LICENCE CONDITIONS FOR
THE PROVISION OF RADIOLOGICAL SERVICES

IMPOSED UNDER SECTION 13(1) OF
THE HEALTHCARE SERVICES ACT 2020

1. Application

1.1 These licence conditions ("**LCs**") apply to all persons which have been licensed under the Healthcare Services Act 2020 (the "**HCSA**") to provide a radiological service (such persons referred to as "**Licensees**").

1.2 For avoidance of doubt, the defined terms as used in these LCs shall have the meanings ascribed to them in the HCSA and any Regulations made thereunder, unless otherwise stated.

1.3 A breach of these LCs may result in regulatory action being taken against Licensees under section 20 of the HCSA, including but not limited to —

(a) suspension or revocation of the Licensee's radiological service licence;

(b) shortening the term of the Licensee's radiological service licence;

(c) a direction requiring the Licensee to rectify the contravention, or prevent a recurrence of the contravention; and/or

(d) a direction requiring the Licensee to pay a financial penalty.

1.4 These LCs do not override a healthcare professional's duty to make clinical decisions that are in the best interests of each patient with their valid consent.

1.5 For avoidance of doubt, the requirements in these LCs are without prejudice, and in addition to the requirements imposed under the HCSA as well as any Regulations and other applicable licensing conditions, directions, codes of practice made thereunder.

2. Requirements Relating to Personnel

2.1 The Licensee shall:

(a) Document and define the minimum qualifications for all positions in its radiological service, including the educational qualifications, skills and experience required of each position;

(b) Document and define the job descriptions, roles and tasks for all positions in its radiological service;

(c) Implement a programme for the training and development of all the personnel in its radiological service. This programme shall minimally cover the following aspects:

(i) specifying and implementing regular training programme(s), supervision by relevant personnel, periodic competency assessment(s), and programme(s) on continuing education that each personnel is required to undergo;

(ii) the corrective actions to be taken against each personnel who fails to attain a satisfactory performance, such as retraining and competency assessment;

(iii) conducting regular trainings, and providing instructions and updates on the radiation safety programme implemented under Regulation 14 of the Healthcare Services (Clinical Laboratory Service and Radiological Service) Regulations 2021 ("**CLSRS Regulations**");

(iv) assigning an experienced person (as defined under Regulation 10(2) of the CLSRS Regulations) to supervise, train and assess the competency of every personnel who requires supervision.

2.2 The Licensee shall ensure that every personnel who operates any irradiating apparatus has undergone all applicable training course(s) and passed all competency assessment(s) on the use of irradiating apparatus and radiation safety prior to operating the irradiating apparatus.

3. Quality Management System

3.1 The Licensee shall ensure that its quality management system, which is established and implemented pursuant to Regulation 11 of the CLSRS Regulations, shall be documented and shall minimally cover the following aspects of the Licensee's provision of its radiological service:

(a) the organisational structure of the Licensee, the roles of and reporting relationships of every key appointment holder, the Principal Officer ("**PO**"), the Clinical Governance Officer ("**CGO**"), the section leader (as appointed under Regulation 8 of the CLSRS Regulations), as well as the delegation of duties to the relevant personnel (where applicable);

(b) the quality control measures such as reject/repeat analysis, phantom tests and optical density tests (see paragraphs 3.6 to 3.8 below);

(c) the key performance indicators for assessing the performance outcomes of the radiological service, including the expected turnaround time needed for each radiological examination conducted and the accuracy of diagnostic reporting;

(d) the protocols implemented to ensure traceability of radiological images kept and/or tested by the Licensee;

(e) validation of critical processes, including:

(i) the evaluation of vendors,

(ii) the evaluation of instruments and equipment used in the provision of the radiological service to ensure that they are functioning in accordance with the vendor's specifications and are fit for patient use,

(iii) the evaluation of any drugs or consumables (e.g. contrast agents) to ensure that they are safe for patient use and are approved by the CGO or another suitably-qualified personnel appointed by the Licensee; and

(f) records retention (including relevant retention durations and access/use safeguards).

