAEA, 2015:35). The departments need to have a fully equipped emergency cart with an SOP to regularly check and replenish drugs and train personnel on basic and advanced life support and available supportive equipment (IAEA, 2015:35).

2.6.10 Assessment of diagnostic imaging procedures

According to the IAEA QUANUM assessment criteria (2015:39) this checklist allows the evaluation of five patient files that have undergone diagnostic imaging procedures that are frequent and relevant. The QUANUM assessment criteria consider the following aspects of the diagnostic procedures in these files.

2.6.10.1 Clinical information

The IAEA QUANUM assessment criteria (2015:39) require detailed appropriate clinical information as stipulated in a corresponding SOP. These include records that inquire about contraindications, allergies, and contrast media (if applicable), documents indicating and justifying the change in procedure other than the one requested by the referring doctor and a record of availability of other imaging (X-ray report) and laboratory results.

2.6.10.2 Technical report

According to the IAEA QUANUM assessment criteria (2015:40) the following gamma camera setup, acquisition and CT parameters, administered radiopharmaceutical and dose, and data management and storage should be included in a SOP.

2.6.10.3 Patient preparation

For patient preparation, the following must be on record and included in an applicable SOP: patient credentials, existing medication, date of end of chemotherapy/radiotherapy, procedure preparation, information on pregnancy and breastfeeding, dose modifications for paediatrics and patient positioning and immobilisation (IAEA, 2015:40-41).

2.6.10.4 Individual procedure quality assurance/quality control as recorded in a patient file

The following information should be recorded according to the applicable SOP. The radiopharmaceutical quality control record in circumstances of external purchasing of the radiopharmaceutical (IAEA, 2015:41- 42); an examination's latest and appropriate QC of the used imaging equipment; whether there was an observation and explanation of misadministration at the infusion site, if any recorded; assessment and processing of QC criteria and the general image quality and proper image dissemination to a referring physician (IAEA, 2015:41- 42); traceable related patient data, including batch numbers, time, and dose administration of procedure relevant pharmaceutical; and documentation of any harmful event/ and that the incident must be recorded according to the appropriate SOP (IAEA, 2015:41- 42).

2.6.10.5 Reporting and follow up

The IAEA QUANUM assessment criteria (2015:42) require the reporting to be structured according to an applicable SOP and should address the clinical question.

2.6.11 Assessment of non-imaging diagnostic procedures

According to IAEA (2015:44-46), the same QUANUM assessment criteria as in 2.6.10 apply but were excluded in the study as non-imaging diagnostic procedures are not performed at the nuclear medicine Sites in Namibia.

2.6.12 General radionuclide therapy

In nuclear medicine, radionuclide therapy utilises radiopharmaceuticals targeting specific tumours, such as thyroid, bone metastases or lymphomas by delivering radiation to cancerous lesions (IAEA, 2015:47-49; Zukotynski, Jadvar, Capala & Fahey, 2016). QUANUM assessment criteria require departments to have written SOPs developed according to national/international guidelines for any category of treatment, for patient preparation for all categories of treatments accessible; excluding pregnancy and breastfeeding before treatment, explaining procurement, preparation QC of radiopharmaceutical/radionuclide; for therapeutic activity including a target to non-target dose estimation per national/international guidelines by a medical physicist/ nuclear medicine physician (IAEA, 2015:47-49). SOPs should include guidelines for in-patient therapy regarding adequate radioprotection procedures for the public, caregivers, contamination, and instructing discharging of patients after treatment ensuring a clear understanding of instructions by the patient/family/caregivers (IAEA, 2015:47-49). A SOP must describe actions required in the event of therapeutic radiopharmaceutical misadministration (IAEA, 2015:47-49).

An in-patient therapy designated Site should have suitable protection barriers, hygiene, and ventilation (IAEA, 2015:47-49). Departments should ensure a 24 hr nursing care staff complement for in-patient therapy and staff should be accessible in case of a medical emergency. Such nursing staff should be trained in radiation science and protection for when taking care of a patient receiving radiopharmaceuticals (IAEA, 2015:47-49). A nuclear medicine physician should have an approved multidisciplinary evaluation of a patient's condition (IAEA, 2015:47-49). Patient records should be checked for contraindications or other potential treatment-interfering conditions and there should be a provision of relevant information and procedures about a patient before and after therapy (IAEA, 2015:47-49). Written instructions on the necessity of contraception during and after therapy and procedures as well as an explanation of informed consent should be available (IAEA, 2015:47-49).

When considering discharging a patient, written directives for patient/caregivers after discharge and procedures and information about radioprotection for the public, caregivers, for paediatrics should be in place (IAEA, 2015:47-49). Dose assignments of administered activity records and the presence of emitted dose rate/patient activity before a patient's release should be on file, and there should be a detailed treatment report issued and made available for both patient and referring physicians (IAEA, 2015:47-49).

2.6.13 Assessment of therapy

The QUANUM assessment criteria allow one to evaluate three patient files that have undergone therapeutic procedures that are frequent and relevant IAEA (2015:50). The QUANUM criteria consider the following aspects of the diagnostic procedures in these files.

2.6.13.1 Clinical information

SOPs should check the justification of treatment requests according to national/international guidelines and treatment according to multidisciplinary evaluation and approved by the physician (IAEA, 2015:50-51). Patient records indicate the observance of contraindicating conditions/interfering conditions to the treatment, pertinent diagnostic procedures, and past radionuclide therapy (IAEA, 2015:50-51).

2.6.13.2 Technical report

IAEA QUANUM assessment criteria (2015:51-52) require the following to be on record, and according to the appropriate SOP. Patient credentials, accurate radiopharmaceutical prescription and activity per estimated target, and non-target tissues dose (IAEA, 2015:51-52). Measured activity prior to administration and monitored technique to avoid maladministration of radiopharmaceuticals (IAEA, 2015:51-52). Observance of ruling out pregnancy and breastfeeding, as well as a clear understanding of the role of contraception during and after treatment imaging of biodistribution of the radiopharmaceutical (if applicable) (IAEA, 2015:51-52).

2.6.13.3 Patient preparation

The patient preparation section requires the following to be on record and according to the appropriate SOP: patient informed consent, instructions on treatment-related medical therapy and other preparations, patient condition/treatment correlated interference, instructions on avoiding pregnancy during and after treatment, appropriate counselling on breastfeeding, and appropriate information on radioprotection given to caregivers for paediatrics (IAEA 2015:52).

2.6.13.4 Individual therapy quality assurance/quality control as in-patient file

The following assessment criteria are a QUANUM requirement. An applicable SOP with respect to appropriate patient preparation; quality control documentation in an event of external purchasing of

the radiopharmaceutical; dose assignment; account for extravasation at the infusion site or adverse events; and traceable related patient data (IAEA, 2015:52-53).

2.6.13.5 Reporting and follow up

Reporting should be structured according to applicable SOP and made available to a patient and all relevant physicians. Documentation of feedback received after treatment should be available (IAEA, 2015:53).

2.6.14 Radiopharmacy

The radiopharmacy also known as nuclear pharmacy is an area where radiopharmaceutical preparations occur and are supplied (Parasuraman, Mueen Ahmed, Bin Hashim, Muralitharan, Kumar, Ping, Syamittra & Dhanaraj; Merriam-Webster's Dictionary, 2023). It requires equipment that ensures the desired quality of radiopharmaceuticals for patient administration (IAEA, 2015:56). Most radiopharmaceuticals are in liquid form and are administered intravenously, some also use other parenteral routes namely, subcutaneous, intraperitoneal, intravenous, intradermal and intramuscular; thus, a sterile environment is needed as it is a requirement for any medicinal product that is administered parenterally (Munjal & Gupta, 2022; Sandle, 2020). A radiopharmacy requires QC procedures and areas to deliver and store radioactive materials and waste before disposal (IAEA, 2015:26). It needs to protect operators from radiation-emitting products and minimise external and internal radiation hazards from ingestion and volatile products' inhalation (IAEA, 2015:56). The product requires protection from chemical, radionuclide, particulate or microbial contamination (IAEA, 2015:56). The IAEA (2015:56), in its 'Operational guidance on hospital radiopharmacy: safe and effective approach radiopharmacy document', defines a hospital radiopharmacy into three levels. The document provides each level's essential details in staffing, the scope of operations, equipment, staff qualifications, recordkeeping, QM and QC level (IAEA, 2015:56).

Table 2.1 below presents the categories of critical operation levels in a hospital radiopharmacy (IAEA,2015:56)

Table 2.1 Hospital radiopharmacy operational levels (IAEA, 2015:56)

Level	Scope
1a	Procurement of unit doses or multiple doses vials radiopharmaceuticals in their final form from a recognised/authorised manufacturer or a centralised radiopharmacy.
1b	Purchasing of liquid or capsule radioiodine preparations from recognised/authorised manufacturers. Typically, no further compounding is required.
2a	Radiopharmaceuticals are prepared and approved from pre-sterilised reagent kits, technetium generators, and radionuclides for diagnostic or therapeutic purposes (closed procedure).
2b	This operational level elaborates laboratory practices and environmental conditions necessary for safe manipulation and radiolabelling of autologous blood cells and components for reinjection into the original donor/patient.
3a	This operational level compounds radiopharmaceuticals from radionuclides used for diagnostic purposes. Making changes to current commercial kits, and creating reagent kits on-site from ingredients are all included at this operational level. Additionally, this level also includes the use of freeze-dried products). Operational level 3a frequently applies to research and development.
3b	This operational level involves compounding radiopharmaceuticals from basic components or unlicensed intermediates and radionuclides for therapeutic use (open procedure) and/or associated research and development.
3c	This operational level covers particle emission tomography radiopharmaceutical synthesis, compounding of radiopharmaceuticals made from illegal or unregistered long-lived generators like (68Ga) gallium or (188Re), and related research and development.

Only operational levels one and two pertain to the nuclear medicine Sites in Namibia since there are no qualified persons (radiochemists/pharmacists) to manufacture specialist products and services (IAEA, 2015:56).

- **Radiopharmacy operational level 1**

Below are the requirements of a radiopharmacy in terms of the IAEA (2015:56-59) QUANUM assessment criteria.

2.6.14.1 Staffing

Nuclear medicine departments should operate under the supervision of an appropriately trained person as defined by local/national regulations, and personnel training manuals for all grades of staff should be available (IAEA, 2015:56-59).

2.6.14.2 Sites

Nuclear medicine Sites should have suitably furnished rooms and a shielded administration area. When operating under operation level 1b (see Table 2.1) there should be an adequately ventilated/shielded administration station for radioiodine capsules and have shielded and validated fume hoods with appropriate filters for radioiodine solutions (IAEA, 2015:56-59).

2.6.14.3 Purchase of materials

A department should have appropriate SOPs and trained staff for procurement of authorised radiopharmaceuticals, and received goods inspected and verified against delivery/order (IAEA, 2015:56-59).

2.6.14.4 Dispensing protocols

When operating under level 1a (see Table 2.1) a nuclear medicine department should have written guidelines for aseptic dispensing and labelling of unit doses prepared to use radiopharmaceuticals (IAEA, 2015:56-59). When operating under operation level 1b there should be a shielded supply station/fume hood equipped with appropriate fillers for hazardous radioactive materials (IAEA, 2015:56-59). Radioiodine capsules should be unpacked from the sealed containers in an adequately ventilated area (IAEA, 2015:56-59). Additionally, under operation level 1b there should be written techniques with well-defined monitoring directives for dispensing of radioiodine solutions or capsules. All records should ensure radiopharmaceutical traceability (IAEA, 2015:56-59).

2.6.14.5 Radiopharmaceutical quality assurance /quality control

Nuclear medicine departments should keep records of periodic radiopharmaceutical quality performance and have a written method for handling products that do not meet the standards or for which complaints were received (IAEA, 2015:56-59)

2.6.14.6 Waste

Nuclear medicine departments should have easily accessible written procedures for radioactive and non-radioactive waste disposal (IAEA, 2015:56-59).

- **Radiopharmacy operational level 2**

2.6.14.7 Staffing

Nuclear medicine personnel should have training and skill assessments that include aseptic practice, provision of training for staff to perform final checks on all products before released for patient administration and confirmed training before the release of radiolabelled red blood cell (RBC) and white blood cell (WBC) preparations (IAEA, 2015:60).

2.6.14.8 Sites

Nuclear medicine Sites should conduct periodic checks on authorised class II type B microbiological safety cabinets placed in demarcated rooms and have records of visual inspections and integrity assessments of gloves or gauntlets in negative isolators before preparations (IAEA, 2015:60).

2.6.14.9 Preparation protocols

Formal approvals of all work systems and relevant records of radiopharmaceutical preparation and processing should be documented in nuclear medicine practices. There should be approved marketing, authorisation, or product license number for all products, kits, and generators (IAEA, 2015:60). The preparation of technetium-99m (Tc-99m) radiopharmaceuticals should be performed in a laminar airflow (LAF) cabinet allowing tracing of individual doses to a specific generator and kits batch number (IAEA, 2015:60). When operating under level 2b the following are required: written procedures for any RBCs and WBCs should include clear instructions on safety, cleaning, decontamination and for preparation and dispensing of radiolabelled biologicals from approved kit formulations (IAEA, 2015:60).

2.6.14.10 Quality assurance /Quality control

Nuclear medicine departments should establish and record QC criteria before the release for preparation prior to patient use and approval by a certified person prior to product patient

administration (IAEA, 2015:60). Under level 2b performance molybdenum-99 (Mo-99) breakthrough assessment on the first eluate, and before the removal of the generator, should be conducted (IAEA, 2015:60). Aluminium ion breakthrough checks on the generator's first eluate, performance of radiochemical purity test on all new or newly delivered batches of pharmaceutical kits and regular microbiological monitoring of preparation, and aseptic dispensing stations should form part of radiopharmaceutical quality control (IAEA, 2015:60). Alterations in the utilisation of kits, vehicles or diluents, syringes, needles, swabs, and sterile containers should be recorded. Records should also be kept of regular pH testing of radiopharmaceuticals. (IAEA, 2015:60). Nuclear medicine practices should adopt rapid alternate methods for swift prospective QC of sensitive radiopharmaceutical preparations like HMPAO (IAEA, 2015:60).

2.7 Quality assurance: a global view

The first clinical audit in history was conducted during the Crimean war in 1853 -1855 by Florence Nightingale. She assessed the effectiveness of cleanliness and its enforcement, reducing hospitalised patients' mortality rates (Bennadi *et al*., 2014:49). Izewska, Coffey, Scalliet Zubizarreta, Santos, Vouldis and Dunscombe (2018:183-190) conducted a study exploring factors that influence quality care in centres audited using the IAEA Quality Assurance Team for Radiation Oncology (QUATRO) in the IAEA European Region. QUATRO's important deliverable is an assessment of practice quality, strengths, identification of areas of improvement. QUATRO reports of over ten years, which included quality defining data, were collected (Izewska *et al*., 2018:183-190). The audit reviewed 759 recommendations and 600 positive findings (Izewska et al., 2018:183-190). Eight centres were recognised as centres of competence since they operated with complete quality systems and adequate personnel for optimal patient care (Izewska et al., 2018:183-190). Other centres presented with excessive staff workload, insufficient equipment levels, and gaps in patient care. The study by Izewska *et al*., (2018:183-190) reported the below barriers to quality care.

- Insufficient staffing, education/training
- Equipment availability and lack of QM

The study also highlighted a correlation between human resources (HR) availability, quality care, and everyday actions to enhance radiotherapy quality (Izewska *et al*., 2018:183-190).

A study conducted by Ilcheva, Souverijns, Achten, Donoso, Shillebeeckx and Jacobs (2021) utilised a clinical audit tool, namely quality assurance audit for diagnostic radiology improvement and learning (QUAADRIL). It was used to assess quality of care, effective use of resources, service delivery, organisation and professional training radiology in regional departments at two university hospitals

(Ilcheva *et al.*, 2021). A multidisciplinary team consisting of a radiologist, radiographer, medical physicist, and quality coordinator used commercially available software to collect information on the quality of the management procedures, infrastructure, patient-related and technical procedures and education, training and research programmes (Ilcheva *et al*., 2021). The findings were that QUAADRIL as a reference tool for clinical audits is efficient and can define baseline values for continuous quality improvement. Furthermore, the study underlined the importance of constant monitoring of patient radiation dose as a means of patient safety evaluation and a source of additional workload or quality-related information (Ilcheva *et al*., 2021).

Dondi *et al*. (2018:299-306) conducted a study focusing on the impact of the implementation of QUANUM on daily routine practices in audited centres. The IAEA previously audited these centres externally and were requested to audit themselves after a year internally. The QUANUM program's rationale assumes that applying auditors' recommendations and implementing the corrective actions defined during first external audits would help audited centres to meet international quality standards and enhance their clinical practice (Dondi *et al*., 2018:299-306). Their study aimed to prove whether the QUANUM program application positively impacted the 37 audited centres. The results showed that clinical services scored the highest LoC (83.7% for imaging and 87.9% for therapy) (Dondi et al., 2018:299-309). In contrast, Radiopharmacy Level 2 scored (56.6%), Computer Systems and Data Handling scored (66.6%), and Evaluation of the Quality Management System (67.6%) had the lowest value (Dondi et al., 2018:299-309). The final audit report contained 1687 recommendations due to the prioritization of non-conformances (Dondi et al., 2018:299-309). The conclusion was that almost all the 37 departments surveyed improved their adherence to internationally recognised standards when regular quality audit programs were followed (Dondi *et al*., 2018:299-309).

A review article by Begum, Begum and Hasan (2018:51) gave an account of the introduction of the QUANUM program at the National Institute of Nuclear Medicine and Allied Sciences (NINMAS) in Bangladesh (Begum et al., 2018:51). The program was introduced as part of a national workshop organised by the Bangladesh Atomic Energy Commission (BAEC) and the IAEA as one of technical cooperation programme (Begum *et al*., 2018:51). The workshop provided an opportunity for orientation with the QUANUM checklist and acted as an anchor to local practice for the future (Begum *et al*., 2018:51): BAEC recommended that non-conformance issues must be addressed with passion and determination (Begum et al., 2018:55). Implementing an audit's recommendations requires adequate planning and administrative backing (Begum et al., 2018:55).

The researcher of this current study hence deemed it important to audit selected Namibian nuclear medicine departments to identify non-conformance and adherence to internationally recognised standards.

2.8 Total quality management as a theoretical framework

The study anchors on the 1980s popular management philosophy/theory known as total quality management (TQM) which is utilised by enterprises to enhance their management capabilities, improve performance, and achieve quality and excellence (Dahlgaard Park, Reyes & Chen, 2018:1). Baidoun, Sarlem, and Omran (2016:2) define TQM as *"a holistic approach that continually improves products and processes by achieving continuous organisational improvement and customer expectations".* The theory is based on the evolving principles contributed by pioneers such as Shewhart, Deming, Juran, Feigenbaum, Crosby, Ishikawa, Taguchi, and Shingo (Dahlgaard Park, Reyes & Chen, 2018:2; Zhang, Moreira & Sousa, 2020:1). Table 2.2 presents four historical stages: quality inspection, quality control, quality assurance, and TQM (Dahlgaard Park, Reyes & Chen, 2018:2).

Table 2.2 Stages of the TQM evolution (Dahlgaard Park, Reyes & Chen, 2018:2)

Stage	Timeline	Description
Quality inspection	1910	Employees performed inspection processes to find poor-quality products, and those products would be scrapped, reworked, or sold as lower quality.
Quality control	1924	Industrial advancements evolved quality management, and quality was controlled through supervised skills, written specification, measurement, and standardisation. The development of control charts by Shewhart (1924–1931) distinguished between two types of process variation: one resulting from casual causes and another resulting from assignable or particular reasons. Monitoring the process variation was very important because where the variation occurred was where the intervention happened.
Quality assurance	1960	Contains all the previous (inspection and control variation process), but, to satisfy customer's needs, more aspects were included: comprehensive quality manuals, use of the cost of quality, development of process control and auditing of quality systems, and a change of emphasis from detection toward prevention of poor quality.
TQM	1980	Involves primary ideas, components, and concepts in every aspect of business activity. This philosophy is enriched by applying quality management methods, tools and techniques.

The effectiveness of the TQM principle lies in its successful implementation in an organisation. Five critical factors hinder it: lack of leadership and top management support for quality, human resource management inconsistent with TQM principles, short customer focus, inadequate planning for quality, and lack of systems or resources supporting such programmes (Zhang, Moreira & Sousa 2020:4). According to Zhang *et al*. (2020:4) implementation of TQM in service industries is more complex than in manufacturing due to labour intensity and customer interaction. Divisions of service industries are:

trade, transportation and utilities, information, finance, professional and business services, education and health services, and others (Zhang *et al*., 2020:4).

According to Erven (2019) applying TQM to internal auditing can achieve total quality auditing. It can have dramatic results that are more forward-thinking, customer-centric, and improvement-oriented. The International Organisation for Standardisation (ISO) 9000 for QMS requires organisations to perform internal audits to determine whether the QMS meets the ISO 9001 standard and the organisation's internal requirements (Chiarini, Castellani, Rosatto & Cobelli, 2020:1). An internal audit is defined as a 'structured method and fundamental process of QMS that can affect the system's performance and improvements' (Castellani *et al*., 2020:1). Castellani *et al*. (2020:3) described internal audits as follows.

- Essential vehicles for corrective and preventative actions.
- Provides recommendations for continued improvement.
- Practice for quality improvement and performance evaluation.
- Practical self-assessments aids in improving and managing their QMS.
- Validates QMS effectiveness.
- Contributes to the attainment of company efficiency.

The QUANUM program which is described above is a holistic approach, same as TQM, which served as the theoretical framework for the existing study. The QUANUM program involves all aspects of nuclear medicine services: administration processes; proper management of human resources including training and clinical competence; QA/QC procedures for relevant equipment; assessment of safety conditions (for patients and staff) concerning radiation exposures, microbiological, mechanical and electrical, amongst others, detailed analysis of components related to patient management and synthetic evaluation of the quality of reports (Dondi *et al*., 2017a:685). This approach is integrated with auditing to ensure continuous improvement through internal and external audits in repeated intervals.

2.9 Summary

The review of literature described in this chapter highlighted the role that the QUANUM tool plays in improving quality assurance in nuclear medicine departments. Literature on conformance criteria, as contained in the QUANUM tool, was discussed as was QA in a holistic view. Total quality management, as a theoretical framework, was discussed. The methodology employed in the study is presented in Chapter Three.

CHAPTER THREE

METHODOLOGY

3.1 Introduction

The purpose of this study was to conduct a quality audit of four nuclear medicine departments in Namibia. In this chapter, the research design, scope, sampling strategies, research instrument, and data collection method employed at each research site are described. Ethical considerations employed during the data collection process are also discussed.

3.2 Overview of the methodology

The study was conducted in four nuclear medicine departments: [redacted] Sites are well equipped and conducive for research purposes. They were considered suitable study sites for data collection as they were conducting a wide range of examinations suitable for using the QUANUM tool. Ethics approval was obtained from the Research Ethics Committee (REC) of the Faculty of Health and Wellness Sciences at the Cape Peninsula University of Technology, and the head of departments (HODs) of the selected study sites.

An onsite auditing team comprised the researcher, and an available senior radiographer/medical physicist/head of administration and a physician. The IAEA audit criteria were used to evaluate all department processes. Additionally, the audit team used the management and operation information. Use was made of inter alia, a quality manual; written SOPs for primary (diagnosis) management and supporting processes; updated copies of licenses/accreditation documents; organisational flow chart and function descriptions; sample of referral letters; copies of data regarding patient waiting times; updated information on waiting lists; copies of quality control data for relevant equipment; copies of quality control data for radiopharmaceuticals; radiation safety records; copies of letters of appraisal/complaints and customer/stakeholder satisfaction surveys. An exit briefing with the HOD was held to convey informal feedback and commitment. This was followed later by a formal report containing the relevant recommendations.

3.3 Research design

The study adopted a positivist paradigm and a quantitative methodological approach. According to Kivunja and Kuyini (2017:30-31), the positivist paradigm relies on deductive logic, explanations, and predictions based on measurable outcomes supported by several assumptions. The latter include determinism, i.e. events observed caused by other factors; empiricism, i.e. a collection of verifiable

data supporting the chosen theoretical framework; parsimony, i.e. explaining in the most economical way possible; and generalisability, i.e. the ability of a researcher to generalise about what can be expected in the world. These assumptions result in the positivist paradigm advocating quantitative research methods as the bedrock for a researcher's ability to describe precisely the parameters and coefficients in the data gathered, analysed and interpreted to understand relationships embedded in the data analysed (Kivunja & Kuyini, 2017:30-31). The study collected verifiable data using the QUANUM tool based on the TQM theoretical framework. This is not the first study globally, and the observed events were caused by other internal factors.

According to Fryer, Larson-Hall, and Stewart (2018:56) a quantitative methodology approach allows a researcher to measure things that can be counted to arrive at a quantity of data in order to perform statistical analysis. The following were audited by the researcher at the selected study sites: administration processes; management of HR's including training and clinical competence; QA/QC procedures for relevant equipment; assessment of safety conditions (for patients and staff) concerning radiation exposures, microbiological, mechanical and electrical, amongst others; detailed analysis of components related to patient management and synthetic evaluation of the quality of reports.

3.4 Research sites

Namibia consists of 14 regions each with their own capital city as shown in Figure 3.1. The study was conducted at four nuclear medicine facilities. The first site caters for 300 patients on a monthly basis. It is equipped with one SPECT gamma camera and one SPECT-CT camera. The staff complement consisted of two physicians, three radiographers, three nurses, one medical physicist and other supporting staff.

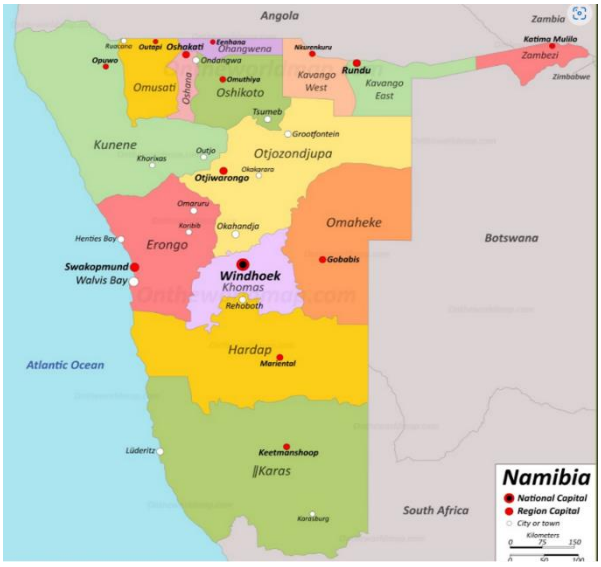


Figure 3.1 Location of research Sites. Source: Ontheworldmap.com (2020).

The second site is equipped with one SPECT gamma camera and has a staff complement of two physicians, one radiographer and supporting. The third site is equipped with one SPECT/CT gamma camera and has a staff complement of one physician, one radiographer and supporting staff. The fourth site is equipped with two SPECT-CT gamma cameras with a staff complement of one physician, two radiographers, one nurse, one medical physicist and supporting staff. All the Sites were well equipped and were conducive for research purposes.

3.5 Sample selection

The researcher personally audited the four study sites. Data sampling was based on permission and mutual convenience of each research site. All four nuclear medicine departments agreed to partake in the study.

3.6 Inclusion criteria

As stated above each site had to provide nuclear medicine services hence all four sites met the inclusion criteria discussed in Section 3.4 above.

3.7 Exclusion criteria

The research study excluded other diagnostic departments, i.e., radiology or radiation therapy in Namibia. Four checklists were excluded in the study, namely, Checklist 8: Computer Systems and Data Handling, Checklist 11: Assessment of non-imaging diagnostic procedure; Checklist 16: Radiopharmacy operational level 3; and Checklist 17: Hormones and tumour markers. Checklist 8 was excluded because the nuclear medicine departments were not equipped with PACS and RIS and the system backups and software protections are not performed within these departments. Checklists 11, 16 and 17 were excluded because the nuclear medicine departments do not conduct these services.

3.8 Validity and reliability

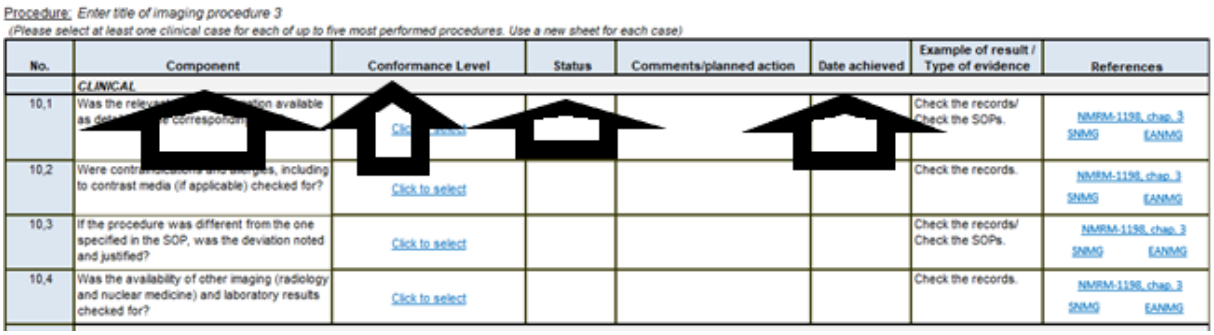
According to Bolarinwa (2015:195) (a) validity pertains to the degree to which a measurement measures what it claims to measure whilst (b) reliability refers to the degree to which the results obtained by measurement and procedure can be reproduced. The QUANUM tool is both valid and reliable as it was developed by the IAEA. The IAEA is a well-recognised and respected world body whose primary purpose is to, among other things, coordinate international cooperation for the regulation of nuclear technology spanning industries such as health, agriculture, energy and hydrology (IAEA, 1998). According to Dondi *et al.* (2017b) the tool was used in auditing 37 nuclear medicine centres worldwide. In view of its global use it was assumed the data collection tool was reliable. The latter however

requires that a researcher ensures rigorous data collection at the research site as per the QUANUM tool prescripts.

To further aid in the validity and reliability of the data an onsite auditing team was used. It comprised the researcher, and an available senior radiographer/medical physicist/head of administration and a physician. Each area on the auditing tool was assigned/supervised by the auditing member responsible for that particular area in the department, i.e. Checklist 12: General radionuclide therapy was assigned/supervised by the physician. The auditing member accompanied the researcher as she audited that area. When the researcher completed the audit, both of them cross-checked the collected data in order to eliminate any researcher bias. This ensured reliability of the data collected.

3.9 QUANUM tool

The audit tool was developed as a Microsoft Excel spreadsheet (XLS). The spreadsheet covers all aspects of nuclear medicine practice under checklist 1 to checklist 15 (see Appendix 1). Each checklist has a set of questions associated with particular components of the nuclear medicine service consisting of seven columns. See Figure 3.2, Table 3.1, and Appendix 1.



Procedure: *Enter title of imaging procedure 3*

(Please select at least one clinical case for each of up to five most performed procedures. Use a new sheet for each case)

No.	Component	Conformance Level	Status	Comments/planned action	Date achieved	Example of result / Type of evidence	References
	CLINICAL						
10,1	Was the relevant [illegible] available as [illegible] correspondence?	Click to select				Check the records/ Check the SOPs.	NMRM-1198, chap. 3 SNMG EANMG
10,2	Were contraindications and allergies, including to contrast media (if applicable) checked for?	Click to select				Check the records.	NMRM-1198, chap. 3 SNMG EANMG
10,3	If the procedure was different from the one specified in the SOP, was the deviation noted and justified?	Click to select				Check the records/ Check the SOPs.	NMRM-1198, chap. 3 SNMG EANMG
10,4	Was the availability of other imaging (radiology and nuclear medicine) and laboratory results checked for?	Click to select				Check the records.	NMRM-1198, chap. 3 SNMG EANMG

Figure 3.2 Excerpt of the Excel sheet illustrating the different elements as explained in Table 3.1 (IAEA, 2015).

Table 3.1 presents the elements on the Excel sheet. Each element was completed for the purpose of the study.

Table 3.1 Description of each component on the data Excel sheet as highlighted by the arrows in Figure 3.2 (IAEA, 2015)

Elements	**Explanations/what it contains**
Component	Contains the research questions for each section of the overall quality system
Conformance level	This is a categorising tool which by clicking reveals six menu items which consisted of the following: 'Not Applicable'; 'Absent or inappropriate'; 'Planned or approximate'; 'Partially conform or

	partially implemented'; 'Largely conform or largely implemented'; and 'Fully conform or fully implemented'.
Status	This section demonstrated each component's non-conformance and conformance status in colours. Red = non-conformance; green = conformance; white = not applicable.
Comments/planned action	This column was for the researcher's comments or any Site's planned action if nothing was in place.
Date achieved	Date on which the component is to be executed or was already executed.
Example of result/ type of evidence	Contains suggestions that act as guidelines for estimating conformance level and considered for assessing the components. It also aids in indicating expected results.
References	These contained links to IAEA publications, i.e., books, papers, and technical reports in the field of nuclear medicine. The links included in all requirements provide complementary information supporting their necessity.

3.10 Data collection method

Each study site was given an alphabetical letter to assist in anonymising the research site. The selected sites were therefore named Site A to D. It should be noted this the data collection occurred amidst the COVID-19 pandemic. The data collection method employed for each site is presented below.

- **The method employed at Site A**

1. The researcher conducted the audit from 15 to 19 November 2021 at Site A. While wearing a mask and maintaining social distance, the researcher met with the HOD to explain what would be done. The HOD introduced the researcher to the personnel. The researcher finalised the agenda, discussed the objective, data collection, and details of the audit and signed a confidentiality agreement.
2. The researcher further requested the senior radiographer for the management and operation information such as, but not limited to the following.
    - A departmental quality manual.
    - Written SOPs utilised in the reception area, radiopharmacy, imaging rooms, equipment, radioiodine treatment and management.
    - Updated copies of licenses/accreditation documents from NRPA.
    - Department flow chart describing the personnel functions/duties.

- Sample of patient referral letters.
- Copies of data regarding patient waiting times.
- Updated information on waiting lists.
- Copies of quality control data for relevant equipment.
- Copies of quality control data for radiopharmaceuticals.
- Radiation safety records.
- Copies of letters of appraisal/complaints.
- Customer/stakeholder satisfaction surveys.

3. The researcher, and, if available, the senior radiographer, junior radiographer, and medical physicist (radiation safety officer) conducted the audit using the IAEA audit criteria.
4. The researcher had an exit briefing with the whole department to convey informal feedback and commitment after data collection was completed.

➢ **The method employed at Site B**

1. The researcher conducted the audit from 22 to 26 November 2021 at Site B. While wearing a mask and maintaining social distance, the researcher met with the HOD who then introduced the researcher to the personnel. The agenda was finalised and the researcher discussed the objective, data collection, and details of the audit and signed a confidentiality agreement.

2. The researcher further requested the radiographer for the management and operation information such as, but not limited to the following.
   - A departmental quality manual.
   - Written SOPs utilised in reception area, radiopharmacy, imaging rooms, equipment, radioiodine treatment and management.
   - Updated copies of licenses/accreditation documents from NRPA.
   - Department flow chart describing the personnel functions/duties.
   - Sample of patient referral letters.
   - Copies of data regarding patient waiting times.
   - Updated information on waiting lists.
   - Copies of quality control data for relevant equipment.
   - Copies of quality control data for radiopharmaceuticals.
   - Radiation safety records.
   - Copies of letters of appraisal/complaints.
   - Customer/stakeholder satisfaction surveys.

3. The researcher, radiographer (radiation safety officer) and head of administration conducted the audit utilising the IAEA audit criteria.
4. The researcher held an exit briefing with the HOD to convey informal feedback and commitment.

➢ **Method employed at Site C**

1. The researcher conducted the audit from 18 to 20 January 2022 at Site C. While wearing a mask and maintaining social distance, the researcher met with the HOD who then introduced the researcher to the personnel. The researcher finalised the agenda, discussed the objective, data collection, and details of the audit and signed a confidentiality agreement.

2. The researcher further requested the senior radiographer for the management and operation information such as, but not limited to the following.
   - A departmental quality manual.
   - Written SOPs utilised in reception area, radiopharmacy, imaging rooms, equipment, radioiodine treatment and management.
   - Updated copies of licenses/accreditation documents from NRPA.
   - Department flow chart describing the personnel functions/duties.
   - Sample of patient referral letters.
   - Copies of data regarding patient waiting times.
   - Updated information on waiting lists.
   - Copies of quality control data for relevant equipment.
   - Copies of quality control data for radiopharmaceuticals.
   - Radiation safety records.
   - Copies of letters of appraisal/complaints.
   - Customer/stakeholder satisfaction surveys.
3. The researcher, and depending on her availability the senior radiographer, junior radiographer, medical physicist (radiation safety officer) and nuclear medicine physician conducted the audit utilising the IAEA audit criteria and evaluated the department's overall activity. During the data collection period scans were not being conducted due the unavailability of the Technetium-99m generator. The physician was only seeing follow up patients at the time of the study as the gamma cameras were out of order.
4. The researcher held an exit briefing with the whole department to convey informal feedback and commitment.

➢ **The method employed at Site D**

1. The researcher conducted the audit from 24 to 26 January 2022 at Site D. While wearing a mask and maintaining social distance, the researcher met with the HOD who introduced the researcher to the personnel. The researcher finalised the agenda, discussed the objective, data collection, and details of the audit and signed a confidentiality agreement.
2. The researcher further requested the radiographer for the management and operation information such as, but not limited to following.

- A departmental quality manual.
- Written SOPs utilised in reception area, radiopharmacy, imaging rooms, equipment, radioiodine treatment and management.
- Updated copies of licenses/accreditation documents from NRPA.
- Department flow chart describing the personnel functions/duties.
- Sample of patient referral letters.
- Copies of data regarding patient waiting times.
- Updated information on waiting lists.
- Copies of quality control data for relevant equipment.
- Copies of quality control data for radiopharmaceuticals.
- Radiation safety records.
- Copies of letters of appraisal/complaints.
- Customer/stakeholder satisfaction surveys.

3. The researcher, senior radiographer, and nuclear medicine physician used the IAEA audit criteria and evaluated the department's overall activity. The Site was not conducting any scans, and the physician was only seeing follow-up patients at the time of the study as there was no ^{99m}Tc generator available.
4. The researcher held an exit briefing with the whole department to convey informal feedback and commitment.

3.11 Data collection

The data collection process is presented below.

3.11.1 Excel spreadsheet analysis

The audit activities were entered into a spreadsheet as shown in Figure 3.2. Description of the data collection section was presented above in section 3.3 as well as Table 3.1. Under the conformance

level the tool makes provision for a dropdown menu whereby the researcher was able to select the scoring as demonstrated in Figure 3.3.

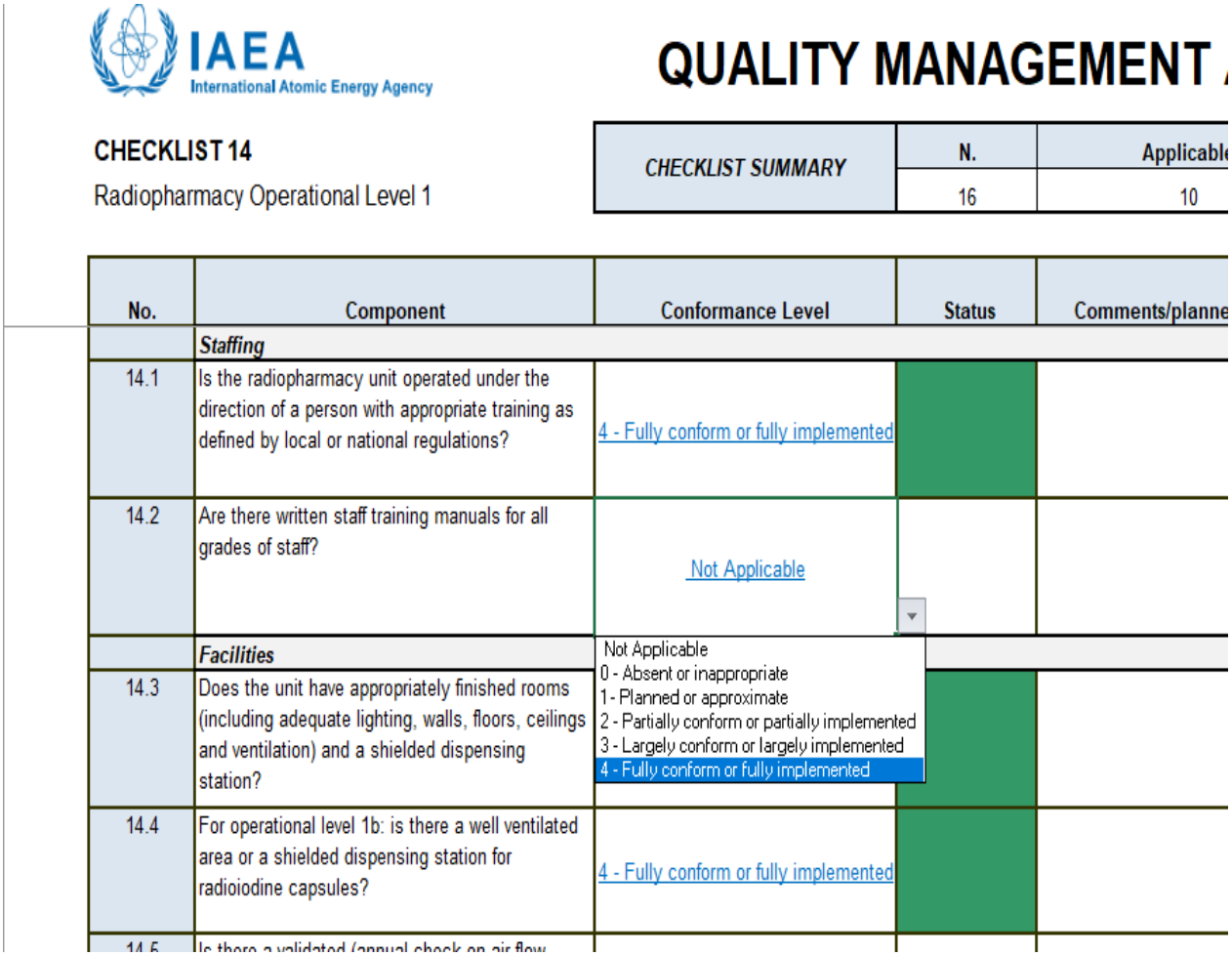


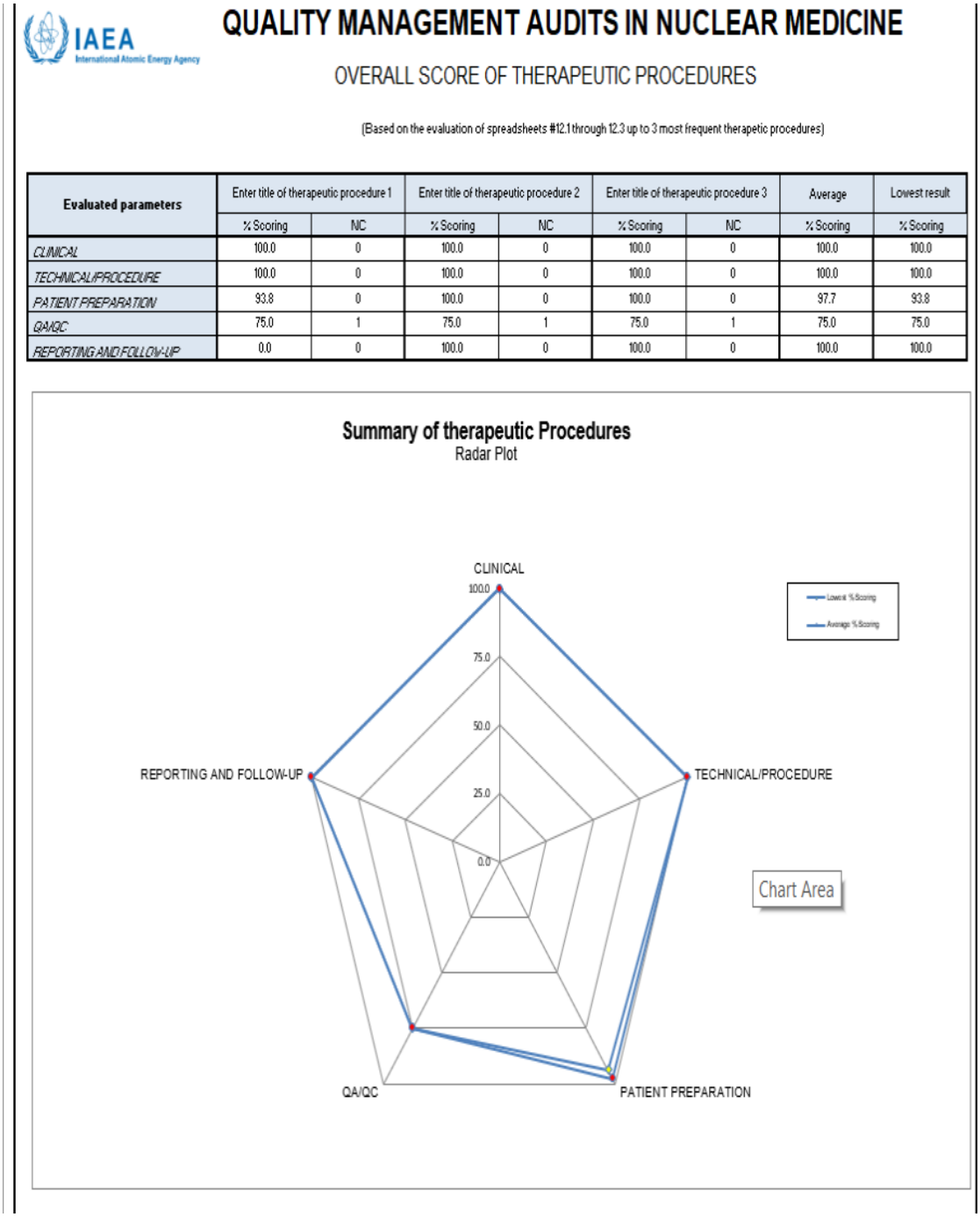
Figure 3.3 Showing an example of dropdown menu from spreadsheet (IAEA,2021)

Table 3.2 provides the definitions of the scoring system that was used. As shown site scores were: 0 to 2 = non-conformance, 3 and 4 = conformance.

