الهيئة العامة للغذاء والدواء
Saudi Food & Drug Authority

MDS-G51

Guidance on Requirements for Licensing Service Providers for Quality Assurance and Ionizing Radiation Measurements in Healthcare Facilities

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Introduction

Purpose

This guidance is intended to clarify SFDA requirements of licensing providers of quality assurance and radiation measurements to healthcare facilities in order to ensure the efficiency, quality and safety of radiological medical devices and the environment in which they operate in from radiation hazards.

Scope

This guideline applies to ionizing radiation protection & safety service providers for healthcare facilities and healthcare providers.

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 licensing service providers of quality assurance and radiation measurements in healthcare facilities in order to ensure the safety and protection of patients, end-users and related parties of the potential hazards resulting to the use of radiation medical devices.

Requirements

General	1	– Providers of quality assurance and radiation measurements service to healthcare facilities may only be authorized after obtaining a license from the SFDA. – SFDA studies the requests and verifies that the applicant fulfills the requirements. – SFDA has the right to suspend or cancel the license for any reason to ensure the quality, efficiency and safety of the radiation emitting medical devices and the surrounding environment from radiological hazards.
SFDA Prerequisite	2	Requirements for the facility submitting the application: – Service providers of quality assurance and radiation measurements in healthcare facilities shall have an establishment account in "GHAD System- Accounts Services". – SFDA implements periodic visits to the licensed facility in order to verify the implementation of the issued requirements.
	3	Requirements for the facility employees: – Bachelor's degree - as a minimum - in biomedical engineering or medical physics or any related specialty, from an accredited scientific reference. – Availability of a licensed radiation protection officer (Saudi). – Provide continuous training and appropriate qualification for all workers to carry out tasks optimally. Provide personal radiation dose badges for all related workers.
	4	Requirements for radioactive sources: – It is prohibited to use unauthorized sources in terms of number, type, and radioactivity. It is important to report any changes in the data under which the license was issued. No adjustments can be made without obtaining written permission by the SFDA. – It is not permissible to transfer / own licensed radioactive sources to any other facility without the approval of the related authorities. – It is not permitted to sell, rent, lend or gift the licensee radioactive sources to any other establishment without obtaining approval from the related authorities.

