CONTENT

FOREWORD 7
Director General of Health, Malaysia
Deputy Director General of Health (Medical), Malaysia

PREFACE 9
Head of Nuclear Medicine Services

LIST OF ABBREVIATIONS 11

PREAMBLE 13

1.0 NUCLEAR MEDICINE SERVICES 15

1.1 Introduction
  1.1.1 Nuclear Medicine Specialty
  1.1.2 Radiopharmaceuticals / Radiotracers

1.2 Scope of Nuclear Medicine Services
  1.2.1 Radionuclide Imaging
    a) SPECT
    b) PET
    c) Hybrid technology
  1.2.2 Targeted Radionuclide Therapy
  1.2.3 Theranostic
  1.2.4 Radiobioassay & Radiochemical Measurements

1.3 The range of Nuclear Medicine Services in Malaysia

1.4 Different categories of Nuclear Medicine facilities under the Ministry of Health

2.0 ORGANIZATION AND MANAGEMENT 26

2.1 Organization Structure

2.2 Organization Chart for the Nuclear Medicine Department

2.3 Human Resource and Scope of Duties
  2.3.1 Nuclear Medicine Physician
  2.3.2 Medical Physicist (Nuclear)
  2.3.3 Nuclear Pharmacist
  2.3.4 Radiobiochemist
  2.3.5 Nuclear Medicine Technologist
  2.3.6 Nuclear Medicine Nurse
3.0 OPERATING POLICIES ON CLINICAL SERVICES IN NUCLEAR MEDICINE

3.1 Scheduling of patients’ appointments
3.2 Movement of patients within the Nuclear Medicine facility
3.3 Management of outpatients in a Nuclear Medicine specialist clinic
3.4 Management of inpatients in a radioactive isolation room / ward
3.5 Management of radioactive patients in medical emergencies
3.6 Examination of staff involved in resuscitation or handling of a radioactive patient
3.7 Drugs and medication management (general)
3.8 Radiopharmaceutical use and management
3.9 Consent for Nuclear Medicine procedures
3.10 Conducting Nuclear Medicine procedures
3.11 Reporting on Nuclear Medicine investigation and treatment
3.12 Archiving / storage of medical record (investigation and treatment record)

4.0 OPERATING POLICIES ON RADIATION SAFETY AND SECURITY IN NUCLEAR MEDICINE

4.1 Radiation safety for the staff at the Nuclear Medicine facility
4.2 Discharge of radioactive patients and protection of general public from radiation exposure
4.3 Use of public transport by the discharged radioactive patients
4.4 Managing death of radioactive patients
4.5 Order, purchase, transportation and security of radioactive sources
4.6 Radioactive waste management
4.7 Radiation accidents in a Nuclear Medicine facility
4.8 Major radiation accidents
4.9 Management of theft, loss or sabotage of radioactive source
4.10 Management of radioactive spills in Nuclear Medicine
   4.10.1 Operational response to a major radioactive spill
   4.10.2 Operational response to a minor radioactive spill
4.11 Management of radiation monitoring equipment failure
4.12 Management of radiation hazard in a fire accident

5.0 GUIDANCE ON THE USE OF NEW RADIOPHARMACEUTICALS OR NUCLEAR MEDICINE DEVICES NOT REGISTERED IN MALAYSIA

5.1 Introduction
5.2 Objective
5.3 Definitions
5.3.1 Medical device
5.3.2 Radiopharmaceutical
5.3.3 Combination product
5.3.4 Relevant authorities

5.4 The roles of the various relevant authorities in regulating the use of radiopharmaceuticals or Nuclear Medicine devices
5.4.1 Medical Radiation Surveillance Division (MRSD)
5.4.2 Pharmaceutical Services Division of the MOH
5.4.3 Drug Control Authority (DCA)
5.4.4 National Pharmaceutical Regulatory Agency (NPRA)
5.4.5 Medical Device Authority (MDA)
5.4.6 National Medical Research Register (NMRR)
5.4.7 Medical Research and Ethics Committee (MREC)

5.5 Basic information required for the radiation regulatory approval

5.6 Temporary clearance and exemption for use of an unregistered drug in a patient
5.6.1 For any unregistered drug used for diagnosis / therapy
5.6.2 For any unregistered drug used in a clinical trial or research study

5.7 Exemption for use of an unregistered medical device in a patient

5.8 A combination product where its classification is in doubt

5.9 Conditions under which different types of approvals are required

6.0 GUIDANCE ON PLANNING AND DESIGN FOR A NUCLEAR MEDICINE FACILITY

6.1 Key considerations
6.2 Site selection
6.3 Key components in the design and layout in a Nuclear Medicine facility
6.3.1 Nuclear imaging room
6.3.2 Cardiac stress-test room
6.3.3 Radiopharmaceutical administration room
6.3.4 Hot waiting area / Post-RP waiting area / Uptake room
6.3.5 PET facility
6.3.6 Cyclotron
6.3.7 Radionuclide therapy ward (radioactive isolation room)
6.3.8 Decay storage room
6.3.9 Radioactive delay and decay tank
6.3.10 Radiopharmacy hot lab

6.4 Lay out for a conventional Level 1sp Nuclear Medicine facility

6.5 Lay out for an inpatient isolation ward in a Level 2 Nuclear Medicine facility
7.0 GUIDANCE ON THE OPERATIONAL TYPES AND
FUNCTIONS OF RADIOPHARMACEUTICAL PREPARATION
FACILITIES (RADIOPHARMACY HOT LABS) IN MALAYSIA

7.1 Operational Type 1 – dispensing only
  7.1.1 Operational Type 1a
  7.1.2 Operational Type 1b
  7.1.3 Operational Type 1c

7.2 Operational Type 2 – compounding / radiolabeling
  7.2.1 Operational Type 2a
  7.2.2 Operational Type 2a plus
  7.2.3 Operational Type 2b
  7.2.4 Operational Type 2c
  7.2.5 Operational Type 2c plus

7.3 Operational Type 3 – cyclotron related setup
  7.3.1 Operational Type 3
  7.3.2 Operational Type 3 mini

7.4 Operational Type 4 – blood cells radiolabeling

7.5 Proposed list of equipment for each operational types
& function of radiopharmaceutical preparation facilities

8.0 MASTER LIST FOR NUCLEAR MEDICINE PROCEDURES 2018

8.1 Instructions
8.2 Diagnostic Procedures
8.3 Therapeutic Procedures
8.4 Day-care Procedure

APPENDICES

Appendix 1 Consent Form for Myocardial Perfusion Imaging
Appendix 2 Consent Form for I-131 Therapy for Hyperthyroidism
Appendix 3 Proposed List of Equipment for Each Operational Types &
Functions of Radiopharmaceutical Preparation Facilities

REFERENCES

DRAFTING COMMITTEE

EXTERNAL REVIEW PANELS
FOREWORD & PREFACE
FOREWORD

Nuclear Medicine is a specialized medical discipline with both diagnostic and therapeutic purposes. With the rapid advancement in Nuclear Medicine technology coupled with the fast expansion of services provided in Malaysia, this specialty plays an important role in patient care primarily in detecting, staging and treatment of diseases.

Nuclear Medicine was first established as a standalone department from the year 2006. Since then, the Nuclear Medicine specialty has progressed to become one of the key services needed in maximizing patient care. For instance, PET scan, a type of Nuclear Medicine imaging is increasingly used for the diagnosis and staging of cancer imaging and has significantly improved the quality of cancer care in Malaysia.

With an increasing importance placed on early diagnosis and treatment, demand for Nuclear Medicine services is expected to escalate. Despite the constraints and challenges that the Ministry of Health of Malaysia face, it is essential to ensure an efficient planning and delivery of health services. It is therefore timely to produce a national operational policy for Nuclear Medicine to serve as a guide in the development of this healthcare service in this country.

I would like to congratulate the Medical Development Division and Nuclear Medicine Services for jointly producing this policy. I commend Dr. Ng Chen Siew and his team for their continuous dedication and commitment in assisting the Ministry of Health to provide and develop these services for the betterment of the community. I hope the quality of our services will continue to improve as per the Ministry’s vision and mission to provide the best healthcare system that is of international standing.

Datuk Dr. Noor Hisham bin Abdullah
Director General of Health
Ministry of Health Malaysia
FOREWORD

Nuclear Medicine is a fast developing medical speciality under the Ministry of Health since its establishment as a separate standalone department at Hospital Pulau Pinang and Hospital Kuala Lumpur in the year 2006. Since then, the services have further expanded to another 4 Nuclear Medicine Centres across Malaysia which provide comprehensive diagnostic and therapeutic procedures which play an important in the overall patient management.

Nuclear Medicine is now one of the most rapidly evolving healthcare speciality worldwide due to the rapid advancement in science and technology. Multiple new imaging and treatment modalities such as PET-CT scan, SPECT-CT scan, targeted radionuclide therapy for neuroendocrine tumor and prostate cancer have been set up throughout Malaysia in recent years. Therefore, it is timely that guidelines are developed in order to provide guidance in the running of Nuclear Medicine Services across the different centres in Malaysia, leading to the production of this book on “Operational Policy in Nuclear Medicine Services”.

This national policy will enable the harmonisation and standardisation of the patient care in Nuclear Medicine Services across the centres under the Ministry of Health Malaysia. The content inside this book will be revised from time to time to reflect the ever-changing healthcare dynamic and landscape, with the new developments in this field.

Lastly, I would like to congratulate the drafting committee and the external reviewers for their unceasing efforts leading to the publication of this book on “Operational Policy in Nuclear Medicine Services”. I also hope that the Nuclear Medicine Services in our Ministry of Health will continue to provide excellent service to our patients and meet the increasing healthcare demand in Malaysia.

Dato' Dr. Hj. Azman bin Hj. Abu Bakar
Deputy Director General of Health (Medical)
Ministry of Health Malaysia
PREFACE

Nuclear Medicine in Malaysia has demonstrated continuous dramatic growth since the year 2002, when the Ministry of Health Malaysia (MOH) took a resolute step in developing this discipline into a medical specialty of its own. The advances made in Nuclear Medicine have brought about major impact to many areas of medicine, notably in the field of oncology and cardiology. Today, Nuclear Medicine has become an integral part of cancer management and the availability of its facilities reflect a high level of cancer care provided in that institution.

During the many years in which Nuclear Medicine has evolved in this country, various pertinent practices, operating protocols, regulatory guidelines and policies have been introduced, modified, improved and reviewed. The purpose of this policy manual is to provide a general guide to Nuclear Medicine physicians, physicists, technologists or any interested users on the infrastructural needs, organizational scheme, administrative functions, operational expectations and professional responsibilities when delivering this medical service in Malaysia.

This manual composes of a total of 8 chapters. Chapter 1 contains a general information about Nuclear Medicine and a brief introduction to its current status under the MOH, Malaysia. Chapter 2 provides information on the organization structure and a list of job descriptions expected for different staff categories in this field. Chapter 3 and 4 cover important procedural policies in the clinical service, radiation safety and security issues.

It is important to note that radionuclides administered to patients for medical purposes have been classified as drugs (radiopharmaceuticals) and shall comply with both the radiation and pharmaceutical acts and regulations in this country. As such, Chapter 5 provides guidelines on the process to obtain necessary regulatory clearance before using any unregistered radiopharmaceuticals or medical devices. Chapter 6 and 7 highlight various key considerations and expected infrastructure requirements in planning and design of a Nuclear Medicine facility, including the radiopharmacy hot lab. In Chapter 8, a list of diagnostic and therapeutic Nuclear Medicine procedures is provided for reference.

The Drafting Committee wishes to thank the External Review Panel for the support and expert assistance extended in the preparation of this manual.

Dr. Ng Chen Siew
Head of Nuclear Medicine Services
Ministry of Health Malaysia
LIST OF ABBREVIATIONS
### LIST OF ABBREVIATIONS

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>AELB</td>
<td>Atomic Energy Licensing Board</td>
</tr>
<tr>
<td>BSRP</td>
<td>Basic Safety Radiation Protection</td>
</tr>
<tr>
<td>CRC</td>
<td>Clinical Research Center</td>
</tr>
<tr>
<td>CTIL</td>
<td>Clinical Trial Import License</td>
</tr>
<tr>
<td>CTX</td>
<td>Clinical Trial Exemption</td>
</tr>
<tr>
<td>DCA</td>
<td>Drug Control Authority</td>
</tr>
<tr>
<td>DMSA</td>
<td>Dimercaptosuccinic acid, a chelating agent used for renal study</td>
</tr>
<tr>
<td>DOTATATE</td>
<td>DOTA-D-Phe1-Tyr3-Thr8-octreotide, an amino acid peptide targeting somatostatin receptors</td>
</tr>
<tr>
<td>DTPA</td>
<td>Diethyl pentaacetic acid, a chelating agent used for renal study</td>
</tr>
<tr>
<td>EDTA</td>
<td>Ethylene diamine tetraacetic acid, a chelating agent used for renal study</td>
</tr>
<tr>
<td>FDG</td>
<td>Fluorodeoxyglucose, a glucose analogue</td>
</tr>
<tr>
<td>FUKKM</td>
<td>Formulari Ubat Kementerian Kesihatan Malaysia</td>
</tr>
<tr>
<td>GFR</td>
<td>Glomerular Filtration Rate</td>
</tr>
<tr>
<td>IRB/IEC</td>
<td>Institutional Review Board / Independent Ethics Committee</td>
</tr>
<tr>
<td>IT</td>
<td>Information Technology</td>
</tr>
<tr>
<td>LAF</td>
<td>Laminar air flow</td>
</tr>
<tr>
<td>MAA</td>
<td>Macro-aggregated albumin</td>
</tr>
<tr>
<td>MAG-3</td>
<td>Mercaptoacetyltrimlycerine, a synthesized ligand used for renal study</td>
</tr>
<tr>
<td>MDA</td>
<td>Medical Device Authority</td>
</tr>
<tr>
<td>MDP</td>
<td>Methyl diphosphonate, a bisphosphonate used for bone study</td>
</tr>
<tr>
<td>MIBG</td>
<td>Metaiodobenzylguanidine, a radiolabelled molecule similar to noradrenaline which can enter into the neuroendocrine cells via the epiphrine transporter.</td>
</tr>
<tr>
<td>MOH</td>
<td>Ministry of Health</td>
</tr>
<tr>
<td>MREC</td>
<td>Medical Research and Ethics Committee</td>
</tr>
<tr>
<td>MRSD</td>
<td>Medical Radiation Surveillance Division</td>
</tr>
<tr>
<td>NIH</td>
<td>National Institute of Health</td>
</tr>
<tr>
<td>NMRR</td>
<td>National Medical Research Register</td>
</tr>
<tr>
<td>NPRA</td>
<td>National Pharmaceutical Regulatory Agency</td>
</tr>
<tr>
<td>PET</td>
<td>Positron Emission Tomography</td>
</tr>
<tr>
<td>PET-MRI</td>
<td>Positron Emission Tomography- Magnetic Resonance Imaging</td>
</tr>
<tr>
<td>PSMA</td>
<td>Prostate specific membrane antigen, a transmembrane glycoprotein expressed in all types of prostatic tissue and a few other tissues.</td>
</tr>
<tr>
<td>QC/QA</td>
<td>Quality Control / Quality Assurance</td>
</tr>
<tr>
<td>RP</td>
<td>Radiopharmaceutical</td>
</tr>
<tr>
<td>RPO</td>
<td>Radiation Protection Officer</td>
</tr>
<tr>
<td>RPS</td>
<td>Radiation Protection Supervisor</td>
</tr>
<tr>
<td>SPECT</td>
<td>Single Photon Emission Computed Tomography</td>
</tr>
</tbody>
</table>
PREAMBLE
PREAMBLE

This policy aims to:

1. Provide a brief history of development and the current status of Nuclear Medicine services in Malaysia.

2. Introduce commonly used Nuclear Medicine equipment and provide fundamental guidelines for setting a Nuclear Medicine department in the hospital.

3. List down the roles and responsibilities of important personnel in a Nuclear Medicine team.

4. Describe the important elements in the operation and scope of Nuclear Medicine services.

5. Underline the concept, regulatory requirements and policies governing Nuclear Medicine services in Malaysia.
NUCLEAR MEDICINE SERVICES
1.0 NUCLEAR MEDICINE SERVICES

1.1 Introduction

1.1.1 Nuclear Medicine Specialty

There are 3 medical specialties that use radiation science to help in combating ionizing radiation sources used. The status of these 3 medical specialties have also been identified and defined under the Atomic Energy Licensing Act 1984 (Act 304) and its related regulations.

<table>
<thead>
<tr>
<th>Source</th>
<th>Types of ionizing radiation</th>
<th>Speciality</th>
</tr>
</thead>
<tbody>
<tr>
<td>Machine-generated X-rays</td>
<td>Low photon energy (e.g. conventional X-ray, CT scan)</td>
<td>Conventional Radiology</td>
</tr>
<tr>
<td>Sealed or solid radioactive sources</td>
<td>Teletherapy / Radiosurgery High photon energy (e.g. LINAC device for teletherapy and radiosurgery)</td>
<td>Radiotherapy/ Oncology</td>
</tr>
<tr>
<td></td>
<td>Source head of the machine is housed with sealed radionuclides (e.g. Co-60 in gamma-knife for steroostatic radiosurgery)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Brachytherapy Sealed radioactive source in the form of insoluble compounds, ceramics or metal foils or wires (e.g. Cs-137 needles)</td>
<td></td>
</tr>
<tr>
<td>Unsealed radioactive sources</td>
<td>For treatment α and β emissions (e.g. Ra-223, Sr-89, Y-90,)</td>
<td>Nuclear Medicine</td>
</tr>
<tr>
<td>(Radioactive medical products / radiopharmaceuticals / radiotracers)</td>
<td>For diagnosis &amp; treatment Both β and γ-rays (e.g. I-131, Re-186, Lu-177)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>For diagnoses γ-rays and positron emissions Imaging (e.g. Tc-99m, In-111, F-18, C-11 etc.) Non-imaging (e.g. Cr-51)</td>
<td></td>
</tr>
</tbody>
</table>
Nuclear Medicine is a specialized medical discipline using radioisotope-labelled compounds, also known as radiopharmaceuticals (RP), which are administered into the body of the patient for diagnostic or therapeutic purposes or both. Following administration, specific RP is able to localize onto specific cells, tissues or organs based on its chemical, biological, metabolic or immunological properties. Since these radioactive molecules are given in small amounts and have the ability to target the tissues or organ of interest, they are also frequently known as radionuclide tracers or just radiotracers.

The radiation emitting out from these radiopharmaceuticals allow them to be easily detected using gamma imaging devices like SPECT and PET machines. This modality offers a unique way of demonstrating the dynamic distribution of radiotracers within the body of the patient, thus providing information on the function of an organ or tissue characteristic of a suspected tumor. At times, it is possible to allow certain selected radioactive molecules to accumulate in such sufficiently high quantity at the target site resulting in elimination of diseased cells and achieving a good treatment outcome.

Over the last two to three decades, this field has developed and transformed itself into an important diagnostic and therapeutic tool in the management of diseases especially in oncology and cardiology. Currently, the field of Nuclear Medicine has become a significant component of what is currently known as molecular imaging.

Adapted from: Essential Nuclear Medicine Physics 2nd Edition by Rachel A. Powsner & Edward R. Powsner
In summary, Nuclear Medicine is a medical specialty that utilizes the nuclear properties of radioactive and stable nuclides to allow diagnostic evaluations of the anatomy and/or patho-physiologic conditions of the body and in some cases, using the radiation to provide treatment options in disease management.

