MINISTRY OF HEALTH
SINGAPORE

STANDARDS FOR THE PROVISION OF
NUCLEAR MEDICINE, IMAGING, THERAPY
AND ASSAY SERVICES

28 May 2019
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PREAMBLE

In order to safeguard patient safety and protect public interest, the Advisory Committee on Nuclear Medicine (see APPENDIX) was appointed by the Director of Medical Services ("DMS"), Ministry of Health ("MOH") in March 2015 to review and draft a set of standards on nuclear medicine, imaging, therapy and assay services ("NM Services"). The Advisory Committee comprises Nuclear Medicine specialists from public and private hospitals and a Medical Physicist.

After reviewing and drawing reference from the relevant international best practices, the Advisory Committee has developed a set of standards that can be applied to our local context (the “Standards”). The Standards assure the safety of patients who are provided with NM services by ensuring that Healthcare Institutions providing NM Services have, amongst other things, adequate personnel, facilities, equipment, product, policy and procedures, and Quality Management Systems; and adopt a “risk-based” approach that tailors the relevant requirements according to the intended use of the radiopharmaceuticals and the type of radiopharmacy tasks being performed.

MOH held a series of stakeholder consultations on the Standards from January to March 2017. The Advisory Committee subsequently deliberated on the feedback received from the consultation sessions and revised the Standards, where appropriate.

Healthcare institutions providing NM Services are recommended to adopt and comply with the Standards, so as to achieve safer and better quality NM services, and to ramp up operational readiness for future regulatory compliance. MOH only intends to enforce the Standards with effect from the second half of 2020.
PART A: APPLICATION AND INTERPRETATION

1. APPLICATION

1.1 This document sets out the minimum standards that Licensees are recommended to adopt and comply with if they intend to provide NM Services in their Healthcare Institutions (“Healthcare Institutions providing NM Services”).

1.2 Some recommendations set out in these Standards are already required under existing laws [e.g. the Private Hospitals and Medical Clinics Act (“PHMCA”) and the Radiation Protection Act (“RPA”)]. These requirements are elaborated in these Standards for completeness, and do not affect the applicability of these existing requirements.

1.3 These Standards do not apply to facilities engaged in the manufacturing or assembly of radiopharmaceuticals, which are classified as category 3C radiopharmacy tasks in TABLE 2 of ANNEX 1.

2. INTERPRETATION

The following definitions shall apply for the purpose of these Standards:

2.1 “Licensee” refers to a holder of a licence issued under the PHMCA.

2.2 “Nuclear medicine, imaging, therapy and assay services”, or “NM Services”, refers to services and laboratory procedures involving the use of radioactive substances, including radionuclides, for medical diagnosis and/or therapy.

2.3 “Radiopharmaceuticals” refer to a group of pharmaceutical drugs that are radioactive and can be used as diagnostic and/or therapeutic agents for medical care.

2.4 “Radiopharmacy Laboratory”, or “Hot Lab”, refers to a facility found in a Healthcare Institution providing NM Services that is used for the preparation, dispensing, radiolabelling, compounding, and quality control of radiopharmaceuticals.

2.5 “Hot Toilets” refer to toilets for the exclusive use of patients after the administration

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Footnotes:

1 For the avoidance of doubt, all local facilities engaged in the manufacturing or assembly of therapeutic products, including radiopharmaceuticals, must be licensed with the Health Sciences Authority (“HSA”) and comply with the relevant legislative and regulatory requirements, and Good Manufacturing Practice (“GMP”) standard. In addition, if the radiopharmaceutical is categorised as a poison under the Poisons Act (Cap. 234), a licence under that Act must be obtained from the HSA as well. If the facility has in its possession and uses equipment containing radioactive material (e.g. Cyclotron), a licence must be also obtained from the National Environment Agency (“NEA”).

2 For example, the use of radioimmunoassay for the detection of Hydroxyvitamin D and Thyroid Stimulating Hormone Receptor Antibody.

3 For example, Positron Emission Tomography (“PET”)/Computed Tomography (“CT”), bone scan, nuclear cardiology, and radioimmunoassay.

4 For example, the use of Iodine-131 for thyroid cancer therapies and Radium-223 therapy for prostate cancer therapies.
of radiopharmaceuticals in a Healthcare Institution providing NM Services.
PART B: NUCLEAR MEDICINE, IMAGING, THERAPY AND ASSAY (NM) SERVICES

3. PERSONNEL
Healthcare Institutions providing NM Services are recommended, at all times, to have personnel that satisfy the minimum requirements set out in Table 1.

