ATOMIC ENERGY COUNCIL

GUIDANCE ON

DOCUMENTING QUALITY ASSURANCE PROGRAMS, RADIOLOGICAL EMERGENCY PLANS AND LOCAL RULES FOR DIAGNOSTIC RADIOLOGY FACILITIES

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1.0 INTRODUCTION

Radiation sources can pose a significant risk to public health and the environment if not managed properly. As a result, facilities that use radiation sources are required to have a comprehensive quality assurance program (QAP) an emergency preparedness and response plan (EPR) and local rules in place to ensure safe operation of their radiation sources.

As a licensing requirement, facilities with diagnostic radiology services must demonstrate that they have well established and maintained QAPs, EPRs and Local rules. This document aims to assist such facilities to establish robust programs, plans and rules that promote safety, compliance and continuous improvement.

1.1 Authority

Under section 74 of the Atomic Energy Act, Council may issue guidelines for operations involving ionizing radiation known as Radiation Safety Guides/Guidelines. This guide has been prepared to supplement the Atomic Energy Regulations on the implementation of the requirements for authorization to possess and use a radiation source.

1.2 Citation

This guide may be cited as Atomic Energy Council guidance on documenting quality assurance programs, radiological emergency plans and local rules for diagnostic radiology facilities.

1.3 Purpose

The purpose of this guide is to provide assistance for documenting quality assurance, radiological emergency plan and local rules for diagnostic radiology facilities.

1.4 Scope

This guideline presents technical information and recommendations related to the documentation and implementation of a quality assurance program, emergency plan and local rules in diagnostic medical facilities with an objective of maintaining quality but not compromising radiation safety.

2.0 GUIDANCE FOR DOCUMENTING A QUALITY ASSURANCE PROGRAM

Quality Assurance, as part of safety assessment, means planned and systematic activities that provide adequate confidence that diagnostic X-ray services offered by a facility are safe and effective and of high quality. The following are the key elements to document;

2.1 Facility information

Please provide the;

a) Name and address (both physical and postal) of the facility,
b) Radiation sources inventory, purpose and their locations.
c) Radiation workers inventory at the facility (Name, qualifications, experience & telephone contacts)

d) Details and appointment date of the radiation safety officer (RSO) (The appointment letter must be attached indicating the specific roles as per the Regulation 30 (1) & (4) of the Atomic Energy Regulations, 2012)
e) Facility layout and design of the installation or imaging room (Attach the lay out)

2.2 Designation of Responsibilities in the department

The roles and responsibilities for persons directly involved in radiation protection and safety should be clearly documented (indicate who is responsible for what).

Such persons may include; Medical practitioners, radiologists, radiographers, darkroom attendants, qualified experts, technicians, Radiation Safety Officer, Radiation Safety Committee, Service/maintenance engineers among others.

2.3 Equipment purchase and acceptance procedure/criteria

The facility is required to document internal procedures and the criteria for the purchase or acquisition of any radiation generating equipment. Furthermore, state the equipment acceptance criteria, acceptance tests and commissioning tests performed (attach the report)

Note: the purchase specifications must meet the national standards (Ministry of Health Standards on Diagnostic Imaging and Therapeutic Imaging in Uganda, 2012)

2.4 Quality control tests/program

Quality Control (QC) refers to the specific test required to ensure effective and safe equipment performance. QC tests check the performance of the equipment under routine clinical conditions, following established protocols for facilities, equipment and procedures.

The facility is therefore required to document a detailed quality control program for the key components of the X-ray system i.e. Performance parameters of the X-ray unit, film-processing, cassettes and grids, viewing boxes, and darkroom where applicable. The quality control program must specify the;

a) Different tests to be performed
b) Written step by step procedures for carrying out each test
c) Equipment used to perform the tests (Name, Model, S/N, Manufacturer);
d) Frequency of the tests;
e) Persons responsible for performing the tests and the role each will play;
f) Expected results;
g) Tolerance values in line with regulatory limits
h) Actions required when the tolerance levels are exceeded

Please note that the following quality control tests should be conducted and results maintained.