1.1.2 Radiopharmaceuticals / radiotracers

As mentioned above, radiopharmaceuticals / radiotracers are radioactive drugs used for diagnosis or therapy in Nuclear Medicine. They can be radioisotopes in their original form (e.g. $^{99m}$Tc, $^{131}$I, $^{18}$F) or by coupling with some pharmaceutical products (e.g. $^{99m}$Tc-MDP, $^{131}$I-MIBG, $^{18}$F-FDG).

It is important to understand the nuclear physics of the radioisotopes together with the chemical properties of the compounds (e.g. $^{123}$I and $^{131}$I have similar chemical properties but with different radiation type; handling and imaging techniques for $^{18}$F-FDG & $^{18}$F-chloride are different even though they are derived from the same radioisotopes). The technical parts of Nuclear Medicine procedure will also vary with the radiation properties and pharmacokinetics of the radiopharmaceuticals (e.g. $^{99m}$Tc-MDP and $^{18}$F-chloride are both bone tracers but the former is scanned with SPECT whereas the latter imaging is done with PET techniques and the timing to do these two procedures also differs).

In general, radioisotopes used in PET technology are many times more radioactive than those used in conventional Nuclear Medicine. For example, radiation exposure to workers for $^{18}$F used in PET could be 6 times higher than those exposed to $^{99m}$Tc.

1.2 Scope of Nuclear Medicine Services

1.2.1 Radionuclide imaging

Two types of imaging machines that are frequently used in this field are SPECT and PET acquisition machines.

a) SPECT

Single-photon emission computed tomography (SPECT) is a Nuclear Medicine tomographic imaging technique detecting radiation (gamma) rays beaming out of the body after radiopharmaceuticals administration. It is very similar to conventional Nuclear Medicine planar imaging using a gamma camera. However, SPECT camera is able to rotate over a 3600 arc around the patient to capture scintillation images at various angles in order to provide 3-D tomographic pictures.
b) **PET**

Positron emission tomography (PET) is also a form of scanning based on Nuclear Medicine principles with a more complex acquisition method in detecting a type of radioactive decay called positron annihilation. Data will be recorded only when a pair of anti-parallel gamma radiation with energy 511keV are detected simultaneously – a process called coincidence detection. Ring detectors are used to facilitate the process. Data are later processed to construct 3-D images and tomograms.

Adapted from: Essential Nuclear Medicine Physics 2nd Edition by Rachel A. Powsner & Edward R. Powsner
c) **Hybrid technology**

With advancement made in science and technology, it is now possible to combine physiological imaging technologies in Nuclear Medicine (e.g. SPECT and PET) with the anatomy imaging (e.g. CT and MRI) in radiology, constituting a hybrid imaging systems like SPECT-CT, PET-CT and PET-MRI. These two different types of pictures (i.e. emission and transmission scans) are then superimposed or fused together, allowing the physiological function from the Nuclear Medicine study to be correlated with the anatomy of the body structure, leading to more precise information and accurate diagnosis.


Image of GEMINI TF PET/CT

A: Non-contrast CT-scan  B: $^{18}$FDG PET image  C: $^{18}$FDG PET/CT fusion image
1.2.2 Targeted Radionuclide Therapy
Radionuclide therapy uses molecules labelled with radionuclides to deliver a toxic level of radiation to disease sites in order to kill cancer cells and shrink tumors by damaging the cells’ DNA, thereby stopping these cells from continuing to grow and divide.

Unlike the commonly known radiotherapy in which the radiation is delivered through exposing patients to an external radiation source, radionuclide therapy is usually delivered like a chemotherapy drug in the form of a systemic treatment. A systemically administered targeted radionuclide therapy uses RP with specific cancer cell tracing features based on the chemical, biological, metabolic or immunological properties, will help to deliver the necessary antitumor effects of ionizing radiation both at the primary tumor site and also to cancer cells that has spread throughout the body, including malignant cell populations undetectable by diagnostic imaging. Another unique feature of radionuclides is that they can exert a “bystander” or “crossfire” effect, potentially destroying adjacent tumor cells even if they lack the specific tumor-associated antigen or receptor.

1.2.3 Theranostic
The term “theranostic” means the integration of diagnostic and therapy capabilities in order to test patients’ reactions to a certain medication and to tailor a personalised treatment plan for them based on the test results. This concept of theranostic is pinned on the belief that diagnostic test results can help to determine whether the patient is likely to benefit from a specific treatment and exclude those cases that are unlikely to benefit from such therapies therefore preventing futile or unnecessary treatment which are often expensive and potentially toxic.
Over the past few years, Nuclear Medicine has contributed to an impressive paradigm shift in cancer theranostic, resulting in optimal patient selection for treatment, therapeutic dose optimization by dosimetry-based mathematic modelling and optimal patient follow-up. The following are some examples:

- specific criteria for assessment of lymphoma (Lugano criteria) & solid tumor response to therapy (PET Response Criteria in Solid Tumors—PERCIST)
- $^{124}\text{I}$ dosimetry scan to assess the optimization of $^{131}\text{I}$ therapeutic efficacy in thyroid cancer
- $^{68}\text{Ga}/^{90}\text{Y}$ or $^{177}\text{Lu}$-labelled somatostatin analogues in neuroendocrine tumors
- $^{68}\text{Ga}/^{177}\text{Lu}$-labelled prostate-specific membrane antigen (PSMA) ligands in prostate cancer
- $^{89}\text{Zn}$-tratuzumab in detection of Human Epidermal Growth Factor Receptor 2 (HER2) expression in breast cancer

Theranostic management in a case of VIPoma. Patient was treated with single cycle of peptide receptor radionuclide therapy (PRRT) using Y-90 DOTATATE after an assessment from a pre-treatment diagnostic Ga-68 DOTATATE scan confirming the radiotracer affinity to the targeted tumor. Follow up on patient showed significant symptomatic improvement. Serial diagnostic scans demonstrated marked reduction of tumor burden. Only a single liver metastasis remained after 1 year (partial remission).

1.2.4 Radiobioassay & Radiochemical Measurements

These are various analytical methodologies used to determine the types, quantities or concentrations and the locations of radioactive material in the human body. The methods of radiobioassay measurement can be classified into two categories:

1. In vivo radiobioassay refers to direct measurement of the amount of radioactive material deposited in organs, tissues or the whole body. Common methods are thyroid counting, lung counting, and whole body counting (e.g. radiation dosimetry).
2. In vitro radiobioassay refers to measuring the amount of radioactive material in a sample taken from the body. The most common method is by urine analysis and other methods are faecal, breath (e.g. urea breath test), and blood analysis (e.g. GFR).

1.3 The range of Nuclear Medicine Services in Malaysia

Master List for Nuclear Medicine Procedures 2018 in Chapter 8 provides a list of Nuclear Medicine procedures that are available or to be introduced in the near future under the MOH, Malaysia.

1.4 Different categories of Nuclear Medicine facilities under the Ministry of Health

The Nuclear Medicine set up under the MOH are categorized into 2 levels:

Level 1: Diagnostic & Outpatient Therapy Service
Level 2: Level 1 + Inpatient Therapy Service

Depending on the availability of equipment and facility, each center is assigned with the following subsets:

Subset s : with SPECT service
Subset p : with PET service
Subset sp : with both SPECT & PET services

Going along with the population distribution in the country, the MOH has taken a regional approach in the delivery of these services in order to optimize them to the fullest and ensure cost-effective use of radiopharmaceuticals.
There are currently 6 regional Nuclear Medicine centers under the MOH:

**Peninsular Malaysia**
- Northern region: Hospital Pulau Pinang (Level 2sp)
- Central region: Hospital Kuala Lumpur (Level 2s) & National Cancer Institute, Putrajaya (Level 2sp)
- Southern region: Hospital Sultanah Aminah Johor Bahru (Level 1s)

**East Malaysia**
- Sarawak: Hospital Umum Sarawak (Level 2s)
- Sabah: Women and Children Hospital, Likas (Level 2s)

Out of the 6 Nuclear Medicine centers under MOH, two are at the central region. Only 2 centers are equipped with PET-CT service (red) and one is still under the category of Level 1 (blue). There is no MOH Nuclear Medicine center at the east coast of Peninsular Malaysia.
Continuous efforts will be made so that:

- Nuclear Medicine services under the MOH will be upgraded at all the existing regional centers to Level 2sp to address the needs for such medical services at their respective regions in the country.
- All oncology centers shall be equipped with a Nuclear Medicine facility of at least Level 1sp
- Based on the population distribution in this country, a proposal will be submitted to set up a Nuclear Medicine Center under MOH at the east coast region of Peninsular Malaysia
ORGANIZATION AND MANAGEMENT
2.0 ORGANIZATION AND MANAGEMENT

2.1 Organization Structure

The National Head of Nuclear Medicine Services shall serve as the advisor to the Ministry of Health on all matters pertaining to this service. The National Head of Nuclear Medicine Service may at his / her discretion call upon other Nuclear Medicine Personnel or form a committee to assist him / her in assessing and resolving related issues. Issues for the following areas have been identified:

i. Nuclear Medicine Posting and Service Coordination
ii. Nuclear Medicine In-service training and Continuous Professional Development
iii. Nuclear Medicine Developmental Planning and Technical Evaluation
iv. Nuclear Medicine Research and Scientific Analysis

The Regional / State Nuclear Medicine Physician shall be appointed by the State Health Director and assist the National Head of Nuclear Medicine Service in all matters pertaining to this field in the state or region.

The Head of Nuclear Medicine Department in the Hospital shall be appointed by the respective Hospital Director. The Head of Department shall be the authority on matters pertaining to the clinical service management related to Nuclear Medicine and the radionuclides utilized. He / She shall be responsible for:

- Supervision and administrative position on matters related to the department.
- Strategic human resource planning for the departmental personnel.
- Optimal management and usage in the departmental budget and resources.
- Planning and future development of the discipline or department.

The Head of Nuclear Medicine Department shall be assisted by medical physicists, nuclear pharmacists, Nuclear Medicine technologists and other related allied health professionals specifically trained in this field. The staff shall complete their training as outlined in the MOH circular (Pekeliling Keperluan Latihan Untuk Personel Dalam Perkhidmatan Perubatan Nuklear), in compliance with the training requirements under the Atomic Energy Licensing Act 1984 (Act 304).

The personnel in the Nuclear Medicine Department shall be involved in any decision making pertaining to Nuclear Medicine services, procurement and the use of radionuclides or its related equipment in the hospital. Appropriate periodic meetings shall be conducted. Special ad-hoc meetings will be carried out as and when necessary.

The Nuclear Medicine Department personnel shall be represented in various committees at hospital level as deemed necessary by the Hospital Director.
2.2 Organization Chart for the Nuclear Medicine Department

Medical Support Services

provide the necessary scientific & pharmaceutical support to permit smooth & effective functioning of Nuclear Medicine services

Clinical Services refer to those services that entail contact and interaction with patient directly.

2.3 Human Resource and Scope of Duties

The objective of human resource planning in Nuclear Medicine is to optimize the human resource contribution to the growth and development of this specialty. It is important to appoint qualified personnel to appropriate positions so as to tap the full potential of the workforce for the benefit of the organization and its staff. Generally, in a standard Nuclear Medicine practice, these are the required multidisciplinary staff:

1. Nuclear Medicine Physician
2. Nuclear Physicist
3. Nuclear Pharmacist
4. Radiobiochemist
5. Nuclear Medicine Technologist
6. Nuclear Medicine Nurse
2.3.1 Nuclear Medicine Physician

Scope of Duty

Head of Department of Nuclear Medicine
Expected to lead and oversee the work of the whole Nuclear Medicine team and shall be able to coordinate all aspects of Nuclear Medicine services. Direct and supervise the drawing up of policies and procedures on the clinical usage of diagnostic and therapeutic radiopharmaceuticals. Responsible in ensuring that the medical services meet the quality standards set by the organization and national regulatory authorities.

Nuclear Medicine Physician
Responsible in all clinical aspects of Nuclear Medicine services that involve the administration of radiopharmaceuticals to patients for diagnosis, therapy or research. This clinical scope of duty include history taking, examination, selection, supervision and reporting of diagnostic investigations, assessing and performing treatment procedure for patients, providing appropriate follow up, attending to clinical emergency associated with radiation and involvement in the triad of audit, research and teaching.

Hold the supervisory role with overall responsibility in handling of unsealed radioactive substances including the following but not limited to:- order, purchase, receive, storage, disposition, preparation, radionuclide quality control, administration, follow-up, dosimetry, authorization for isolation and patient-release, usage, disposal, waste management, emergency response for contamination and radiation safety.

Job Descriptions

1) Familiar with a variety of standard concepts, practices and procedures in the field of Nuclear Medicine.
2) Advise other doctors of the clinical indications, justifications, limitations, assessments, or risks of diagnostic and therapeutic applications of radioactive materials.
3) Interview and physically examine patients prior to any clinical procedure. Review patients’ medical histories and procedure requests to determine applicability of procedures and radiopharmaceuticals to be used.
4) Determine appropriate tests or protocols based on patients’ needs or conditions and develop treatment plans when necessary.
5) Prescribe radionuclides and dosages to be administered to individual patients.
6) Perform cardiovascular Nuclear Medicine procedures such as exercise or pharmacologic stress testing.
7) Calculate necessary numerical data for radiotracer activities; provide input in calculation, measurement, or preparation of radiopharmaceutical dosages.
8) Administer radiopharmaceuticals to clinical patients or research subjects for imaging, treatment or other procedures.

9) Consult with anaesthesiologists/paediatricians regarding recommended dosages or combinations of sedative drugs where applicable.

10) Instruct and direct Nuclear Medicine technologists regarding image acquisition techniques. Check and approve the quality of diagnostic images before patients are discharged.

11) Interpret imaging data for diagnosis or treatment. Collaborate and assist other healthcare professionals to formulate the diagnoses or to plan or provide necessary treatment.

12) Compare and correlate Nuclear Medicine procedures with other types of procedures such as CT, MRI, ultrasonography and angiography. Evaluate treatment options to guide medical decisions.

13) Prepare comprehensive interpretive clinical reports, summarizing patient diagnostic or care activities.

14) Provide appropriate in-patient care during radionuclide therapy, including attending to clinical emergencies when necessary. Authorize patient discharge when appropriate.

15) Provide consultation to patients following Nuclear Medicine procedures, give information and assess outcomes or to recommend further consultation or treatments as appropriate.

16) Ensure appropriate scheduling of patients’ appointment and staff activities for optimum use of medical facility and equipment.

17) Supervise laboratory procedures such as radioimmunoassay studies of blood or urine using radionuclides and analyse the results.

18) Provide continuous medical education for Nuclear Medicine fraternity or other specialties at graduate and post-graduate level.

19) Establish and enforce radiation protection standards for patients and staff. Verify that medical activities or operations meet standards. Determine protocols for medical procedures.

20) Monitor quality control of radionuclide preparation, administration and disposal, ensuring that all activities comply with applicable regulations and standards set by the national regulatory authorities.

21) Ensure all test dosage evaluation instruments and survey meters are operating properly.

22) Supervise handling of radioactive materials to ensure that established SOP is followed. This includes safe management and disposal of hazardous radioactive materials or medical wastes.

23) Ensure that the proper procedures are followed during decontamination activities in the event of radioactive spills.

24) Formulate plans and procedures for the Nuclear Medicine department.

25) Provide advice on the selection of Nuclear Medicine supplies or equipment.
2.3.2 **Medical Physicist (Nuclear)**

**Scope of Duty**
Generally involved in radiation safety and development of quality assurance programme.

**Job Descriptions**
1) Responsible as a radiation protection supervisor (RPS) and/or radiation waste management officer in any Nuclear Medicine Department. Carrying out radiation protection work in order to ensure the safety of the patients, staff and public.
2) Ensure the process of procurement of radioactive items fulfils the legal requirements.
3) Responsible for the acceptance and storage of radioactive material according to the standard regulations. Responsible for overall security of radioactive material.
4) Monitoring radioactive materials' packaging, labeling and transportation according to the regulations.
5) Responsible for the clean-up and monitoring of radioactive spills. Ensuring those decontamination activities are conducted according to proper procedures.
6) Ensure safe management and disposal of hazardous radioactive materials or medical wastes.
7) Monitor the supervised and control areas in order to ensure the level of radiation exposure is within the acceptable limit.
8) Monitoring all radiation worker’s radiation dose record and ensuring they attend the required periodic medical examination.
9) Investigate radiation exposure for any accident or contamination of radioisotope materials.
10) Monitoring of patient undergoing therapy.
11) Notify and report all abnormal exposure to the relevant authority.
12) Involve in the planning of facilities, equipment as well as commissioning and decommissioning of such resources.
13) Responsible for preparation of specification, acceptance testing and quality control of equipment. Development and implementation of appropriate QA procedures in collaboration with other professionals in the department.
14) Provide first line maintenance and help to identify and resolve equipment problems in liaison with the service personnel.
15) Involve in the management of scientific and technical aspects of the service. Responsible for overall supervision of computer system management, provide advice on computer use as well as first line support for application software, assist in computer analysis.
16) Provide technical advice and assist in quantification and dosimetric calculation in Nuclear Medicine.
17) Participate in the teaching and training program as well as continuous professional development at the departmental and hospital level.
18) Involve in Research and Development as necessary for the practice of Nuclear Medicine.
2.3.3 Nuclear Pharmacist

Scope of Duty
Generally involved in handling of radiopharmaceuticals.

Job Descriptions
1) Preparation of radiopharmaceuticals to ensure their safety and efficacy.
2) Responsible for the procurement of pharmaceutical products including radiopharmaceutical, consumable and chemical items suitable and necessary for the practice.
3) Responsible for quality control of radiopharmaceuticals.
4) Responsible for the dispensing of radiopharmaceuticals.
5) Responsible for the provision of information and consultation on radiopharmaceutical products.
6) To ensure the equipment and facilities related to radiopharmaceutical preparation are maintained in the optimal condition.
7) Responsible for Research and Development as necessary for the practice of Nuclear Pharmacy.
8) Participate in the delivery of medical education in Nuclear Medicine training program.
9) Participate in continuous medical education/continuous professional development at the departmental and hospital level.

2.3.4 Radiobiochemist

Scope of Duty
Generally involved in handling bioassay procedures and verification of in-house produced complex radiopharmaceuticals for clinical use.

Job Descriptions
1) To manage the radioimmunoassay lab and perform diagnostic tests using radioactive sources, for example red cell mass, glomerular filtration rate, red cell survival / sequestration study, Schilling test, urea breath test etc.
2) Responsible for quality control of in-house produced complex radiopharmaceuticals.
3) To conduct environment monitoring of ‘clean room’ and also to perform particle count after completion of cleaning process.
4) Ensure lab safety and quality control measures are adhered to.
5) Ensure radiation safety compliance according to the Atomic Energy Licensing Act 1984 (Act 304) and the related regulations.
6) Responsible for Research and Development as necessary for the practice of Nuclear Medicine.
2.3.5 Nuclear Medicine Technologist

Scope of Duty
Generally involved in the technical aspects when handling Nuclear Medicine patients.

Job Descriptions
1) Responsible in performing the scan, data processing and production of good quality images and data archiving.
2) Ensure proper positioning of the patients according to scan requirements.
3) Administration of radiopharmaceutical to patient in certain type of imaging/procedures as delegated by the doctor.
4) Responsible to assist exercise stress test during myocardial perfusion imaging.
5) To perform any in vitro studies and procedures.
6) To provide technical assistance to other professional staff in the Nuclear Medicine team.
7) Participate in teaching/training of junior staff/personnel involved in the Nuclear Medicine training program.
8) Participate in continuous medical education at the departmental and hospital level.
9) Participate in research and development as necessary for the practice of Nuclear Medicine.

