LICENCE CONDITIONS FOR THE
PROVISION OF NUCLEAR MEDICINE IMAGING SERVICES

IMPOSED UNDER SECTION 13(1) OF THE HEALTHCARE SERVICES ACT 2020

1. Application of Licence Conditions

1.1 These licence conditions ("**LCs**") apply to all persons that have been licenced under the Healthcare Services Act 2020 (the "**HCSA**") to provide a nuclear medicine ("**NM**") imaging service (such persons referred to as "**Licensees**").

1.2 For avoidance of doubt, the defined terms as used in these LCs shall have the meanings ascribed to them in the HCSA and any Regulations made thereunder, unless otherwise stated.

1.3 Licensees that intend to provide any service modality as part of a nuclear medicine imaging service but did not specify such intention in their application under section 10(2)(c)(viii) of the HCSA for the grant or renewal of their license to provide a nuclear medicine imaging service are reminded to comply with their obligations at regulation 4(2) of the Healthcare Services (Nuclear Medicine Assay Service and Nuclear Medicine Imaging Service) Regulations 2021 ("**NMSR**") to give written notice to the Director (as defined under Section 2(1) of the HCSA) of such intention no later than one month before the Licensee intends to start providing the service modality.

1.4 A breach of these LCs may result in regulatory action being taken against Licensees under section 20 of the HCSA, including but not limited to:

(a) suspension or revocation of the Licensee's nuclear medicine imaging service licence;

(b) shortening the term of the Licensee's nuclear medicine imaging service licence;

(c) a direction requiring the Licensee to rectify the contravention, or prevent a recurrence of the contravention; and/or

(d) a direction requiring the Licensee to pay a financial penalty.

2. Requirements Relating to Personnel

2.1 The Licensee shall:

(a) Document and define the minimum qualifications for all positions in its nuclear medicine imaging service ("**Service**"), including the educational qualifications, skills and experience required of each position;

(b) Document and define the job descriptions for each position and its roles and tasks in its Service;

(c) Implement a programme for the training and development of all the personnel. This programme shall minimally cover the following aspects:

(i) specifying and implementing regular training programme(s), supervision by relevant personnel, periodic competency assessment(s), and programme(s) on continuing education that each personnel is required to undergo;

(ii) the corrective actions to be taken against each personnel who fails to attain a satisfactory performance, such as retraining and competency assessment(s);

(iii) conducting regular trainings, and providing instructions and updates on:

(1) the Service's safety programme implemented under Regulation 13 of the NMSR;

(2) the Service's radiation safety programme implemented under Regulation 14 of the NMSR, which shall include measures on radioactive substance transport and waste management;

(3) the use of the Service's equipment;

(4) aseptic practices;

(5) infection control measures, and

(iv) assigning an experienced personnel (as described under Regulation 9(2) of the NMSR) to supervise, train and assess the competency of every personnel who requires supervision.

2.2 The Licensee shall ensure that every personnel who operates any irradiating apparatus has undergone all applicable training course(s) and passed all competency assessment(s) on the use of irradiating apparatus and radiation safety prior to operating the irradiating apparatus.

3. Quality Management System

3.1 The Licensee shall ensure that its quality management system, which is established and implemented pursuant to Regulation 10 of the NMSR, and shall minimally cover the following aspects of the Licensee's provision of the Service:

(a) the Licensee's mission statement, objectives and scope of the Service;

(b) the organisation structure of the Licensee, the roles of and reporting relationships of every key appointment holder, the Principal Officer ("**PO**"), the Clinical Governance Officer ("**CGO**"), the section leader, and the personnel listed in Regulation 27 of the NMSR, as well as the delegation of duties to the relevant personnel (where applicable);

(c) policies and procedures relating to personnel including:

(i) training and validation for use of equipment, and

(ii) training on aseptic practices and infection control;

(d) policies and procedures to review and, where applicable, plan for the future development of the Service and personnel needs (e.g. expansion of Service and staff succession planning) to ensure that the Service is provided with accuracy, timeliness and safety at all times;

(e) the quality control measures for the Service's equipment, radioactive substances, and premises (or conveyance, if applicable) ("**Premises**");

(f) the internal audits and their required frequency conducted on the Service's operations, and ensure that appropriate corrective and preventive actions are taken for all deficiencies identified.

