الهيئة العامة للغذاء والدواء
Saudi Food & Drug Authority

MDS-REQ 4

Requirements for the Import and Clearance of Medical Imaging Materials and Particle Accelerators Used in Radioisotopes Formation for Medical Applications

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"Translated Copy"

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Introduction

Purpose

The purpose of this document is to specify and clarify the requirements for importation and clearance of medical imaging materials and particle accelerators used in radioisotopes formation for medical applications.

Scope

This document applies to:

- Medical imaging materials
- Particle accelerators used in radioisotopes formation for medical applications
- Importers of medical imaging materials or particle accelerators used in radioisotopes formation for medical applications.
- Healthcare providers and research centers intending to import medical imaging materials or particle accelerators used in radioisotopes formation for medical applications.

Background

SFDA has issued this document about Article 5 and Article 8 of the "Medical Devices law" published by the Royal Decree No. (M/54) dated 6/7/1442 H, and Articles (2/1), (4/3), (11/7) and (11/9) of the “Executive Regulation of Medical Devices law” issued by Saudi Food and Drug Authority Board of Directors decree No. (3-29-1443) dated 19/2/1443 H.

Requirements

General	1	• Medical imaging materials or particle accelerators used in radioisotopes formation for medical applications shall not be imported or circulated unless after obtaining import permission from the SFDA. • Particle accelerators used in radioisotopes formation for the therapeutic purpose shall obtain medical device marketing authorization (MDMA).
SFDA Prerequisite	2	Importers of medical imaging materials or particle accelerators used in radioisotopes formation for medical applications shall obtain an SFDA establishment license to engage an importation activity according to medical devices establishment licensing requirements.
	3	Healthcare providers and research centers shall create an account through"GHAD System". However, they are not required to obtain an SFDA establishment license.
Submitting the application	4	• Applying through the "GHAD System." • Submit the documents specified in sections (A) and (B) of the "Required Documents". • The SFDA will reviews the request and responds either with acceptance accompanied by the issuance of import permission or rejection with justification.
Clearance at ports of entry	5	• Submit the documents specified in section (C) of the "Required Documents" according to the "Guidance on Requirements of Shipments Clearance at Ports of Entry (MDS-G21)". • Ensure the proper packaging of the product and the availability of appropriate labelling. • Adherence to marking the product information and warning signs on the package with identification of both the sender and the consignee.
Requirements for storage and transportation	6	Commitment to the requirements for storage, transportation and handling of medical devices published on the SFDA's website: 1. Guidance on Requirements for Storage, Handling and Transportation of Medical Devices. 2. Requirements for the Safe Use of Medical Devices inside Healthcare Facilities (MDS-REQ 3)".
	7	For particle accelerators used in radioisotopes formation for diagnostic purpose, adherence to the code for transportation and storage of products is subject to the supervision of the drug sector through customs ports.
Responsibility of importers	8	Adherence with the information provided in the application form for requesting permission to import medical imaging materials or in the "Application form for requesting permission to import particle accelerators used in radioisotopes formation for medical applications".