3.2 The Licensee shall carry out audits on its radiological service's operations as part of its quality management system, and ensure that appropriate corrective and preventive actions are taken for all deficiencies identified. The Licensee shall document:

(a) the required frequency of audits,

(b) the date of each audit,

(c) the deficiency(ies) identified during each audit, and

(d) the corrective and preventive action(s) taken for the deficiency(ies) identified.

3.3 The Licensee shall review the risk assessment of all activities occurring in its radiological service and all its standard operating procedures ("**SOPs**") according to its policies. The Licensee shall, at the minimum, conduct such reviews at the following frequencies:

(a) the review of risk assessment of all activities occurring in its radiological service shall be conducted at least once a year, and

(b) the review of all its SOPs shall be conducted at least once every three years.

3.4 The Licensee shall ensure that independent supervisory reviews are conducted on records relating to:

(a) instrument maintenance and functional checks, and

(b) quality control.

3.5 The independent supervisory reviews (as mentioned in paragraph 3.4 above) shall be conducted by a supervisor who did not perform or record the maintenance, checks and/or quality control. Where applicable, the Licensee shall also take corrective action(s) and troubleshooting action(s) as part of the review.

Quality Control Measures

3.6 The Licensee shall implement the following quality control measures for all the equipment used in the provision of its radiological service:

(a) Perform acceptance testing on the equipment:

(i) at the time of installation and as part of the commissioning procedure, and

(ii) after the equipment has undergone any major maintenance or software upgrades;

(b) Perform quality control tests and preventive maintenance on the equipment in accordance with:

(i) the manufacturer's specifications, requirements and/or recommendations,

(ii) the prevailing international guidelines in relation to the use of the equipment, and

(iii) the procedures implemented and documented by the Licensee;

(c) Designate qualified and trained personnel to monitor the equipment's performance;

(d) Visually inspect and radiographically examine all lead-lined personal protective equipment ("PPE") at least once a year for any physical damage that may compromise the level of protection;

(e) Assess the results of all quality control tests performed on the equipment against established criteria; and

(f) Ensure that appropriate action(s) are taken in the event of:

(i) equipment failure, or

(ii) an unacceptable quality control results before resuming the use of the equipment for radiological examinations.

3.7 The Licensee shall implement the following quality control measures for all radiological images obtained by its radiological service:

(a) Assess all images against established criteria; and

(b) In the event that the image does not satisfy the established criteria, to take appropriate corrective and preventive measures.

3.8 The Licensee shall ensure that all quality control measures implemented, including reject analyses, are documented and reviewed on a regular basis by the CGO, or by a personnel who is designated by the CGO and competent in regularly documenting and reviewing all the implemented quality control measures, to ensure that systemic issues are identified and resolved in a timely manner.

4. Premises, Equipment and Fittings

Premises

4.1 The Licensee shall ensure that in relation to its approved permanent premises, temporary premises, or approved conveyance of its radiological service ("**Premises**"):

(a) there is adequate space in the Premises such that the quality of work and safety of its personnel will not be compromised;

(b) there is adequate space in the Premises for the movement of its personnel;

(c) there is proper segregation of the waiting area, which is accessible by the public, and the procedure area, where the radiological services are performed, within the Premises;

(d) there is at least one changing room located in close proximity with the procedure areas in its Premises, which provides for patients' privacy. The layouts of the changing room(s), sub-waiting area(s) (if any) and imaging procedure room(s) that will be used as part of the patient pathway should permit preservation of the patient's modesty after changing into gown(s);

(e) there is adequate lighting and proper ventilation;

(f) there are adequate environmental controls (such as temperature, humidity, and where applicable, pressure) for its personnel to carry out the radiological service without compromising the quality of work and for the optimal functioning of irradiating apparatus; and

(g) there are no food or drinks stored or consumed in the procedure room(s) in the Premises.

4.2 The Licensee shall, at the minimum, implement the following measures to prevent unauthorised access to the Premises:

(a) install lock(s) and/or security system(s) to ensure that access to procedure room(s) is restricted to authorised personnel only; and

(b) affix warning signage outside the procedure room(s) to indicate that a procedure is in progress. For example, the Licensee may install a red light outside a procedure room which is used for the provision of plain radiography service, such that the red light lights up whenever the plain radiography service is being provided.

