MINISTRY OF HEALTH
SINGAPORE

Stakeholder Consultation on the Healthcare Services (Nuclear Medicine Service) Regulations

Presented by Health Regulation Group

Ministry of Health

Jan 2023

Background

- Nuclear Medicine (NM) service, comprising NM Imaging, NM Therapy and NM Assay (in vivo pre-testing), was slated to be transited to the Healthcare Services Act (HCSA) over two phases.
- NM Imaging was transited under the HCSA in Phase 1 of implementation on 3rd January 2022. NM Therapy and NM Assay (in vivo pre-testing) will be transited in Phase 2 commencing in June 2023.
- This particular set of consultation slides will focus on the **regulatory requirements for new NM services** involving the administration of radiopharmaceuticals to patients (i.e. NM Therapy and NM Assay *in vivo* pre-testing).
- There will be no changes to the prevailing regulatory requirements for NM Imaging under Phase 1 of HCSA.
- However, the licensing framework will be refined for the full suite of NM services, including those whose license were transited during Phase 1 of the HCSA. Please refer to the set of slides titled "Transitioning from PHMCA to HCSA" for more information.

Agenda

Definition of ‘Nuclear Medicine Service’

- “Nuclear Medicine Service” means the service involving the use of radioactive substances (including radionuclides), administered to a patient for the purposes of therapy for any disease or condition, medical diagnosis or monitoring the effects of medical therapy.
  - *“nuclear medicine therapy service” means use of radioactive substances (including radionuclides), administered to a patient for the purpose of therapy for any disease or condition*
  - *“nuclear medicine imaging service” means the use of radioactive substances (including radionuclides), administered to a patient, for the purpose of medical diagnosis or monitoring the effects of medical therapy through the use of an imaging apparatus*
  - *“nuclear medicine assay in vivo pre-testing service” means use of radioactive substances (including radionuclides), administered to a patient with the intent to examine or test any matter derived from the body of the patient, following administration, for the purposes of medical diagnosis or monitoring the effects of medical therapy through the use of an assay*

Overview of Nuclear Medicine Service Regulations

- Regulatory requirements for NM Service have been **adapted from existing requirements** under the Standards for the Provision of Nuclear Medicine, Imaging, Therapy and Assay Services ("the NM Standards")[1] and the Healthcare Services (Nuclear Medicine Assay Service and Nuclear Medicine Imaging Service) Regulations 2021 ("the NMAISR")[2].

Section	Summary
A) Licensing Matters	Requirement to seek MOH's approval for the provision of different modes of service delivery or specified services.
B) Governance, Personnel and Processes	Requirement to appoint a qualified person as Clinical Governance Officer and Section Leader to oversee the service. Requirement of appropriate processes, as well as adequate qualified and competent personnel.
C) Safety Requirements	Requirements to have safety programmes covering matters including but not limited to radiation.
D) Facilities and Equipment	Requirements relating to the facilities and equipment used for the provision of services.
E) Resuscitation Requirements	Requirements for trained personnel, as well as the availability of drugs and equipment to provide essential life-saving measures.
D) Point-of-care (POC) Testing & Imaging	Requirements for the conduct of simple in-vitro diagnostic (IVD) tests and ultrasound imaging.
G) Reports and Documentation	Requirement for issuing of reports to patient or other healthcare providers. Requirement to ensure that all necessary information is documented and kept appropriately.
E) Financial Matters	Requirements for price transparency and financial counselling to ensure that adequate information is provided on charges and services which are expected to generate significant bills.

[1] This may be found at: https://www.moh.gov.sg/docs/librariesprovider5/licensing-terms-and-conditions/standards-for-the-provision-of-nuclear-medicine-services_28052019_final.pdf

[2] This may be found at: https://sso.agc.gov.sg/SL/HSA2020-S1039-2021/Uncommenced/20220102023843?DocDate=20211230&ValidDt=20220103

Modes of Service Delivery (MOSD) and Specified Services (SS) for NM Service

- NM Service may only be provided out of permanent premises (i.e. brick and mortar clinic, hospital or ambulatory care centre).
- There are no sub-services for NM Assay (in vivo, pre-testing) and NM Therapy
- The sub-services under NM imaging are in the table below:

