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HEALTHCARE SERVICES ACT 2020 (ACT 3 OF 2020)

HEALTHCARE SERVICES (NUCLEAR MEDICINE ASSAY SERVICE AND NUCLEAR MEDICINE IMAGING 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 (Nuclear Medicine Assay Service and Nuclear Medicine Imaging 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 nuclear medicine assay service or nuclear medicine imaging service;

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

"collaborative prescribing practitioner" has the meaning given by regulation 56C(6) of the Private Hospitals and Medical Clinics Regulations (Rg 1);

"diagnostic radiographer" means a duly qualified allied health professional who is registered under the Allied Health Professions Act 2011 to practise radiography;

"duly qualified allied health professional" has the meaning given by section 3 of the Allied Health Professions Act 2011;

"examination" means a radiological examination of an individual conducted by a nuclear medicine imaging licensee at the licensed premises of or in the licensed conveyance used by the licensee in connection with the provision of a nuclear medicine imaging service;

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

"image", in relation to a nuclear medicine imaging service, means an image produced in the course of the provision of that service;

"irradiating apparatus", "radioactive material" and "radioactive substance" have the meanings given by section 2(1) of the Radiation Protection Act 2007;

"licensee" means a nuclear medicine assay licensee or a nuclear medicine imaging licensee;

"medical laboratory technologist" means an individual who holds at least a diploma or degree in biomedical science, biological science or medical technology;

"nuclear medicine assay licensee" means a person who holds a licence to provide a nuclear medicine assay service;

"nuclear medicine imaging licensee" means a person who holds a licence to provide a nuclear medicine imaging service;

"nuclear medicine technologist" means an individual who holds at least a diploma or degree in nuclear medicine technology;

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

"radiation safety officer" —

(*a*) where a licensee uses any irradiating apparatus within the meaning given by regulation 2 of the Radiation Protection (Non-Ionising Radiation) Regulations (Rg 1) — means an individual who is appointed by the licensee under regulation 40 of those Regulations as a radiation safety officer; or

(*b*) in any other case — means an individual who is appointed by a licensee under regulation 53 of the Radiation Protection (Ionising Radiation) Regulations (Rg 2) as a radiation safety officer or deputy radiation safety officer;

"radiation therapist" means a duly qualified allied health professional who is registered under the Allied Health Professions Act 2011 to practise radiation therapy;

"radiopharmaceutical" means any radioactive material that is administered to a patient as a diagnostic or therapeutic agent;

"requestor" —

(*a*) in relation to a test of a patient that is provided as part of a nuclear medicine assay service — means a collaborative prescribing practitioner, dentist or medical practitioner who ordered that test for the patient; or

(*b*) in relation to an examination of a patient that is provided as part of a nuclear medicine imaging

service — means a dentist or medical practitioner who ordered that examination for the patient;

"service modality" has the meaning given by regulation 4(3);

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

"test" means an analysis or examination of a specimen conducted by a nuclear medicine assay licensee in the licensed premises of or licensed conveyance used by the licensee in connection with the provision of a nuclear medicine assay service;

"test panel", in relation to a nuclear medicine assay service, means a set of 2 or more tests provided as part of that service.

Application of Regulations

3. Unless otherwise expressly provided in these Regulations, the provisions of these Regulations —

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

(*b*) 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 an applicable service must specify in the licence application every service modality that the applicant provides, or intends to provide, as part of that service.

(2) A licensee who intends to provide any additional service modality as part of the applicable service must, no later than one month before the licensee intends to start providing that service modality, give written notice to the Director of the licensee's intention.

(3) In this regulation, "service modality" —

(*a*) in relation to a nuclear medicine assay service, includes in-vitro assay; and

(*b*) in relation to a nuclear medicine imaging service, includes the following:

(i) planar nuclear medicine imaging and uptake studies;

(ii) positron emission tomography-computed tomography;

(iii) positron emission tomography-magnetic resonance;

(iv) single-photon emission computed tomography-computed tomography.

PART 2

REQUIREMENTS RELATING TO PERSONNEL

Skills and competencies of Clinical Governance Officer for applicable licensee

5.—(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 as a Clinical Governance Officer for an applicable 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 nuclear medicine;

(*c*) at least 5 years of work experience, after obtaining the registration mentioned in sub-paragraph (*b*), in providing the applicable service;

(*d*) a licence to use any radioactive material under section 5(1)(*b*) of the Radiation Protection Act 2007.