2.3.6 Nuclear Medicine Nurse

Scope of Duty
Generally involved in assisting doctors handling clinical Nuclear Medicine cases

Job Descriptions
1) Educate and prepare patients prior to the imaging and therapeutic procedures.
2) Assessment of vital signs and ensuring the well-being of patients undergoing the imaging or treatment procedures.
3) Administration of drugs or injection upon the instruction of doctors.
4) Ensure proper handling of radiopharmaceuticals and radioactive waste together with the pharmacists and technologists.
5) Assisting in various medical procedures.
6) Participate in teaching/training of junior staffs/personnel involved in the Nuclear Medicine training program.
7) Participate in continuous medical education at the departmental and hospital level.
8) Participate in research and development as necessary for the practice of Nuclear Medicine.
OPERATING POLICIES ON CLINICAL SERVICES IN NUCLEAR MEDICINE
3.0 OPERATING POLICIES ON CLINICAL SERVICES IN NUCLEAR MEDICINE

3.1 Scheduling of patients’ appointments
- Request for Nuclear Medicine procedures shall be made by a registered medical / dental practitioner in a written form.
- All requests shall contain clinical information to justify the referral and signed by the requesting doctors.
- Scheduling and appointment will be given by staff of Nuclear Medicine Department on a first come, first serve basis.
- Cases that need urgent or early appointment shall be discussed with the Nuclear Medicine doctor in-charge.
- The Nuclear Medicine consultant in-charge has the overall responsibility for clinical prioritization and categorization of referrals. However, this may be delegated to a member of their team (e.g. medical officer, technologist or nurse) where clearly defined service models and protocols have been agreed on.
- For those requests made within the hospital (internal referrals), the respective wards/clinics will be responsible for informing the patient of the appointment date and time together with any other relevant instructions.
- All pre-procedure preparation instructions will be given by staff from the respective referring ward or clinic concerned. The patients or their relatives may also request for information directly from the Nuclear Medicine Department if needed.
- Patients will be interviewed and examined on the day of the procedure. Consent for the Nuclear Medicine procedure shall be taken by the attending Nuclear Medicine doctor before the procedure is conducted.
- Patients who fail to keep their appointment or arrive late for the procedure may have their procedures cancelled or rescheduled to a new appointment date.

3.2 Movement of patients within the Nuclear Medicine facility
- Outpatients attending the Nuclear Medicine department may be unaccompanied or accompanied by their guardians or next-of-kin.
- All inpatients shall be transported on wheelchairs, trolleys or mobile beds (cots, bassinets, cribs). Ambulant patients may be escorted on foot. The respective department attendants shall be responsible for transporting these patients to the Nuclear Medicine department.
- All the Nuclear Medicine patients must be registered at the reception.
- The movement of patients within the Nuclear Medicine facility shall be monitored.
- The traffic flow for patients must be well-planned and be informed to them prior to the administration of any radiopharmaceuticals thereby, rendering them to become radioactive patients.
- Traffic patterns must be designed to keep movement of radioactive sources and the radioactive patients away from the sensitive imaging equipment.
- Unless specifically permitted, staff and patients from other departments or members of the public, including the guardians or next-of-kin for the Nuclear Medicine patients are not allowed entry into specific designated areas with the patients.
- Proper signage, including no entry and radiation safety signage shall be on display at the entrance gates.
- For security reasons, access into certain areas within the premises shall be restricted.

### 3.3 Management of outpatients in a Nuclear Medicine specialist clinic
- All outpatient visits at the clinic shall be recorded and the records shall be complete, concise, and clear. Only standard medical abbreviations shall be used.
- All health services personnel shall be familiar with the required format for health record entries and policies regarding confidentiality of patient records. Policies regarding confidentiality of patient records shall be followed strictly.
- Minor dependent children shall be accompanied by a parent or legal guardian.
- When a patient cancels or requests to reschedule a fixed appointment, they shall be offered a second opportunity for rescheduling. If the patient cancels this re-scheduled appointment again, they will be discharged back to their referring doctors.
- When a planned outpatient procedure is being withheld or cancelled because of patient’s non-compliance to pre-procedure preparation, a second appointment may be rescheduled after counselling. However, if such incident is repeated, the patients will be discharged back to the referring doctor.
- At the end of each new or review consultation, patients will be discharged unless further expert Nuclear Medicine specialist care is still required.
- For those patients with complex, chronic and non-resolving conditions, care pathways shall be developed for them to receive subsequent follow-up with the Nuclear Medicine specialist so as to ensure that these patient are managed in the most appropriate manner for their current stage of illness.
- Under certain circumstances (for example, patient is considered vulnerable or in need of imminent clinical care), the Nuclear Medicine physician may decide to refer the patient for further management including admission. Additional steps shall be taken to contact the patient’s legal guardian, next-of-kin, referring doctor or other relevant professionals for discussion.
- Any patient who is very ill or considered incapable of a reasonable level of self-care shall NOT be given any radiopharmaceutical.

### 3.4 Management of inpatients in a radioactive isolation room / ward
- For radiation and medical safety purposes, each in-patient therapy shall include pre-therapy counselling, counselling on therapy protocols, explanation on the discharge criteria and discharge counselling.
- The Nuclear Medicine team shall work together to actively plan a complete episode of care and appropriate discharge of patients.
- Patients shall be offered hospital clothes throughout their stay in the radioactive isolation room. The radioactive isolation room shall be equipped with dedicated toilets, showers and washing facilities.
● Unless permissible and specifically arranged, all therapeutic doses of radionuclides must be administered inside the radioactive isolation room, in all cases of radionuclide treatments requiring isolation.

● To facilitate radionuclide discharge through urinary excretion, patients shall be advised to drink freely and void frequently. If the patient is incontinence or has difficulty in emptying the bladder, a bladder catheter shall be inserted prior to the therapy.

● To reduce contamination from the nasal mucosa, patients shall use disposable tissues rather than handkerchiefs.

● All rubbish must be thrown inside a plastic bag and kept in the room.

● Bed sheets, pillow covers, or any used linen shall also be placed in the bag and left within the radioactive isolation room until they are dealt with accordingly by a physicist.

● Meals shall be supplied on disposable plates and consumed using disposable cutlery.

● Patients are not allowed to leave the isolation room except for a planned scan.

● Adult visitors are allowed only if they comply with the regulations set by the center. Children and pregnant women are prohibited from visiting the radioactive patient in the radioactive isolation room / ward.

3.5 Management of radioactive patients in medical emergencies

In the event of medical emergency:

● In a case of cardiac or respiratory arrest,
  a) Do NOT apply direct mouth-to-mouth resuscitation;
  b) staff involved in resuscitation shall use disposable gowns and gloves when handling the patient;
  c) items that have come into direct contact with the patient (e.g. airways, masks, endotracheal tubes, etc.) shall be examined by the nuclear physicist before disposal.

● Even though the patient may still be radioactive, this shall not preclude appropriate clinical management of the case, including transfer to intensive care or the coronary care unit when the situation requires.

● In the intensive care / coronary care unit / operation theatre, all items that have come into direct contact with the patient including suction bottles or urine bags must not be discarded until they are assessed for radioactive contamination. All body fluids (e.g. urine, gastric contents etc.) shall be contained as far as possible by means of absorbent pads, and the pads shall be placed in a contaminated waste bag for examination and subsequent handling by a nuclear physicist.

● In the intensive care unit (ICU) / coronary care unit (CCU) / operation theatre (OT), principles of radiation protection (justification, optimisation, dose limit, time, distance, shielding) shall be applied at all times to reduce the exposure to all members of the public including non-radiation staff. The nuclear physicist shall supervise and advise the relevant staff in the ICU / CCU / OT on issues related to radiation safety.

● All the details regarding radiation exposure from the radioactive patients to the personnel involved must be recorded.
3.6 Examination of staff involved in resuscitation or handling of a radioactive patient:
- Staff who have been directly involved with the radioactive patient will need to be assessed with regards to their potential radiation exposure no matter how low the level might appear to be, by using the best possible estimation of radiation exposure.
- Administration of Lugol’s iodine may be necessary for staff involved in the resuscitation of patients administrated with radioiodine (I-131, I-124) based radiopharmaceuticals. This shall be followed by subsequent measurement of any thyroidal accumulation of radioiodine by thyroid uptake studies.

3.7 Drugs and medication management (general)
- The usage of drugs and medication in the department, including the radiopharmaceuticals shall comply with all applicable laws and regulations by the MOH Malaysia and the hospital policy.
- An appropriately licensed pharmacist, technician, or other trained professional must be available to supervise the medication management system and pharmaceutical use.
- A list of selected medications, including emergency medications must always be stored safely, monitored properly and readily made available for prescribing or administration.
- Prescribing, ordering and transcribing are guided by the hospital policy.
- Prescription needs to be complete and accurate. Medications prescribed and administered must also be written in each patient's record.
- Qualified personnel shall be identified to administer medications.
- Administration of medication shall include a process of drug verification based on the written prescription.
- Medication effects on patients shall be monitored.
- Medication errors shall be reported within the time frame required.

3.8 Radiopharmaceutical use and management
- All radiopharmaceuticals dispensed and administered must be pursuant to an order (e.g. prescription) by an authorized Nuclear Medicine physician.
- There must be a signed and dated written directive for each patient, specifying the quantities in megabecquerel (MBq) or millicurie (mCi) for all radiopharmaceuticals.
- The identity of the radiopharmaceutical, patient and the route of administration must be verified before administration.
- Syringes and outer shields of the containers must be labeled for content verification.
- For diagnostic procedures in adult patients of standard size, the activity administered should not exceed the level recommended in “Malaysian Diagnostic Reference Levels in Medical Imaging (Nuclear Medicine), 2013”. In many cases, it will be possible to administer activities less than these diagnostic reference levels. This is encouraged in line with the principle of ALARA.
However, in certain clinical circumstances, it may be necessary to administer a level exceeding the reference levels e.g. severely obese patients or in situations where fast imaging are required as patients are unable to tolerate standard acquisition time. The guiding principle remains that for the investigation of any subject, the activity administered should be the minimum consistent with acquiring adequate image data for the investigation concerned.

The quantity of each radiopharmaceutical activity must be determined before administration to patients. This shall be consistent with what has been ordered by the Nuclear Medicine physician or as stipulated inside the procedure manual. The quantity of radioactivity administered shall be within 10% of the prescribed activity or within an acceptable dose range.

Radiopharmaceuticals shall not be used beyond the expiry date or time recommended by the manufacturer unless quality control testing demonstrates that the product can still meet the specifications of the pharmacopeia at the time of use.

Radiopharmaceuticals shall be prepared according to the instructions of the manufacturer. The prescribing physician or nuclear pharmacist may deviate from the instructions on the package insert, but in such instances, the involved physician or pharmacist is responsible to ensure that it can meet the pharmacopeia specifications.

All aseptic procedures must be followed when handling the parenteral radiopharmaceutical preparations or their components.

Radiopharmaceuticals prepared on-site should be subjected to quality control testing, especially on the radiochemical purity. Radiopharmaceuticals shall never be administered to any patient if the level of impurity exceeds specifications stated on the package insert or WHO pharmacopeia monograph.

Records on the receipt, use, administration and disposal of all radiopharmaceuticals shall be kept in compliance with licensing requirement, medical record and radiation control regulations.

For those radiopharmaceuticals prepared on-site, record keeping shall include the date and time of preparation; the quantity, volume, and concentration of radioactivity used; reagent lot numbers; quality control data; the expiration time, the name and initial of the individual responsible for the preparation.

For all the radiopharmaceuticals used, the identity of the radiopharmaceutical, the amount of radioactivity administered, the identity of the patient and of individual performing the administration, the route of administration and the date and time of administration must be recorded.

3.9 Consent for Nuclear Medicine procedures

All Nuclear Medicine procedures shall be performed with informed consent from the patients or in cases where patients lack capacity to provide consent, consent must be obtained from a surrogate decision maker who is the legal representative.

The process to obtain an informed consent should fulfill 3 criteria: a) full disclosure of risks, benefits and other alternative options; b) assessing decision-making capacity of the patient / decision maker and c) ensuring voluntariness in decision making.
Before an informed consent is taken, the attending clinician (not a delegated representative) shall disclose and discuss:

i. The diagnosis, if known
ii. The nature and purpose of a proposed treatment or procedure
iii. The risks and benefits of proposed treatment or procedures
iv. Alternatives (regardless of costs or extent covered by insurance)
v. The risks and benefits of alternative procedures and treatments
vi. The risks and benefits of not receiving treatments or undergoing procedures

The following are needed on a written informed consent form (refer to the examples in Appendix 1 & 2):

i. Name and signature of the patient or if appropriate, legal representative as surrogate decision maker (patient's legal guardian or next-of-kin)
ii. Name of the hospital
iii. Name of procedure(s)
iv. Name of all doctors performing the procedure and their individual clinical tasks, if more than one doctor
v. Statement that the procedure was explained to patient or guardian
vi. Statement that the inherent risks and benefits were informed
vii. Name and signature of person who explained the procedure to the patient or guardian
viii. Date and time the consent is obtained
ix. Signature of person witnessing the consent

3.10 Conducting Nuclear Medicine procedures

- All procedures shall be conducted or supervised in the presence of a Nuclear Medicine physician of the department.
- Administration of all diagnostic and therapeutic doses of radiopharmaceuticals shall come under the responsibility of a registered Nuclear Medicine physician.
- Evidence-based clinical practice guidelines (CPG) and standard operating procedures (SOP) for the related Nuclear Medicine procedures shall be developed and implemented.
- Adequate protective and safety measures shall be taken by the Nuclear Medicine technologist when procedures are being carried out in accordance with existing guidelines or protocols.
- For women of child bearing age, the guidelines on radiation protection laid down by the MOH shall be adhered to.
- With the exception of emergency cases, no procedure shall be carried out on a minor dependent child without a parent or legal guardian present. The parent or legal guardian may elect not to be present in the exam room with the patient; however, the parent or legal guardian must remain within the clinic until the procedure is completed.
- An emergency trolley shall be made available at all times. The contents of the trolley shall be checked regularly, and contents replenished accordingly.
- Emergency management and protocols, including those for handling radioactive patients shall be readily available. Nuclear Medicine physicians and other relevant clinic personnel in the Nuclear Medicine facility shall be familiar with these guidelines.
The attending Nuclear Medicine physician shall maintain a state of readiness to handle emergencies and need to respond to all emergency calls or calls for medical assistance.

Quality control as well as quality assurance activities shall be carried out in line with the national guidelines and regulatory requirements in Malaysia.

Accidental medical exposure is considered to have occurred under the following circumstances: if the wrong radiopharmaceutical is used; if any diagnostic exposure given is 50% greater than the intended dose; if the patient receives a dose significantly different from what was intended; if any therapeutic treatment is delivered to the wrong patient or to the wrong tissue of any patient.

All accidental medical exposures need to be notified to the concerned authority in a timely manner, with the investigation instituted, corrective measures taken, and investigation results submitted to the authority within the stipulated time.

### 3.11 Reporting on Nuclear Medicine investigation and treatment

- All patients’ particulars shall be confirmed with the particulars recorded in the Nuclear Medicine study before the reporting begins.
- All relevant investigation results and previous Nuclear Medicine studies shall be referred to if needed and if the information is available or accessible.
- The final reports shall be reviewed and certified by the Nuclear Medicine Physician in-charge.
- All Nuclear Medicine studies shall be reported within the time frame specified in the National Key Performance Indicator (KPI).
- In those cases where there are findings to suggest immediate or urgent intervention, the Nuclear Medicine Physician shall communicate with the respective referring doctor in a timely manner.

### 3.12 Archiving / storage of medical record (investigation and treatment record)

**For IT hospitals**

- All reports will be archived in the Radiology Information System (RIS) whilst the images will be archived in the Picture Archiving and Communication System (PACS) which may form part of the integrated Hospital Information System (HIS).
- The respective referring doctor / team can access the RIS and PACS to view these reports and images.
- Access to information on RIS and PACS shall be controlled and based on policies and laws that govern the disclosure of patient’s medical records.
- All requests for hard copies of patient’s report and / or film by the attending specialist shall be done according to the local hospital standard operating procedures.
- For studies conducted on patients referred from other hospitals, a copy of the report will be sent to the referring team.
For non-IT hospitals
- The collection of the report and film shall be done by the primary referring doctor / team.
- Reports and films which are not collected by the primary referring doctor / team will be dispatched to the respective clinic after two weeks.
- All information on report and film collection and dispatch shall be documented and made available if needed.
- For studies conducted on patients referred from other hospitals, a copy of the report will be sent to the referring team.
OPERATING POLICIES ON RADIATION SAFETY AND SECURITY IN NUCLEAR MEDICINE
4.0 OPERATING POLICIES ON RADIATION SAFETY AND SECURITY IN NUCLEAR MEDICINE

As “unsealed radioactive sources” are used in this field, safety procedure needs to be adhered to and radiation dose needs to be monitored more vigilantly to prevent contamination.

Advice shall be given before administration of any radioactive medical products as patients will be emitting radiation (radioactive patients). This is in contrast to machine generated x-rays where the radiation is usually generated from electrical power therefore, exposure occurs over a very short period of time and is confined to the area of its usage where the radiation risk of x-rays ends once the procedure is completed.

In the interest of public safety and national security, the potential hazards of using unsealed radioactive substances on the patients and the associate radiation risks to staff, public and the environment should be kept in mind. All personnel shall comply with the laws, regulations, local rules and the radiation protection guidelines set by the department.

4.1 Radiation safety for the staff at the Nuclear Medicine facility

- Local rules and procedures shall be established in writing to ensure adequate levels of protection and safety of workers at the Nuclear Medicine facility. All staff shall be aware and comply with the local rules and procedures.

- The working areas shall be classified and delineated into clean areas, supervised areas and controlled areas. Signage with clearly printed instructions and warnings shall be displayed conspicuously in strategic place at the supervised and controlled areas.

- All staff shall be trained for their specific roles and be responsible for radiation safety in the facility in collaboration with the medical physicist / radiation protection officer.

- The allowable exposure dose for a worker shall not exceed the limits spelled out in the Basic Safety Radiation Protection, Regulations 2010 (BSRP 2010). The values set for investigation levels and intervention levels shall be specified along with the procedures and actions to be taken in the event that the recorded dose exceeds this pre-determined level.

- Proper dosimetry monitoring with appropriate record keeping shall be performed on all radiation workers and in the work place to ensure annual radiation dose limits are observed (i.e. personnel monitoring & area monitoring programmes). Additional attention shall be given to pregnant female workers, young persons between sixteen to eighteen years of ages, trainees and invited visitors to the Nuclear Medicine facility.

- Medical surveillance with periodic health reviews on the workers shall be carried out at least once in three years or more frequently as indicated by the worker’s exposure conditions and state of health. These medical records of workers shall be kept and maintained throughout the period of employment and supervision under the licensee.
● The licensee together with the medical physicist / radiation protection officer shall regularly review the safety policy, practices in the department and make the necessary changes.

● Any unusual event which has resulted or has the potential to result in over-exposure to the workers or public shall be promptly reported to the appropriate authority, investigated and corrective measures taken if necessary.

4.2 Discharge of radioactive patients and protection of general public from radiation exposure

Background information: Following administration of any radiopharmaceuticals, the radioactive patient will become an uncontrolled radioactive source that may pose external exposure and contamination risk to the general public. This potential exposure of general public varies depending on the type of the radionuclide, route of administration, individual bio-distribution and daily lifestyle of the patient. In general, this potential risk may be measured and/or calculated.

There are three possible ways of managing these patients

a) Hospitalization with isolation;

b) Discharge the patient with restrictions;

c) Discharge the patient without any restrictions.

