الهيئة العامة للغذاء والدواء
Saudi Food & Drug Authority

MDS-REQ 6

Requirements of Importation and Re-Exportation for Radioactive Materials Used in Medical Applications

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Introduction

Purpose

The purpose of this document is to specify and clarify the requirements for importing and re-exporting radioactive materials used in medical applications.

Scope

This document applies to:

- Radioactive materials used in medical applications.
- Importers and exporters of radioactive materials used in medical applications.
- Healthcare providers and research centers who are willing to import or re-export radioactive materials used in medical applications.

Background

SFDA has issued this document in reference to Article four of the "Medical Devices Law "issued by Royal Decree No. (M/54) dated 06/07/1442 H and Articles (2/1), (4/1) and (4/2) of the Medical Devices Executive Regulation issued by Board Resolution No. (3-29-1443) dated 2/19/1443 H, which state the following:

- Establishments/applicants who are willing to import or re-export radioactive materials must fulfil the SFDA requirements for importing and re-exporting radioactive materials used in medical applications, which are published on the SFDA's website.

- The SFDA issues technical and clinical specifications approvals or rejections within ten days of receiving the request for importation or re-exportation of radioactive medical materials.

Requirements

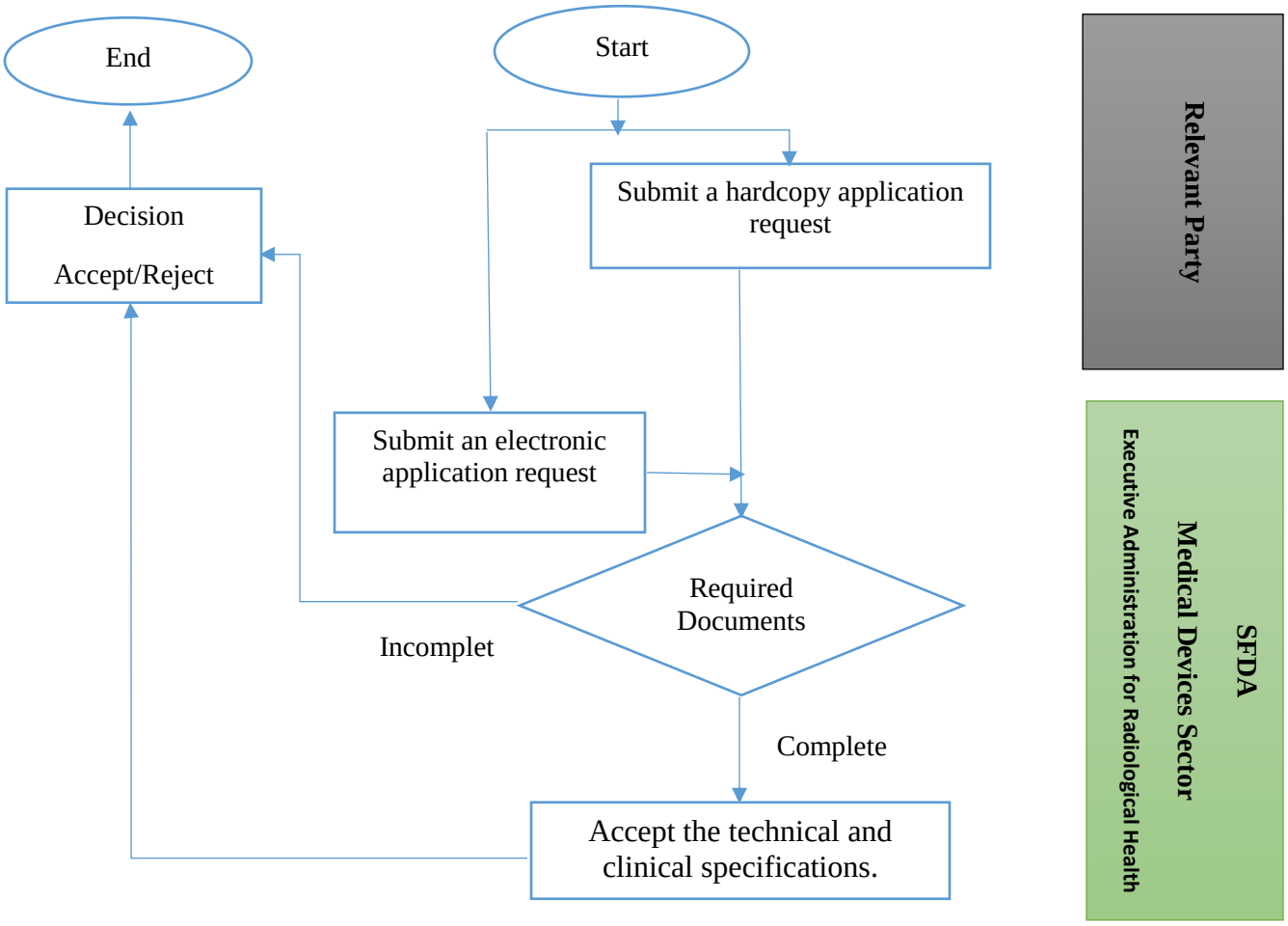
General	1	▪ Radioactive materials used in medical applications can only be imported or re-exported after the SFDA has approved those materials' technical and clinical specifications of those materials. ▪ Medical radioactive materials used in medical applications that are classified as a medical device/supply must obtain a marketing authorization for medical devices (MDMA)
SFDA Prerequisite	2	▪ Importers and exporters of radioactive materials used in medical applications shall have Medical Device Establishment License (MDEL). ▪ Obtaining the necessary licenses from the Nuclear and Radiological Regulatory Commission (NRRC) to practice activities associated with the use of radioactive materials for both beneficiary and carrier facilities as well as fulfilling the requirements of relevant authorities before applying.
	3	Health care providers and research centers wishing to export or re-export radioactive medical materials must register in the unified electronic system (GHAD) and obtain an account number. Meanwhile, obtaining a license to engage in import and/or re-export activities is unnecessary.
Submitting a request	4	▪ Submitting a request to Radioactive Materials Registration System ▪ Submitting the documents referred to in "Required Documents." ▪ The SFDA conducts technical evaluations for the requests, then accepts or rejects the technical and clinical specifications.
Import and re-export facilities responsibility	5	Importers and exporters are obligated by what is stated in the "Application Form of Importation/Re-Exportation for Radioactive Materials."

