First published in the Government *Gazette*, Electronic Edition, on 30 December 2021 at 7 pm.

No. S 1036

HEALTHCARE SERVICES ACT 2020
(ACT 3 OF 2020)

HEALTHCARE SERVICES (CLINICAL LABORATORY SERVICE AND RADIOLOGICAL SERVICE) REGULATIONS 2021

ARRANGEMENT OF REGULATIONS

PART 1

PRELIMINARY

Regulation

PART 2

REQUIREMENTS RELATING TO PERSONNEL

PART 3

PROCESSES, EQUIPMENT AND FITTINGS

In exercise of the powers conferred by section 57 of the Healthcare Services Act 2020, the Minister for Health makes the following Regulations:

PART 1

PRELIMINARY

Citation and commencement

1. These Regulations are the Healthcare Services (Clinical Laboratory Service and Radiological Service) Regulations 2021 and come into operation on 3 January 2022.

Definitions

2. In these Regulations, unless the context otherwise requires —

"applicable service" means a clinical laboratory service or a radiological service, as the case may be;

"business name" has the meaning given by regulation 48(2) of the General Regulations;

"calendar day" includes Saturday, Sunday and every public holiday;

[S 417/2023 wef 26/06/2023]

"Clinical Governance Officer" means a Clinical Governance Officer appointed by a licensee under section 24(2) of the Act;

"clinical laboratory service" has the meaning given by paragraph 2 of the First Schedule to the Act;

[S 417/2023 wef 26/06/2023]

"clinical laboratory service licensee" means a person who holds a licence to provide a clinical laboratory service;

"collaborative prescribing practitioner" has the meaning given by regulation 2 of the Healthcare Services (Collaborative Prescribing Service) Regulations 2023 (G.N. No. S 398/2023);

[S 417/2023 wef 26/06/2023]

"expiry date", in relation to any reagent or testing material, means —

(*a*) the date after which; or

(*b*) the month and year after the end of which,

as the case may be, the reagent or testing material should not be used;

[S 417/2023 wef 26/06/2023]

"General Regulations" means the Healthcare Services (General) Regulations 2021 (G.N. No. S 1035/2021);

"imaging modality" means —

(*a*) any imaging modality set out in paragraph 1(*a*) of Part 2 of the Schedule;

(*b*) bone densitometry; or

(*c*) ultrasound;

[S 417/2023 wef 26/06/2023]

"imaging service" means the use of ionising or non ionising radiation for any of the following purposes:

(*a*) examination of the body, or any matter derived from the body, of an individual;

(*b*) assessment of the health or condition of an individual;

(*c*) observation and diagnosis of a condition, disability, disease, disorder or an injury of the body or mind of an individual;

(*d*) determining, predicting or providing a prognosis of the health or condition of an individual;

[S 417/2023 wef 26/06/2023]

"laboratory discipline" means any laboratory discipline set out in paragraph 1(*a*) of Part 1 of the Schedule;

[S 417/2023 wef 26/06/2023]

"laboratory discipline" has the meaning given by regulation 4(4);

"licence" means a licence under the Act authorising the licensee to provide an applicable service;

"licensee" means a clinical laboratory service licensee or a radiological service licensee;

"patient" —

(*a*) in relation to a clinical laboratory service licensee, means the individual from whose body a specimen is derived for testing by or on behalf of the licensee; or

(*b*) in relation to a radiological service licensee, means the individual for whom a radiological examination is performed by or on behalf of the licensee;

"personnel", in relation to a licensee, means any individual employed or engaged by the licensee to assist the licensee in providing the applicable service;

"radioactive specimen" means any specimen —

(*a*) on which a radioactive substance is applied for the purpose of a test or examination of the specimen; or

(*b*) that is derived, obtained or excreted from an individual who was administered a radiopharmaceutical for the purpose of testing or examining the specimen, whether or not the specimen contains any radioactive substance;

[S 417/2023 wef 26/06/2023]

"radioactive substance" has the meaning given by section 2(1) of the Radiation Protection Act 2007;

[S 417/2023 wef 26/06/2023]

"radiological service" has the meaning given by paragraph 2 of the First Schedule to the Act;

[S 417/2023 wef 26/06/2023]

"radiological service licensee" means a person who holds a licence to provide a radiological service;

"radiopharmaceutical" means any unsealed source (within the meaning given by regulation 2 of the Radiation Protection

(Ionising Radiation) Regulations 2023 (G.N. No. S 85/2023)) that is administered to a patient as a diagnostic agent;

[S 417/2023 wef 26/06/2023]

"requestor", in relation to a patient, means —

(*a*) the medical practitioner, dentist or collaborative prescribing practitioner who ordered a test or radiological examination for the patient; or

(*b*) any person who is approved by the Director-General to request a licensee to conduct a test for the patient without a referral by a medical practitioner, dentist or collaborative prescribing practitioner;

[S 417/2023 wef 26/06/2023]

[*Deleted by S 417/2023 wef 26/06/2023*]

[*Deleted by S 417/2023 wef 26/06/2023*]

[*Deleted by S 417/2023 wef 26/06/2023*]

"simple in vitro diagnostic test" has the meaning given by paragraph 2 of the First Schedule to the Act;

[S 417/2023 wef 26/06/2023]

"specimen" has the meaning given by regulation 2 of the General Regulations;

[S 417/2023 wef 26/06/2023]

"temporary premises" means any premises other than permanent premises;

[S 417/2023 wef 26/06/2023]

"test" means an analysis or examination of a specimen conducted by a licensee in connection with the provision of a clinical laboratory service;

[S 417/2023 wef 26/06/2023]

"testing material" means any test kit, material, device, equipment, instrument or other article that is used to conduct a simple in vitro diagnostic test;

[S 417/2023 wef 26/06/2023]

"testing service" means the examination or testing of any matter derived, obtained or excreted from the body of any individual for the purpose of —

(*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 a condition, disability, disease, disorder 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 condition, disability, disease, disorder or an injury of the body or mind of an individual;

(*e*) ascertaining 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.

[S 417/2023 wef 26/06/2023]

Application of Regulations

3. Unless otherwise expressly provided in these Regulations —

(*a*) the provisions of these Regulations apply in addition to the provisions of the General Regulations; and

(*b*) the provisions of these Regulations prevail if, and to the extent that, there is any inconsistency between these Regulations and the General Regulations insofar as the matter relates to a licensee.

Specified services

4. For the purposes of section 9A(1) of the Act —

(*a*) the services set out in Part 1 of the Schedule are specified services for a clinical laboratory service; and

(*b*) the services set out in Part 2 of the Schedule are specified services for a radiological service.

[S 417/2023 wef 26/06/2023]

Notification of certain imaging modalities

4A.—(1) For the purposes of section 10(2)(*c*)(viii) of the Act, an applicant for the grant or renewal of a licence to provide a radiological service must specify in the licence application whether the applicant provides, or intends to provide an imaging service by bone densitometry or ultrasound as part of that service.

