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HEALTHCARE SERVICES ACT 2020

HEALTHCARE SERVICES (NUCLEAR MEDICINE SERVICE) REGULATIONS 2023

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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 Service) Regulations 2023 and come into operation on 26 June 2023.

Definitions

2.—(1) In these Regulations —

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

"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 licensee at any approved permanent premises of the licensee;

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

"imaging modality" means any imaging modality set out in paragraph 1 of the Schedule;

"in vivo assay procedure" means all of the following activities carried out by a licensee at any approved permanent premises of the licensee:

(*a*) any process relating to the preparation, dispensing, radiolabelling, compounding and quality control of radiopharmaceuticals;

(*b*) the administration of radiopharmaceuticals to a patient;

(*c*) the derivation, after the administration of radiopharmaceuticals, of any specimen from the patient;

"irradiating apparatus", "nuclear medicine service", "radioactive material", "radiopharmaceutical" and "simple in vitro diagnostic test" have the meanings given by paragraph 2 of the First Schedule to the Act;

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

"nuclear medicine imaging", in relation to a nuclear medicine service, means the specified service for that service set out in paragraph 1 of the Schedule;

"nuclear medicine physician" means an individual who is registered under section 22 of the Medical Registration Act 1997 as a specialist in the branch of nuclear medicine;

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

"personnel", in relation to a licensee, means an individual employed or engaged by the licensee to assist the licensee in providing a nuclear medicine service;

"radiation safety officer" —

(*a*) where a licensee uses any irradiating apparatus within the meaning given by regulation 2(1) 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 19 of the Radiation Protection (Ionising Radiation) Regulations 2023 (G.N. No. S 85/2023) 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;

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

"requestor", in relation to an examination, means a dentist or medical practitioner who ordered the examination for the patient;

"specimen" means any matter derived, obtained or excreted from the body of a patient for use in, or in connection with, the provision of a nuclear medicine service.

(2) For the purposes of these Regulations —

(*a*) a nuclear medicine service is provided for an imaging purpose where the service is provided, through the use of an irradiating apparatus, for either of the following purposes:

(i) the medical diagnosis of an individual;

(ii) the monitoring of the effects of medical therapy on an individual;

(*b*) a nuclear medicine service is provided for an in vivo assay purpose where the service is provided to enable or facilitate either of the following through the use of an assay:

(i) the medical diagnosis of an individual;

(ii) the monitoring of the effects of medical therapy on an individual; and

(*c*) a nuclear medicine service is provided for a therapy purpose where the service is provided for the purpose of treating an ailment, or a condition, disease or disorder or an injury affecting any part of the body or mind of an individual.

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.

Notification of addition or removal of purposes for which nuclear medicine service provided

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 nuclear medicine service must specify in the licence application every purpose for which the applicant provides, or intends to provide, the nuclear medicine service.

(2) A licensee that intends to provide a nuclear medicine service for any purpose which was not specified in the licence application mentioned in paragraph (1) must give written notice to the Director-General of the licensee's intention no later than 2 months before the licensee intends to start providing the nuclear medicine service for the purpose concerned.

(3) A licensee that intends to stop providing a nuclear medicine service for any purpose which was specified in the licence application mentioned in paragraph (1) must give written notice to the Director-General of the licensee's intention no later than 10 calendar days before the licensee intends to stop providing the nuclear medicine service for the purpose concerned.

Specified services

5.—(1) For the purposes of section 9A(1) of the Act, the services set out in the Schedule are specified services for a nuclear medicine service.

(2) For the purposes of section 11C(2)(*d*) of the Act, an applicant for approval to provide a specified service must specify every

imaging modality that the licensee provides, or intends to provide, as part of the specified service.

(3) A licensee who is approved to provide nuclear medicine imaging and intends to provide any imaging modality which is not specified in the approval application mentioned in paragraph (2) must give written notice to the Director-General of the licensee's intention no later than 2 months before the licensee intends to start providing the imaging modality concerned.

(4) A licensee who is approved to provide nuclear medicine imaging and intends to stop providing any purpose which was specified in the approval application mentioned in paragraph (2) must give written notice to the Director-General of the licensee's intention no later than 10 calendar days before the licensee intends to stop providing the imaging modality concerned.

Prohibited service delivery modes

6. A licensee must not provide a nuclear medicine service —

(*a*) at any premises other than permanent premises;

(*b*) using a conveyance; or

(*c*) by remote provision.

PART 2

REQUIREMENTS RELATING TO PERSONNEL

Qualifications, skills and competencies of Clinical Governance Officer

7.—(1) For the purposes of section 24(3)(*b*) of the Act and subject to paragraph (2), an individual is suitably qualified to be appointed as a Clinical Governance Officer for a nuclear medicine service or a specified service for a nuclear medicine service, if the individual —

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

(*b*) holds a valid practising certificate under the Medical Registration Act 1997;

(*c*) is registered under section 22 of the Medical Registration Act 1997 as a specialist in the branch of nuclear medicine; and

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

(2) For the purposes of section 24(3)(*b*) of the Act, where —

(*a*) a licensee is approved to provide nuclear medicine imaging for a nuclear medicine service; and

(*b*) the licensee provides nuclear medicine imaging only for cardiac purposes,

an individual is suitably qualified to be appointed as a Clinical Governance Officer for nuclear medicine imaging if the individual —

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

(*d*) holds a valid practising certificate under the Medical Registration Act 1997;

(*e*) is registered under section 22 of the Medical Registration Act 1997 as a specialist in the branch of cardiology;

(*f*) holds a valid certification in nuclear cardiology by the Certification Board of Nuclear Cardiology, United States of America or an equivalent certification acceptable to the Director-General; and

(*g*) has at least 5 years of work experience, after obtaining the certification mentioned in sub-paragraph (*f*), in providing the nuclear medicine imaging service.

