PNRA-RG-904.07
(Rev.0)

October, 2019

RADIATION PROTECTION AND SAFETY IN RADIOTHERAPY

REGULATORY GUIDE

PAKISTAN NUCLEAR REGULATORY AUTHORITY

For Further Details

Directorate of Policies & Procedures
PAKISTAN NUCLEAR REGULATORY AUTHORITY
P.O. Box 1912, Islamabad
www.pnra.org

RADIATION PROTECTION AND SAFETY IN RADIOTHERAPY

ABSTRACT

Justification of application of ionizing radiation for the purpose of treatment of cancer is accepted worldwide. However, radiation detriments to patient, worker and the public also need to be considered as generally high activity & energy radiation sources (sealed radioactive sources and radiation generators) are used for the purpose of radiotherapy. Therefore, it is pertinent to address the radiation protection and safety requirements for radiotherapy facility right from planning or designing to decommissioning.

This Regulatory Guide describes radiation protection and safety requirements in radiotherapy.

TABLE OF CONTENTS

1. INTRODUCTION

Radiotherapy is a therapy technique, in which ionizing radiation are used for the treatment of malignancies or other diseases. There are two main types of radiotherapy. First is external beam radiotherapy (also known as teletherapy), in which radiation exposure is given to the cancer site by an external radiation source (i.e. linear accelerator, Co-60 machine) outside at a distance from the patient body. The second type is internal radiotherapy (also known as brachytherapy) in which small encapsulated radioactive sources are placed directly into or near the tumour to be treated. In radiotherapy, ionizing radiation are used during simulation, treatment, treatment verification and follow up. Since, generally high radiation dose is delivered to human body, purposely to obtain overall societal benefits and cure; therefore, safety and protection is of utmost importance in radiotherapy to avoid any incident, which could lead to an accident.

This Regulatory Guide (RG) is prepared to explain the radiation safety requirements pertaining to radiotherapy. This RG is primarily based on regulatory requirements established under Regulations on Radiation Protection - (PAK/904).

2. OBJECTIVE

The objective of this RG is to help licensees of radiotherapy facilities to implement applicable regulatory requirements for the protection of the patient, radiation workers, general public and the environment.

3. SCOPE

This RG covers the description of regulatory requirements from designing to decommissioning of a radiotherapy facility.

4. ORGANIZATION AND RESPONSIBILITIES

Radiotherapy is a multi-stage and complex process that involves treatment of cancer through utilization of various technologies. The licensee is responsible for radiation safety at the facility as well as effective patient treatment. Therefore, a multidisciplinary team of medical and health professionals is needed at a radiotherapy facility. The facility should have radiation oncologists, medical physicists, Radiation Protection Officers (RPO), radiotherapy technologists and other staff including nurses, maintenance personnel, etc. The radiotherapy staff should be appropriately educated, trained, qualified, and competent. Their qualification criteria and training program is mentioned in section I-A, I-B and I-C of Annexure I. Appropriate number of staff should be available for smooth operation of the facility. The recommended minimum number of staff required in a radiotherapy facility is also mentioned in section I-D of Annexure I.

The licensee should establish a Quality Assurance Program (QAP) to ensure that the requirements relating to protection and safety are satisfied and quality control mechanisms and procedures are in place to review and assess the overall effectiveness of protection and safety measures at the facility. The QAP should cover the organizational arrangements with clearly defined responsibilities, authorities and reporting/ communication lines of staff at various levels within the organization.

The licensee should formulate a Radiation Protection Committee (RPC) for effective oversight and advice on the matters related to radiation protection and regulatory requirements. The RPC is generally composed of head of the facility or his representative, head of the radiotherapy department or a radiation oncologist, RPO, a medical physicist, a biomedical engineer and a senior radiotherapy technologist. The responsibilities of radiation oncologist, medical physicist, radiotherapy technologist, RPO and RPC are mentioned in section II-A, II-B, II-C, II-D and II-E respectively of Annexure II.

The licensee should maintain record of qualification and experience of relevant professionals working in the facility and also submit copy of their Computerized National Identification Card (CNIC), qualification and experience documents to PNRA (when required). Any change in the staff should be intimated to PNRA.

5. FACILITY DESIGN AND EQUIPMENT

5.1 Facility Design

In radiotherapy facilities, patients are treated by using external beam radiotherapy and brachytherapy techniques. The activities associated with them include use of imaging equipment (simulators, CT scanners or both), immobilization equipment (mould room facilities) and treatment planning system. In designing a radiotherapy facility, the main consideration should be to limit the dose to workers and the public. In this regard, choice of shielding material and shielding design is of utmost importance.

The licensee should perform detailed shielding calculations and submit it to PNRA for approval. Appropriate staff and support spaces i.e. office space for physicians and physicists, laboratories, a registration area and a filing room should be clearly defined in the facility. Flexibility and adaptability should be anticipated within the design of the facility to accommodate evolution in technology.

A radiotherapy facility should comprise of examination room, simulator room, treatment planning room, mould room, treatment room and waiting areas. The simulator room, treatment planning room and treatment room should be designed in consultation with the equipment manufacturer or supplier, medical physicists or experts in the relevant field. Brief description of different rooms in a radiotherapy facility is as follows:

5.1.1 Examination Rooms

The examination rooms should be in close proximity to the treatment room and should be provided with appropriate examination couches, a head and neck examination chair, appropriate examination instruments and medical supplies.

5.1.2 Simulator Room

Simulator or imaging room should be large enough to accommodate the simulator, allowing the full range of motion of the treatment table as well as space for cabinets to store devices and quality control (QC) equipment. The door of the room should be wide enough so that patient couch could be entered smoothly. The room should include the means for securely mounting the patient positioning lasers on the wall at points appropriate for projection of lines through the isocentre. A lead glass viewing window should also be provided for the control room of the simulator.

5.1.3 Treatment Planning Room

Treatment planning room should be located preferably in close proximity to the simulator room. The room should be large enough to house the treatment planning computer with its video monitor, a printer and plotter, a digitizer tablet and other required computer equipment. Space for light boxes and a high intensity light for viewing CT scans and X- ray films should also be provided in the room.

5.1.4 Mould Room

A mould room for the fabrication of custom designed blocks and compensators should be in place at the facility. It should be provided with the appropriate space for tools, storage space for supplies of styrofoam, trays and shielding material for custom blocking. Adequate ventilation should be provided if shielding materials are melted in this area. Space for a patient couch should also exist, if immobilization devices are fabricated in the mould room.

5.1.5 Treatment Room

Treatment room should be properly shielded to limit the exposure of the workers as well as the public by giving due consideration to the shielding parameters i.e. occupancy factor, use factor, workload, dose limits, etc. It should be large enough to accommodate the treatment machine, allowing the full range of motion of the treatment table as well as machine gantry. Adequate space should be planned for cabinets to store treatment devices, immobilization devices, blocks and daily used QC equipment, etc. Space for a control console should be large enough to accommodate workspace for the technologist. Besides,

provision should also be made for the following:

i. Warning lights at the entrance of the door;
ii. Patient positioning lasers;
iii. Door interlock or other suitable means to prevent unauthorized access;
iv. System for dimming the room lights;
v. Fixed area monitors;
vi. Motorized entrance door (if applicable);
vii. Intercom and Closed Circuit Television (CCTV) System; and
viii. Ducts for power & air-conditioning.