Table 3.2 Providing the definitions of the scoring system (IAEA, 2021)

Score	Classification	Description
Not applicable	Non-conformance	This checklist/ requirement does not apply
0		Absent or inappropriate
1		Planned or approximate
2		Partial conformance or partial implementation
3	Conformance	Mostly conforming and/or mostly implemented
4		Fully conforming and fully implemented

The Excel software sums up the numerical value corresponding to the conformance status selection. The results with a total score are then indicated in the 'checklist summary' which are used to generate the radar plot. Additionally, the 'checklist summary' provides an overview of the applicable requirements, the percentage of conformance, and the number of non-conformance. The radar plot demonstrates mean and lowest scores. An example is shown in Figure 3.4.



QUALITY MANAGEMENT AUDITS IN NUCLEAR MEDICINE

OVERALL SCORE OF THERAPEUTIC PROCEDURES

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

Evaluated parameters	Enter title of therapeutic procedure 1		Enter title of therapeutic procedure 2		Enter title of therapeutic procedure 3		Average	Lowest result
	% Scoring	NC	% Scoring	NC	% Scoring	NC	% Scoring	% Scoring
CLINICAL	100.0	0	100.0	0	100.0	0	100.0	100.0
TECHNICAL/PROCEDURE	100.0	0	100.0	0	100.0	0	100.0	100.0
PATIENT PREPARATION	93.8	0	100.0	0	100.0	0	97.7	93.8
QA/QC	75.0	1	75.0	1	75.0	1	75.0	75.0
REPORTING AND FOLLOW-UP	0.0	0	100.0	0	100.0	0	100.0	100.0

Figure 3.4 Example of a checklist summary and a radar plot (IAEA, 2021).

The Excel sheet comprised a sheet named prioritisation of non-conformances. This allowed the researcher to summarise and prioritise areas of non-conformances. This was an essential and final step of the QUANUM program requirement that allowed non-conformances to translate into recommendations according to the three prioritisation levels. An example is provided in Figure 3.5. An explanation of the different categories is presented in Section 6.2 in Chapter Six.

Issues of critical priority			
No.	Comment/action	Time frame	Date achieved

Issues of major priority			
No.	Comment/action	Time frame	Date achieved

Issues of minor priority			
No.	Comment/action	Time frame	Date achieved

Figure 3.5 Example categorising non-conformances according to their priority (IAEA, 2021).

3.12 Ethical considerations

The researcher applied the ethical principles as recorded in the Helsinki Declaration (World Medical Association (WMA, 2013). A request for ethical approval of the study was submitted to the REC of the Faculty of Health and Wellness Sciences at the Cape Peninsula University of Technology (CPUT). After receiving their ethical approval, the researcher submitted a letter requesting site permission, as well as a copy of the proposal and letter of approval from the CPUT REC and relevant nuclear medicine facilities for permission to conduct the study at their respective Sites.

The study did not involve any human subjects. The researcher only analysed existing data (primary data) during the study. Furthermore, the study did not interfere with the selected sites' clinical day-to-day activities, such as the patient throughput or workload of radiographers, physicians and nurses. Data collection took place on mutually agreed days that were most convenient to the department to avoid impacting patient care and service delivery. The documents consulted were analysed in a room arranged by the clinical site to be as unobtrusive as possible.

In terms of the WMA (2013) physicians [and radiography researchers] have both ethical and legal obligations to respect the dignity, autonomy, privacy and confidentiality of individuals. They are

stewards protecting information provided by patients. The rights to autonomy, privacy and confidentiality also entitle individuals to exercise control over the use of their personal data and biological material (WMA, 2013). In order to maintain anonymity of patients and the research site, where patients' data were scrutinised, the researcher adhered to strict confidentiality by not recording or revealing such names during the data collection. Confidential information will not be revealed during future publication of the study findings. The researcher did not use any of the clinical departments' resources or consumables during the data collection.

The research site results were coded: each hospital was labelled alphabetically as Site A to D. When dealing with a patient file, personal information was not used. The type of scan the patient underwent was used. In other words, the files of the most frequently done scan in each department were used as the tool only allowed listing the scan type. Hence the scan type was referred to as such throughout the data collection process. For confidentiality purposes, patient files were not taken off-site since the researcher only had onsite access. The collected primary data were locked in a cabinet in the researcher's work office. Only the researcher had access to this primary data. Electronic data were stored on a password-protected laptop/PC with anti-hacking or anti-phishing software.

The researcher was impartial, fair and honest when conducting the study and signed a confidentiality agreement to prevent unwanted information leakage. The names of the research site will be kept confidential and not published in the thesis or subsequent scientific article emanating from the findings of this study. Due to the limited number of nuclear medicine practices/departments in Namibia, the researcher will not reveal the country's name when publishing the results to negate indirect identification or potential link of the findings to the four research sites. In addition, the researcher undertook to provide the research site with a redacted copy of the research findings for their perusal before the publication of the thesis or a scientific article. Where any possible contentious results exist, a discussion between the research team and the research site will be arranged to resolve such issues prior to publication. The researcher committed not to publish any adverse findings that may affect any of the research sites' future clinical work or business. The results generated through this study will form part of a master's degree by research therefore none of the research sites are obligated to accept or implement any of the recommendations made in the research report.

3.13 Summary

This chapter described the research methodology under research design, scope, sampling strategies, research instrument, and data collection method employed at each research site. Ethical considerations employed during the data collection process were explained. The research results are discussed in chapter four.

CHAPTER FOUR

RESULTS

4.1 Introduction

This chapter presents the findings generated from the audits of the four research sites using the IAEA QUANUM tool. The results for each research site are indicated as sites A-D under Checklists 1 – 10 and 12 -15 as these are services offered by the NMS in Namibia. Each checklist has criteria that are referred to as counts in the figures below. Each checklist describes the results under two headings: level of conformance, and overall conformity. The latter is subdivided into non-conformance and conformance of the four research sites and demonstrated as bar charts. A summary of overall conformance and non-conformance results of all the sites is presented in radar plots.

4.2 Checklist 1: Strategies and policy

Checklist 1 contained 12 evaluation criteria/QUANUM criteria. The criteria to which the Sites responded 'not applicable' did not count towards the count of conformance and the total score.

- The results for level of conformance for each Site (A to D) are as follows. Site A scored 8 counts of these criteria as 'absent or inappropriate'; 1 count as 'planned or approximate'; 1 count as 'partially conform or implemented'; 0 counts for largely conform or implemented and 2 counts as 'fully conformed or implemented'. Site B scored 4 counts for 'not applicable'; 2 counts for 'absent or inappropriate'; 0 counts for 'planned or approximate', 'partially conform or implemented' and largely conform or implemented; 6 counts for 'fully conform or implemented'. Site C scored 1 count for 'not applicable'; 4 counts for 'absent or inappropriate'; 1 count for both 'planned or approximate' and; 0 counts for 'partially conform or implemented'; o counts for largely conform or implemented and 6 counts for 'fully conform or implemented'. Site D scored 6 counts for 'not applicable'; 1 count for both 'absent or inappropriate' and 'planned or approximate'; 0 counts for 'partially conform or implemented' and largely conform or implemented and 4 counts for 'fully conform or implemented'.
- The results for overall conformity are as follows. Site A conformed with 2 out of 12 counts, and non-conformed with 10 out of 12 counts. Site B conformed with 6 out of 8 counts, and non-conformed with 2 out of 8 counts. Site C conformed with 6 out of 11 counts, and non-conformed with 5 out of 11 counts. Site D conformed with 4 out of 6 counts, and non-conformed with 2 out of 6 counts.

Figures 4.1a and 4.1b is a summary of the level of conformance and overall conformity for Checklist 1.

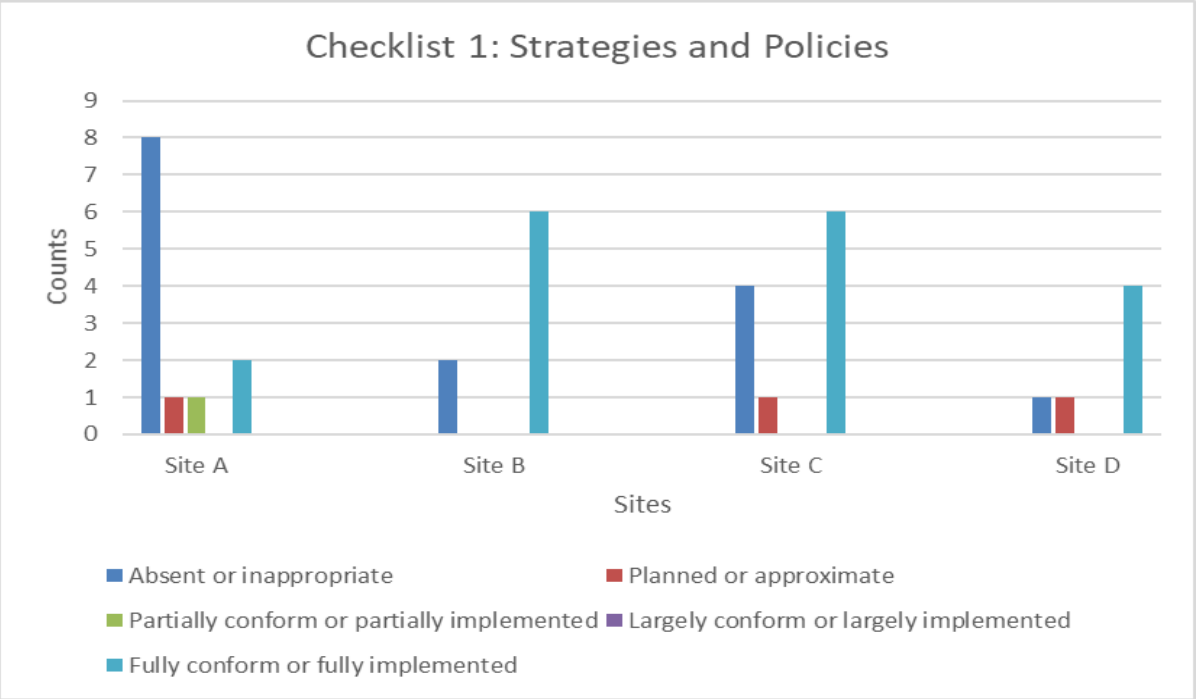


Figure 4.1a Summary of the level of conformance for Checklist 1

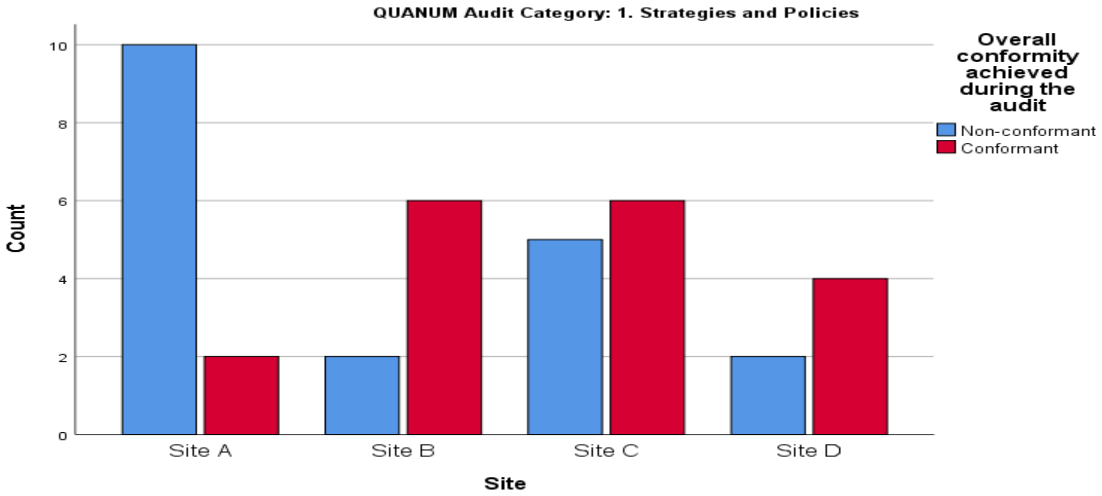


Figure 4.1b Summary of the overall conformity for Checklist 1

4.3 Checklist 2: Administration and management

Checklist 2 contained 17 evaluation criteria/QUANUM criteria, which are referred to as counts. The questions to which the Sites responded 'not applicable' did not count towards the count of conformance and the total score.

- The results for level of conformance are as follows. Site A scored 6 counts of these criteria as 'absent or inappropriate'; 0 counts as 'planned or approximate'; 4 counts as 'partially conform or implemented'; 0 counts largely conform or implemented and 7 counts as 'fully conformed or implemented'. Site B scored 1 count for 'not applicable'; 7 counts for 'absent or inappropriate'; 0 counts for 'planned or approximate'; 5 counts for 'partially conform or implemented'; 0 counts for largely conform or implemented and 4 counts for 'fully conform or implemented'. Site C scored 2 counts for 'absent or inappropriate'; 0 counts for both 'planned or approximate' and 'partially conform or implemented'; 2 for 'largely conform or implemented'; and 13 counts for 'fully conform or implemented'. Site D scored 14 counts for 'absent or inappropriate'; 0 counts for 'planned or approximate', 'partially conform or implemented' and 'largely conform or implemented'; and 3 counts for 'fully conform or implemented'.
- The results for overall conformity are as follows. Site A conformed with 7 out of 17 counts and non-conformed with 10 out of 17 counts. Site B conformed with 4 out of 16 counts and non-conformed with 12 out of 16 counts. Site C conformed with 15 out of 17 counts and non-conformed with 2 out of 17 counts. Site D conformed with 3 out of 17 counts and non-conformed with 14 out of 17 counts.

Figures 4.2a and 4.2b summarises the level conformance and overall conformity for this checklist for the four Sites.

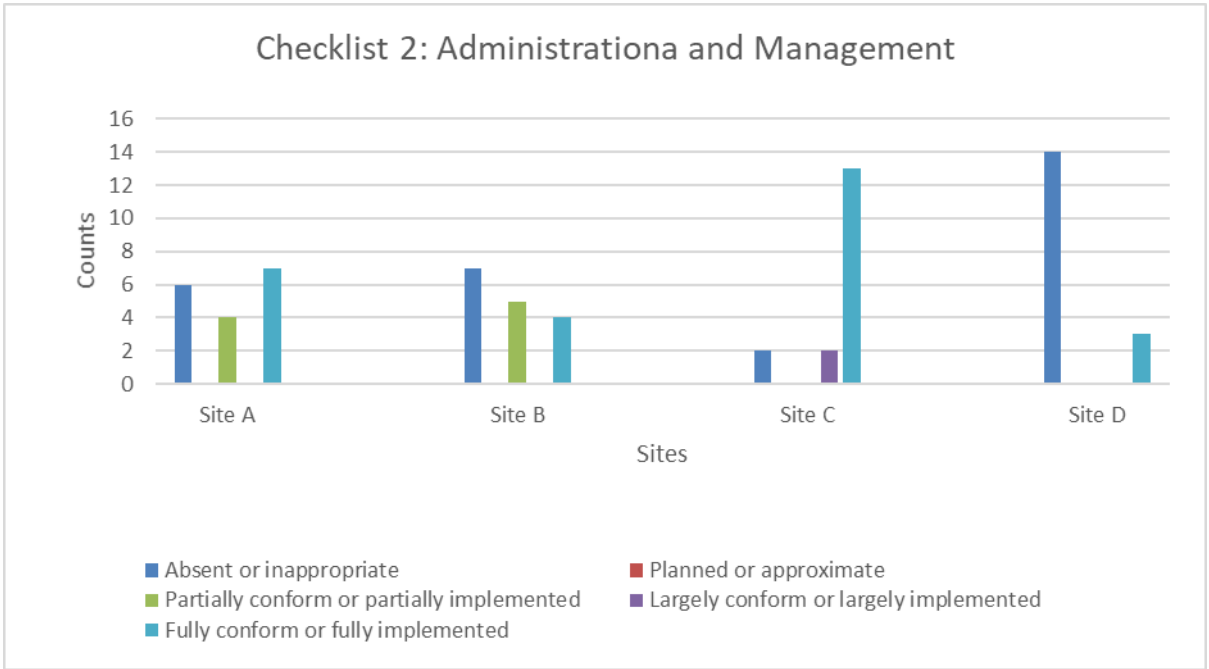


Figure 4.2a Summary of the level conformance under Checklist 2

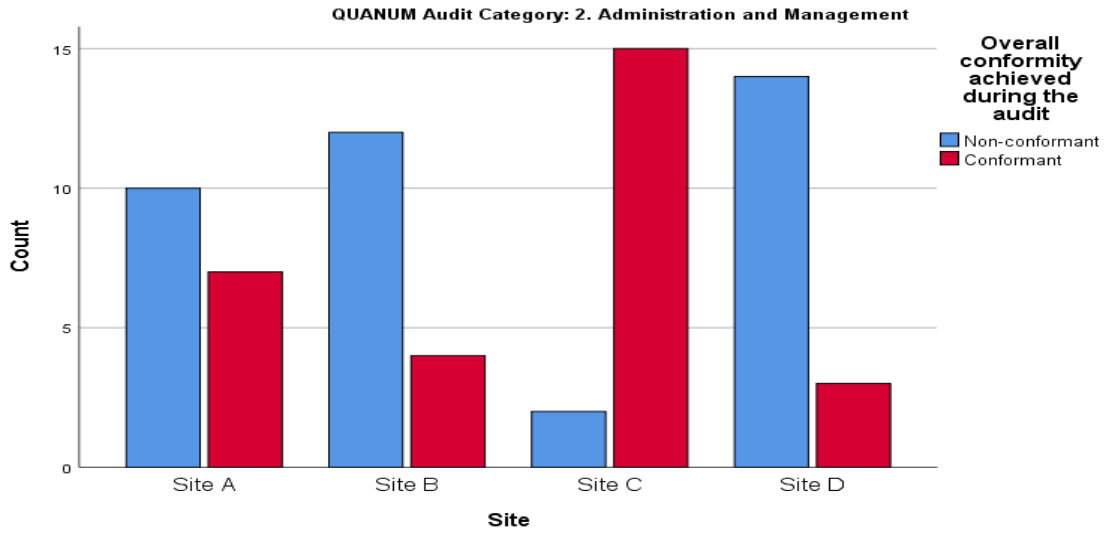


Figure 4.2b Summary of the overall conformity under Checklist 2

4.4 Checklist 3: Human Resource development

Checklist 3 contained 11 evaluation criteria/QUANUM criteria, which are referred to as counts. The criteria to which the sites responded 'not applicable' did not count towards the count of conformance and the total score.

- The results for level of conformance are as follows. Site A scored 3 counts of these criteria as 'absent or inappropriate'; 0 counts for both 'largely conform or implemented' and 'planned or approximate'; 5 counts for 'partially conform or implemented'; 1 count for 'not applicable'; and 2 counts as 'fully conformed or implemented'. Site B scored 3 counts for both 'not applicable' and 'absent or inappropriate; 0 counts for 'planned or approximate'; 1 count for 'partially conform or implemented'; 0 counts for 'largely conform or implemented'; and 4 counts for 'fully conform or implemented'. Site C scored 2 counts for 'not applicable'; 2 counts for 'absent or inappropriate; 0 counts for 'planned or approximate'; 3 counts for 'partially conform or implemented'; 1 count for 'largely conform or implemented'; 3 counts for 'fully conform or implemented'. Site D scored 3 counts for 'not applicable'; 4 counts as 'absent or inappropriate'; 0 counts for 'planned or approximate, partially conform or implemented' and 'largely conform or implemented'; and 4 counts for 'fully conform or implemented'.
- The results of overall conformity are as follows**.** Site A conformed with 2 out of 10 counts and non-conformed with 8 out of 10 counts. Site B conformed with 4 out of 8 counts and non-conformed

with 4 out of 8 counts. Site C conformed with 4 out of 9 counts and non-conformed with 5 out of 9 counts. Site D conformed with 4 out of 8 counts and non-conformed with 4 out of 8 counts.

Figures 4.3a and 4.3b summarises the level conformance and overall conformity under Checklist 3 for the four sites.

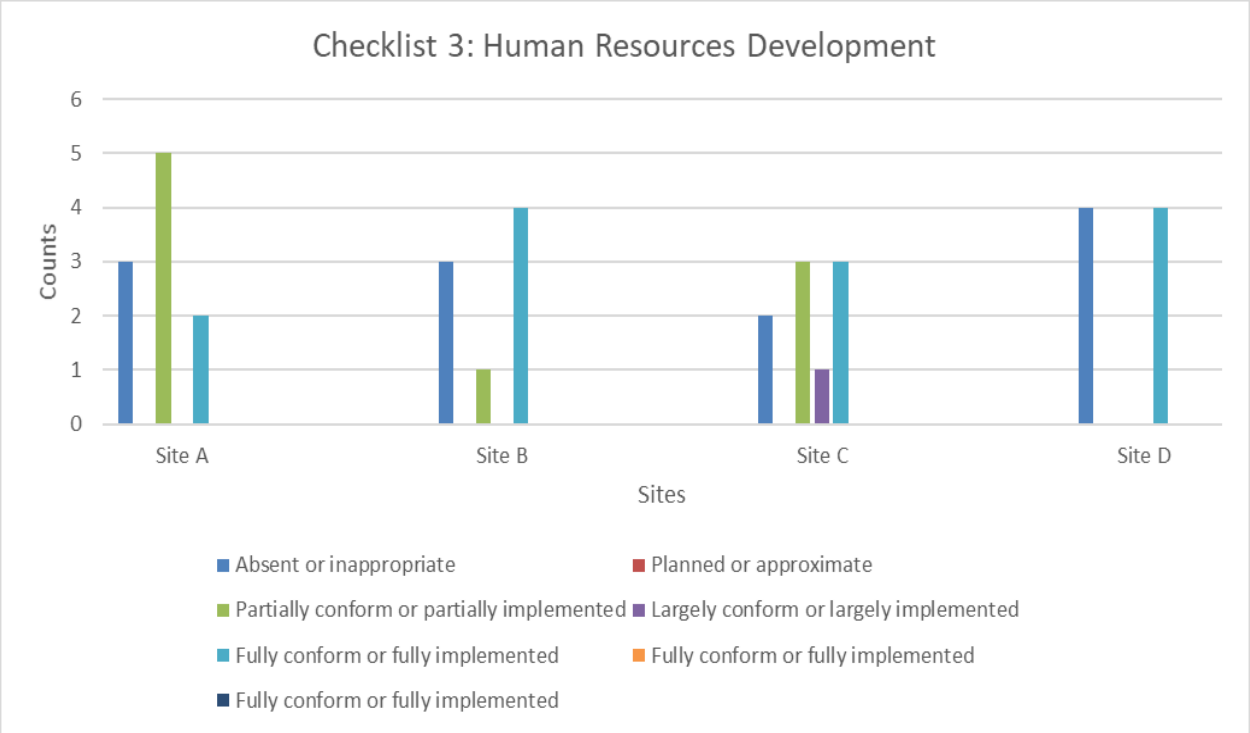


Figure 4.3a Summary of the level conformance under Checklist 3.

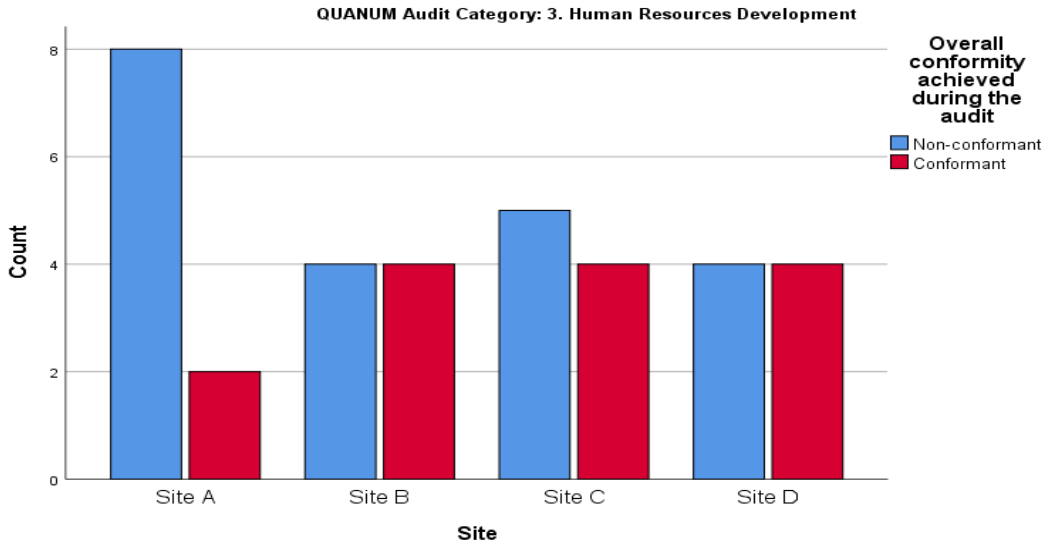


Figure 4.3b Summary of the overall conformity under Checklist 3.

4.5 Checklist 4: Radiation regulations and safety

Checklist 4 contained 25 evaluation criteria/QUANUM criteria, which are referred to as counts. The criteria to which the sites responded 'not applicable' did not count towards the count of conformance and the total score.

- The results for level of conformance are as follows. Site A scored 1 count for 'not applicable'; 7 counts of these criteria as 'absent or inappropriate', 0 counts for 'planned or approximate' and 'largely conform or implemented'; 5 counts for 'partially conform or implemented' and 12 counts as 'fully conformed or implemented'. Site B scored 2 counts for 'not applicable'; 10 counts as 'absent or inappropriate'; 0 counts for 'planned or approximate' and 'partially conform or implemented'; 1 count for 'largely conform or implemented' and 12 counts for 'fully conform or implemented'. Site C scored 1 count for 'not applicable'; 5 counts as 'absent or inappropriate'; 1 count for 'planned or approximate' and 'partially conform or implemented'; 5 counts for 'largely conform or implemented and 12 counts for 'fully conform or implemented'. Site D scored 2 counts for 'not applicable'; 12 counts as 'absent or inappropriate'; 0 counts for 'planned or approximate', 1 count for 'partially conform or implemented', 2 counts for 'largely conform or implemented and 8 counts for 'fully conform or implemented'.
- The results for overall conformity are as follows. Site A conformed with 12 out of 24 counts and non-conformed with 12 out of 24 counts. Site B conformed with 13 out of 23 counts and non-conformed with 10 out of 23 counts. Site C conformed with 17 out of 24 counts and non-conformed with 7 out of 24 counts. Site D conformed with 10 out of 23 counts and non-conformed with 13 out of 23 counts.

Figures 4.4a and 4.4.b summarises the level conformance and overall conformity under Checklist 4 for the four sites.

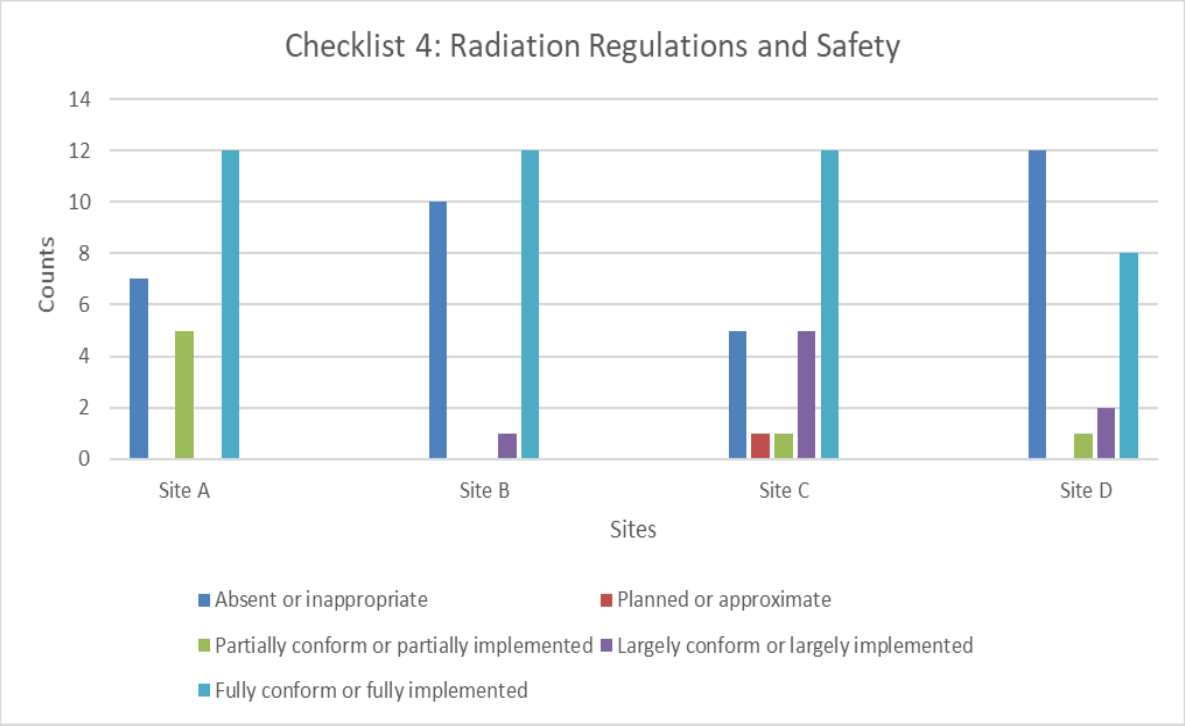


Figure 4.4a Summary of the level conformance under Checklist 4.

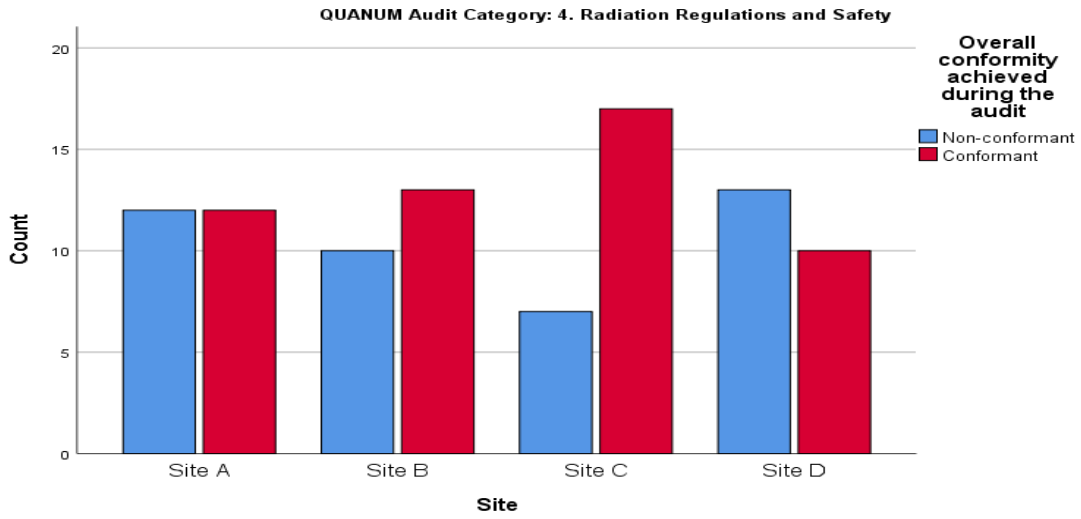


Figure 4.4b Summary of the overall conformity under Checklist 4.

4.6 Checklist 5: Patient radiation protection

Checklist 5 contained 12 evaluation criteria/QUANUM criteria, which are referred to as counts. The criteria to which the Sites responded 'not applicable' did not count towards the count of conformance and the total score.

- The results for the level of conformance are as follows. Site A scored 3 counts of these criteria as 'absent or inappropriate', 0 counts for 'planned or approximate' and 'largely conform or implemented'; 2 counts for 'partially conform or implemented'; and 7 counts as 'fully conformed or implemented'. Site B scored 2 counts for 'not applicable'; 3 counts as 'absent or inappropriate'; 0 counts for 'planned or approximate' and 'partially conform or implemented'; 2 counts for 'largely conform or implemented' and 5 counts for 'fully conform or implemented'. Site C scored 2 counts for 'not applicable'; 5 counts as 'absent or inappropriate'; 0 counts for 'planned or approximate, partially conform or implemented, largely conform or implemented' respectively and 5 counts for 'fully conform or implemented'. Site D scored 7 counts as 'absent or inappropriate'; 0 counts for 'planned or approximate' and 'partially conform or implemented'; 2 counts for 'largely conform or implemented'; and 3 counts for 'fully conform or implemented'.
- The overall conformity results are as follows. Site A conformed with 7 out of 12 counts and non-conformed with 5 out of 12 counts. Site B conformed with 7 out of 10 counts and non-conformed with 3 out of 10 counts. Site C conformed with 5 out of 10 counts and non-conformed with 5 out of 10 counts. Site D conformed with 5 out of 12 counts and non-conformed with 7 out of 12 counts.

Figures 4.5a and 4.5b below summarises the level conformance and overall conformity for this checklist for the four sites.

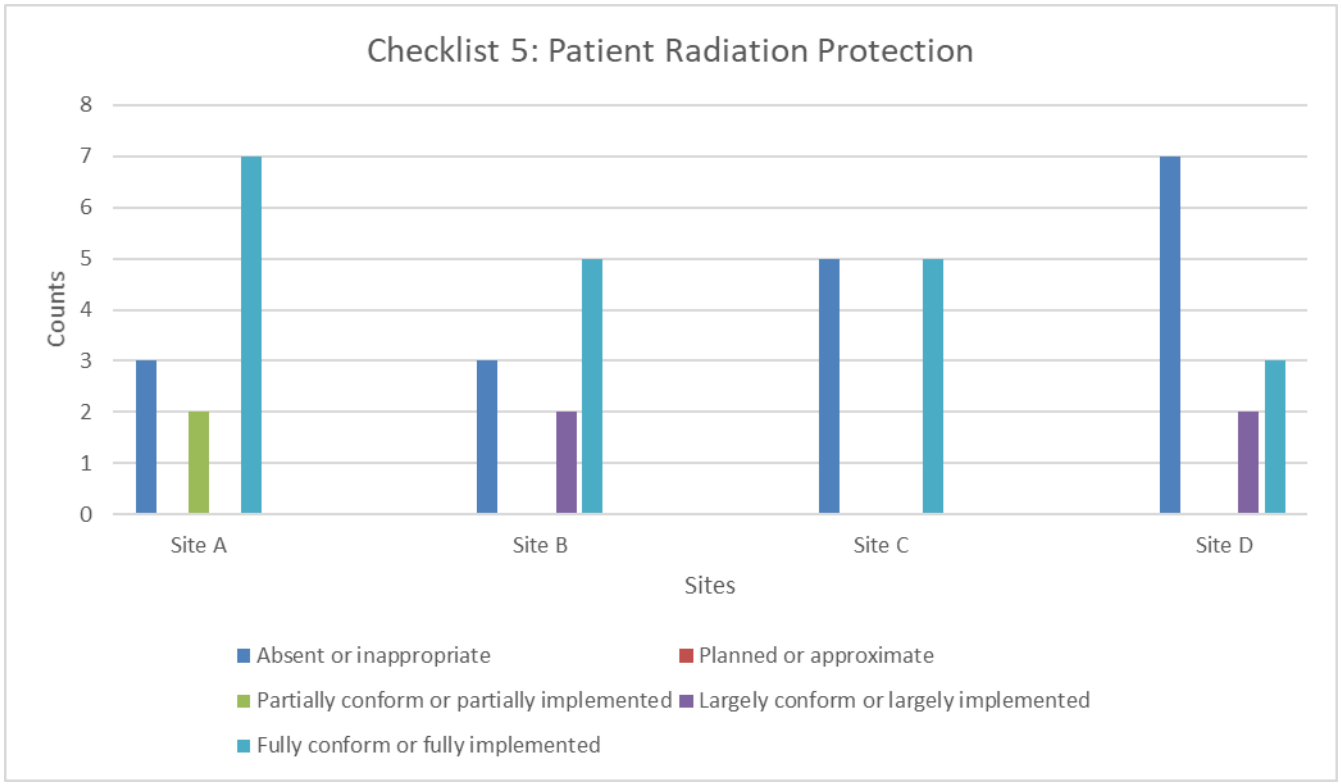


Figure 4.5a Summary of the level conformance under Checklist 5

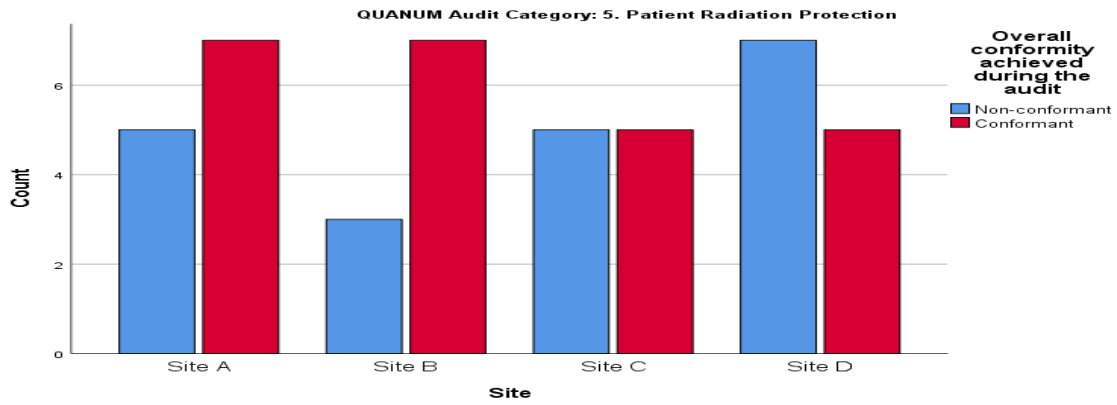


Figure 4.5b Summary of the overall conformity under Checklist 5.

4.7 Checklist 6: Evaluation of quality system

Checklist 6 contained 15 evaluation criteria/QUANUM criteria, which are referred to as counts. The criteria to which the Sites responded 'not applicable' did not count towards the count of conformance and the total score.

- The level of conformance results are as follows. Site A scored 6 counts of these criteria as 'absent or inappropriate'; 1 count for 'planned or approximate'; 0 counts for 'largely conform or implemented'; 2 counts for 'partially conform or implemented'; and 6 counts for 'fully conformed or implemented'. Site B scored 11 counts as 'absent or inappropriate'; 0 counts for 'planned or approximate' and 'partially conform or implemented'; 2 counts for 'largely conform or implemented'; and 2 counts for 'fully conform or implemented'. Site C scored 5 counts as 'absent or inappropriate'; 0 counts for 'planned or approximate' and 'partially conform or implemented'; 3 counts for 'largely conform or implemented'; and 7 counts for 'fully conform or implemented'. Site D scored 11 counts as 'absent or inappropriate'; 1 count for 'planned or approximate'; 0 counts for 'partially conform or implemented'; 1 count for 'largely conform or implemented'; and 2 counts for 'fully conform or implemented'.
- The overall conformity results are as follows. Site A conformed with 6 out of 15 counts and non-conformed with 9 out of 15 counts. Site B conformed with 4 out of 15 counts and non-conformed with 11 out of 15 counts. Site C conformed with 10 out of 15 counts and non-conformed with 5 out of 15 counts. Site D conformed with 3 out of 15 counts and non-conformed with 12 out of 15 counts.

Figures 4.6a and 4.6b summarises the level conformance and overall conformity for this checklist for the four sites.

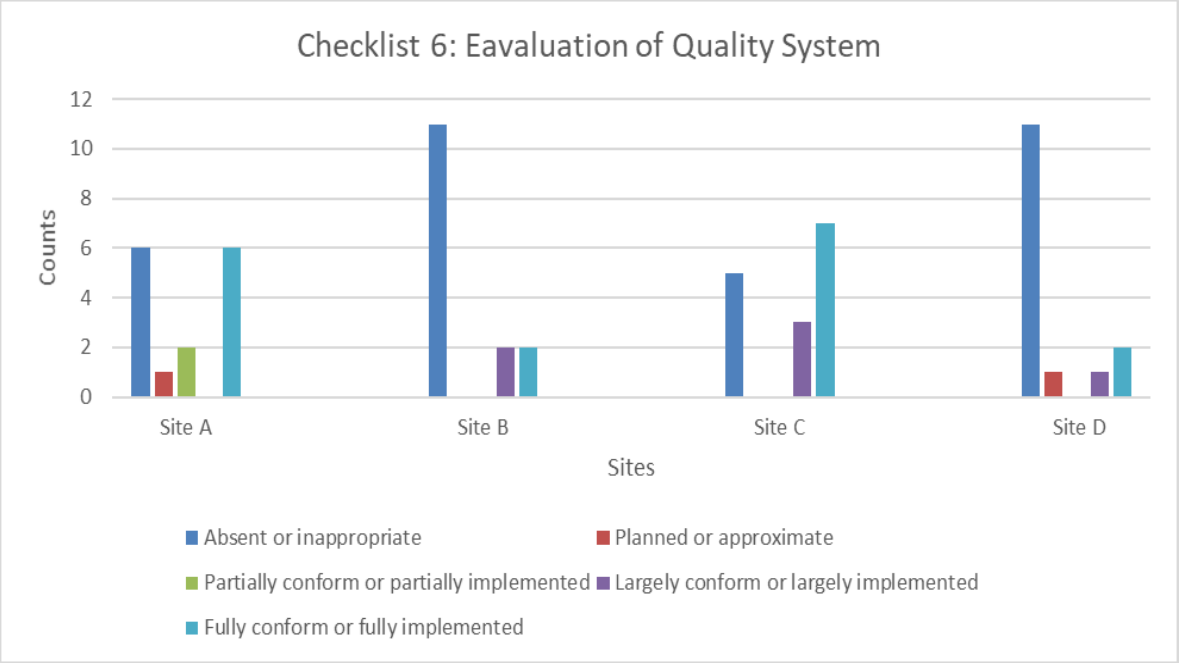


Figure 4.6a Summary of the level conformance under Checklist 6.

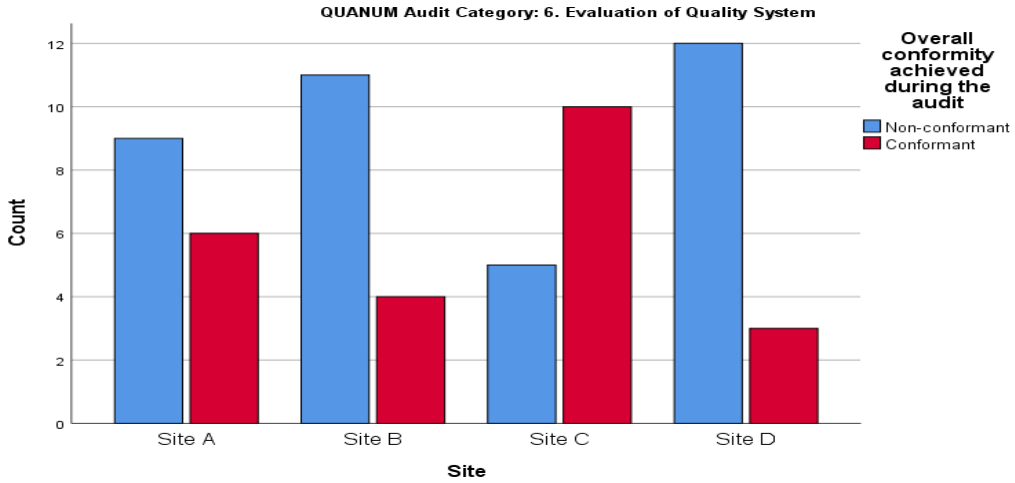


Figure 4.6b Summary of the overall conformity under Checklist 6.

4.8 Checklist 7: Quality control of equipment

Checklist 7 contained 17 evaluation criteria/QUANUM criteria, which are referred to as counts. The criteria to which the Sites responded 'not applicable' did not count towards the count of conformance and the total score.