(2) Where a nuclear medicine imaging licensee provides a nuclear medicine imaging service only for cardiac purposes, the nuclear

medicine imaging licensee may appoint as a Clinical Governance Officer an individual who possesses all of the following skills and competencies:

(*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 cardiology;

(*c*) a valid certification in nuclear cardiology by the Certification Board of Nuclear Cardiology, United States of America;

(*d*) at least 5 years of work experience, after obtaining the certification mentioned in sub-paragraph (*c*), in providing the nuclear medicine imaging service;

(*e*) a licence to use any radioactive material under section 5(1)(*b*) of the Radiation Protection Act 2007.

Duties and responsibilities of Clinical Governance Officer

6.—(1) This regulation applies in addition to regulation 15(1) of the General Regulations.

(2) A Clinical Governance Officer for an applicable service is responsible for —

(*a*) overseeing the conduct of tests under the nuclear medicine assay service or examinations under the nuclear medicine imaging service (as the case may be) by a licensee;

(*b*) ensuring that the tests or examinations (as the case may be) are conducted in accordance with the correct methods and procedures for those tests or examinations, as the case may be;

(*c*) implementing and overseeing a radiation safety programme to ensure the safety of personnel and patients and other individuals within or in the vicinity of the licensed premises of or licensed conveyance used by the

licensee, including the proper handling, use and disposal of radioactive substances; and

(*d*) evaluating new processes the licensee intends to implement for the provision of the applicable service, including processes relating to the preparation, dispensing, radiolabelling, compounding and quality control of radiopharmaceuticals.

(3) A Clinical Governance Officer for a nuclear medicine assay service is responsible, in addition to the matters in paragraph (2), for evaluating any new test that the nuclear medicine assay licensee intends to conduct as part of that service.

(4) A Clinical Governance Officer for a nuclear medicine imaging service is responsible, in addition to the matters in paragraph (2), for evaluating any service modality that the nuclear medicine imaging licensee intends to provide as part of that service, whether or not that service modality is a service modality mentioned in regulation 4(3)(*b*).

Appointment of section leader

7.—(1) A licensee must, in relation to each service modality provided by the licensee, appoint as the section leader a suitably qualified person who resides in Singapore.

(2) A person may be appointed as a section leader for more than one service modality.

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

(4) In this regulation, "suitably qualified person" means —

(*a*) in relation to a service modality provided as part of a nuclear medicine assay service — a medical laboratory technologist who has qualifications that are relevant to that service modality, and at least 5 years of work experience in a clinical laboratory operated by —

(i) a person authorised by a licence under the Act to provide a clinical laboratory service; or

(ii) a person who holds a licence to use any premises as a clinical laboratory under the Private Hospitals and Medical Clinics Act 1980; or

(*b*) in relation to a service modality provided as part of a nuclear medicine imaging service — a diagnostic radiographer, radiation therapist or nuclear medicine technologist who has at least 3 years of work experience in providing that service modality.

Duties of section leader

8. A licensee must ensure that every section leader appointed under regulation 7 does all of the following in relation to the service modality for which the section leader is appointed:

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

(*b*) supervise, train and guide personnel in conducting tests or examinations (as the case may be) in the provision of that service modality;

(*c*) assess and ensure the competency of personnel deployed to perform tasks in relation to the provision of that service 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 examinations (as the case may be) conducted under that service modality, including ensuring the implementation of quality control measures;

(*f*) establish and review policies and procedures for the safe and effective performance of all tests or examinations (as the case may be) conducted in the provision of that service modality;

(*g*) resolve any technical issues that arise from the performance of all tests or examinations (as the case may be) conducted in the provision of that service modality;

(*h*) review all service records in relation to the tests or examinations (as the case may be) conducted in the provision of that service modality.

General requirements relating to personnel

9.—(1) A licensee must ensure that each personnel —

(*a*) has the necessary qualifications, having regard to the type and nature of the work performed by that personnel;

(*b*) attends adequate training on a regular basis in relation to the provision of the applicable service;

(*c*) attends appropriate training on a regular basis in relation to radiation safety awareness; and

(*d*) is assessed periodically on the personnel's competencies and work performance.

