MDS-REQ 6

Requirements for Approval of Technical and Clinical Specifications of Medical Radioactive Materials

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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 approval of the technical and clinical specifications of Medical Radioactive Materials.

Scope

These requirements apply to the following:

- Medical Radioactive Materials
- Medical Radioactive Materials Importer
- Medical Radioactive Materials Transporting Establishments
- Beneficiary Establishments (healthcare providers, and research centers using medical radioactive materials)

Background

SFDA has issued this document in reference to Article 4 of the “Law of Medical Devices” issued by Royal Decree No. (M/54) dated 06/07/1442 H which state the following “Subject to the competencies of the Nuclear and Radiological Regulatory Commission (NRRC) to issue the necessary licenses to practice activities related to the use of medical radioactive materials; the SFDA's approval of the technical and clinical specifications of such materials is required before they are licensed by the NRRC.”. Implementing Regulation of the Law of Medical Devices issued by Board Resolution No. (3-29-1443) dated 19/02/1443 AH, which state the following:

4/1 Establishments and / or applicants involved in importing or re-exporting medical radioactive materials shall fulfill the SFDA's requirements for importing and re-exporting such materials used in medical applications, with these requirements being published on the SFDA's website.".

4/2 The SFDA shall issue the approval or refusal of the technical and clinical specifications within ten (10) days of the SFDA's receipt of the application for importing or re-exporting medical radioactive materials.

Requirements

General	1	• Subject to the competencies of the NRRC in issuing the necessary licenses for activities involving the use of medical radioactive materials, the SFDA approval of the technical and clinical specifications of such materials is required prior to their licensing by the NRRC. • SFDA reserves the right to request any additional documents whenever deemed necessary.
Pre-Application Submission	2	• Establishments involved in activities related to the use of medical radioactive materials—including beneficiary, transporting establishment and importer—shall obtain the required licenses from NRRC. All requirements set by the competent authorities shall also be met before submitting the application. • If the product to be imported is classified as a "medical device", the applicant shall obtain a Medical Device Importer/Distributor license. If the product is classified as a "Drug", the applicant shall obtain a pharmaceutical products Importer/Distributor license. • Medical radioactive materials that are classified as "medical devices" shall obtain a Medical Device Marketing Authorization (MDMA). If the medical radioactive materials are classified as "Drug", a Pharmaceutical Product Registration Certificate shall be obtained.
Application Submission	3	• Beneficiary, transporting establishment and importer shall create an account in the Medical Radioactive Materials Registration system (MRMR). • Importer shall submit the application for approval of the technical and clinical specifications through (MRMR). • All documents listed in the "Required Documents" section shall be submitted. • The SFDA will review the application with respect to the technical and clinical specifications of the medical radioactive materials and will issue either an approval or a rejection. In the event of a rejection, the applicant will be informed of the reasons.

Obligations

1. Compliance with the technical regulations issued by NRRC related to protection from ionizing radiation in the KSA, including the “NRRC Technical Regulations for the Safe Transport of Radioactive Materials”.

2. Obtaining the necessary licenses from the NRRC.

3. The approval letter for the technical and clinical specifications of medical radioactive materials shall be used only for the specific application submitted to the NRRC and may not be reused for other applications.

4. The medical radioactive materials importer shall submit all requests related to the application through (MRMR).

5. Not to sell or loan medical radioactive materials to healthcare facilities or providers.

6. Transporting the medical radioactive materials immediately to the beneficiary facility upon receiving, without any storage of such materials.

7. Medical Radioactive Materials importer shall ensure that the materials are delivered to the beneficiary facility mentioned in the submitted application.

8. Medical Radioactive Materials of unknown origin shall not be used.

9. Medical Radioactive Materials shall be imported from the manufacturer mentioned in the approval letter for the technical and clinical specifications. Changing the mentioned manufacturer without obtaining prior approval from the SFDA is prohibited.

10. Not to import a medical radioactive material as a part of a medical device or any other product without obtaining approval of the technical and clinical specifications from the SFDA.

11. The authorized person for using "Medical Radioactive Materials Registration System (MRMR)" is responsible for maintaining the confidentiality of their login credentials and shall not allow any third party to access or use them. The authorized person bears full responsibility for any misuse.

