

HCS Clinical Laboratory and Radiological Service Regulations

FAQs for Radiological Services

Summary of amendments	Date of change
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Table of Contents

PART A Licensing Matters	3
1. I already hold a radiological service licence. Do I need to apply for a new licence if I intend to provide a new imaging modality?	3
2. 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. I am a radiological service licensee and providing ultrasound and MRI services as part of Phase 1 of HCSA (i.e. before 26 June 2023). Will I need to seek approval or notify MOH regarding these services again?	3
4. I provide the same radiological service in different modes of delivery (e.g. X-ray services in all the permanent premises under the same chain, and mobile X-ray service in conveyances). Can I apply one licence to cover them all?	4
5. I intend to provide bed-side radiological service in various locations such as nursing homes and patient's residence. Do I need to hold multiple radiological service licences?	4
6. I provide point-of-care imaging service in my medical/dental clinic as part of my outpatient medical/dental service licence. Do I need to apply for a radiological service licence?	4
7. I perform image-guided procedures (e.g. breast biopsies, oocyte retrieval) as part of my outpatient medical service or assisted reproduction service licence. Do I need to apply for a radiological service licence?	4
8. I perform image-guided procedures (e.g. angioplasty) as part of my ambulatory surgical centre licence. Do I need to apply for a radiological service licence?	5
9. Does MOH need to be notified if a new equipment (e.g. MRI machine) has been procured for use in the facility?	5
PART B Governance and Personnel.....	5
10. Is the Clinical Governance Officer (CGO) required to be physically present onsite at all times while the service is being provided?	5
11. What's the difference between the CGO and Section Leader?	5
12. What is the role of the Radiation Safety Officer under HCSA?	6
13. How many CGOs need to be appointed?	6

14. I'm a licensee of an Obstetrics & Gynaecology clinic, which is holding an existing PHMCA X-ray laboratory licence to conduct foetal ultrasound only. Can I continue to be the CGO of the ultrasound service moving onto HCSA? 7

PART C Service Provision 7

15. What is the difference between wrong imaging site and wrong anatomical site? 7
16. What is considered adequate and appropriate training for personnel administering intravenous contrast agent? 7
17. How does the licensee ensure outsourced service providers comply with requirements in the Regulations? 7
18. What aspects of radiological services am I allowed to outsource? 8
19. How does the licensee ensure the quality of the outsourced radiological service? .. 8
20. If an adverse event arose as a result of outsourcing, who is held responsible? 8
21. 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
22. Is the issuance of radiological report required for non-diagnostic radiological procedures (e.g. intraoperative imaging in fracture fixation)? 9
23. What does the licensee need to do for incidental findings? 9
24. 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
25. Can nurses and allied health practitioners on the Collaborative Prescribing scheme prescribe appropriate radiological examinations for patients? 9

PART D Systems and Committees 10

26. How can licensees achieve an effective quality management system? 10
27. What do I need to do to audit the operations of the radiological service? 10

PART A Licensing Matters

<p>1. I already hold a radiological service licence. Do I need to apply for a new licence if I intend to provide a new imaging modality?</p>
<ul style="list-style-type: none"> • With the HCSA amendments introduced on 1 May 2023, plain radiography (plain x-ray), mammography, fluoroscopy, computed tomography, cone beam computed tomography and magnetic resonance imaging have been classified as specified services under a radiological service licence. • Licensees do not need to apply for a new licence but are required <u>to apply for approval</u> from MOH at least two months prior to the intended commencement date of additional specified service. Licensees must not start the provision of the additional specified service unless approval has been granted by MOH. • For ultrasound and bone mineral densitometry (BMD), licensees will only need to notify MOH at least 2 months prior to the intended date of provision. Approval from MOH is not required before the start of these services. • MOH may conduct inspections to ensure that the relevant licence conditions are complied with. Where inspection findings show non-compliances, licensees will not be allowed to start the new services or be required to stop the service the non-compliances are satisfactorily rectified.
<p>2. 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?</p>
<ul style="list-style-type: none"> • If an existing licensee would like to provide a new imaging modality that is not in the prescribed list, the licensee need to notify MOH at least 2 months prior to the intended date of provision.
<p>3. I am a radiological service licensee and providing ultrasound and MRI services as part of Phase 1 of HCSA (i.e. before 26 June 2023). Will I need to seek approval or notify MOH regarding these services again?</p>
<ul style="list-style-type: none"> • Existing licensees do not need to seek approval from or notify MOH again for existing services. Your licence information will be mapped from Healthcare Application and Licensing Portal (HALP) database. However, licensees are encouraged to check if the information is mapped over accurately and to inform MOH of any discrepancies. This includes the conduct of minimally invasive image-guided biopsies (breast, thyroid, superficial lump or bump, or any superficial lymph node) which are now classified as a specified service.

