HCS Clinical Laboratory and Radiological Service Regulations

FAQs for Clinical Laboratory Service

Summary of amendments		Date of change
(i)	Reformatted text for Q1 - 6, Q8 - 15, Q19 - 28, Q33 - 36 for clarity.	13 January 2026
(ii)	Amended Q9 for better factual accuracy.	13 January 2026
(iii)	Updated hyperlink for Q7.	13 January 2026
(iv)	Removed Q34 as it is no longer applicable. Subsequent questions are renumbered accordingly.	13 January 2026
(v)	Updated hyperlink in Annex A.	13 January 2026

Table of Contents

PART I General

1. I already hold a clinical laboratory service licence. Do I need to apply for a new licence if I intend to provide a new specified service (previously known as laboratory discipline or specified test)?
• With the HCSA amendments introduced on 1 May 2023, all laboratory disciplines (e.g. chemical pathology, immunology) and specified tests (e.g. HIV screening/confirmation, HbA1c testing) have been classified as specified services under a clinical laboratory service licence. These may be found in Part 1 of the Schedule in the Regulations. • Licensees do not need to apply for a new licence but are required to apply for approval 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. • 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.
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 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 clinical laboratory 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.
3. I intend to provide bed-side clinical laboratory service in various locations such as nursing homes and patient's residence. Do I need to hold multiple clinical laboratory service licences?
• For the conduct of bed-side tests, the licensee will need to hold one clinical laboratory service licence with approval to provide the relevant specified service(s) and for the temporary premises mode of service delivery. • For clarity, an approval to provide the temporary premises mode of service delivery is not required if only specimen collection is performed at the patient's bedside (e.g. phlebotomy done in the nursing home and blood is sent back to the laboratory for testing) and the testing is conducted in the approved permanent premises of the clinical laboratory.

4. I provide point-of-care testing service in my medical/dental clinic as part of my outpatient medical/dental service licence. Do I need to apply for a clinical laboratory service licence?

- If a medical or dental clinic provides testing only for its own patients where (i) it is incidental to the doctor or dentist's management of his patient **and** (ii) the test only involves the use of a simple in vitro diagnostic test[1], the clinic does not need to apply for the clinical laboratory service licence.

- If the clinic accepts any patients from any referrals outside of its own medical/dental clinic or specimens referred from another medical clinic/dental clinic to conduct these tests, the clinic will need to apply for a clinical laboratory service licence.

5. I am a NM service licencee providing NM in vivo assay (e.g. C-14 urea breath test) and intend to test the specimen within my own department/clinic. Do I need to apply for a clinical laboratory service licence?

- NM service licensees providing NM in vivo assay will be able to perform tests on the specimens obtained as part of the procedure. However, (i) these tests must be using only beta scintillation or gamma counting and (ii) the specimen must not be subject to more than minimal manipulation (please refer to Regulation 34 of the Nuclear Medicine Service Regulations).

- All tests that do not fulfil both (i) and (ii) above must be performed under a clinical laboratory service licence.

6. I was issued a NM assay licence during Phase 1 of HCSA (i.e. before 26 June 2023). What will happen to my licence under Phase 2 of HCSA?

- Your NM assay licence will be revoked as the service is now subsumed as part of the clinical laboratory service itself. You will not need a separate approval or licence to conduct these tests but same requirements imposed under the Nuclear Medicine Service Regulation in Phase 1 of HCSA for the conduct of such nuclear medicine tests is still applicable under the Clinical Laboratory Service Regulation.

7. Is a clinical laboratory service 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 for the research subjects, or otherwise any impact on patient clinical care.

[1] "simple in vitro diagnostic test" means an in vitro diagnostic test that is designed to return a test result without the need to interpret raw test data and requires —
(a) no specimen processing;
(b) no more than 3 steps of analytical test procedures;
(c) the use of self-contained reagent cartridges or strips or no precise measurement required for reagent preparation;
(d) no specifications for a controlled testing environment for returning an accurate test result; and
(e) only portable analysers with automated calibration, quality control and self-diagnosing malfunction features when used;

- However, you will need to notify MOH that you are a research institute, in accordance with the Human Biomedical Research Act. Please visit https://www.moh.gov.sg/others/health-regulation/regulation-of-human-biomedical-research for more information.

8. I am a research laboratory. I conduct diagnostic tests as part of the research protocols, 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)[2] is required to hold a clinical laboratory service licence to provide the service under HCSA.
- A clinical laboratory service licence will be required if any of the following criteria are met:
    - The results are used for the clinical management of a human subject;
    - The results are used to make clinical decisions on subject's treatment or other clinical intervention; and
    - The results are returned to principal investigators or any human subjects for health assessments or medical reports on the predisposition for developing a medical condition and/or the detection of a medical condition; or intended to be used to ascertain health status or to diagnose, prognose or treat a medical / health condition.
- A clinical laboratory service licence will not be required for the following purposes:
    - Epidemiological or health systems research studies where the tests are conducted to collect data on the distribution, determinants, causes of health and disease states in the population or the health status of the population; or
    - Studies involving the collection of data, development, validation or evaluation of tests or imaging protocols, where results are not used for any of the purposes mentioned in the preceding paragraph.
- Please also see **Annex A**.