	Permanent Premises	Temporary Premises	Conveyances	Remote
1) Nuclear Medicine Assay (in vivo, pre-testing)	✓	-	-	-
2) Nuclear Medicine Therapy[1]	✓	-	-	-
3) Nuclear Medicine Imaging[2] a) Planar nuclear medicine imaging and uptake studies b) Positron emission tomography-computed tomography c) Positron emission tomography-magnetic resonance d) Single-photon emission computed tomography computed tomography e) Single photon emission computed tomography	✓	-	-	-

[1]*Previously slated to be a special licensable healthcare service requiring an acute hospital or medical service as an underlying licence*

[2]*Currently a licensable service on its own and will be subsumed under the new NM Service. Each "imaging modality" will be considered as a distinct SS.*

Notification of new radiopharmaceuticals to be used for Nuclear Medicine Therapy

- **[NEW]** A licensee shall notify MOH of any **new radiopharmaceutical(s) to be used for NM Therapy** if the radiopharmaceutical(s) meet both the following criteria:
  - is produced in the licensee's in-house radiopharmacy laboratory (i.e. non-commercial product)
  - has not been approved by HSA

- The above applies even if:
  - the raw materials / active ingredients are HSA approved
  - a radiopharmaceutical of the same isotope has been previously notified to MOH (e.g. only ligand has been changed)

Clinical Governance Officer (CGO)

- *Adherence to the recommendations under "Physician-in-charge, or "Clinical Governance Officer" (paragraph 3.1) in the NM Standards and/or requirements in the current NMAISR (regulation 5) would generally satisfy these requirements*

- **A licensee must ensure that a CGO(s) is appointed for the provision of NM service** to provide clinical governance and technical oversight, and **MOH's approval must be sought** for the appointment

Qualification requirement for all SSes	**Experience requirement**
1. Medical practitioner registered as a specialist in nuclear medicine by the Singapore Medical Council under section 22 of the Medical Registration Act (Cap. 174); **OR**	**At least 5 years' qualifying experience* relevant to the service provided** ** For NM Physicians, "qualifying experience" means post-specialist registration clinical working experience in NM service for the particular SS. For Nuclear Cardiologists, it refers to post-CBNC certification working experience*
Qualification requirement applicable if providing NM Imaging for cardiac purposes only ("Nuclear Cardiology")	
1. Medical practitioner registered as a specialist in cardiology by the Singapore Medical Council under section 22 of the Medical Registration Act (Cap. 174) **AND** 2. Holding a valid certification in nuclear cardiology by the Certification Board of Nuclear Cardiology (CBNC), United States of America	

- CGO must also **hold a licence to use any radioactive material granted under section 5(1)(b) of the Radiation Protection Act** (Cap. 262)[1] (i.e. a L6 licence)
- The functions and duties of the CGO are detailed in Annex A.

[1] This may be found at: https://sso.agc.gov.sg/Act/RPA2007

Section Leader (SL)

- *Adherence to the recommendations under "Qualified persons" (paragraph 3.2) in the NM Standards and/or requirements in the current NMAISR (regulation 7) would generally satisfy these requirements*

- **A licensee must ensure that a SL(s) is appointed for the provision of NM service** to oversee the day-to-day operation on the ground**.** The requirements for the SL(s) are listed in the table below:

Qualification requirement for NM Imaging (as stipulated in Reg 7 of the current NMAISR)	**Experience requirement**
1. Diagnostic radiographer, 2. Radiation therapist or 3. Nuclear medicine technologist	**At least 3 years' qualifying experience* relevant to the service provided** **Qualifying experience" refers to clinical working experience in NM service for the particular SS post-specialist registration or as a fully registered Allied Health Professional (where applicable and relevant)*
[NEW] Qualification requirement if providing NM Therapy or NM Assay in vivo pre-testing	
1. Diagnostic radiographer, 2. Radiation therapist, 3. Nuclear medicine technologist, 4. Nuclear medicine physician or 5. Radiochemistry staff	

- The definition of each applicable personnel are detailed in Annex B.
- The functions and duties of the SL are detailed in Annex C.