Equipment

4.3 The Licensee shall ensure all applicable authorizations issued under the Radiation Protection Act 2007 have been obtained for every equipment in the Premises.

4.4 The Licensee shall ensure that all equipment, including but not limited to irradiating apparatus and medical emergency equipment, in the Premises satisfy the following requirements:

(a) The equipment is installed in accordance with the manufacturer's specifications;

(b) The functionality and performance of the equipment have been checked and verified by the relevant vendor(s) to meet the manufacturer's specifications;

(c) The functionality and performance of the equipment have been checked and verified by the Licensee's personnel prior to their use or after any major maintenance, major servicing, or relocation.

4.5 The Licensee shall document and maintain an inventory of all the equipment being operated in the Premises. The inventory shall contain the following information in relation to each piece of equipment:

(a) records in relation to the commissioning and maintenance of the equipment, such as the commissioning certificates, servicing certificates, and preventive maintenance certificates issued by the relevant vendor(s) in relation to the equipment;

(b) records of all modifications made to date to:

(i) the equipment (e.g. hardware upgrades), and

(ii) the equipment's operating software and application(s) (e.g. software upgrades); and

(c) the instruction manual of the equipment.

Radiology Information System, Picture Archiving and Communication System ("PACS"), and Equipment Data

4.6 Where the Licensee implements a radiology information system and/or a PACS for the provision of its radiological service, the Licensee shall implement a policy that covers the following for each system:

(a) the various levels of access control and privilege rights in the system as may be necessary for each of its personnel's job function;

(b) user authentication (i.e. the process of verifying the identity of the user of the system); and

(c) audit trail(s) of access to the system and amendments made to the system.

4.7 The Licensee shall ensure that its radiology information system and PACS are qualified for proper performance prior to their implementation and after any significant modifications made to them.

4.8 The Licensee shall ensure that its radiology information system is evaluated for accurate data transmission from its interfaced imaging systems to its test reports.

Protective Equipment

4.9 The Licensee shall ensure that its Premises have sufficient protective equipment and protective clothing, such as lead aprons and mobile lead screens, available for all personnel at all times.

Emergency and Resuscitation Equipment / Drugs

4.10 If the Licensee provides a radiological examination which requires administration of drugs (including contrast agent, sedative or anaesthetic) to a patient, the Licensee shall ensure that its Premises maintain, at the minimum, the following medical emergency equipment:

(a) Age-appropriate oropharyngeal airways;

(b) Appropriate device for drug delivery of inhaled bronchodilator;

(c) Bag-valve mask;

(d) Infusion set; and

(e) IV Normal saline (0.9%) solution or IV 5% Dextrose saline solution.

4.11 If the Licensee provides a radiological examination which requires administration of drugs (including contrast agent, sedative or anaesthetic) to a patient, the Licensee shall ensure that its Premises maintain, at the minimum, the following medical emergency drugs:

(a) Inhaled bronchodilator;

(b) IV adrenaline;

(c) IV antihistamine e.g. promethazine;

(d) IV atropine;

(e) IV steroid e.g. hydrocortisone; and

(f) Sub-lingual nitroglycerine tablet or spray.

4.12 If the Licensee provides general anaesthesia as part of its radiological service, the Licensee shall ensure that its Premises maintain, at the minimum, the following medical emergency equipment in addition to the equipment listed in paragraph 4.10, when the general anaesthesia procedure is being performed in its Premises:

(a) Defibrillator;

(b) Oxygen supply; and

(c) Suction apparatus.

4.13 If the Licensee provides general anaesthesia as part of its radiological service, the Licensee shall ensure that its Premises maintain, at the minimum, the following medical emergency drugs in addition to the drugs listed in paragraph 4.11, when the general anaesthesia procedure is being performed in its Premises:

(a) IV amiodarone;

(b) IV dopamine;

(c) IV flumazenil;

(d) IV lidocaine;

(e) IV magnesium sulphate;

(f) IV naloxone; and

(g) Management kit for malignant hyperthermia.

4.14 The Licensee shall ensure that all medical emergency equipment and drugs are functional, effective, and comply with established or recommended procedures for their maintenance and use.

