MDS – REQ 3

Requirements for Safe Use of Medical Devices Inside Healthcare Facilities

Version Number: 3.0
Version Date: 30/07/2026

MDS-REQ 3-V3/260730

"Translated Copy"

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Introduction

Purpose

The purpose of this document is to specify and clarify requirements for safe use of medical devices and Medical Radioactive materials inside healthcare facilities, with the aim of ensuring the safety, security, and adequacy of medical devices in diagnosis and treatment.

Scope

This document applies to:

- Healthcare providers, with additional requirements for both Biomedical Technology (BMT) department and radiology departments.
- Medical Devices used inside healthcare facilities, with additional requirements for both: Radiology and Medical Imaging Devices (ionizing and non-ionizing) and Medical Radioactive Materials.
- Medical Devices Maintenance Services Providers contracted by healthcare providers.
- Quality Assurance Services Providers for Radiology and Medical Imaging Devices contracted by healthcare providers.

Background

SFDA issued this document based on the following:

- The "SFDA Law" issued by Royal Decree No. (M/6) dated 25/1/1428 AH, through:
  - Item (5) of Article (3), which stipulates that SFDA shall "Ensure accuracy of specifications and safety of Medical and In-Vitro Diagnostic Devices and that they do not adversely affect human health.".
  - Item (2) within the “Supervisory Tasks" of Article (5), which stipulates that SFDA shall "monitor the compliance of healthcare facilities with international safety standards related to the safe performance of medical devices.".

- The "Law of Medical Devices " issued by Royal Decree No. (M/54) dated 06/07/1442 AH, through:

    - Article (26), which stipulates that "SFDA shall monitor the compliance of healthcare providers in implementing technical regulations inside healthcare facilities, to ensure the safety, security, and adequacy of medical devices in diagnosis and treatment."

- Council of Ministers Decision No. (377) dated 04/07/1442 AH, which stipulates that "Secondly: SFDA shall monitor the compliance of healthcare providers with technical and clinical specifications for Medical Radioactive Materials inside healthcare facilities and refer any detected violations to the Nuclear and Radiological Regulatory Commission, as per its jurisdiction."

- The "Implementing Regulation of the Law of Medical Devices" issued by SFDA Board Decision No. (3-29-1443) dated 19/02/1443 AH, through:

    - Article (5/3), which stipulates that "SFDA shall monitor the compliance of Radiology, Nuclear Medicine and Radiotherapy Departments of healthcare providers to SFDA requirements for the safe use of medical devices published on SFDA's website."

    - Article (10/23), Item (8), which stipulates that providers quality assurance and radiation measurements services for healthcare facilities shall be in " Compliance with SFDA's requirements for safe use published on SFDA's website."

    - Article (26/1), Items (1) and (2), which stipulates that Healthcare providers shall adhere to "The requirements for safe use of medical devices" and the "SFDA requirements for radiology, nuclear medicine and radiotherapy departments published on SFDA's website."

Requirements and Procedures

A.General

1. Not deal with any establishment that engages in any of the activities subject to the Law unless it is registered and holds a valid license in the same field of operation.

2. Ensure that all medical devices used in their facilities have obtained a Medical Devices Marketing Authorization (MDMA) Certificate issued by SFDA.
3. Ensure that Medical Radioactive Materials have obtained SFDA approval of the technical and clinical specifications.

4. Appoint a liaison officer with NCMDR to carry out the tasks, responsibilities and roles outlined in Annex (1), paragraph (A). This is done by filling the "NCMDR Liaison Officer Appointment Form" in Annex (1), paragraph (B), and update the information - as required -.

5. If there are any medical devices used in their facilities have not obtained Medical Devices Marketing Authorization (MDMA) certificate supplied before the effective date of the "Law of Medical Devices" (14 Muharram 1443 AH corresponding to 22 August 2021 AD), or if any medical devices have obtained expired (MDMA) certificate, the measures outlined in the "Healthcare Provider Declaration Form" in Annex (2) shall be implemented.

B. Responsibilities of Healthcare Providers

1. Use the medical device in accordance with to the intended purpose of use that approved by SFDA.
2. Abide by Identifying Information (Labeling) provided by the manufacturer during transportation, storage, installation, maintenance and destruction of medical devices.
3. Do not dispense high-risk medical devices for use outside the healthcare facility without a prescription. Policy, procedure and records shall be established for this commitment that includes the assurance of availability of Instructions for Use (IFU) issued by the manufacturer.
4. Ensure that the medical device has been supplied and accompanied with all accessories set by the manufacturer, and that all Identifying Information (Labeling) and accompanying documentation, including Instructions for Use (IFU), are provided, and verifying that users have been trained on the medical device operation.
5. Abide to the manufacturer's instructions and follow the recommendations outlined in Annex (3) regarding the transport and storage of medical devices.
6. Ensure that electrical plugs of medical devices are compatible with healthcare provider's electrical socket (i.e., no adapter or extension cord is used).
7. Receive all documentation related to setup and installation, including maintenance and usage manuals.
8. Maintain records of user training on operation and technicians training on maintenance.
9. Supervise the execution and frequency of Planned Preventive Maintenance (PPM) in accordance with to the manufacturer's instructions.
10. Provide appropriate labels based on the condition of the medical device (e.g., "Out of Service" label and "Planned Preventive Maintenance (PPM)" data label).
11. Ensure that Clinical Trials conducted inside the healthcare facility have obtained SFDA approval, and that a documented policy for conducting Clinical Trials and researches on medical devices within the facility is established and in compliance with the "Requirements for Clinical Trials of Medical Devices" (MDS-REQ 2); or documenting a written policy confirming that the healthcare provider will not conduct Clinical Trials on medical devices.
12. Ensure that Advertising Materials displayed on the healthcare facility have obtained SFDA approval, and that a documented policy for obtaining such approval is established in compliance with the "Requirements for Advertisement Approval and Launching Awareness and Charity Campaigns for

