MDS-G48

# Guideline of Import and Clearance Requirements for Particle Accelerators Used in Radioisotope Formation for Medical Applications

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# Introduction

## Purpose

This guidance is intended to clarify SFDA requirements of importation and clearance of particle accelerators used in radioisotope formation for medical applications.

## Scope

This guideline applies to healthcare providers and importers of particle accelerators used in radioisotope formation for 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, which entrusted the Saudi Food & Drug Authority to regulate and monitor the food, drug and medical devices & supplies. The SFDA/MDS issued this guide to determine its requirements for importing and and clearance of particle accelerators used in radioisotope formation for medical applications in order to ensure the safety and protection of patients, end-users and related parties of the potential hazards resulting to the use of these devices.

## Requirements

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| General | 1 | • Particle accelerators used in radioisotope formation for medical applications may only be imported after obtaining an import permit from the authority.<br>• SFDA studies the requests and verifies that the applicant fulfills the requirements. |
| SFDA Prerequisite | 2 | Importers of particle accelerators used in radioisotope formation for medical applications should have:<br>- Create an account in the SFDA Unified Electronic System (GHAD): https://ghad.sfda.gov.sa/en/<br>- MDEL license to practice the activity of importing medical devices (issued by the SFDA). |
| | 3 | Classified medical device / product that offered for marketing and/or use within the Kingdom must obtain a medical device & product marketing authorization (MDMA). |
| Submitting to the request | 4 | Applicant shall submit the request of importing particle accelerators used in radioisotope formation for medical applications through the unified system of the SFDA "Ghad System" with the documents specified in "Required Documents", in order to take appropriate decision with regard to agreeing to clear the shipment or not. |
| Clearance at ports of entry | 5 | • Submit the manufacturer invoice.<br>• Ensure the correct packaging and appropriate identification card for each product.<br>• Adherence to marking packages with identification of either the consignee or the recipient, or both.<br>• Shall follow (MDS-G21) Guidance on Requirements of Shipments Clearance at Ports of Entry , Available at: https://www.sfda.gov.sa/sites/default/files/2020-10/MDS-G21e.pdf |
| Written procedures for transporting | 6 | Commitment to the guidelines for storage, transportation and handling of medical devices and products published on the SFDA's website: https://www.sfda.gov.sa/ar/medicaldevices/regulations/DocLib/(MDS-G17)ar.pdf |
| Responsibility of importers and exporters | 7 | Importers shall comply with the provisions of the "Application form for requesting permission to import particle accelerators used in radioisotope formation for medical applications" Appendix (1). |

## Required Documents

| | Required Documents | Notes |
|---|---|---|
| 1 | Copy of the MDEL for importation or distribution activities (issued by SFDA). | • It is required for importers and exporters.<br>• Healthcare providers are excluded. |
| 2 | Copy of the MDMA for imaging material classified as a medical device (issued by the SFDA). | • It is required only if the imaging material classified as a medical device. |
| 3 | Copy of the radiation practice license of the facility beneficiary (issued by King Abdullah City for Atomic & Renewable Energy) or (Nuclear & Radiological Regulatory Commission). | • |
| 4 | Copy of the license of the radiation safety officer at the beneficiary establishment (issued by King Abdullah City for Atomic & Renewable Energy) or (Nuclear & Radiological Regulatory Commission). | • |
| 5 | Letter from the Ministry of Interior requesting the SFDA's views regarding the import of the particle accelerator used in the formation of radioisotopes for medical applications. | • |
| 6 | Bill of Lading (BoL). | • If applicable. |
| 7 | Copy of manufacturer's invoice or profoma invoice. | It shall include:<br>- Shipment description (item names)<br>- Marketing / Scientific names.<br>- Quantity (total / detailed).<br>- Unit weight of each item and gross. Weight of each package.<br>- Unit price of each item.<br>- Production and expiration date.<br>- Batch/lot number. |
| 8 | The original certificate of origin. | • It must be stamped by the trade reference in the country of origin. |
| 9 | Endorsing that the shipment conforms to the SFDA regulations for controlling medical devices and products in relation to the identification card and the conditions of supply and / or use. | • Provide a copy(s) of certificate(s) of compliance with technical safety standards, if applicable. |