_Table 1 – Minimum personnel requirements for the provision of NM services_

<table>
<thead>
<tr>
<th>Personnel</th>
<th>Minimum Requirements</th>
</tr>
</thead>
</table>
| 3.1 Physician-in-charge, or “Clinical Governance Officer” | (a) is a medical practitioner registered with the Singapore Medical Council as a Nuclear Medicine Specialist under the Medical Registration Act (Cap. 174) or is otherwise specifically approved by DMS; **AND**  
(b) has at least **FIVE (5) YEARS** of post-specialist registration clinical working experience in NM services; **AND**  
(c) has a valid L6 licence issued by the NEA under the RPA. |
| 3.2 (1) Qualified Diagnostic Radiographer or Qualified Radiation Therapist  
**OR**  
(2) Qualified NM Technologist | For (1) –  
(a) is a diagnostic radiographer or radiation therapist registered with the Allied Health Professions Council under the Allied Health Professions Act (Cap. 6B); **AND**  
(b) has at least **THREE (3) YEARS** of relevant clinical working experience in NM services.  
**OR**  
For (2) –  
(a) has a Diploma in Nuclear Medicine Technology or other science subjects related to Nuclear Medicine; **AND**  
(b) has at least **THREE (3) YEARS** of relevant clinical working experience in NM services. |
| 3.3 Qualified Medical/ Qualified Radiation Physicist | (a) has a basic degree in Physics; **AND**  
(b) has at least **THREE (3) YEARS** of relevant clinical working experience in NM services. |
| 3.4 Radiation Safety Officer (“RSO”) | As approved under the Radiation Protection (Non-Ionising Radiation) Regulations and/or the Radiation Protection (Ionising Radiation) Regulations of the RPA, as the case may be. |
| 3.5 Qualified Registered Nurse | (a) is a nurse registered with the Singapore Nursing Board under the Nurses and Midwives Act (Cap. 209); **AND**  
(b) has appropriate clinical competency as assessed by the Physician-in-charge; **AND**  
(c) has appropriate radiation safety competency as assessed by the RSO. |

5 Kindly refer to the accompanying FAQs for additional guidance regarding these minimum requirements.
3.6 In addition to the minimum personnel requirements set out in Table 1 above, if Healthcare Institutions providing NM Services wish to:

(1) engage persons who satisfy the requirement under paragraph 3.2(1)(a) but do not satisfy the requirement under paragraph 3.2(1)(b) as Diagnostic Radiographers or Radiation Therapists; or

(2) engage persons who satisfy the requirement under paragraph 3.2(2)(a) but do not satisfy the requirement under paragraph 3.2(2)(b) as NM Technologists, they are recommended to ensure that such persons work under the close supervision of either:

(1) the Physician-in-charge;
(2) a Qualified Diagnostic Radiographer or Qualified Radiation Therapist; or
(3) a Qualified NM Technologist,

when providing NM Services.

4. FACILITIES AND EQUIPMENT

These Standards adopt a “risk-based” approach towards determining the minimum facilities and equipment that each Healthcare Institution providing NM services must have. The relevant requirements vary according to the Licensee’s intended use of radiopharmaceuticals (e.g. diagnostic versus therapeutic) and the type of radiopharmacy tasks being performed in the Hot Lab (e.g. dispensing versus compounding of radiopharmaceuticals). Additional regulatory requirements apply to Healthcare Institutions that provide NM services involving inpatient therapy (see section 4.2 below).

Facilities

4.1 Healthcare Institutions providing NM Services are recommended to have patient and staff areas that:

(1) Have appropriate markings and access controls for areas designated as “restricted” and/or “controlled” in accordance with the requirements under the RPA and its regulations;
(2) Provide adequate secure physical storage areas for patient records;
(3) Provide adequate facilities for patient safety and privacy (e.g. changing rooms);
(4) Provide adequate waiting areas to segregate patients before and after the administration of radiopharmaceuticals;
(5) Provide appropriate lead-lining or other shielding of doors, walls, ceilings, and floors of imaging rooms in accordance with the requirements stipulated under the RPA and its regulations;
(6) Provide adequate Hot Toilets for the exclusive use of patients after the
administration of radiopharmaceuticals;

(7) Provide adequate areas for the procurement, receipt, use, preparation, administration, storage and disposal of radiopharmaceuticals. The areas that are used for the storage and disposal of radiopharmaceuticals, including any radioactive waste, must be controlled and secured. Hot Labs for the handling of radiopharmaceuticals must meet the relevant requirements set out in ANNEX 1; and

(8) Provide adequate decontamination facilities and equipment (e.g. emergency shower, face and eye wash).