5.1.6 Waiting Area

In order to avoid public exposure, the general waiting area should be away from controlled area. There should be adequate sitting arrangement for the patients according to the patient load of the facility. However, sub-waiting rooms should be provided in all the functional areas, i.e. in the clinical consultation area, in the imaging and treatment planning and treatment rooms. Space should also be provided for patients on stretchers.

5.1.7 Source Storage Room

A source storage room should be provided with a locked door to control unauthorized access to the radioactive material. Space for source transportation trolleys should be provided. Provision should be made for proper ventilation, lighting, fire detection system, etc.

5.2 Equipment

In order to deliver the planned exposure accurately and minimize the chances of any unintended exposure, the design of equipment should be such that its performance is always reproducible, accurate and predictable. It should have features that meet the requirements of optimization of patient protection.

Procedures for the purchase, installation, acceptance, commissioning, use, maintenance and quality control of all equipment (hardware and software) should be developed with the involvement of a medical physicist, together with other professionals (e.g. radiation oncologist, technologist, biomedical engineer and IT specialist) and radiation protection committee. The equipment needed to perform radiation therapy, falls into five main categories:

i. Simulation and imaging;
ii. Treatment planning;
iii. Treatment delivery;

iv. Quality Control; and
v. Radiation safety.

5.2.1 Simulator

All performance specifications and tests should conform to the standards of the International Electrotechnical Commission (IEC) for radiotherapy simulators. Simulator should simulate all the set-ups possible on the treatment machines. In radiotherapy, conventional or Computerized Tomography (CT) simulator should be used to enable the correct positioning of the Planning Target Volume (PTV) in radiation beam and to shield the rest of the area.

5.2.2 Treatment Planning Equipment

Treatment planning equipment should meet the needs as determined by the clinical goals of the radiotherapy department. A personal computer including software should be used to calculate treatment times and patients in vivo dose measurements.

5.2.3 Equipment for Treatment Delivery

Following points should be considered at the time of selection of equipment:

i. The manufacturer is of reputed brand and it has a proven record of satisfactory manufacturing of medical equipment and providing "after sale service";
ii. The documents and manuals are normally available in English. If there is need to translate documents and manuals, then it should be done by a professional translator;
iii. The manufacturer is complying with applicable international standards of International Organization for Standardization (ISO) and International Electrotechnical Commission (IEC). Some of the applicable standards for radiotherapy equipment are:
    a. IEC-60601-2-1: Particular requirements for the basic safety and essential performance of electron accelerators in the range 1 MeV to 50 MeV;
    b. IEC-60601-2-11: Particular requirements for the basic safety and essential performance of gamma beam therapy equipment;
    c. IEC-60601-2-17: Particular requirements for the basic safety and essential performance of automatically-controlled brachytherapy afterloading equipment;
    d. IEC-601-2-8: Particular requirements for basic safety and essential performance of therapeutic X-ray equipment operating in the range 10 kV to 1 MV;

e. IEC-60601-2-29: Particular requirements for the basic safety and essential performance of radiotherapy simulators;
f. IEC-62083: Requirements for the safety of radiotherapy treatment planning systems; and
g. IEC-60601-1-4: General Requirements for Safety - Collateral Standard: Programmable Electrical Medical Systems; etc.

iv. A permanent radiation warning sign is posted at the equipment;
v. Provision is made for the interruption of radiation beam from the control panel and inside the bunker. The resumption of radiation should only be available at control panel;
vi. Equipment having radioactive source like Co-60 teletherapy machine, should be provided with a device to push the source manually to shielding in the event of source stuck. For gamma knife, provision should be available for manual closure of shielding door;
vii. The equipment is provided with:
a. Radiation beam control mechanisms, including devices that indicate clearly and in a fail-safe manner whether the beam is 'On' or 'Off';
b. As nearly as practicable, the provision that exposure is limited to the target area using collimators or shielding blocks within beam;
c. QC procedures having tolerance within the limits of International Atomic Energy Agency (IAEA) or American Association of Physicists in Medicine (AAPM) Standards, etc.;
d. Display of operating parameters including time, dose, collimator size, gantry angle, etc. on the control panel; and
e. Provision of “Fail Safe” mode which requires that radioactive sources should come into shielding in case of power failure or any other problem.

viii. High energy Linear Accelerator (LINAC) should have:
a. At least two independent fail to safety systems to stop radiation; and
b. Safety interlock or other means to start the radiation only from control panel; and the safety interlocks may be bypassed only by authorized medical physicists having a code or key to bypass the interlock.

ix. Applicators for brachytherapy should be manufactured specifically for the source to be used or should be compatible with it. Use of Low Dose Rate (LDR) radioactive sources after their working lifetime recommended by the manufacturer, should be continued only after leak testing by the medical physicist or RPO; and
x. Beta-emitting sources, such as Sr-90 and Ru-106 in ophthalmic applicators, should be provided with low atomic number shielding material to minimize bremsstrahlung radiation, while they are in storage and in preparation for use.

5.2.4 Equipment for Quality Control

The radiotherapy facility should have equipment, instruments and test objects appropriate for the type of measurement necessary for beam characterization and quality control. This may include ionization chambers, solid-state detectors, detectors for small field dosimetry, electrometers, thermometers, barometers, phantoms, geometry and mechanical test tools.

5.2.5 Equipment for Radiation Safety and Source Handling

This instrumentation should include an area radiation monitor that is safe against a power failure inside the Co-60 treatment room, brachytherapy room, a Geiger-Muller (GM) survey meter and a large volume ionization chamber. For accelerators with energies of 10 MV and above, a neutron measuring instrument should also be available.

For remote afterloading brachytherapy, the facility should be equipped for source handling in case of failure of the after-loader in retracting the source, a remote manipulator, wire cutters and a suitable radiation monitoring instrument for source localization. A storage container should also be available in the treatment room to serve as an emergency source container.

5.3 Shielding and Safety Interlocks

The shielding assumptions and specifications should be documented, and signed by the medical physicist. All documentations including calculations should be archived for the lifetime of the facility. The shielding of the radiation treatment room should be constructed so that its integrity is not compromised by joints, openings for ducts, pipes or other objects passing through the barriers, or by conduits, service boxes, or other structural elements embedded in the barriers.

The door to the treatment room and the design of the maze for high energy machines requires special consideration to ensure adequate radiation protection without sacrificing operational efficiency.

In addition to the shielding, there are safety interlocks and procedures that need to be considered:

i. The door to the treatment room should have a fail-safe interlock to switch off the radiation beam (i.e. return the source to the shielded position), if the door is opened during a treatment. Restarting irradiation should require both closing of the door and activation of a switch at the control console;

ii. The door to the room should have a sign which indicates that the room contains radiation generators or radioactive sources;
iii. There should be a visible light at the door to the room that shows, if the source is ON. Typically, this will be red when the source is ON and green when it is OFF;
iv. There should be a battery operated detector of scattered radiation inside the room that shows when the source is ON;
v. There should be emergency buttons located inside the room to shut off the radiation, and these should be reachable without passing through the radiation beam; and
vi. There should be audio-video intercommunication with the patient.

6. OCCUPATIONAL EXPOSURE

The licensee should make every possible effort to limit the occupational exposure of the workers through proper arrangements. Any individual under the age of eighteen (18) years should not be allowed to work as a radiation worker. However, individual under the age of eighteen (18) but greater than sixteen (16) years may be allowed to work in a controlled area under the supervision of qualified worker for the purpose of training.