[2] First Schedule HCSA states the following definition:
"clinical laboratory service" means the examination or testing of any matter derived, obtained or excreted from the body of any individual for any of the following purposes:
(a) assessing the health or genetic predisposition of that individual or any other individual;
(b) predicting or providing a prognosis of the health condition of that individual or any other individual;
(c) diagnosing any condition, disability, disease, disorder or injury of that individual or any other individual;
(d) determining the intervention to be taken, or the effect of any intervention taken, of any condition, disability, disease, disorder or injury of an individual;
(e) ascertaining the result of a medical or surgical treatment given to that individual or any other individual;
(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,

9. My laboratory only intends to provide clinical genetic and genomic testing. Do I need to apply for a HCSA licence?

- Laboratories providing genetic and genomic testing must apply for a HCSA clinical laboratory service licence and indicate "Molecular Pathology" under their laboratory discipline, and comply with the Regulations.
- Licensees should also refer to the Code of Practice on the Standards for the Provision of Clinical Genetic/Genomic Testing Services and Clinical Laboratory Genetic/Genomic Testing Services [MOH Circular No. 234/2020] and the Clinical Genetic and Genomic Services (CGGS) Consultation deck for guidance.

10. 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.

PART II Clinical Governance Officer

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

- The role of the CGO for a clinical laboratory should be held by a fully-registered medical practitioner who is either a pathologist, or a haematologist with post-graduate qualifications in pathology. 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.
- Existing PHMCA licensees who are unable to fulfil the CGO qualification and competency requirements may be "grandfathered" as the CGO of the clinical laboratory service. However, this will be limited to their appointment as CGO for the scope of services of the clinical laboratory where they were a PHMCA licensee when PHMCA transited to HCSA. These grandfathered CGOs will not be recognised as qualified for CGO roles in another licensed clinical laboratory under HCSA.
- The grandfathering of these CGOs will also cease when: (i) there is a change of scope of service and his/her expertise is no longer applicable; or (ii) he/she has stepped down from the CGO role in the said entity. In these instances, the licensee must appoint a CGO that meets the requirements under HCSA.

12. 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.

13. 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. There is no minimum number stipulated, but there must be a sufficient number of CGOs to cover the scope of laboratory disciplines 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.

14. 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.

15. 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. For example, the CGO must ensure that:

    - Any new test or test method is evaluated for accuracy before its implementation;

    - Results from external quality assessment programme are reviewed, and appropriate actions taken if necessary;

- Work instructions or SOPs relating to the provision of clinical laboratory 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;
- 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 that 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 specified service, 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 specified service 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 the relevant qualifications and experience in the specified service, 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 in a clinical laboratory practice required is 5 years for both roles. Please note that research-only experience is **not** considered as part of the qualifying experience. The Section Leader can also oversee more than one laboratory discipline, if the person has the relevant qualification and experience in the relevant specified services.

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

- These systems should be reviewed at least annually for effectiveness and in accordance with the licensee's policies and procedures.

PART III Personnel

17. What would constitute an "adequate number of personnel" to provide the service?

- There is no minimum number of personnel stipulated. Adequacy of personnel depends on the scale and complexity of service provided.

- The licensee should assess whether there is a sufficient number of competent personnel to effectively perform the roles required for accurate, timely and safe provision of

services, taking into consideration personnel'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).

18. 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.

19. 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 (with either less than 2 years' relevant work experience or with the requisite work experience but who have not been assessed to be sufficiently competent to perform specific work independently) 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.

20. 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 the qualifications and 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) under his/her purview.

- The qualification of the Section Leader 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.

21. 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 also 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 Facilities and Equipment

22. With reference to Regulation 12, what would constitute as "appropriate safety equipment"?

- Appropriate safety equipment would include safety cabinets, hand basins and emergency shower (or the equivalent in the case of licensees providing services through temporary modes of service delivery).

PART V Laboratory Practices

23. I do not perform any tests using radioactive substances or on radioactive specimens. Do I need to fulfil the requirements (e.g. under QMS, safety programme) regarding those aspects?

- Those requirements will only be applicable to licensees performing those related tests. Licensees not performing those tests will not need to fulfil those requirements.

- Licensees who intend to perform those tests must ensure that the relevant requirements are met before the commencement of services.

24. 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.

25. 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 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.

26. What is required for the confirmation or validation of tests?

- Every test procedure must be evaluated 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 to be fit-for-purpose and approved by the CGO before they are provided as a service.

27. 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;
    - results suspected to be spurious; 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.

28. 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 VI Outsourcing of Clinical Laboratory Services

29. How does the licensee ensure outsourced overseas clinical laboratory service providers, which are not licensed under HCSA, comply with requirements in the Regulations?

- Licensees can undertake a contractual agreement with the outsourced clinical laboratory service provider, with the contract spelling out appropriate clinical laboratory requirements, or making reference to such requirements where available.