<p>4. I provide the same radiological service in different modes of delivery (e.g. X-ray services in all the permanent premises under the same chain, and mobile X-ray service in conveyances). Can I apply one licence to cover them all?</p>
<ul style="list-style-type: none"> • The licensee may apply one licence per permanent premises or conveyance or one licence for all its modes of service delivery. • The licensee, PO and CGO can be the same under all the radiological service licences for the above premises and conveyances if you choose to apply for one licence per permanent premises or conveyance, so long as the requirements are met.
<p>5. I intend to provide bed-side radiological service in various locations such as nursing homes and patient's residence. Do I need to hold multiple radiological service licences?</p>
<ul style="list-style-type: none"> • The licensee will need to hold one radiological service licence with approval to provide the imaging modality (or notified MOH in the case of ultrasound and BMD) <u>and</u> for the temporary premises mode of service delivery. Licensees must ensure that the relevant licences, authorization and/or approval from NEA are obtained as well.
<p>6. I provide point-of-care imaging service in my medical/dental clinic as part of my outpatient medical/dental service licence. Do I need to apply for a radiological service licence?</p>
<ul style="list-style-type: none"> • If a medical or dental clinic provides ultrasound imaging only for its own patients where it is incidental to the doctor or dentist's management of his patient, the clinic <u>does not need</u> to apply for the radiological service licence. • If a dental clinic provides X-ray imaging for dental purposes (including "Periapical X-ray", "Orthopantomogram" and "Dental Cone Beam Computed Tomography"), the clinic <u>does not need</u> to apply for the radiological service licence. • If the clinic accepts any patients from any referrals outside of its own medical/dental clinic to conduct these radiological procedures (except as described in the 2nd paragraph above for a dental clinic), the clinic will need to apply for a radiological service licence.
<p>7. I perform image-guided procedures (e.g. breast biopsies, oocyte retrieval) as part of my outpatient medical service or assisted reproduction service licence. Do I need to apply for a radiological service licence?</p>
<ul style="list-style-type: none"> • Outpatient medical service and assisted reproduction service licensees will not need to hold a radiological service licence to perform any ultrasound-guided procedures. Licensees will be required to adhere to the relevant licence conditions imposed for the provision of such services. • However, a radiological service licence will be required if you intend to perform image-guided procedures using any other imaging modality besides ultrasound (e.g. using fluoroscopy, CT).

8. I perform image-guided procedures (e.g. angioplasty) as part of my ambulatory surgical centre licence. Do I need to apply for a radiological service licence?
<ul style="list-style-type: none"> Ambulatory surgical centre service licensees will not need to hold a radiological service licence to perform any image-guided procedure. Licensees will be required to adhere to the relevant licence conditions imposed for the provision of such services.
9. Does MOH need to be notified if a new equipment (e.g. MRI machine) has been procured for use in the facility?
<ul style="list-style-type: none"> There is no need to notify MOH of any new equipment procured if the corresponding modality (e.g. MRI) is already an existing approved specified service. However, if the new equipment has been procured for the provision of an imaging modality that is not currently in the approved as a specified service under the licence, you will need to seek approval from MOH (or notify MOH in the case of ultrasound and BMD) at least 2 months before the date you plan to commence provision. Please also refer to Q1.

PART B Governance and Personnel

10. Is the Clinical Governance Officer (CGO) required to be physically present onsite at all times while the service is being provided?
<ul style="list-style-type: none"> 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 coverage 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.
11. What's the difference between the CGO and Section Leader?
<ul style="list-style-type: none"> 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. For example, the CGO must ensure that: <ul style="list-style-type: none"> Work instructions or SOPs relating to the provision of radiological services are regularly assessed and updated if necessary;

- All personnel are familiar with their respective job functions and be kept up to date with any changes in workflow; and
- All personnel are regularly trained and assessed to be competent in their respective job functions;
- 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 to maintain oversight and provide adequate supervision and guidance remains with the CGO.
- The Section Leader is in charge of the particular imaging modality, and is 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 when the service is in operation, 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 imaging 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 imaging 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.

12. 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.

13. 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.

14. I'm a licensee of an Obstetrics & Gynaecology clinic, which is holding an existing PHMCA X-ray laboratory licence to conduct foetal ultrasound only. Can I continue to be the CGO of the ultrasound service moving onto HCSA?

- 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 C Service Provision

15. 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.

16. 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.

17. 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.

18. What aspects of radiological services am I allowed to outsource?
<ul style="list-style-type: none"> • 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.
19. How does the licensee ensure the quality of the outsourced radiological service?
<ul style="list-style-type: none"> • 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.
20. If an adverse event arose as a result of outsourcing, who is held responsible?
<ul style="list-style-type: none"> • <u>The licensee is responsible and accountable</u> 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.
21. 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?
<ul style="list-style-type: none"> • 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).

<ul style="list-style-type: none"> As the regulated entity under HCSA, the radiological service licensee remains responsible for ensuring compliance with the Act and relevant standards.
<p>22. Is the issuance of radiological report required for non-diagnostic radiological procedures (e.g. intraoperative imaging in fracture fixation)?</p>
<ul style="list-style-type: none"> 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).
<p>23. What does the licensee need to do for incidental findings?</p>
<ul style="list-style-type: none"> 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.
<p>24. 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)?</p>
<ul style="list-style-type: none"> 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.
<p>25. Can nurses and allied health practitioners on the Collaborative Prescribing scheme prescribe appropriate radiological examinations for patients?</p>
<ul style="list-style-type: none"> 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 D Systems and Committees

26. 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.

27. 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.