4.2 In addition to the requirements in paragraphs 4.1, 4.3 and 4.4, Healthcare Institutions providing NM Services involving inpatient therapy are recommended to have patient and staff areas that:

(1) Provide appropriate designated ward(s) with appropriate markings, surface, shielding, sanitation and ventilation in accordance with the requirements under the RPA and its regulations;

(2) Provide adequate radiation protection measures for family/caregivers, staff and the public; and

(3) Provide adequate sewerage management system for the storage for decay and the controlled discharge of radioactive patient waste.

**Equipment**

4.3 Healthcare Institutions providing NM Services are recommended to:

(1) Provide adequate emergency and resuscitation equipment;

(2) Provide adequate radiation monitoring devices, including dose calibrator/s and radiation survey meter/s;

(3) Provide adequate radionuclide dose calibrators with appropriate lead shielding and calibration of long half-life radionuclide Quality Control (“QC”) sources;

(4) Provide adequate primary and secondary containers for transportation (within and outside the premises) of radioactive materials; and

(5) Provide adequate decontamination kit and personal protective equipment (“PPE”) to manage radioactive spills.

4.4 Healthcare Institutions providing NM Services are recommended to comply with existing requirements and the guidelines issued by the relevant regulatory agencies when procuring and using equipment.

5. **QUALITY MANAGEMENT SYSTEMS**

5.1 Healthcare Institutions providing NM Services are recommended to have an ongoing and systematic quality management programme that provides a mechanism for monitoring, evaluating the compliance and effectiveness of processes, correcting, and improving all activities associated with radiopharmaceuticals, including personnel
training and assessment, and environmental monitoring. In particular, they are recommended to:

1. Conduct a review of system-wide documentation on errors involving radiopharmaceuticals to analyse and aggregate data, identify trends, and develop methods for improving quality in radiopharmaceuticals;
2. Investigate all errors, defects, complaints and other signs indicating problems relating to the quality of the NM Services provided, and put in place adequate measures to ensure that effective remedial action is taken;
3. Routinely conduct risk assessment and evaluation of activities to review and improve existing Standard Operating Procedures (“SOPs”); and
4. Report all serious reportable events to MOH, and report all radiation accidents as defined under the RPA to the NEA.

**Policies and Procedures (Standard Operating Procedures & Work Instructions)**

5.2 Healthcare Institutions providing NM Services are recommended to draw up policies and procedures (e.g. SOPs and Work Instructions) that contain the following:

1. Mission statement, objectives and scope of the NM Services;
2. Current organisation chart of the Healthcare Institution providing NM Services which shall reflect, at minimum, the personnel listed in the Table 1;
3. Future development of NM services and staffing needs (e.g. expansion of NM services);
4. Staff development and education programme;
5. Staff training and validation for use of equipment;
6. Policies and staff training on aseptic practices and infection control;
7. Radiation safety (for all staff, including non-medical staff who have access to areas within the Healthcare Institution that are used for NM Services - e.g. cleaners, porters) and radiopharmaceutical transport and waste management;
8. Facilities and equipment maintenance and operation;
9. Internal audit;
10. Quality control (“QC”) for equipment, radiopharmaceuticals and environment/facility that satisfy paragraphs 5.3 to 5.15 below;
11. Preparation and management of radiopharmaceuticals;
12. Emergency and contingency plans (including the activation timelines of such plans);
13. Serious reportable events and radiation accidents reporting; and
14. Patient instructions, including radiation safety precautions, to be taken after administration of radiopharmaceuticals.

**Quality Control for Equipment**

5.3 Healthcare Institutions providing NM Services are recommended to ensure that acceptance testing for equipment used for NM Services is performed at the time of
installation (as part of the commissioning procedure) and after major maintenance or software upgrades.

5.4 Healthcare Institutions providing NM Services are recommended to properly document their quality control (“QC”) policies and procedures for equipment in their SOPs and shall prepare their equipment in accordance with the equipment manufacturer’s recommendations and/or international guidelines\(^6\). QC policies and procedures must include the acceptance criteria that are used for QC tests and the actions to be taken in the event of an unacceptable result arising from such QC tests. QC policies and procedures must include the minimum QC tests and parameters set out in ANNEX 2.

5.5 Healthcare Institutions providing NM Services are recommended to perform QC tests regularly and in accordance with their QC policies and procedures.