(2) A radiological service licensee who, during the term of the licence, intends to provide an imaging service by bone densitometry or ultrasound as part of the radiological service must, no later than 2 months before the licensee intends to start providing the imaging service by that imaging modality, give written notice to the Director-General of the licensee's intention.

(3) A radiological service licensee who, during the term of the licence, intends to stop providing an imaging service by bone densitometry or ultrasound as part of the radiological service must, no later than 10 calendar days before the licensee intends to stop providing the imaging service by that imaging modality, give written notice to the Director-General of the licensee's intention.

[S 417/2023 wef 26/06/2023]

Prohibited service delivery modes

4B.—(1) A licensee must not provide a clinical laboratory service or radiological service by remote provision.

(2) A clinical laboratory service licensee must not provide any of the following specified services using a conveyance or at temporary premises:

(*a*) a testing service in a laboratory discipline specified in paragraph 1(*a*)(i), (iv), (v), (vii), (ix), (x) or (xi) of Part 1 of the Schedule;

(*b*) a test set out in paragraph 1(*b*)(iii), (iv) or (v) of Part 1 of the Schedule.

(3) A radiological service licensee must not provide any of the following specified services using a conveyance or at temporary premises:

(*a*) an imaging service by an imaging modality specified in paragraph 1(*a*)(iii), (iv), (v) or (vi) of Part 2 of the Schedule;

(*b*) a procedure set out in paragraph 1(*b*) of Part 2 of the Schedule.

[S 417/2023 wef 26/06/2023]

PART 2

REQUIREMENTS RELATING TO PERSONNEL

Skills and competencies of Clinical Governance Officer for clinical laboratory service

5. For the purposes of section 24(3)(*b*) of the Act, an individual is suitably qualified to be appointed a Clinical Governance Officer for a clinical laboratory service if the individual has —

(*a*) all of the following skills and competencies:

(i) registration under section 20(1) or (2) of the Medical Registration Act 1997 as a fully registered medical practitioner;

(ii) registration under section 22 of the Medical Registration Act 1997 as a specialist in the branch of pathology; or

(*b*) all of the following skills and competencies:

(i) registration under section 20(1) or (2) of the Medical Registration Act 1997 as a fully registered medical practitioner;

(ii) registration under section 22 of the Medical Registration Act 1997 as a specialist in the branch of haematology;

(iii) a pass in the Fellowship of the Royal College of Pathology Part 1 and Part 2 examinations or other equivalent exit examinations from a professional board approved by the Director-General;

[S 417/2023 wef 26/06/2023]

(iv) at least 5 years of work experience in a clinical laboratory licensed under the repealed Act or in the provision of a clinical laboratory service licensed under this Act, or another equivalent clinical laboratory outside of Singapore approved by the Director-General.

[S 417/2023 wef 26/06/2023]

[S 842/2023 wef 18/12/2023]

[S 417/2023 wef 26/06/2023]

Skills and competencies of Clinical Governance Officer for radiological service

6.—(1) For the purposes of section 24(3)(*b*) of the Act and subject to paragraph (2), an individual who has all of the following skills and competencies is suitably qualified to be appointed a Clinical Governance Officer for a radiological service:

(*a*) registration under section 20(1) or (2) of the Medical Registration Act 1997 as a fully registered medical practitioner;

(*b*) registration under section 22 of the Medical Registration Act 1997 as a specialist in the branch of diagnostic radiology;

(*c*) at least 5 years of work experience after obtaining the qualification mentioned in sub-paragraph (*b*), in providing a radiological service.

[S 417/2023 wef 26/06/2023]

(2) Where a licensee provides a radiological service only for dental purposes, the licensee may appoint a person registered under

section 14 of the Dental Registration Act 1999 as a Clinical Governance Officer for the radiological service.

[S 417/2023 wef 26/06/2023]

[S 417/2023 wef 26/06/2023]

Additional duties and responsibilities of Clinical Governance Officer

7.—(1) In addition to regulation 14 of the General Regulations, a Clinical Governance Officer appointed by a clinical laboratory service must —

(*a*) before the provision of any test or implementation of any test method, evaluate whether the test or test method performs in accordance with the manufacturer's specifications (if any) and produces accurate results; and

(*b*) implement and oversee the safety programme mentioned in regulation 14.

[S 417/2023 wef 26/06/2023]

[S 417/2023 wef 26/06/2023]

(2) In addition to regulation 14 of the General Regulations, a Clinical Governance Officer appointed by a radiological service must —

(*a*) before the provision of an imaging modality as part of the service, evaluate whether the imaging modality produces images of diagnostic quality; and

(*b*) implement and oversee the safety programme mentioned in regulation 14.

[S 417/2023 wef 26/06/2023]

[S 417/2023 wef 26/06/2023]

Licensee must appoint section leader

8.—(1) A clinical laboratory service licensee must, in relation to each specified service provided by the licensee, appoint as the section leader, a person who resides in Singapore.

[S 417/2023 wef 26/06/2023]

(2) A radiological service licensee must, in relation to each imaging modality or specified service provided by the licensee, appoint as the section leader a radiographer —

(*a*) who resides in Singapore;

(*b*) who is registered under section 16 of the Allied Health Professions Act 2011; and

(*c*) who has at least 3 years of work experience in providing a radiological service in the imaging modality or specified service.

[S 417/2023 wef 26/06/2023]

[S 417/2023 wef 26/06/2023]

(3) A person may be appointed as a section leader —

(*a*) in relation to a clinical laboratory service — for more than one specified service; or

(*b*) in relation to a radiological service — for more than one imaging modality or specified service.

[S 417/2023 wef 26/06/2023]

(4) A Clinical Governance Officer may be appointed as a section leader.

Duties of section leader

9. A licensee must ensure that every section leader appointed under regulation 8 does all of the following in relation to the imaging modality or specified service for which the section leader is appointed:

(*a*) assist the relevant Clinical Governance Officer in the day-to-day technical management of the imaging modality or specified service;

(*b*) supervise, train and guide each personnel under the charge of the section leader in conducting tests or radiological examinations under that imaging modality or specified service;

(*c*) assess and ensure the competency of each personnel deployed to perform tasks for that imaging modality or specified service;

(*d*) evaluate any test or equipment before it is used in the provision of the applicable service;

(*e*) monitor the performance of all tests or radiological procedures carried out under the imaging modality or specified service that the section leader is appointed for, including ensuring the implementation of quality control measures;

(*f*) establish and review policy and procedures for the safe and effective performance of all tests or radiological procedures carried out under the imaging modality or specified service for which the section leader is appointed;

(*g*) resolve any technical issues that arise from the performance of all tests or radiological procedures carried out under the imaging modality or specified service that the section leader is appointed for;

(*h*) review all service records in relation to the tests or radiological procedures carried out under the imaging modality or specified service for which the section leader is appointed.

