MDS-REQ 3

Requirements for Safe Use of Medical Devices Inside Healthcare Facilities

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"Translated Copy"

Content

Introduction

Purpose

The purpose of this document is to specify and clarify the requirements for safe use of medical devices and radioactive medical materials inside healthcare facilities in order to ensure safety, efficiency and quality of them, and reduce potential risks corresponding to use and handle them inside healthcare facilities.

Scope

This document applies to healthcare providers in KSA.

Background

SFDA has issued this document in reference to the following:

- Article (26) of the "Medical Devices Law" issued by the Royal Decree No. (M/54) dated 6/7/1442 H stipulated that “The SFDA shall monitor the compliance of healthcare providers with technical regulations within healthcare facilities in order to ensure the safety and efficacy of medical devices in diagnosis and treatment”.
- Item (2) within the “Monitoring duties” in (Article 5) of the Law of the Saudi Food and Drug Authority, issued by Royal Decree No. (M/6) dated 25/1/1428H stipulated that “Monitoring compliance of health establishments with international standards of safety related to the safe performance of medical devices”.
- Item (5) in (Article 3) of the Law of the Saudi Food and Drug Authority, issued by the issued by the Royal Decree No. (M/6) dated 25/1/1428H stipulated that “Ensure that medical devices and in vitro diagnostic medical devices are accurate, safe and not affect human health”

Requirements

A. General

Healthcare providers shall:

1. Not deal with any Establishment engages in any of the activities subject to the Medical Devices Law, unless it is registered and licensed by the SFDA in the same scope of the dealing.
2. Ensuring that all medical devices located in their facilities have a Marketing Authorization (MDMA) issued by the SFDA.
3. In case of medical devices didn't obtain a Marketing Authorization (MDMA) certificate and when such devices have been purchased or supplied after the "Law of Medical Devices" enters into force), the SFDA would implement the necessary actions accordance to the "Law of Medical Devices" and it's implementing regulation.
4. If the Marketing Authorization (MDMA) certificate validity expires and cannot be renewed according to acceptable justifications (e.g., production line stoppage or manufacturer closing), the following shall be provided:
    a) A statement from the manufacturer guaranteeing the continuity of after-sales services including providing spare parts approved and compatible with the standards and technical specifications of the medical device, and providing the technical support of the medical software throughout the expected service life of the medical device which specified in the statement.
    b) In case the abovementioned manufacturer's statement could not be provided, a proof shall be submitted by the healthcare provider that it would provide spare parts approved and compatible with the standards and technical specifications of the medical device, and providing maintenance, calibration and technical support of the medical software according to the manufacturer instructions by the healthcare facility itself or by another party licensed from the SFDA to provide maintenance services for medical devices throughout the expected service life of the medical device which specified in the instructions provided by the manufacturer.
5. In case of medical devices didn't obtain a Marketing Authorization (MDMA) certificate and when such devices have been purchased or supplied before the "Law of Medical Devices" enters into force (14 Muharram 1443H agreed with 22 August 2021), the requirements mentioned in the item (4) above apply.

B. Healthcare providers responsibilities

Health care providers shall:

1. Using the medical device according to the intended purpose of use approved by the SFDA.
2. Ensuring that Radioactive Medical Materials have been approved by the SFDA in relation to technical and clinical specifications.
3. Medical devices categorized as high risk indicated in the list of medical devices that require a medical prescription may not be dispensed for use outside the facility of the health care provider without prescription.
4. Ensuring that the implant card is provided by the manufacturer and given to the patient after including the following additional information:
    a) The name of the patient and the physician.
    b) Address of the health care facility.
    c) Date of Implantation.
5. Ensuring that the medical device supplied with the accessories provided by the manufacturer, in addition to all the necessary information and documents including instructions for use and maintenance.
6. Ensuring that the clinical trials conducted in their facilities are approved by the SFDA, and that there is a documented policy for conducting the clinical trials within the facility in accordance with the "Requirements for Clinical Trials of Medical Devices (MDS-REQ 2)".
7. Ensuring that the advertising materials displayed in their facilities are approved by the SFDA in accordance with "Requirements for the approval of advertising and conducting awareness or charitable campaigns of medical devices (MDS-REQ 8)".
8. Appointing a contact officer with the NCMDR to carry out the tasks and responsibilities mentioned in the "Requirements for Post-Market Surveillance of Medical Devices (MDS-REQ 11)".
9. Existence of a documented procedure for reporting medical devices incidents and complaints submission in accordance with the "Requirements for Post-Market Surveillance of Medical Devices (MDS-REQ 11)".
10. Adhering to report to the NCMDR immediately about all medical devices related incidents and provide the NCMDR with all information and documents, and comply with the "Requirements for Clinical Trials of Medical Devices (MDS-REQ 2)" in case of reporting and investigating serious adverse event and deficiencies related to medical devices used in conducting clinical trials.
11. Notifying the SFDA about medical devices in violation of the provision of the Law and Regulation; including medical devices that are fraudulent, unregistered, or unauthorized for marketing in accordance with the "Requirements for Post-Market Surveillance of Medical Devices (MDS-REQ 11)".
12. In case there is a safety alert, the medical device shall be dealt in accordance with the recommendations included in the field safety corrective (FSCA) action.