- The results for level of conformance are as follows. Site A scored 2 counts for 'not applicable'; 3 counts of these criteria as 'absent or inappropriate'; 1 count for 'planned or approximate'; 0 counts for 'partially conform or implemented 'and 'largely conform or implemented' and 11 counts for 'fully conformed or implemented'. Site B scored 4 counts for 'not applicable'; 10 counts as 'absent or inappropriate'; 0 counts for 'planned or approximate, partially conform or implemented, and

largely conform or implemented'; and 3 counts for fully conform or implemented. Site C scored 4 counts for 'not applicable'; 2 counts for 'absent or inappropriate'; 0 counts for 'planned or approximate, partially conform or implemented and largely conform or implemented' and 11 counts for 'fully conform or implemented'. Site D scored 2 counts for 'not applicable'; 11 counts as 'absent or inappropriate'; 0 counts for 'planned or approximate, partially conform or implemented and largely conform or implemented'; and 4 counts for 'fully conform or implemented'.

- The overall conformity results are as follows. Site A conformed with 11 out of 15 counts and non-conformed with 4 out of 15 counts. Site B conformed with 3 out of 13 counts and non-conformed with 10 out of 13 counts. Site C conformed with 11 out of 13 counts and non-conformed with 2 out of 13 counts. Site D conformed with 4 out of 15 counts and non-conformed with 11 out of 15 counts.

Figures 4.7a and 4.7b summarises the level conformance and overall conformity for this checklist of the four sites.

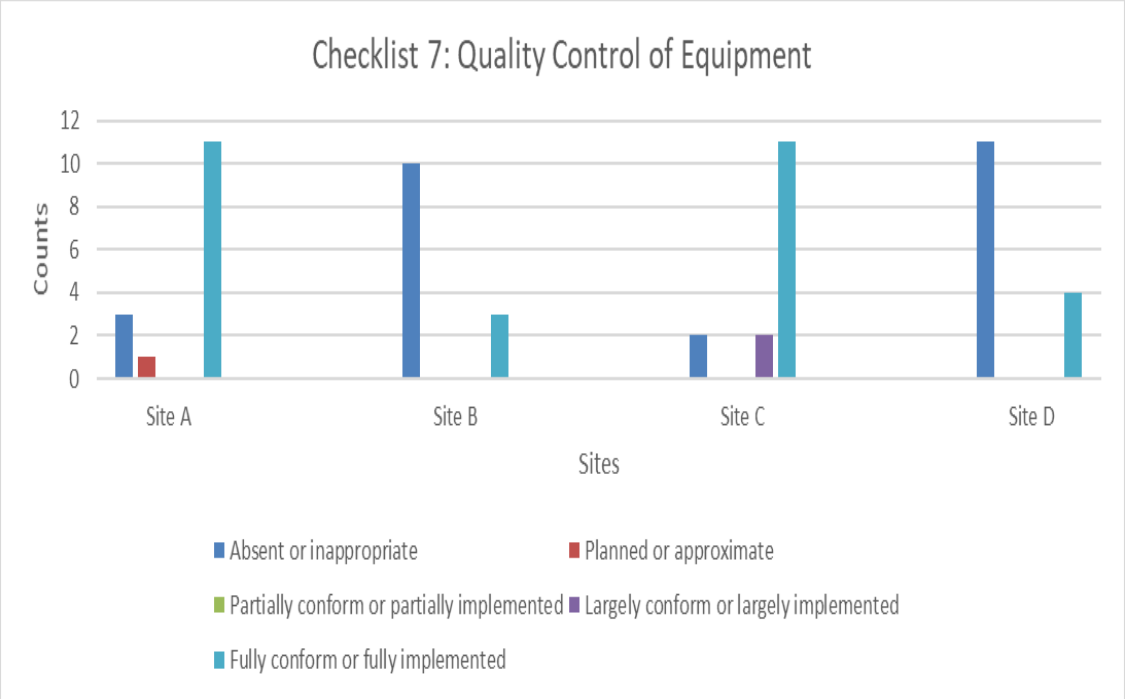


Figure 4.7a Summary of the level conformance under Checklist 7.

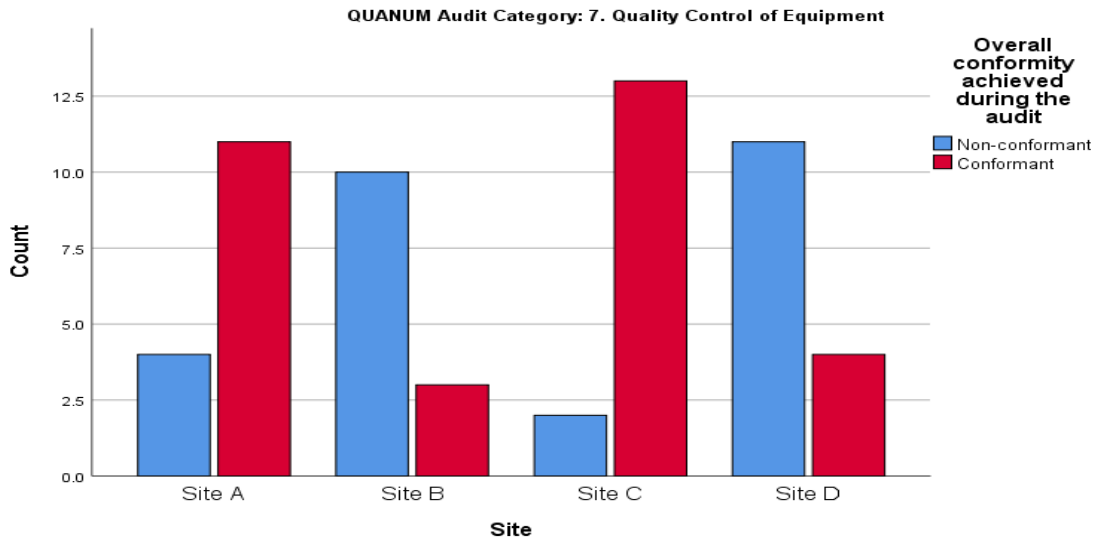


Figure 4.7b Summary of the overall conformity under Checklist 7.

4.9 Checklist 9: General clinical services

Checklist 9 contained 31 evaluation criteria/QUANUM criteria, which are referred to as counts. The criteria to which the Sites responded 'not applicable' did not count towards the count of conformance and the total score.

- The level of conformance results are as follows. Site A scored 10 counts of these criteria as 'absent or inappropriate'; 0 counts for 'planned or approximate'; 6 counts for 'partially conform or implemented'; 2 counts for 'largely conform or implemented'; and 13 counts for 'fully conformed or implemented'. Site B scored 15 counts as 'absent or inappropriate'; 0 counts for 'planned or approximate'; 3 counts for 'partially conform or implemented'; 6 counts for 'largely conform or implemented'; and 7 counts for 'fully conform or implemented'. Site C scored 1 count for 'not applicable'; 13 counts as 'absent or inappropriate'; 0 counts for 'planned or approximate'; 1 count for 'partially conform or implemented'; 6 counts for 'largely conform or implemented' and 10 counts for 'fully conform or implemented'. Site D scored 19 counts as 'absent or inappropriate'; 0 counts for 'planned or approximate'; 3 counts for 'partially conform or implemented'; 3 counts for 'largely conform or implemented'; and 6 counts for 'fully conform or implemented'.
- The results of overall conformity are as follows. Site A conformed with 15 out of 31 counts and non-conformed with 16 out of 31 counts. Site B conformed with 13 out of 31 counts and non-conformed with 18 out of 31 counts. Site C conformed with 16 out of 30 counts and non-conformed with 14 out of 30 counts. Site D conformed with 9 out of 31 counts and non-conformed with 22 out of 31 counts.

Figures 4.8a and 4.8b summarises the level conformance and overall conformity pertaining to this checklist for the four sites.

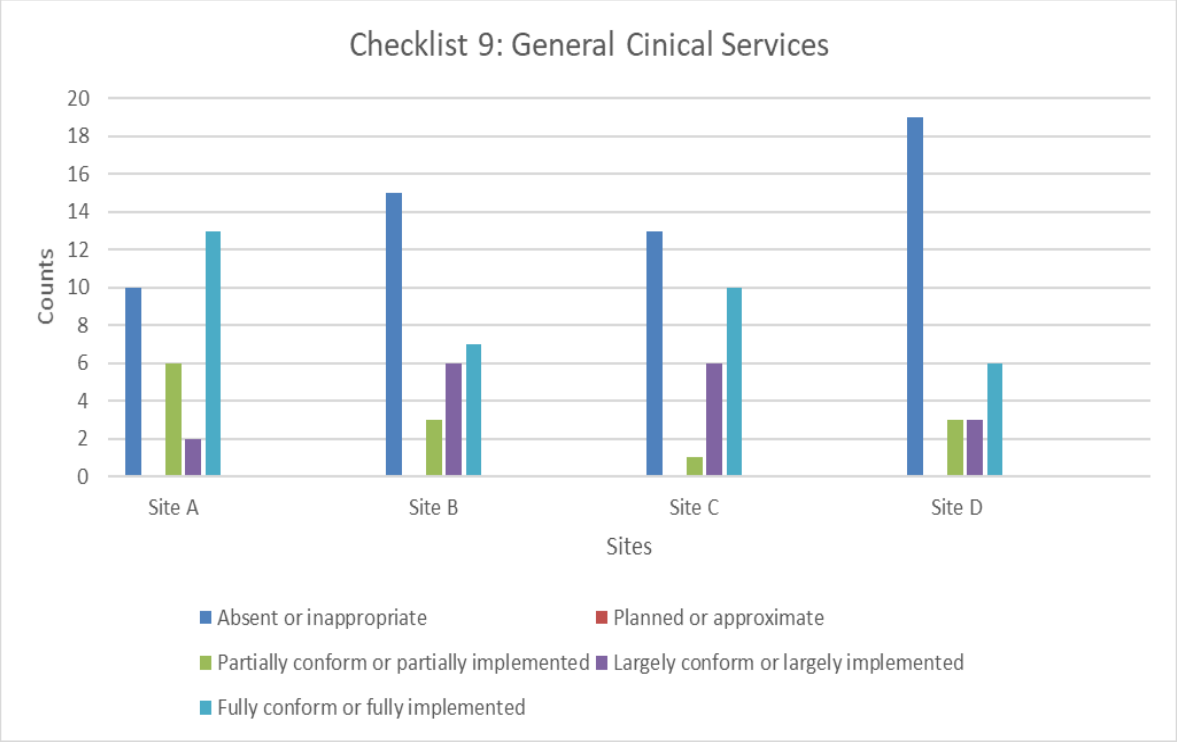


Figure 4.8a Summary of the level conformance under Checklist 9.

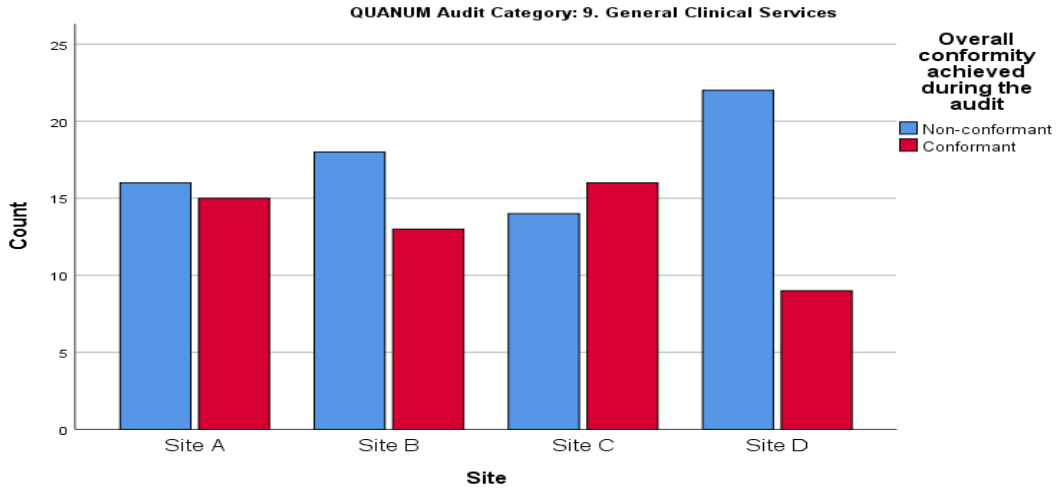


Figure 4.8b Summary of the overall conformity under Checklist 9.

4.10 Checklist 10: Assessment of imaging diagnostic procedure

Checklist 10 evaluated five (n=5) patient files. Each file was evaluated against 30 criteria. This resulted in 150 evaluation criteria/QUANUM criteria, which are referred to as counts. The criteria to which the Sites responded 'not applicable' did not count towards the count of conformance and the total score.

- The results for level of conformance are as follows. Site A scored 40 counts for 'not applicable'; 28 counts of these criteria as 'absent or inappropriate'; 0 counts for 'planned or approximate'; 2 counts for 'partially conform or implemented'; 2 counts for 'largely conform or implemented' and 78 counts for 'fully conformed or implemented'. Site B scored 45 counts for 'not applicable'; 30 counts as 'absent or inappropriate'; 0 counts for 'planned or approximate' and 'partially conform or implemented'; 7 counts for 'largely conform or implemented' and 68 counts for 'fully conform or implemented'. Site C scored 48 counts for 'not applicable'; 22 counts as 'absent or inappropriate'; 0 counts for 'planned or approximate, partially conform or implemented and largely conform or implemented' and 80 counts for 'fully conform or implemented'. Site D scored 40 counts for 'not applicable'; 37 counts as 'absent or inappropriate'; 0 counts for 'planned or approximate', 18 counts for 'partially conform or implemented'; 7 counts for 'largely conform or implemented' and 48 counts for 'fully conform or implemented'.
- Overall conformity results are as follows. Site A conformed with 80 out of 110 counts and non-conformed with 30 out of 110 counts. Site B conformed with 75 out of 105 counts and non-conformed with 30 out of 105 counts. Site C conformed with 80 out of 102 counts and non-conformed with 22 out of 102 counts. Site D conformed with 55 out of 110 counts and non-conformed with 55 out of 110 counts.

Figures 4.9a and 4.9b summarises the level conformance and overall conformity for this checklist for the four Sites.

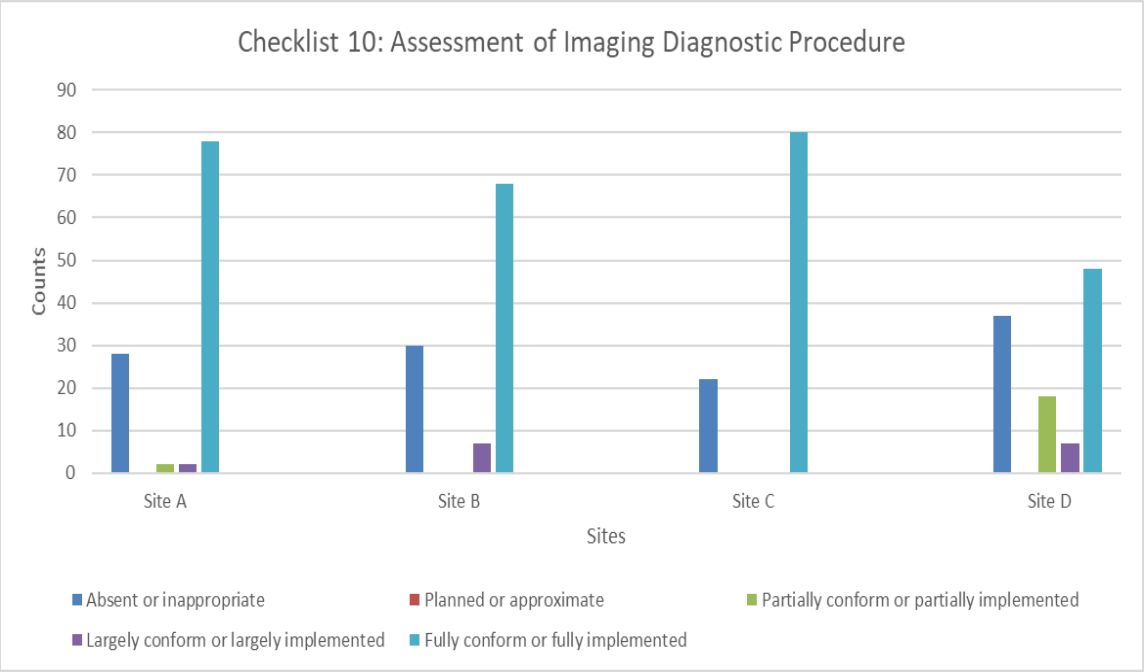


Figure 4.9a Summary of the level conformance under Checklist 10.

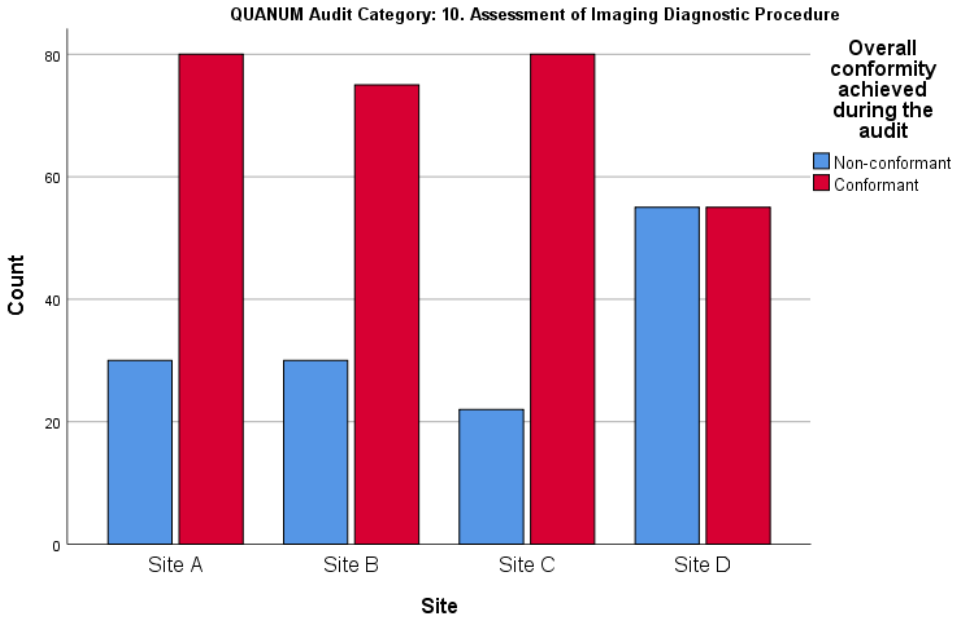


Figure 4.9b summarises the overall conformity checklist 10.

4.11 Checklist 12: General radionuclide therapy

Checklist 12 contained 25 evaluation criteria/QUANUM criteria, which are referred to as counts. The criteria to which the Sites responded 'not applicable' did not count towards the count of conformance and the total score.

- The results of level of conformance are as follows. Site A scored 1 count of these criteria as 'absent or inappropriate'; 0 counts for 'planned or approximate and partially conform or implemented'; 1 count for 'largely conform or implemented'; and 23 counts as 'fully conformed or implemented'. Site B scored 10 counts for 'not applicable'; 5 counts as 'absent or inappropriate'; 0 counts for 'planned or approximate'; 2 counts for 'partially conform or implemented'; 1 count for 'largely conform or implemented' and 7 counts for 'fully conform or implemented'. Site C scored 2 counts as 'absent or inappropriate'; 0 counts for 'planned or approximate and partially conform or implemented'; 3 counts for 'largely conform or implemented'; and 20 counts for 'fully conform or implemented'. Site D scored 10 counts for 'not applicable'; 5 counts as 'absent or inappropriate'; 0 counts for 'planned or approximate'; 1 count for 'partially conform or implemented'; 0 counts for 'largely conform or implemented' and 9 counts for 'fully conform or implemented'.
- Overall conformity results are as follows. Site A conformed with 24 out of 25 counts and non-conformed with 1 out of 25 counts. Site B conformed with 8 out of 15 counts and non-conformed with 7 out of 15 counts. Site C conformed with 23 out of 25 counts and non-conformed with 2 out of 25 counts. Site D conformed with 9 out of 15 counts and non-conformed with 6 out of 15 counts.

Figures 4.10a and 4.10b summarises the level conformance and overall conformity for Checklist 12 for the four Sites.

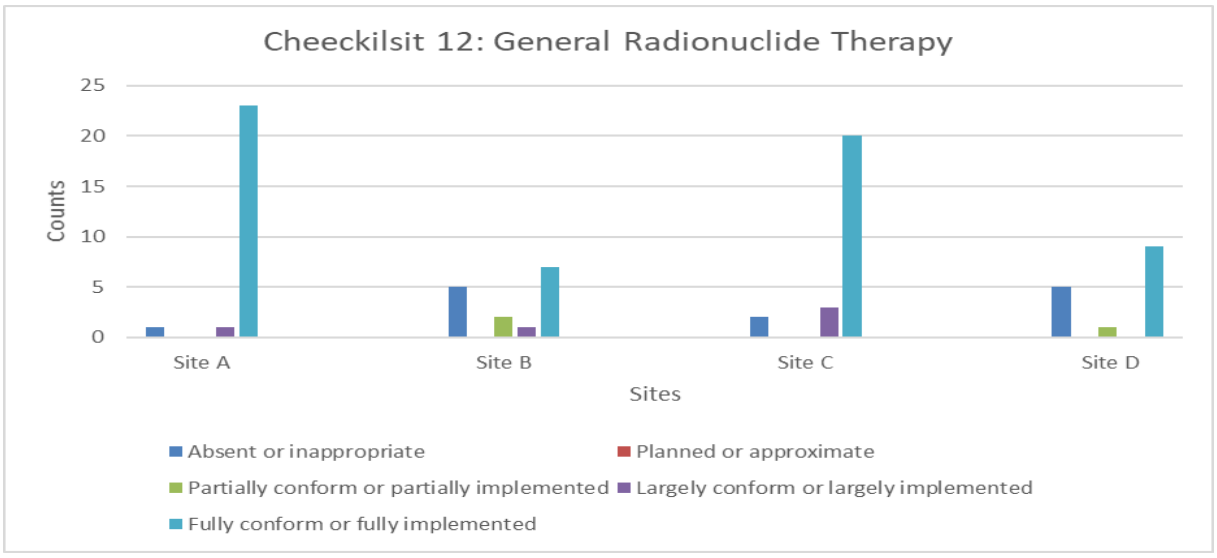


Figure 4.10a Summary of the level conformance under Checklist 12.

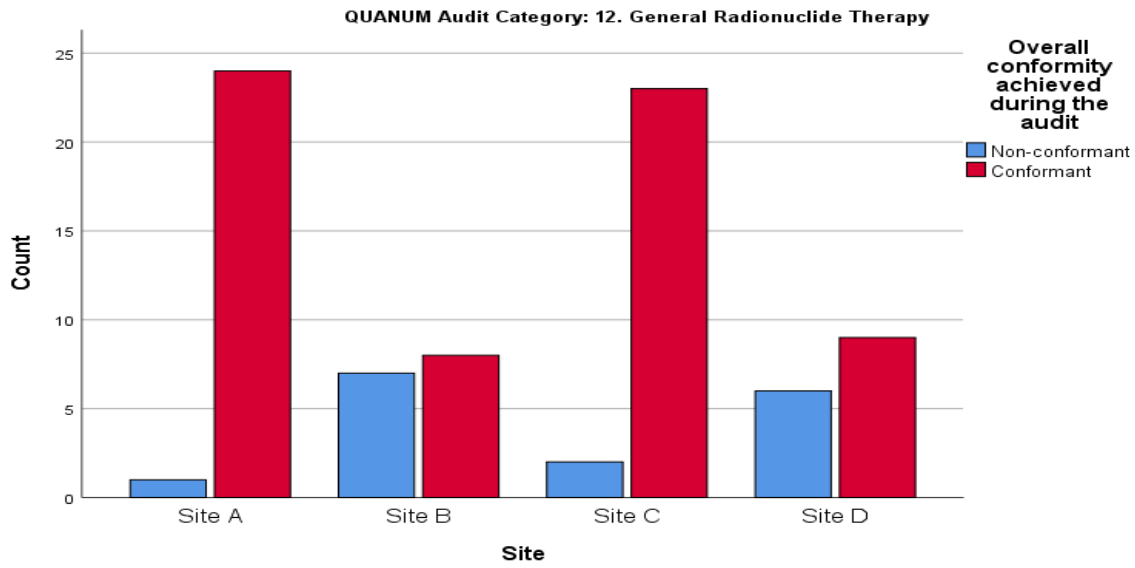


Figure 4.10b Summary of the overall conformity under Checklist 12.

4.12 Checklist 13: Assessment therapy

Checklist 13 evaluated three (n=3) patient files. Each file was evaluated against 25 evaluation criteria which resulted in 75 evaluation criteria/QUANUM criteria, which are referred to as counts. The criteria to which the Sites responded 'not applicable' did not count towards the count of conformance and the total score.

- Level of conformance results are as follows: Site A scored 9 counts for 'not applicable'; 1 count of these criteria as 'absent or inappropriate'; 0 counts for 'planned or approximate, partially conform or implemented and largely conform or implemented' and 65 counts as 'fully conformed or implemented'. Site B scored 15 counts for 'not applicable'; 7 counts as 'absent or inappropriate'; 0 counts for 'planned or approximate and partially conform or implemented'; 3 counts for 'largely conform or implemented' and 50 counts for 'fully conform or implemented'. Site C scored 15 counts for 'not applicable'; 4 counts as 'absent or inappropriate'; 0 counts for 'planned or approximate and partially conform or implemented'; 1 count for 'largely conform or implemented'; and 55 counts for 'fully conform or implemented'. Site D scored 12 counts for 'not applicable'; 10 counts as 'absent or inappropriate'; 0 counts for 'planned or approximate'; 5 counts for 'partially conform or implemented'; 2 counts for 'largely conform or implemented' and 46 counts for 'fully conform or implemented'.
- Overall conformity results are as follows. Site A conformed with 65 out of 66 counts and non-conformed with 1 out of 66 counts. Site B conformed with 53 out of 60 counts and non-conformed with 7 out of 60 counts. Site C conformed with 56 out of 60 counts and non-conformed with 4 out of 60 counts. Site D conformed with 48 out of 63 counts and non-conformed with 15 out of 63 counts.

Figures 4.11a and 4.11b summarises the level conformance and overall conformity under Checklist 13 for the four Sites.

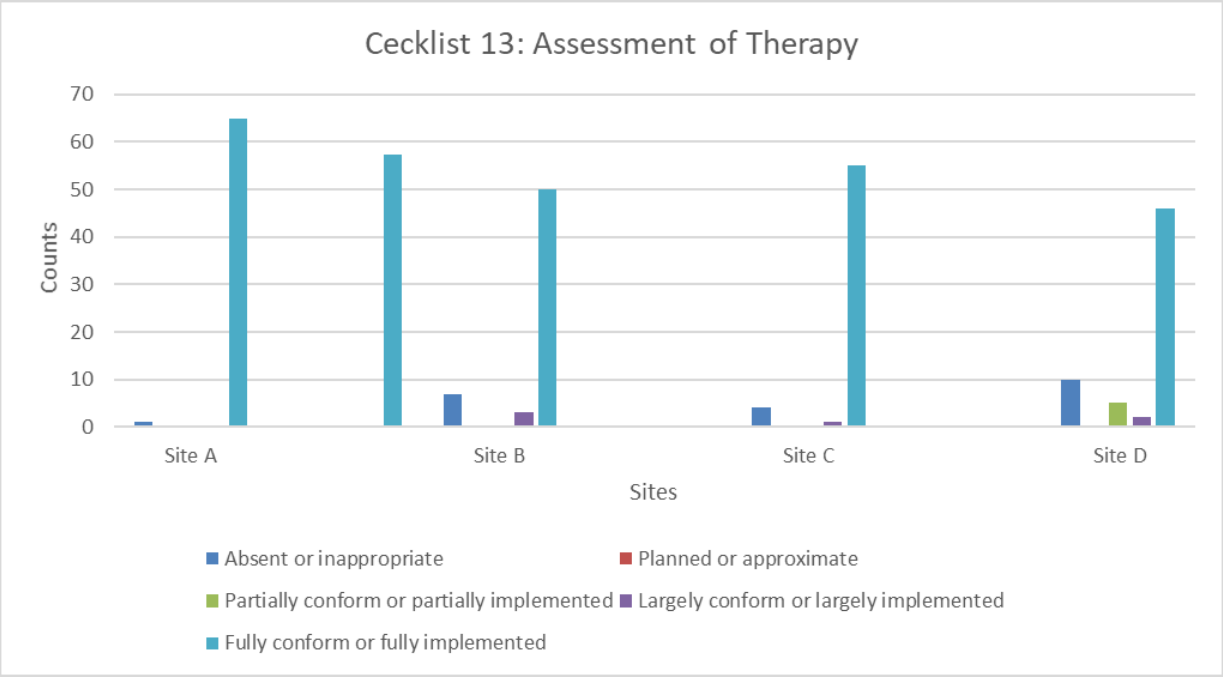


Figure 4.11a Summary of the level conformance under Checklist 13

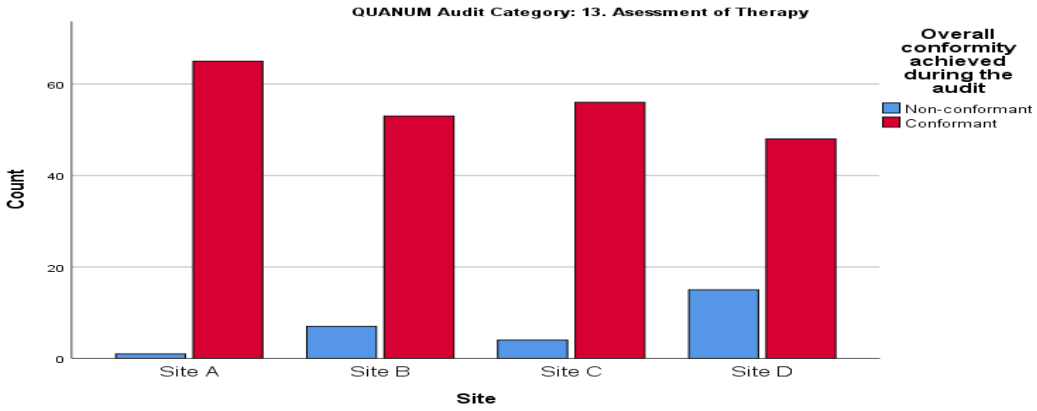


Figure 4.11b Summary of the overall conformity under Checklist 13.

4.13 Checklist 14: Radiopharmacy operational level 1

Checklist 14 contained 16 evaluation criteria/QUANUM criteria, which are represented as counts. The criteria to which the Sites responded 'not applicable' did not count towards the count of conformance and the total score.

- The level of conformance results are as follows. Site A scored 1 count for 'not applicable'; 3 counts of these criteria as 'absent or inappropriate'; 3 counts for 'planned or approximate'; 0 counts for 'partially conform or implemented'; 1 count for 'largely conform or implemented and 8 counts for

'fully conformed or implemented'. Site B scored 1 for 'not applicable'; 5 counts as 'absent or inappropriate'; 0 counts for 'planned or approximate'; 2 counts for 'partially conform or implemented'; 2 counts for 'largely conform or implemented' and 6 counts for 'fully conform or implemented'. Site C scored 4 counts for 'not applicable'; 4 counts as 'absent or inappropriate'; 0 counts for 'planned or approximate'; 1 count for 'partially conform or implemented'; 0 counts for 'largely conform or implemented' and 7 counts for 'fully conform or implemented'. Site D scored 2 counts for 'not applicable'; 4 counts as 'absent or inappropriate'; 0 counts for 'planned or approximate'; 3 counts for 'partially conform or implemented'; 1 count for 'largely conform or implemented' and 6 counts for 'fully conform or implemented'.

- Overall conformity results are as follows: Site A conformed with 6 out of 15 counts and non-conformed with 9 out of 15 counts. Site B conformed with 7 out of 15 counts and non-conformed with 8 out of 15 counts. Site C conformed with 7 out of 12 counts and non-conformed with 5 out of 12 counts. Site D conformed with 7 out of 14 counts and non-conformed with 7 out of 14 counts.

Figures 4.12a and 4.12b summarises the level conformance and overall conformity of Checklist 14 for the four Sites.

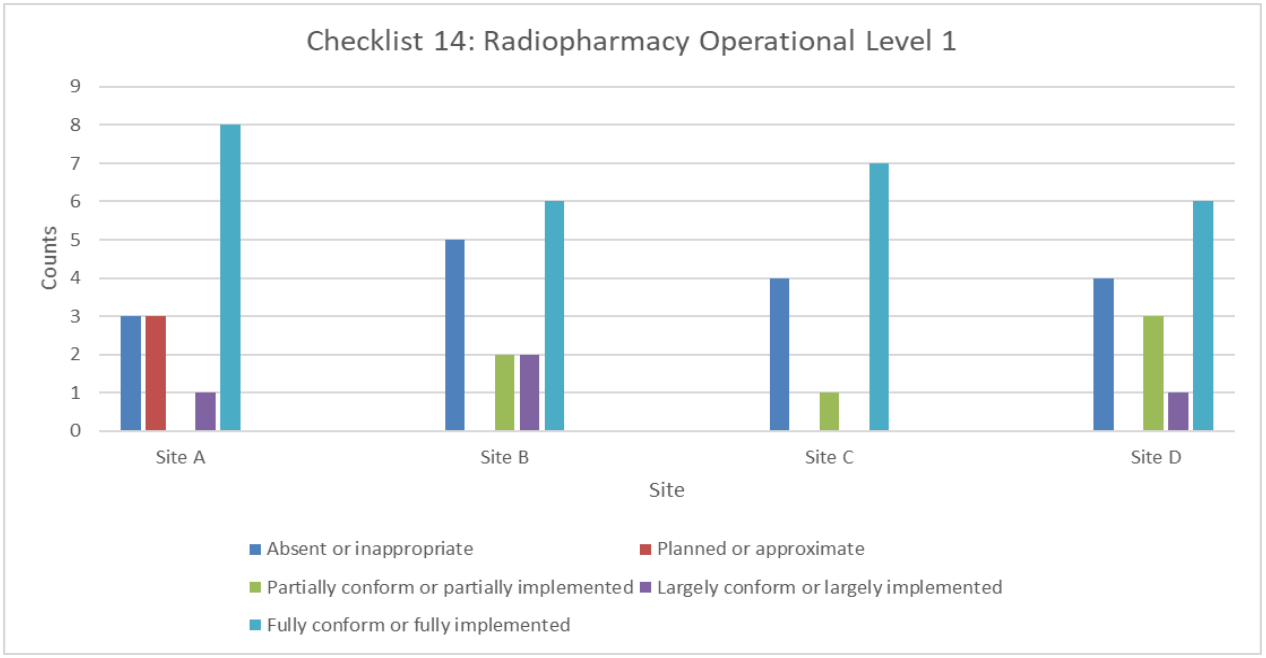


Figure 4.12a Summary of the level conformance under Checklist 14.

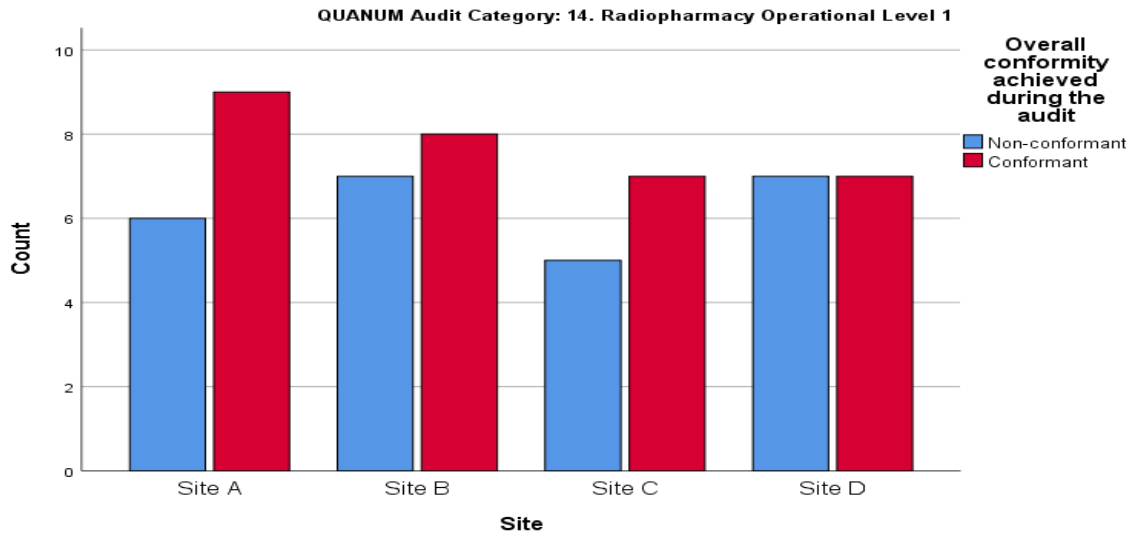


Figure 4.12b Summary of the overall conformity under Checklist 14.

4.14 Checklist 15: Radiopharmacy operational level 2

Checklist 15 contained 20 evaluation criteria/QUANUM criteria, which are referred to as counts. The criteria to which the Sites responded 'not applicable' did not count towards the count of conformance and the total score.

- The results for level of conformance are as follows. Site A scored 6 counts for 'not applicable'; 5 counts of these criteria as 'absent or inappropriate'; 1 count for 'planned or approximate'; 2 counts for 'partially conform or implemented'; 0 counts for 'largely conform or implemented' and 6 counts for 'fully conformed or implemented'. Site B scored 3 counts for 'not applicable'; 9 counts as 'absent or inappropriate'; 1 count for 'planned or approximate'; 0 counts for 'partially conform or implemented'; 1 count for 'largely conform or implemented' and 6 counts for 'fully conform or implemented'. Site C scored 5 counts for 'not applicable'; 8 counts as 'absent or inappropriate'; 0 counts for 'planned or approximate, partially conform or implemented, and largely conform or implemented' and 7 counts for 'fully conform or implemented'. Site D scored 6 counts for 'not applicable'; 9 counts as 'absent or inappropriate'; 0 counts for 'planned or approximate and partially conform or implemented'; 1 count for 'largely conform or implemented'; and 4 counts for 'fully conform or implemented'.
- Overall conformity results are as follows. Site A conformed with 6 out of 14 counts and non-conformed with 8 out of 14 counts. Site B conformed with 7 out of 17 counts and non-conformed with 10 out of 17 counts. Site C conformed with 7 out of 15 counts and non-conformed with 8 out of 15 counts. Site D conformed with 5 out of 14 counts and non-conformed with 9 out of 14 counts.

Figures 4.13a 4.13b summarises the level conformance and overall conformity of Checklist 15 for the four sites.

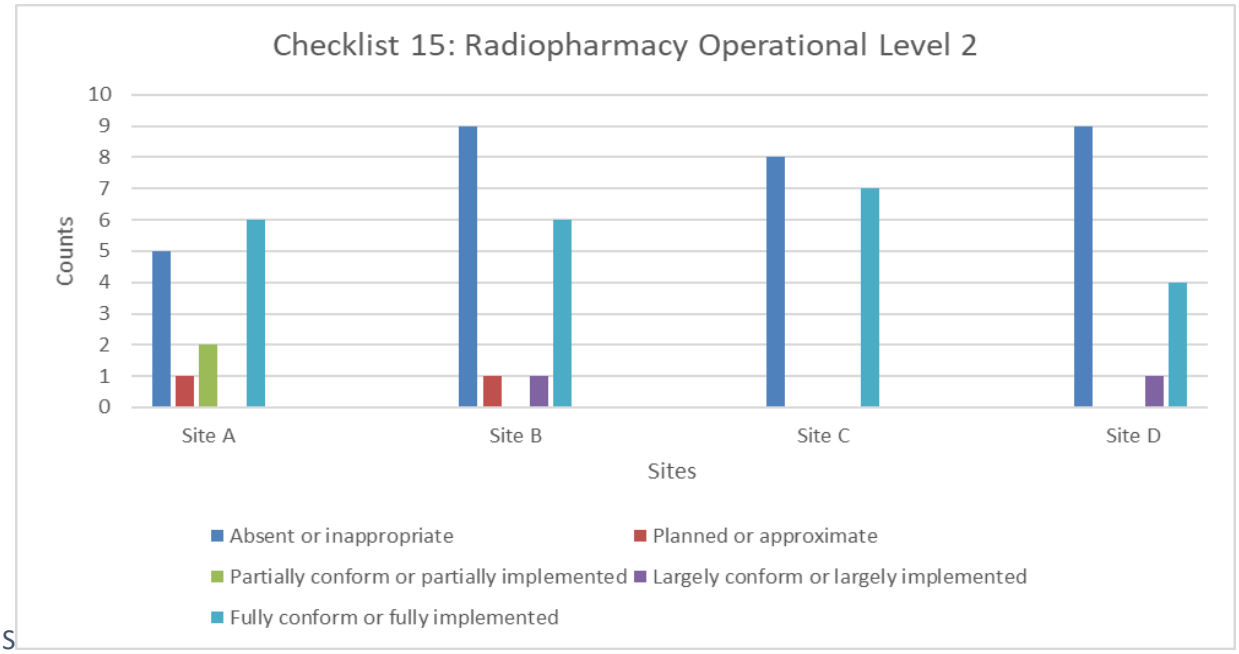


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Figure 4.13a Summary of the level conformance under Checklist 15

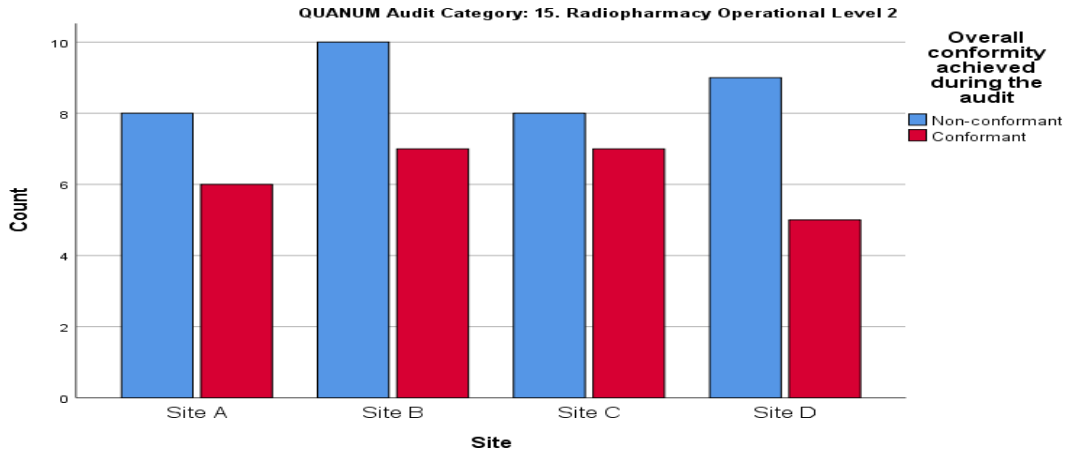

Figure 4.13b Summary of the overall conformity under Checklist 15

4.15 Summary of the level conformance and overall conformity with respect to the checklists during the audit

Figure 4.14 below is a summary of the level of conformance and overall conformity for all the checklists achieved during the audit. Table 4.1 below lists the percentage of the counts. Figure 4.15 below presents a checklist summary and radar plot for Sites A and B. Figure 4.16 below presents a checklist summary and radar plot for Sites C and D.

- Level of conformance results are as follows**.** Site A scored 85 counts as 'absent or inappropriate'; 7 counts for 'planned or approximate'; 29 counts for 'partially conform or implemented'; 6 counts for 'largely conform or implemented'; and 242 counts as 'fully conformed or implemented'. Site B scored 121 counts as 'absent or inappropriate'; 1 count for 'planned or approximate'; 15 counts for 'partially conform or implemented'; 25 counts for 'largely conform or implemented'; and 180 counts for 'fully conform or implemented'. Site C scored 78 counts as 'absent or inappropriate'; 2 counts for 'planned or approximate'; 6 counts for 'partially conform or implemented'; 23 counts for 'largely conform or implemented'; and 236 counts for 'fully conform or implemented'. Site D scored 149 counts as 'absent or inappropriate'; 2 counts for 'planned or approximate'; 32 counts for 'partially conform or implemented'; 19 counts for 'largely conform or implemented'; and 147 counts for 'fully conform or implemented'.

