MDS – G007

Guidance for the Operation and Use of Radiation-Emitting Medical Devices

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Introduction

Purpose

The purpose of this document is to identify and clarify the following:

- The main guidelines of the Saudi Food and Drug Authority (SFDA) to prepare a radiation protection program for medical facilities operating a radiation-emitting medical device or using radioactive material, in either case, for medical purposes.
- The guidelines aim to enhance the performance of radiation-emitting medical devices, boost the efficiency of the radiation protection program, and maintain the quality of images and patient diagnostic data.

Scope

This document applies to the following:

- Providers of quality assurance (QA) services.
- Healthcare providers (HCPs) operating radiation-emitting medical devices or using radioactive materials for medical purposes.
- Biomedical maintenance providers.

Background

SFDA has issued this document in reference to the following:

- Article (26) of the "Medical Devices Law" issued by Royal Decree No. (M/54) dated 6/7/1442H stipulates, "The SFDA shall monitor the compliance of HCPs with technical regulations within HCPs to ensure the safety and efficacy of medical devices in diagnosis and treatment."
- Requirements for Safe Use of Medical Devices inside Healthcare Facilities (MDS-REQ 3).

Chapter One: Medical Radiation Devices and Materials

General	**1**	- HCPs can only provide radiological medical services if they have obtained a practice license from the competent authority. - HCPs using medical radiation sources, whether a device or radioactive material, shall comply with Requirements for Safe Use of Medical Devices inside Healthcare Facilities (MDS-REQ 3). - Medical devices offered for marketing and use within the Kingdom require obtaining medical device marketing authorization (MDMA) following "Requirements for Medical Devices Marketing Authorization (MDS-REQ 1)". - Apply radiation protection principles to control the use of ionizing radiation by: o **Justification**: evaluate the quality of the information provided by the radiological systems, including patient doses. o **Optimization:** establish reference-dosing records, essential in enhancing image information and minimizing unnecessary radiation exposure. o **Dose limits:** evaluate dose, adhere to dose limits for operators and the public, and provide guidance on patient dose reference levels (DRL). - The SFDA has the right to visit medical facilities to ensure the quality, efficiency, and safety of medical devices and products that emit radiation to staff, members of the public, patients and their environment. - All medical radiation devices should include safety features such as emergency stop controls and automatic shutoff mechanisms

Risk Assessment	**2**	- HCPs Shall carry out risk assessment of devices based on: o Level and exposure duration to radiation. o Exposure limits. o Direct or indirect effects on the health and safety of workers, members of the public, and patients exposed to radiation. o Need for alternative equipment designed to reduce radiation exposure levels. o Health monitoring information. o The number of sources emitting radiation. o Information provided by manufacturers of radiation sources.
Management and Organization	**3**	- HCPs shall ensure radiation is as low as reasonably achievable (ALARA) to reduce risks and lower radiation doses for patients, staff, and the public. - HCPs shall comply with engineering controls to reduce occupational and public doses. - Only qualified workers with appropriate practical training and instructions can use the radiation equipment or radioactive materials.
Operators Control	**4**	- In the ionizing radiation departments, operators must wear personal dosimeters such as thermoluminescent, optically stimulated luminescent, radiophoto luminescent, film badges, or electronic dosimeters (limits apply to some dental radiology devices). Staff must ensure the correct functioning of electronic dosimeters in radiation fields. Individual monitoring devices shall be calibrated and traceable to a secondary standard dosimetry laboratory (SSDL). - Operators shall have adequate training in emergency plans, radiation safety, and operating equipment. - Workers operating irradiating devices must ensure that no unnecessary persons are in the controlled areas whenever they use radiation devices or radioactive materials. - Provide portable shielding barriers for use with mobile ionizing radiation devices to protect patients and workers from unjustified exposure to radiation. - As applicable, direct the radiation beam and radioactive material away from occupied areas during operation. - Every room containing a medical device emitting ionizing or non-ionizing radiation should be provided with applicable personal protective equipment (PPE) for both

		staff and patients to protect them from the risk of radiation while adhering to the following: o Adequate number of different sizes (for adults and children) and various uses (e.g., body apron, pelvic apron, thyroid collar, gloves, and glasses) and any other protective equipment. - If ever a person is required to support a patient, staff shall ensure the following: o The supporter shall wear protective facilities, such as an applicable apron and gloves, and avoid the direct beam by, for instance, standing opposite to the direction of radiation emitted by an X-ray tube. o Record the names of staff involved, the date, the number of exposures, and the radiographic techniques used, all to be entered in a provided notebook.
Radiation Protection Aprons	**5**	- Proper handling and care of the radiation-protective aprons can help ensure their effectiveness and longevity. HCP shall implement the following guidelines: o Before Use a. Visually examine aprons for any indication of damage, including fractures, tears, or worn areas. b. Clean the apron with mild detergent and water if it is visibly dirty. Avoid using harsh chemicals or abrasive products that may harm the apron. o During Use a. Ensure the apron is positioned correctly, covering the torso and reproductive organs. The front should face the X-ray source. b. When this is possible, always wear a thyroid collar to protect the thyroid gland. c. If multiple healthcare professionals are working nearby, their aprons should overlap to prevent gaps in coverage. o After Use a. Carefully remove the apron, avoiding contact with the front side to prevent contamination. b. The apron should be stored in a clean, dry area away from direct sunlight and high heat. c. Clean the apron regularly to remove any potential contaminants, even if it does not appear dirty. o Maintenance a. Regular inspections should be conducted for signs of wear and tear.

		b. To guarantee ongoing protection, the apron must be repaired or replaced in case of damage. c. Periodically verify the apron's lead equivalence to guarantee it complies with the required standards. ○ Disposal a. Following local requirements GCC Uniform Law for Medical Waste Management, Executive Regulations of the Waste Management System, the apron must be discarded at the end of its functional lifespan. Due to the presence of lead, specialized handling or disposal protocols may be required.
Quality Assurance Program	**6**	- Conduct QA tests to provide this service and retain the test reports periodically using qualified and trained specialists from the HCP or third parties licensed by the SFDA to provide this service and retain the test reports. - Provide documented policies and procedures about radiation protection and QA programs within radiation departments and review them periodically. - The radiological departments shall not administratively link radiation safety officers (RSOs) and qualified and trained physicists assigned to conduct QA tests. It is possible to contract with SFDA-licensed QA service providers. - Following the manufacturer's instructions, conduct the necessary tests to ensure the medical device's safety, efficacy, and quality, and notify the National Center for Medical Devices Reporting (NCMDR) in case of test failure. - Conduct functional tests of the medical device using test equipment, following the manufacturer's instructions. - If the tested device fails, notify SFDA via the NCMDR and attach a corrective action plan within three working days of receiving the test report. The report recommends limiting the medical device's continuous use. - The person responsible for the radiation device shall verify the following factors: ○ Radiation quality. ○ Absorption component. ○ Equivalent tissues. ○ Mechanical failures.

Inspection & Maintenance	**7**	- Periodic preventative maintenance (PPM):
		  o PPM is required to monitor the proper functioning of the equipment, minimize machine breakdowns, and ensure that the equipment operates within the manufacturer's specifications. This includes routine servicing and part replacement during regularly programmed inspections.
		  o Qualified experts and radiation specialists should be closely associated with the planned PPM program.
		  o HCPs shall advise the qualified expert on the detailed PPM work before any equipment under PPM work is returned for clinical use.
		- Testing frequency:
		  o The relevant regulatory authority should specify any particular parameter's testing frequency, considering the frequency of other tests.
		  o Consider the risk of equipment malfunction or the potential for a measured parameter to deviate from an acceptable tolerance range.
		- Comply with the following Requirements for Safe Use of Medical Devices inside Healthcare Facilities (MDS-REQ 3) requirements:
		  o Have documented policies for:
		  a. Maintenance of medical devices, including PPM, corrective maintenance, calibration, and QA tests.
		  b. Reprocess medical devices by the regulations outlined in the article (20/2) of the Implementing Regulation of the Law of Medical Devices.
		  c. Follow up with safety alerts and corrective actions in the field.
		  o Obtain an installation report demonstrating the device's excellent condition, full functionality, successful completion of all acceptance tests, and proper operation training. The report must be approved by the biomedical technician/engineer and the end user.
		  o Identify appropriate training needs for operation and maintenance.
		  o Ensure that the manufacturer, or a trained individual appointed by the manufacturer, provides appropriate training on the device for both the user and the biomedical engineer or technician while ensuring the retention of training records and certificates.

		○ Following the manufacturer's instructions, conduct the necessary tests to ensure the medical device's safety, efficacy, and quality, and notify the NCMDR in case of test failure. ○ Ensure that the manufacturer, SFDA-licensed maintenance service provider, qualified technical staff with specialized manufacturer training, or a trained maintenance professional performs the maintenance. ○ Determine the requirements for PPM by following the manufacturer's instructions. ○ The obligation to conduct electrical safety tests and PPM is as follows: a. Scheduling PPM is done according to the manufacturer's instructions and medical device availability. b. The medical device should be clean, disinfected (if needed), and functioning correctly. c. Document the PPM details (dates, tool kits) in the medical device record within the maintenance management system and retain this information for at least two years. d. After conducting the PPM, attach a tag to the medical device indicating at least the previous PPM, the date of the next PPM, and the performer. e. The end user must approve the PPM reports, biomedical engineer/technician, or maintenance service provider. ○ Monitor all PPM and corrective maintenance processes. ○ Apply the manufacturer’s instructions for corrective maintenance and calibration. In the absence of instructions, refer to the standards and guidance approved by the SFDA. ○ Establish a record within the maintenance management system for each medical device that includes at least the following information: a. General information about the medical device. b. The PPM: details should include the frequency of the PPM, the updated procedures, the calibration requirements, the used spare parts, the date of each PPM, the test equipment and tools used, the person performing the maintenance, and the total time consumed.

		c. Corrective maintenance: problem date and description, used spare parts, and consumed time. d. The field safety corrective action: includes details such as the safety alert date, the problem description, the necessary corrective action, and the implementation date. ○ Provide appropriate tags based on the medical device condition, such as (Out of Service and PPM).
User	**8**	- Complies with the following requirements of Requirements for Safe Use of Medical Devices inside Healthcare Facilities (MDS-REQ 3): ○ Ensure that the manufacturer, or a trained person by the manufacturer, provides appropriate training on the medical device for both the user and the biomedical engineer or technician and retains the training records and certificates. ○ Staff shall adhere to the following: a. Use PPE if it does not interfere with the imaging procedure. b. Store PPE properly to maintain its efficiency. c. Test PPE periodically to ensure their efficiency and retain test reports. ○ Apply the National Diagnostic Reference Level (NDRL) and keep all relevant records.
Medical Device Room	**9**	- Must comply with the following requirements of MDS-REQ 3: ○ Periodically conduct the necessary tests to ensure the efficiency and quality of shielding of the radiology rooms (that are required to be shielded) and retain the test reports. ○ A mobile X-ray device becomes a stationary unit when assigned to a specific room. Additionally, a radiation survey is necessary to guarantee the safety of the occupants in both controlled and uncontrolled areas. ○ Immediately stop using radiology and medical imaging devices that fail the efficiency and quality of shielding tests, notify SFDA through the NCMDR, and attach a corrective action plan within (3) working days from the date of receiving the test report. ○ Equip the radiation rooms to enable the operator to monitor the patient continuously during the procedure.