i. Performance parameters of X-ray units: kV accuracy and reproducibility, Collimation assessment where applicable, dose output assessments, Beam or laser alignment
ii. Film processing: An index of speed, an index of contrast, Base plus fog, Solution temperatures, film artefact identification.
iii. Cassettes: Film/screen contact, Screen condition, light leaks, artefact identification.

iv. Grids: Alignment and focal distance, Artefact identification
v. View boxes: Consistency of light output with time, Consistency of light output from one box to another, Viewing box surface conditions.
vi. Darkroom: Darkroom integrity, Safe light conditions

2.4.1 Quality control tests on a Computed Tomography machine

Quality Assurance begins with baseline performance data acquired during CT system installation including scanning a phantom under a prescribed set of conditions. These baseline images should be saved and used as a visual comparison with the daily and monthly QA checks. The baseline values will provide an objective way to monitor quality by repeating these tests or procedures on a regular frequency to detect changes in image quality values before the problem affects patient images.
Below are some of the regular quality control tests to be conducted on a Computed Tomography machine to enable early intervention and prevent unnecessary patient exposure to radiation.

i. Low Contrast Resolution
ii. High Contrast Spatial Resolution
iii. Noise
iv. Table Position Indicator Accuracy
v. Scan Increment Accuracy
vi. Computed Tomography Dose Index (CTDI) values,
vii. Spatial resolution
viii. Dose
ix. Beam width,
x. Dose length Product (DLP)
xi. Slice thickness
xii. Linearity among others

2.5 Film reject analysis

Clearly indicate the circumstances under which the developed film might be rejected. Furthermore, state the frequency of recording the rejected films as well as the number of rejects.

2.6 Records

Indicate the availability of a file for Atomic Energy Council (AEC) correspondences.
In addition, state the records maintained at the facility that are related to the radiology practice in line with regulation 34 of AER, 2012. Some of the records to be maintained include; Commissioning test results, Initial acceptance results, Calibration test results, dosimetry records among others.

2.7 Maintenance program

The maintenance program should entail both preventive and corrective monitoring aspects.

2.7.1 Preventive maintenance

The facility should;

i. state the possible maintenance areas,
ii. procedures and frequency for conducting them and the
iii. names of responsible persons for conducting these procedures.

2.7.2 Corrective maintenance

If this is not done by the facility staff, details of the service provider e.g. name of the company, contact details, etc. must be documented indicating whether details of service reports are signed by service engineer and kept on file

2.8 Training program

The facility should provide;

i. A description of the training and retraining program for each category of the radiation workers. State the topics to be covered.
ii. A brief on the training gap analysis and frequency of the training

Note: Copies of training certificates for each radiation worker should be maintained on file.

2.9 Individual monitoring program

The facility should provide a detailed description of the;

i. the individual monitoring devices used,
ii. monitoring period,
iii. service provider,
iv. authorized dose levels,
v. investigation levels and procedures to be followed in the event that such levels are exceeded.
vi. Availability of records of worker monitoring results from the service provider

2.10 Workplace monitoring program

Provide a description of the;

i. Survey instruments used,
ii. Routine monitoring period,
iii. authorized dose levels, investigation levels and procedures to be followed in the event such levels are exceeded.
iv. records of all monitoring results are kept. e.g. dose rates, maintenance firm, calibration dates, test certificates...etc
v. Calibration status and testing of detection equipment done per schedule.

2.11 Safety assessment

A safety assessment is an internationally recognized method of assessing safety and radiation protection related to use of radiation sources. It involves the systematic analysis of normal operation and its effects, of the ways in which failures might occur and of the consequences of such failures. Safety assessments cover the safety measures necessary to control the hazard, and the design and engineered safety features are assessed to demonstrate that they fulfil the safety functions required of them. Radiation dose rates in the surrounding locations of the imaging room should be taken and recorded.

A facility should document the control measures or operator actions required to maintain safety, an initial safety assessment has to be carried out to demonstrate that the arrangements made are robust and that they can be relied on.

2.12 Arrangements for female employees

Clearly indicate detailed procedures for a female employee who may become pregnant to;

i. informing her manager if she is pregnant,
ii. be made for the radiation protection of the fetus.