**Quality Control for Radiopharmaceuticals**

5.6 Healthcare Institutions providing NM Services are recommended to ensure that the procurement, receipt, use, preparation, administration, storage and disposal of radiopharmaceuticals comply with existing requirements and relevant guidelines issued by the relevant regulatory agencies.

5.7 Healthcare Institutions providing NM Services are recommended to develop acceptance/rejection criteria for all radiopharmaceuticals (whether they were procured commercially from appropriately authorized or licensed suppliers or prepared in-house) and are recommended to ensure that these criteria are adhered to.

5.8 Healthcare Institutions providing NM Services are recommended to keep securely all QC documents for all commercially procured radiopharmaceuticals, in accordance with the retention period in its policies.

5.9 Healthcare Institutions providing NM Services are recommended to perform QC tests, record and keep all records of such QC tests for all radiopharmaceuticals that are prepared in-house, in accordance with the retention period in its policies.

5.10 Healthcare Institutions providing NM Services are recommended to properly document all guidelines and formula used for the in-house preparation of radiopharmaceuticals in their SOPs, and are recommended to keep all raw data, in accordance with the retention period in its policies.

**Quality Control for Environment/Facility**

5.11 Healthcare Institutions providing NM Services are recommended to check, at the

\(^6\) International Atomic Energy Agency (IAEA), National Electrical Equipment Manufacturers Association (NEMA) and American Association of Physicist in Medicine (AAPM)
outset of their provision of NM Services, that the Primary Engineering Control (“PEC”) (e.g. the Biosafety Cabinet, Laminar Flow Cupboard, Fume Cupboard) at areas of the facility where radiopharmaceuticals are handled satisfy the qualifications, in order to establish a baseline level of environmental quality. Thereafter, they are recommended to periodically check that the qualifications of the PEC [i.e. Performance Qualification (“PQ”)] are satisfied on an ongoing basis, in accordance with its manufacturer’s recommendations.

5.12 Healthcare Institutions providing NM Services are recommended to establish a monitoring system for radiation levels in the areas of the facility where radiopharmaceuticals are handled.

5.13 Healthcare Institutions providing NM Services are recommended to obtain re-certification by the relevant authority if there are changes to the radiopharmaceutical storage area.

5.14 Healthcare Institutions providing NM Services are recommended to take prompt decontamination corrective actions in response to any radioactive spills.

5.15 Healthcare Institutions providing NM Services are recommended to undertake radiation monitoring following any decontamination to confirm that the radiation levels in the facility are within safe levels.

6. RECORDS (DOCUMENTATION)

Healthcare Institutions providing NM Services are recommended to properly document and retain the following records listed in paragraphs 6.1 to 6.12 below for an appropriate period of time for audit purposes and in accordance with its policies:

Staff
6.1 Job descriptions and qualification(s) of Staff involved in the provision of NM Services;
6.2 Competency assessments and training records (specific to clinical competency and radiation safety competency);

NEA-related records
6.3 NEA licences (e.g. L2, L4, L6, L3, L5) and R1 registration;
6.4 Personal radiation dose records of staff;

Initial qualifications of PEC refer to Installation Qualification (“IQ”), Operation Qualification (“OQ”) and Performance Qualification (“PQ”). IQ ensures PEC has been delivered and installed in accordance with manufacturer’s requirements. OQ ensures PEC is functioning in accordance to specifications. PQ ensures PEC is continuing to meet its specifications.
6.5 Radioactive waste disposal records;

**QC Records**

6.6 Equipment -

1. Preventive maintenance of equipment;
2. Records on testing of the radionuclide dose calibrator for constancy, accuracy, linearity, and geometric variation;
3. Records of all QC parameters;

6.7 Radiopharmaceuticals -

1. Records on the procurement, receipt, use, preparation, administration, storage and disposal of all radiopharmaceuticals;
2. Records on the identity of the radiopharmaceutical, the amount of radioactivity administered, the identity of the patient and of the individual performing the administration; the route of administration; and the date and time of administration;
3. Records on the verification of the identity of the radiopharmaceutical and patient, and the route of administration prior to administration;

6.8 Environment/Facility -

1. Preventive maintenance of PEC;
2. Radiation monitoring records which shall include radiation room surveys; and
3. Records on investigation and follow-up actions of radioactive spillage and management;

**Patient and Personnel Safety**

6.9 Records on investigation of adverse reactions associated with the administration of radiopharmaceuticals; and

6.10 Records on investigation and follow-up actions of incidents;

**Medical Records**

6.11 All medical records are recommended to be retained in accordance with the current National Guidelines.

6.12 Healthcare Institutions providing NM Services are recommended to also implement adequate safeguards (including administrative, technical and physical measures) to ensure that all records containing patients’ information remain confidential.
APPENDIX