		○ Configure a dedicated area for operators of ionizing radiation devices to continuously monitor the patient during the procedure and ensure their safety from ionizing radiation hazards.
Warning Signs	**10**	- Provide visible warning signs or other devices at any general access point to a room to indicate that the room contains an ionizing or non-ionizing radiation hazard. - Automatic warning lights that activate upon the emission of a radiation dose are installed at the entrances of ionizing radiation rooms. - Where possible, warning signs should be at eye level.
Records Control	**11**	- Record keeping: ○ Proper record-keeping is essential to any QA program because it detects long-term trends in equipment dose delivery accuracy or safety. Setting action levels ensures the safety of patients and staff. Control charts show a parameter's behavior over time, making constancy-testing records easy. ○ Equipment records should include the following: a. Results of acceptance testing. b. Results of any constancy tests. c. Failure occurrence leads to unscheduled downtime. d. Radiation incidents. ○ The QA record retention period. To avoid litigation, HCPs should keep acceptance and constancy testing records for at least the equipment's lifetime. Individual HCPs must decide how long to keep these records. - The following records shall be kept within the radiological department for reference: ○ Records of each radiological procedure, along with radiation dose data. ○ Radiation protection program. ○ Documentation of construction justifying the installed shielding. ○ Shielding survey tests (for the last two years). ○ Information on changes, if any. ○ Subsequent survey reports after changes. ○ Personnel dosimetry readings (e.g., TLD, OSL) (for the previous five years). ○ Service manuals. ○ Operating instructions. ○ Offered in-service training.

		○ PPM reports (for the last two years). ○ QC performance tests (for the previous two years). ○ Emergency maintenance reports. ○ Corrective maintenance reports. ○ Electrical safety reports. ○ Protection equipment tests for shield integrity (for the last two years). ○ MDMA certificate.
Disposal of Devices	**12**	- HCPs shall notify the SFDA in writing of selling, transferring, or discontinuing the use of any radiation source. - HCPs shall adhere to chapter 16 of requirements for radiology medical device decommissioning.

Chapter Two: Medical Radiation Protection Program

General	**1**	- HCPs must maintain a documented and approved plan for managing medical radiological devices or radioactive materials.
Dosimetry Program	**2**	- As illustrated in MDS-REQ 3, HCPs must determine when to monitor staff and individuals' ionizing radiation doses and exposure. - Instruct workers exposed to radiation with the following: o Types of personal dosimeters employed, method, and period of use. o Method for controlling personal dosimeters. o Instructions for using dosimeters, including the consequences of improper exposure to the device. o Procedures for reporting pregnant workers. o The department is responsible for preserving the documentation of fetus doses and related documents for the worker who has declared herself pregnant. o The department must keep records of occupational exposure for each worker until the worker turns 75 and for at least 30 years after the worker's last job.
Monitoring and Control Areas	**3**	- Assess and document the need for monitoring the control areas and follow the requirements provided in the Requirements for Safe Use of Medical Devices inside Healthcare Facilities (MDS-REQ 3), which states the obligation to monitor ionizing radiation doses for exposed workers during their work period, according to the following: o Provide each classified worker with two personal dosimeter badges (A&B) that are used alternately when one is sent off for reading. o Throughout the entire work period, keep personal dosimeter records. o Providing additional personal dosimeters for the extremities when exposed to high radiation doses is expected. o Conduct a risk assessment to ascertain the anticipated annual dose for classified workers in dental radiology departments and determine if personal dosimeter badges are necessary.

		○ Regardless of the expected dose level, pregnant workers in radiology departments should wear an additional personal dosimeter at the level of the pelvic area.
Sustain Records and Prepare Reports	**4**	- Institutions shall keep all records, prepare reports, document their requirements, and comply with all standards for conformity, in addition to all radiation protection program records, including auditing and reviewing program content. - Identify the following elements for the process of keeping records: ○ The person responsible for maintaining records. ○ Place of retained records. ○ Record retention template, documentation, and updates. ○ Procedures for maintaining records for additional sites that have received approval, such as Internet and communication service providers, must be followed. - Individual exposure reports must be submitted upon request, and the procedures for issuing these reports must be documented.
Review and Internal Audit Procedures	**5**	- HCPs must regularly review the radiation protection program (at least once every two years). - The following items shall be reviewed and addressed based on the scope of the radiation protection program: ○ Determine the types of audits and review programs to be conducted. ○ Identify the individual(s) responsible for leading the audit and review. ○ Establish the location and time for conducting the audit and revision. ○ Audit Procedures. ○ Instructions for proper use of the medical devices when calibrated internally.
Training and Guidelines for Radiation Protection	**6**	- Provide written radiation device operation and safety policies and procedures. Consider a transparent display on the device or control and operation units for operator convenience. - Document all required employee training, whether exposed or non-exposed, including continuing education programs. - Document radiation protection program reviews, safety meetings, and formal classroom training for staff and visitors.

		- Inform patients, staff, and the public about radiation in controlled areas. - Instruct workers about radiation exposure risks, protection methods, and precautions, and consider the applicable provisions and regulations to protect them from unnecessary radiation. - Instruct workers about appropriate responses to warnings made during any emergency or malfunction that may cause radiation exposure and inform them about radiation exposure reports.

Chapter Three: Radiation Accidents Program

General	**1**	- HCP shall have a documented and approved plan to respond to emergencies or radiation accidents.
Users	**2**	- Workers and trainees must strictly adhere to proper preparation and radiation protocols. - Occupational radiation protection practices must include general education, training, qualification, and competence. - Individuals working with ionizing radiation shall wear whole-body personnel monitoring devices.
RSO	**3**	- RSO shall regularly check that radiation equipment and radioactive material are used following safety procedures. - The RSO is responsible for reporting any instances of non-observance of safety procedures to the head of the radiology department and for any adverse events to the NCMDR. - RSO shall ensure that the dose does not exceed the radiation limits.
Initial Management	**4**	- Patients contaminated by radioactive materials shall have immediate life-/limb-saving actions without regard to contamination. - Decontamination shall not interfere with medical care, and contaminated casualties shall not be barred access to a medical facility if entry is necessary for life-saving care. - After a radiological incident, a casualty entering a medical unit shall be considered contaminated unless verified as non-contaminated. - A quick head-to-toe survey can determine gross contamination. Medical staff can conduct this survey while assessing patient stability. - Radioactive surface decontamination often demands significant time and resources.
Decontamination Personnel Techniques	**5**	- The priority is to ensure the patient is medically stable. - Once the patient has achieved medical stability, the first step involves removing their clothing. - Fold the top sheet over the clothing to create a clean surface for the patient to roll on. Next, shift the patient

		to the opposite side, fold the sheet over the dress, and roll it away from the bed toward the feet. - After removing the sheet, perform a quick radiological survey of the back to identify any prominent areas of contamination. - Ensure to bag the clothing/top sheet and send it out for sampling. - To address the contaminated wound, one should prepare the area for decontamination. Wipe away from the damage to quickly decontaminate the intact skin adjacent to the wound. - Apply drapes to the affected area to prevent contamination from spreading to uncontaminated areas. - Gently rinse the wound using sterile saline or something similar. - After removing the drapes, cover the wound with a clean, absorbent pad and resurvey the affected area. - If the wound remains contaminated, the process must be repeated until no further progress occurs. - Another option is to gently scrub with a soft cloth, tepid water, and soap. The cleaning motion should go from the outside in.
Medical device Decontamination Techniques	**6**	- Storing contaminated medical devices for 7-10 half-lives can effectively decontaminate using short-half-life isotopes. - It is advisable to clean the medical device using a specific decontaminating solution, such as Radiacwash, Count-off, or Lift away. Immersion in this solution for several to 24 hours can eliminate more resistant contaminants. - Before conducting a final inspection, the cleaned medical device must be completely dry. - The cleaner can use organic solvents like ethanol to wipe the medical device. Harsher methods involve soaking in dilute acids or bases. - When cleaning medical device falls below the limits, it becomes necessary to dispose of radioactive waste, which then becomes possible.
Areas Decontamination Techniques	**7**	- Any contaminated areas, such as benchtops or floors, shall be cleaned promptly. The team shall perform a detailed survey to determine the extent of the

		contamination. The team can outline the affected areas with a wax pencil or magic marker. - For tiny areas with dry contamination, masking or duct tape pressed on the area and removed may decontaminate effectively. - The best method for cleaning more significant areas is to apply a decontamination solution and work from low- to high-activity areas. - Use a brush if scrubbing with towels or sponges is insufficient. Other methods involve organic solvents, acids, bases, and abrasives, similar to medical device cleaning. - The specialized team shall clean up any widespread contamination or high-activity areas under RSO supervision. The team is responsible for cleaning the contaminated area below the established limits. If the team cannot clean contamination, removal of surfaces such as floor tiles may be required.
Post-radiation Accidents Response	**8**	- The RSO shall investigate the cause of the accident, prevent it from recurrence, and keep a record of the investigation. - The RSO shall record radiation incidents in the radiology departments and report them to the section head. The section head shall immediately notify SFDA through the NCMDR and report to any related regulatory body. - Keep records of each worker's occupational exposure. - The records must also include information about radioactive waste generated, including activity levels and levels at disposal. - It is necessary to document the activity levels in the delay tank's effluent before disposing it in the public sewerage system. - The sewerage system should also record the total amount of activity disposed of annually. - It is also necessary to document the names of individuals authorized to administer and dispose of radioisotopes. - As soon as possible after a trigger or event, prepare a written report detailing the cause, which includes determining or verifying the dose, corrective or mitigating actions, and instructions or recommendations to prevent recurrence. The radiation

		safety committee and the QA officers shall review this information and inform the SFDA.

Chapter Four: General Radiology Devices

General x-ray	**1**	- The X-ray medical device shall be installed in a dedicated, shielded room to protect staff, the public and patients from radiation exposure. - Adequate ventilation is necessary to prevent the buildup of harmful gases. - If necessary, patients must provide informed consent before undergoing X-ray procedures.
Portable X-ray	**2**	- The head of the general radiology department shall be responsible for ensuring that portable X-ray medical device used in the facility outside the central radiology department operates under written radiation safety procedures. - Users should recognize that the image quality of portable X-rays is lower than that of stationary units. - Carefully transport and handle the medical device to avoid any damage. - Mobile radiation barriers and ionizing radiation medical devices should be used to protect patients and workers from unnecessary radiation exposure. - Make sure to charge the battery fully before using it to avoid disruptions. - Ensure the motor-driven ability is in good condition. - Inspect the braking system to avoid unnecessary injuries. - Ensure the ancillary extension is available and in good condition. - Check the tube placement before and after use. - To minimize exposure, use portable X-rays in areas with minimal patient and staff traffic. - When using mobile X-ray medical devices, the machine worker must ensure that no unnecessary persons are in the controlled area. - The area or room where the X-ray is performed shall be temporarily posted with a "Caution Radiation Sign." - Additional dosimeters for the extremities when exposed to high radiation doses are resected. - During the operation, every effort should be made to direct the X-ray beam away from occupied areas and prevent it from irradiating anyone near the patient. - Mobile X-ray units shall not be handheld. - The operator must not stand in the direction of the primary beam, must be at least 3.00 meters from the X-ray tube, and

		must wear a shielding apron of at least 0.25 mm lead equivalency when the X-ray tube is energized.
		- In a capacitor discharge unit, the residual charge remains in the capacitors after X-ray irradiation. This charge can generate a "dark current" and cause X-ray emission even when the irradiation switch remains engaged. Therefore, the user must fully discharge the residual charge before leaving the unit unattended.
		- Mobile equipment must always be equipped with a key-operated switch to prevent unauthorized persons from generating radiation in the following situations:
		  ○ The medical device can generate radiation without being connected to the electrical main supply.
		  ○ When the medical device is connected to the electrical mains supply for battery charging.
		- Use and position suitable aprons correctly to ensure maximum protection.
		- If the X-ray machine is unused, the HCP shall store the medical device in a clean and dry area.
		- The key must always be strictly controlled and available only to authorized personnel.