13. Providing maintenance services for medical devices, through one the following:
    a) Establishing and developing a specialized department in medical devices to carry the responsibilities mentioned in Section (C).
    b) Supervising the parties who have been contracted to manage and provide maintenance services for medical devices after ensuring that they are licensed to provide the maintenance services for medical devices in accordance to the "Requirements for Medical Devices Establishments Licensing (MDS-REQ 9)".
14. The staff of the specialized department in medical devices should hold academic or technical qualifications in biomedical technology/ engineering or any related specialty.
15. Providing a dedicated and equipped place for the maintenance of medical devices, in case that the health care provider is maintaining medical devices.
16. Adhering with manufacturer instructions, in addition to the requirements for storage and transportation of medical devices described in Annex (2).
17. Single-use medical devices shall not be reprocessed.
18. Complying with the requirements for reprocessing of medical devices mentioned in the "Requirements for Post-Market Surveillance of Medical Devices (MDS-REQ 11)".
19. Complying with the requirement of destruction of used medical devices mentioned in the "Requirements for Post-Market Surveillance of Medical Devices (MDS-REQ 11)".
20. Complying with the requirement of Resale, loaning or donating used medical devices mentioned in the "Requirements for Post-Market Surveillance of Medical Devices (MDS-REQ 11)".
21. Any other requirements published on the SFDA website.

C. Responsibilities of the specialized department in medical devices

1. Existence of documented policies in comply with the "Requirements for Post-Market Surveillance of Medical Devices (MDS-REQ 11)" for each of the following:
    a) Maintenance of medical device, including periodic preventive maintenance (PPM), corrective maintenance and calibration.
    b) Reprocessing of medical devices.
    c) Follow up with safety alerts and field safety corrective actions (FSCA), and provide the NCMDR with all documents and information.
2. Providing pre-installation requirements for the medical device, and all other requirements associated with the medical device (e.g. chemical requirements, medical gas requirements, sterilization or cleaning requirements) as per the manufacturer recommendations.
3. Reviving the medical device and conducting acceptance tests.
4. Supervising the configuration and installation of the medical device at the designated site in accordance with the manufacturer recommendations and the documented related policy.
5. Obtaining an installation report shows that the device has been installed in a good condition, it is fully functional, in addition to that the end user has been trained to operate it. Both the biomedical technician\engineer and the end user shall approve such report.
6. Receiving of all documents related to device configuration and installation.
7. Assigning a control number and affix it on the medical device, along with any other appropriate tags (e.g., the warranty expiry date).
8. Identifying appropriate training needs for operation and maintenance.
9. Receiving specialized training on their medical devices by the manufacturer or a certified body by the manufacturer.
10. Keeping training records and certificates.
11. Conducting the necessary tests to ensure the safety, efficacy and quality of the medical device during use in accordance with the manufacturer instructions, and notify the NCMDR In case of any failure of the tested device.
12. Ensuring that maintenance is provided by:
    a) the manufacturer, or
    b) a person from the department trained by the manufacturer, or
    c) a provider of maintenance services for medical devices licensed from SFDA.
13. Adhering to conducting electrical safety tests, and monitoring tests for quality of image, quality of laser and quality of UV radiation.
14. Determining the requirements for periodic preventive maintenance (PPM) in accordance with the manufacturer instructions.
15. The obligation to periodic preventive maintenance (PPM) procedure as follows:

a) Scheduling periodic preventive maintenance (PPM).
b) The medical device should be clean, disinfected (if needed) and functioning properly.
c) It should be conducted by trained people from the manufacturer, and its procedures and frequency consistent with the manufacturer requirements.
d) Documenting the details of periodic preventive maintenance (PPM) (records, tool kits, etc.) within the medical device log in the maintenance management system, and retain these information for at least five years.
e) Approval of periodic preventive maintenance (PPM) report by the end user and the biomedical engineer/technician or the maintenance service provider.
f) Affixing a tag on the medical device after conducting the periodic preventive maintenance (PPM), indicating at least the date of the previous PPM, the date of the next PPM and who perform it.

16. Monitoring all processes of periodic preventive and corrective maintenance.
17. Providing appropriate testing equipment to calibrate the medical device and test its safety, function and performance efficiency. Such equipment shall comply with the "Law of Measurement and Calibration" and its implementing regulation, and related instructions. This equipment shall be inspected to ensure its calibration and safety before reuse.
18. Applying the manufacturer's instructions of corrective maintenance and calibration. In the absence of instructions, refer to the standards and guidance approved by the SFDA.
19. Providing a maintenance management system and inventory management system to record, store, organize and analyze medical device information, in addition to the necessary spare parts information and a list of all spare parts suppliers authorized by the manufacturer.
20. Reviewing reports issued by the NCMDR or the manufacturer concerning safety alerts and corrective actions.
21. Establishing a record within the maintenance management system for each medical device includes at least the following information:
    a) General information about the medical device.
    b) Periodic preventive maintenance (PPM): frequency of PPM, updated procedures, calibration requirements, used spare parts, date of each PPM, used test equipment and tools, who perform the maintenance and consumed time.
    c) Corrective maintenance: problem date and description, used spare parts and consumed time.
    d) Field Safety Corrective Action (FSCA): date of safety alert, description of the problem and the required corrective action, date of implementation of the field safety corrective action.
22. Providing appropriate tags in accordance to the device condition, for example (Out of Service and PPM).
23. Any other requirements published on the SFDA website.

D. Requirements for the safe use of radiation emitting and imaging devices

1. Providing documented policies and procedures related to radiation protection and safety (Radiation Protection Program), and quality assurance programs for different radiology departments and review them regularly.
2. Applying the National Diagnostic Reference Levels (NDRLs), keeping all relevant records and submitting them to SFDA through the email (NDRL@sfda.gov.sa).
3. Periodically conducting quality control tests for radiation emitting and imaging devices through qualified and trained specialists in the healthcare facilities or third party that is licensed from the SFDA to provide this service in accordance to the "Requirements for Medical Devices Establishments Licensing (MDS-REQ 9)", and retain the test reports where they can be easily obtained upon request
4. Notifying the SFDA through the NCMDR in case of any failure in the quality control tests associated with radiation emitting and imaging devices and attach a corrective action plan within (3 days) from the date of receiving the test report. The continuity of using the device is subjected to the recommendations mentioned in the report.
5. Keeping all quality control test reports, where they can be easily obtained upon request.
6. A risk assessment has to be conducted to any room where ionizing radiation is being used to evaluate the necessity of shielding that room, through specialists qualified and trained within the healthcare facility or one of the bodies licensed to provide this service and retain the risk assessment reports, where they can be easily obtained upon request.
7. Testing the shielding integrity of any shielded room at least once every two years. These tests shall also be carried out after any modifications made to the device or the room that may affect the efficiency of the shielding.
8. For any shielded room that fails shielding integrity tests, immediately stop operating the device inside that room. Then, notify the SFDA through the NCMDR and attach a corrective action plan within (3) working days from the date of receiving the test report. The SFDA's authorization is required to resume the device operation.
9. Applying the "SFDA Requirements for Quality Assurance Programs for radiation emitting and imaging devices".
10. Providing personal protective equipment (PPE) for staff and patients to protect them from the risk of ionizing and non-ionizing radiation, when not interfere with the procedure. The following has to be fulfilled:
    a) Providing adequate number of different sizes (for adult and children) and for various uses in every room that contains a radiation emitting and imaging devices (e.g. full body apron, pelvic apron, thyroid collar, gloves, glasses, etc.).

b) For laser device PPE, providing adequate number of laser safety glasses at least two glasses inside each room in which a laser device is used. Additional backup laser safety glasses shall be available. All laser safety glasses shall be compatible with the device's wavelength.
c) Storing PPE properly according to manufacturer instruction. Damaged PPE shall be immediately replaced.
d) Testing PPE periodically to ensure their efficiency and retain test reports, where they can be easily obtained upon request.