[S 417/2023 wef 26/06/2023]

General requirements relating to personnel

10.—(1) A licensee must ensure all of the following in relation to each personnel:

(*a*) each personnel is adequately trained for the work performed by the personnel and attends regular training in accordance with a continuing training programme;

(*b*) each personnel has the relevant awareness and knowledge of, and attends regular training on, clinical laboratory safety measures or radiation safety, as the case may be;

(*c*) each personnel is assessed periodically on the personnel's competencies and work performance;

(*d*) each of the following personnel is supervised by an experienced person when performing any task or providing any service in relation to the applicable service:

(i) for a clinical laboratory service licensee — any personnel with less than 2 years of work experience in providing a clinical laboratory service;

(ii) for a radiological service licensee — any personnel with less than one year of work experience in providing a radiological service;

(iii) any personnel who has not been assessed by the relevant section leader or Clinical Governance Officer to be able to perform the task or provide the service competently without supervision.

(2) In this regulation, "experienced person" means —

(*a*) the Clinical Governance Officer or the relevant section leader;

(*b*) for a clinical laboratory service licensee — another of the licensee's personnel with at least 5 years of relevant work experience and who is designated by the Clinical Governance Officer or the relevant section leader to provide supervision; or

(*c*) for a radiological service licensee — another of the licensee's personnel with at least 3 years of relevant work experience and who is designated by the Clinical Governance Officer or the relevant section leader to provide supervision.

PART 3

PROCESSES, EQUIPMENT AND FITTINGS

Quality management system

11.—(1) A licensee must establish and implement a quality management system in accordance with this regulation for the

purposes of quality assessment and assurance of the clinical laboratory service or radiological service provided by the licensee.

(2) Without limiting paragraph (1), the quality management system mentioned in paragraph (1) must provide for all of the following:

(*a*) implementation of a system for appropriate accountability, roles, responsibilities and continuing educational programmes;

(*b*) measures to ensure that the provision of the service complies with any written law governing the service and licence conditions imposed under section 13(1) of the Act;

(*c*) implementation of protocols to ensure compliance with Parts 4 to 6 and for the physical safety of the licensee's personnel, patients and visitors;

(*d*) identification of key performance indicators for assessing performance outcomes of the applicable service, including mechanisms for periodic monitoring and evaluation of these indicators;

(*e*) quality control measures for equipment used in the provision of the applicable service, including acceptance testing, quality control tests and regular monitoring of equipment performance;

(*f*) quality control measures for all specimens or radiological images kept or tested by the licensee, as the case may be;

(*fa*) where the licensee provides any testing service on radioactive specimens —

(i) quality control measures for all radioactive substances kept and used by the licensee, including measures pertaining to —

(A) the acceptance, or rejection for quality or safety reasons, of all radioactive substances supplied to the licensee;

(B) the safe and proper preparation, handling, transport and use of the radioactive substances; and

(C) the regular testing of the quality and safety of the radioactive substances;

(ii) the maintenance of adequate and accurate documentation on the licensee's use of radioactive substances;

(iii) the conduct of regular holistic analysis and reviews of all information relating to —

(A) the quality and safety of all radioactive substances kept and used by the licensee; and

(B) the applicable licensee's use of all radioactive substances; and

(iv) the testing and monitoring of the radiation levels in every approved permanent premises to ensure the safety of personnel, patients and visitors;

[S 417/2023 wef 26/06/2023]

(*g*) systems and processes to ensure that regulation 32 is complied with;

(*h*) the investigation of any occurrence or complaint that discloses or may disclose any weakness or inadequacy affecting the quality of the service;

(*i*) the identification and implementation of appropriate and effective actions to address any weakness or inadequacy mentioned in sub-paragraph (*h*) and prevent a recurrence;

(*j*) the conduct of regular risk assessments of every activity conducted as part of the provision of the applicable service and, where necessary, the implementation of appropriate measures to mitigate or manage the risks identified in those assessments;

(*k*) validation of test methods and imaging procedures, as the case may be;

(*l*) validation of all processes relating to the performance of a test or radiological examination, as the case may be;

(*m*) a system to ensure the appropriate and adequate documentation of all quality assurance measures, policies and processes, which includes all of the following features:

(i) regular creation, review and updating of the documentation;

(ii) document control procedures;

(iii) processes to ensure that each personnel complies with sub-paragraphs (i) and (ii).

(3) A licensee must review the effectiveness of the quality management system for the applicable service on an annual basis and ensure that the quality management system is updated periodically.

(4) In addition, a clinical laboratory service licensee must —

(*a*) participate in and perform satisfactorily for the relevant external quality assessment programme for every test provided by the licensee; and

(*b*) ensure that the Clinical Governance Officer or such other suitably qualified personnel designated by the Clinical Governance Officer reviews the results of the quality assessment programmes mentioned in sub-paragraph (*a*) and implements appropriate and effective actions to address any weakness or inadequacy in the provision of the clinical laboratory service.

Equipment and fittings

12.—(1) A licensee must ensure that —

(*a*) every approved permanent premises, approved conveyance and temporary premises where the applicable service is provided has adequate space for the licensee to carry out the applicable service in a safe manner;

(*b*) every approved permanent premises or approved conveyance is adequately secured to prevent

unauthorised access to the approved permanent premises or approved conveyance; and

(*c*) every temporary premises (other than any residential premises) at which the applicable service is provided is adequately secured to prevent unauthorised access to the premises.

[S 417/2023 wef 26/06/2023]

(2) A licensee must ensure that all of the following requirements are satisfied:

(*a*) in relation to the storage of reagents, specimens or other materials and supplies used the provision of the applicable service —

(i) adequate storage space at every approved permanent premises, approved conveyance or temporary premises where the applicable service is provided;

[S 417/2023 wef 26/06/2023]

(ii) the storage space provided is adequately secured; and

(iii) effective measures are in place to prevent any damage to, deterioration of, or unauthorised access to and use of, the reagents, specimens and other materials and supplies;

(*b*) adequate decontamination equipment is provided at every approved permanent premises, approved conveyance or temporary premises where the applicable service is provided to ensure the safety of all personnel, patients and visitors, and prevent any contamination of specimens;

[S 417/2023 wef 26/06/2023]

(*c*) appropriate safety equipment is provided in every approved permanent premises, approved conveyance or temporary premises where the applicable service is provided;

[S 417/2023 wef 26/06/2023]

(*d*) an adequate number of first-aid kits for emergency use that are readily accessible to all personnel.

(3) Where a licensee provides any testing service on radioactive specimens, the licensee must also ensure that all of the following requirements are satisfied:

(*a*) in relation to the receipt, use, preparation, storage and disposal of radioactive substances —

(i) adequate space is provided at every approved permanent premises; and

(ii) the space provided is secure and access to the space is controlled;

(*b*) appropriate radiation shielding is provided at any part of every approved permanent premises where procedures involving the handling and use of radioactive substances are performed;

(*c*) every approved permanent premises complies with the requirements of, and is approved for use in accordance with, any written law relating to the preparation, storage, possession, use and disposal of radioactive substances.

[S 417/2023 wef 26/06/2023]

Additional requirements where applicable service provided using approved conveyances or at temporary premises

12A.—(1) This regulation applies to a licensee that is approved to provide an applicable service using an approved conveyance or at temporary premises.

