Clinical Laboratory Service Regulations FAQs

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PART I General

1. **Do I need to apply for a new licence if I intend to provide a new service modality (laboratory discipline or specified test)?**
    - 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, and should not commence with its provision until the modality is reflected on the licence.
    - Licensees may be inspected for the additional modality before they can be provided to ensure that the relevant requirements are met.
2. **I provide the same clinical laboratory service in different premises (e.g. genetic testing in all the laboratories under the same chain). Can I apply one licence to cover them all?**
    - The licensee must apply one licence per service per premise. Therefore, in the above example, each laboratory under the same chain needs to apply for and hold a separate clinical laboratory service licence.
    - However, the same set of persons can be appointed as the licensee, PO and Clinical Governance Officer (CGO) for all the clinical laboratory service licences under the laboratory chain, so long as the prerequisite requirements are met; and the PO and CGO has the bandwidth and capacity to fulfil their obligations under the regulations for the licensed premises under their charge.
3. **Is a licence required for laboratories involved only in research?**
    - No, you will not require a licence, if none of the testing done has any safety and/or health implications to the research subjects, or otherwise any impact on patient clinical care.
    - However, you will need to notify MOH that you are a research institute, in accordance to the Human Biomedical Research Act. Please visit www.moh.gov.sg/policies-and-legislation/human-biomedical-research-act for more information.
4. **I am a research laboratory. I conduct diagnostic tests as part of my research protocol, e.g. to determine the suitability of the research subject or to study the effect of the treatment under research. Do I need to hold a clinical laboratory service licence?**
    - Any entity providing a healthcare service which meets the service definition for clinical laboratory under the First Schedule of the

Healthcare Services Act (HCSA)[1] is required to hold a clinical laboratory service licence to provide the service under HCSA.

- This includes research laboratories which conduct diagnostic tests with safety and/or health implications to research subjects.
- For example, the test results may be used to make clinical decisions on their treatment, or affect any clinical interventions, e.g. to decide which intervention subjects should be given.

PART II Clinical Governance Officer

5. Can an individual who is not a registered pathologist be appointed as my CGO?

- The role of the CGO is to provide clinical and technical oversight for the safe and ethical provision of clinical laboratory services. It is important that a suitably qualified and competent person be appointed as the CGO to ensure that the roles and responsibilities of the CGO can be discharged effectively.
- Under exceptional circumstances, DMS's approval may be granted to an individual who does not fully meet the stipulated CGO requirements but is assessed to suitably qualified and competent, based on the following principles:
    i. Nature of lab discipline / test(s) provided
    ii. Patient safety risk
    iii. Holistic assessment of the lab's scope of services
    iv. Relevance and adequacy of the individual's qualifications, training and experience to fulfil the duties and responsibilities of a CGO with regard to the lab's scope of services
    v. Minimum years of qualifying working experience

[1] First Schedule HCSA states the following definition:
"clinical laboratory service" means the examination or testing of any matter derived from the body of any individual for the purpose of —
(a) assessing the health, condition or genetic predisposition of that individual or any other individual;
(b) predicting or providing a prognosis of the health or medical condition of that individual or any other individual;
(c) diagnosing a disease, disability or condition or an injury of the body or mind of that individual or any other individual;
(d) determining the intervention to be taken, or the effect of any intervention taken, of a disease, disability or condition or an injury of the body or mind of an individual;
(e) ascertaining the cause of death of that individual or any other individual, or the result of a medical or surgical treatment given to that individual or any other individual; or
(f) assessing the health, condition or suitability of any human biological material that is used, or is intended to be used, in relation to any healthcare service;

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 required to be physically present onsite if the situation so warrants his/her presence in order to fulfil his/her obligations under the regulations. At all other times, 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.
    - For period of his/her absence, there should be a covering arrangement and someone suitably qualified and competent appointed to act on his/her behalf.
    - The CGO remains responsible for his/her stipulated duties and roles.