Medical devices" (MDS-REQ 8); or documenting a written policy confirming that the healthcare provider will not advertise medical devices.

13. Ensure that awareness or charitable campaigns that include the display or use of medical devices hosted inside the healthcare facility have obtained SFDA approval , and that a documented policy for obtaining such approval is established and in compliance with the “Requirements for Advertisement Approval and Launching Awareness and Charity Campaigns for Medical devices” (MDS-REQ 8); or documenting a written policy confirming that the healthcare provider will not host awareness or charitable campaigns that include the display or use of medical devices.

14. Report incidents to NCMDR immediately, and establish a documented policy for reporting incidents, and submitting and handling complaints related to medical devices in compliance with the "Requirements for Post-Market Surveillance of Medical Devices" (MDS-REQ 11), while committing to follow up on the investigation of incidents and providing NCMDR with all relevant information and documents, in addition to maintain an up-to-date reports logs with supporting documentation of preventive or corrective actions taken.

15. Immediately report NCMDR for any Medical Device that violate the provisions and requirements of the Law of Medical Devices and its regulations, including counterfeit and unauthorized Medical Device in accordance with the "Requirements for Post-Market Surveillance of Medical Devices" (MDS-REQ 11).

16. Establish a documented policy for dealing with field safety corrective actions (FSCA) in accordance to the “Requirements for Post-Market Surveillance of Medical Devices” (MDS-REQ 11), and the commitment to respond to weekly safety alert reports and documenting the reports and communication records that have been made with SFDA, manufacturers and establishments, which include information on alerts such as the date of receipt of the alert, affected devices, action taken and date of completion of the implementation of (FSCA).

17. Provide a dedicated and equipped place for the maintenance of Medical Device if the healthcare provider performs maintenance work on its devices.

18. Provide maintenance services for Medical Device through:
    a) The manufacturer
    b) The importer or distributor licensed by SFDA for their own medical devices.
    c) Establish and develop a specialized Biomedical Technology (BMT) department to perform the additional responsibilities outlined in section (c).
    d) Medical Devices maintenance service providers licensed by SFDA.

19. Single use Medical Devices shall not to be reprocessed.

20. The "Requirements for Post-Market Surveillance of Medical Devices" (MDS-REQ 11) shall be followed when reprocess used Medical Device, reprocessing shall be carried out in accordance with the manufacturer's instructions and relevant standards.

21. The "Requirements for Post-Market Surveillance of Medical Devices" (MDS-REQ 11) shall be followed when resale, loan or donate used medical devices.

22. The "Requirements for Post-Market Surveillance of Medical Devices" (MDS-REQ 11) shall be followed when disposing used medical devices, there shall be a documentation of all disposal data, and the disposal records shall be maintained for period of at least three (3) years.

23. Establish a record within the maintenance management system for each medical device, including—at a minimum—the following information:
    a) General information about Medical Device (device name, model, manufacturer name, and serial number).
    b) Date of supply/installation/operation.
    c) Records of completed and scheduled planned preventive maintenance (PPM), corrective maintenance (repair), and calibration.
    d) The party or person who performed the maintenance.

24. Ensure the availability of the implantable medical devices card attached by the manufacturer, which includes the device name, manufacturer name, model number, lot/batch number, and device lifespan, and provide it to the patient after adding the following additional information:
    a) Patient's and physician's names.
    b) Healthcare facility address.
    c) Device implantation date.

25. Maintaining the confidentiality and privacy of information related to Medical Device, particularly complaints, reports, incidents, safety alerts, FSCAs, and other sensitive data and information, and not disclosing them to avoid any confusion or misuse of medical devices within the healthcare facility and other facilities.

