

Healthcare Services (Nuclear Medicine Service) Regulations FAQs

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Licensing Matters

<p>1. What is the purpose of regulating nuclear medicine (“NM”) services?</p> <ul style="list-style-type: none"> Building upon the Standards for the Provision of Nuclear Medicine, Imaging, Therapy and Assay Services (“the NM Standards”) issued on 28 May 2019, the Regulations for NM services are intended to update existing requirements where appropriate, so as to better ensure patient safety and welfare in the provision of NM services. For example, the Regulations prescribe the duties and responsibilities of the Clinical Governance Officer in ensuring proper clinical governance of the service.

- The Regulations stipulate minimum standards for prospective and licensed providers of NM services to have, amongst other things, adequate personnel, facilities, equipment, products (e.g. radiopharmaceuticals, reagents), policy and procedures and Quality Management System.
- More detailed requirements are set out under License Conditions (“LCs”) to complement the Regulations. As with the Regulations, the LCs are also developed based on the prevailing NM Standards. For NM service providers, the Regulations and LCs supersede the applicable requirements under the NM Standards.

2. How were the requirements for the NM services regulations developed?

- The NM services regulations were largely adapted from the NM Standards developed by the Advisory Committee on Nuclear Medicine (“Advisory Committee”), which was appointed by the Director of Medical Services (“DMS”), Ministry of Health (“MOH”).
- Comprising nuclear medicine physicians, medical physicists, a radiochemistry expert and radiographers from the public and private sectors, the Advisory Committee provides guidance to MOH in the review of the NM Standards and have continued to advise MOH on the development and implementation of the various NM Service Regulations under the Healthcare Services Act (“HCSA”).

3. [Updated on 26 June 2023] What licence(s) will I need to hold to provide the different types of NM services?

- NM in vivo assay and NM therapy will be transited from the Private Hospitals and Medical Clinics Act as part of Phase 2 of HCSA (26 June 2023). Licensees will only need to hold a single NM service licence to provide any / all aspects of NM which involves the administration of radiopharmaceuticals to patients (i.e. NM Imaging, NM Therapy and NM in vivo Assay).
- NM imaging which was previously transited as part of Phase 1 of HCSA (3 Jan 2022) will be subsumed under the new NM service licence in Phase 2 of HCSA as a specified service.

4. [New on 26 June 2023] I was issued a NM imaging/assay licence(s) during Phase 1 of HCSA (i.e. before 26 June 2023). What will happen to my licence(s) under Phase 2 of HCSA?

- Your NM imaging licence will be re-issued as a NM service licence with approval granted to provide NM imaging as a specified service.
- Your NM assay licence will be revoked as the service is now subsumed as part of the clinical laboratory service itself. You will not need a separate approval or licence to conduct these tests but same requirements imposed under Phase 1 of HCSA for the conduct of such nuclear medicine tests still applies under the

amended Healthcare Services (Clinical Laboratory Service and Radiological Service) Regulations.
5. [Updated on 26 June 2023] Why do I need to apply for a separate clinical laboratory service licence to provide NM assay service?
<ul style="list-style-type: none"> • NM assays (test where the detection of analyte is based on radioactivity, e.g. radioimmunoassay) will continue to be regulated under the clinical laboratory service as it does not involve the administration of radiopharmaceuticals to patients. • NM Licensees providing NM in vivo assay will be allowed to perform tests on the specimens obtained as part of the procedure. However, (i) these tests must be performed using only beta scintillation or gamma counting and (ii) the specimen must not be subject to more than minimal manipulation (please refer to Regulation 34). Please also refer to Q34 below.
6. [Updated on 26 June 2023] Is a separate radiological service licence required to provide NM imaging?
<ul style="list-style-type: none"> • Licensee intending to <u>solely</u> provide NM imaging (e.g. PET-CT, SPECT-CT) will only need to hold the NM service licence and obtain approval to providing NM imaging as a specified service. Licensees will not need to hold a radiological service licence, notwithstanding that the same equipment or machine may be used for radiological service (e.g. CT). • However, a licensee would still need to hold <u>both</u> a NM service licence as well as a radiological service licence should both types of services be provided (e.g. PET-CT and CT).
7. [New on 26 June 2023] Is a separate outpatient medical service licence required to provide NM therapy?
<ul style="list-style-type: none"> • Licensee intending to <u>solely</u> provide NM therapy (e.g. consultation and treatment related to the use of radiopharmaceuticals like radioiodine therapy) will only need to hold the NM service licence. Licensees will not need to hold an outpatient medical service licence. • However, a licensee would need to hold <u>both</u> a NM service licence as well as an outpatient medical service licence should both types of services be provided i.e. licensee also provides medical consultations and treatments that are not part of the NM service (e.g. treatment of chronic diseases, medical oncology, brachytherapy). • A NM service licence is <u>not</u> required for a healthcare professional to refer patients to a NM service licensee for further care (e.g. medical oncologist under an outpatient medical service referring patient to a NM service licensee for treatment). These includes patient care activities such as:

<ul style="list-style-type: none"> ○ Non-radiopharmaceutical related treatment for the same indication for which NM therapy is provided (e.g. concurrent chemotherapy for cancer); ○ Review or medical consultation by other medical specialities for the same or similar indication for which NM therapy is provided (e.g. assessment of thyroid function for a patient with thyroid cancer, another cancer not treated using radiopharmaceuticals); ○ Review or treatment for any indications not related to the indication for which NM therapy is provided (e.g. diabetes, hypertension).
<p>8. [New on 26 June 2023] Is a NM service licence required to provide brachytherapy / internal radiation therapy?</p>
<ul style="list-style-type: none"> • Licensee intending to provide brachytherapy / internal radiation therapy are not required to hold a NM service licence as these are using sealed sources of radiation. These are regulated under the specified service “Radiation Oncology and Radiation Therapy” under outpatient medical service, ambulatory surgical service and acute hospital service.
<p>9. [New on 26 June 2023] Is a separate ambulatory surgical centre service licence required to perform NM procedures using general anaesthesia?</p>
<ul style="list-style-type: none"> • Licensee intending to use general anaesthesia (GA) as part of a NM procedure is not required to hold an ambulatory service centre service licence. However, licensees must ensure that the facilities, drugs, equipment, processes (including those for emergency purposes) necessary for the safe use of GA are provided. These include, but is not limited to, the requirement for an anaesthesiologist to assess the patient before administration and to perform the administration of GA, and post-procedure monitoring and discharge.
<p>10. [New on 26 June 2023] Do I need to hold a NM service licence if I am already licensed as an acute hospital?</p>
<ul style="list-style-type: none"> • Licensee intending to provide any NM service (i.e. NM in vivo assay, NM imaging or NM therapy) must hold a NM service licence. This is regardless of whether the NM service is intended to be provided in an outpatient setting, inpatient setting, or both.
<p>11. [Updated on 26 June 2023] Does MOH need to be notified if a new equipment (e.g. PET-CT) has been procured for use in the facility?</p>
<ul style="list-style-type: none"> • There is no need to notify MOH of any new equipment procured if the corresponding imaging modality (e.g. PET-CT) has already been notified to MOH as part of the approved scope of the licence. • However, if the new equipment has been procured for the provision of a service modality that MOH has yet to be notified, you will need to notify MOH at least 2

months before the date you plan to commence provision. You may check the imaging modalities already notified to MOH by logging in to HALP.

- Please also refer to Q12 and Q28 on new imaging modalities and other legislations relevant for new equipment respectively.

12. [Updated on 26 June 2023] Is there a need to apply for a new licence to provide a new imaging modality for NM imaging?

