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.

5. **[Updated on 30 Jun 2021] My laboratory only intends to provide clinical genetic and genomic testing. Do I need to apply for a PHMCA or HCSA licence?**
    - Clinical genetic and genomic testing is a clinical laboratory service under HCSA. Hence, a clinical laboratory service licence is needed for its provision under PHMCA before HCSA is implemented, and under HCSA from Phase 1 of its implementation.
    - In Phase 3 of HCSA implementation, licensees providing clinical genetic and genomic testing services are required to obtain the clinical genetic and genomic service licence in addition to their clinical laboratory service licence.
6. **[Updated on 30 Jun 2021] How can licensees participate in national proficiency testing schemes for acid-fast bacilli (AFB) smear testing and glycated haemoglobin (HbA1c) testing?**
    - For AFB smear testing, you may contact the Central Tuberculosis (National TB Reference) Laboratory of the Department of Pathology, Singapore General Hospital at Tel 6222 1391 or 6222 1169.
    - For HbA1c testing, you may contact the Chemical Metrology Laboratory, Health Sciences Authority (CML/HSA) at HSA_CMLEQA1@hsa.gov.sg for enrolment in the External Quality Assurance Programme.

[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;

PART II Clinical Governance Officer

7. **[Updated on 30 Jun 2021] 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. In general, the role of the CGO should be held by a pathologist.
    - 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

8. **[Updated on 30 Jun 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 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. Accordingly, the CGO should generally reside in Singapore.
    - 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.

9. **[Updated on 30 Jun 2021] 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.
- Where multiple CGOs are appointed, each CGO should oversee a different clinical or technical aspect of the service and be clear on his/her roles and responsibilities. The division in roles and responsibilities across multiple CGOs appointed for a licensable healthcare service should be formalised and clearly documented as part of good governance practice.

10. [Updated on 30 Jun 2021] Is there a limit to the number of premises that a CGO can oversee?

- There is no limit to the number of premises that a CGO can oversee, as long as he/she can practically fulfil the roles and responsibilities of the CGO for the premises under his/her oversight.

11. 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 in charge of the particular laboratory discipline and specified tests, 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.

12. 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

13. 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).

14. 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.

15. **[Updated on 30 Jun 2021] 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.

    - The extent of supervision should be tailored based on the staff's competency for their duties. If the supervisor assesses that the staff is able to independently carry out their work in a safe and effective manner, the supervising CGO or Section Leader does not need to physically watch the staff in their work, but must nonetheless remain contactable at all times to provide guidance. If the staff is assessed to require closer supervision, the supervising CGO or Section Leader should be present to effectively monitor and provide guidance in person, or ensure that the staff is supervised by a senior staff who is qualified to do so.

16. **[Updated on 30 Jun 2021] How is the Section Leader under HCSA different from the trained person under PHMCA?**

    - The experience requirement and duties of the trained person under PHMCA are formalised under the Section Leader under HCSA.

    - The Section Leader must have at least 5 years of work experience in a clinical laboratory relevant to the scope of services under the Section Leader's purview (e.g. the specific laboratory discipline or field that he/she is overseeing). He/she must provide oversight on the day-to-day laboratory activities on the ground and close supervision to all staff with less than 2 years of relevant experience for the laboratory discipline(s) and/or specified test(s) under his/her purview.

    - There is no specific requirement on the qualification or professional registration of the Section Leader. It depends on the scope of work involved for the Section Leader to effectively perform his/her role for accurate, timely and safe provision of services.

    - Similar to the trained person, the Section Leader needs to be identified, with his/her details submitted as part of the licence application and renewal.

17. **[Updated on 30 Jun 2021] Does research experience count towards the years of relevant work experience for the various roles under HCSA? What type of work experience is considered to be relevant?**

    - No. The relevant work experience must be at a clinical laboratory (either standalone or under a hospital).
    - The work experience must be relevant to the scope of services under the purview of the person holding the role (e.g. the specific laboratory discipline or field that the CGO or Section Leader is overseeing).