Duties and responsibilities of Clinical Governance Officer

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

(2) A Clinical Governance Officer for a nuclear medicine service is responsible for —

(*a*) overseeing the conduct of examinations and in vivo assay procedures, and the provision of treatment, by the licensee;

(*b*) ensuring that the examinations and in vivo assay procedures are conducted, and the treatment is provided, in accordance with the correct methods and procedures for the examination, in vivo assay procedure or treatment concerned;

(*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 approved permanent premises of the licensee, including the proper handling, use and disposal of radioactive substances;

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

(*e*) where the licensee intends to use any radiopharmaceutical (*X*) for the first time in the provision of the nuclear medicine service for a therapy purpose, evaluating *X* for all of the following:

(i) the safety and efficacy of *X*;

(ii) the necessity, advantages and disadvantages of using *X*, including —

(A) whether the licensee is using any other radiopharmaceutical for the same indication as the indication for which *X* is proposed to be used; and

(B) the comparative advantages and disadvantages of using *X* and the other radiopharmaceutical;

(*f*) where the licensee intends to provide any specified service for the nuclear medicine service, evaluating that specified service before the specified service is provided; and

(*g*) where the licensee is approved to provide nuclear medicine imaging and intends to provide any imaging modality, evaluating that imaging modality before the imaging modality is provided.

(3) Where a licensee appoints a Clinical Governance Officer for nuclear medicine imaging, that Clinical Governance Officer is responsible for —

(*a*) overseeing the conduct of examinations by the licensee in relation to the provision of nuclear medicine imaging;

(*b*) ensuring that the examinations mentioned in sub-paragraph (*a*) are conducted in accordance with the correct methods and procedures for the examinations;

(*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 any part of the approved permanent premises that is used for the provision of nuclear medicine imaging, including the proper handling, use and disposal of radioactive substances;

(*d*) evaluating new processes the licensee intends to implement for the provision of nuclear medicine imaging, including processes relating to the preparation, dispensing, radiolabelling, compounding and quality control of radiopharmaceuticals; and

(*e*) where the licensee is approved to provide nuclear medicine imaging and intends to provide any imaging modality, evaluating that imaging modality before the imaging modality is provided.

(4) Paragraph (3) does not prevent a Clinical Governance Officer for a nuclear medicine service from assuming responsibility for any matter mentioned in that paragraph despite the appointment of a Clinical Governance Officer for nuclear medicine imaging.

Appointment of section leader

9.—(1) A licensee must, in relation to each purpose for which a nuclear medicine service is provided, appoint a suitably qualified person as the section leader for that purpose.

(2) A section leader must be resident in Singapore.

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

(4) For the purposes of this regulation, an individual is a suitably qualified person if any of the following applies:

(*a*) in relation to the provision of the nuclear medicine service for an imaging purpose — the individual is a diagnostic radiographer, nuclear medicine technologist or radiation therapist who has at least 3 years of work experience in providing the nuclear medicine service for that purpose;

(*b*) in relation to the provision of the nuclear medicine service for an in vivo assay purpose — the individual is a diagnostic radiographer, nuclear medicine technologist, radiation therapist or radiochemistry personnel who has at least 3 years of work experience in providing the nuclear medicine service for that purpose;

(*c*) in relation to the provision of the nuclear medicine service for a therapy purpose, the individual is —

(i) a diagnostic radiographer, nuclear medicine technologist, radiation therapist or radiochemistry personnel who has at least 3 years of work experience in providing the nuclear medicine service for that purpose; or

(ii) a nuclear medicine physician who is registered under section 20(1) or (2) of the Medical Registration Act 1997 as a fully registered medical practitioner.

(5) In this regulation, "radiochemistry personnel" means an individual who holds a diploma, degree or any higher educational qualification in chemistry, medical physics, nuclear medicine sciences, pharmaceutical services or radiochemistry.

Duties of section leader

10.—(1) A licensee must ensure that every section leader appointed in relation to the provision of a nuclear medicine service for an imaging purpose or in vivo assay purpose does all of the following:

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

(*b*) supervise, train and guide personnel in the conduct of examinations or performance of in vivo assay procedures, as the case may be;

(*c*) assess and ensure the competency of personnel deployed to perform tasks in relation to the provision of the nuclear medicine service for an imaging purpose or in vivo assay purpose, as the case may be;

(*d*) evaluate any equipment before the equipment is used in the provision of the nuclear medicine service for an imaging purpose or in vivo assay purpose, as the case may be;

(*e*) monitor the performance of all examinations or in vivo assay procedures (as the case may be) conducted or performed, including ensuring the implementation of quality control measures;

(*f*) establish and review policies and procedures for the safe and effective conduct or performance of all examinations or in vivo assay procedures, as the case may be;

(*g*) resolve any technical issues that arise from the conduct or performance of any examinations or in vivo assay procedures, as the case may be;

(*h*) review all service records in relation to all examinations or in vivo assay procedures (as the case may be) conducted or performed.

