LICENCE CONDITIONS
ON CLINICAL LABORATORY SERVICES LICENSEES
FOR THE PROVISION OF ANY TESTING SERVICE ON RADIOACTIVE SPECIMENS

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 licenced under the Healthcare Services Act 2020 (the "**HCSA**") to provide a clinical laboratory service ("**Service**") and provides any testing services on radioactive specimens[1] (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 Service licence;

(b) shortening the term of the Licensee's 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.

[1] For avoidance of doubt, "radioactive specimens" has the meaning in regulation 2 of the Healthcare Services (Clinical Laboratory Service and Radiological Service) Regulations 2021.

2. Requirements Relating to Personnel

2.1 The Licensee shall:

(a) Document and define the minimum qualifications for all positions in its Service who are involved in the provision of any testing services on radioactive specimens, including the educational qualifications, skills and experience required of each position;

(b) Document and define the job descriptions for each position and its roles and tasks in the provision of any testing services on radioactive specimens;

(c) Implement a programme for the training and development of all the personnel who are involved in the provision of any testing services on radioactive specimens. 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(s);

(iii) conducting regular trainings, and providing instructions and updates on:

(1) the Service's safety programme implemented under Regulation 14 of the Healthcare Services (Clinical Laboratory Service and Radiological Service) Regulations 2021 ("CLSRS Regulations"), especially the matters prescribed in Regulations 14(2)(b) and 14(2A);

(2) the use of the Service's equipment;

(3) aseptic practices;

(4) infection control measures, and

(iv) assigning an experienced personnel (as defined under Regulation 10(2) of the CLSRS Regulations) to supervise, train and assess the competency of every personnel who is involved in the provision of any testing services on radioactive specimens and who requires supervision.

Quality Management System

2.2 The Licensee shall ensure that its quality management system, which is established and implemented pursuant to Regulation 11 of the CLSRS Regulations, minimally covers the following aspects of the Licensee's provision of any testing services on radioactive specimens:

(a) the Licensee's mission statement, objectives and scope of the Service in relation to the Licensee's provision of any testing services on radioactive specimens;

(b) policies and procedures relating to personnel who are involved in any testing services on radioactive specimens including:

(i) training and validation for use of equipment, and

(ii) training on aseptic practices and infection control;

(c) policies and procedures to review and, where applicable, plan for the future development of the provision of testing services on radioactive specimens and personnel needs (e.g. expansion of the said testing services and staff succession planning) to ensure that the said testing services are provided with accuracy, timeliness and safety at all times;

(d) the quality control ("**QC**") measures for the equipment used to provide testing services on radioactive specimens, radioactive substances, and its approved permanent premises ("**Premises**");

(e) the internal audits and their required frequency conducted on the Licensee's provision of any testing services on radioactive specimens, and ensure that appropriate corrective and preventive actions are taken for all deficiencies identified;

(f) the escalation and reporting of all radiation accidents as defined under the Radiation Protection Act 2007 ("**RPA**") to the National Environment Agency (NEA); and

(g) the emergency and contingency plans in the event of any clinical incidents, service disruptions, or radiation accidents, including the activation timelines of such plans to ensure the continuity of the Licensee's provision of any testing services on radioactive specimens, and to safeguard patient safety.

QC Measures for Equipment

2.3 The Licensee shall implement the following QC measures for all the equipment used in its provision of any testing services on radioactive specimens:

(a) perform acceptance testing on the equipment:

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

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

(b) perform QC tests and preventive maintenance on the equipment in accordance with:

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

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

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

(c) take corrective and preventative actions to address and rectify all QC test results which are assessed to be unacceptable and to document these actions.

QC Measures for Radioactive Substances

2.4 The Licensee shall implement the following QC measures for all the radioactive substances used in its Service:

(a) retain the QC documents for all commercially procured radioactive substances, in accordance with the retention period specified in the Licensee's policies;

(b) perform QC tests on all radioactive substances that are prepared in-house, and retain all records of the tests for in accordance with the retention period specified in the Licensee's policies;

(c) document in its standard operating procedures ("**SOPs**") all guidelines and formula used for the in-house preparation of radioactive substances, and retain all raw data generated in the course of the

radioactive substance preparation in accordance with the retention period specified in the Licensee's policies.

(d) take corrective and preventative actions to address and rectify all QC test results which are assessed to be unacceptable and to document these actions.