- Licensees do not need to apply for a new licence but are required to seek approval the first time they wish to provide any NM imaging modality. Subsequently, licensees will only need to notify MOH of the intention to provide any additional imaging modality at least 2 months prior to the commencement of the additional service modality.
- MOH may conduct inspections to ensure that the relevant licence conditions are complied with. Where inspection findings show non-compliances, licensees will be required to stop the service and rectify the non-compliances satisfactorily prior to continued provision of the additional service modality. The licensee may be required to submit service-related documents (e.g. equipment commissioning, and licences issued by the National Environment Agency (NEA)). Where appropriate, an additional inspection may also be conducted.

13. [New on 26 June 2023] Is there a need to apply for a new type of radiopharmaceutical to be used for NM therapy?

- Licensees do not need to apply or notify MOH regarding any new radiopharmaceutical to be used as part of NM therapy. The CGO is expected to assess the radiopharmaceutical before its first use and the licensee must keep accurate documentation of the assessment.

General obligations of licensees

14. How are licensees to interpret the provisions on the general obligations of licensees to ensure suitability of premises and equipment and appropriate number of personnel to provide the service in a safe, timely, accurate and effective manner?

- These provisions are non-prescriptive and aim to impose the general obligations on licensees to ensure the safe, timely, accurate and effective provision of the service at all times.
- This is in line with the outcomes-based approach adopted under the HCSA, where licensees are given the flexibility to implement relevant measures to achieve the intended outcomes. As such, the exact measures are not prescribed legislatively. This allows licensees to adopt protocols/ processes that are most suited for their institution to meet the outcomes.

- However, in the event where the licensees' protocols / processes are not meeting the intended outcomes, licensees are expected to investigate the root causes and implement appropriate corrective and preventive measures to address any weaknesses identified.

Governance and Personnel

15. **[Updated on 26 June 2023]** What's the difference between the CGO and Section Leader?

- The CGO provides clinical governance and technical oversight of the service including overseeing and implementing policies, processes and programmes to ensure that the service provided is safe and of acceptable quality. For example, the CGO must ensure that:
 - Work instructions or SOPs relating to the provision of NM services are regularly assessed and updated if necessary;
 - All personnel are familiar with their respective job functions and be kept up to date with any changes in workflow; and
 - All personnel are regularly trained and assessed to be competent in their respective job functions;
- While the CGO oversees the day-to-day technical management of service, it does not mean that the CGO is required to be personally or directly involved in every task or function on the ground. CGO can delegate tasks to other personnel whom he has assessed to be competent and suitable for the functions, e.g. the Section Leader(s). However, the responsibility to maintain oversight and provide adequate supervision and guidance remains with the CGO.
- The Section Leader(s) is in charge of the particular NM aspect (e.g. NM therapy) or imaging modality, and is more closely involved in the day-to-day operation on the ground than the CGO. The Section Leader(s) shall not be absent therefrom for any length of time, unless arrangements are made for the service modality to be placed under the supervision of a person similarly qualified as the Section Leader(s) to provide technical oversight.
- While the Section Leader(s) is required to have relevant qualifications and experience in the specific service modality, the CGO is required to have qualifications and experience relevant to the entire scope of the services under his purview. For example, the CGO can be the NM Physician while Section Leader can be the radiographer or radiochemistry personnel for NM Imaging and NM in vivo assay respectively.
- For smaller settings, CGO and Section Leader can be the same person as long as this person fulfils all the requirements.

