ATOMIC ENERGY COUNCIL

GUIDANCE ON DOCUMENTING AND IMPLEMENTING A QUALITY ASSURANCE PROGRAMME FOR MEDICAL PRACTICES USING FLUOROSCOPY X-RAY MACHINES

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APPROVED BY

Natharius Nimbashabira

Ag. SECRETARY & CHIEF EXECUTIVE OFFICER

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DEFINITIONS

Authorised person: means a person issued an authorisation by Atomic Energy Council under authority from the Atomic Energy Act Cap 154.

Facility: means any assembly of devices, equipment, structures or natural features whether simple or complex which serves some purpose or performs some function, during which radiation is, or is capable of being emitted;

Practice means any human activity that introduces additional sources of exposure pathways or extends exposure to additional people or modifies the network of exposure pathways from existing sources, so as to increase the exposure or the likelihood of exposure of people or the number of people exposed.

Quality Assurance Programme is defined by the World Health Organisation (WHO) as organised effort by the staff operating a facility to ensure that the diagnostic images produced by the facility are of sufficiently high quality so that they consistently provide adequate diagnostic information at the lowest possible cost and with the least possible exposure of the patient to radiation

Quality Control: Is a systematic process that ensures products or services meet specified quality standards and requirements. In the context of radiology imaging equipment, QC involves monitoring and testing imaging systems to verify their performance within defined parameters, thereby producing high-quality diagnostic images while adhering to established medical and regulatory standards to ensure patient safety and diagnostic integrity.

1.0 INTRODUCTION

Quality assurance consists of structured procedures and actions aimed at maintaining a high level of quality in the diagnosis or treatment of patients. The increasing complexity of medical technology requires specialized and systematic verifications to ensure quality images and effectiveness, and to minimize incidents and accidents. Many medical procedures in interventional radiology, interventional cardiology, cardiac electrophysiology, interventional neuroradiology, gastroenterology, musculoskeletal radiology, gynaecology, pulmonology, urology, oncologic surgery, orthopaedics and vascular surgery require the use of fluoroscopy X-ray machine and the procedures is associated with considerable radiation exposure to both workers and patients.

Regulation 28 of the Atomic Energy Regulations, 2012, requires authorised persons to establish quality assurance programmes that provide adequate assurance that the specified requirements relating to protection and safety are satisfied and quality control mechanisms and procedures for reviewing and assessing the overall effectiveness of protection and safety.

Specifically for medical exposure, Regulation 49 (3) of the Atomic Energy Regulations, 2012 lists the major requirements specific for quality assurance in medical exposure. This guide has therefore been prepared to supplement the Atomic Energy Regulations on the implementation of the requirements related to Quality Assurance programmes.

1.1 Authority

Section 73 of the Atomic Energy Act, Cap 154, empowers the Atomic Energy Council to issue guidelines for better carrying into effect the provisions of the Act.

1.2 Purpose

The purpose of this guide is to provide a structured framework for documenting a quality assurance programme for an interventional radiology practice. The guide also provides actions towards implementing the documented quality assurance programme for radiation safety.

1.3 Scope

This guide provides technical information and recommendations for the documentation of a quality assurance programme for medical practices using fluoroscopy X-ray machine.

1.4 Objectives of Quality Assurance in fluoroscopically guided medical practices

i. To produce images that meet the needs of the radiologist or other interpreters without involving unnecessary irradiation of the patient.

ii. To produce images of a consistent quality by reducing the variations in performance of the imaging equipment.

iii. To meet regulatory requirements for radiation safety.

iv. To ensure patient safety and risk management

v. To ensure continuous quality improvement

2.0 ELEMENTS OF THE QUALITY ASSURANCE PROGRAMME

The quality assurance programme for a medical practice using a fluoroscopy machine should comprise the following information.

2.1 Facility information.

Facility information should include the following details:

i. Name and Address: The full name of the facility, along with both physical and postal addresses.

ii. Radiation Sources Inventory: A comprehensive inventory of all radiation sources used within the facility, including their purposes and specific locations.

iii. A list of radiation workers at the facility, detailing each person's name, qualifications, experience, and contact information (telephone and email).