(g) the internal escalation and reporting of all serious reportable events (as defined in Regulation 19 of the Healthcare Services (General) Regulations 2021) to the Ministry of Health ("**MOH**");

(h) the escalation and reporting of all radiation accidents as defined under the Radiation Protection Act 2007 ("**RPA**") to the National Environment Agency ("**NEA**"); and

(i) the emergency and contingency plans in the event of any clinical incidents, service disruptions, or radiation accidents, including the activation timelines of such plans to ensure the continuity of the Licensee's provision of the Service, and to safeguard patient safety.

Quality Control Measures for Equipment

3.2 The Licensee shall implement the following quality control measures for all the equipment in its Service:

(a) perform acceptance testing on the equipment:

(i) at the time of installation as part of the commissioning procedure, and

(ii) after the equipment has undergone any major maintenance or software upgrades;

(b) perform quality control tests and preventive maintenance on the equipment in accordance with:

(i) the manufacturer's specifications, requirements and/or recommendations (as applicable);

(ii) the prevailing international standards in relation to the use of the equipment, and

(iii) the policies and procedures implemented and documented by the Licensee;

(c) perform minimally the quality control tests on the equipment in the frequency and parameters as set out in Table 3. However, where the frequency and parameters as set out in the manufacturer's specifications or the prevailing international standards in relation to the use of the equipment are more stringent than those set out in Table 3, the Licensee shall perform the quality control tests in accordance with the more stringent frequency and parameters; and

(d) take corrective and preventative actions to address and rectify all quality control test results which are assessed to be unacceptable and to document these actions.

Radiology Information System, Picture Archiving and Communication System (PACS), and Equipment Data

3.3 Where the Licensee implements a radiology information system, and/or a picture archiving and communication system ("**PACS**") for the provision of its Service, the Licensee shall implement a policy that covers the following for each system:

(a) the various levels of access control and privilege rights in the system as may be necessary for each of its personnel's job function;

(b) user authentication (i.e. the process of verifying the identity of the user of the radiology information system); and

(c) audit trails(s) of access to the system and amendments made to the system.

3.4 The Licensee shall ensure that its radiology information system and PACS are qualified for proper performance prior to their implementation and after any significant modifications made to them.

3.5 The Licensee shall ensure that its radiology information system is evaluated for accurate data transmission from its interfaced imaging systems, and to its test reports.

Quality Control Measures for Radioactive Substances

3.6 The Licensee shall implement the following quality control measures for all the radioactive substances used in its Service:

(a) retain the quality control documents for all commercially procured radioactive substances, in accordance with the retention period specified in the Licensee's policies;

(b) perform quality control tests on all radioactive substances that are prepared in-house, and retain all records of the tests for in accordance with the retention period specified in the Licensee's policies;

(c) document in its SOPs all guidelines and formula used for the in-house preparation of radioactive substances, and retain all raw data generated in the course of the radioactive substance preparation in accordance with the retention period specified in the Licensee's policies.

(d) take corrective and preventative actions to address and rectify all quality control test results which are assessed to be unacceptable and to document these actions.

Quality Control Measures for Premises

3.7 The Licensee shall implement the following quality control measures for its Premises:

(a) prior to commencement of the Service's operations, check and ensure that the Primary Engineering Control ("**PEC**") (e.g. the Biosafety Cabinet, Laminar Flow Cupboard, Fume Cupboard), at areas in the Premises where radioactive substance are handled, satisfy the initial

qualifications[1], in order to establish a baseline level of environmental quality;

(b) periodically check that the Performance Qualification of the PEC is satisfactory in accordance with its manufacturer's specification;

(c) take corrective and preventative actions to address and rectify all unsatisfactory results in relation to the Performance Qualification of the PEC and to document these actions; and

(d) whenever there are changes to the radioactive substance storage area, to obtain re-certification by the relevant authority(ies).

4. Premises and Equipment

Equipment

4.1 The Licensee shall implement policies and SOPs in respect of the operations and maintenance of all equipment in its Service to ensure that the Service is provided in a safe and appropriate manner.

4.2 The Licensee shall ensure that the Premises have sufficient and appropriate decontamination kit and personal protective equipment ("**PPE**") at all times to manage any radioactive spills. The Licensee shall, at the minimum, maintain sufficient quantities of the following decontamination kit and PPE:

(a) Personal radiation dosimeter;

(b) Disposable gloves;

(c) Overalls or jacket; and

(d) Face and eye wash, if not already provided for under paragraph 4.8(e).

4.3 The Licensee shall provide adequate radionuclide dose calibrators with proper lead shielding and calibration of long half-life radionuclide Quality Control ("QC") sources to all personnel performing measurements of radioactivity of radiopharmaceuticals.

