MDS-G24

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

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Introduction

Purpose

This guidance is intended to clarify SFDA requirements of importation and re-exportation of radioactive materials used in medical applications.

Scope

This guidance applies to importers, exporters and transporters of radioactive materials used in medical applications.

Background

In accordance with “The Law of Saudi Food and Drug Authority” issued by the Royal Decree No. (M/6) dated on 25/1/1428 H, and in accordance with the memorandum of understanding between the MOI and SFDA dated on 21/10/1435 H that aimed to organize the process of importation and re-exportation for radioactive materials used in medical and research applications, SFDA/MDS issued this guidance document to determine SFDA's requirements for importation and re-exportation for radioactive materials used in medical and research applications in order to ensure the safety and protection of patients, users and related parties from radiological hazards of these materials.

Requirements

General	1	SFDA reviews requests received from General Security in Ministry of Interior (MOI), in order to verify that the healthcare provider is in need of the radioactive materials used in medical applications, to verify that the materials comply with the technical specifications and requirements, and to verify that importers, exporters and transporters fulfill the SFDA's requirements.
SFDA Prerequisite	2	Importers, exporters and transporter of radioactive materials used in medical applications shall have the following: - Create an account in the Unified Electronic System issued by the SFDA (GHAD). - MDEL facility license to practice the activity of importation and re-exportation of medical radioactive materials (issued by the SFDA). - Provide all documents related to importation and re-exportation request specified in "Required Documents".
	3	Radioactive material classified as a medical device / product intended for marketing and / or use within the Kingdom must obtain a marketing permission for medical devices and products (MDMA).
Submitting to the request	4	Healthcare providers, importers, exporters and carriers shall register and apply for radioactive materials in medical applications through the electronic system of radioactive materials (MRMR): https://mrmr.sfda.gov.sa
	5	1) Applicant shall submit hard copy of the request of importation or re-exportation of radioactive materials used in medical applications physically to the Public Security with the documents specified in "Required Documents", in addition to the Ministry of Interior (MOI)

		requirements. SFDA reviews the request referred by Ministry of Interior (MOI) then send it back including the technical recommendation to take a decision either to approve for clearance or not. 2) Applicant shall submit an electronic request of importation or re-exportation of radioactive materials used in medical applications through the electronic system of radioactive materials: https://mrmr.sfda.gov.sa
Clearance in Port	6	- Attach a copy of manufacturer's invoice - Ensure the proper packaging and identification card for each product. - Adherence to marking packages with identification of either the sender or the consignee, or both.
Transportation	7	Shall follow the guidelines of storage, transportation and dealing with medical devices & products (MDS-G17) that is poblished at the SFDA website: https://www.sfda.gov.sa/ar/medicaldevices/regulations/DocLib/(MDS-G17)ar.pdf
Importers and exporters	8	Inporter and exporters are obligated by what is stated in the "Undertaking form for importing or re-exporting of medical radioactive materials for medical application use request" in Annex 1.