C. Responsibilities of the Biomedical Technology (BMT) Department

1. Staff working in the (BMT) department shall have scientific or technical qualifications in biomedical technology/engineering or any other related field.
2. Ensure that appropriate training on the medical device is provided by the manufacturer or an entity approved by the manufacturer.
3. Provide all pre-installation requirements for the medical device, and all other requirements related to the device (e.g., generators and electrical wiring, medical gas pipeline systems, flooring, surfaces and insulators, and sterilizers or disinfectors), in accordance with to the manufacturer's instructions.
4. Receive the medical device and conduct acceptance tests.
5. Supervise the setup and installation of the medical device at the designated site in accordance with the manufacturer's instructions and documented policy.
6. Receive a post-installation report for the medical device, proving and explaining that it is in good condition and fully functional, and that the users have received the necessary training on its operation. This report shall be signed by the relevant engineer or technician along with the user. Ensure that all consumables and accessories specified by the manufacturer are provided.
7. Assign and affix the control number to the medical device, along with any other relevant markings (e.g., warranty expiration date).
8. Specify the appropriate training needs for operation and maintenance.
9. Conduct the necessary tests to ensure the safety, efficiency, and quality of the medical device performance during use, in accordance with the manufacturer's instructions. If the device fails any test, NCMDR shall be notified immediately.
10. Commitment to conducting electrical safety tests, image quality monitoring, laser quality monitoring, and ultraviolet quality monitoring.
11. Adherence to conduct periodic preventive maintenance (PPM) as follows:
    a) Scheduling (PPM) appointments.
    b) Ensuring the medical device is clean, disinfected (if needed), and in a good working condition.
    c) Ensuring maintenance is performed by personnel trained by the manufacturer on the specific device, and that the procedures and frequency of maintenance comply with the manufacturer's instructions.
    d) Ensuring the calibration of medical devices after PPM, or receive a calibration certificate if the PPM was conducted by the manufacturer or a medical device maintenance service provider.

e) Record details of PPM, including the date, instrument kits, etc., in the medical device log within the maintenance management system, and maintain these records for at least five (5) years.
f) Affix a label on the medical device after PPM, indicating at least the date of the most recent PPM, the person who performed it, and the date of the next PPM.

12. Follow the manufacturer's instructions regarding corrective maintenance (repair) and calibration. If such instructions are unavailable, refer to recognized Saudi or international standards.

13. Availability of appropriate calibration tools and test equipment and to calibrate, and test function and safety of the medical device, which shall be compatible with the "Law of Measurement and Calibration" issued by Royal Decree No. (M/79) dated 06/03/1445 AH, its Implementing Regulation and relevant instructions. Such tools and equipment shall be adjusted and calibrated before any reuse.

14. Conduct electrical safety test after PPM or corrective maintenance (repair) and before returning the device to service, in accordance with the manufacturer's instructions.

15. Obtain user/operator approval signing for all corrective maintenance (repair) reports.

16. Provide a maintenance management system and an inventory management system to record, store, organize and analyze Medical Device data, including necessary spare parts and a list of all manufacturer-approved spare parts suppliers.

17. Maintain a special log for each medical device within the maintenance management system that include, at a minimum, the following information:
    a) **General information** about the medical device (Device Name, Device Model, Device Accessories and Manufacturer's Data).
    b) **PPM information:** frequency of PPM, updated SOPs, calibration requirements, utilized tools and spare parts, date of each maintenance, the entity or person who conducted the maintenance and the time spent to conduct the maintenance.
    c) **Corrective Maintenance (repair) information:** Date of device malfunction, description of the malfunction, utilized tools and spare parts and time spent to conduct the maintenance.
    d) **FSCA information:** Date of receiving FSCA letter, description of Safety Alert, plan for implementing FSCA and date of completion of FSCA implementation.

D. Requirements for Safe Use of Radiology and Medical imaging device (Ionizing and Non-Ionizing)

1. Provide and implement documented policies and procedures, subject to periodic review, for:
   a) Radiation Protection Program.
   b) Quality Assurance Program.
   c) Management and monitoring of diagnostic medical radiation doses for patients.

2. Apply "National Diagnostic Reference Levels", maintain records proving compliance with the specified levels, and submit these records to SFDA via email (NDRL@sfda.gov.sa).

3. Periodically conduct quality assurance tests for radiology and medical imaging devices through qualified and trained professionals within the healthcare facility or one of the entities licensed by the SFDA to provide this service in accordance to the "Requirements for Licensing of Medical Devices Establishments" (MDS-REQ 9). In case that the device fails to pass any test, the test report shall include a recommendation regarding weather the device could be used or not.

4. Notify SFDA through NCMDR if radiology and medical imaging device fails to pass any quality assurance test, along with a corrective action plan to address the defect, within three (3) days of receiving the test results report. Continued use of the device will be contingent upon the recommendations contained in the report.

5. Maintain quality assurance test reports and records in a readily accessible manner upon request.

6. Conduct risk assessments in rooms where radiological and medical imaging devices are used to determine the necessity of shielding and protection. These assessments shall be carried out by qualified and trained professionals inside the healthcare facility or by a licensed provider of such service. The risk assessment reports and records shall be maintained and readily accessible upon request.

7. Conduct radiation survey tests of the areas surrounding the room where radiological and medical imaging device is used at least (Once every Two years), or whenever any modifications are made to the device or room that may affect shielding efficiency. These tests shall be performed by qualified and trained professionals inside the healthcare facility or by a licensed provider of such service. Reports and records of these tests shall be maintained and readily accessible upon request.