4.4 The Licensee shall comply with all prevailing requirements and guidelines issued by the relevant authority(ies) in relation to the procurement and use of all equipment and drugs.

[1] Initial qualifications of PEC refer to Installation Qualification ("IQ"), Operation Qualification ("OQ") and Performance Qualification ("PQ"). IQ ensures that the PEC has been delivered and installed in accordance with manufacturer's requirements; OQ ensures that the PEC is functioning in accordance with the specifications; and PQ ensures that the PEC continues to meet the specifications.

Emergency and Resuscitation Equipment / Drugs

4.5 The Licensee shall ensure that its Premises maintain, at the minimum, the following medical emergency equipment:

(a) Age-appropriate oropharyngeal airways;

(b) Appropriate device for drug delivery of inhaled bronchodilator;

(c) Bag-valve mask;

(d) Defibrillator;

(e) Infusion set; and

(f) IV Normal saline (0.9%) solution or IV 5% Dextrose saline solution.

4.6 The Licensee shall ensure that its Premises maintain, at the minimum, the following medical emergency drugs:

(a) Aspirin;

(b) Inhaled bronchodilator;

(c) IV adrenaline;

(d) IV antihistamine e.g. promethazine;

(e) IV atropine;

(f) IV steroid e.g. hydrocortisone; and

(g) Sub-lingual nitroglycerine tablet or spray;

4.7 The Licensee shall ensure that all medical emergency equipment and drugs are functional, effective, and comply with established or recommended procedures for their maintenance and use.

Premises

4.8 The Licensee shall ensure that for patient and personnel areas within the Premises:

(a) there are appropriate markings and access controls for areas designated as “restricted” and/or “controlled” in accordance with the requirements under the RPA and its regulations;

(b) there are adequate and secure physical storage areas for storing patient records;

(c) there is at least one changing room located in close proximity with the procedure areas in the Premises, which provide for patients’ privacy. The layouts of the changing room(s), sub-waiting area(s) (if any) and procedure room(s) that will be used as part of the patient pathway should permit preservation of the patient’s modesty after changing into gown(s);

(d) there are 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; and

(e) there are adequate decontamination facilities including emergency shower, face and eye wash, if not already provided for under paragraph 4.2(d).

5. Safety Procedures

5.1 The Licensee shall ensure that its radiation safety programme, which is developed and implemented pursuant to Regulation 14 of the NMSR, shall be documented in the form of its Service’s policies and procedures (such as Standard Operating Procedures and Work Instructions etc), and shall minimally cover the following aspects of the Licensee’s provision of the Service:

(a) radiation safety measures in relation to the transportation of radioactive substance(s) and waste management;

(b) safe and proper preparation and management of radioactive substance(s) in the Premises;

(c) instructions to patients and/or their caregivers post-administration of radiopharmaceuticals, including radiation safety precautions;

(d) in the event of any radioactive spills within the Premises, to take decontamination corrective actions, and thereafter to continue to monitor and ensure that the radiation levels within the Premises are within the safe range.

6. Nuclear Medicine Imaging Service Practices

General Requirements

6.1 The Licensee shall implement a patient identification system which uniquely identifies each patient based on two unique patient identifiers (e.g. full name and identification/passport number).

6.2 The Licensee shall ensure that every patient's identity is verified by the Licensee's personnel:

(a) when the patient presents himself at the Licensee's Premises for an examination, and

(b) at each critical stage of the examination. "Critical stage" refers to any stage of the nuclear medicine imaging examination that will have an impact on the patient's safety, such as the administration of a contrast agent or radiopharmaceuticals to a patient and prior to the conduct of the nuclear medicine imaging procedure.

Consent Taking

6.3 The licensee shall, at the minimum, obtain informed consent in writing before conducting any of the following procedures on the patient as part of its provision of an examination:

(a) the administration on the patient of sedation or anaesthesia;

(b) cardiac stress tests; and

(c) any other examination procedures that are of a higher risk to the patient's safety as determined by the Licensee's internal assessment. The internal assessment shall include considerations of the possible risks posed to a patient's foetus (if applicable).

