MINISTRY OF HEALTH
SINGAPORE

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

Presented by Health Regulation Group

Ministry of Health

April 2021

Agenda

Objectives

This presentation will highlight:

1. **Who** the Nuclear Medicine ("NM") Assay Service Regulations apply to under the Healthcare Services Act ("HCSA")

2. **What** the key changes are for the provision of nuclear medicine assay service under the HCSA, from the existing requirements under the Standards for the Provision of Nuclear Medicine, Imaging, Therapy and Assay Services ("the NM Standards") [1]

[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

HCS Regulations

- In developing HCSA requirements for NM assay service, MOH has reviewed and adapted the existing PHMC Regulations and the NM Standards, in consultation with the NM Advisory Committee

- Regulations are structured into **General Regulations, Advertisement Regulations** and **Service-specific Regulations**

  - **General Regulations and Advertisement Regulations**: General requirements broadly applicable to **all licensees**

  - **Service-specific Regulations**: Unique requirements contextualised to each service or stipulate specific requirements articulated in the General Regulations

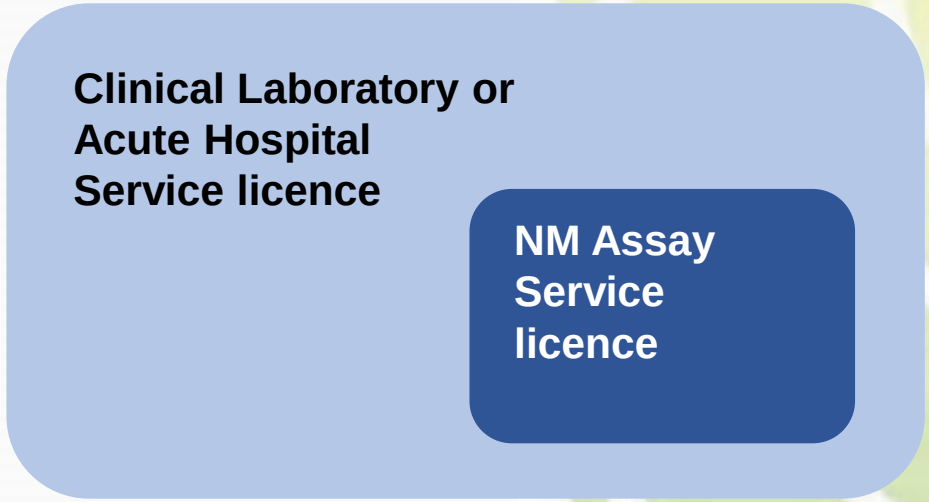
HCS Regulations

Updated on 24 Aug 2021

NM assay service is a Phase 1 **special licensable healthcare service**, with the required underlying licence being a Clinical Laboratory **or** Acute Hospital service licence.

NM assay service licensees must comply with:

- General Regulations;
- Advertisement Regulations;
- Clinical Laboratory or Acute Hospital Service Regulations; **and**
- NM assay service Regulations



[NEW] The Acute Hospital service licence has been added as an underlying licence to the NM Assay service licence, to cater for institutions conducting in-vivo aspects of NM Assay. However, the Acute Hospital service licence will be implemented in HCSA Phase 2. Licensees will be informed of the updated timelines for Phase 2 and 3 in due course.

HCS Regulations

Updated on 24 Aug 2021

- The General Regulations, Advertisement Regulations, Clinical Laboratory service Regulations, and the NM assay service Regulations will be **published by the end of 2021**.
- Licensees must comply with the abovementioned Regulations from **3 January 2022**.
- Regulations **will be complemented with:**
  - **LTCs** that set out specific technical requirements to be met
  - **FAQs** which will help licensees interpret specific requirements that further elaboration is needed on
- Requirements that are “new” or “enhanced” compared to the existing NM Standards are highlighted as such

Requirements under the NM Assay Service Regulations

Updated on 24 Aug 2021

A. General obligations of licensee [NEW]

- Suitability of licensed premises and equipment
- Number and suitability of personnel

B. Governance and personnel

- Skills and competencies of Clinical Governance Officer
- Duties and responsibilities of Clinical Governance Officer [NEW]
- Staff involved in provision of NM assay service [ENHANCED]

C. Facilities and equipment

D. Systems and Committees

- Quality Management System
- Safety requirements for NM assay service

E. Documentation

These requirements apply in addition to the underlying requirements in the Clinical Laboratory or Acute Hospital* Service Regulations 2021

*The Acute Hospital service license will only be implemented in HCSA Phase 2

[NEW] General obligations of licensees to meet intended outcomes

General obligations of licensees

To set out overarching principles or outcomes that licensees should meet

- Licensees must ensure that these general obligations are met at all times in the provision of NM assay service:
  - The **licensed premises and equipment** installed or available are **suitable** for the provision of the service; and
  - There is an **appropriate number of personnel who are qualified, trained and hold the necessary credentials**

  to provide the service in a **safe, timely, accurate and effective** manner.

- Details of certain core technical requirements which are necessary to meet the outcomes will be stipulated in accompanying Licensing Terms and Conditions.