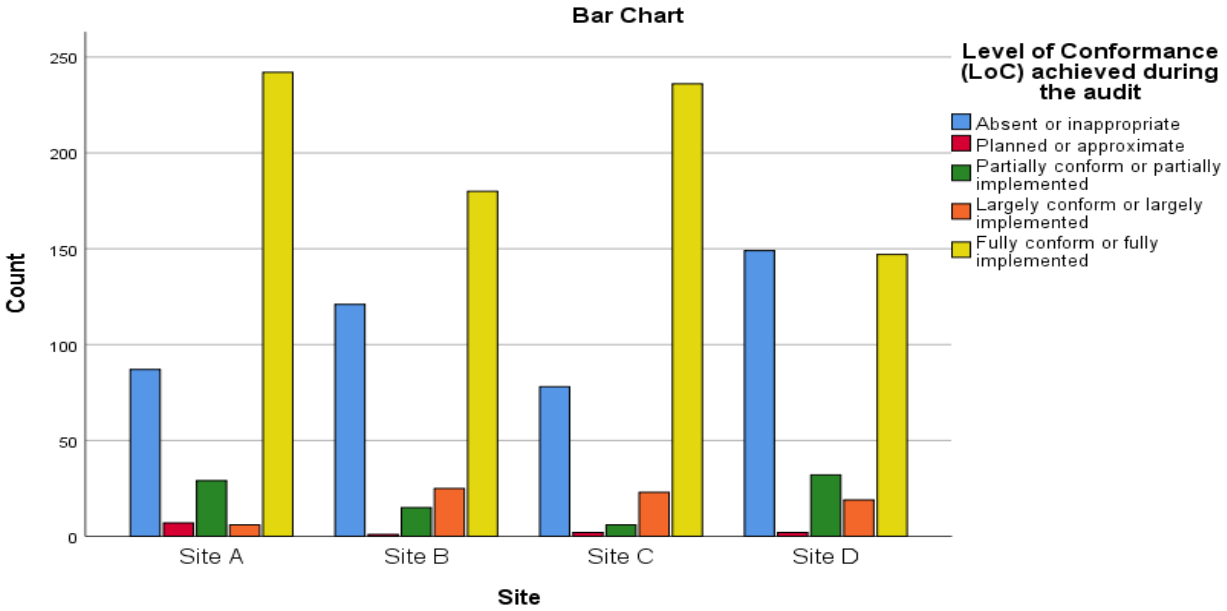

Figure 4.14a Summary of the level of conformance for all the checklists achieved during the audit.

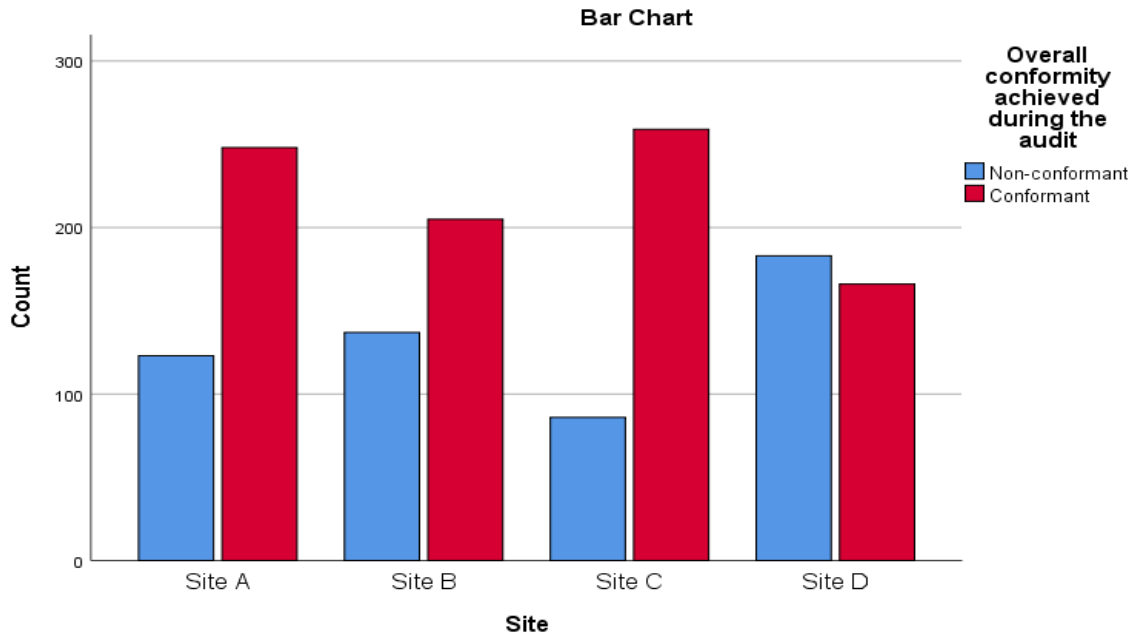

Figure 4.14b Summary of the overall conformity for all the checklists achieved during the audit.

- Overall conformity revealed that Site A conformed with 247 out of 370 (67%) counts and non-conformed with 123 out of 370 (33%) counts whilst Site B conformed with 205 out of 342 (60%) counts and non-conformed with 137 out of 342 counts (40%). Site C conformed with 259 out of 345 (75%) counts and non-conformed with 86 out of 345 (25%) counts. Site D conformed with 166 out of 349 (48%) counts and non-conformed with 183 out of 349 (52%) counts.

Table 4.1 Summary of QUANUM audit components per site in percentages correlating with the radar plots in Figures 4.15 and 4.16

Checklist no	Component	Site/site A	Site/site B	Site/site C	Site/site D
1	Strategies and policies	19%	75%	55%	67%
2	Administration and management	41%	25%	85%	18%
3	Human resource development	50%	50%	42%	50%
4	Radiation regulations and safety	50%	55%	66%	41%
5	Patient radiation protection	58%	65%	50%	38%
6	Evaluation of quality system	40%	27%	62%	18%
7	Quality control of equipment	73%	20%	85%	27%
9	General clinical services	47%	37%	48%	27%
10	Imaging diagnostic services	72%	71%	78%	48%
12	General radionuclide therapy	95%	52%	89%	60%

13	Assessment of radionuclide therapy	98%	87%	93%	75%
14	Radiopharmacy operational level 1	58%	50%	58%	48%
15	Radiopharmacy operational level 2	43%	40%	47%	34%

Checklists 8, 11,16 and 17 was not applicable due to the services not being rendered by these sites and some of the functions are not being performed at departmental level.

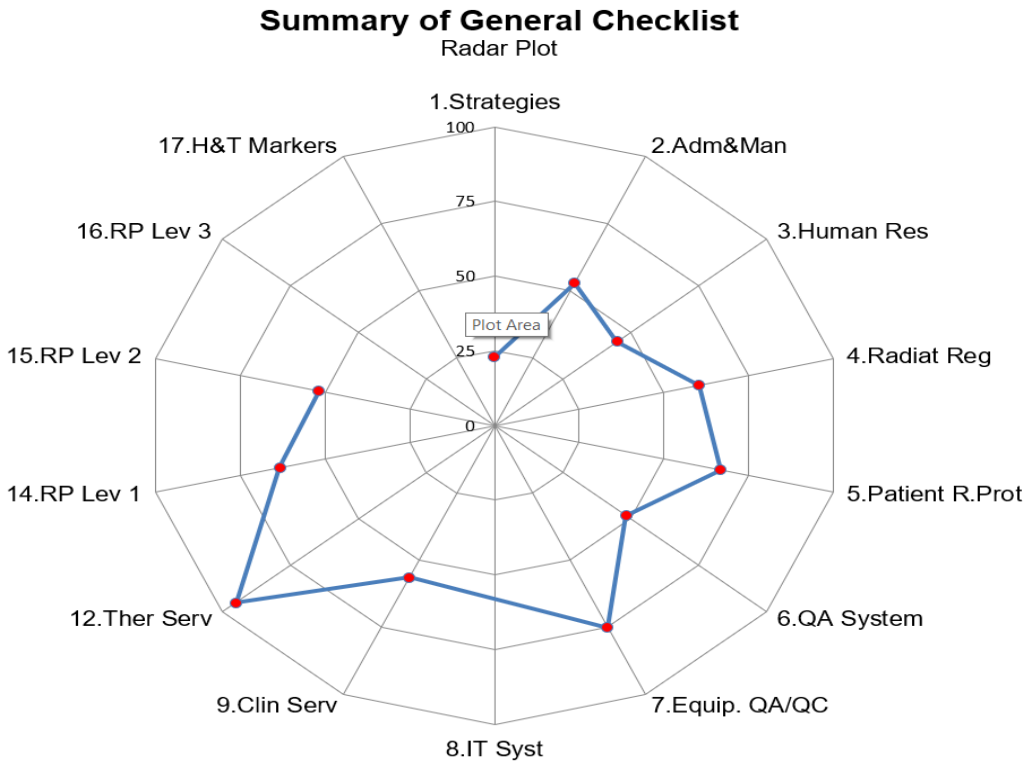

Figure 4.15 Radar plot for Site A showing conformance of 19% for Strategies and 95% for Ther Serve.

Legends for radar plot: 1. Strategies= Strategies and policies; 2. Admin & Man=Administration and management; 3. Human Res= Human resources; 4. Radiation Reg=Radiation regulation and safety; 5. Patient R Prot=Patient radiation protection; 6.QA System= Evaluation of quality assurance system; 7. Equip.QA/QC=Equipment Quality assurance/Quality; 8.IT Syst= Information technology systems (not scored for any research site); 9. Clinical Serv= General clinical services; 12. Ther Serv= General radionuclide therapy; 14. RP Lev 1=Radiopharmacy operation level 1; 15. RP Lev 2= Radiopharmacy operation level 2; 16. RP Lev 3=Radiopharmacy operation level 3; 17. H&T Markers=Hormone and Tumour Markers.

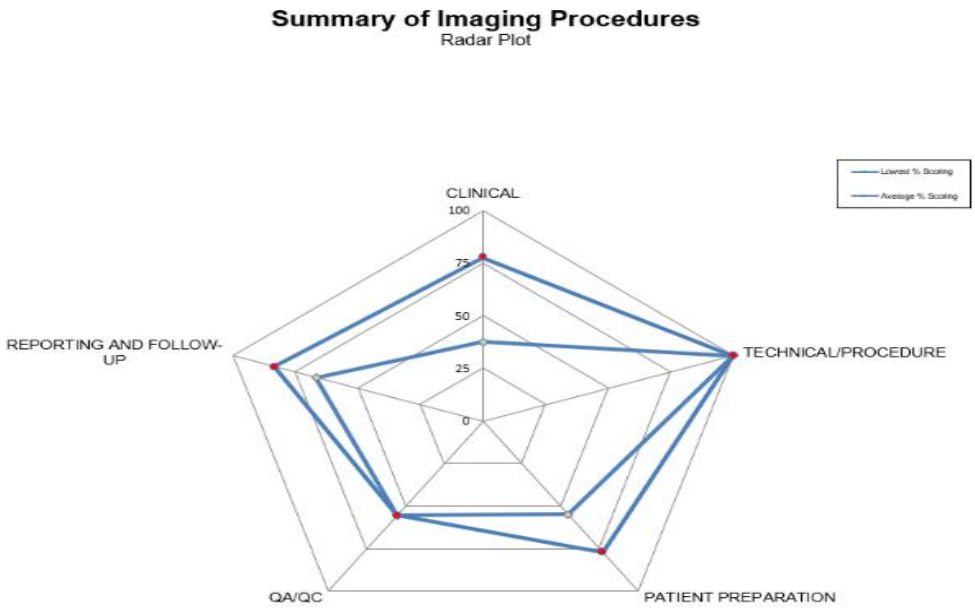

Figure 4.16 Radar plot for Site A showing summary of conformance of Imaging procedure assessments, using patient 5 patient files scoring 72%.

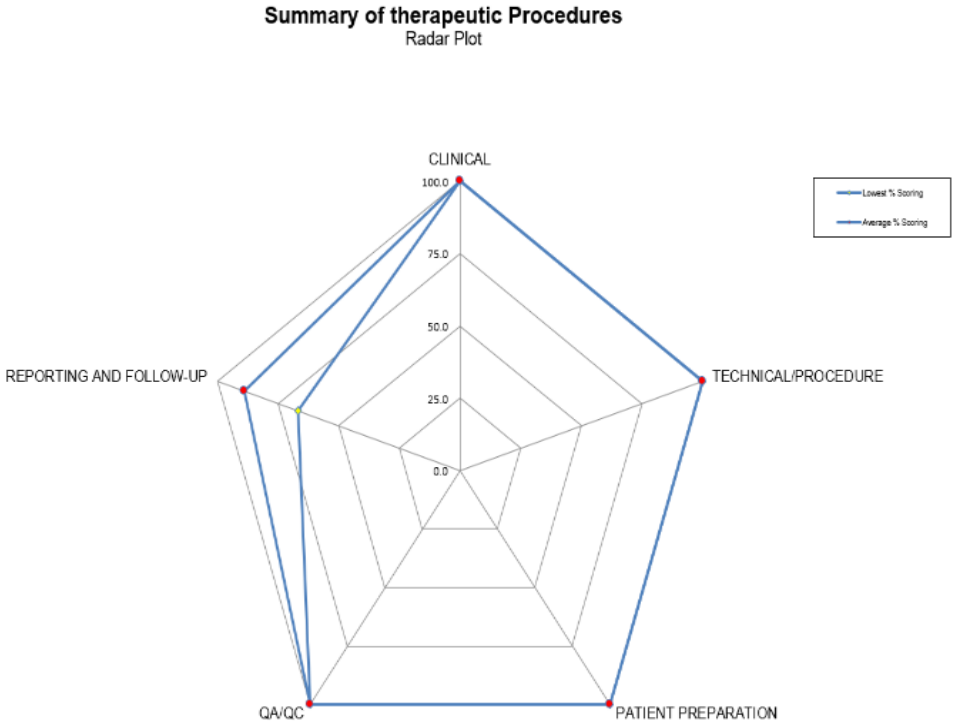

Figure 4.17 Radar plot for Site A showing a summary conformance of Therapeutic procedure assessments, using 3 patient files scoring 98%.

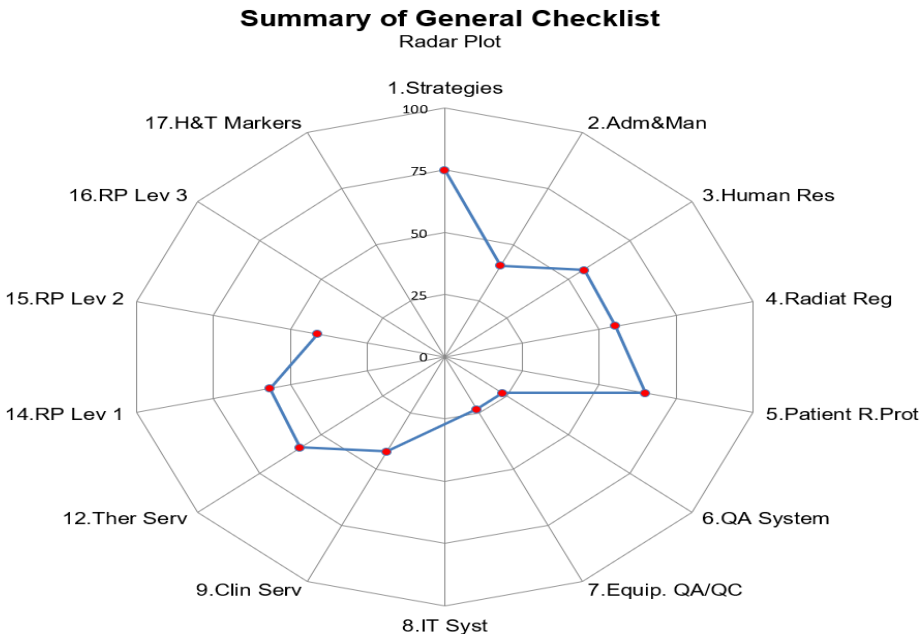

Figure 4.18 Radar plot for Site B showing conformance of 20% for Quality Control of Equipment and 75% for Strategies**.**

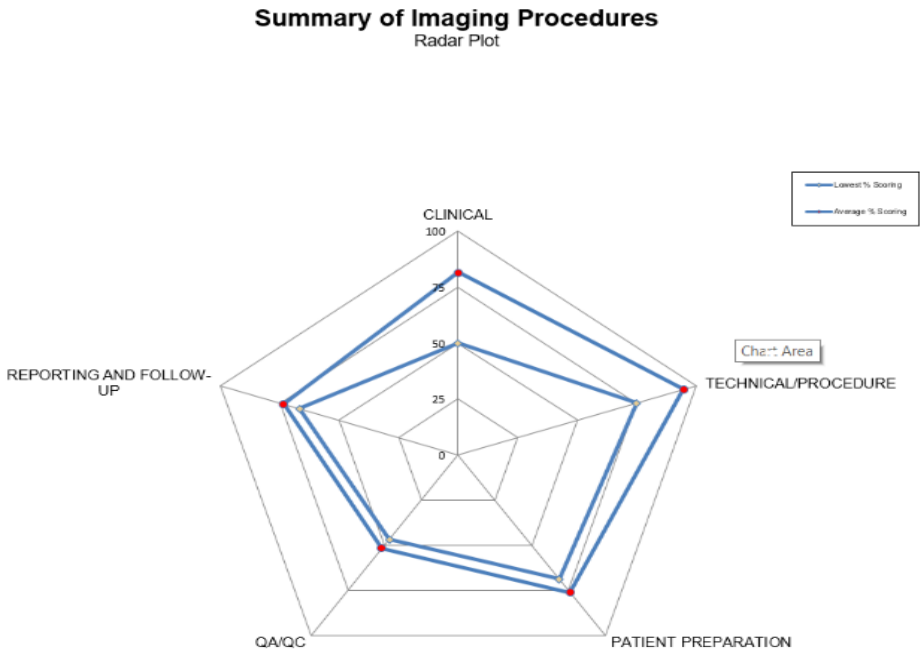

Figure 4.19 Radar plot for Site A showing a summary conformance of Imaging procedure assessments, using 5 patient files scoring 71%.

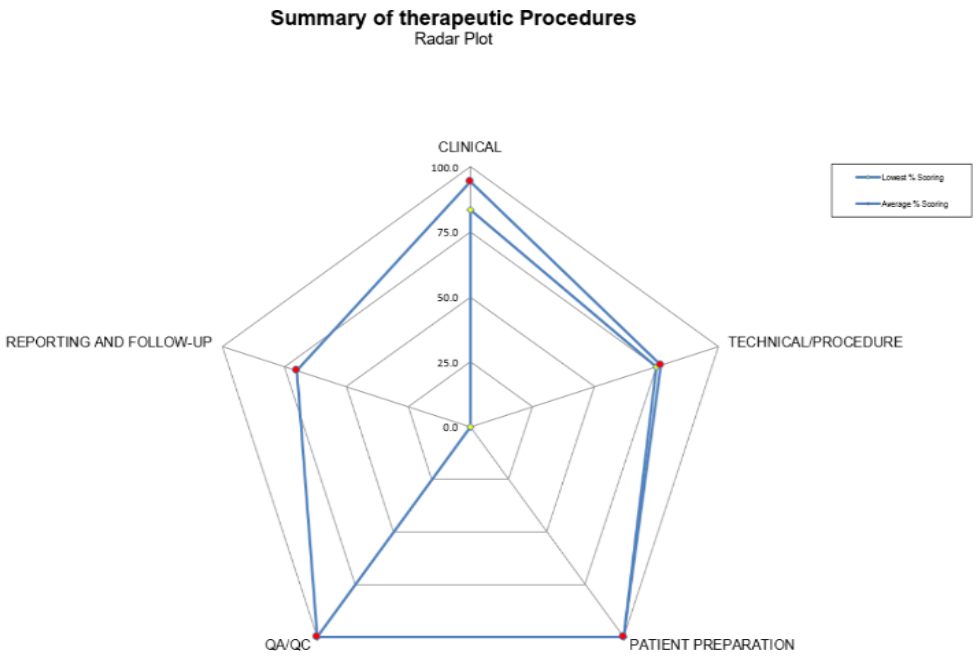

Figure 4.20 Radar plot for Site B showing summary of conformance of Therapeutic procedure assessments, using 3 patient files scoring between 87%.

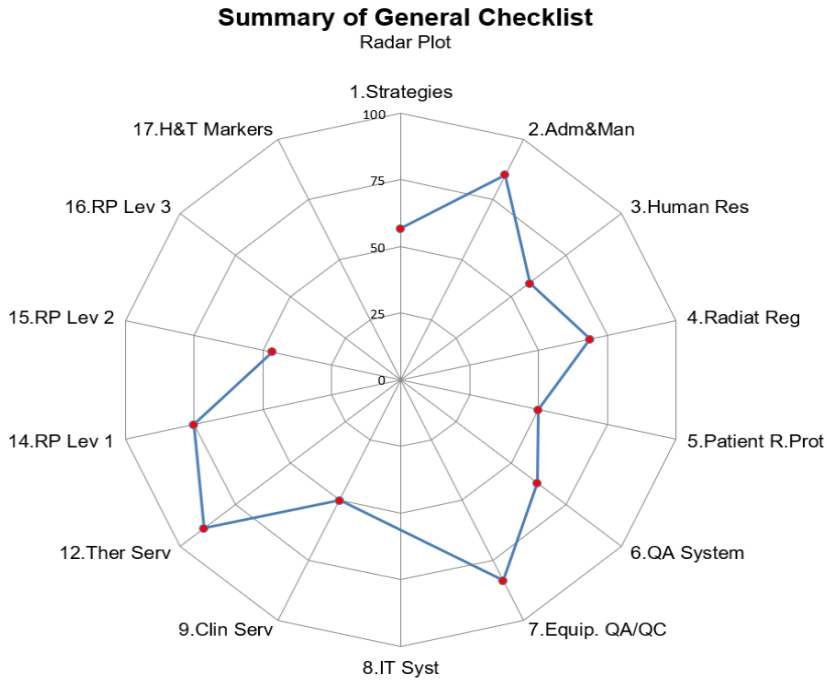

Figure 4.21 Radar plot for Site C showing conformance of 42% for Human Res and 89% for Therapeutic Serv.

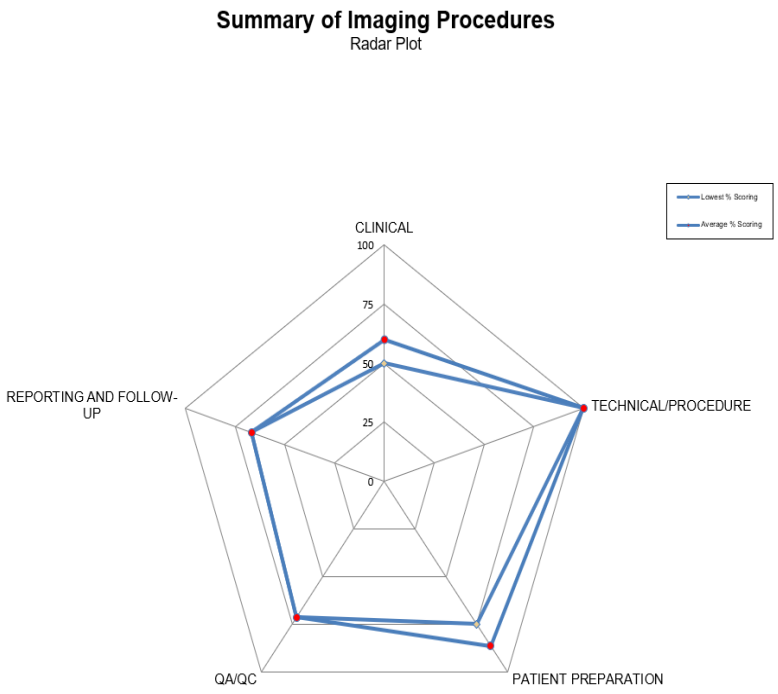

Figure 4.22 Radar plot for Site C showing a summary conformance of Imaging procedure assessments, using 5 patient files scoring 78%.

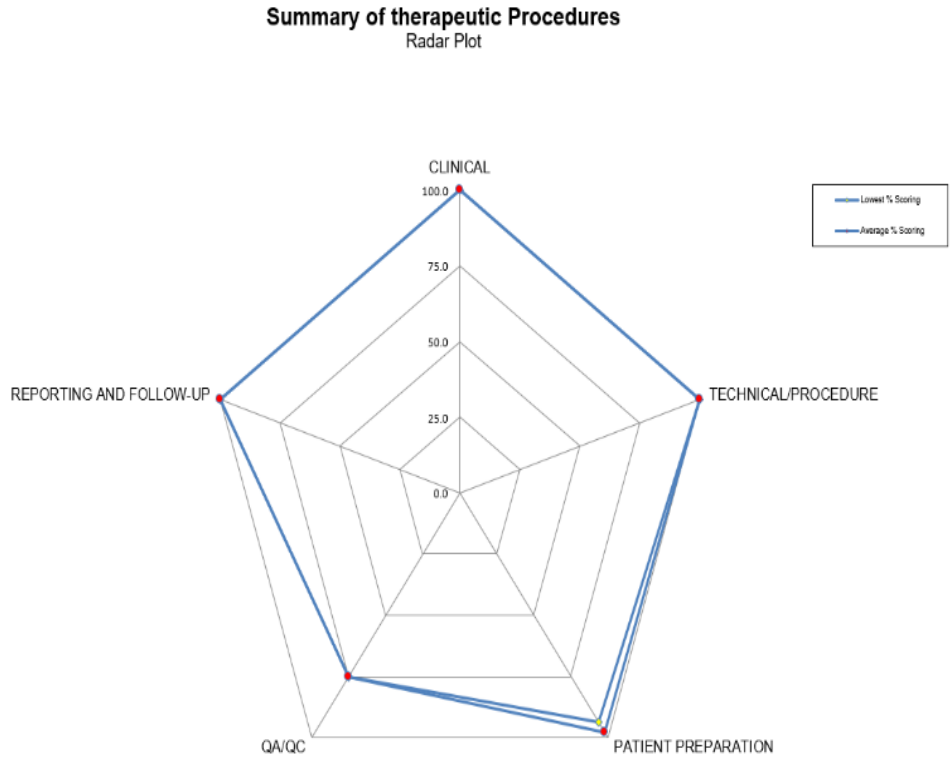

Figure 4.23 Radar plot for Site C showing summary of conformance of therapeutic procedure assessment, using 3 patient files scoring 93%.

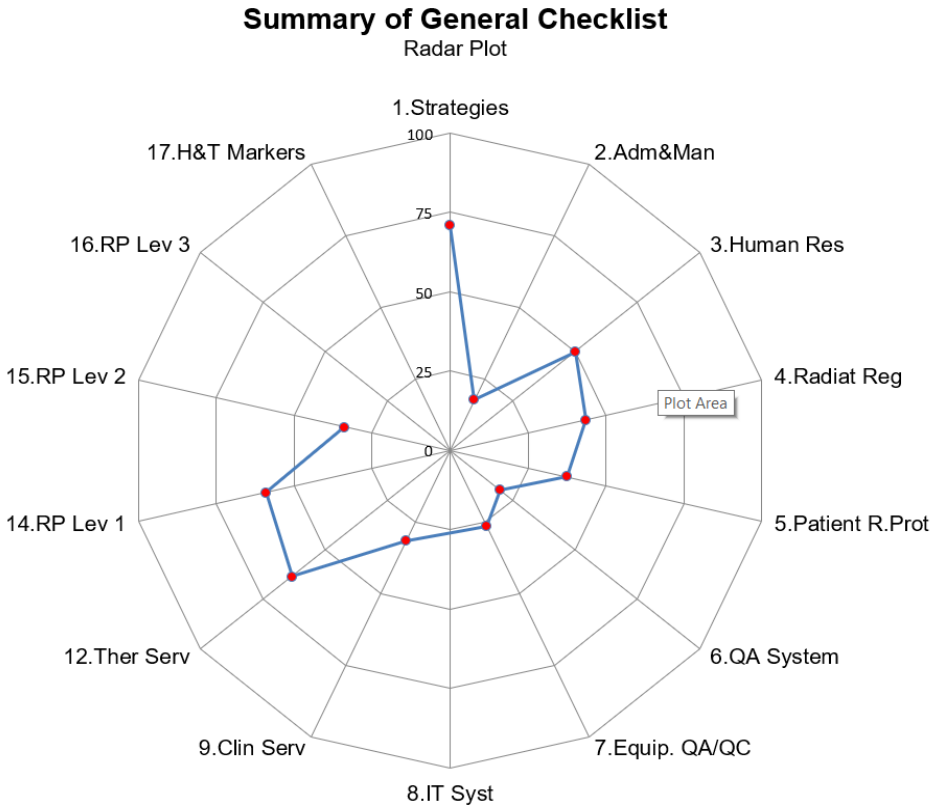

Figure 4.24 Radar plot for Site D showing conformance of 19% for Adm & Man, QA System and 67% for Strategies.

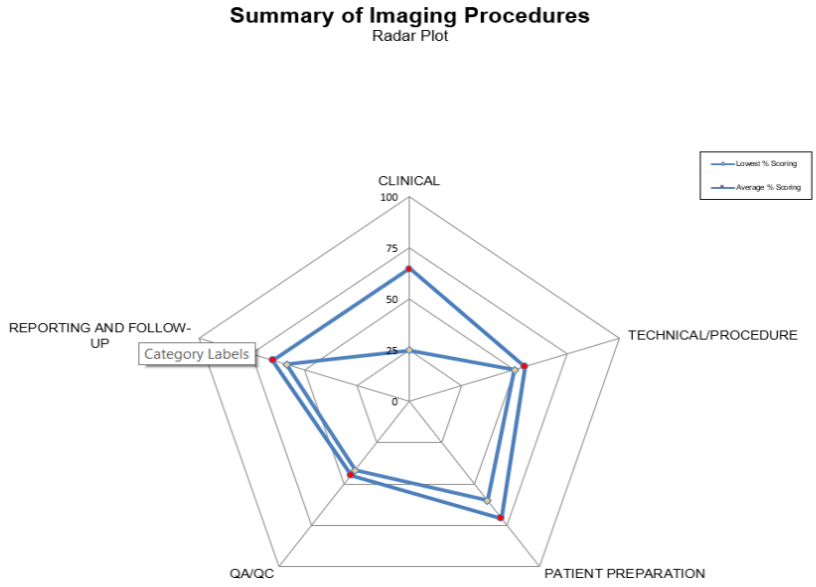

Figure 4.25 Radar plot for Site D showing summary of conformance of Imaging procedure assessment, using patient 5 patient files scoring 48%.

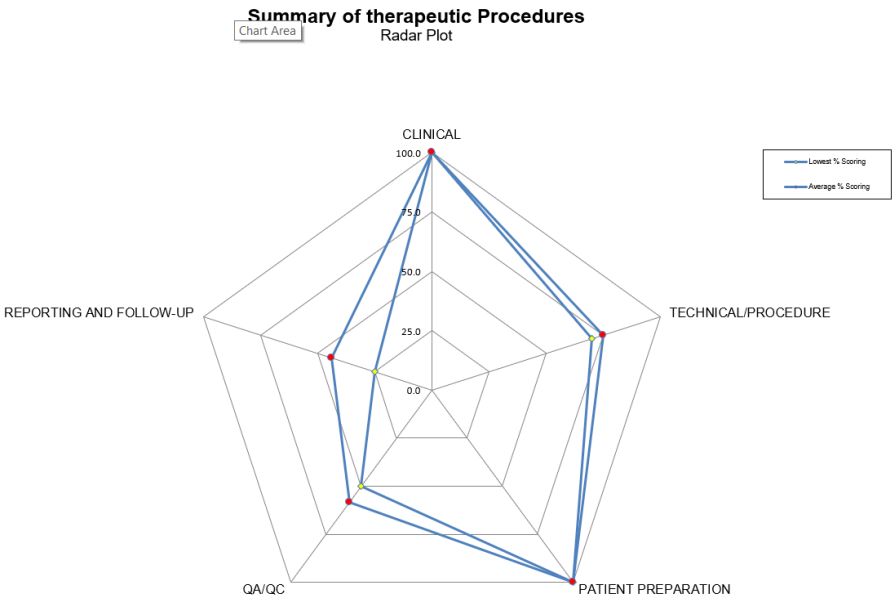

Figure 4.26 Radar plot for Site D showing summary of conformance of Therapeutic procedure assessment, using patient 3 patient files scoring 75%.

4.16 Summary

This chapter presented the results generated from the audits of the four research sites/Sites using the IAEA QUANUM tool. The results for Site A to D for Checklists 1 to 10, and 12 to 15, excluding Checklist 8, 11, 16, 17 was presented as these were the services offered by NMS in Namibia and some of the functions not being performed at departmental level. The interpretation and the implication these results have for clinical practice are discussed in the next chapter.

CHAPTER FIVE

DISCUSSION

5.1 Introduction

This study set out to conduct a quality audit of four nuclear medicine departments in order to compare the QMS statuses of these departments against the standards provided in the IAEA QUANUM tool in order to provide an outline of areas where these QMS standards met these best practice standards and those that did not. Conformities and non-conformities at the research sites are discussed in terms of results presented in Chapter Four. In addition, the impact of the results is underscored in terms of their impact on clinical practice particularly in relation to patient care, staff training, development and support and indirectly the impact thereof on the nuclear medicine Site as a whole.

5.2 Checklist 1: Strategies and policies

According to the IAEA (2015:18) strategies and policies of the NMS should be in line with specific objectives developed at a national/ regional level. National health policies, strategies and plans (NHPSPs) are critical in outlining a country's vision, policy goals, and strategies to safeguard its population's health according to the World Health Organisation (WHO, 2021). In almost every country health policy provide a framework for dealing with a diverse range of issues needed to enhance health outcomes, including those connected to the sustainable development goals (SDGs) and other national priority health challenges like noncommunicable illnesses. Strategic development plans for the NMS's global activities and policies were absent at a departmental level at Sites A, C and D; and there were planned regional expansions at Site B.

According to the IAEA (2015:18), when an NMS does not provide a full range of services, there should be a policy to guide access to such services at another institution with clearly defined responsibilities. Patients are referred to other Sites in this study. However, none had a policy in place at a departmental level.

5.3 Checklist 2: Administration and management

There were no written SOPs in place at Sites A, B and D. SOP's were in place at Site C but were not reviewed and in a proper format. The phrase SOP was coined in the middle of the twentieth century,

it is a specific document formulated after discussing the need to develop regulations (standardisation) for certain normal activities critical to obtaining the desired outcome (Shestopalova & Gololobova, 2018:131). All SOPs share a typical structure and action chain required to complete a routine (repeating) procedure; the latter is part of a broader quality system (Shestopalova & Gololobova, 2018:131). SOPs establish a purpose, define a task, and clarify who is responsible for what, when, and how. They provide a detailed explanation of action chains that must be accomplished. A SOP can include figures, graphs, tables, or photos to help visualise and understand the actions stated in procedures (Shestopalova & Gololobova, 2018:131).

SOPs are frequently created by considering existing standards in a particular field and imaging processes for objective control, both intermediate and final. They reduce the likelihood of employees not fully understanding their roles; they provide comparability and ensure compliance with standard requirements (Shestopalova & Gololobova, 2018:131). A SOP is an effective tool for increasing healthcare quality and safety. Its integration into everyday processes at medical institutions is appropriate and compliant with current standards. SOPs should be updated to reflect current requirements, technical capabilities, and technological and scientific advances (Shestopalova & Gololobova, 2018:131). It can be argued that the absence of SOP's at Sites A, B and D can have a negative impact on service delivery considering these documents serve as guide how certain activities should be executed and the associated accountability.

5.4 Checklist 3: Human resources development

According to the IAEA (2020:77), senior management should ensure that an organisation's operational effectiveness and efficiency are ensured by having essential individual competencies documented as well as ongoing assessment of them. Patient-centred, efficient, effective, safe, timely, and conveniently accessible care is today's healthcare delivery system (Yaqoob, Kvist, Azimirad & Turunen, 2021:87). This is due to escalating technical improvements, rising expectations, and increased demand for sustainability; all are exacerbated by employee shortages, turnover, migration, and potential geopolitical instabilities (Yaqoob *et al*., 2021:87). As a result, worldwide professional regulations have become more stringent (Yaqoob *et al*., 2021:87). Many countries have strengthened competency criteria for healthcare practitioners by establishing minimum standards of knowledge, abilities, and attitudes (Yaqoob *et al*., 2021:87).

The Joint Commission on Accreditation of Healthcare Organisations (JCAHO) has begun enforcing stringent accreditation policies that require hospitals to implement processes to evaluate healthcare system standards, ensuring continuous quality of services, improving patient safety, and upgrading healthcare workers' competency levels (Yaqoob *et al*., 2021:88). These policies and procedures are

primarily concerned with integrating healthcare professional competence standards (Yaqoob *et al*., 2021:87). Continuous assessment of these competency criteria is thus on the top of strategic healthcare planners' agendas (Yaqoob *et al*., 2021:87). All of the sites in this study do not perform any internal review of the competence of staff members.

None of the Sites have mechanisms to provide professional education and development opportunities for all staff categories. Training in nuclear medicine is an ongoing process (IAEA, 2020:77). With good planning and organisation, it should not be difficult to provide further education and training at all professional levels, using, where necessary, the resources of training institutions available (IAEA, 2020:77). Periodic accreditation in nuclear medicine, with an acceptable testing procedure, should be a part of continuing programs in nuclear medicine education and staff training programs (IAEA, 2020:77). This should ensure that employees have the latest knowledge and skills to provide the best possible service to customers and improve morale and confidence (IAEA, 2020:77).

Continuous training in radiation safety and radiation protection is not provided at Sites A, B and D. According to the IAEA (2005), before beginning work with or in the presence of radioactive materials, employees must receive radiation protection training. Annual refresher training should be conducted whenever there is a substantial change in tasks, regulations, license terms, or the type of radioactive material or therapeutic device utilised.

5.5 Checklist 4: Radiation regulations and safety

None of the Sites in the study had classification of areas. According to the IAEA (2005:32), the Sites should designate practice areas as controlled or supervised. A controlled area is defined as any area '*in which specific protection measures or safety provisions are or could be required for: (a) controlling normal exposures and (b) preventing or limiting the extent of potential exposures'* (IAEA, 2005:32). Examples of controlled areas are radiopharmaceutical preparation and administration areas, storage and areas accommodating patients to whom therapeutic amounts of activity have been given (IAEA, 2005:32). A supervised area is defined as *'any area not already designated as a controlled area but where occupational exposure conditions need to be reviewed even though specific protection measures and safety provisions are generally not required'* (IAEA, 2005:33). Examples of supervised areas include examination imaging rooms (with gamma cameras) and waiting rooms for patients who have been injected with radiopharmaceuticals (IAEA, 2005:33)

Some sites did not display radiation signs in the local language at the entrance of a supervised and controlled area. All displayed radiation warning signs should be in appropriate languages in public places, waiting rooms for patients, cubicles and other suitable sites. These signs should also inform pregnant or breastfeeding women to notify the relevant personnel (IAEA, 2005:33).

The radiopharmacy is a sensitive area hence requires routine and location monitoring that includes standard radiation background surveys (IAEA, 2006a: 520). This allows for processes and safety measures, mainly when new radiopharmaceuticals, radionuclides, or additional functions are introduced (IAEA, 2006a: 520). A radiopharmacy should have a permanent monitor scintillation counter or ionisation chamber, with audible volume measurement signals that allow healthcare professionals to know when radiation sources are exposed (IAEA, 2006a: 520). None of the Sites regularly monitor workplace contamination; they lack assessments and surveys of working areas and equipment. The radiation monitoring devices in all the Sites were not calibrated. The Sites need to ensure regular calibration of all radiation detecting devices (IAEA, 2006a: 143). This calibration must be traceable to a recognised primary or secondary standard as they can drift over time and become inaccurate (IAEA, 2006a: 143).

Not all sites had a clear, concise, and definite emergency plan posted visibly in places where their need is anticipated. These plans should entail the preventative measures to be taken in case of lost sources, damage to Tc-99m generators, small and large amounts of radioactivity spillage, medical emergencies involving radioactive patients, requisite for urgent patient attention, including surgery and fires (IAEA, 2005: 66 – 69).

5.6 Checklist 5: Patient radiation protection

Not all of the Sites in the study had SOPs aimed at minimising the risk of multiple radiation exposures. SOP's tackling non-compliance to inpatient exposure, including reporting and corrective action were also missing. The importance of SOPs was discussed in Section 5.3 above.

5.7 Checklist 6: Evaluation of quality system

None of the Sites performed self-assessments or audits. These assessments determine compliance with requirements and evaluate the need for corrective actions, emphasising opportunities for improvement and enhancing performance (IAEA, 2006b: 55). None had a system to assess patient, referring physicians/third party satisfaction. According to the IAEA (2005:78) satisfaction of patients and referring physicians is one component that merits special attention in a quality assurance program. Al-Abri and Al-Balushi, (2014:3-7) identify it as an essential quality indicator used to measure the achievement of the service delivery system.

5.8 Checklist 7: Quality control of equipment

Quality control in any nuclear medicine Site-ensures that equipment functions at the levels indicated by the manufacturer and measured during the acceptance testing procedure throughout its useful life

and that regulatory criteria for radiation safety are met (IAEA, 2009: 34). None of the sites in the study had SOPs about the operation, QA/QC for all imaging equipment in clinical use, including specific instructions on corrective actions in the case of non-conforming results. SOPs are a collection of documents that outline standards that must be adhered to strictly and without exception by all personnel. Only by adhering to SOPs can a department maintain the quality of its goods and services and continue to expand its clientele (Deepak, 2014).

5.9 Checklist 9: General clinical services

None of the sites in the study had SOPs for the below.

- Ensuring that only the most recent manual containing the complete description of all procedures is available and that all staff are aware of this manual and familiarised with its use
- Dealing with the administration of non-licensed or off label radiopharmaceuticals
- Dealing with emergency requests
- Regularly reviewing the number of and reasons for repeated NM examinations

Basic life support (BLS) is a type of first-aid resuscitation that can be performed in an emergency until a patient is transferred to the care of medical personnel (Kviklyte, 2013). BLS is performed when a person appears to be choking, drowning, unconscious, showing an allergic reaction to drugs or medication or in cardiac arrest. Knowing how to do BLS correctly can mean the difference between life and death. BLS training is essential for all medical professionals (Kviklyte, 2013).

Although there is a practice of inquiring about pregnancy and lactation before administering radiopharmaceuticals, none of the Sites have a written procedure for this.

The IAEA, (2022) defines misadministration as:

- administration of radiopharmaceuticals to the wrong patient
- giving the wrong radiopharmaceutical or activity to the patient, or unjustifiable evaluation of pregnant or breastfeeding female patients.
- incorrect doses and extravasation

The use of an incorrect administration route can result in extremely high exposure at the injection site, especially if the volume is small, the activity is high, and the radiopharmaceutical has a long retention time. In most diagnostic applications, a deviation of 25% from the required activity is considered acceptable. None of the Sites had a procedure in place to avoid misadministration of radioactive and non-radioactive pharmaceuticals.

None had a procedure to address and report any adverse event adequately. A patient who has received a radiopharmaceutical may experience an unpleasant reaction in rare instances (IAEA, 2006a:507). This does not necessarily imply that the product is faulty (IAEA, 2006a:507). According to estimates, such reactions occur in 3 out of every 100 000 cases, hence departments may seldom face a similar situation (IAEA, 2006a:507). Fortunately, adverse reactions are usually minor and self-limiting, requiring little or no treatment (IAEA, 2006a:507). Since such incidents are uncommon, they should be reported to the product manufacturer and national authorities. This method creates a database of potential reactions, feedback for improvement on products and information is distributed (IAEA, 2006a:507).

5.10 Checklist 10.1 to 10.5: Assessment of imaging diagnostic procedure

None of the study sites could account for extravasation at the injection site. Extravasation is when a radiopharmaceutical leaks into the tissue around the administration site. It causes quantification errors and a high absorbed dose to underlying tissues and skin (Crowley, Barvi, Greulich & Kiser, 2021: 1-2). Immediate detection of extravasation is vital as early mitigation techniques can be applied, resulting in improved image quality and minimal absorbed dose, thus decreasing latent effects of ionising radiation on healthy tissue (Crowley *et al.*, 2021: 1-2).

None of the study sites conduct QC on radiopharmaceuticals. QC of the generator eluate and radiopharmaceuticals involves testing for molybdenum breakthrough, aluminium ion contamination, sterility, pH and radiochemical purity (IAEA, 2008: 35). Before patient administration, a radiochemical purity test, utilising thin layer chromatography, should be carried out on the first batch of radiopharmaceuticals (IAEA, 2008: 35).

Radiochemical purity is defined as “the proportion of the total radioactivity of the nuclide concerned present in the stated chemical form” (IAEA, 2006a:502). Although not universal, many radiopharmaceuticals are expected to have radiochemical purity greater than 95% (IAEA, 2006: 502). Low radiochemical purity can lead to undesired radiopharmaceutical biodistribution and this may confuse the diagnosis and cause substantial dosimetry issues for therapeutic radiopharmaceuticals (IAEA, 2006: 502). Planar chromatography, utilising stationary phases (e.g., paper or thin layers of silica gel) and mobile phases (e.g., saline, acetone and butanone) used to determine the radiochemical purity of radiopharmaceuticals (IAEA, 2006a: 502).

Controlling the pH is critical to ensure that radiopharmaceuticals stay true to their original specifications (IAEA, 2006a: 505). Some radiopharmaceuticals become colloidal and unsuitable for labelling reactions with a pH rise. Technetium products change their chemical complexes and bio distribution (IAEA, 2006a: 505). All radiopharmaceuticals delivered must be sterile and nonpyrogenic

(IAEA, 2006a: 505). This is accomplished by using an appropriate sterilising process during a radiopharmaceutical preparation (IAEA, 2006a: 505).