<ul style="list-style-type: none"> • A Section Leader can also oversee more than one NM aspect or imaging modality in one or multiple premises, as long as the person has the relevant qualifications and experience in each role, and able to effectively supervise all aspects, imaging modalities and premises under his/her purview.
<p>16. [New on 23 Feb 2022] How many CGOs need to be appointed?</p>
<ul style="list-style-type: none"> • It is up to licensee to decide whether to appoint one or more CGO. • More than one CGO may be appointed if a single CGO is not sufficient to fulfil the duties and responsibilities of CGO stipulated in the General Regulations and individual service regulations for the entire scope of services provided by the licensee. • When multiple CGOs are appointed, licensee must make clear the delineation of responsibilities amongst the CGOs.
<p>17. [Updated on 26 June 2023] Can a medical doctor who is <u>not</u> registered as a Nuclear Medicine Physician under the Medical Registration Act (Cap. 174) (“MRA”) qualify to be the Clinical Governance Officer (“CGO”)?</p>
<ul style="list-style-type: none"> • Medical practitioners who are not registered as Nuclear Medicine Physicians under the MRA may be considered to be the CGO if they are registered as cardiologists under the MRA <u>and</u> hold valid certification in nuclear cardiology by the Certification Board of Nuclear Cardiology (CBNC), United States of America (or meet its equivalence) and the scope of services is for cardiac imaging purposes only. This is only applicable to CGOs appointed for NM Imaging.
<p>18. [Updated on 26 June 2023] What counts as “qualifying experience”? Can overseas experience be considered?</p>
<ul style="list-style-type: none"> • For medical practitioners registered as a specialist in nuclear medicine by the Singapore Medical Council, this refers to at least 5 years of post-specialist experience. • For medical practitioners registered as a cardiologist by the Singapore Medical Council, this refers to at least 5 years of post-specialist experience in NM imaging service, after obtaining the certificate in nuclear cardiology by the Certification Board of Nuclear Cardiology, United States of America (or after meeting its equivalence). • For foreign-trained specialists, the qualifying experience is also at least 5 years of post-specialist experience. Whether overseas experience can be considered will be assessed on a case-by-case basis taking into account the intended scope of services, etc. • For clarity, the requirement does not distinguish between experience accrued in any aspect of nuclear medicine service. For example, a NM Physician with 5

<p>years of experience in NM imaging will also be eligible to be the CGO for NM therapy aspects (or vice versa).</p>
<p>19. Can a medical practitioner with conditional registration be the CGO?</p>
<ul style="list-style-type: none"> No, only fully registered medical practitioners are allowed to be the CGO, subject to the meeting of other requirements. The CGO plays a supervisory role and should not him/herself be subject to requirements to be supervised under the professional registration framework.
<p>20. How regularly do systems for clinical governance, risk management and quality management need to be reviewed?</p>
<ul style="list-style-type: none"> These should be reviewed in accordance with the institution's policies and procedures, so long as it meets the intended outcome that any identified risks affecting or which might affect the safety and welfare of, and the continuity of care, provided to patients, as well as the safety and welfare of personnel providing the service, are mitigated, detected and addressed in a timely manner. As a guide, these systems may be reviewed at least annually for effectiveness.
<p>21. What does a radiation safety programme entail?</p>
<ul style="list-style-type: none"> The radiation safety programme should cover personnel safety, patient safety, public safety and environment and facility monitoring, which should minimally meet NEA's requirements on radiation safety. In addition to adherence to the RPA and Radiation Protection (Ionising Radiation) Regulations, there is also an emphasis on the radiation safety competency of personnel to ensure patient, staff and public safety. This includes proper handling and use of radioactive materials, and having instructions or radiation safety precautions in place for patients after administration of radiopharmaceuticals / radioactive substance, where appropriate. Personnel competency assessments and training records in this respect should also be conducted and documented.
<p>22. [New on 23 Feb 2022] What is the role of the Radiation Safety Officer under HCSA?</p>
<ul style="list-style-type: none"> The role of the Radiation Safety Officer is not prescribed under HCSA. Radiation Safety Officers will continue to play their role specified under the Radiation Protection (Ionising Radiation) Regulations and/or Radiation Protection (Non-Ionising Radiation) Regulations as the case may be, which is to supervise the use/custody of any irradiating apparatus or radioactive substance for any work they are licensed to do.

23.[Updated on 23 Feb 2022] What would constitute an “appropriate number of personnel” to provide the service?

- The appropriate number of personnel required is not prescribed as that will depend on factors such as the scale, scope of service and patient load, which may vary for different licensees.
- Licensees are expected to make a reasonable assessment of the appropriate number of personnel needed to meet the intended outcomes, including the safe, timely, accurate and effective provision of the service, and the requirements in the respective regulations at all times.
- Licensees are required to engage at least one of each type of personnel prescribed for the respective NM service. Please refer to Q24 below.