Clinical Governance Officer (CGO) [1/3]

Skills and competencies of CGO

To provide clinical and technical oversight of technical and complex services by a qualified person

- **CGO is required for NM assay service under the HCS (General) Regulation 15**
  - Supervises the provision of NM assay service
  - No change from the minimum personnel requirements for a physician-in-charge / CGO under paragraph 3.1 of the NM Standards
- **CGO is required to meet the following qualification <u>AND</u> experience requirements:**

Qualification requirement	Experience requirement
a) Medical practitioner registered as a specialist in nuclear medicine by the Singapore Medical Council under section 22 of the Medical Registration Act (Cap. 174); **<u>OR</u>**	**Not less than 5 years' qualifying experience*** in the provision of the service **Qualifying experience" means 5 years of post-specialist registration clinical working experience in NM assay service*
b) Medical practitioner who holds any other registration or qualification as DMS considers appropriate	

- 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)

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

[NEW] Clinical Governance Officer (CGO) [2/3]

Updated on 24 Aug 2021

Duties and responsibilities of a CGO

To specify specific duties and responsibilities of the CGO to increase regulatory clarity on how the CGO can ensure proper clinical governance

- **Set and implement appropriate policies** of the licensee for the safe and ethical provision of the service
- **Oversee tests** conducted or provided by the licensee, and the proper execution of the methods and procedures for those tests/ examinations
- **Ensure that only competent and trained staff carry out any activity** involving the use of any radioactive substance
- Assist the licensee in **ensuring operational and regulatory compliance** with all applicable requirements
- **Ensure the proper storage and maintenance of all materials, equipment and appliances** used for the diagnosis of patients and the provision of the applicable service
- **Implement and oversee a radiation safety programme**

[NEW] Clinical Governance Officer (CGO) [3/3]

Duties and responsibilities of a CGO

To specify specific duties and responsibilities of the CGO to increase regulatory clarity on how the CGO can ensure proper clinical governance

- **Evaluate new tests** to be conducted or provided, or **new processes** to be implemented
- **Supervision of staff** and ensuring:
  - Staff compliance to the clinical and technical standards as well as policies and procedures
  - Only competent and trained staff carry out any activity involving the use of any radioactive substance
  - Staff undergo continuing training and education
- Ensure that all **materials, equipment and appliances are properly kept and maintained**

[ENHANCED] Personnel

Staff involved in provision of applicable service

Expanded requirements on personnel to ensure the licensee's safe provision of service

Adherence to the recommendations under "Personnel" (paragraphs 3.1 to 3.6) in the NM Standards would generally satisfy these requirements

- An **adequate number of staff, with the necessary qualifications having regard to the type and nature of the work**, must be employed or engaged to safely provide the service
- Ensure that all staff attended **appropriate training on radiation safety awareness**
- Staff member who has **less than 3 years' relevant experience must be closely supervised** by the CGO or another staff member with not less than 3 years' relevant experience.
  - For an individual who is a professional registered under a professional regulatory Act, the conditional registration period, where applicable, will count towards the relevant experience

Requirements on facilities and equipment

Updated on 24 Aug 2021

Facilities and equipment

To ensure that service is provided in a safe and suitable environment, using appropriate equipment

Adherence to the recommendations under "Facilities and Equipment" (paragraphs 4.1 to 4.4) in the NM Standards that are applicable to the provision of NM assay service would generally satisfy these requirements

- 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**.
  - **Appropriate radiation shielding** is provided where any laboratory procedures involving the use of radioactive substances are performed
  - **Adequate, controlled and secured space** in relation to the compounding, procurement, receipt, use, preparation, administration, storage and disposal of radioactive materials
  - **Separate waiting areas** with adequate capacity for the segregation of patients before and after administration of radiopharmaceuticals [REQUIREMENT TO BE CONFIRMED]
  - Adequate number of **toilets for the exclusive use of patients** after administration of radiopharmaceuticals

Quality Management System (QMS) [1/2]

Quality Management System

Ensuring safety and quality of radioactive materials, equipment and the environment/ facility

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"

- **Investigation** of any occurrence or complaint that discloses or may disclose any **weakness or inadequacy affecting the quality** of service
- Identification and implementation of **appropriate and effective actions to prevent a recurrence**
- Audit of the provision of the service
- Implementing **quality control measures** for all radioactive materials kept and used, including safe and proper handling of radioactive materials
- **Accurate and timely reporting** of radioimmunoassay results
- Maintaining **adequate and accurate documentation** on use of radioactive materials
- Conducting **regular/ periodic analysis** and reviews of information relating to the quality, safety and use of radioactive materials

Quality Management System (QMS) [2/2]

Ensuring safety and quality of radioactive materials, equipment and the environment/ facility

Generally retained the recommendations relating to Quality Management Systems in the NM Standards ("Quality Control for Radiopharmaceuticals", "Quality Control for Equipment" and "Quality Control for Environment/Facility")

- Implementing **quality control measures for all equipment** used
- **Testing and monitoring of the licensed premises**

Safety requirements for applicable service

To build upon and contextualise radiation safety requirements under the Radiation Protection Act for NM assay service

- Develop and maintain **accurate documentation for a radiation safety programme** that complies with any written law regulating the storage, possession and use of radioactive materials
- Ensure that **staff comply with that radiation safety programme**
- Ensure the **availability of suitable and adequate radiation monitoring devices**, including radiation survey meter(s)
- Ensure **suitable and adequate radiation shields, primary and secondary containers for transportation** (within and outside the premises) of radioactive materials.

Documentation requirements for applicable service

To ensure proper, complete and accurate documentation relating to quality control of the service

Adherence to the recommendations under "Records (Documentation)" (paragraphs 6.6 to 6.8) in the NM Standards would generally satisfy these requirements.

- Maintain proper, complete and accurate **quality control records** in respect of the following:
  - equipment used in the provision of the service;
  - Radioactive materials used in the provision of the applicable service;
  - the licensed premises.
- Ensure **appropriate and adequate documentation** of policies, processes and programmes

Share your feedback with us by 7 May 2021

https://go.gov.sg/hcsa-nm-assay-feedback

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MOH will provide more information along the way

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The End

Thank you

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