

# HCS Clinical Laboratory and Radiological Service Regulations

## FAQs for Radiological Services

### Table of Contents

<b>PART A Licensing Matters</b> .....	<b>3</b>
1. [Updated on 22 Dec 2021] I already hold a Radiological Service Licence. Do I need to apply for a new licence if I intend to provide a new service modality?.....	3
2. [Updated on 22 Dec 2021] What do I need to do if I intend to expand my radiological services to include an imaging modality that is not in the list prescribed by the Regulations?.....	3
3. [Updated on 9 Jun 2021] I provide the same radiological service in different modes of delivery (e.g. X-ray services in all the clinics under the same chain, and mobile X-ray service in trailers). Can I apply one licence to cover them all? .....	3
4. [Updated on 22 Dec 2021] I provide point-of-care imaging service in my medical/dental clinic. Do I need to apply for a radiological service licence?.....	3
5. [Updated on 9 Jun 2021] Does MOH need to be notified if a new equipment (e.g. MRI machine) has been procured for use in the facility? .....	4
6. [Updated on 22 Dec 2021] My clinic conducts image-guided Interventional Radiological procedures (e.g. breast biopsies). Am I required to apply for a Radiological Service licence? .....	4
<b>PART B Governance and Personnel</b> .....	<b>4</b>
7. [Updated on 22 Dec 2021] Is the Clinical Governance Officer (CGO) required to be physically present onsite at all times while the service is being provided? .....	4
8. [Updated on 9 Jun 2021] What's the difference between the CGO and Section Leader?.....	4
9. [Updated on 9 Jun 2021] Is a CGO required to hold an NEA L5 licence (i.e. license to use irradiating apparatus)? .....	5
10. [Updated on 9 Jun 2021] What is the role of the Radiation Safety Officer under HCSA? .....	5
11. [Updated on 22 Dec 2021] How many CGOs need to be appointed? .....	5
12. [Updated on 22 Dec 2021] I'm a licensee of an Obstetrics & Gynaecology clinic, which is holding an existing PHMCA X-ray laboratory licence to conduct fetal ultrasound only. Can I continue to be the CGO of the ultrasound service moving onto HCSA? .....	6
<b>PART D Service Provision</b> .....	<b>6</b>
13. What is the difference between wrong imaging site and wrong anatomical site? .....	6
14. What is considered adequate and appropriate training for personnel administering intravenous contrast agent? .....	6
15. How does the licensee ensure outsourced service providers comply with requirements in the Regulations? .....	7

16. [Updated on 22 Dec 2021] What aspects of radiological services am I allowed to outsource? .....	7
17. [Updated on 22 Dec 2021] How does the licensee ensure the quality of the outsourced radiological service? .....	7
18. If an adverse event arose as a result of outsourcing, who is held responsible? .....	7
19. [Updated on 9 Jun 2021] If a radiological service licensee contracts an external provider for reporting of the radiological images, does the external provider need to hold a radiological service licence? .....	8
20. [Updated on 9 Jun 2021] Is the issuance of radiological report required for non-diagnostic radiological procedures (e.g. intraoperative imaging in fracture fixation)?	8
21. [Updated on 22 Dec 2021] What does the licensee need to do for incidental findings? .....	8
22. [Updated on 9 Jun 2021] Is a referral from a medical practitioner required for radiological services as part of health screening under national initiatives (e.g. Screen for Life Programme)? .....	9
23. [Updated on 9 Jun 2021] Can nurses and allied health practitioners on the Collaborative Prescribing scheme prescribe appropriate radiological examinations for patients? .....	9
<b>PART E Systems and Committees.....</b>	<b>9</b>
24. [Updated on 22 Dec 2021] How can licensees achieve an effective quality management system? .....	9
25. What do I need to do to audit the operations of the radiological service? .....	9

## PART A Licensing Matters

1. **[Updated on 22 Dec 2021] I already hold a Radiological Service Licence. Do I need to apply for a new licence if I intend to provide a new service modality?**
  - In such cases, licensees do not need to apply for a new licence, but are required to notify MOH of the intention to provide the additional modality one month prior to the provision of the additional 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 modality.
2. **[Updated on 22 Dec 2021] What do I need to do if I intend to expand my radiological services to include an imaging modality that is not in the list prescribed by the Regulations?**
  - The list prescribed in the Regulations is non-exhaustive. If an existing licensee would like to provide a new imaging modality that is not in the prescribed list, the licensee should follow the same steps as described in Qn 1 above.
3. **[Updated on 9 Jun 2021] I provide the same radiological service in different modes of delivery (e.g. X-ray services in all the clinics under the same chain, and mobile X-ray service in trailers). Can I apply one licence to cover them all?**
  - The licensee must apply one licence per service per premises or conveyance. Therefore, in the above example, each clinic under the same chain, as well as each conveyance, needs to apply for a radiological service licence.
  - However, the licensee, PO and CGO can be the same under all the radiological service licences for the above premises and conveyances, so long as the requirements are met.
4. **[Updated on 22 Dec 2021] I provide point-of-care imaging service in my medical/dental clinic. Do I need to apply for a radiological service licence?**
  - If the clinic accepts any patients from any referrals outside of its own medical/dental clinic to conduct these radiological procedures, the clinic will need to apply for a radiological service licence.
  - If a dental clinic provides X-ray imaging services for dental purposes (including “Periapical X-ray”, “Orthopantomogram” and “dental Cone Beam Computed Tomography on dental alveolar region”) only for its own patients where it is incidental to the dentist’s treatment of his patient, the clinic does not need to apply for the radiological service licence.