8. Immediately cease using radiological and medical imaging device if the device fails to pass radiation survey test, pending approval from SFDA to resume operation. NCMDR shall be notified within three (3) days of receiving the test results report.

9. Providing personal protective equipment (PPE) for protection of workers and patients from ionizing and non-ionizing radiation, and adhering to use it - unless it conflicts with or affects the procedure - as follows:
    a) Providing a sufficient number of PPE in various sizes (for adults and pediatric) and for various uses in each room containing radiological and medical imaging device (e.g., full body apron, pelvic apron, thyroid collar, gloves, or any other PPE).
    b) Provide at least (Two Pairs) of protective eyewear for non-ionizing radiation such as lasers and UV radiation in each room where these devices are used, and keep spare eyewear for use when needed. Ensure the eyewear matches the wavelength of the device.
    c) Store, handle, and use PPE in accordance to the manufacturer's instructions, and replace any damaged PPE immediately.
    d) Conduct periodic inspections to ensure the effectiveness and quality of PPE, and maintain inspection records that are readily accessible upon request.

10. Adhere to monitor diagnostic radiation doses to which the assigned worker is exposed during their work period as follows:
    a) Provide each classified worker with (Two personal dosimeter badges) (A&B) that used alternately when one of them is sent for reading.
    b) Maintain records of personal dosimeter badges readings for each classified worker, where they can be readily accessible upon request.
    c) Maintain records of personal dosimeter badges readings for each classified worker until the age of (75 years) or for a period of (30 years) from the launching of the records - whichever is longer -.
    d) Provide additional personal dosimeter for extremities when exposure to high radiation dose is expected.
    e) Provide additional personal dosimeter for pregnant worker to be worn at the level of pelvic area.
    f) Conduct risk assessment to predict annual radiation dose for workers in dental radiology department and other departments where they might subject to radiation doses, to determine the need to provide personal dosimeter badge.

11. Equip radiology and medical imaging departments with access restriction means to prevent unauthorized people access.

12. Equip radiology and medical imaging rooms doors in various departments with warning signs for potential risk of radiation (ionizing and non-ionizing) in Arabic and English, with additional warning signs specifically for pregnant women on the doors of ionizing radiation rooms.

13. Equip the entrances to ionizing radiation rooms with an external warning light that activates automatically when a procedure begins.

14. Provide portable shielding barriers for use with portable ionizing radiation device to protect patients and staff from unnecessary radiation exposure.
15. Equip radiology and medical imaging rooms with means that allow the operator to continuously monitor the patient during the procedure.
16. Comply with the additional requirements outlined in Annex (5).
17. Follow the instructions in the "Guidance on SFDA Requirements for Quality Assurance Programs for Radiation Emitting and Imaging Devices " (MDS-G015).
18. Follow the instructions in the "Guidance for the Operation and Use of Radiation-Emitting Medical Devices" (MDS-G007).

E. Requirements for Safe Use of Medical Radioactive Materials

1. Establish and implement documented policies and procedures related to the safe receipt, storage, preparation, transportation, and use of medical radioactive materials, and to handle incidents involving their use, such as radioactive contamination, loss of medical radioactive materials, and other incidents.
2. Document all incidents involving medical radioactive materials (including radioactive contamination, loss of medical radioactive materials, and other incidents involving their use), maintain incident reports and records and relevant investigation findings, and make it available upon request.
3. Install surveillance cameras at the entrance to the medical radioactive materials laboratory (Hot Lab).
4. Provide radiation detection and monitoring equipment equipped with an audible and visual alarm (Area Monitor) inside the Hot Lab and calibrate it regularly, and ensuring the availability of backup monitors.
5. Provide a communication device inside the Hot Lab for use in emergencies.
6. Provide radiation survey meters and calibrate it regularly, ensuring the availability of backup meters.
7. Provide radiation protection and safety equipment for emergencies, including:
   a) Sink and eye washer/shower.
   b) Radiation contamination monitoring kit.
   c) Radioactive decontamination kit.
8. Equip a designated and secure storage area for medical radioactive materials (both active and decaying) to restrict accessibility.
9. Equip the nuclear medicine and radiotherapy departments with access control means to prevent unauthorized personnel.
10. Establish a designated path for the transfer of medical radioactive materials from the receiving area to the Hot Lab.
11. Document the receipt of medical radioactive materials including their serial numbers by the Radiation Safety Officer (RSO) and maintain records inside the department.
12. The Radiation Safety Officer shall accompany the person transporting the medical radioactive materials from the receiving area to the Hot Lab.
13. Comply with the additional requirements outlined in Annex 5.

F. Final Provisions

In the event that there are medical devices that have not obtained MDMA certificate and were supplied after the effective date of the “Medical Devices Law” (14 Muharram 1443 AH corresponding to 22 August 2021 AD), SFDA will apply the necessary procedures in accordance with the Medical Devices Law and its implementing regulation.