6.1 Responsibilities of Workers

The licensee should ensure that workers are informed of, all of their responsibilities for their protection against radiation, which include:

i. Follow local rules and procedures for protection and safety prepared or adopted by the licensee;
ii. Use properly monitoring devices and protective gadgets;
iii. Co-operate with the licensee with respect to radiation safety and the operation of radiological health surveillance and dose assessment programs;
iv. Provide to the licensee such information on their past and current work as is relevant to ensure effective and comprehensive protection and safety for themselves and others;
v. Abstain from any willful and deliberate action that could put themselves or others in situations that contravene the PNRA Regulations and directives;
vi. Accept such information, instruction and training concerning safety as will enable them to conduct their work in accordance with the PNRA Regulations and directives; and
vii. Provide feedback to the licensee on radiation protection matters.

6.2 Dose Limits and Dose Constraints

Radiotherapy facilities are designed in such a way that occupational exposure

remains within the limits in all normal working conditions i.e. during treatment, dosimetry, repair maintenance, etc. However, the licensee is required to establish dose constraints (which are the fraction of dose limits) to further reduce the radiation exposure to workers. The licensee should also consider that workers may be engaged in more than one facility; therefore, dose constraints should be established accordingly.

6.3 Investigation Levels

Investigation levels are different from dose constraints and dose limits. They are used to provide a warning of the need to review procedures and performance, to investigate what is not working as expected and to take timely corrective action. The licensee should establish investigation levels for occupational exposure. These investigation levels trigger investigation process because it indicates unusual or abnormal operation. Following levels may be used in the establishment of investigation levels:

i. 0.4 mSv/month for LINAC or remote control brachytherapy; and
ii. 0.5 mSv/month for Co-60 teletherapy machine or manual brachytherapy.

6.4 Pregnant Workers

The licensee should convey clear instructions to the female workers at the time of joining of facility that are adequate for radiation protection of fetus or embryo. Pregnant workers should notify the licensee about their pregnancy, as soon as they get aware of their condition. The licensee should not consider this notification of pregnancy as a reason to exclude a female worker from work and should assess the likely dose to the fetus of a pregnant employee from each activity.

This usually requires an examination of an employee's personal monitoring records and assessment of likelihood of incident leading to exposure of the fetus. If the fetus could receive more than 1 mSv over the declare term of pregnancy, a change in work practice or job description should be discussed and agreed with the employee. The most appropriate action is to reallocate the duties of the pregnant employee to areas with low risk of radiation exposure.

The pregnant workers should be especially cautious while working with Co-60 or brachytherapy machine and should not be engaged in intervention during radiation emergency conditions.

6.5 Classification of Areas

The licensee is required to classify the areas of the facility into controlled area and supervised area on the basis of dose limits as specified in Regulations on Radiation Protection - (PAK/904). All other rooms and areas that are not so designated are

considered as being in the public domain and levels of radiation in these areas should be low enough to ensure compliance with the dose limits for public exposure.

In a radiotherapy facility, following areas may be classified as controlled areas:

i. X-ray or CT Simulator room;
ii. Source storage room;
iii. Teletherapy room and their operating console;
iv. Operating room dealing with brachytherapy sources; and
v. Brachytherapy patient's room.

Following areas may be designated as supervised areas:

i. Patient waiting area;
ii. Treatment planning room;
iii. Mould room;
iv. Corridors; and
v. All other rooms or areas adjacent to therapy, simulator and source storage room.

It is essential to clearly mark controlled and supervised areas in the radiotherapy facility and access should be controlled in these areas by appropriate administrative measures.

6.6 Individual Monitoring and Exposure Assessment

The licensee should ensure proper arrangements for individual dose monitoring of the workers (i.e. technologist, radiation protection officer, medical physicists, radiation oncologist, source handlers, maintenance staff and any nursing or other staff who spend time with patients with implanted radioactive sources, etc.) working in the controlled area of the facility. Workers should be provided with the dosimeters (i.e. TLD or film badge) and arrangements should be made for information and access to their dose records.

The time span for monitoring (period of dosimeter deployment) may be from one to three months. Where the exposure is from behind fixed structural shielding (such as for LINAC or remote controlled bachytherapy) monitoring period such as three months is generally satisfactory. However, in case of unusual exposure situations with potential for reportable dose occur; the personal monitors should be processed for dose assessment immediately.

Personal monitoring should be considered for workers in supervised area as well. However, workplace monitoring may serve as an alternative of individual dose monitoring for the assessment of occupational exposure of the worker.

6.7 Workplace Monitoring

Workplace monitoring needs to be carried out according to the nature of potential hazards of the source. The licensee should conduct periodic survey of controlled and supervised areas during operation by using calibrated survey meters for evaluation of radiological conditions. It is essential to provide fixed calibrated area monitors in teletherapy (Co-60) and brachytherapy bunkers. Neutron monitoring should be carried in case of high energy LINAC (i.e. greater than 10 MV). Furthermore, workplace monitoring should also be carried at the time of:

i. Acceptance/commissioning of new source (i.e. radioactive source or radiation generator);
ii. Replacement of radioactive source and repair of radiation equipment;
iii. Discharge of patients after brachytherapy procedures;
iv. Removal from or return of sources to the storage room; and
v. Receipt and departure of transport packages.

6.8 Local Rules and Procedures

The licensee should make available to workers local rules and procedures so that they could perform their duties accordingly. A list of activities for which local rules and procedures should be prepared by the licensee is given below:

i. Acceptance Testing;
ii. Commissioning;
iii. Maintenance;
iv. Area survey;
v. Interlock checks;
vi. Response to emergency;
vii. Use of detection equipment;
viii. Investigation of high exposure and error identification;
ix. Leak test;
x. Access control to radiation areas;
xi. QC (including calibration and dosimetry);
xii. Health surveillance; and
xiii. Personal monitoring.

6.9 Investigation and Follow-up

The licensee should have a formal system in place for investigation and follow up in case of following:

i. A worker exceeds dose constraint or investigation level established by the licensee;
ii. A worker is having abnormal (high or low) effective dose comparing with his co-workers; and
iii. Equipment is showing repeated problems and errors e.g. a source fails to return to shielding in Co-60 teletherapy or brachytherapy machine.

The licensee should notify about an incident involving radiotherapy accidental exposure to PNRA as a matter of priority.

6.10 Health Surveillance

Following points should be considered while establishing health surveillance program:

i. The primary purpose of health surveillance is to assess the initial and continuing fitness of workers for their job responsibilities and it is based on general principles of occupational health; and
ii. General health surveillance of radiation workers may be conducted preferably on annual basis. If working conditions are such that doses are expected to be high, in addition to general medical tests, additional specific medical tests need to be conducted as specified in Regulations on Radiation Protection - (PAK/904).

7. MEDICAL EXPOSURE

The licensee should take necessary measures to ensure radiation protection of patients, carers and comforters, and volunteers in biomedical research.