Required Documents

	Required Documents	Notes
1	Copy of MDEL license to practice the activity of importation and re-exportation of medical radioactive materials (issued by the SFDA).	• Healthcare providers and research centers are exempt.
2	Copy of the MDMA for radioactive material classified as a medical device (issued by SFDA).	• Radioactive material that are classified as a medical device.
3	Copy of Radiation Practice License assigned to the Beneficiary	• Issued by NRRC.
4	Copy of Radiation Safety Officer (RSO) License assigned to the radiation protection officer at the beneficiary	• Issued by NRRC. • It must be accompanied by the following: - Copy of the national identity card/residency card. - Proof that the RSO is on the sponsorship of the beneficiary facility or contracted with it.
5	Copy of the licensees of all the RSO in the carrier beneficiary establishment	• Issued by NRRC. • It must be accompanied by the following: - Copy of the national identity card. - Proof that the RSO is under the sponsorship of the beneficiary facility or contracted with it.
6	Copy of facility license for transporting the radioactive material	• Issued by NRRC.
7	Manufacturer invoice	• It must include the following: - Description of the shipment (names of items). - Trade/scientific name. - Quantity (total/detailed). - The radioactivity of each material - Unit weight for each item and total weight for each package. - The unit price for each item. - Production and expiration date. - Batch/operation number.
8	Original certificate of origin	• It must be stamped by the concerned party with trade in the country of origin.
9	Copy of the manufacturer Quality Management System (QMS) certificate in addition to the Good Manufacturer Practice (GMP) certificate.	•
10	Copy of the purchase order (PO) from the beneficiary.	• Healthcare providers and research centers are exempt.
11	An official letter or free sale certificate proving that the materials are sold in the country of origin.	• For importing only.
12	Letter from the relevant party requesting the SFDA approval.	
13	Application form of importation/re-exportation for radioactive materials.	• See Annex (1) • Fill in and print the form in a formal paper of the beneficiary organization.

14	Commitment letter from the manufacturer to receive the radioactive materials after consumption.	• For exportation only. • It shall include: - Importer name. - Radioactive material name.
15	Copy of the radioactive material transportation agreement.	• See Annex (2) • Fill in and print the form in a formal paper of the beneficiary organization.
16	List of Radioactive Materials.	• See Annex (3) - It shall include the serial numbers of radioactive materials if re-export only. - Print the form in a formal paper of the beneficiary organization.