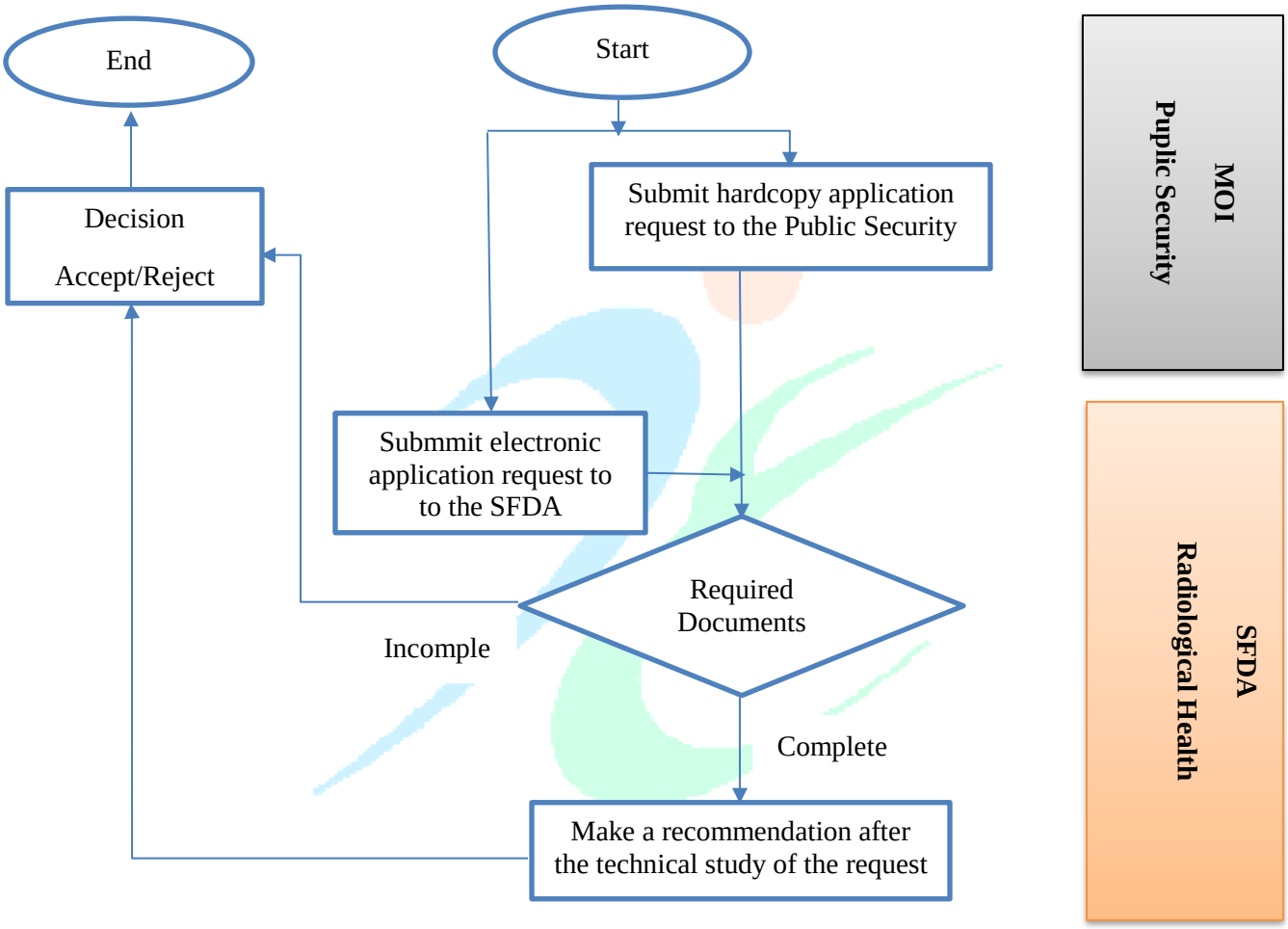
Required Documents

	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).	• Required for importer and exporter. • Healthcare providers and transporters are exempt.
2	Copy of the MDMA for radioactive material classified as a medical device (issued by SFDA).	It is required only if the radioactive material classified as a medical device.
3	Copy of Radiation Practice License assigned to the Beneficiary [issued by King Abdullah City for Atomic and Renewable Energy (KACARE) or Nuclear and Radiological Regulatory Commission (NRRC)].	
4	Copy of Radiation Protection Officer License assigned to the radiation protection officer at the beneficiary [issued by King Abdullah City for Atomic and Renewable Energy (KACARE) or Nuclear and Radiological Regulatory Commission (NRRC)].	It must be accompanied with the following: - Copy of the national identity card / residency card for the RSO. - Proof that the RSO is on the sponsorship of the beneficiary facility or contracted with it.
5	Copy of the licensees of all the radiation safety officers in the carrier beneficiary establishment [issued by King Abdullah City for Atomic and Renewable Energy (KACARE) or Nuclear and Radiological Regulatory Commission (NRRC)].	It must be accompanied with the following: - Copy of the national identity card (Saudi nationality only) - It is required for the RSO to be a Saudi nationality. - Proof that the RSO is working/contracted with the beneficiary facility.
6	Copy of facility license for transporting the radioactive material [issued by King Abdullah City for Atomic and Renewable Energy (KACARE) or Nuclear and Radiological Regulatory Commission (NRRC)].	
7	Letter from Public Security requesting the SFDA's visuals regarding importing or re-exporting of the radioactive materials.	The letter is prepared by the General Department of Weapons and Explosives at Public Security.