(2) A licensee must ensure that every section leader appointed in relation to the provision of a nuclear medicine service for a therapy purpose does all of the following:

(*a*) assist the relevant Clinical Governance Officer in the day-to-day management of all processes relating to the

preparation, dispensing, radiolabelling, compounding and quality control of radiopharmaceuticals (called in this paragraph the applicable processes);

(*b*) supervise, train and guide personnel in the applicable processes;

(*c*) assess and ensure the competency of personnel deployed to perform tasks in relation to the preparation, dispensing, radiolabelling, compounding and quality control of radiopharmaceuticals;

(*d*) evaluate any process relating to the preparation, dispensing, radiolabelling, compounding and quality control of radiopharmaceuticals before the process is used;

(*e*) monitor the performance of all applicable processes;

(*f*) establish and review policies and procedures for the safe and effective performance of all applicable processes;

(*g*) resolve any technical issues that arise from the performance of all applicable processes;

(*h*) review all service records in relation to the applicable processes.

General requirements relating to personnel

11.—(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*) is assessed on the personnel's competencies before the personnel is allowed to perform any task or provide any service in relation to the licensee's provision of the nuclear medicine service;

(*c*) attends adequate training on a regular basis in relation to the provision of the nuclear medicine service;

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

(*e*) 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 a nuclear medicine service except under the close supervision of —

(*a*) a Clinical Governance Officer; or

(*b*) another personnel with at least 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 nuclear medicine 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 the personnel is registered as a healthcare professional or is appointed as a 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 a licensee for or in relation to the provision of the nuclear medicine service under any other written law.

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

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

(*b*) a medical practitioner;

(*c*) a registered nurse, enrolled nurse or registered midwife within the meaning of the Nurses and Midwives Act 1999 who holds a valid practising certificate under that Act; or

(*d*) a pharmacist who is registered under the Pharmacists Registration Act 2007 and holds a valid practising certificate under that Act.

Specific personnel

12.—(1) A licensee must —

(*a*) employ or engage at least one individual who is a diagnostic radiographer, nuclear medicine technologist or 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 service.

(2) A licensee must —

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

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

(3) A 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 a nuclear medicine service; and

(*b*) by any of the following persons appointed by the licensee to have appropriate competency in radiation safety:

(i) a medical physicist;

(ii) a nuclear medicine physician who is registered under section 20(1) or (2) of the Medical Registration Act 1997 as a fully registered medical practitioner;

(iii) a radiation safety officer.

(4) In this regulation —

"medical physicist" means an individual who has a degree in physics;

"registered nurse" has the meaning given by section 2 of the Nurses and Midwives Act 1999.

PART 3

PROCESSES, EQUIPMENT AND FITTINGS

Quality management system

13.—(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 nuclear medicine 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 to ensure that the licensee's personnel have appropriate accountability, roles and responsibilities in relation to the purposes mentioned in paragraph (1) and to provide for appropriate continuing educational programmes for the personnel;

(*b*) measures to ensure that the provision of the nuclear medicine service complies with —

(i) the Act and any other written law governing the nuclear medicine service;

(ii) the licence conditions imposed under section 13(1) of the Act; and

(iii) any conditions imposed on an approval granted under section 11B or 11D of the Act;

(*c*) implementation of protocols to ensure compliance with this Part and Parts 4 to 9 and for the physical safety of personnel, patients and visitors;

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

(*e*) quality control measures for equipment used in the provision of the nuclear medicine 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 licensee's approved permanent premises to ensure the safety of personnel, patients and visitors;

(*j*) systems and processes to ensure that regulations 16(3) and 20 are complied with;

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

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

(*m*) validation of imaging procedures, in vivo assay procedures and methods of treatment;

(*n*) validation of all processes relating to the conduct or performance of any examination, in vivo assay procedure or method of treatment, as the case may be;

(*o*) 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);

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

(*q*) quality control measures for —

(i) all images produced in the provision of the nuclear medicine service for an imaging purpose; and

(ii) all specimens derived in the provision of the nuclear medicine service for an in vivo assay purpose.

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

Equipment and fittings

14.—(1) A licensee must ensure that —

(*a*) every approved permanent premises —

(i) has adequate space for the licensee to provide the nuclear medicine service in a safe manner; and

(ii) is adequately secured to prevent unauthorised access to the approved permanent premises; and

(*b*) every approved permanent premises, including every imaging room in the premises, 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.

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

(*a*) in relation to the storage of materials and supplies used in the provision of the nuclear medicine service —

(i) adequate storage space is provided in every approved permanent premises;

(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 materials and supplies;

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

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

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

(*c*) appropriate radiation shielding is provided in any part of every approved permanent premises where procedures

involving the handling and use of radioactive substances are performed;

(*d*) every approved permanent premises 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*) in relation to the storage of specimens derived in the provision of the nuclear medicine service —

(i) adequate storage space is provided in every approved permanent premises;

(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 specimens;

(*f*) adequate decontamination equipment is provided at every approved permanent premises to ensure the safety of personnel, patients and visitors and prevent any contamination of specimens;

(*g*) adequate safety equipment, including safety cabinets, hand basins and emergency showers, is provided in every approved permanent premises;

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

(3) A licensee must ensure that every approved permanent premises satisfies all of the following requirements:

(*a*) the approved permanent premises provides for the physical segregation of patients to whom radiopharmaceuticals have been administered from other individuals in the premises;

(*b*) a waiting area is provided at the approved permanent premises;

(*c*) the waiting area mentioned in sub-paragraph (*b*) has adequate capacity and is separate from any room used for the administration of radiopharmaceuticals or any imaging room;

(*d*) the approved permanent premises is set up in a manner that ensures the privacy of patients;

(*e*) an adequate number of toilets are provided for the exclusive use of patients to whom radiopharmaceuticals have been administered.