2.2 Designation of Responsibilities in the Department

The roles and responsibilities for each person directly involved in radiation protection and safety should be clearly documented. Such persons may include: Medical practitioners, radiologists, Medical Radiation Technologist (also referred to as Radiographer, X-ray Technologist). Medical physicists, Radiation Safety Officer, Radiation Safety Committee, qualified experts, Service Engineer and Ancillary Personnel like nurses, nursing assistants, technologists, and supplier representatives, among others.

2.3 Equipment purchases and acceptance procedure/criteria.

The facility is required to document its internal procedures and the criteria for purchasing or acquiring any radiation-generating equipment. Furthermore, state the equipment acceptance criteria, acceptance tests, and the commissioning tests to be performed.

2.4 Documenting a Quality Control programme

A Quality control programme is a part of quality assurance that deals with technics used in monitoring and maintaining the technical elements of the systems that affect the quality of the image. The QC programme should contain the different QC tests, the frequency, the procedure description and objectives, the responsible persons, the needed equipment, results analysis and interpretation, baselines and tolerances and corrective actions for the Fluoroscopy X-ray machines.

A QC programme includes the following types of performance testing;

i. Acceptance testing: This is the phase in which tests are performed to ensure that the imaging equipment functions as designed and intended and that it meet all applicable regulatory requirements or standards.

ii. Commissioning: This involves preparing the accepted systems for clinical use. Baselines for performance parameters are set at this stage. Commissioning testing results should be provided to Atomic Energy Council.

iii. Routine or constancy: These tests are routinely conducted throughout the lifetime of the equipment. They vary from simple tests which can be locally conducted to more complicated tests which need special skills and equipment to be performed.

iv. Post repair QC: After repair and before re-using the machine, performance tests have to be performed to confirm safe operation

v. Decommissioning: After useful lifespan, decommissioning should be conducted and a decommissioning report written.

2.5 Quality Control Tests

Periodic quality control tests as documented in the QA programme should be carried out. Quality control (QC) programme includes the following types of performance tests;

i. **Acceptance**: This stage involves the confirmation that equipment specifications and functionalities. Acceptance tests are performed by the installer's and facility representatives especially a medical physicist. This process may involve going through a checklist and any deviations identified are reported to the contractor for correction. The mechanical and electrical safety should also be assessed during acceptance testing.

ii. **Commissioning:** This involves verifying the equipment's readiness for patient care and sets initial benchmark for future routine performance evaluations. Commissioning is performed by a facility's representative, usually a clinical medical physicist with expertise in radiological physics. Following significant upgrades or repairs, such as replacing an X-ray tube or installing a new software, it may be necessary to conduct commissioning tests again to establish updated baseline values

iii. **Constancy or routine tests:** The routine tests are conducted by personnel of varying expertise. They range from simpler and quicker tests which can be conducted by facility personnel using simple equipment whereas more complex tests may require specialised skills and equipment

Measurements of the physical parameters of medical radiological equipment must be documented and conducted by or under the supervision of a clinically qualified medical physicist. Quality Control involves regular testing and must be carried out on each major component of the system to ensure consistent performance from purchase/start to decommissioning.

The format of reporting the QC tests is provided in Annex 1

2.5.1 Performance tests to be performed on Fluoroscopy X-ray machines

The performance tests to be performed on fluoroscopy X-ray machine may include reproducibility of Automatic Exposure Rate Control, X-ray beam alignment and centring, X-ray beam collimation, kVp Accuracy, mAs linearity, Radiation Output reproducibility, Radiation output, Half Value Layer (HVL), Low contrast visibility, High Contrast (spatial) resolution, Patient entrance surface air kerma rate among others

The tests on the film processing systems may include index of speed, index of contrast, Base plus fog, and film artefact identification among others. The tests on the cassettes may include film processing Film/screen contact, Screen condition, light leaks, artefact identification among others. The tests on the view boxes may include consistency of light output with time, Consistency of light output from one box to another, and viewing box surface conditions among others

The tolerance values for the above parameters should be in line with those set by the manufacturer and line with national standards and international standards from International Atomic Energy Agency (IAEA), International Commission on Radiation Units and Measurements (ICRU), American Association of Physicists in Medicine among others recognised by the Council.