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| 10 | Copy of the manufacturer Quality Management System (QMS) certificate in addition to the Good Manufacturer Practice (GMP) certificate. | |
| 11 | Purchase order (PO) or award issued by the beneficiary or customer. | |
| 12 | Official letter or free sell certificate proving that the device and its accessories are sold in the country of origin. | |
| 13 | Survey report of the radiation levels for the used rooms. | • It should not exceed the maximum limits set by local and/or international legislators. |
| 14 | Letter by supplier company to proof the approval for installation place. | |
| 15 | Application form for importing particle accelerators used in radioisotope formation for medical applications. | • See Annex (1),<br>• It should be filled out electronically.<br>• Form shall be printed on official paper of the beneficiary establishment. |
| 16 | Technical specifications of radiation device. | • Copies of the approved design specifications of the radiation device and major associated components and sub-systems. |
| 17 | Technical drawings for radiation device | • Copies of technical drawings for critical components and sub-systems of the radiation device showing general assembly of the device, location(s) of the source(s), shielding and safety features associated accessories to be used with the device.<br>• All drawings should be legible and clearly marked with the release dates, scale, drawing numbers, and an associated parts list or bills of materials. |
| 18 | Technical and safety standards used | • List major technical and safety standards used to design the radiation device, if applicable. Explain how these standards were applied to the design and how compliance to their requirements was verified. |

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| 19 | Design validation and risk assessment records | • Copies of the technical validation records, including test reports, the failure effect mode analyses, and device hazard & risk assessment files.<br>• Copy of the suggested emergency response plan in case of any accidental radiation hazard. |
| 20 | Radiation shielding | • Describe the shielding used in the radiation device.<br>• If the shielding includes depleted uranium, include the weight of this material. |
| 21 | Radiation leakages | • 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.<br>• Describe the measurement or calculation method, technical standards, conditions and instruments used. |
| 22 | Accelerator beam target | • Design specifications for the radiation beam target.<br>• Specify the material(s) and model number(s) to be used.<br>• Include applicable technical drawings, material specifications and part numbers. |
| 23 | Radiation output | • Specify the beam particle type, maximum energy, intensity of radiation, intensity and energy of the contaminating neutrons or photons generated in the primary beam and any limitations to the beam orientation. |
| 24 | Physical size | • Specify the weight and external dimensions of the entire system or all its components separately. |
| 25 | Labelling, safety marks and instructions | • Provide technical drawings, photographs or samples of the safety labelling on the radiation device. |
| 26 | External safety devices | • Describe external safety devices and how these devices are connected in order to prevent, stop, or indicate the production of radiation (door interlocks, Last person out buttons, emergency stop devices, radiation state indicators, etc.).<br>• Include schematics and, if applicable, software flow diagrams. |

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| 27 | Instructions for packaging and transport | • Append or enclose policies, standard operation procedures, drawings and technical specifications for the packaging and transport of the radiation device.<br>• The applicant is required to demonstrate compliance with the SFDA Regulations. |
| 28 | Records and documents of handling, storing, using and operating the radiation device | • Provide the instructions for packing, unpacking and transporting the package given to the end-user.<br>• Provide the radiation safety instructions pertinent to the use, operation and storage of the radiation device. Include copies of the operating manual and radiation safety instructions that is to be provided to the end-user.<br>• Enclose copies of radiation safety manuals, policies and procedures for dealing with radiological emergencies, in which the radiation device may be involved<br>• Description of the quality control procedures with respect to radiation safety.<br>• Provide a copy of the maintenance procedure to be followed if a package is to be re-used.<br>• Enclose copies of procedures for conducting leak tests of any radioactive sources and shielding used (including depleted uranium if any). Provide a copy of the instructions that are to be supplied to the end-user of the radiation device.<br>• Note: a particle accelerator does not require the equipment package information, unless the accelerator, as shipped, incorporates radioactive material. |
| 29 | Inspection, servicing and disposal of the radiation device | • Specify the expected lifetime of use of the radiation device allowed by the design.<br>• Provide details of the recommended inspections, servicing program and disposal instructions for the radiation device that are made available to the end-user. |