5. Radiological Service Practices

General Requirements

5.1 The Licensee shall implement a patient identification system which uniquely identifies each patient based on two unique patient identifiers (e.g. full name and identification/passport number).

5.2 The Licensee shall ensure that every patient's identity is verified by the Licensee's personnel:

(a) when the patient presents himself at the Licensee's Premises for radiological examination; and

(b) at each critical stage of the radiological examination. "Critical stage" refers to any stage of the radiological examination that will have an impact on the patient's safety, such as the administration of a contrast agent to a patient and prior to the conduct of the imaging procedure.

5.3 The Licensee shall ensure that appropriate protective clothing is worn by its personnel and any caregivers of patients who may need to be present in the imaging room, when the said personnel conduct fluoroscopic examinations or other examinations that require close proximity of said personnel and the said caregiver with the primary beam.

Consent Taking

5.4 The Licensee shall document and implement a policy in relation to obtaining consent from patients. The policy shall minimally meet the requirements set out in paragraphs 5.5 to 5.9 of these LCs.

5.5 The Licensee shall, at the minimum, obtain informed consent from a patient in writing before conducting any of the following procedures on the patient as part of its provision of a radiological examination:

(a) the administration on the patient of sedative or anaesthetic; and

(b) any other radiological examination procedures that are of a higher risk to the patient's safety as determined by the Licensee's internal assessment. The internal assessment shall include considerations of the possible risks posed to a patient's foetus (if applicable).

5.6 Where it is necessary to obtain a patient's informed consent in writing before a radiological examination is conducted (see paragraph 5.5 above), the Licensee shall ensure that patient education of the radiological examination is provided to the patient before obtaining the patient's consent, which includes explanations and instructions on:

(a) the process of the radiological examination,

(b) the benefits of undergoing the radiological examination,

(c) the risk(s) involved in undergoing the radiological examination,

(d) the available alternatives to the radiological examination, and

(e) the follow-up post-procedure care required after the radiological examination (if applicable);

5.7 Where it is necessary to obtain a patient's informed consent and the patient is below 21 years old, the Licensee shall obtain and document consent from the patient's parent or legal guardian before conducting the radiological examination. If the Licensee is unable to obtain the consent from the patient's parent or legal guardian despite best efforts, the Licensee must:

(a) assess and ensure that the patient has sufficient understanding and intelligence to understand the procedures and consequences of the radiological examination, and

(b) obtain and document the patient's consent.

5.8 Where it is necessary to obtain a patient's informed consent and the patient is mentally incapacitated, the Licensee shall obtain and document consent from the patient's legal donees or deputies[1] (as applicable) before conducting the radiological examination.

5.9 Before the radiological examination, if despite best efforts the Licensee:

(a) has assessed that it is unable to ensure that the patient has sufficient understanding and intelligence to understand the procedures and consequences of the radiological examination as per paragraph 5.7(a);

(b) is unable to obtain the consent from the patient as per paragraph 5.7(b); or

(c) is unable to obtain the consent from the patient's legal donees or deputies (as applicable) as per paragraph 5.8,

[1] "Donees" and "deputies" refer to the donees and deputies respectively who are authorised to give or refuse consent to the carrying out or continuation of a treatment by a person providing health care for the patient, in accordance with the Mental Capacity Act 2008.

the radiological examination shall only be conducted provided that it is necessary to save the patient's life and is in the best interests of the patient.

Use and Administration of Contrast Agents

5.9 The Licensee shall ensure that the attending diagnostic radiologist(s) shall:

(a) supervise the use or administration of contrast agents to the patient; and

(b) ensure the safety of the patient during the radiological examination, as a result of any use or administration of contrast agents to the patient.

5.10 The Licensee shall establish and document protocols on the use and administration of contrast agents. The protocols shall ensure that only its personnel who have received adequate and appropriate training, and assessed to be competent in venipuncture and administration of contrast agents, may obtain intravenous access for the purpose of administering the contrast agent.