PART IV Laboratory Practices

18. **[Updated on 30 Jun 2021] Can clinical laboratories conduct tests for health screening? Is it necessary for these health screening tests to be ordered, and the test results reviewed, by a doctor?**

    - Laboratory test orders and referrals are required to be made by a registered medical practitioner, a registered dentist or a collaborative prescribing practitioner to ensure that the tests are appropriately ordered and their results appropriately reviewed and followed up on.
    - If the health screening tests are performed as part of a health screening exercise and the test orders are thus not individually signed off by a medical practitioner, there should nonetheless be clinical governance and oversight (e.g. through the appointed healthcare provider and/or organising committee with medical practitioners) to ensure the appropriate ordering of tests and review of results, including follow-up on any abnormal results.

19. **[Updated on 30 Jun 2021] To what extent must the clinical laboratory verify that the test is ordered by a registered medical practitioner, a registered dentist or a collaborative prescribing practitioner before conducting the test? What is required for specimens referred by overseas doctors?**

    - The clinical laboratory service licensee should verify whether the test is referred by a registered medical practitioner or registered dentist (whether it is overseas / local) to the best of their ability. This should at minimum include requesting for the MCR or DCR number of the medical or dental practitioner (where applicable).
    - For tests prescribed by collaborative prescribing practitioners, the clinical laboratory service licensee should work with the licensee to whom they are providing the clinical laboratory service to verify the prescribing rights of the practitioners, such as to set up the system such that it only allows tests to be prescribed by a collaborative prescribing practitioner, if the clinical laboratory is part of a hospital with such practitioners.

20. [Updated on 30 Jun 2021] What is required for the confirmation or validation of tests?

- Every test procedure must be confirmed or validated through internal validation processes, such as through the use of internal quality control materials, or inter-laboratory comparison.
- In addition, the licensee must ensure that the laboratory participates and performs satisfactorily in External Quality Assurance (EQA) programmes for all tests (or perform inter-laboratory comparison if a commercial EQA programme is not available for the test).
- Furthermore, new tests and test methods must be evaluated by the CGO before they are provided as a service.

21. [Updated on 30 Jun 2021] What is meant by "non-concordant test results" in relation to the testing of patient's specimens?

- Non-concordant result could mean the following:
  - the results reported by the laboratory are not the same as that reported by other laboratories;
  - different results at different testing timepoint; or
  - the result does not reflect the patient's clinical presentation accurately.
- The laboratory should carry out an investigation into every non-concordant test result and take appropriate action to address the discrepancy.

22. [Updated on 30 Jun 2021] Are clinical laboratories allowed to use leftover specimens from a clinical laboratory test for research?

- Patient's written consent for the use of the patient's leftover specimens for research purpose must be obtained before using his/her specimen for research.

PART V Outsourcing of Clinical Laboratory Services

23. 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.

24. 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 VI Quality Management System

25. 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.

26. 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.

PART VII Keeping of Records

27. [Updated on 30 Jun 2021] Can clinical laboratory reports be transmitted through electronic means to the referring licensee or practitioner, or must hardcopy laboratory reports be issued?

- The Regulations do not stipulate the form in which the clinical laboratory reports or records are transmitted and stored, as long as all the required information is included and traceable to the patient and relevant personnel (e.g. person who conducted the test), the transmission is secure, and the report is issued to the correct person(s).

28. [Updated on 30 Jun 2021] What should be indicated in the clinical laboratory report under "name of the healthcare professional who requested the test" for COVID-19 tests not ordered by a doctor or dentist?

- Please refer to the latest circular for COVID-19 testing for details on the requirements.
- As of 30 Jun 2021, the latest MOH Circular No. 219/2020 issued on 10 November 2020 requires that laboratories only work with approved swab providers (paragraph 4.1). The requesting swab provider should be indicated in the clinical laboratory report.

29. [Updated on 30 Jun 2021] The samples received by my laboratory are from overseas / some of my patients are not identifiable at the point of specimen collection (e.g. the patient is unconscious), and the patient's name and NRIC number are not available. What information must be included in the clinical laboratory reports and records?

- The specimen and test results must be traceable to either the patient (e.g. using other patient identifiers including hospitalisation number) or the principal investigator where the specimen is tested as part of a research trial, if the patient's full name and identification number are not available or provided by the referring entity at the point of specimen collection or testing.

30. [Updated on 30 Jun 2021] What should be indicated under "name of person who conducted the test" in the test records, if the test is auto-run and auto-verified by the device or system?

- The name of personnel loading the specimen and operating the device or system should be captured in the test records, for tests which are auto-conducted.