PART 4

SAFETY REQUIREMENTS

Safety programme

15.—(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 the licensee's approved permanent premises.

(2) Without limiting paragraph (1), the licensee must ensure that a safety programme contains 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 or performance of any examination or in vivo assay procedure or the provision of any treatment, 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 examination, in vivo assay procedure or treatment, 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 approved permanent premises.

(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 the documentation available to all personnel.

Radiation safety programme

16.—(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 —

(*a*) any written law governing the preparation, storage, possession, use and disposal of radioactive substances; and

(*b*) in relation to the provision of the nuclear medicine service for an imaging purpose, any written law governing the storage, possession, use and disposal of irradiating apparatus.

(3) A licensee must implement policies to protect pregnant personnel against radiation exposure in the course of work and in the licensee's approved permanent premises.

(4) 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 approved permanent premises.

Licensee must ensure personnel comply with safety plans and programmes

17. A licensee must ensure that each personnel complies with the measures and procedures set out in —

(*a*) the safety programme mentioned in regulation 15(1); and

(*b*) the radiation safety programme mentioned in regulation 16(1).

Personal protective equipment must be provided

18. A licensee must provide each personnel performing any work at any approved permanent premises with personal protective equipment that is appropriate for the work performed.

Administration and use of radiopharmaceuticals

19. A licensee must ensure the safe administration and use of radiopharmaceuticals in accordance with safety protocols implemented by the licensee.

Pregnant women

20. A licensee must implement policies on the safe performance of ionising radiological procedures, including the administration of radiopharmaceuticals, on pregnant women or women suspected to be pregnant.

Patients 12 years of age or younger

21. In conducting or performing any examination or in vivo assay procedure on, or providing any treatment to, a patient who is 12 years of age or younger, a licensee must ensure that all personnel involved in conducting or performing the examination or in vivo assay procedure or providing the treatment (as the case may be) use paediatric-appropriate procedures and practices.

Adjunctive measures

22. A licensee must ensure that every patient is provided with adjunctive measures which are appropriate in relation to the radiopharmaceuticals administered to that patient.

Essential life-saving measures must be available

23.—(1) A licensee must —

(*a*) ensure that adequate and appropriate facilities, equipment and drugs for the provision of any essential life-saving measure to a patient are readily available at every approved permanent premises; and

(*b*) at all times, be capable of providing any essential life-saving measure to any patient who is at risk of death.

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

(*a*) only resuscitation drugs that have not passed their expiry dates and are fit for use and resuscitation equipment that is fit for use are made available for use in the provision of any essential life-saving measure; and

(*b*) every personnel who provides any essential life-saving measure to a patient is adequately trained —

(i) to provide the essential life-saving measure in a proper, effective and safe manner; and

(ii) in the use of the equipment that is needed to deliver the essential life-saving measure.

PART 5

ADMINISTRATION AND USE OF ANAESTHETICS AND SEDATIVES

Definitions of this Part

24. In this Part —

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

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

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

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

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

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

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

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

General requirements on administration and use of anaesthetics or sedatives

25. Where the conduct of any procedure in the provision of a nuclear medicine service requires the administration of any anaesthetic or sedative to a patient, a licensee must ensure the safe administration and use of the anaesthetic or sedative, and that all of the following requirements are satisfied:

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

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

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

(*d*) the licensee keeps a record of the administration of the anaesthetic or sedative to the patient.

Anaesthesia service

26.—(1) Where any anaesthetic is administered to a patient for the purpose of conducting any procedure as part of the provision of a nuclear medicine service, a licensee must —

(*a*) ensure that the patient is regularly monitored throughout the procedure by the person who administered the anaesthetic, using the appropriate patient monitoring device; and

(*b*) establish, implement and regularly review processes and procedures to ensure the continued monitoring and care of the patient mentioned in sub-paragraph (*a*) after completion of the procedure mentioned in that sub-paragraph.

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

(3) A licensee must —

(*a*) before administering any type of specified anaesthetic to a patient, properly inform the patient of the risks and benefits of, and (if any) the alternatives to, that type of anaesthetic; and

(*b*) having satisfied the condition mentioned in sub-paragraph (*a*) in respect of a patient, keep and maintain proper and accurate records of this fact.

Specified anaesthetic must be suitable for patient

27.—(1) A licensee must ensure that —

(*a*) a specified anaesthetic is not offered or administered to any patient at any approved permanent premises unless the approved permanent premises has the appropriate equipment and facilities to ensure that the specified anaesthetic may be administered safely and effectively;

(*b*) a specified anaesthetic is not offered or administered to any patient for whom that specified anaesthetic would be inappropriate; and

(*c*) every medical practitioner who offers a specified anaesthetic to a patient documents the reasons for doing so.

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

(3) The licensee must ensure that the assessment mentioned in paragraph (2) includes —

(*a*) the taking of a comprehensive medical history (including previous use of anaesthetics) of the patient;

(*b*) physical examination of the patient; and

(*c*) the conduct of relevant tests and investigations.