(2) The licensee must establish a post-relocation commissioning process to ensure the following:

(*a*) that each piece of equipment used in every approved conveyance or temporary premises is adequate, functional and effective by recalibrating the equipment;

(*b*) that any reagent used for the provision of the applicable service remains safe, suitable and effective for use.

(3) A licensee must implement the post-relocation commissioning process mentioned in paragraph (2) each time before a licensee first provides the applicable service —

(*a*) after the approved conveyance is moved to a new location; or

(*b*) at any temporary premises.

(4) The licensee must establish and implement protocols for the management of any hazardous materials or waste, that are specific to each approved conveyance or temporary premises.

[S 417/2023 wef 26/06/2023]

Services may be provided to patients only where ordered by requestor

13. In the provision of an applicable service, a licensee must not —

(*a*) conduct a test for a patient who resides in Singapore; or

(*b*) conduct a radiological examination in Singapore for a patient,

unless a requestor orders the test or radiological examination for the patient.

PART 4

SAFETY REQUIREMENTS

Safety programme

14.—(1) A licensee must develop and ensure the implementation of a safety programme setting out appropriate and effective safety measures to prevent the occurrence of any adverse incident and reduce any hazard at any approved permanent premises, approved conveyance or temporary premises where an applicable service is provided.

[S 417/2023 wef 26/06/2023]

(2) Without limiting paragraph (1), a safety programme must contain appropriate and effective measures for —

(*a*) electrical safety and safety of water supply and outlets;

(*b*) where any radioactive substance or irradiating apparatus is used in the provision of the service —

(i) radiation safety to ensure the safety of personnel and patients and other individuals within or in the vicinity of any premises used by the licensee for the provision of the service, including the proper handling, use and disposal of radioactive substances; and

(ii) compliance with any written law governing the preparation, storage, possession, use and disposal of radioactive substances and irradiating apparatus;

[S 417/2023 wef 26/06/2023]

(*c*) the handling and disposal of sharp apparatus and objects that can readily puncture or cut human skin when encountered;

(*d*) the safety of all personnel and patients during the conduct of any test or radiological examination;

(*e*) waste management;

(*f*) spills management;

(*g*) ensuring that there is adequate space, ventilation and lighting for every personnel to perform work safely;

(*h*) ensuring that patients are not exposed to unsafe levels of noise when undergoing any test or radiological examination;

(*i*) ensuring that all safety or emergency equipment are kept in good working order and there is an adequate stock of materials required for the handling of any medical emergency or adverse incident; and

(*j*) ensuring the cleanliness of any approved permanent premises, approved conveyance or temporary premises where an applicable service is provided.

[S 417/2023 wef 26/06/2023]

(2A) The safety programme mentioned in paragraph (1) must also include the following:

(*a*) where the licensee is a clinical laboratory service licensee who provides any testing service on radioactive specimens —

(i) policies to protect any personnel who is pregnant against radiation exposure in the course of work and at every approved permanent premises, approved conveyance and temporary premises where the applicable service is provided; and

(ii) measures to ensure that an adequate number of the following are available for use by all personnel:

(A) suitable radiation monitoring devices, including dose calibrators and radiation survey meters;

(B) suitable radiation shields and primary and second containers for transportation of radioactive substances within and outside the approved permanent premises;

(*b*) where the licensee is a radiological service licensee —

(i) policies to protect any personnel who is pregnant against radiation exposure in the course of work and at every approved permanent premises, approved conveyance and temporary premises where the applicable service is provided; and

(ii) policies on the performance of ionising radiological procedures on pregnant women or women suspected to be pregnant.

[S 417/2023 wef 26/06/2023]

(3) A licensee must keep up-to-date documentation of the policies and processes of the safety programme mentioned in paragraph (1) and make such documentation available to every personnel.

Licensee must ensure personnel comply with safety plans

15.—(1) A licensee must ensure that every personnel complies with the measures set out in the safety programme mentioned in regulation 14.

(2) In addition, a clinical laboratory service licensee must ensure that every personnel complies with the chemical hygiene plan mentioned in regulation 23.

Personal protective equipment must be provided

16. A licensee must provide each personnel performing any work in any approved permanent premises, approved conveyance or temporary premises where an applicable service is provided with personal protective equipment appropriate for the work performed.

[S 417/2023 wef 26/06/2023]

PART 5

REQUIREMENTS SPECIFIC TO CLINICAL LABORATORY SERVICES

Instructions for collection of specimens

17. Where, at the time a requestor or patient engages the services of a clinical laboratory licensee, the requestor or patient (as the case may be) does not request the assistance of the clinical laboratory service licensee in the collection of a specimen that is to be tested by the licensee, the licensee must provide the requestor or patient (as the case may be) with —

(*a*) instructions on how and when the specimen is to be collected, packed and labelled; and

(*b*) precautions to be taken to avoid contamination of the specimen.

Acceptance and rejection of specimens

18.—(1) A clinical laboratory service licensee must have in place policies and processes to govern the acceptance of specimens and the handling of rejected specimens that include all of the following:

(*a*) clear criteria for the acceptance and rejection of specimens for traceability, quality and safety reasons;

(*b*) how rejected specimens are to be handled;

(*c*) documentation of the reason or reasons for rejecting a specimen.

(2) Where a specimen is rejected, a clinical laboratory service licensee must ensure that —

(*a*) the rejected specimen is not returned to the requestor except in the circumstances specified in the policy; and

(*b*) the requestor is informed of the rejection of a specimen and the reasons for the rejection.

Handling and transport of specimens

19.—(1) A clinical laboratory service licensee must ensure that every specimen the licensee receives is kept in packaging that is durable, leak-proof and watertight.

(2) If a specimen is reasonably suspected to contain an infectious agent, a clinical laboratory service licensee must ensure that the specimen is kept in proper packaging, labelled, transported and handled in accordance with any written law that governs the packaging, labelling, transportation and handling of such an infectious agent, including but not limited to the Biological Agents and Toxins Act 2005.

(3) Where a specimen that contains any biohazardous or radioactive material has to be transported to another location, a licensee must ensure that the specimen is properly packaged and labelled —

(*a*) with a description of the general nature of the transported item; and

(*b*) with a warning that the transported item contains biohazardous or radioactive material.

Tests must have clinical utility

20. A clinical laboratory service licensee must ensure that every test that is carried out on a specimen from a patient provides information that is relevant for the clinical management of the patient's health or medical condition.

Tests must be accurate

21.—(1) A clinical laboratory service licensee must ensure that every test carried out in the provision of the clinical laboratory service is accurate.

(2) Without limiting paragraph (1), a licensee must ensure that where —

(*a*) a test result for a patient deviates substantially from those earlier reported in respect of the patient; or

(*b*) there is reason to suspect that it is inaccurate given the patient's clinical presentation,

the licensee must investigate the reason for the deviation or the suspected inaccuracy and take appropriate remedial action if applicable.