2.13 Promotion of safety culture

Safety culture represents the set of values, beliefs and behaviors shared by the actors of an organization to control the most important risks of their activity.
A description of how radiation safety culture is promoted in your organization should be documented. Some of the key features are;

i. Ownership and management commitment to making workplace safety a strategic imperative across the organisation
ii. Employee Engagement
iii. Environment of Continuous improvement

2.14 Periodic review of the quality assurance program.

The review can be done internally or by an external entity. Whatever the case, the facility should state;

i. who will review the effectiveness of the quality assurance program and
ii. the frequency of the review (annually or bi-annually).

3.0 GUIDANCE FOR DOCUMENTING AN EMERGENCY PLAN

An emergency plan provides authorized persons with the guidance and instruction to persons who will respond to and manage radiological incidents and accidents in case they occur. The emergency response plan should be prepared by the facility describing the;

a) Possible radiological emergencies and how to mitigate each
b) Persons or organizations or local authorities involved in the response at all stages (including their telephone contacts, mobile and fax numbers, email and postal addresses)
c) Details of the procedures to be followed at various incident phases (i.e initial identification/notification phase, the incident response phase, the recovery phase and the post-accident and follow-up phase)
d) Details of emergency medical support in life threatening situations, and their relevant contact name and telephone numbers e.g. response medical hospital where injured persons will be treated.
e) Available response personnel and the number of personal protective equipment to be used to respond to emergencies: Include a list of the type, availability and location of all emergency equipment.

f) Detailed procedures for communicating and cooperating with other relevant organizations/stakeholders including reporting the Atomic Energy Council within 24hours of occurrence of the incident.
g) Description of the arrangements for informing the public and those who will issue statements to the media concerning measures being taken to limit the consequences of the accident or incident where applicable.
h) Dosimetry requirements during emergency in order to determine the estimates of the doses received by all personnel affected or involved in the incident such as response persons and medical personnel.
i) Description of type and frequency of the training programs and drills/exercises for staff and organizations that will be involved in the response.
j) Arrangements for maintaining, reviewing and updating of emergency plans. Please state the procedures and incorporation of lessons learned from operating experience and emergency drills and exercises.

4.0 GUIDANCE FOR DOCUMENTING LOCAL RULES

Local rules of a facility provide detailed guidance on the use of radiation sources and the facility's radiation safety procedures.

Local rules vary from facility to facility since they depend on the radiological risk, category and nature of the practice. Below is a list of some rules to be documented;

a) Dosimetry Rules:
These rules should include wearing, reading, storage of Thermoluminiscent Dosimeters (TLDs), and dose Investigation levels e.g. In case the radiation dose exceeds the regulatory limit or above average.

b) Personal Protective Equipment & other equipment: These should indicate rules on wearing, maintenance and integrity testing as well as storage of personal protective equipment

c) Access control rules to radiation premises
Facility should clearly describe classification/designation of controlled and supervised areas, patient visitors and comforters, use of warning systems and symbols among others.

d) Rules for Reporting of incidents and accident rules;
This should include rules to stop unsafe operations and faulty equipment, reporting immediately to relevant authorities, and to AEC.

e) Rules for Protection of pregnant workers and patients. Access, timely reporting among others.

f) Rules for interns and unqualified personnel not to operate equipment: Such as darkroom attendants, students, unqualified persons to operate machines

g) Practice specific instructions during treatment/carrying out X-ray examinations; prescription of X-ray examinations, and reduction of dose to sensitive tissues, use of protocols among others.

h) Rules on Records keeping;

Indicate which kind of documentations are kept and their specific locations, and how long

i) Responsibilities;
Indicate duties of the RSO, administrators, operators of the facility.

5.0 CONCLUSION

All diagnostic radiology facilities irrespective of setting must have robust processes for quality assurance and quality control with written processes, procedures and local rules to be ardently followed. These should be during normal operations as well as during emergencies.

However, the effectiveness of the Quality Assurance programme and Quality control testing should be subject to independent scrutiny and audit.