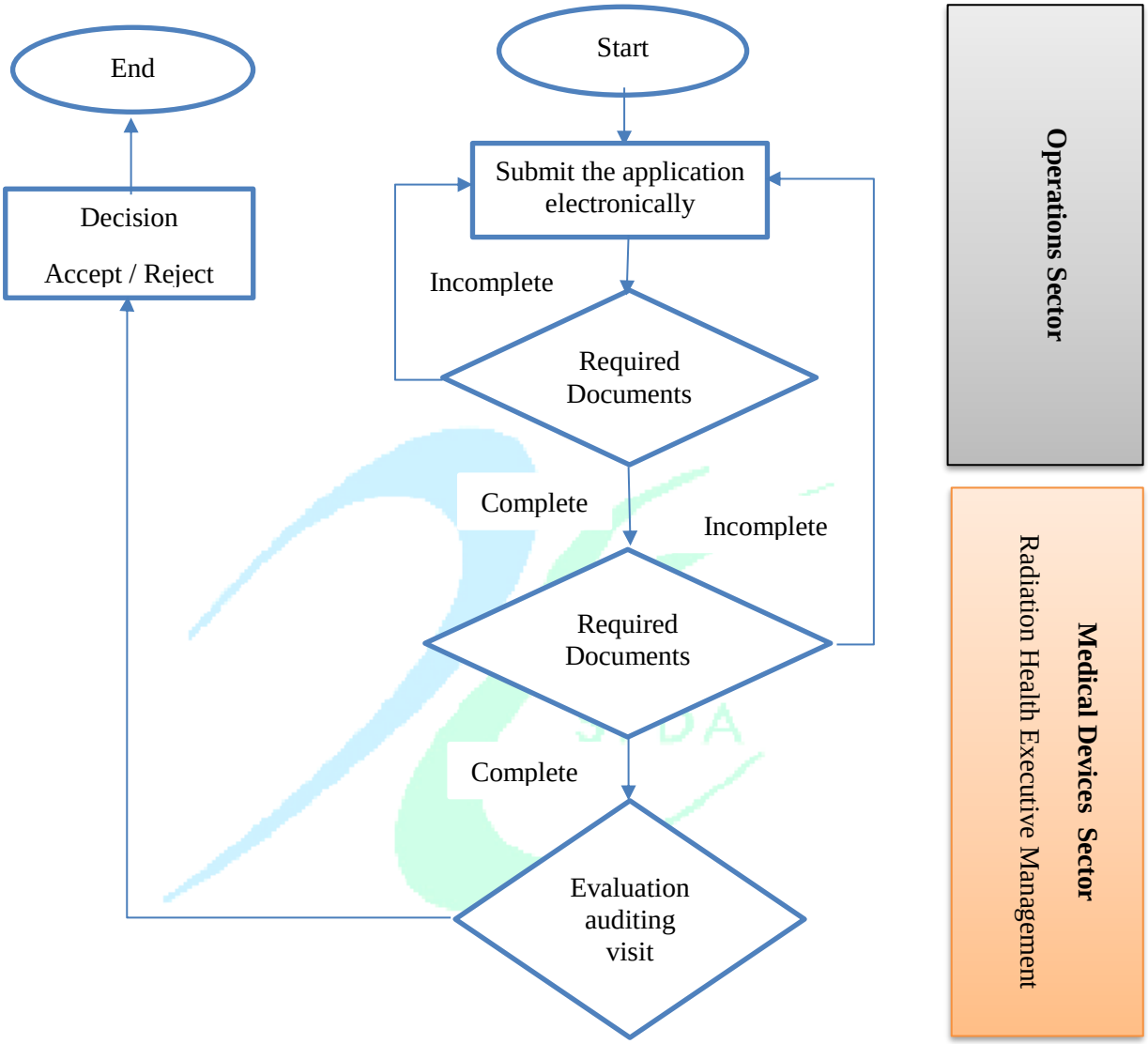
		- It is not permissible to transfer stationary radioactive sources to any other location within the facility without obtaining approval from the related authorities. - In the event that radioactive sources are not required, they shall be disposed of in accordance to the general instructions for managing radioactive waste and general instructions for protection from ionizing radiation in the KSA.
	5	Additional requirements: - After completing all the requirements, the SFDA will conduct, evaluate and audit of the facility applying for the license. - Any additional requirements to be issued later by the SFDA must be fulfilled. - All reports must be approved by an expert in the field. - In the event that the licensed establishment wishes to renew the license later, the establishment must submit a request to the SFDA three months before the expiration of the valid license attaching all required documents with the application. - Any change to the work location or breach of the license will result in the suspension or cancellation of the license.
Request Submitting	6	Applicant shall submit the request of licensing service providers of quality assurance and radiation measurements in healthcare facilities via "GHAD System - Licensing Services" and provide documents specified in "Required Documents".
Written Procedures for Transporting Used Radioactive Materials	7	- Commitment to the "Guidance for Healthcare Providers for Storage, Handling and Transportation of Medical Devices (MDS-G17)" - Adhere to the general instructions for protection from ionizing radiation in the KSA and national instructions for the transport of radioactive materials or any other documents issued by the related authorities later.