Required Documents

#	Required Documents	Remarks
	Creating Importer Account	
1	A copy of the Commercial Registration (CR) that includes the activity "Import of Radioactive Pharmaceuticals"	
2	A copy of the National Address Proof	
3	A Medical Device Importer/Distributor License for establishments importing Medical Radioactive Materials classified as a "medical device" Or A Drug Importer/Distributor License if the product to be imported is classified as a "Drug."	
4	A copy of authorization letter for Medical Radioactive Registration Materials System (MRMR).	• Use the template provided in Annex (1) • Printed on official letterhead including the establishment name, address, and contact information • Shall be recently issued (not exceeding ONE year) • Signed and stamped by the Establishment's authorized official. • Stamped by the Chamber of Commerce (for commercial entities).
5	Form of Data Integrity Attestation	• Printed on official letterhead showing the establishment name, address, contact information, the name of the responsible person registered in the system, date, position, and signature • Recently issued (not exceeding ONE month).

Creating Radioactive Sources Transporting Establishment Account		
1	A Copy of the Commercial Registration (CR)	
2	A Copy of the Transportation Authorization	• Issued by the NRRC and shall be valid.
3	A Copy of Radiation Safety Officer (RSO) License	• Issued by the NRRC and shall be valid. • Specifies the type of practice as "Transport of Radioactive material." • Saudi national.
4	A Copy of Proof that the Radiation Safety Officer (RSO) is employed by the Radioactive Source Transporting Establishment	• Shall be recently issued (not exceeding ONE year). • Printed on official letterhead and including the Establishment name, address, contact numbers, the name of the Radiation Safety Officer (RSO), and the national ID number.
5	A Copy of the Radiation Protection Program	• It shall outline the basic principles of radiation handling, in addition to including an emergency plan in the event of a spill or leakage of the radioactive material. • recently issued (not exceeding 3 years)
6	Authorization Letter for the Radiation Safety Officer (RSO) to use the Medical Radioactive Materials Registration System (MRMR)	• Use the template provided in Annex (1) • Printed on official letterhead including Establishment name, address, contact information, and the RSO's name (registered in the system) and national ID number. • Recently issued (not exceeding ONE year). • Signed and stamped by the Establishment's authorized official. • Stamped by the Chamber of Commerce (for commercial entities).
7	Form of Data Accuracy Attestation	• Printed on official letterhead showing the establishment name, address, contact information, the name of the responsible person registered in the system, date, position, and signature. • Recently issued (not exceeding ONE month).