● Treatment on an out-patient basis, or discharge of an in-patient can only be allowed if the dose to family, close friends and to the general public due to the (residual) activity in the patient is not expected to exceed exposure dose limits stipulated under the BSRP 2010.

● Under the BSRP 2010, patient can be treated as an out-patient or discharged from the hospital if the activity of the Iodine-131 to be administered, does not exceed the maximum activity of 1100MBq.

● For any other novel radioactive substance not listed in BSRP 2010, a patient can be discharged from the hospital if the calculated effective dose due to the (residual) activity from the radionuclide administered, does not exceed 1mSv for a member of public or 5mSv for a person who knowingly assists in the support of that patient (caregiver).

● The Nuclear Medicine physician in-charge is obliged to ensure that inquiries are made about the situation at home and relevant dose measurements are carried out when treating outpatients or discharging inpatients.

● The Nuclear Medicine physician responsible for the administration and discharge shall ensure that all the instructions on restriction if needed, can be understood and followed by the patient and his family or close friends. The patient shall be self-sufficient and capable of cooperating and complying with the instructions as well. These instructions must be given to patients and his family or close friends - both verbally and in writing.

● In the case of a non-self-supporting, non-cooperative or incontinent patient, or a patient who is prone to vomiting, outpatient treatment is not the preferred (safe) option and hospitalization with inpatient isolation shall be considered.
Discharge of a radioactive patient to premises other than a private dwelling

- If a patient is to be transferred to an institution or place of care other than a private dwelling, for example to a nursing home, appropriate notification of the patient’s radioactive status shall be sent to that place at the time of the transfer.
- The notification shall include details of the form and activity of the radionuclide, the time and date of administration of the radionuclide to the patient, the relevant radiation characteristics of the radionuclide, and the precautions that shall be observed for a specified time by the persons who will care for the patient (caregivers).
- The name of the hospital or clinic from which the patient was discharged shall also be provided, together with the name and telephone number of the person who may be contacted in order to obtain further information on radiation protection matters or advice in the event of a medical emergency.

4.3 Use of public transport by the discharged radioactive patients

- The duration of travel by public transport for the patient returning home shall not exceed two hours when the patient is discharged at a maximum ambient dose equivalent rate of 50 μSv/hour at 1 meter, or at the maximum activity granted in BSRP 2010.
- If it is anticipated that the journey would be of a longer duration and that the patient intends to use public transport, then the patient shall remain either in hospital or in the local premises after discharge so that the journey may be deferred until the external ambient dose equivalent rate has fallen to an acceptable level.
- Alternatively, after taking into consideration the possible dose to a caregiver or any other person accompanying the patient, the patient may be advised to travel by means other than public transport. This is of particular importance where the public transport involves confined adjacent seating at a distance considerably less than 1 meter.

4.4 Managing death of radioactive patients

- Diagnostic dose of radionuclide administered to the patient, rarely poses any significant radiation risks to people in the immediate vicinity including members of the household, following patient discharge.
- Therapeutic dose of a radionuclide shall not be given to any patient where impending death is anticipated.
- In the event of death of a patient who has recently received a therapeutic dose of a radionuclide, care has to be taken to ensure that radiation exposure to the surrounding personnel and any persons handling the body is minimized. Precautions and special handling procedures would depend on the estimated residual activity. Expert advice shall be provided by the Nuclear Medicine physician or medical physicist/RPO.
- Cremation of corpses containing a high activity of radioactive material shall be avoided as this will make the ash hazardous. An alternative method shall be considered.
4.5 Order, purchase, transportation and security of radioactive sources

- To ensure that the radioactive sources (including radiopharmaceuticals) and the irradiating apparatus are used in a safe manner, only individuals with the necessary qualifications and knowledge in radiation safety in areas specified under the license are permitted to use them.

- Order and purchase of any radioactive sources used in a Nuclear Medicine department including radiopharmaceuticals shall only be made by a registered Nuclear Medicine physician.

- The chemical form, the name and mass number of radioisotopes, the quantity and principal users shall be thoroughly checked and confirmed by a designated medical physicist.

- All incoming radioactive packages shall be delivered directly to the Nuclear Medicine department where they will be inspected for leakage or contamination and entered into the inventory records.

- Arrival and return of any radioactive sources, including generators will be checked by the designated medical physicist on call that day.

- All unused radioactive sources, including new and old generators will be placed and locked in specific designated location. For security reasons, access into these specific areas shall be restricted.

- Release, transfer or transportation of radioactive source to anyone outside the hospital premise are not permitted without prior approval by the appropriate authority and the knowledge of the registered Nuclear Medicine physician and designated medical physicist.

- Licensee shall be accountable in maintaining proper records of radioactive materials used under his / her charge, including but not limited to: the date of receipt, the nature and form, the activity of the radioactive material at the date specified by the manufacturer and the whereabouts of the radioactive material at any time.

4.6 Radioactive waste management

- Radioactive waste includes all radioactive material intended for disposal, regardless of source activity.

- The method of disposal depends largely on the half-life of the radioisotopes, physical and biological properties of the waste materials.

- In general, radioactive waste may be divided into solid radioactive waste, liquid radioactive waste and human or animal radioactive excreta. Short-lived and long-lived radioisotopes may also be segregated for disposal.

- The regulatory authority allows certain disused radioactive sources with radiation below the clearance/exempt levels, to be disposed away as common or biomedical wastes.

- Appropriate policy and protocols must be available and abided in the disposal of radioactive waste.

- When the radioactive content of wastes has diminished to a level that allows disposal as common biomedical waste, licensees must maintain certain records. Such records related to decay-in-storage must include the date of the disposal, the survey instrument used, the background radiation level, the radiation level measured at the surface of each waste container and the name of the individual who performed the survey.
Licensee shall be accountable in maintaining proper records of radioactive materials used under his / her charge, including but not limited to: the date of receipt, the nature and form, the activity of the radioactive material at the date specified by the manufacturer and the whereabouts of the radioactive material at any time.

4.7 Radiation accidents in a Nuclear Medicine facility
Radiation accidents may occur in the context of medical and non-medical applications of ionizing radiation or radioactive materials.
- In non-medical application, a radiation accident is considered to have occurred if there is:
  i. an unplanned, uncontrolled high level of radiation that have or may have occurred as in the case of theft, loss, sabotage of any radiation source or by damage of the radiation shielding of a radioactive source or from irradiating apparatus; secondary to failure of radiation monitoring equipment; or following a fire accident etc.
  ii. an accidentally release of radioactive material into the environment in excess of the permitted discharge level.
  iii. an individual being exposed to a high or potentially high radiation field by accident.
  iv. a spillage or leakage of unsealed radioactive material causing contamination.
- In medical application, a radiation accident is considered to have occurred if:
  i. the wrong radiopharmaceutical is used.
  ii. any therapeutic treatment is delivered to the wrong patient or to the wrong tissue of any patient.
  iii. the patient is treated with a dose or dose fractionation which differs by more than 10% from the quantity prescribed by the Nuclear Medicine physician in charge of the treatment.
  iv. any diagnostic exposure given is 50% greater than the intended dose or if the patient receives a dose significantly different from that which was intended.
- All incidents shall be investigated, including “near misses”, to minimize the likelihood of such accidents from reoccurring.

4.8 Major radiation accidents
Licensee shall notify the appropriate authorities (police, fire & rescue department etc.) and in all cases, the licensee / Nuclear Medicine physician / RPO shall notify the MRSD / AELB of the accident as soon as possible within 24 hours after the discovery of any of the following events involving radiation accident:
- Any discovery of any theft, loss or sabotage of any radiation source in a Nuclear Medicine facility
- An event that requires unplanned medical treatment at a medical facility of an individual with spreadable radioactive contamination on the individual’s clothing or body.
● A contamination event that requires access to the contaminated area (by workers or the public) to be restricted for more than 24 hours by imposing additional radiological controls or by prohibiting entry into the area.

● A contamination event that requires the access to the area be restricted, for a reason other than to allow radioisotopes with a half-life of less than 24 hours to decay prior to decontamination.

● A contamination event that involves a quantity of radiation source greater than five times the lowest annual limit on intake specified in BSRP 2010; and

● A fire or explosion damaging any radiation source or any device, container, or equipment containing radioactive material when the material involved is greater than five times the lowest annual limit on intake specified in BSRP 2010 and the damage affects the integrity of that material or its container.

4.9 Management of theft, loss or sabotage of radioactive source

● All measures shall be taken to ensure the security and protection of all radiation sources within the Nuclear Medicine facility.

● Upon discovering of any theft, loss or sabotage of any radiation source in his possession or under his control, the licensee has to notify the appropriate authorities (e.g. police, fire & rescue department etc.) and in all cases, the licensee / Nuclear Medicine physician / RPO shall notify the MRSD / AELB of the accident within 24 hours; confirm in writing within 48 hours, investigated with necessary corrective measures taken and submit a complete report of the accident within 30 days after notifications to the appropriate authority.

● The report submitted shall contain:
  i. a description of the radiation source, including its type, quantity and its chemical and physical forms;
  ii. a description of the circumstances under which the theft, loss or sabotage occurred;
  iii. a statement of the location or probable location of the radiation source;
  iv. the possible radiation exposure to individuals, circumstances under which the exposures may occur, and the extent of potential hazard to members of the public;
  v. the actions which have been taken, or will be taken, to recover the radiation source;
  vi. the procedures or measures which have been or will be adopted to prevent a recurrence of the theft, loss or sabotage of the radiation source, and
  vii. any other information as the licensee deems necessary.
4.10 Management of radioactive spills in Nuclear Medicine

- A major spill is legally defined as a spillage equal to or greater than the level listed for the radioactive substance in table below:

<table>
<thead>
<tr>
<th>Radionuclides</th>
<th>Millicuries</th>
<th>Radionuclides</th>
<th>Millicuries</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fluorine-18</td>
<td>10</td>
<td>Strontium-85</td>
<td>10</td>
</tr>
<tr>
<td>Phosphorus-32</td>
<td>10</td>
<td>Technetium-99m</td>
<td>100</td>
</tr>
<tr>
<td>Chromium-51</td>
<td>100</td>
<td>Indium-111</td>
<td>10</td>
</tr>
<tr>
<td>Cobalt-57</td>
<td>10</td>
<td>Iodine-123</td>
<td>10</td>
</tr>
<tr>
<td>Cobalt-58</td>
<td>100</td>
<td>Iodine-125</td>
<td>1</td>
</tr>
<tr>
<td>Iron-59</td>
<td>10</td>
<td>Iodine-131</td>
<td>1</td>
</tr>
<tr>
<td>Cobalt-60</td>
<td>1</td>
<td>Ytterbium-169</td>
<td>10</td>
</tr>
<tr>
<td>Gallium-67</td>
<td>100</td>
<td>Gold-198</td>
<td>10</td>
</tr>
<tr>
<td>Selenium-75</td>
<td>10</td>
<td>Thallium-201</td>
<td>100</td>
</tr>
<tr>
<td>Yttrium-90</td>
<td>100</td>
<td>Samarium-153</td>
<td>100</td>
</tr>
<tr>
<td>Strontium-89</td>
<td>100</td>
<td>Carbon-14</td>
<td>10</td>
</tr>
</tbody>
</table>

- The decision to implement a major spill procedure instead of a minor spill procedure will take into consideration the following factors:
  1) Number of individuals affected;
  2) The radiation energy and exposure rate;
  3) The radiotoxicity of the spilled material;
  4) The likelihood of spread of contamination;
  5) Types of surfaces contaminated and
  6) Other hazards present.

- A minor spill is defined as any spillage where the activity is less than that of a major spill, involving removable contamination of diagnostic dose levels in a controlled area that is not spreading and only a small radiation or contamination hazard to personnel exists.

- For some spills of short-lived radionuclides, the best spill procedure is to impose restricted access pending complete decay of the radionuclide involved.

4.10.1 Operational response to a major radioactive spill

- Inform the people to vacate the area.
- Inform the RPO.
- Confine the area of the spill. Take immediate actions to prevent or limit any contamination from spreading beyond the spill location.
- Attend to the contaminated or potentially contaminated persons and remove them from the site of exposure. They shall stay in one area away from the spill so as to minimize further radiation exposure but at the same time being confined to that area in order to prevent possible spread of radiation contamination, until such time that they have been monitored and shown to be free from contamination.
The physicist is responsible to monitor for any contamination on any suspected area or person. This will involve area monitoring and radiation survey on hands, shoes, clothing and face of any person involved in the incident.

Decontamination of any individual is carried out by removal of any contaminated clothing, washing the contaminated skin areas with water and radio-decontamination solution, measuring surface radiation on the skin and continuous washing until no removable radiation contamination is recorded.

Based on the dose assessment, the physicist will determine if any restriction is to be imposed in an area. The area which dose rate is 10mR/h or above should be cordoned off.

The physicist shall investigate and prepare a full written report of the accident / incident and submit it to the appropriate authority within the stipulated time with proposal on how to minimize the likelihood of such accidents from reoccurring.

4.10.2 Operational response to a minor radioactive spill

- Notify persons in the area that a spill has occurred and evacuate the area immediately
- Prevent the spill from spreading by covering the spill with absorbent paper
- Inform the RPO.
- Physicist will confirm the spillage or radiation leakage by performing radiation survey to the suspected area or person. He will undertake the responsibility to supervise the cleaning, decontamination and radiation dose assessment in the area.
- Decontaminate the area using protective clothing, disposable gloves and absorbent paper.
- Quickly confine the spill with an absorbent paper to prevent it from spreading.
- Wipe the contaminated area with the absorbent paper/material from the outer edges of the contaminated area towards the center.
- Remove the absorbent paper / material from the spill area into a labeled plastic bag for disposal.
- Perform a monitoring using a survey meter and decontaminate the area until readings are less than three times of background radiation.
- After the decontamination procedure, put any contaminated gloves, clothing and absorbent paper into a labeled plastic bag and quarantine it in the store until its radioactivity has reduced to approximately of the background exposure level before disposing it as clinical waste.
- Based on the dose assessment, the physicist will determine if any restriction is to be imposed in an area. The area which dose rate is 10mR/h or above should be cordoned off.
- The physicist shall investigate and prepare a full written report of the accident/incident and submit it to the appropriate authority within the stipulated time with proposal on how to minimize the likelihood of such accidents from reoccurring.
4.11 Management of radiation monitoring equipment failure

- Faults affecting any contamination monitors or radionuclide calibrators shall be reported as soon as possible to the RPO.
- RPO will arrange for rectification and recalibration of the instruments by equipment engineer.
- RPO shall assess probable radiation dose exposure to any potential individuals prior to the reporting.

4.12 Management of radiation hazard in a fire accident

- The normal hospital drill shall be observed, with the safe evacuation of patients, visitors and staff being the most important consideration.
- The attending fire brigade shall be informed of the presence of radioactive materials.
- No one is allowed to re-enter the building until it has been inspected for any radiation contamination. In addition, the fire brigade will also need to do survey monitoring on the building structure before allowing anyone to enter the building.
GUIDANCE ON THE USE OF NEW RADIOPHARMACEUTICALS OR NUCLEAR MEDICINE DEVICES NOT REGISTERED IN MALAYSIA
5.0 GUIDANCE ON THE USE OF NEW RADIOPHARMACEUTICALS OR NUCLEAR MEDICINE DEVICES NOT REGISTERED IN MALAYSIA

5.1 Introduction

The last two decades have seen introduction of many radiopharmaceuticals and radioactive medical devices in Nuclear Medicine and radionuclide therapy. Unlike conventional pharmaceutical drugs or medical devices, there are considerable variations not only on issues in their technical application but also on many additional regulatory laws governing the safe handling during the preparation, transportation, storage, disposal and other processes due to the emitting radiation.

The process for a new pharmaceutical / medical device to complete full registration with the relevant Malaysian authorities involves a significant period of time. However, particularly for those novel radiopharmaceuticals or in cases where treatment has been proven with phase 2 study, there shall be avenue for compassionate patient-usage if such circumstances arise. Fast and early clearance is also needed for research purposes in order to keep abreast with the pace of development in medical science and technology. It is prudent on the part of Nuclear Medicine operators to fully understand the existing regulatory frameworks in expediting the process of securing such approval.

This guidelines contain elements that are mandatory (in accordance with the current laws, regulations and directives) or deemed necessary to obtain such temporary clearance from the relevant authorities, for starting a new procedure or service using radiopharmaceutical or a nuclear medicine device yet to be registered in Malaysia. It is intended to be a dynamic document and shall continue to be reviewed and edited in the future.

5.2 Objective

This document aims to provide guidance to Nuclear Medicine practitioners in obtaining temporary clearance from the relevant authorities before starting any new unregistered or previously unexplored services or procedures at their respective Nuclear Medicine centers.

5.3 Definitions

5.3.1 Medical device:

This includes any product used in healthcare for the diagnosis, prevention, monitoring or treatment of illness or handicap but excludes drugs. It frequently refers to an instrument, apparatus, implant, in vitro reagent or calibrator, or similar or related article that is used to diagnose, prevent, or treat disease or other conditions, by means like physical, mechanical, thermal or radiation action, other than through any pharmacological action within or on the body (ref: Medical Device Act 2012).
5.3.2 Radiopharmaceutical:
It refers to any pharmaceutical product which contains or generates a radioactive substance and when administered to a human being, to utilize the radiation emitted thereof for diagnostic or therapeutic purposes. The radiation effect targeted on the tissues or cells is achieved through the pharmacological, metabolic or immunological means within or on the body. Radiopharmaceuticals are classified as poison under the laws of Malaysia (ref: Poison Act 1952).

5.3.3 Combination product:
It refers to a product with two or more attributes that falls under different regulatory controls. The term includes:

i) A product comprised of two or more regulated components, i.e., drug/device, biological/device, or drug/device/biological, that are physically, chemically, or otherwise combined or mixed and produced as a single entity (e.g. drug-eluting beads, drug-eluting stents, hormonal intrauterine contraceptive devices etc.);

ii) Two or more separate products packaged together in a single package or as a unit and comprised of drug and device products, device and biological products.

A combined product can further be categorized into:

- **Drug-Medical Device Combination Product (DMDCP):**
  Primary mode of action is based on pharmacological, immunological or metabolic action in/on the body where NPRA is the primary agency of the combination product.

- **Medical Device-Drug Combination Product (MDDCP):**
  Primary mode of action in or on the human body is not based on pharmacological, immunological or metabolic means, but that may be assisted in its intended function by such means where MDA is the primary agency of the combination product.

5.3.4 Relevant authorities:
This includes any organization set up to monitor, control and/or enforces the statutory laws, regulations, orders or directives of the governing ministry. In this document, the relevant authorities include but are not limited to the following:

- Medical Radiation Surveillance Division or MRSD
- Pharmaceutical Services Division of the MOH
- Drug Control Authority (DCA)
- National Pharmaceutical Regulatory Agency (NPRA)
- Medical Device Authority (MDA)
- National Medical Research Register (NMRR)
- Medical Research and Ethics Committee (MREC)
5.4 The roles of the various relevant authorities in regulating the use of radiopharmaceuticals or Nuclear Medicine devices

5.4.1 Medical Radiation Surveillance Division (MRSD) (Bahagian Kawalselia Radiasi Perubatan or BKRP) is tasked with providing regulatory control under the provisions of the Act 304 and its related regulations. In Malaysia, regulation and control of atomic energy or any dealing involving the manufacturing, trading, producing, processing, purchasing, owning, using, transporting, transferring, handling, selling, storing, importing or exporting of radioactive material, nuclear material, prescribed substance or irradiating apparatus are governed by the Atomic Energy Licensing Board under the Atomic Energy Licensing Act 1984 (Act 304). However, whenever such activities are conducted for medical purposes, the Director General of Health is given the authority to exercise on behalf of this Board under the same act.

