Updated as at 9 Apr 2021

Healthcare Services (Nuclear Medicine Assay Service) and Healthcare Services (Nuclear Medicine Imaging Service) Regulations FAQs

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General

1. What is the purpose of regulating nuclear medicine ("NM") assay and nuclear medicine imaging services?

- 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 assay and NM imaging services are intended to update existing requirements where appropriate, so as to better ensure patient safety and welfare in the provision of NM assay and NM imaging 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 licensed providers of NM assay and NM imaging services to have, amongst other things, adequate personnel, facilities, equipment, product, policy and procedures, and Quality Management Systems.
- More detailed requirements will be set out under future Licensing Terms and Conditions ("LTCs") to complement the Regulations. As with the Regulations, the LTCs will also be developed based on the prevailing NM Standards. For NM imaging and NM assay providers, the Regulations and LTCs will supersede the applicable requirements under the NM Standards when they come into force.

2. How were the intended requirements for the NM assay and NM imaging services regulations developed?

- The NM assay and NM imaging 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 specialists, medical physicists, and radiographers from the public and private sectors, the Advisory Committee provides guidance to MOH in the review of the NM Standards and will continue to advise MOH on the development and implementation of the various NM Service Regulations under the Healthcare Services Act ("HCSA").

3. For a hospital providing NM Imaging, NM assay as well as NM therapy services, what HCSA licences would the hospital need to apply for?

- Under the HCSA, NM imaging, NM assay and NM therapy service providers are required to hold the requisite underlying licences in order to hold licenses for the respective special licensable healthcare service. These are set out below:

Special licensable healthcare service	Requisite underlying service licence	Implementation phase of HCSA *(tagged to when the underlying service will first come under HCSA)*
NM imaging service	Radiological service	Phase 1 (Sep 2021)
NM assay service	Clinical laboratory service	Phase 1 (Sep 2021)
NM therapy service	Medical clinic service OR Acute hospital service	Phase 2 (Jun 2022)

- Licensees are required to apply for the applicable licenses at the respective implementation phases of HCSA for the services that they provide.

4. Why do I need to apply for separate radiological service licence and clinical laboratory service licence to provide NM imaging service and NM assay service respectively?

- NM imaging service and NM assay service are special licensable healthcare services that can only be provided by licensed radiological service providers and clinical laboratories respectively. Separate licenses for the special licensable healthcare service and the corresponding underlying service will be required.

5. Can I continue to provide NM therapy services under Phase 1 of HCSA? If so, what regulatory requirements will I need to comply with?

- Yes, NM therapy service providers can continue to provide the service under Phase 1 of HCSA, and must continue to adhere to the applicable requirements under the PHMCA and the NM Standards, until the NM therapy service Regulations come into force in Phase 2.

6. Is there a fee bundle if I provide both NM imaging and NM assay services?

- More details on fees will be made available when ready.

Service modalities provided under NM imaging service licence

7. Is there a need to apply for a new licence to provide a new service modality for NM imaging service?

- Licensees do not need to apply for a new licence, but are required to inform MOH of the intention to provide the additional modality at least one month prior to the commencement of the additional modality.

8. After submitting the notification of intention to provide a new service modality, are licensees able to start providing the new service modality once the prescribed one month has passed?
• Following notification, licensees should not commence with provision of the additional modality until the additional modality is reflected on the licence. • 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.

General obligations of licensees

9. 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.
10. 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 of service provision 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.

Requisite qualifications of Clinical Governance Officer

11. Can a medical doctor who is not registered as a Nuclear Medicine Specialist under the Medical Registration Act (Cap. 174) ("MRA") qualify to be the Clinical Governance Officer ("CGO")?

- Medical practitioners who are not registered as Nuclear Medicine Specialists under the MRA may be considered to be the CGO if they apply and obtain specific approval from DMS and satisfy the other requirements as prescribed.
- Each application shall be assessed holistically, taking into consideration among other things:
  - (a) the licensee's intended use of radiopharmaceuticals / radioactive substances (e.g. diagnostic versus therapeutic);
  - (b) the type of tasks being performed (e.g. dispensing versus compounding of radiopharmaceuticals);
  - (c) the qualifications, training and experience in the applicable NM service of the proposed candidate; and whether the candidate holds the requisite licence under the Radiation Protection Act (Cap. 262); and
  - (d) the proposed candidate's experience in carrying out the prescribed duties and responsibilities of a CGO.

12. What counts as "qualifying experience"? Can overseas experience be considered?

- For medical practitioners registered as a specialist in nuclear medicine by the Singapore Medical Council, this would refer to 5 years of post-specialist experience.
- With regard to the qualifying experience for a non-nuclear medicine specialist (and whose registration or qualifications need to be approved by DMS), it has to be no less than 5 years of clinical experience in NM assay service or NM imaging service, as the case may be.
- For foreign-trained specialists, the qualifying experience is also 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.

13. Can a medical practitioner with conditional registration be the CGO?

- 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.

14. What license(s) under the Radiation Protection Act (Cap. 262) ("RPA") is the CGO required to hold personally?
• Minimally, the CGO must personally hold a valid L6 licence issued by the NEA to use radioactive material under section 5(1)(b) of the RPA. The CGO is responsible for the safe use of the radioactive materials by the licensee. • The L5 licence for use of irradiating apparatus (e.g. PET/CT) can be held by others such as a radiologist, while the L4 licence for possession of radioactive materials and L3 licence for possession of irradiating apparatus are held by the institution.

Duties and responsibilities of CGO

15. How regularly do systems for clinical governance, risk management and quality management need to be reviewed?
• These should be reviewed in accordance with the institution's policies and procedures, so long as it meets the intended outcome that any risks affecting 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 detected and addressed in a timely manner. • As a guide, these systems may be reviewed at least annually for effectiveness.
16. What does a radiation safety programme entail?
• The radiation safety programme should cover staff 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 staff to ensure patient 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. • Staff competency assessments and training records in this respect should also be conducted and documented.

Staff involved in provision of applicable service

17. Is there a minimum number of personnel required for the provision of NM assay or NM imaging service?

- To ensure that there are adequate staff for the proper and efficient performance of tests or procedures provided under the licensed service, 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) staff 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).

18. What does "close supervision" of a staff member without the requisite years of relevant experience entail?

- There should be arrangements in place for the sufficiently experienced staff member to, in person, effectively monitor and guide the less experienced staff member in performing NM assay or NM imaging activities, as the case may be.

Facilities and equipment

19. What are the current legislations for the procurement and use of equipment for NM assay or NM imaging service?

- 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. Iodine-131) in Singapore. For details, please refer to https://www.nea.gov.sg/ourservices/radiation-safety/overview.

Quality Management System

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