(2) A licensee must ensure that any personnel who has less than 3 years of relevant experience does not perform any task or provide any service in relation to the provision of an applicable service except under the close supervision of —

(*a*) a Clinical Governance Officer; or

(*b*) another personnel with not less than 3 years of relevant experience.

(3) For the purposes of paragraph (2), the relevant experience of a personnel, in relation to a task performed or service provided in relation to the provision of the applicable service, means —

(*a*) where the task or service may be lawfully performed or provided only by an individual who is a healthcare professional or radiation safety officer — the personnel's working experience in relation to the task or service after becoming a healthcare professional or radiation safety officer, as the case may be; or

(*b*) in any other case — the personnel's working experience in relation to the task or service.

(4) This regulation does not affect any requirement for the appointment of any person by the applicable licensee for or in relation to the provision of the applicable service under any other written law.

(5) In this regulation, "healthcare professional" means —

(*a*) a duly qualified allied health professional;

(*b*) a medical practitioner who is registered under the Medical Registration Act 1997 and holds a valid practising certificate under that Act; or

(*c*) a nurse or midwife who is registered, or an enrolled nurse who is enrolled, under the Nurses and Midwives Act 1999 and holds a valid practising certificate under that Act.

PART 3

PROCESSES, EQUIPMENT AND FITTINGS

Quality management system

10.—(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 applicable 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 applicable service complies with the Act and any other written law governing the applicable service and the licence conditions imposed under section 13(1) of the Act;

(*c*) implementation of protocols to ensure compliance with this Part and Parts 4, 5 and 6 and for the physical safety of 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 those 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 radioactive substances kept and used by the licensee, including measures pertaining to —

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

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

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

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

(*h*) conduct of regular holistic analysis and reviews of all information relating to —

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

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

(*i*) testing and monitoring of the radiation levels in the licensed premises of or licensed conveyance used by the licensee to ensure the safety of personnel, patients and visitors;

(*j*) quality control measures for all specimens or images, as the case may be;

(*k*) systems and processes to ensure that regulations 14(4) and 33 are complied with;

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

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

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

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

(*p*) 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 all personnel comply with sub-paragraphs (i) and (ii);

(*q*) 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.

(3) Without limiting paragraph (1), the quality management system for a nuclear medicine assay service must additionally provide for all of the following in relation to every test provided by the nuclear medicine assay licensee:

(*a*) the nuclear medicine assay licensee's participation in an external quality assessment programme in relation to that test;

(*b*) the review, by a Clinical Governance Officer or such other suitably qualified personnel designated by a Clinical Governance Officer (each referred to as *C*), of the results of the external quality assessment programme;

(*c*) where the nuclear medicine assay licensee's performance does not meet the evaluation criteria determined by the provider of the external quality assessment programme —

(i) the investigation by *C* into the causes of the licensee's unsatisfactory performance; and

(ii) the identification and implementation by *C* of appropriate and effective actions to address the causes identified in *C*'s investigation.

(4) 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.

Equipment and fittings

11.—(1) A licensee must ensure that every licensed premises or 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 or licensed conveyance, as the case may be.

(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 in 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 or use of, the reagents, specimens and other materials and supplies;

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

(i) adequate space is provided in the licensed premises or licensed conveyance; and

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

(*c*) appropriate radiation shielding is provided in any part of the licensed premises or licensed conveyance where any procedures involving the handling and use of radioactive substances are performed;

(*d*) the licensed premises or licensed conveyance complies with the requirements of, and is approved for use in accordance with, any written law relating to the storage, possession, use and disposal of radioactive substances;

(*e*) adequate decontamination equipment is provided at the licensed premises or licensed conveyance to ensure the safety of personnel, patients and visitors and prevent any contamination of specimens, if applicable;

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

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

Referral, etc., needed before services provided to patients

12.—(1) In the provision of a nuclear medicine assay service, a nuclear medicine assay licensee must not conduct a test for a patient who resides in Singapore unless —

(*a*) the patient is referred to the licensee for the test by a collaborative prescribing practitioner, dentist or medical practitioner; or

(*b*) where the licensee is appointed or engaged to conduct the test on behalf of another nuclear medicine assay licensee — the patient was referred to the other licensee for the test by a collaborative prescribing practitioner, dentist or medical practitioner.