The Nuclear Medicine practitioner (licensee) shall obtained approval from the MRSD to purchase, possess, handle, use, store and dispose of any radioactive materials, in any structural or chemical forms and for any intended medical uses either directly or indirectly, before introducing any services involving any radioactive products or medical devices, registered or otherwise, that has previously not been started at that center. The site of recipient, storage and handling of any radionuclides must always be within the domain of the licensed Nuclear Medicine center. This site may be reviewed and inspected by the MRSD if deemed necessary.

Administration of radionuclide to a patient at a site outside the licensed Nuclear Medicine premise but under the domain of its affiliated institution at that same site / address may be allowed (e.g. administering the radionuclide in the ward within the compound of the hospital but outside the Nuclear Medicine department). On the other hand, procedure requiring administration of radionuclides to any patient outside the licensed Nuclear Medicine premise and outside the domain of its affiliated healthcare institution will need additional approval or licensing, as what has been laid out in the legislation.

5.4.2 Pharmaceutical Services Division of the MOH is responsible to ensure that the public gets access to safe, efficacious and quality pharmaceutical products, protecting their interest via enforcement of relevant legislation, and ensuring rational use of medicines by healthcare providers and patients.
5.4.3 **Drug Control Authority (DCA)** is the executive body established under the Control of Drugs and Cosmetics Regulations 1984 under the provision of the Sale of Drugs Act 1952. The main task of this Authority is to ensure the safety, quality and efficacy of pharmaceuticals, health and personal care products that are marketed in Malaysia through:

a) Registration of pharmaceutical products and cosmetics  
b) Licensing of premises for importer, manufacturer and wholesaler  
c) Monitoring the quality of registered products in the market  
d) Adverse Drug Reaction Monitoring.

The National Pharmaceutical Regulatory Agency (NPRA) is the secretariat to the DCA.

5.4.4 **National Pharmaceutical Regulatory Agency (NPRA)** helps to ensure that therapeutic substances approved for the local market are safe, effective and of quality and also to ensure that cosmetic products approved are safe and of quality through the registration and licensing scheme. This is achieved through i) evaluation of scientific data and laboratory tests on all products before they are marketed; ii) a system set-up for drug information service to monitor products in the market and provide information on drugs to medical profession and consumer.

5.4.5 **Medical Device Authority (MDA)** of the MOH is established under the Medical Device Authority Act 2012 (Act 738), to control and regulate medical device, the medical device industry and its activities, and to enforce the medical device laws and its related matters. It strives to ensure that medical devices in Malaysia are of high quality, effective and safe in order to protect the public interest and towards excellent customer satisfaction. It is operating under the provision of the Medical Device Act 2012 (Act 737).

5.4.6 **National Medical Research Register (NMRR)** of MOH is the web based tool designed to support the implementation of the National Institute of Health (NIH) guidelines on the conduct of research in the Ministry of Health Malaysia (MOH). Clinical Research Center (CRC) functions as the clinical research arm of the MOH and aims to provide technical support in clinical databases and registry operations and to improve patients’ health outcomes through ethical and quality clinical research. It aims to assist medical professionals to establish patient registries in their therapeutic areas but stop short of actually running the registry.
5.4.7 **Medical Research and Ethics Committee (MREC)** function as an Institutional Review Board/Independent Ethics Committee (IRB/IEC) for the MOH. It is established in 2002 to provide independent guidance, advice and decision on ethical issues of health research or other specific protocol involving human subjects conducted by staff of the MOH or conducted using facilities of the MOH. The primary purpose is to ensure the protection of the welfare and rights of human participants. MREC may also act as an Independent Ethics Committee for non–MOH institutions. MREC abides by international and local regulatory requirements in the protection of the dignity, rights, safety and well-being of human subjects which includes ICH-GCP, Malaysian GCP and other international guidelines on research involving human subjects.

5.5 **Basic information required for the radiation regulatory approval**

The important roles of the MRSD are: a) to regulate the medical use of radioisotopes as necessary and b) to ensure radiation safety of workers and individual members of the public exposed to patients administrated with radioactive materials. It shall minimize intrusion into medical judgments affecting patients and other areas traditionally considered to be a part of the practice of medicine.

Radiation safety and security clearance will be evaluated from the following perspective:

- the current existing or the proposed Nuclear Medicine set-up and facility
- technical competency in the delivery of such medical care involving radiation

All applications to the relevant authorities shall provide the following data and essential information, including the mode of medical management:

1. Radiation physics and chemical properties attached with the product
   1.1. Radiation physics of the radioisotope used
   1.2. Chemistry of the drug substance or the product
   1.3. Pharmacokinetic properties of the radionuclide used
   1.4. Radiation dosimetry evaluations
   1.5. Pharmacodynamic studies (if relevant) & toxicology profiles
   1.6. Dose activity used: recommended dose, patient-specific dose etc.
   1.7. Physical presentation of the radioactive compound
   1.8. Calibration and preparation for the dose activity

2. Product type and its current status:
   2.1. Radiopharmaceutical
      2.1.1. Unregistered or, registered with DCA but that specific indication is not mentioned
      2.1.2. Unlisted or, listed in the FUKKM but that specific indication is not mentioned (applicable to hospitals under MOH only)
   2.2. Medical device
      2.2.1. Unregistered radioactive, nondrug based medical device
   2.3. Combination product with attributes of drug and medical device
      2.3.1. Unregistered radioactive, DMDCP or MDDCP
3. Purposes
a) Clinical application for diagnosis and/or therapy or,
b) Clinical trial or research study

4. Site of recipient, storage and handling
4.1. Within the domain of the certified Nuclear Medicine premise
4.2. Status of compliance with the minimum requirements
4.3. Layout plan for the current setup and facility

5. Site of final administration to the patient
a) Within the domain of the certified Nuclear Medicine premise or,
b) Outside the certified Nuclear Medicine premise but under the domain of its affiliated healthcare institution or,
c) Outside the certified Nuclear Medicine premise and outside the domain of its affiliated healthcare institution

6. Staff training in handling such radionuclide, including radiolabeling, QC/QA, Good Radiopharmaceutical Practice (GRP), calibration and preparation for the dose activity

7. Patient selection and / or the intended use of the radionuclide

8. Site and mode of administration to the patient

9. Patient’s dosimetry

10. Pre- and post-administration instruction to the patient and the caregiver

11. Discharge / release criteria of patient from licensee control

12. Managing death of radioactive patient

13. Spillage and contamination management for the radioactive materials

14. Disposal of the residual and contaminant

15. Names of the involved parties and copies of their licenses issued under the Atomic Energy Licensing Act 1984 (Act 304)

5.6 Temporary clearance and exemption for use of an unregistered drug in a patient

5.6.1 For any unregistered drug used for diagnosis / therapy
Any drug including radiopharmaceutical which is:

- Unregistered or, registered with DCA but that specific indication is not mentioned or,
- Unlisted or, listed in the FUKKM (Formulari Ubat KKM) but that specific indication is not mentioned - applicable to MOH hospitals only

where, if it is meant to be used for clinical application either for diagnosis and/or therapy, approval from Director General of Health is needed for temporary clearance and exemption for use. The following procedures apply:

- For private or non MOH hospitals: if the drug’s name or indication is not registered with DCA, form BPF/213-1 or its most recent updated version, needs to be filled up and submitted to the Pharmaceutical Services Division, MOH for import permit.
● For MOH hospitals: if the drug’s name or indication is not listed in FUKKM (and in a way has not been registered with DCA), it cannot be purchased using Government Procurement Procedures and Treasury Instruction. In such cases, form BPF/103-KPK01 (Pindaan 3) and/or BPF/103-KPK01S or their most recent updated version, need to be filled and submitted to Pharmaceutical Services Division, MOH for special approval.

5.6.2 For any unregistered drug used in a clinical trial or research study

For the drug of the same category as mentioned above where, if its purpose is for clinical trial or research study, the study proposal must be registered with the NMRR (ref: KKM-55/201/005/01(15) Directive of Director of Pharmaceutical Services CT1-2009) and the investigators have to obtain approval of the IRB/IEC or for those institutions under MOH, the MREC. Concurrently, the Clinical Trial Import License (CTIL) (Form BPFK 442.4 or its most recent updated version) or Clinical Trial Exemption (CTX) (Form BPFK 443.1 or its most recent updated version) needs to be submitted for DCA approval through the NPRA. CTIL application is needed for unregistered import product whereas CTX application is needed for unregistered products manufactured locally.

5.7 Exemption for use of an unregistered medical device in a patient

Any medical device for the purpose of clinical research or for clinical treatment use under special situations, may be exempted from medical device registration requirements in this country, in accordance with the Medical Device (Exemption) Order 2016. However, manufacturer or importer of the device must submit a notification to MDA prior to importation and supplying the device. Further information is available from the Medical Device Guidance Document: “Notification of Exemption from Registration of Medical Devices for the purpose of Clinical Research or Performance Evaluation, MDA/GD/0016, First Edition April 2017”. Related application forms for exemption can be downloaded from the MDA website. An acknowledgement on the notification issued by the MDA will then permits the device to be supplied or imported lawfully for that specific use.

5.8 A combination product where its classification is in doubt

For such a product where its classification is in doubt (i.e. whether the products shall be treated as radiopharmaceutical or radioactive medical device), please refer to “Guideline for Registration of Drug-Medical Device and Medical Device-Drug Combination Products, 2017” or its latest edition. Inside this guideline, the MOH has highlighted that the primary mode of action / the principal mechanism of action by which the claimed effect or purpose of the product is achieved (i.e. via drug or medical device) will determine whether that product falls under MDA or NPRA regulatory oversight.
5.8 Conditions under which different types of approvals are required

The following table lists down the statutory approvals needed under five identified scenarios:

<table>
<thead>
<tr>
<th>Scenario 1:</th>
<th>Statutory Approval Needed</th>
</tr>
</thead>
<tbody>
<tr>
<td>A radioactive combination product with multiple attributes which is yet to be registered (with either the DCA or the MDA), where its classification is in doubt (i.e. either a DMDCP or MDDCP).</td>
<td>Refer to “Guideline for Registration of Drug-Medical Device and Medical Device-Drug Combination Products, 2017” or its latest edition in order to identify the primary / custodian agency (i.e. either MDA or NPRA) in charge of the regulatory oversight.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Scenario 2:</th>
<th>Statutory Approval Needed</th>
</tr>
</thead>
</table>
| For a radiopharmaceutical (including DMDCP) which is i) unregistered or registered with DCA but that specific indication is not mentioned or, ii) unlisted or listed in FUKKM but that specific indication not mentioned (applicable for MOH hospitals only), where, it is meant for clinical application either for diagnosis and / or therapy. | • Approval from the MRSD  
• Approval from the Pharmaceutical Services Division, MOH |

<table>
<thead>
<tr>
<th>Scenario 3:</th>
<th>Statutory Approval Needed</th>
</tr>
</thead>
</table>
| For a radiopharmaceutical (including DMDCP) product which is unregistered with DCA or registered with unapproved indication by DCA, requires CTIL in order to be imported for clinical trial / research study. | • Approval from the MRSD  
• Registration with NMRR & approval of the related IRB/IEC or MREC  
• Approval from the NPRA |

<table>
<thead>
<tr>
<th>Scenario 4:</th>
<th>Statutory Approval Needed</th>
</tr>
</thead>
</table>
| For a radioactive, medical device (including MDDCP) related to Nuclear Medicine procedure which is yet to be registered where, its purpose is for clinical application either for diagnosis and / or therapy. | • Approval from the MRSD  
• Notification to the MDA |

<table>
<thead>
<tr>
<th>Scenario 5:</th>
<th>Statutory Approval Needed</th>
</tr>
</thead>
</table>
| For a radioactive, medical device (including MDDCP) related to Nuclear Medicine procedure which has not been registered where, its purpose is for clinical trial or research study. | • Approval from the MRSD  
• Registration with NMRR & approval of the related IRB/IEC or MREC  
• Notification to the MDA |
Following is a list of application forms (as in July 2018) for the use of:

i) unregistered drug:
   - BPF/213-1 for import permit
   - BPF/103-KPK01 (Pindaan 3) for special DG’s approval
   - BPF/103-KPK01S for special DG’s approval
   - BPFK 442.4 for Clinical Trial Import License
   - BPFK 443.1 for Clinical Trial Exemption

ii) unregistered medical device:
   - Notification to import or supply medical devices for clinical investigational use
   - Notification to import medical devices for clinical use and research supportive use
   - Notification of unregistered medical devices for special access.
GUIDANCE ON PLANNING AND DESIGN FOR A NUCLEAR MEDICINE FACILITY
6.0 GUIDANCE ON PLANNING AND DESIGN FOR A NUCLEAR MEDICINE FACILITY

6.1 Key considerations

The key considerations in the planning and design of a Nuclear Medicine facility are as follow:

i. All efforts must be made to avoid unnecessary radiation exposure to staff, patients and visitors. The radiation exposure dose must be kept within the limits set by the BSRP 2010 (Act 304) and/or the individual departmental local rules.

ii. Traffic patterns must be designed to keep movement of radioactive sources, including radioactive patients away from the staff, unrelated patients or members of the public and also sensitive imaging equipment. Areas shall be arranged in increasing order of the potential radioactivity, in which the entrance to the facility has the lowest possible radioactivity.

iii. Radioactive rooms, wards and areas of radioactive source storage and handling shall be marked with radiation signage and notices denoting the identification of radioactive areas and potential radiation hazards.

iv. Shielding will be required for the walls, doors and observation windows in areas of high activity and possible contamination. Calculation shall be made based on a case-by-case basis, taking into consideration the types of radionuclides used, distance to occupied areas, the rate of occupancy and the estimated workload. Mobile shielding shall be available in order to minimise further radiation exposure in case of any emergency. There shall be an adequate supply of lead containers and shielding lead bricks.

v. Surface areas (floors, work surfaces and walls) of rooms and corridors shall have hard washable, nonporous and leak-proof covering, allowing easy decontamination in case of any accidents. Walls and doors of laboratories shall be painted with good quality washable paint. Work surfaces shall be covered with nonporous and nonreactive material. Floor shall be impervious to liquids.

vi. The ventilation flow of any possible airborne radioactive material must be taken into consideration. Ventilation system shall be of the once-through type with unidirectional airflow from areas of possible lower radioactivity to higher radioactivity. The exhaust from the fume hoods shall be released directly into the open after filtering.

vii. Plumbing shall be planned to ensure direct flow of possible radioactive liquid effluents from active areas either directly to the decay tank or to the ultimate discharge point. Drain pipes and delay tank (for interim storage of high-level radioactive waste) shall be leak-proof and corrosion resistant.

viii. Radionuclide therapy area must be well separated from diagnostic areas and have a separate access where possible. Radiation levels at the nurse station in the ward and outside the isolation rooms shall not exceed 1μSv/hour.

ix. An in-house radiopharmacy hot lab of appropriate type must be available to cater to the designed scopes and services of the proposed Nuclear Medicine facility (ref: Chapter 7).

x. Space must be available for radioactive storage. Radioisotopes shall be stored, used and transported safely and securely at all time. Radioactive wastes disposal and management shall comply with the radiation protection guidelines and regulations.
6.2 Site selection
Ideally, the facility shall be located away from general patient wards and public occupancy areas so that there is no impact of radiation hazards to the general public and environment. For example, it can be placed at the end of the hospital block that is well-connected to other departments.

The space requirement varies according to the planned category of Nuclear Medicine facility (level 1 or level 2). There shall always be a space for an in house radiopharmacy hot lab. The latter may vary from a simple dispensing hot lab unit to a more comprehensive and complex centralized hot lab for the sale, supply and distribution of radiopharmaceuticals to the surrounding hospitals. Whenever possible, all components for the facility shall be on the same floor and contiguous in its design or layout.

6.3 Key components in the design and layout in a Nuclear Medicine facility
6.3.1 Nuclear imaging room
6.3.2 Cardiac stress-test room
6.3.3 RP administration room
6.3.4 Hot waiting area / Post-RP waiting area / Uptake room
6.3.5 PET facility
6.3.6 Cyclotron
6.3.7 Radionuclide therapy ward (radioactive isolation room)
6.3.8 Decay storage room
6.3.9 Radioactive delay and decay tank
6.3.10 Radiopharmacy hot lab

6.3.1 Nuclear imaging room
This is a designated room that will house diagnostic imaging equipment, performing procedures such as SPECT, SPECT/CT or PET/CT. It may consist of the following components:

- Scanning room: This area houses the imaging machine and its gantry.
- Control room: This area houses the image acquisition and data processing workstations
- System component room: This area houses the power components of the machine and computers that support the unit.

The floor area of the scanning rooms shall meet the minimum specifications as per the manufacturer’s recommendations but preferably larger to accommodate patients on stretchers. A larger area may reduce the risk of radiation to staff as well. A tight fitting oversized doors, efficient air-conditioning and humidity control units are also required.

All imaging rooms shall have their own separate power supply and stabilizers. A stable uninterrupted power supply is vital, and it must be secured. Emergency power supply is needed to complete in progress nuclear scans in case of power failure. Air-conditioning is essential to maintain a clean, dust free and dry environment for electronic instruments that are sensitive to heat and moisture changes. An intercom and / or telephone are important to facilitate effective communication.
For SPECT-alone camera, ordinary wall thickness is usually sufficient. Hybrid cameras incorporated with CT components (e.g. SPECT-CT, PET-CT) will require additional shielding for the walls, doors and viewing windows.

6.3.2 Cardiac stress-test room
The cardiac stress laboratory shall be planned near the designated nuclear imaging room. The room shall be equipped with treadmills, bicycles or pharmacological stress studies. Studies shall always be conducted in the presence of a doctor. Drugs and life support equipment shall be available in cases of emergency.

6.3.3 Radiopharmaceutical administration room
This room must be in close proximity to the patient examination rooms, radiopharmacy hot lab, and procedure room(s). Most radiopharmaceuticals are administered to patients intravenously and both ambulatory and non-ambulatory patients will receive injections in this area.

6.3.4 Hot waiting area / Post-RP waiting area / Uptake room
This is a designated special waiting or holding area, which is usually accompanied with toilets facilities and other support spaces, designed for patients who have received radioactive substance. It aims to protect members of the public or other individuals from unnecessary exposure to radiation.

Such specifically designated hot waiting area may not be necessary for Nuclear Medicine procedures that utilize low energy radioisotopes (e.g. in a person up to \(150\text{MBq} \cdot \text{MeV}^*\), i.e. around \(1000\text{MBq}\) of Tc-99m).

Dedicated uptake rooms are needed for patients undergoing PET (refer below) or other Nuclear Medicine procedure using high energy / high activity radiotracer or in conducting studies that require the patients to rest in a quiet surrounding following the administration of radiotracer.

\(^*\text{MBq} \cdot \text{MeV}\) is the product of activity and total gamma energy per disintegration.

6.3.5 PET facility
The PET facility may exist as a part of the main Nuclear Medicine department, or as a stand-alone unit. If the PET facility is part of the main Nuclear Medicine department, space-areas for many components may be shared and requirements are limited mainly to the additional PET imaging room, administration and post-injection uptake rooms. If the PET facility is planned to be a stand-alone unit, the requirement will by itself be exhaustive.

The number of uptake rooms required for each facility will depend on the duration of rest needed after radiotracer administration, the average image acquisition time and the number of PET units in that center. With current technology, a minimum of 4 post-injection uptake rooms are required for each PET unit.
6.3.6 Cyclotron
A cyclotron is a machine designed to accelerate beams of charged particles (e.g. proton H⁻, deuteron D⁻) in a spiral manner, up to a sufficient high velocity so as to hit onto a target, such that the particles and the kinetic energy from these charged particles are incorporated into the nuclei of the atoms of this target to form radioisotopes.