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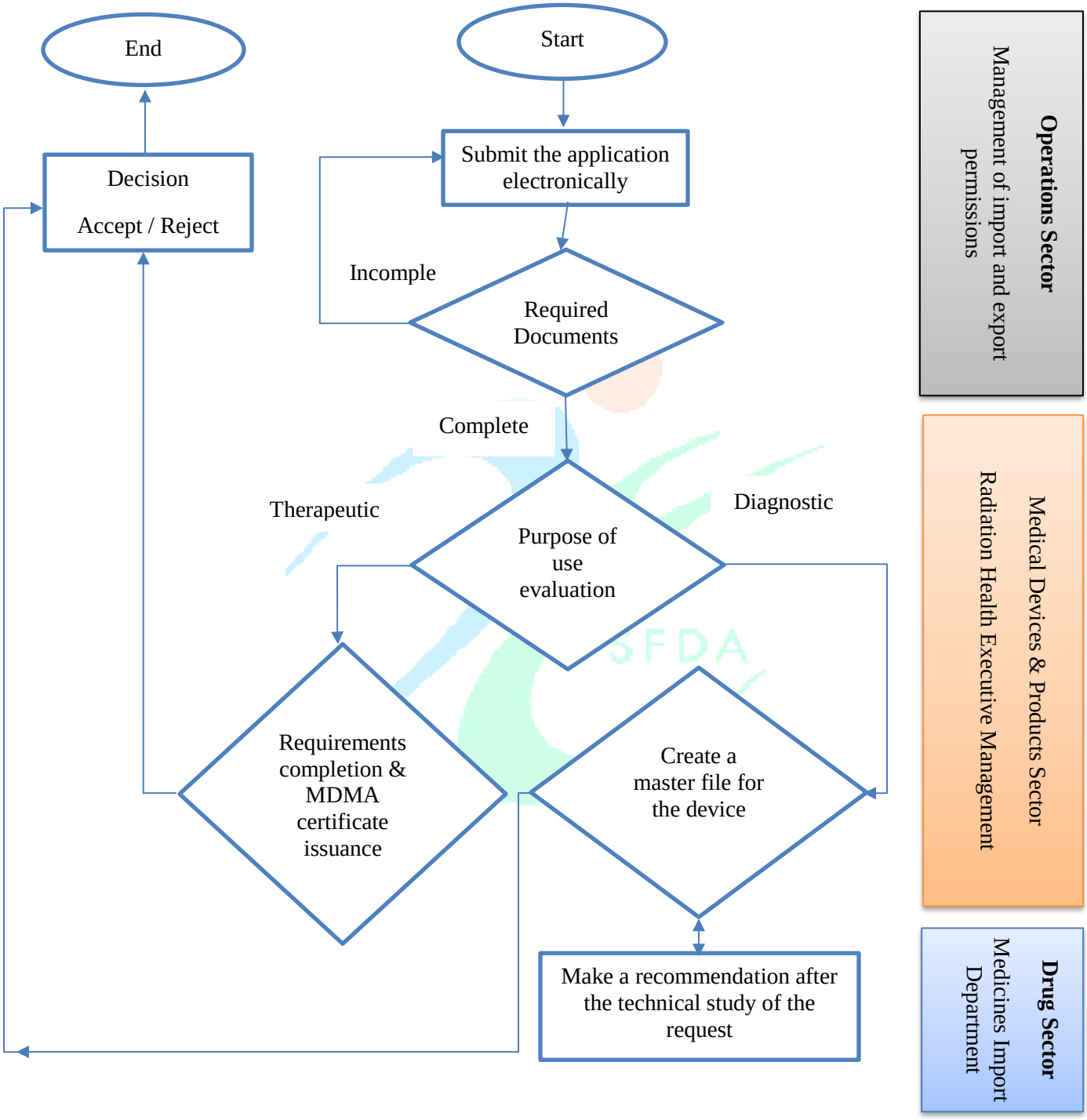
| 30 | Table of radioactive sources | • List all major activation products that may result from the equipment operations, their half-lives and maximum quantities.<br>• Specify the radiation dose rate at 30 cm from the activated components at a given time following the activation (state the conditions of irradiation).<br>• See Annex (1),<br>• It should be filled out electronically.<br>• Form shall be printed on official paper of the beneficiary establishment. |
| 31 | • Fill out the disclosure form.<br>• Fill out the pledge. | • See Annex (2),<br>• Link to guidelines, requirements and fees:<br>https://www.sfda.gov.sa/ar/medicaldevices/regulations/Pages/RequirementsAndConditions.aspx<br>• Link to Disclosure Form of Radioactive Materials, Narcotic Substance or Chemicals Subject to Public Security Control:<br>https://www.sfda.gov.sa/ar/medicaldevices/regulations/DocLib/MD-DisclosureForm.docx |