Personnel

Adherence to the recommendations under "Personnel" (paragraphs 3.1 to 3.6) in the NM Standards, requirements in the current NMAISR (regulation 9 and 27) and/or licence conditions would generally satisfy these requirements

- A licensee must ensure that the minimum number and type of personnel (detailed in Annex D) has been employed or engaged to provide the service.
- A licensee must ensure that all personnel attended **appropriate training on radiation safety awareness** (e.g. in-house radiation safety training, basic radiation safety courses offered by Institutes of Higher Learning[1])
- A licensee must ensure that personnel who have **less than 3 years' relevant experience must be closely supervised** by the CGO or another personnel with not less than 3 years' relevant experience.

[1] Some courses may be found at: https://www.nea.gov.sg/programmes-grants/courses/sei/programmes

Quality Management System (QMS) – 1/2

Generally retained the recommendations relating to Quality Management Systems in the NM Standards, including "Quality Control for Radiopharmaceuticals", "Quality Control for Equipment" and "Quality Control for Environment/Facility", requirements in the current NMAISR (regulation 10) and/or licence conditions.

- A licensee must ensure that a **QMS is established and implemented** and provides for all the following:
  a) Measures to ensure that the **provision of the service complies with the Act and any other written law**
  b) Implementation of protocols for the physical safety of personnel, patients and visitors
  c) Identification of key performance indicators for assessing performance outcomes
  d) Implement **quality control measures for all equipment** used
  e) Implementing **quality control measures for all radioactive substances** kept and used
  f) Conducting **regular holistic analysis** and reviews of all information relating to the quality, safety and use of radioactive substances

Quality Management System (QMS) – 2/2

Generally retained the recommendations relating to Quality Management Systems in the NM Standards, including "Quality Control for Radiopharmaceuticals", "Quality Control for Equipment" and "Quality Control for Environment/Facility", requirements in the current NMAISR (regulation 10) and/or licence conditions.

- A licensee must ensure that a **QMS is established and implemented** and provides for all the following (continued):

  g) Testing and monitoring of the licensed premises

  h) Investigation of any occurrence or complaint that discloses or may disclose any **weakness or inadequacy affecting the quality** of service

  i) Identification and implementation of **appropriate and effective actions to prevent a recurrence**

  j) Maintaining **adequate and accurate documentation** on use of radioactive substances

  k) Conducting **regular risk assessments** of every activity conducted and, where necessary, the implementation of **appropriate measures to mitigate or manage the risks** identified in those assessments

Safety Requirements

- *Generally retained the requirements in the current NMAISR (regulation 13 and 14) and/or licence conditions.*

- Develop and maintain **accurate documentation for a radiation safety programme** that complies with any written law regulating the compounding, storage, possession and use of radioactive materials and irradiating apparatus
- Ensure that **staff comply with the radiation safety programme**
- Ensure the **availability of suitable and adequate radiation monitoring devices**, including dose calibrator(s) and radiation survey meter(s)
- Ensure **suitable and adequate radiation shields, primary and secondary containers for transportation** (within and outside the premises) of radioactive substances.
- Besides radiation safety, the safety programme should also cover other matters relating to the work environment such as **electrical and sharps management**.

Facilities and Equipment

Adherence to the recommendations under "Facilities and Equipment" (paragraphs 4.1 to 4.4) in the NM Standards, requirements in the current NMAISR (regulation 11 and 28) and/or licence conditions that are applicable to the provision of NM service would generally satisfy these requirements.

- A licensee must ensure that the licensed premises and all equipment used must be **safe**, and **suitable and adequate** for the proper and efficient provision of service in an **accurate and timely manner**.
  - Every procedure room complies with the requirements of, and is approved for use in accordance with, any written law regulating the storage, possession and use of radioactive materials and irradiating apparatus
  - **Appropriate radiation shielding** is provided where any procedures involving the use of radioactive substances or irradiating apparatus are performed
  - **Adequate, controlled and secured space** in relation to the compounding,, receipt, use, preparation, administration, storage and disposal of radioactive substances
  - **Separate waiting areas** with adequate capacity for the segregation of patients before and after administration of radiopharmaceuticals*
  - Adequate number of **toilets for the exclusive use of patients** after administration of radiopharmaceuticals*

* Currently being reviewed

Provision of Essential Life-saving Measures

- **[NEW]** When providing **patient-facing aspects of NM Service in a clinical area**, the licensee must ensure that **all registered healthcare professionals^ (HCPs)** should maintain valid certification* in Basic Cardiac Life Support (BCLS) and the use of Automated External Defibrillator (AED).