11. Monitoring the personal radiation exposure during work period as follow:
    a) Providing each classified workers with two personal dosimeter badges (A&B) that used alternately when one of them is sent for reading.
    b) All personal exposure records of the classified workers shall be kept, where they can be easily obtained upon request.
    c) Keeping records of personal exposure until worker become 75 years old and not less than 30 years, after their occupational exposure have ceased.
    d) Providing additional personal dosimeter for extremities when exposure to high radiation dose is expected.
    e) Providing additional personal dosimeter for pregnant worker to be worn at the level of pelvic area.
    f) In dental radiography, the necessity of providing personal dosimeter badge is subjected to the recommendation of risk assessment, which determine the expected personal annual radiation dose.

12. Post radiation warning signs (ionizing and non-ionizing radiation) in Arabic and English to be visible upon entering the room, where the radiation emitting and imaging devices are used, in addition, post pregnancy warning signs for ionizing radiation rooms.
13. Equipping the entrance of any room where ionizing radiation emitting device is being used, with warning lights that automatically illuminate.
14. Providing mobile shielded barriers to be used with mobile ionizing radiation emitting device to protect patients and staff from unjustified radiation exposure.
15. Any radiation emitting and imaging device has to be equipped with means to allow the operator to continuously monitor the patient during procedure.
16. Other additional requirements in Annex (4) has to be fulfilled.
17. Any other requirements published on the SFDA website.

E. Requirements for the safe use of medical radioactive materials

1. Providing documented policies and procedures for the safe use of medical radioactive materials that covers incidents, including but not limited to adverse events related to radioactive contamination or the loss of radioactive material.
2. Adverse events and investigation reports related to medical radioactive materials shall be kept where they can be easily obtained upon request.
3. Installing surveillance cameras outside the hot lab.
4. Installing "area monitor" functioned with audible alarm inside the hot lab, it regularly and provide alternative backup monitors.
5. Installing a communication device inside the hot lab to use in case of emergency.
6. Providing survey meters, calibrate them regularly and provide alternative backup survey meters.
7. Providing radiation safety equipment to use in case of emergency, this includes:
    a) Sink and eye washer/shower.
    b) Radiation contamination monitoring kit.
    c) Radiation Decontamination kit.
8. Assigning a secure place to store medical radioactive materials (active or decayed) restricted for unauthorized personnel.
9. Nuclear medicine and radiotherapy departments shall be restricted for unauthorized personnel.
10. Assigning a designated path for the transfer of medical radioactive material from the receiving area to the hot lab.
11. The RSO shall escort the medical radioactive material from receiving area to the assigned storage area.
12. The RSO shall keep track of all medical radioactive materials with their serial numbers and retain all documentations where they can be easily obtained upon request
13. Complying with the additional requirements shown in Annex (4).

Annexes

Annex (1): Definitions and Abbreviations

KSA	Kingdom of Saudi Arabia
SFDA	Saudi Food and Drug Authority
Regulation	Executive Regulation of the Law.
NCMDR	The National Center for Medical Devices Reporting
RSO	Radiation Safety Officer
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 of a physiological process; supporting or sustaining life; controlling or assisting conception; sterilization of medical devices; providing information for medical or diagnostic purposes by means 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 substances and products used in diagnosis, treatment, prosthetics, orthotics, or in disability cases or other medical uses for humans, including medical gases.
Medical Radioactive Material	A material that emits ionizing radiation either by itself or when used with other medical devices for the purpose of diagnosis and treatment.
Reprocessing	Procedures implemented on a used medical device for safe reuse, such as cleaning, disinfection, sterilization, testing and restoration of its technical functions and safety.
User	A person, whether a professional, lay person, or a patient, who uses a medical device.
Manufacturer	Any national or foreign establishment the purposes of which include designing or manufacturing medical devices for use under its name within the Kingdom or abroad. Manufacturing includes: refurbishing, assembling, packaging, and labelling.
Healthcare Provider	Any government or private establishment that provides healthcare services.
Authorized Representative (AR)	A legal person based in the Kingdom who has written authorization from a manufacturer located outside the Kingdom to represent it in the Kingdom with regard to the implementation of this Law and its Regulation.
License	A document issued by the SFDA to engage in any of the activities subject to this Law.