Annexes

Annex (1): Appointment of a liaison officer

(a) Duties and responsibilities of the liaison officer

Qualifications	- Healthcare Providers shall appoint a liaison officer with NCMDR who is qualified in biomedical engineering/technology or any other medical/health-related specialty, as classified by the Saudi Commission for Health Specialties (SCHS). - The liaison officer shall be proficient in English. - SFDA shall be notified of any changes or updates to the liaison officer's information.
Duties and responsibilities of the liaison officer	- Act as a liaison between the various departments inside the healthcare facility – including procurement and supply – and NCMDR regarding all matters related to medical devices, whether located inside the healthcare facility or dispensed for use outside the facility. - Immediately report to NCMDR any incidents or complaints related to medical devices inside the healthcare facility and provide all relevant information and documentation. - Report incidents and complaints related to medical devices and provide NCMDR with all relevant information and documentation. - Respond to the weekly safety alert report, indicating whether or not medical devices inside the healthcare facility were affected by any safety alert, by replying to the email received from NCMDR. - Communicate with the manufacturer or its authorized representative if medical devices inside healthcare facility are affected by any FSCA. - Provide the required information and reports related to the safety alert, such as updates on the implementation of FSCA, and submit any maintenance or destruction reports for the affected devices. - Ensure that implementation of FSCA on the affected medical device is completed in accordance to the FSCA implementation plan approved by NCMDR. - Cooperate with SFDA in monitoring healthcare providers' compliance with the requirements addressed in this document. - Respond to SFDA surveys and questionnaires regarding medical devices.

(b) NCMDR Liaison Officer Appointment Form

Dear Healthcare Providers

In accordance to the Implementing Regulation of the Medical Devices Law, which stated in article 28/1 the following: "Healthcare providers shall appoint a liaison officer with the NCMDR in accordance with Medical Device Post-Market Surveillance requirements." And based on the "Requirements for Post-Market Surveillance of Medical Devices" (MDS-REQ 11), which stated that "The NCMDR liaison officer shall be scientifically qualified in biomedical engineering/biomedical technology or any medical/health specialty". Therefore, please provide the NCMDR with a letter to nominate the liaison officer with the information in the table below. As an alternative, you may fill, sign and stamp the below table.

Healthcare Provider	
Name	
Phone No.	
E-Mail	
Liaison Officer	
Name	
Scientific Qualification	
Position	
Mobile No.	
E-Mail	
☐ **We pledge to notify SFDA in the event of any change or update to the liaison officer's information.**	

The letter or the form can be sent to the NCMDR email:

(NCMDR.MD@SFDA.GOV.SA)

Best Regards;
NCMDR
Saudi Food & Drug Authority

السادة مقدمي الرعاية الصحية

استنادا إلى اللائحة التنفيذية لنظام الأجهزة والمستلزمات الطبية والتي نصت في المادة 1/28 على التالي "على مقدمي الرعاية الصحية تعيين ضابط اتصال مع المركز وفقًا لمتطلبات رقابة ما بعد التسويق ". وبحسب "متطلبات رقابة ما بعد التسويق للأجهزة والمستلزمات الطبية" (MDS-REQ 11) والتي نصت على أنه "يجب أن يكون ضابط الاتصال مع المركز مؤهلاً علمياً في تخصص الهندسة/التقنية الطبية الحيوية أو أي تخصص طبي/صحي.". عليه يرجى تزويد المركز الوطني لبلاغات الأجهزة والمستلزمات الطبية بخطاب لترشيح ضابط الاتصال وفقاً للبيانات في الجدول أدناه. كما يمكن - بدلًا عن ذلك - تعبئة البيانات في الجدول أدناه والتوقيع والختم على النموذج.

مقدم الرعاية الصحية	
الاسم	
رقم الهاتف	
عنوان البريد الإلكتروني	
ضابط الاتصال	
الاسم	
المؤهل العلمي	
المسمى الوظيفي	
رقم الجوال	
عنوان البريد الإلكتروني	
☐ **نتعهد بإخطار الهيئة في حال تغييروتحديث بيانات ضابط الاتصال**	

يمكن إرسال الخطاب أو النموذج إلى البريد الالكتروني للمركز الوطني لبلاغات الأجهزة والمستلزمات الطبية:

(NCMDR.MD@SFDA.GOV.SA)

مع تحيات،
المركز الوطني لبلاغات الأجهزة والمستلزمات الطبية
الهيئة العامة للغذاء والدواء

Annex (2) Healthcare Provider Declaration Form

☐ Supplying the device or medical supply before the effective date of the Medical Devices Law (14 Muharram 1443 AH corresponding to 22 August 2021 AD).

☐ Marketing authorization certificate has expired.