7.1 Responsibilities of Licensee

The licensee should consider following responsibilities with respect to treatment of patients at radiotherapy facility:

i. Therapeutic medical exposure should not be administered unless the exposure is prescribed by radiation oncologist. The medical physicist and radiotherapy technologist should ensure that prescription of radiation oncologist is available at the time of treatment;
ii. Radiation oncologist is assigned the primary task and obligation of ensuring overall patient protection and safety in the prescription of, and during the delivery of, medical exposure;
iii. Sufficient personnel like medical physicist, radiotherapy technician, biomedical engineer and nursing staff are available for the routine activities;

iv. Qualified radiotherapy medical physicists are available for the calibration, dosimetry, implementation of quality assurance, radiation protection and relevant standards & protocols; and
v. All workers (i.e. medical physicist, radiotherapy technician, radiotherapist, and biomedical engineer) are trained on specific type of technique and machine like Intensity-Modulated Radiation Therapy (IMRT), Image-Guided Radiation Therapy (IGRT), Gamma knife, Cyber knife, etc.

7.2 Justification

Justification of medical exposure to cancer patients is largely accepted worldwide due to its proven advantages. Following points should be considered while recommending a radiotherapy procedure:

i. The efficacy, benefits and risks of alternative treatment modalities, e.g. surgery and chemotherapy, either alone or in combination with radiation therapy needs to be considered; and
ii. Treatment of pregnant females with due care. If possible, the treatment may be avoided to the end of pregnancy.

The exposure of humans for biomedical research is deemed to be not justified unless it is approved by the ethics committee (national or provincial level) and PNRA.

7.3 Optimization

In medical exposure, optimization depends upon several factors; some are applicable directly to the radiological procedure to be performed and other factors provide the support.

In order to ensure optimization during radiological procedures, the licensee should:

i. Ensure that the prescribed absorbed dose is delivered to the Planning Target Volume (PTV) or organ;
ii. Ensure that exposure of normal tissue during radiotherapy is kept as low as reasonably achievable consistent with delivering the required dose to the PTV and organ shielding is used when feasible and appropriate;
iii. Avoid the procedures causing exposure of the abdomen or pelvis of women who are pregnant or likely to be pregnant unless, there are strong clinical indications; and
iv. Plan any therapeutic procedure for pregnant women so as to deliver the minimum radiation dose to any embryo or fetus.

In addition to above recommendations, a number of other factors also play role in optimization. Most of these include calibration of equipment, clinical dosimetry and quality control, which are described below in detail.

7.3.1 Calibration

As per requirements for calibration, the licensee should ensure that:

i. The calibration of sources used for exposure is traceable to a Secondary Standard Dosimetry Laboratory (SSDL);
ii. Each type of radiotherapy equipment (i.e. brachytherapy, teletherapy etc.) is calibrated in terms of the relevant dosimetric quantities and irradiation conditions;
iii. Calibration of radiotherapy equipment is carried out at the time of commissioning, after any maintenance procedure that may affect the calibration and at regular intervals not more than twelve (12) months; and
iv. Representative values of clinical dosimetry parameters are determined and documented.

Along with above mentioned general requirements, the licensee should also ensure that:

i. Sealed sources for radiotherapy purpose is accompanied by source calibration certificate from manufacturer;
ii. All types of equipment and sources have been calibrated and checked by medical physicist before the treatment of the patient;
iii. Protocols for the calibration of sources and equipment (in accordance with manufacturers' recommendations and international standards) are in place and implemented; and
iv. Arrangements of internal audit or cross check of calibration are in place.

New brachytherapy source is calibrated and variation in the measurement of more than five percent (5%) from the manufacturer's certified activity or kerma rate is investigated. The sources should not be used for patient treatment until differences have been investigated and resolved.

7.3.2 Clinical Dosimetry

Clinical dosimetry is an important part of Quality Assurance (QA) and licensee should ensure that following factors are determined and documented:

i. For teletherapy patients:

a. The maximum and minimum absorbed doses to the PTV;
b. The absorbed dose to a relevant point such as the centre of the PTV; and
c. The dose to other relevant points selected by the radiation oncologist.

ii. For brachytherapy treatments, the absorbed doses at selected relevant points in the patient.

7.3.3 Quality Control during Radiotherapy

Quality Control (QC) of radiotherapy equipment is essential to ensure safe and accurate delivery of treatment. After successful installation, acceptance and commissioning of radiotherapy equipment, QC testing of the equipment should be carried out on an ongoing basis for continued reliable performance. Equipment with unsatisfactory safety and quality features should not be operated.

There are several international documents which address the QC procedures of radiotherapy equipment. The licensee should prepare QC procedures in accordance with the recommendations of equipment manufacturers and guidelines of international organizations/ professional bodies like International Atomic Energy Agency (IAEA), American Association of Physicists in Medicine (AAPM) and International Organization for Medical Physics (IOMP), etc.

A medical physicist should perform QC tests of the equipment at a defined frequency to look for any changes that may cause unsafe and ineffective treatment. The licensee should maintain records of all performed QC tests and ensure availability of records at the time of regulatory inspections.

Details of practice wise QC tests for teletherapy and brachytherapy equipment are mentioned in Annexure III.

7.3.4 Release of Patients after Therapeutic Procedure

The license is responsible to ensure that no patient who has undergone a brachytherapy procedure with a radioactive source is discharged from the medical radiation facility unless the activity of radioactive source in the body falls below the activity level as specified in Annexure IV. Any change from these levels should be properly justified and documented. The licensee should also ensure that patient or the guardian of the patient is provided with appropriate written instructions regarding radiation risks and radiation protection measures to reduce doses to other persons.

7.4 Investigation of Unintended or Accidental Medical Exposure

An unintended or accidental medical exposure could be resulted from the following

circumstances:

i. Loss of control on source in brachytherapy, source stuck in teletherapy etc.;
ii. Functional problems in LINAC, simulator, etc.;
iii. Incorrect QC of radiotherapy equipment;
iv. Errors in treatment planning;
v. Incorrect identification of patient or target organ; and
vi. Error in dose fractionation or calculation.

The licensee should have formal system and plans in place for following steps:

i. Investigation regarding repeated equipment failure, accident, error, mishap or other unusual occurrence with the potential for causing a patient exposure significantly different from that intended;
ii. Calculation or estimation of the doses received and their distribution within the patient body in case of accident;
iii. Identification of the corrective measures required to prevent recurrence of such an incident;
iv. Notify PNRA, by quick means like telephone or facsimile on priority, but not later than twenty four (24) hours after discovery, of any incident which has the potential for, or has resulted in, serious injury or death of a patient, or which involves more than one patient;
v. Submission of report to PNRA as soon as possible but not later than thirty (30) days after the incident, which should state the cause of the incident, information on the doses, patient's information, possible consequences of radiation doses, deficiencies in practices, corrective measures and any other relevant information; and
vi. Inform the patient and his referring physician about the incident, its possible consequences on patient's health and further course of action.

8. PUBLIC EXPOSURE

Public exposure in a radiotherapy facility should be constrained by proper shielding design of the facility, shielding of sources and access control.

8.1 Responsibilities of Licensee

The licensee should inform PNRA in case of any modification in radiotherapy equipment or shielding and should not operate the equipment unless verify that dose is within regulatory limits. The licensee should ensure the following:

i. Develop and implement procedures for storage, use and transportation of sources in order to keep the public dose minimum. This should include the provision of access control of public to the supervised and controlled areas;
ii. Perform continuous surveillance of the implementation of procedures; and
iii. Ensure that members of public should be accompanied by a worker, if their visit to controlled areas is essential.