(4) The licensee must keep proper and accurate records of the assessment mentioned in paragraph (2).

Nursing services

28. A licensee must deploy an adequate number of nurses to monitor, at all times, the patients in any approved permanent premises who have been administered any specified anaesthetic, to ensure that there is prompt recognition of and delivery of appropriate medical intervention or treatment to a patient whose condition requires medical intervention or treatment.

Essential life-saving measures

29. Without limiting regulation 23(1), the licensee must, in relation to the administration of any specified anaesthetic, ensure that —

(*a*) there is a comprehensive and detailed response plan to resuscitate, treat and transfer unstable patients;

(*b*) the licensee's personnel promptly assesses a patient who shows any sign of being unwell at any time after any procedure conducted in the provision of a nuclear medicine service during which a specified anaesthetic is administered to the patient and delivers the necessary treatment to stabilise the patient;

(*c*) any patient who remains unwell despite the delivery of treatment to stabilise the patient is transferred to the care of an acute hospital service licensee who is equipped to deliver the appropriate treatment to the patient;

(*d*) all necessary arrangements with one or more acute hospital service licensees are in place to ensure a transfer mentioned in paragraph (*c*) may take place without delay at any time; and

(*e*) any patient who requires conveyance by an emergency ambulance is conveyed by an emergency ambulance operated by an emergency ambulance service licensee.

Post-procedure care

30.—(1) A licensee must ensure that each patient who is administered any anaesthetic is monitored and given appropriate post-procedure care for recovery and management of adverse effects from the administration of anaesthetics.

(2) Without limiting paragraph (1), the licensee must, in relation to each patient, ensure that during the post-procedure observation period —

(*a*) one or more of the licensee's personnel observe and monitor the patient at intervals and for the length of time appropriate to the anaesthetic administered;

(*b*) timely and appropriate post-procedure treatment is given to the patient where necessary;

(*c*) one or more of the licensee's personnel assist the patient with toileting needs where necessary; and

(*d*) adequate nutrition and hydration are given to or made available to the patient.

Recovery and observation area

31. A licensee must ensure that —

(*a*) there are adequate and proper facilities to accommodate patients in every approved permanent premises after they have undergone any procedure conducted in the provision of a nuclear medicine service involving the administration of anaesthetics;

(*b*) the patients mentioned in paragraph (*a*) are observed and monitored by the licensee's personnel;

(*c*) there is adequate space for the movement of personnel for the monitoring of patients and treatment of complications; and

(*d*) the area in which the patients are accommodated have —

(i) adequate furniture for patients to sit or lie down;

(ii) monitoring equipment; and

(iii) a resuscitation trolley.

Discharge of patients

32.—(1) A licensee must ensure that a patient who has been administered a specified anaesthetic is discharged only after he or she has been assessed by a medical practitioner who is the licensee's personnel to be fit for discharge.

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

(*a*) the attending medical practitioner (who is the licensee's personnel) for a patient assesses whether the patient is fit for discharge;

(*b*) where the attending medical practitioner for a patient is not available to assess whether the patient is fit for discharge, another medical practitioner (who is the licensee's personnel) assesses the patient for that purpose instead;

(*c*) a 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; and

(*d*) a patient is not asked to leave the approved permanent premises before the patient is assessed to be fit for discharge.

Post-discharge follow-up

33. A licensee must ensure that —

(*a*) appropriate post-procedure care instructions are given to the patient or the patient's caregiver, including the patient's care needs and the signs and symptoms of possible adverse reactions that the patient may experience after the administration of any type of anaesthetic; and

(*b*) where the patient has been administered any specified anaesthetic, the licensee's personnel also gives the patient or the patient's caregiver information on the appropriate person to contact if the patient has an emergency medical need arising from the administration of the specified anaesthetic.

PART 6

TESTING OF SPECIMENS AND ULTRASOUND IMAGING

Testing of specimens

34.—(1) Except as provided in this regulation, a licensee must not, in relation to the provision of a nuclear medicine service, test any specimen derived from a patient unless all of the following conditions are satisfied:

(*a*) the testing of the specimen is incidental to the provision of the nuclear medicine service;

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

(*c*) a medical practitioner who is a personnel of the licensee orders the test for the patient.

(2) A licensee may, in relation to the provision of a nuclear medicine service for an in vivo assay purpose, test any specimen derived from a patient if all of the following conditions are satisfied:

(*a*) the specimen must not be subject to more than minimal manipulation;

(*b*) the testing must be conducted using beta scintillation or gamma counting.

(3) In paragraph (2), "minimal manipulation" —

(*a*) includes all or any of the following:

(i) measurement;

(ii) separation;

(iii) sterilisation;

(iv) concentration;

(v) purification; and

(*b*) does not include any of the following:

(i) cell culturing;

(ii) cutting or sizing;

(iii) grinding;

(iv) shaping;

(v) soaking in an antibiotic or antimicrobial solution;

(vi) irradiation;

(vii) lyophilisation;

(viii) freezing;

(ix) cryopreservation;

(x) vitrification.