Name of Healthcare Provider:		**Date:**	
City/District:		**Short Address**	
Name of Medical Device:		**Model/Serial Number:**	
Manufacturer or Brand Name:		**Device Supply Date:**	

As the healthcare provider responsible for the medical devices in our possession, we acknowledge the following:		
Acknowledgment (Determine the Procedure that will be Performed from the Following)		**Required Documents**
☐	Obtaining a marketing authorization (MDMA) certificate or renewing the expired (MDMA) certificate.	○ Attach (MDMA) certificate or proof of initiating the process of obtaining or renewing (MDMA) certificate. As soon as possible, in accordance with the relevant requirements and procedures.
☐	Receive a statement from the manufacturer guaranteeing the continuity of after-sales services, including the provision of spare parts compatible with the technical specifications and standards of the medical device, as well as technical support for medical software throughout the lifespan of the medical device specified in the statement.	○ Attach the Manufacturer's Statement. Within one month of its date.
☐	- Provision of spare parts specified by the manufacturer and conforming to the medical device's technical specifications and standards. - Compliance with the manufacturer's instructions for all calibration, maintenance, and technical support operations, and - if these instructions are unavailable – follow the requirements outlined in recognized Saudi or international standards. - Ensuring that all calibration, maintenance and technical support operations are performed by personnel trained by the manufacturer on medical device maintenance or by a medical device maintenance service provider licensed by SFDA. - Commitment to performing calibration, maintenance and technical support throughout the medical device's lifespan.	Attach the maintenance contract and a certificate of license for medical device maintenance service providers. Or a training certificate on the maintenance granted by the manufacturer on the same device. Within one month of its date.
☐	Destruction or disposing of the medical device.	○ A report documenting the destruction of the medical device. ○ Or a medical device handover log to the contracted medical waste collection service provider. Within one month of its date.

☐ I acknowledge that I will provide SFDA - upon request and without delay - with the documents and records proving that one of the above-mentioned procedure(s) has been carried out.

Name: **Job title:**	**Signature/Stamp:**

Annex (3) Transport and Storage of Medical Devices Inside Healthcare Facilities

Storage Area	1	- The storage area for medical devices should meet the following criteria: - Designed or equipped for storing medical devices. - Clean and with sufficient space to allow for cleaning and inspection. - Equipped with a thermometer/hygrometer to monitor temperature and/or humidity changes. - Surfaces and shelves, if present, should be made of or covered with a non-porous material that allows for proper and safe cleaning. - Contain a designated area for isolating damaged, defective, expired, counterfeit, or recalled medical devices. This area should be clearly marked and monitored until a final decision is made regarding their disposal. - Adequate lighting and ventilation should be provided. - an emergency plan should be in place in case of a power outage in the storage area.
Tracking in the Storage Area	2	The healthcare provider should track medical devices in the storage area when SFDA or manufacturer recalls them, using their batch/lot number or serial number.
	3	The expiry dates of medical devices in the storage area should be monitored through periodic inventory to avoid dispensing expired devices by mistake.
Transportation	4	A copy of the transfer form should be sent to the Department of Medical Devices to update the medical device record in order to track the medical device for the purpose of maintenance, use, or assessment of its future needs.
	5	Medical devices should be transported in a manner that ensures they are protected from changes in temperature and/or humidity, thus ensuring their safety, efficiency, quality, and performance for the purpose for which they were made.
	6	The vehicle or container used to transport medical devices should be clean, designed, and equipped in a way that ensures the protection of medical devices from the surrounding environmental and climatic conditions.
	7	When it is necessary to disassemble and reassemble a medical device or product in different locations, this should be done by a qualified and competent person and in accordance with the manufacturer's instructions.
	8	Medical devices should be transported and carried carefully in accordance with to the nature of each device.
	9	Any damage or breakage of medical devices during transport should be reported.

Manufacturer's Instructions	10	Medical devices should be stored and transported in accordance with to the manufacturer's instructions to prevent damage. These instructions relate to one or more of the following: - Temperature (Medical devices should be kept within the temperature range specified by the manufacturer during transport and/or storage). - Humidity and moisture. - Exposure to light. - Correct positioning of the package/container. - Maximum number of packages that can be stacked. Note 1: If the device or medical device's specifications do not include information regarding storage and transportation conditions, the healthcare provider should obtain this information by submitting a request to the manufacturer and/or its authorized representative in the Kingdom. Note 2: If the manufacturer does not specify temperature values and storage and/or transportation conditions in the medical device specifications, refer to Annex (4). Note 3: Storage and transportation conditions (such as temperature and humidity) as required by the manufacturer should be monitored and recorded periodically.
Sterile Medical Devices	11	In addition to the manufacturer's instructions for sterile medical devices, storage and transportation of sterile medical devices shall be protect their packaging from: - Moisture. - Direct sunlight. - Dirt. Note: Sterile medical devices are considered non-sterile if the integrity of their packaging is compromised.
Workers	12	Personnel involved in the storage and transportation of medical devices should possess the following: - The necessary knowledge of these activities. - The ability to handle medical devices that require special transportation and storage conditions.
Written Procedures	13	All healthcare providers involved in the storage and transportation of medical devices should have written procedures outlining the practices to be followed to ensure they are stored and transported in accordance with to the manufacturer's instructions. These written procedures are typically part of a quality management system.