Using Medical Mobile X-Ray Devices outside Healthcare Facilities.	**3**	- HCPs must obtain a license to use mobile medical X-ray devices outside healthcare facilities from the relevant authority. - HCP shall review radiation risk assessment, local rules, and emergency plans. - The HCP shall maintain the mobile X-ray medical devices properly before transfer. - The HCP must equip the site following the SFDA and manufacturer guidelines. - The mobile X-ray medical devices must be transported according to the manufacturer's instructions to prevent deterioration. - The mobile X-ray medical devices must be transported in vehicles that are appropriately designed and equipped to safeguard them from the various environmental and weather conditions in which they operate. - Set up secure methods to use the medical device, keep track of doses, and keep records. - Conduct a radiation survey after relocating the medical device to the final examination site.

		- The department concerned shall send a copy of the transfer form to update the medical device record and track the device for maintenance, use, or assessment of future needs. - Transporting medical devices safely ensures their preservation from temperature and/or humidity changes, ensuring their safety, efficiency, quality, and performance for their intended purpose. - A competent and qualified person must follow the manufacturer's recommendations when dismantling and repackaging a medical device in different locations. - Transport and carry medical portable X-ray devices carefully, considering the nature of each device. - Report any damage or breakage of medical devices noticed during transport. - The mode of transport or container shall be clean and suitable for transportation. - If the medical device label does not contain information regarding storage and transportation conditions, the HCP shall obtain that information by requesting the manufacturer and/or its authorized representative in the Kingdom. - Regularly check and report the manufacturer-specified storage and transportation conditions (such as temperature and humidity ratio). - The availability of a reliable power source is required. - Installing a battery backup system or an uninterruptible power supply will allow you to record the active data during the outage and safely terminate the software. Configure servers to shut down automatically during a power outage. - Employees of the mobile facility should be in charge of granting access. - If the mobile facility incorporates waiting rooms, it must ensure that its safety levels align with the public's exposure limits. While waiting rooms are typical for mobile mammography facilities, they are not for mobile CT facilities.
Computer Tomography	**4**	- Only radiologic technologists shall operate CT systems. - PET/CT or SPECT/CT shall be run by a technologist certified in nuclear medicine. - Establish low-dose protocols that align with NDRL for specific follow-up and screening examinations. - During the activation of the X-ray beam, the doors should remain closed to provide shielding from secondary radiation. To prevent the X-ray beam from directly hitting the entry doors, construct the X-ray chamber using radiography.

		- Throughout an X-ray diagnostic procedure, the medical radiation technician shall always be able to see the patient clearly and speak with them.
		- HCPs and their qualified personnel shall take into consideration the following:
		  o Using contrast agents can increase the radiation dose given to the patient.
		  o Screening patients for allergies and other contraindications is essential when using contrast agents. Follow the manufacturer's instructions when administering contrast agents and closely monitor patients for adverse reactions.
		  o Performing multiple CT scans in a short period can increase the overall radiation exposure.
		  o Consider the weight limits of some CT scanners.
		  o Patients with claustrophobia may benefit from sedation or anesthesia to tolerate the procedure.

Radiology in NICU/PICU/ICU	**5**	- Mindful actions can minimize exposure, including straightforward actions like keeping a reasonable distance of at least 1 to 2 meters between the source of radiation (including the patient) and the operators.
		- The technical protocols for the implementation of radiographic examinations in the neonatal intensive care units (NICUs), pediatric intensive care units (PICUs), and intensive care units (ICUs) must be clearly defined for each hospital and should encompass the following:
		  o Devices.
		  o Optimal collimation position and X-ray beam intensity.
		- Shielding protective gear, such as lead aprons and thyroid shields, shall be provided for the nursing personnel, who might need to carry the neonate during the exposure.
		- The NICU has an open layout with incubators spaced at variable distances. A portable lead barrier shall protect adjacent incubators from the primary beam of lateral shoot-through radiographs.
		- Provide radiation protection equipment for NICU, as mentioned in Pediatric Radiology.
		- Use radiology medical devices with low-dose technology to minimize radiation exposure.
		- Some patients may require sedation or anesthesia to tolerate the procedure.
		- Closely monitor patients both during and after the procedure to ensure their safety.
		- Specific Considerations for NICU/PICU/ICU Patients:

		○ Radiology medical devices should be appropriate for the size and weight of the patient. ○ Patients may be unable to move or cooperate during the procedure. ○ Implement measures to prevent the transmission of infections.
Mammography	**6**	- Mammograms shall be of high quality to ensure accurate diagnosis. - Use shielding barriers to protect patients and staff from unnecessary radiation. - When calculating a barrier requirement, planned and existing structural materials shall be fully considered. - Provide a protective radiation barrier allowing the technologist to observe the patient during the entire procedure and provide attenuation equal to or greater than 0.25 mm Pb equivalent at 50 kVp. The barrier shall be at least 0.6 m wide, 1.85 m high, and reach within 0.15 m above the floor. - During the test, the patient shall wear a shielding apron that covers the torso, including the unexamined chest, abdomen, and reproductive organs, unless this conflicts with the procedure. - The manufacturer must enclose the tube in shielded housing so that the leakage radiation does not exceed 17.5 µGy (2 mR) per hour at 5 cm from any point on the external surface of the housing at every specified rating. - The manufacturer must provide a timing device to terminate the irradiation automatically. - The image receptor support must transmit less than 0.87 Gy (0.1 mR) per irradiation at all operating loading factors, using the minimum source for the image. - The mammographic X-ray equipment shall include a device to maintain firm breast compression. This device must provide adjustable, uniform, and constant breast compression during mammography. The compression plate's X-ray beam attenuation should be less than the 2.5 mm polymethylmethacrylate (PMMA) equivalence. Note that the optimal value of compression remains unknown. However, it must generate a minimum of 20 kg, and only manual control can significantly achieve compression forces of 25 kg or more. - The portable mammography unit must adhere to the exact requirements. However, additional QC and survey tests are necessary to ensure that the unit's movement does not affect

		the medical device's performance. Follow the manufacturer's recommendations for all QC and survey tests.
DEXA	**7**	- In many cases, DEXA will require lead shielding if it is located near a fully occupied area. Lead acrylic barrier or equivalent shall be installed if: o The operator stands at a distance of less than one meter from the outer edge of the scanning table, or o The operator stands at a distance of fewer than two meters from the center of the scanning surface. - The examination room design must meet the manufacturer's specifications. - The examination room's design should guarantee a sufficient room size following the medical device manufacturer's specifications while keeping the radiation levels in the adjacent rooms within the acceptable range for public members and personnel. Accordingly, no additional radiation shielding in the walls is required. - The software on the DEXA devices shall automatically adjust the radiation output based on the patient's size and density. - Consider the weight limits of some DEXA devices.
Fluoroscopy & C-arm	**8**	- Use shielding barriers and lead aprons to protect patients and staff from unnecessary radiation exposure. - Radiation protective equipment shall include: o Shields or drapes to be placed directly on the patient. o Protection equipment for the head and hands. - Proper patient positioning is essential for accurate imaging and to minimize radiation exposure. - To reduce scatter radiation during fluoroscopy, position the patient as close as possible to the image intensifier side of the fluoroscopic equipment and as far away from the tube side. - Patients shall be screened for allergies and other contraindications if contrast agents are used. - Whenever possible, use fluoroscopy in pulsed mode to minimize radiation exposure. - HCPs should monitor the staff dosimetry and dose limits. - The worker shall wear shields whenever fluoroscopy is performed, such as a thyroid collar shield, gonadal shield, apron, and other forms, to provide secondary barriers and protect wearers from secondary or scatter radiation. - The standard lead apron must provide at least 0.5 mm of lead or equivalent structural barriers.

		- A lead apron shall shield the front of the body from the thyroid area to the knees within 10 cm and the sides of the body from the shoulders to below the gluteal. - Personnel wearing leaded glasses shall orient their heads to avoid exposing the sides to the radiation. - If possible, wear shielded gloves or apply bismuth-based X-ray attenuating hand creams. - Position the generator as far away from the patient, surgeon, and device operator to reduce exposure.
Angiography / Cath lab	**9**	- Accessory PPE shall: o Include an active dosimetry system. o Have a tight fit of the thyroid collar around the neck. o Properly fit the facial contour. o Reduce the gap between the lens and frame. o Maximize front, lateral, and angular protection. o The Glasses shall have an optimal thickness of 0.35 mm to 0.5 mm lead. - Operator techniques shall include: o Decreasing frame rate. o Automatic dose rate control (ADRC). o Tubing extensions on contrast injectors. - Environmental radiation protection shall include the following: o Ceiling-mounted upper-body radiation shields and movable table-mounted curtain shields. o Lead aprons and portable radiation shields. - Increase tube filtration to reduce low-energy X-rays and use a lower time frequency in pulse radioscopy. - Specific Considerations for Angiography/Cath Lab Procedures: o Angiography/Cath lab procedures can involve significant radiation exposure. Therefore, it is crucial to follow ALARA principles and use appropriate shielding. o Observe patients for any adverse reactions to contrast agents. o There are potential complications associated with angiography/Cath lab procedures, such as bleeding, stroke, or allergic reactions. o Careful monitoring of hemodynamic parameters is essential during and after the procedure.

Lithotripsy	**10**	- Stone location and size can affect the procedure's success and the amount of radiation exposure. - The ALARA principle should be followed. This means using the minimum shock wave energy necessary to fragment the stone. - Potential complications include pain, hematuria (blood in the urine), and infection. - Pain management strategies should be in place to minimize discomfort during and after the procedure. - Pacemaker patients can undergo lithotripsy with cardiologist approval and safeguards. Lithotripsy can destroy abdominal rate-responsive pacemakers. - Consider the following limitations when performing lithotripsy: o Pregnancy. o Patients on "blood thinners" or with bleeding problems. o Patients with chronic kidney infection may not pass all fragments; therefore, bacteria may not be entirely removed. o Patients with ureter obstruction or scar tissue may block the passage of stone fragments. o Patients that need immediate/complete stone removal. o Patients with stones composed of cysteine and specific types of calcium are unsuitable for lithotripsy, as these stones do not fragment effectively.
Pediatric Radiology	**11**	- Radiation protection equipment shall include, but not be limited to: o Pediatric shielded aprons and thyroid collars. o Pediatric shielded gonad diaper. o Pediatric spinal stole. o Pediatric half apron. o Pediatric shielded mittens. o Pediatric lead eyeglasses. o Head and hand pediatric protection equipment. o The provision of pediatric imaging accessories and supplies. o Proper store of the equipment to ensure its safety and efficiency. o Annual tests of the radiation protection equipment. - HCP shall keep the following records within the radiology department for reference: o Keep a record of each X-ray procedure with radiation dose data.