24.[Updated on 26 June 2023] Is there a minimum number of personnel required for the provision of NM service?

- Licensees are required to engage **at least one** of each type of personnel who meet the minimum qualifications and experience stated in the Regulations.
- For clarity, the licensee may choose to use a different job title from what is stated in the Regulation so long as the above requirement is met. For example, a hospital may use the job title Radiopharmacist for personnel defined as a Radiochemistry Personnel in the Regulations. It would be acceptable so long as there is at least one such personnel as defined and prescribed in Regulation 2 and/or 12 in the Regulations.
- To ensure that there are adequate personnel for the proper and efficient provision of services and for its functions to be performed in an accurate, timely, safe and effective manner, licensees are advised to take into consideration the following non-exhaustive list of factors in their manpower resource planning:
 - (a) the intended use of radiopharmaceuticals / radioactive substance (e.g. diagnostic versus therapeutic);
 - (b) the type of tasks being performed (e.g. dispensing versus compounding of radiopharmaceuticals);
 - (c) the scale and workload of the NM assay or NM imaging service being provided;
 - (d) business / service continuity considerations; and
 - (e) personnel competency and adequacy of supervision.
- Licensees are also recommended to have in place policies and procedures for future development of the service and staffing needs (e.g. expansion of service).

25.[Updated on 30 Jun 2021] What constitutes appropriate training on radiation safety awareness?
<ul style="list-style-type: none"> The scope of radiation safety knowledge will vary among different categories of personnel, based on the nature and type of work they are engaged in. The radiation safety training and annual re-training should be tailored accordingly for each category of personnel and nature of work to ensure that the intended outcomes of safe and effective provision of the service are met.
26.[Updated on 30 Jun 2021] What does “close supervision” of a personnel without the requisite years of relevant experience entail?
<ul style="list-style-type: none"> There should be arrangements in place whereby the suitably qualified personnel can effectively monitor and guide the less experienced personnel in performing NM activities as appropriate. The extent of supervision required (e.g. providing direct supervision on-site, or remaining contactable to give guidance when needed) should be determined by the supervisor based on an assessment of the particular personnel’s level of competency.

Facilities and equipment

27. [Updated on 26 June 2023] What does it mean to provide for the physical segregation of patients and who are the other individuals that patients who have been administered radiopharmaceuticals need to be segregated from?
<ul style="list-style-type: none"> Licensees are required to provide for adequate areas, for the segregation of patients <u>within the licensed NM premises</u> who have been administered radiopharmaceuticals from all other persons who have not been administered radiopharmaceuticals (e.g. other patients, caregivers, members of public). The extent of segregation should be assessed based on the potential for radiation exposure through contact. The above does not preclude the licensee from temporarily releasing patients from their premises (e.g. while awaiting uptake of radiopharmaceuticals for NM imaging) if the assessment has been made that it is safe to do so. This requirement would only be applicable to the licensed NM premises (e.g. NM departments within hospitals and medical clinics providing NM services) but not to other non-NM premises located within the licensed premises of the institution, if applicable (e.g. non-NM healthcare areas, F&B establishments).
28.What are the current legislations for the procurement and use of equipment for NM service?
<ul style="list-style-type: none"> In Singapore, medical devices (e.g. PET/CT machines) are regulated by the Health Sciences Authority (“HSA”) to safeguard public health and safety. The

laws which govern medical devices sold in Singapore are the Health Products Act and Health Products (Medical Devices) Regulations. All product owners are required under these laws to register their medical devices and obtain the dealer's licence with HSA before selling or dealing with them. For details, please refer to <http://www.hsa.gov.sg/content/hsa/en.html>.