Use and Administration of Anaesthetics and Sedatives

5.11 The Licensee shall implement and document the measures that it will adopt for the conduct of radiological examinations that require the administration of an anaesthetic or a sedative to a patient. The measures shall minimally cover the following:

(a) only personnel who are adequately trained and qualified may do any of the following:

(i) assess the patient's suitability to be administered the anaesthetic or sedative (as applicable);

(ii) administer the anaesthetic or sedative (as applicable) to the patient. In particular, only anaesthesiologists may administer general anaesthesia to a patient; and

(iii) monitor and manage the medical condition of the patient during and after the administration of the anaesthetic or sedative (as applicable);

(b) unless trained and authorised by the Licensee (in accordance with the Licensee's requirements for diagnostic radiologists) to prescribe and administer drugs for minimal or moderate sedation, the diagnostic radiologist conducting the radiological examination shall consult with an

anaesthesiologist, an intensivist, and/or a pharmacist (as applicable) regarding:

(i) the appropriate type of anaesthetic or sedative drug to be administered to the patient,

(ii) the appropriate dose of the drug to be administered to the patient, and

(iii) the appropriate rate of administration of the drug to the patient;

(c) the appropriate duration to monitor the patient after the completion of the radiological examination; and

(d) the discharge arrangements for patient(s) who has been administered an anaesthetic or sedative from its Premises.

Errors or Incidents During the Conduct of Radiological Examination

5.12 The Licensee shall implement and document the measures that it will adopt in the event any of the following errors or incidents occur in its Premises:

(a) a radiological examination was conducted on the wrong patient or at the wrong site;

(b) the wrong type or dose of drug(s) (e.g. contrast agents, anaesthetic, sedatives) was administered to a patient; or

(c) any other incidents occurring within the Premises (e.g. falls, medical emergencies) which may affect patient safety or welfare.

5.13 The measures to be implemented and documented under paragraph 5.13 shall minimally cover the following:

(a) the patient(s) who has been affected by the error or incident is given appropriate follow-up care;

(b) an investigation is conducted and documented to ascertain:

(i) the details of the error or incident (e.g. time, location, impact on patient),

(ii) the causal factor(s) behind the error or incident,

(iii) the follow-up actions taken in respect of the affected patient(s),

(iv) the preventive and corrective action(s) taken to prevent such error or incident from recurring,

(v) the effectiveness of the preventive and corrective action(s) taken (if applicable); and

(c) ensure that all relevant regulatory authorities are notified of the error or incident. The relevant authorities include the Ministry of Health (MOH) and the National Environment Agency (NEA).

6. Records

Service Records

6.1 The Licensee shall keep the following records in relation to its operations:

(a) the quality control test results of its radiological service;

(b) the maintenance records of all of its radiological service's equipment; and

(c) records relating to the contrast agents, anaesthetic or sedative used as part of its Service, which include:

(i) the name, lot number and expiry date of the administered contrast agent;

(ii) the name, lot number and expiry date of the administered anaesthetic or sedative; and

(iii) any other information that is necessary for the Licensee to trace and obtain the information stated in Regulation 44(1)(g) of the CLSRS Regulations and paragraph 6.2 of these LCs.

Patient Records

6.2 The Licensee shall keep records of the anaesthetic or sedative administered to every patient (if any), in relation to each radiological examination that the Licensee conducts. The record should minimally cover the following information:

(a) the name and dose of anaesthetic or sedative administered to the patient;

(b) the route and rate of administration of the anaesthetic or sedative to the patient;

(c) the adverse reaction(s) suffered by the patient following the administration of anaesthetic or sedative (if any);

(d) the extent and duration of monitoring of the patient following the administration of anaesthetic or sedative; and

(e) the discharge arrangement(s) for the patient who has been administered the anaesthetic or sedative.

7. Additional Requirements for Computed Tomography ("CT") Modality

7.1 A Licensee that provides CT as an imaging modality shall ensure that:

(a) the Licensee has minimally employed or engaged the following qualified personnel to work in the provision of CT services:

(i) at least one diagnostic radiologist to supervise the provision of CT services. For clarity, the diagnostic radiologist is not required to be on-site but is required to:

(1) remain contactable,

(2) ensure operations are conducted in accordance with the quality assurance manual and SOPs, and

(3) provide guidance in the event of any operational issues raised by the Licensee's personnel, to discharge his/her supervisory duty;

(ii) at least one registered diagnostic radiographer with competency in CT. The said diagnostic radiographer(s) shall be the personnel performing the CT scan at all times; and

(iii) where the provision of the CT service involves the administration of drugs, at least one registered nurse or medical practitioner competent in carrying out resuscitation;

(b) the Licensee has implemented policies to regularly maintain and review the CT scanning protocols to minimise patient radiation exposure, and to document these policies and reviews of the CT scanning protocols;

(c) the Licensee keeps proper documentation of the radiation dose delivered to the patient in every CT examination for at least 6 years.

