



MINISTRY OF HEALTH
SINGAPORE

Stakeholder Consultation for Healthcare Services (Radiological Service) Regulations

Presented by Health Regulation Group
Ministry of Health
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Introduction

- Under the Healthcare Services Act (HCSA), 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 stipulates specific requirements articulated in the General Regulations.
- This presentation gives an overview of the **service requirements** that will apply to Radiological Service providers under HCSA.
 - Most of the requirements have been ported over from the requirements under PHMCR regulations 47 to 56.
 - Technical requirements (e.g. specific requirements for Computed Tomography, Magnetic Resonance Imaging and Cone Beam CT) will be stipulated in the Licensing Terms and Conditions (LTCs).

Requirements under Radiological Service Regulations

A. Licensing matters

- Service modalities provided under licence
- Notice to add new service modality

B. Governance and personnel

- Skills and competencies of Clinical Governance Officer **[NEW]**
- Duties and responsibilities of Clinical Governance Officer **[NEW]**
- Staff involved in provision of radiological service

C. Facilities and equipment

D. Service Provision

- Provision of radiological service to patients upon referral and prescription
- Radiological examination
- Radiological findings and report
- Outsourcing of radiological examination and report
- Price transparency **[NEW]**

E. Systems and Committees

- Quality Management System **[ENHANCED]**
- Safety programme

F. Keeping of records

Definition of “Radiological Service”

“Radiological service” means the use of ionising or non-ionizing radiation for any of the following purposes:

- (a) examination of the body, or any matter derived from the body, of an individual;
- (b) assessment of the health or condition of an individual;
- (c) observation, diagnosis and intervention of a disease, disability or condition or an injury of the body or mind of an individual;
- (d) provision of care for an individual;
- (e) determining, predicting or providing a prognosis of the health or condition of an individual;

Licensing Matters



Service modalities provided under licence and notice to add new service modality

- Licensee must specify in the licence application every service modality the licensee provides or intends to provide.

Service modalities

- Plain X-rays
- Bone densitometry
- Mammography
- Fluoroscopy
- Computed Tomography (“CT”)
- Cone Beam CT
- Ultrasonography
- Magnetic Resonance Imaging (“MRI”)

- Licensees shall inform the Director of their intention to provide additional modalities not indicated at the application at least **one month before provision of the additional modality.**
 - Licensees should not commence with provision of the additional modality until the modality is reflected on the licence.

Governance and Personnel



Layers of governance required

Personnel	Responsibilities	Who can be appointed
Licensee	The licensee is responsible and accountable for overall compliance with HCSA.	Licensee can be a corporation (e.g. the company that owns the Radiological Laboratory Service) or an individual (e.g. CEO of the company). Implications to be considered: the licensee is liable and responsible for non-compliance found/reported (e.g. fine for corporation; fine and/or jail for individual).
Key Appointment Holders	Responsible for the strategic leadership and general management oversight of the licensable service.	Board of Directors For subsidiaries of a corporate entity without their own Board of Directors, e.g. radiological laboratory services in a hospital cluster, the Board of Directors of the owner corporate entity are the KAHs of the subsidiaries.
Principal Officer	Oversees day-to-day management of the licensee and ensures operational compliance with HCSA.	e.g. CEO or COO for larger set-ups, or Lab Manager for smaller set-ups
Clinical Governance Officer	Responsible for technical oversight and implementation of complex services that require specialised expertise.	e.g. diagnostic radiologist
Section Leader	Provides technical oversight of the service modality on the ground .	e.g. radiographer

To ensure oversight of technical aspects of the service by a CGO with specialised expertise

- A Clinical Governance Officer must —
 - a) be registered under section 22 of the Medical Registration Act as a specialist in the branch of diagnostic radiology; and
 - b) has at least 5 years' post-specialist working experience relevant to the scope of the service provided.

- Under special circumstances, Director's approval may be granted to an individual who may not meet the CGO requirement, based on the following principles:
 - Nature of radiological imaging discipline/modality;
 - Patient safety risk;
 - Holistic assessment on the scope of services provided;
 - Relevance of the individual's qualifications, training and experience in fulfilling the duties and responsibilities of a CGO with regard to the scope of services.

[NEW] Duties and responsibilities of the CGO

- Duties of the CGO include:
 - a) assisting the licensee in promoting safe, ethical and appropriate practices in the provision of the applicable service;
 - b) setting and implementing appropriate policies of the licensee for the safe and ethical provision of the applicable service.

[NEW] Duties and responsibilities of the CGO

- The CGO is responsible for —
 - Providing **clinical governance and technical oversight** of the service including overseeing and implementing policies, processes and programmes;
 - Assisting the licensee in the **day-to-day technical management** of service by supervising the operation of the service and to ensure compliance to the various rules and regulations;
 - Ensuring the **implementation and regular review of systems** for clinical governance, risk management and quality management in order to detect and address, in a timely manner, any risks affecting the safety and welfare of, and the continuity of care provided to patients.
 - Ensuring any **weakness or inadequacy in the service** is promptly addressed and remedied;
 - **Evaluating every new service modality** before its implementation;
 - Establishing and implementing policies and procedures for **compliance** by the personnel, and ensuring that personnel comply with them;
 - Ensuring that there is **close supervision and continuous competency assessment** of the personnel in the performance of their work;
 - Ensuring that the personnel receive radiological **training** that is adequate for personnel to acquire the skills to perform their work and ensure safety;
 - Ensuring the implementation of **safety programme**.