MOH ADVISORY COMMITTEE ON NUCLEAR MEDICINE

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ANNEX 1
MINIMUM FACILITY AND PERSONAL PROTECTIVE EQUIPMENT (“PPE”) REQUIREMENTS FOR RADIOPHARMACY LABORATORIES (“HOT LABS”)

Radiopharmacy Laboratories or “Hot Labs” are recommended to meet the minimum requirements set out in this Annex. The requirements contained in this Annex are divided into three sections:

(1) A series of general requirements in relation to the design, structure and layout of the Hot Lab which shall be complied with by all Healthcare Institutions which provide NM Services;

(2) A series of general aseptic practice requirements which shall also be complied with by all Healthcare Institutions which provide NM Services; and

(3) A series of specific requirements that shall apply depending on the categorisation of the Hot Lab as determined in accordance with Table 2 below.

As regard to the third series of specific requirements, a “risk-based” approach is adopted to determine the appropriate level of requirements according to the Licensee’s intended use of radiopharmaceuticals (e.g. diagnostic versus therapeutic) and the type of radiopharmacy tasks being performed in the Hot Lab (e.g. dispensing versus compounding of radiopharmaceuticals). In adopting this “risk-based” framework, Hot Labs are classified into three broad categories which are then further subdivided in specific subcategories. These classifications are based on the guidelines issued by the IAEA for good radiopharmaceutical practices.8,9,10

Healthcare Institutions intending to provide NM Services are recommended to determine the relevant category of their Hot Lab in accordance with Table 2.

A. General Requirements
All Healthcare Institutions providing NM Services are recommended to ensure that their Hot Labs comply with the following general requirements:

(1) The Hot Lab must be in a separate, dedicated and secured area that is close to the imaging and patient injection areas;

(2) The Hot Lab must be specifically designed and maintained to handle unsealed radionuclides in compliance with the requirements stipulated under the RPA and the IAEA Basic Safety Standards (“BSS”)11;

(3) All work surfaces in the Hot Lab shall be smooth and impermeable to permit easy cleaning and decontamination;

(4) All plumbing pipe work and cables located in the Hot Lab shall be encased and adequately laid to facilitate cleaning and decontamination;

(5) There shall be adequate space in the Hot Lab to accommodate all essential equipment

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8 International Organization For Standardization, Clean Rooms and Associated Controlled Environments – Part 1: Classification of Air Cleanliness (ISO class 3, 4, 5, 6, 7 and 8), ISO 4644-1, ISO, Geneva (1999).
and accessories (e.g. shielded Biosafety cabinet, laminar flow hood(s), lead shields for handling radiopharmaceuticals, and pharmaceutical isolator or other environmental cabinet(s));

(6) There shall be adequate space for at least two staff members to operate simultaneously;

(7) The work areas in the Hot Lab shall have adequate lighting, temperature and humidity so as to ensure operator comfort, optimum equipment performance and expected radiopharmaceutical stability;

(8) There shall be adequate waste storage containers in the Hot Lab for sharps and general waste;

(9) Radioactive waste of different half-lives shall be appropriately segregated to ensure safe disposal, to comply with RPA;

(10) All radioactive waste shall be adequately shielded.

B. General Aseptic Practices
All Healthcare Institutions providing NM Services are recommended to ensure that they implement the following general aseptic practices in their Hot Labs:

(1) Food and drinks must not be brought into or stored in the Hot Lab;

(2) Access to the Hot Lab should be restricted to qualified personnel with specific responsibilities or assigned tasks;

(3) There should be adequate disinfection of work surfaces with 70% sterile alcohol before and after work. Regular disinfection of work surface and gloved hands during preparation should also be done;

(4) Personnel should avoid touching critical surfaces (e.g. rubber closures of containers, sterile needle tips, or any surface that comes in contact with the radiopharmaceuticals);

(5) A direct open path should be maintained between the cabinet filter and the area where aseptic manipulations are performed;

(6) The air supply in PEC (e.g. Biosafety Cabinet, Laminar Flow Cupboard, Fume Cupboard) should be on at all times and airflow is to be kept unobstructed. Upon turning on the PEC, it should be left running for a minimum of 15 minutes and disinfected before use;

(7) Only objects required for the preparation should be placed in the PEC. Avoid excessive movement in the PEC other than the lead shielding containers and blocks so as to minimise turbulence and introduction of contaminated air.