(2) In the provision of a nuclear medicine imaging service, a nuclear medicine imaging licensee must not conduct an examination in Singapore for a patient unless —

(*a*) the patient is referred to the licensee for the examination by a dentist or medical practitioner; or

(*b*) where the licensee is appointed or engaged to conduct the examination on behalf of another nuclear medicine imaging licensee — the patient was referred to the other licensee for the examination by a dentist or medical practitioner.

PART 4

SAFETY REQUIREMENTS

Safety programme

13.—(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 the safety of water supply and outlets;

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

(*c*) the safety of all personnel and patients during the conduct of any test or examination, as the case may be;

(*d*) waste management and spills management;

(*e*) ensuring that there is adequate ventilation and lighting for personnel to perform work safely;

(*f*) ensuring that patients are not exposed to unsafe levels of noise when undergoing any test or examination, as the case may be;

(*g*) 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 adverse incident or medical emergency; and

(*h*) ensuring the cleanliness of the licensed premises or licensed conveyance.

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

Radiation safety programme

14.—(1) A licensee must —

(*a*) develop and ensure the implementation of a radiation safety programme;

(*b*) ensure that all personnel comply with the radiation safety programme; and

(*c*) maintain accurate and complete documentation for the radiation safety programme.

(2) The licensee must ensure that the radiation safety programme mentioned in paragraph (1) complies with any written law governing the preparation, storage, possession, use and disposal of radioactive substances.

(3) In addition, a nuclear medicine imaging licensee must ensure that the radiation safety programme mentioned in paragraph (1)

complies with any written law governing the storage, possession, use and disposal of irradiating apparatus.

(4) A licensee must implement policies to protect pregnant personnel against radiation exposure in the course of work and in the licensed premises or licensed conveyance, as the case may be.

(5) A licensee must 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 secondary containers for transportation of radioactive substances within and outside the licensed premises.

Chemical hygiene plan

15.—(1) A licensee must implement a chemical hygiene plan that sets out the safety procedures for every chemical used in the provision of an applicable 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 all personnel.

Licensee must ensure personnel comply with safety plans and programmes

16. A licensee must ensure that each personnel complies with —

(*a*) the measures and procedures set out in —

(i) the safety programme mentioned in regulation 13(1); and

(ii) the radiation safety programme mentioned in regulation 14(1); and

(*b*) the chemical hygiene plan mentioned in regulation 15(1).

Personal protective equipment must be provided

17. A licensee must provide each personnel performing any work in any licensed premises or licensed conveyance with personal protective equipment appropriate for the work performed.

PART 5

REQUIREMENTS SPECIFIC TO NUCLEAR MEDICINE ASSAY SERVICE

Specific personnel

18.—(1) A nuclear medicine assay licensee must —

(*a*) employ or engage at least one medical laboratory technologist; and

(*b*) ensure that the medical laboratory technologist, or where 2 or more medical laboratory technologists are employed or engaged, at least one such individual, has at least 3 years of work experience at a clinical laboratory operated by —

(i) a person authorised by a licence under the Act to provide a clinical laboratory service; or

(ii) a person who holds a licence for a clinical laboratory under the Private Hospitals and Medical Clinics Act 1980.

(2) A nuclear medicine assay licensee must ensure that each medical laboratory technologist is assessed by a radiation safety officer appointed by that licensee to have appropriate competency in radiation safety.

Instructions for collection of specimens

19. Where a requestor or patient informs a nuclear medicine assay licensee that the licensee's assistance is not required 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

20.—(1) A nuclear medicine assay 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, the nuclear medicine assay licensee must ensure that —

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

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

Handling and transport of specimens

21.—(1) A nuclear medicine assay 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 nuclear medicine assay 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) If a specimen has to be transported to another location, a nuclear medicine assay licensee must ensure that the specimen is properly packaged and labelled, and the label contains a description of the

general nature of the transported item, including whether it contains any biohazardous or radioactive material.

Tests must have clinical utility

22. A nuclear medicine assay licensee must ensure that any test that is carried out for a patient provides relevant information for the clinical management of the patient's health or medical condition.

Tests must be accurate

23.—(1) A nuclear medicine assay licensee must ensure that every test carried out in the provision of the nuclear medicine assay service is accurate.

(2) Without limiting paragraph (1), the nuclear medicine assay 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 the test result is inaccurate given the patient's clinical presentation,

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

Standards for reagents

24. A nuclear medicine assay licensee must ensure all of the following in relation to every reagent used in the provision of the nuclear medicine assay 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.