Required Documents

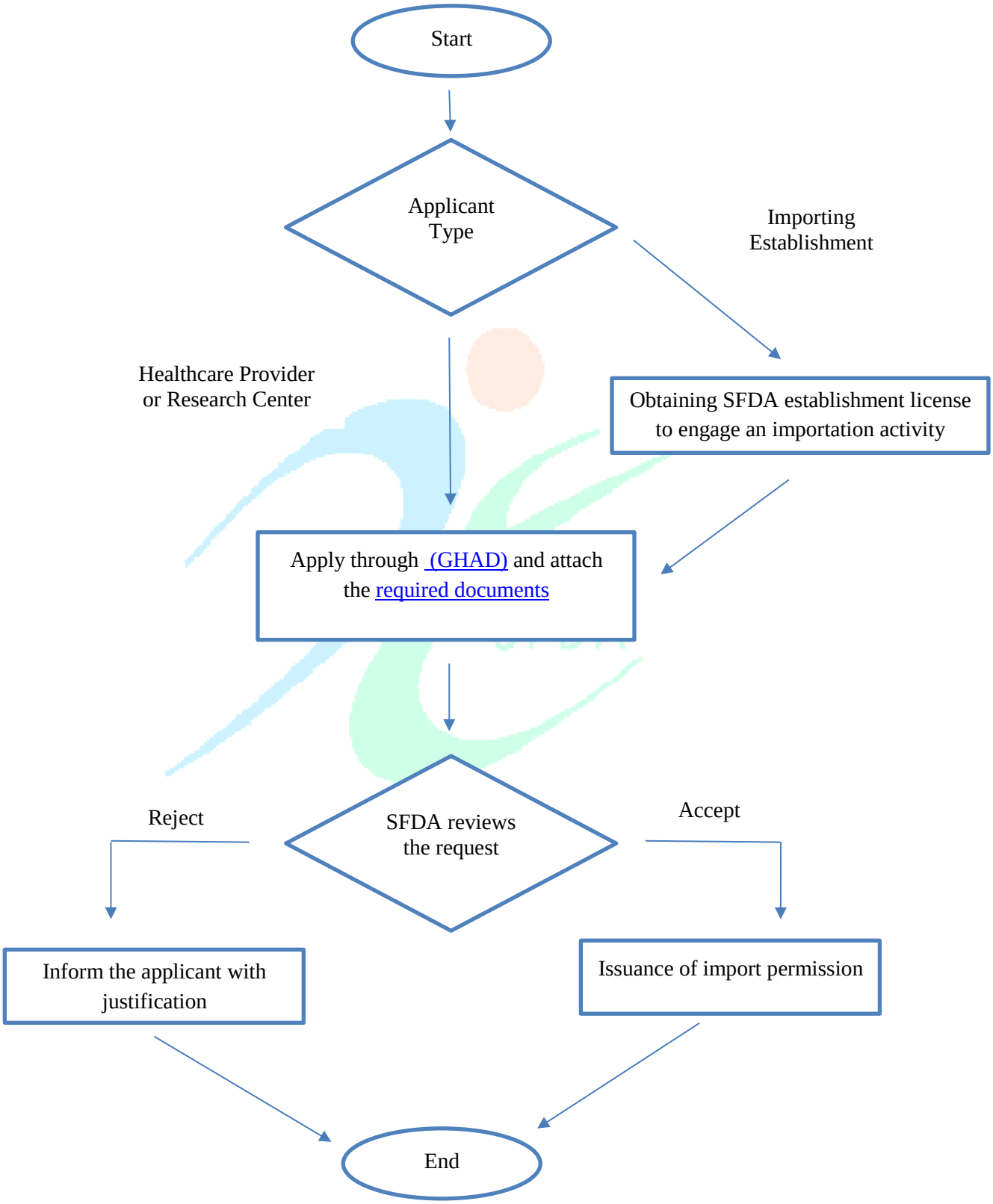
	Required Documents	Notes
A. General documents for requesting import permission for medical imaging materials or particle accelerators used in radioisotopes formation for medical applications.		
1	A copy of the SFDA establishment license to engage an importation activity	- Healthcare providers and research centers are excluded.
2	A copy of the manufacturer's invoice or a quotation	- It shall include: o Shipment description (list of items). o Trade/Scientific names. o Quantity (total/detailed). o Unit weight of each item and gross weight of each bundle. o The unit price of each item. o Production and expiration date. o Batch/lot number.
3	The original certificate of origin	- The competent authority shall stamp it for trade in the country of origin.
4	A declaration that the shipment conforms to the medical devices law and the administrative regulation with the requirements for labelling and the conditions of supply and/or use	- Provide a copy(s) of the declaration of conformity (DoC), if applicable and requested by the SFDA.
5	Purchase order (PO) issued by the beneficiary establishment	- Healthcare providers and research centers are excluded.
6	An official letter or free sales certificate (FSC) proving that the device and its accessories are sold in the country of origin	
7	Application form for permission to import medical imaging materials or particle accelerators used in radioisotopes formation for medical applications	- The form shall be filled out electronically through the "GHAD System" for medical imaging materials import permission request. - For particle accelerators used in radioisotopes formation for medical applications, the application form indicated in Annex (1) shall be printed.
8	▪ A disclosure form for radioactive materials, narcotics, or chemicals is subject to public security control ▪ Applicant's attestation	- See Annex (2 & 3). - Fill out the form and the attestation, and print them on the official paper of the beneficiary establishment.

B. Particular documents for requesting import permission for particle accelerators used in radioisotopes formation for medical applications		
9	A copy of the MDMA issued by the SFDA	- For particle accelerators used in radioisotopes formation for therapeutic purpose.
10	A copy of the radiation practice license for the beneficiary establishment	- Issued by Nuclear & Radiological Regulatory Commission.
11	A copy of the license of the radiation safety officer at the beneficiary establishment	- Issued by Nuclear & Radiological Regulatory Commission. - Shall be attached with the following: o Copy of the national ID/ Muqeem ID. o Proof that the RSO is under sponsorship or contracted with the beneficiary establishment.
12	Survey report of the radiation levels for the simulated used rooms	- It shall not exceed the maximum limits set by local and/or international legislators.
13	Letter by supplier company to prove the approval for installation place	
14	Technical specifications of radiation device	- Copies of the approved design specifications of the radiation device and major associated components and sub-systems. - Determining the weight and external dimensions of the entire system or its components separately.
15	Technical drawings for radiation device	- Copies of technical drawings for critical components and sub-systems of the radiation device show the device's general assembly, location(s) of the source(s), shielding, and safety features associated accessories to be used with the device. - All drawings shall be legible and marked with the release dates, scale, drawing numbers, and an associated parts list or bills of materials.
16	Technical and safety standards used	- If applicable, list major technical and safety standards used to design the radiation device. Explain how these standards were applied to the design and verify compliance with their requirements.

