هيئة البيئة
ENVIRONMENT AUTHORITY

وزارة الصحة

Procedures and Regulatory controls for Supplier of Acceptance Testing and Quality Control Services for Medical Radiology Equipment

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1: The objective:

To ensure that all Licensed companies / entities to acceptance testing and quality control services for radiology equipment in health institutions in the Sultanate of Oman are technically competent, operationally transparent, compliant with regulations, legislation and licensing requirements granted to them, and without any conflict of interest with the facilities being tested.

2: Regulatory and supervisory bodies and their roles:

No.	Entity	role
1	Environment Authority - Radiation Protection Department.	The entity responsible for issuing the service license. - Follow licensees' compliance with regulations, policies, and requirements through field visits. - Reviewing and evaluating periodic reports from relevant authorities. Report shall include calibration certificate, radiation Dose Reports, and a list of all tests performed and their results). Penalizing violators of regulations and requirements.
2	Ministry of Health- General Directorate of Projects and Engineering Services- Medical Physics Section	Evaluating the technical competence of licensees. Issuing approvals technical competence and an approved quality system. Verifying the competence of licensees during acceptance tests and quality control procedures.
3	Ministry of Health - Directorate General of Private Healthcare Institutions. (If the licensee provides the service only to a private healthcare institution)	Verifying the competence of licensees during acceptance testing and quality control procedures in coordination with the Medical Physics Section. Coordinating and supervising between private healthcare institutions and licensees service providers to ensure the efficiency and quality of service delivery.

3: Licensing Requirements:

Applications for a " Supplier of Acceptance Testing and Quality Control Service for medical radiology equipment license are submitted through the Environment Authority's electronic system (www.ea.gov.om), and the supporting documents for the application shall be attached as follows:

1. A cover letter from the applicant addressed to the Director of the Radiation Protection Department at the Environment Authority.
2. A copy of the commercial registration if the applicant is a private company and not a government entity.
3. A copy of the approval from the Medical Physics section at the General Directorate of Engineering Affairs, Ministry of Health, proof technical competence and an approved quality system. (Attachment 1: Requirements for this approval)
4. A list of qualified personnel to conduct acceptance testing and quality control, along with copies of their CVs, qualifications, and professional licenses, provided that at least one of them is a medical physicist.
5. A list of all equipment and tools used in quality control testing, along with calibration certificates for each device.
6. Detailed protocols and procedures for acceptance testing and quality control for each type of targeted radiology equipment, including approved standard reference methods and acceptance testing and quality control report templates.
7. A radiation protection program.
8. Proof of employee participation in the TLD/OSL Personal Radiation Dosimetry Service.

4: License Renewal Requirements:

The aforementioned license is issued for a fee of 100 O.R valid for two years, renewable and exemption period from late payment penalties is 30 days from the license expiry date, as stipulated in the Decision 79/2023 Issuing the Regulation for Radiation Protection and Safety and Security of Radiation and Radioactive Material .If the service beneficiary requests license renewal through the Environment Authority's electronic system (www.ea.gov.om), **they shall attach any supporting documents that have changed from those submitted when initially applying for the license, as mentioned above,** as well as the following:

1. A cover letter requesting renewal, detailing any changes or updates to the service, the institution, or the staff providing the service.
2. Updated calibration certificates for all measuring instruments.
3. A service performance report for the licensee, certified and issued by the Medical Physics section of the General Directorate of Projects and Engineering Services at the Ministry of Health.

5: Requirements and Controls for the Operational Mechanism After Obtaining the License:

1. Contracts between the testing company and the healthcare facility shall be clear, separate, and detailed, includes the scope of work, responsibilities, and pricing. A copy of these contracts shall be available upon request.

2. The company shall ensure that all required documents for quality control testing requests are available, in coordination with the beneficiary facility. These documents include: the technical specifications of the radiology equipment, the approved layout of the facility and the radiology room, and the radiology room shielding certificate.

3. All quality control tests shall be conducted during official working days and hours, in accordance with the Ministry of Health's regulations.

4. An engineer from the company supplying the radiology equipment shall be present during quality control tests to provide technical support, ensure proper setup of the machine, and address any technical issues.

5. A qualified medical physicist, accredited by the Ministry of Health and licensed by the Environment Authority, is responsible for conducting all quality control tests for radiology equipment. This physicist shall be present on-site during these tests.

6. Quality control tests are conducted using equipment with valid calibration certificates. The calibration certificates shall not have expired at the time of testing.

7. Any calibration, repair, or modification required during testing of the radiology equipment is the responsibility of the supplier (the company that provided the equipment), not the licensee.