C. Specific Requirements
Healthcare Institutions intending to provide NM Services are recommended to determine the relevant category of their Hot Lab, and the respective minimum facility and PPE requirements they are to abide by in accordance with Table 2 below:
<table>
<thead>
<tr>
<th>Category</th>
<th>Description of Hot Lab (based on the Licensee’s intended use of radiopharmaceuticals and the type of radiopharmacy tasks being performed)</th>
<th>Minimum facility requirements</th>
<th>Minimum PPE requirements</th>
</tr>
</thead>
<tbody>
<tr>
<td>1a</td>
<td>Hot Labs involved in the dispensing of radiopharmaceuticals purchased or supplied in their final form from recognized and/or authorized manufacturers or centralized radiopharmacies, including: (1) unit (department/centre) doses or multiple doses of prepared radiopharmaceuticals for which no compounding is required; and (2) ready to use injections of strontium, Rhenium, Yttrium, Samarium or others for pain palliation or other uses.</td>
<td>(1) A radionuclide dose calibrator with appropriate lead shielding; and (2) A shielded dispensing station.</td>
<td>i. Personal radiation dosimeter; ii. Disposable gloves; and iii. Overalls or jacket.</td>
</tr>
<tr>
<td>1b</td>
<td>Hot Labs involved in the dispensing of radioiodine and other ready to use radiopharmaceuticals that can produce radioactive vapours.</td>
<td>(1) The minimum facility requirements for a Category 1a facility; (2) a shielded fume cupboard with suitable filters that can handle radioactive vapours (e.g. from liquid $^{131}$I solutions); and (3) a radiation exhaust monitor.</td>
<td></td>
</tr>
<tr>
<td>2a</td>
<td>Hot Labs involved in the preparation of radiopharmaceuticals from prepared and approved reagent kits, generators and radionuclides (closed procedure)</td>
<td>(1) The minimum facility requirements for a Category 1a facility; and (2) a shielded Class II vertical laminar air flow (LAF) or a shielded Biosafety cabinet/isolator.</td>
<td></td>
</tr>
<tr>
<td>2b</td>
<td>Hot Labs involved in the manipulation and radiolabelling of autologous blood cells and components for re-injection into the patient. This includes radiolabelling of red blood cells, platelets and white cells commonly used for infection or inflammation imaging.</td>
<td>(1) The minimum facility requirements for a Category 2a facility; and (2) a centrifuge for spinning down of blood products.</td>
<td></td>
</tr>
<tr>
<td>3a</td>
<td>Hot Labs involved in the compounding of</td>
<td>(1) The minimum facility</td>
<td></td>
</tr>
</tbody>
</table>

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13 A closed procedure is a procedure whereby a sterile pharmaceutical is prepared by the addition of sterile ingredients into a pre-sterilized container via a system closed to the atmosphere (e.g. by injection with a syringe and needle through the rubber bung) using aseptic technique.
14 This is the most common activity in nuclear medicine departments in Singapore, with routine use of a technetium generator and reconstitution of pre-sterilized radiopharmaceutical cold kits. This is where Tc99m or other radionuclides based closed manipulations or compounding is to be performed.
<table>
<thead>
<tr>
<th>Category</th>
<th>Description of Hot Lab (based on the Licensee’s intended use of radiopharmaceuticals and the type of radiopharmacy tasks being performed)</th>
<th>Minimum facility requirements</th>
<th>Minimum PPE requirements</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>radiopharmaceuticals from ingredients and radionuclides for diagnostic applications, including: -</td>
<td>requirements for a Category 2a facility.</td>
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</tr>
<tr>
<td></td>
<td>(1) open procedures&lt;sup&gt;15&lt;/sup&gt;;</td>
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<td></td>
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<td></td>
<td>(2) modification to existing commercial kits;</td>
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<td></td>
<td>(3) in-house production of reagent kits from ingredients, including freeze dried operation;</td>
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<tr>
<td></td>
<td>(4) related research and development (e.g. Ga 68 PET radiopharmaceutical compounding)</td>
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<td></td>
</tr>
<tr>
<td>3b</td>
<td>Hot Labs involved in the compounding of radiopharmaceuticals from ingredients and radionuclides for therapeutic and diagnostic applications, including: -</td>
<td>(1) The minimum facility requirements for a Category 2a facility; and</td>
<td></td>
</tr>
<tr>
<td></td>
<td>(1) open procedures; and</td>
<td>(2) a separate fume hood</td>
<td></td>
</tr>
<tr>
<td></td>
<td>(2) related research and development (e.g. radio-iodination of meta-iodobenzyl guanidine (MIBG-iobenguane) and rhenium labelled lipiodol).</td>
<td>externally ducted for radio-iodination with appropriate safety systems sited in a separate environment with appropriate shielding (for gamma as well as beta radiation).</td>
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<tr>
<td><em>NOTE:</em> The Standards do not apply to Hot Labs that fall within Category 3c below as these are facilities that are engaged in the manufacturing or assembly of radiopharmaceuticals. For the avoidance of doubt, all local facilities engaged in the manufacturing or assembly of therapeutic products, including radiopharmaceuticals, must be licensed with the HSA and comply with the relevant legislative and regulatory requirements, and GMP standard. In addition, if the radiopharmaceutical is categorised as a poison under the Poisons Act (Cap. 234), a licence under that Act must be obtained from the HSA as well. If the facility has in its possession and uses equipment containing radioactive material (e.g. Cyclotron), a licence must be also obtained from the NEA.</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>3c</td>
<td>Hot Labs involved in the synthesis of PET radiopharmaceuticals. This includes the fludeoxyglucose (18F-FDG) used in PET-CT.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<sup>15</sup> An open procedure is a method of preparation that is not a closed procedure whereby at some stage the radiopharmaceutical or other ingredients may be exposed to the controlled environment.
ANNEX 2