- If a medical clinic provides ultrasound imaging services only for its own patients where it is incidental to the doctor's management of his patient, the clinic does not need to apply for the radiological service licence.
5. **[Updated on 9 Jun 2021] Does MOH need to be notified if a new equipment (e.g. MRI machine) has been procured for use in the facility?**
- There is no need to notify MOH of any new equipment procured if the corresponding modality (e.g. MRI) is already reflected in the approved scope of the licence.
  - However, if the new equipment has been procured for the provision of a modality that is not currently reflected in the approved scope of the licence, you will need to notify MOH at least one month before the date you plan to commence provision. Please also refer to Q1.
6. **[Updated on 22 Dec 2021] My clinic conducts image-guided Interventional Radiological procedures (e.g. breast biopsies). Am I required to apply for a Radiological Service licence?**
- Providers of image-guided Interventional Radiological (IR) procedures listed in the definition of 'radiological service' are required to take up the Radiological Service licence under HCSA and comply with the requirements for radiological services under the Clinical Laboratory and Radiological Service Regulations in Phase 1.

## **PART B Governance and Personnel**

7. **[Updated on 22 Dec 2021] Is the Clinical Governance Officer (CGO) required to be physically present onsite at all times while the service is being provided?**
- The CGO is required to be accessible, which means being contactable at all times while the service is being provided, to oversee the service and provide directions/advice as appropriate.
  - The CGO must be able to attend to issues onsite expediently if the situation so requires.
  - For the period of his absence, there should be a covering arrangement and someone suitably qualified and competent appointed to act on his behalf. The CGO remains responsible for his stipulated duties and roles.
  - In addition, the CGO must be a resident in Singapore so as to be able to effectively carry out his/her functions and duties.
8. **[Updated on 9 Jun 2021] 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. 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. However, the responsibility and accountability of such oversight remains with the CGO.

- The Section Leader is in charge of the particular service modality, and may be more closely involved in the day-to-day operation on the ground than the CGO. The Section Leader 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 to provide technical oversight.
- While the Section Leader 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 diagnostic radiologist while Section Leader can be the radiographer.
- For smaller settings, CGO and Section Leader can be the same person as long as this person fulfils all the requirements.
- A Section Leader can also oversee more than one service modality in one or multiple premises, as long as the person has the relevant qualifications and experience in the relevant service modalities, and able to effectively supervise all modalities and premises under his/her purview.

**9. [Updated on 9 Jun 2021] Is a CGO required to hold an NEA L5 licence (i.e. license to use irradiating apparatus)?**

- Under HCSA, there is no requirement for the CGO to possess an NEA L5 licence. However, if a radiologist is required by NEA to apply for L5 licence to operate radiation emitting equipment and substances, the radiologist should continue to do so.

**10. [Updated on 9 Jun 2021] What is the role of the Radiation Safety Officer under HCSA?**

- 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, which is to supervise the use/custody of any irradiating apparatus or radioactive substance for any work they are licensed to do.

**11. [Updated on 22 Dec 2021] How many CGOs need to be appointed?**

- 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.

**12. [Updated on 22 Dec 2021] I'm a licensee of an Obstetrics & Gynaecology clinic, which is holding an existing PHMCA X-ray laboratory licence to conduct fetal ultrasound only. Can I continue to be the CGO of the ultrasound service moving onto HCSA?**

- Current licensees of existing Radiological Services licensed under the PHMCA can be grandfathered as the CGO of the Radiological Services even if they do not meet the prescribed requirements in the Clinical Laboratory Service and Radiological Service Regulations.
- However, the grandfathering will be limited to their appointment as CGO in the HCSA entity and scope of services ported over from the PHMCA i.e. the clinic or X-ray laboratory where they are working, and this allowance will cease when:
  - There is a change of scope of service and his/her expertise is no longer applicable; or,
  - He/she has stepped down from the CGO role in the said entity.