8.2 Radiation Survey

In a radiotherapy facility, members of public are usually present in the vicinity of radiotherapy equipment. Therefore, the RPO of the facility should ensure that radiation doses in all clinics, Out Patient Department (OPD), waiting areas, stores, offices, corridors, etc. are in accordance with the regulatory limits for public (i.e.1 mSv/year). The area survey of radiotherapy facility should be performed at regular intervals and in particular, after the installation of a new radioactive source or radiation generator.

9. EMERGENCY PREPAREDNESS AND PLANNING

Radiotherapy facilities have high energy radiation generators, high activity radioactive sources and a complex system of treatment planning and delivery, a number of accidents associated with radiotherapy facilities have been reported so far, right from the developing countries to developed countries.

The licensee should ensure that following arrangements are in place for accident prevention and emergency preparedness and planning as per Regulations on Management of a Nuclear or Radiological Emergency - (PAK/914).

9.1 Accident Prevention

Accident prevention should be the top priority of the licensee. The licensee should:

i. Ensure that system of defense in depth (i.e. multi layer) to cope with identified events and evaluation of the reliability of the safety systems (like emergency stop, treatment planning verification, proper QA, etc.) is established. It should include administrative and operational procedures, equipment and facility design;
ii. Incorporate in plans and procedures, operational experience and lessons learned from:
    a. Accidents reported worldwide and available in IAEA reports and website; and
    b. Identification of errors in maintenance and QA programs.
iii. Establish reporting mechanism in case of accidents.

9.2 Mitigation and Planning

Radiation accidents are probable during operation and repair & maintenance of radiotherapy equipment. The licensee should foresee potential accidents in radiotherapy and get himself prepared for such conditions. In general, following types of accidents are most probable or reported:

i. Source stuck;
ii. Error in treatment planning, dose calculations and delivery;
iii. Error in calibration and dosimetry;
iv. Error in patient identification;
v. Contamination and leakage of source;
vi. Transport accident(s);
vii. Fire, flood, earth quake, etc.; and
viii. Security related accident(s).

The licensee should consider all above scenarios (including all others as well learned from experience feedback) and prepare emergency plan as per guidelines of PNRA. The plan should be submitted to PNRA, periodically revised at least once in five years or whenever necessary in the light of lessons learned and verified through exercises and drills.

10. TRANSPORTATION

The licensee should ensure that following arrangements for the transportation (i.e. handling, loading, carriage, storage, unloading and receipt) of radioactive material are in place:

i. Handling equipment for the transport of package containing radioactive material e.g. cranes, forklift, vehicles, etc.;
ii. Availability of calibrated radiation monitoring equipment;
iii. Measurements of dose rate around the transport package;
iv. Checking of correct transport labels on the package;
v. Availability of trained and sufficient staff;
vi. Availability of radiation protection and quality assurance programs ; and
vii. Valid design approval certificate of transport package (if applicable).

11. SECURITY OF RADIOACTIVE SOURCES

The licensee using radioactive sources for radiotherapy should submit physical protection plan to PNRA as per Regulations on Security of Radioactive Sources - (PAK/926).

12. DECOMMISSIONING OF RADIOTHERAPY FACILITIES

The licensee using radioactive sources for radiotherapy should submit decommissioning plan to PNRA as per Regulations on Decommissioning of Facilities using Radioactive Material - (PAK/930) and perform decommissioning accordingly.

13. RECORDS

The licensee should establish a system of maintaining and retaining of records. List of records to be maintained along with minimum retention time is given in Annexure V.

14. REFERENCES

1. Regulations on Radiation Protection - (PAK/904) Pakistan Nuclear Regulatory Authority (PNRA), Islamabad, 2004.
2. Regulations for the Safe Transport of Radioactive Material - (PAK/916) Pakistan Nuclear Regulatory Authority (PNRA), Islamabad, 2019.
3. Radiation Protection and Safety in Medical Uses of Ionizing Radiation, Specific Safety Guide (SSG) No. 46, International Atomic Energy Agency (IAEA), Vienna, 2018.
4. Safety in Radiotherapy, Guide ST 2.1, Radiation and Nuclear Safety Authority (STUK), Finland, 2003.
5. Safety Guide on Radiation Protection in Radiotherapy, Radiation Protection Series No. 14.3. Australian Radiation Protection and Nuclear Safety Agency (ARPANSA), 2008.
6. Setting up a Radiotherapy Program: Clinical Medical Physics Radiation protection and Safety Aspects, International Atomic Energy Agency (IAEA), Vienna, 2008.
7. Regulations on Management of a Nuclear or Radiological Emergency - (PAK/914) Pakistan Nuclear Regulatory Authority (PNRA), Islamabad, 2008.
8. Preparation of Radiation Emergency Plan for Radiation Facilities and Activities (PNRA-RG-914.02), Pakistan Nuclear Regulatory Authority (PNRA), Islamabad, 2016.
9. Radiation Safety Officer Qualification for Medical Facilities, Task Group 160 Report. American Association of Physicists in Medicine (AAPM), 2010.
10. Comprehensive QA for Radiation Oncology, Task Group 40 Report, American Association of Physicists in Medicine (AAPM), 1994.
11. AAPM, Quality Assurance of Medical Accelerators, Task Group 142 Report, American Association of Physicists in Medicine (AAPM), 2009.
12. AAPM, Quality Assurance for Robotic Surgery, Task Group 135 Report, American Association of Physicists in Medicine (AAPM), 2011.
13. Quality Assurance for Gamma Knives, NUREG/CR-6324, U.S. Nuclear Regulatory Commission (USNRC), 1995.
14. Radiation Protection in Design of Radiotherapy Facilities, Safety Report Series No. 47, International Atomic Energy Agency (IAEA), Vienna, 2006.
15. Medical Use of Byproduct Material 10 CFR Part-35, U.S. Nuclear Regulatory Commission (USNRC), 2019.

ANNEXURE I

Qualification and Training of Staff at Radiotherapy Facility

I-A. Qualification of Workers

As per Regulations on Radiation Protection - (PAK/904)

I-B. Qualification of Radiation Protection Officer

As per Regulations on Radiation Protection - (PAK/904)

I-C. Training of Workers

The licensee should ensure that:

i. Training program is in place for each type of worker keeping in view their job responsibility;
ii. Radiation protection training is in place with proper contents and duration;
iii. The training program include initial training, re-training and evaluation procedures; and
iv. Exercises are conducted as a part of training.

The general contents of radiation protection training are given below:

i. Radiation physics and instrumentation;
ii. Radiation protection;
iii. Mathematics pertaining to the use and measurement of radioactivity;
iv. Radiation biology;
v. Radiation dosimetry;
vi. Shipping and receiving of transport packages and performing radiation surveys;
vii. Performing checks for proper operation of survey meters and instruments used to determine the activity of radionuclides;
viii. Prevention of mistakes in the administration of brachytherapy radioactive sources;
ix. Control and handling of radioactive contamination;
x. Emergency preparedness and planning; and
xi. Disposal of radioactive material.

I-D. Staff at Radiotherapy Facility

The recommended minimum number of radiotherapy staff is given below[2]:

S. No.	Designation	Work Force Requirement
1	Radiation Oncologist	I. One for 250 patients treated annually. ii. No more than 30 patients under treatment by a single physician at any one time.
2	Medical Physicist	I. One for 400 patients treated annually. ii. 1-2 additional medical physicists should be available where specialized treatment techniques like Intensity Modulated Radiotherapy, Stereotactic Radiotherapy are used. iii. 1-2 additional medical physicists should be available where brachytherapy and radionuclide therapy are used.
3	Radiotherapy Technologist	i. Two per each therapy machine at the time of treatment. ii. Two per each simulation machine at the time of treatment.
4	Biomedical, Service, Maintenance Engineer or Technician	Optional but preferable.