Standards for reagents

22. A clinical laboratory service licensee must ensure all of the following regarding every reagent used in the provision of the clinical laboratory service:

(*a*) regular evaluation of every reagent to ensure that it is capable of consistently producing accurate results in any test that it is intended to be used;

(*b*) a reagent is not used in a test after its expiry date, or if there is any other reason for any personnel to suspect that the reagent is no longer suitable to be used in a test.

[S 417/2023 wef 26/06/2023]

Chemical hygiene plan and facilities

23.—(1) A clinical laboratory licensee must implement a chemical hygiene plan that sets out the safety procedures for every chemical used in the provision of the clinical laboratory service.

(2) A licensee must keep up-to-date documentation of the policies and processes of the chemical hygiene plan mentioned in paragraph (1) and make such documentation available to every personnel.

Tests on radioactive specimens

23A. A clinical laboratory licensee must not carry out any test or examination in relation to a radioactive specimen in any conveyance or at any premises other than the licensee's approved permanent premises.

[S 417/2023 wef 26/06/2023]

Documentation relating to tests

24. A clinical laboratory service licensee must ensure proper documentation of all of the following:

(*a*) each step of the procedure undertaken in the testing of any specimen;

(*b*) the source or reference for the procedure undertaken;

(*c*) the date the procedure is last reviewed;

(*d*) the calibration standards and controls required;

(*e*) the criteria used for the acceptance of quality control of the testing of specimens, and any results and actions to be taken when the quality control is unacceptable;

(*f*) the instructions for handling of any specimen;

(*g*) how test results are to be issued to the requestor.

Quality control of tests

25. A clinical laboratory service licensee must, in relation to each test it provides as part of the clinical laboratory service —

(*a*) perform the test using a quality control material and at an appropriate frequency, to ensure the accuracy of the test;

(*b*) establish acceptance criteria for test results;

(*c*) document any results that are outside of the acceptance criteria; and

(*d*) where there is reason to suspect that the test is not accurate, ensure that remedial actions are taken to ensure the accuracy of the test before conducting the test on a specimen from a patient.

PART 6

REQUIREMENTS SPECIFIC TO RADIOLOGICAL SERVICES

Facilities and equipment

26. A radiological service licensee must ensure all of the following in relation to every approved permanent premises, approved conveyance and temporary premises (other than residential premises) where a radiological service is provided:

(*a*) a waiting area for patients must be provided at the approved permanent premises or in the vicinity of the approved conveyance or temporary premises;

[S 417/2023 wef 26/06/2023]

(*b*) the waiting area must have adequate capacity and must be separate from any room used for taking radiological images;

(*c*) any examination room or area must be set up in a manner that ensures the patient's privacy when the patient is undergoing a radiological examination.

[S 417/2023 wef 26/06/2023]

Required qualifications for conducting radiological examinations

27.—(1) A radiological service licensee must ensure all of the following in the provision of the radiological service:

(*a*) any specified procedure must be conducted by a medical practitioner who is registered under section 22 of the Medical Registration Act 1997 as a specialist in the branch of diagnostic radiology;

(*b*) a sonographer must not conduct any radiological examination other than an ultrasound scan;

(*c*) a dentist must not conduct any radiological examination other than for dental imaging.

(2) In this regulation, "specified procedure" means a procedure mentioned in paragraph (*e*) of the definition of "radiological service" in paragraph 2 of the First Schedule to the Act.

[S 417/2023 wef 26/06/2023]

Handling of radiological images

28. A radiological service licensee must implement quality control measures for radiological images, including measures pertaining to all of the following:

(*a*) acceptance and rejection of images including setting the criteria and ensuring compliance with the criteria;

(*b*) analysis and review of rejected images, and keeping proper documentation of the reasons for the rejection;

(*c*) traceability of images, including ensuring the correct tagging of the images to the patients.

General safeguards for radiological examinations

29.—(1) A radiological service licensee must implement safeguards to ensure that —

(*a*) every radiological examination is conducted on the correct patient; and

(*b*) for any patient, the radiological examination is conducted at the part of the body or the site of the body part in accordance with the prescription of a medical practitioner or dentist.

(2) In conducting any radiological examination on a patient, a radiological service licensee must ensure that —

(*a*) there are protocols in place to ensure that the patient's exposure to radiation is kept to a minimum; and

(*b*) there are appropriate safety measures in place to protect any other person against exposure to radiation.

(3) In conducting any radiological examination on a patient who is 12 years of age or younger, a radiological service licensee must

ensure that the personnel involved in the radiological examination use paediatric-appropriate procedures and practices.

Specific safeguards where radiological examination involves contrast agent

30. Where a radiological examination requires the administration of a contrast agent to a patient, a radiological service licensee must ensure the safe administration and use of the contrast agent, and that all of the following requirements are satisfied:

(*a*) the administration and use of the contrast agent is in accordance with safety protocols implemented by the licensee;

(*aa*) the contrast agent is administered to the patient only at any of the licensee's approved permanent premises;

[S 417/2023 wef 26/06/2023]

(*b*) there are in place at the approved permanent premises resuscitation measures to be taken immediately for the patient (if required), including ensuring that —

(i) resuscitation equipment and resuscitation drugs are available for emergency use at the approved permanent premises; and

(ii) one or more competent personnel are present at the approved permanent premises to carry out resuscitation on the patient;

[S 417/2023 wef 26/06/2023]

(*c*) the licensee keeps a record of the administration of the contrast agent to the patient.

Specific safeguards where radiological examination involves anaesthesia or sedation

31.—(1) Where a radiological examination requires the administration of an anaesthesia or a sedative to a patient, a radiological service licensee must ensure the safe administration and use of the anaesthesia or sedative, and that all of the following requirements are satisfied:

(*a*) the administration and use of the anaesthesia or sedative is in accordance with safety protocols implemented by the licensee, including a protocol requiring the minimal use of any anaesthesia or sedative for patients who are 12 years of age or younger;

(*b*) appropriate equipment is provided to sedate patients before the radiological examination;

(*c*) an appropriate device to monitor the patient's vital signs is available for use during and after the administration of the anaesthesia or sedative to the patient;

(*d*) the patient's vital signs are monitored during and after the administration of the anaesthesia or sedative and for an appropriate period after such administration;

(*e*) there are in place at any approved permanent premises, approved conveyance or temporary premises where the radiological service is provided resuscitation measures to be taken immediately for the patient (if required), including ensuring that —

(i) resuscitation equipment and resuscitation drugs are available for emergency use at the approved permanent premises, approved conveyance or temporary premises; and

(ii) one or more competent personnel of the licensee are present at the approved permanent premises, approved conveyance or temporary premises to carry out resuscitation on the patient;

[S 417/2023 wef 26/06/2023]

(*f*) the licensee keeps a record of the administration of the anaesthesia or sedative to the patient;

(*g*) the patient is discharged from the licensee's care in accordance with the licensee's policy on when a patient can be discharged after anaesthesia or sedation.

[S 417/2023 wef 26/06/2023]

(2) A radiological service licensee must ensure that the administration of any specified anaesthetic to a patient is performed in the provision of a radiological service only by an anaesthesiologist.