- For registered HCPs who are not medically fit to perform essential life-saving measures, they are still required to maintain valid BCLS and AED certification, but only for the theory component.
  - ‘Not medically fit’ refer to HCPs who are:
    a) Pregnant; or
    b) Medically certified as not fit to perform BCLS

- ‘Patient-facing aspects of NM Service in a clinical area refers to the entire premises, including the waiting area, but excludes administrative areas (e.g., administrative offices, lifts and walkways in large compounds such as in hospitals and national centres).

- As lead-time will be needed for the training of all registered HCPs in BCLS and AED, MOH will be providing a **3-year sunrise period** from 1st Jan 2024 for the implementation of this requirement (i.e., **enforcement will only commence from 1st Jan 2027**).

^Registered HCPs refer to registered medical practitioners, dentists, nurses, pharmacists and allied health professionals. In addition, MOH would also like to encourage all non-registered HCPs to be trained in Cardiopulmonary Resuscitation (CPR) and the use of AED.
**Validate certification in BCLS and AED should include both the theory and practical components*

Maintenance and Use of Resuscitation Drugs and Equipment

- *Retained the requirements for maintenance of resuscitation drugs and equipment in the licence conditions*

Resuscitation Drugs	Resuscitation Equipment
1. Aspirin; 2. Inhaled bronchodilator; 3. IV adrenaline; 4. IV antihistamine e.g. promethazine; 5. IV atropine; 6. IV steroid e.g. hydrocortisone; and 7. Sub-lingual nitroglycerine tablet or spray;	1. Age-appropriate oropharyngeal airways; 2. Appropriate device for drug delivery of inhaled bronchodilator; 3. Bag-valve mask; 4. Defibrillator; 5. Infusion set; and 6. IV Normal saline (0.9%) solution or IV 5% Dextrose saline solution.

- **[NEW]** All **registered medical practitioners should be trained in the use of resuscitation drugs and equipment** above.
  - To assist licensees in meeting the requirement, MOH will be **developing a course** to train doctors in the use of resuscitation drugs and equipment. More details on the course will be released when ready.
  - As lead-time will be needed for the development of the course and the training of doctors, MOH will be providing a **3-year sunrise period** from 1st Jan 2024 for the implementation of this requirement i.e. **enforcement will only commence from 1st Jan 2027.**

Conduct of POC Simple In-Vitro Diagnostic (IVD) tests*

- **[NEW]** A licensee may only conduct simple IVD tests **for his own patients during the course of providing an NM service** to that patient (e.g., POC blood glucose to monitor a patient's blood glucose prior to surgery; POC INR to measure a patient's coagulation parameters prior to surgery). A licensee who performs **testing of specimens beyond simple IVD tests** would be required to **hold the HCSA Clinical Laboratory Service licence** (e.g., Full blood count, renal and liver function tests).
  - ➢ Collection of specimens for all types of tests are allowed under the HCSA NM Service licence.

- **[NEW]** If the licensee requires the patient to perform **self-collection of specimens**, the licensee must provide the patient with instructions on how and when the specimen is to be collected, and precautions to be taken to avoid contamination and degradation of the specimen.

- **[NEW]** A licensee must ensure that any simple IVD test conducted must be —
  a) using testing material, where —
     i. the expiry date or shelf life of the testing material has not passed, whichever is earlier
     ii. the personnel who is administering the test does not suspect or have any reason to suspect that the testing material is no longer fit for use; and
  b) in accordance with the **instructions specified by the manufacturer** of the testing material.

- **[NEW]** A licensee must ensure that any testing material used to conduct any simple IVD test is **stored and handled** in the manner specified by the manufacturer so as to lower the risk deterioration due to unnecessary exposure to the environment.

- The use of simple IVD tests must also be in **compliance with the Health Products Act**.