8	Application form of importation/re-exportation for radioactive materials.	- See Annex (1), click here for printable and editable version. - Application should be filed electronically. - Print the form in formal paper of beneficiary organization.
9	Copy of the purchase order (PO) from the beneficiary.	- For importing only.
10	Commitment letter from the manufacturer to receive the radioactive materials after consuming (if it is exporting).	- For exportation only. It shall include: - Importer name. - Radioactive material name.
11	Copy of the radioactive material transportation agreement.	- See Annex (2), click here for printable and editable version. - Print the form in formal paper of beneficiary organization.
12	List of Radioactive Materials.	- See Annex (3), click here for printable and editable version. - It should be filled out electronically. - It shall include the serial numbers for the consumed and re-exported radioactive materials (if it is re-export only). - Print the form in formal paper of beneficiary organization.
13	Copy of the manufacturer Quality Management System (QMS) certificate in addition to the Good Manufacturer Practice (GMP) certificate.	For importing only.
14	Official letter or free sale certificate proving that the materials are sold in the country of origin.	For importing only.
15	Acknowledgment that the shipment conforms to the regulations for controlling medical devices and products of the SFDA in relation to the identification card and the terms and conditions of supply and / or use.	Link to the requirements: https://www.sfda.gov.sa/ar/medicaldevices/regulations/Pages/RequirementsAndConditions.aspx

16	Fill out the disclosure form.	- See Annex 4 - Link to disclosure form of narcotic substance or chemicals subject to Public Security control: https://www.sfda.gov.sa/ar/medicaldevices/regulations/DocLib/MD-DisclosureForm.docx - Link to guidelines, requirements and fees: https://www.sfda.gov.sa/ar/medicaldevices/regulations/Pages/RequirementsAndConditions.aspx
17	Fill out the undertaking form.	See Annex 5

Flowchart


End
Start
MOI
Puplic Security
Decision
Accept/Reject
Submit hardcopy application request to the Public Security
Submmit electronic application request to to the SFDA
Required Documents
Incomple
Complete
SFDA
Radiological Health
Make a recommendation after the technical study of the request

Annexes

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

Click here for printable and editable version

بيانات المنشأة المستفيدة			
اسم المنشأة		الفرع / القسم	
رقم ترخيص الممارسة		نوع الممارسة	
تاريخ إصدار الرخصة	/ / ١٤هـ	تاريخ إنتهاء الرخصة	/ / ١٤هـ
الهاتف	تحويلة	الفاكس	تحويلة
ص. ب	الرمز البريدي	المدينة	

بيانات مسؤول الحماية من الإشعاع للمنشأة المستفيدة			
الاسم		رقم الترخيص	
نوع رخصة الممارسة		تاريخ انتهاء الرخصة	/ / ١٤هـ
الهاتف	تحويلة	رقم الجوال	
الفاكس	تحويلة	البريد الالكتروني	
التوقيع		التاريخ	/ / ١٤هـ

المصادر المطلوب استيرادها / تصديرها (حسب جدول المصادر المرفق)			
بيانات الشحنة			
الشركة الصانعة		الدولة	
طريقة الاستيراد / التصدير	☐ جواً ☐ براً ☐ بحراً	منفذ الاستيراد / التصدير داخل المملكة	

الناقل داخل المملكة			
الجهة الناقلة أو المصدرة		الفرع	
رقم ترخيص الممارسة		تاريخ انتهاء الرخصة	/ / ١٤هـ
مسؤول الحماية من الإشعاع		رقم الترخيص	
تاريخ إصدار الرخصة	/ / ١٤هـ	تاريخ انتهاء الرخصة	/ / ١٤هـ
الهاتف	تحويلة	رقم الجوال	
الفاكس	تحويلة	البريد الالكتروني	
		ختم الجهة	

مقدم الطلب للمنشأة المستفيدة			
أنا الموقع أدناه ،أقر بصحة البيانات الواردة في هذا الطلب ، وذلك على مسؤوليتي الشخصية ، وأتعهد بالالتزام بجميع الاشتراطات والضوابط الواردة في كتاب التعليمات العامة للحماية من الإشعاعات المؤينة في المملكة العربية السعودية.			
مدير (رئيس) المنشأة	التاريخ	التوقيع	ختم المنشأة
	/ / ١٤هـ		

Annex (2): Form of Radioactive Material Transportation Agreement

Click here for printable and editable version

تم الاتفاق بين كل من:

الطرف الأول:	الطرف الثاني:
يمثلها مسؤول الحماية من الإشعاع:	يمثلها مسؤول الحماية من الإشعاع:
العنوان: رقم التواصل:	العنوان: رقم التواصل:
رقم رخصة ممارسة النقل الآمن للمواد المشعة:	رقم رخصة مزاولة الطب النووي:

تم الاتفاق بين الطرفين الأول والثاني على ما يلي:

أولاً (الناقل): يلتزم الطرف الأول بنقل المصادر المشعة المذكورة الخاصة بالاستخدام في الطب النووي حال وصولها دون تأخير وذلك من مقر الوصول إلى مقر الاستلام، وتوفير وسائل السلامة والنقل الآمن بحسب تعليمات ومواصفات ما لديه من ترخيص في النقل الآمن للمواد المشعة.