MINIMUM QUALITY CONTROL (“QC”) TESTS AND PARAMETERS THAT MUST BE PERFORMED ACCORDING TO INSTRUMENT/EQUIPMENT TYPE IN NUCLEAR MEDICINE & PET

Healthcare Institutions providing NM Services shall perform and comply with the minimum QC tests and parameters set out in Table 3 below and in accordance with the methods and acceptance criteria specified in the equipment manufacturers’ operation manuals or the National Electrical Manufacturers’ Association (NEMA) and IAEA standards\textsuperscript{16,17,18}. Healthcare Institutions providing NM Services shall also ensure that their QC policies and procedures include these minimum QC tests and parameters. They shall properly document their compliance with these minimum QC tests and parameters, and retain those records for an appropriate period of time for audit purposes, in accordance with its policies.

Table 3: Minimum QC tests and parameters

<table>
<thead>
<tr>
<th>S/N</th>
<th>Type of Instrument Or Equipment</th>
<th>Frequency of Check</th>
<th>QC Parameters to be checked</th>
<th>Standard or Reference Materials/ Equipment &amp; Methods</th>
<th>Acceptance Criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Gamma Camera</td>
<td>Daily</td>
<td>Photopeak &amp; Energy Window Setting</td>
<td>57\textsuperscript{Co} flood source or 99m\textsuperscript{Tc} unsealed check source or other suitable sources</td>
<td>Photopoeak centered for radionuclide with a 20% energy window.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Daily</td>
<td>Uniformity (Extrinsic or Intrinsic)</td>
<td>57\textsuperscript{Co} flood source or 99m\textsuperscript{Tc} point source or other suitable sources</td>
<td>Central &amp; useful Field of View (“FOV”) integral &amp; differential uniformity are &lt;10%.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Daily (For SPECT/CT)</td>
<td>CT Tube Warm Up &amp; Air Calibration</td>
<td>N.A.</td>
<td>Pass according to manufacturer’s recommendation.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Quarterly or during preventive maintenance (For SPECT/CT)</td>
<td>CT Number</td>
<td>CT Phantom</td>
<td>CT Number &lt;±5 Hounsfield units or according to manufacturer’s recommendation (whichever is more stringent).</td>
</tr>
</tbody>
</table>