Required Documents

#	Required Documents	Notes
Requirements for the facility submitting the application		
1	Copy of the radiation protection and safety program	– It shall be provided in both Arabic and English – It shall be approved by the facility – Description of the applied radiation protection system – Copy of the suggested emergency response plan in case of any accidental radiation hazard – Technical consulting service providers for radiology are exempt
2	Fill out the quality assurance and radiation measurements service providers licensing form (OPS-F-410-001)	– See Annex (1), click here for printable and editable version – All fields must be filled with the descriptive and relevant information – It shall be filled out electronically – In case of an update, amendment or addition to the form information, the quality assurance and radiation measurements service providers license form must be re-filled and a copy sent via email to: rh.md@sfda.gov.sa
Requirements for the facility employees		
3	Copies the training certificates and educational qualifications for all workers in the radiation protection and safety services at the requesting facility	– It must be accompanied with the following: o A copy of the national identity card / residency card and CV o It is required that the specialists and experts are holders of Saudi nationality only
4	Personal radiation dose reports for all related workers	– Records shall be kept for at least 5 years. – Working periods for new employees are exempt
5	Copy of the licensees for all the radiation safety officers in the beneficiary establishment	– It must be accompanied with the following: o Copy of the national identity card / residency card for the RSO. o Proof that the RSO is on the sponsorship of the beneficiary facility or contracted with it

Requirements for radioactive sources		
6	Copy of the radiation practice license for the facility beneficiary	- It is required for service providers
7	Copy of the schematic diagram of the radioactive source storage area	
Requirements for measuring and calibration devices		
8	Copies of the calibration certificates from accredited laboratories for all in service measuring devices	- Description of the measurement or calculation method, technical standards, terms and tools used
Additional requirements		
9	Copy of the procedures and steps used to implement each service whose license is requested	- Clarify the approved scientific reference for the method of conduct tests
10	If any of the required documents updated, modified or corrected, a copy shall be sent via email to: rh.md@sfda.gov.sa	
11	If any radiation protection and safety test fails, the SFDA must be notified and detailed copy of the report shall be sent within three working days, via email to: rh.md@sfda.gov.sa	

Flowchart


End
Start
Submit the application electronically
Decision
Accept / Reject
Incomplete
Required Documents
Complete
Incomplete
Required Documents
Complete
Evaluation auditing visit
Operations Sector
Medical Devices Sector
Radiation Health Executive Management

Annexes

Annex (1): Quality Assurance and Radiation Measurements Service Providers Licensing Form (OPS-F-410-001)

Click here for printable and editable version

All fields must be filled with descriptive and relevant information in this request.

نوع وتاريخ الطلب	
☐ جديد ☐ تجديد ☐ تعديل	التاريخ:
بيانات المنشأة	
اسم المنشأة:	نوع المنشأة: ☐ حكومية ☐ خاصة
رقم السجل التجاري:	رقم السجل الوطني:
المدينة:	الحي:
اسم الشارع:	رقم المبنى:
البريد الإلكتروني:	رقم الهاتف:
العنوان الوطني:	
المسؤول الإداري للمنشأة:	الجوال:
الوظيفة:	البريد الإلكتروني:
مسؤول الحماية من الإشعاع:	الجوال:
الوظيفة:	البريد الإلكتروني:
رقم الهوية:	
رقم ترخيص مسؤول الحماية من الإشعاع:	نوع الترخيص:
تاريخ انتهاء الرخصة:	
أنشطة المنشأة (المقابل المالي لكل نشاط ٥٠٠٠ ريال لمدة ثلاث سنوات)	
☐ توكيد الجودة النوعية لأجهزة الأشعة الطبية	☐ المسح الإشعاعي
☐ خدمات التدريع لإقسام الأشعة	☐ قياس الجرعة الشخصية الإشعاعية
☐ الاستشارات الفنية لأقسام الأشعة	