5.11 Checklist 12: General radionuclide therapy

There was no SOP for patient preparation concerning all types of treatments and misadministration of therapeutic radiopharmaceuticals at Sites B and D**.** None of the study sites had SOPs describing the purchasing, preparation and QC of therapeutic radionuclides, and they do not offer multidisciplinary follow up post treatment. Sites A, B and D, respectively, did not have a SOP to rule out pregnancy and lactation prior to therapy. Site B did not include instructions on the requirement and the period of ongoing contraceptives after therapy and did not have a process of obtaining informed consent before therapy. It should be noted that the absence of SOPs, instructions and written procedure does not mean a department is not performing these duties.

5.12 Checklist 13: Assessment therapy

This assessment was carried out using patient treatment files. All of the treatment files in the various Sites did not indicate how they identified their patients as there was no SOP was not in place. Although the treatment report was drafted according to a format, there was no reference to a specific SOP for all the Sites. None of the treatment reports had documentation on handling any incidents or adverse events recorded in the files. None of them had a post treatment feedback system in place.

At Site D there was a record with respect to how they determine patient preparation; there was no traceability of all patient related data in the five hospital files sampled. Some of Site B's files did not have an indication of the availability and checks for any potential interference with the current radionuclide therapy.

5.13 Checklist 14 and 15: Radiopharmacy operational levels 1 and 2

None of the Sites perform the following:

- a molybdenum breakthrough measurement performed on the first eluate of each technetium-99m generator and repeated when the generator is moved.
- aluminium ion breakthrough checked on the first eluate from a technetium-99m generator, and radiochemical purity test performed on all new batches or newly delivered radiopharmaceutical kits before patient administration.

- routine microbiological monitoring of the preparation and aseptic dispensing area in the radiopharmacy.
- pH tests carried out regularly.
- rapid alternative methods employed for swift prospective QC: for example, for the determination of the radiochemical purity of ^{99m}Tc-hexamethyproyleneamine oxime.

The importance of performing all these procedures/tests was discussed above in Section 5.11.

5.14 The Assessment of the ease of use of the QUANUM Tool

This section describes the authors reflections on the use of the QUANUM Tool during the data collection of this research project.

5.14.1 Lack of Clarity

Checklist 1

Audit criterion 1.8 dealing with strategic development plan for global activities was not clearly understood by the researcher and research sites.

Checklist 2

Audit criterion 2.1 the processing map was not clearly explained and understood by the researcher and research sites.

Checklist 5

Audit criterion 5.12 dealing with pregnant and breastfeeding women, not clear on what aspect needs to be addressed.

Checklist 14

Audit criterion 14.2 deals with training manuals for all grades of staff but the audit tool does not give guidance as to the specific areas of training required for different cadres of staff.

Audit criterion 14.5 deals safety and challenge testing of the fume hood. It is not specified what kind of challenge test is required.

Audit criterion 14.6 dealing with suitable protocols for trained staff for the purchase of approved or market-authorized radiopharmaceuticals. The audit references are not specific regarding what type of training is required for the purchasing of the products.

Audit criterion 14.8 deals with written procedures for aseptic dispensing and labelling of unit doses of ready to use radiopharmaceuticals, the interpretation of ready to use products would mean that no aseptic dispensing is necessary.

Audit criterion 14.14 deals with periodic quality checks on radiopharmaceuticals. This does not refer to specific test required and whether the quality checks are meant to be performed before or after preparation.

5.14.2 Suggested exclusion/combinations

Checklist 1

Audit criteria 1.1 and 1.2 dealing with strategies at hospital and regional/national level should be combined as these strategies are the same.

Audit criteria 1.5 and 1.6 dealing with clinical demand and emergency requests should be combined because clinical demand deals with both emergency and normal workflow.

Checklist 10

Audit criterion 10.30 regarding feedback after the issuing of the final report, should be excluded from assessment of diagnostic services as it is only effective in radionuclide therapy.

In conclusion the QUANUM audit tool is comprehensive and valuable. To make the audit references more understandable and to improve the site responses, they should be divided into smaller sections.

5.15 Summary

Non-conformities at the research sites were discussed. Their impact on patients, staff, and nuclear medicine practice was underscored. Non-compliance was discussed under the different checklists as highlighted in the results in Chapter Four. The highest compliance was the clinical service offered under radionuclide therapy. There was a lack of SOPs in most of the nuclear medicine departments. The recommendations, categorised according to each Site and level of priority, are presented in chapter six.

CHAPTER SIX

RECOMMENDATIONS

6.1 Introduction

In this chapter the three priority areas under which the recommendations are categorised are defined. Each recommendation is categorised according to Site and the level of priority. Conclusions drawn from the study are discussed. Suggestions are made or future research based on the findings of the study.

6.2 Prioritisation of recommendations

- **Critical priority.**

  These are issues/requirements affecting the safety of patients, staff, caregivers and environment and should be addressed promptly within days or weeks.

- **Major priority**

  These are issues affecting a nuclear medicine service's capacity to perform its activities and should be addressed in a timely manner within 3-6 months.

- **Minor priority**

  Issues that may be the object of optimisation, to be accomplished within a defined time period and re-evaluated during the next audit.

6.2.1 Recommendations according to each Site and level of priority

Recommendations and level of priority for each Site are listed in Table 6.1.

Table 6.1 Recommendations according to each Site and level of priority

Audit Component	Priority	Recommendations	Site A	Site B	Site C	Site D
Strategies and policies	Major	Develop strategies following specific objectives developed by the hospital management	×		×	
	Major	Documentation that clearly defines the coordination with other services, i.e., Radiology	×		×	
	Major	Regularly update organisational charts with clear channels of communication and lines of authority	×		×	×
	Major	Ensure that diagnostic imaging and therapeutic services are consistent with the clinical demand.		×		×
	Major	Conduct internal/external clinical audits for quality improvement	×	×	×	×
	Minor	Develop strategies plans for global activities of the NM service	×	×	×	×
	Critical	Ensure new developments in Diagnosis and therapy	×		×	
	Minor	Develop a strategy/policy guiding access to Nuclear Medicine services not offered at own Site.	×	×	×	

	Major	Ensure responsibilities are clearly defined when providing services provided by other hospitals and institutions.	×	×	×	
Administration and management	Major	Put in place clearly defined primary management and support processes.	×	×	×	
	Major	Put written standard operating procedure (SOPs) for management, support services, diagnosis, and therapy.	×	×	×	×
	Major	Put in place written SOPs identifying the responsibility level of operators involved in the processes	×		×	×
	Major	Review of SOPs used in the reception area.	×	×	×	×
	Critical	Develop instructions dealing with particular categories of patients (i.e., those with disabilities, or pregnant or breastfeeding females) incomplete patient requests and to accommodate peak scheduling demands	×	×	×	×
	Major	Review the time interval between the request and performance of the study and delays of the waiting list, the time between the performance of the examination and the delivery of the report and use it in managerial processes	×	×	×	×
	Major	Put into place mechanisms dealing with unforeseen events in management, administrative activities and staff concerns	×		×	
	Major	Regular review of QMS by a radiopharmacist	×	×	×	×
	Minor	Employ a radiopharmacist	×	×	×	×
Human resource development	Major	Ensure availability of written job descriptions with clear duties and responsibilities for all staff	×			×

	Major	Ensure all the staff are appropriately trained and qualified as specified in the job description	×		×	
	Major	Organise specialised training for nurses	×		×	
	Minor	Develop a mechanism to provide continuous professional development and education for all staff members	×	×	×	×
	Minor	Regularly review competencies to identify training needs	×	×	×	×
	Critical	Ongoing training in radiation safety and protection for all staff members		×		×
Radiation regulations and safety	Critical	Ensure the Site is Licensed/authorised by a competent national institution			×	×
	Critical	Develop SOPs for radiation safety and protection referring to national or international guidelines or regulations	×	×	×	×
	Critical	All staff should receive instructions and training on local procedure and safety precautions for security and staff during orientation/induction		×		×
	Critical	Ensure all staff should sign and confirm, read, and understand local policies and SOPs	×	×	×	×
	Critical	Ensure all radioactive materials are identified, kept, controlled, and stored as requested in licenses and SOPs				×
	Critical	Ensure all sealed sources for calibration are periodically cross-accounted and checked for leakage	×		×	
	Critical	Create an adequate room/space for the administration of radiopharmaceuticals, therapy and radioactive aerosols, including radiation protection tools	×			

	Critical	Separate waiting areas for patients before and after administration of radiopharmaceuticals		×		×
	Critical	Classify areas as 'supervised' or 'controlled' according to basic safety standards (BSS)	×	×		×
	Critical	Procedures for regular monitoring and dealing with contamination/spillage handling of patient specimens' devices, including radiation and microbiological safety aspects, should be developed	×	×	×	×
	Critical	Develop a means to prevent unauthorised access to supervised and controlled areas	×		×	×
	Critical	Ensure prominent display of radiation signs (in local languages at the entrance of supervised and controlled areas.		×		×
	Critical	Perform formal risk assessments and surveys of working areas and equipment	×	×	×	×
	Critical	Ensure the availability of functional and calibrated radiation monitoring devices	×	×	×	×
	Major	Develop a formal emergency plan in case of fire, floods, power blackouts etc.	×	×	×	×
Patient radiation protection	Critical	Develop SOPs that ensure correct patient identification before administration of the radiopharmaceutical	×		×	
	Critical	Develop SOPs and appropriate signage alerting potential pregnancy and breastfeeding	×		×	×
	Critical	Make available written and verbal instructions for before and after administration of the radiopharmaceutical				×
	Major	Develop SOPs to ensure relevant dose indicators from X-rays in case of multimodality imaging does not exceed reference levels as specified in BSS and national or international regulations or guidelines	×			×

	Major	Ensure there are trained personnel to estimate effective patient radiation dose after administration of the radiopharmaceutical		×		×
	Major	Ensure there are trained personnel to estimate effective patient radiation dose due to X-ray exposure in case of multimodality imaging			×	×
	Critical	Develop SOPs to reduce the risk of misadministration of a radiopharmaceutical and multiple radiation exposures	×	×	×	×
	Critical	Develop specific SOPs addressing non-compliance in-patient exposures, reporting and corrective actions	×	×	×	×
	Major	Develop a specific SOP dealing with pregnant and breastfeeding women who need nuclear medicine procedures	×			×
Evaluation of quality system	Major	Define objectives and set standards for service performance				×
	Major	Set in place systems for verifying compliance with standards	×	×	×	×
	Major	Perform regular self-assessments/audits	×	×	×	×
	Major	Set in place a system for assessing satisfaction/dissatisfaction (i.e., patient or referring clinician satisfaction/dissatisfaction	×	×	×	×
	Major	Develop SOPs for non-compliance, recording, and correction/prevention	×		×	×
	Minor	Develop mechanisms for monitoring of data to ensure quality improvement	×	×	×	×
	Major	Organise regular formal quality monitoring and reviewing for all staff members				×

	Minor	Develop a QA program including regular calibration and inspection of all equipment according to BSS, national or international standards	×		×	×
	Minor	Organise regular formal review of quality data by the management	×			×
	Major	Develop a procedure ensuring discontinued use of equipment or material that has failed the quality test unless authorised by a designated staff member	×			×
	Minor	Defined responsibilities and levels of action to determine equipment repair, replacement and discontinuation	×	×	×	
	Minor	Participate in external QM/QA/QC programmes	×	×	×	×
Quality control of equipment	Major	Put in place written policies that specify, procure and test new equipment		×		×
	Major	Policies ascertaining the need for certification of all acquired equipment approved by an international or national authority should be developed		×		×
	Major	Policies in line with recommendations made in IAEA/international/national manufacturers' association publication should be put in place		×		×
	Minor	Independent assessment of the performance of actually delivered equipment performed and documented against the specification of the tender should be put in place		×	×	×
	Major	The result of the acceptance test and initial performance assessment should be used in the establishment of a baseline reference level for routine QA/QC		×		
	Major	Written operational and QA/QC SOPs available for all imaging equipment	×	×	×	×
	Major	SOPs should be developed according to manufacturers' instruction manuals			×	×

	Major	Put in place an internal QA program that regularly checks, reviews, and records QA/QC procedures of relevant planar/SPECT/multimodality parameters		×		
	Minor	Develop QA/QC SOPs that include recording results of non-conformance and corrective actions	×		×	×
General clinical services	Major	Put in place a mechanism that regularly updates internal SOPs according to international /national policies and medical evidence	×	×		×
	Minor	Develop an SOP for distribution of documents/manuals containing all procedures that are offered and ensure that all staff are aware and familiar with its contents	×	×	×	×
	Critical	Put in place a written procedure that enquires about pregnancy and lactation before any radiopharmaceutical administration	×	×	×	×
	Critical	Ensure radiopharmaceutical dose identifies with individual patient and traceability		×		×
	Critical	Ensure that procedures to avoid misadministration of radioactive and non-radioactive pharmaceuticals are in place	×	×	×	×
	Major	Develop a protocol dealing with the administration of a non-licensed or off labelled radiopharmaceutical	×	×	×	×
	Critical	Put in place SOPs for dealing with an emergency request	×	×	×	×
	Critical	Develop SOPs for specific preparation relevant to paediatrics, i.e. sedation		×		×
	Critical	Develop SOPs for appropriate medical supervision during interventions (diuretics, stress testing)				×
	Critical	Develop written procedures that address and report adverse reactions/events	×	×	×	×

	Major	Develop a written procedure for timely reporting of any finding to referring physician for critical patient management	×	×	×	×
	Major	Develop a policy on patient surveillance during their visits, preparation, and waiting times	×	×	×	×
	Critical	Ensure there is a fully equipped emergency cart with SOPs to check and replenish regularly			×	×
	Critical	Ensure staff are trained on basic and advanced life support and use of available equipment	×	×	×	×
	Critical	Ensure there is a regular update of appropriate training in basic and advanced life support	×	×	×	×
	Major	Develop a written procedure describing a mechanism dealing with reporting an incident and introducing corrective action	×		×	×
	Minor	Introduce a procedure documenting additional information/feedback after the completion of the examination	×	×	×	×
	Minor	Develop a SOPs that will regularly review the number of and reasons for repeated nuclear medicine examinations	×	×	×	×
Assessment of imaging diagnostic procedure using patient files	Critical	Document the availability of other imaging (X-ray report) and laboratory results	×	×	×	×
	Critical	Document the availability of exclusion of pregnancy and information on lactation and counselling	×			

	Critical	Document results QC of radiopharmaceuticals	×	×	×	×
	Critical	Document the latest QC of imaging equipment relevant for the specific examination		×	×	×
	Critical	Check and account for extravasation at the injection site Document QC of processing parameters and analysis	×	×	×	×
	Critical	Document QC of processing parameters and analysis	×	×	×	×
	Critical	Document handling of any adverse events or another incident (patient-related or not)	×	×	×	×
	Major	Document any feedback received after reporting and managed	×	×	×	×
	Critical	Ensure relevant clinical information is available according to the SOPs				×
	Critical	Ensure scanner set (imaging device, collimator, energy window settings) up is done according to SOPs and documented				×
	Critical	Ensure acquisition parameters (time from administration, positioning, acquisition mode, a matrix is according to the SOPs and documented				×
	Critical	Document current medication/date of last chemo/date end of radiotherapy	×	×	×	×
	Critical	Document any patient condition and/or treatment-related interference with procedure		×		×
General radionuclide therapy	Critical	Develop SOPs for patient preparation regarding all types of treatment		×		×
	Critical	Develop SOPs to rule out pregnancy and to deal with lactation before therapy		×		×

	Major	Develop SOPs describing the procurement, preparation and QC of therapeutic radiopharmaceuticals/ radionuclides	×	×	×	×
	Critical	Develop SOPs dealing with misadministration of therapeutic radiopharmaceuticals		×		×
	Major	Ensure multidisciplinary clinical follow up of patients is provided	×	×	×	×
Assessment therapy using patient files	Critical	Document handling of any adverse events or other incidents (patient-related or not)	×	×	×	×
	Critical	Ensure information about ongoing medical therapy is available and checked for any potential interference with the current radionuclide therapy		×		×
	Major	Ensure traceability of all patient-related data, name of technologist and medical doctor in charge				×
Radiopharmacy operational level 1	Minor	Develop suitable protocols and train staff for the purchase of approved or authorized radiopharmaceuticals		×		×
	Critical	Ensure availability of written procedures for aseptic dispensing and labelling of unit doses ready-to-use radiopharmaceutical		×	×	×
	Critical	Ensure availability of fume cupboards with suitable filters for volatile radioactive materials	×	×		×
	Critical	Ensure that radioiodine capsules are handled and opened in a well-ventilated area	×			×
	Critical	Ensure written procedures contain coherent safety and monitoring instructions for dispensing radioiodine capsules or solutions		×		×

	Critical	Ensure the document traceability of each radiopharmaceutical batch from prescription to the actual individual patient administration		×	×	×
	Critical	Ensure quality checks are performed on radiopharmaceuticals	×	×	×	×
	Major	Ensure there are written procedures for dealing with products that do not meet the standards and complaints received	×	×	×	×
	Major	Ensure written procedures for the disposal of radioactive and non-active waste				×
Radiopharmacy operational level 2	Major	Ensure there is specific staff training and assessment of competencies, including aseptic practice	×	×	×	×
	Critical	Conduct regular checks on validated Class II type B microbiological safety cabinets			×	
	Critical	Ensure that the preparation of 99m- technetium products are carried out in a laminar airflow cabinet	×	×		×
	Critical	Ensure QC of generator eluate and radiopharmaceuticals are performed	×	×	×	×

6.3 Limitations of the research study

The first limitation of this study was lack of previous research studies in Namibia. This impacted the study as it hindered the reliability and scope of the research. The researcher had to find the use of the QUANUM tool in other countries and different studies which employed auditing tools used in other fields of radiology (i.e. radiotherapy and conventional X-rays). The second limitation was lack of training in the QUANUM tool. Some of the questions in the tool were difficult to understand, making it challenging to select conformity or non-conformity. What helped in the study and made the results reliable was that two nuclear medicine physicians were trained to use the QUANUM tool. The researcher suggests that for future studies training on the QUANUM tool by the IAEA should be done or a pilot study should be conducted before the use of the tool commences at nuclear medicine Sites. Thirdly, an older version of the QUANUM tool was used for this study. Checklist numbers and titles therefore differ between the original and updated 2019 version of the tool. Comparisons of follow up compliance/assessments might therefore be complicated when comparing these to the results of this study. However, despite this, the researcher is of a view that the majority of the findings in this thesis is a true reflection of each Site's conformance and non-conformance.

6.4 Outline of anticipated further benefit and investigation

Three suggestions for future research are presented.

- Future research projects should be done to assess whether the recommendations were followed and evaluate their impact on the various nuclear medicine practices.
- Future research projects should be done to investigate whether the QUANUM tool is user friendly and fit for purpose in an African context.
- Future research should be done to assess the perceptions and opinions of nuclear medicine radiographers and physicians regarding the QUANUM tool.

6.5 Conclusion

Implementing a QMS should be a calculated choice to raise the level of treatment offered by any nuclear medicine service. Different requirements, limitations, specific goals, type of services offered, procedures used, and the size and structure of a nuclear medicine Site all impact on the design and implementation of a QMS. If implemented, adequately recorded, and kept up to date, QMS would continually enhance their performance to meet the standards set by accrediting, regulating, and professional authorities.

According to the knowledge gained through the IAEA QUANUM program during this study, therapy, administration and management, and human resource management demonstrated good compliance with international standards. Aspects about strategies and policies, radiation protection, quality systems, computer systems and data handling all need attention.

The study highlighted the absence of SOPs. Stricter adherence to SOPs should be encouraged when available, and more detailed training on creating them should be given. SOPs that should be compiled to ensure more organised and standardised everyday activities. Implementing routine internal audits and, as necessary, follow-up external audits should help with radiation safety without the need for significant expenses. Managers of the research sites can use the findings of this study to assess areas where improvement in service delivery or operational matters can be brought about. Such improvements will not only benefit the patients they serve but may potentially also bring about positive changes amongst the professional practise standards of staff. In conclusion, relevant feedback was provided to the selected Namibian nuclear medicine practices in the study regarding their status and conformance to international reference standards.

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APPENDICES

Appendix 1: IAEA CHECKLIST

GENERAL DATA OF AUDIT	
Name of Audited Institution:	Enter name of audited institution
Physical Address:	Enter address of audited institution
City:	Enter city where audited institution is located
Country:	Enter country where audited institution is located
Main Audit Contact/Focal Point:	Enter name and data of main audit contact
Telephone Number:	Enter telephone number of main audit contact/focal point
E-Mail Address:	Enter e-mail address of main audit contact/focal point
Audit Date	Enter the audit date
Audit Type	Click to Select
Audit Code	Enter the audit code

AUDIT TEAM INFORMATION	
Nuclear Medicine Physician:	Enter name of Nuclear Medicine Physician auditor
Medical Physicist:	Enter name of Nuclear Medicine Physicist auditor
Technologist:	Enter name of Nuclear Medicine Technologist auditor
Radiopharmacist/Chemist:	Enter name of Radiopharmacist auditor
Others:	Enter name of auditors not included above

CHECKLIST INFORMATION		
Checklist	*Filled by*	*Audited by*
1	Staff member in charge of checklist 1	Name of auditor evaluating checklist 1
2	Staff member in charge of checklist 2	Name of auditor evaluating checklist 2
3	Staff member in charge of checklist 3	Name of auditor evaluating checklist 3
4	Staff member in charge of checklist 4	Name of auditor evaluating checklist 4
5	Staff member in charge of checklist 5	Name of auditor evaluating checklist 5
6	Staff member in charge of checklist 6	Name of auditor evaluating checklist 6
7	Staff member in charge of checklist 7	Name of auditor evaluating checklist 7
8	Staff member in charge of checklist 8	Name of auditor evaluating checklist 8
9	Staff member in charge of checklist 9	Name of auditor evaluating checklist 9
10	Staff member in charge of checklist 10	Name of auditor evaluating checklist 10
11	Staff member in charge of checklist 11	Name of auditor evaluating checklist 11
12	Staff member in charge of checklist 12	Name of auditor evaluating checklist 12
13	Staff member in charge of checklist 13	Name of auditor evaluating checklist 13
14	Staff member in charge of checklist 14	Name of auditor evaluating checklist 14
15	Staff member in charge of checklist 15	Name of auditor evaluating checklist 15
16	Staff member in charge of checklist 16	Name of auditor evaluating checklist 16
17	Staff member in charge of checklist 17	Name of auditor evaluating checklist 17

CLINICAL PROCEDURES	
Imaging Procedure 1:	*Enter title of imaging procedure 1*
Imaging Procedure 2:	*Enter title of imaging procedure 2*
Imaging Procedure 3:	*Enter title of imaging procedure 3*
Imaging Procedure 4:	*Enter title of imaging procedure 4*
Imaging Procedure 5:	*Enter title of imaging procedure 5*
Non-imaging Procedure 1:	*Enter title of non-imaging procedure 1*
Non-imaging Procedure 2:	*Enter title of non-imaging procedure 2*
Non-imaging Procedure 3:	*Enter title of non-imaging procedure 3*
Therapeutic Procedure 1:	*Enter title of therapeutic procedure 1*
Therapeutic Procedure 2:	*Enter title of therapeutic procedure 2*
Therapeutic Procedure 3:	*Enter title of therapeutic procedure 3*

Appendix 1.1: Checklist 1 Strategies and Policy

CHECKLIST 1
Strategies and Policy

CHECKLIST SUMMARY	N. of Req.	Applicable	Total score	% Scoring	NC
	12	0	0	0,0	0

No.	Component	Conformance Level	Status	Comments/planned action	Date achieved	Example of result / Type of evidence	References
1.1	Is the strategy of the nuclear medicine service in acccordance with specific objectives developed on the national/regional level?	Click to Select				Written documents showing the strategies of the NMS and the objectives at national /regional level.	SS-GS-3.1, par. 2.5,2.19,3.13 HHS No. 11, par. 2.1-2.3 NMRM-1198, chap. 3.2.1
1.2	Is the strategy of the nuclear medicine service in accordance with specific objectives developed by the hospital management?	Click to Select				Written documents showing the NMS and institutional strategies.	SS-GS-3.1, par. 2.5,2.19,3.13 HHS No. 11, par. 2.1-2.3 NMRM-1198, chap. 3.2.1
1.3	Is the coordination with the other services of the institution defined (radiology, oncology, cardiology, pediatrics, surgery, etc.)?	Click to Select				Written documents describing agreements conditions with other services.	NMRM-1198, chap. 3 HHS No. 11, par 2.1-2.3
1.4	Does the nuclear medicine service have an updated written organizational chart, indicating channels of communication and lines of authority?	Click to Select				Copy of the organizational chart (It could be also verified on the Quality Manual).	SS-GS-3.1, chap. 4, par 5.4 NMRM-1198, chap. 2 http://www-pub.iaea.org
1.5	Do the nuclear medicine diagnostic imaging and therapeutic services match with the clinical demand?	Click to Select				Check the patient roster/Verify if there is a waiting list.	NMRM-1198, chap. 3 HHS No. 11, par 2.2.1, 2.2.3

No.	Component	Conformance Level	Status	Comments/planned action	Date achieved	Example of result / Type of evidence	References
1.6	Do the objectives of the nuclear medicine service include sufficient flexibility to accommodate with urgent requests and emergency examinations?	Click to Select				Check the relevant SOPs and patient workflow.	NMRM-1198, chap. 2,3
1.7	Do the objectives of the nuclear medicine service include commitment to quality improvement through use of internal / external clinical audit?	Click to Select				Check the quality objectives of the NMS.	SS-GS-3.1, par. 6.4-6.44 QUANUM, chap. 1
1.8	Does the NMS have a strategic development plan for its global activities?	Click to Select				Written documents establishing the strategic development plans.	NMRM-1198, chap. 2,3 HHS No. 11, par 2.2.2
1.9	Does the service have a plan to provide new developments in diagnosis and therapy?	Click to Select				Written documents describing the new developments (it could be verified on the QM).	NMRM-1198, 9.3.1-9.3.3 HHS No. 11, par 2
1.10	If the NMS does not provide a full range of nuclear medicine services, is there a strategy/policy to guide access to such services in another institution?	Click to Select				Written agreements with other NM Services/General SOPs for clinical and therapeutic services.	NMRM-1198, chap. 2,3 HHS No. 11, par 2

No.	Component	Conformance Level	Status	Comments/planned action	Date achieved	Example of result / Type of evidence	References
1.10	If the NMS does not provide a full range of nuclear medicine services, is there a strategy/policy to guide access to such services in another institution?	Click to Select				Written agreements with other NM Services/General SOPs for clinical and therapeutic services.	NMRM-1198, chap. 2,3 HHS No. 11, par 2
1.11	When providing services (e.g. technical and clinical) by using services of other hospitals, are responsibilities clearly defined?	Click to Select				Check the definitions of responsibilities in the SOP of the offered services.	NMRM-1198, chap. 2,3 HHS No. 11, par 2
1.12	Is there a formal process ensuring participation of the service in decision making of the hospital/institution?	Click to Select				Written SOP describing the process to ensure the role of NMS in hospital decision making.	NMRM-1198, chap. 2,3 HHS No. 11, par 2

LEGEND (Status):	
	Conformance
	Non-Conformance

Appendix 1.2: Checklist 2 Administration and Management

CHECKLIST 2
Administration and Management

CHECKLIST SUMMARY	N.	Applicable	Total score	% Scoring	NC
	17	0	0	0,0	0

No.	Component	Conformance Level	Status	Comments/planned action	Date achieved	Example of result / Type of evidence	References
2.1	Has the service defined the primary, management and supporting processes (process map)?	Click to Select				Check the process map.	SS-GS-3.1, par. 5.26
2.2	Does the service have written standard operating procedures (SOPs) for all tasks regarding the management processes?	Click to Select				Check the SOPs related to management processes.	SS-GS-3.1, par. 5.26
2.3	Does the service have written standard operating procedures (SOPs) for all tasks of the supporting processes?	Click to Select				Check the SOPs related to supporting processes.	SS-GS-3.1, par. 5.26
2.4	Do the SOPs identify the responsibility level of operators involved in the process?	Click to Select				Check the definitions of responsibilities in the SOPs.	SS-GS-3.1, par. 5.14-5.17
2.5	Does the service have written standard operating procedures (SOPs) for all tasks regarding diagnosis and therapy (primary processes)?	Click to Select				Check the SOPs related to diagnosis and therapy.	NMRM-1198, chap. 3 SNMG EANMG SS-GS-3.1, par. 5.26

No.	Component	Conformance Level	Status	Comments/planned action	Date achieved	Example of result / Type of evidence	References
2.6	Is there a regular review of the standard operating procedures (SOPs) used in the reception areas?	Click to Select				Check in the written procedure the data regarding the document updates.	SS-GS 3.1, par. 2.50 NMRM-1198, chap. 3.2.5 (a-d,f,g,k)
2.7	Is there an instruction for dealing with special categories of patients (disabilities, children, pregnancy, etc.)?	Click to Select				Check the instruction for dealing with special categories of patients.	BSS, par. 3.156 NMRM-1198, chap. 3.2.5(d)
2.8	Is there an instruction for dealing with incomplete request forms?	Click to Select				Check the instruction for dealing with incomplete request forms.	EANMP-60, 1.4.1 NMRM-1198, chap. 3.2.5(g)
2.9	Is there an instruction in place to accommodate peak scheduling demands?	Click to Select				Check the instruction to accommodate peak scheduling demands.	NMRM-1198, chap. 3.2.5(c)
2.10	Does the final responsibility for a nuclear medicine procedure lie with a qualified physician?	Click to Select				Check the definitions of responsibilities in the clinical SOPs.	BSS, par. 1,8, 3.150(a-c)

No.	Component	Conformance Level	Status	Comments/planned action	Date achieved	Example of result / Type of evidence	References
2.11	Is the time between request and performance of the study, the existence and delays of waiting lists regularly reviewed and are measures identified to shorten the delays?	Click to Select				Check the records/reports of the periodic management reviews.	NMRM-1198, chap. 3.2.5(i)
2.12	Is the time-interval between the performance of any examination and the delivery of the report to the referring physician regularly reviewed?	Click to Select				Check the records/reports of the periodic reviews.	SS-GS-3.1, par. 6.19
2.13	Are the indicators 2.11 and 2.12 as well as other performance parameters of the NMS used in managerial processes?	Click to Select				Check the records/reports of the periodic manager reviews.	SS-GS-3.1, par. 6.45-6.49
2.14	Is there a mechanism for dealing with any kind of unforeseen/unintended events regarding non-conforming situations in the service's management and administration activities?	Click to Select				Check the written instructions to deal with the unforeseen events.	SS-GS-3.1, par. 3.18
2.15	Is there a mechanism for dealing with staff concerns (e.g. periodic meetings)?	Click to Select				Check the written instructions to deal with the staff's concerns.	SS-GS-3.1, par. 3.18
2.16	Is there a regular review of the QMS by a qualified professional in medical physics?	Click to Select				Check the organizational chart and responsibilities definitions.	BSS, par. 3.153b TCS-50 EANMP-43
2.17	Is there a regular review of QMS by a qualified professional in radiopharmacy?	Click to Select				Check the organizational chart and responsibilities definitions.	BSS, par. 3.153b TCS-39

LEGEND (Status):	
	Conformance
	Non-Conformance

Appendix 1.3: Checklist 3 Human Resource Development

CHECKLIST 3
Human Resources Development

CHECKLIST SUMMARY	N.	Applicable	Total score	% Scoring	NC
	11	0	0	0,0	0

No.	Component	Conformance Level	Status	Comments/planned action	Date achieved	Example of result / Type of evidence	References
3.1	Do all staff members have a written job description, which clearly sets out their duties and responsibilities?	Click to Select				Example of a record (job description).	SS-GS-3.1, par 4.6 - 4.17 NMRM-1198, chap. 2.1-2.7
3.2	Are all staff members appropriately trained and qualified as specified in their job description?	Click to Select				Example of a record (personnel card).	BSS, par. 2.21-2.23,2.32,2.44 SS-GS-3.1, par 4.6-4.17 NMRM-1198, chap. 2,1-2.7
3.3	Does the service offer specific training for technologists to work in nuclear medicine?	Click to Select				Example of a record (training report).	EANMP-60 SNMP-11 BSS, par. 1.20(i) NMRM-1198, chap. 2.2.2
3.4	Does the service offer specific training for nurses to work in nuclear medicine?	Click to Select				Example of a record (training report).	BSS, par. 1.20(i) NMRM-1198, chap. 2.9
3.5	Are all staff members suitably trained in handling radioactive sources?	Click to Select				Example of a record (training report).	SRS No. 40, par 2.3.4, 4.5 BSS, par. 1.20(i), 2.5.1

No.	Component	Conformance Level	Status	Comments/planned action	Date achieved	Example of result / Type of evidence	References
3.6	Does the service have adequate tools for objective monitoring of any training?	Click to Select				Check written instructions describing the tools for training monitoring.	SS-GS-3.1, par 4.6-4.25
3.7	Does the service have mechanisms to provide professional education and development opportunities for all staff categories?	Click to Select				Check the training SOP.	NMRM-1198, chap. 2.1-2.7
3.8	Is there a regular internal review of competences in order to identify training needs?	Click to Select				Check the training SOP.	SS-GS-3.1, par 4.6-4.25
3.9	Does the service provide continuing training in radiation safety and radiation protection?	Click to Select				Example of a record (personnel card).	SRS No. 40, par 2.3.4, 4.5 BSS, par. 1.20(i), 2.5.1
3.10	Do staff members have access to educational and scientific resources?	Click to Select				Check available educational materials.	NMRM-1198, chap. 4.6.2, 9.4
3.11	Is quality management part of the training programmes for professionals involved in nuclear medicine?	Click to Select				Example of a record (personnel card).	SS-GS-3.1, par 4.6-4.25 NMRM-1198, chap. 9.4

LEGEND (Status):	
	Conformance
	Non-Conformance

Appendix 1.4: Checklist 4 Radiation Regulations and Safety (Page 1)

CHECKLIST 4
Radiation Regulations and Safety

CHECKLIST SUMMARY	N.	Applicable	Total score	% Scoring	NC
	25	0	0	0,0	0

No.	Component	Conformance Level	Status	Comments/planned action	Date achieved	Example of result / Type of evidence	References
4.1	Is the service formally authorized/licensed by competent national institutions?	Click to Select				Copy of the license.	SRS No. 40, par 2.1 BSS, par. 3.5 - 3.8
4.2	Do the SOPs dealing with radiation safety and protection refer to national guidelines or cross-refer to international regulations?	Click to Select				Cross-check references in SOPs with the first page of the law/regulation.	SRS No. 40, par 2.1.4 BSS, par. 1.9
4.3	Do all personnel of the NMS receive instructions and training on local procedures, safety precautions for the protection of the patient and staff when they start working in nuclear medicine?	Click to Select				Check/copy the records.	SRS No. 40, par 2.3.4, 4.5 BSS, par. 2.5.1, 3.94
4.4	Have all staff members signed in order to confirm that they have read and understood the local policies and SOPs?	Click to Select				Example of a record.	SRS No. 40, par 4.4 BSS, par. 2.51 - 3.94
4.5	Are all radioactive materials kept, identified, controlled and stored as specified in licenses and SOPs?	Click to Select				Observation on site/ photos.	SRS No. 40, par 3.4 BSS, par. 3.49 - 3.60
4.6	Are sealed calibration sources checked periodically, cross-accounted and checked for any leakage?	Click to Select				Observation on site/ photos/logbook.	SRS No. 40, par 3.4 BSS, par. 3.49 - 3.60
4.7	Is there routine nuclear medicine personnel monitoring for radiation exposure (e.g. whole body badges, hand/finger monitoring, etc., as appropriate)?	Click to Select				Observation on site/ copy of the records.	SRS No. 40, par 4.7 BSS,par.3.74-3.76, 3.99-3.102
4.8	Is staff personal dosimetry monitoring regularly reviewed and communicated, including reporting and initiating appropriate actions in the case of unexpected results?	Click to Select				Check/copy the records.	SRS No. 40, par 4.1-4.5 BSS, par. 3.99, 3.103-3.107
4.9	Are there appropriate health surveillance procedures for the exposed workers, in accordance with the local regulatory body?	Click to Select				Check/copy the records.	SRS No. 40, par 4.11 BSS,par.3.76,3.79,3.108-3.109
4.10	Is protective clothing (e.g. gloves, syringe shields, handling tongs, etc.) available?	Click to Select				Observation on site/ photos.	SRS No. 40, par 4.1,4.6 BSS, par. 3.76, 3.90-3.95
4.11	Are there adequate facilities for administration of radiopharmaceuticals, therapy and radioactive aerosols, including radiation protection tools as necessary?	Click to Select				Observation on site/ photos.	SRS No. 40, par 3.1.3 BSS, par. 3.76, 3.88 - 3.92
4.12	Are there adequate separate waiting areas for patients before and after administration of radiopharmaceuticals?	Click to Select				Observation on site/ photos.	SRS No. 40, par 3.1.3 BSS, par. 3.76, 3.88 - 3.92
4.13	Are diagnostic rooms adequately equipped (e.g. air conditioning, ventilation, surfaces, structural shielding or mobile barriers, etc.)?	Click to Select				Observation on site/ photos.	SRS No. 40, par 3.1.3 BSS, par. 3.76, 3.88 - 3.92
4.14	Have areas been classified as 'supervised' or 'controlled' according to the BSS (Basic Safety Standards) and/or local regulations?	Click to Select				Observation on site/ photos.	SRS No. 40, par 3.1.3 BSS, par. 3.88 - 3.98
4.15	Is there a procedure for regular monitoring of workplace contamination ?	Click to Select				Check the procedure.	SRS No. 40, par 4.8 BSS, par. 3.96

Appendix 1.5: Checklist 4 Radiation Regulations and Safety (Page 2)

No.	Component	Conformance Level	Status	Comments/planned action	Date achieved	Example of result / Type of evidence	References
4.16	Is there a procedure for dealing with a spillage or contamination incident?	Click to Select				Check the procedure/ Check the decontamination kit.	SRS No. 40, par 7.4.2-7.4.3 BSS, par. 3.88 - 3.98
4.17	Are there means to prevent unauthorized access to supervised and controlled areas?	Click to Select				Observation on site/ photos.	SRS No. 40, par 6.2 BSS, par. 3.90 - 3.92
4.18	Are radiation signs (in local language(s)) prominently displayed at the entrance to supervised and controlled areas?	Click to Select				Observation on site/ photos.	SRS No. 40, par 6.2 BSS, par. 3.90 - 3.92
4.19	Are formal risk assessments and surveys of working areas and equipment performed and documented by designated staff?	Click to Select				Check the procedure.	SRS No. 40, par 2.1,3.2 BSS, par. 3.9, 3.30 - 3.36
4.20	Are there suitably calibrated and functional radiation monitoring devices available?	Click to Select				Observation on site/ photos.	SRS No. 40, par 3.1.3 BSS, par. 3.38 - 3.76

No.	Component	Conformance Level	Status	Comments/planned action	Date achieved	Example of result / Type of evidence	References
4.21	Are there detailed procedures provided to handle patients' specimens (blood, urine, etc.), devices (syringes, urine bags, etc.), including both radiation and microbiological safety aspects?	Click to Select				Check the procedure/ Observation on site.	SRS No. 40, par 3.2 BSS, par. 3.1.5 - 3.88-3.95
4.22	Are there formal procedures provided for the management (storage and disposal) of liquid and solid radioactive waste, including considerations of chemical and biological hazard safety aspects?	Click to Select				Observation on site/ photos/Check the procedure.	SRS No.40,par 2.1.4,3.1.3, 6.4 BSS, par. 3.1.131-3.1.134
4.23	Is the level of waste regularly checked against the authorized disposal limit and recorded?	Click to Select				Check the procedure/ Check the records.	SRS No.40,par 2.1.4,3.1.3, 6.4 BSS, par. 3.1.131-3.1.134
4.24	Is there a policy on the transportation (within and outside the service) of radioactive material?	Click to Select				Check the procedure.	SRS No. 40, par 4.5, 4.6 BSS, par. 3.49 - 3.60
4.25	Is there a formal emergency plan provided regarding action in the case of accidents (fire, floods, power blackout etc.)?	Click to Select				Check the procedure.	SRS No. 40, par 4.5, 4.10 BSS,par.3.43 - 3.44,3.110,3.127

LEGEND (Status):		
		Conformance
		Non-Conformance

Appendix 1.6: Checklist 5 Patient Radiation Protection

CHECKLIST 5
Patient Radiation Protection

CHECKLIST SUMMARY	N.	Applicable	Total score	% Scoring	NC
	12	0	0	0,0	0

No.	Component	Conformance Level	Status	Comments/ planned action	Date achieved	Example of result / Type of evidence	References
5.1	Are there standard operating procedures (SOPs) available to ensure correct identification of the patient prior to administration of the radiopharmaceutical?	Click to Select				Check the procedure/ Observation on site.	SRS No.40, par 3.2.1, 5.2,5.3 BSS, par. 3.156
5.2	Are there SOPs and appropriate signage for alerting female patients of child bearing age to report any potential pregnancy or breast-feeding?	Click to Select				Check the procedure/ Observation on site.	SRS No.40,par 2.3.3,5.3.1,5.3.2 BSS, 3.151,3.165,3.174-3.176
5.3	Are written instructions available and verbal instructions given to patients before and after administration of radiopharmaceuticals?	Click to Select				Observation on site/ copy of the instructions.	SRS No. 40, par 3.2.1,5.2,5.3 BSS, par. 3.150 - 3.152
5.4	Is the activity of each patient dose measured prior to administration and entered into the patient's record?	Click to Select				Observation on site/ copy of the instructions.	SRS No. 40, par 5.1,5.3 BSS, par. 3.153 - 3.162,3.164
5.5	Is there an SOP to ensure that the administered amounts of radioactivity do not exceed the reference values given in the Basic Safety Standards (BSS), national or international regulations or guidelines?	Click to Select				Check the procedure/ Check the Manual.	SRS No. 40, par 5.3, Apdx VI BSS, par. 3.168

No.	Component	Conformance Level	Status	Comments/ planned action	Date achieved	Example of result / Type of evidence	References
5.6	In case of multimodality imaging: is there an SOP to ensure that effective doses from X-ray do not exceed the reference values given in the Basic Safety Standards (BSS), national or international regulations or guidelines?	Click to Select				Check the procedure/ Check the Manual.	SRS No. 40, par 5.3 http://www-pub.iaea.org/
5.7	Is there a trained person available to estimate the effective radiation dose to patients following administration of radiopharmaceuticals?	Click to Select				Observation on site/ Check the job description.	SRS No. 40, par 5.2 BSS, par. 3.167
5.8	In the case of multimodality imaging: is there a trained person available to estimate the effective radiation dose to patients due to the X-ray exposure?	Click to Select				Observation on site/ Check the job description.	SRS No. 40, par 5.2 BSS, par. 3.167
5.9	Are there adequate SOPs to minimize the risk of misadministration of radiopharmaceuticals?	Click to Select				Check the procedure/ Observation on site.	SRS No. 40, par 7.1, Apdx VII BSS, par. 3.154 - 3.159
5.10	Are there adequate SOPs to minimize the risk of multiple radiation exposures?	Click to Select				Check the procedure.	SRS No. 40, par 5.2, 5.7 BSS, par. 3.156

No.	Component	Conformance Level	Status	Comments/ planned action	Date achieved	Example of result / Type of evidence	References
5.11	Is there a specific SOP addressing non-compliance in patient exposures, including reporting and corrective actions?	Click to Select				Check the procedure.	SRS No. 40, par 5.2, 5.7 BSS, par. 3.156
5.12	Is there a specific SOP for dealing with pregnant and breast-feeding women who need a nuclear medicine examination?	Click to Select				Check the procedure.	SRS No.40,par.2.3.3,5.3.1,5.3.2 BSS, 3.151 - 3.165,3.174-6

LEGEND (Status):	Conformance
	Non-Conformance

Appendix 1.7: Checklist 6 Evaluation of Quality System

CHECKLIST 6
Evaluation of Quality System

CHECKLIST SUMMARY	N.	Applicable	Total score	% Scoring	NC
	15	0	0	0,0	0

No.	Component	Conformance Level	Status	Comments/ planned action	Date achieved	Example of result / Type of evidence	References
6.1	Are objectives defined and standards set for the NMS performance?	Click to Select				Check the established objectives and standards.	NMRM-1198, chap. 2,3 HHS No. 11, par 2.1-2.3
6.2	Are there systems for monitoring compliance with standards, with defined criteria of acceptability?	Click to Select				Check the procedures and examples of the criteria used for acceptability.	SS-GS 3.1, par. 6.50, 6.77 QUANUM, chap. 1
6.3	Does the service regularly perform self-assessments/audits?	Click to Select				Check the audit records and reports/Check the audit procedures.	SS-GS 3.1, par. 6.23-6.25 QUANUM, chap. 1
6.4	Is there a system to assess satisfaction (patient, referring physicians/third party)?	Click to Select				Check the procedures for assessing satisfaction/Check the records .	SS-GS 3.1, par. 3.6, 3.8 SS-GS 3.1, Apdx VI.2