QC Measures for Premises

2.5 The Licensee shall implement the following QC measures for its Premises:

(a) prior to commencement of the Service's operations, check and ensure that the Primary Engineering Control ("**PEC**") (e.g. the Biosafety Cabinet, Laminar Flow Cupboard, Fume Cupboard), at areas in its Premises where radioactive substance are handled, satisfy the initial qualifications[2], in order to establish a baseline level of environmental quality;

(b) periodically check that the Performance Qualification of the PEC is satisfactory in accordance with its manufacturer's specification;

(c) take corrective and preventative actions to address and rectify all unsatisfactory results in relation to the Performance Qualification of the PEC and to document these actions; and

(d) whenever there are changes to the radioactive substance storage area, to obtain re-certification by the relevant authority(ies).

3. Premises and Equipment

Equipment

3.1 The Licensee shall implement policies and SOPs in respect of the operations and maintenance of all equipment in its provision of any testing services on radioactive specimens to ensure that the said testing services are provided in a safe and appropriate manner.

3.2 The Licensee shall ensure that its Premises which are used for the provision of any testing services on radioactive specimens have sufficient and appropriate decontamination kits, personal protective equipment ("**PPE**") and radiation monitors at all times to manage any radioactive spills. The Licensee shall, at the minimum, maintain sufficient quantities of the following decontamination kits, PPE and radiation monitors:

[2] Initial qualifications of PEC refer to Installation Qualification ("IQ"), Operation Qualification ("OQ") and Performance Qualification ("PQ"). IQ ensures that the PEC has been delivered and installed in accordance with manufacturer's requirements; OQ ensures that the PEC is functioning in accordance with the specifications; and PQ ensures that the PEC continues to meet the specifications.

(a) Radiation survey meter;

(b) Disposable gloves;

(c) Protective clothing (e.g. overalls, jackets, gowns, coats); and

(d) Face and eye wash, if not already provided for under paragraph 3.5(d).

3.3 The Licensee shall provide adequate radionuclide dose calibrators with proper lead shielding and calibration of long half-life radionuclide QC sources to all personnel performing measurements of radioactivity of radioactive substances.

3.4 The Licensee shall comply with all prevailing requirements and guidelines issued by the relevant authority(ies) in relation to the procurement and use of all equipment and reagents in its provision of any testing services on radioactive specimens.

Premises

3.5 The Licensee shall ensure that for patient and personnel areas within its Premises which are used for the provision of any testing services on radioactive specimens:

(a) there are appropriate markings and access controls for areas designated as “supervised” and/or “controlled” in accordance with the requirements under the RPA and its regulations;

(b) there are adequate and secure physical storage areas for storing patient records;

(c) there are appropriate lead-lining or other shielding of doors, walls, ceilings, and floors of imaging rooms in accordance with the requirements stipulated under the RPA and its regulations; and

(d) there are adequate decontamination facilities including emergency shower(s), face and eye wash, if not already provided for under paragraph 3.2(d).

4. Safety Procedures

4.1 The Licensee shall ensure that its safety programme, which is developed and implemented pursuant to Regulation 14 of the CLSRS Regulations, shall be documented in the form of its Service’s policies and procedures (such as SOPs and Work Instructions etc), and shall minimally cover the

following aspects of the Licensee's provision of any testing services on radioactive specimens:

(a) radiation safety measures in relation to the transportation of radioactive substance(s) and waste management;

(b) safe and proper preparation and management of radioactive substance(s) in its Premises;

(c) in the event of any radioactive spills within its Premises, to take decontamination corrective actions, and thereafter to continue to monitor and ensure that the radiation levels within its Premises are within the safe range.

5. Service Records

5.1 The Licensee shall properly document and retain the following records in relation to its provision of any testing services on radioactive specimens for audit purposes in accordance with the retention period stipulated in any applicable laws and in the Licensee's policies:

(a) the preventive maintenance and servicing records of all equipment used in its provision of any testing services on radioactive specimens;

(b) records on testing of the radionuclide dose calibrator for constancy, accuracy, linearity, and geometric variation;

(c) QC parameters and test results, and troubleshooting measures performed (if applicable);

(d) records relating to all radioactive substances which include:

(i) the procurement, receipt, use, preparation, storage and disposal of all radioactive substances, and

(ii) the identity of the radioactive substance;

(e) records relating to its Premises used for the provision of any testing services on radioactive specimens, including:

(i) preventive maintenance of PEC,

(ii) radiation monitoring records which shall include radiation room surveys, and

(iii) investigation, follow-up actions and management of any radioactive spillage;

(f) records relating to patient and personnel safety, which include investigation and follow-up actions of any incidents concerning patient and/or personnel safety; and

(g) records relating to the internal audits conducted under paragraph 2.2(e), which include:

(i) the date of each audit,

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

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