Marketing Authorization	A document issued by the SFDA permitting the circulation of a medical device in the market.
Quality Assurance	A set of technical tests, measurements, and calibrations approved by the SFDA to verify the safety and effectiveness of radiological medical device and the accuracy, and quality of images
Technical Regulation	Mandatory documents issued by the SFDA for medical devices which specify the principles of safety, performance, and manufacturing, and provide relevant instructions, including terms and symbols as well as packaging and labelling requirements.
Technical and Clinical Specification	A set of criteria that determine the quality, effectiveness, and safe use of a radioactive material in medical applications.
Safety Alert	A notification issued by the NCMDR indicating the risk associated with a medical device and the corrective actions to be taken to mitigate the associated risk Field Safety
Field Safety Corrective Action (FSCA)	An action taken by the manufacturer to eliminate or reduce the risks affecting the safety of a medical device.
Medical Devices Incidents	Any defect, malfunction or change in the characteristics or performance of a medical device that may directly or indirectly cause or contribute to the death or serious injury of a user.
Medical Imaging Materials	Materials used to enhance the contrast of medical imaging equipment.
Advertising	Any written, audible or visible or other displays intended to promote medical device or its technology, or to direct or indirect sale.
Corrective Action	An action taken to solve nonconformity reasons for the establishment, manufacture or medical device.
Implantable Medical Device	A medical device intended to be totally surgically introduced into the human body or to replace superficial/epithelial surface or the surface of the eye. Including those partially or wholly absorbed and remain in place after the medical surgical intervention and include those devices that partially surgically introduced for a purpose of 30 days or more.
Medical Gases	Gases that are used to operate or sterilize medical devices, or that are used for treatment or diagnosis while do not interact by pharmacological, immunological or metabolic means to achieve its intended purpose.
Radiological Departments	Any department inside healthcare facilities that use radiology and medical imaging devices (ionizing and non-ionizing) included, but not limited to, radiology department, nuclear medicine, radiotherapy, dental radiology, laser therapy and dermatology.
Classified worker/s	Any worker inside health care facility that may exposed to an expected annual dose of more than (1) mSv.
Calibration	The required corrective adjustments to medical devices and testing equipment to maintain its performance accuracy according to a standard.

Testing equipment	The Equipment or tools used to perform functional tests or calibration for medical devices.
Maintenance Management Systems	A Computer-based software system that is used to automate processes related to technical support of medical devices, the inventory management system, corrective maintenance, periodic preventive maintenance (PPM) and contracts management; and provides a wide range of data reports (such as downtime, life cycle cost and inventory reports related to device type, location or selected manufacturers related to the medical device lifecycle.
Corrective Maintenance (CM)/ Repair	An unscheduled process or procedure to correct or repair malfunctions of medical device or its components, including repair, restore or replace used components or systems to restore safety and performance of a medical device
the specialized department in medical devices	The department concerned with all issues related to the medical device lifecycle from purchase to disposal. This includes planning, setting technical specifications, evaluation, maintenance and inventory management, follow-up of supply chains and suppliers, training and other related tasks.
Periodic Preventive Maintenance (PPM)	A scheduled process or procedure at specific intervals includes specific maintenance processes such as lubrication, cleaning or replacing parts that are expected to wear or which have a finite life. The procedures and intervals are usually specified by the manufacturer
Liaison Officer	A designated person by health care provider who works as a liaison with the National Center for Medical Devices Reporting (NCMDR)
Control Number	A set of letters, numbers and symbols, placed on the medical device for monitoring and tracking, It is included in the maintenance management system database inside the health care facility.
Radiation Safety Officer (RSO)	a licensed person in radiation protection and safety in the medical field.
Radiation emitting devices	Any medical devices that emit ionizing or non-ionizing radiation and are used for diagnosis or treatment or for cosmetic purposes.
"As low as reasonably achievable (ALARA)" principle	Achieving the goal by a lower radiation exposure.

