

Guidance on Radiation Protection and Safety Requirements for Healthcare Providers

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The logo for the Saudi Food & Drug Authority (SFDA) is centered on the page. It features a stylized human figure composed of two curved, overlapping shapes: a light blue one on the left and a light green one on the right. Above the figure's head is a solid orange circle. The letters 'SFDA' are printed in a light green, sans-serif font to the right of the figure's lower body.

SFDA

Chapter One

Introduction

Article One

For the purpose of these requirements, the following definitions apply:

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| ALARA | Low as reasonably achievable. |
| HCP | Healthcare Provider. |
| KSA | Kingdom of Saudi Arabia. |
| MDMA | Medical Device Marketing Authorization. |
| PPM | Planned preventive maintenance. |
| QC | Machine Quality Control. |
| RAM | Radioactive Materials. |
| REMD | Any ionizing or nonionizing radiation emitting medical device used for diagnostic, therapeutic or cosmetic purposes. |
| RH | Radiological Health Executive Department. |
| RPP | Radiation Protection Program. |
| RSO | Radiation Safety Officer. |
| SCFHS | Saudi Commission for Health Specialties. |
| SFDA | Saudi Food and Drug Authority. |

Article Two

The purpose of this document is to simplify the SFDA requirements in respect of using ionizing and/or nonionizing radiation emitting medical device for diagnostic, therapeutic or cosmetic purposes in healthcare facilities.

The Saudi Food and Drug Authority (SFDA) cover all medical regulatory aspects of ionizing and non-ionizing radiation for all practices and intervention requirements. Healthcare providers (HCP) and users of the ionizing or nonionizing radiation emitting medical devices shall apply and comply with these essential requirements with their own practices as appropriate.

- A) Justification, optimization and limitation are the basics of radiation protections and safety. This requirement shall be implemented within each healthcare provider. The goal of this document is to ensure and promote the efficiency of the radiation protection program, and to minimize the radiation risks by reducing the amount of radiation doses used in diagnosis while maintaining the image quality and its diagnostic information. This is to protect patients from unjustified excessive radiation doses during examination.
- B) Protecting and maintaining the public health within the kingdom of Saudi Arabia by implementing provisions to ensure a high level of safety and health protection to users, patients and public in Healthcare facilities from ionizing and/or nonionizing radiation.
- C) Ensuring that any ionizing or nonionizing radiation medical device used for diagnostic, therapeutic or cosmetic purposes is operating at a high level of quality and safety.
- D) Limiting the use of radiation emitting medical device (REMD) to specialized medical centre, ensuring that a physician and/or qualified specialist direct supervision in the use of REMD as appropriate.
- E) Radiation Exposures shall be kept as low as reasonably achievable (ALARA). To reduce the amount of radiation doses used in diagnosis while maintaining the image quality.

Article Three

HCP shall apply all the requirements stated in this document as appropriate and when applicable. This document is subject to be changed, revised or updated without any previous notice. This document covers the following department:

- A) General Radiology, Lithotripsy and Cath-lab.
- B) Dental Radiography.
- C) Dermatology and Cosmetic Radiology.
- D) Nuclear Medicine.
- E) Radiotherapy.

Chapter Two

General Requirements

Article Four

It is the responsibility of the HCP to apply the following requirements to any ionizing and/or nonionizing radiation medical device (REMD) used for diagnostic, therapeutic or cosmetic purposes:

1. Any REMD shall have Medical Device Marketing Authorization (MDMA). The HCP shall immediately stop using any REMD that does not have MDMA until registration and licensing of this REMD by SFDA is complete. REMD shall only be used according to the approved intended purposes. This is to ensure the safeness and high quality performance of these devices.
2. Machine Quality Control (QC) tests shall be done routinely by a third party, who shall be licensed by the SFDA and shall include the Basic QC Tests for Medical Imaging Devices. However, if the HCP has in house qualified and trained medical physicist personal, they may perform such tests after submitting their qualification to SFDA. The QC records shall be kept in the department.
When any of the QC tests fails, the HCP shall immediately stop using these devices and notify the SFDA along with the corrective action plan to fix the failure within 3 working days from receiving the QC report. The failure shall be corrected within 30 days of accepting the corrective action plan. All correspondences shall be sent to: rh.md@sfda.gov.sa.
3. Planned preventive maintenance (PPM) shall be done as per the manufacturer requirements and intervals by qualified and trained personnel. PPM records attached by checklists shall be kept in the department. The REMD shall be tagged indicating the date of the PPM and the next due date.
4. Personal dosimeter badges:
5. The HCP shall monitor the staff exposure to ionizing radiation. Setting a trigger exposure level below the limit, and investigate the incident that exceeds the trigger

exposure level is a recommended method to stop any malpractice, find vulnerabilities in the department and protect the staff.