		○ Pediatric radiation protection program. ○ Documentation of X-ray exam justification. - Protection equipment tests for shield integrity (for the last two years).

Chapter Five: Nuclear Medicine Devices

Procedures Control	**1**	- To ensure both patients and operators are safe when using nuclear medicine devices and radioactive materials, the HCP and RSO shall have procedures for the following: o Wearing, handling, and storing personal dosimeters. o The HCP and RSO must determine the values for any relevant investigation or authorized level and follow the appropriate procedure if any applicable value exceeds the limit. o Ordering radionuclides, unpacking, and verifying shipments. o Radioactive waste. o Administration of radiopharmaceuticals. o Patient examinations. o Care of radioactive patients. o Actions to minimize radiation exposure during unusual events, such as accidental contamination. o Implement strategies and techniques to cleanse individuals, gadgets, and surfaces while restricting activities allowed in areas where sources are stored and handled, such as refraining from eating, drinking, or smoking. o Manage sources by swiftly extracting them from transport containers and verifying their integrity. o Checking the correctness of labels. o Checking for contamination. o Radiation, radioactivity, pregnancy, and breastfeeding signs. o Radiation investigation levels for staff exposure.
Operators Control	**2**	- The department must secure its doors with a card or access code to prevent unauthorized access. - A qualified expert and/or RSO should provide radiation safety tuition for all staff caring for nuclear medicine patients. - Install adequate shielding in the radioactive materials room. If the room's intended use, the type of work, the radionuclides, and their intended activities change, the patient workload shifts, or the occupancy of the surrounding room alters, additional assessments are necessary. - Installing a visible radiation monitor from the outside area is mandatory in the room that uses radioactive material. Additionally, all survey meters and radiation monitors used

		for workplace monitoring must be calibrated and traced back to the SSDL. - Install a communication device inside the hot lab for use in an emergency. - Install a surveillance camera inside the hot lab. - Maintaining a high level of hygiene and cleanliness in the working environment is essential.
Radiation Protection	**3**	- Protective devices shall be available for use within the nuclear medicine department but shall not be limited to the following: o Lead barriers with lead glass windows (fixed or removable). o Benchtop shields. o Shielded syringes. o Vial Shields. o Lead walls or castles for shielding. o Shielded containers for the transport of radioactive materials or waste inside the institution. o Forceps and tongs to maintain a safe distance from the sources. o Protective clothing, such as lab coats, laboratory gowns, waterproof gloves, and masks for aseptic work. o Fume cupboards. o Barriers incorporating Perspex shields for work with beta emitters. o Radiation and contamination monitoring equipment. o Drip trays to minimize the spread of contamination in the case of spillage. o Dose calibrator. o Fume hoods. o Radioactive waste storage containers. o Sealed calibration sources (for dose calibrator, well counter, and gamma camera). o Well counter. o Whole-body/ring dosimeters for all authorized users. o Each room should have its exhaust systems and activated charcoal gas traps. - Emergency kits that shall be provided include: o Protective clothing, such as overshoes and gloves. o Decontamination supplies for the impacted regions, incorporating absorbent materials to clean up spills. o Decontamination materials for people. o Warning notices.

		○ Portable monitoring equipment. ○ Bags for waste, tape, labels, and pencils. ○ Sink and eye washer/shower. - The design of the nuclear medicine department shall ensure the following: ○ Safety of radiological sources. ○ Optimized reduction of radiation exposure of staff, patients, and the public. ○ Prevention of the uncontrolled spread of contamination. ○ Maintaining a low background where it's most needed. ○ The requirements for pharmaceutical work are met.
Imaging Room	**4**	- The size of the imaging room depends on the gamma camera, SPECT/CT, and other equipment and accessories, but it should typically be at least 25 m^2. - Separate the imaging room from the dispensing laboratory and shield it adequately from radiation sources other than the patient.
Hot Lab	**5**	- Laboratory size must be sufficient for ease of use. Different surfaces should be available for radioactive materials and bookwork. - The hot lab should be positioned away from public places, office areas, and areas where it cannot guarantee security. - Any workbench that handles radioactive materials must have a shielded workstation with a lead glass screen or lead Perspex for gamma radiation and Perspex or another clear plastic for beta radiation.
Isolation Rooms	**6**	- An inpatient treated with more than 400 MBq of I^{131} shall be in a single bedroom equipped with a toilet, shower, and bathroom. - The flooring shall be smooth, continuous, and non-absorbent. - Cover the walls and furniture with a non-absorbent surface for ease of decontamination. - The bed must be located away from other hospital beds in neighboring rooms. Depending on the wall construction, additional shielding may be required. However, the design should ensure that a non-radiotherapy patient in the following neighboring bed receives less than 0.3 mSv/procedure while a single therapy patient is present. - Before conducting a contamination check, provide temporary storage containers for used utensils and linen. - Terminate the drainpipes from the bathroom in a delay tank. - Equip rooms with movable shields.

Quality Assurance Program	**7**	- QA in nuclear medicine shall include the following: ○ Acceptance, commissioning, and quality control (QC) of devices and software. ○ QC of radiopharmaceuticals, radionuclide generators, and other unsealed radionuclides. ○ Selection of the correct procedures for the patients. ○ Appointment and patient information. ○ Clinical dosimetry. ○ Optimization of the examination protocol. ○ Waste management procedures. ○ Staff training and continues learning. ○ Record keeping and report writing. ○ Clinical audit. ○ General outcomes of nuclear medicine services.
Medical Exposures	**8**	- Unless justified and documented, therapeutic patients cannot be discharged from the hospital before radioactive substance activity in the body falls below 400 MBq. - Before their discharge from the hospital, the patient shall receive written and verbal instructions regarding contact with others and pertinent radiation protection precautions. - To protect radionuclide therapy patients and individuals, the department must control visitors and provide adequate information and instructions before they enter the room. - Optimized measures must be implemented, as appropriate, to limit public exposure to contamination in publicly accessible areas for sources under the HCP's purview. - Before administering a nuclear medicine test to pregnant patients, it is necessary to perform a risk assessment; if justified, the administered activity should be as low as possible, provided it delivers the required diagnostic information. - Shall guide the breastfeeding patient on the appropriate time to spend near the child to mitigate external radiation. Upon receiving this advice, the child shall receive an effective dose of less than one mSv. Recommend discontinuing breastfeeding for a brief period. - Regarding radiation accidents, please refer to the SFDA guidelines for the radiation accident prevention plan for radioactive accidents in healthcare facilities.
Radioactive Sources and Waste	**9**	- Internal transport shall include, but not be limited to, the following:

		○ Procedures shall who is always responsible for the radioactive material. ○ The HCP shall carry out a prior risk assessment to consider the consequences of reasonably foreseeable incidents and how to protect against them. ○ Transport the radioactive material in a suitable container. ○ The radioactive material shall be doubly contained in a rigid outer container designed to prevent leakage should the primary container break. ○ Line the container with absorbent material to contain spills and offer sufficient defense against external radiation. ○ Avoid leaving the radioactive material container unattended in public areas or with staff not involved in its transportation. ○ Label containers appropriately, ensuring the label contains details about the transported radionuclide. The HCP is responsible for removing labels from empty containers. - If HCP loses radioactive sources or damages the radioactive container, report the incident immediately to the RSO, the SFDA through the NCMDR, and all relevant bodies. - Radioactive material storage shall include, but not be limited to, the following: ○ Protection against environmental conditions. ○ Provision of storage solely intended for radioactive materials. ○ Provide sufficient shielding. ○ Resistant to fire. ○ Securing the radioactive materials.
Record Control	**10**	- The department must maintain, but not be limited to, the following records: ○ Certificate of authorization, application documentation, and licensee-regulatory authority correspondence. ○ Patient records. ○ Patient discharge surveys for patients receiving radionuclide therapy. ○ Personal dose monitoring (to be kept for the previous five years). ○ Results of area monitoring. ○ Acceptance test. ○ Medical devices and instrument QC tests and calibration. ○ Installation, maintenance, and repair work. ○ Facility modification.

		○ Inventory of unsealed and sealed sources. ○ Transportation: a. Package documentation. b. Package surveys. c. Transfer/receipt documents. d. Details of shipments dispatched. ○ Radiactive waste disposal reports. ○ Incident and accident investigation reports for the working period. ○ Audits and reviews of the radiation safety program. ○ Workers' training certifications.

Chapter Six: Radiotherapy Devices

Pregnant Patient Receives Radiotherapy	**1**	- After consulting a radiation oncologist, radiotherapy may be used to treat cancers other than the pelvis.
		- Cancers in the pelvis will require careful consideration. The oncologist must discuss whether to:
		  ○ Proceed with radiotherapy.
		  ○ Delay the treatment until after birth.
		  ○ Terminate the pregnancy.
		  ○ Use alternative therapy.

Linear Accelerator Safety	**2**	- Independent assessment to verify measurements made by the medical physics department. - Staff shall conduct safety checks of the machinery's dose calibrations and body positioning features every morning before treatment. They shall also conduct monthly mechanical and imaging medical device checks and annual comprehensive QA/QC testing.
Treatment Planning	**3**	- Radiation therapy physicians and senior therapists shall independently review all patients' treatment plans. - The first step is to deliver intensity-modulated radiation therapy (IMRT) plans on a test basis to a plastic model (the phantom) to ensure the LINAC will accurately provide the planned treatment.
Treatment Delivery	**4**	- The treatment planning system automatically transfers the dose and radiation beam shape settings to the LINAC to prevent transcription errors or miscommunications. - Video monitors enable staff to view radiotherapy treatments in progress. - As the patient enters the department, an automated bar-coding system ensures proper patient identification. The LINAC displays treatment information. A mandatory safety pause occurs before the first treatment. - Perform high-level review of proposed new treatments. - All proposed new treatments require the approval of a committee that includes senior representatives from each department section. The committee shall review proposed new treatments' policies, procedures, and safety records and recommend necessary resources. - The room system should automatically provide additional extract ventilation when exposure to radioactive gases or vapors, such as radon or thoron arises.