\textsuperscript{16} National Electrical Manufacturers’ Association ("NEMA") NU 1-1994 Performance Measurements of Scintillation Cameras; NEMA NU2-2001 PET performance standards; and IAEA Human Health Series No.6 Quality Assurance for SPECT Systems 2009
\textsuperscript{17} International Atomic Energy Agency Human Health Series No. 1, Vienna, 2009, Quality Assurance For PET And PET/CT Systems
\textsuperscript{18} International Atomic Energy Agency Human Health Series No. 6, Vienna, 2009, Quality Assurance For SPECT Systems
<table>
<thead>
<tr>
<th>S/N</th>
<th>Type of Instrument Or Equipment</th>
<th>Frequency of Check</th>
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</tr>
<tr>
<td>1</td>
<td>Centre of Rotation (COR) Only for SPECT Gamma Cameras</td>
<td>Bi-Weekly</td>
<td>99mTc Technetium check source</td>
<td>COR error &lt;0.5 pixels or &lt; 2 mm or according to manufacturer’s recommendation (whichever is more stringent).</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Spatial Resolution</td>
<td>Half-yearly</td>
<td>To determine Full Wave Half Maximum (&quot;FWHM&quot;) = 1.75 x smallest resolvable spacing using the 4-quadrant bar phantom or by any other suitable method.</td>
<td>Spatial Resolution values meet equipment specification.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>CT Uniformity, CT Contrast &amp; CT Artefact</td>
<td>Quarterly or during preventive maintenance (For SPECT/CT)</td>
<td>CT phantom</td>
<td>Pass CT Uniformity and Contrast and no artifact/s seen.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Energy &amp; Uniformity correction tables/files/maps</td>
<td>Quarterly or during preventive maintenance</td>
<td>57Co Cobalt flood source or 99mTc Technetium point source</td>
<td>Performed.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Sensitivity</td>
<td>At acceptance testing</td>
<td>99mTc Technetium source</td>
<td>Sensitivity meets equipment specification.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Count Rate Characteristics</td>
<td>At acceptance testing</td>
<td>Varying 99mTc Technetium activities. Measure &amp; plot observed count rate versus activity.</td>
<td>Count Rate Characteristics meet equipment specification.</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>Dose calibrator</td>
<td>Daily</td>
<td>Constancy with Long Half-Life Radionuclides</td>
<td>Calibrated &amp; traceable sealed reference sources of 137Cesium &amp; 57Cobalt</td>
<td>Percentage difference between measured &amp; theoretical activities &lt;5% for 137Cesium &amp; 57Cobalt.</td>
</tr>
<tr>
<td></td>
<td>Linearity Response to 99mTc Technetium or 18Fluorine</td>
<td>Semi annually</td>
<td>Method 1: Measure the decaying 99mTc Technetium or 18Fluorine for a minimum of two half-lives. Plot activity time graph to determine half-life of radionuclide.</td>
<td>Measured radionuclide half-life is &lt; ±10% of theoretical value.</td>
<td></td>
</tr>
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<td></td>
<td></td>
<td></td>
<td>OR Method 2: Varying attenuation sleeves for a fixed activity of $^{99m}$Technetium or $^{18}$Fluorine.</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>PET/CT</td>
<td>Daily</td>
<td>CT Tube Warm Up &amp; Air Calibration</td>
<td>N.A.</td>
<td>Pass according to manufacturer’s recommendation.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Quarterly or during preventive maintenance</td>
<td>CT Number</td>
<td>CT Phantom</td>
<td>CT Number $&lt;\pm 5$Hounsfield units or according to manufacturer’s recommendation (whichever is more stringent).</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Quarterly or during preventive maintenance</td>
<td>Radioactivity - counts calibration</td>
<td>SUV phantom or water filled phantom with $^{18}$Fluorine or $^{68}$Galium.</td>
<td>Pass according to manufacturer’s recommendation.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Daily</td>
<td>PET detector stability / constancy</td>
<td>$^{68}$Germanium or $^{22}$Sodium</td>
<td>Pass according to manufacturer’s recommendation.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Daily (for TOF PET)</td>
<td>PET Daily Coincidence Timing Resolution</td>
<td>$^{68}$Germanium or $^{22}$Sodium</td>
<td>Pass according to manufacturer’s recommendation.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Quarterly or during preventive maintenance (For SPECT/CT)</td>
<td>CT Uniformity, CT Contrast &amp; CT Artefact</td>
<td>CT phantom</td>
<td>Pass CT Uniformity and Contrast and no artifact/s seen.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>At acceptance testing</td>
<td>Accuracy of PET/CT Image Registration</td>
<td>$^{18}$Fluorine filled image quality phantom and heavy weights to simulate a patient</td>
<td>Within $\pm 1$ pixel when using a $512 \times 512$ matrix or according to manufacturer’s recommendation (whichever is more stringent).</td>
</tr>
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<tr>
<td></td>
<td></td>
<td>At acceptance testing</td>
<td>Sensitivity Test</td>
<td>¹⁸Fluorine Line source and aluminium sleeves</td>
<td>Pass according to manufacturer’s recommendation.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>At acceptance testing</td>
<td>Spatial Resolution Test</td>
<td>¹⁸Fluorine Point sources and NEMA source holder</td>
<td>Pass according to manufacturer’s recommendation.</td>
</tr>
</tbody>
</table>

REFERENCES


3. International Atomic Energy Agency Human Health Series No. 1, Vienna, 2009, Quality Assurance For PET And PET/CT Systems.


10. Radiation Protection Act (Cap. 262) and Regulations.