6.4 Where it is necessary to obtain a patient's informed consent in writing before an examination is conducted (see paragraph 6.3 above), the Licensee shall ensure that patient education of the examination is provided to the patient before obtaining the patient's consent, which includes explanations and instructions on:

(a) the process of the examination,

(b) the benefits of undergoing the examination,

(c) the risk(s) involved in undergoing the examination,

(d) the available alternatives to the examination, and

(e) the follow-up post-procedure care required after the examination (if applicable);

6.5 If the patient below 21 years old, the Licensee shall obtain and document consent from the patient's parent or legal guardian before conducting the examination. If the Licensee is unable to obtain the consent from the patient's parent or legal guardian despite best efforts, the Licensee must:

(a) assess and ensure that the patient has sufficient understanding and intelligence to understand the procedures and consequences of the examination, and

(b) obtain and document the patient's consent;

6.6 If the patient is mentally incapacitated, the Licensee shall obtain and document consent from the patient's donees or deputies[2] (as applicable) before conducting the examination;

6.7 If informed consent cannot be obtained from the patient or, in the case of a patient who is mentally incapacitated or below 21 years old, from the patient's legal donee(s), deputy(ies), parent(s) or legal guardian(s) (as applicable under the relevant law(s), including but not limited to the Mental Capacity Act 2008 and/or the Guardianship of Infants Act 1934), before the examination despite best efforts, the examination shall only be conducted provided that it is necessary to save the patient's life and is in the best interests of the patient.

6.8 The Licensee shall ensure that appropriate protective clothing are worn by its personnel who may need to be present in the imaging room, when the said personnel conducts any examinations that require close proximity of the said personnel with the primary beam.

Use and Administration of Contrast Agents

6.9 The Licensee shall ensure that the attending Nuclear Medicine Physician or Nuclear Cardiologist, as the case may be, shall:

(a) supervise the use or administration of contrast agents to the patient; and

[2] "Donees" and "deputies" refer to the donees and deputies respectively who are authorised to give or refuse consent to the carrying out or continuation of a treatment by a person providing health care for the patient, in accordance with the Mental Capacity Act 2008.

(b) ensure the safety of the patient during the examination, as a result of any use or administration of contrast agents to the patient.

6.10 The Licensee shall establish and document protocols on the use and administration of contrast agents. The protocols shall ensure that only its personnel who have received adequate and appropriate training, and assessed to be competent in venipuncture and administration of contrast agents may obtain intravenous access for the purpose of administering the contrast agents.

Use and Administration of Radiopharmaceuticals

6.11 The Licensee shall ensure that the attending Nuclear Medicine Physician or Nuclear Cardiologist holding an NEA L6 licence, as the case may be, shall:

(a) supervise the use or administration of radiopharmaceuticals in the provision the Service, and

(b) ensure the safety of the patient during the examination, as a result of any use or administration of radiopharmaceuticals to the patient.

6.12 The Licensee shall specify and document the responsibilities of the personnel mentioned in paragraph 6.11, which shall minimally cover the following:

(a) determining the appropriate dose of the radiopharmaceutical to be administered;

(b) ensuring that the radiopharmaceutical is administered to the correct patient;

(c) ensuring that the radiopharmaceutical is administered at the correct dose, at the correct time and through the correct route;

(d) ensuring that the patient is appropriately monitored for possible adverse reaction after the administration of radiopharmaceuticals; and

(e) ensure that the patient and/or the patient’s caregiver is properly instructed on radiation safety precautions as referred to in paragraph 5.1(c).

Use and Administration of Sedation and Anaesthesia

6.13 The Licensee shall implement and document the measures that it will adopt for the conduct of examinations that require the administration of an anaesthesia or a sedative to a patient. The measures shall minimally cover the following:

(a) that only personnel who are adequately trained and qualified may do any of the following:

(i) assess the patient's suitability to be administered the anaesthesia or sedative (as applicable);

(ii) administer the anaesthesia or sedative (as applicable) to the patient. In particular, only anaesthesiologists may administer general anaesthesia to a patient; and

(iii) monitor and manage the medical condition of the patient during and after the administration of the anaesthesia or sedative (as applicable);

(b) unless trained and authorised by the Licensee (in accordance with the Licensee's requirements) to prescribe and administer drugs for minimal or moderate sedation, the attending Nuclear Medicine Physician or Nuclear Cardiologist conducting the examination shall consult with an anaesthesiologist, an intensivist, and/or a pharmacist (as applicable) regarding:

(i) the appropriate type of anaesthesia or sedative drug to be administered to the patient,

(ii) the appropriate dose of the drug to be administered to the patient and

(iii) the appropriate rate of administration of the drug to the patient;

(c) the appropriate duration to monitor the patient after the completion of the examination; and

(d) the discharge arrangements for patient(s) who has been administered an anaesthesia or sedative from its Premises.