** "simple in vitro diagnostic test" means an in vitro diagnostic test that is designed to return a test result without the need to interpret raw test data and requires —*
a) no specimen processing;
b) no more than 3 steps of analytical test procedures;
c) the use of self-contained reagent cartridges or strips or no precise measurement required for reagent preparation;
d) no specifications for a controlled testing environment for returning an accurate test result; and
e) only portable analysers with automated calibration, quality control and self-diagnosing malfunction features when used;

Conduct of POC Imaging

Ultrasound Imaging

- **[NEW]** A licensee may only conduct ultrasound imaging **for his own patients during the course of providing an NM Service** to that patient (e.g., abdominal ultrasound prior to treatment).

- **[NEW]** A licensee must ensure that any ultrasound imaging conducted on a patient is conducted by —
  a) A medical practitioner trained in the conduct of ultrasound imaging
  b) A dentist trained in the conduct of ultrasound imaging
  c) A radiologist
  d) A radiographer
  e) A sonographer

- **[NEW]** A licensee must **hold a HCSA Radiological Service licence** for the conduct of any other imaging modalities (e.g., plain X-rays, CTs, MRI). This applies even if the licensee is approved to provide a similar SS under the NM Service licence (e.g., PET-CT, PET-MRI).

Allowable Scope of Testing and Imaging

- **[NEW]** The table below summarises the scope allowed for POC testing and imaging:

	For licensee's own patients	For patients of other licensees
POC Simple IVD Tests	✓	**Not allowed** unless licensee also holds a HCSA Clinical Laboratory Service licence.
POC Ultrasound Imaging		**Not allowed** unless licensee also holds a HCSA Radiological Service licence.
Testing of Specimens beyond simple IVD tests	**Not allowed** unless licensee also holds a HCSA Clinical Laboratory Service licence.	
Other Imaging Modalities (e.g., X-ray, MRI, CBCT, CT)	**Not allowed** unless licensee also holds a HCSA Radiological Service licence.	

Healthcare Services (Clinical Laboratory Service and Radiological Service) Regulations 2021 can be found here: https://sso.agc.gov.sg/SL/HSA2020-S1036-2021?DocDate=20211230
Licence Conditions for HCSA Clinical Laboratory Service: https://www.moh.gov.sg/hcsa/resources

Reports to be Issued

Generally retained the requirements in the current NMAISR (regulation 34 to 40)

- A licensees must issue a report for:

  a) every examination conducted as part of NM imaging, and
  b) [NEW] every treatment cycle / dose administered as part of NM Therapy

- A licensee must ensure the following in relation to the issuance of reports:

  a) Only qualified personnel may issue reports
  b) Written reports must be provided to the requestor and/or any other relevant party(ies)[1]
  c) Reports must contain all relevant information (Annex E)
  d) All relevant results or findings that discloses that the patient's safety or wellbeing may be adversely affected without immediate medical treatment or intervention must be brought to the attention to the requestor and/or any other relevant party(ies)[1]
  e) All potentially clinically significant and abnormal incidental findings must be brought to the attention to the requestor and/or any other relevant party(ies)[1]
  f) All error(s) discovered in a report after being issued must be notified to the requestor and/or any other relevant party(ies)[1]. An addendum to the report to correct the error must also be issued.
  g) Processes to ensure that the issuance of reports are not affected by any disruption or maintenance (scheduled or otherwise) to the licensee's information system

[1] Other relevant party(ies) may include the patient, a medical practitioner designated by requestor, the healthcare institution that employs or engages the requestor or another medical practitioner not mentioned above depending on the service and scenario.

Documentation

Adherence to the recommendations under "Records (Documentation)" (paragraphs 6.6 to 6.8) in the NM Standards, requirements in the current NMAISR (regulation 44 and 45) and/or licence conditions would generally satisfy these requirements.

- A licensee must maintain proper, complete and accurate **quality control records** in respect of the following:
  - equipment used in the provision of the service;
  - radioactive substances used in the provision of the service;
  - personnel involved in the provision of the service
  - the licensed premises and facilities.
- A licensee must maintain proper, complete and accurate documentation of every programme, policy, system, measure, protocol or process, and the activities undertaken under them.