Chart Checks	**5**	- Patient medical charts shall be initially reviewed by a quality chart therapist. During chart or new patient rounds, all radiation therapy staff and representatives from each department section shall peer-review all patient charts and treatment plans.
Inspection and Certification Program for Radiation Therapy Systems	**6**	- Medical physicists shall conduct safety checks of the machinery's radiation output, beam-shaping devices, imaging, and body-positioning features every morning before treatment. A weekly, monthly, and annual measurement schedule guides the execution of more extensive tests. - Qualified LINAC system engineers shall perform PPM quarterly per the manufacturer's guidelines. Manufacturer engineers may be consulted and brought in as needed. - For area monitoring, it is helpful to stipulate specific radiation fields derived from the actual radiation field. - Internal rules for the operation, entry, and movement of material shall be written and reviewed regularly; they shall include: o Name of the responsible person. o Round the clock emergency procedures in the event of an accident or incident in the radioactive sources store.
Equipment Servicing	**7**	- The equipment supplier or the organization housing the equipment may employ equipment service personnel. In either case, the responsibility to comply with the organization's protection requirements and procedures remains the same. The equipment-servicing agency must employ appropriately trained and licensed personnel to service the equipment. Its personnel should: o Meet the training and certification requirements endorsed by the relevant professional body and any authorization required by the appropriate regulatory authority. o The personnel in charge of installing and maintaining equipment shall adhere to the relevant specifications outlined in the contract between the supplier and the radiotherapy facility or between the service firm and the facility. o Undertake ongoing professional development to ensure the knowledge and skill base remain current. o In addition to any formal qualifications and training required by the relevant professional body, service

		personnel should attend training courses offered by the manufacturers to install new or upgraded equipment. When equipment updates or function warnings occur, manufacturers should notify all service personnel. This applies equally if a contractor is involved in equipment maintenance. - Equipment servicing agencies should retrofit safety modifications as soon as possible. - Maintaining a higher level of hygiene and tidiness in the work environment is necessary.
Radiation Safety	**8**	- This instrumentation should include an area radiation monitor safe against a power failure inside the treatment room, a Geiger-Müller (GM) survey meter, and a large-volume ionization chamber. Access to a neutron-measuring instrument is required for accelerators with energies of 15 MV and above. - Perform the shielding survey tests every two years or after any significant modification. Conduct the survey in accordance with the manufacturer's recommendation and ensure thorough documentation. The radiotherapy department shall maintain the records. - Bunkers and brachytherapy rooms must have visible radiation monitors outside. Furthermore, an SSDL must calibrate all survey meters and radiation monitors used for workplace monitoring. - The department must secure its doors with a card or access code to prevent unauthorized access.
Quality Assurance – Clinical	**9**	- Acceptance testing of radiotherapy equipment: o At initial installation, the radiotherapy and associated systems need to undergo a series of acceptance tests to ensure that the equipment's performance agrees with the manufacturer's specifications, complies with local and/or international standards (where applicable), and follows any requirements of the relevant regulatory authority. o A qualified expert must perform or supervise the calibration and dosimetry. o Thorough documentation of the acceptance test results is necessary. They partially define the acceptable parameter range to monitor in subsequent constancy testing. - Special calibrations:

		○ In some exceptional cases, response measurements similar to those of a typing test are necessary for unique calibrations. - Routine calibrations: ○ These aim to establish a calibration factor suitable for the regular use of the dosimeter. ○ Could confirm a routine calibration by either verifying the calibration the manufacturer performed with the dosimeter or by verifying the calibration factor's stability over extended use. - Clinical protocols and treatment policies: ○ The person responsible for protocols shall ensure that no radiation procedure is carried out unless justified and approved for each individual. In practice, the radiation medical practitioner will collaborate with other staff members, including the qualified expert and the radiation therapists, who will undertake these functions. ○ Each facility should develop and implement a comprehensive program of clinical protocols or treatment policies for patient care. Such protocols should be widely available and regularly updated. ○ Protocols and policies should include details of the radiotherapy prescription and the required procedures for planning, verification, dose delivery, and QA activities. Detailed evidence supporting the protocol or procedure may also be helpful.
Constancy Testing	**10**	- Constancy Testing: ○ Following acceptance, HCP shall perform regular constancy tests to assess the system's subsequent performance. ○ Regularly review the results of constancy testing by a qualified expert and promptly report any abnormal results to the person responsible for the QA program. ○ If the constancy testing shows that the systems exceeds acceptable tolerance, identify the cause and take appropriate remedial action, including replacement.
Ward Staff	**11**	- A qualified expert and/or an RSO should provide radiation safety tuition for all staff caring for brachytherapy patients. - Nursing staff should be familiar with the precautions for brachytherapy patients, including safety requirements for domestic staff and visitors and the nature and duration of the hazard.

		- The qualified expert, or RSO, should provide individual protocols for the different types of brachytherapy and actions to take when unexpected interruptions occur. - Staff should have quick access to radiation safety practices and documentation on treatment procedures. - Nursing staff should be instructed to wear a personal dose meter. - Nursing staff should refrain from participating in patient care involving sealed radionuclides if they suspect they are pregnant or use of I^{131}. - In certain circumstances (such as when routine nursing care is required), using a roster system of duties to reduce individual doses may be desirable, but this should differ from standard radiation protection practices.
Personal Monitoring	**12**	- All persons operating or otherwise dealing with radiotherapy equipment or radioactive sources for radiotherapy purposes should be monitored with personal radiation monitors (such as film or optically stimulated luminescence (OSL) dosimeters or thermoluminescent dosimeters (TLD)) unless it can be shown that the exposure is controlled by integral shielding with an adequate dose below one millisievert (mSv) per year. - An SFDA-recognized service provider shall assess the monitoring and provide it. - Typically, the monitors should be worn on the trunk, between the waist and the shoulder, and under protective garments. - In some circumstances, a personal direct-reading electronic dosimeter may be better than or in addition to individual radiation monitors. Ward nurses may want to use one instead of the monitor, or facilities like high-dose-rate (HDR) brachytherapy may wish to have one in an emergency. - The time to allocate a monitor will depend on the expected doses received during the wearing period. Regularly changing personal radiation monitors, along with the type of radiation and procedures performed, should determine the appropriate monitoring period. The exposure occurs behind fixed structural shielding (such as linear accelerators or remotely controlled brachytherapy); a monitoring period of three months is generally satisfactory. Operator skill is required to keep doses as low as possible during the

		exposure (e.g., manual brachytherapy or source handling); we recommend a shorter monitoring period of one month. - If an unusual exposure situation arises with the potential for a reportable dose, it is essential to adjust the monitor and provide a replacement immediately. - For some brachytherapy and source handling procedures, monitoring extremity doses is advisable if the dose to the hands is likely to exceed 1/10 of the appropriate dose limit. Although the fingertip will usually receive the maximum dose, wearing the monitor at the base or middle of the finger is customary. Wearing it on the fingertip may harm tactile functions.
Room Design	**13**	- The floors, walls, ceilings, and doors must be built using materials that ensure adequate radiation protection for workers in a fixed facility. - Shielding designs should sufficiently attenuate the dose inside and outside the examination room. - Documentation of the construction details must justify the installation of shielding. - Treatment rooms should have emergency switches controlling the primary power source for the radiotherapy equipment to allow for emergency termination of radiation exposure. - The emergency switches should be visible and easily accessible to staff from anywhere in the treatment room. They should be of a ‘mushroom' or similar simple 'hit-it' type. - Installation of the emergency switches is to be such that each switch will cut off all power, including radiation exposure and gantry movement, to ensure 'latch out' safety. These devices might be used, for example, to terminate patient treatment: ○ in the event of uncontrolled movement of the patient, ○ in the event of a staff member being accidentally left in the treatment room after the commencement of the treatment, or ○ To allow urgent access to the patient. - The appropriate manager should familiarize staff members with the positions of all "emergency off" buttons before allowing them to operate the unit. - For rooms containing linear accelerators offering the possibility of photonuclear (neutron-producing) reactions, all controlled area doors should have a 6.2 cm-thick plate of

		5% borated polyethylene sandwiched between two sheets of lead or an equivalent thickness. - The purpose of the maze in a radiotherapy room is to attenuate the photons and neutrons that the primary beam produces when it interacts with the surfaces and patients inside the space. - During radiation exposure, the operator (usually a radiation therapist technologist) must observe the patient and couch area. The usual method involves closed-circuit TV monitoring the patient beside the control panel. - An intercom system should allow two-way audible communication between the operator and the patient. - The radiotherapy department should have surveillance cameras installed. - Waiting areas: o There should be separate waiting areas for clinic patients and those awaiting treatment. o Each physician's waiting clinic area should be limited to approximately eight patients. o The waiting treatment area should be adjacent to the room, limited to approximately twelve people per device. o Stretcher patients should be kept apart from ambulatory patients beside the treatment area. o The area should be large enough to accommodate three stretchers. o Patients will often have to remove some of their clothing for treatment. As such, provision should be made for appropriate changing facilities close to the treatment room entrance. These should be protected from the view of other patients and visitors, also negating patients from having to undress in the treatment room. This will shorten the duration of each patient's treatment.
Security, Storage, and Handling	**14**	- Security: o The responsible person should provide the local fire service with details of the location of any sealed source safe or store and instructions in case of a fire. o For the benefit of emergency personnel, radiation warning signs should be installed at all access points to the store, relevant rooms, and other sites within and outside the building. These signs should include the contact details of the RSO or another representative of the responsible person.

		- Storage and Handling: o Responsibility for the brachytherapy sources are to be held under a specified qualified individual, their contact details being clearly identified. The responsible person must maintain a register of the sealed sources. For accounting purposes, the sealed source register should always track all movement of the sources. o The details about the sealed source(s) must be attached to the outer case of the brachytherapy system or sealed source container. This should include the radionuclide, activity, date of activity measurement, and, if applicable, source identification numbers such as serial numbers. Label each container with a radiation trefoil. o Each radioactive source used for radiotherapy needs to be safely and securely stored when it is not in use and should be subject to the following requirements: a. A locked and fixed container or device holding the source. b. The storage room must be secured, keeping the container safe from unauthorized individuals. c. Control access to the storage room must be maintained. d. The process must involve identifying and preventing any unauthorized entry or removal of the source. e. There must be the ability to respond promptly to such detection.

Chapter Seven: Medical Radioactive Materials

General	**1**	- Radioactive medical material shall obtain approval from the SFDA of technical and clinical specifications before starting importing/exporting processes. - A package shall not contain items other than those necessary for the use of the radioactive medical material. According to the transport conditions applicable to the design, interaction between these items shall not compromise the safety and security of the package.
Labelling	**2**	- Labelling general requirements: o Package type. o Sender/receiver. o UN number. o Design ID and serial number. - The label type is determined by: o Surface dose rate (dose at the surface). o Transport index (max dose rate at a distance of 1 m (uSv/hr) /10). - Label categories are: o White label-I: a. Surface dose less than 5 uSv/hr. b. Dose rate at 1 m less than 0.05 uSv/hr. c. Transport index = zero. o Yellow label-II: a. Less than 500 uSv/hr and greater than 5 uSv/HR at the surface. b. Less than 10 uSv/hr at 1 m. c. Zero < TI < 1. o Yellow label-III: a. Surface dose rate greater than 500 uSv/hr and less than 2000 uSv/. b. Dose rate at 1 m greater than 10 uSv/hr and less than 100 uSv/hr. c. One < TI < 10.
Storage	**3**	- All radioactive medical materials stored in the designated storage shall be securely enclosed in appropriate containers to allow safe handling and treated as sealed sources. - The radioactive medical storage area must be isolated from other potential hazards and non-radioactive material stores to ensure safety.