No.	Component	Conformance Level	Status	Comments/ planned action	Date achieved	Example of result / Type of evidence	References
6.5	Is there an SOP for handling non-compliance, including recording and correction/prevention?	Click to Select				Check the SOP/Check the records/Check the list of corrections/ prevention plans.	SS-GS 3.1, par. 6.66-6.77
6.6	Is there a mechanism for monitoring data to ensure quality improvement?	Click to Select				Check the procedures describing the mechanism to ensure quality improvements.	SS-GS 3.1, par. 6.78, 6.84
6.7	Are formal quality monitoring and reviewing organized for all staff members?	Click to Select				Check the records of the monitoring and reviewing.	SS-GS-3.1, par. 6.45-6.49
6.8	Are all goods and equipment purchased according to specifications set up by all involved parties?	Click to Select				Check the purchase procedure/Review the records.	HHS No.6, par. 1.4 BSS, par. 3.153
6.9	Are technical specifications used for the acceptance testing of goods and equipment?	Click to Select				Check the procedure/ Observation on site.	http://www-pub.iaea.org/MT HHS No.1, par 4.1 HHS No.6, par. 1.4

No.	Component	Conformance Level	Status	Comments/ planned action	Date achieved	Example of result / Type of evidence	References
6.10	Is there a quality assurance programme, with regular calibration and inspection of all equipment (e.g. activity-meter, beta and gamma counters and probes, radiation survey monitors, imaging equipment, aerosol delivery systems, etc.) in accordance with the BSS, international/local standards and regulations?	Click to Select				Observation on site/ Check the procedure/ Check the records.	HHS No.1, par 4.3 HHS No.6, par. 1.8
6.11	Does a formal managerial review of the quality data exist?	Click to Select				Check the records.	SS-GS-3.1, par. 6.45-6.49
6.12	Is there a procedure to ensure that any equipment or material that fails a quality test is not used unless specifically authorized by a designated member of staff?	Click to Select				Check the records/ Check the procedures.	HHS No.1, chap. 5,6 HHS No.6, par.2.2, chap.2,3,4,5
6.13	Are action levels and responsibilities defined to determine when equipment should be repaired, replaced, or taken out of service?	Click to Select				Check the procedures/ Check the organizational chart and job descriptions.	HHS No.1, chap. 4.3.4 HHS No.6, par. 1.11, 6.2.4.6

No.	Component	Conformance Level	Status	Comments/ planned action	Date achieved	Example of result / Type of evidence	References
6.14	Are there plans for maintenance (preventive/corrective) and replacement for all major equipment?	Click to Select				Check the procedures/ Check the records.	HHS No.6, par.1.3, 1.6 HHS No.1, chap. 4.4
6.15	Does the service participate in external quality management, quality assurance/quality control (QM, QA / QC) programmes?	Click to Select				Check the records related to the external QM, QA, QC programmes/Check the audit reports.	HHS No.1, chap. 4 HHS No.6, par.6.2.4.8

LEGEND (Status):	
	Conformance
	Non-Conformance

Appendix 1.8: Checklist 7 Quality Control of Equipment (Page 1)

CHECKLIST 7
Quality Control of Equipment

CHECKLIST SUMMARY	N.	Applicable	Total score	% Scoring	NC
	17	0	0	0,0	0

No.	Component	Conformance Level	Status	Comments/ planned action	Date achieved	Example of result / Type of evidence	References
7.1	Are there written policies for specifying, procuring and testing new imaging equipment?	Click to Select				Check the procedure.	BSS, par. 3.49, 3.153 SRS No.40, par 2.3.2, 5.3.1 SS-GS 3.1, par. 5.34
7.2	Do these policies require the certification of all equipment, which will be acquired (e.g. 'CE' mark, FDA clearance or approval by a national authority)?	Click to Select				Check the procedure.	HHS No.1, par 4.1 HHS No.6, par. 1.4
7.3	Are the above policies in line with the recommendations made in the IAEA/IEC/NEMA publications?	Click to Select				Check the procedure.	HHS No.1, par 4.1 HHS No.6, par. 1.4
7.4	Is an independent assessment of the performance of the actual delivered equipment performed and documented against the specifications of the tender?	Click to Select				Check the procedure.	HHS No.1, par 4.2 HHS No.6, par. 1.7
7.5	In the case of gamma cameras: have detailed acceptance tests been performed and the most relevant planar performance parameters been recorded?	Click to Select				Observation on site/Example records/Check the procedure.	HHS No.1, chap. 5 HHS No.6, par. 2.3,4.3,5.3

No.	Component	Conformance Level	Status	Comments/ planned action	Date achieved	Example of result / Type of evidence	References
7.6	In the case of SPECT systems: have detailed acceptance tests been performed and the most relevant tomographic performance parameters been recorded?	Click to Select				Observation on site/Example records/Check the procedure.	HHS No.1,chap 5 HHS No.6, par. 2.3,4.3,5.3
7.7	In the case of PET systems: have detailed acceptance tests been performed and the most relevant emission tomographic performance parameters been recorded?	Click to Select				Observation on site/Example records/Check the procedure.	HHS No.1,chap 5 HHS No.6, par. 2.3,4.3,5.3
7.8	In the case of multimodality equipment: have detailed acceptance tests been performed for all components and the most relevant performance parameters been recorded?	Click to Select				Observation on site/Example records/Check the procedure.	HHS No.1,chap 5 HHS No.6, par. 2.3,4.3,5.3
7.9	Are the results of acceptance tests and initial performance assessment used to establish baseline reference values for routine QA/QC?	Click to Select				Observation on site/Check log book/Check the procedures.	HHS No.1,chap 5 HHS No.6, par. 2.3,4.3,5.3
7.10	Are there written SOPs available on the operation, QA/QC for all imaging equipment in clinical use?	Click to Select				Check the procedures.	HHS No.1, par 4.3 HHS No.6, par. 1.8

No.	Component	Conformance Level	Status	Comments/ planned action	Date achieved	Example of result / Type of evidence	References
7.11	Are these SOPs in agreement with the manufacturers' instruction manuals?	Click to Select				Check the procedures.	HHS No.1, par 4.1, 4.3 HHS No.6, par. 1.3, 1.4
7.12	Is there a policy on long term storage of QA/QC results?	Click to Select				Observation on site/Example records/Check the procedure.	HHS No.6, par. 2.1,4.5
7.13	Is there a regular physical inspection of the hardware including the detector head(s), collimator(s), shielding, etc.?	Click to Select				Observation on site/Example records/Check the procedure.	HHS No.1, par. 5.2.4 HHS No.6, par. 2.3.1, 4.3.1
7.14	Are the most relevant planar/SPECT parameters regularly checked, reviewed and recorded, including trend analysis: uniformity, spatial resolution, COR, SPECT performance, as well as other parameters considered critical in the internal QA programme?	Click to Select				Observation on site/Example records/Check the procedures.	HHS No.6,par.2.2, chap. 2,3,4,5

Appendix 1.9: Checklist 7 Quality Control of Equipment (Page 2)

No.	Component	Conformance Level	Status	Comments/ planned action	Date achieved	Example of result / Type of evidence	References
7.15	Are the most relevant QA/QC procedures for PET systems regularly checked, reviewed and recorded, including trend analysis: daily QC according to manufacturer's instructions, detectors normalization, 2D-3D radioactivity concentration calibration, as well as other parameters considered critical in the internal QA programme?	Click to Select				Observation on site/Example records/Check the procedures.	HHS No.1, chap. 5,6, Apdx. I
7.16	Are the most relevant QA/QC procedures for multimodality imaging systems regularly checked, reviewed - including trend analysis - and recorded : all parameters listed in 7.14 or 7.15, CT parameters (CT number, image uniformity, image noise, image artifacts, high contrast modulation), CT radiation dose, image registration and other parameters considered critical in the internal QA programme?	Click to Select				Observation on site/Example records/Check the procedures.	HHS No.1, chap. 5,6, Apdx. II
7.17	Do the QA/QC SOPs include specific instructions on corrective actions in the case of non-conforming results?	Click to Select				Check the SOPs.	HHS No.1, chap. 5,6 HHS No.6, par.2.2, chap.2,3,4,5

LEGEND (Status):	
	Conformance
	Non-Conformance

Appendix 1.10: Checklist 8 Computer Systems and Data Handling

CHECKLIST 8
Computer Systems and Data Handling

CHECKLIST SUMMARY	N.	Applicable	Total score	% Scoring	NC
	11	0	0	0,0	0

No.	Component	Conformance Level	Status	Comments/ planned action	Date achieved	Example of result / Type of evidence	References
8.1	Are there written policies available for specifying, procuring and testing of new RIS, PACS and image processing and analysis workstations?	Click to select				Check the procedure.	SRS No.40, par 2.3.2, 5.3.1 BSS, par. 3.49, 3.153
8.2	Do these policies require the certification of all equipment, which will be acquired (e.g. 'CE' mark, FDA clearance or approval by a national authority)?	Click to select				Check the procedure.	HHS No.1, par 4.1 HHS No.6, par. 1.4
8.3	Are the above policies in line with the recommendations made in the IAEA/IEC/NEMA publications?	Click to select				Check the procedure.	HHS No.1, par 4.1 HHS No.6, par. 1.4
8.4	Is an independent assessment of the performance of the actual delivered equipment performed and documented against the specifications of the tender?	Click to select				Observation on site/Example records/Check the procedure.	HHS No.1, par 4.2 HHS No.6, par. 1.7
8.5	Is there a policy for security assessment of all IT (information technology) systems (against viruses, intruders, etc.)?	Click to select				Check the procedure.	HHS No.1, par 4.3.4 HHS No.6, chap. 6

No.	Component	Conformance Level	Status	Comments/ planned action	Date achieved	Example of result / Type of evidence	References
8.6	Is there a policy for ensuring integrity, security and privacy of data, including remote access?	Click to select				Check the procedure.	HHS No.6, chap. 6
8.7	For PACS systems: is there an SOP for monitoring and correcting mismatches between image files and patient data and/or other non-conforming situations?	Click to select				Observation on site/Example records/Check the procedure.	HHS No.6, chap. 6, par.6.1.6
8.8	For PACS systems: is there an SOP for QA/QC of image display monitors?	Click to select				Observation on site/Example records/Check the procedure.	HHS No.1, par 5.3.2 HHS No.6, chap. 7
8.9	Is there a policy to ensure consistency of data acquisition, processing and analysis protocols after major software revisions, also taking into account any site customization?	Click to select				Check the procedure.	HHS No.6, chap. 6, par. 6.1.6
8.10	Is there a policy on QM of 'in-house' or non-registered software intended to support clinical use?	Click to select				Observation on site/Example records/Check the procedure.	HHS No.6, chap. 6

No.	Component	Conformance Level	Status	Comments/ planned action	Date achieved	Example of result / Type of evidence	References
8.11	Is there a policy for granting backup and maintaining patient data files?	Click to select				Check the procedure.	HHS No.6, chap. 6, par. 6.1.6

LEGEND (Status):	
	Conformance
	Non-Conformance

Appendix 1.11: Checklist 9 General Clinical Services (Page 1)

CHECKLIST 9
General Clinical Services

CHECKLIST SUMMARY	N.	Applicable	Total score	% Scoring	NC
	31	0	0	0,0	0

No.	Component	Conformance Level	Status	Comments/planned action	Date achieved	Example of result / Type of evidence	References
9,1	Are written standardized operating procedures (SOPs) based on national/international guidelines in place for all types of examinations performed ?	Click to select				Check the clinical SOPs or procedure manual.	NMRM-1198, chap. 5 SNMG EANMG HHS No. 11, Apdx.VI.1
9,2	Is a mechanism in place to regularly update internal SOPs according to national/international guidelines and medical evidence?	Click to select				Written documents describing the mechanism to update the clinical SOPs.	SS-GS 3.1, par. 2.46, 2.50 SNMG EANMG
9,3	Is there an SOP on document distribution ensuring that only the most recent manual containing the complete description of all procedures is available at all work places?	Click to select				Check the SOPs for document distribution and check the distributed documents.	SS-GS 3.1, par. 2.45-2.51 HHS No. 11, Apdx.VI.1
9,4	Is there an SOP to make sure that all staff is aware of this manual and familiarized with its use?	Click to select				Check the SOP/Observation on site.	SS-GS 3.1, par. 2.45-2.51 HHS No. 11, Apdx.VI.1
9,5	Is every request checked for justification and approved by a NM physician?	Click to select				Check some records including the authorization of the NM physician.	BSS, par. 3.150(a-c) NMRM, par.5.2-5.13 HHS No. 11, Apdx.VI.1

No.	Component	Conformance Level	Status	Comments/planned action	Date achieved	Example of result / Type of evidence	References
9,6	Are instructions in place to check for contraindications preventing the examination or parts of it?	Click to select				Check the instructions/ Observation on site.	SNMG EANMG NMRM, par.5.2-5.13 HHS No. 11, Apdx.VI.1
9,7	Are procedures in place for the correct identification of patients throughout all steps of the examination?	Click to select				Check the procedures for identifying patients during the examinations/ Observation on site.	EANMP-60, 6.2
9,8	Are instructions for patient preparation given at the time of appointment and before the examination is performed?	Click to select				Check the written instructions.	SNMP-11, V3.1.I EANMP-60, 1 SNMG EANMG
9,9	Is patients' privacy and intimacy maintained during his/her permanence in the NMS (e.g. appropriate coverage of women's chest during stress test)?	Click to select				Observation on site.	NMRM-1198, chap. 3.2.5(d)

No.	Component	Conformance Level	Status	Comments/planned action	Date achieved	Example of result / Type of evidence	References
9,10	Is a procedure in place to inquire about pregnancy and lactation before any administration of radiopharmaceuticals?	Click to select				Check the written procedure.	BSS, par. 3.156 NMRM-1198, chap. 8.6,8.7
9,11	Does every patient receive appropriate information (written/oral, according to national/local regulations) related to the examination including risk evaluation, preparation and aftercare details (if applicable) before giving informed consent?	Click to select				Check the written procedures describing the information provided to the patients.	BSS, par. 3.150d EANM-59 NMRM, par.5.2-5.13 SNM-12, par.VI.B.3-5 SNMG EANMG
9,12	Do all procedure protocols (SOPs) also include detailed information on radiopharmaceuticals, CT settings and contrast media, if applicable?	Click to select				Check the SOPs.	EANMP-57 EANMP-60, 1 SNMG EANMG NMRM, par.5.2-5.13

No.	Component	Conformance Level	Status	Comments/planned action	Date achieved	Example of result / Type of evidence	References
9,13	Is the radiopharmaceutical dose clearly identified in relation to the individual patient and traceability ensured?	Click to select				Check the instruction for dose assignments and traceability.	OGHR-1342, par.9.4.1,9.5.2 EANMP-56, chap. 8,9 SNMP-13, chap. IIIA
9,14	Are there instructions to optimize radiopharmaceutical activity according to body habitus (e.g. weight), with special attention to paediatric patients (e.g. EANM dosing card, SNM Consensus Guidelines)?	Click to select				Check the instruction for dose assignments and patient records.	OGHR-1342, par.8.5, 9.1 EANMP-56, chap. 8,9 SNMP-13, chap. III.A.8
9,15	Are procedures in place to avoid misadministration of radioactive and non-radioactive pharmaceuticals?	Click to select				Check the written procedures.	OGHR-1342, par.8.2, 8.3
9,16	Is there an SOP available for dealing with the administration of non-licensed or off label radiopharmaceuticals?	Click to select				Check the procedures.	OGHR-1342, par.8.5

Appendix 1.12: Checklist 9 General Clinical Services (Page 2)

No.	Component	Conformance Level	Status	Comments/planned action	Date achieved	Example of result / Type of evidence	References
9,17	Is an SOP in place to deal with emergency requests?	Click to select				Check the SOP.	HHS No. 11, Apdx.VI.1 SCP Emergency
9,18	Is there a process to ensure that physicians or appropriate staff are available to answer patients' questions?	Click to select				Check written documents establishing the availability of medical doctors to answer patient's questions.	SS-GS-3.1, par. 5.26
9,19	Are there SOPs for specific measures applicable to paediatric patients (e.g. inserting IV line, sedation, anesthesia, bladder catheter, pharmacological challenge, etc.)?	Click to select				Check the SOPs.	NMRM, par.5.4.1.1 EANMP: 30-39 SNMP: 32-36 BSS, par. 3.156
9,20	Is appropriate medical supervision available during nuclear medicine interventions such as diuretics, ACE inhibitors, stress testing, etc.?	Click to select				Check the clinical SOPs.	NMRM, par.3.2.7

No.	Component	Conformance Level	Status	Comments/planned action	Date achieved	Example of result / Type of evidence	References
9,21	Are procedures in place to properly address and report any adverse event?	Click to select				Check the written procedures.	NMRM, par.3.2.7
9,22	Are procedures in place to timely report any finding potentially critical for appropriate patient management to the referring physician?	Click to select				Check the written procedures.	NMRM, par.3.2.13a
9,23	Is there a policy on surveillance of patients during their presence in the nuclear medicine service, including preparation and waiting times?	Click to select				Check the written procedures/ Observation on site.	NMRM, par.3.2.7
9,24	Are a fully equipped emergency cart, oxygen and suction pump available?	Click to select				Check the available equipment.	NMRM, par.3.2.7
9,25	Is there an SOP to ensure that the emergency cart is checked and replenished on a regular basis?	Click to select				Check the SOP.	EANMP-60, 4.2.5 NMRM, par.3.2.7

No.	Component	Conformance Level	Status	Comments/planned action	Date achieved	Example of result / Type of evidence	References
9,26	Is staff trained in basic life support and use of available equipment?	Click to select				See SOP and check a record (personal card).	EANMP-60, 4.2.5 NMRM, par.3.2.7
9,27	Is there a regular update of training in basic and advanced life support, as appropriate?	Click to select				See SOP and check a record (personal card).	EANMP-60, 4.2.5 NMRM, par.2.1.2
9,28	Are procedures in place for obtaining rapid assistance in case of emergency? Are corresponding phone numbers readily displayed?	Click to select				Check the written procedures/ Observation on site.	NMRM, par.3.2.7
9,29	Is a mechanism of incident reporting and consecutive introduction of corrective actions in place?	Click to select				Check the written procedure describing the mechanism.	SS-GS 3.1, par. 2.50
9,30	Is there a procedure in place to document additional information and/or feedback received after the examination was performed/reported?	Click to select				Check the written procedure.	NMRM, par.3.2.13a
9,31	Is there an SOP to regularly review the number of and reasons for repeated NM examinations?	Click to select				Check the SOP.	HHS No. 11, Apdx.VI.1 SS-GS-3.1, par. 5.26

LEGEND (Status):		
		Conformance
		Non-Conformance

Appendix 1.13: Checklist 10.1 Assessment of Imaging Diagnostic Procedure (Page 1)

CHECKLIST 10_1

Assessment of Imaging Diagnostic Procedure

Checklist Summary	N.	Applicable	Total score	% Scoring	NC
Clinical A	4	0	0	0,0	0
Technical	6	0	0	0,0	0
Patient preparation	7	0	0	0,0	0
QA/QC	10	0	0	0,0	0
Report	3	0	0	0,0	0

Procedure: *Enter title of imaging procedure 1*

(Please select at least one clinical case for each of up to five most performed procedures. Use a new sheet for each case)

No.	Component	Conformance Level	Status	Comments/planned action	Date achieved	Example of result / Type of evidence	References
	CLINICAL						
10,1	Was the relevant clinical information available as detailed in the corresponding SOP?	Click to select				Check the records/ Check the SOPs.	NMRM-1198, chap. 3 SNMG EANMG
10,2	Were contraindications and allergies, including to contrast media (if applicable) checked for?	Click to select				Check the records.	NMRM-1198, chap. 3 SNMG EANMG
10,3	If the procedure was different from the one specified in the SOP, was the deviation noted and justified?	Click to select				Check the records/ Check the SOPs.	NMRM-1198, chap. 3 SNMG EANMG
10,4	Was the availability of other imaging (radiology and nuclear medicine) and laboratory results checked for?	Click to select				Check the records.	NMRM-1198, chap. 3 SNMG EANMG

Procedure: *Enter title of imaging procedure 1*

(Please select at least one clinical case for each of up to five most performed procedures. Use a new sheet for each case)

No.	Component	Conformance Level	Status	Comments/planned action	Date achieved	Example of result / Type of evidence	References
10,5	Scanner set up (Imaging device, collimator, energy window settings, as applicable).	Click to select				Check the records/ Check the SOPs.	NMRM-1198, chap. 3 SNMG EANMG
10,6	Radiopharmaceutical and activity administered.	Click to select				Check the records/ Check the SOPs.	EUROATOM, Art. 55 (4) BSS, par. 3.184(c)
10,7	If contrast medium was used: type, concentration, administration route, injection speed if IV.	Click to select				Check the records / Check the SOPs.	NMRM-1198, chap. 3 SNMG EANMG
10,8	Were acquisition parameters (time from administration, positioning, acquisition mode, matrix) concordant to the SOP?	Click to select				Check the records/ Check the SOPs.	NMRM-1198, chap. 3 SNMG EANMG

Procedure: *Enter title of imaging procedure 1*

(Please select at least one clinical case for each of up to five most performed procedures. Use a new sheet for each case)

No.	Component	Conformance Level	Status	Comments/planned action	Date achieved	Example of result / Type of evidence	References
10,9	CT parameters, if applicable.	Click to select				Check the records / Check the SOPs.	NMRM-1198, chap. 3 SNMG EANMG
10,10	Data processing and archiving.	Click to select				Check the records / Check the SOPs.	NMRM-1198, chap. 3 SNMG EANMG
	PATIENT PREPARATION: Check if done according to SOP						
10,11	Patient identification.	Click to select				Check the records/ Check the SOPs.	EANMP-60, 6.2
10,12	Current medication/date of last chemo/date of end of radiotherapy.	Click to select				Check the records/ Check the SOPs.	NMRM-1198, chap. 3 SNMG EANMG

Procedure: *Enter title of imaging procedure 1*

(Please select at least one clinical case for each of up to five most performed procedures. Use a new sheet for each case)

No.	Component	Conformance Level	Status	Comments/planned action	Date achieved	Example of result / Type of evidence	References
10,13	Patient condition and/or treatment-related interference with the procedure? If yes, note in the comments section.	Click to select				Check the records/ Check the SOPs.	NMRM-1198, chap. 3 SNMG EANMG
10,14	Study preparation.	Click to select				Check the records/ Check the SOPs.	BSS, par. 3.150d NMRM, par.5.2-5.13
10,15	Exclusion of pregnancy, information on lactation and counselling, if applicable.	Click to select				Check the records/ Check the SOPs.	BSS, par. 3.156 NMRM-1198, chap. 3.2.5
10,16	For paediatric patients: dose adjustment (radiopharmaceuticals, other medication), sedation, etc.	Click to select				Check the records/ Check the SOPs.	OGHR-1342, par.8.5, 9.1 EANMP-56, chap. 8.9

Appendix 1.14: Checklist 10.1 Assessment of Imaging Diagnostic Procedure (Page 2)

Procedure: *Enter title of imaging procedure 1*

(Please select at least one clinical case for each of up to five most performed procedures. Use a new sheet for each case)

No.	Component	Conformance Level	Status	Comments/planned action	Date achieved	Example of result / Type of evidence	References
10,17	Patient positioning and containment.	Click to select				Check the records/ Check the SOPs.	NMRM-1198, chap. 3 SNMG EANMG
	QA/QC: Check if done according to SOP						
10,18	QC of the radiopharmaceutical(s).	Click to select				Check the records/ Check the SOPs.	OGHR-1342, chap. 7
10,19	Documentation of QC in case of external procurement of radiopharmaceutical.	Click to select				Check the records/ Check the SOPs.	OGHR-1342, chap.7
10,20	Latest QC of imaging equipment relevant for the specific examination.	Click to select				Check the records/ Check the SOPs.	HHS No.1, par 4.3 HHS No.6, par. 1.8

Procedure: *Enter title of imaging procedure 1*

(Please select at least one clinical case for each of up to five most performed procedures. Use a new sheet for each case)

No.	Component	Conformance Level	Status	Comments/planned action	Date achieved	Example of result / Type of evidence	References
10,21	Check and account for extravasation (infiltration) at the injection site.	Click to select				Check the records/ Check the SOPs.	EANMP-60, 6.2
10,22	QC of processing parameters and analysis.	Click to select				Check the records/ Check the SOPs.	NMRM-1198, chap. 3 SNMG EANMG
10,23	Overall quality of images, e.g. patient movement, regions of interest, gating, etc.	Click to select				Check the records/ Check the SOPs.	EANMP-60, 6.2
10,24	Overall quality and adequacy of images for distribution to the referring physician.	Click to select				Check the records/ Check the SOPs.	NMRM-1198, chap. 3 SNMG EANMG

Procedure: *Enter title of imaging procedure 1*

(Please select at least one clinical case for each of up to five most performed procedures. Use a new sheet for each case)

No.	Component	Conformance Level	Status	Comments/planned action	Date achieved	Example of result / Type of evidence	References
10,25	Traceability of all patient-related data, e.g. radiopharmaceutical, administered activity and injection site, acquisition parameters, name of technologist and MD in charge.	Click to select				Observation on site/ Check all the records showing traceability.	SNMP-13, chap. IIIA EANMP-56, chap. 8,9
10,26	Filing of batch number, dosing and time of administration of any study-related pharmaceutical.	Click to select				Check the records.	OGHR-1342, 7.3 EANMP-60, 7.6
10,27	Handling and documentation of any adverse event or other incident (patient-related or not).	Click to select				Check the records.	EANMP-60, 8.5
	REPORTING AND FOLLOW-UP						
10,28	Was the report structured as requested in the SOP?	Click to select				Check the records/ Check the SOPs.	NMRM, chap. 1

Procedure: *Enter title of imaging procedure 1*

(Please select at least one clinical case for each of up to five most performed procedures. Use a new sheet for each case)

No.	Component	Conformance Level	Status	Comments/planned action	Date achieved	Example of result / Type of evidence	References
10,29	Does the final report address the clinical question?	Click to select				Check the records.	NMRM-1198, 3.2.13, 5
10,30	Was any feedback received after reporting properly documented and managed?	Click to select				Check the records.	NMRM-1198, 3.2.13, 5

LEGEND (Status):	
	Conformance
	Non-Conformance

Appendix 1.15: Checklist 10.2 Assessment of Imaging Diagnostic Procedure (Page 1)

CHECKLIST 10_2

Assessment of Imaging Diagnostic Procedure

Checklist Summary	N.	Applicable	Total score	% Scoring	NC
Clinical A	4	0	0	0,0	0
Technical	6	0	0	0,0	0
Patient preparation	7	0	0	0,0	0
QA/QC	10	0	0	0,0	0
Report	3	0	0	0,0	0

Procedure: *Enter title of imaging procedure 2*

(Please select at least one clinical case for each of up to five most performed procedures. Use a new sheet for each case)

No.	Component	Conformance Level	Status	Comments/planned action	Date achieved	Example of result / Type of evidence	References
	CLINICAL						
10,1	Was the relevant clinical information available as detailed in the corresponding SOP?	Click to select				Check the records/ Check the SOPs.	NMRM-1198, chap. 3 SNMG EANMG
10,2	Were contraindications and allergies, including to contrast media (if applicable) checked for?	Click to select				Check the records.	NMRM-1198, chap. 3 SNMG EANMG
10,3	If the procedure was different from the one specified in the SOP, was the deviation noted and justified?	Click to select				Check the records/ Check the SOPs.	NMRM-1198, chap. 3 SNMG EANMG
10,4	Was the availability of other imaging (radiology and nuclear medicine) and laboratory results checked for?	Click to select				Check the records.	NMRM-1198, chap. 3 SNMG EANMG

Procedure: *Enter title of imaging procedure 2*

(Please select at least one clinical case for each of up to five most performed procedures. Use a new sheet for each case)

No.	Component	Conformance Level	Status	Comments/planned action	Date achieved	Example of result / Type of evidence	References
	TECHNICAL/PROCEDURE: Check if done according to SOP						
10,5	Scanner set up (Imaging device, collimator, energy window settings, as applicable).	Click to select				Check the records/ Check the SOPs.	NMRM-1198, chap. 3 SNMG EANMG
10,6	Radiopharmaceutical and activity administered.	Click to select				Check the records/ Check the SOPs.	EUROATOM, Art. 55 (4) BSS, par. 3.184(c)
10,7	If contrast medium was used: type, concentration, administration route, injection speed if IV.	Click to select				Check the records/ Check the SOPs.	NMRM-1198, chap. 3 SNMG EANMG
10,8	Were acquisition parameters (time from administration, positioning, acquisition mode, matrix) concordant to the SOP?	Click to select				Check the records/ Check the SOPs.	NMRM-1198, chap. 3 SNMG EANMG

Procedure: *Enter title of imaging procedure 2*

(Please select at least one clinical case for each of up to five most performed procedures. Use a new sheet for each case)

No.	Component	Conformance Level	Status	Comments/planned action	Date achieved	Example of result / Type of evidence	References
10,9	CT parameters, if applicable.	Click to select				Check the records/ Check the SOPs.	NMRM-1198, chap. 3 SNMG EANMG
10,10	Data processing and archiving.	Click to select				Check the records/ Check the SOPs.	NMRM-1198, chap. 3 SNMG EANMG
	PATIENT PREPARATION: Check if done according to SOP						
10,11	Patient identification.	Click to select				Check the records/ Check the SOPs.	EANMP-60, 6.2
10,12	Current medication/date of last chemo/ date of end of radiotherapy.	Click to select				Check the records/ Check the SOPs.	NMRM-1198, chap. 3 SNMG EANMG

Procedure: *Enter title of imaging procedure 2*

(Please select at least one clinical case for each of up to five most performed procedures. Use a new sheet for each case)

No.	Component	Conformance Level	Status	Comments/planned action	Date achieved	Example of result / Type of evidence	References
10,13	Patient condition and/or treatment-related interference with the procedure? If yes, note in the comments section.	Click to select				Check the records/ Check the SOPs.	NMRM-1198, chap. 3 SNMG EANMG
10,14	Study preparation.	Click to select				Check the records/ Check the SOPs.	BSS, par. 3.150d NMRM, par.5.2-5.13
10,15	Exclusion of pregnancy, information on lactation and counselling, if applicable.	Click to select				Check the records/ Check the SOPs.	BSS, par. 3.156 NMRM-1198, chap. 3.2.5
10,16	For paediatric patients: dose adjustment (radiopharmaceuticals, other medication), sedation, etc.	Click to select				Check the records/ Check the SOPs.	OGHR-1342, par.8.5, 9.1 EANMP-56, chap. 8.9

Appendix 1.16: Checklist 10.2 Assessment of Imaging Diagnostic Procedure (Page 2)

Procedure: *Enter title of imaging procedure 2*

(Please select at least one clinical case for each of up to five most performed procedures. Use a new sheet for each case)

No.	Component	Conformance Level	Status	Comments/planned action	Date achieved	Example of result / Type of evidence	References
10,17	Patient positioning and containment.	Click to select				Check the records/ Check the SOPs.	NMRM-1198, chap. 3 SNMG EANMG
	QA/QC: Check if done according to SOP						
10,18	QC of the radiopharmaceutical(s).	Click to select				Check the records/ Check the SOPs.	OGHR-1342, chap. 7
10,19	Documentation of QC in case of external procurement of radiopharmaceutical.	Click to select				Check the records/ Check the SOPs.	OGHR-1342, chap.7
10,20	Latest QC of imaging equipment relevant for the specific examination.	Click to select				Check the records/ Check the SOPs.	HHS No.1, par 4.3 HHS No.6, par. 1.8

Procedure: *Enter title of imaging procedure 2*

(Please select at least one clinical case for each of up to five most performed procedures. Use a new sheet for each case)

No.	Component	Conformance Level	Status	Comments/planned action	Date achieved	Example of result / Type of evidence	References
10,21	Check and account for extravasation (infiltration) at the injection site.	Click to select				Check the records/ Check the SOPs.	EANMP-60, 6.2
10,22	QC of processing parameters and analysis.	Click to select				Check the records/ Check the SOPs.	NMRM-1198, chap. 3 SNMG EANMG
10,23	Overall quality of images, e.g. patient movement, regions of interest, gating, etc.	Click to select				Check the records/ Check the SOPs.	EANMP-60, 6.2
10,24	Overall quality and adequacy of images for distribution to the referring physician.	Click to select				Check the records/ Check the SOPs.	NMRM-1198, chap. 3 SNMG EANMG

Procedure: *Enter title of imaging procedure 2*

(Please select at least one clinical case for each of up to five most performed procedures. Use a new sheet for each case)

No.	Component	Conformance Level	Status	Comments/planned action	Date achieved	Example of result / Type of evidence	References
10,25	Traceability of all patient-related data, e.g. radiopharmaceutical, administered activity and injection site, acquisition parameters, name of technologist and MD in charge.	Click to select				Observation on site/ Check all the records showing traceability.	SNMP-13, chap. IIIA EANMP-56, chap. 8,9
10,26	Filing of batch number, dosing and time of administration of any study-related pharmaceutical.	Click to select				Check the records.	OGHR-1342, 7.3 EANMP-60, 7.6
10,27	Handling and documentation of any adverse event or other incident (patient-related or not).	Click to select				Check the records.	EANMP-60, 8.5
	REPORTING AND FOLLOW-UP						
10,28	Was the report structured as requested in the SOP?	Click to select				Check the records/ Check the SOPs.	NMRM, chap. 1

Procedure: *Enter title of imaging procedure 2*

(Please select at least one clinical case for each of up to five most performed procedures. Use a new sheet for each case)

No.	Component	Conformance Level	Status	Comments/planned action	Date achieved	Example of result / Type of evidence	References
10,29	Does the final report address the clinical question?	Click to select				Check the records.	NMRM-1198, 3.2.13, 5
10,30	Was any feedback received after reporting properly documented and managed?	Click to select				Check the records.	NMRM-1198, 3.2.13, 5

LEGEND (Status):		
		Conformance
		Non-Conformance

Appendix 1.17: Checklist 10.3 Assessment of Imaging Diagnostic Procedure (Page 1)

CHECKLIST 10_3

Assessment of Imaging Diagnostic Procedure

Checklist Summary	N.	Applicable	Total score	% Scoring	NC
Clinical A	4	0	0	0,0	0
Technical	6	0	0	0,0	0
Patient preparation	7	0	0	0,0	0
QA/QC	10	0	0	0,0	0
Report	3	0	0	0,0	0

Procedure: *Enter title of imaging procedure 3*

(Please select at least one clinical case for each of up to five most performed procedures. Use a new sheet for each case)

No.	Component	Conformance Level	Status	Comments/planned action	Date achieved	Example of result / Type of evidence	References
	CLINICAL						
10,1	Was the relevant clinical information available as detailed in the corresponding SOP?	Click to select				Check the records/ Check the SOPs.	NMRM-1198, chap. 3 SNMG EANMG
10,2	Were contraindications and allergies, including to contrast media (if applicable) checked for?	Click to select				Check the records.	NMRM-1198, chap. 3 SNMG EANMG
10,3	If the procedure was different from the one specified in the SOP, was the deviation noted and justified?	Click to select				Check the records/ Check the SOPs.	NMRM-1198, chap. 3 SNMG EANMG
10,4	Was the availability of other imaging (radiology and nuclear medicine) and laboratory results checked for?	Click to select				Check the records.	NMRM-1198, chap. 3 SNMG EANMG

Procedure: *Enter title of imaging procedure 3*

(Please select at least one clinical case for each of up to five most performed procedures. Use a new sheet for each case)

No.	Component	Conformance Level	Status	Comments/planned action	Date achieved	Example of result / Type of evidence	References
10,5	Scanner set up (Imaging device, collimator, energy window settings, as applicable).	Click to select				Check the records/ Check the SOPs.	NMRM-1198, chap. 3 SNMG EANMG
10,6	Radiopharmaceutical and activity administered.	Click to select				Check the records/ Check the SOPs.	EUROATOM, Art. 55 (4) BSS, par. 3.184(c)
10,7	If contrast medium was used: type, concentration, administration route, injection speed if IV.	Click to select				Check the records/ Check the SOPs.	NMRM-1198, chap. 3 SNMG EANMG
10,8	Were acquisition parameters (time from administration, positioning, acquisition mode, matrix) concordant to the SOP?	Click to select				Check the records/ Check the SOPs.	NMRM-1198, chap. 3 SNMG EANMG
10,9	CT parameters, if applicable.					Check the records/	

Procedure: *Enter title of imaging procedure 3*

(Please select at least one clinical case for each of up to five most performed procedures. Use a new sheet for each case)

No.	Component	Conformance Level	Status	Comments/planned action	Date achieved	Example of result / Type of evidence	References
10,9	CT parameters, if applicable.	Click to select				Check the records/ Check the SOPs.	NMRM-1198, chap. 3 SNMG EANMG
10,10	Data processing and archiving.	Click to select				Check the records/ Check the SOPs.	NMRM-1198, chap. 3 SNMG EANMG
	PATIENT PREPARATION: Check if done according to SOP						
10,11	Patient identification.	Click to select				Check the records/ Check the SOPs.	EANMP-60, 6.2
10,12	Current medication/date of last chemo/date of end of radiotherapy.	Click to select				Check the records/ Check the SOPs.	NMRM-1198, chap. 3 SNMG EANMG

Procedure: *Enter title of imaging procedure 3*

(Please select at least one clinical case for each of up to five most performed procedures. Use a new sheet for each case)

No.	Component	Conformance Level	Status	Comments/planned action	Date achieved	Example of result / Type of evidence	References
10,13	Patient condition and/or treatment-related interference with the procedure? If yes, note in the comments section.	Click to select				Check the records/ Check the SOPs.	NMRM-1198, chap. 3 SNMG EANMG
10,14	Study preparation.	Click to select				Check the records/ Check the SOPs.	BSS, par. 3.150d NMRM, par.5.2-5.13
10,15	Exclusion of pregnancy, information on lactation and counselling, if applicable.	Click to select				Check the records/ Check the SOPs.	BSS, par. 3.156 NMRM-1198, chap. 3.2.5
10,16	For paediatric patients: dose adjustment (radiopharmaceuticals, other medication), sedation, etc.	Click to select				Check the records/ Check the SOPs.	OGHR-1342, par.8.5, 9.1 EANMP-56, chap. 8.9

Appendix 1.18: Checklist 10.3 Assessment of Imaging Diagnostic Procedure (Page 2)

Procedure: *Enter title of imaging procedure 3*

(Please select at least one clinical case for each of up to five most performed procedures. Use a new sheet for each case)

No.	Component	Conformance Level	Status	Comments/planned action	Date achieved	Example of result / Type of evidence	References
10,17	Patient positioning and containment.	Click to select				Check the records/ Check the SOPs.	NMRM-1198, chap. 3 SNMG EANMG
	QA/QC: Check if done according to SOP						
10,18	QC of the radiopharmaceutical(s).	Click to select				Check the records/ Check the SOPs.	OGHR-1342, chap. 7
10,19	Documentation of QC in case of external procurement of radiopharmaceutical.	Click to select				Check the records/ Check the SOPs.	OGHR-1342, chap.7
10,20	Latest QC of imaging equipment relevant for the specific examination.	Click to select				Check the records/ Check the SOPs.	HHS No.1, par 4.3 HHS No.6, par. 1.8

Procedure: *Enter title of imaging procedure 3*

(Please select at least one clinical case for each of up to five most performed procedures. Use a new sheet for each case)

No.	Component	Conformance Level	Status	Comments/planned action	Date achieved	Example of result / Type of evidence	References
10,21	Check and account for extravasation (infiltration) at the injection site.	Click to select				Check the records/ Check the SOPs.	EANMP-60, 6.2
10,22	QC of processing parameters and analysis.	Click to select				Check the records/ Check the SOPs.	NMRM-1198, chap. 3 SNMG EANMG
10,23	Overall quality of images, e.g. patient movement, regions of interest, gating, etc.	Click to select				Check the records/ Check the SOPs.	EANMP-60, 6.2
10,24	Overall quality and adequacy of images for distribution to the referring physician.	Click to select				Check the records/ Check the SOPs.	NMRM-1198, chap. 3 SNMG EANMG

Procedure: *Enter title of imaging procedure 3*

(Please select at least one clinical case for each of up to five most performed procedures. Use a new sheet for each case)

No.	Component	Conformance Level	Status	Comments/planned action	Date achieved	Example of result / Type of evidence	References
10,25	Traceability of all patient-related data, e.g. radiopharmaceutical, administered activity and injection site, acquisition parameters, name of technologist and MD in charge.	Click to select				Observation on site/ Check all the records showing traceability.	SNMP-13, chap. IIIA EANMP-56, chap. 8,9
10,26	Filing of batch number, dosing and time of administration of any study-related pharmaceutical.	Click to select				Check the records.	OGHR-1342, 7.3 EANMP-60, 7.6
10,27	Handling and documentation of any adverse event or other incident (patient-related or not).	Click to select				Check the records.	EANMP-60, 8.5
	REPORTING AND FOLLOW-UP						
10,28	Was the report structured as requested in the SOP?	Click to select				Check the records/ Check the SOPs.	NMRM, chap. 1

Procedure: *Enter title of imaging procedure 3*

(Please select at least one clinical case for each of up to five most performed procedures. Use a new sheet for each case)

No.	Component	Conformance Level	Status	Comments/planned action	Date achieved	Example of result / Type of evidence	References
10,29	Does the final report address the clinical question?	Click to select				Check the records.	NMRM-1198, 3.2.13, 5
10,30	Was any feedback received after reporting properly documented and managed?	Click to select				Check the records.	NMRM-1198, 3.2.13, 5

LEGEND (Status):		
		Conformance
		Non-Conformance

Appendix 1.19: Checklist 10.4 Assessment of Imaging Diagnostic Procedure (Page 1)

CHECKLIST 10_4

Assessment of Imaging Diagnostic Procedure

Checklist Summary	N.	Applicable	Total score	% Scoring	NC
Clinical A	4	0	0	0,0	0
Technical	6	0	0	0,0	0
Patient preparation	7	0	0	0,0	0
QA/QC	10	0	0	0,0	0
Report	3	0	0	0,0	0

Procedure: *Enter title of imaging procedure 4*

(Please select at least one clinical case for each of up to five most performed procedures. Use a new sheet for each case)

No.	Component	Conformance Level	Status	Comments/planned action	Date achieved	Example of result / Type of evidence	References
	CLINICAL						
10,1	Was the relevant clinical information available as detailed in the corresponding SOP?	Click to select				Check the records/ Check the SOPs.	NMRM-1198, chap. 3 SNMG EANMG
10,2	Were contraindications and allergies, including to contrast media (if applicable) checked for?	Click to select				Check the records.	NMRM-1198, chap. 3 SNMG EANMG
10,3	If the procedure was different from the one specified in the SOP, was the deviation noted and justified?	Click to select				Check the records/ Check the SOPs.	NMRM-1198, chap. 3 SNMG EANMG
10,4	Was the availability of other imaging (radiology and nuclear medicine) and laboratory results checked for?	Click to select				Check the records.	NMRM-1198, chap. 3 SNMG EANMG

Procedure: *Enter title of imaging procedure 4*

(Please select at least one clinical case for each of up to five most performed procedures. Use a new sheet for each case)

No.	Component	Conformance Level	Status	Comments/planned action	Date achieved	Example of result / Type of evidence	References
	TECHNICAL/PROCEDURE: Check if done according to SOP						
10,5	Scanner set up (Imaging device, collimator, energy window settings, as applicable).	Click to select				Check the records/ Check the SOPs.	NMRM-1198, chap. 3 SNMG EANMG
10,6	Radiopharmaceutical and activity administered.	Click to select				Check the records/ Check the SOPs.	EUROATOM, Art. 55 (4) BSS, par. 3.184(c)
10,7	If contrast medium was used: type, concentration, administration route, injection speed if IV.	Click to select				Check the records/ Check the SOPs.	NMRM-1198, chap. 3 SNMG EANMG
10,8	Were acquisition parameters (time from administration, positioning, acquisition mode, matrix) concordant to the SOP?	Click to select				Check the records/ Check the SOPs.	NMRM-1198, chap. 3 SNMG EANMG

Procedure: *Enter title of imaging procedure 4*

(Please select at least one clinical case for each of up to five most performed procedures. Use a new sheet for each case)

No.	Component	Conformance Level	Status	Comments/planned action	Date achieved	Example of result / Type of evidence	References
10,9	CT parameters, if applicable.	Click to select				Check the records/ Check the SOPs.	NMRM-1198, chap. 3 SNMG EANMG
10,10	Data processing and archiving.	Click to select				Check the records/ Check the SOPs.	NMRM-1198, chap. 3 SNMG EANMG
	PATIENT PREPARATION: Check if done according to SOP						
10,11	Patient identification.	Click to select				Check the records/ Check the SOPs.	EANMP-60, 6.2
10,12	Current medication/date of last chemo/date of end of radiotherapy.	Click to select				Check the records/ Check the SOPs.	NMRM-1198, chap. 3 SNMG EANMG