2.5.2 Submission of quality Control tests to Atomic Energy Council

Results of periodic quality control tests should be submitted to AEC periodically.

2.5.3 Corrective Maintenance

If corrective maintenance is not performed by the facility staff, it is crucial to document the details of the service provider, including the company's name and contact information. Additionally, it should be indicated whether service reports are signed by the service engineer and securely filed. This documentation is vital for ensuring accountability and maintaining a high standard of quality assurance, as it helps to track the history and effectiveness of maintenance activities that impact equipment performance and safety.

2.6 Optimisation of image quality and radiation Dose

This section documents the measures in place to achieve clear visualisation of anatomical structures while balancing the associated radiation risks. It describes the strategies employed to ensure that high-quality images are produced while minimising the dose to the patient.

These measures may include the adjustment of technical parameters, the use of radiation protection tools embedded within the equipment system, use of image processing software, and utilisation of post-processing options and software algorithms. Additionally, the impact of physical and clinical factors that affect image quality is taken into consideration to enhance overall imaging outcomes while optimising the radiation dose to the patient.

2.7 Training Programme

A robust training programme is essential for ensuring the competence of personnel operating within a medical interventional radiology facility. The three categories of trainees to be considered include equipment operators (e.g., radiographers and medical imaging technologists), non-operator radiation workers (e.g., surgeons, nurses, anaesthetists, etc.), and non-radiation workers with access (e.g., cleaning staff, equipment maintenance and servicing personnel, building maintenance staff, etc.).

A comprehensive description of the training and retraining programme for each category of radiation workers should specify the topics to be covered. This ensures that all personnel are well-informed about the latest protocols and safety measures, thereby enhancing their competency and contributing to overall patient safety. The training programme should be specific to each category and aligned with clinical needs.

Additionally, a training gap analysis should be developed to indicate the current training gaps and the frequency of training sessions. Identifying any gaps in knowledge and providing regular training reinforces the commitment to quality assurance, ensuring that radiation workers remain knowledgeable and compliant with current standards.

Note: Copies of training certificates for each radiation worker should be maintained at the facility as part of the quality assurance documentation. This not only validates their training but also serves as a reference for ongoing professional development and compliance with regulatory requirements.

2.8 Individual monitoring programme.

Provide a detailed description of the individual monitoring devices used, monitoring period, service provider, dose results in relation to the regulatory dose limits, state the facility investigation levels, and procedures to be followed if such levels are exceeded, and availability of records of worker monitoring results from the service provider.

2.9 Workplace monitoring programme

Describe the Survey instruments used, the routine monitoring period, authorized dose levels, investigation levels, and procedures to be followed in the event such levels are exceeded.

2.10 Radiation Safety Culture

Radiation Safety culture refers to the shared values, beliefs, and behaviours within an organization that prioritize safety in all operational activities. It encapsulates how safety is perceived, valued, and acted upon by all members of an organization, from leadership to frontline staff. Highlight how safety culture is promoted at the facility and how it facilitates quality in terms of patient diagnosis and treatment. The key traits of a strong radiation safety culture include; Individual Responsibility, Questioning Attitude, Respectful Work Environment, Leadership Responsibility, Decision-Making, Effective Safety Communication, Continuous Learning, Problem Identification and Resolution and Environment for Raising Concerns

2.11 Records

The following records should be maintained

i. Inventory of the X-ray systems and personnel

ii. Results of acceptance testing and commissioning

iii. Results of the period calibration of the testing and measuring equipment

iv. Records of all monitoring results are kept. e.g., dose rates, maintenance firm, calibration dates, test certificates, etc. Calibration status and testing of detection equipment performed

v. Any action (quality control, corrective action, etc) should be reported and documented,

2.12 Review of the Quality Assurance Programme

Specify the period during which the Quality Assurance programme will be reviewed, along with any circumstances that may require its review before the scheduled time.

2.13 Authentication/Approval

The Quality Assurance programme document should be authenticated by the facility representative or their delegate.

ANNEX 1: FORMAT OF REPORTING QC TESTS

#	Physical Parameter	Date Conducted	Equipment used (Name, Model, Manufacturer, Serial number, Calibration Date)	Tolerance	Measured value	Comment
1	e.g kV accuracy at specific kV values					