- Two personal dosimeter badges (A&B) shall be assigned to each classified worker. When the primary badge is handed for reading, the secondary badge shall be given to the worker.
 - Personal dosimetry records for the last 5 years shall be kept in the department. Lifetime records shall be archived.
 - When extremities are expected to receive high doses of radiation, additional personal dosimeter shall be worn on the targeted extremity.
 - In dental radiography, risk assessment shall be performed to determine the expected yearly dose limit. If this anticipated exposure level may exceed 1 mSv/year, personal dosimeter shall be provided to the workers.
 - Pregnant workers who are working within an ionizing radiation environment shall be educated for the associated risk. They shall use personal and fetal dosimeter badges regardless of anticipated exposure levels.
6. Personal protective Equipment:
7. The HCP shall provide lead aprons (adults & pediatric sizes), pelvic, thyroid-protective collar, shielded gloves, shielded goggles and/or any other special protector as appropriate in each room where the X-ray device is being used. They shall be:
- Provided and used when they do not interfere with the exam.
 - Stored properly inside the room.
 - Tested periodically, and its records shall be kept in the department.

Article Five

Other HCP responsibilities:

1. Ensure the department obtains valid practice license by the proper authority as appropriate.
2. Ensure the operators and /or medical staff are licensed by the SCFHS in their relevant specialty.
3. Ensure the Radiation Protection Program (RPP) is available in the department. RPP shall be reviewed periodically.
4. Essential training programs shall be implemented and must involve all operators, maintenance personnel, cleaning crew and any other medical or administrative staff within the department. This training shall include operating REMD, emergency incidents and safety training. Copies of the training certificates shall be kept in the department. These training programs shall be reviewed periodically and revised as necessary.
5. Conducting an investigation of any accident, adverse events or unsafe practice that involve REMD, documenting the investigation and notify the SFDA within 5 working days of the incident. All correspondences shall be sent to: rh.md@sfda.gov.sa.
6. Ensure any incident victim related to REMD accident receive the proper medical treatment and report it to SFDA within 5 working days.

7. Identifying the causes of the REMD accident and set a corrective action plan to prevent this accident from happening in the future. The corrective action plan shall be sent to SFDA within 10 working days of the incident. All correspondences shall be sent to: rh.md@sfda.gov.sa.
8. Any REMD advertisement and/or marketing materials shall be approved by the SFDA.

Article Six

The medical staff responsibilities:

1. The physician and/or radiologist shall make sure that the benefits of any patient exposure to REMD outweigh the risk after considering other modalities as appropriate.
2. The physician and/or radiologist shall be aware of a patient's history and physical state, including pregnant and/or previous exposure to REMD. This shall be documented.
3. The physician and/or radiologist shall disclose and discuss with the patient any possible side effect, procedure's hazards and pre and post procedure instructions. This shall be documented as consent form, and signed by the patient.
4. If a patient is found to be pregnant, the supervising radiologist and/or medical physicist must conduct a risk-benefit assessment before allowing the patient to enter the scanning room, including the potential use of other nonionizing modalities or postponed until after delivery. However, if the benefit is deemed to outweigh the risk, then the scan may be cautiously performed. This shall be documented and signed by the patient.

Chapter Three

General Radiology, Operating Rooms and Cath-lab

Article Seven

It is the responsibility of the HCP to apply the following requirements (In addition to the general requirements stated in chapter two) to any (REMD) in the general radiology department, operating rooms and cath-lab:

1. Radiation survey test to all X-ray rooms shall be done at least once every two years. The test must be repeated right after any modification to the X-ray device or the room. The radiation survey test shall be done by a third party, who shall be licensed by the SFDA. However, if the HCP has in house qualified and trained medical physicist personal, they may perform such tests after submitting their qualification to SFDA. The radiation survey records shall be kept in the department.

When any of the radiation survey tests fails, HCP shall immediately stop using any of the ionizing radiation devices that fails the radiation survey tests. In addition, the HCP shall notify the SFDA along with the corrective action plan to fix the failure within 3 working days from receiving the radiation survey report. The failure shall be corrected within 30 days of accepting the corrective action plan. All correspondences shall be sent to rh.md@sfda.gov.sa.