Procedure: *Enter title of imaging procedure 4*

(Please select at least one clinical case for each of up to five most performed procedures. Use a new sheet for each case)

No.	Component	Conformance Level	Status	Comments/planned action	Date achieved	Example of result / Type of evidence	References
10,13	Patient condition and/or treatment-related interference with the procedure? If yes, note in the comments section.	Click to select				Check the records/ Check the SOPs.	NMRM-1198, chap. 3 SNMG EANMG
10,14	Study preparation.	Click to select				Check the records/ Check the SOPs.	BSS, par. 3.150d NMRM, par.5.2-5.13
10,15	Exclusion of pregnancy, information on lactation and counselling, if applicable.	Click to select				Check the records/ Check the SOPs.	BSS, par. 3.156 NMRM-1198, chap. 3.2.5
10,16	For paediatric patients: dose adjustment (radiopharmaceuticals, other medication), sedation, etc.	Click to select				Check the records/ Check the SOPs.	OGHR-1342, par.8.5, 9.1 EANMP-56, chap. 8.9

Appendix 1.20: Checklist 10.4 Assessment of Imaging Diagnostic Procedure (Page 2)

Procedure: *Enter title of imaging procedure 4*

(Please select at least one clinical case for each of up to five most performed procedures. Use a new sheet for each case)

No.	Component	Conformance Level	Status	Comments/planned action	Date achieved	Example of result / Type of evidence	References
10,17	Patient positioning and containment.	Click to select				Check the records/ Check the SOPs.	NMRM-1198, chap. 3 SNMG EANMG
	QA/QC: Check if done according to SOP						
10,18	QC of the radiopharmaceutical(s).	Click to select				Check the records/ Check the SOPs.	OGHR-1342, chap. 7
10,19	Documentation of QC in case of external procurement of radiopharmaceutical.	Click to select				Check the records/ Check the SOPs.	OGHR-1342, chap.7
10,20	Latest QC of imaging equipment relevant for the specific examination.	Click to select				Check the records/ Check the SOPs.	HHS No.1, par 4.3 HHS No.6, par. 1.8

Procedure: *Enter title of imaging procedure 4*

(Please select at least one clinical case for each of up to five most performed procedures. Use a new sheet for each case)

No.	Component	Conformance Level	Status	Comments/planned action	Date achieved	Example of result / Type of evidence	References
10,21	Check and account for extravasation (infiltration) at the injection site.	Click to select				Check the records/ Check the SOPs.	EANMP-60, 6.2
10,22	QC of processing parameters and analysis.	Click to select				Check the records/ Check the SOPs.	NMRM-1198, chap. 3 SNMG EANMG
10,23	Overall quality of images, e.g. patient movement, regions of interest, gating, etc.	Click to select				Check the records/ Check the SOPs.	EANMP-60, 6.2
10,24	Overall quality and adequacy of images for distribution to the referring physician.	Click to select				Check the records/ Check the SOPs.	NMRM-1198, chap. 3 SNMG EANMG

Procedure: *Enter title of imaging procedure 4*

(Please select at least one clinical case for each of up to five most performed procedures. Use a new sheet for each case)

No.	Component	Conformance Level	Status	Comments/planned action	Date achieved	Example of result / Type of evidence	References
10,25	Traceability of all patient-related data, e.g. radiopharmaceutical, administered activity and injection site, acquisition parameters, name of technologist and MD in charge.	Click to select				Observation on site/ Check all the records showing traceability.	SNMP-13, chap. IIIA EANMP-56, chap. 8,9
10,26	Filing of batch number, dosing and time of administration of any study-related pharmaceutical.	Click to select				Check the records.	OGHR-1342, 7.3 EANMP-60, 7.6
10,27	Handling and documentation of any adverse event or other incident (patient-related or not).	Click to select				Check the records.	EANMP-60, 8.5
	REPORTING AND FOLLOW-UP						
10,28	Was the report structured as requested in the SOP?	Click to select				Check the records/ Check the SOPs.	NMRM, chap. 1

Procedure: *Enter title of imaging procedure 4*

(Please select at least one clinical case for each of up to five most performed procedures. Use a new sheet for each case)

No.	Component	Conformance Level	Status	Comments/planned action	Date achieved	Example of result / Type of evidence	References
10,29	Does the final report address the clinical question?	Click to select				Check the records.	NMRM-1198, 3.2.13, 5
10,30	Was any feedback received after reporting properly documented and managed?	Click to select				Check the records.	NMRM-1198, 3.2.13, 5

LEGEND (Status):		
		Conformance
		Non-Conformance

Appendix 1.21: Checklist 10.5 Assessment of Imaging Diagnostic Procedure (Page 1)

CHECKLIST 10_5

Assessment of Imaging Diagnostic Procedure

Checklist Summary	N.	Applicable	Total score	% Scoring	NC
Clinical A	4	0	0	0,0	0
Technical	6	0	0	0,0	0
Patient preparation	7	0	0	0,0	0
QA/QC	10	0	0	0,0	0
Report	3	0	0	0,0	0

Procedure: *Enter title of imaging procedure 5*

(Please select at least one clinical case for each of up to five most performed procedures. Use a new sheet for each case)

No.	Component	Conformance Level	Status	Comments/planned action	Date achieved	Example of result / Type of evidence	References
	CLINICAL						
10,1	Was the relevant clinical information available as detailed in the corresponding SOP?	Click to select				Check the records/ Check the SOPs.	NMRM-1198, chap. 3 SNMG EANMG
10,2	Were contraindications and allergies, including to contrast media (if applicable) checked for?	Click to select				Check the records.	NMRM-1198, chap. 3 SNMG EANMG
10,3	If the procedure was different from the one specified in the SOP, was the deviation noted and justified?	Click to select				Check the records/ Check the SOPs.	NMRM-1198, chap. 3 SNMG EANMG
10,4	Was the availability of other imaging (radiology and nuclear medicine) and laboratory results checked for?	Click to select				Check the records.	NMRM-1198, chap. 3 SNMG EANMG

Procedure: *Enter title of imaging procedure 5*

(Please select at least one clinical case for each of up to five most performed procedures. Use a new sheet for each case)

No.	Component	Conformance Level	Status	Comments/planned action	Date achieved	Example of result / Type of evidence	References
10,5	Scanner set up (Imaging device, collimator, energy window settings, as applicable).	Click to select				Check the records/ Check the SOPs.	NMRM-1198, chap. 3 SNMG EANMG
10,6	Radiopharmaceutical and activity administered.	Click to select				Check the records/ Check the SOPs.	EUROATOM, Art. 55 (4) BSS, par. 3.184(c)
10,7	If contrast medium was used: type, concentration, administration route, injection speed if IV.	Click to select				Check the records/ Check the SOPs.	NMRM-1198, chap. 3 SNMG EANMG
10,8	Were acquisition parameters (time from administration, positioning, acquisition mode, matrix) concordant to the SOP?	Click to select				Check the records/ Check the SOPs.	NMRM-1198, chap. 3 SNMG EANMG

Procedure: *Enter title of imaging procedure 5*

(Please select at least one clinical case for each of up to five most performed procedures. Use a new sheet for each case)

No.	Component	Conformance Level	Status	Comments/planned action	Date achieved	Example of result / Type of evidence	References
10,9	CT parameters, if applicable.	Click to select				Check the records/ Check the SOPs.	NMRM-1198, chap. 3 SNMG EANMG
10,10	Data processing and archiving.	Click to select				Check the records/ Check the SOPs.	NMRM-1198, chap. 3 SNMG EANMG
	PATIENT PREPARATION: Check if done according to SOP						
10,11	Patient identification.	Click to select				Check the records/ Check the SOPs.	EANMP-60, 6.2
10,12	Current medication/date of last chemo/date of end of radiotherapy.	Click to select				Check the records/ Check the SOPs.	NMRM-1198, chap. 3 SNMG EANMG

Procedure: *Enter title of imaging procedure 5*

(Please select at least one clinical case for each of up to five most performed procedures. Use a new sheet for each case)

No.	Component	Conformance Level	Status	Comments/planned action	Date achieved	Example of result / Type of evidence	References
10,13	Patient condition and/or treatment-related interference with the procedure? If yes, note in the comments section.	Click to select				Check the records/ Check the SOPs.	NMRM-1198, chap. 3 SNMG EANMG
10,14	Study preparation.	Click to select				Check the records/ Check the SOPs.	BSS, par. 3.150d NMRM, par.5.2-5.13
10,15	Exclusion of pregnancy, information on lactation and counselling, if applicable.	Click to select				Check the records/ Check the SOPs.	BSS, par. 3.156 NMRM-1198, chap. 3.2.5
10,16	For paediatric patients: dose adjustment (radiopharmaceuticals, other medication), sedation, etc.	Click to select				Check the records/ Check the SOPs.	OGHR-1342, par.8.5, 9.1 EANMP-56, chap. 8.9

Appendix 1.22: Checklist 10.5 Assessment of Imaging Diagnostic Procedure (Page 2)

Procedure: *Enter title of imaging procedure 5*

(Please select at least one clinical case for each of up to five most performed procedures. Use a new sheet for each case)

No.	Component	Conformance Level	Status	Comments/planned action	Date achieved	Example of result / Type of evidence	References
10,17	Patient positioning and containment.	Click to select				Check the records/ Check the SOPs.	NMRM-1198, chap. 3 SNMG EANMG
	QA/QC: Check if done according to SOP						
10,18	QC of the radiopharmaceutical(s).	Click to select				Check the records/ Check the SOPs.	OGHR-1342, chap. 7
10,19	Documentation of QC in case of external procurement of radiopharmaceutical.	Click to select				Check the records/ Check the SOPs.	OGHR-1342, chap.7
10,20	Latest QC of imaging equipment relevant for the specific examination.	Click to select				Check the records/ Check the SOPs.	HHS No.1, par 4.3 HHS No.6, par. 1.8

Procedure: *Enter title of imaging procedure 5*

(Please select at least one clinical case for each of up to five most performed procedures. Use a new sheet for each case)

No.	Component	Conformance Level	Status	Comments/planned action	Date achieved	Example of result / Type of evidence	References
10,21	Check and account for extravasation (infiltration) at the injection site.	Click to select				Check the records/ Check the SOPs.	EANMP-60, 6.2
10,22	QC of processing parameters and analysis.	Click to select				Check the records/ Check the SOPs.	NMRM-1198, chap. 3 SNMG EANMG
10,23	Overall quality of images, e.g. patient movement, regions of interest, gating, etc.	Click to select				Check the records/ Check the SOPs.	EANMP-60, 6.2
10,24	Overall quality and adequacy of images for distribution to the referring physician.	Click to select				Check the records/ Check the SOPs.	NMRM-1198, chap. 3 SNMG EANMG

Procedure: *Enter title of imaging procedure 5*

(Please select at least one clinical case for each of up to five most performed procedures. Use a new sheet for each case)

No.	Component	Conformance Level	Status	Comments/planned action	Date achieved	Example of result / Type of evidence	References
10,25	Traceability of all patient-related data, e.g. radiopharmaceutical, administered activity and injection site, acquisition parameters, name of technologist and MD in charge.	Click to select				Observation on site/ Check all the records showing traceability.	SNMP-13, chap. IIIA EANMP-56, chap. 8,9
10,26	Filing of batch number, dosing and time of administration of any study-related pharmaceutical.	Click to select				Check the records.	OGHR-1342, 7.3 EANMP-60, 7.6
10,27	Handling and documentation of any adverse event or other incident (patient-related or not).	Click to select				Check the records.	EANMP-60, 8.5
	REPORTING AND FOLLOW-UP						
10,28	Was the report structured as requested in the SOP?	Click to select				Check the records/ Check the SOPs.	NMRM, chap. 1

Procedure: *Enter title of imaging procedure 5*

(Please select at least one clinical case for each of up to five most performed procedures. Use a new sheet for each case)

No.	Component	Conformance Level	Status	Comments/planned action	Date achieved	Example of result / Type of evidence	References
10,29	Does the final report address the clinical question?	Click to select				Check the records.	NMRM-1198, 3.2.13, 5
10,30	Was any feedback received after reporting properly documented and managed?	Click to select				Check the records.	NMRM-1198, 3.2.13, 5

LEGEND (Status):	
	Conformance
	Non-Conformance

Appendix 1.23: Overall Score of Imaging Diagnostic Procedures

OVERALL SCORE OF IMAGING DIAGNOSTIC PROCEDURES

Based on the evaluation of spreadsheets #10.1 through 10.5 on up to 5 most frequent diagnostic procedures

Evaluated parameters	Enter title of imaging procedure 1		Enter title of imaging procedure 2		Enter title of imaging procedure 3		Enter title of imaging procedure 4		Enter title of imaging procedure 5		Average	Lowest result
	% Scoring	NC	% Scoring	NC	% Scoring	NC	% Scoring	NC	% Scoring	NC	% Scoring	% Scoring
CLINICAL	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0,0
TECHNICAL/PROCEDURE	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0,0
PATIENT PREPARATION	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0,0
QA/QC	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0,0
REPORTING AND FOLLOW-UP	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0	0,0	0,0

Appendix 1.24: Checklist 12 General Radionuclide Therapy (Page 1)

CHECKLIST 12
General Radionuclide Therapy

CHECKLIST SUMMARY	N.	Applicable	Total score	% Scoring	NC
	25	0	0	0,0	0

No.	Component	Conformance Level	Status	Comments/planned action	Date achieved	Example of result / Type of evidence	References
12,1	Are written standardized operating procedures (SOPs) based on national/international guidelines available for any type of treatment ?	Click to select				Check the SOPs for radionuclide therapy.	NMRM-1198, chap. 3 SNMG EANMG HHS No. 11, Apdx.VI.1
12,2	Has the decision to treat been taken after multidisciplinary evaluation of the patient's condition and fully approved by the NM physician in charge of the treatment?	Click to select				Check the patient's records.	BSS, par. 3.150(a-c) NMRM, par.6.4-6.13 HHS No. 11, Apdx.VI.1
12,3	Are SOPs available for patient preparation regarding all types of treatment?	Click to select				Check the instructions or SOPs for patient preparation.	NMRM, par.6.4-6.13 SNMG EANMG
12,4	Are contraindications (e.g. allergies) and other conditions (medical, psychological, social) potentially interfering with the treatment checked for?	Click to select				Check the SOPs instructions and the patient's records.	SNMG EANMG NMRM, par.6.4-6.13
12,5	Does every patient receive appropriate information about the treatment including indication, other treatment options, expected/possible early and late side effects, preparation, detailed therapy procedure, hospitalization and isolation, if applicable, and aftercare?	Click to select				Check the procedures and the information provided to the patients before and after therapy.	BSS, par. 3.150d EANM-59 SNM-12, par.VI.B.3-5 NMRM, par.6.4-6.13
12,6	For paediatric patients: were relatives/caregivers clearly informed about the radioprotection measures to be taken and the risks inherent with attending the child during therapy?	Click to select				Observation on site/ Check the therapeutic procedures/Check the written instructions.	BSS, par. 3.156 NMRM, par.6.1.1
12,7	Is an SOP in place to rule out pregnancy and to deal with lactation before therapy?	Click to select				Check the SOP.	NMRM, par.6.2.8(a) BSS, par. 3.175, 3.176
12,8	Does patient information include instructions on necessity and duration of on-going contraception after therapy?	Click to select				Check the written instructions to the patients.	NMRM, par.6.2.8(a)
12,9	Are procedures in place describing the process of obtaining informed consent before therapy?	Click to select				Check the written procedures of obtaining informed consent.	NMRM, par.6.2.8(b)
12,10	Is there a written SOP describing the procurement, preparation and QC, if applicable, of therapeutic radiopharmaceuticals/radionuclides?	Click to select				Check the written SOPs.	OGHR-1342, 10.6
12,11	Is the therapeutic activity prescribed taking into account the target and non-target dose estimated by a medical physicist, nuclear medicine physician or equivalent specialist, in accordance with national/international guidelines?	Click to select				Check the SOPs for activity assigments.	BSS, par. 3.163 SNMG: (MIRD 1-18) EANMP: (4 - 8) EUROATOM, Art. 55 (1)
12,12	Is the administered activity individually measured and checked in an activity-meter, which has been specifically calibrated and quality checked for the given radionuclide?	Click to select				Check the records.	EUROATOM, Art. 55 (4) BSS, par. 3.184(c)

Appendix 1.25: Checklist 12 General Radionuclide Therapy (Page 2)

No.	Component	Conformance Level	Status	Comments/planned action	Date achieved	Example of result / Type of evidence	References
12,13	In case of in-patient therapy: are designated facilities (with appropriate surface, shielding, sanitation, ventilation etc.) available ?	Click to select				Observation on site.	SRS No.63, par. 3.2.2.1 NMRM, par.6.1.3
12,14	In case of in-patient therapy: are SOPs and appropriate radioprotection measures (concerning caregivers and public, contamination, transport, waste etc.) in place?	Click to select				Check the SOPs and written documents/ Observation on site.	BSS, par. 3.153(a), 3.129-30
12,15	In case of in-patient therapy: is 24h/day nursing care provided?	Click to select				Check the SOPs and written documents/ Observation on site.	BSS, par. 3.153(c)
12,16	Has the nursing staff received appropriate training in radiation science and radiation protection to take care of patients during treatment with radiopharmaceuticals?	Click to select				Check the corresponding SOPs and the nurses personal cards.	BSS, par. 3.153(b,c)
12,17	In case of in-patient therapy: is qualified staff accessible for managing medical emergency situations 24h per day?	Click to select				Observation on site/ Check the SOPs and the organizational chart.	BSS, par. 3.153(c)

No.	Component	Conformance Level	Status	Comments/planned action	Date achieved	Example of result / Type of evidence	References
12,18	In case of in-patient therapy: is a qualified person available outside normal working hours to handle urgent radioprotection issues?	Click to select				Observation on site/ Check the SOPs and the organizational chart.	BSS, par. 3.153(a-c)
12,19	Do the SOPs provide clear instructions for discharging patients in accordance with national regulations?	Click to select				Check the SOPs.	BSS, par. 3.148(b), 3.177 SRS No.63
12,20	Is patient's activity/emitted dose-rate measured and recorded in the patient's file before discharge from the NMS?	Click to select				Check the written instruction/Check the patient's records.	BSS, par. 3.177 SRS No.63, chap.3.1-3.3
12,21	Are written instructions available for the patient and family/caregivers after discharge?	Click to select				Check the written instructions/Check the patient's records.	BSS, par. 3.177 SRS No.63, chap. 5.1-5.4
12,22	Are procedures in place to make sure that these instructions have been understood by the patient/family/caregivers?	Click to select				Check the SOP.	BSS, par. 3.177 SRS No.63, cahp. 5.1

No.	Component	Conformance Level	Status	Comments/planned action	Date achieved	Example of result / Type of evidence	References
12,23	Are there specific SOPs dealing with misadministration of therapeutic radiopharmaceuticals?	Click to select				Check the SOP.	OGHR-1342, par.8.4
12,24	Is a comprehensive treatment report issued and made available to all involved physicians and, if applicable, to the patients?	Click to select				Check an example of report.	BSS, par. 3.184(c,d)
12,25	Is multidisciplinary clinical follow-up of patients provided?	Click to select				Check a patient record.	NMRM, par.6.4-6.13

LEGEND (Status):	Conformance
	Non-Conformance

Appendix 1.26: Checklist 13.1 Assessment of Therapy (Page 1)

CHECKLIST 13_1

Asessment of Therapy

Checklist Summary	N.	Applicable	Total score	% Scoring	NC
Clinical A	6	0	0	0,0	0
Technical	6	0	0	0,0	0
Patient preparation	5	0	0	0,0	0
QA/QC	5	0	0	0,0	0
Report	3	0	0	0,0	0

Procedure: *Enter title of therapeutic procedure 1*

(Please select at least one clinical case for each of up to three most performed procedures. Use a new sheet for each case)

No.	Component	Conformance Level	Status	Comments/planned action	Date achieved	Example of result / Type of evidence	References
	CLINICAL						
13,1	Was the decision to treat this patient based on national/international guidelines?	Click to select				Check the records/ Check the SOPs/ Check the related international guidelines.	SNMG EANMG BSS, par. 3.150(a)
13,2	Was the appropriateness of this therapy based on a multidisciplinary evaluation and formally approved by the physician in charge of the treatment?	Click to select				Check the patient records.	BSS, par. 3.150(a-c) SNMG EANMG
13,3	Have any other issues (patient condition, allergies, concurrent diseases, socio-economic issues, etc.) possibly interfering with or contraindicating the radionuclide therapy been identified?	Click to select				Check the patient records/Check the SOPs.	SNMG EANMG NMRM, par.6.4-6.13

Procedure: *Enter title of therapeutic procedure 1*

(Please select at least one clinical case for each of up to three most performed procedures. Use a new sheet for each case)

No.	Component	Conformance Level	Status	Comments/planned action	Date achieved	Example of result / Type of evidence	References
13,4	Were the results of all relevant diagnostic procedures available?	Click to select				Check the records/ Observation on site.	NMRM, par.6.4-6.13 SNMG EANMG
13,5	Was information about previous treatments including previous radionuclide therapy, available?	Click to select				Check the records.	NMRM, par.6.4-6.13 SNMG EANMG
13,6	Was information about on-going medical therapy available and checked for any potential interference with the current radionuclide therapy?	Click to select				Check the records.	NMRM, par.6.4-6.13 SNMG EANMG
	TECHNICAL/PROCEDURE: Check if done according to SOP						
13,7	Has the patient been identified according to the SOP?	Click to select				Check the records/ Check the SOPs.	EANMP-60, 6.2

Procedure: *Enter title of therapeutic procedure 1*

(Please select at least one clinical case for each of up to three most performed procedures. Use a new sheet for each case)

No.	Component	Conformance Level	Status	Comments/planned action	Date achieved	Example of result / Type of evidence	References
13,8	Was the correct radiopharmaceutical prescribed and was the activity based on the estimated dose to target and non-target tissues?	Click to select				Check the records/ Check the SOPs.	BSS, par. 3.163 EANMP: (4 - 8)
13,9	Was the activity measured before administration?	Click to select				Check the records.	EUROATOM, Art. 55 (4) BSS, par. 3.184(c)
13,10	Was the procedure to avoid misadministration of the radiopharmaceutical followed?	Click to select				Check the records/ Check the SOPs.	OGHR-1342, par.8.4
13,11	Was pregnancy/lactation excluded and understanding of information concerning subsequent contraception checked?	Click to select				Check the records.	BSS, par. 3.175, 3.176 NMRM, par.6.2.8(a)

Appendix 1.27: Checklist 13.1 Assessment of Therapy (Page 2)

Procedure: *Enter title of therapeutic procedure 1*

(Please select at least one clinical case for each of up to three most performed procedures. Use a new sheet for each case)

No.	Component	Conformance Level	Status	Comments/planned action	Date achieved	Example of result / Type of evidence	References
13,12	Was imaging performed, if appropriate, to check the biodistribution of the radiopharmaceutical?	Click to select				Check the records.	SNMG: (MIRD 1-18) EUROATOM, Art. 55 (1)
	PATIENT PREPARATION: Check if done according to SOP						
13,13	Has the patient been fully informed and has consent been obtained as described?	Click to select				Check the records/ Check the SOPs/ Observation on site.	BSS, par. 3.150d EANM-59 SNMP-12, par.VI.B.3-5
13,14	Were instructions concerning treatment-related medical therapy (hormones, bisphosphonates, calcium, thyroid blocking medications, etc.) and any other preparations (hydration, fasting, etc.) given?	Click to select				Check the records/ Check the SOPs/ Observation on site.	SNMG EANMG NMRM, par.6.4-6.13

Procedure: *Enter title of therapeutic procedure 1*

(Please select at least one clinical case for each of up to three most performed procedures. Use a new sheet for each case)

No.	Component	Conformance Level	Status	Comments/planned action	Date achieved	Example of result / Type of evidence	References
13,15	Were patient condition and/or treatment-related interference with the procedure checked?	Click to select				Check the records/ Check the SOPs.	SNMG EANMG NMRM, par.6.4-6.13
13,16	Were patients instructed on the necessity of avoiding pregnancy during and for a specified time after therapy? Was relevant counselling on lactation given?	Click to select				Check the records/ Check the SOPs.	NMRM, par.6.2.8(a) BSS, par. 3.175, 3.176
13,17	For paediatric patients: were relatives/caregivers appropriately informed about radiation protection issues?	Click to select				Check the records/ Check the SOPs.	BSS, par. 3.156 NMRM, par.6.1.1
	QA/QC: Check if done according to SOP						
13,18	Patient preparation ascertained.	Click to select				Check the records/ Observation on site.	NMRM, par.6.4-6.13 SNMG EANMG

Procedure: *Enter title of therapeutic procedure 2*

(Please select at least one clinical case for each of up to three most performed procedures. Use a new sheet for each case)

No.	Component	Conformance Level	Status	Comments/planned action	Date achieved	Example of result / Type of evidence	References
13,19	Documentation of QC of the radiopharmaceutical including in the case of external procurement.	Click to select				Check the records/ Check the SOPs.	OGHR-1342, 10.6
13,20	Filing of batch number, dosing and time of administration of any therapy-related pharmaceutical.	Click to select				Check the records.	OGHR-1342, 11.5.5
13,21	Handling and documentation of any incidents (spilling, extravasation at the injection site, vomiting etc.) or adverse events (patient-related or not).	Click to select				Check the records/ Check the SOPs.	NMRM, par.6.4-6.13 SNMG EANMG

Procedure: *Enter title of therapeutic procedure 2*

(Please select at least one clinical case for each of up to three most performed procedures. Use a new sheet for each case)

No.	Component	Conformance Level	Status	Comments/planned action	Date achieved	Example of result / Type of evidence	References
13,22	Traceability of all patient-related data, e.g. radiopharmaceutical, administered activity and injection site (if applicable), name of technologist and MD in charge.	Click to select				Observation on site/ Check all the records showing traceability.	OGHR-1342, par.9.4.1,9.5.2 EANMP-56, chap. 8.9 SNMP-13, chap. IIIA
	REPORTING AND FOLLOW-UP						
13,23	Was a comprehensive treatment report issued and made available to all involved parties?	Click to select				Check the report/ Check the SOPs.	NMRM, par.6.4-6.13 SNMG EANMG
13,24	Was the report drafted as specified in the relevant SOP?	Click to select				Check the report/ Check the SOPs.	NMRM, par.6.4-6.13 SNMG EANMG
13,25	Was any feedback received after therapy properly documented and managed?	Click to select				Check the records/ Check the SOPs.	NMRM, par.6.4-6.13 SNMG EANMG

LEGEND (Status):		
		Conformance
		Non-Conformance

Appendix 1.28: Checklist 13.2 Assessment of Therapy (Page 1)

CHECKLIST 13_1

Asessment of Therapy

Checklist Summary	N.	Applicable	Total score	% Scoring	NC
Clinical A	6	0	0	0,0	0
Technical	6	0	0	0,0	0
Patient preparation	5	0	0	0,0	0
QA/QC	5	0	0	0,0	0
Report	3	0	0	0,0	0

Procedure: *Enter title of therapeutic procedure 1*

(Please select at least one clinical case for each of up to three most performed procedures. Use a new sheet for each case)

No.	Component	Conformance Level	Status	Comments/planned action	Date achieved	Example of result / Type of evidence	References
	CLINICAL						
13,1	Was the decision to treat this patient based on national/international guidelines?	Click to select				Check the records/ Check the SOPs/ Check the related international guidelines.	SNMG EANMG BSS, par. 3.150(a)
13,2	Was the appropriateness of this therapy based on a multidisciplinary evaluation and formally approved by the physician in charge of the treatment?	Click to select				Check the patient records.	BSS, par. 3.150(a-c) SNMG EANMG
13,3	Have any other issues (patient condition, allergies, concurrent diseases, socio-economic issues, etc.) possibly interfering with or contraindicating the radionuclide therapy been identified?	Click to select				Check the patient records/Check the SOPs.	SNMG EANMG NMRM, par.6.4-6.13

Procedure: *Enter title of therapeutic procedure 1*

(Please select at least one clinical case for each of up to three most performed procedures. Use a new sheet for each case)

No.	Component	Conformance Level	Status	Comments/planned action	Date achieved	Example of result / Type of evidence	References
13,4	Were the results of all relevant diagnostic procedures available?	Click to select				Check the records/ Observation on site.	NMRM, par.6.4-6.13 SNMG EANMG
13,5	Was information about previous treatments including previous radionuclide therapy, available?	Click to select				Check the records.	NMRM, par.6.4-6.13 SNMG EANMG
13,6	Was information about on-going medical therapy available and checked for any potential interference with the current radionuclide therapy?	Click to select				Check the records.	NMRM, par.6.4-6.13 SNMG EANMG
	TECHNICAL/PROCEDURE: Check if done according to SOP						
13,7	Has the patient been identified according to the SOP?	Click to select				Check the records/ Check the SOPs.	EANMP-60, 6.2

Procedure: *Enter title of therapeutic procedure 1*

(Please select at least one clinical case for each of up to three most performed procedures. Use a new sheet for each case)

No.	Component	Conformance Level	Status	Comments/planned action	Date achieved	Example of result / Type of evidence	References
13,8	Was the correct radiopharmaceutical prescribed and was the activity based on the estimated dose to target and non-target tissues?	Click to select				Check the records/ Check the SOPs.	BSS, par. 3.163 EANMP: (4 - 8)
13,9	Was the activity measured before administration?	Click to select				Check the records.	EUROATOM, Art. 55 (4) BSS, par. 3.184(c)
13,10	Was the procedure to avoid misadministration of the radiopharmaceutical followed?	Click to select				Check the records/ Check the SOPs.	OGHR-1342, par.8.4
13,11	Was pregnancy/lactation excluded and understanding of information concerning subsequent contraception checked?	Click to select				Check the records.	BSS, par. 3.175, 3.176 NMRM, par.6.2.8(a)

Appendix 1.29: Checklist 13.2 Assessment of Therapy (Page 2)

Procedure: *Enter title of therapeutic procedure 1*

(Please select at least one clinical case for each of up to three most performed procedures. Use a new sheet for each case)

No.	Component	Conformance Level	Status	Comments/planned action	Date achieved	Example of result / Type of evidence	References
13,12	Was imaging performed, if appropriate, to check the biodistribution of the radiopharmaceutical?	Click to select				Check the records.	SNMG: (MIRD 1-18) EUROATOM, Art. 55 (1)
	PATIENT PREPARATION: Check if done according to SOP						
13,13	Has the patient been fully informed and has consent been obtained as described?	Click to select				Check the records/ Check the SOPs/ Observation on site.	BSS, par. 3.150d EANM-59 SNMP-12, par.VI.B.3-5
13,14	Were instructions concerning treatment-related medical therapy (hormones, bisphosphonates, calcium, thyroid blocking medications, etc.) and any other preparations (hydration, fasting, etc.) given?	Click to select				Check the records/ Check the SOPs/ Observation on site.	SNMG EANMG NMRM, par.6.4-6.13

Procedure: *Enter title of therapeutic procedure 1*

(Please select at least one clinical case for each of up to three most performed procedures. Use a new sheet for each case)

No.	Component	Conformance Level	Status	Comments/planned action	Date achieved	Example of result / Type of evidence	References
13,15	Were patient condition and/or treatment-related interference with the procedure checked?	Click to select				Check the records/ Check the SOPs.	SNMG EANMG NMRM, par.6.4-6.13
13,16	Were patients instructed on the necessity of avoiding pregnancy during and for a specified time after therapy? Was relevant counselling on lactation given?	Click to select				Check the records/ Check the SOPs.	NMRM, par.6.2.8(a) BSS, par. 3.175, 3.176
13,17	For paediatric patients: were relatives/caregivers appropriately informed about radiation protection issues?	Click to select				Check the records/ Check the SOPs.	BSS, par. 3.156 NMRM, par.6.1.1
	QA/QC: Check if done according to SOP						
13,18	Patient preparation ascertained.	Click to select				Check the records/ Observation on site.	NMRM, par.6.4-6.13 SNMG EANMG

Procedure: *Enter title of therapeutic procedure 2*

(Please select at least one clinical case for each of up to three most performed procedures. Use a new sheet for each case)

No.	Component	Conformance Level	Status	Comments/planned action	Date achieved	Example of result / Type of evidence	References
13,19	Documentation of QC of the radiopharmaceutical including in the case of external procurement.	Click to select				Check the records/ Check the SOPs.	OGHR-1342, 10.6
13,20	Filing of batch number, dosing and time of administration of any therapy-related pharmaceutical.	Click to select				Check the records.	OGHR-1342, 11.5.5
13,21	Handling and documentation of any incidents (spilling, extravasation at the injection site, vomiting etc.) or adverse events (patient-related or not).	Click to select				Check the records/ Check the SOPs.	NMRM, par.6.4-6.13 SNMG EANMG

Procedure: *Enter title of therapeutic procedure 2*

(Please select at least one clinical case for each of up to three most performed procedures. Use a new sheet for each case)

No.	Component	Conformance Level	Status	Comments/planned action	Date achieved	Example of result / Type of evidence	References
13,22	Traceability of all patient-related data, e.g. radiopharmaceutical, administered activity and injection site (if applicable), name of technologist and MD in charge.	Click to select				Observation on site/ Check all the records showing traceability.	OGHR-1342, par.9.4.1,9.5.2 EANMP-56, chap. 8.9 SNMP-13, chap. IIIA
	REPORTING AND FOLLOW-UP						
13,23	Was a comprehensive treatment report issued and made available to all involved parties?	Click to select				Check the report/ Check the SOPs.	NMRM, par.6.4-6.13 SNMG EANMG
13,24	Was the report drafted as specified in the relevant SOP?	Click to select				Check the report/ Check the SOPs.	NMRM, par.6.4-6.13 SNMG EANMG
13,25	Was any feedback received after therapy properly documented and managed?	Click to select				Check the records/ Check the SOPs.	NMRM, par.6.4-6.13 SNMG EANMG

LEGEND (Status):		
		Conformance
		Non-Conformance

Appendix 1.30: Checklist 13.3 Assessment of Therapy (Page 1)

CHECKLIST 13_3

Asessment of Therapy

Checklist Summary	N.	Applicable	Total score	% Scoring	NC
Clinical A	6	0	0	0,0	0
Technical	6	0	0	0,0	0
Patient preparation	5	0	0	0,0	0
QA/QC	5	0	0	0,0	0
Report	3	0	0	0,0	0

Procedure: *Enter title of therapeutic procedure 3*

(Please select at least one clinical case for each of up to three most performed procedures. Use a new sheet for each case)

No.	Component	Conformance Level	Status	Comments/planned action	Date achieved	Example of result / Type of evidence	References
	CLINICAL						
13,1	Was the decision to treat this patient based on national/international guidelines?	Click to select				Check the records/ Check the SOPs/ Check the related international guidelines.	SNMG EANMG BSS, par. 3.150(a)
13,2	Was the appropriateness of this therapy based on a multidisciplinary evaluation and formally approved by the physician in charge of the treatment?	Click to select				Check the patient records.	BSS, par. 3.150(a-c) SNMG EANMG
13,3	Have any other issues (patient condition, allergies, concurrent diseases, socio-economic issues, etc.) possibly interfering with or contraindicating the radionuclide therapy been identified?	Click to select				Check the patient records/Check the SOPs.	SNMG EANMG NMRM, par.6.4-6.13

Procedure: *Enter title of therapeutic procedure 3*

(Please select at least one clinical case for each of up to three most performed procedures. Use a new sheet for each case)

No.	Component	Conformance Level	Status	Comments/planned action	Date achieved	Example of result / Type of evidence	References
13,4	Were the results of all relevant diagnostic procedures available?	Click to select				Check the records/ Observation on site.	NMRM, par.6.4-6.13 SNMG EANMG
13,5	Was information about previous treatments including previous radionuclide therapy, available?	Click to select				Check the records.	NMRM, par.6.4-6.13 SNMG EANMG
13,6	Was information about on-going medical therapy available and checked for any potential interference with the current radionuclide therapy?	Click to select				Check the records.	NMRM, par.6.4-6.13 SNMG EANMG
	TECHNICAL/PROCEDURE: Check if done according to SOP						
13,7	Has the patient been identified according to the SOP?	Click to select				Check the records/ Check the SOPs.	EANMP-60, 6.2

Procedure: *Enter title of therapeutic procedure 3*

(Please select at least one clinical case for each of up to three most performed procedures. Use a new sheet for each case)

No.	Component	Conformance Level	Status	Comments/planned action	Date achieved	Example of result / Type of evidence	References
13,8	Was the correct radiopharmaceutical prescribed and was the activity based on the estimated dose to target and non-target tissues?	Click to select				Check the records/ Check the SOPs.	BSS, par. 3.163 EANMP: (4 - 8)
13,9	Was the activity measured before administration?	Click to select				Check the records.	EUROATOM, Art. 55 (4) BSS, par. 3.184(c)
13,10	Was the procedure to avoid misadministration of the radiopharmaceutical followed?	Click to select				Check the records/ Check the SOPs.	OGHR-1342, par.8.4
13,11	Was pregnancy/lactation excluded and understanding of information concerning subsequent contraception checked?	Click to select				Check the records.	BSS, par. 3.175, 3.176 NMRM, par.6.2.8(a)

Appendix 1.31: Checklist 13.3 Assessment of Therapy (Page 2)

Procedure: *Enter title of therapeutic procedure 3*

(Please select at least one clinical case for each of up to three most performed procedures. Use a new sheet for each case)

No.	Component	Conformance Level	Status	Comments/planned action	Date achieved	Example of result / Type of evidence	References
13,12	Was imaging performed, if appropriate, to check the biodistribution of the radiopharmaceutical?	Click to select				Check the records.	SNMG: (MIRD 1-18) EUROATOM, Art. 55 (1)
	PATIENT PREPARATION: Check if done according to SOP						
13,13	Has the patient been fully informed and has consent been obtained as described?	Click to select				Check the records/ Check the SOPs/ Observation on site.	BSS, par. 3.150d EANM-59 SNMP-12, par.VI.B.3-5
13,14	Were instructions concerning treatment-related medical therapy (hormones, bisphosphonates, calcium, thyroid blocking medications, etc.) and any other preparations (hydration, fasting, etc.) given?	Click to select				Check the records/ Check the SOPs/ Observation on site.	SNMG EANMG NMRM, par.6.4-6.13

Procedure: *Enter title of therapeutic procedure 3*

(Please select at least one clinical case for each of up to three most performed procedures. Use a new sheet for each case)

No.	Component	Conformance Level	Status	Comments/planned action	Date achieved	Example of result / Type of evidence	References
13,15	Were patient condition and/or treatment-related interference with the procedure checked?	Click to select				Check the records/ Check the SOPs.	SNMG EANMG NMRM, par.6.4-6.13
13,16	Were patients instructed on the necessity of avoiding pregnancy during and for a specified time after therapy? Was relevant counselling on lactation given?	Click to select				Check the records/ Check the SOPs.	NMRM, par.6.2.8(a) BSS, par. 3.175, 3.176
13,17	For paediatric patients: were relatives/caregivers appropriately informed about radiation protection issues?	Click to select				Check the records/ Check the SOPs.	BSS, par. 3.156 NMRM, par.6.1.1
	QA/QC: Check if done according to SOP						http://www-pub.iaea.org/MTCD/p
13,18	Patient preparation ascertained.	Click to select				Check the records/ Observation on site.	NMRM, par.6.4-6.13 SNMG EANMG

Procedure: *Enter title of therapeutic procedure 3*

(Please select at least one clinical case for each of up to three most performed procedures. Use a new sheet for each case)

No.	Component	Conformance Level	Status	Comments/planned action	Date achieved	Example of result / Type of evidence	References
13,19	Documentation of QC of the radiopharmaceutical including in the case of external procurement.	Click to select				Check the records/ Check the SOPs.	OGHR-1342, 10.6
13,20	Filing of batch number, dosing and time of administration of any therapy-related pharmaceutical.	Click to select				Check the records.	OGHR-1342, 11.5.5
13,21	Handling and documentation of any incidents (spilling, extravasation at the injection site, vomiting etc.) or adverse events (patient-related or not).	Click to select				Check the records/ Check the SOPs.	NMRM, par.6.4-6.13 SNMG EANMG
13,22	Traceability of all patient-related data, e.g. radiopharmaceutical, administered activity and injection site (if applicable), name of technologist and MD in charge.	Click to select				Observation on site/ Check all the records showing traceability.	OGHR-1342, par.9.4.1,9.5.2 EANMP-56, chap. 8,9 SNMP-13, chap. IIIA

Procedure: *Enter title of therapeutic procedure 3*

(Please select at least one clinical case for each of up to three most performed procedures. Use a new sheet for each case)

No.	Component	Conformance Level	Status	Comments/planned action	Date achieved	Example of result / Type of evidence	References
	REPORTING AND FOLLOW-UP						
13,23	Was a comprehensive treatment report issued and made available to all involved parties?	Click to select				Check the report/ Check the SOPs.	NMRM, par.6.4-6.13 SNMG EANMG
13,24	Was the report drafted as specified in the relevant SOP?	Click to select				Check the report/ Check the SOPs.	NMRM, par.6.4-6.13 SNMG EANMG
13,25	Was any feedback received after therapy properly documented and managed?	Click to select				Check the records/ Check the SOPs.	NMRM, par.6.4-6.13 SNMG EANMG

LEGEND (Status):	Conformance
	Non-Conformance

Appendix 1.32: Checklist 14 Radiopharmacy Operational Level 1 (Page 1)

CHECKLIST 14
Radiopharmacy Operational Level 1

CHECKLIST SUMMARY	N.	Applicable	Total score	% Scoring	NC
	16	0	0	0,0	0

No.	Component	Conformance Level	Status	Comments/planned action	Date achieved	Example of result / Type of evidence	References
	Staffing						
14,1	Is the radiopharmacy unit operated under the direction of a person with appropriate training as defined by local or national regulations?	Click to select				Check the job description and the personal card of the person in charge.	TCS-39 NMRM, epig.2.3
14,2	Are there written staff training manuals for all grades of staff?	Click to select				Check the training SOP/Check the personal cards.	NMRM, epig.2.3; 7.1-7.13
	Facilities						
14,3	Does the unit have appropriately finished rooms (including adequate lighting, walls, floors, ceilings and ventilation) and a shielded dispensing station?	Click to select				Evaluation on site.	NMRM, epig.3.4 OGHR-1342, par.5 ; 9 ; 10
14,4	For operational level 1b: is there a well ventilated area or a shielded dispensing station for radioiodine capsules?	Click to select				Evaluation on site.	NMRM, epig.3.4 OGHR-1342, par.5 ; 9 ; 10
14,5	Is there a validated (annual check on air flow, safety and challenge testing) fume hood with suitable filters for handling radioiodine solutions?	Click to select				Check the records/ Evaluation on site.	NMRM, epig.3.4 OGHR-1342, par.5 ; 9 ; 10
	Purchase of materials						
14,6	Are there suitable protocols and trained staff for the purchase of approved or marketing authorized radiopharmaceuticals?	Click to select				Check the purchase SOPs/Check the job description and the personal cards.	OGHR-1342, par.6.6; 9.5 TCS-39
14,7	Are all goods received checked and recorded against the order for correctness of delivery?	Click to select				Check the records/ Check the purchase SOPs.	OGHR-1342, par.6.6; 9.5
	Dispensing protocols						
14,8	Under operational level 1a: are there written procedures for the aseptic dispensing and labelling of unit doses of ready-to-use radiopharmaceuticals?	Click to select				Check the SOPs.	OGHR-1342, par.9 ; 10
14,9	For operational level 1b: is a shielded dispensing station and/or a fume hood available?	Click to select				Evaluation on site.	OGHR-1342, par.9 ; 10
14,10	Is there a fume cupboard with suitable filters for volatile radioactive materials such as ^{131}I solutions?	Click to select				Evaluation on site.	OGHR-1342, par.9 ; 10
14,11	If only radioiodine capsules are handled, is the package opened in a well-ventilated area?	Click to select				Evaluation on site.	OGHR-1342, par.9 ; 10
14,12	For operational level 1b: do the written procedures contain clear safety and monitoring instruction for dispensing radioiodine solutions or capsules?	Click to select				Check the SOPs.	OGHR-1342, par.9 ; 10
14,13	Can the documentation for each radiopharmaceutical batch be traced from the prescription to the actual administration of individual patient doses?	Click to select				Check the records / Evaluation on field of radiopharmaceutical traceability.	OGHR-1342, par.9 ; 10

Appendix 1.33: Checklist 14 Radiopharmacy Operational Level 1 (Page 2)

No.	Component	Conformance Level	Status	Comments/planned action	Date achieved	Example of result / Type of evidence	References
	QA/QC						
14,14	Are quality checks on radiopharmaceuticals performed?	Click to select				Check the records/ Check the SOPs.	OGHR-1342, par.7 ; 9 ; 10
14,15	Is there a written procedure for dealing with products that do not meet the required standards and/or for which a complaint has been received?	Click to select				Check the procedures.	OGHR-1342, par.7 ; 9 ; 10
	Waste						
14,16	Are there written procedures for the disposal of radioactive and non-active waste specific to the radiopharmacy?	Click to select				Check the procedures/ Observation on site.	OGHR-1342, par. 9 ; 10

LEGEND (Status):	
	Conformance
	Non-Conformance

Appendix 1.34: Checklist 15 Radiopharmacy Operational Level 2 (Page 1)

CHECKLIST 15
Radiopharmacy Operational Level 2

CHECKLIST SUMMARY	N.	Applicable	Total score	% Scoring	NC
	20	0	0	0,0	0

No.	Component	Conformance Level	Status	Comments/planned action	Date achieved	Example of result / Type of evidence	References
	Staffing						
15,1	Is there specific staff training and assessment of competency at operational level 2, including aseptic practice?	Click to select				Check the training SOP/ Check the personal cards.	TCS-39 NMRM, epig.2.3
15,2	Is there training provided for staff required to perform final checks on all products prepared before release for patient use?	Click to select				Check the personal cards.	TCS-39 NMRM, epig.2.3; 7.1-7.13
15,3	Before release of radiolabelled RBC (red blood cells) and WBC (white blood cells) labelling is there confirmation of training?	Click to select				Check the training SOP.	TCS-39 NMRM, epig.2.3
	Facilities						
15,4	For operational level 2: are there regular checks on validated Class II type B microbiological safety cabinets located in a dedicated room?	Click to select				Check the records.	NMRM, epig.3.4 OGHR-1342, par.5 ; 11 ; 12
15,5	For negative pressure isolators: before preparation takes place, are gloves or gauntlets visually inspected and integrity tests carried out and recorded?	Click to select				Check the records/ Evaluation on site.	NMRM, epig.3.4 OGHR-1342, par.5 ; 11 ; 12
	Preparation protocols						
15,6	In practice: have all systems of work and documentation related to radiopharmaceutical preparation and processing been formally approved?	Click to select				Check the approved documentation.	OGHR-1342, par.7 ; 11 ; 12
15,7	Do all products, kits and generators have product approval, marketing authorization, or bear a product licence number?	Click to select				Check the records/ Check the purchase SOP.	OGHR-1342, par.7 ; 11 ; 12
15,8	Is the preparation of ^{99m}Tc radiopharmaceuticals from kits and generators carried out in a laminar air flow (LAF) cabinet?	Click to select				Evaluation on site.	OGHR-1342, par.7 ; 11 ; 12
15,9	Can each individual patient dose be traced to a specific generator and kit batch number?	Click to select				Check the records/ Evaluation on field of traceability.	OGHR-1342, par.7 ; 11 ; 12
15,10	Under operational level 2b: do the written procedures for any autologous preparation, e.g. RBCs and WBCs, include clear instructions on safety, cleaning and decontamination?	Click to select				Check the SOPs/ Observation on site.	OGHR-1342, par. 7 ; 11 ; 12
15,11	Are there written procedures for the preparation and dispensing of radio-labelled biologicals, e.g. monoclonal antibodies, peptides from approved kit formulations?	Click to select				Check the procedures/ Observation on site.	OGHR-1342, par. 7 ; 11 ; 12
	QA/QC						
15,12	Are there set QC criteria before release for preparation before patient use?	Click to select				Check the procedures.	OGHR-1342, par. 11 ; 12
15,13	Is a record of approval/release made by an authorized person before a product is administered to a patient?	Click to select				Check the records.	OGHR-1342, par. 11 ; 12
15,14	For operational level 2: is ^{99}Mo molybdenum breakthrough measurement performed on the first eluate of each ^{99m}Tc generator and repeated when the generator is moved?	Click to select				Check the procedures/ Check the records.	OGHR-1342, par. 11 ; 12

Appendix 1.35: Checklist 15 Radiopharmacy Operational Level 2 (Page 2)

No.	Component	Conformance Level	Status	Comments/planned action	Date achieved	Example of result / Type of evidence	References
15,15	Is aluminium ion breakthrough checked on the first eluate from a ^{99m}Tc generator?	Click to select				Check the procedures/ Check the records.	OGHR-1342, par. 11 ; 12
15,16	Before patient use, are radiochemical purity tests performed on all new batches or newly delivered radiopharmaceutical kits?	Click to select				Check the procedures/ Check the records.	OGHR-1342, par. 11 ; 12
15,17	Is there routine microbiological monitoring of preparation and aseptic dispensing area in the radiopharmacy?	Click to select				Check the procedures/ Check the records.	OGHR-1342, par. 11 ; 12
15,18	Are changes in the use of kits, diluents or vehicles, needles, syringes, swabs and sterile containers recorded?	Click to select				Check the procedures/ Check the records.	OGHR-1342, par. 11 ; 12
15,19	Are pH tests carried out regularly?	Click to select				Check the procedures/ Check the records.	OGHR-1342, par. 11 ; 12
15,20	Are rapid alternative methods employed for swift prospective QC, e.g. for the determination of the radiochemical purity of ^{99m}TcHMPAO?	Click to select				Check the procedures/ Check the records.	OGHR-1342, par. 11 ; 12

LEGEND (Status):	
	Conformance
	Non-Conformance

APPENDIX 2: Letter requesting permission to conduct research study at State facility:

PO Box 1158

Okahandja

Namibia

10 February 2021

Dear Sir

I am a postgraduate student registered for a Masters in Science Degree Radiography (Nuclear Medicine) within the Faculty of Health and Wellness Sciences at the Cape Peninsula University of Technology, Cape Town, South Africa. I am also employed as Chief Radiographer in Quality Assurance for Radiographic Services: Tertiary Health Care and Clinical Support Services Directorate of Ministry of Health and Social Services, Namibia.