Different cyclotrons may come with different capacities. Medical cyclotron usually referred to those designed and constructed specifically for production of PET or SPECT radioisotopes. A typical medical cyclotron usually has an energy capacity of 30MeV or less. Mini-cyclotron has a capacity much lower than this (at around 7.5MeV) and its production is just adequate for in-house use of one or two patients with each session of bombardment / production. The decision for an institution to have a cyclotron depends on the clinical, academic and research demands as well as the desired ability to distribute PET radiotracers to nearby Nuclear Medicine facilities.

6.3.7 Radionuclide therapy ward (radioactive isolation room)
The isolation room in the ward must preferably be air-conditioned with an attached toilet. For adequate protection, the following shall be considered:

- The shielding for the isolation room shall ensure that radiation level outside the room where there is potential for exposure, should be within prescribed limits for the general public (i.e. 1mSv/year).
- If the room is located at the ground level or if there is a free passage outside the room, the windows on the separating wall shall be at a height of 2m from the floor. For the room which is located at higher level where there is no accessible standing space behind the wall, a common open window will suffice.
- Preferably, a minimum room size of 3 X 5 m² (distance factor used to reduce radiation level) is used. If the room is small, mobile lead shields shall be used.
- Adequate buffer area shall be considered outside the ward for movement of other staff.
- Nurse station / room shall be located at a suitable distance to avoid exposure but still suitably placed to monitor the patients’ movement and condition or attend to their needs.
- Dose administration room shall be adjacent to the isolation ward, shall have well-ventilated fume-hood for storage and dispensing of liquid radioiodine. The duct from the fume-hood shall open into the atmosphere outside with a minimum distance of 2m height from the roof of the building.
- The drainage from the toilets in the isolation ward shall allow the waste to be discharged through the radioactive waste delay and decay tank. This will allow large amount of radioactivity in the toilet waste to decay before it is discharged into the public sewerage system.
6.3.8 Decay storage room
A decay storage room is usually set up beside or within a radiopharmacy hot lab, allowing radioactive wastes or contaminated items to decay to a sufficiently low level for disposal as common biomedical waste. The time period for such radioactive waste storage depends on the type of waste and the radioisotopes. In general, radioactive wastes with half-lives of $\leq 120$ days are appropriate for decay-in-storage.

The storage facilities must be designed with adequate space. Storage space requirements may be minimized if the waste is segregated according to physical half-life. Segregation of waste is accomplished by depositing waste of shorter physical half-lives in containers separately from those containers used to store waste with longer physical half-lives. Waste with shorter half-lives will take less time to decay and thus may be disposed of in shorter periods of time, freeing storage space. The licensees must maintain all relevant records of storage and disposal. Precautions must also be taken to secure decay-storage room from unauthorized access.

6.3.9 Radioactive delay and decay tank
When radionuclide therapy with high activity is instituted in the nuclear medical department, a large quantity of radioactive sewage is generated. The radioactive wastewater could not be discharged immediately into the public sewer, but must be stored until radioactivity has decayed below the legally defined safe limit. A decontamination plant with radioactive delay and decay tanks will be designed according to the requirements of the respective Nuclear Medicine setup. The scale of this decay plant is also dependent on the anticipated daily water volume discharged from the facility.

In addition to the above, due to the possible long retention time of the wastewater inside the decay tank, the wastewater is periodically aerated to prevent an anaerobe process that might generate harmful biogas.

With modern technology, the radioactive waste decay systems will be equipped with modern central control system including visualization of the process regulating the plant so as to guarantees a high safety standard.

6.3.10 Radiopharmacy hot lab
The preparation of radiopharmaceuticals requires special attention and special precautions. Radiopharmacy hot lab is a restricted area to which the public and the patients do not have any access. The authorized personnel must have received special training in the handling of unsealed radioactive sources, together with the preparation and QC of sterile and pyrogen-free pharmaceuticals, both for patient safety and personnel safety.
It is recommended to have a separate quality control room in a radiopharmacy hot lab. A center having different operational types of radiopharmacy hot labs may share a common dedicated quality control room equipped with all the required QC apparatus. A quality control program must be established.

Based on the radio-physics of the radioisotopes, chemical properties of the radionuclides and the technical complexity that may be involved, radiopharmacy hot labs are grouped into the following operational types*:

**Type 1**: involves dispensing of those ready to be used radiopharmaceuticals where no further compounding / radiolabeling is necessary
- **Type 1a**: involved commonly used SPECT radiotracers
- **Type 1b**: involved volatile radioactive substance, notably radiiodine
- **Type 1c**: involved PET radiotracers

**Type 2**: involves further compounding/ radiolabeling of radiopharmaceuticals
- **Type 2a**: involved commonly used SPECT radiotracers, need further upgrading to 2a plus for handling of open vial procedure
- **Type 2b**: involved volatile radioactive substance, notably radiiodine
- **Type 2c**: involved PET radiotracers, need further upgrading to 2c plus for handling of open vial procedure

**Type 3**: involves cyclotron setup and production of related radiopharmaceuticals
- **Type 3**
- **Type 3 mini**

**Type 4**: involves radiolabeling of blood and blood products

*Details on the operational types, functions and equipment for radiopharmacy hot labs are provided in Chapter 7.
6.4 Lay out for a conventional Level 1sp Nuclear Medicine facility

[Diagram showing the layout of a conventional Level 1sp Nuclear Medicine facility, including reception, general waiting, clinic & exam, thyroid uptake, RIA sample collecting, radio-bioassay unit, staff & administrative, control room, SPECT-CT nuclear imaging room, SPECT nuclear imaging room, cardiac stress, stretcher/holding, post-scan waiting, uptake rooms, patient toilet, hot waiting area, RP ad room, radiopharmacy hot lab, and PET-CT nuclear imaging room.]
6.5 Lay out for an inpatient isolation ward in a Level 2 Nuclear Medicine facility

[Diagram of an isolation ward layout with labels for Soiled waste, Soiled linen, Others, Nurse Station, Controlled Area, Public Domain, Isolation Room, Store-room, Toilets, Decay Tank]
GUIDANCE ON THE OPERATIONAL TYPES AND FUNCTIONS OF RADIOPHARMACEUTICAL PREPARATION FACILITIES (RADIOPHARMANCY HOT LABS) IN MALAYSIA
7.0 GUIDANCE ON THE OPERATIONAL TYPES AND FUNCTIONS OF RADIOPHARMACEUTICAL PREPARATION FACILITIES (RADIOPHARMACY HOT LABS) IN MALAYSIA

This chapter explains in greater detail about the types and functions of various radiopharmaceutical preparation facilities (radiopharmacy hot labs) in Malaysia. Further information on the design, layout, facility and equipment is published in the latest edition of “Guides for the Development of Radiopharmaceutical Facilities for Healthcare Establishments”, or the related guides published by the Pharmaceutical Services Program, MOH.

7.1 Operational Type 1 – dispensing only

7.1.1 Operational Type 1a
Operational Type 1a deals with the dispensing of radiopharmaceuticals purchased or supplied in their final form from recognized and/or authorized manufacturers or centralized nuclear pharmacy. No further compounding or radiolabeling is required. This includes unit doses supplied in syringe or in a single dose vial or in a multi-dose vial. This includes ready-to-use radiopharmaceuticals such as injections of strontium (Sr-89) chloride and samarium (Sm153) lexidronam for pain palliation, yttrium (Y-90) citrate and rhenium (Rh-186) sulphide for radiosynovectomy. There shall be a dose calibrator with appropriate lead shielding. A shielded dispensing station shall be available for use in a designated hygienic clean area.

7.1.2 Operational Type 1b
Operational Type 1b allows the dispensing of radioiodine in capsule form, multi-dose vial radioiodine in liquid form and also commercially ready-to-use radiopharmaceutical in a single dose form such as 131I-MIBG purchased or supplied in their final form from recognized and/or authorized manufacturers or centralized nuclear pharmacy. This shall be conducted in a well-ventilated room, equipped with a shielded fume cupboard fitted with suitable filters, the dose calibrator and radioactive waste container that can handle volatile radioactive materials.

7.1.3 Operational Type 1c
Operational Type 1c enables the dispensing of PET radiopharmaceuticals purchased or supplied in their final form from an authorized manufacturer or centralized radiopharmacy. No radiolabeling is required. This includes unit doses supplied in syringe or in a single dose vial or in a multi-dose vial. There shall be a dose calibrator with appropriate lead shielding. A shielded dispensing station shall be available for use in a designated hygienic clean area.

Note:
Ideally, separate workstations for different categories of type 1 operation is preferred. However in case of space constraint, shared workstation may be use provided that there is a procedure control to avoid cross contamination between types of radiopharmaceutical.
7.2 Operational Type 2 – compounding / radiolabeling

7.2.1 Operational Type 2a
Operational Type 2a deals with the preparation of radiopharmaceuticals from prepared and approved reagent kits, generators and radionuclides for diagnostic or therapeutics purposes (closed method*). This is the most common radiolabeling activity performed in a Nuclear Medicine department, with routine use of a technetium generator, reconstitution of pre-sterilized radiopharmaceutical cold kits and at time modifying the chemical properties of some pre-existing commercial kits. The radiopharmaceutical labeling / preparation for clinical application requires the use of:

- lead-lined isolator in a dedicated room meeting the European Union Grade D (ISO 8) level of cleanliness, or
- lead-lined biosafety cabinet with sliding lead glass barrier, in a dedicated room meeting the European Union Grade C (ISO 7) level of cleanliness.

Built-in dose calibrator, generator elution port and radioactive waste container must be incorporated in the design of the isolator or biosafety cabinet. Appropriate internal finish is needed in the room to allow effective sanitization to reduce particulate and microbiological contamination of the environment.

7.2.2 Operational Type 2a plus
Operational Type 2a plus involves the preparation of radiopharmaceuticals in an open vial (open method*) for clinical application and/or related research and development. The radiopharmaceutical labeling / preparation for clinical diagnosis or therapeutic requires the use of:

- lead-lined isolator in a dedicated room meeting the European Union Grade D (ISO 8) level of cleanliness, or
- lead-lined biosafety cabinet with sliding lead glass barrier, in a dedicated room meeting the European Union Grade B (ISO 5) level of cleanliness.

Built-in dose calibrator, generator elution port and radioactive waste container must be incorporated in the design of the isolator or biosafety cabinet. Appropriate internal finish is needed in the room to allow effective sanitization to reduce particulate and microbiological contamination of the environment.

7.2.3 Operational Type 2b
Operational Type 2b involves the preparation and dispensing of I-131 radiolabelled radiopharmaceutical. This include the labeling of radiopharmaceuticals from ingredients and radioiodine for therapeutic application (including open method*) together with related research and development. Examples include radio-iodination of meta-iodobenzylguanidine (MIBG), iodine-131 rituximab and rhenium (Rh-186) labelled lipiodol. This preparation required:

- lead-lined isolator in a dedicated room meeting the European Union Grade D (ISO 8) level of cleanliness, or
- lead-lined biosafety cabinet with sliding lead glass barrier, in a dedicated room meeting the European Union Grade B (ISO 5) level of cleanliness.
Suitable filters that can handle volatile radioactive materials of iodine-131 solutions, built-in dose calibrator and radioactive waste container must be incorporated in the design of the isolator or biosafety cabinet. Appropriate internal finish is needed in the room to allow effective sanitation to reduce particulate and microbiological contamination of the environment.

7.2.4 Operational Type 2c
Operational Type 2c deals with the preparation of PET radiopharmaceuticals from reagent kits with generator-produced PET radiotracers (e.g. Ga-68) (closed method*). Preparation of radiopharmaceutical for clinical diagnosis requires the use of automated radiosynthesis module in hot cell in a dedicated room meeting the European Union Grade C (ISO 7) level of cleanliness next to a European Union Grade A (ISO 5) LAF work bench used for dispensing.

7.2.5 Operational Type 2c plus
Operational Type 2c plus is related to the preparation of PET radiopharmaceuticals from reagent kits with generator-produced PET radiotracers (e.g. Ga-68) (open method*). Preparation of radiopharmaceutical for clinical diagnosis requires the use of semi-automated radiosynthesis module or manual reconstitution of pre-sterilized radiopharmaceutical reagent kits or manual manipulation of reagents kit in biosafety cabinet; lead-lined with sliding lead glass barrier, built-in dose calibrator, generator elution port and radioactive waste container in a dedicated room meeting the European Union Grade B (ISO 5) level of cleanliness with appropriate internal finish to allow effective sanitation to reduce particulate and microbiological contamination of the environment.

Note:
*Closed method of preparation – preparation process that does not directly expose the material or product with the environment” (e.g. drawing the contents from a sealed vial into a syringe through the septum would be viewed as a closed method of preparation.)

*Open method of preparation – preparation process where material may be handled or transferred using open vials exposing the product to the environment”.
7.3 Operational Type 3 – cyclotron related setup

7.3.1 Operational Type 3

Operational Type 3 involves the synthesis and manufacturing of PET and/or SPECT radiopharmaceuticals produced by a cyclotron and to be used locally or distributed to other centers. This includes the increasingly utilised fludeoxyglucose (F-18) injections (FDG). Hot cells and complete chemistry systems are essential for PET. Ideally, the synthesis boxes and hot cells shall be placed in a European Union Grade C (ISO 7) environment next to a European Union Grade A (ISO 5) LAF work bench used for dispensing. Suitable shielding, according into account and validation of cabinet performance shall be performed.

7.3.2 Operational Type 3 mini

Operational Type 3 mini is related to the compounding of PET radiopharmaceuticals from radionuclide produced by a low proton acceleration cyclotron (<10MeV), having a self-contained, fully automated system from irradiation to final product preparation (radionuclide production, synthesis, quality control and final product release). E.g. a fully automated, self-contained “mini”-cyclotron for low activity (dose on demand) FDG. Preparation of radiopharmaceutical for clinical diagnosis shall be performed in a dedicated room meeting the European Union Grade C (ISO 7) level of cleanliness. There shall be a dose calibrator with appropriate lead shielding. A shielded dispensing station shall be available for use.

7.4 Operational Type 4 – radiolabeling of blood and blood products

Operational Type 4 handle work related to the radiolabeling of autologous blood cells. This includes radiolabeling of red bloods cells, platelets and white cells commonly used for infection or inflammation imaging. Manipulation of cells requires the use of:

- lead-lined isolator in a dedicated room meeting the European Union Grade D (ISO 8) level of cleanliness, or
- lead-lined biosafety cabinet with sliding lead glass barrier, in a dedicated room meeting the European Union Grade B (ISO 5) level of cleanliness

Built-in dose calibrator and radioactive waste container must be incorporated in the design of the isolator or biosafety cabinet. Appropriate internal finish is needed in the room to allow effective sanitation to reduce particulate and microbiological contamination of the environment.

7.5 Proposed List of Equipment for Each Operational Types & Functions of Radiopharmaceutical Preparation Facilities

- Refer to the Appendix 3 -
MASTER LIST FOR NUCLEAR MEDICINE PROCEDURES 2018
8.0 MASTER LIST FOR NUCLEAR MEDICINE PROCEDURES 2018

8.1 Instructions

- Trace a procedure according to the body system, choose the appropriate procedure that will be or was carried out, and record down the code number and the full name of this procedure. If there is an instruction for referral (e.g. refer PET-CT item D12.2), then the code number and the name of the procedure that are being referred to should be used instead.

- Diagnostic or therapeutic procedure is documented as a completed case only when a radiopharmaceutical(s) has been administered and the purpose of administering such radiopharmaceutical(s) has been achieved. Faulty procedure requiring a repeat study will also be included but this is also recorded separately as one of the Nuclear Medicine KPI indicator for monitoring.

- A unit of case is defined as a service entity listed in the Master List. It takes into consideration the types and the number of times radiotracers is given to the patient; and in cases when more than one radiotracer is used, whether the radiotracers are given in the same sitting (i.e. patient remains on the camera couch) or required a separate time frame for the procedure.

- There should not be any repeated entry for a unit of case, in which the process may require it to span over a period of time for completion of that procedure (e.g. when an additional 72-hr whole body scan (WBS) is done following a routine 48-hr I-131 WBS study or, a HIDA scan for a baby where a next-day imaging was necessary) as it should be documented as a single case only; or when the final report comes with some readily calculated functional parameters (e.g. renal DTPA scintigraphy with Gate’s eGFR, myocardial perfusion scintigraphy with calculated EF).

- When a protocol of a procedure has been modified, in which certain technical part/ component of other similar procedure has been incorporated, the case shall be taken as one single unit of case based on the original primary procedure (e.g. when a parathyroid scintigraphy using subtraction technique (D7.6) is modified to incorporate a delay imaging section similar to that of a dual phase study (D7.5), this should be taken as a single unit of case based on the original parathyroid scintigraphy-subtraction technique (D7.6) and not to be recorded as two unit of cases (D7.6+D7.5)). Repetitive entry of a case shall not be allowed.

- Those new services not registered in the Master List should be recorded under the “Others” with written descriptions.