30. 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 the 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 met. 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 VII Quality Management System

31. 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 Licensing Conditions 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.

32. 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 with their stipulated QMS.

PART VIII Keeping of Records

33. Can clinical laboratory reports be transmitted through electronic means to the referring licensee or practitioner, or must hardcopy laboratory reports be issued?

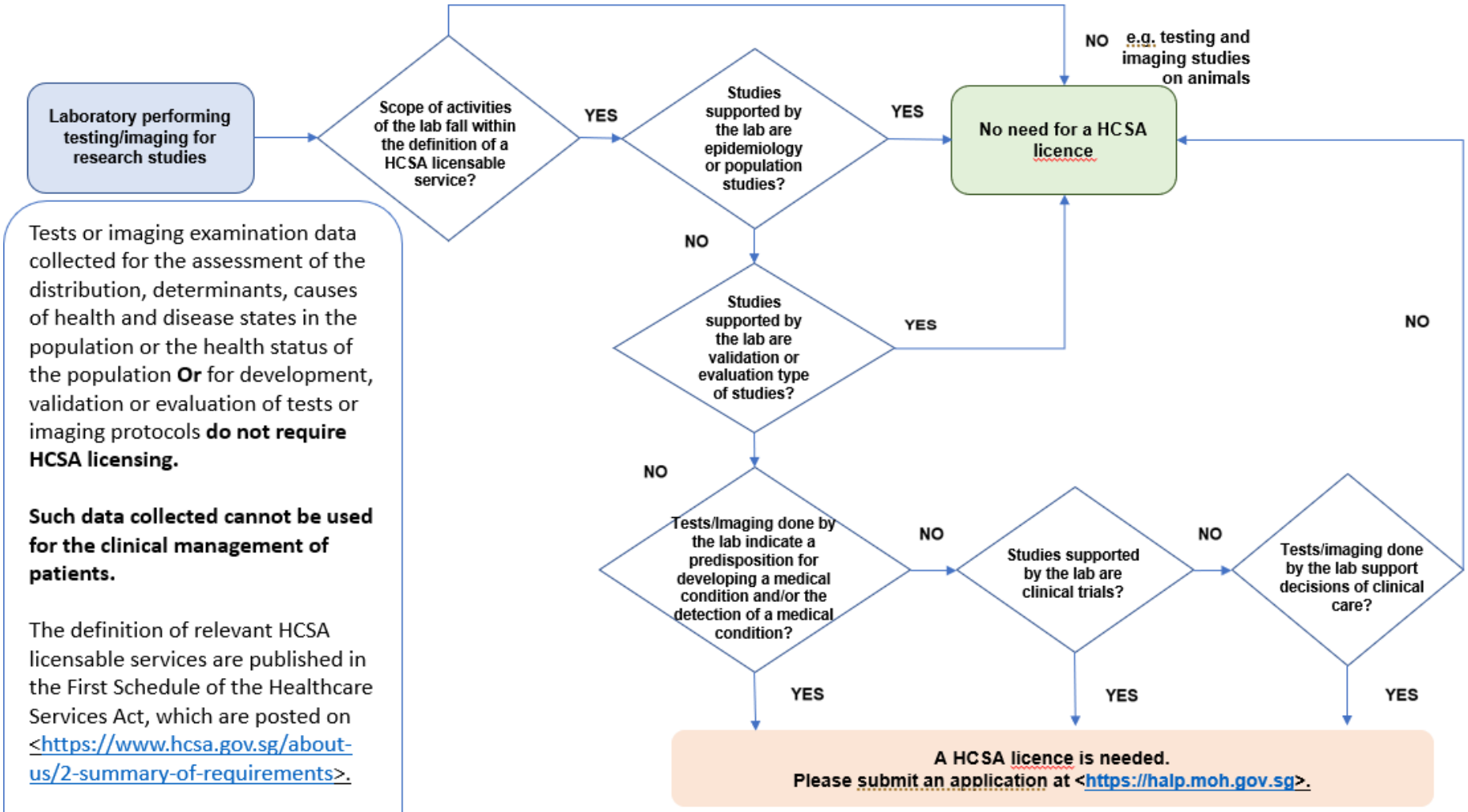
- The Regulations do not stipulate the form in which the clinical laboratory reports or records are transmitted and stored, as long as all the required information is included and traceable to the patient and relevant personnel (e.g. person who conducted the test), the transmission is secure, and the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

34. 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.
35. 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-verified.

Annex A



Tests or imaging examination data collected for the assessment of the distribution, determinants, causes of health and disease states in the population or the health status of the population **Or** for development, validation or evaluation of tests or imaging protocols **do not require HCSA licensing.**

Such data collected cannot be used for the clinical management of patients.

The definition of relevant HCSA licensable services are published in the First Schedule of the Healthcare Services Act, which are posted on <https://www.hcsa.gov.sg/about-us/2-summary-of-requirements>.

For more enquires, you may email <HCSA_Enquiries@moh.gov.sg>.