		- Dose rates outside the storage area must be restricted so that they do not exceed10 uSv/hr at any accessible point on its external surface fore occupationally exposed persons and 0.5 uSv/hr at any accessible point on its outer surface of members of the public. - It is recommended to use radiation shielding on external walls and internal partitioned areas to define spaces dedicated to specific types of sources, ensuring safe separation between different categories of radioactive medical materials. - If there is a possibility that any contents of storage area may release significant amounts of radioactive gas or vapor (such as radon or thoron), an automatic additional ventilation system capable of extracting air during opening must be provided. - Clear warning signs and labels must be displayed on the doors and walls inside the storage area. - Storage warning sign shall include: o A warning sign of ionizing radiation. o A sign that prohibits unauthorized entry. o A warning sign indicating caution: radioactive material. - Access to the storage must be subject to strict controls and must include defined procedures for handling emergency situations. - The storage shall be under personal supervision. - A monitoring system for radioactive medical material storage area must be provided, including measuring devices and alarm equipment to ensure early detection of any leakage or unauthorized increase in radiation levels.
Handling	**4**	- Shall provide containers with radioactive medical material with a label that includes: o The Ionizing radiation warning symbol. o Contained radionuclide. o The activity of the contents. o Measured data of the radioactive medical material. o Name and affiliation of the person responsible for the container. o The label should provide clear instructions for the safe transportation of the radioactive medical material. - Write and regularly review internal rules for the entry and movement of material. It shall include written internal procedures for the entry and movement of radioactive

		medical materials that must be established, implemented, and reviewed periodically. These procedures shall include: o Name of the responsible person. o Clearly defined emergency procedures to be followed in the event of an incident or accident within the storage area. - All personnel working with or in proximity to radioactive medical materials must practice ALARA at all times. This principle aims to minimize radiation exposure through the following key measures: o Time. o Distance. o Shielding. - The following procedure must be followed when opening packages containing radioactive medical material: o All radioactive packages received by the radiology department must be inspected within four (4) hours of arrival, or immediately upon commencement of the department's official working hours. o Personnel must wear protective gloves to prevent hand contamination during unpacking. o All areas within the hot lab (radioactive work area) where packages are to be received and opened must be fully prepared and secured. o Packages containing radioactive medical material must be equipped with a tamper-evident security seal. o Upon receipt, all packages must be inspected for type I, II, and III labels at a distance of 1m from the package surface. o If the measured exposure rate of a package containing radioactive medical material exceeds the level indicated on the label, the SFDA and the final delivery carrier must be notified immediately. o Any visual evidence of damage, moisture, or leakage must result in immediate containment of the package and notification of the radiation safety officer (RSO). o A wipe test should be performed on all six sides of the package, covering a minimum area of no less than 300 cm^2. o A second visual inspection must be conducted inside the package, covering an area of no less than 300 cm². o Immediate notification must be issued to the licensee and the transport provider if radiation levels exceed

		2000 uSv/hr at any point on the surface of the container or 100 uSv/hr at a distance of 1 m from the surface. ○ The contents must be removed using tongs or other appropriate tools, and the empty shipping container must be surveyed for residual radioactive contamination. ○ Each licensee must establish, maintain, and retain a written procedure for safe opening of packages containing radioactive medical materials. This procedure must be regularly updated and retained as part of the facility's radiation safety records, ensuring full compliance with all outlined requirements.
Transfer	**5**	- All radioactive medical materials ordered shall be listed on the license, and their quantities or activity levels must not exceed the authorized limits specified in the license. - The RSO is required to review and approve any order of radioactive medical materials prior to receipt or use. - Procedures for receiving radioactive medical materials should detail how the delivery will reach the radiology department. - The receiving of packages containing radioactive medical material at the hospital must be conducted exclusively by the RSO or an authorized representative under their supervision. - The package delivery location must be secured, shielded, and monitored.
Disposing of radioactive medical material	**6**	- Radioactive sources could be disposed of using several methods, in accordance with the manufacturer's recommendations, such as: ○ Materials may be stored in a licensed radioactive waste storage area until they decay to safe levels, following the ten-half-life rule. ○ Radioactive materials may be diluted and dispersed into the atmosphere or discharged into a sanitary sewer system, in compliance with applicable legislative restrictions imposed on disposal activities. ○ Return the spent material to the manufacturer or supplier. - Disposal of empty containers : ○ A wipe test must be performed on both the interior and exterior surfaces of the empty container.

		○ All radiation labels, symbols, and markings must be removed or obliterated to prevent any potential misuse or confusion. ○ An empty label along with the UN 2910 must be affixed to the container prior disposal. - Returning radioactive medical materials to manufacturer or supplier: ○ Arrangements for returns should be made in advance, in accordance with the applicable requirements, and coordinated directly with the manufacturer or supplier, who must provide the necessary paperwork. ○ The source must be properly packaged, labeled, and transferred in compliance with the requirements and approval of the RSO. ○ Any radioactive medical materials that are no longer usable must be returned to the approved receiving bodies within 90 days from the date of assessment by the RSO. - Disposal of solid radioactive medical waste: ○ HCPs may store solid waste with half- life of 120 days or less for extended period to allow for radioactive decay before final disposal. ○ Carefully monitor, label, and stored securely until their activity level fall to background radiation levels. ○ If the material has decayed to less than twice the natural background level, it may be transferred to the appropriate regular waste stream for disposal. ○ Prior to disposal, all radiation signs, labels, and symbols must be defaced or completely removed to avoid any unintended reuse. - Disposal of Liquid radioactive medical waste: ○ Small quantities of liquid radioactive medical waste that are soluble or dispersible in water can be discharged into a designated sink connected to a sanitary sewer system, provided the total annual discharge does not to exceed (1Ci (37 GBq) / per year). ○ The maximum permissible concentration specified of radionuclides allowed for release is determined based on the licensee's overall wastewater discharge rates and the total amount of radioactive activity released annually.
Records	**7**	- The licensee, owner, and responsible person shall maintain an up-to-date record of all stored radioactive medical materials and a record of their location at all times.

		- All records related to the use and handling of radioactive medical materials must be retained for specified period as follows: o Personnel instructions of patient care for brachytherapy - 3 years. o Disposal of radioactive medical materials by decay during storage - 3 years. o Iodine-131 thyroid bioassay record – until license termination. o Patient dosage records - 3 years. o Patient care personnel instructions for iodine-131 therapies - 3 years. o Procedure for patient identification - duration of the license. o Procedure for verification of patient identity - duration of the license. o Record of administered patient doses - 3 years. o Record of sealed source inventory - 3 years. o Record of sealed source leak test - 3 years. o Records of decay in storage disposal - 3 years. o Records of patient release - 3 years. o Written directives - 3 years. o Date of disposal, type, and amount of radioactive medical materials – until license termination.

Chapter Eight: Medical Imaging Materials

General	**1**	- The medical physics department shall be responsible for the full oversight of the safe use of medical imaging materials (MIMs). - HCPs shall regularly review radiation risk, local rules, and emergency plans. - The MIMs packaging must include clear and accurate labeling, including the intended use, dosage, precautions, and potential side effects. - Manufacturers must provide detailed instructions for HCPs regarding administration of the MIMs, including appropriate dosages, contraindications, monitoring, and safety requirements.
Importation	**2**	- Ensure full compliance with the Requirements for the Import and Clearance of Medical Imaging Materials and Particle Accelerators Used in Radioisotopes Formation for Medical Applications (MDS-REQ 4).
Transfer	**3**	- The manufacturer's instructions for transportation must be followed to ensure safety, efficiency, quality, and performance. - HCP should handle the MIMs carefully to prevent contamination.
Quality	**4**	- MIMs must comply with specific quality standards to ensure clear diagnostic imaging and sustainability for clinical interpretation.
Use	**5**	- Patients must sign an informed consent form before receiving an MIM that includes information about the risks, benefits, and alternatives. - An appropriate dosage of MIMs must be administered in accordance with the manufacturers. - Patients may require direct medical monitoring during and after administration of the imaging agent to detect any potential of adverse reactions. - HCP must report any serious adverse events associated with the use of MIMs to the NCMDR.
Storage	**6**	- MIMs must be stored in accordance with the conditions specified by the manufacturer, to maintain their potency and stability.

		- Storage area must be ensured to provide a secure and controlled environment to prevent unauthorized access or physical damage to the materials. - Must maintain a stable temperature and humidity level as recommended by the manufacturer to avoid image quality degradation. - Tracking and documenting the storage phase is crucial for MIMs, as they are susceptible to expiration, recall, or improper storage.
Risk assessment	**7**	- A comprehensive risk assessment of patient must be conducted, weighing the potential radiation risk against the diagnostic benefits of the MIM-assisted examination. - Use imaging alternatives that offer comparable or superior diagnostic data should be considered.
Pregnant patient	**8**	- The use of MIMs in pregnant or potentially pregnant patients must be strictly controlled and closely monitored, taking into account any potential fetal radiation exposure. - Administration of MIMs during pregnancy should be regarded as a high-risk procedure, and must only be performed if the expected diagnostic benefit clearly outweighs any potential unknown risks to the fetus.
Disposal	**9**	- If MIMs are used in glass bottles, they are considered hazardous sharp material, even if undamaged, and must be disposed of in biohazard buckets as puncture-proof containers.

Chapter Nine: Dental Intraoral and Panorama X-ray Devices

Management and Organization	**1**	- Medical physics department shall manage dental X-ray practices within hospital services. - HCP shall periodically review radiation risk assessment, local rules, and emergency plans.
User	**2**	- Comply with the following Requirements for Safe Use of Medical Devices inside Healthcare Facilities (MDS-REQ 3): o Providing personal protection supplies from the risk of ionizing and non-ionizing radiation for workers and patients, committing to using them, as follows: a. Provide an adequate number of different sizes (for adults and children) and uses (e.g., full body apron, thyroid collar) and any other protective equipment in each room containing an ionizing radiation-emitting medical device. Thyroid protectors can be used during intraoral and portable X-ray procedures, while full-body protectors are appropriate with panoramic devices. b. Use PPE if it does not interfere with the imaging procedure. c. Store PPE according to manufacturer instructions and replace damaged items immediately. d. Test PPE periodically to ensure their efficiency and retain test reports. - Patients should be informed about the radiation dose administered and clear explanation of possible outcomes. - Conduct a risk assessment to estimate the annual radiation dose expected for classified workers in dental radiology departments, and determine whether personal dosimeter badges are necessary. - Pregnant operators shall use personal radiation dosimetry and/or appropriate PPE.
Device Room	**3**	- Comply with the following requirements: o Equip panorama room's doors with ionizing radiation warning signs in Arabic and English, including pregnancy warning signs.