المتطلبات
○ خطاب طلب الترخيص على الورق الرسمي للمنشأة موجه إلى مدير إدارة ترخيص المنشآت.
○ تعبئة نموذج ترخيص تقديم خدمات الحماية والسلامة من الإشعاع.
○ صورة من إثبات الهوية لجميع موظفي المنشأة.
○ صورة من شهادات الهيئة السعودية للتخصصات الصحية لموظفي المنشأة.
○ تقديم إثبات عمل المعايرة والصيانة للأجهزة بشكل دوري من جهة أو مختبر معتمد.
○ صورة من سجل قراءات الجرعة الإشعاعية الشخصية لموظفي المنشأة الممارسة.
○ إرفاق نسخة من رخصة الممارسة للمواد المشعة إن وجدت.
○ صورة من شهادات التدريب والخبرة لجميع موظفي المنشأة مع مراعاة الحصول على درجة البكالوريوس كحد أدنى في التخصصات (الفيزياء الطبية، هندسة الأجهزة الطبية) أو تخصص ذو علاقة من جهة علمية معتمدة.
○ صورة من رخصة مسؤول الحماية من الإشعاع.
○ إرفاق نسخة من برنامج الحماية والسلامة الإشعاعية باللغتين (العربية والإنجليزية) ومعتمدة لدى المنشأة.
○ تقدم كافة المستندات لإدارة الاتصالات الإدارية بالهيئة العامة للغذاء والدواء.

التعهدات	
أتعهد بأن جميع البيانات المقدمة بهذا النموذج صحيحة.	
أتعهد بإبلاغ الهيئة بأي تغيير في المعلومات المقدمة سابقاً.	
أتعهد بأن جميع الوثائق المرفقة والمختومة بختم المنشأة هي نسخة طبق الأصل، وإذا ظهر خلاف ذلك فإني أقر بارتكاب التزوير في الوثائق وأتحمل ما يترتب على ذلك من الجزاء النظامي.	
أطلعت على لائحة رقابة الأجهزة والمنتجات الطبية والقواعد الإجرائية المكملة لها الصادرة بقرار بمجلس إدارة الهيئة العامة للغذاء والدواء رقم (١-٨-١٤٢٩) وتاريخ ١٤٢٩/١٢/٢٩هـ، وأتعهد بالالتزام بما جاء فيها وبأي تعاميم وقرارات صدرت من الهيئة. كما أتعهد بالالتزام بأي تنظيمات مستقبلية تقرها الهيئة العامة للغذاء والدواء.	
اطلعت على دليل متطلبات الهيئة العامة للغذاء والدواء الخاصة بترخيص مقدمي خدمات توكيد الجودة لأجهزة الأشعة الطبية وخدمات الحماية الإشعاعية للمنشآت الصحية.	
التقيد بمتطلبات الهيئة العامة للغذاء والدواء للممارسة الآمنة في المنشآت الصحية.	
اسم المالك (أو الشخص المفوض):	الجوال:
التوقيع:	ختم المنشأة:

بيانات العاملين المؤهلين							
م	الاسم	الجنسية	الوظيفة	المؤهل العلمي	السجل المدني/الإقامة	رقم ترخيص الممارسة	تاريخ الانتهاء
١							
٢							
٣							

بيانات أجهزة القياس									
م	الجهاز	الموديل	الرقم التسلسلي	الشركة الصانعة	بلد المنشأ	تاريخ المعايرة		جهة المعايرة	ملاحظات
						الحديثة	القادمة		
١									
٢									
٣									

بيانات المصادر المشعة						
م	المصدر المشع	الرمز	الحالة الفيزيائية	النشاطية (Ci)/ (Bq)	العدد	الشركة الصانعة	رقم التسلسل المصنعي
١							
٢							
٣							

Annex (2): Definitions & Abbreviations

KSA	Kingdom of Saudi Arabia
SFDA	Saudi Food and Drug Authority
MDS	Medical Devices Sector
MDEL	Medical Device Establishment License
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: 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 KSA and deals with radiation emitting devices and products.
Related authorities	Ministry of Interior, King Abdullah City for Atomic and Renewable Energy, or King Abdulaziz City for Science and Technology or the Saudi Food and Drug Authority.
Carrier	Person or facility that transfers radiation - certified device / product by any licensed mode of transportation.
Worker	Person whose job requires being in the areas containing the radiation emitting device / product.
Radiation emitting device / product.	Radiation emitting medical device / product or radioactive device / product used for diagnostic, therapeutic, cosmetic or medical calibration applications.
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.