[S 417/2023 wef 26/06/2023]

(3) A radiological service licensee must ensure that before a specified anaesthetic is administered to a patient, an anaesthesiologist assesses that the patient is a suitable candidate for the administration of specified anaesthetics.

[S 417/2023 wef 26/06/2023]

(4) In this regulation —

"deep sedation" means a drug-induced depression of a patient's consciousness —

(*a*) during which the patient cannot be easily aroused but will respond purposefully following repeated or painful stimulation;

(*b*) where the patient's ability to independently maintain ventilatory function may be impaired;

(*c*) where the patient may require assistance in maintaining a patent airway and spontaneous ventilation may be inadequate; and

(*d*) where the patient's cardiovascular function is usually maintained;

"general anaesthesia" has the meaning given by paragraph 2 of the First Schedule to the Act;

"neuraxial anaesthesia" means the anaesthesia that is caused in a patient by the administration of an anaesthetic around the nerves of the central nervous system of the patient;

"specified anaesthetic" means an anaesthetic used to cause deep sedation, general anaesthesia or neuraxial anaesthesia.

[S 417/2023 wef 26/06/2023]

Testing of specimen

32. A radiological service licensee must not test any specimen for a patient unless —

(*a*) a medical practitioner or dentist who is the licensee's personnel orders the test for the patient;

(*b*) the testing of the specimen only involves the conduct of a simple in vitro diagnostic test; and

(*c*) the testing of the specimen is provided only as a service incidental to the provision of the radiological service.

[S 417/2023 wef 26/06/2023]

Conduct of simple in vitro diagnostic test

32A.—(1) A radiological service licensee must ensure that any simple in vitro diagnostic test on a specimen or patient must be conducted —

(*a*) using testing material in respect of which —

(i) the expiry date has not passed; and

(ii) the personnel who is administering the test does not suspect or have any reason to suspect that the testing material is no longer fit for use; and

(*b*) in accordance with the instructions specified by the manufacturer of the testing material.

(2) A radiological service licensee must ensure that any testing material that is used to conduct any simple in vitro diagnostic testing is stored under the conditions, and handled in the manner, specified by the manufacturer of the testing material so as to lower the risk of contamination, unnecessary exposure of the testing material to the environment and early deterioration of the testing material.

[S 417/2023 wef 26/06/2023]

Instructions for self-collection of specimens

32B. Where any specimen is to be collected from a patient by the patient himself or herself, for the purpose of conducting any test on it

(whether or not the test is to be self-administered by the patient), a radiological service licensee must provide the patient with —

(*a*) instructions on how and when the specimen is to be collected; and

(*b*) the precautions that are to be taken to avoid contamination and degradation of the specimen.

[S 417/2023 wef 26/06/2023]

PART 7

REPORTING OF RESULTS

Who is qualified person in relation to reports

33.—(1) In this Part, "qualified person" means —

(*a*) in relation to a test — a Clinical Governance Officer or a person who is suitably qualified to certify and interpret the test results and appointed by a Clinical Governance Officer to do so;

(*b*) in relation to any radiological examination —

(i) a medical practitioner registered under section 22 of the Medical Registration Act 1997 as a specialist in the branch of diagnostic radiology; or

(ii) a medical practitioner who is —

(A) a diagnostic radiology resident; and

(B) a member of the Fellowship of the Royal College of Radiologists or any equivalent professional association of radiologists; and

[S 417/2023 wef 26/06/2023]

(*c*) in addition to paragraph (*b*) —

(i) in relation to a fetal ultrasound — a medical practitioner registered under section 22 of the Medical Registration Act 1997 as a specialist in the branch of obstetrics and gynaecology;

(ii) in relation to a dental radiological examination — a dentist;

[S 417/2023 wef 26/06/2023]

(iii) in relation to a plain radiography image — a person who —

(A) is duly authorised or registered to practise as a medical practitioner in a state or territory other than Singapore by a foreign authority having the function conferred by law of authorising or registering persons to practise as a medical practitioner in that state or territory;

(B) has a degree of Bachelor of Medicine, Bachelor of Surgery or equivalent; and

(C) is a member of the Fellowship of the Royal College of Radiologists or any equivalent professional association of radiologists; and

[S 417/2023 wef 26/06/2023]

[S 417/2023 wef 26/06/2023]

(iv) in relation to a plain radiography image — a medical practitioner who —

(A) is a diagnostic radiology resident; and

(B) has passed the National Plain Film Test administered by the College of Radiologists, Singapore.

[S 417/2023 wef 26/06/2023]

[S 417/2023 wef 26/06/2023]

(2) In this regulation, "diagnostic radiology resident" means a medical practitioner who is receiving training under a diagnostic radiology residency programme that is accredited by the Joint Committee on Specialist Training appointed by the Specialists Accreditation Board established under section 34(1) of the Medical Registration Act 1997.

[S 417/2023 wef 26/06/2023]

Written reports must be issued

34.—(1) A clinical laboratory service licensee must —

(*a*) issue a written clinical laboratory report for every test requested for a patient; and

(*b*) without undue delay, give the report to the requestor (or another medical practitioner, dentist or collaborative prescribing practitioner designated by the requestor to receive the report).

(2) Subject to paragraph (3), a radiological service licensee must —

(*a*) appoint a qualified person to interpret and report the findings of any radiological examination;

(*b*) ensure that a written radiological report is issued for every radiological examination conducted for a patient for diagnostic purpose; and

(*c*) without undue delay, give the report to the requestor (or another medical practitioner, dentist or collaborative prescribing practitioner designated by the requestor to receive the report).

(3) Where a radiological service licensee appoints, under paragraph (2)(*a*), a qualified person who is not employed by the licensee, the licensee must take all reasonable steps (including the implementation of appropriate processes) to transmit to the qualified person a copy of the radiological images that is of the same resolution and quality as the originals captured by the licensee.

Contents of reports

35.—(1) A clinical laboratory report or radiological report mentioned in regulation 34(1) or (2), other than a clinical laboratory report mentioned in paragraph (2), must contain all of the following information:

(*a*) the following information about the licensee issuing the report:

(i) the licensee's name and the business name (if different from the licensee's name) by which the licensee provides the applicable service;

(ii) the licensee's address;

[S 417/2023 wef 26/06/2023]

(*b*) all of the following identifying information:

(i) the patient's name;

(ii) the patient's identification number or passport number;

(iii) where the information in sub-paragraphs (i) and (ii) is not known to the licensee — other information identifying the patient;

(*c*) subject to paragraph (1A), the address of the premises at which or the vehicle number of the approved conveyance in which the test or radiological examination is conducted;

[S 417/2023 wef 26/06/2023]

(*d*) the date the test or radiological examination is conducted;

(*e*) the name of the requestor;

(*f*) the description and findings of the test or radiological examination;

(*g*) for a clinical laboratory report —

(i) where the information is known to the clinical laboratory service licensee — the date and time the specimen was derived from the patient;

(ii) [*Deleted by S 417/2023 wef 26/06/2023*]

(iii) for a tissue specimen — the anatomical site of the specimen; and

(iv) any other necessary information for the interpretation of results, including the established norms and ranges applicable to the test results;

(*h*) the date the report is issued;

[S 417/2023 wef 26/06/2023]

(*i*) the name and signature (including an electronic signature) of the qualified person certifying the test results or interpreting and reporting the findings of the radiological examination.