[2]Mainly taken from Safety in Radiotherapy", Guide ST 2.1, Radiation and Nuclear Safety Authority (STUK), Finland, 2003.

ANNEXURE II

Responsibilities of Workers

II-A. Radiation Oncologist

The responsibilities of the radiation oncologist may include:

i. Ensure overall radiation protection of the patients;
ii. Prescribe and justify diagnosis and therapy in writing, taking into account relevant information from previous examinations;
iii. Ensure that the exposure of patients is the minimum required to achieve the intended objective;
iv. Provide consultation and clinical evaluation of patients;
v. Establish optimized protocols for therapeutic procedures, in consultation with the medical physicist;
vi. Evaluate any radiation incident or accident from a medical point of view; and
vii. Provide criteria to manage the examination of the pregnant women, pediatric patients, medico-legal procedures, occupational health examinations and medical and biomedical research.

II-B. Medical Physicist

The responsibilities of the medical physicist may include:

i. Design, implement and supervise QA procedures including calibration, dosimetry and all types of QC of the equipment;
ii. Perform treatment planning, dose calculations, etc.;
iii. Participate in the review of the radiotherapy resources (including budget, equipment and staffing), operations, policies and procedures;
iv. Plan in conjunction with the Radiation Oncologist and RPO, the facilities for radiotherapy practices;
v. Prepare performance specifications for equipment with regard to radiation protection;
vi. Carry out acceptance testing and commissioning of equipment;
vii. Supervise equipment maintenance;
viii. Participate in the investigation and evaluation of incidents and accidents; and
ix. Contribute to the radiation protection training program.

II-C. Radiotherapy Technologist

The responsibilities of the radiotherapy technologist may include:

i. Ensure that patients are identified correctly and that the appropriate

information is obtained from patients and correctly recorded;

ii. Provide information to patients about the procedures that they will be undertaking;
iii. Provide necessary information to persons accompanying patients and to staff attending patients;
iv. Ensure that nursing mothers are given information about discontinuation of breast feeding, if required;
v. Verify the patient identification and machine parameters to be used;
vi. Perform regular quality control of the radiotherapy equipment (i.e. daily checks) following established protocols;
vii. Perform regular workplace monitoring according to the instruction of the RPO;
viii. Inform the RPO in the case of an incident or accident; and
ix. Position patient as per the directives of Radiation Oncologist.

II-D. Radiation Protection Officer (RPO)

The responsibilities of the RPO may include:

i. Implement all applicable Regulations and directives of PNRA;
ii. Coordinate with PNRA and facilitate regulatory inspections and investigations;
iii. Provide a link between the Radiation Protection Committee (RPC) and the users of radiation within the institution;
iv. Monitor source security, receive sources and maintain source inventory;
v. Develop Radiation Protection Program (RPP) and supervise its implementation at the facility;
vi. Identify deficiencies in implementation of the RPP, reporting these to the management and supervise the corrective actions in this regard;
vii. Ensure that tasks requiring specific training and experience are only performed by staff fulfilling the requisite criteria;
viii. Identify, develop and implement approved standard operating procedures;
ix. Identify that enough and appropriate radiation monitoring instruments are available and that they are calibrated and serviced periodically as required;
x. Implement a personal and workplace monitoring program at the facility;
xi. Ensure that arrangements are made for proper use of personal protective items and personal monitoring equipment;
xii. Inform all radiation workers of their personal doses and ensuring that these are consistent with optimization;
xiii. Ensure that appropriate measures are taken to control the exposure of pregnant workers, if applicable;
xiv. Assess potential hazards from foreseeable incidents and accidents and

developing radiation emergency plan;

xv. Conduct exercises according to approved radiation emergency plans;
xvi. Ensure that appropriate action is taken when an employee reports a matter which can compromise radiation protection;
xvii. Maintain records of occupational exposures, workplace monitoring and health surveillance, etc.;
xviii. Maintain a system for using experience feedback; and
xix. Communicate to management for any training or course necessary for workers to achieve safety and quality.

II-E. Responsibilities of Radiation Protection Committee

The responsibilities of the radiation protection committee may include:

i. Review and oversight the compliance with the regulations and directives of PNRA;
ii. Review and oversight compliance with the implementation of the radiation protection program;
iii. Formulate radiation protection policies, update them as technology improves and review the radiation protection program after updates;
iv. Provide guidance to radiation protection officer on operational aspects of the radiation protection program;
v. Recommend actions to correct identified deficiencies;
vi. Review new uses of radiation sources that may lead to modifications;
vii. Periodically review the training program; and
viii. Hold periodic meetings and perform internal audits (at least once per year).

ANNEXURE III

Quality Control

QC tests[1] to be performed on radiotherapy equipment are given below:

Table 1: QC of Radiotherapy Simulator

Frequency	Test	Tolerance[a]
Daily	Localizing lasers	2 mm
	Optical distance indicator (ODI)	2 mm
Monthly	Field size indicator	2 mm
	Gantry/collimator angle indicators	1°
	Cross-hair centering	2 mm diameter
	Focal spot-axis indicator	2 mm
	Fluoroscopic image quality	Baseline
	Emergency/collision avoidance	Functional
	Coincidence of light and radiation fields	2 mm or 1%
	Film processor sensitometry	Baseline
Annually	**Mechanical checks**	
	Collimator rotation isocentre	2 mm diameter
	Gantry rotation isocentre	2 mm diameter
	Couch rotation isocentre	2 mm diameter
	Coincidence of collimator, gantry, couch axes and isocentre	2 mm diameter
	Table top sag (for 80 kg mass evenly distributed)	2 mm
	Vertical travel of couch	2 mm
	Radiographic checks	
	Exposure rate	Baseline
	Table top exposure with fluoroscopy	Baseline
	kVp and mAs calibration	Baseline
	High and low contrast resolutions	Baseline

[a]The tolerance mean that the parameter exceeds the tabulated value (e.g., the measured isocenter under gantry rotation exceeds 2 mm diameter).

Table 2: QC of Co-60 Machine

Frequency	Test	Tolerance[a]
Daily	**Safety**	
	Door interlock	Functional
	Radiation room monitor	Functional
	Audiovisual monitor	Functional
	Mechanical	
	Localizing lasers	2 mm
	Optical distance indicator (ODI)	2 mm
Weekly	Check of source positioning	3 mm

[1]The tables have been adopted from IAEA, NUREG and AAPM documents to provide guidance to licensees. However, licensee s are advised to consult with the manufacturer before adopting any particular protocol for machines' QC.