- In Singapore, the NEA's Radiation Protection & Nuclear Science Department ("RPNSD") is the national authority for radiation protection. It administers and enforces the RPA and Regulations through a system of licensing, notification, authorisation, inspection and enforcement. Service providers are required to apply for the respective radiation licence(s) from RPNSD prior to the possession, operation and/or use of Ionising Radiation (IR) Irradiating Apparatus (e.g. PET/CT machines) and radioactive materials (e.g. I-131) in Singapore. For details, please refer to <https://www.nea.gov.sg/ourservices/radiation-safety/overview>.

Systems and Committees

29. Can a hospital's existing Quality Assurance Committee (QAC) meet the QAC requirements under the HCSA for NM service?

- A hospital can choose to have separate QACs for each service or have one QAC to cover all services. The hospital will need to ensure that the QAC(s) meet all the requirements for the various services and that the composition is appropriate.

30. [New on 23 Feb 2022] How can licensees achieve an effective quality management system?

- The licensees are required to establish an effective Quality Management System (QMS) for the purpose of quality assessment and assurance of the safe delivery of the service.
- The QMS should include comprehensive plans to meet all the requirements stated in the Regulations and LCs where applicable, and the plans should be implemented.
- There should be records on workflows such as the coverage of duties, patient acceptance criteria, quality control for each modality, etc.
- There should be indicators and targets established to monitor the service's key quality parameters (e.g. turnaround time for reporting, image rejection rate, key performance indicators)
- There should be an annual review of the QMS to ensure ongoing effectiveness.

31.[New on 23 Feb 2022] What do I need to do to audit the operations of the nuclear medicine service?

- In addition to the audits conducted by MOH, the licensee must also review their operations (e.g. internal audits) and ensure that it is in operating in accordance to their stipulated QMS.
- Examples of internal audits are clinical audit (e.g. reporting of scans), audits on documentation of dispensing records, radiopharmaceutical purity, equipment quality control records, environmental surveys, infection control practices, staff radiation exposure records, processes and compliance to Policies and Procedures (P&P).

Service Provision

32.[Updated on 26 June 2023] What does the licensee need to do for incidental findings as part of NM imaging and NM in vivo assay?

- Licensee should ensure that the medical practitioner who is interpreting and reporting the findings state in the report any incidental findings that are clinically significant based on professional judgement.
- Licensee should also put in place a process to ensure that the incidental findings are brought to the attention of the healthcare professional who ordered the test or examination, as the case may be, for the patient, so the healthcare professional could take the necessary follow-up actions.

33.[Updated on 26 June 2023] With reference to Regulation 72 of the Nuclear Medicine Service Regulations 2023, is outsourcing allowed for NM Services?

- Outsourcing is not allowed for NM service except for certain aspects of NM in vivo assay (see Q34 below). This is to ensure **all** key aspects of the services are provided by licensees and there is proper governance and accountability for the NM services. In the context of NM service, key aspects of the services refer to the administration of radiopharmaceuticals, conduct examinations and the reporting of images.
- For avoidance of doubt, employing or engaging of external personnel by the licensee to support the provision of the licensee's NM service, whether that individual is under another licensee or not (i.e. freelance), is not considered as outsourcing. However, licensees should ensure that the individual employed or engaged for such purposes should meet all the applicable requirements or qualifications for the role, such as being registered with the Singapore Medical Council as a NM Physician.

- Referrals to another licensee for the provision of NM services, whether in its entirety or in parts are also not considered as outsourcing **if** the services are provided by the other licensee in-house.
- For clarity, Regulation 72 does not preclude licensees, in the event of an unforeseen service disruption (e.g. equipment malfunction, lack of consumables, unavailability of personnel for image reporting) from referring the patient, or images to another licensee as the case may be. Similarly, this also applies to peace time scenarios for the timely and safe management of patients (e.g. referral of patients for imaging to manage long turnaround time).

34. [New on 26 June 2023] With reference to Regulation 72 of the Nuclear Medicine Service Regulations 2023, what can I provide vs outsource as part of NM in vivo assay?