- An add-on case refers to those additional procedure performed on the same patient following or along with the principal diagnostic or therapeutic nuclear medicine procedure (e.g. D1.1+D13.1, D12.3+D13.2, T1.2+D13.3 etc.). No additional dose activity of radiotracer will be administered to the patient.
### 8.2 Diagnostic Procedures

<table>
<thead>
<tr>
<th>D1. Skeletal System</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>D1.1 Skeletal System: Bone scintigraphy, Tc-99m based radionuclide - Whole body and/or Regional</td>
<td></td>
</tr>
<tr>
<td>D1.2 Skeletal System: Bone scintigraphy, Tc-99m based radionuclide - 3 Phase</td>
<td></td>
</tr>
<tr>
<td>D1.3 Skeletal System: Bone scintigraphy, F-18 based radionuclide (refer PET-CT item D12.2)</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>D2. Genitourinary system</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>D2.1 Genitourinary system: Dynamic renal scintigraphy - Tc-99m DTPA</td>
<td></td>
</tr>
<tr>
<td>D2.2 Genitourinary system: Dynamic renal scintigraphy - Tc-99m DTPA with captopril challenge</td>
<td></td>
</tr>
<tr>
<td>D2.3 Genitourinary system: Dynamic renal scintigraphy - Tc-99m DTPA with GFR radiobioassay</td>
<td></td>
</tr>
<tr>
<td>D2.4 Genitourinary system: Dynamic renal scintigraphy - Tc-99m MAG-3</td>
<td></td>
</tr>
<tr>
<td>D2.5 Genitourinary system: Dynamic renal scintigraphy - Tc-99m MAG-3 with captopril challenge</td>
<td></td>
</tr>
<tr>
<td>D2.6 Genitourinary system: Cortical renal scintigraphy - Tc-99m DMSA</td>
<td></td>
</tr>
<tr>
<td>D2.7 Genitourinary system: Direct radionuclide cystography, Tc-99m based radionuclide</td>
<td></td>
</tr>
<tr>
<td>D2.8 Genitourinary system: Testicular scan, Tc-99m pertechnetate</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>D3. Cardiovascular system</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>D3.1 Cardiovascular system: Myocardial perfusion scintigraphy - Stress study using Tc-99m based radionuclide</td>
<td></td>
</tr>
<tr>
<td>D3.2 Cardiovascular system: Myocardial perfusion scintigraphy - Rest study using Tc-99m based radionuclide</td>
<td></td>
</tr>
<tr>
<td>D3.3 Cardiovascular system: Multigated blood pool scintigraphy, Tc-99m based radionuclide</td>
<td></td>
</tr>
<tr>
<td>D3.4 Cardiovascular system: Myocardial metabolic Study (refer PET-CT item D12.6)</td>
<td></td>
</tr>
<tr>
<td>D3.5 Cardiovascular system: Cardiac shunt / first pass scintigraphy, Tc-99m based radionuclide</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>D4. Gastrointestinal and hepatobiliary system</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>D4.1 Gastrointestinal and hepatobiliary system: Salivary gland scintigraphy, Tc-99m based radionuclide</td>
<td></td>
</tr>
<tr>
<td>D4.2 Gastrointestinal and hepatobiliary system: Meckel's diverticulum scintigraphy, Tc-99m based radionuclide</td>
<td></td>
</tr>
<tr>
<td>D4.3 Gastrointestinal and hepatobiliary system: Hepatobiliary scintigraphy, Tc-99m based radionuclide</td>
<td></td>
</tr>
<tr>
<td>D4.4 Gastrointestinal and hepatobiliary system: Gastric emptying scintigraphy (solid-meal), Tc-99m based radionuclide</td>
<td></td>
</tr>
<tr>
<td>D4.5 Gastrointestinal and hepatobiliary system: Liver/spleen scintigraphy, Tc-99m based radionuclide</td>
<td></td>
</tr>
<tr>
<td>D4.6 Gastrointestinal and hepatobiliary system: Gastrointestinal tract (GIT) bleed scan, Tc-99m sulphur colloid</td>
<td></td>
</tr>
<tr>
<td>D4.7 Gastrointestinal and hepatobiliary system: Gastrointestinal tract (GIT) bleed scan, Tc-99m based radionuclide – RBC-tagged (in-vivo, in-vitro or in-vitro)</td>
<td></td>
</tr>
<tr>
<td>D4.8 Gastrointestinal and hepatobiliary system: Hepatic intra-arterial Tc-99m MAA scintigraphy (does not include hepatic intra-arterial procedure)</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>D5. Respiratory system</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>D5.1 Respiratory system: Lung ventilation scintigraphy, Tc-99m based radionuclide</td>
<td></td>
</tr>
<tr>
<td>D5.2 Respiratory system: Lung perfusion scintigraphy, Tc-99m based radionuclide</td>
<td></td>
</tr>
<tr>
<td>D6. Central nervous system</td>
<td></td>
</tr>
<tr>
<td>---------------------------</td>
<td>--</td>
</tr>
<tr>
<td>D6.1 Central nervous system: Brain perfusion scintigraphy using Tc-99m based radionuclide</td>
<td></td>
</tr>
<tr>
<td>D6.2 Central nervous system: Brain death scintigraphy using Tc-99m DTPA / pertechnetate</td>
<td></td>
</tr>
<tr>
<td>D6.3 Central nervous system: Ventriculo-peritoneal (VP) shunt scintigraphy, Tc-99m based radionuclide</td>
<td></td>
</tr>
<tr>
<td>D6.4 Central nervous system: Cerebral metabolism scintigraphy (refer PET-CT item D12.7)</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>D7. Endocrine system</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>D7.1 Endocrine system: Thyroid uptake scan using I-131</td>
<td></td>
</tr>
<tr>
<td>D7.2 Endocrine system: Thyroid scintigraphy using Tc-99m pertechnetate</td>
<td></td>
</tr>
<tr>
<td>D7.3 Endocrine system: Diagnostic whole body scan - I-131 (note that in case of post-therapy scintigraphy, use Add-on item D13.3)</td>
<td></td>
</tr>
<tr>
<td>D7.4 Endocrine system: Whole body scan - I-124 (refer PET-CT item D12.5)</td>
<td></td>
</tr>
<tr>
<td>D7.5 Endocrine system: Parathyroid scintigraphy - Dual phase study using Tc-99m based radionuclides</td>
<td></td>
</tr>
<tr>
<td>D7.6 Endocrine system: Parathyroid scintigraphy - Subtraction technique using two types of radiotracers</td>
<td></td>
</tr>
<tr>
<td>D7.7 Endocrine system: Adrenal medullary scintigraphy (refer Tumor imaging item D9.1)</td>
<td></td>
</tr>
<tr>
<td>D7.8 Endocrine system: Medullary thyroid cancer scintigraphy (refer Tumor imaging item D9.2)</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>D8. Hematologic and Lymphatic System</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>D8.1 Hematologic and Lymphatic System: Lymphoscintigraphy, Tc-99m based radionuclide</td>
<td></td>
</tr>
<tr>
<td>D8.2 Hematologic and Lymphatic System: Sentinel node scintigraphy (excludes intra-operative gamma probe support service), Tc-99m based radionuclide</td>
<td></td>
</tr>
<tr>
<td>D8.3 Hematologic and Lymphatic System: Liver/spleen scintigraphy, Tc-99m based radionuclide (refer gastrointestinal and hepatobiliary item D4.5)</td>
<td></td>
</tr>
<tr>
<td>D8.4 Hematologic and Lymphatic System: Pre-therapy I-131 rituximab mapping &amp; dosimetry</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>D9. Tumor Imaging</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>D9.1 Tumor Imaging: Adrenal medullary scintigraphy using I-131 MIBG</td>
<td></td>
</tr>
<tr>
<td>D9.2 Tumor Imaging: Medullary thyroid cancer scintigraphy, Tc-99m DMSA(V)</td>
<td></td>
</tr>
<tr>
<td>D9.3 Tumor Imaging: Post-therapy scintigraphy, Lu-177, Sm-153 or I-131 based (refer Add-on item D13.3)</td>
<td></td>
</tr>
<tr>
<td>D9.4 Tumor Imaging: Post-therapy bremsstrahlung scintigraphy, β-emitters (refer Add-on item D13.4)</td>
<td></td>
</tr>
<tr>
<td>D9.5 Tumor Imaging: Post-therapy PET-CT scintigraphy, Y-90 based (refer PET-CT item D13.5)</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>D10. Infection</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>D10.1 Infection: Tc-99m based antigranulocyte antibody (besilesomab)</td>
<td></td>
</tr>
<tr>
<td>D10.2 Infection: F-18 FDG scintigraphy (refer PET-CT item D12.1)</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>D11. Other System/Organ</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>D11.1 Other System/Organ: Lacrimal duct scintigraphy (dacryoscintigraphy), Tc-99m pertechnetate</td>
<td></td>
</tr>
<tr>
<td>D11.2 Other System/Organ: Peritoneal Scintigraphy (LeVeen Shunt Study), Tc99m based radionuclide</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>D12. PET-CT Scintigraphy</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>D12.1 PET-CT Scintigraphy: Oncology and Infection - F-18 FDG</td>
<td></td>
</tr>
<tr>
<td>D12.2 PET-CT Scintigraphy: Oncology and Infection - F-18 fluoride</td>
<td></td>
</tr>
<tr>
<td>D12.3 PET-CT Scintigraphy: Oncology and Infection - Ga-68 DOTA-peptide</td>
<td></td>
</tr>
<tr>
<td>Code</td>
<td>Description</td>
</tr>
<tr>
<td>-------</td>
<td>-----------------------------------------------------------------------------</td>
</tr>
<tr>
<td>D12.2</td>
<td>PET-CT Scintigraphy: Oncology and Infection - F-18 fluoride</td>
</tr>
<tr>
<td>D12.3</td>
<td>PET-CT Scintigraphy: Oncology and Infection - Ga-68 DOTA-peptide</td>
</tr>
<tr>
<td>D12.4</td>
<td>PET-CT Scintigraphy: Oncology and Infection - Ga-68 PSMA</td>
</tr>
<tr>
<td>D12.5</td>
<td>PET-CT Scintigraphy: Oncology - I-124</td>
</tr>
<tr>
<td>D12.6</td>
<td>PET-CT Scintigraphy: Cardiology - F-18 FDG</td>
</tr>
<tr>
<td>D12.7</td>
<td>PET-CT Scintigraphy: Neurology - F-18 FDG</td>
</tr>
<tr>
<td>D12.8</td>
<td>PET-CT Scintigraphy: Add-on Post-therapy PET-CT scintigraphy, Y-90 based</td>
</tr>
<tr>
<td></td>
<td>(refer Add-on item D13.5)</td>
</tr>
<tr>
<td>D12.9</td>
<td>PET-CT Scintigraphy: Ancillary support in PET-CT simulation for RT planning</td>
</tr>
<tr>
<td></td>
<td>- F-18 FDG</td>
</tr>
<tr>
<td>D13.1</td>
<td>Add-on with CT following SPECT for lesion localization, attenuation correction and quantification (irrespective of the number of CT performed in the same sitting)</td>
</tr>
<tr>
<td>D13.2</td>
<td>Add-on sequential SPECT-CT / PET-CT scans for dosimetry calculation</td>
</tr>
<tr>
<td>D13.3</td>
<td>Add-on Post-therapy scintigraphy, I-131, Sm-153 or Lu-177 based</td>
</tr>
<tr>
<td>D13.4</td>
<td>Add-on Post-therapy bremsstrahlung scintigraphy, β-emitters</td>
</tr>
<tr>
<td>D13.5</td>
<td>Add-on Post-therapy PET-CT scintigraphy, Y-90 based</td>
</tr>
<tr>
<td>D13.6</td>
<td>Add-on Intra-operative gamma probe support service</td>
</tr>
<tr>
<td>D13.7</td>
<td>Add-on Coronary Flow Reserve study (inclusive of both stress &amp; rest studies)</td>
</tr>
<tr>
<td>D14.1</td>
<td>Diagnostic non-imaging: Glomerular filtration rate (GFR) bioassay, Cr-51 EDTA</td>
</tr>
<tr>
<td>D14.2</td>
<td>Diagnostic non-imaging: Glomerular filtration rate (GFR) bioassay, Tc-99m DTPA</td>
</tr>
<tr>
<td>D14.3</td>
<td>Diagnostic non-imaging: Calcitonin, 125-I labelled antibody</td>
</tr>
</tbody>
</table>

"Code number highlighted in **RED** denotes the same procedure with other code number that is described elsewhere in the Master List. It will not appear in the data/statistical report as the other reference code mentioned will be used instead".

"Add-on procedure highlighted in **BLUE**, is done following an initial principal / primary diagnostic or therapeutic nuclear medicine procedure and **by itself cannot exist solely on its own**. To perform these add-on procedures, there is no need to administer any extra radiotracer to the patient."
### 8.3 Therapeutic Procedures

<table>
<thead>
<tr>
<th>T1. Thyroid Therapy</th>
</tr>
</thead>
<tbody>
<tr>
<td>T1.1 Thyroid Therapy: Iodine-131 (I-131) ablation for thyroid cancer (out-patient)</td>
</tr>
<tr>
<td>T1.2 Thyroid Therapy: Iodine-131 (I-131) ablation for thyroid cancer (in-patient)</td>
</tr>
<tr>
<td>T1.3 Thyroid Therapy: Iodine (I-131) treatment for thyrotoxicosis</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>T2. Palliative Bone Therapy</th>
</tr>
</thead>
<tbody>
<tr>
<td>T2.1 Palliative Bone Therapy: Strontium-89 (Sr-89)</td>
</tr>
<tr>
<td>T2.2 Palliative Bone Therapy: Samarium-153 based (Sm-153)</td>
</tr>
<tr>
<td>T2.3 Palliative Bone Therapy: Phosphorus-32 (P-32)</td>
</tr>
<tr>
<td>T2.4 Palliative Bone Therapy: Radium-223 (Ra-223)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>T3. Radiosynovectomy</th>
</tr>
</thead>
<tbody>
<tr>
<td>T3.1 Radiosynovectomy: Yttrium-90 (Y-90) - does not include intraarticular injection</td>
</tr>
<tr>
<td>T3.2 Radiosynovectomy: Rhenium-186 (Re-186) - does not include intraarticular injection</td>
</tr>
<tr>
<td>T3.3 Radiosynovectomy: Erbium-169 (Er-169) - does not include intraarticular injection</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>T4. MIBG Therapy</th>
</tr>
</thead>
<tbody>
<tr>
<td>T4.1 I-131 MIBG Therapy (in-patient)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>T5. Peptide Radionuclide Receptor Therapy (PRRT)</th>
</tr>
</thead>
<tbody>
<tr>
<td>T5.1 Peptide Radionuclide Receptor Therapy: Lutetium-177 (Lu-177) labelled somatostatin analogue</td>
</tr>
<tr>
<td>T5.2 Peptide Radionuclide Receptor Therapy: Yttrium-90 (Y-90) labelled somatostatin analogue</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>T6. Radioimmunotherapy (RIT)</th>
</tr>
</thead>
<tbody>
<tr>
<td>T6.1 Radioimmunotherapy: Iodone-131 (I-131) Rituximab (in-patient)</td>
</tr>
<tr>
<td>T6.2 Radioimmunotherapy: Yttrium-90 (Y-90) Ibritumomab</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>T7. Selective Internal Radiation Therapy (SIRT)</th>
</tr>
</thead>
<tbody>
<tr>
<td>T7.1 Selective Internal Radiation Therapy (SIRT) (does not include hepatic intra-arterial procedure): Yttrium-90 (Y-90) based microsphere</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>T8. PSMA radionuclide therapy</th>
</tr>
</thead>
<tbody>
<tr>
<td>T8.1 PSMA radionuclide therapy: Lutetium-177 (Lu-177) or Actinium-225 (Ac-225) labelled</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>T9. Other Radionuclide Therapy</th>
</tr>
</thead>
<tbody>
<tr>
<td>T9.1 Radionuclide Therapy for polycythemia vera - Phosphorus-32 (P-32)</td>
</tr>
</tbody>
</table>

### 8.4 Day-care Procedure

A day-care procedure should fulfill the following 4 criteria*:

1. Patients are scheduled to undergo a procedure.
2. The scheduled procedure has been done.
3. Procedures carried out require a short recovery period with complete documentation on the patients’ progress during this observation period.
4. Patients discharged from the observation ward in the same calendar day.

APPENDICES
Appendix 1

JABATAN PERUBATAN NUKLEAR

HOSPITAL __________________

Nama Pesakit : ____________________________
No. K/P : _________________________________
Jantina : _________________________________
Tarikh : _________________________________

Borang Keizinan Pesakit untuk Skan Perfusi Jantung
Consent Form for Myocardial Perfusion Imaging

Saya bersetuju menjalankan ujian ini dan telah memberi maklumat yang diperlukan kepada doktor dan juga kakitangan lain yang berkaitan apabila diminta.
I have given my consent to have this test done on me and I have given all the required information when being asked by the concerned doctor or medical staff.

Saya telah dimaklumkan berkenaan risiko yang terlibat termasuk risiko radiasi, risiko ujian stres jantung (stress test) dan kemungkinan serangan sakit jantung (kira-kira 2 orang bagi setiap 10,000). Saya juga telah diberi peluang untuk membuat pertanyaan dan soalan-soalan ini telah dijawab dengan memuaskan.
I have been informed of the risks involved including the radiation risk, risk of stress testing and possibility of heart attack (approximately 2 people per 10,000). I have also been given the opportunity to ask questions and have these questions answered to my satisfaction.

Sekiranya terdapat skan tambahan yang diperlukan oleh doktor, saya faham tentang keperluan ini dan bersetuju supaya skan diambil dari sudut pandangan tertentu atau diulangi.
In the event that any additional scan images are required by the doctor, I understand and accept the need for certain views to be retaken or repeated.

Tidak ada jaminan yang telah diberi kepada saya bahawa prosedur ini akan dijalankan oleh mana-mana pengamal perubatan tertentu.
There is no guarantee given to me that this procedure will be conducted by any particular medical practitioner.
Tanda lagi Pesakit/ Ibu bapa/ Penjaga*
Signature of Patient / Parent / Guardian*

Tuliskan Nama Ibu bapa / Penjaga (jika berkaitan)
Print Name of Parent / Guardian (if applicable)

Tali Persaudaraan
Relationship to Patient

* potong yang tidak berkenaan. Sebarang pemotongan dan tambahan atau pindaan kepada borang ini hendaklah dibuat sebelum borang ini dikemukakan untuk ditandatangani. (strike through if it is not relevant. Any edition or alteration on this form should be done before presenting it for signature.)

Peringatan: Jika seseorang itu memberi keizinan sebagai seorang penjaga, hendaklah tali persaudaraannya dijelaskan di bawah tandatangannya. (Reminder: Any person giving the consent as a guardian must clearly write down his / her relationship with the patient below the signature.)

Keizinan ini diambil oleh:
Consent taken by:

Nama & Tandatangan Pengamal Perubatan
Name & Signature of Medical Practitioner

Nama & Tandatangan Saksi
Name & Signature of the Witness

Sekiranya proses keizinan ini diambil dengan bantuan penterjemah dalam bahasa lain selain daripada bahasa bertulis ini, tolong nyatakan:
If this consent process has been done in a language other than that on this written form, with the assistance of a translator, indicate:

Bahasa yang digunakan
Language used
Consent Form
I-131 Therapy for Hyperthyroidism

Your attending doctor has asked us to give you radioactive I-131 treatment for your thyroid disease. You would have had your medications for treatment of the thyroid disease earlier.

I-131 destroys the functioning thyroid tissue by releasing radiation (electrons or beta particles) and will destroy the remainder of your thyroid gland. Normally only one treatment is enough to treat your thyroid disease, but occasionally a second dose is required. I-131 treatment has been given successfully for 50 years and is very safe. However, you should not have this treatment if you are pregnant or if breast feeding.

Time
After you have taken the capsule / liquid I-131, you are most radioactive in the first few days. This will last for a short time (1 week or so) and as the time passes it will decrease. You will be required to remain in relative isolation till your radioactive levels are safer for your family and general public.

Contamination
Some of the dose is excreted in the saliva, in the urine and the faeces. Therefore, to avoid spreading the radioactive iodine avoid lip kissing, be vigilant of general hygiene, wash hands, shower or bathe daily for the first 1 week. During this period of time, use separate utensils from rest of the family. When using the toilet, if possible do not stand and urinate, remember to flush twice and wash your hands.

With this treatment, these simple precautions should be followed to minimize the small amount of radiation received by members of your family and the public, particularly small children or pregnant women. The radiation dose family members and others receive is very small and has never been shown to be harmful, but it is sensible to minimize this if we can.

HOW TO REDUCE RADIATION EXPOSURE TO OTHER PEOPLE

The important principles are time and distance. You will lower the radiation dose received by others if you minimize the time you are close to others and increase the distance between yourself and them, since the radiation is absorbed in the air.

Therefore till _______________ observe the following precaution.
- Maintain a distance of at least 1 m from other person around you
- Minimise close proximity to few minutes – quick hugs are okay
- Do not go on long trips (bus, air or train).
- Avoid public places, shopping centers, cinema, library or school
• While with the family or if watching TV, sit in a separate chair
• Sleep alone or sleep in a separate bed, make sure there is distance of 2 m between yourself and the other person
• Drink plenty of fluid. You may use sugar free lemon candies to promote saliva too
• Use a separate toilet if available, always flush twice and wash your hands
• Maintain separate eating utensil
• Do not prepare food
• Avoid contact with babies and pregnant women
• Refrain from sexual activity. This may resume after one week, but an appropriate birth control method should be used
• If you are planning to become pregnant, you should wait for at least 6 months after treatment
• If you have been breast feeding your baby, you must stop because I-131 is secreted in breast milk
• Male patients should avoid fathering a child for at least 2 months following the treatment

Resume school / work after _____________________________________________________

Iodine 131 dose ___________________________ MBq.  Date___________________________

___________________________________ Date:
Signature of Patient / Parent / Guardian*

___________________________________
Print Name of Parent / Guardian (if applicable)

________________________________________________________________________
Relationship to Patient

* strike through if it is not relevant. Any edition or alteration on this form should be done before presenting it for signature.
Reminder: Any person giving the consent as a guardian must clearly write down his / her relationship with the patient.