2. When any mobile X-ray or C-arm device is assigned to a particular room, this unit is considered as a stationary unit. Thus, this room shall be shielded, as appropriate. In addition, radiation survey shall be done to insure that the occupants in the surrounding areas (controlled/uncontrolled areas) are safe.
3. When a mobile x-ray machine is used in an unshielded room where another patient may be exposed to unnecessary radiation, especially in (NICU), portable radiation barriers shall be available.
4. Working exposure warning light outside any room, where ionizing radiation is being used, shall be installed.
5. Hard-material caution signs, including signs of pregnancy shall be posted on the doors in both Arabic and English.
6. Leaded glass window and/or surveillance camera shall be installed, allowing the operator to continuously monitor the patient during the procedure.
7. Examination room's doors shall be completely locked during the procedure.
8. Certified RSO shall be available. RSO shall not follow radiology department administratively. Thus, RSO shall report to a higher management. The RSO may contact SFDA regarding any radiation safety aspects. All correspondences shall be sent to: rh.md@sfda.gov.sa. All correspondence will be confidential.

Chapter Four

Dental Radiography

Article Eight

It is the responsibility of the HCP to apply the following requirements (In addition to the general requirements stated in chapter two) to any (REMD) in dental radiography:

1. For panoramic, 3D and/or cephalometric, the radiation survey test shall be done every four years. The test must be repeated right after any modification to the X-ray device or the room. The radiation survey test shall be done by a third party, who shall be licensed by the SFDA. However, if the HCP has in house qualified and trained medical physicist personal, they may perform such tests after submitting their qualification to SFDA. The radiation survey records shall be kept in the department.

When any of the radiation survey tests fails, HCP shall immediately stop using any of the ionizing radiation devices that fails the radiation survey tests. In addition, the HCP shall notify the SFDA along with the corrective action plan to fix the failure within 3 working days from receiving the radiation survey report. The failure shall be corrected within 30 days of accepting the corrective action plan. All correspondences shall be sent to rh.md@sfda.gov.sa.

2. For panoramic, 3D and/or cephalometric, the exposure switch shall be located outside the room or behind a shielded barrier while maintaining the shielding integrity.
3. For panoramic, 3D and/or cephalometric, a leaded glass window and/or surveillance camera shall be installed, allowing the operator to continuously monitor the patient during the procedure.
4. When the operator of the panoramic and/or cephalometric machine is operating the machine in the room, behind a shielded barrier, working exposure warning light should be installed outside the panorama room.
5. For panoramic and/or cephalometric, hard-material radiation and pregnancy, caution signs in both Arabic and English shall be posted on the door.

Chapter Five

Dermatology and Cosmetic

Article Nine

It is the responsibility of the HCP to apply the following requirements (In addition to the general requirements stated in chapter two) to any (REMD) in the dermatology and cosmetic departments:

1. The dermatologist shall examine the patient or the client before any treatment and/ or procedure using any energy transmitting device which may include laser, ultra-violet, radio-frequency, or ultrasound. It is strictly prohibited to perform such procedures without consulting the dermatologist first.
2. The HCP is requested to immediately stop using any REMD that missed its PPM schedule.
3. Adequate number of eyewear, at least (3), shall be provided in each room where laser device is being used. The operator shall:
 - Ensure that the eyewear's wavelength matches and covers the device's wavelength.
 - Immediately stop using any broken or cracked eyewear.
4. Hard-material laser warning signs in Arabic and English shall be posted on each clinic door.
5. Any reflecting object of the laser beam such as mirrors, metal and any other shall be covered or removed.
6. Quick operating procedures for using any energy transmitting device shall be posted in each clinic.
7. Operating any energy transmitting device shall be limited to trained, and qualified personnel.

Chapter Six

Nuclear Medicine

Article Ten

It is the responsibility of the HCP to apply the following requirements (In addition to the general requirements stated in chapter two) to any (REMD) and (RAM) in the nuclear medicine departments:

Article Eleven

The HCP shall implement policies, procedures and quality assurance program that covers but not limited to the following aspects:

1. Preventing misadministration of radiopharmaceutical, which may lead to deliver an unnecessary dose to the patients, either by delivering the wrong dose or the wrong radiopharmaceutical.
2. Cautiously administrate radiopharmaceutical to pregnant patients after doing the risk-benefit assessment.
3. Maintaining and continually improving the quality assurance program, including:
 - Acceptance test.
 - The devices quality control and performance tests.
 - The radiopharmaceuticals quality control tests
4. Directly supervising any intern or trainee during procedures or the administration of radiopharmaceutical.
5. For survey, monitoring and decontamination, the HCP shall:
 - Provide area monitor/s and survey meters.
 - Survey meters and area monitor shall be calibrated. When they are sent for calibration, a backup survey meters and area monitor shall be provided.
 - Implement periodically radiation survey.
 - Survey any potential contamination, and then decontaminate any contaminated areas.
 - Define decontamination procedures.
6. Limiting and restricting the access of relatives, friends or members of the public to the nuclear medicine department to avoid unnecessary exposure.
7. Manage the radioactive waste.
8. Document all policies, contamination, incidents and test's reports.