7. **Am I allowed to appoint more than one CGO? What is the minimum number of CGOs that I need to appoint?**

    - Licensees can appoint one or more CGOs for the licensable healthcare service, as deemed necessary. There is no minimum number stipulated, but there must be sufficient number of CGOs to cover the scope of services provided.
    - On top of fulfilling any stipulated requirements for CGOs, licensees are responsible for taking into consideration the competency, bandwidth and capacity of the appointed CGOs as part of assessing their suitability and ability for the role.

8. **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. 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 deemed 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 <u>in charge of the particular laboratory discipline and specified tests</u>, and should be more closely involved in the technical aspects of the day-to-day operation on the ground. The Section Leader shall not be absent from the licensed premises 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 laboratory discipline and specified tests, the CGO is required to have qualifications and experience relevant to the entire scope of the services under his/her purview. The minimum number of years of qualifying experience required is 5 years for both roles.
- For smaller settings, the CGO can also take on the role of the Section Leader if the individual can discharge both roles effectively. The Section Leader can also oversee more than one laboratory discipline or specified test(s), if the person has the relevant qualification and experience in the relevant service modality.
- Staff with less than 2 years' relevant work experience must perform any task or provide any service under the close supervision of either a CGO or a Section Leader.

9. How often do systems for clinical governance, risk management and quality management need to be reviewed?

- These systems should be reviewed in accordance with the licensee's policies and procedures, so long as it meets the intended outcome that any risks affecting the safety and welfare of, and the continuity of care provided to, patients, as well as the safety and welfare of staff, are detected and addressed in a timely manner.
- As a guide, these systems may be reviewed at least annually for effectiveness.
- For the Quality Management System (QMS), it must be reviewed at least annually and updated periodically.

PART III Personnel

10. What would constitute an "adequate number of staff" to provide the service?

- There is no fixed minimum number of staff stipulated. Adequacy of staff depends on the scale and complexity of service provided.
- The licensee should assess whether there are sufficient number of competent staff to effectively perform the roles required for accurate, timely and safe provision of services, taking into consideration staff's qualifications, competencies and experience.
- Licensees are also recommended to have in place policies and procedures for future development of the service and staffing needs (e.g. expansion of service).

11. What do "necessary professional registration, qualifications and competencies" needed for every staff member refer?

- There is no exhaustive list of professional registration and qualifications needed for each role in the clinical laboratory under HCSA. The requirement depends on the scope of work involved for each role.
- The licensee should assess whether each staff member has the relevant professional registration, qualifications and competencies to effectively perform the roles required for accurate, timely and safe provision of services.
- Licensees are also recommended to have in place internal policies and procedures to define the requisite requirements for each role.

12. What does "close supervision" of a staff member with less than 2 years of relevant experience by a CGO or Section Leader entail?

- There should be an arrangement in place whereby a CGO or Section Leader can, in person, effectively monitor and guide the less experienced staff member in performing the latter's role in the provision of clinical laboratory services.

PART IV Outsourcing of Clinical Laboratory Services

13. How does the licensee ensure outsourced foreign 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 clinical laboratory requirements, or making reference to such requirements where available.

14. If an adverse event arose as a result of outsourcing (e.g. wrong diagnosis due to inaccurate test result or contaminated specimen), who is held responsible?

- The licensee is responsible and accountable for overall compliance with HCSA, including where he/she has engaged an outsourced provider for his/her 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 relevant clinical laboratory requirements are carried out. This includes confirming or validating every test result using internal quality control materials or other validation process, and reporting any condition that may affect the validity of the test results in the clinical laboratory report issued. Licensees can consider achieving this via a formal contractual agreement which states clearly the obligations of the outsourced service provider.

PART V Quality Management System

15. 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 QMS should include comprehensive policies and processes 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, specimen acceptance and rejection criteria, quality control measures for each modality, etc.

16. What do I need to do to audit the operations of the clinical laboratory 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 QMS.