Annex (2): Storage and Transportation of Medical Devices for Healthcare Provider

Storage Area	1	The storage area for medical devices should be: o Designed or adapted for the storage of medical devices. o Clean and enough space to allow cleaning and inspection o Equipped with thermometers/hygrometers to monitor changes in temperature and/or humidity. o All surfaces and shelves, if applicable, should be made of or covered by an impermeable material to enable proper and safe cleaning. o Include/contain a physically separate area for keeping damaged, defect, expired, counterfeit or recalled medical devices. This area should be clearly labeled and controlled to prevent the use of these devices until a final decision is taken on their fate. o Adequately lit and ventilated. o Emergency plan set up and used in case of an electricity shutdown (power outage).
Traceability in the Storage Area	2	In the case of a recall/field safety notice by the SFDA or the manufacturer, the healthcare providers should be able to trace a product in the storage area by its lot/batch/serial number.
	3	The expiry dates of medical devices in the storage area should be monitored through periodic inventories to avoid unintended dispatch of expired medical devices.
Transportation	4	A copy of the transfer form should be sent to the department responsible for medical devices to update the medical device record in order to track for the purpose of maintaining, use, or future evaluation needs.
	5	Medical devices should be transported in such a manner that does NOT allow exceeding of appropriate temperature and relative humidity conditions which could negatively affect the integrity and quality.
	6	Vehicles used to transport medical devices should be properly designed and equipped to ensure protection from different environmental and weather conditions in which it operates.
	7	When the medical device needs to be disassembled and reassembled in different locations, it should be done by a qualified person and under conditions specified by the manufacturer's recommendations.
	8	Medical devices should be transported and carried carefully in a manner that corresponds to the special transport precautions for each medical device's nature.

	9	Any case of spoilage or breakage should be reported.
	10	The transporting vehicle or containers should be adequately suitable for the intended purpose and cleaned.
Manufacturer's Instructions/ Requirements	11	Medical devices should be stored and transported under conditions specified by the manufacturer's instructions/requirements to prevent deterioration. These conditions might be related to one or more of the following: ○ Temperature (all the medical devices should be kept during storage and/or transportation at temperature ranges specified by the manufacturer) ○ Moister and humidity ○ Exposure to light ○ The direction the package should face ○ The maximum number of packages stacked above each other ○ Other specific instructions/requirements Note 1: If the packaging labelling do not include information about the required storage and transportation conditions of a medical device, healthcare providers should obtain such information from the manufacturer and/or its authorized representative located within the KSA. Note 2: If the manufacturer does not specify the temperature values or not define the storage conditions on the packaging labelling, see (Annex 3) to determine these values and the set of storage definitions. Note 3: Healthcare providers should monitor and periodically record these conditions (such as temperature and humidity).
Sterile Medical Devices	12	In addition to manufacturer-specific instructions, medical devices that are dispatched in a sterile state, should be stored and transported in a manner that protect their packaging from: ○ Exposure to moisture. ○ Direct sunlight. ○ Dust. Note: Sterile medical devices should be considered unsterile if packaging loses its integrity.
Staff	13	Staff involved in the storage and transport of medical devices should: ○ Have proper knowledge about these activities, and ○ Be able to deal with those devices that have different storage and transportation requirements.

Written Procedures	14	Healthcare providers should have a written procedure that describes the practices taken to ensure those medical devices are stored and transported based on the manufacturer's instructions/requirements. The written procedure ideally should be part of a quality management system.

Annex (3): Temperature Rates Related to Medical Devices Storage Conditions

ON THE LABELLING	GUIDANCE VALUES
Freezer	The temperatures are between -20 °C and -10 °C
Refrigerator	The temperatures are between 2 °C and 8 °C
Cold Place	The temperatures do not exceed 8 °C
Cool Place	The temperatures are between 8 °C and 15 °C
Room Temperature	The temperatures are between 15 °C and 30 °C
Warm Place	The temperatures are between 30 °C and 40 °C
Excessive Heat	The temperature are above 40 °C
Do not store over 8 °C	The temperatures are between +2 °C to +8 °C
Do not store over 15 °C	The temperatures are between +2 °C to +15 °C
Do not store over 25 °C	The temperatures are between +2 °C to +25 °C
Do not store over 30 °C	The temperatures are between +2 °C to +30 °C
Do not store below 8 °C	The temperatures are between +8 °C to +25 °C
Protect from moisture	No more than 60% relative humidity in normal store conditions; to be provided to the user in a moisture-resistant container
Protect from light	To be provided to the user in a light-resistant container