Price Transparency and Display of Charges

Adherence to the requirements in the current NMAISR (regulation 46 and 47) would generally satisfy these requirements.

- A licensee must, upon request by a requestor or patient, inform the requestor or patient of the following information:
  a) of the amount of each fee (including any administrative fee) that the licensee charges, or intends to charge, for the provision of service

- A licensee must ensure that the charges payable for the following components of service provided by the licensee are displayed or made available at the licensed premises where the service is provided (where applicable):
  a) radiopharmaceuticals and other consumables;
  b) imaging procedures;
  c) contrast fees;
  d) sedation procedures

Price Transparency and Display of Charges

- **[NEW]** A licensee must inform the patient or caregiver about the status of the **licensee's accreditation or participation in a public scheme**, where applicable. Public schemes include, but are not limited to:
  a) An approved institution for MediSave withdrawal;
  b) An approved institution for the purposes of the MediShield Life Scheme Act;
  c) An accredited clinic under the Community Health Assist Scheme (CHAS) or any other similar public scheme.

- **[NEW]** A licensee must **issue a bill** to the patient after the provision of NM Service, unless the patient declines.
  - In the event that a patient is able to tap on third party payors or government subsidies and ends up with zero out-of-pocket (OOP) payment, the licensee should still be able to generate a bill to list the services provided if the patient requests (a sample of such a bill can be found in Annex F). If the patient declines the bill as no payment is required, a bill does not need to be issued.
  - We understand that for TPAs, this may be a challenge due to contractual agreements and we will engage them separately on this.
  - If the bill cannot be generated instantaneously, it is acceptable for licensees to inform the patient of the delay and provide the bill at a later date as soon as available.

Financial Counselling for Nuclear Medicine Therapy[1]

- **[NEW]** A licensee must, as soon as reasonably practicable, conduct financial counselling (FC) to the patient or the patient's authorised representative on the fees chargeable for the treatment or procedure if the fee information is new to the patient, including where —
  - the patient is a new patient of the licensee;
  - the patient is advised by the licensee to undergo a new treatment or procedure; or
  - there is a change in the licensee's fees for the treatment or procedure that the patient is undergoing.

- **[NEW]** Financial counselling must include giving the patient or the patient's authorised representative all of the following information:
  - an estimated price or price range for the treatment of the patient's condition or the procedure that the patient undergoes or intends to undergo[2] (e.g., estimated facility charges, doctor's fees and other relevant fees);
  - the MOH fee benchmark (if available) for the same or similar treatment or procedure[3].
  - the estimated MediSave withdrawal limits and coverage by MediShield Life[4].

- **[NEW]** A licensee must record all financial counselling that is conducted for any patient, and obtain the written acknowledgement of the patient or the patient's authorised representative upon the completion of the financial counselling (see Annex G for a sample of the financial counselling form for doctors' fees that can be used).

[1] *There is no need to conduct FC for any NM Imaging and NM Assay SSes*

[2] *If there are services that may span across different settings (e.g. patient is jointly seen by a Medical Service licensee), both the Medical Service licensee and the NM licensee should conduct FC for their respective services, and it is encouraged for the NM service provider to check if FC had been done by the Medical Service licensee upon consultation of the patient.*

[3] *MOH Fee Benchmarks can be found here: https://www.moh.gov.sg/cost-financing/fee-benchmarks-and-bill-amount-information. Today, there are no fee benchmarks published for NM Therapy procedures.*

[4] *Licensees are required to share MediSave withdrawal limits and MediShield Life coverage even if the coverage is nil.*

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The End

Thank you

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Annexes

Annex A: Functions and Duties of Clinical Governance Officer (CGO)