17	Design validation and risk assessment records	- Copies of the technical validation records including test reports, failure effect mode analyses, and device hazard & risk assessment files. - Copy of the risk assessment file. - A copy of the suggested emergency response plan in case of any accidental radiation hazard.
18	Radiation protection data of the device	- Describe the shielding used in the radiation device. - If the shielding includes depleted uranium, verify the weight of this material.
19	Radiation survey of the device	- Provide the maximum expected photon and neutron radiation dose rates around the radiation device that would result from leakage and scatter in all modes of operation. - Describe the measurement or calculation method, technical standards, conditions, and instruments used.
20	Accelerator beam target specifications	- Design specifications for the radiation beam target. - Specify the material(s) and model number(s) to be used. - Include applicable technical drawings, material specifications, and part numbers.
21	Radiation output	- Specify the beam particle type, maximum energy, radiation intensity, intensity and energy of the contaminating neutrons or photons generated in the primary beam and any limitations to the beam orientation.
22	Labelling, safety marks, and instructions	- Provide technical drawings, photographs, or samples of the safety labelling on the radiation device.
23	External safety devices	- Describe external safety devices and how these devices are connected to prevent, stop, or indicate the production of radiation (door interlocks, Last person out buttons, emergency stop devices, radiation state indicators, etc.). - Include schematics and, if applicable, software flow diagrams.

24	Records and documents of storing, transporting, using and operating the radiation device	- Provide the instructions for packing, unpacking, and transporting the package given to the end-user. - Provide the radiation safety instructions of the radiation device's use, operation, and storage. Include copies of the operating manual and radiation safety instructions to the end-user. - Enclose copies of radiation safety manuals, policies, and procedures for dealing with radiological emergencies involving the radiation device. - Description of the quality control procedures for radiation safety. - Provide a copy of the maintenance procedure to be followed if a package is re-used. - Enclose copies of procedures for conducting leak tests of any radioactive sources and shielding used (including depleted uranium, if any). - Note: a particle accelerator does not require the equipment package information unless the accelerator, as shipped, incorporates radioactive material.
25	Inspection and servicing	- Provide the recommended inspections, servicing program made available to the end-user.
26	Disposal of the radiation device	- Specify the expected lifetime of the radiation device in accordance with the manufacturer's instructions.
27	Table of radioactive sources	- See Annex (1).
C. Required documents for clearance at ports of entry		
28	A copy of the manufacturer invoice	
29	A copy of Bill of Lading (BoL)	
30	A copy of the import permission	
31	A copy of medical device marketing authorization (MDMA)	- For particle accelerators used in radioisotopes formation for therapeutic purpose.

Flowchart


Start
Applicant Type
Importing Establishment
Healthcare Provider or Research Center
Obtaining SFDA establishment license to engage an importation activity
Apply through (GHAD) and attach the required documents
SFDA reviews the request
Reject
Accept
Inform the applicant with justification
Issuance of import permission
End

Annexes

Annex (1): Application form for permission to import particle accelerators used in radioisotopes formation for medical applications

The applicant shall fill all fields with descriptive and relevant information in the following form:

Data of the beneficiary			
Facility Name		Branch / Department	
Practice license number		Practice type	
License issue date	/ / / /	License expiry date	/ / / /
Phone number		Phone extension	
Building no.		District name	
Street name			
Zip code		City	
Secondary No.		Country	

Data of the RSO of the beneficiary facility			
Name		Practice license number	
Practice type		License expiry date	/ / / /
Phone number		Phone extension	
Mobile number		E-mail	
Signature		Date	/ / / /

Data of the importing beneficiary			
Facility name			
Legal representative name			
Authorized distributor name			
License issue date	/ / / /	License expiry date	/ / / /
Phone number		Phone extension	
Building No.		District Name	
Street Name			
Zip Code		City	
Secondary No.		Country	

Devices to import			
Shipment data			
Manufacturer		Country	
Zip code		City	
Postal code		Phone number	
Phone extension		E-mail	
Export method	☐ by air ☐ overland ☐ by sea	Import port inside the Kingdom	
Device name(s)		Model	
Production date		Purpose of use	☐ Therapeutic ☐ Diagnostic
Explanation of the intention of using the device	....		

