

Radiological Service Regulations FAQ

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PART A Licensing Matters

1. **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 inform MOH of the intention to provide the additional modality one month prior to the provision of the additional modality.
 - Licensees should not commence with provision of the additional modality until the new modality is reflected in the licence by the Ministry.
2. **[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 premise 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 prerequisite requirements are met.
3. **Is a licence required for radiological services conducting only research-based activities?**
 - You will not require a licence. However you will need to notify MOH that you are a research institute, in accordance to the Human Biomedical Research Act. Please visit [MOH website](#) for more information.
4. **I provide point-of-care imaging service in my medical/dental clinic. Do I need to apply for a radiological service licence?**
 - If the medical/dental clinic licensee conducts the following Point-of-Care diagnostic imaging and the service is **only provided for its own patients**, the licensee does not need to apply for the radiological service licence:
 - i. Ultrasound for bedside diagnosis
 - ii. Dental x-ray
 - If you accept any patients from any referrals outside of your own medical/dental clinic to conduct these radiological procedures, you will need to apply for a radiological service licence.
 - The list of point-of-care imaging is under review and more details will be shared in due course.

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. You should not start to provide this additional modality until it is reflected on the licence.

PART B Governance and Personnel

6. **Is the Clinical Governance Officer (CGO) required to be physically present onsite at all times while the service is being provided?**
- The CGO is minimally 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.
 - 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.
7. **[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.

8. [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.

9. [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.

PART D Service Provision

10. 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.

11. What is considered adequate and appropriate training for personnel administrating 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, competencies and experience.

12. 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 appropriate teleradiology requirements, or making reference to such requirements where available. Licensees may take reference from the Teleradiology Guidelines issued by the College of Radiologists Singapore in 2007.

13. If an adverse event arose as a result of outsourcing (e.g. wrong diagnosis due to poor image quality or wrong image transmitted), who is held responsible?

- The licensee is responsible and accountable for overall compliance with HCSA, including where he has engaged an outsourced provider 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. 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.
- In the example stated in the question, the licensee should implement measures to ensure that the images transferred are of the same quality and standards, as an on-site radiologist would expect to receive. This could be done via a formal contractual agreement which states clearly the obligations of the outsourced service provider. Such obligations can include the protocols that the outsourced service provider has to comply with, specific to each examination type being performed, including references to the following:
 - The examination
 - Acquisition method including resolution
 - Compression type and level for each examination
 - Image orientation
 - Image sequence selection
 - Urgency of examination

- Transmission time
- The number of images in the series
- The personnel responsible for the examination at the examination capture site

14. [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, such a provider is not required to possess a radiological service licence as 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 reporting must be interpreted and 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.

15. [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).

16. [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.

17. [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

18. 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.

19. 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 and ensure that it is in accordance to their stipulated Quality Management System.