Instructions for self-collection of specimens by patient

35. Where any specimen is to be collected from a patient by the patient himself or herself, the licensee must provide the patient with —

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

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

Conduct of simple in vitro diagnostic tests

36. A licensee must ensure that any simple in vitro diagnostic test conducted on a specimen must be conducted —

(*a*) using testing material, where —

(i) the earlier of the following dates has not passed:

(A) the expiry date of the testing material;

(B) the shelf life of the testing material; and

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

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

Testing material for simple in vitro diagnostic tests

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

Conduct of ultrasound imaging

38. A licensee must not, in relation to the provision of a nuclear medicine service, conduct any ultrasound imaging on a patient unless —

(*a*) the conduct of the ultrasound imaging is incidental to the provision of the nuclear medicine service;

(*b*) a medical practitioner who is a personnel of the licensee orders the ultrasound imaging for the patient;

(*c*) the ultrasound imaging is conducted at the licensee's approved permanent premises; and

(*d*) the ultrasound imaging is conducted by a person who is —

(i) a medical practitioner who is trained in the conduct of ultrasound imaging;

(ii) a radiographer who is a duly qualified allied health professional; or

(iii) a sonographer.

PART 7

ADDITIONAL REQUIREMENTS FOR PROVISION OF NUCLEAR MEDICINE SERVICE FOR IMAGING PURPOSE

Application of this Part

39. This Part applies in relation to the provision of a nuclear medicine service for an imaging purpose by a licensee.

Division 1 — Provision of nuclear medicine service for imaging purpose

Handling of images

40. A 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

41.—(1) A licensee must implement safeguards to ensure that —

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

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

(2) In conducting any examination on a patient, a 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.

Referral required before service provided to patients

42. A licensee must not conduct an examination 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 licensee — the patient was referred to the other licensee for the examination by a dentist or medical practitioner.

Administration and use of contrast agents

43. Where an examination requires the administration of a contrast agent to a patient, a 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*) the licensee keeps a record of the administration of the contrast agent to the patient.

Records — examinations

44.—(1) A 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;

(*e*) in relation to the examination —

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

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

(A) the person to whom the image was provided; and

(B) the mode by which the image was provided to that person;

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

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

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

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

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

Division 2 — Reporting of results or findings of examinations

Definition of this Division

45. In this Division, "qualified person", in relation to an examination, means any of the following individuals:

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

(*b*) a Clinical Governance Officer for a nuclear medicine service or a specified service for a nuclear medicine service;

(*c*) where the examination is carried out for a cardiac purpose, a medical practitioner who —

(i) is registered under section 22 of the Medical Registration Act 1997 as a specialist in the branch of cardiology; and

(ii) is appointed by a Clinical Governance Officer for a nuclear medicine service to interpret and report the findings of the examination.

Written imaging reports

46. A 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 that contains the information mentioned in regulation 47; 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 imaging reports

47. An imaging report in respect of any examination must contain all of the following information:

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

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

(ii) the licensee's address;

(*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 — any other information identifying the patient;

(*c*) the address of the approved permanent premises at which the examination is conducted;

(*d*) the date the examination is conducted;

(*e*) the name of the requestor;

(*f*) the description and findings of the examination;

(*g*) the date 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 examination.

Urgent notification of results or findings in emergency

48. Where any result or finding of any examination discloses that the patient's safety or wellbeing may be adversely affected without immediate medical treatment or intervention, a 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

49. A licensee must —

(*a*) ensure that the qualified person mentioned in regulation 47(*h*) states in an imaging report in respect of any 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 errors

50. If a licensee discovers any error in an imaging report in respect of any examination after it is issued, the licensee must immediately —

(*a*) notify the requestor (or another dentist or medical practitioner designated by the requestor to receive the report) of the error; and

(*b*) issue an addendum to the report to correct the error.

Processes to ensure prompt reporting

51. A licensee must —

(*a*) implement processes to ensure that the reporting of any examination is not affected by any disruption or maintenance (scheduled or otherwise) to the licensee's radiological information system; and

(*b*) keep up-to-date documentation of the processes mentioned in paragraph (*a*).

PART 8

ADDITIONAL REQUIREMENTS FOR PROVISION OF NUCLEAR MEDICINE SERVICE FOR IN VIVO ASSAY PURPOSE

Definition of this Part

52. In this Part, "applicable test" means a test conducted by a licensee in accordance with regulation 34(2).

Division 1 — Provision of nuclear medicine service for in vivo assay purpose

Referral needed before service provided to patients

53. A licensee must not perform an in vivo assay procedure on a patient who resides in Singapore unless —

(*a*) the patient is referred to the licensee for the in vivo assay procedure by a medical practitioner; or

(*b*) where the licensee is appointed or engaged to conduct the in vivo assay procedure on behalf of another licensee — the patient is referred to the other licensee for the in vivo assay procedure by a medical practitioner.

Acceptance and rejection of specimens

54. A 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.

Handling and transport of specimens

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

(2) If a licensee reasonably suspects that a specimen contains an infectious agent, the 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) A licensee must ensure that a specimen that has to be transported to another location 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 material or radioactive material.

Applicable tests must be accurate

56.—(1) A licensee must ensure that every applicable test carried out is accurate.

(2) Without limiting paragraph (1), 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 licensee must investigate the reason for the deviation or the suspected inaccuracy and take appropriate remedial action if applicable.

Standards for reagents

57. A licensee must ensure all of the following in relation to every reagent used in an applicable test:

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

(*b*) a reagent is not used in an applicable 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 an applicable test.

Documentation relating to applicable tests

58. A 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 for applicable tests are to be issued to the requestor.

Quality control of applicable tests

59. A licensee must, in relation to each applicable test the licensee provides —

(*a*) perform the applicable test using a quality control material and at an appropriate frequency, to ensure the accuracy of the applicable 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 applicable test is not accurate, ensure that remedial actions are taken to ensure the accuracy of the test before conducting the applicable test on any specimen.