My research project is titled 'Quality assessment of Nuclear Medicine Practices in Namibia'. This study focuses on conducting a quality audit of four Nuclear Medicine practices in Namibia using the IAEA Quality Management Audit Tool for Nuclear Medicine (QUANUM). This study will benefit Namibia by providing baseline information on quality management in public hospitals Nuclear Medicine departments.

They are the only two public hospitals that provide the service and are well-equipped for the research study. The study will be conducted at the above research sites only, and no part of the study will be experimenting or involve any human subjects. The researcher will only analyse existing data (primary data) during the study.

Furthermore, the study will not interfere with the Nuclear Medicine clinical departments' day-to-day activities such as the patient throughput or workload of radiographers, physicians and nurses. The data collection will be on mutually agreed days that will be most convenient to the department to avoid impacting patient care and service delivery. The documents consulted will be analysed in a quiet room arranged by the clinical site to be as unobtrusive as possible.

Where any patients' data will be scrutinised, the researcher will adhere to strict confidentiality by not recording or revealing such names during the data collection or publication of the results, respectively. The researcher will not use any of the clinical departments' resources or consumables when collecting the data.

The research site results will be coded whereby each hospital will be labelled alphabetically, i.e., Site A, B, etc. When dealing with a patient file, it will be marked, i.e.1, 2, etc., and be referred to as such throughout the data collection process until publication to avoid the individual identification of the respective Nuclear Medicine Sites. The patient files will not leave the research sites, and the researcher will only have access to them onsite. The collected data will be locked in a safe whereby the researcher will only have access to it. Electronic data will be stored on a password-protected laptop/PC with anti-hacking or anti-phishing software.

The researcher will be impartial, fair and honest when conducting the study and signing confidentiality agreements to prevent unwanted information leakage. The names of the research site will be kept confidential and not published in the thesis or subsequent scientific article emanating from the findings of this study. Due to the limited number of Nuclear Medicine Practices/Departments in Namibia, we will also not reveal the country's name when publishing the results to negate indirect identification or potential link of the findings to the four research sites. In addition, we will undertake to provide you with a detailed copy of the research findings for your perusal before the publication of the thesis or the scientific article. Where any potential contentious findings exist, a discussion between the research team and the research site will be arranged to resolve such issues prior to publication. We commit not to publish any adverse findings which may affect your future clinical or business work. Considering that the findings generated through this study will form part of a Masters degree by research, none of the research sites will be obligated to accept or implement any of the recommendations made in the research report. We acknowledge that Nuclear Medicine is a scarce skill, especially in a middle-income country like Namibia. As explained before, the ultimate aim of this study is to obtain a Masters degree. It is certainly not aimed to cause reputation damage or financial losses to your practice or any other Nuclear Medicine Sites in Namibia.

It is against this background that I request permission from the Ministry of Health and Social Services to carry out my research at the two public Nuclear Medicine departments.

A copy of my proposal and ethics certificate granted by the REC of CPUT is attached for your perusal.

Should you have any further queries related to this letter's content, please feel free to contact the undersigned or my appointed supervisors.

Yours faithfully

Magdalena Lutaka

Magdaowoses@yahoo.com

Cell: 0813657201

Principle Supervisor:

Dr. A. Speelman

Tel: 027 21 959 6538

Co-supervisor:

Dr. R. Hamunyela

Tel: +264 61 2063474

Co-supervisor:

Dr S. Naidoo

Tel: 027 31 373 2875

APPENDIX 3: Letter requesting permission to conduct research study at State Facility

PO Box 1158

[redacted]

Namibia

27 October 2021

Dr [redacted]

Medical Superintendent

[redacted]

Dear Sir

RE: REQUEST FOR PERMISSION TO CARRY OUT A RESEARCH STUDY AT THE NUCLEAR MEDICINE DEPARTMENT AT [redacted]

I am a postgraduate student registered for a Masters in Science Degree Radiography (Nuclear Medicine) within the Faculty of Health and Wellness Sciences at the Cape Peninsula University of Technology, Cape Town, South Africa. I am also employed as Chief Radiographer in Quality Assurance for Radiographic Services: Tertiary Health Care and Clinical Support Services Directorate of Ministry of Health and Social Services, Namibia.

My research project is titled 'Quality assessment of Nuclear Medicine Practices in Namibia'. This study focuses on conducting a quality audit of four Nuclear Medicine practices in Namibia using the IAEA Quality Management Audit Tool for Nuclear Medicine (QUANUM). This study will benefit Namibia by providing baseline information on quality management in public hospitals Nuclear Medicine departments.

I have selected the two Nuclear Medicine departments at to conduct my study. They are the only two public hospitals that provide the service and are well-equipped for the research study. The study will be conducted at the above research sites only, and no part of the study will be experimenting or involve any human subjects. The researcher will only analyse existing data (primary data) during the study.

Furthermore, the study will not interfere with the Nuclear Medicine clinical departments' day-to-day activities such as the patient throughput or workload of radiographers, physicians and nurses. The data collection will be on mutually agreed days that will be most convenient to the department to avoid impacting patient care and service delivery. The documents consulted will be analysed in a quiet room arranged by the clinical site to be as unobtrusive as possible.

Where any patients' data will be scrutinised, the researcher will adhere to strict confidentiality by not recording or revealing such names during the data collection or publication of the results, respectively. The researcher will not use any of the clinical departments' resources or consumables when collecting the data.

The research site results will be coded whereby each hospital will be labelled alphabetically, i.e., Site A, B, etc. When dealing with a patient file, it will be marked, i.e.1, 2, etc., and be referred to as such throughout the data collection process until publication to avoid the individual identification of the respective Nuclear Medicine Sites. The patient files will not leave the research sites, and the researcher will only have access to them onsite. The collected data will be locked in a safe whereby the researcher will only have access to it. Electronic data will be stored on a password-protected laptop/PC with anti-hacking or anti-phishing software.

The researcher will be impartial, fair and honest when conducting the study and signing confidentiality agreements to prevent unwanted information leakage. The names of the research site will be kept confidential and not published in the thesis or subsequent scientific article emanating from the findings of this study. Due to the limited number of Nuclear Medicine Practices/Departments in Namibia, we will also not reveal the country's name when publishing the results to negate indirect identification or potential link of the findings to the four research sites. In addition, we will undertake to provide you with a detailed copy of the research findings for your perusal before the publication of the thesis or the scientific article. Where any potential contentious findings exist, a discussion between the research team and the research site will be arranged to resolve such issues prior to publication. We commit not to publish any adverse findings which may affect your future clinical or business work. Considering that the findings generated through this study will form part of a Masters degree by research, none of the research sites will be obligated to accept or implement any of the recommendations made in the research report. We acknowledge that Nuclear Medicine is a scarce skill, especially in a middle-income country like Namibia. As explained before, the ultimate aim of this study is to obtain a Master's degree. It is certainly not aimed to cause reputation damage or financial losses to your practice or any other Nuclear Medicine Sites in Namibia.

It is against this background that I request permission from [redacted] to carry out the research study.

A copy of my proposal and ethics certificate granted by the REC of CPUT is attached for your perusal.

Should you have any further queries related to this letter's content, please feel free to contact the undersigned or my appointed supervisors.

Yours faithfully

Magdalena Lutaka

Magdaowoses@yahoo.com

Cell: 0813657201

Principle Supervisor:

Dr A. Speelman

Tel: 027 21 959 6538

Co-supervisor:

Dr R. Hamunyela

Tel: +264 61 2063474

Co-supervisor:

Dr S. Naidoo

Tel: 027 31 373 2875

APPENDIX 4: Letter requesting permission to conduct research [redacted]

[redacted]
PO Box 1158
Okahandja
Namibia

2 December 2021

Dear Sir

RE: REQUEST FOR PERMISSION TO CARRY OUT A RESEARCH STUDY AT [redacted]

I am a postgraduate student registered for a Masters in Science Degree Radiography (Nuclear Medicine within the Faculty of Health and Wellness Sciences at the Cape Peninsula University of Technology, Cape Town, South Africa. I am also employed as Chief Radiographer in Quality Assurance for Radiographic Services: Tertiary Health Care and Clinical Support Services Directorate of Ministry of Health and Social Services, Namibia.

My research project is titled 'Quality assessment of Nuclear Medicine Practices in Namibia.' This study focuses on conducting a quality audit of four Nuclear Medicine practices in Namibia using the IAEA Quality Management Audit Tool for Nuclear Medicine (QUANUM). This study will benefit Namibia as it will provide baseline information on quality management in Nuclear Medicine departments.

I have selected [redacted] to conduct my study. [redacted] that provides a Nuclear Medicine service and is well equipped to conduct the research study. The study will be conducted at the above research sites only, and no part of the study will be experimenting or involve any human subjects. The researcher will only analyse existing data (primary data) during the study.

Furthermore, the study will not interfere with the Nuclear Medicine clinical departments' day-to-day activities such as the patient throughput or workload of radiographers, physicians and nurses. The data collection will be on mutually agreed days that will be most convenient to the department to avoid impacting patient care and service delivery. The documents consulted will be analysed in a quiet room arranged by the clinical site to be as unobtrusive as possible.

Where any patients' data will be scrutinised, the researcher will adhere to strict confidentiality by not recording or revealing such names during the data collection or publication of the results, respectively. The researcher will not use any of the clinical departments' resources or consumables when collecting the data.

The research site results will be coded whereby each hospital will be labelled alphabetically, i.e., Site A, B, etc. When dealing with a patient file, it will be marked, i.e.1, 2, etc., and be referred to as such throughout the data collection process until publication to avoid the

individual identification of the respective Nuclear Medicine Sites. The patient files will not leave the research sites, and the researcher will only have access to them onsite. The collected data will be locked in a safe whereby the researcher will only have access to it. Electronic data will be stored on a password-protected laptop/PC with anti-hacking or anti-phishing software.

When conducting the study, the researcher will be impartial, fair, and honest and sign a confidentiality agreement to prevent unwanted information leakage. The names of the research site will be kept confidential and not published in the thesis or subsequent scientific article emanating from the findings of this study. Due to the limited number of Nuclear Medicine Practices/Departments in Namibia, we will also not reveal the country's name when publishing the results to negate indirect identification or potential link of the findings to the four research sites. In addition, we will undertake to provide you with a detailed copy of the research findings for your perusal before the publication of the thesis or the scientific article. Where any potential contentious findings exist, a discussion between the research team and the research site will be arranged to resolve such issues prior to publication. We commit not to publish any adverse findings which may affect your future clinical or business work. Considering that the findings generated through this study will form part of a Masters degree by research, none of the research sites will be obligated to accept or implement any of the recommendations made in the research report. We acknowledge that Nuclear Medicine is a scarce skill, especially in a middle-income country like Namibia. As explained before, the ultimate aim of this study is to obtain a Masters degree. It is certainly not aimed to cause reputation damage or financial losses to your practice or any other Nuclear Medicine Sites in Namibia.

The study will not interfere with the day-to-day activities and will be on the most convenient days to avoid interruption of service delivery. I will also not interfere with any clinical examinations conducted on patients. I will also maintain patient confidentiality, as should I come across personal patient data during this research study. I will uphold all ethical principles such as preserving privacy, anonymising data, and non- revelation of the research sites when publishing the results.

It is against this background that I request permission to conduct my research at the [redacted]

A copy of my proposal and ethics certificate granted by the REC of CPUT is attached for your perusal.

Should you have any further queries related to this letter's content, please feel free to contact the undersigned or my appointed supervisors.

Yours faithfully

Magdalena Lutaka

Magdaowoses@yahoo.com

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Principle Supervisor:

Dr A. Speelman

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Co-supervisor:

Dr R. Hamunyela

Tel: +264 61 2063474

Co-supervisor:

Dr S. Naidoo

Tel: 031 373 2875

APPENDIX 5: Letter requesting permission to conduct research study at [redacted]

PO Box 1158

Okahandja

Namibia

10 February 2021

[redacted]

Dear Sir

RE: REQUEST FOR PERMISSION TO CARRY OUT A RESEARCH STUDY AT [redacted]

I am a postgraduate student registered for a Masters in Science Degree Radiography (Nuclear Medicine within the Faculty of Health and Wellness Sciences at the Cape Peninsula University of Technology, Cape Town, South Africa. I am also employed as Chief Radiographer in Quality Assurance for Radiographic Services: Tertiary Health Care and Clinical Support Services Directorate of Ministry of Health and Social Services, Namibia.

My research project is titled 'Quality assessment of Nuclear Medicine Practices in Namibia'. This study focuses on conducting a quality audit of four Nuclear Medicine practices in Namibia using the IAEA Quality Management Audit Tool for Nuclear Medicine (QUANUM). This study will be beneficial to Namibia as it will provide baseline information on quality management in Nuclear Medicine departments

I have selected [redacted] to conduct my study. It is the only private site that provides a Nuclear Medicine service and is well equipped to conduct the research study. The study will be conducted at the above research sites only, and no part of the study will be experimenting or involve any human subjects. The researcher will only analyse existing data (primary data) during the study.

Furthermore, the study will not interfere with the Nuclear Medicine clinical departments' day-to-day activities such as the patient throughput or workload of radiographers, physicians and nurses. The data collection will be on mutually agreed days that will be most convenient to the department to avoid impacting patient care and service delivery. The documents

consulted will be analysed in a quiet room arranged by the clinical site to be as unobtrusive as possible.

Where any patients' data will be scrutinised, the researcher will adhere to strict confidentiality by not recording or revealing such names during the data collection or publication of the results, respectively. The researcher will not use any of the clinical departments' resources or consumables when collecting the data.

The research site results will be coded whereby each hospital will be labelled alphabetically, i.e., Site A, B, etc. When dealing with a patient file, it will be marked, i.e.1, 2, etc., and be referred to as such throughout the data collection process until publication to avoid the individual identification of the respective Nuclear Medicine Sites. The patient files will not leave the research sites, and the researcher will only have access to them onsite. The collected data will be locked in a safe whereby the researcher will only have access to it. Electronic data will be stored on a password-protected laptop/PC with anti-hacking or anti-phishing software.

The researcher will be impartial, fair and honest when conducting the study, sign a confidentiality agreement to prevent unwanted information leakage. The names of the research site will be kept confidential and not published in the thesis or subsequent scientific article emanating from the findings of this study. Due to the limited number of Nuclear Medicine Practices/Departments in Namibia, we will also not reveal the country's name when publishing the results to negate indirect identification or potential link of the findings to the four research sites. In addition, we will undertake to provide you with a detailed copy of the research findings for your perusal before the publication of the thesis or the scientific article. Where any potential contentious findings exist, a discussion between the research team and the research site will be arranged to resolve such issues prior to publication. We commit not to publish any adverse findings which may affect your future clinical or business work. Considering that the findings generated through this study will form part of a Masters degree by research, none of the research sites will be obligated to accept or implement any of the recommendations made in the research report. We acknowledge that Nuclear Medicine is a scarce skill, especially in a middle-income country like Namibia. As explained before, the ultimate aim of this study is to obtain a Masters degree. It is certainly not aimed to cause reputation damage or financial losses to your practice or any other Nuclear Medicine Sites in Namibia.

It is against this background that I request permission to conduct my research at [redacted]

A copy of my proposal and ethics certificate granted by the REC of CPUT is attached for your perusal.

Should you have any further queries related to this letter's content, please feel free to contact the undersigned or my appointed supervisors.

Yours faithfully

Magdalena Lutaka

Magdaowoses@yahoo.com
Cell: 0813657201

Principle Supervisor:
Dr A. Speelman
Tel: 027 21 959 6538

Co-supervisor:
Dr R. Hamunyela
Tel: +264 61 2063474

Co-supervisor:
Dr S. Naidoo
Tel: 027 31 373 2875

APPENDIX 6: Letter requesting ethical approval to conduct research study CPUT Research Ethics Committee

PO Box 1158

Okahandja

Namibia

10 February 2021

Ms C Lackay
Chairperson
Research Ethics Committee
Faculty of Health and Wellness Sciences
Cape Peninsula University of Technology
PO Box 1906
Bellville
7535

Dear Ms Lackay

RE: REQUEST FOR ETHICAL APPROVAL TO CONDUCT ~~A~~ RESEARCH STUDY AT NAMIBIAN NUCLEAR MEDICINE DEPARTMENTS

I am a postgraduate student registered for a Masters in Science Radiography (Nuclear Medicine) within the Faculty of Health and Wellness Sciences at the Cape Peninsula University of Technology (student number 206212411).

My research project is titled 'Quality assessment of Nuclear Medicine Practices in Namibia'. This research study focuses on conducting a quality audit of four Nuclear Medicine practices in Namibia using the IAEA Quality Management Audit tool for Nuclear Medicine (QUANUM). This study will benefit Namibia as it will provide baseline information on quality management in Nuclear Medicine departments. This letter seeks your ethical approval to conduct this study at the above stated Nuclear Medicine departments.

In addition to this request, the researcher will also seek permission from the four Nuclear Medicine departments in Namibia. These departments are located

The study will be conducted at the above research sites only, and no part of the study will be experimenting or involve any human subjects. The researcher will only analyse existing data (primary data) during the study.

Furthermore, the study will not interfere with the Nuclear Medicine clinical departments' day-to-day activities such as the patient throughput or workload of radiographers, physicians and nurses. The data collection will be on mutually agreed days that will be most convenient to the department to avoid impacting patient care and service delivery. The documents consulted will be analysed in a quiet room arranged by the clinical site to be as unobtrusive as possible.

Where any patients' data will be scrutinised, the researcher will adhere to strict confidentiality by not recording or revealing such names during the data collection or publication of the

results. The researcher will not use any of the clinical departments' resources or consumables when collecting the data.

The research site results will be coded whereby each hospital will be labelled alphabetically, i.e., Site A, B, etc. When dealing with a patient file, it will be marked, i.e.1, 2, etc., and be referred to as such throughout the data collection process until publication to avoid the individual identification of the respective Nuclear Medicine Sites. The patient files will not leave the research sites, and the researcher will only have access to them onsite. The collected data will be locked in a safe whereby the researcher will only have access to it. Electronic data will be stored on a password-protected laptop/PC with anti-hacking or anti-phishing software.

The researcher will be impartial, fair and honest when conducting the study and sign confidentiality agreements to prevent unwanted information leakage. The names of the research site will be kept confidential and not published in the thesis or subsequent scientific article emanating from the findings of this study. Due to the limited number of Nuclear Medicine Practices/Departments in Namibia, we will also not reveal the country's name when publishing the results to negate indirect identification or potential link of the findings to the four research sites. In addition, we will undertake to provide you with a detailed copy of the research findings for your perusal before the publication of the thesis or the scientific article. Where any potential contentious findings exist, a discussion between the research team and the research site will be arranged to resolve such issues prior to publication. We commit not to publish any adverse findings which may affect your future clinical or business work. Considering that the findings generated through this study will form part of a Masters degree by research, none of the research sites will be obligated to accept or implement any of the recommendations made in the research report. We acknowledge that Nuclear Medicine is a scarce skill, especially in a middle-income country like Namibia. As explained before, the ultimate aim of this study is to obtain a Masters degree. It is certainly not aimed to cause reputation damage or financial losses to your practice or any other Nuclear Medicine Sites in Namibia.

It is against this background that I request permission from CPUT Research Ethics Committee to carry out my research at the Namibian Nuclear Medicine departments.

A copy of my proposal and ethics certificate granted by the REC of CPUT is attached for your perusal.

Should you have any further queries related to the content of this letter, please feel free to contact the undersigned or my appointed supervisors.

Yours faithfully

Magdalena Lutaka
Magdaowoses@yahoo.com
Cell: +264813657201

Principle Supervisor:
Dr A. Speelman
Tel: 027 21 959 6538

Co-supervisor:
Dr R. Hamunyela
Tel: +264 61 2063474

Co-supervisor:
Dr S. Naidoo
Tel: 027 31 373 2875

APPENDIX 7: Confidentiality Agreement between Magdalena Lutaka (researcher) and Site (1/2/3/4)

I, Magdalena Lutaka, a postgraduate student, registered for a Masters in Science Radiography (Nuclear Medicine) within the Faculty of Health and Wellness Sciences at the Cape Peninsula University of Technology, Cape Town, South Africa. My research project is titled '**Quality Audits of Nuclear Medicine Practices in Namibia'.**

Hereby agree to do the following while researching your Site:

- I will maintain patient confidentiality as should I come across personal patient data during this research study,
- The study will be conducted at the above research sites only, and no part of the study will be experimenting or involve any human subjects.
- The researcher will only analyse existing data (primary data) during the study.
- Furthermore, the study will not interfere with the Nuclear Medicine clinical departments' day-to-day activities such as the patient throughput or workload of radiographers, physicians and nurses.
- The data collection will be on mutually agreed days that will be most convenient to the department to avoid impacting patient care and service delivery.
- The documents consulted will be analysed in a quiet room arranged by the clinical site to be as unobtrusive as possible.
- Where any patients' data will be scrutinised, the researcher will adhere to strict confidentiality by not recording or revealing such names during the data collection or publication of the results, respectively.
- The researcher will not use any of the clinical departments' resources or consumables when collecting the data.
- The research site results will be coded whereby each hospital will be labelled alphabetically, i.e., Site A, B, etc.
- When dealing with a patient file, it will be marked, i.e.1, 2, etc., and be referred to as such throughout the data collection process until publication to avoid the individual identification of the respective Nuclear Medicine Sites.
- The patient files will not leave the research sites, and the researcher will only have access to them onsite. The collected data will be locked in a safe whereby the researcher will only have access to it.
- Electronic data will be stored on a password-protected laptop/PC with anti-hacking or anti-phishing software.
- The researcher will be impartial, fair and honest when conducting the study and signing confidentiality agreements to prevent unwanted information leakage.
- The names of the research site will be kept confidential and not published in the thesis or subsequent scientific article emanating from the findings of this study. Due to the limited number of Nuclear Medicine Practices/Departments in Namibia, we will also not reveal the country's name when publishing the results to negate indirect identification or potential link of the findings to the four research sites. In addition, we will undertake to provide you with a detailed copy of the research findings for your perusal before the publication of the thesis or the scientific article. Where any potential contentious findings exist, a discussion between the research team and the

research site will be arranged to resolve such issues prior to publication. We commit not to publish any adverse findings which may affect your future clinical or business work. Considering that the findings generated through this study will form part of a Masters degree by research, none of the research sites will be obligated to accept or implement any of the recommendations made in the research report. We acknowledge that Nuclear Medicine is a scarce skill, especially in a middle-income country like Namibia. As explained before, the ultimate aim of this study is to obtain a Masters degree. It is certainly not aimed to cause reputation damage or financial losses to your practice or any other Nuclear Medicine Sites in Namibia.

…….
Researcher

……
Date

…….
Head of Department

…….
Date

APPENDIX 8: Letter requesting permission to use the QUANUM tool from the IAEA

PO Box 1158

Okahandja

Namibia
9 March 2021

Mr Enrique Estrada-Lobato

Nuclear Medicine and Diagnostic Imaging Section

IAEA

P.O. Box 100

1400 Vienna

Austria

Dear Mr Estrada-Lobato

RE: REQUEST FOR PERMISSION TO USE QUANUM TOOL FOR RESEARCH PROJECT

I am a postgraduate student registered for a Masters in Science Degree Radiography (Nuclear Medicine) within the Faculty of Health and Wellness Sciences at the Cape Peninsula University of Technology, Cape Town South Africa. I am also employed as Chief Radiographer in Quality Assurance for Radiographic Services: Tertiary Health Care and Clinical Support Services Directorate of the Ministry of Health and Social Services, Namibia.

My research project is entitled 'An assessment of overall QMS (QMS) in Nuclear Medicine Practices in Namibia'. The focus of this research study is to conduct a quality audit of four Nuclear Medicine practices in Namibia using the IAEA Quality Management Audit Tool for Nuclear Medicine (QUANUM). This study will be beneficial to Namibia as it will provide baseline information of quality management in Nuclear Medicine departments.

It is against this background that I request permission to use the QUANUM tool to conduct this study. I will give appropriate recognition to the IAEA for using the QUANUM tool when publishing the findings of this research study.

Should you have any further queries related to the content of this letter, please feel free to contact the undersigned or my appointed supervisors.

Yours faithfully

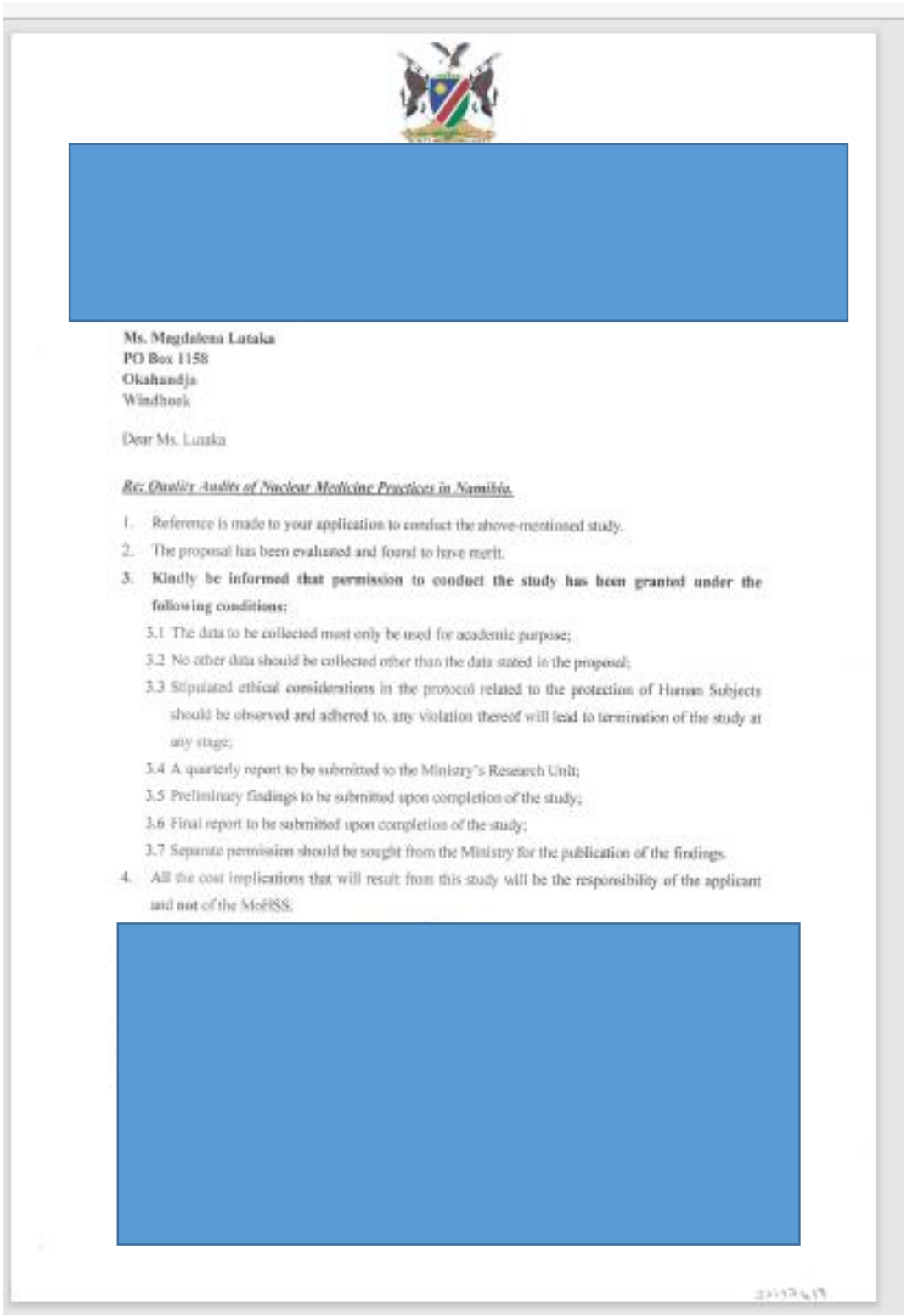
Magdalena Lutaka
Magdaowoses@yahoo.com
Cell: +264 0813657201

Principle Supervisor:
Dr. A. Speelman
Tel: 027 21 959 6538

Co-supervisors:
Dr. R. Hamunyela
Tel: +264 61 2063474

Co-supervisors:
Dr. S. Naidoo
Tel: 027 31 373 2875

APPENDIX 9: Ministry and Health and Social Services, Executive Director's approval to conduct the research study at both State Sites.



[redacted]

Ms. Magdalena Lutaka
PO Box 1158
Okahandja
Windhoek

Dear Ms. Lutaka

Re: Quality Audits of Nuclear Medicine Practices in Namibia.

1. Reference is made to your application to conduct the above-mentioned study.
2. The proposal has been evaluated and found to have merit.
3. **Kindly be informed that permission to conduct the study has been granted under the following conditions:**
   - 3.1 The data to be collected must only be used for academic purpose;
   - 3.2 No other data should be collected other than the data stated in the proposal;
   - 3.3 Stipulated ethical considerations in the protocol related to the protection of Human Subjects should be observed and adhered to, any violation thereof will lead to termination of the study at any stage;
   - 3.4 A quarterly report to be submitted to the Ministry's Research Unit;
   - 3.5 Preliminary findings to be submitted upon completion of the study;
   - 3.6 Final report to be submitted upon completion of the study;
   - 3.7 Separate permission should be sought from the Ministry for the publication of the findings.
4. All the cost implications that will result from this study will be the responsibility of the applicant and not of the MoHSS.

[redacted]

APPENDIX 10: Approval to conduct the research study at both private Sites

[redacted]

Quality Audit Nuclear Medicine in Namibia

26 January 2022

Dear Mrs Lutaka,

Having reviewed your research proposal, you are hereby granted permission to conduct your research at our premises in Windhoek and Swakopmund, under the terms as per your proposal.

[redacted]

[redacted]

Sincerely

[redacted]

[redacted]

[redacted]

APPENDIX 11: University Research Ethics Committee Approval

Cape Peninsula
University of Technology

HEALTH AND WELLNESS SCIENCES RESEARCH ETHICS COMMITTEE (HWS-REC)
Registration Number NHREC: REC- 230408-014

P.O. Box 1906 • Bellville 7535 South Africa
Symphony Road Bellville 7535
Tel: +27 21 959 6917
Email: sethn@cput.ac.za

8 October 2021
REC Approval Reference No:
CPUT/HW-REC 2021/H25

Faculty of Health and Wellness Sciences

Dear Ms M Lutaka

Re: APPLICATION TO THE HW-REC FOR ETHICS CLEARANCE

Approval was granted by the Health and Wellness Sciences-REC to **Ms M Lutaka** for ethical clearance. This approval is for research activities related to research for **Ms M Lutaka** at Cape Peninsula University of Technology.

TITLE: **Quality audits of Nuclear Medicine Practices in Namibia**

Supervisors: Mr A Speelman and Dr R Hamunyela

Comment: Communication of results with study sites before publication is noted as a strategy to reduce the risk of reputational harm to the study sites. Measures should be taken to ensure that these interactions do not unduly influence the findings to be published.

Approval will not extend beyond 9 October 2022. An extension should be applied for 6 weeks before this expiry date should data collection and use/analysis of data, information and/or samples for this study continue beyond this date.

The investigator(s) should understand the ethical conditions under which they are authorized to carry out this study and they should be compliant to these conditions. It is required that the investigator(s) complete an **annual progress report** that should be submitted to the HWS-REC in December of that particular year, for the HWS-REC to be kept informed of the progress and of any problems you may have encountered.

Kind Regards

Carolynn Lackay
Chairperson – Research Ethics Committee
Faculty of Health and Wellness Sciences

APPENDIX 12: IAEA approval to use the IAEA QUANUM tool for a research project

IAEA
Atoms for Peace and Development
الوكالة الدولية للطاقة الذرية
国际原子能机构
International Atomic Energy Agency
Agence internationale de l'énergie atomique
Международное агентство по атомной энергии
Organismo Internacional de Energía Atómica

Vienna International Centre, PO Box 100, 1400 Vienna, Austria
Phone: (+43 1) 2600 • Fax: (+43 1) 26007
Email: Official.Mail@iaea.org • Internet: http://www.iaea.org

In reply please refer to:
Dial directly to extension: (+43 1) 2600-22957

Ms Madgalena Lutaka

Faculty of Health and Wellness Science
Cape Peninsula University of Technology
CAPE TOWN
SOUTH AFRICA

30 March 2021

Dear Ms Lutaka,

The QUANUM Programme provides a tool to perform independent quality audits of nuclear medicine departments through comprehensive reviews of organizations and their clinical practice.

I hereby confirm that the QUANUM tool materials may be used for your research activity with the proviso that the IAEA is to be acknowledged in any resulting publications or presentations.

When you finish your research, please send us the draft or drafts for clearance.

The QUANUM tool does not require any installation since it's not a software. Copy the XLS "Quanum Tool" available at the following link which includes all components to be immediately operational:

https://humanhealth.iaea.org/HHW/NuclearMedicine/QUANUM_2.0_Excel_Tool_and_QNUMED/QUANUM_Tool_2019.xlsb

As well as the QUANUM manual:

https://humanhealth.iaea.org/HHW/NuclearMedicine/QUANUM_2.0_Excel_Tool_and_QNUMED/QUANUM_Advance_Publishing_Copy.pdf

Should you have any further questions, please contact HumanHealthCampus@iaea.org.

Yours sincerely,

Mr Enrique Estrada
Nuclear Medicine Physician
Division of Human Health
Department of Nuclear Sciences and Application

M-1.2Rev.11 (Jan 20)

APPENDIX 13: Signed Confidentiality Agreements between Magdalena Lutaka (researcher) and research Sites 1 and 3

APPENDIX 6: Confidentiality Agreement between Magdalena Lutaka (researcher) and research site (1/2/3/4)

I, Magdalena Lutaka, a postgraduate student, registered for a Masters in Science Radiography (Nuclear Medicine) within the Faculty of Health and Wellness Sciences at the Cape Peninsula University of Technology, Cape Town, South Africa. My research project is titled **'Quality Audits of Nuclear Medicine Practices in Namibia'.**

Hereby agree to do the following while researching your facility:

- I will maintain patient confidentiality as should I come across personal patient data during this research study,
- The study will be conducted at the above research sites only, and no part of the study will be experimenting or involve any human subjects.
- The researcher will only analyse existing data (primary data) during the study.
- Furthermore, the study will not interfere with the Nuclear Medicine clinical departments' day-to-day activities such as the patient throughput or workload of radiographers, physicians and nurses.
- The data collection will be on mutually agreed days that will be most convenient to the department to avoid impacting patient care and service delivery.
- The documents consulted will be analysed in a quiet room arranged by the clinical site to be as unobtrusive as possible.
- Where any patients' data will be scrutinised, the researcher will adhere to strict confidentiality by not recording or revealing such names during the data collection or publication of the results, respectively.
- The researcher will not use any of the clinical departments' resources or consumables when collecting the data.
- The research site results will be coded whereby each hospital will be labelled alphabetically, i.e., Facility A, B, etc.
- When dealing with a patient file, it will be marked, i.e.1, 2, etc., and be referred to as such throughout the data collection process until publication to avoid the individual identification of the respective Nuclear Medicine facilities.
- The patient files will not leave the research sites, and the researcher will only have access to them onsite. The collected data will be locked in a safe whereby the researcher will only have access to it.
- Electronic data will be stored on a password-protected laptop/PC with anti-hacking or anti-phishing software.
- The researcher will be impartial, fair and honest when conducting the study and signing confidentiality agreements to prevent unwanted information leakage.
- The names of the research site will be kept confidential and not published in the thesis or subsequent scientific article emanating from the findings of this study. Due to the limited number of Nuclear Medicine Practices/Departments in Namibia, we will also not reveal the country's name when publishing the results to negate indirect identification or potential link of the findings to the four research sites. In addition, we will undertake to provide you with a detailed copy of the research findings for your perusal before the publication of the thesis or the scientific article. Where any potential contentious findings exist, a discussion between the research team and the research site will be arranged to resolve such issues prior to publication. We commit not to publish

any adverse findings which may affect your future clinical or business work. Considering that the findings generated through this study will form part of a Masters degree by research, none of the research sites will be obligated to accept or implement any of the recommendations made in the research report. We acknowledge that Nuclear Medicine is a scarce skill, especially in a middle-income country like Namibia. As explained before, the ultimate aim of this study is to obtain a Masters degree. It is certainly not aimed to cause reputation damage or financial losses to your practice or any other Nuclear Medicine facilities in Namibia.

Researcher

02/12/2021

Date

Head of Department

02/12/2021

Date

APPENDIX 14: Signed Confidentiality Agreements between Magdalena Lutaka (researcher) and research Sites 2 and 4.

APPENDIX 6: Confidentiality Agreement between Magdalena Lutaka (researcher) and research site (1/2/3/4)

I, Magdalena Lutaka, a postgraduate student, registered for a Masters in Science Radiography (Nuclear Medicine) within the Faculty of Health and Wellness Sciences at the Cape Peninsula University of Technology, Cape Town, South Africa. My research project is titled **'Quality Audits of Nuclear Medicine Practices in Namibia'.**

Hereby agree to do the following while researching your facility:

- I will maintain patient confidentiality as should I come across personal patient data during this research study,
- The study will be conducted at the above research sites only, and no part of the study will be experimenting or involve any human subjects.
- The researcher will only analyse existing data (primary data) during the study.
- Furthermore, the study will not interfere with the Nuclear Medicine clinical departments' day-to-day activities such as the patient throughput or workload of radiographers, physicians and nurses.
- The data collection will be on mutually agreed days that will be most convenient to the department to avoid impacting patient care and service delivery.
- The documents consulted will be analysed in a quiet room arranged by the clinical site to be as unobtrusive as possible.
- Where any patients' data will be scrutinised, the researcher will adhere to strict confidentiality by not recording or revealing such names during the data collection or publication of the results, respectively.
- The researcher will not use any of the clinical departments' resources or consumables when collecting the data.
- The research site results will be coded whereby each hospital will be labelled alphabetically, i.e., Facility A, B, etc.
- When dealing with a patient file, it will be marked, i.e.1, 2, etc., and be referred to as such throughout the data collection process until publication to avoid the individual identification of the respective Nuclear Medicine facilities.
- The patient files will not leave the research sites, and the researcher will only have access to them onsite. The collected data will be locked in a safe whereby the researcher will only have access to it.
- Electronic data will be stored on a password-protected laptop/PC with anti-hacking or anti-phishing software.
- The researcher will be impartial, fair and honest when conducting the study and signing confidentiality agreements to prevent unwanted information leakage.
- The names of the research site will be kept confidential and not published in the thesis or subsequent scientific article emanating from the findings of this study. Due to the limited number of Nuclear Medicine Practices/Departments in Namibia, we will also not reveal the country's name when publishing the results to negate indirect identification or potential link of the findings to the four research sites. In addition, we will undertake to provide you with a detailed copy of the research findings for your perusal before the publication of the thesis or the scientific article. Where any potential contentious findings exist, a discussion between the research team and the research site will be arranged to resolve such issues prior to publication. We commit not to publish

any adverse findings which may affect your future clinical or business work. Considering that the findings generated through this study will form part of a Masters degree by research, none of the research sites will be obligated to accept or implement any of the recommendations made in the research report. We acknowledge that Nuclear Medicine is a scarce skill, especially in a middle-income country like Namibia. As explained before, the ultimate aim of this study is to obtain a Masters degree. It is certainly not aimed to cause reputation damage or financial losses to your practice or any other Nuclear Medicine facilities in Namibia.

Researcher

02/12/2021

Date

Head of Department

02/12/2021

Date