- Licensees providing NM in vivo assay are allowed to provide perform all aspects of NM in vivo assay – the administration of radiopharmaceutical, the retrieval of specimen and the testing of said specimen. However, for the testing of specimens in the NMS, licensees are limited to (i) using only beta scintillation or gamma counting and (ii) the specimen must not be subject to more than minimal manipulation (please refer to Regulation 34)
- If the testing of specimen does not meet (i) or (ii) above (or both), it must be done by clinical laboratory service licensee (e.g. if the testing process requires cell culturing).
- For clarity, a testing that meets both (i) and (ii) above, can still be sent to a clinical laboratory service licensee for testing if licensees do not wish to conduct the tests as part of the scope of the NM service.

35. [New on 23 Feb 2022] Will “Hot Labs” be regulated under HCSA?

- “Hot Labs”, or radiopharmacy laboratories, will be regulated under HCSA. The relevant requirements can be found in the LCs to be issued subsequently. Only Hot Labs of categories 1A to 3B will be regulated under HCSA. Category 3C Hot Labs that are engaged only in the manufacturing or assembly of radiopharmaceuticals will be regulated by HSA instead.

Facilities and equipment (Hot Lab)

36. [New on 26 Jun 2023] Are the requirements for category 1A “Hot Lab” used for the dispensing of radiopharmaceuticals for SPECT (e.g. Tc-99) and PET Tracers (e.g. F-18) the same?

- The minimum facility requirements apply to both tracers but the level of lead shielding for L shields differs (see Table A below). The shielding for PET Tracers (e.g. F-18) radiopharmaceuticals thus requires 20 times more thickness of lead than SPECT Tracers (e.g. Tc-99) radiopharmaceuticals.

Table A: Half value layer (HVL) in lead for different types of tracers

Tracers	Half value layer (HVL) of tracers in lead
SPECT tracers (e.g. Tc-99)	0.3 mm
PET Tracers (e.g. F-18)	6 mm

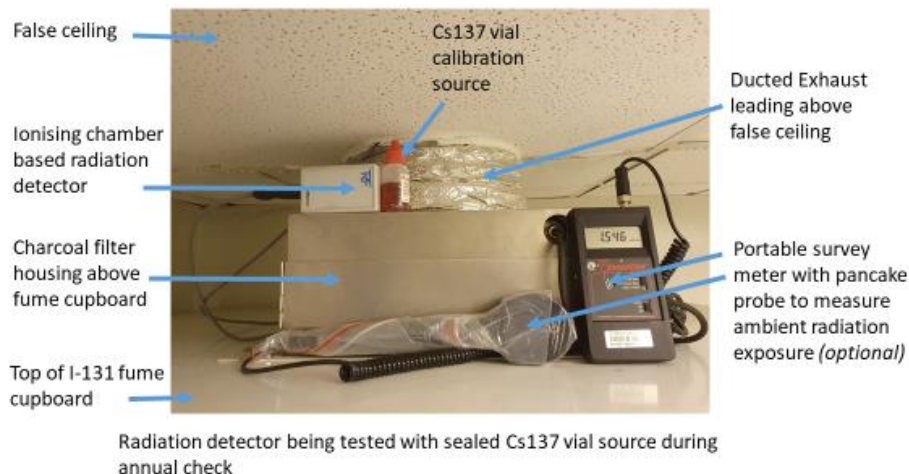
37. [New on 26 Jun 2023] Is a clean room set up required for a category 3A or 3B “Hot Lab” engaged in the compounding of radiopharmaceuticals?

- No, a clean room set up is not required but the room must be clean with proper general aseptic practices as prescribed under the LCs (Section 8). The minimum facility requirements are similar to Category 2A, with additional requirement of an externally ducted fume hood in a separate environment if radio-iodination is performed.

38. [New on 26 June 2023] What is an example of a radiation exhaust monitor for Category 1B radiopharmacy lab as mentioned in Table 1 of the LCs “Specific facility requirements for Hot Labs according to category of radiopharmacy tasks”?