Records — specimens

60. A licensee must keep records of all of the following information in relation to each specimen that the licensee derives from any patient for the purposes of an applicable test:

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

(i) the patient's name;

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

(*b*) the patient's gender;

(*c*) the date and time the specimen was derived from the patient;

(*d*) the type of specimen;

(*e*) in relation to a tissue specimen — the anatomical site of the specimen;

(*f*) 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 derived the specimen from the patient;

(*g*) the relevant clinical status of the patient (where required), including whether the patient had fasted before the derivation of the specimen;

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

(*i*) the name of the requestor.

Records — applicable tests

61. A licensee must keep records of all of the following information in relation to each applicable test of a specimen that the licensee conducts:

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

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

(*c*) the results of the applicable test;

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

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

Division 2 — Reporting of results

Definitions of this Division

62. In this Division —

"applicable requestor" means a medical practitioner mentioned in regulation 53(*a*) or (*b*);

"qualified person" means a medical practitioner who is registered under section 22 of the Medical Registration Act 1997 as a specialist in the branch of nuclear medicine.

Written clinical laboratory reports

63. In respect of each applicable test conducted in respect of a patient, a licensee must —

(*a*) issue a written clinical laboratory report for the applicable test, that contains the information mentioned in regulation 64; and

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

Contents of reports

64. A report in respect of any applicable test must contain all of the following information:

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

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

(ii) the licensee's address;

(*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 — any other information identifying the patient;

(*c*) the address of the approved permanent premises at which the applicable test is conducted;

(*d*) the date the applicable test is conducted;

(*e*) the name of the applicable requestor;

(*f*) the description and findings of the applicable test;

(*g*) the date 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 applicable test.

Urgent notification of results or findings in emergency

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

(*a*) the applicable requestor; or

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

Identification and review of incidental or abnormal findings

66. A licensee must —

(*a*) ensure that the qualified person mentioned in regulation 64(*h*) states, in a clinical laboratory report in respect of any applicable test, all incidental findings that are potentially clinically significant and abnormal findings; and

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

Notification of errors

67. If a licensee discovers any error in a clinical laboratory report in respect of any applicable test after the report is issued, the licensee must immediately —

(*a*) notify the applicable requestor (or another medical practitioner designated by the applicable requestor to receive the report) of the error; and

(*b*) issue an addendum to the report to correct the error.

Processes to ensure prompt reporting

68. A licensee must —

(*a*) implement processes to ensure that the reporting of any applicable test is not affected by any disruption or maintenance (scheduled or otherwise) to the licensee's laboratory information system; and

(*b*) keep up-to-date documentation of the processes mentioned in paragraph (*a*).

PART 9

ADDITIONAL REQUIREMENTS FOR PROVISION OF NUCLEAR MEDICINE SERVICE FOR THERAPY PURPOSE

Application of this Part

69. This Part applies in relation to the provision by a licensee of a nuclear medicine service for a therapy purpose.

Pre-treatment counselling and assessment

70.—(1) A licensee must, before providing any treatment to an individual —

(*a*) provide or arrange for the provision, by a medical practitioner, of pre-treatment counselling to the individual;

(*b*) conduct or arrange for the conduct, by a nuclear medicine physician, of an adequate and appropriate assessment of the individual's suitability for the treatment to be provided; and

(*c*) obtain the individual's informed consent for the treatment to be provided.

(2) For the purposes of paragraph (1)(*a*), the licensee must provide the individual with accurate and relevant information on all matters relating to the treatment to be provided to the individual.

(3) The licensee must ensure that clear and accurate documentation of the activities mentioned in paragraph (1) is kept and maintained.

Post-treatment protocols

71.—(1) A licensee must ensure that appropriate protocols are developed and implemented in relation to the following matters relating to a patient who receives treatment provided by the licensee:

(*a*) monitoring of the patient's condition after the treatment is provided;

(*b*) discharge of the patient, including the provision of a written report on the treatment provided to the patient.

(2) For the purposes of paragraph (1), the protocols must have regard to the following matters:

(*a*) the patient's safety, including —

(i) the disease or condition for which the patient receives treatment; and

(ii) the condition of the patient's health;

(*b*) radiation safety, including —

(i) the types and amounts of radiopharmaceuticals administered to the patient; and

(ii) the radiation risk that the patient poses to other persons after administration of the radiopharmaceuticals.

PART 10

MISCELLANEOUS

Outsourcing prohibited

72.—(1) Except as provided in this regulation, a licensee must not appoint any person to provide, on the licensee's behalf, a nuclear medicine service or any aspect of the nuclear medicine service.

(2) A licensee may appoint any person who holds a licence under the Act to provide a clinical laboratory service to test any specimen derived from a patient where —

(*a*) the specimen is not subject to more than minimal manipulation; and

(*b*) the testing is conducted using beta scintillation or gamma counting.

(3) In paragraph (2), "minimal manipulation" has the meaning given by regulation 34(3).