- The functions and duties of a CGO are prescribed in HCS (General) Regulation 15 and they are:
  a) to provide clinical governance and technical oversight over the licensable healthcare service;
  b) to assist the licensee in the day-to-day management of the clinical and technical aspects of the licensable healthcare service;
  c) to ensure the implementation and regular review of policies and systems for clinical governance, clinical risk management, effective quality management systems and any other clinical and technical related matters, so as to detect and address in a timely manner any risks affecting the safety and welfare of, or the continuity of care provided to, patients;
  d) to ensure that any weakness or inadequacy related to any clinical or technical aspect of the licensable healthcare service is promptly identified and remedied, including informing the licensee of the weakness or inadequacy, and proposing and implementing measures to prevent the recurrence of the weakness or inadequacy;
  e) to ensure that the licensee's personnel involved in the clinical or technical aspect of the licensable healthcare service comply with the appropriate policies and processes concerning clinical and technical standards;
  f) to ensure that there is close supervision, adequate training and regular competency assessments of the licensee's personnel involved in the clinical or technical aspect of the licensable healthcare service, to enable them to perform their work effectively and safely;
  g) to immediately notify the licensee of any matter within the Clinical Governance Officer's purview that may affect compliance of any licence condition applicable to the licensable healthcare service.

Annex A: Functions and Duties of Clinical Governance Officer (CGO)

- Additional functions and duties of a NM Imaging CGO are currently prescribed in HCS (Nuclear Medicine Assay Service and Nuclear Medicine Imaging Service) Regulation 6 and they are:
  a) overseeing the conduct of examinations under the nuclear medicine imaging service by a licensee;
  b) ensuring that the examinations are conducted in accordance with the correct methods and procedures for those examinations;
  c) implementing and overseeing a radiation safety programme to ensure the safety of personnel and patients and other individuals within or in the vicinity of the licensed premises of used by the licensee, including the proper handling, use and disposal of radioactive substances; and
  d) evaluating new processes the licensee intends to implement for the provision of the applicable service, including processes relating to the preparation, dispensing, radiolabelling, compounding and quality control of radiopharmaceuticals.
  e) evaluating any service modality that the nuclear medicine imaging licensee intends to provide as part of that service

- The additional functions and duties of a NM Therapy and NM Assay in vivo pre-testing CGO will mirror that of the NM Imaging CGO listed above but in relation to the conducting of "treatment" or "pre-test procedures[1]" respectively (instead of "examinations").

[1] *"Pre-test procedures" refers to the processes (1) relating to the preparation, dispensing, radiolabelling, compounding and quality control of radiopharmaceuticals, (2) the administration of radiopharmaceuticals, (3) the extraction of specimen from the patient and (4) transportation of specimen to testing site.*

Annex B: Applicable Personnel as Section Leader (SL)

- “diagnostic radiographer” means a duly qualified allied health professional who is registered under the Allied Health Professions Act 2011 to practise radiography;
- “duly qualified allied health professional” has the meaning given by section 3 of the Allied Health Professions Act 2011;
- “nuclear medicine physician” means an individual registered under section 20(1) or (2) of the Medical Registration Act as a medical practitioner, and section 22 of the Medical Registration Act 1997 as a specialist in the branch of nuclear medicine;
- nuclear medicine technologist” means an individual who holds at least a diploma or degree in nuclear medicine technology;
- “radiation therapist” means a duly qualified allied health professional who is registered under the Allied Health Professions Act 2011 to practise radiation therapy;
- “radiochemistry staff” means an individual who holds at least a diploma or degree or in chemistry, radiochemistry, pharmaceutical sciences or equivalent

Annex C: Functions and Duties of Section Leader (SL)

- The functions and duties of a NM Imaging SL are currently prescribed in HCS (Nuclear Medicine Assay Service and Nuclear Medicine Imaging Service) Regulation 8 and they are to:
  a) assist the relevant Clinical Governance Officer in the day to day technical management of that service modality;
  b) supervise, train and guide personnel in conducting examinations in the provision of that service modality;
  c) assess and ensure the competency of personnel deployed to perform tasks in relation to the provision of that service modality;
  d) evaluate any equipment before it is used in the provision of the applicable service;
  e) monitor the performance of all examinations conducted under that service modality, including ensuring the implementation of quality control measures;
  f) establish and review policies and procedures for the safe and effective performance of all examinations conducted in the provision of that service modality;
  g) resolve any technical issues that arise from the performance of all examinations conducted in the provision of that service modality;
  h) review all service records in relation to the examinations conducted in the provision of that service modality.

- The additional functions and duties of a NM Therapy and NM Assay in vivo pre-testing CGO will mirror that of the NM Imaging SL listed above but in relation to the “radiopharmaceutical processes[1]” or “pre-test procedures[2]” respectively (instead of “examinations”).