Errors or Incidents During the Conduct of Examination

6.14 The Licensee shall implement and document the measures that it will adopt in the event any of the following errors or incidents occur in its Premises:

(a) an examination was conducted on the wrong patient or at the wrong site;

(b) the wrong type or dose of drug(s) (e.g. radiopharmaceutical, contrast agents, anaesthesia, sedatives) was administered to a patient; or

(c) any other incidents occurring within the Premises (e.g. falls, medical emergencies) which may affect patient safety or welfare.

6.15 The measures to be implemented and documented under paragraph 6.14 shall minimally cover the following:

(a) the patient(s) who has been affected by the error or incident is given appropriate follow-up care;

(b) an investigation is conducted and documented to ascertain:

(i) the details of the error or incident (e.g. time, location, impact on patient),

(ii) the causal factor(s) behind the error or incident,

(iii) the follow-up actions taken in respect of the affected patient(s),

(iv) the preventive and corrective action(s) taken to prevent such error or incident from recurring;

(v) the effectiveness of the preventive and corrective action(s) taken (if applicable); and

(c) ensure that all relevant regulatory authorities are notified of the error or incident. The relevant authorities include the Ministry of Health (MOH), and the National Environment Agency (NEA).

7. Records

7.1 The Licensee shall properly document and retain the following records listed in paragraphs 7.2 to 7.3 below for audit purposes in accordance with the retention period stipulated in any applicable laws and in the Licensee's policies.

Service Records

7.2 The Licensee shall keep the following records in relation to its operations:

(a) personnel records including:

(i) job descriptions and qualification(s) of every personnel, and

(ii) competency assessments and training records of every personnel in relation to his/her competency in the Service's safety programmes, patient care, and in conducting the relevant examinations;

(b) records that are required under the RPA, which include:

(i) a copy of all the licences that the Licensee has obtained under the RPA;

(ii) records of each personnel's personal radiation dose;[3] and

(iii) radioactive waste disposal records;

(c) the preventive maintenance and servicing records of all equipment in its Service;

(d) records on testing of the radionuclide dose calibrator for constancy, accuracy, linearity, and geometric variation;

(e) quality control parameters and test results, and troubleshooting measures performed (if applicable);

(f) records relating to radioactive substance which include (where applicable):

(i) the procurement, receipt, use, preparation, administration, storage and disposal of all radioactive substance;

(ii) the identity of the radiopharmaceutical,

(iii) the amount of radioactivity administered,

(iv) the identity of the patient to whom the radiopharmaceutical was administered,

(v) the personnel performing the administration of the radiopharmaceutical,

(vi) the route of administration of the radiopharmaceutical,

(vii) the date and time of administration of the radiopharmaceutical, and

[3] As defined in the Radiation Protection (Ionising Radiation) Regulations.

(viii) the verification of the identity of the radiopharmaceutical, patient, and the route of administration prior to administration;

(g) records relating to the Premises including:

(i) preventive maintenance of PEC,

(ii) radiation monitoring records which shall include radiation room surveys, and

(iii) investigation, follow-up actions and management of any radioactive spillage;

(h) records relating to patient and personnel safety, which include:

(i) investigation of adverse reactions associated with the administration of radiopharmaceuticals, and

(ii) investigation and follow-up actions of any incidents concerning patient and/or personnel safety.

(i) records relating to the internal audits conducted under paragraph 3.1(f), which include:

(i) the date of each audit,

(ii) the deficiency(ies) identified during each audit, and

(iii) the corrective and preventive action(s) taken for the deficiency(ies) identified;

Patient Records

7.3 The Licensee shall keep the following records in relation to each examination that the Licensee conducts:

(a) the patient's health records, which include:

(i) information about the side of the anatomic site imaged;

(ii) the informed consent obtained from the patient in relation to the conduct of the examination;

(iii) if images are provided directly by the Licensee to another person along with the imaging report, records of:

(1) the person(s) to whom the images were provided to, and

(2) the mode of transfer of these images;

(b) records of the contrast agent administered to the patient (if any). The record should minimally cover the following information:

(i) the name, lot number and expiry date of the administered contrast agent,

(ii) the dose of contrast agent administered to the patient,

(iii) the route and rate of administration of the contrast agent to the patient, and

(iv) the adverse reaction(s) suffered by the patient following the administration of contrast agent (if any).

(c) records of the anaesthesia or sedative administered to the patient (if any). The record should minimally cover the following information:

(i) the name, lot number and expiry date of the administered anaesthesia or sedative;

(ii) the dose of anaesthesia or sedative administered to the patient;

(iii) the route and rate of administration of the anaesthesia or sedative to the patient;

(iv) the adverse reaction(s) suffered by the patient following the administration of anaesthesia or sedative (if any);

(v) the extent and duration of monitoring of the patient following the administration of anaesthesia or sedative; and

(vi) the discharge arrangement(s) for the patient who has been administered the anaesthesia or sedation.