Records — conduct of examinations, performance of in vivo assay procedures and provision of treatment

73. A licensee must keep and maintain records of all of the following information in relation to every examination conducted or in vivo assay procedure performed on, or the treatment provided to, every patient, as the case may be:

(*a*) information relating to any radiopharmaceutical, anaesthetic or sedative administered to the patient;

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

(i) any adverse reaction experienced by any patient following or associated with the administration of any radiopharmaceutical, anaesthetic or sedative, including any investigation into the cause of the adverse reaction; and

(ii) any incident occurring in the course of or in relation to any examination conducted or in vivo assay procedure performed on, or any treatment provided to, any patient (as the case may be) that affected or potentially affected the safety of the patient or any personnel, including any investigation and follow-up action taken.

Records — other matters

74.—(1) A licensee must keep and 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 nuclear medicine service;

(*b*) the quality management activities and measures taken by the licensee in connection with the provision of the nuclear medicine 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 nuclear medicine service;

(ii) the radioactive substances used in the provision of the nuclear medicine service;

(*e*) the procurement, receipt, use, preparation, administration, storage and disposal of all radioactive substances in relation to the provision of the nuclear medicine service.

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

(*a*) information relating to the quality management system mentioned in regulation 13;

(*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 13, 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 nuclear medicine service; and

(*f*) all quality control measures implemented.

Price transparency

75. A licensee must, upon request by a patient or requestor, 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, in vivo assay procedure or treatment, as the case may be.

Display of charges

76. A licensee must ensure that the charges payable for the following components of a nuclear medicine service provided by the licensee are displayed or made available at every approved permanent premises:

(*a*) radiopharmaceuticals and other consumables;

(*b*) sedation procedures, if applicable;

(*c*) where the nuclear medicine service is provided for an imaging purpose —

(i) imaging procedures; and

(ii) contrast fees.

Disclosure of approved institution status

77.—(1) A licensee who is an approved institution must display or otherwise make available at every approved permanent premises the fact that the licensee is an approved institution.

(2) A licensee who is not an approved institution must not —

(*a*) represent to any person or give any person the impression that the licensee is an approved institution; or

(*b*) otherwise mislead any person as to whether the licensee is an approved institution.

(3) In this regulation, "approved institution" means any of the following:

(*a*) an approved medical institution within the meaning of regulation 2(1) of the Central Provident Fund (Medisave Account Withdrawals) Regulations (Rg 17);

(*b*) an approved medical institution approved by the Minister under the MediShield Life Scheme Act 2015;

(*c*) an accredited clinic under the scheme established by the Government known as the Community Health Assist Scheme or any other similar public scheme providing financial assistance established by the Government.

Financial counselling

78.—(1) This regulation applies in relation to the provision of any claimable NMT service by a licensee to a patient.

(2) A licensee must, before providing any claimable NMT service to a patient, provide information on the fees charged by the licensee for the claimable NMT service to the patient or (if the patient is a minor or lacks mental capacity) a next-of-kin or carer of the patient.

(3) For the purposes of paragraph (2), the information on the fees for a claimable NMT service must include —

(*a*) the estimated range of fees for the claimable NMT service;

(*b*) the fee benchmark for the same or similar claimable NMT service that is published on the website of the Ministry of Health at https://www.moh.gov.sg (if available);

(*c*) whether any part of the fees mentioned in sub-paragraph (*a*) may be —

(i) deducted from any medisave account;

(ii) reimbursed under the MediShield Life Scheme; or

(iii) reduced by any subsidy or grant under a public scheme; and

(*d*) any other benefit that the MediShield Life Scheme provides to the patient in respect of the NMT service, if any.

(4) The licensee need not comply with paragraph (2) if the patient needs to receive the claimable NMT service immediately and without delay.

(5) The licensee must, after providing the information mentioned in paragraph (3) to the patient or the next-of-kin or carer of the patient, obtain an acknowledgment from the patient, next-of-kin or carer (as the case may be) and keep the acknowledgment as part of the patient's patient health record.

(6) In this regulation —

"claimable NMT service" means an NMT service provided by a licensee to a patient who may claim under the MediShield Life Scheme for reimbursement (whether wholly or in part) of the charges incurred in receiving the service;

"medisave account" means a medisave account maintained under section 13 of the Central Provident Fund Act 1953;

"NMT service" means a nuclear medicine service provided for a therapy purpose.

Offences

79.—(1) A person who contravenes regulation 13(1), 14(1), (2) and (3)(*a*) and (*e*), 15(1), 16(1), (2), (3) or (4), 17, 19, 20, 21, 23(1), 25, 26(1), (2) or (3), 27(1), (2), (3) or (4), 29, 30(1), 31, 32(1), 40, 41(1) or (2), 42, 43, 46, 48, 49, 50, 53, 55(1), (2) or (3), 56(1), 57, 59, 65, 66, 67, 70(1) or 71(1) shall be guilty of an offence.

(2) A person who 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.

Revocation

80. Revoke the Healthcare Services (Nuclear Medicine Assay Service and Nuclear Medicine Imaging Service) Regulations 2021 (G.N. No. S 1039/2021).

THE SCHEDULE

Regulations 2(1) and 5(1)

SPECIFIED SERVICES

1. The provision of a nuclear medicine service for an imaging purpose by any of the following imaging modalities:

   (*a*) planar nuclear medicine imaging and uptake studies;

   (*b*) positron emission tomography-computed tomography;

   (*c*) positron emission tomography-magnetic resonance;

   (*d*) single-photon emission computed tomography;

   (*e*) single-photon emission computed tomography-computed tomography.

Made on 19 June 2023.

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

[MH 78:44/1; AG/LEGIS/SL/122E/2020/31 Vol. 2]