Device accessories and supplies	
Part number	**Model number**

Nuclides and radioactive waste are expected from the device				
Material name	**Half-life**	**The maximum amount produced/day**	**The radiation dose rate at 30 cm of activating elements**	**Medical purpose, if used**

Applicant from the beneficiary establishment			
I, the undersigned, acknowledge the correctness of the data contained in this application, at my responsibility, and pledge to abide by all the requirements and controls included in the book of general instructions for protection from ionizing radiation in the Kingdom of Saudi Arabia.			
Director (chief) of the facility	**Signature**	**Date**	**Facility stamp**
		/ / / /	

Annex (2): Disclosure Form of Radioactive Materials, Narcotic Substance or Chemicals Subject to Public Security Control

The applicant shall fill all descriptive and relevant information in the disclosure form via the following link:

https://www.sfda.gov.sa/ar/medicaldevices/regulations/DocLib/MD-DisclosureForm.docx

Annex (3): Applicant Attestation

☐	I certify that the information provided in this document is complete, accurate, and correct.
☐	I pledge not to import any of the mentioned products to a user other than the primary authorized importer and not to use them other than the purpose for which they were imported.
☐	I pledge that all items included in the request follow international requirements and specifications and the requirements for the SFDA.
☐	I pledge to abide by the guidelines issued by the SFDA related to storage, transport, and handling.
☐	According to public security regulations, I certify that the shipment does not contain radioactive materials, drugs, explosives, or any other prohibited material.
☐	I now declare that the contents of this shipment are thoroughly and accurately described in the name of the appropriate shipping, classified, packed, labelled, and placed identification card / installed the card on the device. Materials in all respects are suitable for transporting under national and international requirements and government regulations.

Are all or one of the products classified as a medical device/product?		
Yes ☐		No ☐
If yes, product name:	…….	
Classification type:	☐ High risk	……
	☐ Low risk	……

Applicant Name	**Applicant Signature**	**Date**

Annex (4): Definitions & Abbreviations

KSA	Kingdom of Saudi Arabia
SFDA	Saudi Food and Drug Authority
MDS	Medical Devices Sector
MDMA	Medical Devices Marketing Authorization
Beneficiary Establishment	Healthcare providers and research centers.
Healthcare Providers	Any government or private establishment that provides healthcare services.
Medical device	Any machine, instrument, application device, culture device, laboratory reagents, laboratory calibration materials, software or operating materials for medical devices, or any similar or related device manufactured alone or in combination with other devices. It is used in the diagnosis, prevention, monitor, control, treatment, mitigation, palliation, or compensation of injuries, as well as in an examination, replacement, modification, anatomical support, influence on the functions of body organs, support or enablement of life (vital functions for humans) to continue, organize or assist pregnancy, sterilize medical devices and supplies, and give information - for a medical or diagnostic purpose - extracted from laboratory tests of samples taken from the human body, as well as that cannot achieve the goal for which they were made in or on the human body. It is mediated by the drug or the immune factor or metabolic transformations but only helps achieve their interactions.
Medical Imaging Materials	Anything used to improve contrast that can be obtained using medical imaging techniques.
Radiation Safety Officer	A scientifically qualified person with practical experience and who holds a license to practice radiation protection and safety in the medical field.
Labelling	Any written statement, information, or illustration printed on a medical device, including identifying information, technical description, method of use, and manner of storage and transportation.

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

Number & Date of the Previous Version	Changes Description

MDS-G48
2.0
15/11/2020
 	
MDS-G52
2.0
01/01/2021
	• Update and merge the following two guidelines:
	  ○ Guideline for Import and Clearance Requirements for Particle Accelerators for Radioisotope Formation for Medical Applications (MDS-G48)
	  ○ Guidance on Requirements for Import / Re-export Medical Imaging Materials (MDS-G52)
	
	• Amending the requirement related to obtaining an establishment license to the requirements of getting an establishment license to import medical imaging materials or particle accelerators used in radioisotopes formation for medical applications, in light of paragraph (b.) of item "First" in Article (2/1) of the Executive Regulations of the Medical Devices Law issued by Board Resolution No. (3-29-1443) dated February 18, 2021
	• Deletion of requirements for re-export of medical imaging materials.
	
	• Add the documents required for clearance at the customs ports.
	
	• Amending the flowchart according to the updated requirements and procedures.
	
	• Delete the annex designated for the electronic form of medical imaging materials import and re-export permission request. Only refer to the link to fill out the (GHAD) form.
	
	• Updating and amending the definitions and abbreviations in the light of the law of medical devices and the executive regulations.