Article Twelve

The HCP shall implement the following security requirements:

1. Radioactive materials (RAM), active or decayed, shall be secured from unauthorized access. RAM shall be kept in a shielded storage.
2. Surveillance cameras shall be installed in the hot lab.
3. Doors within the Nuclear Medicine Department shall be secured either card activated or access code.
4. A designated path for the hot isotopes from the vendor to the hot lab shall be assigned.
5. The RSO shall escort the radioactive material from the parking lot.
6. The RSO shall keep track of all RAM and their serial numbers when applicable.
7. The RSO shall make sure that proper clearance is provided by the vendor in order to receive or hand for exportation.

Article Thirteen

The HCP shall implement the following requirements:

8. Certified RSO in nuclear medicine shall be available. RSO shall not follow nuclear medicine department administratively. Thus, RSO shall report to a higher management. The RSO may contact SFDA regarding any radiation safety aspects. All correspondences shall be sent to: rh.md@sFDA.gov.sa. All correspondence will be confidential.
9. Hard-material caution signs, including signs of pregnancy in Arabic and English shall be posted on the department entrance and within the department.
10. The work environment must be kept at the highest level of hygiene and tidiness.
11. It is recommended that the area monitor can be seen from outside of the room to verify the reading before entering the hot lab, or at least can be seen upon entering the room. The area monitor shall be equipped with an audible alarm to be heard from outside the room when radiation activity is detected.
12. A communication device shall be installed in the hot lab. Thus, the worker can contact the RSO in case of emergency.
13. Radiation emergency safety equipment shall be available before and throughout the treatment.
14. Wash-up sink, eye-wash or shower shall be available to be used in case of contamination or spills.

Chapter Seven

Radiotherapy

Article Fourteen

It is the responsibility of the HCP to apply the following requirements (In addition to the general requirements stated in chapter two) to any (REMD) in the radiotherapy departments:

Article Fifteen

The HCP shall implement policies, procedures and quality assurance program that covers but not limited to the following aspects:

1. Clearly identify the responsibilities of medical staff including radiation oncologists, radiation therapist, medical physicists, dosimetrists, referring physicians, etc.
2. Maintaining and continually improving the quality assurance program, including:
 - Acceptance test, commissioning and decommissioning
 - The devices routine quality control and performance tests.
3. Clearly identify radiation therapy procedures and protocols.
4. Document all policies, incidents and test's reports.

Article Sixteen

The HCP shall implement the following requirements:

1. Certified RSO in radiation therapy shall be available. RSO shall not follow radiotherapy department administratively. Thus, RSO shall report to a higher management. The RSO may contact SFDA regarding any radiation safety aspects. All correspondences shall be sent to: rh.md@sfda.gov.sa. All correspondence will be confidential.
2. The radiation survey test shall be done periodically unless modification has been done to the room, which require performing radiation survey test after any modification. The radiation survey test shall be done by a certified third party. However, if the HCP has in house qualified and trained medical physicist personal, they may perform such tests after submitting their qualification to SFDA. The radiation survey records shall be kept in the department.

When any of the radiation survey tests fails, HCP shall immediately stop using any of the ionizing radiation devices that fails the radiation survey tests. In addition, the HCP shall notify the SFDA along with the corrective action plan to fix the failure within 3 working days from receiving the radiation survey report. The failure shall be corrected within 30 days of accepting the corrective action plan. All correspondences shall be sent to rh.md@sfda.gov.sa.

3. Calibrated area monitors shall be installed and survey meters shall be available. When they sent for calibration, a backup area monitor shall be provided.

4. Hard-material caution signs, including signs of pregnancy in Arabic and English shall be posted on the department entrance and within the department.

Article seventeen

The HCP shall implement the following security requirements:

1. Surveillance cameras shall be installed within the department.
2. Doors within the department shall be secured either card activated or access code.
3. When applicable, a designated path for the hot isotopes from the vendor to the hot lab shall be assigned.
4. When applicable, the RSO shall escort the radioactive material from the parking lot.
5. When applicable, the RSO shall keep track of all RAM and their serial numbers.
6. When applicable, the RSO shall make sure that proper clearance is provided by the vendor in order to receive or hand for exportation.
7. A communication device and surveillance cameras shall be installed in every radiotherapy room. Thus, the operator can contact and see the patient remotely. When applicable.
8. When applicable, Radiation emergency safety equipment shall be available before and throughout the treatment.

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