Annex (4): Additional Requirements for Different Radiology Departments

Principles of radiation protection	1	○ Apply the main principles and means of radiation protection, when performing any procedure that involve radiation emitting and imaging device and medical radioactive materials. ○ Applying the ALARA principle. ○ Restrict the use of radiation emitting and imaging device to specialized medical centers and ensure that the operator is qualified and trained to use these devices. ○ The physician and/or radiologist shall ensure that the benefits of radiation exposure outweigh the potential risks. ○ The physician and/or radiologist shall be aware of and document the patient's medical history and health status, including pregnancy and/or previous exposure to radiation-emitting devices. ○ When using any radiation emitting and imaging device, potential side effects and risks involved, as well as pre- and post-procedure instructions, shall be addressed and explained to the patient, and they shall be documented in the declaration form signed by the patient. ○ In case of a pregnant patient, risks should be assessed before allowing her to enter the examination room, including the possibility of using other non-ionizing radiological alternatives or postponing the examination until after delivery. If the benefits outweigh the risks, the examination is performed with caution, and it shall be documented and signed by the patient.
Responsibilities of healthcare provider	2	○ Ensuring that the department obtains the required licenses from the competent authorities. ○ Ensuring that workers and/or medical staff are licensed by the Saudi Commission for Health Specialties in their field of work. ○ Ensuring that the radiation protection program is available in the department and that is reviewed periodically. ○ Provide basic training programs inside the facility for all operators, maintenance staff, cleaning workers, and any medical or administrative personnel within the department. These programs shall also include, emergency plans, and safety

		training. These programs shall be reviewed periodically, and the training of all employees shall be documented.
Requirements of dermatology and laser departments	3	○ The client/patient shall be examined by a dermatologist before performing any procedure that involves the use of radiation-emitting devices such as lasers, ultraviolet rays, radio waves, or ultrasound. ○ Cover or remove any laser-reflecting objects inside the room, such as mirrors or metals. ○ Operating instructions for radiation emitting medical device shall be provided inside the room.
Requirements of Nuclear Medicine department and Radiotherapy department	4	○ Radiation safety officer who is licensed in nuclear medicine shall be assigned to the department. The RSO shall not follow the department administratively. ○ Radiation safety officer who is licensed in radiotherapy shall be assigned to the department. The RSO shall not follow the department administratively. ○ The responsibilities of the medical staff, including oncologists, radiation therapists, medical physicists, radiation dose personnel, referring physicians, shall be clearly defined. ○ Provide medical radioactive materials injection management policies, which include dealing with pregnant patients. ○ Develop and continually review the quality assurance program. ○ Direct supervision of any trainee within the department's facilities. ○ Provide policies and procedure for surveying, monitoring and decontamination of medical radioactive materials, including: − Conduct periodic radiation survey. − Conduct radiation survey when radioactive contamination is suspected. − Decontaminate any contaminated area. ○ Document any radiation accident. ○ Provide policies and procedure for managing radioactive waste. ○ Provide an updated record of medical radioactive materials in the department containing the name of the material, serial number, manufacturer name, radioactivity, receiving date and time, and detected level of radiation.

Annex (5): List of Changes on the Previous Version and the Replaced Documents

Number & Date of the Previous Version	Changes Description
1 13/01/2022	• Modification on the “Requirements”, A. General. • Modification on the “Requirements”, D. Requirements for the safe use of radiation emitting and imaging devices. • Modification on the “Requirements”, E. Requirements for the safe use of medical radioactive materials. • Addition to the “Annexes”, Annex 4: Additional Requirements for Different Radiology Departments
Number & Date of the Previous Version	**List of Replaced Documents**
2,0 23/12/2019	• The following documents have been replaced and the requirements are included in this document: ○ Requirements on Radiation Protection and Safety for Healthcare Providers