Documentation relating to tests

25. A nuclear medicine assay 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

26. A nuclear medicine assay licensee must, in relation to each test it provides as part of the nuclear medicine assay 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 any specimen.

PART 6

REQUIREMENTS SPECIFIC TO NUCLEAR MEDICINE IMAGING SERVICE

Specific personnel

27.—(1) A nuclear medicine imaging licensee must —

(*a*) employ or engage at least one individual who is a diagnostic radiographer, a nuclear medicine technologist or a radiation therapist (called in this paragraph the relevant individual); and

(*b*) ensure that the relevant individual, or where 2 or more relevant individuals are employed or engaged, at least one such individual, has at least 3 years of work experience in providing a nuclear medicine imaging service.

(2) The nuclear medicine imaging licensee must —

(*a*) employ or engage at least one individual who has a degree in physics (called in this paragraph the radiation physicist); and

(*b*) ensure that the radiation physicist, or where 2 or more radiation physicists are employed or engaged, at least one such individual, has at least 3 years of work experience in providing a nuclear medicine imaging service.

(3) The nuclear medicine imaging licensee must employ or engage at least one registered nurse who is assessed —

(*a*) by a Clinical Governance Officer to have appropriate competency in providing patient care in relation to the provision of the nuclear medicine imaging service; and

(*b*) by a radiation safety officer appointed by the nuclear medicine imaging licensee to have appropriate competency in radiation safety.

(4) In this regulation, "registered nurse" has the meaning given by section 2 of the Nurses and Midwives Act 1999.

Facilities and equipment

28. A nuclear medicine imaging licensee must ensure that —

(*a*) every licensed premises or licensed conveyance, including every imaging room in the licensed premises or licensed conveyance, complies with the requirements of, and is approved for use in accordance with, any written law relating to the storage, possession, use and disposal of irradiating apparatus;

(*b*) the licensed premises or licensed conveyance must provide for the physical segregation of patients to whom radiopharmaceuticals have been administered from other individuals in the licensed premises or in the vicinity of the licensed conveyance;

(*c*) a waiting area for patients is provided at the licensed premises or in the vicinity of the licensed conveyance, as the case may be;

(*d*) the waiting area for patients mentioned in paragraph (*c*) must have adequate capacity and must be separate from any room used for taking images;

(*e*) any examination room or area must be set up in a manner that ensures the patient's privacy when the patient is undergoing an examination; and

(*f*) an adequate number of toilets must be provided for the exclusive use of patients after the administration of radiopharmaceuticals to them.

Handling of images

29. A nuclear medicine imaging licensee must implement quality control measures for all 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 patients.

General safeguards for examinations

30.—(1) A nuclear medicine imaging licensee must implement safeguards to ensure that —

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

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

(2) In conducting any examination on a patient, a nuclear medicine imaging 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 individual against exposure to radiation.

(3) In conducting any examination on a patient who is 12 years of age or younger, a nuclear medicine imaging licensee must ensure that all personnel involved in the examination use paediatric-appropriate procedures and practices.

Specific safeguards — use of contrast agent or radiopharmaceuticals

31. Where an examination requires the administration of a contrast agent or radiopharmaceutical to a patient, a nuclear medicine imaging licensee must ensure the safe administration and use of the contrast agent or radiopharmaceutical (as the case may be), and that all of the following requirements are satisfied:

(*a*) the administration and use of the contrast agent or radiopharmaceutical (as the case may be) 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 or radiopharmaceutical (as the case may be) to the patient.

Specific safeguards — use of anaesthesia or sedation

32. Where an examination requires the administration of an anaesthesia or a sedative to a patient, a nuclear medicine imaging 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 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 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

33. A nuclear medicine imaging licensee must implement policies on the safe performance of ionising radiological procedures on pregnant women or women suspected to be pregnant.

PART 7

REPORTING OF RESULTS

Who is qualified person

34. In this Part, "qualified person" means —

(*a*) in relation to an examination —

(i) a medical practitioner who is registered under section 22 of the Medical Registration Act 1997 as a specialist in the branch of nuclear medicine; or

(ii) a medical practitioner who is registered under section 22 of the Medical Registration Act 1997 as a specialist in the branch of cardiology and holds a valid certification in nuclear cardiology by the Certification Board of Nuclear Cardiology, United States of America; or

(*b*) in relation to a test — a Clinical Governance Officer for a nuclear medicine assay service or a person who is suitably qualified to certify and interpret the test results and is appointed by such a Clinical Governance Officer to do so.