To ensure staff providing care are qualified, competent and adequate

- Licensee must ensure that **the number and competency** of staff can support the service, **commensurate with the scale and complexity of the service**.
 - E.g. licensee must employ an adequate number of staff with the relevant qualifications and competencies to assist the licensee in providing the applicable service in a safe manner; and
 - ensure that every staff member has relevant professional registration if applicable.
- Staff that meet the relevant qualifications but are newly registered, on conditional registration or otherwise lack significant relevant working experience (i.e. 2 year or less) shall work only under the close **supervision** of any staff with at least 3 years of relevant working experience.
- Licensee must ensure that every service modality is overseen by a **Section Leader** (also known as trained person under PHMCA), who has relevant qualifications and at least 3 years of relevant working experience providing the specific service modality.
 - E.g. CGO is the diagnostic radiologist and Section Leader is the radiographer

To ensure staff providing care are qualified, competent and adequate

A licensee must ensure that every staff member —

- (a) is adequately trained for the work performed by the staff member and attends regular training in accordance with a continuing training programme;
- (b) has the relevant awareness and knowledge of, and attends regular training on, radiation safety; and
- (c) is assessed periodically on the staff member's competencies and work performance.

Facilities and Equipment



Facilities and equipment

To ensure that patients receive care in a safe and suitable environment, using appropriate equipment

The premises and equipment are suitable, safe and adequate for the proper and efficient performance of examinations with accuracy, timeliness and safety.

- Proper segregation of waiting area accessible by public with patient/procedure areas.
- All equipment, appliances and materials used must be properly maintained and checked to ensure that they operate normally and accurately at all times.
- Adequate storage space is provided, and secured, with measures put in place to prevent any damage or deterioration of the supplies in the storage space.
- Appropriate equipment is provided for use in the sedation of patients before any procedure and in the monitoring of patients after sedation.
- Appropriate resuscitation equipment and drugs are provided to deal with any emergency arising from the intravenous administration of contrast agents to patients or to treat any adverse reaction.
- Adequate decontamination facilities and equipment.

Provision Of Radiological Services



Provision of radiological services to patients upon referral and prescription

- Licensee can conduct a radiological examination for a patient only if
 - the patient is **referred** to the licensee by a medical practitioner or dentist; and
 - that radiological examination is **prescribed** by the medical practitioner or dentist.
- Exception: Where a licensee provides radiological services to licensee(s) approved under the Collaborative Prescribing framework (e.g. the radiological facility is part of the hospital, or in a contractual arrangement to provide radiological services to the hospital), the licensee can also conduct radiological examinations prescribed by a healthcare practitioner (e.g. nurse or pharmacist) credentialed as a Collaborative Prescribing Practitioner.
- For walk-in patients without the above referral, the licensee must either
 - i. refer them to a registered medical practitioner or dentist, or
 - ii. have a medical practitioner or dentist on-site to review the patient's case and provide the patient with medical counselling on the implications of the test results (including abnormal results)
 - iii. if necessary, the licensee must refer the patient to another medical practitioner for follow-up medical advice or treatment, e.g. due to abnormal results.

Patients should receive safe and good quality service

- A radiological examination is conducted by, or under the supervision of, a diagnostic radiologist.
- There are safeguards in place to ensure radiological examinations are conducted on the correct patient, and correct part of the body or the site of the body part as prescribed by a medical practitioner or dentist.

Protection against radiation exposure

Licensees should have safeguards to sufficiently protect persons against radiation exposure:

- Protocols in place to ensure that patient radiation exposure is kept “As Low As Reasonably Achievable”;
- Safety measures in place to protect any other person against exposure to radiation;
- Enhanced safeguards pertaining to individuals with higher radiation exposure risks:
 - a) For performing ionising radiological procedures on pregnant women or women suspected to be pregnant;
 - b) To protect pregnant staff against radiation exposure; and
 - c) To ensure the use of paediatric-appropriate practices and parameters when preparing for imaging of paediatric patients

Administration and use of contrast agents

To ensure the appropriate and safe use and administration of contrast agents:

- Administration and use of the contrast agent is in accordance with safety protocols;
- The contrast agent is administered only by a staff member who has attended adequate and appropriate training and assessed by the licensee to be competent to administer it;
- Immediate access for resuscitation measures, where it is necessary;
- Trained and qualified staff to provide resuscitation measures in cases of emergencies; and
- Records of the contrast agent received by the patient.