ثانياً (المنشأة الصحية المستفيدة): يلتزم الطرف الثاني بأن تكون المصادر المشعة المراد نقلها واستخدامها حسب المواصفات التي ينص عليها فسح الاستيراد وترخيص مزاولة الطب النووي، وتنسيق وتوفير من يقوم باستلام المصادر المشعة مباشرة حال وصولها دون تأخير في مقر الاستلام، ويتحمل المسؤولية كاملة أمام الجهات الأمنية في حال عدم الالتزام أو الإخلال بما ورد من مواصفات المصادر المشعة أو استخداماتها.

ثالثاً: يلتزم الطرفان بإتباع برنامج الحماية من الإشعاع المعتمد لنقل واستلام واستخدام المصادر المشعة.

اسم أو رمز كل النويدات المشعة:	
الحالة الفيزيائية:	
النشاط الإشعاعي:	
فئة الطرد:	
مقر/منفذ الوصول:	
مقر الاستلام:	
كيفية النقل :	
نوع العربة: اللوحة:	
الوقت و التاريخ المتوقع للنقل :	

الطرف الأول	الطرف الثاني
الاسم:	الاسم:
التوقيع:	التوقيع:
الختم	الختم
التاريخ	التاريخ

Annex (3): Form of List of Radioactive Materials

Click here for printable and editable version

المـــواد							
م	اسم النظير المشع	رمز النظير المشع	الحالة الفيزيائية	النشاطية المطلوبة		الشركة الصانعة	العدد المطلوب تصديره	الرقم التسلسلي
				GBq	mCi			
١								
٢								
٣								
٤								
٥								
٦								
٧								
٨								
٩								

الأجـــهزة						
م	اسم الجهاز	موديل الجهاز	الطاقة (KeV)	شدة التيار (mA)	النويدة الهدف	عدد الأجهزة المصدرة
١						
٢						
٣						
٤						
٥						
٦						
٧						

بيانات مسئول الحماية من الإشعاع				
الاسم		التاريخ		١٤هـ
التوقيع		ختم المنشأة		

Annex **(4):** Disclosure Form of Narcotic Substance or Chemicals Subject to Public Security Control

All fields must be selected and filled with descriptive and relevant information in the disclosureform via the following link:

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

Annex (5): Attestation form

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

Is the Radioactive materials or product/s classified as a medical device	
☐No	☐Yes
.....	If yes, please write the name of the Medical Device
.....	Registration Number of Medical Device (MDMA)

_____	_____	_____
Applicant name	**Applicant Signature**	**Date**

Annex (6): Definitions & Abbreviations

KSA	Kingdom of Saudi Arabia
SFDA	Saudi Food and Drug Authority
MDS	Medical Device Sector
MOI	Ministry of Interior
KACARE	King Abdullah City for Atomic and Renewable Energy
Radioactive Material	Material that emits ionizing radiation naturally.
Medical Devices National Registry (MDNR)	Database of registered establishments and the medical devices they manufacture or import or distribute.
Establishment National Registry Number	means the number issued to a person by the SFDA under the establishment registration provisions of the Medical Devices Interim Regulation.
MDEL	Medical Device Establishment License
MDMA	Medical Devices Marketing Authorization
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 of a physiological process, - Supporting or sustaining life, - Control of conception, - Disinfection of medical devices, - Providing information for medical or diagnostic purposes by means of 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.

Healthcare facilities	Governmental or private agency provides health care services in the Kingdom and deals with radiation emitting devices and products.
Carrier	Person or facility that transfers radiation - certified device / product by any licensed mode of transportation.
Radiation Protection Officer	Scientifically qualified person with practical experience, holding a practice license in the field of radiation protection and safety in the medical field.

Annex (7): List of Changes on the Previous Version

Number & Date of the Previous Version	Changes Description
1.0 10/04/2018	• General editorial • Modifications on SFDA Prerequisite in reguirement • Add to Required Documents: - Clearance in Port - Transportation - Importers and exporters • Update Required Documents table • Modified the flowchart • Add Annex (4): Disclosure Form of Narcotic Substance or Chemicals Subject to Public Security Control • Add Annex (5): Attestation form