		○ Conduct the necessary periodic tests to ensure the shielding efficiency and structural integrity of panoramic rooms, and retain all test reports. ○ Panoramic rooms should have a lockable entrance.
Handheld Dental X-ray	**4**	- A handheld medical X-ray device shall be within reasonable limits (2.2–5.0 kg), so it needs to be handled with due care and caution to avoid accidents. - Designation areas for using handheld medical X-ray devices shall be identified, along with its specific safety control. - Patients should be transferred to a fixed unit or a mobile unit shall be used instead for examinations in which the handheld unit is considered impractical or medically unacceptable. - Must secure and lock handheld X-ray equipment to prevent reasonably foreseeable loss, theft, or unauthorized use. - HCPs must report any critical incidents involving handheld X-ray devices to the (NCMDR), such as: ○ Instances where equipment damage compromises internal shielding. ○ Accidental exposure of a person (other than the patient) to the X-ray beam. ○ Failure of the timer to terminate the exposure. ○ Loss or theft of the equipment.
Training	**5**	- Dental practice staff (e.g., dentists, nurses, hygienists, and therapists) will need to update their radiation safety training following the introduction of handheld X-ray equipment. - Operators shall undergo an appropriate practical training course and be provided with handheld X-ray equipment instructions.
Records	**6**	○ Periodic QA tests shall be conducted on dental X-ray devices by qualified and trained specialists from the HCP or licensed third parties service provider approved by the SFDA, and test reports must be retained. ○ Personnel dosimetry readings (e.g., TLD, OSL) for panorama X-ray operators must be kept on file for at least five years as a reference and available when requested.

Chapter Ten: Medical Diagnostic Dose Tracking System

General	**1**	– HCPs using ionizing radiation-based medical imaging devices should have radiation dose monitoring software that automatically tracks and analyzes patients' ionizing radiation dose information, imaging protocol data, and patient demographics, including age, gender, and weight.
Purpose	**2**	– Radiation dose data shall be monitored, collected, and analyzed to: o Achieve acceptable image quality with the lowest reasonable radiation dose (the ALARA principle). o Implementing NDRLs. o Find the facility's reference level (FRL). o Compare FRL with NDRL. o Limit the annual number of radiological examinations per patient. o Determining the total ionizing radiation doses received by each patient across all procedures. o Compare the patient dose data with population-level diagnostic radiation exposure data.
Management and Organization	**3**	– Comply with requirements for Safe Use of Medical Devices inside Healthcare Facilities (MDS-REQ 3) (Sections B, C, and D). – HCP must apply for and commit to updated NDRLs values, and retain all relevant records accordingly. – Appoint a qualified authorized person to manage the follow-up program of the NDRLs in the facility in association with the following: o Head of the radiology department. o Medical physicist. o RSO. – Upon request, the authorized representative shall submit HCP-registered doses reports to the SFDA within 90 days from request date, and sent via email to: NDRL@sfda.gov.sa.
Inspection & Maintenance	**4**	– Justifications shall be given when NDRLs are exceeded, and the following shall be performed: o Ensure the success of QA tests. o Perform PPM in accordance with manufacturer's instructions.

		○ Ensure the data and dose reports submitted to the SFDA are accurate, including correct unit calibration and complete form filling. ○ Have imaging protocols reviewed jointly by the medical physicist, chief technician, and radiologist.
User	**5**	– Ionizing radiation dose data can also be manually collected, monitored, and analyzed, with access made: ○ Radiological imaging device directly. ○ The picture archiving and communication system (PACS). ○ The radiology information system (RIS).

Chapter Eleven: Medical Lasers

User	**1**	– Provide PPE for both staff and patients to protect them against the risk of non-ionizing radiation while adhering to the following: ○ Each room containing a medical laser device emitting non-ionizing radiation should have at least three appropriate protective eyewear units for each medical laser device and any other protective equipment. ○ The wavelength response of the eyewear must match the specific wavelength emitted by the medical laser device. ○ Avoid using any damaged eyewear. ○ PPE should be used whenever it does not interfere with the imaging procedure. ○ Store PPE properly to maintain its efficiency. ○ Periodic testing of PPE must be conducted to ensure functionality, and test records must be retained. – The laser departments should have radiation-warning signs (laser non-ionizing radiation) in Arabic and English on the doors of the laser rooms.
Operators Control	**2**	– Physicians prescribing laser based diagnostic or therapeutic procedures must conduct a risk-benefit assessment, ensuring that the medical benefits outweigh any potential risks. – Before each laser procedure session, patients must sign a consent form indicating their understanding of pre-session preparation instructions, side effects, and contraindications and keep signed forms within the department for at least five years. – Staff members must be aware of the potential health risks associated with laser operation and use, and must utilize all available preventive measures and protective devices during work. – Each clinic should have clear accessible operating procedure for the safe use of medical laser device.
Advertisement	**3**	– Obtain prior approval from the SFDA for all advertising materials promoting the use of medical devices and remove all unapproved advertising materials. – Energy-based devices used for vaginal "rejuvenation" or cosmetic vaginal procedures must not be used unless they have received a formal approval from the SFDA

		demonstrate that their safety and effectiveness have been clinically established.
Risk Assessment	**4**	- A risk assessment must be conducted regarding potential occupational health and safety impacts resulting from interactions between laser radiations and photosensitizing chemical substances in the workplace.

Chapter Twelve: Medical Magnetic Resonance Imaging Devices

Inspection & Maintenance	**1**	- Comprehensive safety measures must be implemented to ensure the safety of both the patient and the medical device from the potential hazards associated with the MRI's potent static magnetic fields, pulsed magnetic field gradients, and radiofrequency fields. This commitment to safety should instill a sense of security and protection in all involved. - Workers must be provided with an explanation of the MRI device program, outlining its duration and content. - MRI techniques must include proper positioning, coils, pulse sequences, and contrast agent administration.
User	**2**	- When using MRI devices, users must comply with documented policies and procedures related to magnetic field protection and safety.
Device Room	**3**	- The doors of MRI rooms must be equipped with warning signs (MRI non-ionizing radiation) in Arabic and English. - A dedicated safe zone must be assigned for MRI device operators to ensure their safety from potential radiation hazards. - Medical imaging and radiology rooms must be equipped with systems that allow the operator to continuously monitor the patient during scanning procedures. - Other requirements: o Clinical MRI and research systems must have effective radiofrequency (RF) shielding on their walls, windows, and doors. o The entrance to Zone 3, a designated safety zone, must be access controlled to prevent unauthorized access. o MRI-compatible fire safety equipment must be provided. o Ferromagnetic detector system (including handheld detector). o The following are general RF shielding sense frequencies: a. The RF flooring should incorporate monolithic copper, modular cell type, or pan form. b. A filter is required when dealing with electrical wires.

		c. If fluid (air or liquid), a waveguide is required. d. Emergency exhaust fans and pressure relief/pressure equalization grilles. e. Outward-swinging doors.
Quality Control	**4**	- The radiologist must participate in a continuous QA procedure to assess the quality of the MRI interpretation. Such a program should incorporate the following features: o Dual reading involves two physicians interpreting the same test. o The process should enable regular review of a random sample of studies. o Tests and procedures are descriptive of the actual clinical preparation of each physician. o The reviewer must assess whether the report aligns with the subsequent surgical, pathological, or review findings. o Classification of the peer-reviewed conclusions based on the severity of quality issues. o Provision of concise details and comparative analyses for every physician in each modality.

User	**1**	- Users of ultrasound equipment should strictly adhere to the specific safety guidelines provided by the manufacturer. - Operators should be fully aware of the potential thermal and mechanical bio-effects of ultrasound. - Users should implement ALARA principles and move the transducer continuously to prevent tissue overheating. Exam durations should be minimized to achieve effective diagnostic results. - Consider age, weight, and underlying medical conditions when performing ultrasound scans. - Ultrasound intensity should be adjusted to the minimum level required to obtain a clear image. - Set the device's acoustic output power control to a low default value. If a low default setting is impossible, set it low after turning it on. Choose a modest setting for new patients. Increase the study output only to achieve a decent result. - Avoid holding the probe longer than necessary and remove it from the patient when not acquiring real-time images or spectral Doppler. Use a freeze frame or cine loop to review and discuss photographs without continuing exposure. - Focused ultrasound treats specific tissues with high-intensity ultrasound. Only experienced physicians should perform it in a controlled setting. - Within 24 hours of extracorporeal shock wave lithotripsy, avoid using gas contrast compounds in a diagnostic ultrasonography examination. - Avoid using damaged probe. - Probe must be sanitized after each utilization. - Ensure the acoustic coupling gel is completely dry after each examination. - Use cleaning materials that comply with the manufacturer's instructions. - Use a soft, damp cloth to remove remaining contaminants from the probe. Avoid using soap, detergents, or enzymatic cleaning agents on clothing or reusable cloths. - Avoid exposing the system connector to liquids or moisture if cleaning procedures is required.

Device	**2**	- The maximum acceptable values for the derated spatial peak time average intensity ($I_{spta.3}$) and the mechanical index (MI) are 1.9 and 720 mW/cm², respectively. - Maintaining low MI values is crucial for obtaining diagnostically adequate pictures. - Ocular or general-purpose devices used in the eye should have a maximum allowable thermal index (TI) value of less than or equal to one. The MI value should not exceed 0.23. The highest permitted derated) $I_{spta.3}$) , must not exceed 50 mW/cm². - Real-time visualization of MI can help implement the ALARA principle when assessing the danger of capillary bleeding. If multiple MIs exist, the devices must meet the output requirements and administer the MI in B-mode. - During air operation, if the probe exhibits significant self-heating, do not use endo-cavitary probes, such as vaginal, rectal, or esophageal probes. This applies to all probes; however, special attention is required when using trans-vaginal probes to examine a pregnancy within the first 10 weeks post-LMP.
Pregnancy Test Limitations	**3**	- Sonography is must be conducted during pregnancy only when there is a medically justified indication, and using the lowest ultrasonic exposure setting is utilized for essential diagnostics.
Pediatric Test Limitations	**4**	- Use the shortest possible exposure time and the lowest possible intensity. - Consider using specialized pediatric transducers and techniques. - Caution must be exercised when employing Doppler ultrasound, particularly during fetal examinations, as it can elevate the likelihood of tissue inflammation. - The output display standard does not require real-time output displays within the maximum allowable TI. Fetal heart rate monitors should have a maximum spatial and temporal average intensity at the transducer face of less than 20 mW/cm² for both continuous and pulsed devices. - Special attention must be given to mitigate the danger of thermal hazards while subjecting the following to diagnostic ultrasound: ○ An embryo under eight weeks post-conception;

		○ The head, brain, or spine of any fetus or neonate; ○ An eye (regardless of the subject's age).
Quality Control	**5**	- HCPs must participate in a continual QA program to assess the quality of ultrasound interpretation. Such a program should include the following features: ○ Image Quality. ○ Spatial resolution. ○ Contrast resolution. ○ Uniformity. ○ Doppler performance. ○ Velocity accuracy. ○ Sensitivity and range.
Storage	**6**	- Store transducers cleanly in accordance to the manufacturer's instructions to prevent contamination or damage between mutilations. Probes could, for instance, be mounted vertically on a covered rack or in an enclosed transducer storage cabinet. - Ensure the probes are completely dry before storing them to reduce microbial growth. Avoid storing probes in plastic bags or their original packaging, as this may cause moisture entrapment, leading to microbial proliferation. - Following high-level disinfection (HLD), avoid letting the disinfected probe parts encounter surfaces, such as the unclean probe cable or storage rack. - Create guidelines and protocols for monitoring HLD or sterilizing probes. - To preserve sterility, keep sterile probes in their original, sealed packaging. - Avoid storing the probes in areas susceptible to damage or cross-contamination.