## Flowchart


End
Start
Decision
Accept / Reject
Submit the application electronically
Incomple
Required Documents
Complete
Therapeutic
Diagnostic
Purpose of use evaluation
Requirements completion & MDMA certificate issuance
Create a master file for the device
Make a recommendation after the technical study of the request
Operations Sector
Management of import and export permissions
Medical Devices & Products Sector
Radiation Health Executive Management
Drug Sector
Medicines Import Department

# Annexes

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

All fields must be filled with descriptive and relevant information in this request for permission to import.

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

| بيانات مسؤول الحماية من الإشعاع للمنشأة المستفيدة | | | |
|---|---|---|---|
| الاسم | | رقم الترخيص | |
| نوع رخصة الممارسة | | تاريخ انتهاء الرخصة | / / ١٤هـ |
| الهاتف | | تحويله | |
| البريد الإلكتروني | | رقم الجوال | |
| التوقيع | | التاريخ | / / ١٤هـ |

| بيانات المنشأة الموردة | | | |
|---|---|---|---|
| اسم المنشأة الموردة | | | |
| اسم الممثل القانوني | | | |
| اسم الموزع المعتمد | | | |
| ترخيص منشأة أجهزة طبية الصادر من الهيئة | | | |
| تاريخ إصدار الرخصة | / / ١٤هـ | تاريخ انتهاء الرخصة | / / ١٤هـ |
| الهاتف | | تحويلة | |
| ص. ب | الرمز البريدي | المدينة | |

| الأجهزة المطلوب استيرادها | | | |
|---|---|---|---|
| بيانات الشحنة | | | |
| الشركة الصانعة | | الدولة | |
| ص. ب | الرمز البريدي | المدينة | |
| الهاتف | | تحويلة | |
| البريد الإلكتروني | | | |
| طريقة التصدير | ☐ جواً ☐ براً ☐ بحراً | منفذ الاستيراد داخل المملكة | |
| أسم الجهاز | | الموديل | |
| تاريخ التصنيع | | الغرض من الاستخدام | ☐ علاجي ☐ تشخيصي |

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|---|---|
| شرح للغرض من استخدام الجهاز | ..... ..... ..... |

| ملحقات ومستلزمات الجهاز | |
|---|---|
| اسم القطعة | رقم الموديل |
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| النويدات والنفايات المشعة المتوقعة الصادرة من الجهاز | | | | |
|---|---|---|---|---|
| اسم المادة | نصف العمر | الكمية القصوى الناتجة / يوم | معدل جرعة الإشعاع عند ٣٠ سم من العناصر المنشطة | الغرض الطبي في حال استخدامها |
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**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): Disclosure Form of Radioactive Materials, Narcotic Substance or Chemicals Subject to Public Security Control

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

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

## Annex (3): The attestation

### Attestation

| | |
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| ☐ | 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. |

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

## Annex (4): Definitions & Abbreviations

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| **KSA** | Kingdom of Saudi Arabia |
| **SFDA** | Saudi Food and Drug Authority |
| **MDS** | Medical Devices Sector |
| **MDEL** | Medical Device Establishment License |
| **MDMA** | Medical Devices Marketing Authorization |
| **Facility file number in the unified system** | Number issued by the SFDA to the entity in accordance with the Medical Devices Interim Regulation. |
| **Medical device** | means any instrument, apparatus, implement, machine, appliance, implant, in vitro reagent or calibrator, software, material or other similar or related article:<br>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:<br>- Diagnosis, prevention, monitoring, treatment or alleviation of disease,<br>- Diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap,<br>- Investigation, replacement, modification, or support of the anatomy or of a physiological process,<br>- Supporting or sustaining life,<br>- Control of conception,<br>- Disinfection of medical devices,<br>- Providing information for medical or diagnostic purposes by means of in vitro examination of specimens derived from the human body;<br>and<br>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. |
| **Drug product** | Any product manufactured in a pharmaceutical form that contains one or more substances which are used, externally or internally, to treat human or animal diseases or prevent them. |

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

| Number & Date of the Previous Version | Changes Description |
|---|---|
| 1.0<br>31/03/1434H | – The entire document has been updated |