Administration of sedation/ anaesthesia

Licenseses to implement policies and procedures for safe management and use of sedation or anaesthesia:

- The administration and use of the anaesthesia or sedative is in accordance with safety protocols
- An appropriate monitoring device is available for use during the administration of the anaesthesia or sedative to the patient;
- The patient's vital signs are monitored during the administration of the anaesthesia or sedative and for an appropriate period after such administration;
- A record of the administration of the anaesthesia or sedative to the patient;
- A documented policy for the discharge of patients who have been sedated/ anaesthetised

Radiological findings and reports

- **Licensee must ensure that a radiological report is issued for every radiological examination conducted for a patient for diagnostic purpose.**
- **Radiological test findings are interpreted and reported by a qualified person**
 - A diagnostic radiologist, who is trained in the type of radiological examination
 - A medical practitioner who has attended such training in the type of radiological examination that is acceptable by the Director
 - A dentist, for dental radiology.
- Radiological reports must contain the following information
 - name and address of the licensed radiological service issuing the report; or in the case of conveyance, the vehicle number as well;
 - the patient's name and national registration identity card number or passport number;
 - date of the radiological examination;
 - name of the medical practitioner who requested the test;
 - description and findings of the radiological examination;
 - records of the administration of any medication and / or contrast agent;
 - date and time the report is issued;
 - name and signature of the reporting person.

Radiological findings and reports (continued)

- Licensee must implement appropriate processes to ensure the **prompt review and return of all radiological findings, normal or otherwise**, to the healthcare practitioner who ordered the test for the patient, or if the referring practitioner has authorised another healthcare practitioner to receive the findings – that other healthcare practitioner as the case may be.
- Licensee must implement processes to identify and bring to the attention of the healthcare practitioner who ordered the examination any **abnormal or incidental findings** in the radiological report.
- If a licensee discovers any **error** in a radiological report after it is issued, the licensee must immediately notify the referring practitioner of the error and issue an addendum to the report.
- If it is necessary for a copy or reproduction of a radiological report issued by a licensee to be made, the licensee must ensure that the report is copied or reproduced in its entirety.

Outsourcing of radiological reporting

- Where outsourcing of **radiological examination** is performed, the outsourced entity must hold a valid radiological service licence under the Act.
- Where outsourcing of **radiological reporting** is performed, the licensee has processes in place to ensure the quality of radiological reporting:
 - the reporting must be interpreted and issued by a diagnostic radiologist.
- Licensee must implement protocols to ensure accurate and complete transmission of imaging data at the transmitting and receiving sites appropriate to the scope of examinations being performed.
- **Licensees are accountable and responsible for any outsourced services.**

[NEW] Display of common charges and bill itemisation

Patients are provided with accurate information about charges for price transparency to make informed choices

- Base requirements are stipulated in HCSA General Regulations Section 32-34 Price Transparency (please refer to the consult materials for General Regulations).
- Additional service-specific requirements:
 - Common charges to display must include:
 - Imaging procedures;
 - Contrast fees; and
 - Consumables
 - Broad categories of itemised billing:
 - Imaging fees;
 - Sedation fees;
 - Total fees.

Systems



[ENHANCED] Quality Management System

To establish an effective Quality Management System (QMS) for the purpose of quality assessment and assurance of the safe delivery of the service

- **[ENHANCED]** The licensee shall **establish and implement a QMS** to provide for the following:
 - Investigation of any weakness or inadequacy affecting the quality of the service;
 - Identification and implementation of actions to address any weakness or inadequacy;
 - Auditing the provision of the service;
 - Implementing quality control measures for equipment;
 - Implementing quality control measures for diagnostic images;
 - Implementing systems and processes to ensure the prompt review and return of all radiological findings.
- **[ENHANCED]** The QMS is updated periodically and reviewed annually for effectiveness.

Safety Programme

- A licensee must develop and implement a safety programme setting out appropriate and effective safety measures to prevent the occurrence of any adverse incident.
- Licensee should include the following for their safety programme:
 - a) Radiation safety programme;
 - b) Waste management;
 - c) Electrical safety;
 - d) Safety of water supply and outlets;
 - e) Safety of equipment;
 - f) Handling and disposal of sharp apparatus and objects which can readily puncture or cut human skin when encountered;
 - g) Ensure every staff is provided with personal protective equipment appropriate for the work assigned;
 - h) Ensure adequate number of first-aid kits for emergency use and are readily accessible.
- Licensee must ensure that every staff member complies with the safety programme.

Keeping of records



Keeping of records

- Licensee must maintain proper, complete and accurate records in respect of the following:
 - (a) competencies of and training attended by staff;
 - (b) quality management activities and measures implemented;
 - (c) safety measures implemented;
 - (d) every radiological image issued by the licensee. The imaging record must contain all the following information:
 - (i) The date, time and type of radiological examination;
 - (ii) The name of the person who conducted the radiological examination;
 - (iii) The name of the person who reported and issued the radiological report;
 - (iv) The radiological image(s) from the radiological examination.
- Licensee must ensure confidentiality, integrity and security of all records is maintained.

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The End

Thank you