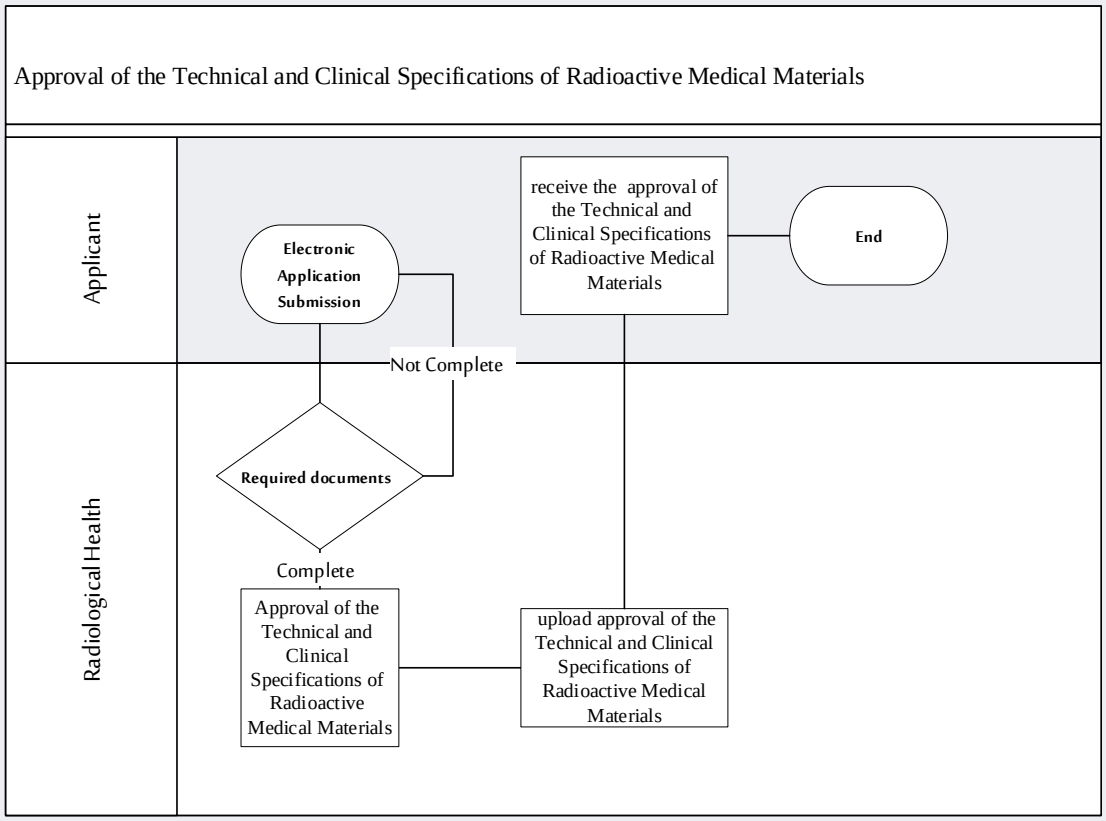
Creating Beneficiary Account (Healthcare Provider or Research Center)		
1	A Copy of the Radiation Practice License	• Issued by the NRRC and shall be valid. • The radiation practice shall correspond to the specialty of the radiology department.
2	A Copy of the Radiation Safety Officer (RSO) License	• Issued by the NRRC and shall be valid. • The radiation practice shall correspond to the specialty of the radiology department.
3	A Copy of Proof that the Radiation Safety Officer (RSO) is Employed by the Beneficiary.	• Shall be recently issued (not exceeding ONE year). • Printed on official letterhead and including the establishment name, address, contact numbers, the name of the Radiation Safety Officer (RSO), and the national ID number.
4	A Building Layout for the Radiology Department	• The layout shall clearly indicate the location of the Hot Lab.
5	A Copy of Radiation Protection Program	• The program shall outline all basic principles of radiation handling, including dose limits/ policies for pregnant patients and pregnant workers, and procedures in case a worker exceeds the permissible dose. • If there are non-Arabic-speaking staff members, an English version of the program shall be provided. • Recently issued (not exceeding 3 years).
6	Authorization Letter for the Radiation Safety Officer (RSO) to use the Medical Radioactive Materials Registration System (MRMR)	• Use the template provided in Annex (1) • Printed on the Establishment's official letterhead stating: establishment name, Address, Contact information, Name and national ID number of the Radiation Protection Officer (RSO) • Shall be recently issued (not exceeding ONE year). • Signed and stamped by the establishment's authorized official. • Stamped by the Chamber of Commerce stamp (for commercial entities).

7	Form of Data Accuracy Attestation	• Printed on official letterhead showing the establishment name, address, contact information, the name of the responsible person registered in the system, date, position, and signature. • Recently issued (not exceeding ONE month).
Request for Approval of the Technical and Clinical Specifications of Medical Radioactive Materials		
1	Radioactive Material Transportation Agreement	• Printed on the Establishment's official letterhead. • Shall include the information of the radioactive material transporting Establishment and the beneficiary licensed by the NRRC. • Shall include the details of the responsible personnel from both the transporting establishment and the beneficiary, along with their signatures. • Stamped by both parties.
2	Form of Data Accuracy Attestation	• Use the template provided in Annex (2). • Printed on official letterhead showing the establishment name, address, contact information, the name of the responsible person registered in the system, date, position, and signature. • Recently issued (not exceeding ONE month).
3	Product Registration Certificate	Submit one of the following valid certificates: • Medical Device Marketing Authorization (MDMA) for Medical Radioactive Materials Classified as a "Medical Device". • Pharmaceutical Product Registration for Medical Radioactive Materials Classified as a "Drug". • other than those mentioned above, accompanied by a copy of the classification decision from the authority proving that the product is not classified as a "medical device/supply" or "medicine" • Product registration in the country of manufacture issued by the competent authority with a copy of the classification