Annex (4) Transport and/or Storage Conditions

Freezer	Temperature between -20 and -10 °C
Refrigerator	Temperature between 2 and 8 °C
Cold Place	Temperature not exceeding 8 °C
Cool Place	Temperature between 8 and 15°C
Room Temperature	Temperature between 15 and 30°C
Warm Place	Temperature between 30 and 40 °C
Excessive Heat	Temperature exceeding 40 °C
Do not store over 8 °C	Temperature between 2 and 8 °C
Do not store over 15 °C	Temperature between 2 and 15 °C
Do not store over 25 °C	Temperature between 2 and 25 °C
Do not store over 30 °C	Temperature between 2 and 30 °C
Do not store below 8 °C	Temperature between 8 and 25 °C
Protect from moisture	The humidity level should not exceed 60% under normal storage conditions. It is delivered to the user in a moisture-resistant container.
Protect from light	Delivered in a light-resistant package

Annex (5) Additional Requirements for Different Radiology Departments

Essential principles of Radiation Protection	1	- Restrict the use of Radiological and medical imaging device to specialized medical centers, complexes, and clinics, and ensure that the equipment operator is qualified and trained in its use. - Include the following in the radiation protection program policy: - Adherence to the main principles of radiation protection and the use of radiation shielding during any medical procedure involving Radiological and medical imaging device or radioactive materials, unless this conflicts with the procedure. - Application of the “ALARA” principle. - Ensure that the benefits of radiation exposure outweigh the potential risks, while exploring the possibility of using other medical imaging equipment. - A suitable mechanism for explaining the potential side effects and risks associated with radiological examinations, and providing necessary pre- and post-procedure instructions, in accordance with to the level of risk, with documentation where appropriate. - A suitable mechanism for reviewing and documenting relevant clinical information before radiological examinations, including the patient's medical history and current health status, and previous radiation exposures, with documentation where appropriate. - An appropriate mechanism for managing cases in which there is a possibility of pregnancy in women before conducting radiological examinations in accordance with to the level of risk, including reassessing the need for examination, considering non-ionizing alternatives or postponing the examination when possible, and if the benefits outweigh the risks, the examination is carried out cautiously with the application of radiation protection measures, with documentation of the decision and action taken.
Healthcare Provider Responsibilities	2	- Ensure the department has obtained the necessary licenses from the relevant authorities. - Ensure that all staff and/or medical personnel are licensed by the Saudi Commission for Health Specialties and the Nuclear and Radiological Regulatory Authority in their respective fields. - Ensure the department has a radiation protection and safety program in place and reviews it regularly. - Provide basic training programs within the facility for all operators, maintenance staff, cleaning staff, and any medical or administrative

		personnel in the various radiology departments. These programs should include emergency plans and safety drills. These programs must be reviewed regularly, and the training of all personnel must be documented.
Requirements for Dermatology and Laser Departments	3	- The client must be examined by a dermatologist before any procedure using radiation-emitting devices such as lasers, ultraviolet rays, radio waves, and ultrasound. - Any objects that reflect laser beams inside the room, such as mirrors or metal, must be covered or removed. - Instructions and operating procedures for the device must be provided inside the room.
Requirements for Nuclear Medicine and Radiation Therapy Department	4	- Appoint a Radiation Safety Officer licensed in nuclear medicine by the Nuclear and Radiological Regulatory Authority, who is not administratively affiliated with the department. - Appoint a Radiation Safety Officer licensed in radiotherapy by the Nuclear and Radiological Regulatory Authority, who is not administratively affiliated with the department. - Clearly define the responsibilities of medical staff, including oncologists, radiation therapists, medical physicists, radiation dose officers, referring physicians, etc. Establish policies for the administration of radioactive material, including for pregnant patients. - Continuously develop and review quality assurance programs and policies. - Directly supervise any trainee within the department's facilities. - Establish policies and procedures for surveying, detecting, and removing radioactive contamination, including: - Conducting periodic radiological surveys. - Conducting radiological surveys whenever radioactive contamination is suspected. - Decontaminating any radioactively contaminated areas. - Ensuring that the equipment, including the examination table and scanner area, is free from any radioactive contamination, and that radiation levels are safe and secure before admitting the next patient. - Documenting radiological incidents. - Establishing policies and procedures for managing radioactive waste. - Maintaining an up-to-date log of medical radioactive materials in the department, including the material name, serial number, manufacturer, radioactivity, date and time of receipt, and emitted radiation level.