Consent taken by:

___________________________________ Date:
Name & Signature of Medical Practitioner

___________________________________ Date:
Name & Signature of the Witness

If this consent process has been done in a language other than that on this written form, with the assistance of a translator, indicate:

___________________________________
Language used
## Appendix 3

### PROPOSED LIST OF EQUIPMENT FOR EACH OPERATIONAL TYPES & FUNCTIONS OF RADIOPHARMACEUTICAL PREPARATION FACILITIES

<table>
<thead>
<tr>
<th>OPERATIONAL TYPES OF RADIOPHARMACEUTICAL PREPARATION (RP) FACILITY IN MALAYSIA</th>
<th>TYPE I - DISPENSING</th>
<th>TYPE II - COMPOUNDING &amp; RADIOLABELING</th>
<th>TYPE III - CYCLOTRON SETUP</th>
<th>TYPE IV - BLOOD PRODUCT</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>DISPENSING ROOM / PREPARATION ROOM / PRODUCTION ROOM</strong></td>
<td>1a</td>
<td>1b</td>
<td>1c</td>
<td>2a</td>
</tr>
<tr>
<td>Grade A Radiopharmaceutical Isolator OR Radiopharmaceutical Laminar Flow Safety Cabinet; lead-lined with sliding lead glass barrier, built-in dose calibrator, generator elution port and radioactive waste container</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Grade A Radiopharmaceutical Isolator OR Radiopharmaceutical Laminar Flow Safety Cabinet with suitable filters; lead-lined with sliding lead glass barrier, built-in dose calibrator and radioactive waste container</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Grade A Hot cells for critical activity such as dispensing/filling into product vials</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Automated Synthesis Module in Hot cells for synthesis of PET Radiopharmaceuticals</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Blood Radiolabeling Isolator OR Radiopharmaceutical Laminar Flow Safety Cabinet; lead lined, with sliding lead glass barrier, built-in dose calibrator generator elution port and radioactive waste container</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Radiopharmaceutical Fume Hood; lead lined with disposable activated carbon filter and sliding lead glass barrier</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Dose calibrator</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Lead brick for SPECT or PET radiopharmaceutical (whichever applies)</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>L-shape lead barrier for SPECT or PET radiopharmaceuticals (whichever applies)</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Lead vial container for SPECT or PET radiopharmaceuticals (whichever applies)</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Lead syringe shield for SPECT or PET radiopharmaceuticals (whichever applies)</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Component Room</td>
<td>Personnel Gowning Room</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>----------------</td>
<td>------------------------</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lead carrier for SPECT or PET radiopharmaceuticals (whichever applies)</td>
<td>✓ ✓ ✓ ✓ ✓ ✓ ✓ ✓ ✓ ✓</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Handling aids (e.g.: tongs, forceps)</td>
<td>✓ ✓ ✓ ✓ ✓ ✓ ✓ ✓ ✓ ✓</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Table top centrifuge</td>
<td>✓ ✓ ✓ ✓ ✓ ✓ ✓ ✓ ✓ ✓</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rotator</td>
<td>✓ ✓ ✓ ✓ ✓ ✓ ✓ ✓ ✓ ✓</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Heating block or Hot plate or water bath; lead shielded</td>
<td>✓ ✓ ✓ ✓ ✓ ✓ ✓ ✓ ✓ ✓</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pipettes (1-2000ul, 200-1000ul, 1-5ml)</td>
<td>✓ ✓ ✓ ✓ ✓ ✓ ✓ ✓ ✓ ✓</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Trolley; two tiers, heavy duty (200kg load), stainless steel</td>
<td>✓ ✓ ✓ ✓ ✓ ✓ ✓ ✓ ✓ ✓</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lead syringe holder</td>
<td>✓ ✓ ✓ ✓ ✓ ✓ ✓ ✓ ✓ ✓</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Work bench; phenolic top OR other suitable equivalent material</td>
<td>✓ ✓ ✓ ✓ ✓ ✓ ✓ ✓ ✓ ✓</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Intercom system</td>
<td>✓ ✓ ✓ ✓ ✓ ✓ ✓ ✓ ✓ ✓</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sanitizable stool with wheels and adjustable height</td>
<td>✓ ✓ ✓ ✓ ✓ ✓ ✓ ✓ ✓ ✓</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Radiation environment detector; wall mounted</td>
<td>✓ ✓ ✓ ✓ ✓ ✓ ✓ ✓ ✓ ✓</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Stop watch</td>
<td>✓ ✓ ✓ ✓ ✓ ✓ ✓ ✓ ✓ ✓</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tray; stainless steel</td>
<td>✓ ✓ ✓ ✓ ✓ ✓ ✓ ✓ ✓ ✓</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lead shielded waste container; stainless steel</td>
<td>✓ ✓ ✓ ✓ ✓ ✓ ✓ ✓ ✓ ✓</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Waste container; stainless steel</td>
<td>✓ ✓ ✓ ✓ ✓ ✓ ✓ ✓ ✓ ✓</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pharmaceutical refrigerator connected to an essential power supply</td>
<td>✓ ✓ ✓ ✓ ✓ ✓ ✓ ✓ ✓ ✓</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Components Room**

| Pharmaceutical refrigerator connected to an essential power supply | ✓ ✓ ✓ ✓ ✓ ✓ ✓ ✓ ✓ ✓ |
| Pharmaceutical refrigerator connected to an essential power supply | ✓ ✓ ✓ ✓ ✓ ✓ ✓ ✓ ✓ ✓ |
| Pharmaceutical refrigerator connected to an essential power supply | ✓ ✓ ✓ ✓ ✓ ✓ ✓ ✓ ✓ ✓ |
| Pharmaceutical refrigerator connected to an essential power supply | ✓ ✓ ✓ ✓ ✓ ✓ ✓ ✓ ✓ ✓ |
| Pharmaceutical refrigerator connected to an essential power supply | ✓ ✓ ✓ ✓ ✓ ✓ ✓ ✓ ✓ ✓ |

**Personnel Gowning Room**

| Pharmaceutical refrigerator connected to an essential power supply | ✓ ✓ ✓ ✓ ✓ ✓ ✓ ✓ ✓ ✓ |
| Pharmaceutical refrigerator connected to an essential power supply | ✓ ✓ ✓ ✓ ✓ ✓ ✓ ✓ ✓ ✓ |
| Pharmaceutical refrigerator connected to an essential power supply | ✓ ✓ ✓ ✓ ✓ ✓ ✓ ✓ ✓ ✓ |
### PERSONNEL CHANGING ROOM

<table>
<thead>
<tr>
<th>Item</th>
<th>√</th>
<th>√</th>
<th>√</th>
<th>√</th>
<th>√</th>
<th>√</th>
<th>√</th>
<th>√</th>
<th>√</th>
<th>√</th>
</tr>
</thead>
</table>
| Sink with elbow tap; stainless steel                                 | √ | √ | √ | √ | √ | √ | √ | √ | √ | √  
| Cabinet (to hang street clothes)                                     | √ | √ | √ | √ | √ | √ | √ | √ | √ | √  
| Liquid soap dispenser (foot operated)                                | √ | √ | √ | √ | √ | √ | √ | √ | √ | √  
| Electrical hand dryer                                                | √ | √ | √ | √ | √ | √ | √ | √ | √ | √  
| Six feet long mirror; wall mounted                                   | √ | √ | √ | √ | √ | √ | √ | √ | √ | √  
| Cross over bench                                                     | √ | √ | √ | √ | √ | √ | √ | √ | √ | √  
| Hand and foot contamination detector (to be placed in the common    | √ | √ | √ | √ | √ | √ | √ | √ | √ | √  
| corridor within the facility)                                        | √ | √ | √ | √ | √ | √ | √ | √ | √ | √  
| Emergency shower & eye wash station (to be placed in the common     | √ | √ | √ | √ | √ | √ | √ | √ | √ | √  
| corridor within the facility)                                        | √ | √ | √ | √ | √ | √ | √ | √ | √ | √  |

### FINISH PRODUCT ROOM

<table>
<thead>
<tr>
<th>Item</th>
<th>√</th>
</tr>
</thead>
<tbody>
<tr>
<td>Survey Meter</td>
<td></td>
</tr>
<tr>
<td>Rack/shelves; stainless steel</td>
<td>√</td>
</tr>
<tr>
<td>Lead transport Box</td>
<td>√</td>
</tr>
<tr>
<td>Trolley; platform, heavy duty (200kg load)</td>
<td></td>
</tr>
</tbody>
</table>

### QUALITY CONTROL LABORATORY

<table>
<thead>
<tr>
<th>Item</th>
<th>√</th>
<th>√</th>
<th>√</th>
<th>√</th>
<th>√</th>
<th>√</th>
<th>√</th>
<th>√</th>
<th>√</th>
<th>√</th>
</tr>
</thead>
</table>
| Handling aids (e.g.: tongs, forceps)                                 | √ | √ | √ | √ | √ | √ | √ | √ | √ | √  
| Gamma counter / multi-channel analyzer                              | √ | √ | √ | √ | √ | √ | √ | √ | √ | √  
| Dose calibrator                                                     | √ | √ | √ | √ | √ | √ | √ | √ | √ | √  
| Bench top shield                                                    | √ | √ | √ | √ | √ | √ | √ | √ | √ | √  
| Laboratory glass wares (e.g. beakers, test tubes, measuring cylinders, pipettes, burettes, conical flask etc.) | √ | √ | √ | √ | √ | √ | √ | √ | √ | √  
| Sink with elbow tap; stainless steel                                | √ | √ | √ | √ | √ | √ | √ | √ | √ | √  
| Radiation detector / survey meter                                   | √ | √ | √ | √ | √ | √ | √ | √ | √ | √  
| Lead shielding / lead glass / Lead bricks                           | √ | √ | √ | √ | √ | √ | √ | √ | √ | √  
| Radioactive waste container                                          | √ | √ | √ | √ | √ | √ | √ | √ | √ | √  
<p>| Cabinet for solid chemical                                           | √ | √ | √ | √ | √ | √ | √ | √ | √ | √  |</p>
<table>
<thead>
<tr>
<th>Equipment</th>
<th>✔</th>
<th>✔</th>
<th>✔</th>
<th>✔</th>
<th>✔</th>
<th>✔</th>
<th>✔</th>
<th>✔</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cabinet for flammable chemical</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Chemical/laboratory fume hood</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
</tr>
<tr>
<td>PET L-Shield</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Radio-Thin Layer Chromatography</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
</tr>
<tr>
<td>Gas Chromatography*</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Radio-high Performance Liquid Chromatography*</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
</tr>
<tr>
<td>pH meter</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
</tr>
<tr>
<td>Rapid Bacterial Endotoxin Test</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Analytical balance</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Laboratory Oven</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pharmaceutical refrigerator connected to an essential power supply</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
</tr>
<tr>
<td>Pharmaceutical freezer connected to an essential power supply</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
</tr>
<tr>
<td>Vacuum pump and filter apparatus</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rack/shelves/cabinet/work bench</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
</tr>
<tr>
<td>Bubble point test apparatus</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Radioactive waste shielded container</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Burettes</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pipettes (1-2000ul, 200-1000ul, 1-5ml)</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
</tr>
<tr>
<td>Water filter</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Water deionizer</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Stool with wheels and adjustable height</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
</tr>
<tr>
<td>Chromatography developing chamber</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Table top centrifuge</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**RADIOACTIVE STORE**

<table>
<thead>
<tr>
<th>Equipment</th>
<th>✔</th>
<th>✔</th>
<th>✔</th>
<th>✔</th>
<th>✔</th>
<th>✔</th>
<th>✔</th>
<th>✔</th>
</tr>
</thead>
<tbody>
<tr>
<td>Radioactive Cabinet</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Trolley; Platform, Heavy Duty (200kg Load)</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
</tr>
<tr>
<td>Forceps, Tongs</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
</tr>
</tbody>
</table>
### NON-RADIOACTIVE STORE

<table>
<thead>
<tr>
<th>Item</th>
<th>✔</th>
<th>✔</th>
<th>✔</th>
<th>✔</th>
<th>✔</th>
<th>✔</th>
<th>✔</th>
<th>✔</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pharmaceutical refrigerator and deep freezer; connected to an essential power supply</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rack / shelves</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
</tr>
<tr>
<td>Trolley; platform heavy duty (200kg load)</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
</tr>
<tr>
<td>Trolley; two tiers, heavy duty (200kg load)</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
</tr>
</tbody>
</table>

### RADIOACTIVE WASTE ROOM

<table>
<thead>
<tr>
<th>Item</th>
<th>✔</th>
<th>✔</th>
<th>✔</th>
<th>✔</th>
<th>✔</th>
<th>✔</th>
<th>✔</th>
<th>✔</th>
</tr>
</thead>
<tbody>
<tr>
<td>Drums, waste tank</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Survey meter</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Decontamination kit</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* Depends on the types of radiopharmaceuticals produced in that facility
** Items required in a Centralized Nuclear Pharmacy and/or GMP facility
REFERENCES
REFERENCES


   - Pekelingan Keperluan Latihan Untuk Personel Dalam Perkhidmatan Perubatan Nuklear Di Bawah Akta Perlesenan Tenaga Ataom 1984 (Akta 304)
   - Buku Log Bagi Personel Baru (Ahli Fizik Perubatan, Ahli Radiokimia, Juruteknologi Perubatan Nuklear Dan Jururawat)

3. EANM Guidance on Current Good Radiopharmacy Practice (CGRPP) for the small-scale preparation of radiopharmaceuticals

4. EANM Guidelines on Current Good Radiopharmacy Practice (CGRPP) in the preparation of radiopharmaceuticals


8. IAEA Operational Guidance on Hospital Radiopharmacy – a safe and effective approach


10. IAEA Safety Standards for protecting people and the environment Specific Safety Requirements No. SSR-6 (Rev. 1): Regulations for the Safe Transport of Radioactive Material, 2018


12. Malaysian Diagnostic Reference Levels in Medical Imaging (Nuclear Medicine), 2013


20. SNMMI Procedure Guideline for the Use of Radiopharmaceuticals 4.0


22. US Pharmacopeia <797> Pharmaceutical Compounding – sterile preparation

DRAFTING COMMITTEE
FOR OPERATIONAL POLICY IN NUCLEAR MEDICINE SERVICES

Advisors

Datuk Dr. Noor Hisham bin Abdullah
Director General of Health
Ministry of Health Malaysia

Dato' Dr. Hj. Azman bin Hj. Abu Bakar
Deputy Director General of Health (Medical)
Ministry of Health Malaysia

Chairperson

Dr. Ng Chen Siew
Head of Nuclear Medicine Services, Ministry of Health &
Head of Department of Nuclear Medicine
Hospital Sultanah Aminah Johor Bahru

Coordinators

Dr. Melvyn Edward Anthony
Senior Principal Assistant Director
Medical Development Division,
Ministry of Health Malaysia

Dr. Olivia Tan Yen Ping
Senior Principal Assistant Director
Medical Development Division,
Ministry of Health Malaysia

Members

Dr. Siti Zarina bt. Amir Hassan
Head of Department of Nuclear Medicine
Hospital Kuala Lumpur

Dr. Zuzila binti Sulaiman
Head of Department of Nuclear Medicine
Women and Children Hospital, Likas

Dr. Fadzilah binti Hamzah
Head of Department of Nuclear Medicine
Hospital Pulau Pinang
Pulau Pinang

Dr. Zool Hilmi B. Awang
Nuclear Medicine Specialist
Department of Nuclear Medicine
National Cancer Institute, Putrajaya

Dr. Lee Boon Nang
Head of Department of Nuclear Medicine
National Cancer Institute, Putrajaya
Putrajaya

Dr. Khor Phay Phay
Nuclear Medicine Specialist
Department of Nuclear Medicine
Sarawak General Hospital
Pn. Fatan Hamimah Jamal
Nuclear Medicine Physicist,
Hospital Sultanah Aminah Johor Bahru

En Mohd Hizwan bin Mohd Yahya
Nuclear Medicine Physicist,
Hospital Pulau Pinang

Pn. Noor Diana binti Dolmat
Nuclear Medicine Physicist,
Hospital Kuala Lumpur

Pn. Dayang Masury Ahmad Saib
Nuclear Medicine Physicist,
National Cancer Institute, Putrajaya

Cik Charlene Wong Muh Yiing
Nuclear Medicine Physicist,
Sarawak General Hospital

Pn. Norli binti Abu Zahid
Nuclear Medicine Technologist
(Radiographer),
Hospital Sultanah Aminah Johor Bahru

En. Syazrul Syahrin bin Said
Nuclear Medicine Technologist
(Medical Assistant),
Hospital Kuala Lumpur

En. Mohd Nazir bin Razali
Nuclear Medicine Technologist
(Medical Assistant),
Women and Children Hospital, Likas

Pn. Nor Safinah binti Mohamed Noor
Sister for Nuclear Medicine Department,
Hospital Pulau Pinang

Dr. Zaitulhusna binti Md Safee
Nuclear Pharmacist,
Hospital Kuala Lumpur

En. Ahmad Bazli bin Ahamad Zikrileh
Nuclear Pharmacist,
Hospital Sultanah Aminah Johor Bahru

En. Amir Firdaus bin Abdul Aziz
Nuclear Pharmacist,
Hospital Pulau Pinang

En. Ikrami bin Mohd Yusof
Nuclear Pharmacist,
Sarawak General Hospital

En. Vincent Yong Chun Vui
Nuclear Pharmacist,
Women and Children Hospital, Likas

En. Saiful Rizal bin Sukar
Nuclear Medicine Technologist
(Medical Assistant),
National Cancer Institute, Putrajaya

En. Muhd. Ludfi bin Abd. Samad
Nuclear Medicine Technologist
(Medical Lab Technologist),
Hospital Pulau Pinang

En. Mustaffa bin Hamidon
former Nuclear Medicine Technologist
(Medical Assistant),
Hospital Pulau Pinang

Pn. Sanin Ak Siot
Sister for Nuclear Medicine Department,
Sarawak General Hospital
EXTERNAL REVIEW PANELS

En. Zunaide bin Kayun @ Farni
Deputy Director
Medical Radiation Surveillance Division
Ministry of Health Malaysia

Dr. Sarene Chu binti Saifuddin
Senior Principal Assistant Director
Medical Radiation Surveillance Division
Ministry of Health Malaysia

Pn. Fajaratun binti Abdul Sani
former Principal Assistant Director
Pharmacy Practice & Development Division
Ministry of Health Malaysia

Pn. Fazillahnor binti Ab Rahim
Senior Principal Assistant Director
National Pharmaceutical Regulatory Agency
Center for Compliance & Licensing
Ministry of Health Malaysia

Pn. Idamazura binti Idris@Harun
Medical Device Control Division
Pre-Market Unit
Ministry of Health Malaysia

Dr. Rusilawati bt Jaudin
Senior Assistant Director
Medical Development Division
Hospital Management Services Unit
Ministry of Health Malaysia

Dr. Siti Aula binti Turmid
Senior Principal Assistant Director
Planning Division
Health Facility Planning Section
Ministry of Health Malaysia

Pn. Nurulbalkis bt Hamdan
Pharmacist
Planning Division
Health Facility Planning Section
Ministry of Health Malaysia

Dr. Fatimah Azaahra binti Kamarudin
Principal Assistant Director
Planning Division
Health Facility Planning Section
Ministry of Health Malaysia

Dr. Hazrina binti Hamzah
Senior Assistant Director
Planning Division
Health Facility Planning Section
Ministry of Health Malaysia

Cover Design: Pn. Nurul Nadiah binti Rapie, Nuclear Medicine Physicist, HKL