(1A) Where the premises at which the test or radiological examination is conducted are temporary premises that are residential premises, the licensee issuing the report may, instead of stating the address of those premises in the clinical laboratory report or radiological report (as the case may be), indicate that the test or radiological examination was conducted at residential premises.

[S 417/2023 wef 26/06/2023]

(2) A clinical laboratory report mentioned in regulation 34(1) issued for any test in relation to COVID-19 must contain the information set out in paragraph (1)(*b*), (*d*), (*f*) and (*h*).

(3) Where a licensee appoints or engages another person (*A*) to conduct a test or radiological examination on the licensee's behalf under regulation 41, the clinical laboratory report or radiological report (as the case may be) must also include the following:

(*a*) *A*'s name;

(*b*) the address of the premises in which the test or radiological examination (as the case may be) was performed;

(*c*) the original clinical laboratory report or radiological report (as the case may be) issued by *A*, if any.

Urgent notification of results or findings in emergency

36. Where any result or finding in a test or radiological examination discloses that the patient's safety or wellbeing may be adversely affected without immediate medical treatment or intervention, the licensee must make all reasonable efforts to immediately bring the relevant results or findings to the attention of —

(*a*) the requestor; or

(*b*) where the requestor cannot be contacted — the healthcare institution that employs or engages the requestor.

[S 417/2023 wef 26/06/2023]

Identification and review of incidental or abnormal findings

37.—(1) Subject to paragraph (2), a licensee must —

(*a*) ensure that the qualified person mentioned in regulation 35(1)(*i*) states in the clinical laboratory report or radiological report all incidental findings that are potentially clinically significant and abnormal findings; and

(*b*) bring the incidental or abnormal findings to the attention of the requestor.

[S 417/2023 wef 26/06/2023]

(2) Paragraph (1) does not apply in relation to an incidental finding in any genetic test if the patient in respect of whom the clinical laboratory report is issued or the requestor informs the licensee that the patient does not wish to be informed of any incidental finding.

[S 417/2023 wef 26/06/2023]

Notification of error

38. If a licensee discovers any error in a clinical laboratory report or radiological report after it is issued, the licensee must immediately notify the requestor (or another medical practitioner, dentist or collaborative prescribing practitioner designated by the requestor to receive the report) of the error and issue an addendum to the report to correct the error.

Copies of reports must be complete

39. Where a licensee makes a copy of or reproduces a clinical laboratory report or radiological report issued by the licensee or retained by the licensee under regulation 41(2), the licensee must ensure that the report is copied or reproduced in its entirety.

Processes to ensure prompt reporting

40.—(1) A licensee must implement processes to ensure that the reporting of any test or radiological examination is not affected by any disruption or maintenance (scheduled or otherwise) to the licensee's laboratory information system or radiological information system, as the case may be.

(2) The licensee must keep up-to-date documentation of the processes mentioned in paragraph (1).

PART 8

MISCELLANEOUS

Outsourcing of tests or radiological examinations

41.—(1) A clinical laboratory service licensee may only appoint or engage any of the following persons to conduct a test on the licensee's behalf:

(*a*) any other person who holds a clinical laboratory service licence under the Act;

(*b*) a person who operates a clinical laboratory outside Singapore that is accredited by an accreditation body approved by the Director-General;

[S 417/2023 wef 26/06/2023]

(*c*) where none of the persons mentioned in sub-paragraph (*a*) or (*b*) is willing or able to conduct the test, a person who operates a clinical laboratory that is approved by the Director-General.

[S 417/2023 wef 26/06/2023]

(2) Where a clinical laboratory service licensee (*A*) has engaged another licensee (*B*) under paragraph (1) to conduct the test on behalf of *A*, a copy of the clinical laboratory report issued by *B* must be retained by *A*.

(3) To avoid doubt, a clinical laboratory service licensee who appoints another person to provide, on the clinical laboratory service licensee's behalf, a licensable healthcare service remains responsible to comply with the licence conditions and the duties of a licensee under the Act, these Regulations and any other regulations made under the Act.

(4) Subject to paragraph (5), a radiological service licensee must not appoint any person to provide, on the licensee's behalf, a radiological service or any aspect of the radiological service.

(5) A radiological service licensee may, under regulation 34(2)(*a*), appoint a qualified person who is not employed by the licensee to interpret and report the findings of any radiological examination conducted by the licensee.

Clinical laboratory service licensee — records to be kept for each specimen

42. A clinical laboratory service licensee must keep records of all of the following information in relation to each specimen that the licensee receives:

(*a*) all of the following identifying information:

(i) the patient's name;

(ii) the patient's identification number or passport number;

(iii) where the information in sub-paragraphs (i) and (ii) is not known to the clinical laboratory service licensee — other information to enable the specimen to the traced to the patient;

(*b*) the gender of the patient;

(*c*) where the information is known to the clinical laboratory service licensee — the date and time the specimen was derived from the patient;

(*d*) the date and time of the receipt of the specimen by the licensee;

(*e*) the type of specimen;

(*f*) for a tissue specimen, the anatomical site of the specimen;

(*g*) where the specimen is derived from a patient for the purposes of blood grouping, crossmatching, tissue typing or genetic testing — the name of the person who took the specimen from the patient;

(*h*) the relevant clinical status of the patient (where required), including whether the patient has fasted before the taking of the specimen;

(*i*) the characteristics of the specimen that may provide information that is relevant to the interpretation of the test results;

(*j*) the name of the requestor.

Clinical laboratory service licensee — records to be kept for each test

43. A clinical laboratory service licensee must keep records of all of the following information in relation to each test of a specimen that the licensee conducts:

(*a*) the date, time and type of the test conducted;

(*aa*) where the test was conducted at temporary premises that are residential premises — the address of those residential premises;

[S 417/2023 wef 26/06/2023]

(*b*) the name of the person who conducted the test;

(*c*) the results of the test;

(*d*) the name of the person who certified the test;

(*e*) all data and workings, including instrument raw data and laboratory worksheets, relied upon in the issuance of the clinical test report.