Annex (6): Definitions and Abbreviations

Kingdom	Kingdom of Saudi Arabia
SFDA	Saudi Food and Drug Authority.
NCMDR	The National Center for Medical Devices Reporting.
Medical Device	Any machine, instrument, applicator, implanter, laboratory reagent, laboratory calibration materials, software, operating materials for medical devices, or any similar or related device, whether manufactured alone or in conjunction with other devices, used in the diagnosis, prevention, monitoring, control, treatment, alleviation, relief, or compensation of diseases or injuries; also used in examination, replacement, modification, anatomical support, influencing the functions of body organs, supporting or enabling life (human vital functions) to continue, regulating or assisting pregnancy, sterilizing medical devices, and providing information. For medical or diagnostic purposes - derived from laboratory tests of samples taken from the human body, as well as those that cannot achieve the purpose for which they were made in or on the human body by means of the drug, immune factor or metabolic transformations, but only help to achieve their effects.
Medical supplies	Medical materials and products used in diagnosis, treatment, replacement, orthodontics, disability, or other human medical uses, including medical gases.
Implantable Medical Device	A medical device surgically introduced into the human body or to replace a superficial / epithelial surface, or the surface of the eye and intended to remain in place after the surgical procedure. This includes devices intended to: - be partially or wholly absorbed. - remain in the body for thirty (30) days or more.
Single use Medical Device	Manufactured for the purpose of use on one patient during a single procedure, and then disposed thereof.
Medical radioactive materials	A material from which ionizing radiation is emitted, whether by itself, or in other medical devices used for diagnosis and treatment.
Manufacturer	Any national or foreign establishment whose purposes include designing or manufacturing medical devices to offer them for use in its own name, whether inside or outside the Kingdom. Manufacturing includes: refurbishing, assembling, packaging, wrapping and labelling.
Authorized Representative	A legal person based in the Kingdom who is authorized, in writing, by a Manufacturer located outside the Kingdom to represent it within the Kingdom with regard to the implementation of the "Medical Devices Law ".
Healthcare Provider	Any government or private establishment that provides healthcare services.
Liaison officer	A designated healthcare provider acts as a liaison with the NCMDR.
User	A professional, lay person, or a patient who uses a medical device.
Biomedical Technology (BMT) department	The department or section concerned with everything related to the medical device or equipment within the healthcare facility, from supply and receipt to disposal, including setting and evaluating needs and technical specifications, managing maintenance, inventory, training, and other related tasks.
Various radiology departments	Any department inside healthcare facilities that uses radiology and medical imaging device (ionizing and non-ionizing), including but not limited to radiology, nuclear medicine, radiotherapy, dental radiology, lasers and cosmetics.
“ALARA” principle	Achieving the purpose of using radiation-emitting medical devices with the least possible radiation exposure.
Classified worker	Every worker who works within healthcare facilities may have an expected annual exposure to more than (1) millisievert.
License	A document issued by the SFDA to practice any of the activities subject to the Law.

Marketing Authorization (MDMA)	A document issued by SFDA for any medical device it allows to be traded in the markets.
Quality Assurance	A set of technical tests, measurements and calibration adopted by SFDA, to ensure the safety and security of medical radiography devices, as well as the accuracy and quality of radiographs, in order to ensure the efficacy and adequacy of diagnosis and treatment.
Technical and Clinical specifications	Documentation that determines the quality, efficacy and safety of specified devices or substances.
Medical Device Adverse event	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.
Safety Alert	A notification issued by NCMDR indicating the risk associated with a medical device and the corrective action to be taken to mitigate the associated risk.
Filed Safety Corrective Action	An action taken by the Manufacturer to eliminate or reduce the risks affecting the safety of a medical device.
Corrective Action	An action taken to address nonconformity reasons for the establishment, manufacturer, or medical device
Corrective maintenance (repair)	It is an unscheduled process or procedure to correct and repair deficiencies in a medical device or one of its components; this procedure includes repairing or replacing consumable components or parts used in order to restore the integrity and performance of the medical device.
Regular preventive maintenance	It is a routine procedure or process scheduled at specific intervals, and includes specific maintenance operations such as: lubrication, cleaning, or replacement of consumable parts.
Calibration	Corrective adjustments required to readings and measurements of medical devices or testing equipment to maintain performance accuracy in accordance with a standard reference.
Reprocessing	Measures made on the previously used medical device to be reused safely, including: • cleaning; • disinfection; • sterilization; and • testing and restoring the technical and safety functions related to it.
Test equipment	The means or tools used to conduct safety, performance or calibration tests for medical devices.
Radiation Safety Officer	A person licensed in radiation protection and safety in the medical field who works for a healthcare facility.
Maintenance management system	An electronic portal used to manage operations related to the maintenance and technical support of medical devices.
Advertising	Any written, audible, or visible or other media displays intended to promote a medical device or its technology, or to facilitate a direct or indirect sale.
Labelling	Any statement or information drawn, photographed, written or printed on the device and medical equipment, including information about its identification, technical description, how to use it, and methods of storing and transporting it.
Control number	A set of letters, numbers, and symbols is affixed to the medical device for monitoring and tracking, and is entered into the maintenance management system database.

Annex (7): List of amendments to the previous version

Previous Version Number and Date	Description of Modification
Version 2 **15/05/2023**	• Amendment to the Scope. • Amendment to the Background. • Additions to Section A. General. • Additions to Section B. Responsibilities of Healthcare Providers. • Inclusion of Section F. Final Provisions. • Inclusion of Annex (1): Appointment of a liaison officer ○ (a) Duties and Responsibilities of the Liaison Officer ○ (b) NCMDR Liaison Officer Appointment Form • Inclusion of Annex (2): Healthcare Facility Declaration Form.