8. Radiopharmaceutical Laboratory

MINIMUM FACILITY AND PERSONAL PROTECTIVE EQUIPMENT REQUIREMENTS FOR RADIOPHARMACY LABORATORIES ("HOT LABS")

8.1 The Licensee shall ensure that the area(s) within its Premises that is used for the preparation, dispensing, radiolabelling, compounding and quality control of radiopharmaceuticals (also referred to and commonly known as "**Radiopharmacy Laboratory**" or "**Hot Lab**") meets the minimum requirements set out in paragraphs 8.2 to 8.5.

8.2 The Licensee shall determine the relevant category (as set out in Table 1) its Hot Lab falls under, and ensure that its Hot Lab complies with all

minimum requirements applicable to that category in accordance with Table 1.

8.3 The Licensee shall ensure that its Hot Lab complies with the following requirements:

(a) the Hot Lab shall be in a separate, dedicated and secured area within the Premises that is close to the areas for imaging and radiopharmaceutical administration to patient;

(b) the Hot Lab shall 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**");[4]

(c) all work surfaces in the Hot Lab shall be smooth and impermeable for easy cleaning and decontamination;

(d) all plumbing pipe works and cables located in the Hot Lab shall be encased and adequately laid to facilitate cleaning and decontamination;

(e) the Hot Lab shall have adequate space to accommodate all essential equipment and accessories (e.g. shielded Biosafety cabinet, laminar flow hood(s), lead shields for handling radiopharmaceuticals, and pharmaceutical isolator or other environmental cabinet(s));

(f) the Hot Lab shall have adequate space for at least two personnel to operate simultaneously and safely in the Hot Lab;

(g) 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;

(h) the Hot Lab shall have adequate waste storage containers for the disposal of sharps and general waste;

(i) all radioactive waste disposed in the Hot Lab and of different half-lives shall be appropriately segregated to ensure safe disposal and in accordance with the requirements in the RPA; and

(j) all radioactive waste disposed in the Hot Lab shall be adequately shielded.

[4] Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards; IAEA Safety Standards Series No. GSR Part 3 (2014).

8.4 The Licensee shall ensure that all its personnel who access and/or work in its Hot Lab adopt the following general aseptic practices:

(a) not to store or consume food and drinks in the Hot Lab;

(b) restrict access to the Hot Lab to only qualified personnel with specific responsibilities, competencies or assigned tasks that could only be performed in the Hot Lab;

(c) disinfect all work surfaces with 70% sterile alcohol before and after work. During preparation of radiopharmaceuticals, to use gloves and regularly disinfect the work surfaces;

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

(e) maintain a direct open path between the cabinet filter and the area where aseptic manipulations are performed;

(f) ensure that there is air supply in PEC (e.g. Biosafety Cabinet, Laminar Flow Cupboard, Fume Cupboard) at all times when performing radiopharmacy tasks, and ensure that the airflow is kept unobstructed. Upon the air supply in PEC being switched on, the PEC should be left running for a minimum of 15 minutes and disinfected before use; and

(g) ensure only objects required for the preparation are 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.

8.5 The Licensee shall provide at the minimum, the following PPEs for all its personnel:

(a) Personal radiation dosimeter;

(b) Disposable gloves; and

(c) Overalls or jacket.

Table 1 – Specific facility requirements for Radiopharmacy Laboratories according to the category of radiopharmacy tasks

Category	Description of Hot Lab	Minimum requirements

	(based on the Licensee's intended use of radiopharmaceuticals and the type of radiopharmacy tasks being performed)	
1a	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.	1) A radionuclide dose calibrator with appropriate lead shielding; and 2) A shielded dispensing station.
1b	Hot Labs involved in the **dispensing** of radioiodine and other ready to use radiopharmaceuticals that can produce radioactive vapours.	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.
2a	Hot Labs involved in the **preparation** of radiopharmaceuticals from prepared and approved reagent kits, generators and radionuclides (closed procedure[5,6])[7].	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.
2b	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.	1) The minimum facility requirements for a **Category 2a** facility; and 2) a centrifuge for spinning down of blood products
3a	Hot Labs involved in the **compounding** of radiopharmaceuticals from ingredients and radionuclides for diagnostic applications, including: 1) open procedures[8]; 2) modification to existing commercial kits; 3) in-house production of reagent kits from ingredients, including freeze dried operation; and 4) related research and development (e.g. Ga 68 PET	1) The minimum facility requirements for a Category 2a facility.