Written reports of examinations must be issued

35.—(1) A nuclear medicine assay licensee must —

(*a*) issue a written clinical laboratory report for every test conducted in respect of a patient; and

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

(2) A nuclear medicine imaging licensee must —

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

(*b*) ensure that a written imaging report is issued for every examination conducted of a patient for diagnostic purposes; and

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

Contents of reports

36.—(1) A report in respect of any test or examination 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 examination (as the case may be) is conducted;

(*d*) the date the test or examination (as the case may be) is conducted;

(*e*) the name of the requestor;

(*f*) the description and findings of the test or examination, as the case may be;

(*g*) the date and time the report is issued;

(*h*) the name and signature (including an electronic signature) of the qualified person certifying the results or interpreting and reporting the findings of the test or examination, as the case may be.

(2) A report in respect of any test must contain, in addition to the information mentioned in paragraph (1), all of the following information:

(*a*) where the information is known to the nuclear medicine assay licensee who conducted the test — the date and time the specimen was derived from the patient;

(*b*) the type of specimen that is tested;

(*c*) for a tissue specimen — the anatomical site of the specimen;

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

Urgent notification of reports in emergency

37. Where any result or finding in a report in respect of any test or 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.

Identification and review of incidental or abnormal findings

38. A licensee must —

(*a*) ensure that the qualified person mentioned in regulation 36(1)(*h*) states in a report in respect of any test or examination 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

39. If a licensee discovers any error in a report in respect of any test or examination after it is issued, the licensee must immediately notify the requestor (or another dentist or medical practitioner designated by the requestor to receive the report) of the error and issue an addendum to the report to correct the error.

Processes to ensure prompt reporting

40.—(1) A licensee must implement processes to ensure that the reporting of any test or examination (as the case may be) 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 prohibited

41. A licensee must not appoint any person to provide, on the licensee's behalf, an applicable service or any aspect of the applicable service.

Nuclear medicine assay licensee — records to be kept for each specimen

42. A nuclear medicine assay 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 nuclear medicine assay licensee — other information to enable the specimen to be traced to the patient;

(*b*) the gender of the patient;

(*c*) where the information is known to the nuclear medicine assay 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 nuclear medicine assay 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.

Nuclear medicine assay licensee — records to be kept for each test

43. A nuclear medicine assay 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.

Nuclear medicine imaging licensee — records to be kept for examinations

44.—(1) A nuclear medicine imaging licensee must keep records of all of the following information in relation to each examination that the licensee conducts:

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

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

(*c*) the name of the person who reported and issued the imaging report in respect of the examination;

(*d*) each image obtained from the examination.

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

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 attended and competency assessments completed) 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;

(*d*) the monitoring of radiation levels in relation to the following:

(i) the equipment used in the provision of the applicable service;

(ii) the radioactive substances used in the provision of the applicable service.

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

(*a*) information relating to the quality management system mentioned in regulation 10;

(*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 12, 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*) all quality control measures implemented; and

(*g*) for a nuclear medicine assay licensee —

(i) validation of every test method used in the provision of the nuclear medicine assay service; and

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

Price transparency

46.—(1) A nuclear medicine assay 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 nuclear medicine assay 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 nuclear medicine imaging 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.

Display of charges

47.—(1) Where a patient is present at the licensed premises of or licensed conveyance used by a nuclear medicine assay 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 nuclear medicine assay service is provided.

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

(*a*) imaging procedures, including radiopharmaceuticals and other consumables;

(*b*) contrast fees;

(*c*) sedation procedures, if applicable.

Offence

48.—(1) Any person who contravenes regulation 10(1), 11, 12, 13(1), 14, 15, 16, 21, 22, 23, 24, 25, 26, 28(*a*), (*b*) or (*f*), 29, 30, 31, 32, 33, 35, 37, 38, 39 or 41 shall be guilty of an offence.

(2) A person who is guilty of an offence under paragraph (1) shall be liable on conviction to a fine not exceeding $20,000 or to imprisonment for a term not exceeding 12 months or to both and, 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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