Flowchart


End
Start
Relevant Party
Decision
Accept/Reject
Submit a hardcopy application request
Submit an electronic application request
Required Documents
Incomplet
Complete
Accept the technical and clinical specifications.
SFDA
Medical Devices Sector
Executive Administration for Radiological Health

Annexes

Annex (1): Application Form of Importation/Re-Exportation for Radioactive Materials

Click here for a printable and editable version

Beneficiary			
Facility Name		Branch / Department	
Practice license number		Practice type	
License issue date	/ /	License expiry date	/ /
Phone number		Fax	
P.O. Box	Zip code	City	

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

Radioactive material to import/export (as an attached list)			
Shipment data			
Manufacturer		Country	
Export/Import method	Air □ Overland □ Sea □	Importation port inside the Kingdom	

Transporter within the Kingdom			
Facility name		Branch	
Practice license number		License expiry date	/ /
RSO name		RSO license number	
RSO license issue date	/ /	RSO license expiry date	/ /
Phone number		Mobile number	
Fax		E-mail	
Facility stamp			

Applicant from the beneficiary establishment

I, the undersigned, acknowledge the correctness of the data 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	Date	Signature	Facility stamp
	/ /		

Annex (2): Form of Radioactive Material Transportation Agreement

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Agreement by:

First party:	**Second-party:**
RSO name:	**RSO name:**
Address: **Contact number:**	**Address:** **Contact number:**
Nuclear medicine license number:	**Transportation license number:**

It was agreed between the first and second parties on the following:

First (the carrier):The first party is obligated to transport the aforementioned radioactive materials for use in nuclear medicine upon their arrival with no delay, from the place of arrival to the receipt site, and provide safety procedures and safe transportation according to the instructions and specifications their licenses in the safe transport of radioactive materials.

Second (the beneficiary healthcare facility):The second party is obligated to ensure that the radioactive materials to be transferred and used are according to the specifications stipulated in the import clearance and the practice nuclear medicine license, and to coordinate and provide who will receive the radioactive material immediately upon their arrival at the place of receipt, and bear full responsibility in front of the security departments if non-compliance or breach of what is stated in the specifications of radioactive material or their uses.

Third: Two parties are obligated to follow the approved radiation protection program for the transfer, receipt and use of radioactive material.

Name or symbol of all radionuclides:	
Physical condition:	
Radioactivity:	
Package category:	
Arrival port:	
Receiving location:	
Transfer method:	
Vehicle type: Plate number:	
Expected time and date of transportation:	

First party
Name:
Signature:
Stamp
Date

Second party
Name:
Signature:
Stamp
Date

Annex (3): Form of List of Radioactive Materials

Click here for a printable and editable version

Radioactive Material								
Radionuclide name		Radionuclide symbol	Physical condition	Radioactivity		Manufacturer	Amount to export	Serial number
				mCi	GBq			
1								
2								
3								
4								
5								
6								
7								
8								
9								

Devices						
Device name		Device model	Current (mA)	Voltage (KeV)	Targeted Radionuclide	Amount of radiation-emitting devices
1						
2						
3						
4						
5						
6						
7						

RSO						
Name		Date				14h
Signature		Facility Stamp				

Annex (4): Definitions & Abbreviations

KSA	Kingdom of Saudi Arabia
SFDA	Saudi Food and Drug Authority
MDS	Medical Device Sector
MDMA	Medical Devices Marketing Authorization
Beneficiary Organization	Healthcare providers or research centres
Healthcare Provider	The governmental or private agency provides health care services in the Kingdom and deals with radiation-emitting devices and products.
Medical Devices	means any instrument, apparatus, implement, machine, appliance, implant, in vitro reagent or calibrator, software, material, or other similar or related article: A) Intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the specific purpose(s) of: - Diagnosis, prevention, monitoring, treatment or alleviation of disease, - Diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap, - Investigation, replacement, modification, or support of the anatomy or a physiological process, - Supporting or sustaining life, - Control of conception, - Disinfection of medical devices, - Providing information for medical or diagnostic purposes using in vitro examination of specimens derived from the human body; and B) Which does not achieve its primary intended action in or on the human body by pharmacological, immunological, or metabolic means, but which may be assisted in its intended function by such means.
Radioactive Material	Material that emits ionizing radiation
Carrier	Person or facility that transfers radiation-certified device/product by any licensed mode of transportation.
Radiation Safety Officer	A scientifically qualified person with practical experience, holding a practice license in radiation protection and safety in the medical field.
RSO	Radiation Safety Officer
NRRC	Nuclear and Radiological Regulatory Commission
MDEL	Medical Device Establishment License

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

Number & Date of the Previous Version	Changes Description
MDS-G24 2.0 01/01/2021	• General amendments in light of Paragraph (B.) of Item "First" in Article (2/1) of the Regulations Concerning Business and Medical Supplies, Board of Directors No. (3-29-1443) dated 2/19/1443 AH. • Updating and amending the "Access" and "Required Documents" sections. • Delete the disclosure form • Delete the declaration of commitment • Updating and amending tariffs in light of the medical devices and supplies system and the preliminary regulation.