Monthly	**Dosimetry**	
	Output constancy	2%
	Mechanical checks	
	Coincidence of light and radiation fields	3 mm
	Field size indicator (collimator setting)	2 mm
	Gantry and collimator angle indicator	1^{o}
	Cross-hair centering	1 mm
	Latching of wedges and trays	Functional
	Safety interlocks	
	Emergency off switches	Functional
	Wedge interlocks	Functional
Annually	**Dosimetry**	
	Output constancy (should be traceable to SSDL)	2%
	Field size dependence of output constancy	2%
	Central axis dosimetry parameter constancy (PDD/TAR)	2%
	Transmission factor constancy for all standard accessories	2%
	Wedge transmission factor constancy	2%
	Timer linearity and error	1%
	Output constancy versus gantry angle	2%
	Beam uniformity versus gantry angle	3%
	Safety interlocks	
	Follow test procedures of manufacturer	Functional
	Mechanical checks	
	Collimator rotation isocentre	2 mm diameter
	Gantry rotation isocentre	2 mm diameter
	Couch rotation isocentre	2 mm diameter
	Coincidence of collimator, gantry and couch axes with isocentre	2 mm diameter
	Coincidence of radiation and mechanical isocentres	2 mm diameter
	Table top sag (for 80 kg mass evenly distributed)	2 mm
	Vertical travel of table	2 mm
	Field intensity of light	Functional

[a]The tolerances listed in the table should be interpreted to mean that if a parameter either: (1) exceeds the tabulated value (e.g., the measured isocenter under gantry rotation exceeds 2 mm diameter): or (2) that the change in the parameter exceeds the nominal value (e.g., the output changes by more than 2%), then an action is required. The distinction is emphasized by the use of term constancy for the latter case. Moreover, for constancy, percent values are ± the deviation of the parameter with respect to its nominal value; distances are referenced to the isocenter or nominal SSD.

Table 3: QC of LINAC (Daily Checks)

Procedure	Machine Type Tolerance		
	Non-IMRT	IMRT	SRS/SBRT
Dosimetry			
X-ray output constancy (all energies) Electron output constancy (weekly, except for machines with unique e-monitoring requiring daily)	-	3%	-

Mechanical			
Laser localization	2 mm	1.5 mm	1 mm
Optical distance indicator (ODI) @ iso	2 mm	2 mm	2 mm
Collimator size indicator	2 mm	2 mm	1 mm
Safety			
Door interlock (beam off)	-	Functional	-
Door closing safety	-	Functional	-
Audiovisual monitor	-	Functional	-
Stereotactic interlocks (lockout)	NA	NA	Functional
Radiation area monitor (if used)	-	Functional	-
Beam on indicator	-	Functional	-

Table 4: QC of LINAC (Monthly Checks)

Procedure	Machine Type Tolerance		
	Non-IMRT	IMRT	SRS/SBRT
Dosimetry			
X-ray output constancy	-	2%	-
Electron output constancy	-		-
Backup monitor chamber constancy	-		-
Typical dose rate[a] output constancy	NA	2% (@ IMRT dose rate)	2% (@ stereo dose rate, MU)
Photon beam profile constancy	-	1%	-
Electron beam profile constancy	-	1%	-
Electron beam energy constancy	-	2%/2 mm	-
Mechanical			
Light/radiation field coincidence[b]	-	2 mm or 1% on a side	-
Light/radiation field coincidence (asymmetric)[b]	-	1 mm or 1% on a side	-
Distance check device for lasers compared with front pointer	-	1mm	-
Gantry/collimator angle indicators (@ cardinal angles); (digital only)	-	1.0°	-
Accessory trays (i.e. port film graticle tray)	-	2mm	-
Jaw position indicators (symmetric)[c]	-	2mm	-
Jaw position indicators (asymmetric)[d]	-	1mm	-
Cross-hair centering (walkout)	-	1mm	-
Treatment couch position indicators[e]	2 mm/1°	2 mm/1°	1 mm/0.5°
Wedge placement accuracy	-	2 mm	-
Compensator placement accuracy[f]	-	1mm	-
Latching of wedges, blocking tray[g]	-	Functional	-
Localizing lasers	±2mm	±1mm	< ±1mm
Safety			
Laser guard-interlock test	-	Functional	-
Respiratory gating			
Beam output constancy	-	2%	-
Phase, amplitude beam control	-	Functional	-

In-room respiratory monitoring system	-	Functional	-
Gating interlock	-	Functional	-

[a]Dose monitoring as a function of dose rate.

[b]Light/ radiation field coincidence need only be checked monthly if light field is used for clinical setups.

[c]Tolerance is summation of total for each width or length.

[d]Asymmetric jaws should be checked at settings of 0.0 and 10.0.

[e]Lateral, longitudinal and rotational.

[f]Compensator based IMRT (solid compensators) require a quantitative value for tray position (wedge or blocking tray slot) set at a maximum deviation of 1.0 mm from the center of the compensator tray mount and the cross hairs.

[g]Check at collimator/gantry angle combination that places the latch toward the floor.

Table 5: QC of LINAC (Annual Checks)

Procedure	Machine Type Tolerance		
	Non-IMRT	IMRT	SRS/SBRT
Dosimetry			
X-ray flatness change from baseline	-	1%	-
X-ray symmetry change from baseline	-	±1%	-
Electron flatness change from baseline	-	1%	-
Electron symmetry change from baseline	-	±1%	-
SRS arc rotation mode (range: 0.5–10 MU/deg)	NA	NA	Monitor units set vs. delivered: 1.0 MU or 2% (whichever is greater) Gantry arc set vs. delivered: 1.0° or 2% (whichever is greater)
X-ray/electron output calibration (AAPM TG-51)[a]	-	±1% (Absolute)	-
Spot check of field size dependent output factors for x ray (two or more FSs)	-	2% for field size <4x4 cm^2, 1% > 4x4 cm^2	-
Output factors for electron applicators (spot check of one applicator/energy)	-	±2% from baseline	-
X-ray beam quality (PDD_{10} or TMR^{20}_{10})	-	±1% from baseline	-
Electron beam quality (R_{50})	-	±1 mm	-
Physical wedge transmission factor constancy	-	±2%	-
X-ray monitor unit linearity (output constancy)	±2% ≥ 5 MU	±5% (2-4) MU, ±2% ≥ 5 MU	±5% (2-4) MU
Electron monitor unit linearity (output constancy)	-	±2% ≥ 5 MU	-
X-ray output constancy vs dose rate	-	±2% from baseline	-
X-ray output constancy vs gantry angle	-	±1% from baseline	-
Electron output constancy vs gantry angle	-	±1% from baseline	-
Electron and x-ray off-axis factor constancy vs gantry angle	-	±1% from baseline	-
Arc mode (expected MU, degrees)	-	±1% from baseline	-

TBI/TSET mode	-	Functional	-
PDD or TMR and OAF constancy	-	1% (TBI) or 1 mm PDD shift (TSET) from baseline	-
TBI/TSET output calibration	-	2% from baseline	-
TBI/TSET accessories	-	2% from baseline	-
Mechanical			
Collimator rotation isocenter	-	±1 mm from baseline	-
Gantry rotation isocenter	-	±1 mm from baseline	-
Couch rotation isocenter	-	±1 mm from baseline	-
Electron applicator interlocks	-	Functional	-
Coincidence of radiation and mechanical isocenter	±2 mm from baseline	±2 mm from baseline	±1 mm from baseline
Table top sag	-	2 mm from baseline	-
Table angle	-	1°	-
Table travel maximum range movement in all directions	-	±2 mm	-
Stereotactic accessories, lockouts, etc.	NA	NA	Functional
Safety			
Follow manufacturer's test procedures	-	Functional	-
Respiratory gating			
Beam energy constancy	-	2%	-
Temporal accuracy of phase/amplitude gate on	-	100 ms of expected	-
Calibration of surrogate for respiratory phase/amplitude	-	100 ms of expected	-
Interlock testing	-	Functional	-

[a]AAPM, "Protocol for clinical reference dosimetry of high-energy photon and electron beams", TG-51.