8. Additional Requirements for Magnetic Resonance Imaging ("MRI") Modality

8.1 A Licensee that provides MRI as an imaging modality shall ensure that:

(a) the Licensee has minimally employed or engaged the following qualified personnel to work in the provision of MRI services:

(i) at least one diagnostic radiologist to supervise the provision of MRI services. For clarity, the diagnostic radiologist is not required to be on-site but is required to:

(1) remain contactable;

(2) ensure operations are conducted in accordance with the quality assurance manual and SOPs;

(3) provide guidance in the event of any operational issues raised by the Licensee's personnel, to discharge his/her supervisory duty;

(ii) at least one registered diagnostic radiographer with competency in MRI. The diagnostic radiographer(s) shall be the personnel performing the MRI scan at all times; and

(iii) where the provision of MRI service involves the administration of drugs, at least one registered nurse or medical practitioner competent in carrying out resuscitation;

(b) the Premises are safe for its personnel, patients and other visitors, by minimally implementing the following measures in the Premises:

(i) clear demarcation of the zones within the Premises that provide radiological examination to restrict access;

(ii) installation of suitable warning signs to indicate that the MRI magnet is always switched on;

(iii) retention of a magnetic resonance site-specific field map indicating the Gauss lines;

(iv) protocols to ensure that any person with any type of electrically, magnetically or mechanically activated device remains outside the 0.5 mT (5 Gauss) line;

(c) all the equipment used in the provision of MRI services are suitable, adequate and functional, by minimally implementing the following measures:

(i) the equipment's specifications and performance comply with the manufacturer's and/or vendor's specifications;

(ii) the MRI-conditional accessories and equipment are used in accordance with the respective manufacturer's and/or vendor's specifications as documented in the user manual(s);

(iii) prior to using super-conducting MRI, ensure that the cryogen venting, helium level monitoring and emergency exhaust are installed in accordance with the specifications set by original equipment's manufacturer;

(d) all of its personnel and patients are protected against magnetic resonance – induced harm, by minimally implementing processes to ensure the following measures:

(i) perform a screening on all person(s) for possible contraindications prior to conducting the MRI scanning;

(ii) document the screening performed on the patient and the acknowledgement by the patient;

(iii) check and ensure that all person(s) entering the procedure room or undergoing an MRI procedure remove all readily removable metallic personal belongings and devices on or in them before entering the procedure room or undergoing the procedure;

(iv) provide adequate and appropriate ear protection for all of its personnel and patients who need to remain inside the magnet room during scan acquisition;

(v) establish for personnel, guidelines on managing patients who may have claustrophobia or anxiety related to MRI procedures;

(vi) measures to prevent thermal injuries from conductive wires, including ECG leads and wires from other monitoring devices, with careful insulation and orientation of the wires/leads from direct contact with the patient;

(e) the Licensee implements and documents safety guidelines and policies. The safety guidelines and policies shall minimally cover the following:

(i) conduct checks to avoid any potential interactions of ferromagnetic objects in the magnetic field of the scanner;

(ii) restrict access by patients and personnel to the MRI magnet and its immediate surrounding areas;

(iii) conduct checks to avoid any potential hazards posed by cardiac pacemakers and other objects implanted in the patient;

(iv) conduct checks to avoid any potential hazards arising from interaction with the radiofrequency and gradient field;

(v) perform patient and non-MRI personnel screenings and checks as prescribed in paragraphs 8.1(d)(i) and (iii) before allowing their entry into the procedure room;

(vi) conduct checks on the pregnancy status of patients where relevant and provide appropriate protection for the pregnant patient and the foetus against radiation exposure during MRI scanning; and

(vii) monitor sedated patients undergoing MRI procedures.