- Please refer to the attached picture of an example of a radiation exhaust monitor placed on top of a ducted fume cupboard with suitable filters that can handle radioactive vapours (e.g. from liquid I-131 solutions) in a Category 1B radiopharmacy lab.

Radiation detector for ducted exhaust of I-131 fume cupboard



- In the case of a ductless fume cupboard, the detection and measurement of radioactive vapours could be performed using a portable survey meter at the

exterior surface of the charcoal filter assembly in place of a radiation exhaust monitor to ensure safe operational status of the fume cupboard. The radiation exposure of the filter assembly could be checked with a portable survey meter **after every use** of this fume cupboard for managing radioactive aerosols (e.g. I-131). In the event of a significant exposure reading of >10microSv/h, prompt decontamination corrective actions must be taken and radiation monitoring of decontamination to confirm that the radiation levels are within safe limits must be carried out before the use of the fume cupboard to ensure staff safety.

- Both ducted and ductless fume cupboards should have surfaces that are smooth and cleanable, and constructed of materials that are impervious and resistant to water and chemicals. The fume cupboard should also have a negative flow rate capability during use. The work surface should have a slightly raised margin/edge to contain any spills.

39. [New on 26 June 2023] Is a radiation exhaust monitor required to be used with a ducted fume cupboard if a radiopharmacy laboratory only dispenses radioiodine capsules and not liquid radioiodine?

- As small amounts of radioactive vapour could still be released from capsules during dispensing, a radiation exhaust monitor is required to be used with a ducted fume cupboard in a Category 1b radiopharmacy laboratory involved in the dispensing of radioiodine capsules and any other ready to use radiopharmaceuticals that produce radioactive vapours to ensure radiation safety. Similarly, a portable survey meter to detect and measure radioactive vapours should also be used in the case of a ductless fume cupboard.

Quality Control Tests and Parameters

40. [New on 26 June 2023] Is Centre of Rotation (COR) quality control check required every 2 weeks for all Gamma Cameras?

- COR quality control check is required every 2 weeks only for rotating SPECT Gamma Cameras. There is no need for COR tests for solid state Dedicated Cardiac Systems (e.g. Cadmium Zinc Telluride or CZT) as there is no rotation of detector when acquiring images.

41. [New on 26 June 2023] Why is it necessary to test the dose calibrator constancy Quality Control (QC) using two radionuclides such as Caesium-137 and Cobalt-57 as mentioned in Table 3 of the LCs titled “Minimum QC tests and parameters”?

- This is to ensure accurate assessment of the constancy response for a dose calibrator’s whole operating energy range from a low to a high energy keV (e.g. 120keV to 660keV).

42. [New on 26 June 2023] What is the minimum frequency of the Radioactivity-Counts Calibration using a Standardized Uptake Value (SUV) phantom?

- This Radioactivity-Counts Calibration for PET-CT is termed differently by various vendors and references. Some common names used for this calibration are: Well Counter, Cross Calibrator, Standardized Uptake Value (SUV) & 2D-3D. This calibration value is likely to change with time and needs to be updated to optimize system performance and ensure the accuracy of SUV values. It shall be performed every 3 months as prescribed in Table 3 of the LCs.

43. [New on 26 June 2023] What is the recommended frequency of the Gamma Camera uniformity correction tables/files/maps?

- The Gamma Camera uniformity correction tables/files/maps should be performed when the integral and/or differential uniformity values are >5%.

44. [New on 26 June 2023] What is the rationale of performing the Gamma Camera uniformity correction tables/files/maps when the uniformity value is >5%?

- The Gamma Camera uniformity correction tables/files/maps are used to improve acquired images automatically to remove artefacts due to inhomogeneity of photomultiplier tube gains, scintillation crystal response and electronic noise within detectors. Thus, when the uniformity values are >5%, uniformity correction tables/files/maps have to be updated to improve the image.

Miscellaneous

45. [New on 23 Feb 2022] Under records keeping, what does “identification number” refer to?

- Identification number refers to a patient’s National Registration Identity Card (NRIC) number or Foreign Identification Number (FIN) as the case may be.