5 Peter F. Sharp, Howard G. Gemmell, Alison D. Murray, Practical Nuclear Medicine, Springer Science & Business Media, 2006.

6 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.

7 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

8 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.

	radiopharmaceutical compounding)	
3b	Hot Labs involved in the **compounding** of radiopharmaceuticals from ingredients and radionuclides for therapeutic and diagnostic applications, including: - 1) open procedures; and 2) related research and development (e.g. radio-iodination of meta-iodobenzyl guanidine (MIBG-iobenguane) and rhenium labelled lipiodol).	1) The minimum facility requirements for a Category 2a facility; and 2) a separate fume hood externally ducted for radio-iodination with appropriate safety systems sited in a separate environment with appropriate shielding (for gamma as well as beta radiation).
3c	Hot Labs involved in the synthesis of PET radiopharmaceuticals. This includes the fludeoxyglucose (18F-FDG) used in PET-CT.	1) Category 3c Hot Labs must comply with GMP standard.
*NOTE: These LCs do not apply to Hot Labs that are licensed by HSA to manufacture radiopharmaceuticals under section 12 the Health Products Act 2007. However, these LCs shall apply to Hot Labs that have been excepted from holding a manufacturer's licence pursuant to Regulation 46 of the Health Products (Therapeutic Products) Regulations 2016. If the Hot Lab has in its possession and/or uses equipment containing radioactive material (e.g. Cyclotron), a licence must be also obtained from the NEA.		

Table 2: Specific personnel requirements for Radiopharmacy Laboratories according to the category of radiopharmacy tasks

Radiopharmacy Laboratory Level	Minimum Personnel
1A and 1B	1. Registered Nuclear Medicine Physician, Qualified Radiographer, Radiation Therapist, NM Technologist, Radiochemistry Staff, Medical / Radiation Physicist, **or** Registered Nurse.
2A and 2B	1. Registered Nuclear Medicine Physician; 2. Qualified Medical / Radiation Physicist; **and** 3. Any one of the following Allied Health Professional / ancillary staff: a. Qualified Radiographer, Radiation Therapist, NM Technologist; or b. Qualified Radiochemistry Staff;
3A and 3B	1. Registered Nuclear Medicine Physician; 2. Qualified Medical / Radiation Physicist; **and** 3. Any one of the following Allied Health Professional / ancillary staff: 1. Qualified Radiographer, Radiation Therapist, NM Technologist; or 2. Qualified Radiochemistry Staff; These levels to be supervised by and under authority of a more senior Registered Nuclear Medicine Physician, Radiochemistry Staff or other equivalently qualified personnel with similar professional training and experience. The supervising Radiochemistry Staff should have at least 5 years of relevant clinical working experience in NM services instead.
3C	NOT APPLICABLE
Minimum qualifications required for Radiochemistry Staff A qualified Radiochemistry Staff as prescribed above, shall have: (a) a basic degree or diploma in Chemistry, Radiochemistry, Pharmaceutical Sciences or equivalent*; and (b) at least THREE (3) YEARS of relevant clinical working experience in NM services if holding a degree mentioned in (a) and FIVE (5) YEARS if having a diploma mentioned in (a). *Other equivalent qualifications refer to Medical Physics and Nuclear Medicine Sciences	

9. Quality Control Tests and Parameters

MINIMUM QUALITY CONTROL ("QC") TESTS AND PARAMETERS THAT MUST BE PERFORMED ACCORDING TO INSTRUMENT/EQUIPMENT TYPE

9.1 The Licensee shall perform QC tests on its instrument/equipment in accordance with the parameters set out in Table 3 below, or 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[9,10,11] if

(a) the parameters are not provided for in Table 3 or,

(b) where the parameters or criteria specified in the equipment manufacturers' operation manuals, the NEMA or IAEA standards are more stringent than the parameters provided in Table 3.

9.2 The Licensee shall also ensure that its QC policies and procedures include, at the minimum, the QC tests and parameters as prescribed in paragraph 9.1 above. The Licensee shall properly document its compliance with these minimum QC tests and parameters, and retain those records for audit purposes, in accordance with its policies.