		decision from the SFDA confirming that the product is not classified as a "medical device/supply" or "Drug", and including the following: ○ Product name ○ Product registration number ○ Product type or category ○ Manufacturer details ○ Date of issuance of the registration certificate ○ Registration expiry date
4	Quality Management System (QMS) Certificate for the Manufacturer of Medical Radioactive Materials Classified as a "Medical Device". or Good Manufacturing Practices (GMP) certificate for the Manufacturer of Medical Radioactive Materials Classified as not "Medical Device".	• It shall state the name and address of the manufacturer. • It shall describe the manufacturer's operations and the scope of the certificate, including coverage of radioactive materials. • It shall indicate that the certificate is valid.
5	Certificate of Origin	• It shall state the product description, name and details of the manufacturer and country of origin. • Certificate date of issuance. • Official signature and stamp of the issuing authority. Note: If the product is under production or scheduled for manufacture after approval is issued, the supplier shall submit an undertaking on official letterhead to provide the SFDA with a certificate of origin immediately upon its issuance.
6	Purchase Order Issued by the Beneficiary	• Shall include the importer's name, the radioactive material name, the required quantity, and the radioactivity. • Shall be recently issued (not exceeding 2 years). If the issuance date exceeds 2 years, a justification shall be provided.

7	An undertaking Letter from the Manufacturer to Retrieve the Medical Radioactive Materials after use, or a letter confirming that returning them to the manufacturer after use is not required.	• It shall include mentioning of: - Importer name. - Radioactive material name.

Flowchart



Annexes

Annex (1): Form Letter for Authorization to Use the Medical Radioactive Materials Registration System (MRMR)

Authorization to Use the Medical Radioactive Materials Registration System (MRMR)

(To be printed on the Establishment's official *letterhead*)

To Saudi Food and Drug Authority (SFDA)

With Best Greetings and Wishes,

We, ----- *<Name of Importer / Transporting Establishment / Beneficiary >*----- (*<Establishment National Registration Number>*) authorize ----------, a holder of national ID No.: ----------, employed with us as ----------, to use the *"Medical Radioactive Materials Registration System (MRMR)"* which includes providing the required information and uploading the necessary documents for registration, in order to fulfill the requirements for obtaining approval of the technical and clinical specifications of medical radioactive materials.

We appreciate your kind cooperation.

Establishment Authorized Official	**Establishment Stamp**

Name:

Date:

Signature

Annex (2): Form for Declaration and Undertaking for Importer of Medical Radioactive Materials

Form for Declaration and Undertaking for Importer of Medical Radioactive Materials

(To be printed on the importer establishment's official letterhead)

To Saudi Food and Drug Authority (SFDA)

With Best Greetings and Wishes,

We, --------- *<Name of importer Establishment>* ---------- (*<Establishment National Registry Number>*), hereby declare that all information and documents submitted through the Medical Radioactive Materials Registration System (MRMR) as part of the application for obtaining approval of the technical and clinical specifications of medical radioactive materials for the benefit of ---------- *<Name of Beneficiary Medical Establishment>*---------- are accurate and correct.

We also undertake to immediately notify the Executive Department of Radiological Health at the SFDA of any changes to the submitted data or documents via email: RH.MD@SFDA.GOV.SA.

We appreciate your kind cooperation.

Authorized Person to Use the Medical Radioactive Materials Registration System (MRMR)

Name:

Date:

Signature:

Establishment Stamp

Annex (3): Abbreviations and Definitions

KSA	Kingdom of Saudi Arabia
SFDA	Saudi Food and Drug Authority
MDMA	Medical Devices Marketing Authorization
NRRC	Nuclear and Radiological Regulatory Commission
Beneficiary	Healthcare providers and research centers seeking to import medical radioactive materials
Healthcare Provider	The governmental or private agency provides health care services
Medical Devices	Any instrument, apparatus, applied devices, implant devices, in vitro diagnostic reagent or calibrator, software, or material used for operating medical devices, any other similar or related article, intended to be used alone or in combination with other devices for diagnosis, prevention, monitoring, controlling, treatment, or alleviation of disease or injury, or for compensation for an injury; investigation, replacement, modification, or support of the anatomy or a physiological process; supporting or sustaining life; controlling or assisting conception; sterilization of medical devices; providing information for medical or diagnostic purposes by means of in vitro examination of specimens derived from the human body; and does not achieve its primary intended action by pharmacological, immunological or metabolic means, in return it may be assisted in its intended function by such means.
Medical Supplies	Medical materials and products used in diagnosis, treatment, replacement, modification, disability cases or other medical uses for humans, including medical gases.
Radioactive Material	Materials that emit ionizing radiation, whether alone or as part of other medical devices or supplies, used for diagnosis and treatment.
Transporting Establishment	Establishment licensed by the Nuclear and Radiological Regulatory Commission (NRRC) to transports medical radioactive materials by any means of transport.
Radiation Safety Officer (RSO)	Qualified and experienced person, holding practice license from the Nuclear and Radiological Regulatory Commission (NRRC) to practice in the field of radiation protection and safety in the medical sector.

Annex (4): List of Changes on the Previous Version

Number & Date of the Previous Version	Changes Description
MDS – REQ 6 Version number: 2,0 2025/11/17	• The request to use Form Annex 2 has been removed, and a declaration of data accuracy is now sufficient for the following: - Creating Importer Account - Creating Radioactive Sources Transporting Establishment Account - Creating Beneficiary Account • The renewal deadline for the radiation protection officer's license has been removed. • The requirements for a product registration certificate are consolidated into one of the following: - Medical Device Marketing Authorization (MDMA) for Medical Radioactive Materials Classified as a "Medical Device". - Pharmaceutical Product Registration for Medical Radioactive Materials Classified as a "Drug". - Product registration in the country of manufacture issued by the competent authority with a copy of the classification decision from the SFDA confirming that the product is not classified as a "medical device/supply" or "Drug". • Combine the requirement for a Quality Management System (QMS) certification or Good Manufacturing Practices (GMP) certification into one requirement. • Add a note to the certificate of origin: (If the product is under production or scheduled for manufacture after approval is issued, the supplier shall submit an undertaking on official letterhead to provide the SFDA with a certificate of origin immediately upon its issuance.)
MDS – REQ 6 Version number: 1,1 2023/07/18	• Changing document title from “Requirements for Importing and Re-Exporting Medical radioactive Materials Used in Medical Applications” into “Requirements for Approval of Technical and Clinical Specifications of Medical Radioactive Materials”. • Changing the “Purpose” to reflect the new document title. • Adding “Medical radioactive materials transporting establishments to the “Scope”. • Modifying the “Requirements” as follows: ○ **General**: • Adding: The SFDA reserves the right to request any additional documents whenever deemed necessary.

	○ **Pre-Application Requirements:** • Adding: If the product to be imported is classified as a “Drug,” a license for a pharmaceutical products Importer/Distributer is required. • Adding: Medical Radioactive Materials that are classified as a “Medical Device” shall obtain a Medical Device Marketing Authorization (MDMA). • Medical Radioactive Materials that are classified as a “Drug” shall obtain a Pharmaceutical Product Registration Certificate. ○ **Application Submission:** • Adding: Importing establishments shall submit the application for approval of the technical and clinical specifications through Medical Radioactive Materials Registration system (MRMR). • Adding the Clouse "Obligations". • Amendment to the "Required Documents" by adding the followings: ○ Creating Importer Account ○ Creating Radioactive Sources Transporting Establishment Account ○ Creating Beneficiary Account for (Healthcare Provider or Research Center) ○ Application for Approval of the Technical and Clinical Specifications of Medical Radioactive Materials • Modifying the "Flowchart" • Adding Annex 1 “Authorization to Use the Medical Radioactive Materials Registration System" (MRMR). • Adding Annex 2 “Declaration and Undertaking Form for Importer of Medical Radioactive Materials ". • Deleting Annex "Application Form for Importing/Re-Exporting Medical radioactive Materials" • Deleting annex "Agreement for the Transfer of Radioactive Sources" • Deleting annex "Table of Radioactive Sources"