[1] ”Radiopharmacetical processes” refers to the processes relating to the preparation, dispensing, radiolabelling, compounding and quality control of radiopharmaceuticals

[2] “Pre-test procedures” refers to the processes (1) relating to the preparation, dispensing, radiolabelling, compounding and quality control of radiopharmaceuticals, (2) the administration of radiopharmaceuticals, (3) the extraction of specimen from the patient and (4) transportation of specimen to testing site.

Annex D: Minimum Personnel for NM Service

- Licensees shall ensure that they have <u>at least one</u> personnel from rows 1 to 5 in the table below.

S/N	Personnel	Remarks
1	Nuclear medicine physician (or nuclear cardiologist if applicable)	Can be the CGO
2	Diagnostic radiographer, nuclear medicine technologist or radiation therapist	At least 3 years of work experience
3	Radiation physicist - individual who has a degree in physics	At least 3 years of work experience
4	Registered nurse - as defined in section 2 of the Nurses and Midwives Act 1999	Must be deemed competent by the CGO in matters relating to patient care Must be deemed competent by the licensee or RSO in matters relating to radiation safety
5	Radiation Safety Officer* (RSO) To be further updated	The RSO need not be a full time job appointment

Annex E: Information to be Included in Reports

S/N	NM Imaging	NM Therapy
1	the name and address of the licensee* issuing the report, and the business name (if different from the name of the licensee) by which the licensee provides the applicable service *where the licensee is an individual, the business name and address will suffice	
2	all of the following identifying information: i. the patient's name; ii. the patient's identification number or passport number; iii. where the information in sub-paragraphs (i) and (ii) is not known to the licensee — other information identifying the patient;	
3	the address of the licensed premises in which the treatment or examination is conducted;	
4	the date the treatment or examination is conducted	
5	the date and time the report is issued	
7	the name of the requestor or prescribing medical practitioner	
6	the name and signature (including an electronic signature) of the qualified person certifying the report of the treatment or examination	
8	the description and findings of examination	the description of the treatment which minimally includes; i. name of radiopharmaceutical administered ii. dose of radiopharmaceutical administered
9		any further actions required with regard to the treatment of the patient

Annex F: Sample of $0 Bill

Consultation	**$WW**
Medications	$XX
Investigations	$YY
Others	$ZZ
Govt Subsidy/TPA reimbursement	- $AA
Total Amount Payable	**$0.00**

Annex G: Sample Financial Counselling Form* for Doctor's Fees

DOCTORS' FEES FINANCIAL COUNSELLING FORM (To be conducted by Doctors not employed by hospital)

A copy of this form must be given to the patient and a copy kept in the hospital/ clinic's patient medical records.

Name of Patient	NRIC/FIN No
A. Details of Hospitalisation	
Name of Principal Doctor and Clinic	Name of Hospital/Surgery Centre
Date of Admission	Est. Length of Stay (No. of days)
Provisional Diagnosis	
TOSP Code(s) with description	

B. Best Estimated Costs	Estimated Fee Range *(S$)*	MOH Fee Benchmarks^ *(Without GST)*
1. Total Professional Fees Breakdown as:	.....	.....
a) Primary Surgeon b) Assistant Surgeon / Surgical Nurse	.....	.....
c) Anaesthetist fees	.....	.....
d) Other Doctor(s)	.....	.....
2. Total Attendance Fees	.....	.....
3. Total of Other Fees (Please specify): Breakdown as: a) b) c)	....	
4. GST^	.....	
TOTAL	.....	

^Where applicable

MOH Fee Benchmarks is a reference for reasonable fee range for routine and typical cases, published by Ministry of Health. Doctors may charge outside of the Fee Benchmarks with valid justification and should inform the patient and the insurer (where applicable). Insurers may use the Fee Benchmarks to assess if the claim is reasonable. More information can be found on www.moh.gov.sg/billsandfees.

C. Acknowledgement	
..... **Name & Signature of *Doctor / Clinic Staff and Date**	..... **Name & Signature of *Patient / Next-of-Kin and Date**

*To delete where appropriate

**The use of this financial counselling form for doctor's fees is suggested but not mandatory.*