Table 3: Minimum QC tests and parameters

S/N	Type of Instrument or Equipment	Minimum Frequency of Check	QC Parameters to be checked	Standard or Reference Materials/ Equipment & Methods	Acceptance Criteria
1	Gamma Camera	Daily	Photopeak & Energy Window Setting	^{57}Cobalt flood source or ^{99m}Technetium unsealed check source or other suitable sources	Photopeak centered for radionuclide with a 20% energy window.
		Daily	Uniformity (Extrinsic or Intrinsic)	^{57}Cobalt flood source or ^{99m}Technetium point source or other suitable sources	The integral &/or differential uniformity values are < 10% for the Central &/or Useful Field of View ("FOV"). While the Gamma Camera is still usable for planar imaging if the integral &/or differential uniformity values falls between 6% to 10%, it is recommended that the energy & uniformity

9 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

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

11 International Atomic Energy Agency Human Health Series No. 6, Vienna, 2009, Quality Assurance For SPECT Systems

				correction tables/files/maps be updated using 57Cobalt flood source or 99mTechnetium point source if the values fall between 6% to 10% to adjust it back to the optimal range of <5%, especially for SPECT imaging.
		Daily (For SPECT/CT)	CT Tube Warm Up & Air Calibration	N.A.	Pass according to manufacturer's recommendation.
		Every 3 months (For SPECT/CT)	CT Number	CT Phantom	CT Number < ±5 Hounsfield units or according to manufacturer's recommendation (whichever is more stringent).
		Every 2 weeks	Centre of Rotation (COR) Only for rotating SPECT Gamma Cameras	^{99m}Technetium check source	COR error <0.5pixels or < 2mm or according to manufacturer's recommendation (whichever is more stringent).
		Every 6 months	Spatial Resolution	To determine Full Wave Half Maximum ("FWHM") = 1.75 x smallest resolvable spacing using the 4-quardrant bar phantom or by any other suitable method.	Spatial Resolution values meet equipment specification.
		Every 3 months (For SPECT/CT)	CT Uniformity, CT Contrast & CT Artefact	CT phantom	Pass CT Uniformity and Contrast and no artifact/s seen.
		At acceptance testing	Sensitivity	^{99m}Technetium source	Sensitivity meets equipment specification.

		At acceptance testing	Count Rate Characteristics	Varying ^{99m}Technetium activities. Measure & plot observed count rate versus activity.	Count Rate Characteristics meet equipment specification.
2	Dose calibrator	Daily	Constancy with Long Half-Life Radionuclides	Calibrated & traceable sealed reference sources of ^{137}Cesium & ^{57}Cobalt	Percentage difference between measured & theoretical activities <5% for ^{137}Cesium & ^{57}Cobalt.
		Every 6 months	Linearity Response to ^{99m}Technetium or ^{18}Fluorine	Method 1: Measure the decaying ^{99m}Technetium or ^{18}Fluorine for a minimum of two half-lives. Plot activity time graph to determine half-life of radionuclide. **OR** Method 2: Varying attenuation sleeves for a fixed activity of ^{99m}Technetium or ^{18}Fluorine.	Measured radionuclide half- life is < ±10% of theoretical value.
3	PET/CT	Daily	CT Tube Warm Up & Air Calibration	N.A.	Pass according to manufacturer's recommendation.
		Every 3 months	CT Number	CT Phantom	CT Number < ±5Hounsfield units or according to manufacturer's recommendation (whichever is more stringent).
		Every 3 months	Radioactivity - counts calibration	SUV phantom or water filled phantom with ^{18}Fluorine or ^{68}Galium.	Pass according to manufacturer's recommendation.

		Daily	PET detector stability / constancy	^{68}Germanium, ^{22}Sodium or ^{176}Lutetium	Pass according to manufacturer's recommendation.
		Daily (for TOF PET)	PET Daily Coincidence Timing Resolution	^{68}Germanium or ^{22}Sodium	Pass according to manufacturer's recommendation.
		Every 3 months (For SPECT/CT)	CT Uniformity, CT Contrast & CT Artefact	CT phantom	Pass CT Uniformity and Contrast and no artifact/s seen.
		At acceptance testing	Accuracy of PET/CT Image Registration	^{18}Fluorine filled image quality phantom and heavy weights to simulate a patient	Within ±1 pixel when using a 512 x 512 matrix or according to manufacturer's recommendation (whichever is more stringent).
		At acceptance testing	Sensitivity Test	^{18}Fluorine Line source and aluminium sleeves	Pass according to manufacturer's recommendation.
		At acceptance testing	Spatial Resolution Test	^{18}Fluorine Point sources and NEMA source holder	Pass according to manufacturer's recommendation.