Chapter Fourteen: Medical Ultraviolet Devices

User	**1**	- Compliance with documented radiation protection and safety policies and procedures is mandatory when handling ultraviolet (UV) radiation devices.
		- HCPs must provide PPE for both staff and patients to protect them from the risk of non-ionizing radiation and adhere to the following:
		  o Adequate sizes (for both adults and children), various uses (e.g., protective clothing, eye/face protection, and gloves), and any other protective equipment in every room containing ultraviolet non-ionizing radiation.
		  o In the use of PPE, these should not interfere with the imaging procedure.
		  o Store PPE properly to maintain its efficiency.
		  o Test PPE periodically to ensure their efficiency and retain test reports.
		- Configure a dedicated area for operators of non-ionizing radiation devices to ensure their safety from radiation hazards.

Device Room	**2**	- The device room must adhere to the following requirements outlined in Section (d) of Requirements for Safe Use of Medical Devices inside Healthcare Facilities (MDS-REQ 3):
		  o Install warning lights at the entrances of non-ionizing radiation rooms, activated upon radiation release.
		  o Doors of the UV rooms should be equipped with radiation warning signs (UV non-ionizing radiation) in Arabic and English.
		  o Enable continuous patient monitoring in UV rooms.

Chapter Fifteen: New Technologies in Radiology and Medical Imaging

Regulatory Compliance	**1**	- Full compliance with Guidance on Artificial Intelligence (AI) and Machine Learning (ML) Technologies-Based Medical Devices (MDS-G010) requirements. - All AI medical devices shall conform to specific requirements, such as risk assessment and clinical evaluation. - It is crucial to monitor and update AI systems to ensure compliance with ongoing regulations and best practices. This provides a sense of security and keeps the HCP well-informed.
Classification	**2**	- The regulation of AI and ML technologies as medical devices depends on their intended applications. The product specifications and instructions for use, as well as any information provided by the product developer, are used to determine the intended use. - AI medical devices shall be classified based on their risk level. - Specific AI applications require premarket review and approval before gaining MDMA.
Data Privacy	**3**	- Patient data must be protected, including anonymization and secured storage. - Data privacy systems must address data sharing and cross-border transfer issues.
Algorithm Bias	**4**	- Prevention of bias in AI algorithms is required, as it can result in unfair or inaccurate outcomes. - Ensure training data to be representative of diverse populations.
Clinical Validation	**5**	- Rigorous testing and validation of AI algorithms are required to ensure their accuracy and effectiveness. - Demonstrable clinical utility and safety in real-world settings are required.
Transparency and Explainability	**6**	- Transparent communication about system limitations and potential risks must be provided to reassure stakeholders and build trust in AI-driven solutions.

		- It must be ensured that clinicians can understand how AI algorithms arrive at their conclusions.
Ethical Considerations	**7**	- Address ethical concerns related to the use of AI in healthcare, such as autonomy, beneficence, and justice.
Intended Purpose	**8**	- The intended purpose of AI should be to enhance disease diagnosis, treatment, or prediction, which could potentially improve patient healthcare or human well-being. - AI, ML, or DL should be helpful tools for end users, showcasing reliability, speed, and accuracy to enhance patient outcomes. - Manufacturers should ensure that the medical devices meet their intended purpose.
Data Security	**9**	- HCPs should implement suitable security measures to safeguard sensitive personal data related to patient healthcare during: o The collection phase. o The production phase. o Anonymization and pseudonymization. - HCPs should conduct a privacy impact assessment (PIA) to safeguard personal data integrity, security, and confidentiality. - Cybersecurity and data protection measures should be practiced.
Monitoring	**10**	- HCP should remain aware and compliant on regulatory aspects. - End-users should know the strengths and weaknesses of AI, ML, or DL-based analysis. - Individuals must identify the data type utilized in the models to enhance clinical application decisions.
Training	**11**	- Ensure that radiologists and other healthcare professionals receive adequate training and education on the use of AI in radiology. - AI developers must ensure they deeply understand radiology principles and clinical workflows.
Information System	**12**	- AI, ML, or DL could be integrated into hospital information systems (HIS) and PACS to enhance the user experience.
Quality Control	**13**	- Software must undergo QC checks to detect reactions related to motion artefacts, signal-to-noise characteristics, multimodality adaptability, misregistration, and other potential biases.

		- QA measures must be implemented to monitor the performance of AI systems over time. - It is important to continuously improve AI algorithms based on feedback and data analysis, to enhance innovation, technical flexibility, and future-oriented thinking.
Risk Management	**14**	- A comprehensive risk assessment must be carried out to identify potential risks associated with AI implementation in radiology departments. - HCPs should develop and implement strategies to mitigate identified risks.

Chapter Sixteen: Radiology Medical Device Decommissioning

General	**1**	- HCPs can only provide radiological medical services if they have obtained a practice license from the competent authority. - HCPs handling medical radiation sources, whether an X-ray generator or radioactive medical material, shall comply with sections (d) and (e) of the requirements for Safe Use of Medical Devices inside Healthcare Facilities (MDS-REQ 3). - Follow the Guidance on Manufacturing Paths of Medical Devices and Supplies (MDS-G011).
Management and Organization	**2**	- HCPs shall ensure radiation is ALARA to reduce risks and lower radiation doses for patients, staff, and the public. - HCPs shall comply with engineering controls to reduce occupational and public doses. - Establish a decommissioning strategy .The common steps for establishing a plan include: o Identifying or distinguishing a responsible individual . o Coordinate with relevant security and regulatory bodies throughout the process. o Establish a clear and feasible timeline for decommissioning activities. o Gathering all relevant data regarding the radiological information on facilities to be decommissioned . o Identifying options for safe disposal of the various facilities. o Identifying opportunities for waste management . o Establishing operational and financial aspects. o Collecting records and documents.
Dosimetry Program	**3**	- As shown in Section (d) of the Requirements for Safe Use of Medical Devices inside Healthcare Facilities (MDS-REQ 3), HCPs must decide when to monitor radiation exposure and staff ionizing radiation doses.
Disposal of Devices	**4**	- HCPs shall notify the SFDA in writing of selling, transferring, or discontinuing the use of any radiation source.
Records	**5**	- The decommissioning report must include the following information: o Device name, o Medical device type or device class (as appropriate), o Manufacturer/supplier, country of origin,

		○ Package type and size, quantity, model, serial number or batch number, expiry date (as appropriate), ○ Original location (such as radiology departments, general ward, operation rooms (ORs), and intensive care unit), ○ Date and/or period of decommissioning, ○ Condition of the device before decommissioning, ○ Selected decommissioning option and reasons for decommissioning or disposal, ○ Decommissioning process, ○ End status of the device, ○ Official transfer document pertains to devices that have been donated or sold. ○ Receipt for sold or traded-in device, purchase value, and other relevant information, ○ Personnel tasked with decommissioning - All third-party decommissioning or disposal reports must include the following information: ○ Name and address of the decommissioning or disposal firm. ○ Date of the request. ○ Name and address of the service requester. - Devices disposed of, donated, sold, or traded should be removed from the list of devices and archived in the inventory database.The inventory must be updated when internal reassignment or reprocessing takes place.

Annexes

Annex (1): Definitions and Abbreviations

KSA	Kingdom of Saudi Arabia
SFDA	Saudi Food and Drug Authority
Marketing Authorization	A document issued by the SFDA permits the circulation of a medical device on the market.
Medical Device	Any instrument, apparatus, implement, implant, in vitro reagent or calibrator, software, or material used for operating medical devices, or any other similar or related article, intended to be used alone or in combination with other devices for diagnosis, prevention, monitoring, controlling, treatment, or alleviation of disease or injury, or for compensation for an injury; investigation, replacement, modification, or support of the anatomy or a physiological process; supporting or sustaining life; controlling or assisting conception; sterilization of medical devices; providing information for medical or diagnostic purposes by mean of in vitro examination of specimens derived from the human body; and does not achieve its primary intended action by pharmacological, immunological or metabolic means, but which may be assisted in its intended function by such means.
Medical Supply	A medical material or product used in diagnosis, treatment, replacement, or bracing; or in disability cases or other medical uses for humans, including medical gases.
MDMA	Medical Device Marketing Authorization
Manufacturer	Any national or foreign establishment that designs or manufactures medical devices for use under its name within the Kingdom or abroad. Manufacturing includes refurbishing, assembling, packaging, and labeling.
Classified Worker	Any worker in a health care facility may be exposed to an expected annual dose of more than 1 mSv.
ALARA	As Low as Reasonably Achievable
B-mode	Brightness modulation
FRL	Facility Reference Level
HIS	Hospital Information Systems
I spta.3	Spatial peak temporal average intensity
MI	Mechanical Index
NDRL	National Diagnostic Reference Level
PACS	Picture Archiving and Communication System
PIA	Privacy Impact Assessment
RIS	Radiology Information System
TI	Thermal Index
HCPs	Healthcare Providers
HLD	high-level disinfection
HDR	high-dose-rate

ICUs	Intensive Care Units
IMRT	Intensity-modulated Radiation Therapy
MBq	Mega Becquerel is a measuring unit for radioactivity.
MIM	Medical Imaging Material
mSv	Millisievert is a measurement unit for whole-body radiation dose.
NCMDR	SFDA National Center for Medical Devices Reporting
NICUs	Neonatal Intensive Care Units
OR	Operation Room
PICUs	Pediatric Intensive Care Units
PPM	Periodic Preventive Maintenance
QA	Quality Assurance
QC	Quality Control
Regulation	Executive Regulation of the Law.
RSO	Radiation Safety Officer
SPTA	Spatial Peak Temporal Average
SSDL	Secondary standard dosimetry laboratory.
UV	Ultraviolet

Annex (2): List of Changes on the Previous Version

Number & Date of the Previous Version	Changes Description
1.0 19/12/2022	• Replace the following document: ○ Essential Requirements for Medical Radiation Protection Programs. ○ Requirements for a Bone Density Measuring Device ○ Requirements for the Safe Use of Medical Ultraviolet Radiation. ○ Requirements for the Safe Use of Mammography Devices. ○ Guidelines for the Safe Use of the X-ray Bone Densitometry Device. • The following amendments and additions have been made to the content of the document: ○ Updating the requirements in Chapters 1 and 4: Essential Guidelines for Medical Radiation Protection Programs – Guidelines for the Operation and Use of Medical Ultraviolet Radiation Devices. ○ Integrating Chapters 2 and 3 (Guidelines for the Operation and Use of X-ray Bone Densitometry Devices – Guidelines for the Operation and Use of Mammography Devices) with the General X-ray Device requirements. ○ Adding fourteen (14) new chapters to the Guidelines for the Operation and Use of certain Radiation-Emitting Devices to ensure performance quality, improve the efficiency of radiation protection programs, and maintain image quality and patient diagnostic information. ○ Editorial amendment to the “Required Documents” section. ○ Editorial amendment to the “Definition and Abbreviations” annex. Updating (2) annex.