Radiological service licensee — records to be kept in relation to each radiological examination

44.—(1) A radiological service licensee must keep records of all of the following in relation to each radiological examination that the licensee conducts:

(*a*) the date, time and type of radiological examination;

(*b*) where the radiological examination was conducted at temporary premises that are residential premises — the address of those residential premises;

(*c*) the name of the person who conducted the radiological examination;

(*d*) the name of the person who reported and issued the radiological report;

(*e*) each radiological image obtained from the radiological examination;

(*f*) in relation to the examination —

(i) information about the site of the anatomic site imaged; and

(ii) where any images are provided by the licensee directly to another person together with the radiological report —

(A) the person to whom the images were provided; and

(B) the mode by which the images were provided to that person;

(*g*) in relation to any contrast agent administered to a patient during the examination —

(i) the name and dose of the contrast agent;

(ii) the route and rate of administration of the contrast agent; and

(iii) any adverse reaction experienced by the patient following or associated with the administration of the contrast agent;

(*h*) where the radiological examination involves the administration of any anaesthetic or sedative to the patient —

(i) information relating to the anaesthetic or sedative administered; and

(ii) information relating to the safety of patients and personnel, including information relating to —

(A) any adverse reaction experienced by any patient following or associated with the administration of any anaesthetic or sedative,

including any investigation into the cause of the adverse reaction; and

(B) any incident occurring in the course of or in relation to the examination of any patient that affected or potentially affected the safety of the patient or any personnel, including any investigation and follow-up action taken.

(2) The radiological service licensee must keep an accurate and complete copy of the radiological report of each radiological examination that the licensee conducts.

[S 417/2023 wef 26/06/2023]

Tracing of records from report

44A. A licensee must, in relation to any report mentioned in regulation 34(1) or (2) for a test or radiological examination, implement a system that enables the licensee to retrieve all records mentioned in regulation 42, 43 or 44 relating to the test or radiological examination.

[S 417/2023 wef 26/06/2023]

Keeping of other records

45.—(1) A licensee must maintain proper, complete and accurate records in respect of all of the following:

(*a*) the qualifications and competencies (including training and competency assessments) of each personnel, that are relevant to the provision of the applicable service;

(*b*) the quality management activities and measures taken by the licensee in connection with the provision of the applicable service (called in this regulation a quality record);

(*c*) every programme, policy, system, measure, protocol or process that the licensee is required to implement under these Regulations, and every activity undertaken under that programme, policy, system, measure, protocol or process.

(2) A quality record mentioned in paragraph (1)(*b*) must contain —

(*a*) information relating to the quality management system mentioned in regulation 11;

(*b*) a master list of the initials and signatures of each personnel;

(*c*) the job descriptions, training and competency assessments for each personnel;

(*d*) all information and documents related to the review of policies and processes implemented under regulation 11, and documentation of changes made to different versions of those documents;

(*e*) details regarding the maintenance and calibration of each piece of equipment and instrument used in the provision of the applicable service;

(*f*) quality control measures for each test, piece of equipment and instrument used in the provision of the applicable service; and

(*g*) for a clinical laboratory service licensee —

(i) validation of every test method used in the provision of the clinical laboratory service; and

(ii) proficiency testing and external quality assurance programme performance.

Price transparency

46.—(1) A clinical laboratory service licensee must, upon request by a requestor or patient, inform the requestor or patient of the following information:

(*a*) the amount of each fee (including any administrative fee) that the clinical laboratory service licensee charges, or intends to charge, for any test or test panel;

(*b*) in the case of a test panel, the tests that are included in that test panel.

(2) A radiological service licensee must, upon request by a requestor or patient, inform the requestor or patient of the amount of each fee (including any administrative fee) that the licensee charges, or intends to charge, for any examination.

(3) In this regulation, "test panel", in relation to a clinical laboratory service, means a set of 2 or more tests provided as part of that service.

Display of charges

47.—(1) Where a patient is present at the licensed premises of or licensed conveyance used by a clinical laboratory service licensee for the purpose of a test or test panel to be conducted by the licensee for the patient, the licensee must display or make available the charges payable for the test or test panel at the licensed premises or in the licensed conveyance where the clinical laboratory service is provided.

(2) A radiological service licensee must ensure that the charges payable for the following components of a radiological service provided by the licensee are displayed or made available at the licensed premises or in the licensed conveyance where the radiological service is provided:

(*a*) imaging procedures, including consumables;

(*b*) contrast fees;

(*c*) sedation procedures, if applicable.

Offence

48.—(1) Any person that contravenes regulation 11(1), 12(1), (2) or (3), 12A(2), (3) or (4), 13, 14(1), 15(1) or (2), 19(1), (2) or (3), 20, 21(1), 22, 23(1), 23A, 25, 27(1), 28, 29(1), (2) or (3), 30, 31(1), (2) and (3), 32, 34(2), 36, 37, 38 or 41(1) or (4) shall be guilty of an offence.

[S 417/2023 wef 26/06/2023]

(2) A person that is guilty of an offence under paragraph (1) shall be liable on conviction —

(*a*) to a fine not exceeding $20,000 or to imprisonment for a term not exceeding 12 months or to both; and

(*b*) in the case of a continuing offence, to a further fine not exceeding $1,000 for every day or part of a day during which the offence continues after conviction.

THE SCHEDULE

Regulations 2, 4 and 4B

PART 1

SPECIFIED SERVICES FOR CLINICAL LABORATORY SERVICE

1. The following are specified services for a clinical laboratory service:

(*a*) a testing service in any of the following laboratory disciplines:

(i) anatomic pathology;

(ii) chemical pathology, excluding the provision of the test set out in sub-paragraph (*b*)(vi);

(iii) clinical toxicology;

(iv) cytology;

(v) cytogenetics;

(vi) haematology, excluding the provision of the test set out in sub-paragraph (*b*)(vii);

(vii) histocompatibility;

(viii) immunology, excluding the provision of the tests set out in sub-paragraph (*b*)(i) and (ii);

(ix) medical microbiology, excluding the provision of the tests set out in sub-paragraph (*b*)(v) and (viii);

(x) transfusion medicine;

(xi) molecular pathology, excluding the provision of the tests set out in sub-paragraph (*b*)(iii) and (iv);

(*b*) the provision of any of the following tests:

(i) human immunodeficiency virus screening;

(ii) human immunodeficiency virus confirmation;

(iii) pre-implantation genetic testing for monogenic or single gene defects;

(iv) pre-implantation genetic testing for chromosomal structural rearrangements;

THE SCHEDULE — *continued*

(v) acid-fast bacilli smear testing;

(vi) glycated haemoglobin (haemoglobin A1c) testing;

(vii) malaria parasite testing;

(viii) molecular SARS-CoV-2 testing for Coronavirus Disease 2019 (COVID-19).

PART 2

SPECIFIED SERVICES FOR RADIOLOGICAL SERVICE

1. The following are specified services for a radiological service:

(*a*) the provision of an imaging service by any of the following imaging modalities, excluding the provision of any procedure mentioned in paragraph (*b*):

(i) plain radiography;

(ii) mammography;

(iii) fluoroscopy;

(iv) computed tomography;

(v) cone beam computed tomography;

(vi) magnetic resonance imaging;

(*b*) the provision of minimally invasive image-guided biopsy of breast, thyroid, superficial lump or bump, or any superficial lymph node.

[S 417/2023 wef 26/06/2023]

Made on 28 December 2021.

CHAN YENG KIT
Permanent Secretary,
Ministry of Health,
Singapore.

[MH 78:44/1; AG/LEGIS/SL/122E/2020/19 Vol. 1]