Table 6: QC of Cyber Knife

Daily QC	
Procedure	**Tolerance**
Safety interlocks (Door, console EMO, Key)	Functional
CCTV cameras and monitors	Functional
Audio monitor	Functional
Collimator assembly collision detector	Functional
Accelerator warm-up: 6000 MU for open chambers, 3000 MU for sealed chambers	NA
Accelerator output	<2%: no change needed >2%: adjust calibration
Detection of incorrect and missing secondary collimator	Functional
Visual check of beam laser and a standard floor mark.	<1mm

AQA test	<1mm from baseline
Monthly QC	
Safety interlocks	Functional
Energy constancy	2%
Beam symmetry	>3%
Beam shape	>2% Compared to beam data
Output	> 2%
Imager alignment	1 mm or center pixel ±2 pixels
Contrast, noise, and spatial resolution of amorphous silicon detector Homogeneity/bad pixels	To be decided by user based on available literature
Custom CT model: CT QA (spatial accuracy, electron density)	As per Standards[a]
Verify relative location of beam laser vs. radiation CAX has not changed	0.5 mm
Visually check isocentric plan to verify beam laser illuminates isocrystal; rotate through path sets each month	Laser on isocrystal for each node
Intracranial and extracranial E2E; set schedule to cycle through each clinically used tracking method and path	<0.95 mm or <1.5 mm for motion tracking
Non isocentric patient QA or DQA; ideally performed quarterly	DTA 2 mm/2%; Synchrony DTA 3%/3mm
Observe Synchrony treatment or simulation; listen for unusual noise and visually check for vibrations	No significant change
Annual QC	
EPO button	Functional
Secondary independent check[a]	Adjust calibration if >1% difference is found
Beam data checks on at least three collimators, including largest and smallest collimator (TPR or PDD, OCR, output factors)	To be decided by user
Dose output linearity to lowest MU/beam used	1%
Imager kVp accuracy, mA station exposure linearity, exposure reproducibility, focal spot size	As per Standards[b]
Signal to noise ratio, contrast-to-noise ratio, relative modulation transfer function, imager sensitivity stability, bad pixel count and pattern, uniformity corrected images, detector centering, and imager gain statistics	Compare to baseline
Treatment planning software	As per Standards[c]
CT QC (in addition to monthly)	As per Standards[b]
Data security and verification	Functional
2nd Order Path Calibration; currently only possible with the help of a service engineer	Each node < 0.5 mm RMS < 0.3 mm
Check noise level of optical markers	<0.2 mm
Run Synchrony E2E test with at least 20 deg phase shift; analyze penumbra spread	To be decided by user
Monthly QC	In addition to tolerances listed above, update all parameters and checklists
Daily QC	Update parameters

[a]AAPM, "Quality assurance for computed- tomography simulators and the computed-tomography-simulation process", TG-66.

[b]AAPM, "Quality Control in Diagnostic Radiology", Report No. 74.

[c]AAPM, "Quality assurance for clinical radiotherapy Treatment planning", TG-53.

Table 7: QC of Gamma Knife

Daily QC	
Procedure	**Tolerance**
Door interlock	≤0.5 cm of trip position
Radiation monitors	≤10% of annual calibration
Monthly QC	
Timer Linearity	≤2%; Correl.=0.999
Timer accuracy	≤2 sec
On-off Error	-(0.03-0.05) min
Trunnion centricity	±(0.2-0.5) mm
Radiation output	≤2 %
Anticipated output Vs measured	≤(2-3)%
Computer output Vs measured	≤(2-4)%
Helmet micro switch	±0.1 mm of trip point
Couch movement time deviation	±10 sec. from initial calibration
Semi-Annual QC	
Leak tests	<0.005 mCi
Annual QC	
Dose profiles	±1 mm on 50% line
Radiation/mechanical isocentre coincidence	± (0.3-0.4) mm
Collimator factors	≤(2-5)%

Table 8: QC of Brachytherapy Sources

Type of source	Test	Frequency	Tolerance
Long half-life: description	Physical and chemical form Source encapsulation	Initial purchase	Documented
	Radionuclide distribution and source uniformity	Initial purchase	Documented
	Location of radionuclide	Initial purchase	1 mm
Long half-life: calibration	Mean of batch	Initial purchase	3%
	Deviation from mean	Initial purchase	5%, Documented
	Verification of calibration	At every use	Visual check of source colour code or measurement in a calibrator
Short half-life: description	Physical/chemical form	Initial purchase	Documented
	Source encapsulation	Initial purchase	Documented
Short half-life: calibration	Mean of batch	At every use	3%
	Deviation from mean (not mandatory for short lived isotopes)	At every use	5%
	Radionuclide distribution and source uniformity	At every use	Visual check, autoradiograph or ionometric check

Table 9: QC of Brachytherapy Applicators

Type of Applicator	Test	Frequency	Tolerance
Intra-cavitary	Source location	Initial use, repair and yearly	Documented
	Coincidence of dummy and active sources	Initial use, repair	1 mm
	Location of shields	Initial use, repair	Documented
Interstitial	Coincidence of dummy and active sources	Initial use, repair and visual inspection	1 mm

Table 10: QC of Brachytherapy Unit (Afterloader)

Frequency	Procedure	Tolerance
Each treatment day	Room safety door interlocks, lights and alarms	Functional
	Console functions, switches, batteries and printer	Functional
	Visual inspection of source guides	Free of kinks and firmly attached
	Verify accuracy of ribbon preparation	Autoradiograph
Weekly	Accuracy of source and dummy loading (dummies used for spacing and/or simulation/verification)	1 mm
	Source positioning	1 mm
At each source change or Quarterly	Calibration	3%
	Timer function	1%
	Check accuracy of source guides and connectors	1 mm
	Mechanical integrity of applicators (by X-ray if appropriate)	Functional
Annually	Dose calculation algorithm (at least one standard source configuration for each isotope)	3%, 1 mm
	Simulate emergency conditions (as per procedure)	
	Verify source inventory (as per procedure)	

ANNEXURE IV

Activity Levels

Radionuclide	Activity (MBq)
Au-198	3500
Cr-51	4800
I-125	250
Sm-153	26000

ANNEXURE V

Record Keeping

S. No.	Record	Minimum Retention Time
i.	Personal dosimetry	75 years (age of worker) or 30 years after termination of work (as applicable by Regulations - (PAK/904))
ii.	Health surveillance	5 years
iii.	Calibration of monitoring equipment from SSDL	5 years
iv.	Calibration of dosimetry equipment from SSDL	5 years
v.	Area survey	5 years
vi.	QC of radiotherapy equipment	5 years
vii.	Beam output measurement from SSDL	5 years
viii.	Import record of radioactive sources and radiation generators	Until possession
ix.	Export or disposal record of radioactive sources and radiation generators	10 years
x.	Transfer of radioactive source to PINSTECH or KANUPP	10 years
xi.	Survey record at the time of arrival/departure of source container	5 years
xii.	Qualification of workers	All record of current workers and 5 years after their leaving
xiii.	Leak test	10 years
xiv.	Training and re-training of workers	5 years
xv.	Emergency drills	5 years
xvi.	Audit and reviews of radiation protection program	5 years
xvii.	Incidents and accidents	10 years

PAKISTAN NUCLEAR REGULATORY AUTHORITY
P.O. Box 1912, Islamabad
www.pnra.org