8. The licensee conducting the tests is responsible for addressing any issues related to the implementation of quality control tests for the equipment. This includes repeating some tests if the results are not approved by the Medical Physics section, without the beneficiary healthcare institution incurring any additional financial costs.

9. The licensee conducting the tests is obligated to submit the final quality control test report, using the approved form, to the healthcare institution within five working days of the test date.

10. The implementing company shall keep an electronic and printed copy of each test report issued by it for a period of no less than three years, and submit it upon request to the competent authorities in the Ministry of Health and the Environment Authority.

If the service is to be provided to a private healthcare facility:

- The private healthcare facility shall submit the test request to the General Directorate of Private Healthcare Facilities at least five days before the scheduled test date agreed upon with the licensed provider. To ensures the completion of all necessary regulatory and technical procedures. All required documents shall be included, such as: the cover letter, the name of the company implementation the test, the technical specifications of the equipment, the approved layout of the radiology room, and the radiology room shielding certificate. The request will then be forwarded via the Barwa System to the Medical Physics section at the General Directorate of Projects and Engineering Services for review and coordination with the licensee to schedule the test.

- The licensee shall submit the acceptance testing and quality control reports as hard copies to the Medical Physics section for final approval. These reports are then uploaded to the Private Healthcare Institutions Directorate's AlBarwa System for the Directorate of Private Health Institutions system, which forwards them to the beneficiary healthcare institution. The licensee shall also provide the beneficiary healthcare institution with a hard copy of the Medical Physics section's certified report to be retained for at least ten years.

6: Conflict of Interest and Ethical Requirements:

It is strictly prohibited for a licensee conducting acceptance testing and quality control to any commercial, financial, service-related, ownership, or partnership have relationship with the healthcare facility being examined. This includes:

- Not being involved in providing, selling, or supplying radiology equipment to the private healthcare facility.

- Not combining the roles of supplier and test service provider.

7: Follow up and Evaluation:

1. The licensee is required to submit a semi-annual report to the Environment Authority containing a summary of all tests and their results conducted during that period.

2. The Environment Authority and the Ministry of Health have the right to conduct random field inspections at healthcare facilities where quality control tests were carried out by the licensee, to ensure the accuracy of the results and compliance with approved standards.

3. In the event of discovering any Technical malfunction, violation in the implementation of the test, or falsifying report results, the necessary legal measures will be taken against the company, including

- Issuing violations against the licensee by the Environment Authority.
- Suspension or cancellation of the license granted to the entity, according to the procedures followed by the Environment Authority.
- Taking any other acations as required.

4. The quality of performance of licensees is evaluated based on the accuracy of the data in the submitted test reports, their adherence to approved protocols, and their fulfilment of all required technical standards. A performance record is keep for each licensee and is updated periodically.

8: Related Legislation:

- Radiation Protection and Safety and Security of Radiation and Radioactive Material Regulation issued by Administrative Decision No. (79/2023).
- Licensing Requirements for Radiology Equipment Acceptance Testing and Quality Control Service Suppliers.
- Procedures of Licensing Radiography Services Requirements Guide to (GUD/019/Vers.01), issued by the Directorate General of Private Health Institutions at the Ministry of Health.

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Appendix No. (1): Documents required to obtain approval for technical competence and a certified quality system from the Medical Physics Section, General Directorate of Projects and Engineering Services, Ministry of Health.

1. Company's commercial registration (shall include the activity of radiological quality control and acceptance testing services).
2. Company address, location, and contact information:

- Provide the relevant authority with the address of the company's headquarters and its branches within the Sultanate of Oman (if any).
- Attach official contact phone numbers and a valid email address to facilitate coordination and avoid delays.

3. CVs of the medical physicists employed by the company and responsible for conducting acceptance and quality control tests, along with the following:

- Proof of professional registration from the Ministry of Labour.
- Training certificates in the field of (Acceptance Testing/QA/Radiation Protection) or a certificate of experience in this field.

4. List of devices and equipment used:

- Submit a detailed and up-to-date list of all devices and measuring instruments that will be used during the tests, specifying: (Device name/Model/Serial number/Date of last calibration/Accredited calibration body).
- Valid and certified copies of calibration certificates shall be attached. Results from devices not listed or not calibrated will not be accepted.

5. The following technical documents shall be provided:

- Acceptance Testing Protocols for each device type.
- Routine Quality Assurance (QA) Protocols.
- Tolerance limits (rejection and acceptance) and evaluation according to IAEA/IEC/AAPM standards.
- Ready-made and approved report templates.
- Non-Conformity Handling Procedures Manual.