## **PART D Service Provision**

**13. What is the difference between wrong imaging site and wrong anatomical site?**

- Anatomical site refers to the general area, e.g. the hand, while imaging site refers to a more specific area within that anatomical site, e.g. a specific finger. There should be safeguards in place to prevent radiological examinations performed on the wrong imaging site or wrong anatomical site.

**14. What is considered adequate and appropriate training for personnel administering intravenous contrast agent?**

- The personnel should have adequate and appropriate training in venepuncture and the administration of contrast agents. The licensee should assess whether the personnel can effectively perform the role, taking into consideration his/her qualifications, training, competencies and experience.

**15. How does the licensee ensure outsourced service providers comply with requirements in the Regulations?**

- Licensees can undertake a contractual agreement with the outsourced service provider, with the contract spelling out regulatory requirements to be complied with, and the services standards expected by the licensee, or making reference to such requirements where available; and implement processes to audit or ensure compliance to the contractual terms.

**16. [Updated on 22 Dec 2021] What aspects of radiological services are allowed to outsource?**

- Reporting of radiological images can be outsourced to qualified persons, as defined in the CLRSR.
- Other aspects of the radiological service that may be outsourced include cleaning and waste disposal.

**17. [Updated on 22 Dec 2021] How does the licensee ensure the quality of the outsourced radiological service?**

- Teleradiology is the electronic transmission of all radiological images from one geographical location to another for purposes of interpretation and/or consultation.
- For measures to ensure the quality of teleradiology, licensees may take reference from the Teleradiology Guidelines issued by the College of Radiologists Singapore in 2007.

**18. If an adverse event arose as a result of outsourcing, who is held responsible?**

- The licensee is responsible and accountable for overall compliance with HCSA, including where he has engaged an outsourced provider to support the provision of the licensable service for his patients. While the responsibility of a licensee is non-delegable, Key Appointment Holders (KAHs), Principal Officers (POs) and CGOs also assist the licensee to ensure compliance with the regulations.
- While a licensee will always be liable should an adverse event occur, the degree of culpability depends on the facts of the case. If the facts of the case suggest that KAHs, PO and/or CGO may also be culpable, actions against these key officeholders along with licensee may also be considered (please refer to consult materials for General Regulations for further details).
- In addition, the licensee may choose to take action on its own against an outsourced provider if it established that the lapse was on the part of the outsourced provider. However, the practicality of doing so varies, of

which a key factor would be the presence of a formal contractual agreement with the outsourced provider.

**19. [Updated on 9 Jun 2021] If a radiological service licensee contracts an external provider for reporting of the radiological images, does the external provider need to hold a radiological service licence?**

- Where the external provider is contracted to report radiological images, the external provider is not required to possess a radiological service licence if the provider is not performing radiological examinations on patients.
- However, both the radiological service licensee and the external service provider in question must ensure that processes are in place to ensure quality in the reporting of radiological findings (e.g. the radiological images must be interpreted and the radiological report must be issued by a diagnostic radiologist).
- As the regulated entity under HCSA, the radiological service licensee remains responsible for ensuring compliance with the Act and relevant standards.

**20. [Updated on 9 Jun 2021] Is the issuance of radiological report required for non-diagnostic radiological procedures (e.g. intraoperative imaging in fracture fixation)?**

- Radiological reports are not required for such procedures, as they are meant to guide the practitioner during the procedure. These include image intensifiers, intra-operative fluoroscopy, intraoperative CT and intraoperative MRI.
- However, a report must be issued if the radiological procedure involves a diagnostic element (e.g. intra-operative cholangiogram).

**21. [Updated on 22 Dec 2021] What does the licensee need to do for incidental findings?**

- Licensee should ensure that the medical practitioner who is interpreting and reporting the radiological findings state in the radiological 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 radiological examination for the patient, so the healthcare professional could take the necessary follow-up actions.

**22. [Updated on 9 Jun 2021] Is a referral from a medical practitioner required for radiological services as part of health screening under national initiatives (e.g. Screen for Life Programme)?**

- For national health screening initiatives, a referral from a medical practitioner is not required. This is because X-ray centres that wish to provide health screening for national programmes are first required by Health Promotion Board to have systems in place to ensure that patients receive timely follow-ups on the screening results from the appropriate medical practitioner(s).
- For any other health screening, a referral from a medical practitioner is required.

**23. [Updated on 9 Jun 2021] Can nurses and allied health practitioners on the Collaborative Prescribing scheme prescribe appropriate radiological examinations for patients?**

- Yes. The institutions employing Collaborative Prescribing Practitioners will need to develop and implement mechanisms to verify the identity of these individuals and inform the radiological services, before allowing them to prescribe radiological examinations for their patients.

## **PART E Systems and Committees**

**24. [Updated on 22 Dec 2021] 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 quality management system should include comprehensive plans to meet all the requirements stated in the Regulations and LTCs 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.

**25. What do I need to do to audit the operations of the radiological 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 Quality Management System.