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HEALTHCARE SERVICES ACT 2020 (ACT 3 OF 2020)

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

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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;

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

"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 56C(6) of the Private Hospitals and Medical Clinics Regulations (Rg 1);

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

"imaging modality" has the meaning given by regulation 4(4);

"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;

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

"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 to request a licensee to conduct a test for the patient without a referral by a medical practitioner, dentist or collaborative prescribing practitioner;

"specified test" has the meaning given by regulation 4(4);

"specimen" means any matter derived from the body of an individual;

"test" means an analysis or examination of a specimen conducted by a licensee in the licensee's licensed premises in connection with the provision of the clinical laboratory service.

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.

Specific services provided under licence

4.—(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 clinical laboratory service must specify in the licence application every

laboratory discipline or specified test that the applicant provides, or intends to provide, as part of that service.

(2) 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 every imaging modality that the applicant provides, or intends to provide, as part of that service.

(3) A licensee who intends to provide any laboratory discipline, specified test or imaging modality (as the case may be) as part of the applicable service must, no later than one month before the licensee intends to start providing the laboratory discipline, specified test or imaging modality, give written notice to the Director of the licensee's intention.

(4) In this regulation —

"imaging modality" includes —

(*a*) plain X-ray;

(*b*) bone densitometry;

(*c*) mammography;

(*d*) fluoroscopy;

(*e*) computed tomography;

(*f*) cone beam computed tomography;

(*g*) ultrasonography; and

(*h*) magnetic resonance imaging;

"laboratory discipline" includes —

(*a*) anatomic pathology;

(*b*) chemical pathology;

(*c*) clinical toxicology;

(*d*) cytology;

(*e*) cytogenetics;

(*f*) haematology;

(*g*) histocompatibility;

(*h*) immunology;

(*i*) medical microbiology;

(*j*) transfusion medicine; and

(*k*) molecular pathology;

"specified test" means any of the following:

(*a*) human immunodeficiency virus screening;

(*b*) human immunodeficiency virus confirmation;

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

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

(*e*) acid-fast bacilli smear testing;

(*f*) glycated haemoglobin (haemoglobin A1c) testing;

(*g*) malaria parasite testing;

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

PART 2

REQUIREMENTS RELATING TO PERSONNEL

Skills and competencies of Clinical Governance Officer for clinical laboratory service licensee

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 licensee 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;

(iv) at least 5 years of work experience in a clinical laboratory licensed under the Private Hospitals and Medical Clinics Act 1980 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.

Skills and competencies of Clinical Governance Officer for radiological service licensee

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 licensee:

(*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.

(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.

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 licensee 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 the safety programme mentioned in regulation 14.

(2) In addition to regulation 14 of the General Regulations, a Clinical Governance Officer appointed by a radiological service licensee 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 the safety programme mentioned in regulation 14.

Licensee must appoint section leader

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

(2) A radiological service licensee must, in relation to each imaging modality 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.

(3) A person may be appointed as a section leader for more than one laboratory discipline or imaging modality.

(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 laboratory discipline or imaging modality for which the section leader is appointed:

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

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

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

(*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 laboratory discipline or imaging modality 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 laboratory discipline or imaging modality 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 laboratory discipline or imaging modality that the section leader is appointed for;

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

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;

(*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 every licensed premises and licensed conveyance —

(*a*) has adequate space for the licensee to carry out the applicable service in a safe manner; and

(*b*) is adequately secured to prevent unauthorised access to the licensed premises and licensed conveyance.

(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 is provided at the licensed premises or licensed conveyance;

(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 the licensed premises or licensed conveyance to ensure the safety of all personnel, patients and visitors, and prevent any contamination of specimens;

(*c*) safety equipment, including safety cabinets, hand basins and emergency showers, is provided in the licensed premises or licensed conveyance;

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

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 licensed premises or licensed conveyance.

(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*) radiation safety if there are radioactive materials or irradiating equipment used in the provision of the service;

(*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 the licensed premises or licensed conveyance.

(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 the licensed premises or licensed conveyance with personal protective equipment appropriate for the work performed.

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 date of expiry or beyond its shelf life, 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.

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.

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 licensed premises and licensed conveyance:

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

(*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.

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 minimally invasive image-guided biopsy of breast, thyroid, any superficial lump or bump or any superficial lymph node.

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;

(*b*) there are in place at the licensed premises or licensed conveyance 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 licensed premises or licensed conveyance; and

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

(*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. 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 the licensed premises or licensed conveyance 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 licensed premises or licensed conveyance; and

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

(*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.

Safety policies regarding pregnant women

32. A radiological service licensee must implement all of the following policies:

(*a*) policies on the performance of ionising radiological procedures on pregnant women or women suspected to be pregnant;

(*b*) policies to protect any personnel who is pregnant against radiation exposure in the course of work and in the licensed premises or licensed conveyance.

PART 7

REPORTING OF RESULTS

Who is qualified person in relation to reports

33. 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 — a medical practitioner registered under section 22 of the Medical Registration Act 1997 as a specialist in the branch of diagnostic radiology; and

(*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; and

(iii) in relation to a plain x-ray 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.

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 name and address of the licensee issuing the report, and the business name (if different from the name of the licensee) by which the licensee provides the applicable service;

(*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*) the address of the licensed premises at or the vehicle number of the licensed conveyance in which the test or radiological examination is conducted;

(*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) the type of specimen that is tested;

(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 and time the report is issued;

(*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.

(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 reports in emergency

36. Where any result or finding in a clinical laboratory report or radiological report 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.

Identification and review of incidental or abnormal findings

37. 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.

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;

(*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.

(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;

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

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

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

(*e*) the radiological report.

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) or (2), 13, 14(1), 15(1) or (2), 19(1), (2) or (3), 20, 21(1), 22, 23(1), 24, 25, 27(1), 28, 29(1), (2) or (3), 30, 31, 32, 34(1) or (2), 36, 37, 38 or 41(1) or (4) shall be guilty of an offence.

(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.

Made on 28 December 2021.

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

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